MINUTES OF 282nd MEETING OF CENTRAL LICENSING BOARD HELD ON 31st AUGUST, 2021

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282nd meeting of the Central Licensing Board (CLB) was held on 31st August, 2021 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad. Dr Hafsa Karam Ellahi, Representative Division of Quality Assurance and Laboratory Testing Division/Member Central Licensing Board, Drug Regulatory Authority of Pakistan, Islamabad presided the meeting in the absence of Chairman as provided under Rule 8(8) of the Drugs (Licensing, Registering & Advertising) Rules, 1976. Following members attended the meeting:-

S.No	Name & Designation	Status
1	Mr. Abid Ali, Law Expert, Ministry of Law & Justice Division, Islamabad	Member
2	Mr. Azhar Jamal Saleemi, Chief Drug Controller, Primary and Secondary Health Department, Government of Punjab, Lahore	Member
3	Mr. Zahid Ali Khan, Chief Drug Inspector Peshawar, Govt of KPK, Peshawar.	Member
4	Mr. Manzoor Ali Bozdar, Addl Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
5	Mr. Saboor Ahmad, Representative of PPMA.	Observer
6	Mr. Tipu Sultan Akram, Representative of PPMA.	Observer
7	Mr. Atif Iqbal, Representative, PCDA	Observer
8	Mr.Nadeem Alamgir Representative of Pharma Bureau.	Observer

The meeting started with the recitation of Holy verses. The Chairperson stated that all the legal and codal formalities would be taken into account for disposal of cases and respective Divisions shall be responsible for the contents, errors and omissions of agenda and minutes thereof. The Central Licensing Board considered, discussed and decided cases on merit. Secretary Licensing Board presented the agenda before the Board. Mr. Muhammad Asad Malik, Deputy Director (Licensing), Mr. Muhammad Usman, AD (Lic), Mr. Abdullah Bangash, AD (Lic), Ms. Zunaira Faryad, AD (Lic), Ms. Haleema Shareef AD (Lic) Mr. Sanaullah Babar, AD (QC), Mr. Adil Saeed, AD (QA) and Mr. Hasan Afzaal AD (QA) DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 281ST MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 281st meeting of the Central Licensing Board (CLB) which was held on 25th August, 2021.

A. DRUG LICENSING DIVISION

Item-I: **GRANT OF NEW DRUG MANUFACTURING LICENSE.**

The respective panel of experts for grant of Drug Manufacturing License has forwarded following cases. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Mili Vet Pharmaceuticals (Pvt) Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore. **Sections (02)** i. Oral Powder Section (Veterinary ii. Oral Liquid Section (Veterinary)	09-10-2020 & 23-04-2021	**Good**	1) Dr. Ikram Ul Haq, Expert Member. 2) Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 3) Mrs. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.

Recommendations of the panel:

"Keeping in view the improvements done by the firm, the facilities like building, HVAC, equipment, instrument, personnel, documentation, quality control and testing facilities. The panel of inspectors **recommends** the grant of drug manufacturing license to M/s Mili-Vet Pharmaceutical (Pvt) Ltd, Situated at Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore for following two sections only.

1. Oral Powder Section (Veterinary).
2. Oral Liquid Section (Veterinary).

Decision of the Central Licensing Board in 282nd meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Mili Vet Pharmaceuticals (Pvt) Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore on the recommendations of the panel of experts for the following sections:

Sections (2)

1. Oral Powder Section (Veterinary).

	2. Oral Liquid Section (Veterinary).			
2.	M/s Fleming Pharmaceutical, 23-Km Lahore-Sheikhupura Road, Lahore. **Sections (05):** i. Oral Dry Powder for Suspension (Penicillin) ii. Capsule (Penicillin) iii. Tablet (Penicillin) iv. Dry Powder for Injectables (Penicillin) v. Dry Powder for Injectables (Carbapenem).	**10-06-2021**	**Good**	1) Dr. Ikram Ul Haq, Expert Member. 2) Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 3) Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: "The panel of inspectors **recommends** the grant of Drug Manufacturing License by way of Formulation in respect of above-mentioned sections to M/s Fleming Pharmaceutical, situated at 23-Km Lahore-Sheikhupura Road, Sheikhupura." **Decision of the Central Licensing Board in 282nd meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Fleming Pharmaceutical, 23-Km Lahore-Sheikhupura Road, Lahore on the recommendations of the panel of experts for the following sections: **Sections (5)** 1. Oral Dry Powder for Suspension (Penicillin) 2. Capsule (Penicillin) 3. Tablet (Penicillin) 4. Dry Powder for Injectables (Penicillin) 5. Dry Powder for Injectables (Carbapenem).			
3.	M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad. **Name of API:** i. Alprazolam	28-03-2019	Good	1. Dr. Gul Majeed Khan, Professor of Pharmacy, Quaid-e-Azam University, Islamabad. 2. Additional Director/Deputy Director (QC-I), DRAP, Islamabad. 3. Area, FID, DRAP, Islamabad.
	RECOMMENDATIONS: Keeping in view the above facts on records, the panel unanimously recommended the approval of Drug Manufacturing License by way of Basic Manufacturing to M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Humak, Islamabad for the applied active pharmaceutical ingredient. The manufacturer shall also be responsible and liable under the			

	relevant laws of Narcotics Division (under the Minister of Interior) and policies/SOPs/regulations of DRAP of Controlled Drugs Division of DRAP. Section officer (Controlled Substances), M/o Narcotic Control, Islamabad has forwarded NOC of M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad (By Way of Basic Manufacturing) regarding manufacturing of Controlled substance, Alprazolam vide letter No. 9-1498/2019-CS dated 28th May, 2021. **Decision of the Central Licensing Board in 282nd meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Basic Manufacture in the name of M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad. on the recommendations of the panel of experts for the following API 1. Alprazolam			
4.	M/s Sami Pharmaceuticals (Pvt) Ltd., Plot No. 140/A, S.I.T.E Karachi . Sections : 1. Spansules (General) 2. Ware House (General) 3. Quality Control Laboratory	07-04-2021	**Good**	1. Dr. Abdullah Dayo, Expert Member. 2. FID, Karachi. 3. Ms. SanamKausar, Assistant Director, DRAP, Karachi.
	Recommendation of panel : Keeping in view the good facilities of storage, production, quality control, sanitation and hygiene, HVAC operations, calibration, validation of all equipment and process and other utilities, the panel recommends the grant of Drug Manufacturing License, by way of formulation facility for following section: 1. Spansules (General) 2. Ware House 3. Quality Control Lab **Decision of the Central Licensing Board in 282nd meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Sami Pharmaceuticals (Pvt) Ltd., Plot No. 140/A, S.I.T.E Karachi on the recommendations of the panel of experts for the following section: **Sections (01)** 1. Spansules (General)			

5.	M/s Pinnacle Biotech (Pvt) Ltd., Plot No. . FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. Sections : 1. Tablet (General) 2. Capsule (General) 3. Sachet (General) 4. Ware House (General) 5. Quality Control Laboratory 6. Research & Development Laboratory.	24-08-2021	**V. Good**	1. CDI, Govt of Sindh, Karachi. 2. Federal Inspector of Drugs, DRAP, Karachi. 3. Ms. Krishan Das, AD DRAP, Karachi.

6. **Recommendation of panel :**

"M/S Pinnacle Biotech (Pvt.) Limited Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi was inspected in connection with grant DML (FORMULATION). **During the inspection, panel observed that the firm has constructed as per layout plan approved by the DRAP authorities (Annex-C). At, present Tablet (general), Capsule (General) and Sachet (General) sections are ready for the inspection while Liquid Syrup (General) and Cream/ointment/gel (general) sections are not ready for inspection**. Firm observed maintained at a good level of cleanliness and very well equipped with necessary production and quality control machinery/equipment required for manufacturing and test/analysis of the products registered. Adequate technical personnel also seen onsite that were observed well conversant with the GMP requirements and concepts. HVAC system observed installed and seen operational in the production sections. Safety measures were also undertaken by the firm. Emergency exits were also provided and maintained with alarm system and evacuation plan. Ware house was also observed maintained with HVAC system, emergency arrangements including sprinkle, fire hose wheels.

Based on the inspected, the people met and the documents reviewed and considering the findings of the inspection and vision of the management for international certifications, panel recommends the grant of the Drug Manufacturing License by way of formulation for the below mentioned sections:

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Sachet (General)	4.	Ware House (General)
5.	Quality Control &	6.	Research & Development

	Microbiology		Laboratory	

Decision of the Central Licensing Board in 282nd meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/S Pinnacle Biotech (Pvt.) Limited Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi on the recommendations of the panel of experts for the following section:

Sections (04)

1. Tablet (General)
2. Capsule (General)
3. Sachet (General)
4. Research & Development Laboratory.

7.	M/s Qadir Pharmaceuticals, situated at Veerum Fateh Garh Sahuwala Road, Sialkot.	27-01-2021 & 08-06-2021	**Good**	1.Dr. Farzama Chaudhary, Expert Member. 2.Mr. Ajmal Sohail Asif, FID, DRAP, Lahore. 3.Ms. Uzma Barkat, AD, DRAP, Lahore.

Based on the areas inspected, the technical personnel met and the documents reviewed, and considering the findings of the inspection the panel verifies that the firm possessed the facility for the manufacturing of products by way of formulation as per following sections:

i. Tablet (General).
ii. Capsule (General).
iii. Oral Liquid (General).
iv. Liquid Injectable – Vial & Ampoule (General).
v. Capsule (Cephalosporin).
vi. Oral Dry Powder Suspension (Cephalosporin).
vii. Dry Powder Injectable (Cephalosporin).

The Panel of inspectors recommends the grant of Drug Manufacturing License by way of formulation in respect of above-mentioned sections to M/s Qadir Pharmaceuticals, situated at Veerum Fateh Garh Sahuwala Road, Sialkot.

Disclaimer; the report is limited to verification of manufacturing and quality control facility as per above mentioned sections for enlistment of manufacturing unit only and not to the enlistment of any particular product. Panel could not guarantee the strength of building and safety of installed electric panels. The verification of strength of building and safety of installed electric panels is a technical job and pertains to civil and electrical engineers and Building Control Authorities (BCA).

Decision of the Central Licensing Board in 282nd meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Qadir Pharmaceuticals, situated at Veerum Fateh Garh Sahuwala Road, Sialkot on the recommendations of the panel of experts for the following

	section: **Sections (07)** 1. Tablet (General). 2. Capsule (General). 3. Oral Liquid (General). 4. Liquid Injectable – Vial & Ampoule (General). 5. Capsule (Cephalosporin). 6. Oral Dry Powder Suspension (Cephalosporin). 7. Dry Powder Injectable (Cephalosporin).			
8.	M/s Vetrox Pharmaceuticals, Chak No. 388-JB, 12-KM Toba – Jhang Road, Near M-4 Interchange, Toba Tek Singh.	28-05-2021	**Good**	1. Mr. Muhammad Shamoon, Expert Member. 2. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore. 3. Dr. Akbar Ali, AD, DRAP, Lahore.
	Based on the areas inspected, the technical staff met and the documents reviewed, and considering the findings of the inspection the panel verifies that the firm possessed the facility for the manufacturing of veterinary pharmaceutical products as per following sections: 1. Oral Liquid (General) 2. Oral Powder (General). 3. Oral Powder (Penicillin). The Panel of inspectors **recommends** the grant of Drug Manufacturing License by way of formulation (Vet) in respect of above-mentioned sections to M/s Vetrox Pharmaceuticals, Chak No. 388-JB, 12-KM Toba – Jhang Road, Near M-4 Interchange, Toba Tek Singh. **Decision of the Central Licensing Board in 282nd meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Vetrox Pharmaceuticals, Chak No. 388-JB, 12-KM Toba – Jhang Road, Near M-4 Interchange, Toba Tek Singh on the recommendations of the panel of experts for the following sections: **Sections (03)** 1. Oral Liquid (General) 2. Oral Powder (General). 3. Oral Powder (Penicillin).			
9.	M/s Swera Pharmaceuticals, Plot No. 27, Street No. S-4, Industrial Area, Rawat.	**30-06-2021**	**Satisfactory**	1. Mr. Muhammad Arif Choudhry, Additional Director (CD), DRAP, Islamabad. 2. Mr. Babar Khan, FID-III, DRAP, Islamabad. 3. Ms. Haleema Sharif, Assistant Director (Lic-II),

			DRAP, Islamabad.

"Keeping in view the above facts on record and the people met during the visit, the panel unanimously recommended the approval of following section of M/s Swera Pharmaceuticals, Plot No. 27, Street No. S-4, RCCI, Industrial Estate, Rawat, Rawalpindi:

i. Tablet (General)
ii. Capsule (General)
iii. Sachet (General)
iv. Cream / Gel (General)
v. Lotion Section (General)
vi. Dry Powder Injection (General)

Note:

1. The approval of Dry Powder Injection (General) Section is subject to compliance of firm to the panel advices regarding quality of water being used for washing of vial & area maintenance with respect to temperature, humidity & clean room classification requirements before start of production.
2. The Licensing Division letter No.F.1-42/2011-Lic. Dated 20th May, 2021 mentions section at S. No. 6 as Ointment / Lotion Section while the firm named it as "Ointment / Cream / Gel". The panel was of opinion that since the facility for manufacturing of Ointment was not available, which requires different equipment for ointment manufacturing, the section should be approved as "Cream / Gel" (excluding Ointment).
3. HVAC system needs verification since at some places temperature / humidity needs to be maintained. Hence, panel was of opinion that installation qualification of HVAC should be verified by area FID before start of production.

Procceding and Decision of the Central Licensing Board in 282nd meeting

Mr. Babar Khan, Federal Inspector of Drugs, Islamabad briefed the Board that firm has all available facility for manufactur and Quality control of Drugs and it may be ratedas Good. He further stated that satisfactory rating was made due to misunderstanding regarding previous observation of the Board regarding rating. The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Swera Pharmaceuticals, Plot No. 27, Street No. S-4, Industrial Area, Rawat on the recommendations of the panel of experts for the following sections:

Sections (05)

i. Tablet (General)
ii. Capsule (General)
iii. Sachet (General)
iv. Cream / Gel (General)
v. Lotion Section (General)
vi. Dry Powder Injection (General)

	The Board further directed the Federal Inspector of Drugs to ensure CAPA and compliance of his minor observations before commencing of production acitivity in the facility.			
10.	M/s World Biz Pharmaceuticals Company (Pvt) Ltd, Plot No. 340, Multan Industrial Estate, Multan.	**11-03-2021 and 25-06-2021**	**Good**	1. Dr. Zaka-ur-Rehman, Chief Operating Officer, PDTRC, Lahore. 2. Mr. Abdul Rashid Sahikh, Area Federal Inspector of Drugs, Lahore. 3. Dr. Akbar Ali, AD, DRAP, Lahore.
	"Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control, Testing Facilities, Technical Personnel met and documentation, the panel of inspectors recommends the grant of Drug Manufacturing License by way of Formulation to M/s World Biz Pharmaceuticals Company, Plot No. 340, Phase-II, Industrial Estate, Multan for **Oral Liquid Syrup Section (General)** only. **Decision of the Central Licensing Board in 282nd meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s World Biz Pharmaceuticals Company (Pvt) Ltd, Plot No. 340, Multan Industrial Estate, Multan on the recommendations of the panel of experts for the following section: **Sections (01)** 1. **Oral Liquid Syrup Section (General)**			
11.	M/s Akhsah Pharmaceuticals (Pvt) Ltd, Plot No.47, Street No. S-10, RCCI Industrial Estate, Rawat. **Sections(3):** i. Tablet Section (General) ii. Capsule Section (General) iii. Cream/Ointment Section	**24-08-2021**	**Good**	1) Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad. 2) Mr. Babar Khan, Federal Inspector of Drugs-III, DRAP, Islamabad. 3) Ms. Zunaira Faryad, AD (Lic), DRAP, Islamabad.
	Recommendations of the panel: "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the approval of DML by the way of Formulation to M/s Akhsah			

	Pharmaceuticals (Pvt) Ltd, Plot No.47, Street No. S-10, RCCI Industrial Estate, Rawat with following sections of:" 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointment Section." **Decision of the Central Licensing Board in 282nd meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Akhsah Pharmaceuticals (Pvt) Ltd, Plot No.47, Street No. S-10, RCCI Industrial Estate, Rawat on the recommendations of the panel of experts for the following sections: **Sections (03)** 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointment Section."

Item-II: **GRANT OF ADDITIONAL SECTIONS / EXPANSION / AMENDMENTS ETC.**

The respective panel of experts for grant of additional sections/expansion / amendments etc has forwarded following cases. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Hilton Pharma (Pvt) Ltd, Plot No. 13,14 &43, Sector 15, Korangi Industrial Area, Karachi. DML No.000136 (Formulation) **Section (01):** Ware House (General) - **Revised**	**23-06-2021**	**Good**	1) Dr. Abdullah Dayo, Expert Member. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, AD, DRAP, Karachi.

Recommendation of panel :

"During the inspection the panel physically inspected in detailed the amended dispensing and sampling booth areas and found the facilities built as per approved design. The facilities are provided clean environmental conditions. Other required facilities and amenities are also well provided in the areas. Documents regarding installation of equipment & HVAC System like qualification and validation were reviewed in detail during the course of inspection. Necessary SOPs for cleaning & maintenance were in place.

Based on the stated facts, people met & documents reviewed during the inspection the panel unanimously recommends the regularization of amendments in the facilities made as per approved design.

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of following revised section/ facility in the name of M/s Hilton Pharma (Pvt) Ltd, Plot No. 13,14 &43, Sector 15, Korangi Industrial Area, Karachi under DML No.000136 (Formulation) on the recommendations of the panel of experts.

Section / facility (01):

Ware House (General) - **Revised**

2.	M/s Genix Pharma (Pvt) Ltd, 44,45-B, Korangi Creek Road, Karachi. DML No. 000351 (Formulation) Sections : Tablet (General) – **Revised.** Packing Hall along with quarantine –**New**	**15-06-2021**	**Good**	1) CDI, Govt of Sindh. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) M. Awais Ahmed, AD, DRAP, Karachi.

Recommendations of the panel:

Based on the people met, documents reviewed and observation made during the inspection, panel recommends the renewal of DML and regularization for the sections as mentioned in the aforementioned DRAP letters and are being reproduced as under:

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Tablet (General) -Revised*	*2.*	*Liquid Injection (Ampoule, Vial, Infusion) (General)-renewal*
3.	*Capsule (General)*	*4.*	*Ophthalmic Drops*
5.	*Ointment/Cream/Gel/Lotio*	*6.*	*Dry Powder Injection (General)*
7.	*Sachet (General)*	*8.*	*Beta Lactam (Penem) Injection*
9.	*Oral Liquid (General)*	*10.*	*Packing Hall alongwith quarantine -New*
11.	*Dry Powder Suspension (General)*	*12.*	**********

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of following addional /revised section/ facility in the name of M/s Genix Pharma (Pvt) Ltd, 44,45-B, Korangi Creek Road, Karachi under DML No.000351 (Formulation) on the recommendations of the panel of experts.

Section / facility (02):

1. Tablet (General) – **Revised.**
2. Packing Hall along with quarantine –**New**

3.	M/s Dow Institute of Life Sciences ,Ojha campus, Off Main University Road, Karachi. DML No. 000915 (Formulation) Sections : 1. Sterile Liquid Injectable	**01-07-2021**	**Good**	1) Mr. Ch Zeeshan Ahmed, Additional Director (Biologicals) DRAP, Islamabad. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Ms. SanamKausar, AD, DRAP, Karachi.

	SVP -Vaccine Products RTF – **New.**			
	Recommendations of the panel: "keeping in view the above facts, detailed visit of facility and supporting documents provided by the technical staff, the panel unanimously recommended the firm M/s Dow Institute of Life Sciences, off University Road, Gulzar-e-Hijra, Scheme-33, Karachi for the grant of additional section namely **Sterile Liquid Injectable SVP-Vaccine Products RTF**." **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional section in the name of M/s Dow Institute of Life Sciences ,Ojha campus, Off Main University Road, Karachi under DML No.000915 (Formulation) on the recommendations of the panel of experts. **Section (01):** **1. Sterile Liquid Injectable SVP-Vaccine Products RTF**.			
4.	M/s Geofman Pharmaceuticals, Plot No. 20, Sector 23, Korangi Industrial Area, Karachi. DML No. 000090 (Formulation) Sections : 1. Injectable (Steroid Hormone) (SVP) Ampoule– **New.** 2. Tablet (Steroid) - **New**	**12-07-2021**	**Good**	1) Director DTL, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Ms. Affan Ali, AD CDL, Karachi.
	Recommendations of the panel: *"Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection and vision of the management for export, panel recommends the grant of renewal of the Drug Manufacturing License by way of formulation and grant of additional sections as per DRAP letter No. F.2-11/85-Lic-pt(Vol-I), dated 25th June 2021.* **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional sections in the name of M/s Geofman Pharmaceuticals, Plot No. 20, Sector 23, Korangi Industrial Area, Karachi under DML No.000090 (Formulation) on the recommendations of the panel of experts. **Section (02):** 1. Injectable (Steroid Hormone) (SVP) Ampoule– **New.** 2. Tablet (Steroid) - **New**			

5	M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10, Quaid-e- Azam Industrial Estate, Kot Lakhpat, Lahore. DML No.000150 (Formulation). **Sections (01):** i. Liquid Injectable (Ampoule) (Psychotropic) Section (New).	**22-03-2021** **&** **03-05-2021**	**Good**	4) Dr.IkramUlHaq, Expert Member. 5) Ms. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore. 6) Mr. Shahrukh Ali, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, water treatment system, personnel and documentation etc the panel **recommends** the grant of additional section i.e. Liquid Injectable Psychotropic Section (Ampoule) to M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10-Induestrial Estate Kot Lakhpat, Lahore by way of Formulation." **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional sections in the name of M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10, Quaid-e- Azam Industrial Estate, Kot Lakhpat, Lahore under DML No.000150 (Formulation) on the recommendations of the panel of experts subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;. **Sections (01):** 1. Liquid Injectable (Ampoule) (Psychotropic) Section (New).			
6	M/s Horizon Healthcare (Pvt) Ltd, Plot No.35-A, Small Industrial Estate, Taxila. DML No. 00000856 (Formulation). **Section/Facility(06):** **i.** Capsule (General) Section (Revised). **ii.** Tablet (General) Section (Revised). **iii.** Injectable lyophilized Section (New). **iv.** Liquid Injectable (LVP) Section (New). **v.** Warehouse (Revised). **vi.** Change room (Revised).	**26-05-2021** **&** **01-06-2021**	**Unsatisf actory**	1) Mr. Muhammad Akhtar Abbas Khan Additional Director (Quality Assurance & Lab Testing), DRAP, Islamabad. 2) Mrs. Tehreem Sara, Federal Inspector of drugs, DRAP, Islamabad. 3) Mr. Tahir Waqas, Assistant Director (I & E), DRAP Islamabad.

	Recommendations of the panel: "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **reject the grant** of additional section Liquid vial Section (LVP). The firm informed that they have withdrawn application f or grant of lyophilized section. However, they are advised to remove the shortcomings pointed out in Revised Tablet and Capsule sections. It is further recommended that the firm may not be granted any further registration s till the enhancement of their storage facilities." **The case is hereby submitted for consideration and orders of the Board, please.**			
7	M/s Curatech Pharma (Pvt) Ltd, 35-Km, Multan Road, Lahore. DML No. 000619 (Formulation) **Sections (04)** i. Tablet (General) Section (Revised). ii. Tablet (Psychotropic) Section (Revised). iii. Sachet (General) Section (New). **iv.** Capsule (Psychotropic) Section (New).	**18-02-2021**	**Good**	1) Dr. Farzana Chaudhry, Expert Member. 2) Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3) Dr. Akbar Ali, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "The panel of inspectors **recommends** the grant of additional sections as above in favour of M/s Curatech Pharma (Pvt) Ltd, 35-Km, Multan Road, Lahore under DML No.000619." **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional/ revised sections in the name of M/s Curatech Pharma (Pvt) Ltd, 35-Km, Multan Road, Lahore under DML No.000619 (Formulation) on the recommendations of the panel of experts subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for Tablet (Psychotropic) Section (Revised) and Capsule (Psychotropic) Section (New) ;. **Sections (04)** 1. Tablet (General) Section (Revised). 2. Tablet (Psychotropic) Section (Revised). 3. Sachet (General) Section (New). 4. Capsule (Psychotropic) Section (New).			
8	M/s Himedic Pharmaceutical (Pvt) Ltd., 19-Km, Link Multan Road, Lahore.	03-06-2021	**Good**	1) Dr. Ikram Ul Haq, Expert Member. 2) Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3) Ms. Uzma Barkat, Assistant

	DML No.000824 (Formulation) **Section (01):** i. Sachet (Cephalosporin) (**New**).			Director, DRAP, Lahore.
	Recommendations of the panel: "The panel of inspectors **recommends** the renewal of DML bearing No.000824 and grant of new manufacturing section in favour of M/s Himedic Pharmaceutical (Pvt) Ltd, Situated at 19 Km, Link Multan Road, Lahore." i. Dry Powder for Oral Suspension (Cephalosporin). ii. Capsule (Cephalosporin). iii. Dry Powder for Injection (Cephalosporin). iv. Sachet (Cephalosporin) (**New**). **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional sections in the name of M/s Himedic Pharmaceutical (Pvt) Ltd., 19-Km, Link Multan Road, Lahore under DML No.000824 (Formulation) on the recommendations of the panel of experts;. **Sections (01)** 1. Sachet (Cephalosporin) (**New**).			
9	M/s Universal Pharmaceuticals (Pvt) Ltd., 131-A, Hayatabad Industrial Estate, Peshawar. DML No. 000545 (Formulation) **Name of Sections (06).** 1) Capsule (Cephalosporin) Section 2) Dry Powder (Cephalosporin) Section 3) Raw Material (Cephalosporin) Store	**22-02-2021**	**Good**	1) Prof. Dr. Jamshed Ali Khan, Member CLB. 2) Area Federal Inspector of Drugs, DRAP, Peshawar. 3) Mr.Saleem Khan, DG Drugs, Khyber Pakhtunkhwa
	Recommendations of the panel: - Reference DRAP's letter No.3-2/2001-Lic (Vol-II) dated 04th February, 2021 the constituted panel inspected the firm M/s Universal Pharmaceuticals (Pvt) Ltd., 131-A, Hayatabad Industrial Estate, Peshawar on the prescribed evaluation form for the purpose of verification of revised layout plan for already existing sections i.e Capsule (Cephalosporin) Sections and Dry Powder (Cephalosporin) Sections alongwith Raw Material Store for Cephalosporin. The panel observed that the firm has revised their above-mentioned sections and stores as per layout plan approved by DRAP. They have installed HVAC systems in the sections. Proper Machinery/equipment, QC instruments already exist with the firm. They are advised to replace the manual dry powder filling machine with automatic filling machine. The firm has approved technical staff for the supervision of manufacturing and test/analysis of starting materials, in process materials			

	and finished products. The panel therefore unanimously recommends the approval of following revised sections to the firm; i. Capsule (Cephalosporin) Section ii. Dry Powder (Cephalosporin) Section iii. Raw Material (Cephalosporin) Store **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional sections in the name of M/s Universal Pharmaceuticals (Pvt) Ltd., 131-A, Hayatabad Industrial Estate, Peshawar under DML No.000545 (Formulation) on the recommendations of the panel of experts;. **Sections (02)** 1. Capsule (Cephalosporin) Section 2. Dry Powder (Cephalosporin) Section			
10	Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad, DML No. 000239 (Formulation) **Section;** i. Dry Powder Inhaler Capsule Steroidal **(New).** ii. Soft Gel Capsule General **(New).**	**21-12-2020**	**Good**	1. Additional Director (QA/LT), DRAP, Islamabad on behalf of member CLB. 2. Deputy Director (QC-II), DRAP, Islamabad. 3. Area FID, DRAP, Islamabad.
	Recommendations of the panel: - Inspection of the premises was conducted with reference to Licensing Division letter for Grant of Additional Sections. Panel verified the establishment of sections as per approved layout plan. Keeping in view premises inspected, utilities verified and documents renewed, the panel unanimously recommended the approval of following additional sections; iii. Dry Powder Inhaler Capsule Steroidal **(New).** iv. Soft Gel Capsule General **(New).** **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional sections in the name of Wilson's Pharmaceuticals, Plot No.387-388, Sector I-9, Industrial Area, Islamabad under DML No.000239 (Formulation) on the recommendations of the panel of experts;. **Sections (02)** 1. Dry Powder Inhaler Capsule Steroidal **(New).** 2. Soft Gel Capsule General **(New).**			

11	M/s Variant Pharmaceuticals (Pvt) Ltd, Plot No. 5, M2-Pharma Zone, 26 KM Lahore Sharkpur Road, Sheikhupura. DML No. 000914 (Formulation). **Section (01):** i. Liquid Injectable – Ampoule & Vial (General).	**01-06-2021**	**Good**	i. Dr. Ikram ul Haq, Expert Member. ii. Mr. Ajmal Sohail Asif, FID, Lahore. iii. Ms. Maham Misbah, Assistant Director, Lahore.
	Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verifies that the firm possessed the facility for the manufacturing of products as per following section: i. Liquid Injectable – Ampoule & Vial (General). The Panel of inspectors recommends the grant of additional section as above in favour of M/s Variant Pharmaceuticals (Pvt) Ltd, Plot No. 5, M2-Pharma Zone, 26 KM Lahore Sharkpur Road, Sheikhupura under DML No. 000914. **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional sections in the name of M/s Variant Pharmaceuticals (Pvt) Ltd, Plot No. 5, M2-Pharma Zone, 26 KM Lahore Sharkpur Road, Sheikhupura under DML No.000914 (Formulation) on the recommendations of the panel of experts;. **Sections (01)** 1. Liquid Injectable – Ampoule & Vial (General).			
12	M/s Saffron Pharmaceuticals (Pvt) Ltd, 19-KM, Sheikhpura Road, Faisalabad. DML No. 000616 (Formulation). **Section (01):** i. Dedicated section of manufacturing of Hormone (Steroidal) Tablets.	**18-06-2021**	**Good**	i. Mr. Muhammad Shamoon Chaudhary, Expert Member. ii. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore. iii. Dr. Akbar Ali, Assistant Director, DRAP, Lahore.
	Based on the areas inspected, the technical people met and the documents reviewed, and considering the findings of the inspection the panel verified that the firm has developed the following facilities as per amended layout plan: i. Dedicated section of manufacturing of Hormone (Steroidal) Tablets. The Panel of inspectors recommends the approval of above mentioned section in favour of M/s Saffron Pharmaceuticals (Pvt) Ltd, under DML bearing No. 000616. **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional sections in the name of M/s			

	Saffron Pharmaceuticals (Pvt) Ltd, 19-KM, Sheikhpura Road, Faisalabad under DML No.000616 (Formulation) on the recommendations of the panel of experts;. **Sections (01)** 1. Tablet (Steroidal Hormone) Secttion			
13	M/s Zenith Chemical Industries (Pvt) Ltd, Moza Donday, Jia Baga, Raiwind Road, Lahore. DML No. 000733. **Section (01).** i. Ketamine Hydrochloride	**14-07-2021**	**Good**	i. Mr. Muhammad Shamoon Chaudhary, Expert Member. ii. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore. iii. Dr. Akbar Ali, Assistant Director, DRAP, Lahore.
	The Panel of inspectors recommends the grant of additional section for manufacturing of Ketamine Hydrochloride by way of semi-basic manufacturing under Drug Manufacturing License No. 000733 issued in favor of M/s Zenith Chemical Industries (Pvt) Ltd, 6 KM off Raiwind Road, Jia Baga, Moza Donday. **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional API in the name of M/s Zenith Chemical Industries (Pvt) Ltd, Moza Donday, Jia Baga, Raiwind Road, Lahore under DML No.000733 (Formulation) on the recommendations of the panel of experts;. **API (01)** 1. Ketamine Hydrochloride			
14	M/s Pharma Zone Chemical (Pvt) Ltd, Plot No. 37, Sunder Industrial Estate, Lahore. DML No. 000861 (Formulation) **Section (00):**	**24-05-2021.**		1) Dr. IkramUlHaq, Expert Member. 2) Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3) Ms. Mehwish Jamil Butt, Assistant Director, DRAP, Lahore.
	Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verifies that the firm possessed the facility for the manufacturing of following pellets and granules products: **PELLETS:** 1. Pantoprazole Sodium Pellets: Delayed Release. 2. Diclofenac Potassium Pellets: Sustained Release, Immediate Release, Delayed Release. 3. Itraconazole IR Pellets: Immediate Release. 4. Duloxetine HCI Pellets: Delayed Release. 5. Fluoxetine Pellets: Delayed Release, Sustained Release, Immediate Release. 6. Orlistate Pellets: Delayed Release, Sustained Release, Immediate Release. 7. Rabeprazole Sodium Pellets: Delayed Release.			

8. Venlafaxine HCI Pellets: Sustained Release.
9. Tamsulosin HCI Pellets: Sustained Release.
10. Mebeverine HCI Pellets: Sustained Release, Immediate Release.
11. Itopride HCI Pellets: Sustained Release.
12. Domperidone Pellets: Sustained Release.
13. Doxycycline Hyclate Pellets: Delayed Release, Immediate Release.
14. Fexofenadine HCI Pellets: Sustained Release, Immediate Release.

TASTE MASKED GRANULES:

15. Loratidine Taste Masked Granules.
16. Voriconazole Taste Masked Granules.
17. Linezolid Taste Masked Granules.

The Panel of inspectors recommends the M/s Pharma Zone Chemical (Pvt) Ltd, Plot No. 37, Sunder Industrial Estate, having DML No. 000861 the grant of Extension of Area and Additional Pellets and granules manufacturing mentioned above.

***It is submitted that following observations has been observed regarding certain APIs. The detail of which is mentioned below:-

S.#	API in Inspection report	Category of API applied by firm
1.	Diclofenac Potassium Pellets: Sustained Release, Immediate Release, Delayed Release.	Firm has submitted documents for only **Diclofenac Potassium Delayed Release Pellets** as per record of licensing division but panel has also given recommendations for **Sustained Release & Immediate Release pellets**.
2.	Itraconazole IR Pellets: Immediate Release.	Firm has submitted documents for only **Itraconazole Delayed Release Pellets** as per record of licensing division instead of **Immediate Release.**
3.	Fluoxetine Pellets: Delayed Release, Sustained Release, Immediate Release.	Firm has submitted documents for only **Fluoxetine Delayed Release Pellets** as per record of licensing division instead of **Sustained Release, Immediate Release**.
4.	Orlistat Pellets: Delayed Release, Sustained Release, Immediate Release.	Firm has submitted documents for only delayed release pellets as per record of licensing division instead of Sustained Release, Immediate Release.
5.	Mebeverine HCI Pellets: Sustained Release, Immediate Release.	Firm has submitted documents for only **Mebeverine HCI Sustained Release Pellets** as per record of licensing division but panel has also recommended **Immediate Release pellets**.
6.	Domperidone Pellets: Sustained Release.	Firm has submitted documents for only **Domperidone Immediate Release pellets** as per record of licensing division but panel has also recommended **Sustained Release Pellets**
7.	Doxycycline Hyclate Pellets: Delayed Release, Immediate Release.	Firm has submitted documents for only **Sustained Release Pellets** as per record of licensing division instead of **Delayed Release & Immediate Release pellets**
8.	Fexofenadine HCI Pellets:	Firm has submitted documents for only **Fexofenadine**

	Sustained Release, Immediate Release.	**Immediate Release pellets** as per record of licensing division but panel has also given recommendations for **Sustained Release pellets.**

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of following additional APIs and rrevised facility as per approved Lay out plan in the name of M/s Pharma Zone Chemical (Pvt) Ltd, Plot No. 37, Sunder Industrial Estate, Lahore under DML No.000861 (Formulation) on the recommendations of the panel of experts;.

API (01)

PELLETS:

1. Pantoprazole Sodium Pellets: Delayed Release.
2. Diclofenac Potassium Pellets: Delayed Release.
3. Duloxetine HCI Pellets: Delayed Release.
4. Fluoxetine Pellets: Delayed Release,
5. Orlistate Pellets: Delayed Release,
6. Rabeprazole Sodium Pellets: Delayed Release.
7. Venlafaxine HCI Pellets: Sustained Release.
8. Tamsulosin HCI Pellets: Sustained Release.
9. Mebeverine HCI Pellets: Sustained Release,
10. Itopride HCI Pellets: Sustained Release.
11. Fexofenadine HCI Pellets: Immediate Release.

TASTE MASKED GRANULES:

1. Loratidine Taste Masked Granules.
2. Voriconazole Taste Masked Granules.
3. Linezolid Taste Masked Granules.

The Board also decided to advise the firm to submit propoer application for delayed release and immediate release pellets for formal approval.

15	M/s Medifine Laboratories (Pvt) Ltd., Plot No.A-11, New Industrial Area, **Mirpur, AJ&K** **Sections** 1. Cream/Ointment (General) 2. Sachet (General)	29-07-2021	**Good**	1) Additional Director (Bio), DRAP, Islamabad. 2) Deputy Director (Lic), DRAP, Islamabad. 3) Federal Inspector of Drugs, DRAP, Islamabad.

Recommendations of the panel:

"Keeping in view the above facts on record and people met during the visit, the panel unanimously recommended the following 2 new/additional & renewal (of Existing section) of DML No. 000673 (By way of Formulation) of M/s Madifine Laboratories (Pvt). Ltd, Plot No. A-11 new

	industrial area Mirpur Azad Kashmir. i. Cream/Ointment (General) ii. Sachet (General) **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional sections in the name of M/s Medifine Laboratories (Pvt) Ltd., Plot No.A-11, New Industrial Area, **Mirpur, AJ&K** under DML No.000673 (Formulation) on the recommendations of the panel of experts;. **Sections (02)** 1. Cream/Ointment (General) 2. Sachet (General)			
16	M/s Glitz Pharma Plot No.265, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.	17-06-2021	**Good**	1-Additional Director (Biological Drugs) DRAP, Islamabad. 2-Area FID, DRAP, Islamabad. 3-Mr Abdullah Bangash, Assistant Director (Licensing) DRAP, Islamabad.
	Recommendations: Keeping in view the above facts, documents reviewed & the people met during the visit, the panel unanimously recommended i) the renewal of Drug Manufacturing License by way of Formulation ii) regularization of sections iii) **revision/Amendment of sections iv) grant of additional sections** of M/s Glitz Pharma Plot# 265, Industrial Triangle, Kahuta Road Islamabad DML# 000571 for the following sections **1. Revised/Amendment Sections** **2.** Conversion of old Quality Control Department of ground floor to Research & development & Validation department **3.** Installment of one extra dispensing room in RMS situated on ground floor **4.** Shifting of existing Quality Control Department alongwith Microbiology lab from ground floor to first floor. **5.** External preparation (Pyodine iodine) in the basement **Additional Section** 1. Sachet (Cephalosporin) Section **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional sections in the name of M/s Glitz Pharma Plot# 265, Industrial Triangle, Kahuta Road Islamabad under DML No.000571			

(Formulation) on the recommendations of the panel of experts;.

Sections (05)

1. Research & development & Validation Department [**Ground Floor**]
2. Dispensing Room-II [**Ground floor**]
3. Shifting of existing Quality Control Department [**First floor**].
4. External Preparation (Pyodine iodine) [**Basement**]
5. Sachet (Cephalosporin) Section - **New**

17	M/s Bio-Labs (Pvt.) Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.	08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021	**Good**	1. Mr. Akhtar Abbas Sb. Add. Dir. (QA/LT) HQ DRAP) 2. Ms. Saadia Mahwish, FID, DRAP, Islamabad 3. Mr. Abdullah Bangash, AD, DRAP, Islamabad

Recommendations:

Keeping in view the above facts, documents reviewed & the people met during the visit, the panel unanimously recommended i) the renewal of Drug Manufacturing License by way of Formulation ii)regularization of layout plan iii**) grant of additional section** as well as changes in section of M/s Bio-Labs (Pvt) Ltd 145, Industrial Triangle, Kahuta Road Islamabad DML# 000296 for the following sections

A. Human Pharmaceuticals:

1. Ointment/Gel (Steroid) (in place of licensed Vaccine Veterinary Section)
2. Ointment/Gel (General) (in place of licensed Vaccine Veterinary Section)
3. Lotion (General) (in place of licensed Vaccine Veterinary Section)
4. Dry Vial Injection (General) (Additional Section)

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of following additional sections in the name of M/s Bio-Labs (Pvt.) Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad under DML No.000296 (Formulation) on the recommendations of the panel of experts;.

Sections (05)

1. Ointment/Gel (Steroid) (in place of licensed Vaccine Veterinary Section)
2. Ointment/Gel (General) (in place of licensed Vaccine Veterinary Section)
3. Lotion (General) (in place of licensed Vaccine Veterinary Section)
4. Dry Vial Injection (General) (Additional Section)

18	M/s Bajwa Pharmaceuticals (Pvt) Ltd, 36-Km, Lahore Gujranwala Road, Khori, District Sheikhupura. DML No. 000805 (Formulation). **Section/Facility (01):** i. Liquid Injectable (Vial) (General) Section.	**08-06-2021**	**Good**	1) Dr. Ikram Ul Haq, Expert Member. 2) Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 3) Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: "The panel of inspectors **recommend**s the renewal of DML bearing No. 000805 issued in favor of M/s Bajwa Pharmaceuticals (Pvt) Ltd., in respect to already existing/approved section i.e. Liquid Injectable Ampoule (General). However, the panel **did not recommend** the grant of new additional section i.e. Liquid Injectable vial (General) on the basis of observations made in report." **Decision of the Central Licensing Board in 282nd meeting** The Board considered and **did not approve** the grant of following additional sections in the name of M/s Bajwa Pharmaceuticals (Pvt) Ltd, 36-Km, Lahore Gujranwala Road, Khori, District Sheikhupura under DML No.000805 (Formulation) on the recommendations of the panel of experts;. **Sections (01)** **1.** Liquid Injectable (Vial) (General) Section. The firm may proceed in the ligt of Rule 10 (4) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 after making improvements as suggested by the panel of Inspectors.			
19	M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, Phool Nagar, District Kasur. DML No. 000429 (Semi Basic Manufacture) **API (02):** i. Cloxacillin Sodium (BP) ii. Flucloxacillin Sodium (BP)	**24-06-2021**	**Good**	1) Dr. Farzana Chaudhry, Expert Member. 2) Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore. 3) Ms. Uzma Barkat, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: M/s Citi Pharma (Pvt) Ltd 3-Km Head Balloki Road, Phool Nagar Kasur has been granted a Drug Manufacturing License No 000429 by Way of Semi Basic Manufacturing under the Drugs Act 1976. Panel had thoroughly inspected the unit, evaluated the documentation provided by the firm on			

	demand and discussed various technical aspects at length. Laboratory scale accelerated stability studies were conducted by the firm. On the panel's query firm has given an undertaking that long term stability studies shall be conducted before start of commercial manufacturing of these new APIs (Original undertaking of the firm is attached with this report for perusal of Central Licensing Board). Manufacturing processes, process flow charts, list of materials / chemicals intended to be used, undertaking by the firm to ensure the authorized use of all materials / chemicals with proper records, details of equipment of production and quality control and list of technical staff duly signed by the management of the firm are attached with this report for perusal of the Central Licensing Board. In view of the technical discussion held at length with the firm's management, documentations scrutinized as submitted by the management of by the firm, physical inspection of the Penicillin Block of the unit; Panel **recommends** the grant of approval for the following two new APIs by way of semi basic manufacturing method. i. Cloxacillin Sodium (BP) ii. Flucloxacillin Sodium (BP) **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional APIs in the name of M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, Phool Nagar, District Kasur under DML No.000429 (Semi Basic Manufacture) on the recommendations of the panel of experts;. **Sections (02)** 1. Cloxacillin Sodium (BP) 2. Flucloxacillin Sodium (BP)			
20	M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, Phool Nagar, District Kasur. DML No. 000512 (Formulation) **Section/ Facility (04)** **i.** Capsule (Cephalosporin) section. **ii.** Oral Dry Powder Suspension (Cephalosporin). **iii.** Dry Powder Injection (Cephalosporin). **iv.** Quality Control Laboratory	**13-08-2021**	**Good**	1) Dr. Zaka Ur Rehman COO, PDTRC, Lahore. 2) Dr. Syed Zia Husnain, Federal Inspector of Drugs, Lahore. 3) Mr. Akbar Ali, Assistant Director, DRAP, Lahore.

	(Cephalosporin Block).			

Recommendations of the panel:

"Firm has established a new dedicated cephalosporin block under their Formulation License. Panel has thoroughly inspected the unit, assessed the documents provided by the firm. Various technical aspects were discussed with the management of the firm in detail. Details of equipment of production and quality control department and list of technical staff duly signed by the firm members are attached with this report for perusal of central licensing Board. Firm has not yet established the oral Liquid (General) new section hence small shall stands deferred.

On the basis of depiction mentioned above, documentations revealed and submitted by the firm, physical panel inspection of the unit; Panel has **recommended** the facility M/s Citi Pharma (Pvt) Ltd, 3-Km Head Balloki Road, Phool Nagar, District Kasur for grant of Capsule (Cephalosporin) section, Oral Dry Powder Suspension (Cephalosporin) section and dry Powder Injection (Cephalosporin) section under Drug Manufacturing License No.000512(Formulation). Panel has also recommended the new facility of Quality Control Laboratory (Cephalosporin Block).

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of following additional sections in the name of M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, Phool Nagar, District Kasur under DML No.000512 (Formulation) on the recommendations of the panel of experts;.

Section/ Facility (04)

1. Capsule (Cephalosporin) Section.
2. Oral Dry Powder Suspension (Cephalosporin).
3. Dry Powder Injection (Cephalosporin).

21	M/s Pharmatec Pakistan (Pvt) Ltd, Plot No. D-86/A, S.I.T.E, Karachi. DML No.000024 (Formulation) **Section (02):** **1.** Tablet (General) – **Revised** 2. Warehouse (General) **Revised**	**05-08-2021**	**Good**	1. CDI, Government of Sindh. 2. Federal Inspector of Drugs, DRAP, Karachi. 3. Mr. Krishan Das, AD, DRAP, Karachi.

	Recommendation of panel : "Based on the areas inspected, the technical staff met & the documents reviewed and considering the findings of the inspection M/s Pharmatec Pakistan (Pvt) Ltd, may be granted approval of the following revised sections under DML No. 000024. 1. Tablet (General) Section-Revised 2. Warehouse (General) Revised **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following revised sections in the name of M/s Pharmatec Pakistan (Pvt) Ltd, Plot No. D-86/A, S.I.T.E, Karachi under DML No.000024 (Formulation) on the recommendations of the panel of experts;. **Section/ Facility (02)** 1. Tablet (General) Section-Revised 2. Warehouse (General) Revised			
22	M/s ICI Pakistan Limited S-33, Hawkes Bay Road, Karachi. DML No. 000006 (Formulation) **Section/Facility (01)** : Finished Goods Store –**New**	**23-08-2021**	**Good**	1. CDI, Govt of Sindh. 2. Federal Inspector of Drugs, DRAP, Karachi. 3. M. Awais Ahmed, AD, CDL, Karachi.
	Recommendations of the panel: "Keeping in view overall GMP compliance and positive intention towards improvement, Panel unanimously recommend the renewal of (DML No. 000006) by way of formulation to the firm M/s ICI Pakistan Ltd, Karachi for the following sections.: 1. Tablet (General) 2. Liquid Syrup (General) 3. Packaging Material Store 4. Quality Control Laboratory 5. Finished Good Store (Newly Established) **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following additional section/ facility in the name of M/s ICI Pakistan Limited S-33, Hawkes Bay Road, Karachi under DML No.000006 (Formulation) on the recommendations of the panel of experts;.			

	Section/ Facility (01) Finished Goods Store –**New**

23	M/s Wilson's Pharmaceuticals Plot No 387-388 & 366, Sector I-9. Industrial Area, Islamabad. DML N0. 000239 (Formulation)	**27-08-2021**	**Good**	1) Mr. Malik Muhammad Asad, (Deputy Director (Lic), DRAP, Islamabad. 2) Mrs. Tehreem Sara, Area FID, DRAP, Islamabad. 3) Mr. Abdullah, AD (Lic) Islamabad.

REMARKS AND CONCLUSION

The raw material store is meant for the storage of bulk raw material as informed by the management. The area is well maintained with temperature mapping .data loggers, smoke detectors are also provided. validation and calibration record has also been submitted. However, the following is observation is made by the panel

- **i-** **The HVAC system is not provided**, the epoxy is done in the flooring of the raw material store. temperature is controlled by the installation of 'DAIKIN CASETTE TYPE AIR CONDITIONERS' and total **19 AIR CONDITIONERS** are provided **(**copy attached)
- **ii-** the humidity is controlled by the placement of dehumidifiers and **04 dehumidifiers** of 11Amperes is provided to control the humidity
- **iii-** the firm is further advised to revise their alert limit and action limits as observed in the validation and process control as in the data the alarm settings is done at temperature 50 ° C and humidity is 80% and
    - temperature limit: 30°C
    - relative humidity: 45%

The firm is advised to set the alert and action limit accordingly and they agree to revise the same prior to start operation in this section. Furthermore, few suggestions related to sampling area, washing area and dispensing area is given which the management agreed to comply with.

The panel of inspectors / experts unanimously decided that in the existing condition the firm meets the requirement of temperature and humidity. The report is hereby forwarded to the Licensing Board for consideration for the grant of this section without installation of proper HVAC system in raw material store.

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of following revised section/ facility in the name of M/s Wilson's Pharmaceuticals Plot No 387-388 & 366, Sector I-9. Industrial Area, Islamabad. under

	DML No.000239 (Formulation) on the recommendations of the panel of experts. **Section / facility (01):** Ware House (General) - **New**			
24	M/s Winbrains Research Laboratories, Plot No. 69/1 Block B, Phase I-ii, Industrial Estate Hattar. DML No. 000725(Formulation) **Sections (01)** **Dry Powder Inhaler Capsule (General) Section.**	**26/08/2021**	**Good**	1) Mr. Khalid Javed, Director, DTL, Peshawar, Peshawar 2) Mr. Faisal Shahzad, Area Federal Inspector of Drugs, DRAP, Peshawar. 3) Mr., Adnan Shahid Ullah, Assistant Director, DRAP, Peshawar.
	General remarks, Good and Weal points and Recommendation of Inspector(s) "Based on documentation reviewed, technical/management people met, materials/processes flow and detailed physical inspection including HVAC system,the unanimously **recommends grant of new section namely DPI capsule** as per approved layout plan, by way of imported ready to fill material and local encapsulation. **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of following revised section/ facility in the name of M/s Winbrains Research Laboratories, Plot No. 69/1 Block B, Phase I-II, Industrial Estate Hattar.. under DML No.000725 (Formulation) on the recommendations of the panel of experts. **Section / facility (01):** **Powder Inhaler Capsule (General) Section.-New**			

Item-III: **GRANT OF RENEWAL OF DML.**

Following cases have been forwarded by the respective panel of experts for grant of Renewal of Drug Manufacturing Licenses. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s The Searle Company Limited, 32-KM, Multan Road, Lahore DML No.000647 (Formulation) Period: Commencing on 24-10-2018 ending on 23-10-2023.	**16-03-2021**	**Good**	1) Dr. Farzana Chaudhary, Member, Appellate Board, DRAP, Islamabad. 2) Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3) Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "The Panel of inspectors recommends the renewal of Drug Manufacturing License bearing No. 000647 in respect of M/s The Searle Company Limited, 32-KM Multan Road, Lahore". **Decision of the Central Licensing Board in 228nd meeting** The Board considered and approved the grant of renewal of DML No. 000647 by way of formulation in the name of M/s The Searle Company Limited, 32-KM, Multan Road, Lahore on the recommendations of the panel of experts for the period Commencing on 24-10-2018 ending on 23-10-2023 for the following sections: - **Section (0)**			
2.	M/s Sunshine Pharmaceuticals, Emanabad, G.T. Road, Gujranwala DML No.000662 (Formulation) Period: Commencing on 29-06-2019 ending on 28-06-2024.	**09-06-2021** **&** **07-07-2021**	**Good**	1. Dr. Zaka-ur-Rehman, COO, PRDTC, Lahore. 2. Dr. Syed Zia Huysnain, Federal Inspector of Drugs, DRAP, Lahore. 3. Mehwish Jamil Butt, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "Firm has also planned to further extend their facility and in this regard layout has also been approved by the Licensing Division of DRAP, Islamabad dated 05-04-2021, however construction was not yet initiated by the firm for said purpose for new additional section and extension of raw material store. Firm has revised the already licensed and operational Tablet (General-I) Section as per approved Layout. On the query of the panel, firm informed that they had got layout approval of			

	revision, new additional sections including Tablet (General-II) Section, Capsule (General) Section and extended raw material store section recently dated 05-04-2021 and same were also in the planning of firm for urgent construction in near future. Panel was of the view that upon establishment of new additional sections and construction of extension of raw material store as per approved layout plan, panel may be constituted for verification of raw material store extension and new additional sections subsequently. Accordingly, evaluation to the extent of new additional sections and extension in raw material store was stands deferred. Panel inspected the already established, operational licensed facility of the firm for Tablet (General-I) revised Section. Under the explained circumstances mentioned above, based on the physical inspection of the unit, evaluation of the documents and discussion with the technical staff, Panel has recommended the facility for renewal of Drug Manufacturing License of M/s Sunshine Pharmaceutical, Emanabad, GT Road, Gujranwala for the already operational and licensed Tablet (General-I) Section only". **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000662 by way of formulation in the name of M/s Sunshine Pharmaceuticals, Emanabad, G.T. Road, Gujranwalaon the recommendations of the panel of experts for the period Commencing on 29-06-2019 ending on 28-06-2024 for the following section: - **Section (01)** 1. Tablet (General-I)			
3.	M/s Zakfas Pharmaceuticals (Pvt) Ltd, 12-KM, Lutaf Abad Bosan Road, Multan. DML No.000603 (Formulation) Period: Commencing on 21-03-2017 ending on 20-03-2022.	**15-06-2021**	**Good**	1. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 2. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab. 3. Mr. Abdul Rashid Shaikh, Area Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: "Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control and Microbiology Laboratory, Testing Facilities, Technical Personnel met and documentation, the panel of inspectors recommends the approval of newly upgrade (revised) Bolus Section (Veterinary) and renewal of Drug Manufacturing License by way of Formulation for the following sections to M/s Zakfas Pharmaceuticals (Pvt) Ltd, 12-KM, Bosan Road, Multan: 1. Dry Powder Section (General) (Veterinary). 2. Dry Powder Section (Antibiotic) (Veterinary). 3. Liquid Injectables Section (Antibiotics) (Veterinary). 4. Liquid Injectables Section (General) (Veterinary). 5. Oral Liquid Section (Veterinary).			

	6. Ointment Section (Veterinary). 7. Spray Section (Veterinary). 8. Powder Repacking Section (Veterinary). **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000603 by way of formulation in the name of M/s Zakfas Pharmaceuticals (Pvt) Ltd, 12-KM, Lutaf Abad Bosan Road, Multan on the recommendations of the panel of experts for the period Commencing on 21-03-2017 ending on 20-03-2022 for the following section: - **Section (08)** 1. Dry Powder Section (General) (Veterinary). 2. Dry Powder Section (Antibiotic) (Veterinary). 3. Liquid Injectables Section (Antibiotics) (Veterinary). 4. Liquid Injectables Section (General) (Veterinary). 5. Oral Liquid Section (Veterinary). 6. Ointment Section (Veterinary). 7. Spray Section (Veterinary). 8. Powder Repacking Section (Veterinary).			
4.	M/s NovaMed Pharmaceuticals (Pvt) Ltd, 28-KM, Ferozepur Road, Lahore. DML No.000590 (Formulation) Period: Commencing on 08-04-2021 ending on 07-04-2026.	**06-08-2021**	**Good**	1. Dr. Zaka-ur-Rehman, Chief Operating Officer, PDTRC, Lahore. 2. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore.
	Conclusions: "In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery / equipment, material, management, air handling water treatment system, personnel and documentation etc the panel recommends the renewal of Drug Manufacturing License and regularization of the following sections to M/s NovaMed Pharmaceuticals (Pvt) Ltd, 28-KM, Ferozepur Road, Lahore by way of formulation: 1. Capsule (General). 2. Cream Ointment / Gel / (General). 3. Eye Drops (General). 4. Oral Liquid. 5. Tulle Dressing. 6. Dry Suspension (General) -Revised. 7. Tablet (General)-Revised. 8. Tablet (Psychotropic) -Revised. 9. Capsule (Cephalosporin) - Revised.			

	10. Dry Suspension (Cephalosporin) - Revised. 11. Dry Powder Injection (Cephalosporin) - Revised. 12. Liquid Injectable Ampoule / Vial General - Revised. **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000590 by way of formulation and regularization of lay out plan in the name of M/s NovaMed Pharmaceuticals (Pvt) Ltd, 28-KM, Ferozepur Road, Lahore on the recommendations of the panel of experts for the period Commencing on 08-04-2021 ending on 07-04-2026 for the following section subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*: - **Section (12)** 1.Capsule (General). 2.Cream Ointment / Gel / (General). 3.Eye Drops (General). 4.Oral Liquid. 5.Tulle Dressing. 6.Dry Suspension (General) -Revised. 7.Tablet (General)-Revised. 8.Tablet (Psychotropic) -Revised. 9.Capsule (Cephalosporin) - Revised. 10. Dry Suspension (Cephalosporin) - Revised. 11. Dry Powder Injection (Cephalosporin) - Revised. 12. Liquid Injectable Ampoule / Vial General - Revised. **The Board decided to forwarded inspection report in respect of** Tulle Dressing tp MDMc Division for further necessary action at their end.			
5.	M/s Sharex Laboratories (Pvt) Ltd, KIP Road, Sharex Colony, Sadiqabad, District Rahim Yar Khan. DML No.000079 (Formulation) Period: Commencing on 30-09-2020 ending on 29-09-2025.	**13-04-2021** **&** **14-04-2021**	**Good**	1.Dr. Zaka-ur-Rehman, Chief Operating Officer, PDTRC, Lahore. 2.Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3.Rao Imran Zafar, Drug Inspector, Sadiqabad.
	Conclusions/ Recommendation: "In view of above inspection proceedings improvements and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery / equipment,			

	material, management, air handling, personnel and documentation etc the panel recommends the renewal of Drug Manufacturing License No. 000079 (By way of Formulation) to M/s Sharex Laboratories (Pvt) Ltd, P.O. Box No. 11-Sharex Colony, Sadiqabad for following sections:- 1. Tablet (General). 2. Capsule Section (General). 3. Liquid Syrup Section (General). 4. Topical Preparation / Cream and Ointment Section (General). 5. Sachet / Powder Section. 6. Injectable Section (General). 7. Capsule Section (Cephalosporin). 8. Dry Powder Injection (Cephalosporin). 9. Dry Powder Suspension (Cephalosporin). **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000079 by way of formulation in the name of M/s Sharex Laboratories (Pvt) Ltd, KIP Road, Sharex Colony, Sadiqabad, District Rahim Yar Khan on the recommendations of the panel of experts for the period Commencing on 30-09-2020 ending on 29-09-2025 for the following section: - **Section (09)** 1. Tablet (General). 2. Capsule Section (General). 3. Liquid Syrup Section (General). 4. Topical Preparation / Cream and Ointment Section (General). 5. Sachet / Powder Section. 6. Injectable Section (General). 7. Capsule Section (Cephalosporin). 8. Dry Powder Injection (Cephalosporin). 9. Dry Powder Suspension (Cephalosporin).			
6.	M/s Sante (Pvt) Ltd, Plot No. A-97, S.I.T.E Super Highway, Karachi. DML No.000702 (Formulation) Period: Commencing on 25-02-2021& ending on24-021-2026.	**29-07-2021**	**Good**	1) Professor Rafiq Ala, Expert Member. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, AD, DRAP, Karachi.
	Recommendations of the panel: "Based on the stated observations and attitude of the management towards constant improvements the panel unanimously recommends the grant of renewal of DML No. 000702 (Formulation) for the next five years for following sections and also recommends the regularization of current layout plan:" i. Tablet (G) ii. Capsule (G)			

iii. Sterile Ophthalmic Drops (G)
iv. Ear/Nasal Drops (G)
v. Cream/Ointment (G)

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000702 by way of formulation in the name of M/s Sante (Pvt) Ltd, Plot No. A-97, S.I.T.E Super Highway, Karachi on the recommendations of the panel of experts for the period Commencing on 25-02-2021& ending on24-021-2026 for the following section: -

Section (05)

1. Tablet (G)
2. Capsule (G)
3. Sterile Ophthalmic Drops (G)
4. Ear/Nasal Drops (G)
5. Cream/Ointment (G)

7.	M/s High-Q Pharmaceuticals, Plot No. 224 & 225/1, Sector 23, Korangi Industrial Area, Karachi. DML No.000597 (Formulation) Period: Commencing on 05-07-2021 & ending on 04-07-2026.	**30-06-2021**	**Good**	1) Dr. Abdullah Dayo, Expert Member. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Ms. Sanam Kausar, AD, DRAP, Karachi.

Recommendations of the panel:

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection and vision of the management for exports, panel recommends the grant of renewal of the Drug Manufacturing License by way of formulation and regularization of the Layout for the below mentioned sections:

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Tablet-I (General)*	*2.*	*Capsule (General)*
3.	*Tablet-II (General)*	*4.*	*Tablet (Psychotropic)*
5.	*Liquid Syrup (General)*	*6.*	*Sachet (General)*
7.	*Quality Control Laboratory*	*8.*	*Ware House (General)*
9.	*Product Development Laboratory*	*10.*	*Ware House (Cephalosporin)*
11.	*Dry Powder Suspension (Cephalosporin)*	*12.*	*Capsule (Cephalosporin)*
13.	*Dry Powder Injectable (Cephalosporin)*	*14.*	*Dry Powder Suspension (General)*
15.	*Dry Powder Injection (Carbapenem)*	- -	

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000597 by way of formulation in the name of M/s High-Q Pharmaceuticals, Plot No. 224 & 225/1, Sector 23, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 05-07-2021 & ending on 04-07-2026 for the following section subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*: -

Section (15)

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Tablet-I (General)*	*2.*	*Capsule (General)*
3.	*Tablet-II (General)*	*4.*	*Tablet (Psychotropic)*
5.	*Liquid Syrup (General)*	*6.*	*Sachet (General)*
7.	*Quality Control Laboratory*	*8.*	*Ware House (General)*
9.	*Product Development Laboratory*	*10.*	*Ware House (Cephalosporin)*
11.	*Dry Powder Suspension (Cephalosporin)*	*12.*	*Capsule (Cephalosporin)*
13.	*Dry Powder Injectable (Cephalosporin)*	*14.*	*Dry Powder Suspension (General)*
15.	*Dry Powder Injection (Carbapenem)*	*--*	' '

8.	M/s Nextar Pharma (Pvt) Ltd, Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi. DML No.000777 (Formulation) Period: Commencing on 15-03-2018& ending on 14-03-2023.	**20-05-2021**	**Good**	1) Additional Director (E&M) DRAP, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, AD, DRAP, Karachi.

Recommendations of the panel:

"M/s Nextar Pharma (Pvt) Ltd, was inspected by the panel as per directions contained in DRAP, Islamabad letter no. F.2-4/2004-Lic (Vol-I), dated 6th May, 2021. Following are the observations:

1. Ms. Nextar Pharma (Pvt) Ltd, is constructed as per lay out plan approved by DRAP, Islamabad.
2. Firm has provided all necessary equipments and machinery required for production, Quality Control & Storage of the registered Bio Pharmaceutical products, Relevant technical exports

	were also found available. Firm has installed requisite HVAC system in production, QC and QA areas under Building Management system and were observed operational. Keeping in view people met, documents reviewed and finding of inspection and positive intention of the management toward further compliance of DRAP Act 2012 and efforts towards exports to various countries, the panel **recommends** renewal of Drug Manufacturing License No. 000777 to Ms. Nextar Pharma (Pvt) Ltd, for following sections: i. Pre-Filled Syringes ii. Injectable Ampoule Section. **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000777 by way of formulation in the name of M/s Nextar Pharma (Pvt) Ltd, Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi on the recommendations of the panel of experts for the period Commencing on 15-03-2018& ending on 14-03-2023 for the following section: - **Section (02)** 1. Pre-Filled Syringes 2. Injectable Ampoule Section.			
9.	M/s Adamjee Pharmaceuticals (Pvt) Ltd, Plot No. 39, Sector 15, Korangi Industrial Area, Karachi. DML No. 000236 (formulation) Period: Commencing on 10-02-2021 & ending on 09-02-2026.	**02-06-2021**	**Good**	1) CDI, Govt of Sindh. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Ms. Sanam Kausar, AD, DRAP, Karachi.
	Recommendations of the panel: "Prior physical inspection of unit the panel reviewed in detail their organogram, approved lay out plan HVAC Design, QA System including market complaint records, recall, change control, controlling the deviations, OOS, failures, RCA, CAPA, training records, several working SOPs, training records, practices in QC lab including testing of every incoming materials, intermediates, bulks, packaging material and finished testing with protocols and specifications. Practices in Production and stores were also discussed at length. After that a detailed physical inspection of the unit and utilities was carried out. The panel found an adequate level of GMP compliance after thorough review of their system. HVAC system was seen well installed appropriately maintained. Based on the stated facts and observations, production facilities, QA System, QA Lab, stores, Utilities and people met during the inspection, the panel unanimously recommended as follows: Grant of renewal of DML No. 000236 (Formulation) for the next five years for the following section: 1. Tablet (General) 2. Tablet (Psychotropic)			

	3. Capsule (General/Antibiotic) 4. Capsule (Cephalosporin) 5. Dry Powder Suspension (General) 6. Dry Powder Suspension (Cephalosporin) 7. Liquid Syrup (General) **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000236 by way of formulation in the name of M/s Adamjee Pharmaceuticals (Pvt) Ltd, Plot No. 39, Sector 15, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 10-02-2021 & ending on 09-02-2026 for the following section subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*: - **Section (07)** 1. Tablet (General) 2. Tablet (Psychotropic) 3. Capsule (General/Antibiotic) 4. Capsule (Cephalosporin) 5. Dry Powder Suspension (General) 6. Dry Powder Suspension (Cephalosporin) 7. Liquid Syrup (General)			
10.	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd, Plot No. 50, Sector 28, Korangi Industrial Area, Karachi. DML No. 000144 (Formulation) Period: Commencing on 03-04-2021 & ending on 02-04-2026.	**29-04-2021**	**Good**	4) CDI, Govt of Sindh. 5) Federal Inspector of Drugs, DRAP, Karachi. 6) Mr. Krishan Das, AD, DRAP, Karachi.
	Recommendations of the panel: "The panel inspected the firm in detail including all the manufacturing sections, stores and QC Lab and found the facility as per approved lay out plan. The facility has been provided with necessary utilities, machineries and equipment required for the production and test/analysis of the products being manufactured. Necssary documents relating to QC, QA and HVAC and other utilities were also seen in place. Firm is also exporting the products to Afghanistan and in process of obtaining registrations/ licenses in various countries of the world like Maynmar, Phillipines etc. Based on the people met, documents reviewed, and observations made during the inspection, the panel recommends the grant of renewal of Drug Manufacturing License by way of formulation for following sections:-			

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	6.	Capsule (Cephalosporin)
2.	Oral Liquid (General)	7.	Dry Powder Suspension (Penicillin)
3.	Ointment/Cream/Gel/(General)	8.	Dry Powder Suspension (Cephalosporin)
4.	Capsule (General)	9.	Capsule (Penicillin)
5.	Tablet (Penicillin)	----	**********

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000144 by way of formulation in the name of M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd, Plot No. 50, Sector 28, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 03-04-2021 & ending on 02-04-2026 for the following section:-

Section (09)

1. Tablet (General)
2. Oral Liquid (General)
3. Ointment/Cream/Gel/(General)
4. Capsule (General)
5. Tablet (Penicillin)
6. Capsule (Cephalosporin)
7. Capsule (Cephalosporin)
8. Dry Powder Suspension (Penicillin)
9. Capsule (Penicillin)

11.	M/s S.J & G Fazul Ellahie (Pvt) Ltd, F/46, S.I.T.E Karachi. DML No. 000083(Formulation) Period: Commencing on 29-09-2020 & ending on 28-09-2025.	**24-05-2021**	**Good**	1) Dr. Abdullah Dayo, Expert Member. 2) CDI, Govt of Sindh. 3) Federal Inspector of Drugs, DRAP, Karachi.

Recommendations of the panel:

"During inspection panel reviewed documents and SOPs relating to QA System like organogram, JDs of working personnel, vendor qualification system, VMP, self-audit, market complaint, Control mechanism etc. The panel found good compliance in documentation practices. The panel physically inspected their manufacturing, QC lab and storage facilities. The firm has adequate machineries in all approved production sections. In QC lab adequate equipment are given, necessary log books and calibration plan for every equipment, was in place.

Keeping in view the above stated facts, documents reviewed, personnel met and attitude of the management towards constant improvements the panel unanimously recommends the

regularization of the layout plan and renewal of DML N0.000083 (Formulation) of M/s S.J & G Fazul Ellahie (Pvt) Ltd for the following section.

1. Tablet (General)
2. Capsule (Cephalosporin),
3. Capsule (General)
4. Dry Powder Suspension (Cephalosporin)
5. Ointment/Cream/Gel (General),
6. Dry Powder Injectable (Cephalosporin),
7. Dry Powder Suspension (General),
8. Oral Liquid (Syrup /suspension General)
9. Warehouse (General)
10. liquid injectable ampoule, vial & infusion,
11. Tablet (Cephalosporin),
12. Lyophilization (sterile area)
13. Oral liquid veterinary (General),
14. Dry powder injectable (General),
15. Oral powder veterinary (General),
16. Tablet (veterinary)
17. Dry powder injectable (Carbapenem)
18. Liquid injectable (veterinary),
19. Quality control
20. Warehouse (Cephalosporin),
21. warehouse (veterinary)

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000144 by way of formulation in the name of M/s S.J & G Fazul Ellahie (Pvt) Ltd, F/46, S.I.T.E Karachi on the recommendations of the panel of experts for the period Commencing on 29-09-2020 & ending on 28-09-2025 for the following section:-

Section (17)

1. Tablet (General)
2. Capsule (Cephalosporin),
3. Capsule (General)
4. Dry Powder Suspension (Cephalosporin)
5. Ointment/Cream/Gel (General),
6. Dry Powder Injectable (Cephalosporin),
7. Dry Powder Suspension (General),
8. Oral Liquid (Syrup /suspension General)
9. liquid injectable ampoule, vial & infusion,
10. Tablet (Cephalosporin),
11. Dry Powder Inection (Lyophilization) (sterile area)
12. Oral liquid veterinary (General),
13. Dry powder injectable (General),
14. Oral powder veterinary (General),
15. Tablet (veterinary)
16. Dry powder injectable (Carbapenem)
17. Liquid injectable (veterinary),

12.	M/s Epla Laboratories (Pvt) Ltd, D-12, Estate Avenue, S.I.T.E, Karachi. DML No. 000071 (Formulation) Period: Commencing on 13-08-2020 & ending on 12-08-2025.	**24-06-2021**	**Good**	1) CDI, Govt of Sindh. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, AD, DRAP, Karachi.

Recommendations of the panel:

"Keeping in view the good facilities of storage, production, quality control, sanitation and hygiene, HVAC operations, calibration, validation of all equipment, GMP training of the staff and positive intention of firm towards improvement, panel unanimously recommend the renewal of (DML No. 000071) by way of formulation to the firm M/s EplaLaboratoreis (Pvt) Ltd, Plot No. D-12 Estate Avenue S.I.T.E for following sections:-

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Tablet general*	*2.*	*Liquid Syrups (General)*
3.	*Capsule (Penicilin)*	*4.*	*Capsule (General)*
5.	*Dry Powder Suspension (Penicillin)*	*6.*	*Nasal Solution (General)*
7.	*Dry Powder General*	*8.*	*Cream/Ointment (General)*

- ***Re-inspection for renewal of liquid section veterinary and powder section veterinary subject to completion of maintenance/renovation in this section is recommended by the panel on request of the firm. (letter annexed)"***

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000071 by way of formulation in the name of M/s Epla Laboratories (Pvt) Ltd, D-12, Estate Avenue, S.I.T.E, Karachi on the recommendations of the panel of experts for the period Commencing on 13-08-2020 & ending on 12-08-2025 for the following section:-

Section (08)

1. Tablet (General)
2. Liquid Syrups (General)
3. Capsule (General)
4. Nasal Solution (General)
5. Dry Powder (General)
6. Cream/Ointment (General)
7. Capsule (Penicilin)
8. Dry Powder Suspension (Penicillin)

The Board considered the case pertaining to **liquid section veterinary and powder section veterinary** and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

M/s Genix Pharma (Pvt) Ltd, 44,45-B, Korangi Creek Road, Karachi. DML No. 000351 (Formulation) Period: Commencing on 22-09-2020 & ending on 21-09-2025.	**15-06-2021**	**Good**	1) CDI, Govt of Sindh. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Awais Ahmed, AD, DRAP, Karachi.

Recommendations of the panel:

Based on the people met, documents reviewed and observation made during the inspection, panel recommends the renewal of DML and regularization for the sections as mentioned in the

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Tablet (General) -Revised*	*2.*	*Liquid Injection (Ampoule, Vial, Infusion) (General)- renewal*
3.	*Capsule (General)*	*4.*	*Ophthalmic Drops*
5.	*Ointment/Cream/Gel/Lotion*	*6.*	*Dry Powder Injection (General)*
7.	*Sachet (General)*	*8.*	*Beta Lactam (Penem) Injection*
9.	*Oral Liquid (General)*	*10.*	*Packing Hall alongwith quarantine -New*
11.	*Dry Powder Suspension (General)*	*12.*	**********

aforementioned DRAP letters and are being reproduced as under:

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000351 by way of formulation in the name of M/s Genix Pharma (Pvt) Ltd, 44,45-B, Korangi Creek Road, Karachi on the recommendations of the panel of experts for the period Commencing on 22-09-2020 & ending on 21-09-2025 for the following section:-

Section (10)

1. Liquid Injection (Ampoule, Vial, Infusion) (General)- renewal
2. Capsule (General)
3. Oral Liquid (General)
4. Dry Powder Suspension (General)
5. Ophthalmic Drops
6. Ointment/Cream/Gel/Lotion
7. Dry Powder Injection (General)
8. Sachet (General)
9. Dry Powder Injection (Penem) Injection

13.	M/s Efroze Chemical Industries (Pvt) Ltd. 146/23, Korangi Industrial Area, Karachi. DML No. 000151 (Formulation) Period: Commencing on 08-04-2020 & ending on 07-04-2025.	17-03-2021	Good	1) CDI, Govt of Sindh. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Affan Ali, AD CDL, DRAP, Karachi.

Recommendations of the panel:

"M/s Efroze Chemical Industries (Pvt) Ltd, situated at plot No. 146/23, Korangi Industrial Area, Karachi-Pakistan was inspected in detail on 17-03-2021 in compliance to the directions contained in DRAP, Islamabad letter No. F. 2-11/2000-Lic(Vol-V) dated 20th January, 2021 in connection with renewal of DML by way of formulation.

The panel inspected the firm in detail including all the manufacturing sections, stores and AC Lab and observed that the firm is built as per layout plan approved by the DRAP authorities. The facility has been provided with necessary utilities, machineries and equipment and personnel as per required under the guidelines. Necessary documents relating to QC, QA and installation qualification of machines, HVAC and other utilities were also seen in place. Firm is also exporting the products in various countries of the world.

Based on the people met, documents reviewed, and observations made during the inspection, the panel recommends the regularization of Tablet(Hormone) section and grant of renewal of Drug Manufacturing License No. 000151 by way of formulation for following section:-

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Oral Liquid Syrup (General)	4.	Dry Powder Suspension (General)
5.	Sachet (General)	6.	Tablet (Hormone)
7.	Ware House (General)	8.	Raw Material Store (Hormone)
9.	Quality Control Laboratory	-----	**********

The panel of experts was given mandate for inspection regarding regularization of manufacturing facility however in the panel inspection report panel has only recommended the regularization of Tablet (Hormone) section and recommendations of the panel regarding regularization of other sections are not mentioned.

Decision of the Central Licensing Board in 282nd meeting

The Board considered and deferred the grant of renewal of DML No. 000151 by way of formulation in the name of M/s Efroze Chemical Industries (Pvt) Ltd. 146/23, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 08-04-2020 & ending on 07-04-2025 fo seeking clarification from panel of experts regarding not reporting other sections mandated for regularization.

14.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi. DML No. 000267 (Formulation) Period: Commencing on 09-02-2021 & ending on 08-02-2026.	**08-07-2021**	**Good**	1) Dr. Abdullah Dayo, Expert Member. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Ms. SanamKausar, AD, DRAP, Karachi.

Recommendations of the panel: -

"During the detailed inspection the panel physically inspected in detailed their entire production areas, QC Lab, QA, R&D facilities & stores. The premises were found constructed as per approved design and have been provided with required necessary machineries, equipment and adequate utilities. Certain new amendments are made as per approved design for better compliance. A better flow of men and materials were seen in place. A robust, well-monitored and well-maintained HVAC System is in place to prevent the chances of contamination among the products as per approved SOP. Dedicated sections are carefully monitored to reduce the chances of cross-contamination. A stringent QA System is seen in place whereby quality of drugs is carefully assessed with approved SOPs right from starting materials till finished product. Instant documents in this regards were carefully checked and noted an optimal level of compliance. Stores are well-defined & spacious as pre approve design. The firm has sufficient qualified and experienced persons in production, QC, QA and other departments.

Based on the stated facts, observations and keeping in view the dedications of the entire management of the firm for constant improvements the panel unanimously recommends the grant of renewal of DML No.000267 (Formulation) for the next five years for the following sections:"

1. *Tablet (G)*
2. *Capsule (G)*
3. *Dry Powder Suspension (G)*
4. *Sachet (G)*
5. *Tablet (Psychotropic)*
6. *Oral Liquids*
7. *Capsule (Cephalosporin)/ Cephalosporin Injection Vials Secondary packing*
8. *Dry Powder Inhaler (DPI) (G) Capsule*

The panel of expert was given mandate for inspection of the firm for renewal of DML and for sections including capsule (cephalosporin) , however, in the panel inspection report panel **has mentioned/recommended the renewal of DML for capsule (cephalosporin / cephalosporin injection vial secondary packing) area** and however as per record the firm **does not have licensed section** namely **Injection (cephalosporin)**.

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000267 by way of formulation in the name of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 09-02-2021 & ending on 08-02-2026 for the following sections subject to submission of NOC from

	Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*: - **Section (08)** 1. *Tablet (G)* 2. *Capsule (G)* 3. *Dry Powder Suspension (G)* 4. *Sachet (G)* 5. *Tablet (Psychotropic)* 6. *Oral Liquids* 7. *Capsule (Cephalosporin)* 8. *Dry Powder Inhaler (DPI) (G) Capsule* The Board also decided to seek clarification regarding secondary packaging of *Cephalosporin Injectables*			
15.	M/s Geofman Pharmaceuticals, Plot No. 20, Sector 23, Korangi Industrial Area, Karachi. DML No. 000090 (Formulation) Period: Commencing on 05-03-2021 & ending on 04-03-2026. **Sections (19)** i. Tablet (General) Section. ii. Capsule (General) Section. iii. Liquid Syrup (General) Section iv. Liquid Injectable (General) Section. v. Large Volume Parenteral (General) Section. vi. Nasal Drop Section. vii. Tablet (General Antibiotic) Section. viii. Capsule (General Antibiotic) Section.	**12-07-2021**	**Good**	1) Director DTL, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Ms. Affan Ali, AD CDL, Karachi.

	ix. Dry Syrup (Cephalosporin) Section. x. Capsule (Cephalosporin) Section. xi. Sachet (Cephalosporin) Section. xii. Dry Powder Injectable (Cephalosporin) Section. xiii. Small Volume Parenteral (General)Section xiv. Capsule Pellet Filling (General)Section xv. Injectable (Hormone) Section xvi. Tablet (Penicillin) Section xvii. Capsule (Penicillin) Section xviii. Dry Suspension (Penicillin) Section xix. Cream/Ointment section			

Recommendations of the panel: -

"Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection and vision of the management for export, panel ***recommends*** *the grant of renewal of the Drug Manufacturing License by way of formulation and grant of additional sections as per DRAP letter No. F.2-11/85-Lic-pt (Vol-I), dated 25th June 2021.*

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000090 by way of formulation in the name of M/s Geofman Pharmaceuticals, Plot No. 20, Sector 23, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 05-03-2021 & ending on 04-03-2026 for the following sections:-

Sections (19)

i. Tablet (General) Section.
ii. Capsule (General) Section.
iii. Liquid Syrup (General) Section
iv. Liquid Injectable SVP (General) Section-I.

	v. Liquid Injectable LVP (General) Section.. vi. Nasal Drop Section. vii. Tablet (General Antibiotic) Section. viii. Capsule (General Antibiotic) Section. ix. Dry Suspension (Cephalosporin) Section. x. Capsule (Cephalosporin) Section. xi. Sachet (Cephalosporin) Section. xii. Dry Powder Injectable (Cephalosporin) Section. xiii. Liquid Injectable SVP (General) Section-II. xiv. Capsule Pellet Filling (General)Section xv. Liquid Injectable SVP (Hormone) Section xvi. Tablet (Penicillin) Section xvii. Capsule (Penicillin) Section xviii. Dry Suspension (Penicillin) Section xix. Cream/Ointment section (General)			
16.	M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, Plot No. A-46,S.I.T.E., Karachi. DML No. 000490 (Formulation) Period: Commencing on 01-01-2022& ending on31-12-2026. **Section :** Tablet (Hormone)	**16-08-2021**	**Good**	1) CDI, Govt of Sindh, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Ms. Krishan Das, AD DRAP, Karachi.
	<u>Recommendations of the panel: -</u> "Based on the above stated observations, people met and documents reviewed during the inspection, the panel unanimously recommends that grant of DML No. 000490 by way of formulation for the next five years.. **<u>Decision of the Central Licensing Board in 282nd meeting</u>** The Board considered and approved the grant of renewal of DML No. 000490 by way of formulation in the name of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, Plot No. A-46,S.I.T.E., Karachi on the recommendations of the panel of experts for the period Commencing on 01-01-2022 & ending on 31-12-2026 for the following sections:- **<u>Section (01)</u>** 1. Tablet (Hormone)			

17.	M/s Himedic Pharmaceutical (Pvt) Ltd., 19-Km, Link Multan Road, Lahore. DML No.000824 (Formulation) Period: Commencing on 30-07-2020& ending on 29-07-2025.	03-06-2021	**Good**	1) Dr. IkramUlHaq, Expert Member. 2) Mr.Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3) Ms. UzmaBarkat, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

"The panel of inspectors **recommends** the renewal of DML bearing No.000824 and grant of new manufacturing section in favour of M/s Himedic Pharmaceutical (Pvt) Ltd, Situated at 19 Km, Link Multan Road, Lahore."

i. Dry Powder for Oral Suspension (Cephalosporin).
ii. Capsule (Cephalosporin).
iii. Dry Powder for Injection (Cephalosporin).
iv. Sachet (Cephalosporin) (**New**).

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000824 by way of formulation in the name of M/s Himedic Pharmaceutical (Pvt) Ltd., 19-Km, Link Multan Road, Lahore on the recommendations of the panel of experts for the period Commencing on 30-07-2020& ending on 29-07-2025 for the following sections:-

Section (03)

1. Dry Powder for Oral Suspension (Cephalosporin).
2. Capsule (Cephalosporin).
3. Dry Powder for Injection (Cephalosporin).

18.	M/s Bio-Oxime Pharmaceuticals, Plot No. 31&32, Millat Garment City, Dry Port Road, Faisalabad. DML No. 000812 (Formulation) Period: Commencing on 02-04-2020& ending on 01-04-2025.	**24-02-2021**	**Good**	1) Dr. Farzana Chaudhry, Expert Member. 2) Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3) Mr. Akbar Ali, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

"The panel of inspectors **recommends** the renewal of Drug Manufacturing License bearing No.000812 by way of Formulation (Vet) in respect of below-mentioned sections issued in favour of M/s Bio-oxime Pharmaceuticals, situated at plot No.31 and 32, Millat Garment City, Dry Port

	Road, Faisalabad." i. Oral Powder (General) (Veterinary) Section. ii. Oral Liquid (General) (Veterinary) Section. **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000812 by way of formulation in the name of M/s Bio-Oxime Pharmaceuticals, Plot No. 31&32, Millat Garment City, Dry Port Road, Faisalabad on the recommendations of the panel of experts for the period Commencing on 02-04-2020& ending on 01-04-2025 for the following sections:- **Section (02)** 1. Oral Powder (General) (Veterinary) Section. 2. Oral Liquid (General) (Veterinary) Section.			
19.	M/s Jinnah Pharmaceuticals (Pvt) Ltd, 13-Km Lahore Road, Multan. DML No. 000578 (Formulation) Period: Commencing on 12-05-2020 & ending on11-05-2025.	**17-06-2021**	**Good**	1) Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 2) Mrs. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3) Mr.Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: "Keeping in view the manufacturing facility like building, HVAC System, sanitation, production machinery, equipment in Quality Control and Microbiology Laboratory, testing facilities, technical personnel met and documentation, the panel of inspectors **recommends** the renewal of Drug Manufacturing License by way of formulation for the following sections to M/s Jinnah Pharmaceuticals (Pvt) Ltd, 13-Km Lahore Road, Multan: i. Tablet Section (General) ii. Capsule Section (General) iii. Sachet Section (General) iv. Oral Liquid/ Suspension Section (General) v. Tablet (Psychotropic/Narcotic) Section" **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000578 by way of formulation in the name of M/s Jinnah Pharmaceuticals (Pvt) Ltd, 13-Km Lahore Road, Multan on the recommendations of the panel of experts for the period Commencing on 12-05-2020 & ending on11-05-2025 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated			

	06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*::- **Section (05)** 1. Tablet Section (General) 2. Capsule Section (General) 3. Sachet Section (General) 4. Oral Liquid/ Suspension Section (General) 5. Tablet (Psychotropic/Narcotic) Section			
20.	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan. DML No.000194 (Formulation) Period: Commencing on 29-12-2019& ending on 28-12-2024.	**16-06-2021**	**Good**	1) Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 2) Mrs. Majida Mujahid, Area Federal Inspector of Drugs, DRAP, Lahore. 3) Mr. Abdul Rashid Shaikh, Area Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: Keeping in view the manufacturing facilities like Building, HVAC System, Sanitation, Production Machinery, Equipment, Testing Facilities in Quality Control, Technical Personnel met and documentation, the panel of inspectors **recommends** the renewal of Drug Manufacturing License to M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan by way of formulation for following sections: i. Tablet Section (General) ii. Capsule Section (General) iii. Dry Powder Section iv. Cream / Ointment Section (General/Steroidal) v. Liquid Syrup Section (General) vi. Repacking Section (Liquid/Powder) vii. External Liquid Preparation Section (General). It is pertinent to mention here that as per available record of Licensing Division, firm possess following sections: i. Tablet Section (General) ii. Capsule Section (General) iii. Dry Powder **Suspension (General)** Section iv. Cream / Ointment Section (**General**) v. Liquid Syrup Section (General) vi. Repacking Section (**Liquid**) vii. External Liquid Preparation Section (General). **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000194 by way of formulation in the name of M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan on the recommendations of the panel of experts for the period Commencing on 29-12-2019& ending			

	on 28-12-2024 for the following sections :- **Section (07)** 1. Tablet Section (General) 2. Capsule Section (General) 3. Dry Powder **Suspension (General)** Section 4. Cream / Ointment Section (**General**) 5. Liquid Syrup Section (General) 6. Repacking Section (**Liquid**) 7. External Liquid Preparation Section (General).			
21.	M/s Batala Pharmaceuticals, 23/B, Small Industrial Estate, No.2, NearWapda Town, Khiyali Bypass, Gujranwala. DML No.000477(Formulation) Period: Commencing on 03-06-2020 & ending on 02-06-2025. **Sections (03)** i. Tablet (General) Section. ii. Capsule (General) Section. iii. Cream/Ointment (General) Section.	**14-07-2021**	**Good**	1) Dr. Zaka Ur Rehman COO, PDTRC, Lahore. 2) Ms. Maham Misbah, Assistant Director, DRAP, Lahore 3) Dr. Syed Zia Husnain, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: "Panel inspected the unit and has evaluated various documents in connection with production, Quality Control and Quality Assurance. Various technical aspects were also discussed with the firm management at length. Based on the physical inspection of the unit, evaluation of the documents and discussion with the technical staff, Panel has **recommended** the facility for renewal of Drug manufacturing License of M/s Batala Pharmaceuticals, 23/B, Small Industrial Estate, No.2, Near Wapda Town, Khiyali Bypass, Gujranwala w.e.f. 03-06-2020 to 02-06-2025." **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000477 by way of formulation in the name of M/s Batala Pharmaceuticals, 23/B, Small Industrial Estate, No.2, NearWapda Town, Khiyali Bypass, Gujranwala on the recommendations of the panel of experts for the period Commencing on 03-06-2020 & ending on 02-06-2025 for the following sections :- **Section (03)** 1. Tablet (General) Section. 2. Capsule (General) Section. 3. Cream/Ointment (General) Section.			

22.	M/s Sayyed Pharmaceutical (Pvt) Ltd., Plot No.67/2, Phase-3, Industrial Estate, Hattar. DML No.000697 (Formulation) Tenure: Commencing on 09-09-2020& ending on 08-09-2025	**23-06-2021**	**Good**	i. Mr. Zahid Khan, Chief Drug Inspector, Peshawar. ii. Federal Inspector of Drugs, DRAP, Peshawar. iii. Syed Adnan Ali Shah, AD, DRAP, Peshawar.

Recommendations of the panel:

"Based on documentation reviewed, technical/management people met, materials/processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab and allied facilities, the panel is of the view that he firm is operating at satisfactory level of GMP compliance and unanimously ***recommends grant of renewal of Drug Manufacturing*** *License to the firm from 09.09.2020 for following mentioned nine sections;*

Se	***Name of Section***		***Name of Section***
1.	*Tablet (General)*	*6.*	*Capsule (Cephalosporin)*
2.	*Capsule (General)*	*7.*	*Dry Powder Suspension (Cephalosporin)*
3.	*Dry Powder Suspension (General)*	*8.*	*Dry Powder Injection (Cephalosporin)*
4.	*Liquid Syrup (General)*	*9.*	*Tablet (Psychotropic)*
5.	*Sachet (General)*	----------	

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000578 by way of formulation in the name of M/s Sayyed Pharmaceutical (Pvt) Ltd., Plot No.67/2, Phase-3, Industrial Estate, Hattar on the recommendations of the panel of experts for the period Commencing on 09-09-2020& ending on 08-09-2025 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*::-

Section (09)

1. *Tablet (General)*
2. *Capsule (General)*
3. *Dry Powder Suspension (General)*
4. *Liquid Syrup (General)*
5. *Sachet (General)*
6. *Capsule (Cephalosporin)*
7. *Dry Powder Suspension (Cephalosporin)*
8. *Dry Powder Injection (Cephalosporin)*
9. *Tablet (Psychotropic)*

23.	M/s Astellas Pharmaceutical (Pvt) Ltd., 15-C, Industrial Estate, Hayatabad, Peshawar. DML No.000677 (Formulation) Tenure: Commencing on 19-12-2019& ending on 18-12-2024 <u>Sections</u> 1. Dry Suspension Section (Cephalosporin) **2.** Capsule Section (Cephalosporin) 3. Dry Powder for Injection (Cephalosporin) 4. Ampoule Section (General). 5. Infusion Section (General). 6. Tablet Section (General). 7. Dry Suspension Section (General). **8.** Capsule Section (General). 9. Liquid Syrup Section.(General)	**06-07-2021**	**Good**	i. Prof. Dr. Jamshed Ali Khan, Expert Member. ii. Mr. Saleem Khan, DG (Drug Controller), Khyber PakhtunKhwa. iii. Area Federal Inspector of Drugs, DRAP, Peshawar.

<u>Recommendations of the panel:</u>

"Firm was advised to improve Cleaning validation Protocol.

Firm was advised to Develop SOP (Procedure) for Quality Risk Management.

Firm was advised to Increase Pharmacists in quality Assurance Section.

Another HPLC was also advised for the strengthening of QC Lab.

Based on the areas inspected, the people met, documents reviewed, the intension towards further improvements and the corrective and preventive action taken, the firm is considered to be operating at good level of compliance with cGMP guide lines as per drug act, 1976 and rules framed thereunder.

As per manufacturing/testing equipment installed in the production, quality control, microbial lab, utilities, engineering as well as the cGMP compliance status of the firm the panel ***unanimously recommended the grant of renewal of DML No.000677 by way of formulation."***

<u>Decision of the Central Licensing Board in 282nd meeting</u>

	The Board considered and approved the grant of renewal of DML No. 000677 by way of formulation in the name of M/s Astellas Pharmaceutical (Pvt) Ltd., 15-C, Industrial Estate, Hayatabad, Peshawar on the recommendations of the panel of experts for the period Commencing on 19-12-2019& ending on 18-12-2024 for the following sections:- **Sections (09)** 1. Dry Suspension Section (Cephalosporin) **2.** Capsule Section (Cephalosporin) 3. Dry Powder Injection (Cephalosporin) 4. Ampoule Section (General). 5. Liquid Infusion Section SVP (General). 6. Tablet Section (General). 7. Dry Suspension Section (General). **8.** Capsule Section (General). 9. Liquid Syrup Section.(General)			
24.	M/s MKB Pharmaceutical (Pvt) Ltd., 66-Industrial Estate, Hayatabad, Peshawar. DML No.000617 (Formulation) Tenure: Commencing on 12-04-2017& ending on 11-04-2022. Sections 1. Tablet Section (General). **2.** Capsule Section (General). 3. Dry Powder for Suspension Section (General). 4. Sachet (General) **5.** Capsule Section (Cephalosporin) 6. Dry Suspension Section (Cephalosporin) 7. Liquid Syrup Section.(General)	**05-05-2021** **25-06-2021**	**Good**	i. Prof. Dr. Muhammad Saeed, Faculty of Pharmacy, Peshawar University, Peshawar. ii. Chief Drugs Inspector, KPK, Peshawar. iii. Area Federal Inspector of Drugs, DRAP, Peshawar. iv. Dr. Muhammad Yaqoob Kakar, Assistant Director (Licensing), DRAP, Islamabad. However, panel inspection was conducted by following three members, i. Prof. Dr. Muhammad Saeed, Faculty of Pharmacy, Peshawar University, Peshawar. ii. Chief Drugs Inspector, KPK, Peshawar. iii. Area Federal Inspector of Drugs, DRAP, Peshawar.
	Recommendations of the panel: *"Keeping in view the above, the panel unanimously recommends the grant of renewal of DML No.000617 by way of Formulation to M/s MKB Pharmaceutical (Pvt) Ltd., Hayatabad, Peshawar."* **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000617 by way of			

	formulation in the name of M/s MKB Pharmaceutical (Pvt) Ltd., 66-Industrial Estate, Hayatabad, Peshawar on the recommendations of the panel of experts for the period Commencing on 12-04-2017& ending on 11-04-2022 for the following sections:- **Sections (07)** 1. Tablet Section (General). **2.** Capsule Section (General). 3. Dry Powder for Suspension Section (General). 4. Sachet (General) **5.** Capsule Section (Cephalosporin) 6. Dry Suspension Section (Cephalosporin) 7. Liquid Syrup Section.(General)			
25.	M/s Stanley Pharmaceuticals (Pvt) Ltd, Plot No.84-B, Industrial Estate, Jamrud Road, Peshawar DML No.000434 (Formulation) Tenure: Commencing on 16-06-2019 & ending on 15-06-2024. Sections 1. Table (General/Antibiotic) 2. Capsule (General/Antibiotic) 3. Oral liquid (General)	**03-06-2021**	**Good**	i. Mr. Zahid Khan, CDI, Peshawar. ii. Additional Director (E&M), DRAP, Peshawar. iii. Federal Inspector of Drugs, DRAP, Peshawar.
	Recommendations of the panel: *"Based on the areas inspected, the people met, documents reviewed, the intension towards further improvements and the corrective and preventive action taken, the firm is considered to be operating at good level of compliance with cGMP guide lines as per drug act, 1976 and rules framed there under.* *Keeping in view the above, the panel unanimously recommended the grant of renewal of DML No.000434 by way of formulation to M/s Stanley Pharmaceuticals (Pvt) Ltd., Plot No.84-B, Industrial Estate, Hayatabad, Peshawar."* **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000617 by way of formulation in the name of M/s Stanley Pharmaceuticals (Pvt) Ltd, Plot No.84-B, Industrial Estate, Jamrud Road, Peshawar on the recommendations of the panel of experts for the period Commencing on 16-06-2019 & ending on 15-06-2024 for the following sections:-			

	Sections (03) 1. Table (General/Antibiotic) 2. Capsule (General/Antibiotic) **3.** Oral liquid (General)			
27	M/s Medifine Laboratories (Pvt) Ltd Plot No.A-11, New Industrial Area, **Mirpur, AJ&K** DML No.000672 (Formulation) Tenure: Commencing on 15-10-2019 & ending on 14-10-2024	29-07-2021	**Good**	1) Additional Director (Bio), DRAP, Islamabad. 2) Deputy Director (Lic), DRAP, Islamabad. 3) Federal Inspector of Drugs, DRAP, Islamabad.
	Recommendations of the panel: "Keeping in view the above facts on record and people met during the visit, the panel unanimously recommended the following 2 new/additional **& renewal (of Existing section) of DML No. 000673** (By way of Formulation) of M/s Madifine Laboratories (Pvt). Ltd, Plot No. A-11 new industrial area Mirpur Azad Kashmir. i. Tablet (General) ii. Capsule (General) iii. Tablet (Psychotropic) **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000578 by way of formulation in the name of M/s Medifine Laboratories (Pvt) Ltd Plot No.A-11, New Industrial Area, **Mirpur, AJ&K** on the recommendations of the panel of experts for the period Commencing on 15-10-2019 & ending on 14-10-2024 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*::- **Section (03)** 1. Tablet (General) 2. Capsule (General) 3. Tablet (Psychotropic)			

28	Nortech Pharmaceuticals (Pvt).Ltd. 203, Industrial Triangle, Kahuta Road Islamabad. DML No.000792 (Formulation) Tenure: Commencing on 03-02-2019 & ending on 02-02-2024	15-03-2021 29-04-2021	**Good**	**1. Dr. Hafsa Karam Elahi,** Additional Director (QA&LT-1), DRAP, Islamabad 2. **Ms. Saadia Mahwish**, (Federal Inspector of Drugs-I), DRAP, Islamabad **3. Mr. Abdullah Bangash** Assistant Director (Licensing), DRAP, Islamabad
	Recommendations of the panel: **Recommendations:** Keeping in view the above facts, documents reviewed & the people met during the visit, the panel unanimously **recommended the renewal of Drug Manufacturing License by way of Formulation** of M/s**.** Nortech Pharmaceuticals (Pvt).Ltd.203, Industrial Triangle, Kahuta Road Islamabad for the following sections 1. Tablet (General) 2. Capsule (General) 3. Ointment/Cream/Gel (Non-Steroidal) 4. Dry Powder Suspension (General) 5. Ampoule/Vial (General Liquid SVP) **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000792 by way of formulation in the name of Nortech Pharmaceuticals (Pvt).Ltd. 203, Industrial Triangle, Kahuta Road Islamabad on the recommendations of the panel of experts for the period Commencing on 03-02-2019 & ending on 02-02-2024 for the following sections:- **Section (05)** 1. Tablet (General) 2. Capsule (General) 3. Ointment/Cream/Gel (Non-Steroidal) 4. Dry Powder Suspension (General) 5. Liquid Injectable Ampoule/Vial SVP (General)			
29	M/s Glitz Pharma Plot No.265 Industrial Triangle, Kahuta Road, Islamabad, Pakistan.	17-06-2021	**Good**	1-Additional Director (Biological Drugs) DRAP, Islamabad. 2-Area FID, DRAP, Islamabad. 3-Mr Abdullah Bangash, Assistant

	DML No.000571 (Formulation) Tenure: Commencing on 13-05-2020 & ending on 12-05-2025			Director (Licensing) DRAP, Islamabad.
	Recommendations: Keeping in view the above facts, documents reviewed & the people met during the visit, the panel unanimously recommended i**) the renewal of Drug Manufacturing License by way of Formulation ii)** regularization of sections iii) revision/Amendment of sections iv) grant of additional sections of M/s Glitz Pharma Plot# 265, Industrial Triangle, Kahuta Road Islamabad DML# 000571 for the following sections **A. Renewal of Sections** **1.** Tablet (Psychotropic) Section **<u>Decision of the Central Licensing Board in 282nd meeting</u>** The Board considered and approved the grant of renewal of DML No. 000792 by way of formulation in the name of M/s M/s Glitz Pharma, Plot No.265 Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the period Commencing on 13-05-2020 & ending on 12-05-2025 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*::-:- **<u>Section (01)</u>** **1.** Tablet (Psychotropic) Section			
30	Bio-Labs (Pvt.) Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad. DML No.000296 (Formulation) Tenure: Commencing on 05-10-2019 & ending on 04-10-2024	08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021	**Good**	1. **Mr. Akhtar Abbas Sb.** (Add. Dir. (QA/LT) HQ DRAP) 2. **Ms. Saadia Mahwish** (Area FID, DRAP, Islamabad) **3. Mr. Abdullah Bangash**, (AD, DRAP, Islamabad)
	Recommendations: Keeping in view the above facts, documents reviewed & the people met during the visit, the panel			

unanimously recommended i) **the renewal of Drug Manufacturing License by way of Formulation** ii)regularization of layout plan iii) grant of additional section as well as changes in section of M/s Bio-Labs (Pvt) Ltd 145, Industrial Triangle, Kahuta Road Islamabad DML# 000296 for the following sections

A. Human Pharmaceuticals:

1. Oral Liquid Syrup (General) Section
2. Tablet Psychotropic Section
3. Tablet (General/Antibiotic) Section
4. Capsule (General) Section
5. Liquid Ampoule (General) Section
6. Liquid Infusion 100ml (General) Section
7. Lyophilized Vial (General) Section
8. Oral Dry Powder Suspension (General) Section
9. Capsule (Cephalosporin) Section
10. Oral Dry Powder Suspension (Cephalosporin) Section
11. Dry Powder Injection (Cephalosporin) Section
12. Quality Control Lab (changes)

B. Veterinary Pharmaceuticals:

1. Oral Liquid Section (General) Liquid Injection (General)
2. Dry Powder Injection (Penicillin Section)
3. Oral Dry Powder (Penicillin Section)
4. Liquid Injection (Penicillin Section)

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000296 by way of formulation in the name of M/s Bio-Labs (Pvt.) Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the period Commencing on 05-10-2019 & ending on 04-10-2024 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*:-

Section (16)

C. Human Pharmaceuticals:

1. Oral Liquid Syrup (General) Section
2. Tablet (Psychotropic) Section
3. Tablet (General) Section
4. Capsule (General) Section
5. Liquid Ampoule (General) Section
6. Liquid Infusion SVP (General) Section

	7. Lyophilized Vial (General) Section **8.** Oral Dry Powder Suspension (General) Section **9.** Capsule (Cephalosporin) Section **10.** Oral Dry Powder Suspension (Cephalosporin) Section **11.** Dry Powder Injection (Cephalosporin) Section **D. Veterinary Pharmaceuticals:** **1.** Oral Liquid Section (General) Liquid Injection (General) **2.** Dry Powder Injection (Penicillin Section) **3.** Oral Dry Powder (Penicillin Section) **4.** Liquid Injection (Penicillin Section)			
31	M/s Medicraft Pharmaceuticals (Pvt) Ltd, 126-B, Hayatabad Industrial Estate, Peshawar DML No. 000390 (Formulation) Tenure: Commencing on 05-10-2019 & ending on 04-10-2024	22-04-2021	**Good**	1. Prof. Dr. Jamshed Ali Khan, Department of Pharmacy, Peshawar University, Peshawar (Expert Member) 2. Dr. Muhammad Abbas, Chief Drug Inspector Khyber Pakhtun Khwa, Peshawar; 3. Mr. Atiq Ul Bari, Area Federal Inspector of Drugs, DRAP, Peshawar
	<u>Conclusion:</u> Based on the areas inspected, the people met, documents reviewed, the intension towards further improvements and the corrective and preventive action taken, the firm is considered to be operating at good level of compliance with cGMP guide lines as per drug act, 1976 and rules framed there under. As per manufacturing / testing equipment installed in the production, quality control, microbial labs, utilities, engineering as well as the cGMP compliance status of the firm, the panel unanimously **<u>recommended the grant of renewal of DML No. 000390</u>** by way of formulation. The firm informed that they would make changes in the lay out plan with the approval of Licensing Division DRAP Islamabad and requested to defer the inspection of following newly established section. (i) Sachet Section (Cephalosporin) Detailed observations are also recorded on prescribed Performa for renewal of DML. 1. Tablet (General) 2. Tablet (Psychotropic) 3. Capsule (General)			

	4. Dry Powder Suspension (General) 5. Liquid syrup (General) 6. Ampoule/ Infusion Microdose (General) 7. Injection (Psychotropic) 8. Dry Powder Injection (Cephalosporin) 9. Capsule (Cephalosporin) 10. Dry Powder Suspension (Cephalosporin) 11. Dry Powder Injection(Carbapenem) **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000390 by way of formulation in the name of M/s Medicraft Pharmaceuticals (Pvt) Ltd, 126-B, Hayatabad Industrial Estate, Peshawar on the recommendations of the panel of experts for the period Commencing on 05-10-2019 & ending on 04-10-2024 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*:- **Section (11)** 1. Tablet (General) 2. Tablet (Psychotropic) 3. Capsule (General) 4. Dry Powder Suspension (General) 5. Liquid syrup (General) 6. Liquid Ampoule/ Infusion SVP (General) 7. Injection (Psychotropic) 8. Dry Powder Injection (Cephalosporin) 9. Capsule (Cephalosporin) 10. Dry Powder Suspension (Cephalosporin) 11. Dry Powder Injection(Carbapenem)			
32.	M/s Bajwa Pharmaceuticals (Pvt) Ltd, 36-Km, Lahore Gujranwala Road, Khori, District Sheikhupura. DML No. 000805 (Formulation). Period: Commencing on 02-12-	**08-06-2021**	**Good**	1) Dr. Ikram Ul Haq, Expert Member. 2) Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 3) Mr. Ajmal Sohail Asif,

	2019 & ending on 01-12-2024.			Federal Inspector of Drugs, DRAP, Lahore.

Recommendations of the panel:

"The panel of inspectors **recommend**s the renewal of DML bearing No. 000805 issued in favor of M/s Bajwa Pharmaceuticals (Pvt) Ltd., in respect to already existing/approved section i.e. Liquid Injectable Ampoule (General), however, the panel **did not recommend** the grant of new additional section i.e. Liquid Injectable vial (General) on the basis of observations made in report."

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000805 by way of formulation in the name of M/s Bajwa Pharmaceuticals (Pvt) Ltd, 36-Km, Lahore Gujranwala Road, Khori, District Sheikhupura on the recommendations of the panel of experts for the period Commencing on 02-12-2019 & ending on 01-12-2024 for the following section:-

Section (01)

1. Liquid Injectable Ampoule (General),

33	M/s ICI Pakistan Limited S-33, Hawkes Bay Road, Karachi. DML No. 000006 (Formulation) **Tenure :** Period: Commencing on 31-03-2020& ending on 30-03-2025.	**23-08-2021**	**Good**	1) CDI, Govt of Sindh. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) M. Awais Ahmed, AD, CDL, Karachi.

Recommendations of the panel:

"Keeping in view overall GMP compliance and positive intention towards improvement, Panel unanimously recommend the renewal of (DML No. 000006) by way of formulation to the firm M/s ICI Pakistan Ltd, Karachi for the following sections.:

1. Tablet (General)
2. Liquid Syrup (General)
3. Packaging Material Store
4. Quality Control Laboratory
5. Finished Good Store (Newly Established)

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of renewal of DML No. 000006 by way of formulation in the name of M/s ICI Pakistan Limited S-33, Hawkes Bay Road, Karachi on the recommendations of the panel of experts for the period Commencing on 31-03-2020& ending on 30-03-2025 for the following section:-

	Sections (2) 1. Tablet (General) 2. Liquid Syrup (General)			
34	M/s Alza Pharmaceuticals, Alshifa Trust Eye Hospital, Jhelum Road, Rawalpindi. DML No.000423 (Formulation) Period: Commencing on 11-08-2020 & ending on 10-08-2025.	**08-03-2021**	**Good**	1) Dr. Hafsa Karam Elahi, Additional Director (QA/LT), DRAP, Islamabad. 2) Mr. Malik Muhammad Asad, Deputy Director (Licensing), DRAP, Islamabad. 3) Mr. Khalid Mahmood, Area Federal Inspector of Drugs, Islamabad.
	Recommendations of the panel: Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the Panel unanimously **recommends** M/s Alza Pharmaceuticals, Alshifa Trust Eye Hospital, Jhelum Road, Rawalpindi under DML No.000423 as of today as per mandate given vide letter No.F.1-16/1995-Lic for following existing sections namely: i. Eye Drops (Steroidal) ii. Skin cream/Ointment (Steroidal) iii. Ophthalmic Drops (General) iv. Cream/Ointment/Gel (General). **Decision of the Central Licensing Board in 282nd meeting** The Board considered and approved the grant of renewal of DML No. 000423 by way of formulation in the name of M/s Alza Pharmaceuticals, Alshifa Trust Eye Hospital, Jhelum Road, Rawalpindi on the recommendations of the panel of experts for the period Commencing on 11-08-2020 & ending on 10-08-2025 for the following section:- **Sections (2)** 1. Eye Drops (Steroidal) 2. Skin cream/Ointment (Steroidal) 3. Ophthalmic Drops (General) 4. Cream/Ointment/Gel (General).			
35	M/s Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, National Industrial Zone, Rawat DML No.000625 (Formulation) Period: Commencing on 25-09-2017 ending on 24-09-2022.	**05-07-2021** **&** **26-08-2021**	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QALT), DRAP, Islamabad. 2. Mr. Babar Khan, Federal Inspector of Drugs-III, DRAP, Islamabad. 3. Ms. Haleema Sharif, Assistant Director, DRAP,

	(Sections-09): i. Dry Powder Suspension (General). ii. Liquid Ampoule (General). iii. Tablet (General). iv. Dry Powder Suspension (Cephalosporin). v. Cream / Ointment (General). vi. Small Volume Parenteral. vii. Capsule (General). viii. Capsule (Cephalosporin). ix. Dry Powder Injection (Cephalosporin).			Islamabad.

Recommendations of the Panel:

"Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the approval of renewal of (DML # 000625 by way of Formulation) of M/s Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, National Industrial Zone, Rawat with following approved sections:

1. Dry Powder Suspension (General).
2. Liquid Ampoule (General).
3. Tablet (General).
4. Dry Powder Suspension (Cephalosporin).
5. Cream / Ointment (General).
6. Small Volume Parenteral.
7. Capsule (General).
8. Capsule (Cephalosporin).
9. Dry Powder Injection (Cephalosporin).

ase is hereby submitted for consideration and orders of the Board, please.

Decision of the Central Licensing Board in 282nd meeting

Board considered and approved the grant of renewal of DML No. 000625 by way of formulation in the name of M/ Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period Commencing on 25-09-2017 & ending on 24-09-2022 for the following section:-

Section (10)

1. Dry Powder Suspension (General).
2. Liquid Ampoule (General).
3. Tablet (General).
4. Dry Powder Suspension (Cephalosporin).
5. Cream / Ointment (General).
6. Small Volume Parenteral.

	7. Capsule (General). 8. Capsule (Cephalosporin). 9. Dry Powder Injection (Cephalosporin).

Item-IV: **MISCELLANEOUS CASES.**

Case No.01 REGULARIZATION OF LAYOUT PLAN OF M/S SANTE (PVT) LIMITED, A-79, S.I.T.E SUPER HIGHWAY, KARACHI.

M/s Sante (Pvt) Ltd, Plot No. A-97, S.I.T.E Super Highway, Karachi. Under DML No.000702 (Formulation) had applied for regularization of layout plan of running facility for their existing sections. Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1) Professor Rafiq Ala, Expert Member.
2) Federal Inspector of Drugs, DRAP, Karachi.
3) Mr. Krishan Das, AD, DRAP, Karachi.

Accordingly, Panel has inspected the premises and verified the below mentioned section.

Recommendations of the panel:

"Based on the stated observations and attitude of the management towards constant improvements the panel unanimously recommends the grant of renewal of DML No. 000702 (Formulation) for the next five years for following sections and also recommends the regularization of current layout plan:"

i. Tablet (G)
ii. Capsule (G)
iii. Sterile Ophthalmic Drops (G)
iv. Ear/Nasal Drops (G)
v. Cream/Ointment (G)

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the regularization of lay out plan in the name of M/s Sante (Pvt) Ltd, Plot No. A-97, S.I.T.E Super Highway, Karachi under DML No.000702 (Formulation) on the recommendation of panel of experts for the following sections:-

Sections (05)

1. Tablet (G)
2. Capsule (G)
3. Sterile Ophthalmic Drops (G)

4. Ear/Nasal Drops (G)
5. Cream/Ointment (G)

Case No.02 REGULARIZATION OF LAYOUT PLAN OF M/S HIGH-Q PHARMACEUTICALS, PLOT NO. 224 & 225/1, KORANGI INDUSTRIAL AREA, KARACHI.

M/s High-Q Pharmaceuticals, Plot No. 224 & 225/1, Korangi Industrial Area, Karachi. Under DML No.000597 (Formulation) had applied for regularization of layout plan of running facility for their existing sections. Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1) Dr. Abdullah Dayo, Expert Member.
2) Federal Inspector of Drugs, DRAP, Karachi.
3) Ms. SanamKausar, AD, DRAP, Karachi.

Accordingly, Panel has inspected the premises and verified the below mentioned section.

Recommendations of the panel:

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection and vision of the management for exports, panel recommends the grant of renewal of the Drug Manufacturing License by way of formulation and regularization of the Layout for the below mentioned sections:

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet-I (General)	2.	Capsule (General)
3.	Tablet-II (General)	4.	Tablet (Psychotropic)
5.	Liquid Syrup (General)	6.	Sachet (General)
7.	Quality Control Laboratory	8.	Ware House (General)
9.	Product Development Laboratory	10.	Ware House (Cephalosporin)
11.	Dry Powder Suspension (Cephalosporin)	12.	Capsule (Cephalosporin)
13.	Dry Powder Injectable (Cephalosporin)	14.	Dry Powder Suspension (General)
15.	Dry Powder Injection (Carbapenem)	--	**********

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the regularization of lay out plan in the name of M/s High-Q Pharmaceuticals, Plot No. 224 & 225/1, Korangi Industrial Area, Karachi under DML No.000597 (Formulation) on the recommendation of panel of experts for the following sections:-

Sections (15)

Sr #	Name of Section	Sr. #	Name of Section

1.	Tablet-I (General)	2.	Capsule (General)
3.	Tablet-II (General)	4.	Tablet (Psychotropic)
5.	Liquid Syrup (General)	6.	Sachet (General)
7.	Quality Control Laboratory	8.	Ware House (General)
9.	Product Development Laboratory	10.	Ware House (Cephalosporin)
11.	Dry Powder Suspension (Cephalosporin)	12.	Capsule (Cephalosporin)
13.	Dry Powder Injectable (Cephalosporin)	14.	Dry Powder Suspension (General)
15.	Dry Powder Injection (Carbapenem)	--	**********

Case No.03. <u>REGULARIZATION OF LAYOUT PLAN OF M/S S.J & G FAZUL ELLAHIE (PVT) LIMITED, F-46, S.I.T.E KARACHI UNDER DML NO. 000083 (FORMULATION).</u>

M/s S.J& G FazulEllahie (Pvt) Ltd, F/46, S.I.T.E Karachi. under DML No.000083 (Formulation) had applied for regularization of layout plan of running facility for their existing sections. Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1) Dr. Abdullah Dayo, Expert Member.
2) CDI, Govt of Sindh.
3) Federal Inspector of Drugs, DRAP, Karachi.

Accordingly, Panel has inspected the premises and verified the below mentioned section.

<u>Recommendations of the panel:</u>

"During inspection panel reviewed documents and SOPs relating to QA System like organogram, JDs of working personnel, vendor qualification system, VMP, self-audit, market complaint, Control mechanism etc. The panel found good compliance in documentation practices. The panel physically inspected their manufacturing, QC lab and storage facilities. The firm has adequate machineries in all approved production sections. In QC lab adequate equipment are given, necessary log books and calibration plan for every equipment, was in place.

Keeping in view the above stated facts, documents reviewed, personnel met and attitude of the management towards constant improvements the panel unanimously recommends the regularization of the layout plan and renewal of DML N0.000083 (Formulation) of M/s S.J & G FazulEllahie (Pvt) Ltd for the following section.

1. Tablet (General), 2. Capsule (Cephalosporin), 3. Capsule (General) 4. Dry Powder Suspension (Cephalosporin) 5. Ointment/Cream/Gel (General), 6. Dry Powder Injectable (Cephalosporin), 7. Dry Powder Suspension (General), 8. Oral Liquid (Syrup /suspension General) 9. Warehouse (General) 10. liquid injectable ampoule, vial & infusion, 11. Tablet (Cephalosporin),12. Lyophilization (sterile area) 13. Oral liquid veterinary (General), 14. Dry powder injectable (general), 15. Oral powder veterinary (General), 16. Tablet (veterinary) 17. Dry powder

injectable (Carbapenum) 18. Liquid injectable (veterinary), 19. Quality control 20. Warehouse (Cephalosporin), 21. warehouse (veterinary)

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the regularization of lay out plan in the name of M/s S.J& G FazulEllahie (Pvt) Ltd, F/46, S.I.T.E Karachi under DML No.000083 (Formulation) on the recommendation of panel of experts for the following sections:-

Sections (17)

1. Tablet (General)
2. Capsule (Cephalosporin),
3. Capsule (General)
4. Dry Powder Suspension (Cephalosporin)
5. Ointment/Cream/Gel (General),
6. Dry Powder Injectable (Cephalosporin),
7. Dry Powder Suspension (General),
8. Oral Liquid (Syrup /suspension General)
9. liquid injectable ampoule, vial & infusion,
10. Tablet (Cephalosporin),
11. Dry Powder Injection (Lyophilized) (sterile area)
12. Oral liquid veterinary (General),
13. Dry powder injectable (General),
14. Oral powder veterinary (General),
15. Tablet (veterinary)
16. Dry powder injectable (Carbapenem)
17. Liquid injectable (veterinary),

CASE NO. 4 GLITZ PHARMA, PLOT NO.265 INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD, PAKISTAN.

Glitz Pharma, Plot No.265 Industrial Triangle, Kahuta Road, Islamabad, Pakistan.. DML No. 000571 (Formulation) had applied for regularization of layout plan of running facility for their existing sections. Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1-Additional Director (Biological Drugs) DRAP, Islamabad.

2-Area FID, DRAP, Islamabad.

3-Mr Abdullah Bangash, Assistant Director (Licensing) DRAP, Islamabad.

Accordingly, Panel has inspected the premises and verified the below mentioned section.

Recommendations of the panel:

Keeping in view the above facts, documents reviewed & the people met during the visit, the panel unanimously recommended i) the renewal of Drug Manufacturing License by way of Formulation ii**) regularization of sections** iii) revision/Amendment of sections iv) grant of

additional sections of M/s Glitz Pharma Plot# 265, Industrial Triangle, Kahuta Road Islamabad DML# 000571 for the following sections

A. Regularization of Section

1. Liquid Syrup/Suspension (General) Section
2. Ointment/cream/Gel/Lotion (General) Section
3. Tablet (General) Section
4. Tablet (Antibiotic) Section
5. Dry Powder for Injection (Cephalosporin) Section
6. Dry Powder Suspension (Cephalosporin) Section
7. Capsule (Cephalosporin) Section
8. Capsule (General) Section
9. Dry powder/Sachet (General) Section

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the regularization of lay out plan in the name of Glitz Pharma, Plot No.265 Industrial Triangle, Kahuta Road, Islamabad, Pakistan.. DML No. 000571 (Formulation) on the recommendation of panel of experts for the following sections:-

Sections (09)

1. Liquid Syrup/Suspension (General) Section
2. Ointment/cream/Gel/Lotion (General) Section
3. Tablet (General) Section
4. Tablet (Antibiotic) Section
5. Dry Powder for Injection (Cephalosporin) Section
6. Dry Powder Suspension (Cephalosporin) Section
7. Capsule (Cephalosporin) Section
8. Capsule (General) Section
9. Dry powder/Sachet (General) Section

Case No. 5 BIO-LABS (PVT.) LTD. PLOT # 145, INDUSTRIAL TRIANGLE,KAHUTA ROAD, ISLAMABAD..

Bio-Labs (Pvt.) Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000296 (Formulation) had applied for regularization of layout plan of running facility for their existing sections. Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1. Mr. Akhtar Abbas (Add. Dir. (QA/LT) HQ DRAP)
2. Ms. Saadia Mahwish (Area FID, DRAP, Islamabad)
3. Mr. Abdullah Bangash, (AD, DRAP, Islamabad)

Accordingly, Panel has inspected the premises and verified the below mentioned section.

Recommendations of the panel:

Recommendations:

Keeping in view the above facts, documents reviewed & the people met during the visit, the panel unanimously recommended i) the renewal of Drug Manufacturing License by way of Formulation **ii)regularization of layout plan** iii) grant of additional section as well as changes in section of M/s Bio-Labs (Pvt) Ltd 145, Industrial Triangle, Kahuta Road Islamabad DML# 000296 for the following sections

1. Oral Liquid Section (General) (regularization of section)
2. Oral Dry Powder Section (Veterinary) (Regularization of Section)

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the regularization of lay out plan in the name of M/s Bio-Labs (Pvt.) Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000296 (Formulation) on the recommendation of panel of experts for the following sections:-

Sections (02)

1. Oral Liquid Section (General)
2. Oral Dry Powder Section (Veterinary)

CASE NO. 6 SITE VERIFICAATION AND SITE APPROVAL OF M/S SHARQ PHARMA,

M/s Sharq Pharma, **Plot No. Na Class No. 119, Deh Tore, TapoKonkar, Gadap Town, District Malir (Off Main Super highway at M9 Toll Plaza adjacent Agility Ware House) Karachi** submitted application for site verification of proposed plot. After application was completed by the firm, area FID was requested to conduct site inspection of proposed plot and submit report regarding suitability of plot for establishment of pharmaceutical unit.
The FID submitted inspection report which is reproduced below :

1. The purposed site is situated at Plot No. Na Class No. 119, Deh Tore, TapoKonkar, Gadap Town, District Malir (Off Main super Highway M9 Tall Plaza), Karachi and measuring about 04.00 Acres, which will be utilized for industrial purpose as per Mukhttiarkar, Malir letter No. 184/2021 dated 28-01-2021(Annexure-A).
2. This is open land with a boundary wall and no construction work was seen inside the plot.
3. The plot surrounded by a warehouse form South; A Madarsa from North: an open plot from East and A wide road form West.
4. The said plot is termed as non-classified and is open to be used for any purpose. However, the firm has got it converted for industrial purpose after obtaining necessary conversion certificate from respective revenue office (copy attached).

5. The plot will be provided with necessary utilities from respective departments upon request.
6. Based on the above observation, the plot may be considered for the establishment of a pharmaceutical unit as it qualified the provision as laid down under paragraph-1 of Section 1 of Schedule B SRO.470(1)98 darted 15-05-1998) under Rule 15(a) and 16(a) of Drugs (Licensing, Registration & Advertising) Rules 1976 of Drug Act, 1976.

After the evaluation of the submitted report, the FID was requested to submit site inspection report with clear and candid recommendations regarding suitability of site for establishment of pharmaceutical unit.

In reply the FID Mr. Abdul Rasool Sheikh forwarded the site inspection report the contents of which are reproduced below :

> *"In continuation to this office letter of even number dated 18th February, 2021 regarding the above cited subject wherein, the true picture and location of the proposed plot was mentioned. The site seems unfit for the establishment of a pharmaceutical unit as it is surrounded by un-classified plots from three sides, which may be critical in future if the same are used other than industrial purposed.*
>
> *The subject plot* ***does not comply the provision as laid down under paragraph****-1 of Section1 of Schedule-B SRO.470(I)/98 dated 15-05-1998) under Rule 15(a) and 16(a) of Drugs (Licensing, Registering & Advertising) Rules 1976 of Drug Act, 1976, hence considered not suitable for establishment of pharmaceutical unit.*
>
> *Submitted for your kind information and further necessary action as per rules, please."*

Submitted for consideration of the Board, please.

Decision of the Central Licensing Board in 280th meeting

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to the firm Sharq Pharma in the upcoming meeting of the CLB, please.
The firm is also called for Personal Hearing vide letter dated 17th August 2021.
The case is submitted for consideration of the board.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr. Iqbal Riffat, General Manager appeared before the Board that plotting was made by the Government long time ago and plot of different sizes were allotted to the allottees. Some of allottees ahave established long units like a big industrial unit of agility is nearby. He further argued that there is madrsah on one plot which is not so near. He further argued that plot is located in industrial area, however on the address mentioned in site verification application lacking industrial aspect. He argued that they have leeter of allotment wherein it is mentioned that industrial polt is mentioned. He further submitted that panel of two members may be constituted to verify the site in the light of documents supporting industrial nature of the plot. The Board after hearing the representative of the firm decided to inspection of site verifivation by the following panel in the light of additional documents.

1. Additional director (E&M), DRAP, Karachi
2. Federal Inspector of Drugs, DRAP, Karachi

CASE NO. 7. <u>RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000034 (FORMULATION) OF M/s MEDICURE LABORATORIES, KARACHI.</u>

M/s Medicure Laboratories, Plot No. F/109, Hub River Road, S.I.T.E, Karachi had applied for renewal of DML No. 000034 by way of Formulation for the period of 30-04-2020 to 29-04-2025on 24-04-2020. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 11th August , 2020under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Application for renewal of DML on Prescribed Form-1A dully signed and stamped by management of the firm along with dully attested all annexures and also submit dully retained fee challan by STO DRAP, Islamabad.

No reply was received from the firm and a reminder letter dated 28th January 2021 was issued to the firm for submission of above mentioned documents for completion of application for renewal of DML.
No reply is received from the firm as of today and the application for renewal of DML No. 000034 (Formulation) is still deficient of above mentioned documents.

<u>Decision of the Central Licensing Board in 280th meeting</u>

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000034 (by way of formulation) of M/s Medicure Laboratories, Plot No. F/109, Hub River Road, S.I.T.E, Karachi may not be suspended or cancelled by the Central Licensing Board.

In compliance to the decision of the CLB show cause notice dated 11th June 2021 was issued to the firm.
In reply to the show cause notice, the firm submitted documents for completion of application for renewal of DML No. 000034 (Formulation) and also applied for change/approval of Production in charge Mr. Zafar Abbas and Quality Control In charge Mr. Jamal Akbar.
The documents were evaluated and the application for renewal of DML No. 000034 (Formulation) for the tenure **commencing on 30-04-2020& ending on 29-04-2025** is still found deficient of following documents :

i. All attested annexure/enclosure of Form-1A i.e, Nothing due certificate regarding CRF from STO (Updated), Detail of management, if any change, apply for change of management, detail of machinery in Production, Equipments in Quality Control, Detail of premises (section approval letters) etc.

i. Detail Mark Certificate of proposed QC In charge of Mr. Jamal Akbar.
ii. Undertaking on stamp paper signed by both management/director of firm & by Production in charge and QC In charge respectively regarding whole time employment.

In the meanwhile, panel inspection report of the inspection conducted by Mr. Sajjad Ahmed Abbasi FID Karachi, Mr. Abdul Rasool Sheikh FID Karachi and Mr. Awais Ahmed AD Karachi is also received from Quality Control Division DRAP Islamabad and reproduced as below :

Complaint No. SD 120120-6301211

Nature of Complaint : The firm offers huge amount as giving bribe to regulators for hiding their irregularities , illegalities and wrong practices.

Findings of Investigation :

. The firm is holding a valid DML No. 000034 (formulation) issued by DRAP Islamabad vide Letter No. F.2-28/84-Lic (Vol-IV) dated 5th July 2019 as the above given addres.

. The firm has manufacturing facilities for certain human and veterinary drugs.

. During physical inspection the panel observed static production conditions in pharmaceutical sections.

. Inside the premises the firm had separate lock and seal warehouse for storage of denatured spirit . Firm was asked to open those for verification but they seemed reluctant to open as the keys were with Excise area inspector. However, upon inquiry firm informed that firm is holding another valid license at the same premises for commercial selling of spirit/alcohol issued by Excise & Taxation department Government of Sindh.

. Sale and purchase records in this connection were seen and taken from the management.

. Later on, Mr. Hakim Masood Area FID was asked to join the panel to help in verification/ investigation in the subject matter. He was requested to verify the above mentioned observations as an area FID but he informed that he was un-aware about the commercial license possessed by the firm for selling alcohol.

. During investigation and discussion with management of the firm the panel could not find any material evidence in support of the said complaint.

. Panel is of the opinion that the firm can not keep both the licenses at the same premises as it seems violation of conditions of license and respective schedule specified under Drugs Act 1976 and Drugs (L,R&A) Rules, 1976.

Recommendations :

Keeping in view the above stated facts the firm was found involved in the un-authorized stocking/sale of spirit/Alchol for commercial purposes at the same DML facility which seems sheer violation of the Drugs Act, 1976 & Rules framed there under. In view of the above, the panel unanimously recommends the cancellation of their DML No. 000034 (Formulation) in larger public interest.

The firm is called for personal hearing vide letter dated 17th August 2021.

Submitted for Consideration of the Board, please.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr. Shabbir Shah, CEO and Dr. Fatima Sultan, GM Operations appeared before the Board. He contended that after the demise of his father he had short of resources. They contended that thye are striving hard to run the factory. He further stated that they got sucession certificate and time is required for preparation of legal documents. He also stated that they have also submitted documents for issuance of NOC for CRF.

On a querry, he also stated that they had permission from Excise and Taxation Department, Government of Sindh for selling of denatured spirit which they purchase from Habib Sugar Mills, Nawabshah. He further narrated names of leading pharmaceutical companies as client for denatured spirit.

The Board considering the facts on the record and after thread bare deliberation decided to cancel the Drug Manufacturing License No 000034 (by way of formulation) of M/s Medicure Laboratories, Plot No. F/109, Hub River Road, S.I.T.E, Karachi under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for carrying unauthorized and illegal commercial acitivity and not complying the provision of Rule, 5, Rule 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976

CASE NO. 8 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000116 (FORMULATION) OF M/S ZUMARS PHARMA FTY (PVT) LTD, 02-MALIR INDUSTRIAL AREA, KARACHI

M/s. Zumars Pharma FTY. (Pvt) Ltd, Karachi submitted application for renewal of DML No. 000116 (Formulation) for the tenure commencing on 24-08-2020 and ending on 23-08-2025. The application was evaluated and a letter dated 05-10-2020 was issued to the firm to submit following documents for completion of application for renewal of DML.

i. Detail of licensed sections on firm's letter head along with approval lettersissued from the CLB or if not available then submit layout plan for regularization of manufacturing facility.
ii. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
iii. Prescribed fee for change of management (if the management is changed from the last renewal of DML).
iv. Name & approval letters of production In charge Mr. Altaf Ali Sahito& Quality Control In chargeMr. Mukhtiar Ali or if not available then submit complete set of attested documents (as per checklist).
v. Updated NOC of CRF issued from statistical officer DRAP.

The firm submitted reply/documents on 09-12-2020 which were evaluated and after evaluation Reminder **dated 04-01-2021** was issued to the firm to submit following documents:

i. Detail / names of licensed sections as per dosage forms on firm's letter head.
ii. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
iii. Prescribed fee for change of management (if the management is changed from the last renewal of DML).
iv. Submit complete set of attested documents (as per checklist) for approval of production in charge and QC In charge.
v. Updated NOC of CRF issued from statistical officer DRAP.

In reply to reminder firm has only submitted documents of QC Incharge which are evaluated and following documents are found still found deficient and application for renewal of DML is still deficient of following documents:

i. Detail / names of licensed sections as per dosage forms on firm's letter head.
ii. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
iii. Prescribed fee for change of management (if the management is changed from the last renewal of DML).
iv. Submit complete set of attested documents (as per checklist) for approval of production in charge.
v. Updated NOC of CRF issued from statistical officer DRAP.
vi. Relevant experience certificates of proposed QC In charge.
vii. Resignation / retirement/Deathof earlier QC In charge.
viii. Job acceptance letter by the proposed QC In charge.
ix. Resignation or termination letter of QC Incahrge from the previous firm / promotion letter / transfer letter from the same firm.
x. Undertaking as whole time employee of proposed QC In charge.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) & Rule 16 and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000116 (by way of formulation) of M/s. Zumars Pharma FTY. (Pvt) Ltd, Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML under Rule 5(2A) may not be rejected.

The show cause notice dated 12th March 2021 was issued to the firm. The reply of the show cause notice was received from the firm and the documents submitted by the firm in reply to show cause notice dated 12th March 2021 **are evaluated and the application for renewal of DML is still found deficient of following documents:**

i. Updated (Original) Certified True Copy of Form-29 & Form-A issued from SECP.
ii. Updated NDC of CRF issued from statistical officer, DRAP
iii. Details of all licensed sections as per dosage form on firm's letter head.
iv. Relevant experience certificates of Proposed QC Incharge Mr. Liaqat Mugheri.
v. Resignation of previous QC In charge.

vi. Prescribed fee for change of Production In charge Mr. Altaf Hussain.
vii. Attested documents of proposed Production In charge including notarized
viii. Undertaking signed by the appointee and the management of the firm.

The firm is also called for personal hearing vide letter dated 13th April 2021.

Proceedings and Decision of Central Licensing Board in 256th meeting.

Mr. Muhammad Yaseen Director of the firm appeared before the Board. He contended that there the required documents are submitted to the Division of Licensing. The documents were received on the day of meeting 26-04-2021. The Board after perusal of record and facts mentioned above and deliberations made by representative of the firm decided to defer the case till next meeting of the CLB to check compliance of the firm in the light of submitted documents.

The firm also submitted documents for completion of application for renewal of DML No. 000116 (formulation) **in response to show cause notice**which were evaluated and the application for renewal of DML is still found deficient of following documents:

i. Updated Original Certified True Copy of Form-29 & Form-A issued by SECP.
ii. Approval letters of licensed sections namely Tablet (Psychotropic), Tablet (Antibiotic), Liquid External Preparation, External preparation (Powder), Oral Vitamin Powder (Vet) **[The names /detail of the licensed sections is mentioned by the firm on letter head Page 188/Corr& approval letter of licensed sections is present at Page 38/Corr]** .
iii. Relevant experience certificates of Proposed QC In charge Mr. Liaqat Mugheri.
iv. Resignation of previously appointed/approved QC In charge.

The firm is also called for Personal Hearing vide letter dated 17th August 2021.
The case is submitted for consideration of the board.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr. Yaseen Riaz appeared before the Board. He contended that he had already submitted documents and ready to submit again. He was informed that the Central Licensing Board in its 280th meeting deferred the case for checking the compliance but documents found incomplete. The Board after hearing the representative of the firm decided to suspend the Drug Manufacturing License No 000116 (by way of formulation) of M/s. Zumars Pharma FTY. (Pvt) Ltd, 02-Malir Industrial area, Karachi under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) & Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till completion of codal formalities/submission of required documents. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 9. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDICEENA PHARMA (PVT) LTD, LAHORE.

M/s Mediceena Pharma (Pvt) Ltd, 27-Km, Raiwind Road, Lahore had applied for renewal of DML No. 000475 by way of Formulation for the period of 05-05-2020 to 04-05-2025 on 04-05-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 23rd June, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Nothing due certificate regarding CRF from STO (Updated).
iii. Detail of management, if any change, apply for change of management alongwith all pre-requisites.
iv. Duly attested CNIC copies of all Directors.
v. Latest certified true copy of Form-29duly attested by SECP (original).
vi. Section approval letters of all sections approved by Central Licensing Board, if not available, apply for regularization of Layout Plan.

The firm did not reply to this letter and reminder letter was issued on 28thSeptember, 2020 to the firm for completion of application:

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Nothing due certificate regarding CRF from STO (Updated).
iii. Detail of management, if any change, apply for change of management alongwith all pre-requisites.
iv. Duly attested CNIC copies of all Directors.
v. Latest certified true copy of Form-29 duly attested by SECP (original).
vi. Section approval letters of all sections approved by Central Licensing Board, if not available, apply for regularization of Layout Plan.
vii. Duly attested valid / renewed copy of registration certificate from pharmacy council of Production Incharge.
viii. Complete set of duly attested documents of proposed Quality Control Incharge (as per checklist) (except undertaking as whole-time employee).

The firm replied to reminder on 19thOctober, 2020 but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest certified true copy of Form-29 duly attested by SECP (original).
ii. Section approval letters of all sections approved by Central Licensing Board, if not available, apply for regularization of Layout Plan.
iii. Properly filled, signed & stamped Form-1A (as per format).

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000475 (by way of formulation) of M/s Mediceena Pharma (Pvt) Ltd, 27-Km, Raiwind Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause Notice was issued to M/s Mediceena Pharma (Pvt) Ltd, 27-Km, Raiwind Road, Lahore on 1st January, 2021.

The firm replied but application is still deficient of following documents:

i. Latest certified true copy of Form-29 duly attested by SECP without stamp that SECP does not take responsibility of contents of Form. (original).
ii. Section approval letters of all sections approved by Central Licensing Board, if not available, apply for regularization of Layout Plan.
iii. Properly filled, signed & stamped Form-1A (as per format).

A letter of Personal hearing has been issued on 17th August, 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Riaz ali Accountant appeared before the Board. He contended that they have submitted required documents but Form 29 issued by the SECP contains the disclaimer which is beyond their control. He further submitted that Central Licensing Board may seek clarificationfrom SECP regarding their disclaimer. The Board after hearing the representative of the firm and considering case background decided to seek clarification from the SECP before taking any final decision.

CASE NO. 10 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ANEEB PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore had applied for renewal of DML No. 000555 by way of Formulation for the period of 01-11-2019 to 31-10-2024 on 28-10-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 19thFebruary, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Detail of management, if any change, apply for change of management.
iii. Latest certified true copy of Form-29 (duly attested by SECP).
iv. Duly attested CNIC copies of all Directors.
v. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.
vi. Nothing due certificate regarding CRF from STO (Updated).

The firm replied to this letter on 21st April, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 19thMay, 2020 to the firm for completion of application:

i. Properly filled, signed & stamped Form-1A (as per format).

ii. Latest certified true copy of Form-29 duly attested by SECP (original)
iii. Section approval letters, if not available, apply for regularization of Layout Plan of Cream / Ointment, Sachet & Dry Powder Syrup Sections.
iv. Nothing due certificate regarding CRF from STO (Updated).
v. Prescribed fee of 50,000/- for change in management, as there is change in management of the firm.

The firm did not reply to reminder and application for renewal of DML is still incomplete with following documents being deficient.

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 duly attested by SECP (original)
iii. Section approval letters, if not available, apply for regularization of Layout Plan of Cream / Ointment, Sachet & Dry Powder Syrup Sections.
iv. Nothing due certificate regarding CRF from STO (Updated).
v. Prescribed fee of 50,000/- for change in management, as there is change in management of the firm.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000555 by way of formulation of M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore, may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause Notice was issued to M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore on 12th November, 2020.

The firm replied but application is still deficient of following documents:

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 duly attested by SECP (original)
iii. Section approval letters, if not available, apply for regularization of Layout Plan of Cream / Ointment, Sachet & Dry Powder Syrup Sections.
iv. Nothing due certificate regarding CRF from STO (Updated).

A letter of Personal hearing has been issued on 17th August, 2021.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr. Atif Sahrief, Managing Director of the Company appeared before the Board. He contended that he had submitted documents and taken up the matter with Budget and Accounts for issuance of nothing due certificate. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000555 by way of

formulation of M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till completion of codal formalities/submission of required documents. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 11 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/s IPRAM INTERNATIONAL RAWAT.

M/s Ipram International, Plot No. 26, Street SS-3, National Industrial Zone, Rawat had applied for renewal of DML No. 000551 by way of Formulation for the period of 27-08-2019to 26-08-2024on 26-08-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 9th October, 2020under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

For Renewal of DML.

ii. Form 1A duly signed and stamped by CEO of the firm along with annexure.
iii. Detail of management at the time previous renewal and present renewal.
iv. Proof of Licensed Section from CLB.
v. Nothing due certificate regarding CRF from STO upto 2019.

For Change of Management.

i. Request for change of management on letter head of the firm.
ii. Fee Challan Rs.50,000/- retained by STO, DRAP, Islamabad.
iii. Revised / New partnership deed along with CNIC (s) copies of all directors.
iv. Form-C from registrar of firm.

The firm did not reply and Final reminder letter was issued on 26th October, 2020 to the firm for completion of application:

For Renewal of DML.

i. Form 1A duly signed and stamped by CEO of the firm along with annexure.
ii. Detail of management at the time previous renewal and present renewal.
iii. Proof of Licensed Section from CLB.
iv. Nothing due certificate regarding CRF from STO upto 2019.

For Change of Management.

i. Request for change of management on letter head of the firm.
ii. Fee Challan Rs.50,000/- retained by STO, DRAP, Islamabad.
iii. Revised / New partnership deed along with CNIC (s) copies of all directors.
iv. Form-C from Registrar of firms.

The firm replied to reminder on 10th November, 2020but the application for renewal of DML is still incomplete with following documents being deficient.

i. Nothing due certificate regarding CRF from STO.
ii. Proof of Licensed Section from CLB.
iii. Detail of management at the time previous renewal and present renewal.
iv. Request for change of management on letter head of the firm.
v. Prescribed fee of Rs.50,000/- for change of management.
vi. Duly attested Form-C from Registrar of firms, revised partnership deed and CNIC copies of all partners.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000551(by way of formulation) of M/s Ipram International, Plot No. 26, Street SS-3, National Industrial Zone, Rawat may not be suspended or cancelled by the Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause Notice was issued to M/s Ipram International, Plot No. 26, Street SS-3, National Industrial Zone, Rawat on 6th July, 2021.

The firm replied but application is still deficient of following documents:

i. Nothing due certificate regarding CRF from STO.
ii. Proof of Licensed Section from CLB.
iii. Detail of management at the time previous renewal and present renewal.
iv. Request for change of management on letter head of the firm.
v. Prescribed fee of Rs.50,000/- for change of management.
vi. Duly attested Form-C from Registrar of firms, revised partnership deed and CNIC copies of all partners.

Moreover, the firm has submitted an undertaking stating that Ch. Pervaiz Ahmed is sole proprietor of the firm but their regulatory representative submitted wrong documents of partnership deed.

A letter of Personal hearing has been issued on 17th August, 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Choudhary Pervaiz Ahmad, CEO of the firm and Mr. Nadeem Ahmad, Manager HR & Regulatory appeared before the Board. He contended that he had submitted that partnership deed has been submitted inadvertently and emphasized that he is sole propriter of the firm. On quarry, he replied that partnership deed was prepared for other purpses which did not disclose. He further stated that matter has been taken up with Budget and Accounts for issuance of nothing due certificate as soon as certificate is issued he would submit the Secreatriat. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000551(by way of formulation) of M/s Ipram International, Plot No. 26, Street SS-3, National Industrial Zone, Rawat under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till completion of codal formalities/submission of required documents. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 12 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ALI INDUSTRIES, LAHORE.

M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore had applied for renewal of DML No. 000222 by way of Formulation for the period of 24-10-2018 to 23-10-2023 on 16-10-2018.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 7th November, 2018 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed & stamped Form-1A as per format.
ii. Detail of management at the time of previous renewal and at present if any change, prescribed fee of Rs. 50,000/ alongwith proper application for change of management.
iii. CNIC Copies of all Partners.
iv. Copy of partnership deed issued by the Registrar of firm.
v. Proof of Sections approved by CLB, If not available, apply for regularization of layout plan.
vi. Approval letters of technical staff.

vii. All documents should be duly attested.

The firm replied to this letter on 24th February, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 18th August, 2020 to the firm for completion of application:

i. Copy of partnership deed.
ii. Copy of final sale deed.
iii. Copy of CNIC Copies of all participants mentioned in provisional sale deed.
iv. Copy of succession certificate as mentioned in provisional sale deed
v. **All documents should be notarized.**

The firm replied to reminder on 4th September, 2020 and application for renewal of DML is still incomplete with following documents being deficient.

i. Copy of final sale deed.
ii. Copy of succession certificate as mentioned in provisional sale deed
iii. All documents should be notarized.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000222 by way of formulation of M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause Notice was issued to M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore on 12th November, 2020.

The firm replied but application is still deficient of following documents:

i. Copy of final sale deed.
ii. All documents should be notarized.

A letter of Personal hearing has been issued on 17th August, 2021.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

No person appeared on behalf of the firm. The Baord decided to serve final opportunity to the firm for the sake of fair trial and justice.

CASE NO. 13. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDI-VET (PVT) LTD, LAHORE.

M/s Medi-Vet (Pvt) Ltd, 16-Km, Sheikhupura Road, Lahore had applied for renewal of DML No. 000269 by way of Formulation for the period of 22-12-2019 to 21-12-2024 on 24-10-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 19th February, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Classes of drugs & dosage forms of drugs.
iii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).
v. Duly attested CNIC copies of all Directors.
vi. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm replied to this letter on 11th March, 2020but application was incomplete with following shortcomings and reminder letter was issued on 8th May, 2020 to the firm for completion of application:

i. Properly filled, signed & stamped Form-1A (as per format) signed by management.
ii. Classes of drugs & dosage forms of drugs.
iii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).
v. Duly attested CNIC copies of all Directors.
vi. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm submitted documents on 28th July, 2020 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Properly filled, signed & stamped Form-1A (as per format)filled by Mr. Saeed Iqbal and signed by Mr. HarisSaeed.
ii. Prescribed fee of Rs. 50,000/- as there is change in management of the firm.
iii. Latest certified true copy of Form-29 duly attested by SECP.
iv. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

Proceedings and Decision by the Central Licensing Board in 276th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medi-Vet (Pvt) Ltd, 16-Km, Sheikhupura Road, Lahore Drug Manufacturing License No. 000269 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The show CauseNotice dated 25th September, 2020 was issued to M/s Medi-Vet (Pvt) Ltd, 16-Km, Sheikhupura Road, Lahore.
The firm replied to show cause Notice but following documents are still deficient in the application for renewal of Drug Manufacturing License.

i. Latest certified true copy of Form-29 duly attested by SECP.
ii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

A letter of Personal Hearing was issued to the firm on 8thOctober, 2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

No person appeared on behalf of the firm. The Board deliberated the case and decided to afford final opportunity for personal hearing to the firm in the next meeting of the Central Licensing Board before taking decision.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

A letter of Personal hearing has been issued on 17th August, 2021.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Harsi Saeed, Managing Director appeared before the Board. He contended that due covid he could not submit documents in time. He argued that time may be given for submission of documents. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000269 (by way of formulation) of M/s Medi-Vet (Pvt) Ltd, 16-Km, Sheikhupura Road, Lahore under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till completion of codal formalities/submission of required documents. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

Case No.14. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S PHARMEDIC PHARMACEUTICAL INDUSTIES, LAHORE.

Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> "(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit.

It is submitted that M/s Pharmedic Pharmaceuticls Industries (Pvt) Ltd., 17KM, Multan Road, Lahore under DML No. 000853 (by way of Formulation) has not submitted CRF till to date. However, firm has failed to submit nothing due certificate for the further period which is mandatory under Rule 12 of the Drugs (Licensing, Registering & Advertising) Rules, 1976. The case was placed before the Central Licensing Board in its 269th meeting held on 26-02-2019 and decided as under:-

> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licencee may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Pharmedic Pharmaceuticls Industries (Pvt) Ltd., 17KM, Multan Road, Lahore under DML No. 000853 (by way of Formulation) on 30th September, 2020 but firm has not submitted CRF since the grant of DML.

The case may be placed in agenda of next meeting of Central Licensing Board for its consideration, please.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Muhammad Saeed Kamran, Production Manager appeared before the Board. He argued that they had taken up the mtter with Division of Budget and Accounts and as soon as nothing due certicate is recived it would be submitted with the Secretariat of CLB.

The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000853 (by way of formulation) of M/s Pharmedic Pharmaceuticls Industries (Pvt) Ltd., 17KM, Multan Road, Lahore under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 12 of the Drugs (Licensing, Registering and

Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

Case No.15 . <u>NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S WEZEN PHARMACEUTICALS, PLOT NO. 23-24, PHASE S1, INDUSTRIAL ESTATE, RAWAT.</u>

FR is received from Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit.

It is submitted that M/s Wezen Pharmaceuticals, Plot No. 23-24, Phase S1, Industrial Estate, Rawat having DML No. 000882 has never submitted CRF since the grant of DML which is mandatory under Rule 12 of the Drugs (Licensing, Registering & Advertising) Rules, 1976. It is therefore proposed that case may be placed before the Central Licensing Board for its consideration, please.

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Wezen Pharmaceuticals, Plot No. 23-24, Phase S1, Industrial Estate, Rawat on 16th May, 2019 but firm has not submitted CRF since the grant of DML.

The case may be placed in agenda of next meeting of Central Licensing Board for its consideration, please.

<u>Proceedings and Decision of the Central Licensing Board in 282nd meeting</u>

Mr Rana Taimoor, Regulatory Manager, appeared before the Board. He argued that firm was licensed in 2019 and running in the loss. They have, therefore, not submitted the CRF. He further

argued that they may be given time to submit required document. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000882 (by way of formulation) of M/s Wezen Pharmaceuticals, Plot No. 23-24, Phase S-1, Industrial Estate, Rawa under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

Case No. 16 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S LOTUS PHARMACEUTICALS (PVT) LTD., ISLAMABAD

The firm, M/s Lotus Pharmaceuticals (Pvt) Ltd., Islamabad , has submitted application for renewal of Drug Manufacturing License No. 000551 (by way Formulation). The application was received on 29-05-2019and due date of renewal of DML 16/06/2019. The firm has submitted a fee of Rs. 50,000. The application was evaluated as per Drugs (Licensing, Registering & Advertising) Rules 1976 and found following shortcomings;

i. Classes of drugs.
ii. Dosage forms of drugs.
iii. Name(s) of registered drugs.
iv. Detail of management at the time previous renewal and present renewal.
v. Latest original Form-29 and Form-21 certified true copy issued by SECP alongwith CNIC (s) copies of all directors.
vi. Proof of licensed section(s) from Central Licensing Board.
vii. Detail of machinery for QC lab and section wise.
viii. Up-to-date Nothing Due Certificate regarding CRF issued from STO up to 2020.

Accordingly, shortcoming letter No. 1-2/2017-Lic dated 07/11/2019 was issued to the firm to rectify above mentioned shortcomings.

In response to this office shortcoming letter, the firm has not submitted any reply and as per SOP, final reminder was issued to the firm vide No. 1-2/2017-Lic dated 10/06/2020

After issuance of shortcoming letter and final reminder, till date,the firm has not rectified following shortcomings;

i. Classes of drugs.
ii. Dosage forms of drugs.
iii. Name(s) of registered drugs.
iv. Detail of management at the time previous renewal and present renewal.
ix. Latest original Form-29 and Form-21 certified true copy issued by SECP alongwith CNIC (s) copies of all directors.
x. Proof of licensed section(s) from Central Licensing Board.
xi. Detail of machinery for QC lab and section wise.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000551(by way of formulation) of M/s Lotus Pharmaceuticals (Pvt) Ltd., Islamabad may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.
Show-Cause Notice to the firm was issued on 08-01-2021.

The firm submitted their response. However, upon evaluation following shortcomings are still observed;

i. Section(s) approval letter(s) from Central Licensing Board are not attached.
ii. The management of the firm seems to be changed as under;

Previous management as per Form-A & Form-29 dated 31-10-2014	**New Management as per Form-A & Form-29 dated 23-09-2020**
1. Khadim Hussain. 2. Shaukat Ullah 3. Aamir Mehboob. 4. Muhammad Umair.	1. Khadim Hussain. 2. Aamir Mehboob. 3. Muhammad Umair.

Accordingly, a personal hearing letter was issued to the firm on 24-08-2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Muhammad Umair, Director and Mr. Ismael Khan, Production Manager appeared before the Board. He argued that his father Mr Khadim Hussain (late) who was looking after the afairs of the company is died. They are in process of seeking succession certificate. He further argued that as soon as succession certificate is arranged and accordingly partnership deed would be amended. He argued that time may be given on humanitarian ground. The Board after hearing the representative of the firm and considering case background decided to defer the case till next meeting of the Board.

Case No. 17 **RENEWAL OF OF M/S ALEN PHARMACEUTICALS (PVT) LTD, RISALPUR**

The firm M/s Alen Pharmaceuticals (Pvt) Ltd, Risalpur has submitted the application for renewal of Drug Manufacturing No. 000435 (Formulation). The application was received on 18-09-2019 which is 03 (three) days late as validity of License is 15-09-2019. Upon evaluation of application Drugs (Licensing, Registering and advertising) Rules 1976 following

shortcoming were found and same were conveyed to the firm vide letter no. 3-3/96-Lic dated 22-10-2019

i. Late fee @ 5,000/- per day as application for renewal of Drug Manufacturing License is three (03) days late.
ii. Form-1A dully signed and stamped by CEO of the firm.
iii. Classes of Drugs.
iv. Dosage form of drugs.
v. Names of registered drugs.
vi. Detail of management at the time of previous renewal and present renewal.
vii. Latest original certified true copy of Form-29 and Form-21 issued by S.E.C.P. alongwith CNIC's copies of all director(s).
viii. Proof of Licensed section (s) from Central Licensing Board.
ix. Section wise detail of equipment and machinery for manufacturing and QC Lab.
x. Approval letter of Production Incharge.
xi. All documents should be duly attested.

The firm, in response to this Division's shortcoming letter has submitted the shortcoming documents but did not rectified following shortcomings for which final reminder were issued dated 27-04-2020

i. Form-1A as per prescribed format and dully signed and stamped by MD/CEO of the firm.
ii. Late fee @ 5,000/- per day as application for renewal of Drug Manufacturing License is three (03) days late.
iii. Latest original certified true copy of Form-29 and Form-21 issued by S.E.C.P. along with CNIC's copies of all director(s).
iv. Proof of approval of previous management from Central Licensing Board.
v. Complete set of attested documents for change of management alongwith prescribed fee.

In response to final reminder the firm has submitted their reply and also submitted request for change of management but till date the following shortcoming has not been rectified;

i. Latest original certified true copy of Form-29 and Form-21 issued by S.E.C.P.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000435 (by way of formulation) of M/s Alen Pharmaceuticals (Pvt) Ltd, Risalpur may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected.

Accordingly, a personal hearing letter was issued to the firm on 17-08-2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Shoukat Ali Managing Director and Mr. Adbul Rasheed, Production Manager appeared before the Board and submitted original Form 29 issued by the SECP. The Board after hearing the representative of the firm and considering case background decided to cease the operation of showcause notice to the firm.

CASE NO. 18 NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S MOON PHARMACEUTICALS, PLOT NO. 5, SS-4 ROAD, NATIONAL INDUSTRIAL ZONE, RAWAT UNDER DML NO. 000833 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> "(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing License may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Moon Pharmaceuticals, Plot No. 5, SS-4 Road, National Industrial Zone, Rawat on23rd September, 2020 as the firm has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Sayed Hussain on behalf of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

A letter of Personal hearing has been issued on 17th August, 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Sayed Hussain, Accounts Officer, appeared before the Board. He argued that due to Covid-19 they could not pusue the case, therefore, they may be given time for submission of required document. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000833 (by way of formulation) of M/s Moon Pharmaceuticals, Plot No. 5, SS-4 Road, National Industrial Zone, Rawat under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 19 NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S DIVINE PHARMACEUTICALS, PLOT NO. 226-A, SUNDER INDUSTRIAL ESTATE, LAHORE UNDER DML NO. 000850 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above-mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing License may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore 23rd September, 2020 as the firm has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 19th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Aamir Farooq son of Director of the firm appeared before the Board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

A letter of Personal hearing has been issued on 17th August, 2021.

Budget & Accounts Division, DRAP Islamabad has issued nothing due certificate w.r.t CRF to the firm.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

The Board after considering case background decided to cease the operation of showcause notice to the firm M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore.

CASE NO. 20. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s BLISS INDUSTRIES (PVT) LTD, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000086 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its

due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Bliss Industries (Pvt) Ltd, Karachi on 30th September, 2020 but firm has not submitted CRF since 2013. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Submitted for consideration and orders of the Board.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person on behalf of the firm appeared before the board. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

NDC of CRF is still not received from the firm .

The firm is also called for Personal Hearing vide letter dated 17th August 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

No person appeared on behalf of the company. The Board after considering case background decided to suspend the Drug Manufacturing License 000086 (by way of formulation) of M/s Bliss Industries (Pvt) Ltd, Karachi under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 21. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s AL-KEMY PHARMACEUTICALS, HYDERABAD UNDER DRUG MANUFACTURING LICENSE NO. 000131 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Al-KemyPharmaceuticals Hyderabadon23rd September, 2020 but firm has not submitted the CRF since year 2014. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person appeared before the board on behalf of the firm. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

NDC of CRF Updated is still not received from the firm .
The firm is also called for Personal Hearing vide letter dated 17th August 2021.
The case is submitted for consideration of the board.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Faraz Ahmed, Managing Director appeared before the Board. He argued that he had submitted required documents with Budget and Accounts Division, therefore, they may be given time for submission of required document. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000131 (by way of formulation) of M/s Al-Kemy Pharmaceuticals Hyderabad under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 22. RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000814 OF M/S RUKHA PHARMACEUTICAL LABORATORIES (PVT) LTD, PLOT NO. 537-D&E, SUNDER INDUSTRIAL ESTATE, RAIWIND ROAD, LAHORE.

Case Background:

M/s Rukha Pharmaceutical Laboratories (Pvt) Ltd, Plot No. 537-D&E, Sunder Industrial Estate, Raiwind Road, Lahore had applied for renewal of DML No. 000753 by way of formulation for the period of 12-09-2017 to 11-09-2022 on 30-08-2017. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 5th October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form-29 duly attested from S.E.C.P (Updated)
2. Detail of management at the time of previous renewal of DML and at present Renewal alongwith copies of CNIC of all Directors.
3. Nothing due certificate regarding CRF from STO (Updated).
4. All documents should be duly attested.

The firm submitted their reply on 17th October, 2017.After evaluation of the submitted documents, Final reminder was issued on 08th November, 2017 to the firm with following shortcomings (Page 45/Corr (PUC): -

1. Prescribed fee of Rs. 50,000/- for change of management / directors as it seems management is changed from last renewal till at present renewal.
2. Form-29 duly attested from S.E.C.P (Updated) alongwith CNIC copies of all Director.
3. Nothing due certificate regarding CRF from STO (Updated).
4. **All documents should be duly attested.**

Firm submitted documents on 21st November, 2017 in reply to Final Reminder but following documents are still deficient /short and application for renewal of DML is still incomplete.

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Form-29 duly attested from S.E.C.P for year 2017 alongwith CNIC copies of all Director.
iii. Copy of CNIC of appointee (Production Incharge).
iv. Undertaking as whole time employee on stamp paper (Production Incharge).
v. All documents should be duly attested.

Proceedings and Decision of CLB in 259thmeeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Rukha Pharmaceutical Laboratories (Pvt) Ltd, Plot No. 537-D&E, Sunder Industrial Estate, Raiwind Road, Drug Manufacturing Licence No. 000753 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of CLB.

The Show Cause notice dated 27th April, 2018 was issued to the M/s Rukha Pharmaceutical Laboratories (Pvt) Ltd, Plot No. 537-D&E, Sunder Industrial Estate, Raiwind Road, Lahore.

The firm has submitted the documents in reply of the show cause notice. Application for renewal of DML is complete however, Form-29 issued by SECP is not certified true copy due to a pending Court case and only issued on the request of the firm and the matter of change of management is sub-judice and pending in SECP. A letter of Personal hearing has been issued on 02nd August, 2018.

The case was placed before the Central Licensing Board in its 265th meeting of Central Licensing Board held on 9th & 10th August, 2018. The Board decided that:-

Proceedings and Decision of Central Licensing Board in 265th meeting

Mr. Abdul Sattar Bajwa (Production Incharge) and Mrs. Rukha Rafique (Director) of the firm appeared before the Central Licensing Board and presented documents and requested for giving one month time for submission of documents. However, the Board after scrutiny of the documents directed the firm to submit certified copies of the same at the earliest. The Board after hearing the representative of the firm decided to defer the case till next meeting of Central Licensing Board.

Firm has not submitted latest Form-29 till to date in compliance the decision of 265th meeting of Central Licensing Board held on 9th & 10th August, 2018.

A letter of personal hearing is to be served to the said firm for 282nd meeting of Central Licensing Board schedule to be held on 31st August, 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Dr Khalid Choudhary, CEO and Ms Rukha Naseem, Director of the company appeared before the Board. They contended that there is litigation among successors of the owner of the company therefore, Form-29 issued by the SECP is issued with disclaimer. They further argued that they may be given time submission of the rest of documents which they could not submit due to Covid-19. The Board after hearing the representative of the firm and considering case background decided to seek clarification from the SECP before taking any final decision.

CASE NO. 23 RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000407 (BASIC-MANUFACTURE) OF M/s DRUG PHARMA CHEMICALS (PVT) LTD KARACHI.

M/s Drug Pharma Chemicals (Pvt) Ltd, Karachi had filled application for renewal of DML No. 000407 (Basic Manufacture) for the period commencing on 16-07-2020 and ending on 15-07-

2025. The application was received on 16-07-2020. The application for the renewal of DML of the firm was evaluated. Following documents were found deficient.

i. Additional surcharge fee of Rs. 5,000 for late submission (01 day) of application for renewal of DML.
ii. Dully retained fee challan by AD (Revenue) DRAP, Islamabad.
iii. All attested annexure/enclosures of Form-1A.
iv. Approval letters of API's issued by CLB or if not available then submit layout plan for regularization of manufacturing facility.
v. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
vi. Complete set of attested documents (as per checklist) for approval of production In charge & Quality Control In charge as required under Rule 15 of the Drugs (L,R&A) Rules, 1976.
vii. Updated NOC of CRF issued from statistical officer DRAP, Islamabad

A letter dated 06th October 2020 was issued to the firm to submit the above mentioned shortcoming/deficient documents.
No reply was received from the firm and a Reminder dated 25th January 2021 was issued to the firm to submit the said documents but no reply/response is received from the firm and the application for renewal of DML is still deficient of above mentioned documents.
Submitted for consideration of the Board, please.

Decision of the Central Licensing Board in 280th meeting
The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule, 12, Rule, 15 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000407 (by way of Basic Manufacture) of M/s Drug Pharma Chemicals (Pvt) Ltd, Karachi, may not be suspended or cancelled by the Central Licensing Board.

The show cause notice dated 31st May 2021 was issued to the firm. No reply is received from the firm and the application for renewal of DML is still incomplete.
The firm is also called for Personal Hearing vide letter dated 24th August 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Maj (Rtd) Mubashar Jamal, Manager Regulatory appeared before the Board. He contended that no letter of shortcoming and showcause Notice is received in the Company. He further contended that he had come to know regardrding personal hearing through a friend. He requested for giving further time for submission of documents.

The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000407 (by way of basic manufacture of Drug Pharma Chemicals (Pvt) Ltd, Karachi under Section 41 of the Drugs Act, 1976 read with Rule,

12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12, Rule 15 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till completion of codal formalities / submission of documents. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 24. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 M/S IPP (PVT) LTD., SWAT

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s IPP (Pvt) Ltd., Swat DML No.000244 (Formulation) on dated 13-05-2019 as the firm has never submitted CRF.

In response to Show Cause Notice the firm has responded vide letter No. IPP2/07/19 dated 02/07/2019 which is reproduced as under;

"In Continuation to your Letter No. F3-10/2011-Lic 27/06/2019 dated 13 May 2019. Dispatched on 26 june 2019 Received on 27/6/2019.

Regarding this connection We have already provided Audit report to office of the statistical officer DRAP.

Also a photo copy of the Audit reports/ financial statement for the year June 30/2016 June 30/17 and June 30/2018 is also enclosed here with for your . office proceeding and record

purpose

Thanking you and assuring you the best of our cooperation at all time."

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Waseem Jawad Partner of the firm appeared before the Board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

Accordingly, a personal hearing letter was issued to the firm on 24-08-2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Waseem Javed, Managing Director appeared before the Board. He argued that he had submitted required documents with Budget and Accounts Division, therefore, they may be given time for submission of required document. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000244 (by way of formulation) of M/s IPP (Pvt) Ltd., Swat under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 25 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ENVOY PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Envoy Pharmaceuticals (Pvt) Ltd, 27-Km, Multan Road, Maraka Lahore had applied for renewal of DML No. 000607 by way of Formulation for the period of 21-03-2017 to 20-03-2022 on 14-03-2017 and approval of production Incharge.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 21st April, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form-29 from SECP.
ii. Fee for change of management.
iii. Detail of previous and new management contents & their attested CNIC copies and concerns.
iv. Experience certificates as under Drugs (Licensing, Registering, Advertising) Rules, 1976 (Not less than 10 years).
v. Resignation or termination letter of appointee from previous firm/promotion letter/transfer letter from same firm.
vi. All documents should be duly attested.

The firm did not reply to this letter and final reminder letter was issued on 26th February, 2020 to the firm for submission of following documents:

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 (duly attested by SECP).
iii. Duly attested CNIC copies of all Directors.
iv. Prescribed fee of Rs. 50,000/- for change in management of the firm as there has been change in management of the firm.
v. Complete set of duly attested documents of proposed Production Incharge (as per checklist)
vi. Updated Nothing Due Certificate regarding CRF from STO (R&D),DRAP.
vii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm did not reply and application for renewal of DML is still incomplete with following documents being deficient.

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 (duly attested by SECP).
iii. Duly attested CNIC copies of all Directors.
iv. Prescribed fee of Rs. 50,000/- for change in management of the firm as there has been change in management of the firm.
v. Complete set of duly attested documents of proposed Production Incharge (as per checklist)
vi. Updated Nothing Due Certificate regarding CRF from STO (R&D),DRAP.
vii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No.

000607 by way of formulation of M/s Envoy Pharmaceuticals (Pvt) Ltd, 27-Km, Multan Road, Maraka Lahore may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause Notice was issued to M/s Envoy Pharmaceuticals (Pvt) Ltd, 27-Km, Multan Road, Maraka Lahore on 12th November, 2020.

The firm did not reply and application is still deficient of following documents:

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 (duly attested by SECP).
iii. Duly attested CNIC copies of all Directors.
iv. Prescribed fee of Rs. 50,000/- for change in management of the firm as there has been change in management of the firm.
v. Complete set of duly attested documents of proposed Production Incharge (as per checklist)
vi. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP.
vii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

A letter of Personal hearing has been issued on 25th August, 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Imran Haider, General Manager appeared before the Board. He stated that he could not submit documents due to Covid-19. He requested for giving further time for submission of documents. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000607 (by way of Formulation) of M/s Envoy Pharmaceuticals (Pvt) Ltd, 27-Km, Multan Road, Maraka Lahore under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till completion of codal formalities / submission of documents. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 26 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S DELTA PHARMA (PVT) LTD., RISALPUR

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Delta Pharma (Pvt) Ltd., Risalpur DML No. 000446 (formulation) dated 25-09-2020 but as per available record in licensing Division, the firm has not submitted CRF till date. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Ashfaq Paracha CEO of the firm and Mr. Musa Ashfaq appeared before the board and contended that firm will submit NDC of CRF. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

Accordingly, a personal hearing letter was issued to the firm on 24-08-2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Musa Ashfaq, Director appeared before the Board. He argued that he had submitted required documents with Budget and Accounts Division, therefore, they may be given time for submission of required document. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000446 (by way of formulation) of M/s Delta Pharma (Pvt) Ltd., Plot No. 09, Nowshera Industrial Estate

(SIZ), Risalpur under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

Case No. 27. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S SIMAX CHEMICAL, PESHAWAR

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Simax Chemical, Peshawar DML No.000843 (Re-Packing) dated 13-05-2019 but firm has not submitted CRF till 2019.

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Muhammad Shahzad CEO and Mr. Arshad Parvez appeared before the board on behalf of the firm and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

Accordingly, personal hearing letter to the firm was issued on 24-08-2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr. Muhammad Shahzad CEO appeared before the Board. He argued that he had submitted required documents with Budget and Accounts Division, therefore, they may be given time for submission of required document. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000843 (by way of formulation) of M/s Simax Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Peshawar under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 28. M/S. HEALER LABORATORIES (PVT) LTD., PLOT NO. 96/102, SMALL INDUSTRIAL ESTATE, KOHAT ROAD

Inspection of the firm M/s. Healer Laboratories (Pvt) Ltd., Plot No. 96/102, Small Industrial Estate, Kohat Road, Peshawar was conducted by Mr. Atiq-Ul-Bari, FID-II, DRAP, Peshawar on 04.09.2018 to verify the GMP compliance and production activities.

Action taken by DRAP:

2. The firm M/s. Healer Laboratories (Pvt) Ltd., Peshawar was served Show Cause Notice Order No.F.4-22/92-QA on 23.10.2018.

3. The case was placed before 267thmeeting of Central Licensing Board. Wherein the Board decided as under: -

Decision of the 267thMeeting of CLB

After thorough discussion/deliberations, the Central Licensing Board decided to: -

i. Constitution of following panel of experts for detailed GMP inspection of the firm: -

a) Prof. Dr. Jamshaid Ali Khan, Member, CLB
b) The Area Federal Inspector of Drugs, Peshawar

ii. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 04.09.2018, with clear and candid recommendations.

4. The decision was conveyed to the quarter concerned vide letter dated 22.01.2019.

5. The panel conducted inspection of the firm M/s. Healer Laboratories (Pvt) Ltd, Peshawar on 26.03.2019 and concluded as under: -

"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance."

The panel further recommended the firm to: -

i. Provide an Air conditioner in Raw Material Quarantine area.
ii. Calibrate balances from external sources and provide digital balances in process QC and Capsule filling Section.
iii. Provide room for retention samples.

Proceedings of 271st Meeting: -

Quality Assurance Division presented the case before the Board, keeping in view the recommendations of panel in its report dated 26.03.2019. The Board raised query regarding the further recommendations made by the firm.

Decision of the 271st Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to: -

i. Re-Inspect the firm by same panel of experts, constituted in 267th meeting of CLB, to verify the following improvements suggested by the panel in its report dated 26.03.2019:-

a) Provide an Air conditioner in Raw Material Quarantine area.
b) Calibrate balances from external sources and provide digital balances in process QC and Capsule filling Section.
c) Provide room for retention samples.

ii. The panel shall submit detailed inspection report including rectification status of the observations with clear and candid recommendations.

iii. Production of the firm M/s. Healer Laboratories (Pvt) Ltd, Peshawar shall remain suspended till recommendation by panel and subsequent approval by the CLB.

6. The decision was conveyed to the quarter concerned vide letter dated 01.10.2019 and reminder on 16.09.2020.

Panel Inspection

7. Panel comprising of Prof. Dr. Jamshaid Ali Khan, Member CLB and the Area FID, DRAP, Peshawar in compliance to the decision of 271st meeting of CLB conducted inspection of the firm M/s. Healer Laboratories (Pvt) Ltd, Peshawar on 16.12.2020 and concluded as under:-

"Based on the area inspected, the people met and documentations reviewed and considering the findings of inspection, the panel unanimously decided to recommend the resumption of production of M/s. Healer Laboratories (Pvt) Ltd. Peshawar.

It is pertinent to bring on record that, at present, the total size of the plot of the firm is less than 2000sq. yard, as described in Drug (Licensing, Registration and Advertising) Rules, 1976. The management of the firm informed that due to this reason they are in process of shifting the manufacturing facility and had already submitted lay-out of their new site to Licensing Division."

The case is placed before the CLB in compliance to the decision of 267th & 271st meeting of CLB and keeping view the recommendation of panel of experts in its report dated 16.12.2020 for resumption of production of M/s. Healer Laboratories (Pvt) Ltd, Peshawar.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considered the case and decided to defer the resumption of production. The Board further decided that Licensing Division may issue show cause notice under section 41 of the Drugs Act, 1976 read with Rule 12 for non compliance of Rule 16 of the Drugs (L,R&A) Rules,1976 for the matter referred by the panel of inspectors in its concluding remarks in its inspection report dated 16-12-2020.

Accordingly, show-Cause Notice was issued to the firm on 11-06-2021.

The firm M/s Healer Laboratories (Pvt.) Ltd, Peshawar submitted their reply to the show cause notice issued dated 11-06-2021. The reply of the firm is re-produced as under;

"This refer to Show Cause Notice No.F.3-1/90-Lic dated 11th June 2021, in which the decision regarding resumption of our production was deferred due to the concluding remarks in the Inspection Report dated 16-12-2020.

In this regard we respectfully submit as under;

1. *That the concluding remarks in the inspection report were about the area of the premises of M/s Healer Laboratories (Pvt) Ltd., located at Plot No.96/102-C, Kohat Road, Peshawar. All the other deficiencies were rectified by us, as pointed out in the previous inspection report.*
2. *That we are already in the process of relocation of the unit, from the existing premises to Plot No.78, Industrial Estate, Hayatabad, Peshawar. In this regards, the site verification as well as the layout plan has already been approved by the DRAP vide letter No.F.3-4/2019-Lic dated 28-07-2021. Copy of the same is attached herewith for ready reference.*
3. *That we have already started work on the new site and assure you sir, that we will complete the construction within 15 months from the date of approval.*
4. *That we have spent a huge amount on the existing premises to remove the deficiencies pointed out in the inspection report, to resume our production.*

It is therefore requested to consider our case sympathetically and resume our production, to save us from heavy financial loss and to secure the jobs of our employees. We have already faced a huge financial loss due to long suspense on of our license."

Accordingly, personal hearing letter to the firm was issued on 24-08-2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr. Mustafa Bashir, Chief Executive appeared before the Board. He stated that they are ready to shift in compliance of the observation of the DRAP. He further argued that they have also got site and Lay out plan approval at new site qualifying the provisions of the law. He further requested that he may be given reasonable time for construction and shifting to new site. On query, he submitted that reasonable time of 18 months may be given for the shifting to new premises.

The Board after hearing the representative of the firm and past precedents decided to allow M/s Healer Laboratories (Pvt.) Ltd, 96/102-C, SIE, Kohat Raod, Peshawar to shift to new premises withina period of 18 months. The Board further advised that firm may submit quarterly report to CLB through area Federal Inspector of Drugs.

CASE NO. 29. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S IPP,ISLAMABAD

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s IPP, Islamabad DML No. 000370 (Formulation) on dated 14-05-2019 as the firm but firm has not submitted CRF till 2019

In response to Show Cause Notice, the firm has responded vide letter No. IPP/05/19 dated 02/05/2019 which is reproduced as under;

> *"With references to your letter # 1-16/94-Lic (vol-l) dated 14th May 2019 received on 21st May, 2019. this is you that have NOC regarding above mention that our account is up to 30-6-216. Photo copy of NOC issued by you is attached for ready reference.*
> *It is therefore requested to please amend your record . we are also attaching the receipt CRF regarding 2017 2018.*
>
> *Thanking you and assuring you best of our co-operation at all the time."*

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Ms. Rukhsana Partner /Director of the firm appeared before the board and contended that problem of license ownership is resolved and would submit report within one month. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

Accordingly, a personal hearing letter was issued to the firm on 25-08-2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Ms. Rukhsana Javed CEO appeared before the Board. She argued that he had submitted required documents with Budget and Accounts Division, therefore, they may be given time for submission of required document. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000370 (by way of formulation) of M/s IPP, 34, Industrial Triangle, Kahuta Raod, Islamabad under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 30. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY VANTAGE LABORATORIES (PVT) LTD, FAISALABAD.

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Vantage Laboratories (Pvt) Ltd, Faisalabad on 30th September, 2020 but firm has not submitted CRF till 2019. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person appeared before the board on behalf of the firm. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

Now Nothing Due Certificate is received from Assistant Director (Revenue) B&A, DRAP, Islamabad in respect of M/s Vantage Laboratories (Pvt) Ltd, Faisalabad.

Decision of the Central Licensing Board in 282nd meeting

The Board after perusal of the record decided to cease the operation of Show Cause Notice issued in the name of M/s Vantage Laboratories (Pvt) Ltd, Plot No. 54 RB, Sarhali 6 KM, Sangla Hill Shahkot Road, Faisalabad

CASE NO. 31. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976BY M/S TRILLIUM, FAISALABAD.

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is

misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Trillium, Faisalabad on 30th September, 2020 but firm has not submitted CRF till 2019. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

"Mr. Mulazim Hussain CEO of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm."

Nothing Due Certificate is received from Assistant Director (Revenue) B&A, DRAP, Islamabad in respect of M/s Trillium, Faisalabad.

Decision of the Central Licensing Board in 282nd meeting

The Board after perusal of the record decided to cease the operation of Show Cause Notice issued in the name of M/s Trillium Pharmaceuticals (Pvt) Ltd, C-3 & C-4, Value Addition City, Khurrianwala, Faisalabad

CASE NO. 32 **APPROVAL OF PRODUCTION INCHARGE UNDER DRUG MANUFACTURING LICENCE NO. 000901 (SEMI-BASIC MANUFACTURE) OF M/s CARRYFOR PHARMACEUTICAL (PVT) LTD, KARACHI.**

M/s Carryfor Pharmaceutical (Pvt) Ltd, Plot No. E-81, North Western Industrial Zone, Port Qasim , Karachi had applied for approval of production in charge Mr. Wasi Ahmed S/o Muhammad Shafi (M.SC Chemistry) CNIC No. 42101-3206838-3. The application was evaluated and a letter was issued to the firm on 22-05-2019 under Rule 15 of Drugs (Licensing, Registering, Advertising) Rules, 1976 to submit complete set of attested documents (as per checklist) for approval of Production in charge.

The reply was received from the firm on 29th August 2019 which was evaluated and a reminder letter dated 15th October 2019 was issued to the firm for submission of following documents for completion of application for approval of Production incharge.

i. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of appointee.
ii. Resignation of previously approved Production in charge.

In response firm submitted documents for approval of new Production in charge Mr. Faheem Khan S/o Sardar Khan which were again evaluated and a letter of Final Opportunity dated 24-03-2021 was issued to the firm to submit complete set of attested documents (as per checklist) for approval of new Production in charge as the proposed Production in charge Mr. Faheem Khan does not possess the relevant experience as required under Rule 15 (c) of the Drugs (L,R&A) Rules, 1976.

In response firm has submitted documents ofproduction in charge Mr. Wasi Ahmed S/o Muhammad Shafi (M.SC Chemistry) which are evaluated and following documents are still deficient in application for approval of Production in charge.

i. Prescribed fee of Rs. 5000 for approval of new Production in charge.
ii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of appointee.

Submitted for consideration of the Board, please.

Decision of the Central Licensing Board in 280th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 15 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000901 (by way of Semi-Basic Manufacture) of M/s Carryfor Pharmaceutical (Pvt) Ltd, Plot No. E-81, North Western Industrial Zone, Port Qasim ,Karachimay not be suspended or cancelled by the Central Licensing Board.

The show cause notice was issued to the firm and in response to show cause notice the firm submitted the required shortcoming documents for approval of Production in charge and the production in charge fulfilled the requirement of Rule 16 of the Drugs (L,R&A) Rules, 1976 in terms of required experience and qualification and was approved accordingly.

Decision of the Central Licensing Board in 282nd meeting

The Board after perusal of the record decided to cease the operation of Show Cause Notice issued in the name of M/s Carryfor Pharmaceutical (Pvt) Ltd, Plot No. E-81, North Western Industrial Zone, Port Qasim ,Karachi

CASE NO. 33 CHANGE OF MANAGEMENT OF M/S TREAT PHARMACEUTICAL INDUSTRY (PVT) LTD., A-37, SMALL INDUSTRIAL ESTATE, TOWNSHIP, KOHAT ROAD, BANNU.

M/s Treat Pharmaceutical Industry (Pvt) Ltd., A-37, Industrial Estate, Township, Kohat Road, Bannu, under DML No. 000352 by way of formulation has submitted request for

change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management as per Form-29	New management as per Form-A
1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9 2. Mr. Maqbool Khan S/o Lal Mir, CNIC No. 17301-2252149-9.	1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9 2. Mr. Naeem Hayat S/o Hayat Mir, CNIC No. 11101-2863761-7

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/sTreat Pharmaceutical Industry (Pvt) Ltd., A-37, Industrial Estate, Township, Kohat Road, Bannu,,under DML No. 000352 (By way of Formulation) as under;

Previous management as per Form-29	New management as per Form-A
1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9 2. Mr. Maqbool Khan S/o Lal Mir, CNIC No. 17301-2252149-9.	1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9 2. Mr. Naeem Hayat S/o Hayat Mir, CNIC No. 11101-2863761-7

However, as the firm has Psychotropic Section and the firm has not submitted NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 which was inadvertently not mentioned in the agenda 280th meeting of CLB and same could not reflected in the decision of the said meeting.

Decision of the Central Licensing Board in 282nd meeting:

The Board re-considered and accepted for record the change of management of M/sTreat Pharmaceutical Industry (Pvt) Ltd., A-37, Industrial Estate, Township, Kohat Road, Bannu,,under DML No. 000352 (By way of Formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020

Previous management as per Form-29	New management as per Form-A
1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9 2. Mr. Maqbool Khan S/o Lal Mir, CNIC No. 17301-2252149-9.	1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9 2. Mr. Naeem Hayat S/o Hayat Mir, CNIC No. 11101-2863761-7

CASE NO.34. CHANGE OF MANAGEMENT OF M/S BLOOM PHARMACEUTICALS 9PVT) LTD., PLOT NO.30, PHASE-I & II, INDUSTRIAL ESTATE, HATTAR.

M/s Bloom Pharmaceuticals (Pvt) Ltd, Plot No.30, Phase-I & II, Industrial Esate, Hattar, under DML No. 000374 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management as per Form-A & Form-29	New management as per Form-A & Form-29
1. Mrs. Parveen Amjad Qureshi, CNIC No.32102-4340790-0 2. Mrs. Zaib-Un-Nisa, CNIC No. 37405-9974325-8 3. Mr. Ahmed Raza, CNIC No. 35202-8599970-7 4. Sajid Zahoor, CNIC No. 35202-8075941-7	1. Mr. Ahmed Raza S/o Khawaja Abdul Rehman, CNIC No.35202-8599970-7 2. Mr. Junaid Amjad Siddiqui S/o Amjad Saeed Siddiqui, CNIC No.32102-8400418-1 3. Mr. Sajid Zahoor S/o Chaudhary Zahoor Din, CNIC No. 35202-8075941-7

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/sBloom Pharmaceuticals (Pvt) Ltd, Plot No.30, Phase-I & II, Industrial Esate, Hattar, under DML No. 000374 (By way of Formulation) as under;

Previous management as per Form-A & Form-29	New management as per Form-A & Form-29
1. Mrs. Parveen Amjad Qureshi, CNIC No.32102-4340790-0 2. Mrs. Zaib-Un-Nisa, CNIC No. 37405-9974325-8 3. Mr. Ahmed Raza, CNIC No. 35202-8599970-7 4. Sajid Zahoor, CNIC No. 35202-8075941-7	1. Mr. Ahmed Raza S/o Khawaja Abdul Rehman, CNIC No.35202-8599970-7 2. Mr. Junaid Amjad Siddiqui S/o Amjad Saeed Siddiqui, CNIC No.32102-8400418-1 3. Mr. Sajid Zahoor S/o Chaudhary Zahoor Din, CNIC No. 35202-8075941-7

However, as the firm has Psychotropic Section and the firm has not submitted NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 which was inadvertently not mentioned in the agenda 280th meeting of CLB and same could not reflected in the decision of the said meeting.

Decision of the Central Licensing Board in 282nd meeting:

The Board re-considered and accepted for record the change of management of M/s Bloom Pharmaceuticals (Pvt) Ltd, Plot No.30, Phase-I & II, Industrial Esate, Hattar, under DML No.

000374 (By way of Formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020

Previous management as per Form-A & Form-29	New management as per Form-A & Form-29
1. Mrs. Parveen Amjad Qureshi, CNIC No.32102-4340790-0 2. Mrs. Zaib-Un-Nisa, CNIC No. 37405-9974325-8 3. Mr. Ahmed Raza, CNIC No. 35202-8599970-7 4. Sajid Zahoor, CNIC No. 35202-8075941-7	1. Mr. Ahmed Raza S/o Khawaja Abdul Rehman, CNIC No.35202-8599970-7 2. Mr. Junaid Amjad Siddiqui S/o Amjad Saeed Siddiqui, CNIC No.32102-8400418-1 3. Mr. Sajid Zahoor S/o Chaudhary Zahoor Din, CNIC No. 35202-8075941-7

CASE NO. 35 <u>CHANGE OF MANAGEMENT OF DRUG MANUFACTURING LICENSE NO. 000433 (FORMULATION) OF M/S AHAD INTERNATIONAL PHARMACEUTICAL LTD., DERA ISMAIL KHAN.</u>

M/s Ahad International Pharmaceutical, Dera Ismail Khan, under DML no. 000433 by way of formulation has submitted request for change in management of the firm as per form-29 with prescribed fee challan of rs.50,000/-. The detail of management of the firm is as under;

Previous Management (para 33(i)/N P. 3/Corr	Current management as per Form-29 (P. 282/Corr)
1. Mr. Karamatullah Khan, 2. Haji Manzoor Ahamd, 3. Mr. Muhammad Abid Khan, 4. Mr. Muhammad Arif Khan, 5. Mr. Mumtaz Hussain Khan, 6. Mr. Muhammad Naeem Iqbal, 7. Mrs. Farah Karamat, Honourary	1. Mr. Muhammad Abid Khan CNIC No. 1210109583291 2. Mr. Karamatullah Khan CNIC No. 1210153193617 3. Mr. Mumtaz Hussain CNIC No.4230187550615

<u>Decision of the Central Licensing Board in 282nd meeting:</u>

The Board considered and accepted for record the change of management of M/s Ahad International Pharmaceutical, Dera Ismail Khan, under DML no. 000433 (By way of Formulation) as under

Previous Management (para 33(i)/N P. 3/Corr	Current management as per Form-29 (P. 282/Corr)
1. Mr. Karamatullah Khan, 2. Haji Manzoor Ahamd,	1. Mr. Muhammad Abid Khan CNIC No. 1210109583291

3. Mr. Muhammad Abid Khan, 4. Mr. Muhammad Arif Khan, 5. Mr. Mumtaz Hussain Khan, 6. Mr. Muhammad Naeem Iqbal, 7. Mrs. Farah Karamat, Honourary	2. Mr. Karamatullah Khan CNIC No. 1210153193617 3. Mr. Mumtaz Hussain CNIC No.4230187550615

CASE NO. 36. <u>CHANGE OF MANAGEMENT OF M/S IMCO PHARMACEUTICAL LABORATORIES (PVT) LTD., 73, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR</u>

M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar under DML No. 000317 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.75,000/-. The detail of management of the firm is as under;

Previous management as per Form-29	Current management as per Form-H &partnership Deed
1. Mr. Imtiaz Khan, 2. Mrs. Nasreen Imtiaz	1. Mr. Imtiaz Khan s/o Asad Malok Khan CNIC No. 11101-1480874-7, 2. Mr. Muhammad Zumer S/o Imtiaz Khan CNIC No. 17301-4299463-9

<u>Decision of the Central Licensing Board in 282nd meeting:</u>

The Board considered and accepted for record the change of management of M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar under DML No. 000317 (by way of formulation) as under:-

Previous management as per Form-29	Current management as per Form-H &partnership Deed
3. Mr. Imtiaz Khan, 4. Mrs. Nasreen Imtiaz	3. Mr. Imtiaz Khan s/o Asad Malok Khan CNIC No. 11101-1480874-7, 4. Mr. Muhammad Zumer S/o Imtiaz Khan CNIC No. 17301-4299463-9

CASE NO. 37 <u>CHANGE OF MANAGEMENT OF M/S. ICE BERG PHARAMCEUTCIALS (PVT) LTD., RISALPUR.</u>

M/s Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No/ 144, Nowshera Industrial Estate, Risalpur, under DML No. 000816 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management as per Form-29	**New management as per Form-29**
1. Mr. Muhammad Fayaz, CNIC. No. 17101-	1. Mr. Muhammad Fayaz, CNIC. No. 17101-

7193842-7 2. Mr. Najeeb Ullah, CNIC. No. 17301-8989720-9 3. Mr. Muhammad Tahir, CNIC. No. 16101-9356882-3	7193842-7 2. Mr. Najeeb Ullah, CNIC. No. 17301-8989720-9

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/ Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No/ 144, Nowshera Industrial Estate, Risalpur ,under DML No. 000816 (By way of Formulation) as under;

Previous management as per Form-29	New management as per Form-29
1. Mr. Muhammad Fayaz, CNIC. No. 17101-7193842-7 2. Mr. Najeeb Ullah, CNIC. No. 17301-8989720-9 3. Mr. Muhammad Tahir, CNIC. No. 16101-9356882-3	1. Mr. Muhammad Fayaz, CNIC. No. 17101-7193842-7 2. Mr. Najeeb Ullah, CNIC. No. 17301-8989720-9

However, name of Mr. Adil Hussain was inadvertently not mentioned in the agenda and minutes of 280th meeting of CLB held on 26-27thApril, 2021. Detail of management of the firm is as under;

Previous management as per Form-29 (Pages-155/Corr)	New management as per Form-29 (Pages-158/Corr)
1. Mr. Muhammad Fayaz, CNIC. No. 17101-7193842-7 2. Mr. Najeeb Ullah, CNIC. No. 17301-8989720-9 3. Mr. Muhammad Tahir, CNIC. No. 16101-9356882-3	1. Mr. Muhammad Fayaz, CNIC. No. 17101-7193842-7 2. Mr. Najeeb Ullah,CNIC No. 17301-8989720-9, 3. Mr. Adil Hussain CNIC# 17301-6770360-3

Decision of the Central Licensing Board in 282nd meeting:

The Board re-considered and accepted for record the change of management of M/ Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No/ 144, Nowshera Industrial Estate, Risalpur ,under DML No. 000816 (By way of Formulation) as under:-

Previous management as per Form-29 (Pages-155/Corr)	New management as per Form-29 (Pages-158/Corr)
4. Mr. Muhammad Fayaz, CNIC. No. 17101-7193842-7 5. Mr. Najeeb Ullah, CNIC. No. 17301-8989720-9 6. Mr. Muhammad Tahir, CNIC. No.	4. Mr. Muhammad Fayaz, CNIC. No. 17101-7193842-7 5. Mr. Najeeb Ullah,CNIC No. 17301-8989720-9, 6. Mr. Adil Hussain CNIC# 17301-

16101-9356882-3	6770360-3

CASE NO. 38 CHANGE OF MANAGEMENT OF M/S BRYON PHARMACEUTICALS (PVT) LTD., 48-INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR

M/s Bryon Pharmaceuticals (Pvt) Ltd., 48-Industrial Estate, Hayatabad, Peshawar under DML No. 000388 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Old Management as per Form-1A	New Management as per Form-29
i. Mr. Amjad Hussain Siddiqi ii. Mr. Muhammad Jaffar Siddiqui, iii. Mr. Muhammad Shakir Siddiqi iv. Mr. Muhammad Haroon Siddiqi v. Mr. Muhammad Umar Siddiqui vi. Mr. Muhammad Aamir Siddiqi vii. Sajida Parveen viii. Mr. Muhammad Jawad ix. Mr. Muhammad Arshad Anjum	i. Mr. Amjad Hussain Siddiqi S/o Mian Ghulam Hussain Siddiqi, CNIC No.17301-4839583-1. ii. Mr. Muhammad Nasir Siddiqi S/o Muhammad Jaffar Siddiqui, CNIC No.17301-3267403-7. iii. Mr. Muhammad Shakir Siddiqi S/o Mian Ghulam Hussain, CNIC No.17301-1557181-9. iv. Mr. Muhammad Haroon Siddiqi S/o Mian Ghulam Hussain Siddiqi, CNIC No.17301-1539357-3 v. Mr. Muhammad Umar Siddiqui S/o Muhammad Haroon Siddiqui, CNIC No.17301-1531494-1. vi. Mr. Muhammad Aamir Siddiqi S/o Muhammad Jaffar Siddiqi, CNIC No.17301-3266271-7. vii. Sajida Parveen W/o Muhammad Habib Ullah Khan, CNIC No.35202-2553981-2. viii. Mr. Muhammad Jawad S/o Muhammad Kafeel, CNIC No.17301-7087426-9. ix. Mr. Muhammad Arshad Anjum S/o Ghulam Muhammad, CNIC No.61101-1974783-9.

Decision of the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s Bryon Pharmaceuticals (Pvt) Ltd., 48-Industrial Estate, Hayatabad, Peshawar under DML No. 000388, under DML No. 000816 (By way of Formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 :-

Old Management as per Form-1A	New Management as per Form-29
1. Mr. Amjad Hussain Siddiqi 2. Mr. Muhammad Jaffar Siddiqui, 3. Mr. Muhammad Shakir Siddiqi 4. Mr. Muhammad Haroon Siddiqi 5. Mr. Muhammad Umar Siddiqui 6. Mr. Muhammad Aamir Siddiqi 7. Sajida Parveen 8. Mr. Muhammad Jawad 9. Mr. Muhammad Arshad Anjum	1. Mr. Amjad Hussain Siddiqi S/o Mian Ghulam Hussain Siddiqi, CNIC No.17301-4839583-1. 2. Mr. Muhammad Nasir Siddiqi S/o Muhammad Jaffar Siddiqui, CNIC No.17301-3267403-7. 3. Mr. Muhammad Shakir Siddiqi S/o Mian Ghulam Hussain, CNIC No.17301-1557181-9. 4. Mr. Muhammad Haroon Siddiqi S/o Mian Ghulam Hussain Siddiqi, CNIC No.17301-1539357-3 5. Mr. Muhammad Umar Siddiqui S/o Muhammad Haroon Siddiqui, CNIC No.17301-1531494-1. 6. Mr. Muhammad Aamir Siddiqi S/o Muhammad Jaffar Siddiqi, CNIC No.17301-3266271-7. 7. Sajida Parveen W/o Muhammad Habib Ullah Khan, CNIC No.35202-2553981-2. 8. Mr. Muhammad Jawad S/o Muhammad Kafeel, CNIC No.17301-7087426-9. 9. Mr. Muhammad Arshad Anjum S/o Ghulam Muhammad, CNIC No.61101-1974783-9.

CASE NO. 39 <u>CHANGE OF MANAGEMENT OF M/S ETERNA PHARMA (PVT) LTD., PLOT NO.99,100,101&198-C, SECTOR D1, OLD INDUSTRIAL ESTATE, AZAD JAMMU & KASHMIR</u>

M/s Eterna Pharma (Pvt) Ltd., Plot No.99,100,101&198-C, Sector D1, Old Industrial Estate,Azad Jammu & Kashmir, wherein the firm has submitted the application for change of management. The firm has deposited fee of Rs.75,000/- for change of management. The detail is as under;

Old management as per Form-29	New management as per Form-29 (Govt of AJK)
1. Mr. ZeejahFazli S/o Fazal Ur Rehman Yousuf Fazli, CNIC No.61101-6888842-1. 2. Mrs. Faiza Zeejah W/o ZeejahFazli, CNIC No. 61101-1724093-4	1. Mr. Khalid Naseer S/o Muhammad Hanif, CNIC No.36502-3224581-7. 2. Mr. ZeejahFazli S/o Fazal Ur Rehman Yousuf Fazli, CNIC No.61101-6888842-1.

Decision of the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s Eterna Pharma (Pvt) Ltd., Plot No.99,100,101&198-C, Sector D1, Old Industrial Estate,Azad Jammu & Kashmir ,under DML No. 000923 (By way of Formulation) as under:-

Old management as per Form-29	New management as per Form-29 (Govt of AJK)
1. Mr. Zeejah Fazli S/o Fazal Ur Rehman Yousuf Fazli, CNIC No.61101-6888842-1. 2. Mrs. Faiza Zeejah W/o ZeejahFazli, CNIC No. 61101-1724093-4	1. Mr. Khalid Naseer S/o Muhammad Hanif, CNIC No.36502-3224581-7. 2. Mr. ZeejahFazli S/o Fazal Ur Rehman Yousuf Fazli, CNIC No.61101-6888842-1.

CASE NO. 40 CHANGE OF MANAGEMENT OF M/S WERRICK HARMACEUTICALS, LOT NO. 216-217, I/10-3, INDUSTRIAL AREA, ISLAMABAD.

M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad under DML No. 000340 by way of formulation has submitted request for change in management of the firm with prescribed Fee Challan of Rs.75,000/-. The detail of management of the firm is as under;

Previous management	New management as per Partnership deed
1. Mr, Muhammad Awais S/o Muhammad Shafi 2. Mr. Ali Amin S/o Noor ul Amin 3. Mr, Muhammad Bilal S/o Tahir Hamid 4. Mr, Muhammad Umair S/o Tahir Hamid 5. Mr. Farooq Owais S/o Muhammad Awais	1. Mr. Ali Amin S/o Noor ul Amin CNIC No.61101-0909202-7. 2. Mr, Muhammad Bilal S/o Tahir Hamid, CNIC No.61101-1856273-3. 3. Mr, Muhammad Umair S/o Tahir Hamid, CNIC No.61101-7964040-9. 4. Mr. Farooq Owais S/o Muhammad Awais, CNIC No.61101-1929057-5.

Decision of the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad under DML No. 000340 by way of formulation as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020

:-

Previous management	New management as per Partnership deed
1. Mr, Muhammad Awais S/o Muhammad Shafi 2. Mr. Ali Amin S/o Noor ul Amin 3. Mr, Muhammad Bilal S/o Tahir Hamid 4. Mr, Muhammad Umair S/o Tahir Hamid 5. Mr. Farooq Owais S/o Muhammad Awais	1. Mr. Ali Amin S/o Noor ul Amin CNIC No.61101-0909202-7. 2. Mr, Muhammad Bilal S/o Tahir Hamid, CNIC No.61101-1856273-3. 3. Mr, Muhammad Umair S/o Tahir Hamid, CNIC No.61101-7964040-9. 4. Mr. Farooq Owais S/o Muhammad Awais, CNIC No.61101-1929057-5.

CASE NO.41 CONVERSION/CHANGE OF TITLE OF EYE DROPS (GENERAL) INTO EYE/EAR/NASAL DROP (GENERAL).M/S WINBRAINS RESEARCH LABORATORIES, PLOT NO. 69/1 BLOCK B, PHASE I-II, INDUSTRIAL ESTATE HATTAR UBEDR DML NO. 725.

M/s Winbrains Research Laboratories, Plot No. 69/1 Block B, Phase I-II, Industrial Estate Hattar ubedr DML No. 725. has requested for conversion/change of title of Eye Drops (General) into Eye/Ear/Nasal Drop (General).

It is submitted fro information that on the recommendations of the panel of experts, the Central Licensing Board in its 252nd meeting held on 15th March, 2017 has considered and approved the grant of Eye Drops (General)

Submitted for consideration of the Board.

Decision of the Central Licensing Board in 282nd meeting:

The Board considered and approved change in name of the Section in the name of M/s Winbrains Research Laboratories, Plot No. 69/1 Block B, Phase I-II, Industrial Estate Hattar under DML No. 725 by way of Formulation as under:-

1. Eye Drops (General) into Eye/0Ear/Nasal Drop (General).

CASE NO. 42 M/S MEDICON PHARMACEUTICAL INDUSTRIES (PVT) LTD., B-1/11, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR

The firm, M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar submitted the application for renewal of DML No. 000215 by way of formulation on 26-05-2016 for the period of 14-06-2016 to 13-06-2021, which was well on time. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. To submit renewal of Drug Manufacturing License application on prescribed Form-1A (copy enclosed).
ii. To submit detail of management / owners with attested copies of CNIC's and Form-29 (previous and current).

a. With reference to above letter, it is mentioned that as per available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. Licensing Division issued final reminder on for completion of application of renewal of DML to the firm for information / documents as under;
    i. To submit renewal of Drug Manufacturing License application on prescribed Form-1A (copy enclosed).
    ii. To submit detail of management / owners with attested copies of CNIC's and Form-29 (previous and current).

b. No response of the firm was received with reference to above mentioned letter and final reminder and case was considered in 253rd meeting of the Central Licensing Board.

c. Decision of CLB in its 253rd meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar

DML No. 000440 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

(The Drug Manufacturing Number of the firm was erroneously written as "**000440**" instead of the correct Drug Manufacturing License Number i.e. "**000215**" which was corrected **in 255th meeting)**

d. Reply of Firm to Show Cause Notice

We may refer show cause notice dated 21-09-2017, which is received on 25-09-2017, we are sending following documents for consideration

i. Application for renewal of DML on prescribed Form-1A
ii. Detail of management /owners with attested CNICs and Form-29, previous and current alongwith Challan for Rs. 50,000/- being fee of Change of management.

e. The firm has fulfilled rest of the codal formalities for renewal of Drug Manufacturing Licensee excluding proof of approved sections.
f. Proceedings and Decision of Central Licensing Board in 256th meeting.

Dr. Maqbool Ahmed, Chief Executive of the firm appeared before the Board and contended that all codal formalities has been completed and showcause notice may be withdrawn. The Board after hearing representative of the firm advised him to comply the legal requirements in time in future and also decided to cease the operation of the show cause notice issued to the firm.

g. In light of the decision of Central Licensing Board letter was issued to the firm.

h. The firm has submitted LOP for regularization of the following sections;

i. Tablet Section (General)
ii. Capsule Section (General)
iii. Syrup Section (General)
iv. Sachet Section (General)
v. Tablet Section (Psychotropic)
vi. Capsule Section (Penicillin)
vii. Dry Powder Suspension Section (Penicillin)
viii. Capsule Section (Cephalosporin)
ix. Dry Powder Suspension Section (Cephalosporin)
x. Quality Control Lab
xi. Warehouse

i. . The above submitted LOP for regularization was discussed in LOP committee and following shortcomings have been observed;

i. The firm has deposited fee of Rs. 50000/- only whereas there are eleven sections in LOP under discussion and remaining fee of Rs. 5000/- needs to be deposited.
ii. Door for entry from male change room to general production corridor has not been given.
iii. The area for storage of non active material in raw material store (general) needs to be segregated.
iv. Sachet Section (General) needs to be divided into mixing and filling areas.
v. Man and material flow in Syrup Section (General) is not in order i.e. the entry is through packing hall and manufacturing area is away from filling area.
vi. Granulation and drying area has not been provided in Tablet Section (Psychotropic).
vii. Solution preparation area has not been provided with coating area in Tablet Section (Psychotropic).
viii. Door for entering to change room of penicillin area has not been given.
ix. Step over bench has not been shown in change room of penicillin area.
x. Transfer window needs to be installed between bottle blowing and Dry Powder Suspension filling area of Dry Powder Suspension Section (Penicillin).
xi. Sampling and dispensing areas has not been provided with raw material store of penicillin area.
xii. Entry of raw and packing material to the cephalosporin area is not in order.
xiii. Transfer window needs to be installed between bottle blowing and Dry Powder Suspension filling area of Dry Powder Suspension Section (Cephalosporin).

j. The firm was advised to submit revised LOP vide letter NO. 3-7/91-Lic (Vol-III) dated 19/02/2018 and 18/05/2019. However, LOP for regularization was not approved so for because the firm has not submitted Revised LOP for approval.

Now QA/LT Division, DRAP's has informed vide file No. 4-43/89-QA that Area FID, DRAP, Peshawar has conducted routine cGMP of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar on 14-12-2020. In the inspection report the Area FID has given following recommendation;

i. To follow up their application for renewal of DML and remove deficiencies if any pending on the part of firm.
ii. To shift their penicillin sections to separate block.
iii. To regularize their layout plan with consultation of Licensing Divi ion of DRAP Islamabad.
iv. To improve their Microbiology Lab.
v. To purchase primary reference standards initially for three top selling products and then gradually for remaining products.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar DML No. 000215 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

In the light of Central Licensing Board's decision a Show Cause Notice was issued to the firm M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar DML No. 000215(Formulation)dated 10-03-2021.

The firm, M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar submitted revise LOP relocation of Penicillin Section from Ground Floor to First Floor vide letter No. nil dated 20/04/2021 along with fee of Rs 5000/=.

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person on behalf of the firm appeared before the Board.. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000215 (by way of formulation) of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar, till fulfilment of the codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

The firm submitted shortcoming documents which were are evaluated and the application for renewal of DML was found complete as per Form-1A and in compliance to the decision of the CLB orders dated 25-05-2021 regarding resumption of production/ ceasing of suspension orders were issued and a panel of experts was also constituted for inspection of the firm for renewal of DML and for regularization of manufacturing facility.

Submitted for consideration and ratification of the Board.

Decision of the Central Licensing Board in 282nd meeting:

The Board considered and ratified the decision of the Secretary, Central Licensing Board regarding ceasing of the suspension for further period and resumption of production in the name of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar.

CASE NO. 43 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S IMCO PHARMACEUTICAL LABORATORIES (PVT) LTD., 73, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR**

The firm, M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar wherein the firm has submitted the application for renewal of Drug Manufacturing No. 000317 (by way of Formulation). The application was received on **13/02/2020.** The firm has submitted a fee of Rs. 50,000**.** The application was evaluated as per Drugs (Licensing, Registering & Advertising) Rules 1976 and found following shortcomings;

i. Form-1A as per prescribed format (attached) duly signed and stamped by CEO/Owner of the firm.
ii. Name(s) of registered drugs.
iii. Detail of management at the time of previous renewal and current renewal.
iv. Updated Form-29 issued and certified true copy by S.E.C.P.
v. Attested copy of CNIC's of all Directors.
vi. Proof of section approval from Central Licensing Board.
vii. Approved master Layout Plan
viii. Attested copy of list of registered Drugs.
ix. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.
x. For approval of proposed production Incharge, submit application as per SOP along with documents and prescribed fee.

Accordingly, shortcoming letter No. 3-4/91-Lic (Vol-II) dated 24/08/2020 was issued to the firm to rectify above mentioned shortcomings.

In response to shortcoming letter the firm has submitted their reply. The same was evaluated and found following shortcoming for which final reminder vide letter No. 3-4/91-Lic (Vol-II) dated 04/11/2020 was issued to rectify these shortcomings;

i. Form-1A as per prescribed format (attached) duly signed and stamped by CEO/Owner of the firm.
ii. Name(s) of registered drugs.
iii. Detail of management at the time of previous renewal and current renewal.
iv. Updated Form-29 issued and certified true copy by S.E.C.P.
v. Attested copy of CNIC's of all Directors.
vi. Proof of section approval from Central Licensing Board.
vii. Approved master Layout Plan
viii. Attested copy of list of registered Drugs.
ix. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.
x. For approval of proposed production Incharge, submit application as per SOP along with documents and prescribed fee.

In response to final reminder the firm submitted their reply, however, as of today, the firm did not rectify following shortcomings;

i. Updated Form-29 issued and certified true copy by S.E.C.P.
ii. Proof of section approval from Central Licensing Board.
iii. Approved master Layout Plan.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 19 and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000317(by way of formulation) of M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar may not be suspended or cancelled by Central Licensing Boardor application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to the firm M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar dated 08-01-2021.

In response to Show Cause Notice, the firm submitted their reply which is reproduced as under;

> *"We have deposited the letter alongwith the relevant documents and approved map in the office of DRAP, Islamabad on 13-02-2020 and 19-11-2020. Moreover, request you to call me for personal hearing to explain my position properly."*

Meanwhile another reply is received on 22-04-2021 from the firm which is re-produced as under;

> *Your office pointed out the following short of the following documents/information*
>
> 1. ***Updated form 29***
> *We have applied for form "H" and after the long procedure we received form H (copy attached)*
>
> 2. ***Proof of section wise approval***
> *We have approved layout plan in 2005 in which the detail of all sections mentioned moreover we provide you the inspection report of our firm in which the inspection team mention the sections of our firm*
>
> a. *Renewal inspection report of 13/11/2008 in which the sections are approved by panel (Copy attached)*
> b. *Inspection report of F.I.D Peshawar 7/4/2014 in which he approved the sections in inspection book (Copy attached)*
> c. *Inspection report of F.I.D Peshawar in 14/5/2018 in which he mention the section of our firm in inspection book (Copy attached)*
>
> 3. ***Approval of layout plane***

We provide you the copy of the letter of approval of layout plane in 2/4/2005 Our firm is established in 1992 and that time only approval of layout plane is issued by the minister of health and the panel team or F.I.D have no objection on the approval of sections at that time if there is any short coming we are ready to overcome the shortcoming.

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Imtiaz Ahmed CEO of the firm appeared before the board and contended that the documents are already submitted to the division of Drug Licensing . The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000317 (by way of formulation) of M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar till fulfillment of codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

The firm submitted shortcoming documents which were are evaluated and the application for renewal of DML was found complete as per Form-1A and in compliance to the decision of the CLB orders dated 17-06-2021 regarding resumption of production/ ceasing of suspension orders were issued and a panel of experts was also constituted for inspection of the firm for renewal of DML and for regularization of manufacturing facility.

Submitted for consideration and ratification of the Board.

Decision of the Central Licensing Board in 282nd meeting:

The Board considered and ratified the decision of the Secretary, Central Licensing Board regarding ceasing of the suspension for further period and resumption of production in the name of M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar

CASE NO.44 **CHANGE OF TITLE/NATURE OF OF M/S IMCO PHARMACEUTICAL LABORATORIES (PVT) LTD., 73, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR undeDML No. 000317 (Formulation)**

The firm, M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar submitted application for change of title/type of business from "IMCO Pharmaceutical Laboratories (Pvt) Ltd" to "IMCO Pharmaceutical Laboratories" . The firm submitted Fee Rs 75,000.

Name of the firm as per Form-H is as under;

IMCO Pharmaceutical Laboratories, 73, Industrial Estate, Hayatabad, Peshawar.

Submitted for consideration of the Board.

Decision of the Central Licensing Board in 282nd meeting:

The Board considered and approved the correction in the title of the firm as per Form H as under:

IMCO Pharmaceutical Laboratories, 73, Industrial Estate, Hayatabad, Peshawar

CASE NO. 45. SITE VERIFICATION OF M/S STEFANIE PHARMACEUICALS PLOT/BLOCK NO.69-B, LARGE INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR .

M/s Stefanie Pharmaceuticals, Peshawar vide their application dated Nil has forwarded a request for approval of site to establish a pharmaceutical unit located at Plot/Block No.69-B, Large Industrial Estate, Hayatabad, Peshawar. Accordingly Area FID, DRAP, Peshawar was directed vide letter dated 19th April, 2018 for verification of site. Area FID, DRAP, Peshawar, after visiting the site has forwarded site verification report of the said firm. The recommendation of the Area FID, DRAP, Peshawar is as under;

Size of the plot:
The management has already submitted "Transfer Lease" for the proposed site which shows it is 1.0 (one) Acres plot and dimensions are (370' 0 ½" X 115' 3") which measures about 44464.0 sq. Ft. However, the management has spared 150627.73 Sq. Ft for M/s Stefanie Health Care" and rest for "M/s Stefanie Pharmaceutical" i.e 28457.27 Sq. Ft. the rest for the offices i.e 944.00.

Location:
The proposed site is located at Hayatabad Industrial Estate, Peshawar, the boundaries are as under;

Surroundings:
On North side is Plot No.69B (M/s Oriental Enterprises).
On South side is Plot No.69C. (M/s Shanghai UPVC)
On East side is Plot No.70 and 70A (M/s United Rubber (Pvt) Ltd.)
On West side is Road S/3

Environment:
Smoke pollution is seen from in its surrounding (east side) as the Rubber factory is emitting dense black fumes at the time of visit.

Conclusion:
As per requirement laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(I)/98 dated 15.05.1998) under rule 16(a) of the Drugs (Licensing, Registering & Advertising) Rules, 1976, the proposed premises is**not suitable** to construct a pharmaceutical unit as of today.
Sketch of plot and its adjoining area is attached as desired.

2. Meanwhile, another application is received from M/s Stefanie Pharmaceutical, Peshawar for re-inspection of the site alongwith prescribed fee of Rs.5,000/- and he has also submitted an affidavit wherein he has stated that he will install HVAC system in the building.

Decision by the Central Licensing Board in 272nd meeting:

The Board considered and decided to call the representative of the firm for personal hearing before taking final decision.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board

Accordingly, a letter for personal hearing was issued on 7th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Ehsan Ullah, CEO of the firm appeared before the Board and contended thatRubber factory which was emitting smoke has taken precautionary measures to avoid smoke contamination & he also presented provisional NOC from EPA.The Board after hearing the representative of the firm decided to re-inspect the firm for site verification after submission of NOC from EPA.

Accordingly, a letter for re-inspect the firm for site verification was issued on 20-02-2020.

In response to this office letter No. F. 3-1/2018-Lic dated 20/02/2020 issued in light of Decision of CLB in its 273rdmeeting held on 15thJanuary, 2020, the Area FID, Peshawar has submitted Inspection report for site verification of M/s Stefanie Pharmaceutical, Large Industrial Estate, Hayatabad Peshawar.

In the above inspection report it is stated that;

i. The Area FID and Additional Director (E&M), DRAP Peshawar inspected the proposed site for M/s Stefanie Pharmaceutical, Large Industrial Estate, Hayatabad Peshawar.

ii. The owner of the firm Mr.Ahsan Ullah briefed that they have taken following measures/changes after rejection of the site by the Panel earlier in February, 2019.

   a. They have obtained an Environmental Approval/Decision Note on Environmental Impact Assessment (EIA) from Environmental Protection Agency Khyber Pakhtunkhwa vide their letter No. EPA/EIA/Pharma/Stefanie/Pesh/20/819-20 dated 02/07/2020 wherein it has been stated that "After careful review and upon feasibility of external and internal environmental conditions, the Environmental protection Agency, Govt. of Khyber Pakhtunkhwa has decided to accord approval of the Environmental Impact Assessment of the firm in line with the Khyber Pakhtunkhwa Environmental Protection Act, 2014 and IEE/EIA Regulations, 2000 subject to some terms & conditions" (Copies letter from EPA and Decision on EIA attached as Annexure-I)

   b. The firm had two separate plots i.e Plot No. 69-B/2 measuring 2.5 Kanals and Plot No. 69-B/1 measuring 5.50 Kanals. Initially the firm intended to establish a neutraceutical unit on Plot No. 69-B/2 measuring 2.5 Kanals and an allopathic Pharmaceutical unit on Plot No. 69-B/1 measuring 5.50 Kanals. Later on the investor in their neutraceutical project (M/s Stefanie Healthcare) left the project and they

withdrew their project with written application to Director H & OTC Division DRAP (copy of letter attached as annexure-II). Now they have merged the two plots together and changed the name of the unit as Stefanie Pharmaceuticals. (Copy of merger of Plots attached as annexure-III),

c. They requested the neighboring rubber industry M/s United Rubber (Pvt) Ltd. to amend in their plant to reduce the amount of smoke particles emitted in the chimney of their plant. Now they have done certain changes in their plant due to which the amount of smoke particles emitted in the chimney have been reduced significantly. (Copy of letter from the rubber factory attached as annexure-IV, copy of undertaking on stamp paper attached as annexure-V),

d. They will install HEPA filters in the premises of their Pharmaceutical unit to avoid contamination of end products. They will comply all the guidelines of DRAP and WHO etc of clean rooms required for relevant sections of a Pharmaceutical Unit. They will also do design qualification of HVAC system keeping in view the surrounding environment and user requirement specification (URS). (copy of undertaking on stamp paper attached as annexure-V)

iii. Now the specifications/dimensions of the plot are as under:

Total Area: 2.5 Kanals (Plot No. 69-B/2) and 5.50 Kanals (Plot No. 69-B/1 measuring) = 8 Kanals**{Plot No. 69-B/2 has already a three floors building each floor has a covered area of 8427.583 Sq. Ft.}**

Location:-

The proposed plot is locatedin the industrial Estate of Hayatabad Peshawar. The boundaries are as under:

Surroundings:

East:	Plot No. 70 and 70A (M/s United Rubber (Pvt) Ltd.)
West:	Road S-3
North:	Plot No. 69B (M/s Marks Razmak)
South:	Plot No. 69C (M/s Shanghai UPVC & Pumps (Pvt) Ltd)

Environment: The plot is situated in the industrial Estate of Hayatabad Peshawar. The rubber factory on the east side **now emits less dense black fumes**.

iv. Based on above mentioned description, and submission of the firm as mentioned in para 03 above the case for approval of proposed plot may be placed before Central Licensing Board for consideration of a Pharmaceutical unit as per requirement laid down under paragraph 1 of section 1 of Schedule "B" (SRO. 470(I)/98 dated 15.05.1998) under rule 16(a) of the Drugs (Licensing, Registering & Advertising) Rules, 1976. Sketch of plot and its adjoining area is attached as desired.

Paragraph 1 of Section 1of Schedule B

1.2. **Surroundings:** Premises shall be situated in an environment that, when considered together with measures to protect the manufacturing processes, presents minimum risk of causing any contamination of materials or products. It shall be away from filthy surroundings and shall not be adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or

obnoxious odour or fumes or large quantities of soot, dust or smoke which may contaminate the drugs being manufactured or adversely affect their quality. Existing units shall keep the surroundings under their control to be clean.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the case and decided to provide last opportunity to applicant before taking any final decision.

In light of above decision, FID was asked for updated status of the proposed site and inspection thereof vide letter No. dated. The Area FID, Peshawar vide letter No. 1-02/2019-DRAP(P)1661 dated 07/05/2021 has submitted inspection report of M/s Stefanie pharmaceutical, Peshawar. The said report is reproduced as under;

"Dear Sir,

Please refer to your letter No. F. 3-1/2018-Lic dated 15th March, 2021 on the captioned subject and in continuation of this office letter of even No. dated 1 7th September, 2020.

2. The undersigned inspected the proposed site M/s Stefanie Pharmaceutical, Large Industrial Estate, Hayatabad Peshawar.

3. The owner of the firm Mr. Ahsan Ullah provided copy of another NOC from the Environmental Protection Agency 'Khyber Pakhtunkhwa vide their letter No. EPA/EIA/Pharma/Stefanie/pesh/20/1878-79 dated 21/12/2020 (Copy attached) wherein it has been verified that the EPA conducted Ambient Air Particulate Matter (PM) through High Volume Air Sampler which Shows compliance of National Ambient Air Quality Standards (NAAQS), 2010. The EPA has concluded that the premises is situated in an Environment that presents minimum risk of causing any contamination of material or finished product and they have no objection on the installation of Pharmaceutical unit on the said premises.

4. The specifications/dimension of the plot have already been forwarded.

5. Based on already forwarded description, and submission of the firm as mentioned in para 03 above and as per requirement laid down under paragraph I of Section I of Schedule "B" (SRO dated 15.()5.1998) under rule 16(a) of' the drugs (Licensing, Registration & Advertising) Rules. 1976. the proposed premises may be considered suitable to construct a pharmaceutical unit as of today subject to the compliance of their following commitment/undertaking on Stamp paper:

"They will install HEPA filters in the premises of their Pharmaceutical unit to avoid contamination of end products. they will comply all the guidelines of DRAP and WHO etc of clean rooms required for relevant sections of a Pharmaceutical unit. they will also do design qualification of HVAC system keeping in view the surrounding environment and user requirement specification (URS)"

Sketch of plot and its adjoining area has already been forwarded

In light of powers delegated by Central Licensing Board in its 278th meeting held on 10th& 11th December, 2020, Secretary Central -licensing Board site approval letter for the proposed site to establish pharmaceutical unit at Plot No. 69-B, Large Industrial Estate, Hayatabad, Peshawar was issued on 15-03-2021.

Submitted for information of the Board.

Decision of the Central Licensing Board in 282nd meeting:

The Board considered and perused the case.

CASE NO. 46 CHANGE OF MANAGEMENT OF M/S SWAT PHARMACEUTICALS, VALLEY ROAD, SHERARI GULKADA NO. 3, SAIDU SHARIF SWAT KHYBER PAKHTOONKHWA.

The Drug Manufacturing License No. 0000035 of M/s Swat Pharmaceuticals, was granted/transfer from old premises situated at Saidu Sharif Road, Amankot Mingora, Swat to new premise situated at Valley Road, Sherarai Gulkada No.3, Saidu Sharif Swat by CLB in its 277th meeting held on 15-16th October, 2020, accordingly with following detail.

Name, DML #, address and Sections	Sections	Type of Firm	Management	Rent agreement (Page/17
M/s Swat Pharmaceuticals, Valley Road, SherariGulkada No. 3, Saidu Sharif Swat Khyber Pakhtoonkhwa.	1. Tablet (General), 2. Tablet (Psychotropic), 3. Capsule (General), 4. Syrup (General), 5. Cream/ointment (General), 6. Sachet (General).	Sole proprietorship	Mr. Mubarak Ali S/o Alamgir CNIC No. 15602-0482661-1 **(Sole Proprietor)**	Rent agreement between Mr. Shahid Fazal S/O Fazal Rabi (owner of the land) and Mr. Mubarak Ali S/o Alamgir for 25 year

Mr. Javed Waseem vide letter No. SP/Lic/008/20 dated 23-11-2020has submitted that management of the firm M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat has been changed and requested for change of management. The applicant also submitted following document with application;

i. Notarized copy of sale agreement (100/100) between Mr. Shahid Fazal Rabi , Mr Javeed Waseem and Mangnaish Kumar,
ii. Notarized copy of sale of share agreement (18/100) between Mr. Mubarak Ali S/o Alamgir and Mr. Shaid Fazal Rabi and Mr Javeed Waseem,
iii. Photocopy of NTN of the firm M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat,

iv. fee of Rs.50,000/- for change of management.

Detail of management is as under;

Previous Management Sole Proprietor Page 59/Corr	Current Management
1. Mr. Mubarak Ali S/o Alamgir CNIC No. 15602-0482661-1	1. Mr. Mangnaish Kumar S/o Mr. Ram Saroop CNIC No. 15602-3006910-9

Mr. Mubarak Ali CEO/Sole Proprietor of M/s Swat Pharmaceuticals, Valley Road, SherarаiGulkada No.3, Saidu Sharif Swat vide letter No. Nil dated Nil has informed the Licensing Division, DRAP that the information submitted by Mr. Jawed Wasim are **totally wrong**. Mr. Mubarak Ali has further submitted that the application submitted by Mr. Waseem Javid for change of management **may not be processed.** Mr. Mubarak Ali CEO/Sole Proprietor of M/s Swat Pharmaceuticals, Valley Road, SherarаiGulkada No.3, Saidu Sharif Swat filed an application in the Court of Senior Civil Judge, Swat. The application is in Urdu language and reproduced as under;

بعدالت جناب سینئر سول جج صاحب/اعلیٰ علاقہ قاضی صاحب سوات

مبارک علی ولد عالمگیر سکنہ گل کدہ نمبر 2 سیدو شریف ضلع سوات۔ ----------(مدعی)

بنام

(۱) ڈائریکٹر ڈرگ لائسنسنگ رجسٹریشن سنٹرل لائسنسنگ بورڈ ڈرگ ریگولیٹری اتھارٹی پاکستان۔

(۲) ایڈیشنل ڈائریکٹر ڈرگ لائسنسنگ سیکرٹری لائسنسنگ بورڈ ڈرگ ریگولیٹری اتھارٹی پاکستان۔

(۳) آسسٹنٹ ڈائریکٹر لائسنسنگ ڈرگ ریگولیٹری اتھارٹی بمقام اسلام آباد۔ بمقام T.F کمپلیکس G.9/4 اسلام آباد۔

(۴) شاہد فضل ولد فضل ربی سکنہ ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف ضلع سوات۔

(۵) وسیم جاوید ولد جاوید اقبال، I.P.P پرائیویٹ لمیٹڈ ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف سوات۔ ----------(مدعا علیہم)

دعویٰ صدور ڈگری:

(ا) استقرار حق بدیں مراد کہ من مدعی کو مجاز اتھارٹی نے Drug Manufacturing لائسنس مورخہ MS، 26/10/2020 سوات فارماسیوٹیکلز ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف ضلع سوات کیلئے لائسنس دی ہے۔ اور مدعا علیہم مجاز نہ ہیں کہ وہ مذکورہ لائسنس کو من مدعی کے نام اور ملکیت تسلیم کرنے سے انکار کریں اور مذکورہ لائسنس کے تحت دوائیاں بنانے کے کاروبار میں کوئی دخل مداخلت کریں۔ نیز مدعا علیہ نمبر 5 نے مدعا علیہم نمبر 1 تا 3 کو مذکورہ لائسنس اپنے نام کرنے کیلئے جو درخواست دی ہے اور اُس کیساتھ جو دستاویزات منسلک کیے ہیں، وہ غلط اور غیر قانونی، جعلی، فرضی اور خود ساختہ ہیں، اور حقوق من مدعی پر کالعدم اور غیر موثر ہوتے ہوئے قابل منسوخی ہیں۔

(ب) صدور حکم امتناعی دوامی بنام مدعا علیہم بدیں طور کہ وہ لائسنس مذکورہ بالا من مدعی کے نام اور ملکیت تسلیم کر کے، اُس میں ردوبدل کرنے سے باز و ممنوع رہیں۔ (جاری)

مالیت بغرض کورٹ فیس واختیار سماعت مبلغ 200 روپے مقرر کی جاتی ہے۔

بنائے دعویٰ عرصہ چند یوم قبل بعد از انکار مدعا علیہم اندر حدود و اختیار سماعت عدالت ہذا پیدا شد۔

جناب عالی! حسب ذیل عرض ہے۔

۱۔ یہ کہ من مدعی نے بمقام ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف ضلع سوات، دوائیاں بنانے کیلئے کارخانہ تعمیر کرنے کا ارادہ کیا، اور اس سلسلے میں مدعا علیہ نمبر 4 سے اُس کی ملکیتی اراضی بمقام شیراڑئی گل کدہ نمبر ۳ سوات، بروئے اقرار نامہ محررہ **22/7/2017**، 25 سال کیلئے لیز پر لے لیا۔ (نقل اقرار نامہ لف ہے)۔

۲۔ یہ کہ بعد ازاں مدعی نے اراضی مذکورہ پر فارماسیوٹیکلز یونٹ کے تعمیر کیلئے مجاز حکام کو درخواست دی، جس پر کاروائی کرتے ہوئے، فیڈرل انسپکٹر آف ڈرگ پشاور نے آسسٹنٹ ڈائریکٹر لائسنسنگ ڈرگ ریگولیٹری اتھارٹی کے احکامات کے روشنی میں موقع ملاحظہ کیا اور جائے مذکورہ فارماسیوٹیکلز یونٹ کے تعمیر کیلئے بروئے رپورٹ محررہ **26/8/2017**، موزوں قرار دی۔ (نقل رپورٹ لف ہے)۔

۳۔ یہ کہ جس کے بعد من مدعی نے دوسرے کوائف کو پورا کرنے کیلئے جائے مذکورہ بالا کا نقشہ بنایا اور مبلغ **-/30,000** روپے مطلوبہ فیس جمع کی، جو کہ متعلقہ حکام نے بروئے لیٹر محررہ **29/11/2017** منظور کیا ہے۔ (نقولات درخواست و منظوری لیٹر لف ہیں)۔

۴۔ یہ کہ بعد ازاں یونٹ میں ایزادگی کرنے کیلئے دوسرا نقشہ بنایا اور اس کے منظوری کیلئے مورخہ **01/01/2019**، مجاز حکام کو درخواست دی اور مبلغ **5000** روپے مطلوبہ فیس جمع کیا، اور جس کی منظوری بروئے لیٹر محررہ **04/02/2019** دی گئی۔ (نقولات درخواست، بینک رسید اور لیٹر، نقشہ لف ہیں)۔

(جاری)

۵۔ یہ کہ اس دوران من مدعی نے مجاز حکام کے ہدایت کی روشنی میں پہلے بمورخہ **31/01/2018** اور پھر بمورخہ **23/07/2018** ، پراگریس رپورٹس دے دی۔ (نقولات رپورٹس لف ہیں)۔

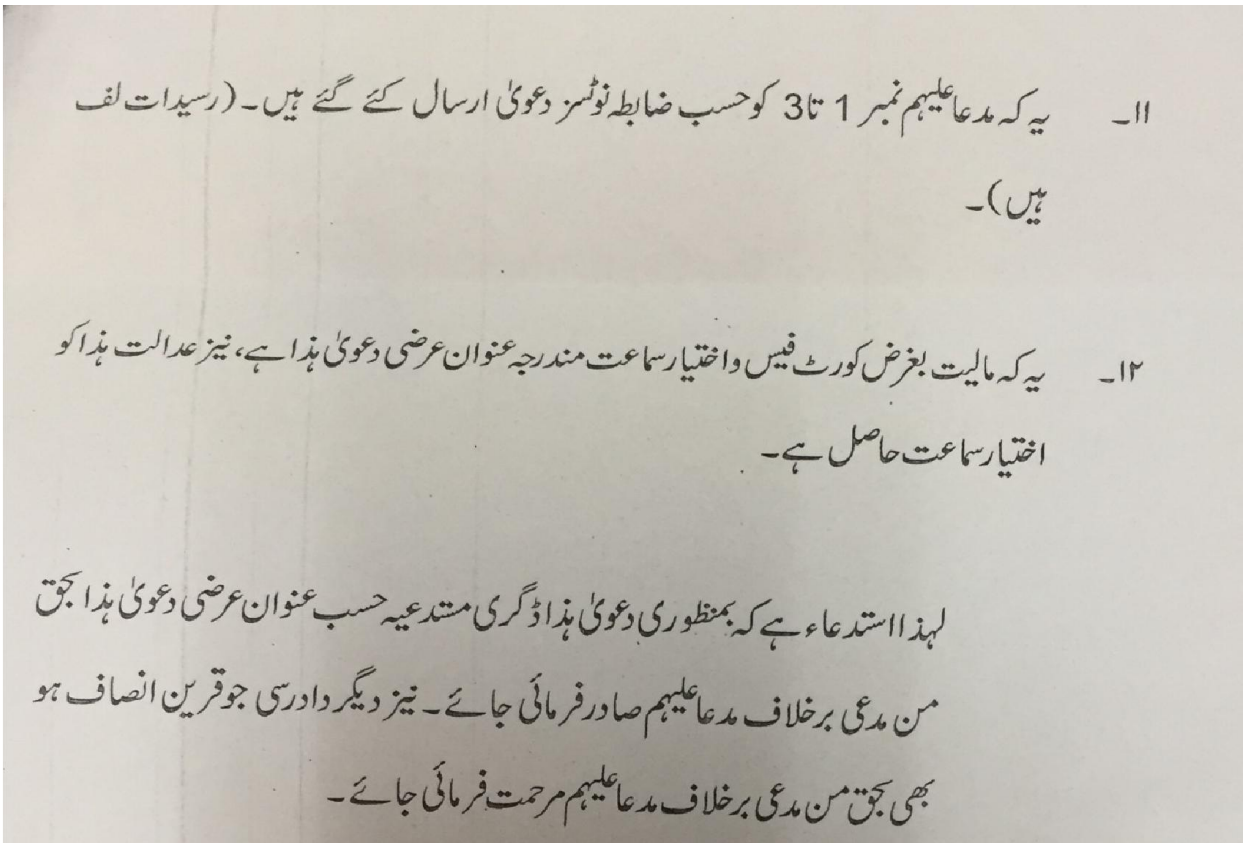
۶۔ یہ کہ بعدازاں مدعاعلیہ نمبر 3 کو لائسنس کے حصول کیلئے مروجہ فارم (**الف**) بھر کر درخواست دے دی، اور جس کیلئے بھی مطلوبہ فیس مبلغ **ایک لاکھ** روپے جمع کئے۔ (نقولات لف ہیں)۔

۷۔ یہ کہ جس کے بعد ڈرگ ریگولیٹری اتھارٹی آف پاکستان کے مقرر کردہ Panel نے ستمبر **2020** میں سائٹ کا آخری انسپکشن کیا اور جن کے رپورٹ کے بنیاد پر من مدعی کو لائسنس مذکورہ بالا دی گئی۔ (نقل لائسنس لف ہے)۔

۸۔ یہ کہ بعدازاں مدعاعلیہ نمبر 4 کے نیت میں فتور آکر من مدعی کو فارماسیوٹیکلز یونٹ مذکورہ بالا سے محروم کرنے کے درپے ہوا، اور اس دوران مدعاعلیہ نمبر 5 نے جعلی اور فرضی دستاویزات تیار کر کے جن کے بنیاد پر مدعاعلیہم نمبر 1 تا 3 کو لائسنس مذکورہ میں تبدیلی کیلئے درخواست دی ہے، جس کی وہ ہرگز مجاز نہ ہے۔

۹۔ یہ کہ مدعاعلیہ نمبر 5 کے درخواست پر ہر قسم کے کاروائی غلط، غیر قانونی، جعلی، فرضی اور مبنی بر بد نیتی اور بلاجواز ہے۔

۱۰۔ یہ کہ مدعاعلیہم کو کہا گیا کہ وہ مدعاعلیہ نمبر 5 کے درخواست پر من مدعی کے لائسنس مذکورہ بالا کی نسبت ہر قسم کی کاروائی سے باز و ممنوع رہیں، پہلے تو مدعاعلیہم ٹال مٹول کرتے رہیں اور اب چند یوم قبل صاف انکاری ہوئے، لہذا دعویٰ ہذا کی ضرورت لاحق ہوئی۔



۱۱۔ یہ کہ مدعا علیہم نمبر 1 تا 3 کو حسب ضابطہ نوٹسز دعویٰ ارسال کئے گئے ہیں۔ (رسیدات لف ہیں)۔

۱۲۔ یہ کہ مالیت بغرض کورٹ فیس و اختیار سماعت مندرجہ عنوان عرضی دعویٰ ہذا ہے، نیز عدالت ہذا کو اختیار سماعت حاصل ہے۔

لہذا استدعاء ہے کہ بمنظوری دعویٰ ہذا ڈگری مستدعیہ حسب عنوان عرضی دعویٰ ہذا بحق من مدعی برخلاف مدعا علیہم صادر فرمائی جائے۔ نیز دیگر دادرسی جو قرین انصاف ہو بھی بحق من مدعی برخلاف مدعا علیہم مرحمت فرمائی جائے۔

Three summons dated 09/12/2020 were received in Licensing Division, DRAP from Honorable Civil Judge-IV, Mrs. Sidra Aslam, Swat. In these summons, Director Drug Licensing Division/Chairman CLB, Additional Director, Drugs Licensing Division/Secretary CLB, DRAP and Assistant Director Drugs Licensing Division, DRAP were directed to appear before the Honorable Civil Judge, Swat on 04th January, 2021.

Now the firm M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat vide letter NO. SPS/Lic/0001/21, dated 21/02/2021 submitted application for change of management. The firm **has not** deposited fee of Rs.50,000/- for change of management. The detail of management is as under;

Previous Management Sole Proprietor Page 59/Corr	Current (Proposed) Management
2. Mr. Mubarak Ali S/o Alamgir CNIC No. 15602-0482661-1	2. Mr. Mangnaish Kumar S/o Mr. Ram Saroop CNIC No. 15602-3006910-9

The firm has also submitted following documents namely;

i. NOC from Sole proprietor Mr. Mubarak Ali S/o Alamgir wherein he has stated that he has no objection on the transfer of ownership of DML No.

000035 to the name of Mr. Nlangnesh Kumar, NIC No 15602-3006910-9

ii. Swat Civil Court Order 05 dated 06/01/2021 where request for withdrawal of plaintiff is dismissed as withdrawn

iii. Agreement between following
   a. Mr. Mubarak Ali S/o Alamgir,
   b. Mr. Shaid Fazal Rabi S/o Fazal Rabi,
   c. Mr. Waseem Javed S/o Javed Iqbal.

In light of above, documents submitted by Mr. Mubarak Ali S/o Alamgir for site verification and application of FORM-I as per Drugs(Licensing Registering &advertining) Rules 1976, for grant of DML and now application of change of management, it is revealed that the Sole Proprietor of the firm, Mr. Mubarak Ali S/o Alamgir has welling/intentionally concealed ownership/management of the firm.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000035 by way of formulation in the name of M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat may not be suspended or cancelled by Central Licensing Board.

In the light of Central Licensing Board's decision a Show Cause Notice was issued to the firm M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swatdated 19-03-2021 .

In response to Show cause Notice the firm submitted their response vide letter No.02/21/Lic./DRAP dated 05-04-2021 which is reproduced as under;

"Kindly refer to Show Cause Notice bearing No. F. 3-1/2016-Lic, dated 19th March,2021.

Although responding to the subject Show Cause Notice is responsibility of the existing owner, but being the new buyer of the Pharmaceutical Unit (M/S Swat Pharmaceuticals) the applicant wants to explain his point of view for your kind consideration, hence the applicant humbly submits as under:

1. *That the applicant purchased the pharmaceutical unit (M/S Swat Pharmaceuticals DML No. 000035) vide Sale Deed 19.11.2020. (Attested copy of the Sale Deed attached as Annexure "A").*
2. *That the applicant got the building of the said pharmaceutical unit on lease from the original owners of the building/land. (Copy of Lease agreement attached as Annexure*

3. *That subsequently the applicant submitted an application for the change of the management of the said Pharmaceuticals firm but in the meanwhile a financial dispute arose among the current owners/sellers. The current owner/CEO (MR. Mubarak Ali) filed a Civil Declaratory Suit Against Mr. waseemJwaid and Mr. Shahid Fazal in the court of Civil Judge-VII Swat which was mutually settled through arbitration in the honorable Court vide Court Order dated 06.01_2021. (Attested copies of the court order and otherrelevant documents attached as Annexure*
4. *That the applicant again submitted application for the of management after getting a fresh NOC 18.01-2021 from the current Owner/CEO (Mr. Mubarak Ali)(Copy of NOC attached as Annexure)*
5. *That in the meanwhile the Subject Show Cause Notice was issued to the said pharmaceutical unit. to which is the responsibility of the as applicant has nothing to do wah internal financial disputes current owners/sellers.*
6. *That the applicant is buyer of the said pharmaceutical firm and incase of suspension or cancellation of license, the current owners/sellers will have nothing to lose but he applicant will be the only to but the sufferer and loser with no fault his part.*
7. *That Swat is underdeveloped area having been hit by terrorism for many years and unemployment is also rising due to lack of industries, as Swat Pharmaceuticals is currently providing jobs to many technical/skilled and unskilled workers including male and female so any unfavorable any decision will deprive innocent employees and works of their source of bread.*

In view of above it is humbly requested to kindly consider the submissions of the

Applicant on the n humanitarian ground grounds, and grant approval for the management as requested earlier"

Accordingly, a personal hearing letter was issued to the firm on 15th April, 2021.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

Mr. Rashid Ahmed Marketing Manager and Mr. Mangnaish Kumar new Owner of the firm on behalf of the firm appeared before the Board.The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000035 (by way of formulation) of firm M/s of M/s Swat Pharmaceuticals, Valley Road, SherarаiGulkada No.3, Saidu Sharif Swat till rectifications of documents.

Now the firm has completed/rectified requisite documents and the case is complete now. Detail of the management is as under:

Previous Management Sole Proprietor Page 59/Corr	Current Management
3. Mr. Mubarak Ali S/o Alamgir CNIC No. 15602-0482661-1	3. Mr. Mangnaish Kumar S/o Mr. Ram Saroop CNIC No. 15602-3006910-9

Submitted for consideration of the Board.

Decision of the Central Licensing Board in 282nd meeting:

The Board considered the case and decided to cease the suspension of M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat Drug Manufacturing License No 000035 (by way of formulation) for further period. The Board also allowed resumptionof production.

The Board also accepted for record change of management of M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat Drug Manufacturing License No 000035 (by way of formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 :

Previous Management Sole Proprietor Page 59/Corr	Current Management
1. Mr. Mubarak Ali S/o Alamgir CNIC No. 15602-0482661-1	1. Mr. Mangnaish Kumar S/o Mr. Ram Saroop CNIC No. 15602-3006910-9

Case No. 47 **NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S FASSGEN PHARMACEUTICALS, HATTAR**

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their

Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Fassgen Pharmaceuticals, Hattar DML No. 000646 (Formulation) dated 15-05-2019.

In response to Show Cause Notice, the firm has responded vide letter No. Nil dated 19/05/2019 which is reproduced as under;

"With reference to Show cause Notice # F-3-1 1/2006-Lic of dated 15.05.2019: Please find

the fact as:-

That we had deposited the updated CRF on 22.03.2019 & (whose receiving copies are attached herewith), & still waiting for the Certificate from the Revenue department of your own esteemed organization.

Now if you call us for personal hearing, we can present the original

application.

Thanks & Regards"

However, as per available record in Licensing Division, the firm has not submitted CRF till date.

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Zeeshan Director of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Bufget and Accounts Division.

Now the firm has submitted CRF upto 31-12-2021.

Decision of the Central Licensing Board in 282nd meeting

The Board after perusal of the record decided to cease the operation of Show Cause Notice issued in the name of M/s Fassgen Pharmaceuticals, Plot No 67/1, Block A, Phase III, Industria Estate. Hattar DML No. 000646 (Formulation) dated 15-05-2019.

Case No. 48. <u>RENEWAL OF DRUG MANUFACTURING LICENCEM/S ALSON PHARMACEUTICAL, 169, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR.</u>

The firm M/s Alson Pharmaceutical, 169, Road No.7-B, Industrial Estate, Hayatabad Peshawar has submitted application for renewal of DML No.000522 by way of Formulation. The application was received on **17-09-2018** which is well on time as validity of License is **22-09-2018**. The firm has submitted a fee of **Rs. 50,000**. The application was evaluated and found following shortcoming;

i. Form-1A dully attested and stamped alongwith enclosures/Annex/Flags.
ii. Class(es) of drugs (un-attested).
iii. Dosage (s) form of drugs (un-attested).
iv. Name(s) of drugs registered (un-attested).
v. Detail of management at the time of previous renewal and present renewal.
vi. Partnership deed alongwith CNIC(s) of directions in case partnership company.
vii. Declaration of firm on stamp paper in case of sole proprietor company.
viii. Copy of approved layout plan.
ix. Proof of licensed section(s) from Central Licensing Board.
x. Section wise equipment and machinery for manufacture and QC Lab.
xi. Approval letter of Production Incharge (Mr. Fazal Hameed) in case of change then submit required documents alongwith prescribed fee as per checklist (attached).

A shortcoming letter was issued to the firm to rectify above mentioned **shortcoming** vide letter No.F.3-5/2000-Lic (Vol-II) on 05th December, 2018as per Drug (LR&A) Rules 1976.

In response to shortcoming letter, the firm submitted their reply but following shortcomings were not rectified for which finale reminder was issue on 27/04/2020.

i. Proof of licensed section(s) from Central Licensing Board.
ii. Up-to-date Nothing Due Certificate regarding CRF from STO, DRAP, Islamabad.

It is submitted that the firm did not rectify above mentioned shortcoming as of today

<u>Proceedings and Decision by the Central Licensing Board in 282nd meeting:</u>

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000522 (by way of formulation) of M/s Alson Pharmaceutical, 169, Road No.7-B, Industrial Estate, Hayatabad Peshawar may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 49 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S SHAZAL'SPHARMACEUTICALS, PLOT NO.41/1-A, PHASE-I, INDUSTRIAL ESTATE, HATTAR.

M/s Shazal's Pharmaceuticals, 41/1-A-1, Phase-1, Industrial Estate, Hattar had applied for renewal of DML No. 000592 by way of formulation for the period from 15-10-2019 to 14-10-2024 on 31-10-2019. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 12th February, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Late fee i.e. Rs.5,000/- per day as the application is 15 days late.
2. Form 1A duly signed and stamped/notarized by CEO of the firm alongwith annexure.
3. Detail of management at the time of re-grant and present renewal.
4. Declaration of firm on stamp paper in case of sole proprietorship company alongwith CNIC copy of owner.
5. Copy of approved layout plan.
6. Proof of Licensed Section(s) from Central Licensing Board.
7. Up-to-date Nothing Due Certificate from STO, DRAP, Islamabad.

The firm submitted their reply on 21st February, 2020. After evaluation of the submitted documents, a final reminder was issued on 18th September, 2020 to the firm with following shortcomings: -

1. Form-IA as per prescribed format duly signed and stamped by CEO/Owner of the firm.
2. Attested/notarized copy of CNIC of Proprietor.
3. Undertaking on stamp paper as "Sole Proprietor" where sole proprietorship is clearly mentioned.
4. Copy of approved master layout plan.
5. Updated Nothing due certificate regarding CRF from STO, DRAP, Islamabad.

The firm has submitted their reply to Final Reminder on 05-10-2020. After evaluation of the submitted documents, following shortcomings were still observed in the application: -

1. Proof of sections approved from Central Licensing Board (Approval letters).
2. Updated Nothing due certificate regarding CRF from STO, DRAP, Islamabad.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12 and Rule 16of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000592 (by way of formulation) of M/s Shazal's Pharmaceuticals, 41/1-A-1, Phase-1, Industrial Estate, Hattar may not be suspended or

cancelled by Central Licensing Board under Rule 5(2A)of the Drugs (Licensing, Registering and Advertising) Rules, 1976 or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Proceeding of Licensing Division in compliance to the decision of Central Licensing Board.

In light of Decision of The Central Licensing Board held on 10th& 11th December, 2020 was issued to the firm vide letter No. dated 11-01-2021.

The firm M/s Shazal's Pharmaceuticals, 41/1-A-1, Phase-1, Industrial Estate, Hattar has rectified above mentioned shortcomings.

Decision of the Central Licensing Board in 282nd meeting

The Board after perusal of the record decided to cease the operation of Show Cause Notice issued in the name of M/s Shazal's Pharmaceuticals, 41/1-A-1, Phase-1, Industrial Estate, Hattar DML No. 000592 (Formulation).

Case No. 50 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S YOUSUF ALI SHAH CHEMICAL INDUSTRIES (PVT) LTD., SWABI

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12

of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Yousuf Ali Shah chemical Industries (Pvt) Ltd., Swabi DML No.000371(Formulation) dated 25-09-2020, but firm has not submitted CRF till 2019. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Riaz Quality Control Inhcarge of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Bufget and Accounts Division.

Now the firm has submitted CRF upto 31-12-2021.

Decision of the Central Licensing Board in 282nd meeting

The Board after perusal of the record decided to cease the operation of Show Cause Notice issued in the name of M/s Yousuf Ali Shah chemical Industries (Pvt) Ltd., Swabi DML No. 000371 (Formulation).

CASE NO. 51 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HIZAT PHARMACEUTICAL INDUSTRY, PESHAWAR

The firm, M/s Hizat Pharmaceutical Industry, Peshawar, has submitted application for renewal of Drug Manufacturing No. 000315 (Formulation). The application was received on **05-12-2019** which is well on time as validity of License is **11-12-2019**. The firm has submitted a fee of **Rs. 50,000**. The application for renewal of DML was evaluated as per Drugs (Licensing, registering & advertising) Rules 1976 and found following shortcomings;

i. Latest verified copy of partnership deed and registration of firm in the Office of Registrar of Firms.
ii. Copies of CNICs of all director(s).
iii. Complete details of previous management and current management of the firm.

Accordingly, shortcoming letter was issued vide letter No.F.3-3/90-Lic dated 23-04-2020.

In response to above quoted letter, the firm has submitted their reply however did not rectified fowling shortcoming. Subsequently final reminder vide letter No.F.3-3/90-Lic dated 18-09-2020 was issued to rectify following shortcomings;

i. Form-IA as per prescribed format duly signed and stamped by CEO/Owner of the firm.
ii. Section approval letter/proof of approval of sections from Central Licensing Board.

In response to above quoted final reminder, the firm has submitted their reply, however, till date, the firm has not rectified fowling shortcoming

i. Form-IA as per prescribed format duly signed and stamped by CEO/Owner of the firm.
ii. Section approval letter/proof of approval of sections from Central Licensing Board.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000315 (by way of formulation) of M/s Hizat Pharmaceutical Industry, Peshawar, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In light of Decision of The Central Licensing Board held on 10th& 11th December, 2020 was issued to the firm vide letter No. dated 08-01-2021.

The firm M/s Hizat Pharmaceutical Industry, Peshawar, has rectified above mentioned shortcomings.

Decision of the Central Licensing Board in 282nd meeting

The Board after perusal of the record decided to cease the operation of Show Cause Notice issued in the name of M/s Hizat Pharmaceutical Industry, Peshawar DML No. 000315 (Formulation).

CASE NO. 52 CORRECTION IN NAME OF LICENSED SECTION OF M/S VISION PHARMACEUTICALS (PVT) LTD, PLOT NO. 22-23, INDUSTRIAL TRIANGLE, KAHUTA ROAD

M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad has requested for correction in the covering letter for renewal of DML.

It is submitted that the change of name of sections "small volume parenteral and large volume Parental" was approved to "Large Volume Parenteral" (General) in 240th meeting of CLB held on 6th Mar-2015. Further, in the inspection report for renewal of DML submitted by Area FID, DRAP Islamabad, both LVP and SVP Parenteral were mentioned. However, name of the Section *"Small Volume Parenteral (General)"* was inadvertently mentioned instead of *"Large Volume Parenteral (General)"* in the agenda of 278th meeting of CLB and same was reflected in the decision of the said meeting.

Decision of the Central Licensing Board in 282nd meeting

The Board considered the case and decided to approve the correction in the name of section and section tile may be read as under:

1. *Liquid Injectables SVP (General)*

CASE NO. 53 CHANGE OF MANAGEMENT OF M/S MACTER INTERNATIONAL LTD, PLOT NO. F-216, S.I.T.E. KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000141 (FORMULATION).

M/s Macter International Ltd, Plot No. F-216, S.I.T.E. Karachi has submitted request for Change of management with fee of Rs.50,000/-. The pre-requisite documents of the change of name / title and management are as under: -

Existing Management	**New Management as per Form- 29 Year 2020**
1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3	1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3
2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5	2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5
3. Mr. Sheikh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1	3. Mr. Sheikh Muhammad Waseem S/o Sheikh Muhammad Shafi CNIC No. 42301-0823818-1
4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5	4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5.
5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9	5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9

6. Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5 7. Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 8. Miss Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0 9. Mr. Islahuddin Siddiqui S/o Allaudin Siddiqui CNIC No. 42301-6572835-1	6. Mr. Muhammad Yahya Chawla S/o Abdul Salam CNIC No.42201-6477549-5. 7. Mr. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1. 8. Miss.Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0 9. Mr. Tariq Wajid S/o Syed Wajid Ali Shah CNIC No. 42301-0366936-1.

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for the change of management of M/s Macter International Ltd, Plot No. F-216, S.I.T.E. Karachi under DML No. 000141 (By way of Formulation) as under;

Existing Management	**New Management as per Form- 29 Year 2020**
1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3 2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5 3. Mr. Sheikh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5 5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9 6. Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5 7. Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 8. Miss Masarrat Misbah D/o MisbahuddinKhan CNIC No. 42301-0983750-0 9. Mr. Islahuddin Siddiqui S/o Allaudin Siddiqui CNIC No. 42301-6572835-1	1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3 2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5 3. Mr. Sheikh Muhammad Waseem S/o Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5. 5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9 6. Mr. Muhammad Yahya Chawla S/o Abdul Salam CNIC No.42201-6477549-5. 7. Mr. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1. 8. Miss.Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0 9. Mr. Tariq Wajid S/o Syed Wajid Ali Shah CNIC No. 42301-0366936-1.

It is pertinent to mention that the firm has not submitted NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020

which was inadvertently not mentioned in the agenda 280th meeting of CLB and same could not be reflected in the decision.

Decision of the Central Licensing Board in 282nd meeting:

The Board re-considered and accepted for record the change of management of M/s Macter International Ltd, Plot No. F-216, S.I.T.E. Karachi under DML No. 000141 (By way of Formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020

Existing Management	New Management as per Form- 29 Year 2020
10. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3	10. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3
11. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5	11. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5
12. Mr. Sheikh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1	12. Mr. Sheikh Muhammad Waseem S/o Sheikh Muhammad Shafi CNIC No. 42301-0823818-1
13. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5	13. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5.
14. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9	14. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9
15. Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5	15. Mr. Muhammad Yahya Chawla S/o Abdul Salam CNIC No.42201-6477549-5.
16. Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7	16. Mr. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1.
17. Miss Masarrat Misbah D/o MisbahuddinKhan CNIC No. 42301-0983750-0	17. Miss.Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0
18. Mr. Islahuddin Siddiqui S/o Allaudin Siddiqui CNIC No. 42301-6572835-1	18. Mr. Tariq Wajid S/o Syed Wajid Ali Shah CNIC No. 42301-0366936-1.

CASE NO. 54. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S GABA PHARMACEUTICAL LABORATORIES, KARACHI.

M/s Gaba Pharmaceutical Laboratories, S-76, S.I.T.E, Maripur Road, Karachi, has applied for renewal of DML No. 000168 by way of formulation for the period of 29-06-2015 to 28-06-2020 on 15th May, 2015.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 9th September, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Legal status of firm i.e. sole proprietor, partnership, private limited or public limited company.
ii. Detail of management / partners /directoralong with CNIC copies and relevant Form i.e. Form-C,D or Form-29 (whichever is applicable).
iii. Form-1A duly signed / stamped by Authorized person.
iv. Detail of premises including layout plan.
v. NOC of CRF issued from statistical officer of DRAP (Updated).
vi. Resignation / retirement of earlier Production Incharge.
vii. Complete set of attested documents (as per check list) of proposed QC Incharge previous approved QC Incharge in B.Sc. and Current requirement is M.Sc.
viii. Complete set of attested documents for 10 year experience.

Later on with reference to above shortcomings / deficiencies a reminder letter was issued on 7thFebruary, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

i. Complete set of attested documents of proposed QC Inchargeholding degree in M.S.C. (Chemistry) or Pharmacy and with relevant experience.
ii. Latest NOC of CRF.
iii. Approval letter of sections issued from CLB along with copy of approved L.O.P.
iv. Attested experience certificate of 10 years of proposed Production Incharge according to Drugs (L,R&A) Rules, 1976.
v. Resignation letter of previously appointed Production Incharge.
vi. Resignation letter of Production Incharge Mr. Riaz Husain from previous firm.
vii. Attested CNIC copy of proposed Production Incharge.
viii. Attested Appointment letter and Joining Report of Production Incharge.
ix. Undertaking by Production Incharge.
x. Prescribed Fee for change of Production Incharge Mr. Riaz Husain.

Later on with reference to above shortcomings / deficiencies a final reminder letter was issued on 27th March, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

i. Detail of premises including approved layout plan / Proof of Section from CLB.
ii. Nothing due certificate regarding CRF from STO (Updated).
iii. Fee of Rs. 5,000/- for proposed Quality Control Incharge.
iv. Fee challan should be retained by STO (R&D), DRAP, Islamabad (Production Incharge).
v. Provide name of approved Quality Control Incharge and Production Incharge. In case of new nominees, provide complete set of documents for Proposed Quality Control Incharge and Production Incharge with names as per check list.
vi. All documents should be duly attested.

The firm has submitted their reply on 23rd February, 2017 and 10th April, 2017 which is evaluated and still found following shortcomings / deficiencies:-

i. Detail of premises including approved layout plan / Proof of Section from CLB.
ii. Nothing due certificate regarding CRF from STO (Updated).
iii. Fee of Rs. 5,000/- for proposed Quality Control Incharge.
iv. Complete Set of documents of proposed Quality Control Incharge and production Incharge (as per check list)

Decision of Central Licensing Board in 254th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000168 by way of formulation of M/s Gaba Pharmaceutical Laboratories, S-76, S.I.T.E, Maripur Road, Karachi, may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause notice dated 22nd June, 2017 was issued to the M/s Gaba Pharmaceutical Laboratories, S-76, S.I.T.E, Maripur Road, Karachi.

A letter of Personal hearing has been issued on 17th January,2018.

The reply of the firm is received on 24-01-2018 which is as under;
I would like to inform you that entire business of Gaba Pharmaceutical Laboratories has been shut down/closed completely due to certain family issues among the partners. It is not out of place to mention here that some litigation are also pending in the courts of law. Under these circumstances, we are unabale to attend your scheduled meeting. It is therefore requested to grant minimum three months time for personal appearance before the central licensing board. Your cooperation in this regard is highly appreciated.

Decision of Central Licensing Board in 257th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to suspend Drug Manufacturing Licence No. 000168 by way of formulation in the name of M/s Gaba Pharmaceutical Laboratories, S-76, S.I.T.E, Maripur Road, Karachiunder Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of codal formalities.

The Drug Manufacturing License No. 000168 by way of formulation was suspended and the validity period of the DML commencing on 29-06-2015 and ending on 28-06-2020 has expired and the application for renewal of DML No. 000168 (Formulation) of M/s Gaba Pharmaceutical Laboratories, S-76, S.I.T.E, Maripur Road Karachi for the next tenure commencing on 29-06-2020 and ending on 28-06-2025 is not made after the expiry of the period of validity of License, therefore, Drug Manufacturing License DML No. 000168 (Formulation) is no more valid as under Rule 5 & 6 of the Drugs (L,R&A) Rules, 1976.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record and after thread bare deliberation decided to cancel the Drug Manufacturing Licence No. 000168 by way of formulation in the name of M/s Gaba Pharmaceutical Laboratories, S-76, S.I.T.E, Maripur Road, Karachi under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

CASE NO. 55. **RENEWAL OF DRUG MANUFACTURING LICENCE No. 000425 (FORMULATION) BY M/S EPOCH PHARMACEUTICALS , KARACHI.**

M/s Epoch Pharmaceutical, Plot No. 83-85, Sector 15, Korangi Industrial Area, Karachi, has applied for renewal of DML No. 000425 by way of formulation for the period of 25-3-2021 to 24-03-2026 on 1st March 2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 7th May , 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Name / detail of directors/partners on letter head along with attested CNIC copies of all partners.
(ii) Dully attested annexure/enclosure of Form-1A.
(iii) Dully attested updated partnership deed.
(iv) Detail of all sections of firm on firm's letter head along with approval letters of all sections issued from CLB of if not available then submit layout plan for regularization.
(v) Updated NDC of CRF.

Later on firm submitted reply / documents which were evaluated and a reminder letter was issued on 2nd July 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

(i) Detail of all sections of firm on firm's letter head along with approval letters of all sections issued from CLB of if not available then submit layout plan for regularization.
(ii) Attested documents regarding management including attested CNIC copies of partners.

The firm has submitted their reply received on 15th July 2021 which is evaluated and application for renewal of DML is still found following shortcomings / deficiencies:-

i. Approval letters of all licensed sections issued from the CLB or submit layout plan for regularization of manufacturing facility in the light of approved layout plan as the firm only **possess approval letters of only four (04) sections** namely Human Liquid Injection amp & vial

(General) , Ophthalmic Drop (General) , Liquid Injection Vet (Gen antibiotic), Oral Veterinary.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000425 by way of formulation of M/s Epoch Pharmaceutical, Plot No. 83-85, Sector 15, Korangi Industrial Area, Karachi, may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

CASE NO.56 RENEWAL OF DRUG MANUFACTURING LICENCE No. 000147 (FORMULATION) BY M/S EROS PHARMACEUTICALS (PVT) LTD, KARACHI.

M/s Eros Pharmaceuticals (Pvt) Ltd, Plot No. 93-95, Sector 23, Korangi Industrial Area, Karachi, has applied for renewal of DML No. 000147 by way of formulation for the period commencing on 21-08-2020 and ending on 20-08-2025.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 31stAugust , 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
(ii) Application on Prescribed Form-1A signed by the current management / director of the firm.
(iii) Documents for approval of Proposed QC In charge Mr. Asif Hussain as already communicated vide letter dated 23-07-2020.
(iv) Detail of all sections of firm on firm's letter head along with approval letters of all sections issued from CLB .
(v) Updated NDC of CRF.

Later on no reply was received from the firm and a reminder letter was issued on 9th March 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976 to submit the above mentioned documents for completion of the application for renewal of DML.

The firm has submitted their reply received on 16th June 2021 which is evaluated and application for renewal of DML is still found deficient of following shortcomings / deficiencies:-

i. Application is not submitted on Prescribed Form-1A.
ii. Updated Original Form-29 & Form-A issued by the SECP.
iii. Clarify the name/dosage form of section namely Antiseptic (General)
iv. Status regarding ready for inspection of licensed sections in the light of approved layout plan.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000147 (by way of formulation) of M/s Eros Pharmaceuticals (Pvt) Ltd, Plot No. 93-95, Sector 23, Korangi Industrial Area, Karachi,may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

CASE NO. 57. WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTION BY M/S ZEPHYR PHARMATEC (PVT) LTD , PLOT NO. A-39, S.I.T.E II, SUPER HIGHWAY KARACHIUNDER DML NO. 000403 BY WAY OF FORMULATION.

M/s Zephyr Pharmatec (Pvt) Ltd , Plot No. A-39, S.I.T.E II, Super Highway Karachi under DML No. 000403 by way of Formulation has submitted request for withdrawal of following licensed section namely:

i. *Capsule (Penicillin).*
ii. Dry Powder suspension (Penicillin)
iii. Ware House (Penicillin)

The firm had got approval of Layout Plan of new general block in place of above mentioned penicillin section.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation accede the request of the firm regarding withdrawal/voluntary surrender of following licensed sections :

i. *Capsule (Penicillin).*
ii. Dry Powder suspension (Penicillin)
iii. Ware House (Penicillin)

The Drug Registration Board shall be informed for necessary action at theie end.

CASE NO. 58. <u>WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTION BY M/s ICI PAKISTAN LIMITED S-33, HAWKES BAY ROAD, KARACHI.UNDER DML NO. 000006 BY WAY OF FORMULATION.</u>

M/s ICI Pakistan Limited S-33, Hawkes Bay Road, Karachi under DML No. 000006 by way of Formulation has submitted request for withdrawal of following licensed section namely:

i. *Tazocin Bulk Packaging Section*

The firm applied and got approval of Liquid Syrup (General) Section Expansion in place of said section.

The case is hereby submitted for consideration and orders of the Board, please.

<u>Proceedings and Decision by the Central Licensing Board in 282nd meeting:</u>

The Board considering the facts on the record and after thread bare deliberation acceded the request of the firm regarding withdrawal/voluntary surrender of following section :

i. *Tazocin Bulk Packaging Section*

The Drug Registration Board shall be informed for necessary action at theie end.

Case No.59. <u>RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000245 (FORMULATION) OF M/S ELKO ORGANIZATION (PVT) LTD, PLOT No. 27 & 28, SECTOR 12/B, NORTH KARACHI INDUSTRIAL AREA, KARACHI</u>

M/s Elko Organization (Pvt) Ltd, Plot No. 27 & 28, Sector 12/B, North Karachi Industrial Area, Karachi has filled/submitted application for renewal of DML No. 000245 (Formulation) for the period commencing on 27-04-2020 and ending on 26-04-2025.. The application for the renewal of DML of the firm was evaluated and a letter dated 08th August 2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Application on Prescribed From-1A along with duly attested enclosures.
ii. Original certified true copy of Form-29 & From-A for year 2020 issued from SECP along with attested CNIC copies of all directors.
iii. Detail/names of all licensed sections on firm's letter head along with approval letters of all sections issued from CLB. Or if not available then submit layout plan for regularization of manufacturing facility.
iv. Name and approval letter of QC In charge or if not available then submit complete set of attested documents (as per checklist) for approval.
v. Prescribed fee for change of management (as the management is changed from the last renewal of DML).

In reply firm submitted the shortcoming documents which were evaluated and following documents were still found deficient for which a Reminder dated 19thNovember 2020 was issued to the firm :

i. Application on Prescribed From-1A.

ii. Original & Updated certified true copy of Form-29 & From-A for year 2020 issued from SECP along with attested CNIC copies of all directors.
iii. Status of sections whether they are ready for inspection in the light of approved layout plan for regularization dated 06th September 2010.
iv. Name and approval letter of QC In charge or if not available then submit complete set of attested documents (as per checklist) for approval.
v. Prescribed fee for change of management (as the management is changed from the last renewal of DML).

The firm submitted reply/shortcoming documents which are evaluated and the application for renewal of DML is still deficient of following documents :

i. Prescribed fee for change of management (as the management is changed from the last renewal of DML).
ii. Complete set of attested documents (as per checklist) for approval of QC In charge Mr. Ayyaz Baig.
iii. Submit revised layout plan for regularization of existing manufacturing facility after rectification of observations already communicated and for which reply is awaited.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000245 (by way of formulation) of M/s Elko Organization (Pvt) Ltd, Plot No. 27 & 28, Sector 12/B, North Karachi Industrial Area, Karachi, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

CASE NO. 60 CHANGE OF TITLE OF LICENSED SECTION BY M/S INVENTOR PHARMA KARACHI , PLOT NO. K/196, S.I.T.E (SHW),PHASE II KARACHIUNDER DML NO. 000866 BY WAY OF FORMULATION.

M/s Inventor Pharma (Pvt) , Plot No. K/196, S.I.T.E , Super HighwayPhase II, KarachiunderDML No. 000966 by way of Formulation has submitted request for change of title of following licensed section ;

Existing Title	New Title
Liquid Vial Injectable (General)	Liquid Vial Injectable SVP (General)

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation acceded the request of the firm change of title of following licensed section ;

Existing Title	New Title
Liquid Vial Injectable (General)	Liquid Vial Injectable SVP (General)

CASE NO. 61 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000081 (FORMULATION) OF M/S SPECIFIC RESEARCH LABORATORIES, KARACHI

M/s Specific Research Laboratories, Plot No. S/21, Estate Avenue Road, S.I.T.E Karachi has filled/submitted application for renewal of DML No. 000081 (Formulation) for the period commencing on 30-09-2020 and ending on 29-09-2025.The application for the renewal of DML of the firm was evaluated and a letter dated 19thNovember 2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Detail of licensed sections on firm's letter head along with approval letters issued from the CLB or if not available then submit layout plan for regularization.
ii. Approval letter of Q.C. In-charge Feryal Vali Mohammad and Production in-charge Mr. Mushtaq Noorwalaor if not available then submit complete set of attested documents (as per checklist) for approval.
iii. N.D.C of CRF (Updated) issued by statistical officer DRAP, Islamabad.
iv. Attested Section wise detail of machinery for manufacture & Quality control.
v. Names of drugs/products for grant of repacking along with prescribed fee and proof/approval letter of repacking section.
vi. Clarify the legal status of firm (whether sole proprietor ship or partnership) and submit Copy of Partnership deed duly notarized (in case of partnership firm) and undertaking on stamp paper (in case firm is sole-proprietorship firm) along with attested CNIC copy of sole proprietor /partner.

No reply was received from the firm and a Reminder dated 18thMay 2021 was issued to the firm to submit the said documents but no reply/response is received from the firm and the application for renewal of DML is still deficient of above mentioned documents.

Submitted for consideration of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of

the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , , Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000081 (by way of formulation) of M/s Specific Research Laboratories, Plot No. S/21, Estate Avenue Road, S.I.T.E Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

CASE NO. 62. <u>RENEWAL OF DRUG MANUFACTURING LICENCE No. 000025 (FORMULATION) BY M/S PFIZER PAKISTAN LTD, KARACHI.</u>

M/s Pfizer Pakistan Limited, Plot No. B-2, S.I.T.E., Karachi, has applied for renewal of DML No. 000025 by way of formulation for the period of 22-06-2020 to 21-06-2025 on 18th June 2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 7th May , 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Application on Prescribed From-1A.
(ii) Original & Updated certified true copy of Form-29 & From-A issued from SECP along with attested CNIC copies of all directors.
(iii) Prescribed fee for change of management.
(iv) Updated NDC of CRF.
(v) Name and approval letter of Production In charge or if not available then submit complete set of attested documents (as per checklist) for approval.
(vi) Attested section wise machinery for QC Laboratory and of Production.

Later on firm submitted reply / documents which were evaluated and a reminder letter was issued on 18th December 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

(i) Original & Updated certified true copy of Form-29 & From-A issued from SECP along with attested CNIC copies of all directors.

The firm has submitted their reply which is evaluated and application for renewal of DML is still found deficient of following shortcomings / deficiencies: -

i. Updated Certified true of Form-29 & Form-A issued by the SECP as the firm has submitted Form-29 issued by the SECP on which the stamp stated :

"**Certified true copy of the document as filed by the company However this office does not take any responsibility for correctness of the contents of the documents**."

<u>Submitted for consideration of the Board.</u>

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000025 (by way of formulation) of M/s Pfizer Pakistan Limited, Plot No. B-2, S.I.T.E., Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

CASE NO. 63. RENEWAL OF DRUG MANUFACTURING LICENCE No. 000074 (FORMULATION) BY M/S KARACHI PHARMACEUTICAL LABORATORTIES, PLOT NO. S/54, HAWKES BAY ROAD, **KARACHI**

M/s Karachi Pharmaceutical Laboratorties, Plot No. S/54, Hawkes Bay Road, Karachi, has applied for renewal of DML No. 000074 by way of formulation for the period of 30-09-2020 to 29-09-2025 on 30th July 2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 27th January, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Detail of all sections of firm on firm's letter head along with approval letters of all sections issued from CLB of if not available then submit layout plan for regularization.
(ii) Undertaking on stamp paper regarding sole proprietor ship along with attested CNIC copy of Sole Proprietor.
(iii) Updated NDC of CRF.
(iv) Complete set of attested documents (as per checklist) for approval of QC In charge.

Later on firm submitted reply / documents which were evaluated and a reminder letter was issued on 5thMay 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

(i) Submit layout plan for regularization of manufacturing facility along with Prescribed fee as the firm does not possess the approval letters of licensed sections issued from the CLB.
(ii) Complete set of attested documents (as per checklist) for approval of QC In charge who fulfills the requirement of Rule 16 (e) of the Drugs (L,R&A) Rules, 1976 as the proposed QC In charge Ms. Seema Ashqeen possess the degree in B.SC Chemistry and does not fulfil the requirement of Rule 16 (e) of the Drugs (L,R&A) Rules, 1976 in terms of required qualification.
(iii) Updated NDC of CRF.

The firm has submitted their reply which is evaluated and application for renewal of DML is still found deficient of following shortcomings / deficiencies: -

i. Updated NDC of CRF issued from the statistical officer, DRAP, Islamabad.
ii. Complete set of attested documents **(as per checklist)** for approval of Mrs. Amna Mehboob as Proposed Production in charge along with prescribed fee.
iii. Proof of sections/approval letters of all sections issued by the Central Licensing Board or if not available then submit layout plan for regularization of manufacturing facility.
iv. Prescribed fee for change of QC In charge for approval of new proposed QC In charge Mr. Hasan Adil.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000074 (by way of formulation) M/s Karachi Pharmaceutical Laboratorties, Plot No. S/54, Hawkes Bay Road, Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 64. RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000811 (FORMULATION) OF M/S ICI PAKISTAN LIMITED, LAHORE.

M/s ICI Pakistan Limited Life Sciences, 45-Km, Off Multan Road, Lahore. DML No. 000811(Formulation) Period: Commencing on **02-04-2020** and ending on **01-04-2025**.	**10-11-2020**	**Good**	i. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. ii. Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore.

Recommendations of the panel:

Panel has physically inspected the unit and evaluated various documents in detail. Various technical aspects were discussed with the management of the firm at length. Some advises were also given for further up-gradation. After thorough evaluation panel **recommended** the renewal of Drug Manufacturing License (000811) of M/s ICI Pakistan Limited Life Sciences, 45-Km, Off Multan Road, Lahore for the following sections.

1. Liquid Injectable Section (SVP) (Veterinary) Section.
2. Oral Dry Powder (General) (Veterinary) Section.

3. Oral Liquid (General) (Veterinary) Section.

Decision of the Central Licensing Board in 278th meeting

The Board considered and approved the grant of renewal of (DML No. 000811) by way of formulation in the name M/s ICI Pakistan Limited Life Sciences, 45-Km, Off Multan Road, Lahoreon the recommendations of the panel of experts for the period commencing **02-04-2020** and ending on **01-04-2025** for the following sections: -

SECTIONS (03)

1. Liquid Injectable Section (SVP) (Veterinary) Section.
2. Oral Dry Powder (General) (Veterinary) Section.
3. Oral Liquid (General) (Veterinary) Section

It is submitted that title of the firm was inadvertently written as "ICI Pakistan Limited Life Sciences" instead of correct title i.e, "ICI Pakistan Limited".

Case is submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation allowed the correction in title of the firm from M/s ICI Pakistan Limited Life Sciences to M/s ICI Pakistan Limited.

CASE NO. 65 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000438 (FORMULATION) OF M/S SWISS PHARMACEUTICALS (PVT) LTD, PLOT No. A-159, S.I.T.E. II, SUPER HIGHWAY, KARACHI

M/s Swiss Pharmaceuticals (Pvt) Ltd, Karachihas filled application for renewal of DML No. 000438 (Formulation) for the period commencing on 08-09-201907-08-2020 and ending on 07-09-2024.. The application for the renewal of DML of the firm was evaluated and a letter dated 03-01-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Submit layout plan for regularization of manufacturing facility along with prescribed fee.
ii. Detail of current management/directors on firm's letter head along with attested CNIC copies of all directors.
iii. Updated original certified true copy of Form-29 & Form-A issued by SECP.

The reply of the firm was received on 13-10-2020 and the documents submitted by the firm were evaluated and a Reminder dated 04-12-2020 was issued to the firm to submit following documents:

i. Updated original certified true copy of Form-29 & Form-A issued by SECP.
ii. Prescribed fee for change of management.
iii. Detail of all licensed sections on firm's letter head along with prescribed fee and two copies of layout plan for the purpose of regularization.

In response to this Division's Reminder, the firm has not submitted the required documents and instead has submitted letter dated 05-01-2021 and has stated that firm has applied to SECP for issuance of updated Form-29 & Form-A and has requested to give one month time to submit the

document of Form-29 along with prescribed fee for change of management and the application is still found deficient of following documents:

i. Updated original certified true copy of Form-29 & Form-A issued by SECP.
ii. Prescribed fee for change of management.
iii. Detail of all licensed sections on firm's letter head along with prescribed fee and two copies of layout plan for the purpose of regularization.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000438(by way of formulation) of M/s Swiss Pharmaceuticals (Pvt) Ltd, Plot no. A-159, S.I.T.E. II, Super Highway,Karachimay not be suspended or cancelled by the Central Licensing Board.

The show cause notice was issued to the firm in compliance to decision of the CLB. The documents submitted by the firm M/s Swiss Pharmaceuticals (Pvt) Ltd, Karachi after issuance of show cause notice dated 12th March 2021 were evaluated and the application for renewal of DML No. 000438 (Formulation) is still found deficient of following documents :

i. Updated (Original) Form- 29 & Form-A issued by the SECP ..
ii. Submit revised layout plan for regularization in light of the observations/shortcomings in layout plan communicated vide letter dated 19th March 2021.

The firm is called for personal hearing vide letter dated 13th April 2021.

Proceedings and Decision of Central Licensing Board in 256th meeting.

Mr. Huzaifa Umair Director of M/s Swiss Pharmaceuticals (Pvt) Ltd, Karachi, & Mr. Rashid Muneer Advocate appeared before the Board. He contended that there the required documents are submitted to the Division of Licensing. The documents were received on the day of meeting 26-04-2021. The Board after perusal of record and facts mentioned above and deliberations made by representative of the firm decided to defer the case till next meeting of the CLB to check compliance of the firm in the light of submitted documents.

The submitted documents by the firm were evaluated and the application for renewal of DML No. 000438 (Formulation) for the tenure **commencing on 08-09-2019 & ending on 07-09-2024 is complete as per Form-1A.**

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO. 66 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S UNI-TIECH PHARMACEUTICALS (PVT) LTD, KARACHI UNDER DRUG MNAUFACTURING LICENSE NO. 000356 (FORMULATION)

M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd Karachi Plot No. 4/116-119, Sector 21, Korangi Industrial Area, Karachi, had applied for renewal of DML No. 000356 by way of formulation for the period of 04-10-2019 till 03-10-2024.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 20-12-2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Application on Prescribed Form 1A dully signed by current management of the firm along with dully attested enclosure/annexures.
(ii) Original Certified True Copy of Form-29 & Form-A for the year 2019 issued by SECP.
(iii) Detail/names of all directors on firm's letter head along with attested CNIC copies of all directors.
(iv) Detail of all licensed sections on firm's letter head along with approval letters of sections issued from the Central Licensing Board & if not available then submit layout plan for Regularization of facility.

The firm submitted their reply on 16th April 2020. After evaluation of the submitted documents, Final reminder was issued on 19h May 2020. to the firm to submit following shortcomings: -

1. Application on Prescribed Form 1A dully signed by current management of the firm along.
2. Original Certified True Copy of Form-29 & Form-A (Updated) issued by SECP.
3. Prescribed fee for change of management as the management is changed from last renewal.
4. Detail of all licensed sections on firm's letter head along with approval letters of sections issued from the Central Licensing Board & if not available then submit layout plan for Regularization of facility.
5. **All documents should be duly attested.**

Reply of the firm was received on 10-0-2020 which was evaluated and application for renewal of DML was still found deficient of following documents.

1. Application on Prescribed Form 1A dully signed by current management of the firm.
2. Original Certified True Copy of Form-29 & Form-A (Updated) issued by SECP.
3. Detail of all licensed sections on firm's letter head along with approval letters of sections issued from the Central Licensing Board & if not available then submit layout plan for Regularization of facility.

proceedings and Decision by the Central Licensing Board in 276th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000356 by way of formulation of M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd Karachi Plot No. 4/116-119, Sector

21, Korangi Industrial Area, Karachi , may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Accordingly, the show cause notice Dated : 30-09-2020 was issued to the firm.
Firm has submitted layout plan for regularization of manufacturing facility which was discussed in the LOP committee and observations were observed in the layout plan which are communicated to the firm vide letter Dated : 13-10-2020.
In the meanwhile approved Quality control In charge of the firm Ms. Amir Zadi as forwarded her resignation stating that she has resigned from the post of Quality control In charge of M/s Uni-Tiech Pharmaceutical (Pvt) Ltd, Karachi with effect from 15-08-2020.
The firm is called for personal hearing vide letter Dated : 08-10-2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

No person appeared on behalf of the firm. The Board deliberated the case and decided to afford final opportunity for personal hearing to the firm in the next meeting of the Central Licensing Board before taking decision.
The firm also submitted documents for completion of application for renewal of DML which are evaluated and the application for renewal of DML No. 000356 (Formulation) is still found deficient of following documents :

i. Firm does not possess approval letters of licensed sections issued from the CLB and had submitted layout plan for regularization of manufacturing facility which was discussed in LOP committee and a letter regarding shortcomings in layout plan was issued to the firm for which firm has not submitted the revised layout plan.
ii. Updated (Original) Form- 29 & Form-A issued by the SECP containing the names of current directors of the firm.
iii. Prescribed fee for change of management.
iv. Submit complete set of attested documents of new proposed QC In charge (as per checklist) in response to this office letter dated 14th October 2020 as the approved QC In charge Ms. Amir Zadi has resigned from the firm and has forwarded her resignation to Licensing Division, DRAP.

The firm is called for Personal Hearing vide letter dated 13th April 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person on behalf of the firm appeared before the Board.. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000356 (by way of formulation) of M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd Karachi Plot No. 4/116-119, Sector 21, Korangi Industrial Area , Karachi till fulfilment of the codal formalities with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16& Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In compliance to the decision of the CLB the orders of suspension dated of the DML were issued to the firm.
In the mean while firm has submitted the shortcoming documents **for completion of application for renewal of DML No. 000356 (Formulation)**which are evaluated and the application for renewal of DML No. 000356 (Formulation) for the tenure commencing on 04-10-2019& ending on 03-10-2024 **is now complete.**
The case is submitted for consideration of the board.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the the suspension orders for the further period issued to the firm and allowed the resumption of production activites of M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd Karachi Plot No. 4/116-119, Sector 21, Korangi Industrial Area , Karachi under DML No. 000356 (Formulation).

CASE NO. 67. RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000148 (FORMULATION) OF M/S MARVI PHARMACEUTICALS, PLOT No. 70, SECTOR 24, KORANGI INDUSTRIAL AREA, KARACHI

M/s Marvi Pharmaceuticals , Karachi has filled/submitted application for renewal of DML No. 000148 (Formulation) for the period commencing on 10-07-2020 and ending on 09-07-2025.. The application for the renewal of DML of the firm was evaluated and a letter dated 08-10-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Application on Prescribed From-1A.
ii. Status of sections whether ready for inspection or otherwise in the light of approved layout plan for regularization vide letter Dated : 16-03-2018.
iii. Detail/names of directors of firm on firm's letter headattested CNIC copies of all directors.
iv. Notarized Updated Partnership deed.
v. Prescribed fee for change of management (if the management is changed from the last renewal of DML).
vi. Updated NOC of CRF issued from statistical officer DRAP.

No reply was received from the firm and a Reminder dated 05th January 2021 was issued to the firm to submit the said documents but no reply/response is received from the firm and the application for renewal of DML is still deficient of above mentioned documents.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 Rule 12 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000148(by way of formulation) of M/s Marvi Pharmaceuticals Plot no. 70, Sector 24, Korangi Industrial Area, Karachi may not be suspended or cancelled by the Central Licensing Board.

The show cause notice was issued to the firm in compliance to decision of the CLB. No reply is received from the firm .
The firm is called for personal hearing vide letter dated 13th April 2021.

Proceedings and Decision of Central Licensing Board in 256th meeting.

Mr. Adnan Saeed Production manager of the firm appeared before the board and contended that the firm is arranging documents for completion of application The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000148 (by way of formulation) of M/s Marvi Pharmaceuticals Plot no. 70, Sector 24, Korangi Industrial Area,Karachi till fulfillment of codal formalities/submission of shortcoming documents under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

In compliance to the decision of the CLB the orders of suspension dated 11-06-2021 of the DML were issued to the firm.

In the meanwhile, the shortcoming documents were submitted by the firm which were are evaluated and the application for renewal of DML No. 000148 (Formulation) for the tenure **commencing on 10-07-2020 & ending on 09-07-2025** was found complete as per Form-1A and in compliance to the decision of the CLB orders dated 09-08-2021 regarding resumption of production/ ceasing of suspension orders were issued and a panel of experts was also constituted for inspection of the firm for renewal of DML and for regularization of manufacturing facility.

The case is submitted for ratification of the board.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation ratified the decision regarding resumption of production/ ceasing of suspension orders issued in the name of M/s Marvi Pharmaceuticals Plot no. 70, Sector 24, Korangi Industrial Area,Karachi under DML No. 000148 (Formulation).

Case No. 68 . CHANGE OF MANAGEMENT OF M/S MARTIN DOW MARKER LIMITED. 07 JAILROAD QUETTA UNDER DRUG MANUFACTURING LICENSE NO. 000028 (FORMULATION).

M/s Martin Dow Marker Limited, 07 Jail Road Quetta under DML No. 000028by way of formulation has submitted request for change in management of the firm as per Form-29 &

Form-A with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Current Management (Year 2020)	New Management as per Form-29 of SECP (Year 2021)
1. Mr. Ali Aamir S/o Abid Ali CNIC No.42301-0740467-9. 2. Syed Anis Ahmed Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870.	1. Mr. Javed Ghulam Muhammad S/o Ghulam Muhammad CNIC No. 42201-0556944-9. 2. Mr. Ali Akhai S/o M. Jawed Akhai CNIC No. 42000-3326827-5. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870.

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/s Martin Dow Marker Limited, 07 Jail Road Quetta under DML No. 000028 (By way of Formulation) as under;

Current Management (Year 2020)	New Management as per Form-29 of SECP (Year 2021)
1. Mr. Ali Aamir S/o Abid Ali CNIC No.42301-0740467-9. 2. Syed Anis Ahmed Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870	1. Mr. Javed Ghulam Muhammad S/o Ghulam Muhammad CNIC No. 42201-0556944-9. 2. Mr. Ali Akhai S/o M. Jawed Akhai CNIC No. 42000-3326827-5. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870

It is pertinent to mention that the firm has not submitted NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 which was inadvertently not mentioned in the agenda 280th meeting of CLB and same could not be reflected in the decision.

Submitted for consideration of the Board.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board re-considered and accepted for record the change of management of M/s Martin Dow Marker Limited, 07 Jail Road Quetta under DML No. 000028 (By way of Formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;

Current Management (Year 2020)	New Management as per Form-29 of SECP (Year 2021)
1. Mr. Ali Aamir S/o Abid Ali CNIC No.42301-0740467-9. 2. Syed Anis Ahmed Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870	1. Mr. Javed Ghulam Muhammad S/o Ghulam Muhammad CNIC No. 42201-0556944-9. 2. Mr. Ali Akhai S/o M. Jawed Akhai CNIC No. 42000-3326827-5. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870

Case No.69 . <u>NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s MARVI PHARMACEUTICALS KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000148 (FORMULATION)..</u>

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

<u>Decision by the Central Licensing Board in 269th meeting:</u>

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Marvi Pharmaceuticals, Karachi on24th September, 2020 but firm has not submitted CRF from year 2016. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Submitted for consideration and orders of the Board.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Adnan Saeed Production manager of the firm appeared before the board and contended that the documents are submitted to Budget & Account Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

In the meanwhile Updated NDC of CRF is received form the Budget & Account Division, DRAP, Islamabad.

Submitted for consideration of the Board.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO. 70 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s MULTI CAPS, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000876 (SEMI-BASIC MANUFACTURE)..

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Multicaps, Karachi on25th September, 2020 but firm has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person appeared before the board on behlf of the firm. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

In the meanwhile Updated NDC of CRF is received from the Budget & Account Division, DRAP Islamabad.

The case is submitted for consideration of the board.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO. 71 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s KOHS PHARMACEUTICALS (PVT) LTD HYDERABAD UNDER DRUG MANUFACTURING LICENSE NO. 000132 (FORMULATION)..

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12

of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Kohs Pharmaceuticals (Pvt) Ltd, Hyderabad on30th September, 2020 but firm has not submitted CRF from year 2012. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person appeared before the board and a letter was received from the firm that the owner of the firm was COVID Positive and copy of report was also forwarded along with the letter. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

In the meanwhile, Updated NDC of CRF is received from the Budget & Account Division, DRAP Islamabad.

The case is submitted for consideration of the board.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO. 72 RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000809 (FORMULATION) OF M/s MISSION PHARMACEUTICALS, KARACHI.

M/s Mission Pharmaceuticals, Plot No. A-94, S.I.T.E. Super HighwayKarachi had applied for renewal of DML No. 000809 by way of Formulation for the period of 25-02-2020 to 24-02-2025on 07-01-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 27thFebruary , 2020under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Application for renewal of DML on Prescribed Form-1A dully signed and stamped by current management of the firm.
ii. Name & Attested CNIC Copy of Sole proprietor along with undertaking on stamp paper regarding sole proprietorship.
iii. Detail/names of all licensed sections on firm's letter head along with approval letters of all sections issued from CLB.
iv. Documents should be duly attested.

No reply was received from the firm and a reminder letter dated 02nd April 2021 was issued to the firm for submission of above mentioned documents for completion of application for renewal of DML.

No reply is received from the firm as of today and the application for renewal of DML No. 000809 (Formulation) is still deficient of above mentioned documents.

Decision of the Central Licensing Board in 280th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000809 (by way of formulation) of M/s Mission Pharmaceuticals, Plot No. A-94, S.I.T.E. Super HighwayKarachimay not be suspended or cancelled by the Central Licensing Board.

The show cause notice was issued to the firm in compliance to decision of the CLB.
In response to show cause notice ,the firm submitted documents for completion for renewal of DML . The submitted documents by the firm were evaluated and the application for renewal of DML No. 000807 (Formulation) for the tenure **commencing on 08-09-2019 & ending on 07-09-2024 is complete as per Form-1A.**

The case is submitted for consideration of the board.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO. 73 CHANGE OF MANAGEMENT OF M/S. NAWAN LABOROATIRES (PVT) LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000442 (FORMULATION)

M/s Nawan Laboratories (Pvt) Ltd Karachi underDML No. 000442 (By way of formulation) has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 75,000/-. The detail of management is as under:-

Existing Management	**New Management/Director as per Form-29**
1. Mr. Naseer Ahmed Awan 2. Mrs. Talat Naseer 3. Mr. Ehsan Naseer Awan	1. Mr. Ehsan Naseer Awan S/o Naseer Ahmad awan CNIC No. 42301-11037824-9. 2. Mrs. Ayesha Ehsan AwanW/o Ehsan Naseer Awan CNIC No. 42201-0103641-0.

Submitted for Consideration of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s Nawan Laboratories (Pvt) Ltd Karachi underDML No. 000442 (By way of Formulation) as under;

Existing Management	New Management/Director as per Form-29
1. Mr. Naseer Ahmed Awan 2. Mrs. Talat Naseer 3. Mr. Ehsan Naseer Awan	1. Mr. Ehsan Naseer Awan S/o Naseer Ahmad awan CNIC No. 42301-11037824-9. 2. Mrs. Ayesha Ehsan AwanW/o Ehsan Naseer Awan CNIC No. 42201-0103641-0.

CASE NO. 74 CHANGE OF MANAGEMENT OF M/S UNI-TIECH PHARMACEUTICALS (PVT) LTD, KARACHI UNDER DRUG MNAUFACTURING LICENSE NO. 000356 (FORMULATION)

M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd Karachi Plot No. 4/116-119, Sector 21, Korangi Industrial Area, Karachi has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 75,000/-. The detail of management is as under:-

Existing Management (Page 21/Corr. Main File)	New Management/Director as per Form-29(Year 2020)
1. Mr. Muhammad Taufeeq S/o Qasim Ahmed 2. Mr. Gul Muhammad Kodvani S/o Qasim Ahmed 3. Mr. Muhammad Farooq Kodvani. S/o Qasim Ahmed 4. Mr. Muhammad Sohail S/o Qasim Ahmed	1. Mr. Muhammad Taufeeq S/o Qasim Ahmed CNIC No. 42301-0853346-3.. 2. Mr. Gul Muhammad Kodvani S/o Qasim CNIC No. 42301-0629879-1. 3. Mr. Muhammad Farooq Kodvani S/o QasimKodvani CNIC No. 42301-3224533-1.

Submitted for Consideration of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd Plot No. 4/116-119, Sector 21, Korangi Industrial Area, Karachi (By way of Formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;

Existing Management	New Management/Director as per Form-29
1. Mr. Muhammad Taufeeq S/o Qasim Ahmed 2. Mr. Gul Muhammad Kodvani S/o Qasim Ahmed 3. Mr. Muhammad Farooq Kodvani. S/o Qasim Ahmed 4. Mr. Muhammad Sohail S/o Qasim Ahmed	1. Mr. Muhammad Taufeeq S/o Qasim Ahmed CNIC No. 42301-0853346-3.. 2. Mr. Gul Muhammad Kodvani S/o Qasim CNIC No. 42301-0629879-1. 3. Mr. Muhammad Farooq Kodvani S/o QasimKodvani CNIC No. 42301-3224533-1.

CASE NO. 75 CHANGE OF MANAGEMENT OF M/S OPAL LABORATORIES (PVT) LTD, KARACHI

M/s Opal Laboratories (Pvt) Ltd, Karachi, DML No. 000046 by way of formulation has submitted request for change in management of the firm as per Form-29 from S.E.C.P along with prescribed Fee as under:-

Existing Management as per form-29	**Proposed Management as per form-29**
1. Mr. Ali Afzal S/o Muhammad Afzal Butt CNIC No. 42201-0758185-5. 2. Mr. Jehanzeb S/o Muhammad Akram Khokhar CNIC No. 42301-3290621-7.	1. Mr. Ali Afzal S/o Muhammad Afzal Butt CNIC No. 42201-0758185-5. 2. Mr. Jehanzeb S/o Muhammad Akram Khokhar CNIC No. 42301-3290621-7. 3. Mr. Syed Zeeshan Mobin S/o Syed Mobin Shaukat CNIC No. 42301-6467474-3. 4. Mr. Farrukh Ansari S/o Salah Uddin Ansari CNIC No. 42301-7421032-5. 5. Mr. Danish Elahi S/o Arif Elahi CNIC No. 42301-4760782-7.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s Opal Laboratories (Pvt) Ltd, Karachi, under DML No. 000046 (By way of Formulation) as under;

Existing Management as per form-29	**Proposed Management as per form-29**
1. Mr. Ali Afzal S/o Muhammad Afzal Butt CNIC No. 42201-0758185-5. 2. Mr. Jehanzeb S/o Muhammad Akram Khokhar CNIC No. 42301-3290621-7.	1. Mr. Ali Afzal S/o Muhammad Afzal Butt CNIC No. 42201-0758185-5. 2. Mr. Jehanzeb S/o Muhammad Akram Khokhar CNIC No. 42301-3290621-7. 3. Mr. Syed Zeeshan Mobin S/o Syed Mobin Shaukat CNIC No. 42301-6467474-3. 4. Mr. Farrukh Ansari S/o Salah Uddin Ansari CNIC No. 42301-7421032-5. 5. Mr. Danish Elahi S/o Arif Elahi CNIC No. 42301-4760782-7.

CASE NO. 76 CHANGE OF MANAGEMENT OF M/S ATCO LABORATORIES LTD, KARACHI

M/s Atco Laboratories Ltd, Karachi, B-18, S.I.T.E KarachiDML No. 000188by way of formulation has submitted request for change in management of the firm as per Form-29 from S.E.C.P along with prescribed Fee as under:-

Current Management (Page # 29-32/Corr)	**New Management as per Form-29 of SECP Year 2021 (Page 29 - 32/Corr)**
i. Mr. S.M. Salman Ilyas Allawala CNIC 42201-4740292-9, Director ii. Mr. S.M. Yousuf Ilyas Allawala, CNIC 42201-6570619-5, Director iii. Mr. Aslam Usman Allawala, CNIC 42201-2315122-1, Director iv. Mr. Saeed Allawala, CNIC 42201-0791586-1, Director v. Mr. S.M. Naseem Allawal, CNIC 42201-5457306-5, Director vi. Mr. Khalid Ahmed Asghar, CNIC 42101-1731898-5, Secretary	i. Mr. Khalid Ahmed Asghar, CNIC 42101-1731898-5, Director ii. Mr. S.M. Yousuf Ilyas Allawala, CNIC 42201-6570619-5, Director iii. Mr. Aslam Usman Allawala, CNIC 42201-2315122-1, Director iv. Mr. Saeed Allawala, CNIC 42201-0791586-1, Director v. Mr. S.M. Naseem Allawal, CNIC 42201-5457306-5, Director

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s Atco Laboratories Ltd, Karachi, B-18, S.I.T.E Karachi under DML No. 000188 (By way of Formulation) as under;

Current Management	**New Management as per Form-29 of SECP Year 2021**
i. Mr. S.M. Salman Ilyas Allawala CNIC 42201-4740292-9, Director ii. Mr. S.M. Yousuf Ilyas Allawala, CNIC 42201-6570619-5, Director iii. Mr. Aslam Usman Allawala, CNIC 42201-2315122-1, Director iv. Mr. Saeed Allawala, CNIC 42201-0791586-1, Director v. Mr. S.M. Naseem Allawal, CNIC 42201-5457306-5, Director vi. Mr. Khalid Ahmed Asghar, CNIC 42101-1731898-5, Secretary	i. Mr. Khalid Ahmed Asghar, CNIC 42101-1731898-5, Director ii. Mr. S.M. Yousuf Ilyas Allawala, CNIC 42201-6570619-5, Director iii. Mr. Aslam Usman Allawala, CNIC 42201-2315122-1, Director iv. Mr. Saeed Allawala, CNIC 42201-0791586-1, Director v. Mr. S.M. Naseem Allawal, CNIC 42201-5457306-5, Director

CASE NO. 77 <u>CHANGE OF MANAGEMENT OF M/S SWISS PHARMACEUTICALS (PVT) LTD, KARACHI</u>

M/s Swiss Pharmaceuticals (Pvt) Ltd, Karachi,Plot No. A/159, S.I.T.E Super Highway Karachi under DML No. 000438 by way of formulation has submitted request for change in management of the firm as per Form-29 from S.E.C.P along with prescribed Fee as under:-

Current Management	New Management as per Form-29& Form-A
1. Mr. Hafiz Ferozuddin 2. Mr. H.M.Umair 3. Mr. H.M. Saad	1. Mr. Muhammad Umair S/o Hafiz Ferrozuddin CNIC No. 42000-0375898-3 2. Mr. Taha Umair S/o MuhammadUmair CNIC No. 42000-6788132-3 3. Mr. Huzaifa Umair S/oMuhammad Umair CNIC No. 42000-6777682-3.

<u>Proceedings and Decision by the Central Licensing Board in 282nd meeting:</u>

The Board considered and accepted for record the change of management of M/s Swiss Pharmaceuticals (Pvt) Ltd, Plot No. A/159, S.I.T.E Super Highway Karachi under DML No. 000438 (By way of Formulation) as under;

Current Management	New Management as per Form-29& Form-A
1. Mr. Hafiz Ferozuddin 2. Mr. H.M.Umair 3. Mr. H.M. Saad	1. Mr. Muhammad Umair S/o Hafiz Ferrozuddin CNIC No. 42000-0375898-3 2. Mr. Taha Umair S/o MuhammadUmair CNIC No. 42000-6788132-3 3. Mr. Huzaifa Umair S/oMuhammad Umair CNIC No. 42000-6777682-3.

CASE NO. 78 <u>CHANGE OF MANAGEMENT OF M/S HIGHNOON LABORATORIES LTD, 17.5-KM, MULTAN ROAD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000155 (FORMULATION).</u>

M/s Highnoon Laboratories Ltd, 17.5-Km, Multan Road, Lahore has submitted request for Change of Management of the firm as per Form-29 with prescribed fee of Rs.50,000/- The detail of the management is as under: -

Current Management	New Management as per Form-29

1. Mr. Jawaid Tariq Khan (Chairman) 2. Mr. Mir Tausif Ahmad Khan 3. Mr. Anees Ahmad Khan 4. Mr. Aslam Hafiz 5. Mr. Ghulam Hussain Khan 6. Mr. Mian Muhammad Ashraf 7. Mrs.NosheenRiaz Khan 8. Mrs. Zainub Abbas	1. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7. 2. Mrs. Zainub Abbas D/o Tausif Ahmad Khan CNIC No. 35202-2649546-6. 3. Mr. Adeel Abbas HaideriS/o Zaighum Abbas HydrieCNIC No. 35201-9490548-1. 4. Mr. Ghulam Hussain Khan S/o Haji Abdul Jalil KhanCNIC No. 35201-3787935-7. 5. Mr. ShazibMasudS/o Syed MehmoodMasud CNIC No. 35202-0873913-7. 6. Mr.Taufiq Ahmad Khan S/o Jawaid Tariq Khan CNIC No.35201-9273258-3. 7. Mr. Romesh Alexander Iddamalgoda Elapata S/o Samuel Alexander Iddamalgoda Elapata Passport No. 538661630.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s Highnoon Laboratories Ltd, 17.5-Km, Multan Road, Lahore (By way of Formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020

;

Current Management	New Management as per Form-29
1. Mr. Jawaid Tariq Khan (Chairman) 2. Mr. Mir Tausif Ahmad Khan 3. Mr. Anees Ahmad Khan 4. Mr. Aslam Hafiz 5. Mr. Ghulam Hussain Khan 6. Mr. Mian Muhammad Ashraf 7. Mrs.NosheenRiaz Khan 8. Mrs. Zainub Abbas	1. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7. 2. Mrs. Zainub Abbas D/o Tausif Ahmad Khan CNIC No. 35202-2649546-6. 3. Mr. Adeel Abbas HaideriS/o Zaighum Abbas HydrieCNIC No. 35201-9490548-1. 4. Mr. Ghulam Hussain Khan S/o Haji Abdul Jalil KhanCNIC No. 35201-3787935-7. 5. Mr. ShazibMasudS/o Syed MehmoodMasud CNIC No. 35202-0873913-7. 6. Mr.Taufiq Ahmad Khan S/o Jawaid Tariq Khan CNIC No.35201-9273258-3. 7. Mr. Romesh Alexander Iddamalgoda Elapata S/o Samuel Alexander Iddamalgoda Elapata Passport No. 538661630.

CASE NO. 79 CHANGE OF MANAGEMENT OF M/S ALZA PHARMACEUTICALS, ALSHIFA TRUST EYE HOSPITAL, JHELUM ROAD, RAWALPINDI UNDER DRUG MANUFACTURING LICENSE NO. 0000423 (FORMULATION).

M/s Alza Pharmaceuticals, Alshifa Trust Eye Hospital, Jhelum Road, Rawalpindi underDML No. 0000423 by way of formulation has submitted request for change in management of the firm as per Board Resolution with prescribed Fee of Rs.50,000/-. The detail of management of the firm is as under;

Current Management	New Managements per Board Resolution
1. Lt Gen (Retd) Hamid Javaid 2. Mr. Saeed A. Qureshi 3. Maj Gen (Retd) M. Rahim Khan 4. Mian Muhammad Javed 5. Mian Muhammad Iqbal Farid 6. Maj Gen (Retd) Ch Muhammad Nawaz 7. Mr. Aizad Hassan Mir 8. Mr. Mohsin Hafeez 9. Mr. Jahan Zeb Khan 10. Mr. Abdullah Yusaf 11. Mr. Justice (Retd) Mansoor Ahmed 12. Maj Gen ® Rehmat Khan 13. Ms. Samia Abbas 14. Mr. M Younis Bhatti. 15. Mr. Khalid Usman. 16. Mr. Muhammad Tariq Chaudhary.	1. Mr. Fahim Ahmad Khan S/o Irshad Ahmed Khan CNIC No. 61101-6905603-5.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s Alza Pharmaceuticals, Alshifa Trust Eye Hospital, Jhelum Road, Rawalpindi underDML No. 0000423 (By way of Formulation) as under;

Current Management	New Managements per Board Resolution
1. Lt Gen (Retd) Hamid Javaid 2. Mr. Saeed A. Qureshi 3. Maj Gen (Retd) M. Rahim Khan	1. Mr. Fahim Ahmad Khan S/o Irshad Ahmed Khan CNIC No. 61101-6905603-5.

4. Mian Muhammad Javed 5. Mian Muhammad Iqbal Farid 6. Maj Gen (Retd) Ch Muhammad Nawaz 7. Mr. Aizad Hassan Mir 8. Mr. Mohsin Hafeez 9. Mr. Jahan Zeb Khan 10. Mr. Abdullah Yusaf 11. Mr. Justice (Retd) Mansoor Ahmed 12. Maj Gen ® Rehmat Khan 13. Ms. Samia Abbas 14. Mr. M Younis Bhatti. 15. Mr. Khalid Usman. 16. Mr. Muhammad Tariq Chaudhary.	

CASE NO. 80 <u>CHANGE OF MANAGEMENT OF M/S ETHICAL LABORATORIES (PVT) LTD, 14-KM, THOKAR NIAZ BAIG, MULTAN ROAD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000100 (FORMULATION).</u>

M/s Ethical Laboratories (Pvt) Ltd, 14-Km, ThokarNiazBaig, Multan Road, Lahore under DML No. 000100 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee of Rs.50,000/-. The detail of management of the firm is as under;

Current Management	New Management As per Form-29
1. Mr. Sheikh Hafeez-Uddin 2. Mr. Sheikh Amin-Uddin 3. Mr. Sheikh Aziz-Uddin 4. Mr. Sheikh Laiquddin 5. Mr. Sheikh Mugheesuddin 6. Mr. IftikharAlam Ch. 7. Mr. Shahid Altaf 8. Mr. Abdul Waheed Sheikh 9. Mr. Fasihuddin	1. Mr. Abdul Waheed Sheikh S/o Sheikh Hafeezuddin (Late) CNIC No.35202-2864953-3. 2. Mr. Sheikh Mughisuddin S/o Sheikh Samiuddin CNIC No.35202-2448979-9. 3. Mr. Hafiz Sheikh Aminuddin S/o Haji S.Ameer Din (Late) CNIC No.35202-2972218-9. 4. Mr. Sheikh Azizuddin S/o Haji S.Ameer Din (Late) CNIC No.35202-5871736-3. 5. Mr. IftikharAlamChaudhary S/o Ch. Muhammad Saeed (Late) CNIC No.35202-7220664-5. 6. Mr. Sheikh Laiquddin S/o Sheikh Moinuddin (Late) CNIC No.37405-2309789-5. 7. Mr. Fasihuddin S/o Sheikh Aliuddin (Late) CNIC No.35201-8936993-1. 8. Mr. Atif Altaf S/o Shahid Altaf (Late) CNIC No. 35202-2847873-9.

Case is submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s Ethical Laboratories (Pvt) Ltd, 14-Km, ThokarNiazBaig, Multan Road, Lahore under DML No. 000100 (By way of Formulation) as under;

Current Management	New Management As per Form-29
1. Mr. Sheikh Hafeez-Uddin 2. Mr. Sheikh Amin-Uddin 3. Mr. Sheikh Aziz-Uddin 4. Mr. Sheikh Laiquddin 5. Mr. Sheikh Mugheesuddin 6. Mr. IftikharAlam Ch. 7. Mr. Shahid Altaf 8. Mr. Abdul Waheed Sheikh 9. Mr. Fasihuddin	1. Mr. Abdul Waheed Sheikh S/o Sheikh Hafeezuddin (Late) CNIC No.35202-2864953-3. 2. Mr. Sheikh Mughisuddin S/o Sheikh Samiuddin CNIC No.35202-2448979-9. 3. Mr. Hafiz Sheikh Aminuddin S/o Haji S.Ameer Din (Late) CNIC No.35202-2972218-9. 4. Mr. Sheikh Azizuddin S/o Haji S.Ameer Din (Late) CNIC No.35202-5871736-3. 5. Mr. IftikharAlamChaudhary S/o Ch. Muhammad Saeed (Late) CNIC No.35202-7220664-5. 6. Mr. Sheikh Laiquddin S/o Sheikh Moinuddin (Late) CNIC No.37405-2309789-5. 7. Mr. Fasihuddin S/o Sheikh Aliuddin (Late) CNIC No.35201-8936993-1. 8. Mr. Atif Altaf S/o Shahid Altaf (Late) CNIC No. 35202-2847873-9.

CASE NO. 81 CHANGE OF MANAGEMENT OF M/S BAARIQ PHARMACEUTICALS, PLOT NO.600, SUNDER INDUSTRIAL ESTATE, SUNDER RAIWIND ROAD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000715 (FORMULATION).

M/s Baariq Pharmaceuticals, Plot No.600, Sunder Industrial Estate, Sunder Raiwind Road, Lahore under DML No. 000715 by way of formulation has submitted request for change in management of the firm as per Partnership Deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Old Management	New Management As per Partnership Deed
1. Mr. Bilal Ahmed S/o Riaz Ahmed. 2. Mr. Malik Muhammad Anwar UlHaq S/o Malik Shahjehan	1. Mr. Bilal Ahmed S/o Riaz Ahmed CNIC No. 42501-9264769-1. 2. Mrs. Areesh Bilal W/o Bilal Ahmed CNIC No. 42201-6643112-4.

	3. Mr. Malik Muhammad Anwar UlHaq S/o Malik Shahjehan CNIC No. 41406-0249942-7. 4. Mr. Malik Muhammad Qazafi S/o Malik Shahjehan CNIC No. 41409-1847208-3. 5. Mr.Malik Muhammad Imran Awan S/o Malik Shahjehan CNIC No. 41406-9114215-3.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s M/s Baariq Pharmaceuticals, Plot No.600, Sunder Industrial Estate, Sunder Raiwind Road, Lahore as under;

Old Management	New Management As per Partnership Deed
1. Mr. Bilal Ahmed S/o Riaz Ahmed. 2. Mr. Malik Muhammad Anwar UlHaq S/o Malik Shahjehan	1. Mr. Bilal Ahmed S/o Riaz Ahmed CNIC No. 42501-9264769-1. 2. Mrs. Areesh Bilal W/o Bilal Ahmed CNIC No. 42201-6643112-4. 3. Mr. Malik Muhammad Anwar UlHaq S/o Malik Shahjehan CNIC No. 41406-0249942-7. 4. Mr. Malik Muhammad Qazafi S/o Malik Shahjehan CNIC No. 41409-1847208-3. 5. Mr.Malik Muhammad Imran Awan S/o Malik Shahjehan CNIC No. 41406-9114215-3.

CASE NO. 82 CHANGE OF MANAGEMENT OF M/S GT PHARMA (PVT) LTD, PLOT NO.713, SUNDER INDUSTRIAL ESTATE, SUNDER RAIWIND ROAD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000829 (FORMULATION).

M/s GT Pharma (Pvt) Ltd, Plot No.713, Sunder Industrial Estate, Sunder Raiwind Road, Lahore under DML No. 000829 by way of Formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee of Rs.50,000/-. The detail of management of the firm is as under;

Current Management	New Management As per Form-29
1. Mr. Ghulam Abbas Bassi S/o ManzoorSabir CNIC No.35202-2878272-1. 2. Ms. Uzma Abbas Bassi W/o Ghulam Abbas Bassi CNIC No.35202-8450194-	1. Mr. AhsanUlHaqMirza S/o Mirza Bashir Ahmad CNIC No. 35202-2855551-3. 2. Mr. Ghulam Abbas Bassi S/o ManzoorSabir CNIC No.35202-

4.	2878272-1. 3. Ms. Uzma Abbas Bassi W/o Ghulam Abbas Bassi CNIC No.35202-8450194-4.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s GT Pharma (Pvt) Ltd, Plot No.713, Sunder Industrial Estate, Sunder Raiwind Road, Lahore under DML No. 000829 as under;

Current Management	New Management As per Form-29
1. Mr. Ghulam Abbas Bassi S/o ManzoorSabir CNIC No.35202-2878272-1. 2. Ms. Uzma Abbas Bassi W/o Ghulam Abbas Bassi CNIC No.35202-8450194-4.	1. Mr. Ahsan Ul HaqMirza S/o Mirza Bashir Ahmad CNIC No. 35202-2855551-3. 2. Mr. Ghulam Abbas Bassi S/o ManzoorSabir CNIC No.35202-2878272-1. 3. Ms. Uzma Abbas Bassi W/o Ghulam Abbas Bassi CNIC No.35202-8450194-4.

CASE NO. 83 NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S LIVEN PHARMACEUTICALS (PVT) LTD, SRAY ROAD, 49-KM, MULTAN ROAD, PHOOL NAGAR, DISTRICT KASUR UNDER DML NO. 000881 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> "(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The

management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing License may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Liven Pharmaceuticals (Pvt) Ltd, Sray Road, 49-Km, Multan Road, Phool Nagar, District Kasur on 23rd September, 2020 but firm has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Kashif Hussain Director of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

Budget & Accounts Division, DRAP Islamabad has issued nothing due certificate w.r.t CRF valid upto 31-12-2021.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO. 84. NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S ALBERT PHARMACEUTICALS (PVT) LTD, PLOT NO. 127, SUNDER INDUSTRIAL ESTATE, LAHORE UNDER DML NO. 000865 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> "(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Albert Pharmaceuticals (Pvt) Ltd, Plot No. 127, Sunder Industrial Estate, Lahore on 30th September, 2020as firm has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Umar Habib, Managing Director of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

Budget & Accounts Division, DRAP Islamabad has issued nothing due certificate w.r.t CRF valid upto 31-12-2021.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO. 85 SITE VERIFICAATION AND SITE APPROVAL OF M/S DUAA PHARMA,

M/s Duaa Pharma, **Khewat No. 1131, 1200 Khasra No. 1201, Tehsil Fateh Jang, District Attock** submitted application for site verification of proposed plot. After application was completed by the firm, area FID was requested to conduct site inspection of proposed plot and submit report regarding suitability of plot for establishment of pharmaceutical unit.

The FID submitted inspection report which is reproduced below:

The inspection was conducted on 07-07-2021. Report of Inspection of this site is described as under as per format laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(1)/98 dated 15-5-1998 under rule 16 (a) of the Drugs (Licensing, Registering and Advertisement) Rules, 1976.

Requirement as laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(1)/98 dated 15-5-1998 under rule 16 (a) of the Drugs (Licensing, Registering and Advertisement) Rules, 1976	**Observation(s) by the Inspector**
1. Location and surroundings: -	**1. Location and surroundings: -**
1.1 Location: The premises shall be located preferably in an industrial area and in any case not in any residential or commercial area.	**1.1 Location:** The premises of **M/s Duaa Pharma, Khewat No 1131,1200 Khasra No 1201, Tehsil Fateh Jang ,District Attock** which is an unclassified area. The site is near from residential area of the village KhairiMorat.
1.2 Surroundings: Premises shall be situated in an environment that, when considered together with measures to protect the manufacturing process, presents minimum risk of causing any contamination of materials or products. It shall be away from filthy surroundings and shall not be adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odor or fumes or large quantities of soot, dust or smoke which may contaminate the drugs being manufactured or adversely affect their quality. Existing units shall keep the surroundings under their control to be clean.	**1.2 Surroundings:** Premises/Plot (at present) is situated in a clean & open environment near to residential and un classified area. although at present away from filthy surroundings and is not adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odor or fumes or large quantities of soot, dust or smoke (causing unsuitability of surrounding) which could contaminate the drugs being manufactured or adversely affect their quality.The firm is responsible in future for the same measures to avoid any contamination which may affect the quality of product to be manufactured in the unit.

1.3 Size The size of the plot shall not be less than **2000 square yards**.	**1.3 Size** Total area of the plot is17120 square feet =**1902.22 square yards** = 3.2 kanals (as mentioned in the copy registry provided by the firm. (copy attached) • **The area is less than the prescribe area.**

2. Other Observations noted by the inspector(s):

2.1 The plot is of irregular shape at the time of inspection, at present, **in-front** of the site there is a street road and open area having residential area of KhiariMorat village. **at the back** there is an agricultural field/land, side by side a house attached with the plot on **the right is** the mosque **& left side** there is also an agricultural field/land. There is a house in the nearby vicinity. (The sketch of the plot and its adjoining area is attached with report).

2.2 The Registry of Possession of Plot is in the name of Syed NajumulHusnain S/O Munir Shah.

2.3 Mr. Syed Najam -ul- Huanain c/o M/S Duaa Pharma Located at Khewat No 1131,1200 Khasra No 1201, Tehsil Fateh Jang, District Attock was present at the site and accompanied during the visit.

2.4 The undersigned observed a mosque and residence adjacent to the right side and back side respectively in the present site .

3. Conclusion and Recommendations:

The location under consideration is **"not suitable"** to establish a pharmaceutical unit as per requirements laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(1)/98 dated 15-5-1998 under rule 16 (a) of the Drugs (Licensing, Registering and Advertisement) Rules, 1976 at present.

Case is submitted for consideration and orders of the Board please.

Decision of the Central Licensing Board in 282nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to the firm M/s Duaa Pharma, **Khewat No. 1131, 1200 Khasra No. 1201, Tehsil Fateh Jang, District Attock** in the upcoming meeting of the Board.

CASE NO. 86 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FARMIGEA PAKISTAN (PVT) LTD, LAHORE.

M/s Farmigea Pakistan (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahore had applied for renewal of DML No. 000471 by way of Formulation for the period of 02-03-2020 to 01-03-2025 on 24-02-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 1st September, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).

iii. Duly attested CNIC copies of all Directors.
iv. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letter of Production Incharge.

The firm did not reply and reminder letter was issued on 3rd February,2021 to the firm for completion of application.

The firm did not reply to reminder and application for renewal of DML is still incomplete with following documents being deficient.

i. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Duly attested CNIC copies of all Directors.
iv. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letter of Production Incharge.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000471 (by way of formulation) of M/s Farmigea Pakistan (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

CASE NO. 87 APPROVAL OF PRODUCTION INCHARGE OF M/S MEDLEY PHARMACEUTICAL, WAH CANTT.

M/s Medley Pharmaceutical,Plot No. 41/A, Punjab Small Industrial Estate, JhangBahtar Road, Wah Cantt had applied for approval of Production Incharge on 06-08-2018.

The application was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on13-09-2018 under Rule 16 of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Duly attested experience certificates as under Drugs (L, R & A) rules, 1976.
ii. Resignation of appointee from previous firm (Shawan Pharmaceuticals).

The firm replied to this letter on 12-03-2019 but application was incomplete and reminder letter was issued on 12-04-2019 to the firm for submission of following documents:

i. Duly attested experience certificates as under Drugs (L, R & A) rules, 1976.
ii. Resignation of appointee from previous firm (Shawan Pharmaceuticals).

Reply to reminder was received on 23-04-2019but application is still incomplete with following documents being deficient:

i. Duly attested experience certificates as under Drugs (L,R & A) rules, 1976.
ii. Resignation of appointee from previous firm (Shawan Pharmaceuticals).

Case is submitted for consideration and orders of the Board please.
Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000237 (by way of formulation) of M/s Medley Pharmaceutical,Plot No. 41/A, Punjab Small Industrial Estate, JhangBahtar Road, Wah Cantt may not be suspended or cancelled by Central Licensing Board .

CASE NO. 88 APPROVAL OF QUALITY CONTROL INCHARGE OF M/S MEDPHARM RESEARCH LAB, LAHORE.

M/s Med Pharm Research Lab, 28-Km, Ferozepur Road, Lahore had applied for approval of Quality Control Incharge on 07-02-2020.

The application was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 02-03-2020 under Rule 16 of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Appointment letter.
ii. Job acceptance letter by the appointee.
iii. Copy of academic degree of M.Sc. Chemistry.
iv. Resignation/retirement of earlier Quality Control Incharge.
v. Document should be duly attested.

The firm did not reply and reminder letter was issued on 19-05-2021 to the firm for submission of following documents:

i. Appointment letter.
ii. Job acceptance letter by the appointee.
iii. Copy of academic degree of M.Sc. Chemistry.
iv. Resignation/retirement of earlier Quality Control Incharge.
v. **Document should be duly attested.**

Reply to reminder was received on 21-06-2021 but application is still incomplete with following documents being deficient:

i. Appointment letter.
ii. Job acceptance letter by the appointee.
iii. Copy of academic degree of M.Sc. Chemistry.
iv. Resignation/retirement of earlier Quality Control Incharge.
v. **Document should be duly attested.**

Case is submitted for consideration and orders of the Board please.
Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000878 (by way of formulation) of M/s Med Pharm Research Lab, 28-Km, Ferozepur Road, Lahore may not be suspended or cancelled by Central Licensing Board .

CASE NO. 89 APPROVAL OF PRODUCTION INCHARGE OF M/S MEDPHARM RESEARCH LAB, LAHORE.

M/s Med Pharm Research Lab, 28-Km, Ferozepur Road, Lahore had applied for approval of Production Incharge on 02-09-2019.

The application was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 23-01-2020 under Rule 16 of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Resignation / retirement of earlier Production Incharge.
ii. Resignation or termination letter of Production Incharge from the previous firm / promotion letter / transfer letter from the same firm.
iii. All Documents should be duly attested.

The firm did not reply and reminder letter was issued on 27-07-2021 to the firm for submission of following documents:

i. Resignation / retirement of earlier Production Incharge.
ii. Resignation or termination letter of Production Incharge from the previous firm / promotion letter / transfer letter from the same firm.
iii. All Documents should be duly attested.

The firm did not reply and application is still incomplete with following documents being deficient:

i. Resignation / retirement of earlier Production Incharge.
ii. Resignation or termination letter of Production Incharge from the previous firm / promotion letter / transfer letter from the same firm.
iii. All Documents should be duly attested.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision

of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000878 (by way of formulation) of M/s Med Pharm Research Lab, 28-Km, Ferozepur Road, Lahore may not be suspended or cancelled by Central Licensing Board .

CASE NO. 90 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FRESH PHARMACEUTICAL, RAWAT.

M/s Fresh Pharmaceutical, Plot No.7, Street No. S-6, National Industrial Zone, Rawat had applied for renewal of DML No. 000827 by way of Formulation for the period of 07-10-2020 to 06-10-2025 on 08-10-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 29-10-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Late Fee surcharge of Rs. 10,000/- as the application is two (02) days late.
ii. Properly filled, signed & stamped Form-1A (as per format) along with its all annexures.
iii. Detail of management, if any change, apply for change of management.
iv. Section approval letters of all sections approved by Central Licensing Board.
v. Approval letters of Production Incharge & Quality Control Incharge.
vi. Nothing due certificate regarding CRF from STO (Updated).
vii. Duly attested CNIC copies of all partners.
viii. Duly attested partnership deed.

The firm replied to this letter on 13-11-2020 but application was incomplete and reminder letter was issued on 04-01,2021 to the firm for submission of following documents:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management along with proper application and prescribed fee.
iii. Legal status of the firm, if sole proprietor, Undertaking on stamp paper, if partnership firm, duly attested copy of partnership deed.
iv. Duly attested CNIC copies of owner/ partners.
v. Duly attested appointment letter, CNIC copy of appointee & Undertaking as whole-time employee on stamp paper.

Reply to reminder was received on 16-03-2021 and application for renewal of DML is still incomplete with following documents being deficient.

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management along with proper application and prescribed fee.
iii. Legal status of the firm, if sole proprietor, Undertaking on stamp paper, if partnership firm, duly attested copy of partnership deed.
iv. Duly attested CNIC copies of owner/ partners.

v. Duly attested CNIC copy of appointee.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000827 (by way of formulation) of M/s Fresh Pharmaceutical, Plot No.7, Street No. S-6, National Industrial Zone, Rawat may not be suspended or cancelled by Central Licensing Board.

CASE NO. 91 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S KOHINOOR INDUSTRIES, SAHIWAL.

M/s Kohinoor Industries, 159-160/B, Small Industrial Estate, Sahiwal had applied for renewal of DML No. 000197 by way of Formulation for the period of 25-10-2020 to 24-10-2025 on 24-08-2020. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 25-09-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Classes of Drugs.
iii. Section approval letters of External Preparation & Repacking sections approved by CLB, if not available, apply for regularization of layout plan.
iv. Detail of Machinery in all Production departments.
v. Approval letter of Quality Control Incharge, if not already approved, submit complete application along with prescribed fee.
vi. Detail of equipments in Laboratory (Quality Control and Microbiology).

The firm did not reply and reminder letter was issued on 05-05-2021 to the firm for submission of following documents:

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Classes of Drugs.
iii. Section approval letters of External Preparation & Repacking sections approved by CLB, if not available, apply for regularization of layout plan.
iv. Detail of Machinery in all Production departments.
v. Approval letter of Quality Control Incharge, if not already approved, submit complete application along with prescribed fee.
vi. Detail of equipments in Laboratory (Quality Control and Microbiology).

Reply to reminder was received on 04-06-2021 and application for renewal of DML is still incomplete with following documents being deficient.

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Approval letterof Quality Control Incharge, if not already approved, submit complete application along with prescribed fee.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5, Rule 16, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000197 (by way of formulation) of M/s Kohinoor Industries, 159-160/B, Small Industrial Estate, Sahiwal may not be suspended or cancelled by Central Licensing Board.

CASE NO. 92 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S LAWRENCE PHARMA (PVT) LTD, LAHORE.

M/s Lawrence Pharma (Pvt) Ltd, 10.5-Km, Sheikhupura Road, Lahore had applied for renewal of DML No. 000322 by way of Formulation for the period of 19-10-2020 to 18-10-2025 on 15-06-2020. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13-08-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Approval letters of Production Incharge and Quality Control Incharge, if not already approved, submit their complete application alongwith prescribed fee.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Duly attested CNIC copies of owner / partners.
iv. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management.
v. Proof of sections/section approval letters approved by CLB, if not available, apply for regularization of layout plan.
vi. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
vii. Documents should be duly attested.

The firm replied to this letteron 08-09-2020 and reminder was issued on 28-09-2020 to the firm for submission of following documents:

i. Updated NDC regarding CRF from STO, DRAP, Islamabad.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Copy of Form-29 for year 2015 issued & attested by SECP, if any change in management since 2015, apply for change of management alongwith prescribed fee of Rs. 50,000/-.
iv. Section approval letters approved by CLB, if not available, apply for regularization of layout plan.

The firm did not reply to reminder and application for renewal of DML is still incomplete with following documents being deficient.

i. Updated NDC regarding CRF from STO, DRAP, Islamabad.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).

iii. Copy of Form-29 for year 2015 issued & attested by SECP, if any change in management since 2015, apply for change of management along with prescribed fee of Rs. 50,000/-.
iv. Section approval letters approved by CLB, if not available, apply for regularization of layout plan.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5, Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000322 (by way of formulation) of M/s Lawrence Pharma (Pvt) Ltd, 10.5-Km, Sheikhupura Road, Lahore may not be suspended or cancelled by Central Licensing Board.

CASE NO. 93 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FERROZA INTERNATIONAL PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur Road, Lahore had applied for renewal of DML No. 000389 by way of Formulation for the period of 26-06-2021 to 25-06-2026 on 23-06-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 01-09-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management at the time of previous renewal, if any change, apply for change of management with proper application and prescribed fee.
iii. Duly attested CNIC copies of all Directors.
iv. Sections approval letters approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letters of Production Incharge and Quality Control Incharge.

The firm did not reply and reminder was issued on 08-10-2020 to the firm for submission of following documents:

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management at the time of previous renewal, if any change, apply for change of management with proper application and prescribed fee.
iii. Duly attested CNIC copies of all Directors.
iv. Sections approval letters approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letters of Production Incharge and Quality Control Incharge.
vi. Documents should be duly attested.

The firm replied to reminder on 27-10-2020 but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest certified true copy of Form-29 duly attested by SECP (Original).
ii. Sections approval letters approved by CLB, if not available, apply for regularization of layout plan.
iii. Complete set of duly attested documents (as per checklist except CNIC & experience certificates) of proposed Production Incharge and Quality Control Incharge along with prescribed fee.
iv. Documents should be duly attested.

Moreover, it is pertinent to mention here that the firm has been carrying out production activities without approved Quality Control Incharge since 2015 and without approved Production Incharge since 2013 as reflected in certificates submitted by the firm.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000389 (by way of formulation) of M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur Road, Lahore may not be suspended or cancelled by Central Licensing Board.

CASE NO. 94. RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000117 (FORMULATION) OF M/S HELICON PHARMACEUTEK PAKISTAN (PVT) LTD, FAISALABAD.

Drug Manufacturing License No. 000117 (Formulation) was issued to M/s Helicon Pharmaceutek Pakistan (Pvt) Ltd, Model Town Road, Faisalabad. It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *"if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 75,00/- per day the application is delayed and thereafter until orders are passed on such application"*. But, in this case the application for renewal of DML for the period of 14-11-2020 to 13-11-2025 has not been received till date. Therefore, DML No. 000117 (Formulation) of M/s Helicon Pharmaceutek Pakistan (Pvt) Ltd, Faisalabad is no more valid.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record and after thread bare deliberation decided that the Drug Manufacturing Licence No. 000117 by way of formulation in the name of M/s Helicon Pharmaceutek Pakistan (Pvt) Ltd, Model Town Road, Faisalabad stands cancelled under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and

Advertising) Rules, 1976 as an application for renewal of the Drug manufacturing Licence is not submitted as prescribed unde the Rules.

CASE NO. 95 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000451 (FORMULATION) OF M/S CAYLEX PHARMACEUTICALS (PVT) LTD, LAHORE.

Drug Manufacturing License No. 000451 (Formulation) was issued to M/s Caylex Pharmaceuticals (Pvt) Ltd, 27-Km Main Raiwind Road, Lahore. It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *"if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 75,00/- per day the application is delayed and thereafter until orders are passed on such application"*. But, in this case the application for renewal of DML for the period of 01-08-2020 to 31-07-2025 has not been received till date. Therefore, DML No. 000451 (Formulation) of M/s Caylex Pharmaceuticals (Pvt) Ltd, 27-Km Main Raiwind Road, Lahore is no more valid.

Moreover, Ms. Aisha Irfan, Federal Inspector of Drugs, Lahore conducted inspection of the firm on 03-06-2021 to check cGMP compliance of the firm. However, upon arrival it was noted that the factory was closed. A watchman was there and he informed that the factory was closed for more than one year. The owner Mr. Riyasat Bhatti was contacted on telephone and he informed that the factory was closed due to renovation work etc. However, no labour and renovation was seen, everywhere there was cobwebs and lizards were seen. Furthermore, the owner of the firm did not inform DRAP office regarding closure of factory. The Inspection book was also not provided after repeated demand.

Case is submitted for consideration and orders of the Board, please.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record and after thread bare deliberation decided that the Drug Manufacturing Licence No. 000451 by way of formulation in the name of M/s Caylex Pharmaceuticals (Pvt) Ltd, 27-Km Main Raiwind Road, Lahore.stands cancelled under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as an application for renewal of the Drug manufacturing Licence is not submitted as prescribed unde the Rules.

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CASE NO. 96 GRANT OF ADDITIONAL SECTION OF M/S LINTA PHARMACEUTICALS (PVT) LTD, RAWAT.

M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No. 3, Street No. S-5, National Industrial Zone, Rawat. DML No. 000810 (Formulation) **Section (01)** 1) Tablet (Psychotropic) Section (New).	**16-02-2021** **&** **25-02-2021**	**Good**	1) Mr. Akhtar Abbas, Additional Director (QA &LT), DRAP, Islamabad. 2) Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad. 3) Ms. Zunaira Faryad, Assistant Director (Lic), DRAP, Islamabad.

Recommendations of the panel:

"Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the following 1 new/additional & renewal (of the existing 5 sections) of DML No.000810 (By way of formulation) of M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No.3 Street No. S-5, National Industrial Zone Rawat, Islamabad:

New Additional Sections
1) Tablet Psychotropic (New Section).

Existing Sections
1) Tablet (General) Section.
2) Cream/Ointment/Gel (General) Section.
3) Capsule Section (Cephalosporin).
4) Dry Suspension Section (Cephalosporin).
5) Capsule (General) Section.

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of following new section in the name of M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No. 3, Street No. S-5, National Industrial Zone, Rawatunder DML No.000810 (Formulation)on the recommendations of the panel of experts.

Section (01)

1 Tablet (Psychotropic) Section (New).

It is pertinent to mention that the firm has not submitted NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 which was inadvertently not mentioned in the minutes of 280th meeting of CLB. The firm was asked vide letter dated 26-08-2021 to submit NOC from Ministry of Narcotic Control, Islamabad for further processing of the case.

Decision of Central Licensing Board in 282nd meeting.

The Board considered and approved the grant of following new section in the name of M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No. 3, Street No. S-5, National Industrial Zone, Rawatunder

DML No.000810 (Formulation)on the recommendations of the panel of experts subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;

Section (01)

1 Tablet (Psychotropic) Section (New).

CASE NO. 97. GRANT OF ADDITIONAL SECTION OF M/S CITI PHARMA (PVT) LTD, KASUR.

M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, BhaiPheru, District Kasur. DML No. 000512 (Formulation). **Section (01)** i. Tablet (Psychotropic) Section.	**16-12-2020**	**Good**	1) Dr. Farzana Chaudhary, Expert Member. 2) Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3) Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore.

Recommendations of the panel:

"Panel has thoroughly inspected the unit, evaluated the documents shown by the firm and discussed various technical aspects in detail. Details of equipments of Production and Quality Control departments and list of technical staff duly signed by the firm members are attached with this report for perusal of Central Licensing Board.

On the basis of depiction mentioned above, documentations revealed and submitted by the firm, physical panel inspection of the unit, panel has unanimously **recommended** the facility added by M/s Citi Pharma (Pvt) Ltd,3-Km, Head Balloki Road, BhaiPheru, Kasur for grant of Tablet (Psychotropic) Section under Drug Manufacturing License No. 000512 (Formulation)."

Decision of the Central Licensing Board in 279th meeting

The Board considered and approved the grant of following new section in the name of M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, BhaiPheru, District Kasur. under DML No. 000512 (Formulation) on the recommendations of the panel of experts;

Sections/Facility (01)

i. Tablet (Psychotropic) Section- New

It is pertinent to mention that the firm has not submitted NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 which was inadvertently not mentioned in the minutes of 279th meeting of CLB. The firm was asked vide letter dated 28-06-2021 to submit NOC from Ministry of Narcotic Control, Islamabad for further processing of the case.

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the grant of following new section in the name of M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, BhaiPheru, District Kasur. under DML No. 000512 (Formulation) on the recommendations of the panel of experts subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;

Sections/Facility (01)

i. Tablet (Psychotropic) Section- New

CASE NO. 98 GRANT OF SIGNED PROCESS FLOW CHART OF IRON PROTEIN SUCCINYLATE SECTION OF M/S HIMONT PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore. DML No. 000621 (Basic Manufacture) Period: Commencing on 30-07-2017& ending on 29-07-2022.	**13-07-2020**	**Good**	1) Dr. Farzana Chowdhary, Expert Member. 2) Chief Drug Controller, Member Central Licensing Board. 3) Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore.

Recommendations of the panel:

"Keeping in view, the above-mentioned facility, equipments/Machines and the Process Flow the panel of experts is the opinion to **recommend**the renewal of DML (000621) to M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore by way of Basic Manufacture."

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000621) by way of Basic Manufacture in the name of M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahoreon the recommendations of the panel of experts for the period commencing on 30-07-2017& ending on 29-07-2022.

A panel of experts constituted for renewal of DML was authorized to inspect the firm for the purpose of renewal of DML and grant of process flow chart of Iron Protein Succinylate. Inspection report was received but no copy of signed process flow chart was enclosed with the report. Additional Director (E &M), DRAP, Lahore was requested to direct FID to submit the signed process flow chart. FID has now submitted signed process flow chart of Iron Protein Succinylate.

Decision of the Central Licensing Board in 282nd meeting

The Board considered and approved the process flow chart of Iron Protein Succinylate in the name of M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore. under DML No. 000621 (Basic Manufacture) on the recommendations of the panel of experts.

CASE NO. 99 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000798 (FORMULATION) OF M/S HAWK BIO PHARMA (PVT) LTD, RAWAT.

M/s Hawk Bio (Pvt) Ltd, Plot No. 10, Street No. S-6, National industrial Estate, RCCI, Rawat. DML No. 000798 (Formulation) Period: Commencing on **03-07-2019** and ending on **02-07-2024**.	19-11-2020	Good	1. Dr. Hafsa Karam Elahi, Additional Director (QA &LT),DRAP, Islamabad. 2. Mr. Manzoor Ali Bozdar Additional Director, (Licensing Division) DRAP, Islamabad. 3. Mr. Hassan Afzaal, Federal Inspector of Drugs, DRAP, Islamabad.

Recommendations of the panel:

Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s. Hawk Bio Pharma (Pvt) Ltd, Plot No. 10, S-6, RCCI, Rawat, Rawalpindi for the Grant of Drug Manufacturing License (Formulation) for the following sections namely"

1. Veterinary oral Liquid (General)
2. Veterinary oral liquid (Antibiotic)
3. Veterinary oral powder (General)
4. Veterinary oral powder (Antibiotic)

And the grant of revised facility;

i. Packing Material Store (Expansion) (Ground Floor Veterinary)
ii. Expansion of Quality Control Laboratory.

Decision of the Central Licensing Board in 278th meeting

The Board considered and approved the grant of renewal of DML No. 000798 by way of formulation in the M/s Hawk Bio (Pvt) Ltd, Plot No. 10, Street No. S-6, National industrial Estate, RCCI, Rawat on the recommendations of the panel of experts for the period commencing on **03-07-2019** and ending on **02-07-2024**for the following sections: -

Sections (04)

1. Veterinary oral Liquid (General)
2. Veterinary oral liquid (Antibiotic)
3. Veterinary oral powder (General)
4. Veterinary oral powder (Antibiotic)

It is submitted that title of the firm was inadvertently written as "M/s Hawk Bio (Pvt) Ltd" instead of correct title i. e, "M/s Hawk Bio Pharma (Pvt) Ltd".

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation allowed the correction in title of the firm from "M/s Hawk Bio (Pvt) Ltd" to "M/s Hawk Bio Pharma (Pvt) Ltd".

CASE NO. 100 CHANGE OF MANAGEMENT OF M/S PRAYS PHARMACEUTICALS, PLOT NO. 10, STREET SS/4, NATIONAL INDUSTRIAL ZONE, RCCI, RAWAT UNDER DRUG MANUFACTURING LICENSE NO. 000719 (FORMULATION).

M/s Prays Pharmaceuticals, Plot No. 10, Street SS/4, National Industrial Zone, RCCI, Rawat, Islamabad, DML No.000719 by way of formulation has submitted request for change in management of the firm as per partnership deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management at page 276/Corr.	Outgoing Management as per partnership deed at page 299/Corr.	New Management at page 295/Corr.
1. Mr. Basit Abbasi S/o Muhammad Khalil Abbasi CNIC No. 37405-1139012-1. 2. Mr. Ahmed Bilal Adil S/o Muhammad Aqleen Sheikh CNIC No. 37405-0579211-1. 3. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-248331-5.	Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-248331-5.	1.Mr. Basit Abbasi S/o Muhammad Khalil Abbasi CNIC No. 37405-1139012-1. 2.Mr. Ahmed Bilal Adil S/o Muhammad Aqleen Sheikh CNIC No. 37405-0579211-1.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management of M/s Prays Pharmaceuticals, Plot No. 10, Street SS/4, National Industrial Zone, RCCI, Rawat, Islamabad underDML No. 000719 (By way of Formulation) as under;

Previous Management at page 276/Corr.	Outgoing Management as per partnership deed at page 299/Corr.	New Management at page 295/Corr.
1. Mr. Basit Abbasi S/o Muhammad Khalil Abbasi CNIC No. 37405-1139012-1.	Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-248331-5.	1.Mr. Basit Abbasi S/o Muhammad Khalil Abbasi CNIC No. 37405-1139012-1.

2. Mr. Ahmed Bilal Adil S/o Muhammad Aqleen Sheikh CNIC No. 37405-0579211-1. 3. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-248331-5.		2.Mr. Ahmed Bilal Adil S/o Muhammad Aqleen Sheikh CNIC No. 37405-0579211-1.

CASE NO. 101. <u>CHANGE OF MANAGEMENT OF M/S WELL & WELL PHARMA (PVT) LTD, PLOT NO. 7, STREET NO. S-8, NATIONAL INDUSTRIAL ZONE, RCCI, RAWAT UNDER DRUG MANUFACTURING LICENSE NO. 000687 BY WAY OF (FORMULATION).</u>

M/s Well & Well Pharma (Pvt) Ltd, Plot No. 7, Street No. S-8, National Industrial Zone, RCCI, Rawat, DML No.000687 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management as per Form-29 at page 118-150/Corr.	New Management as per Form-29 at page 118-150/Corr.
1. Brig ® Badar Munir Rehman. 2. Brig ® Fazal Nawaz Khan. 3. Mr. Khalid Shaukat. 4. Usman Yousaf.	1. Shazma W/o Muhammad Tahir, CNIC No. 17103-0589785-4. 2. Mr. Asghar Ali S/o Yousuf Khan, CNIC No. 17101-328405-9. 3. Mr. Sher Afsar Khan S/o Nawar Khan, CNIC No.16202-8473709-7. 4. Rehan Pari W/o Muzaffar Shah, CNIC No. 16102-2190592-2. 5. Mr. Muhammad Ihsan Ullah S/o Abdul Hakim, CNIC No. 15302-0908198-5.

<u>Case is submitted for consideration and orders of the Board please</u>

<u>Proceedings and Decision by the Central Licensing Board in 282nd meeting:</u>

The Board considered and accepted for record the change of management M/s Well & Well Pharma (Pvt) Ltd, Plot No. 7, Street No. S-8, National Industrial Zone, RCCI, Rawat underDML No. 000687 (By way of Formulation) as under;

Previous Management as per Form-29	New Management as per Form-29
1. Brig ® Badar Munir Rehman. 2. Brig ® Fazal Nawaz Khan. 3. Mr. Khalid Shaukat. 4. Usman Yousaf.	1. Shazma W/o Muhammad Tahir, CNIC No. 17103-0589785-4. 2. Mr. Asghar Ali S/o Yousuf Khan, CNIC No. 17101-328405-9. 3. Mr. Sher Afsar Khan S/o Nawar Khan, CNIC No.16202-8473709-7. 4. Rehan Pari W/o Muzaffar Shah, CNIC No. 16102-2190592-2. 5. Mr. Muhammad Ihsan Ullah S/o Abdul Hakim, CNIC No. 15302-0908198-5.

CASE NO.102 **CHANGE OF MANAGEMENT OF M/S SURGE LABORATORIES (PVT) LTD, 10-KM, FAISALABAD ROAD, BIKHI, DISTRICT SHEIKHUPURA UNDER DRUG MANUFACTURING LICENSE NO. 000484 BY WAY OF (FORMULATION).**

M/s Surge Laboratories (Pvt) Ltd, 10-KM, Faisalabad Road, Bikhi, District Sheikhupura, DML No.000484 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Existing management	New management
1. Mr. Abdul Majid S/o Ch. Ghulam Nabi CNIC No. 42301-0969191-7. 2. Ms. Saleha Sultana W/o Dr. Abdul Majid CNIC No. 42301-0512065-8. 3. Mr. Muhammad Ali Majid S/o Dr. Abdul Majid CNIC No. 42301-5590648-9. 4. Mr. Abdullah Majid S/o Dr. Abdul Majid CNIC No. 42301-1356206-7. 5. Ms. Humera Jawad W/o Jawad Saeed CNIC No. 42301-8539616-8.	1. Ms. Saleha Sultana W/o Dr. Abdul Majid CNIC No. 42301-0512065-8. 2. Mr. Muhammad Ali Majid S/o Dr. Abdul Majid CNIC No. 42301-5590648-9 3. Mr. Abdullah Majid S/o Dr. Abdul Majid CNIC No. 42301-1356206-7. 4. Ms. Humera Jawad W/o Jawad Saeed CNIC No. 42301-8539616-8.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and accepted for record the change of management M/s Surge Laboratories (Pvt) Ltd, 10-KM, Faisalabad Road, Bikhi, District Sheikhupura, DML No.000484 by way of formulation as under;

Existing management	New management
1. Mr. Abdul Majid S/o Ch. Ghulam Nabi CNIC No. 42301-0969191-7. 2. Ms. Saleha Sultana W/o Dr. Abdul Majid CNIC No. 42301-0512065-8. 3. Mr. Muhammad Ali Majid S/o Dr. Abdul Majid CNIC No. 42301-5590648-9. 4. Mr. Abdullah Majid S/o Dr. Abdul	1. Ms. Saleha Sultana W/o Dr. Abdul Majid CNIC No. 42301-0512065-8. 2. Mr. Muhammad Ali Majid S/o Dr. Abdul Majid CNIC No. 42301-5590648-9 3. Mr. Abdullah Majid S/o Dr. Abdul Majid CNIC No. 42301-1356206-7. 4. Ms. Humera Jawad W/o Jawad Saeed CNIC No. 42301-8539616-8.

Majid CNIC No. 42301-1356206-7. 5. Ms. Humera Jawad W/o Jawad Saeed CNIC No. 42301-8539616-8.	

CASE NO. 103 <u>CHANGE OF MANAGEMENT OF M M/S SHAROOQ PHARMACEUTICALS (PVT) LTD, FEROZEPUR ROAD, NEAR MASJID IBRAHIM, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000577 BY WAY OF (FORMULATION).</u>

M/s Sharooq Pharmaceuticals (Pvt) Ltd, Ferozepur Road, Near Masjid Ibrahim, Lahore, DML No.000577 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management	In-coming Management	New management as per Form-29.
1. Dr. Riaz Ahmed S/o Habib Ur Rehman CNIC No. 34603-2285414-3 2. Mrs. Anjum Riaz W/o Riaz Ahmed CNIC No. 34603-2184510-8.	Mr. Usharib Riaz S/o Riaz Ahmd CNIC No. 34603-9748357-9.	1.Dr. Riaz Ahmed S/o Habib Ur Rehman CNIC No. 34603-2285414-3 2.Mrs. Anjum Riaz W/o Riaz Ahmed CNIC No. 34603-2184510-8. 3.Mr. Usharib Riaz S/o Riaz Ahmd CNIC No. 34603-9748357-9.

<u>Proceedings and Decision by the Central Licensing Board in 282nd meeting:</u>

The Board considered and accepted for record the change of management M/s Sharooq Pharmaceuticals (Pvt) Ltd, Ferozepur Road, Near Masjid Ibrahim, Lahore, DML No.000577 by way of formulation as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020

;

Previous management	In-coming Management	New management as per Form-29.

1. Dr. Riaz Ahmed S/o Habib Ur Rehman CNIC No. 34603-2285414-3 2. Mrs. Anjum Riaz W/o Riaz Ahmed CNIC No. 34603-2184510-8.	Mr. Usharib Riaz S/o Riaz Ahmd CNIC No. 34603-9748357-9.	1. Dr. Riaz Ahmed S/o Habib Ur Rehman CNIC No. 34603-2285414-3 2.Mrs. Anjum Riaz W/o Riaz Ahmed CNIC No. 34603-2184510-8. 3.Mr. Usharib Riaz S/o Riaz Ahmd CNIC No. 34603-9748357-9.

CASE No. 104 <u>CHANGE OF MANAGEMENT OF M/S PHARMAGEN LIMITED, 34-KM, FERZEPUR ROAD, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000325 BY WAY OF (FORMULATION).</u>

M/s Pharmagen Limited, 34-KM, Ferzepur Road, Lahore, DML No.000325 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management as per Form-29 at Page 305-306/Corr.	**New management as per Form-A at Page 425/Corr. dated 27th October, 2020.**
1. Mr. Parvez Hussain Sufi CNIC No. 35201-7011690-1. 2. Dr. Sarfraz Ahmad CNIC No. 37405-9285976-9. 3. Maj. Gen (Retd) Rahim Khan CNIC 37405-0486576-5. 4. Mr. Muhammad Rasheed Khan CNIC No. 42301-3219089-1. 5. Mr. Mushtaq Ahmed CNIC No. 61101-1948466-1. 6. Col. ® M. Naseer Khan S/o Sardar M Qasim Khan (Late) CNIC No. 61101-8700269-1. 7. Mr. Usman Hussain Sufi CNIC No. 35201-490323-3.	1. Mr. Usman Hussain Sufi CNIC No. 35201-490323-3. 2. Dr. Sarfraz Ahmad CNIC No. 37405-9285976-9. 3. Mr. Mushtaq Ahmed CNIC No. 61101-1948466-1. 4. Mr. Muhammad Rasheed Khan CNIC No. 42301-3219089-1. 5. Mr. Parvez Hussain Sufi CNIC No. 35201-7011690-1. 6. Mr. Amanullah Khan CNIC No. 35202-2761884-1. 7. Mr. Asad Hussain Sufi CNIC 35201-0929173-5. 8. Mr. Shamim Ahmed CNIC No. 42201-0709868-3. 9. Mr. Junaid Shamim CNIC No.42201-0709876-3. 10. Mr. Shoaib Shamim CNIC No. 42201-0709871-7.

<u>Proceedings and Decision by the Central Licensing Board in 282nd meeting:</u>

The Board considered and accepted for record the change of management M/s Pharmagen Limited, 34-KM, Ferzepur Road, Lahore, DML No.000325 by way of Semi Basic Manufacture as under;

Previous Management as per Form-29	New management
1. Mr. Parvez Hussain Sufi CNIC No. 35201-7011690-1. 2. Dr. Sarfraz Ahmad CNIC No. 37405-9285976-9. 3. Maj. Gen (Retd) Rahim Khan CNIC 37405-0486576-5. 4. Mr. Muhammad Rasheed Khan CNIC No. 42301-3219089-1. 5. Mr. Mushtaq Ahmed CNIC No. 61101-1948466-1. 6. Col. ® M. Naseer Khan S/o Sardar M Qasim Khan (Late) CNIC No. 61101-8700269-1. 7. Mr. Usman Hussain Sufi CNIC No. 35201-490323-3.	1. Mr. Usman Hussain Sufi CNIC No. 35201-490323-3. 2. Dr. Sarfraz Ahmad CNIC No. 37405-9285976-9. 3. Mr. Mushtaq Ahmed CNIC No. 61101-1948466-1. 4. Mr. Muhammad Rasheed Khan CNIC No. 42301-3219089-1. 5. Mr. Parvez Hussain Sufi CNIC No. 35201-7011690-1. 6. Mr. Amanullah Khan CNIC No. 35202-2761884-1. 7. Mr. Asad Hussain Sufi CNIC 35201-0929173-5. 8. Mr. Shamim Ahmed CNIC No. 42201-0709868-3. 9. Mr. Junaid Shamim CNIC No.42201-0709876-3. 10. Mr. Shoaib Shamim CNIC No. 42201-0709871-7.

CASE NO. 105 <u>CHANGE OF MANAGEMENT OF M/S SEATLE (PVT) LTD, 45-KM, MULTAN ROAD, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000481 BY WAY OF (FORMULATION).</u>

M/s Seatle (Pvt) Ltd, 45-KM, Multan Road, Lahore, had applied for renewal of DML No. 000481 by way of formulation on 06-08-2020 for the period of 29-09-2020 to 28-09-2025. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 5th October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

<u>For Renewal of DML.</u>

i. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
ii. Attested CNIC's copies of all Directors.
iii. Latest Certified true copy of Form-29 (Attestation by SECP).

iv. Evidence of Lotion Section (Steroidal).

v. Evidence of Gel, Lotion, Liquid, Solution Section (General).

vi. Up-to-date nothing due certificate regarding CRF from STO.

For Production Incharge (Mr. Toqueer Ahmad).

i. Appointment letter.

ii. Job acceptance letter by the appointee.

iii. Resignation letter of appointee from the previous firm or promotion letter from same firm.

iv. Experience Certificate as under Drugs (Licensing, Registering and advertising) Rules, 1976 not less than 06 years.

All documents should be duly attested.

On scrutiny of application for change of management following observations has been noted Firm has changed their management several times without endorsement of Central Licensing Board. :-

A letter was issued to the firm on 9th June, 2021 with following observations: -

> "In your application for the change of management it is observed that your firm has changed their management several times without endorsement of Central Licensing Board. You are required to clarify your position for not submitting required documents in time. Moreover, submit certified true copy of consolidated Form-29 attested by SECP for new management".

In response to above mentioned letter Firm has submitted certified true copy of Form-29 attested by SECP for current management. Furthermore, firm has submitted assurance in future that they will get timely endorsement from CLB against change in management and to follow DRAP protocol and SOPs. The detail of current management is as under: -

New management as per Form-29 at Page 195-212/Corr Dated 10th June, 2021.
1. Ali Akhai S/o M. Javed Akhai CNIC No.42000-3326827-5.
2. Mr. Javed Ghulam Muhammad S/o Ghulam Muhammad CNIC No. 422010-556944-9.
3. Mr. Muqtadir Muhammad Ali Jawad S/o Shafiq Ahmed CNIC No. 42201-5392112-5.
4. Syed Dawood S/o Syed Fashiuddin Ahmed CNIC No. LB9262870.

It is submitted that on scrutiny of reply of the firm in response to this division's letter dated 9th June, 2021 it is observed that firm has not provided consolidated Form-29 for previous changes in management; moreover, firm has not submitted date wise break-up of the management and their tenure, on letter head and entire data submitted by the firm is difficult to comprehend. They have changed the management almost ten times without endorsement of CLB, the detail is as under:

S.#	Change of management.	Page No.	Status	Fee
1.	As per Form-29 dated 24-12-2020.	Page 117/Corr.	Management changed without endorsement of Central Licensing Board.	Requisite Fee required.
2.	As per Form-29 dated 01-10-2019.	Page 118/Corr.	-do-	-do-
3.	As per Form-29 dated 12-01-2017.	Page 128/Corr.	-do-	-do-
4.	As per Form-29 dated 08-05-2017.	Page 126/Corr.	-do-	-do-
5.	As per Form-29 dated 04-08-2017.	Page 136/Corr.	-do-	-do-
6.	As per Form-29 dated 15-05-2017.	Page 165/Corr.	-do-	-do-
7.	As per Form-29 dated 25-04-2017.	Page 167/Corr.	-do-	-do-
8.	As per Form-29 dated 06-01-2017.	Page 169/Corr.	-do-	-do-
9.	As per Form-29 dated 23-05-2016.	Page 171/Corr.	-do-	-do-
10.	As per Form-29 dated 02-09-2014.	Page 141/Corr.	-do-	-do-

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The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and after delibearations decided to seek the Prescribed fee and consolidated Form-29 & Form-A issued by the SECP.

CASE NO. 106. SITE VERIFICAATION OF SNAM LABORATORIES, LAHORE,

Site verification report of M/s SNAM Laboratories, Mouza Ghawindi, Tehsil Lahore Cantt, Distt, Lahore. The inspection was conducted by Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore on 20-04-2021, in response to this office letter dated 9th February, 2021. The recommendations of the inspection report are as under:-

i. **Location:** The proposed site was located at Mouza Ghawindi, Tehsil Lahore Cantt, Distt. Lahore and was approached through 30 feet wide, metaled Badian Barki Road, at 7 KM away from Haddira.

ii. **Surrounding:** On the front side of the site there was 30 feet wide metaled road. On the across of the 30 feet wide road there was 1st Defense line of security agencies. On the right, left and back side of the said site there was agricultural land.

iii. **Size:** The total area of the site was 04 kanals as per documents provided by the applicant. The dimension of the plot is annexed along with the report.

iv. **Recommendations** The firm was located in the jurisdiction of Security Agencies so, the firm was directed to provide NOC from Security Agencies for construction, as no contraction is allowed in the Jurisdiction of Security Agencies.
So the report is submitted herewith for consideration of the Board please.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered and after delibearations decided to direct the FID to submit inspection with clear recommendations report regarding suitability of site for establishment of pharmaceutical unit and advise the firm the submit NOC as recommended by the Federal Inspector of Drugs, Lahore at the earliest.

CASE NO. 107 APPROVAL OF QUALITY CONTROL INCHARGE OF M/S PAKHIEM INTERNATIONAL PHARMA (PVT) LTD, LAHORE.

The firm, M/s Pakheim International Pharma (Pvt) Ltd, 28-KM, Ferozepur Road, Lahore has submitted application for approval of proposed Quality Control Incharge Muhammad Ishfaque. The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

1. Attested copy of CNIC of appointee.
2. Attested copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
3. Attested copies of Experience Certificate as under Drugs (Licensing, Registering & Advertising Rules), 1976.
4. Attested copy of Resignation / retirement of earlier QC Incharge.
5. Attested copy of Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
6. Undertaking as whole time employee on stamp paper as per check list (Notarized), signed by both appointee and management.

Accordingly, a shortcoming letter was issued to the firm on 16th November, 2020 to rectify above mentioned shortcoming. In response to this Division's letter firm has submitted their reply

upon evaluation of submitted documents shortcoming has been still observed and a final reminder was issued to the firm on 7th January, 2021 with following observations:-

1. Copy of CNIC of appointee.
2. Copy of academic degrees, as required under Drugs (Licensing, Registering and Advertising) Rules, 1976.
3. Copies of Experience Certificate as under Drugs (Licensing, Registering & Advertising Rules), 1976.
4. Copy of Resignation / retirement of previous QC Incharge.
5. Resignation or termination letter of appointee from the previous firm.

Meanwhile the firm has submitted application for approval of another QC Incharge Syed Muhammad Ali Zaidi instead of Mr. Muhammad Ishfaque. Upon evaluation of application for approval of proposed QC Incharge per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Resignation letter of earlier Quality Control Incharge.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000 (by way of formulation) of M/s Pakheim International Pharma (Pvt) Ltd, 28-KM, Ferozepur Road, Lahore may not be suspended or cancelled by Central Licensing Board .

CASE NO. 108 GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000575 OF M/S SYNCHRO PHARMACEUTICALS, 77-INDUSTRIAL ESTATE KOT LAKHPAT, LAHORE.

Case Background:

M/s Synchro Pharmaceuticals, 77-Industrial Estate KotLakhpat, Lahore had applied for renewal of DML No. 000575 by way of formulation for the period of 14-05-2020 to 13-05-2025. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 21st October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form 1A alongwith enclosure / annexure / flags.
2. Classes of Drugs attested.
3. Dosage form of drugs attested.
4. Name(s) of drugs registered / approved.
5. Detail of management at the time of previous renewal and present renewal.
6. Partnership deed alongwith CNICs of all directors.
7. Detail of premises including layout plan

8. Proof of licensed sections from CLB.
9. Attested copies of approval letters of QC and Production Incharge.
10. Up to date nothing due certificate regarding CRF from STO.

All documents should be duly attested.

The firm submitted their reply on 11th November, 2020. After evaluation of the submitted documents, final reminder was issued on 30th November, 2020 to the firm with following shortcomings: -

i. Up to date Nothing Due Certificate regarding CRF from STO.
ii. Proof of licensed sections from CLB, if not available then submit application for regularization.
iii. Submit complete application for change of management along with requisite fee.

All documents should be duly attested.

The firm submits their reply on 22nd February, 2021 in response to this Division's Final Reminder. On scrutiny of submitted documents following shortcomings has been still observed:-

i. Application for change of management along with requisite fee is not provided.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

"The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000575 (by way of formulation) of M/s Synchro Pharmaceuticals, 77-Industrial Estate KotLakhpat, Lahore may not be suspended or cancelled by the Central Licensing Board".

M/s Synchro Pharmaceuticals, 77-Industrial Estate Kot Lakhpat, Lahore, has submitted required documents in response to this Division's Show Cause Notice 28th May, 2021 for renewal of Drug Manufacturing License. The application for renewal of Drug Manufacturing License No. 000575 for the period from 14-05-2020 to 13-05-2025 is now complete.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO. 109 **APPROVAL OF TECHNICAL STAFF PRODUCTION AND QUALITY CONTROL INCHARGE OF M/S ORTA LABORATORIES (PVT) LTD, 24-KM, MULTAN ROAD, OFF DEFENCE ROAD, MOHALANWAL, NEAR BAHRIA TOWN BRIDGE, LAHORE.**

The firm, M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohalanwal, Near Bahria Town Bridge, Lahore has submitted application for approval of proposed Production and Quality Control Incharge. The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found some deficiencies and shortcomings has conveyed to firm. Firm has submitted their reply, after evaluation of the submitted documents, final reminder was issued on 10th February, 2021 to the firm with following shortcomings: -

For Production Incharge (Mr. Atta Ur Rehman).

1. Job acceptance letter by appointee.
2. Resignation letter of appointee from previous firm and also mention name of firm.

For Quality Control Incharge (Mr. Muhammad Ziaqat).

1. Resignation letter of earlier QC Incharge.
2. Resignation letter of appointee from previous firm.

All documents should be duly attested.

Meanwhile the firm has submitted application for approval of another QC Incharge Omer Mahmood instead of Mr. Muhammad Ziaqat. Upon evaluation of application for approval of proposed QC Incharge per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

For QC Incharge (Omer Mahmood).

i. Readable copy of CNIC.

ii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 not less than six years.

iii. Undertaking of whole time employee on stamp paper signed by both Management & QC Incharge (Notrized).

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of

the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000075 (by way of formulation) of M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohalanwal, Near Bahria Town Bridge, Lahore may not be suspended or cancelled by Central Licensing Board.

CASE NO. 110 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000830 OF M/S SKIMS PHARMACEUTICALS,10-B, VALUE ADDITION CITY, KHURRIANWALA, FAISALABAD.**

Case Background:

M/s Skims Pharmaceuticals,10-B, Value Addition City, Khurrianwala, Faisalabad had applied for renewal of DML No. 000830 by way of formulation for the period of 03-12-2020 to 02-12-2025. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 7th January, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Classes of Drugs, dosage form of drugs, name of drugs registered / approved.
ii. Section wise detail of machinery for manufacture.
iii. Up to date nothing due certificate regarding CRF from STO.
iv. CNIC's copies of all directors.
All documents should be duly attested.

The firm submitted their reply on 21st January, 2021. After evaluation of the submitted documents, final reminder was issued on 10th February, 2021 to the firm with following shortcomings: -

i. Up to date Nothing Due Certificate regarding CRF from STO.

No reply is received from the firm as of today and the application for renewal of DML No. 000830 (Formulation) is still deficient of above mentioned documents.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to

why Drug Manufacturing License No 000830 (by way of formulation) of M/s Skims Pharmaceuticals,10-B, Value Addition City, Khurrianwala, Faisalabad may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

CASE NO.111 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000364 OF M/S SPECTRUM LABORATORIES (PVT) LTD, 8-KM, RAIWIND ROAD, LAHORE.**

Case Background:

M/s Spectrum Laboratories (Pvt) Ltd, 8-Km, Raiwind Road, Lahore had applied for renewal of DML No. 000364 by way of formulation for the period of 16-09-2020 to 15-09-2025. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 2nd December, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

1. Class of Drugs as per requirement of Form 1A.
2. Detail of management at the time of previous renewal and at present.
3. Latest Certified true copy of Form-29 (Attestation by SECP).
4. Up to date nothing due certificate regarding CRF from STO.
   All documents should be duly attested.

The firm submitted their reply on 28th December, 2021. After evaluation of the submitted documents, final reminder was issued on 28th January, 2021 to the firm with following shortcomings: -

i. Consolidated Form-29 or Form-A alongwith detail of all directors (attested by SECP / latest certified true copy).

No reply is received from the firm as of today and the application for renewal of DML No. 000364 (Formulation) is still deficient of above mentioned documents.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to

why Drug Manufacturing License No 000364 (by way of formulation) of M/s Spectrum Laboratories (Pvt) Ltd, 8-Km, Raiwind Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

CASE NO. 112 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000482 OF M/S SEAGULL PHARMA, TOWER POINT BEG COLONY GOJRA ROAD, JHANG.**

Case Background:

M/s Seagull Pharma, Tower Point Beg Colony Gojra Road, Jhang had applied for renewal of DML No. 000482 by way of formulation for the period of 19-12-2020 to 18-12-2025. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 30th December, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management with CNICs of all directors.
ii. Proof of licensed sections from CLB.
iii. Up-to-date nothing due certificate regarding CRF from STO.
iv. Submit classes of drugs, dosage form of drugs, name of registered / approved drugs.

All documents should be duly attested.

The firm submitted their reply on 4th February, 2021. After evaluation of the submitted documents, final reminder was issued on 5th April, 2021 to the firm with following shortcomings: -

For Renewal of DML.

i. Up-to-date nothing due certificate regarding CRF from STO.
ii. Classes of drugs, dosage form of drugs, list of registered / approved drugs, if any, please.

All documents should be duly attested.

The firm submitted their reply on 22nd April, 2021 in response to this Division's Final Reminder. After evaluation of the submitted documents, the application of Renewal of Drug Manufacturing License is still deficient for following documents: -

i. Up-to-date nothing due certificate regarding CRF from STO.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000482 (by way of formulation) of M/s Seagull Pharma, Tower Point Beg Colony Gojra Road, Jhang may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

CASE NO. 113 **GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000469 OF M/S PERFECT PHARMA (PVT) LTD, 5-KM, MANGA ROAD, RAIWIND, LAHORE.**

Case Background:

M/s Perfect Pharma,5-KM, Manga Road, Raiwind, Lahore had applied for renewal of DML No. 000469 by way of formulation. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 16th September, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Latest Certified true copy of Form-29 (Attestation by SECP).
ii. Detail of premises including layout plan.
iii. Proof of licensed sections from CLB.
iv. Name and Qualification of Production Incharge.
v. Up-to-date nothing due certificate regarding CRF from STO.
All documents should be duly attested.

The firm submits their reply on 22nd December, 2020 in response to this Division's letter dated 20th November, 2020. On scrutiny of submitted documents following shortcomings has been still observed and Final Reminder has been issued on 19th January, 2021:-

For Renewal of DML.

i. Latest Certified true copy of Form-29 (Attestation by SECP).
ii. Up-to-date nothing due certificate regarding CRF from STO.

The firm submits their reply on 23nd February, 2021 in response to this Division's Final Reminder. On scrutiny of submitted documents following shortcomings has been still observed:-

i. Latest Certified true copy of Form-29 (Attestation by SECP) without statement that "SECP accept no responsibility as to the correctness of the detail given in the document".

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000469 (by way of formulation) of M/s Perfect Pharma (Pvt) Ltd, 5-Km, Manga Road, Raiwind, Lahore may not be suspended or cancelled by the Central Licensing Board.

M/S Perfect Pharma (Pvt) Ltd, 5-Km, Manga Road, Raiwind, Lahore, has submitted required documents in response to this Division's Show Cause Notice 28th May, 2021 for renewal of Drug Manufacturing License. The application for renewal of Drug Manufacturing License No. 000469 for the period from 14-05-2020 to 13-05-2025 is now complete. The application for renewal of DML for the period 01-03-2020 to 31-02-2025 is now complete.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO. 114 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000814 OF M/S PCP LABORATORIES, 98-KM, AKHTARABAD, DISTRICT OKARA.

Case Background:

M/s PCP Laboratories, 98-Km, Akhtarabad, District Okara had applied for renewal of DML No. 000814 by way of formulation for the period of 23-06-2015 to 22-06-2020. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 5th October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Detail of management at the time of previous renewal and at present, if any change apply for change of management.
ii. Partnership deed alongwith CNIC's of all partners.
iii. Detail of premises including layout plan.
iv. Proof of licensed sections from CLB.
v. Approval letter of Quality Control Incharge in case of change than submit required documents as per check list.
vi. Form 1A as per prescribed formate.
vii. Up-to-date nothing due certificate regarding CRF from STO.

All documents should be duly attested.

For Production Incharge (Mr. Rehmat Jamil).

i. Copy of appointment letter of appointee.
ii. Copy of job acceptance letter by the appointee.
iii. Readable copy of registration certificate from pharmacy council.
iv. Copy of resignation letter of earlier production incharge.
v. Copy of resignation letter of appointee from previous firm.
vi. Undertaking as whole time employee on stamp paper signed by both appointee & management.

All documents should be duly attested.

The firm submitted their reply after evaluation of the submitted documents, final reminder was issued on 3rd March, 2021 to the firm with following shortcomings: -

For Renewal of DML.

i. Detail of management at the time of previous renewal and at present, in case of any change apply for change of management.
ii. Partnership deed alongwith copies of CNIC of all partners.
iii. Detail of premises including layout plan.
iv. Proof of licensed sections from CLB.
v. Approval letter of Quality Control Incharge, in case of change, submit required documents as per check list.
vi. Form 1A as per prescribed format.
vii. Up-to-date nothing due certificate regarding CRF from STO.

All documents should be duly attested.

No reply is received from the firm as of today and the application for renewal of DML No. 000814 (Formulation) is still deficient of above mentioned documents.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000814 (by way of formulation) of M/s PCP Laboratories, 98-Km, Akhtarabad, District Okara may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

CASE NO. 115. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY SARCO CHEMICAL INDUSTRIES, 17-KM, PEERWALA MORR, QADER PUR BAN, KHANWAL ROAD, DISTRICT MULTAN.

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Sarco Chemical Industries, 17-Km, Peerwala Morr, Qader Pur Ban, Khanwal Road, District Multan on 30th September, 2020 but firm has not submitted CRF till 2013.

Now Nothing Due Certificate is received from Assistant Director (Revenue) B&A, DRAP, Islamabad in respect of M/s Sarco Chemical Industries, 17-Km, Peerwala Morr, Qader Pur Ban, Khanwal Road, District Multan.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO. 116 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S RELIZON PHARMACEUTICALS, PLOT NO. 118-SUNDAR INDUSTRIAL ESTATE, RAIWIND ROAD, LAHORE.

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Relizon Pharmaceuticals, Plot No. 118-Sundar Industrial Estate, Raiwind Road, Lahore on 30th September, 2020 but firm has not submitted CRF till grant of DML.

Now Nothing Due Certificate is received from Assistant Director (Revenue) B&A, DRAP, Islamabad in respect of M/s Relizon Pharmaceuticals, Plot No. 118-Sundar Industrial Estate, Raiwind Road, Lahore.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO. 117 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S PHARMA ZONE CHEMICALS (PVT) LTD, PLOT NO. 37, SUNDER INDUSTRIAL ESTATE, LAHORE.

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Pharma Zone Chemicals (Pvt) Ltd, Plot No. 37, Sunder Industrial Estate, Lahore on 30th September, 2020 but firm has not submitted CRF since the grant of DML. A Show Cause Notice was issued to the firm on 30th September, 2020 but firm has not submitted CRF till to date.

Now Nothing Due Certificate is received from Assistant Director (Revenue) B&A, DRAP, Islamabad in respect of M/s Pharma Zone Chemicals (Pvt) Ltd, Plot No. 37, Sunder Industrial Estate, Lahore.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice issued to the firm.

CASE NO.118 GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000290 OF M/S SYNTEX PHARMACEUTICALS, KAMRA ROAD, ATTOCK CITRY.

Case Background:

The Central Licensing Board in its 267th meeting held on 31st December, 2018 has considered the facts on the record and after thread bare deliberation decided to suspend the Drug Manufacturing Licensing No. 000290 (Formulation) of M/s Syntex Pharmaceuticals, Kamra Road, Attock City, (Extract at Flag-A) and decided as under:-

Proceedings and Decision of Central CLB in 267thmeeting.

Abdul Rahim Mirza CEO of the firm appeared before the board and contended that his existing facility is located in residential area. He further contended that he has submitted application for establishment of pharmaceutical unit at new site and he will submit short comings documents in the application for new site within one week. He also contended he will submit the layout plan for the new site till the end of February 2019 and will submit application for grant of Drug manufacturing license till November 2019. The Board after hearing the representative of the firm and considering the facts on the record and after thread bare deliberation decided to suspend the Drug Manufacturing License No. 000290 by way of formulation under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 issued in the name of "M/s Syntex Pharmaceuticals Kamra Road Attock City till shifting of the firm to new premises" shall be read as "M/s Syntex Pharmaceuticals Kamra Road Attock City till completion of codal formalities. However, the firm shall shift to new premises in given time as mentioned above".

It is submitted that the firm could not file application for renewal of Drug Manufacturing License for the tenure 07-01-2020 to 06-01-2025 as per record of Licensing Division's receiving available in computer.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record and after thread bare deliberation decided to cancel the Drug Manufacturing Licence No. 000290 by way of formulation in the name of M/s Syntex Pharmaceuticals, Kamra Road, Attock City under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as an application for renewal of the Drug manufacturing Licence is not submitted as prescribed unde the Rules.

CASE NO. 119 **CHANGE OF TITLE / NAME OF M/S NEWLAND LABORATORIES, POT NO. 17, SS-2, RCCI, RAWAT.**

M/s Newland Laboratories, Pot No. 17, SS-2, RCCI, Rawat submitted request for Change of Name / Title with fee of Rs.75,000/- on the said DML. The pre-requisite documents of the change of name / title is as under: -

Previous Title of the firm.	Current Title of the firm.

M/s Newland Laboratories, Plot No.17, Street No.SS-2, RCCI, Industrial Estate, Rawat.	M/s D-Maarson Pharmaceuticals, Plot No.17, Street No.SS-2, RCCI, Industrial Estate, Rawat.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record and after thread bare deliberation acceded the request of the firm change of title of the firm as under ;

Previous Title of the firm.	Current Title of the firm.
M/s Newland Laboratories, Plot No.17, Street No.SS-2, RCCI, Industrial Estate, Rawat.	M/s D-Maarson Pharmaceuticals, Plot No.17, Street No.SS-2, RCCI, Industrial Estate, Rawat.

Case No. 120. **GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S. APEX PHARMACEUTICALS (PVT) LTD, KARACHI**

	M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachi. DML No. 000746 (Formulation) **Period**: 27-08-2017 to 26-08-2022	**08-08-2018**	**N/A**	1. Dr. Abdullah Dayo, Member CLB. 2. Additional Director (E & M) DRAP, Karachi.. 3. Area FID, DRAP, Karachi.
	Recommendations of the panel: - The panel conducted inspection on 08-08-2018 and noted following observations; Observations: 1. During inspection the panel came to know that the firm had been granted DML No. 000746 (Formulation) in the year 2012 and in the subsequent years the firm got almost 16 registrations in all four approved sections that are Tablet (General), Capsule (General), Capsule (Cephalosporin) and Dry Powder Suspension (Cephalosporin). 2. The panel observed that firm had not manufactured a single batch of any of their registered products. The in complete documents were shown purporting the only trial batch of Cefixime manufacturing during past six years. 3. The panel observed the unit under inoperable conditions and management was of the view that due to high operational cost and limited number of registrations they were unable to start it for commercial purpose. 4. The panel observed that the firm had relocated some of their storage areas and provided HVAC aimlessly in those sections. The additional section of Cream/Ointment was noted incomplete during inspection. 5. It was very difficult for the panel to asses their current GMP compliance lever amid such inactive conditions although firm possesses sufficient number of registrations and could have started production to meet the national regulatory requirements.			

Conclusion. Based on the above observations the panel decided to defer the grant of renewal of their DML, grant of additional section of Cream/Ointment and regularization of their existing LOP. Panel further requests the board concerned to see the current inactive status of their DML under DRAP Act, 2012/Drug Act, 1976.

Decision by the Central Licensing Board in 267th meeting

The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The show cause notice dated 29th January, 2019 was issued to the firm. The reply of the show cause notice is not received. The firm is called for personal hearing vide letter dated 19thFebruary, 2019.

Decision by the Central Licensing Board in 269th meeting

Syed Azhar ul Hassan, General Manager of M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachi appeared before the Board. He contended that most of the rectifications have been made as pointed out by the panel and Lay out plan as per advice of the panel has been revised and submitted with Division of Licensing for approval. As soon as Lay out plan is approved they would make improvements and accordingly one-month time may be given.

The Board after hearing the representative of the firm decided to give one month period to the firm to make improvements as per revised Lay out plan. The company shall submit request for re-inspection of the unit once improvements and rectification are made and accordingly a panel would be constituted to conduct inspection for consideration of the Board. Meanwhile Licence of the company shall remain suspended for the said period. Production shall be resumed after approval by the Central Licensing Board.

The decision of the Board was communicated to the firm vide letter Dated : 29-03-2019.

The firm then applied for regularization of layout plan and same was approved vide letter Dated : 04-02-2020). Later on, firm informed that sections are now ready for inspection and the firm requested to constitute a panel of experts for renewal of DML and regularization of revised / approved layout plan.

A panel of experts was constituted comprising of following members was constituted and panel has submitted its report .

1. Dr. Abdullah Dayo, Member CLB.
2. Additional Director (E & M) DRAP, Karachi..
3. Area FID, DRAP, Karachi.

The recommendations of the panel are mentioned below:

"***Recommendations of the panel**: -*

Based on people met, documents reviewed the panel recommends the grant of

renewal of Drug Manufacturing License NO. 000746 by way of formulation for following sections; commencing from 27-08-2017. The panel further recommends the regularization of their current layout plan.

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Capsule (General)
iii.	Capsule (Cephalosporin)	iv.	Dry Powder Suspension (Cephalosporin)
v.	Cream/Ointment **(Additional Section)**		**********

Decision of the Central Licensing Board in 278th meeting

The Board considered and approved the grant of renewal of DML No. 000746 by way of formulation in the name of M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachi on the recommendations of the panel of experts for the period commencing **27-08-2017** and ending on **26-08-2022** for the following sections:-

SECTIONS (01)

1. Tablet (General)
2. Capsule (General)
3. Capsule (Cephalosporin)
4. Dry Powder Suspension (Cephalosporin)

It is submitted that the as per opinion/remarks of Legal Affair Division, DRAP Division, Rule 18(8) of the Drugs (Licensing Registering & Advertising) Rules 1976 prescribe that in case of absence of the Chairman, the Board may elect one of the members to preside over the meeting. Therefore, in case of absence of the Chairman, the Presiding member of the CLB may sign the Drug manufacturing License. 278th meeting of CLB was presided over by Dr. Ikram ul Haq and currently he is abroad. Case is placed before the CLB for the orders of the Board regarding issuance of the renewal of DML of the firm.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record ,after thread bare deliberation and in the light of opinion/remarks of Legal Affair Division, DRAP allowed the Presiding Member of the 282nd meeting of the CLB to sign the Drug manufacturing License in absence of the Chairman CLB.

Case No. 121 RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S. MASS PHARMA(PVT) LTD, LAHORE.

M/s Mass Pharma (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore. DML No.000444 (Formulation) Period : Commencing on **24-11-2019** and ending on **23-11-2024**	**23-09-2020**	**Very Good**	4) Dr. Ikram Ul Haq, Member Central Licensing Board, 5) Mr. Azher Jamaal Saleemi, Chief Drugs Controller, Punjab 6) Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.

Recommendations of the panel:

Keeping in view the continuous improvements by the firm, the panel of the Inspectors **Recommends** renewal of M/s Mass Pharma (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore under DML No.000444 (Formulation) of the following approved sections.

i.	Tablet (General) Section.	ii.	Table (General Antibiotics) Section.
iii.	Liquid Injectable Ampoule (General) Section.	iv.	Cream / Ointment / Gel (Steroidal) Section
v.	Cream / Ointment / Gel (General) Section	vi.	Capsule (Cephalosporin) Section.
vii.	Oral Dry Powder Suspension (Cephalosporin) Section.	viii.	Dry Powder Injectable (Vial) (Cephalosporin) Section.
ix.	Capsule (General) Section.	x.	Injectable (Vial) (SVP) (General) Section.
xi.	Soft Gelation Capsule.	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	

Decision of the Central Licensing Board in 278th meeting

The Board considered and approved the grant of renewal of (DML No. 000444) by way of formulation in the name of M/s Mass Pharma (Pvt) Ltd, 17-Km, Ferozepur Road, Lahoreon the recommendations of the panel of experts for the period commencing on **24-11-2019** and ending on **23-11-2024**for the following sections:-

i.	Tablet (General) Section.	ii.	Table (General Antibiotics) Section.
iii.	Liquid Injectable Ampoule (General) Section.	iv.	Cream / Ointment / Gel (Steroidal) Section
v.	Cream / Ointment / Gel (General) Section	vi.	Capsule (Cephalosporin) Section.
vii.	Oral Dry Powder Suspension (Cephalosporin) Section.	viii.	Dry Powder Injectable (Vial) (Cephalosporin) Section.
ix.	Capsule (General) Section.	x.	Injectable (Vial) (SVP) (General) Section.
xi.	Soft Gelation Capsule.	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	

It is submitted that the as per opinion/remarks of Legal Affair Division, DRAP Division, Rule 18(8) of the Drugs (Licensing Registering & Advertising) Rules 1976 prescribe that in case

of absence of the Chairman, the Board may elect one of the members to preside over the meeting. Therefore, in case of absence of the Chairman, the Presiding member of the CLB may sign the Drug manufacturing License. 278th meeting of CLB was presided over by Dr. Ikram ul Haq and currently he is abroad. Case is placed before the CLB for the orders of the Board regarding issuance of the renewal of DML of the firm.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record ,after thread bare deliberation and in the light of opinion/remarks of Legal Affair Division, DRAP allowed the Presiding Member of the 282nd meeting of the CLB to sign the Drug manufacturing License in absence of the Chairman CLB.

CASE NO. 122 <u>RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000167 (FORMULATION) OF M/S MEDIATE PHARMACEUTICAL (PVT) LTD, PLOT No. 150-151, SECTOR 24, KORANGI INDUSTRIAL AREA, KARACHI</u>

10.	M/s Mediate Pharmaceutical (Pvt) Ltd, Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi. DML No. 000167 (Formulation) **Period**. 18-11-2020 till 17-11-2025	**09-10-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Chief Drugs Inspector, Govt of Sindh, Karachi. 3. Area FID, DRAP, Karachi.

***Recommendations of the panel**: -*

Based on the people met, documents reviewed and observation made during the inspection, panel recommends the grant of renewal of Drug Manufacturing License No. 000167 by way of Formulation for following sections:-

Sr. No	Name of Sections	Sr. No	Name of Sections
1.	Tablet (General)	2.	Tablet (Quinolone)
3.	Tablet (Psychotropic)	4.	Liquid syrup (General)
5.	Ointment	6.	Liquid ampoule (General)
7.	Liquid Injection (Psychotropic)	8.	Infusion (General Antibiotic)
9.	Dry Powder Injectable (Cephalosporin)	10.	Capsule (Cephalosporin)

11.	Oral Dry Powder Suspension (cephalosporin)	12.	Capsule(General)
13.	Oral Dry Powder Suspension antibiotic (General)	14.	Dry Powder (General) Injection
15.	Dry Powder Suspension (Penicillin)	16.	Capsule (Penicillin)

Decision of the Central Licensing Board in 277th meeting

The Board considered and approved the grant of renewal of (DML No. 000167) by way of formulation in the name of M/s Mediate Pharmaceutical (Pvt) Ltd, Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachion the recommendations of the panel of experts for the period commencing on 18-11-2020 and ending on 17-11-2025 for the following sections:-

SECTIONS (16)

Sr. No	Name of Sections	Sr. No	Name of Sections
1.	Tablet (General)	2.	Tablet (Quinolone)
3.	Tablet (Psychotropic)	4.	Liquid syrup (General)
5.	Ointment	6.	Liquid ampoule (General)
7.	Liquid Injection (Psychotropic)	8.	Infusion (General Antibiotic)
9.	Dry Powder Injectable (Cephalosporin)	10.	Capsule (Cephalosporin)
11.	Oral Dry Powder Suspension (cephalosporin)	12.	Capsule(General)
13.	Oral Dry Powder Suspension antibiotic (General)	14.	Dry Powder (General) Injection
15.	Dry Powder Suspension (Penicillin)	16.	Capsule (Penicillin)

It is submitted that before issuance of DML to the firm, Dr. Masud ur Rehman got transferred. As per opinion/remarks of Legal Affair Division, DRAP Division, Rule 18(8) of the Drugs (Licensing Registering & Advertising) Rules 1976 prescribe that in case of absence of the Chairman, the Board may elect one of the members to preside over the meeting. Therefore, in case of absence of the Chairman, the Presiding member of the CLB may sign the Drug

manufacturing License Now, the post of Director (Licensing) is vacant, therefore, case of the firm is placed before the CLB for the orders of the Board regarding issuance of the renewal of DML of the firm.

Decision of Central Licensing Board in 282nd meeting.
The Board considering the facts on the record ,after thread bare deliberation and in the light of opinion/remarks of Legal Affair Division, DRAP allowed the Presiding Member of the 282nd meeting of the CLB to sign the Drug manufacturing License in absence of the Chairman CLB.

CASE NO.123 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000680 (FORMULATION) OF M/S GRAND PHARMA (PVT) LTD, RAWAT.**

M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat. DML No. 000680 (Formulation) **Period**: 04-02-2020 to 03-02-2025	04-08-2020 & 12-08-2020	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT-I), DRAP, Islamabad. 2. Dr. Muhammad Usman, Member, Central Licensing Board. 3. Mr. Khalid Mahmood, Federal Inspector of Drugs, DRAP, Islamabad.

Recommendations of the panel: -

Keeping in view the above facts, detail visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat, Rawalpindi for renewal of Drug Manufacturing License No. 000680 (Formulation) as of today as per mandate given vide letter No.F. 1-36/2006-Lic (Vol-II) dated 1st June, 2020 for following section in addition to already approved section by Central Licensing Board in mid of 2019 as above also. Request for inspection of Add. Sections (Liq. Vial Vet (Gen))& Steroid submitted by the firm as per LOP.

1. Oral Liquid Section (Veterinary).
2. Viral Vaccine Section (Live)
3. Viral Vaccine Section (Killed)
4. Bacterial Killed Vaccine Section.
5. Bolus Section (General) (Veterinary).
6. Oral Powder Section (General) (Veterinary).
7. Oral Liquid Section (General) (Veterinary)
8. Oral Powder Section (Penicillin) (Veterinary).
9. Dry Powder Injection Section Vials(Penicillin) (Veterinary)
10. Liquid Injection Section Vials (Penicillin) (Veterinary).

DISCLAIMER:- *The assessment for strength of building does not fall under the ambit mandate and*

scope of the inspection for which the firm has been advised to get certification form relevant Building Control Authorities (BCA) as per prevailing laws and ensure proper emergency exits along with firefighting equipment in the premises. The quality of individual batches of registered products and their safety shall remain the responsibility of the manufacturer as envisaged under the Drug Act, 1976 read with DRAP Act, 2012.

Decision of the Central Licensing Board in 276th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period commencing on 04-02-2020 and ending on 03-02-2025 for the following sections:

1. Oral Liquid Section (Veterinary).
2. Viral Vaccine Section (Live).
3. Viral Vaccine Section (Killed)
4. Bacterial Killed Vaccine Section.
5. Bolus Section (General) (Veterinary).
6. Oral Powder Section (General) (Veterinary).
7. Oral Liquid Section (General) (Veterinary)
8. Oral Powder Section (Penicillin) (Veterinary).
9. Dry Powder Injection Section Vials(Penicillin) (Veterinary)
10. Liquid Injection Section Vials (Penicillin) (Veterinary).

Moreover, the Board decided that Dr. Hafsa Karam Elahi shall come up with opinion after consulting Federal Inspector of Drugs with respect to Disclaimer.

It is submitted that before issuance of DML to the firm, Dr. Masud ur Rehman got transferred. As per opinion/remarks of Legal Affair Division, DRAP Division, Rule 18(8) of the Drugs (Licensing Registering & Advertising) Rules 1976 prescribe that in case of absence of the Chairman, the Board may elect one of the members to preside over the meeting. Therefore, in case of absence of the Chairman, the Presiding member of the CLB may sign the Drug manufacturing License Now, the post of Director (Licensing) is vacant, therefore, case of the firm is placed before the CLB for the orders of the Board regarding issuance of the renewal of DML of the firm.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record ,after thread bare deliberation and in the light of opinion/remarks of Legal Affair Division, DRAP allowed the Presiding Member of the 282nd meeting of the CLB to sign the Drug manufacturing License in absence of the Chairman CLB.

CASE NO. 124 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000639 (FORMULATION) OF M/S BIOGEN PHARMACEUTICALS, RAWALPINDI.**

M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Khan Road, Rawat, Rawalpindi. DML No. 000639 (Formulation) **Period**: Commencing on 19-06-	**25-11-2019**	**Good**	1. Dr. Muhammad Usman, Member, CLB. 2. Abdul SattarSohrani, Deputy Director (QC-I), DRAP, Islamabad. 3. Khalid Mahmood, FID-II, DRAP, Islamabad.

2018 &ending 18-06-2023.			

Recommendations of the panel: -
Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Road, Rawat, Rawalpindi for the grant of Drug Manufacturing License No. 000639 (Formulations) w.e.f. 19th June, 2018.

Decision by the Central Licensing Board in 273rd meeting
The Board considered and approved the renewal of Drug Manufacturing License 000639 (Formulation) in the name of M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Khan Road, Rawat, Rawalpindi on the recommendations of the panel of experts for the further period of five years Commencing on 19-06-2018 ending 18-06-2023 for following sections:-

i. Oral Liquid (General) veterinary
ii. Oral Powder (General) Veterinary
iii. Liquid Injection (Vial) (General) Section veterinary
iv. Tablet (General) Section (Human)
v. Cream/Ointment/Gel (General) Human

It is submitted that before issuance of DML to the firm, Dr. Masud ur Rehman got transferred. As per opinion/remarks of Legal Affair Division, DRAP Division, Rule 18(8) of the Drugs (Licensing Registering & Advertising) Rules 1976 prescribe that in case of absence of the Chairman, the Board may elect one of the members to preside over the meeting. Therefore, in case of absence of the Chairman, the Presiding member of the CLB may sign the Drug manufacturing License Now, the post of Director (Licensing) is vacant, therefore, case of the firm is placed before the CLB for the orders of the Board regarding issuance of the renewal of DML of the firm.

Decision of Central Licensing Board in 282nd meeting.
The Board considering the facts on the record ,after thread bare deliberation and in the light of opinion/remarks of Legal Affair Division, DRAP allowed the Presiding Member of the 282nd meeting of the CLB to sign the Drug manufacturing License in absence of the Chairman CLB.

Case No. 125 RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S. CITI PHARMA(PVT) LTD, KASUR.

M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, Bhai Pheru, District Kasur. DML No. 000429 (Semi Basic Manufacture) Period: Commencing on 27-02-2018 & ending on 26-02-2023.	**17-12-2020**	**Good**	1) Dr. Farzana Chaudhary, Expert Member. 2) Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3) Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore.

Recommendations of the panel:

"Panel has thoroughly inspected the unit, evaluated the documents provided by the management and discussed various technical aspects at length. Details of equipments of Production and Quality Control departments and copies of flow chart and list of technical staff duly signed by the firm are attached with this report for perusal of the Central Licensing Board.

Based on the details mentioned above, documentations revealed and submitted by the management, physical panel inspection of the unit, panel has **recommended** the facility M/s Citi Pharma (Pvt) Ltd,3-Km, Head Balloki Road, Bhai Pheru, Kasur for renewal of DML No. 000429 by way of Semi Basic Manufacturing."

Decision of the Central Licensing Board in 279th meeting

The Board considered and approved the grant of renewal of DML No. 000429 by way of Semi Basic Manufacture in the name of M/s Citi Pharma (Pvt) Ltd,3-Km, Head Balloki Road, Bhai Pheru, District Kasur on the recommendations of the panel of experts for the period Commencing on27-02-2018 & ending on 26-02-2023.

It is submitted that the as per opinion/remarks of Legal Affair Division, DRAP Division, Rule 18(8) of the Drugs (Licensing Registering & Advertising) Rules 1976 prescribe that in case of absence of the Chairman, the Board may elect one of the members to preside over the meeting. Therefore, in case of absence of the Chairman, the Presiding member of the CLB may sign the Drug manufacturing License. 278th meeting of CLB was presided over by Akhter Abbas and currently he is abroad. Case is placed before the CLB for the orders of the Board regarding issuance of the renewal of DML of the firm.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record ,after thread bare deliberation and in the light of opinion/remarks of Legal Affair Division, DRAP allowed the Presiding Member of the 282nd

meeting of the CLB to sign the Drug manufacturing License in absence of the Chairman CLB.

CASE NO.126 . RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S. M/S WILSHIRE LABORATORIES (PVT) LTD, 124/1, INDUSTRIAL ESTATE, KOTLAKHPAT, LAHORE.

16.	M/s Wilshire Laboratories (Pvt) Ltd, 124/1, Industrial Estate, KotLakhpat, Lahore. DML No. 000232 (Formulation) **Period**: Commencing on **21-07-2020** and ending on **20-07-2025**	**05-10-2020 & 08-10-2020**	Good	1. Dr. Farzana Chowdhary, , Expert Member. 2. Aisha Irfan, FID, DRAP, Lahore. 3. Azhar Jamal Saleemi, Chief Drug Controller, Punjab.

"In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery equipment, material, management, air handling, water treatment system, personnel and documentation etc the panel of inspectors recommends the renewal of Drug Manufacturing License to M/s Wilshire Labs (Pvt) Ltd, by way of Formulation of the following sections;

1. Tablet Section (Narcotic & Psychotropic).
2. Capsule Section (Narcotic & Psychotropic).
3. Capsule Section (Cephalosporin).
4. Dry Powder Suspension (Cephalosporin).
5. Dry Powder Injectable (Cephalosporin).
6. Tablet Section (General).
7. Capsule Section (General).
8. Dry Powder Injectable Section (General).
9. Liquid Injectable (General).
10. Injectable Ampoule (Narcotic / Psychotropic) Section.
11. Sachet (General).
12. Dry Powder Suspension (General).

Decision of the Central Licensing Board in 278th meeting

The Board considered and approved the grant of renewal of (DML No. 000232) by way of formulation in the name M/s Wilshire Laboratories (Pvt) Ltd, 124/1, Industrial Estate, KotLakhpat, Lahore.on the recommendations of the panel of experts for the period commencing on**21-07-2020** and ending on **20-07-2025**for the following sections:-

SECTIONS (12)

1. Tablet Section (Narcotic & Psychotropic).
2. Capsule Section (Narcotic & Psychotropic).
3. Capsule Section (Cephalosporin).

	4. Dry Powder Suspension (Cephalosporin). 5. Dry Powder Injectable (Cephalosporin). 6. Tablet Section (General). 7. Capsule Section (General). 8. Dry Powder Injectable Section (General). 9. Liquid Injectable (General). 10. Injectable Ampoule (Narcotic / Psychotropic) Section. 11. Sachet (General). 12. Dry Powder Suspension (General).

It is submitted that the as per opinion/remarks of Legal Affair Division, DRAP Division, Rule 18(8) of the Drugs (Licensing Registering & Advertising) Rules 1976 prescribe that in case of absence of the Chairman, the Board may elect one of the members to preside over the meeting. Therefore, in case of absence of the Chairman, the Presiding member of the CLB may sign the Drug manufacturing License. 278th meeting of CLB was presided over by Dr. Ikram ul Haq and currently he is abroad. Case is placed before the CLB for the orders of the Board regarding issuance of the renewal of DML of the firm.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record ,after thread bare deliberation and in the light of opinion/remarks of Legal Affair Division, DRAP allowed the Presiding Member of the 282nd meeting of the CLB to sign the Drug manufacturing License in absence of the Chairman CLB.

Case No. 127: <u>GRANT OF LICENSE TO MANUFACUTRING DRUGS FOR EXPERIMENTAL PURPOSEON NEW PREMISES:</u>

The Licensing Division of DRAP is receiving multiple applications for grant of Drug Manufacturing License for Experimental Purpose and following documents are being sought from the applicants prior to inspection of the premises:

i. Application on prescribed Form-3 as under Rule 21 of Drugs (L, R &A) rules, 1976 countersigned by the Head of Institution.

ii. Name and Qualification of qualified persons responsible for manufacturing for experimental purpose.

iii. List of machinery and equipment in production and Quality Control departments.

iv. Facility Layout Plan for manufacturing and Quality Control of Experimental Drug.

v. Manufacturing Process.

vi. Testing Method.

vii. Working SOPs.

viii. Affidavit on stamp paper in the light of rule 21-23 of Drugs (L, R &A) rules, 1976.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considering the facts on the record and after thread bare deliberation allowed to the following documents to be sought from the applicants prior to inspection of the premises for the purpose of grant of license to manufacture drugs for experimental purpose at new premises:

i. Application on prescribed Form-3 as under Rule 21 of Drugs (L, R &A) rules, 1976 countersigned by the Head of Institution.

ii. Name and Qualification of qualified persons responsible for manufacturing for experimental purpose.

iii. List of machinery and equipment in production and Quality Control departments.

iv. Facility Layout Plan for manufacturing and Quality Control of Experimental Drug.

v. Manufacturing Process.

vi. Testing Method.

vii. Working SOPs.

viii. Affidavit on stamp paper in the light of rule 21-23 of Drugs (L, R &A) rules, 1976.

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Case No. 128:GRANT OF LICENSE TO MANUFACUTRING DRUGS FOR EXPERIMENTAL PURPOSE BY M/S GT PHARMA (PVT) LTD, LAHORE (ON ALREADY LICENSED PREMISES):

Application for grant of DML for experimental purpose is received from M/s GT Pharma (Pvt) Ltd, Lahore which is reproduced as under:

"M/s GT Pharma (Pvt) Ltd, Lahore is a licensed manufacturer of medicinal products as per the Drug Manufacturing License No: 000829 issued by DRAP.

In reference to our submitted application on dated 28th April, 2021 to DRAP (Acknowledgement attached). We would like to have your kind attention that we are licensed to manufacture the product ED-3injection (Cholecalciferol EUR.P) 5mg/ml Oral/I.M. Ampoule for Pakistan market and the registration number allotted for it is: 80881

We have been approached by the Principal Investigator Dr. Javeria Saleem, of Punjab University for providing the product ED-3 as Investigational product (IP) to be used in the clinical trial to be conducted by them after approval from the Pharmacy Division of DRAP. They also require a placebo (as per protocol summary of the trial protocol given below) to be used in the trial.

Both IP and Placebo will be named as "ViDiSAM" and the trial name will only be used for this clinical trial use only.

Randomization code shall be provided by the data management and shall be placed on each packaging and ampoule. This shall be differentiating between IP and Placebo known to them, and shall be used to compile the results at the end of the trial maintaining blinding.

Dosage: 1st ampoule on the day of discharge and 2nd after 2 weeks of the first dose

TOTAL ampoules: 250 x 2 = 500

Required ampoules: Active = 300* (250) and Placebo = 300* (250)

Please find the attached Summary of Protocol in Annexure - A and IP and Placebo details and packaging in Annexure - B for your kind reference.

The manufacturing of the IP and Placebo may please be allowed to be done."

The case is hereby submitted for consideration and deliberation of the Board, please.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board considered the case and noted that Rule 21 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 provides that Drug Manufacturing Licence holders do not require Licence to manufacture by way of experimental purpose and in the instant case M/s GT Pharma, Lahore is a licensed Unit under the Drugs (Licensing, Registering and Advertising) Rules, 1976.

The Board, therefore, decided to advise the applicant to approach Drug Registration Board for permission for manufacture of particular quantity of Drugs for trial purpose..

Case No. 129: <u>RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S SCHAZOO PHARMACEUTICAL LABORATORIES (PVT) LTD, DISTRICT, SHEIKHUPURA.</u>

	M/s Schazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalalwala Stop, 20-KM, Lahore-Jaranwala Road, District, Sheikhupura. DML No. 000019 (Formulation) Tenure. Commencing on11-06-2019 and ending on 10-06-2024.	**26-02-2021**	**Good**	1. Dr. Ikram Ul Haq, Member CLB. 2. Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 3. Mrs. Majida Mujahid, Area Federal Inspector of Drugs.

<u>Recommendations of the panel:</u>

"In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery / equipment, material, management, air handling personnel and documentation etc., the panel recommends the Renewal of Drug Manufacturing License No. 000019 by way of (Formulation) to M/s Schazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalalwala Stop, 20-KM, Lahore-Jaranwala Road, District, Sheikhupura for following sections:-

1. General Solid Oral Dosage form for Tablet, Capsule & Sachet.
2. Oral Liquid Section for suspension and Syrup.
3. (Ampoule) General & Psychotropic Injectable Section.
4. Ophthalmic & Nasal Drops Section.
5. Tablet, Capsule and Oral Dry Powder Suspension (Cephalosporin).

Note: It is submitted that following sections in the inspection report are approved with following nomenclature as per record of Licensing Division at page 89/Corr.

In Inspection Report.	*As per Licensing Division.*
1. Oral Liquid Section for Suspension & Syrup.	*1. Oral Liquid Syrup.* *2. Liquid Ampoule.*

2. Ampoule (General & Psychotropic) Injectable Section.	

It is further submitted that Sachet Section in inspection report is not approved as per record of Licensing Division as it been checked from last renewal letter, from layout plan submitted by firm with renewal application and from panel inspection letter for renewal of DML.

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000019) by way of Formulation in the name of M/SSchazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalalwala Stop, 20-KM, Lahore-Jaranwala Road, District, Sheikhupuraon the recommendations of the panel of experts for the period commencing on 11-06-2019 and ending on 10-06-2024..for following sections :

1. Tablet (General)
2. Capsule (General)
3. Sachet (General)
4. Oral Liquid Section for suspension and Syrup.
5. (Ampoule) General & Psychotropic Injectable Section.
6. Ophthalmic & Nasal Drops Section.
7. Tablet, Capsule and Oral Dry Powder Suspension (Cephalosporin).

The Board defferd following sections for clarification

1. Oral Liquid Section for Suspension & Syrup.
2. Ampoule (General & Psychotropic) Injectable Section.
3. Sachet Section.

*It is submitted that the following sections have been written inadvertently both in the list of approved and deferred sections while drafting of minutes: -

1. Oral Liquid Section for Suspension & Syrup.
2. Ampoule (General & Psychotropic) Injectable Section.
3. Sachet Section.

The case is hereby submitted for consideration and orders of the Board, please.

Decision of the Central Licensing Board in 282nd meeting

The Board considered and ratified the correction.

QUALITY ASSURANCE CASES

Item No. I. GMP non-compliance cases

Case No. I:- M/s Servier Research & Pharmaceutical (Pakistan) Pvt Ltd. Lahore.

Background:-

Mr. Abdul Rashid Shaikh, FID, Lahore conducted routine GMP inspection of M/s Servier Research & Pharmaceutical (Pakistan), 9 KM Sheikhupura Road, Lahore (DML No. 000472) on 25-11-2019 and 26-11-2019.

2. **OBSERVATION:**

i. Most of the JDs were found without confirmed communication to the person concerned.
ii. Most of the responsibilities were overlapping.
iii. In organogram it was advised to review and upgrade their responsibilities by keeping in view conflict of interest.
iv. Batch release was only by quality control manager and plant head.
v. It was advised to review and upgrade the SOPs accordingly.
vi. Develop separate and independent quality assurance department under. The senior technical person without fail.
vii. It was observed the plant head is also approved technical person as incharge production however, practically Mr. Muhammad Rizwan Akhter was looking after the responsibilities of production.
viii. It was advised to ensure segregation in storage of APIs as the space constraint was also observed.
ix. Ensure the metal detector with tablet compression machines, old ZP 25 tablet compression machine also need to replace with new machine.
x. It was observed that many batches were kept in in-process store so it is advised to avoid such practice by removing bottle neck problem in packing of their products.
xi. The equipment in Quality Control Laboratory needs active upgradation.
xii. Upgrade dissolution test apparatus.
xiii. Ensure Double beam spectrophotometer
xiv. Ensure installation of printer with analytical balance.
xv. Upgrade the karl-Fischer
xvi. Replace the Polarimeter with the new one.
xvii. To ensure availability of additional HPLC
xviii. Remove wooden fixture and furniture from the premises.
xix. Make the microbiology lab functional and appoint a microbiologist as early as possible.

xx. The change rooms need to improve, like proper lockers for placement of workers belongings and ensure the ventilation in the worker change rooms.
xxi. In raw material/ packing material store, active improvements are needed;
xxii. Improve the false ceiling.
xxiii. Ensure vacuum cleaner in the receiving area for de-dusting.
xxiv. Upgrade the dispensing hood and also install printer with the dispensing balances.
xxv. Ensure close trolleys for the transportation of dispensed batches from dispensing area to production floor.
xxvi. Install safety grill around the cone mixers.
xxvii. During visit it was observed that the rejected/ de-blistered tablet and other waste powder and drugs were found placed in the outer area of factory without any control so, it is directed;
xxviii. Upgrade their SOPs for handling of waste/rejected materials properly and also SOPs for health and safety system and needs their strict compliance.
xxix. Ensure SS containers for the storage of in-process materials

CONCLUSION OF THE REPORT

"It is advised to overcome their shortcomings and the compliance report submit to the authorities, so re-inspection will be conducted accordingly."

Action Taken by DRAP:

3. Accordingly, the firm was issued explanation letter vide letter dated 06.05.2020.

4. The firm vide letter dated 11.06.2020 submitted CAPA and requested for verification of the observations noted by the panel. The matter was presented before the board in its 277th meeting (due to vacancy on post of the Director QA&LT) and the board decided as under;

Decision of 277th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view CAPA submitted by the firm, the Central Licensing Board decided to: -

i. Constitute following panel of experts for verification of rectification status of the observations noted by the FID in its report dated 25.11.2019 & 26.11.2020: -

a) Dr. Ikram Ul Haq, Member, CLB.
b) Ch. Zeeshan Nazir, Deputy Director, DRAP, Islamabad
c) Area FID, DRAP, Lahore

Updated status:

5. The above panel inspected the premises of M/s. Servier Research & Pharmaceutical (Pakistan), 9-KM, Sheikhupura Road, Lahore on 04.06.2021 in compliance to decision of 277th meeting of Central Licensing Board. The conclusion of report is reproduced below;

Conclusion:

"In view of above findings, it was observed that the firm has rectified most of the shortcomings pointed out in previous inspection and also is of the opinion that the firm was operating at the satisfactory level of cGMP compliance at the day of visit. The management has shown the positive attitude for further improvement as they shown the future plan for implement to the panel of inspectors too."

Proceeding of 282nd meeting:

6. The Division of QA & LT presented the case for information of the Board.

Item No. II **Personal Hearings**

Case No.I:- **M/s Perfect Pharma (Pvt.) Ltd. Lahore.**

Background

An inspection of M/s. Perfect Pharma (Pvt.) Ltd., Located at 5-KM, Manga Raiwind Road, Lahore (DML No.00469) was conducted with reference to DRAP Islamabad's Letter No. F. 13-196/2019-QC (Vol-I) dated 27-04-2021 on the subject titled, ***"MANUFACTURING / SALE OF UNREGISTERED DRUGS BY M/S. PERFECT PHARMA (PVT) LTD., 5-KM, MANGA RAIWIND ROAD, LAHORE."*** by Mrs. Majida Mujahid, Area Federal Inspector of Drugs, DRAP, Lahore and Ms. Maham Misbah, Assistant Director, DRAP, Lahore on 08-06-2021. The panel has reported the case background, which has been reproduced hereunder:-

"The firm was asked about the production of its purported product Nrufen Suspension. The firm's management responded that they had recently taken over the firm from the previous management. The Central Licensing Board in its 273rd meeting held on 15-01-2020 had endorsed the change of management and the decision had been communicated vide DRAP, Islamabad letter No. F.1-15/98-Lic (Vol-III) dated 10-06-2020. ***(Letter of change of management attached, Annex 2)****. The CEO of the firm informed the panel that his firm had not manufactured Nrufen Suspension (Ibuprofen Suspension) since the change of management neither had they received any record of production (BMR) of Nrufen Suspension from the previous management, at the time of change of management. He further stated that his team did not receive any registration letter of Nrufen Suspension from the previous management, therefore, the same could not be reproduced before the panel. Nrufen Suspension was not included in the Section-wise registered product list of the firm, as shown to the panel. No Ibuprofen API, unit carton or label of Nrufen suspension was found in the premises at the time of inspection. Further, no production record of Nrufen Suspension, testing record of Ibuprofen API, testing record of finished Nrufen suspension or any retained samples of Nrufen Suspension were found in the premises at the time of inspection".*

2. The panel conducted inspection to check cGMP compliance of the firm. The observations of the panel are as follows:

Change Rooms:

i. The entry into male and female change rooms was through the toilets.
ii. Toilet doors were open. Toilets needed repair.
iii. There was no exhaust, AC or HVAC supply in the workers' change rooms.
iv. Change-over instructions, hand sanitizer, etc were not displayed / available.
v. In the executive change area, air conditioner was not operational.
vi. Disposable overalls were not available for visitors.
vii. Hand sanitizer was not installed.
viii. SOPs for change-over were not available.

ix. Firm was directed to develop and implement SOPs for change over as per cGMP requirement without fail.

Material Entry / Material Receiving:

i. There were recesses in the doors of the material receiving.
ii. No vacuum cleaner or cloth was available for de-dusting of the incoming material.
iii. There were long cracks in the walls of material receiving area.
iv. Paint was chipping off.
v. Printed labels were stored without lock and key in the material receiving area.
vi. PET bottles were also stored in the area.
vii. Even rejected unit cartons were found in this area.

Raw Material Quarantine Area:

i. Material was stored in haphazard manner.
ii. HVAC supply or return was not given.
iii. There was no thermo-hygrometer installed in the area.
iv. Released material was also present in the quarantine area.
v. Temperature and humidity was not maintained and firm failed to produce any temperature and humidity record before the panel.

Sampling:

i. Entrance to the sampling area was partially obscured with packing material.
ii. Entry to the sampling area was from de-dusting area without any door in between.
iii. Fungal growth was seen on the walls of sampling area.
iv. A thick layer of dust was observed in the area.
v. Paint was chipping off from the walls.
vi. Moreover, shippers were stored on the floor in this area.
vii. The shippers were also stacked inside the sampling hood.
viii. Temperature and humidity was not maintained; HVAC and thermo-hygrometer were not installed. Sampling tools were not present.
ix. It seemed that the area had not been used for sampling since long.

Raw Material Store:

i. The raw material store was congested.
ii. Lighting and working space was inadequate.
iii. Materials were stored haphazardly.
iv. Multiple materials were stored on same rack without physical partition.
v. There was no segregation between API's and excipients.
vi. Thermo-hygrometer was not installed.
vii. There was no log of temperature and humidity only AC was installed.
viii. Empty gelatin capsules were also stored in the same area / conditions without fulfilling the storage requirements.
ix. Walls, floor and roof of this room needed repair.
x. A thick layer of dust had accumulated on the containers and pellets in the store.
xi. Firm was directed improve the conditions and maintain log of environmental conditions and materials present in the store

Rejected Material Store:

i. The rejected material area was a small cabin
ii. Materials were stored haphazardly inside.
iii. There was no log/ record of the materials stored inside.
iv. The rejected goods area was not locked.

Dispensing:

i. Dispensing hood was installed.
ii. A few scoops were placed inside the hood for dispensing.
iii. Civic work was required in the area.

Packing Materials Store:

i. It was advised to rearrange the packing material store and maintain temperature and humidity conditions.

Production Areas:

i. Cartons containing finished goods were stacked on the floor in the production corridors.
ii. There was no supply of HVAC in the production corridors.

Oral Liquid Section:

Bottle Blowing / De-Cartoning Area:

i. HVAC was not operational.
ii. The conditions in the area were unsanitary and unhygienic.

Oral liquid manufacturing:

i. In the oral liquid manufacturing area, HVAC was not operational at the time of inspection.
ii. There seemed to be fungal growth on the roof of the manufacturing area.
iii. Firm was directed to ensure platform for workers, improve epoxy flooring and civic work ensure buffing of all machines / equipment and replace all rusted equipment with new one.
iv. Further directed to make HVAC functional and install GMP compliant drains.
v. Also directed to label water supply and remove all plastic containers from the area.

Oral Liquid Filling:

i. There was open drain in filling area.
ii. Civic work needed a lot of improvement. HVAC was not functional.
iii. Firm was directed to immediately replace all material transfer pipes with SS line for material transfer.

Oral Liquid Packing and Labeling:

i. It was directed to ensure partitioning between filling and packing area.
ii. Further directed to provide SS stools for personnel in packing area.

Tablet Section (General):

Mixing:

i. HVAC was not operational at the time of inspection.
ii. Temperature and humidity was 27.1C and 54% respectively.
iii. Firm was directed to ensure functional HVAC and maintain log of temperature and humidity.
iv. Further advised to get all manometers calibrated and repaired immediately and to maintain pressure differential.
v. Also directed to ensure buffing of all equipment regularly.

Drying:

i. One FBD was installed in the drying area.
ii. It was directed to calibrate the gauge of FBD.

iii. Management was further directed to ensure proper partitioning between mixing and drying area.

Final Mixing:

i. A single cone mixer was installed in the final mixing area.
ii. The area was small and not suitable for operation of the cone mixer.
iii. It was advised to place the cone mixer in a suitable area.

In-Process Quarantine:

i. The in-process quarantine area was not maintained.
ii. In-process materials was stored haphazardly inside the area.
iii. The management was directed to ensure proper storage of materials in the area and maintain log of all materials in the area.

IPQC Lab:

i. There was no proper IPQC Lab.
ii. Only a balance and friability tester were placed openly in the corridor outside the compression rooms.
iii. It was directed to develop proper IPQC lab.

Compression Area:

i. There were three compression rooms.
ii. The HVAC was not operational in the area at time of inspection.
iii. The management was directed to immediately replace the installed machines with GMP compliant compression machines.

Capsule Section:

i. Manometers were not installed.
ii. Mixing and filling equipment needed buffing and repair.
iii. Capsule polisher was not installed.
iv. At the time of inspection, the temperature and humidity in the filling area was 27 C and 57% respectively, which was not suitable for hard gel capsules.

External Preparations (Repacking) Section:

i. HVAC was not installed in the section.
ii. The management was directed to improve civic work immediately and ensure seamless floor, roof and walls.
iii. It was also directed to immediately repair and maintain the filling machine and storage vessels.

Psychotropic Tablet Section:

i. This section was located on the first floor.
ii. The firm informed that they had not manufactured any psychotropic tablets till date due to the unavailability of quota.
iii. The overall conditions of the section were unhygienic.
iv. HVAC was not operational. Equipment needed immediate repair / maintenance and / or replacement.
v. Packing of General Tablet, Femozine (Famotidine) 20mg (Batch no. 537, Mfg date 05/21, Expiry 05/23) was being done in the packing hall of psychotropic section.

Semi-Solid Section:

i. The area not maintained. HVAC was not operational.
ii. The equipments were unclean and needed immediate repair.
iii. Firm's management was directed to immediately undertake civic work in the area.
iv. The air return grills in the manufacturing area was not fitted properly.
v. There was a big gap in the wall though which air from outside environment could directly enter into the area.

Quality Control Lab:

i. In the Quality control lab, the management was directed to install proper fume hood and emergency shower.
ii. Further directed to install chemical resistant worktops in the wet chemistry lab.
iii. The FTIR was out of order.
iv. The QC analyst informed the panel that the FTIR had been out order for the last one year.
v. No work order could be shown to the panel in this regard.
vi. Therefore, it seemed that the firm had not done identification test of incoming raw materials since last one year.
vii. Only one HPLC was installed.
viii. Column oven was not available even though firm required 35C column temperature for testing of one of its products (Diclofenac Potassium Tablets).
ix. Firm was directed to conduct complete testing of all raw and packing materials and finished goods as per pharmacopoeia.
x. Two stability chambers were installed.
xi. There was no electricity backup / UPS for the chambers, as informed by the QC team.

Retained Sample Area:

i. The management was directed to develop log of all product samples which were stored in the area.

Training and Personnel:

i. The technical personnel required training and refresher course on GMP.
ii. It was advised to ensure atleast one pharmacist in each section.
iii. ***Further advised to immediately appoint Quality Assurance Manager with relevant experience,*** as required and to develop a Quality Assurance team.

Documentation:

i. Poor documentation was seen with regards to production and Quality Control.
ii. Firm was directed to immediately develop organogram and update all job descriptions of key personnel.
iii. It was also directed to the management to submit report / record of all equipment calibrations, process validations, cleaning validations, analytical method validations, internal audit, self-inspection and Annual Product Quality Review.
iv. The panel further directed the management to submit record of complaint handling, product recalls, OOS results and medical fitness of employees to this office within three working days, without fail.

Conclusion:

*"Overall, the sanitary and hygienic conditions of the firm were **poor** at the time of inspection. The civic work, working of HVAC and condition of equipment was found **unsatisfactory** at the time of inspection. Firm **did not comply** with the current GMP requirements as per Schedule B-II of the Drugs (Licensing, Registration and Advertisement) Rules, 1976."*

3. A letter vide REF. No: PPL/212/2021 dated 15.06.2021 from M/s. Perfect Pharma (Pvt) Ltd, 5-KM, Manga Road, Raiwind, Lahore received, wherein the firm has informed that they had stopped their production on 15.06.2021 due to periodic upgradation in their factory with reference to FID's inspection on 08.06.2021. They further informed that the information regarding voluntary stoppage of production had been submitted to FID on 15.06.2021.

4. Keeping in view the observations, the firm was issued a show cause notice vide No. 4-43/98-QA (pt) dated 08.07.2021 along with directions to not to resume production prior to the approval of this Directorate, subject to relevant proceeding as deemed necessary by the Competent Authority.

5. The firm submitted reply to this office show cause notice vide letter REF. NO. PPL/238/2021 dated 15.07.2021 wherein they have stated that they have already voluntarily stopped all kind of Production in their factory since 15.06.2021 in order to make improvements and to remove all the deficiencies with reference to FID's guidance on her visit on 08.06.2021 and communicated to FID, Lahore through their Letter No: PPL/192/2021 dated 15.06.2021. Letter to stop production voluntarily also submitted in DRAP through their Letter No: PPL/212/2021 dated 28.06.2021. The firm has informed that they have removed all the deficiencies in their factory as pointed out by FID in her visit and always ready to make further improvements. The management of the firm has requested to ask FID to visit their factory and check the improvements they have made and allow them to resume Production in their factory.

Proceedings of the 282nd meeting of the Central Licensing Board.

6. Mr. Ashfaq General Manager and Mr. Salman Shafique CEO of the firm M/s. Perfect Pharma (Pvt) Ltd, 5-KM, Manga Road, Raiwind, Lahore appeared before the board and informed that they have rectified all the observations noted by the FID during her inspection dated 08.06.2021 and are ready for re-inspection.

Decision of 282nd meeting of the Central Licensing Board.

7. After thorough deliberation, considering compliance report of the firm and personal hearing of the firm's representatives, the Board decided as under;

i. Following panel of experts is constituted for inspection of the firm M/s. Perfect Pharma (Pvt) Ltd, 5-KM, Manga Road, Raiwind, Lahore to verify of rectification of observations reported by the FID in her report dated 08.06.2021;
    a. Mr. Azhar Jamal Saleemi, Chief Drug Controller Punjab.
    b. Area FID DRAP Lahore.
    c. Ms. Maham Misbah, Assistant Director, DRAP Lahore.
ii. The Additional Director QA&LT shall pass orders based on recommendations of the panel of experts regarding production activities and present case in subsequent meeting of Central Licensing Board for ratification.

Case No. II:- M/s. Effort Pharmaceutical (Pvt) Ltd., 28 Km Ferozepur Road, Lahore.

A Letter vide No.4136/2021-DRAP (L-V) dated 18.03.2021, was received from Ms. Aisha Irfan FID DRAP lahore, attached along with was inspection report of M/s. Effort Pharmaceutical (Pvt) Ltd., 28 Km Ferozepur Road, Lahore, conducted on 13.03.2021 for assessment of the GMP compliance. As per report following the observations/ advises were noted by the FID: -

a. Building and Facility

i. To install smoke detectors and fire alarm in whole building.

b. Changing Areas

i. To install sensor sin air curtains.
ii. To provide closed shoes and refill the hand sanitizer in the dispensers.
iii. changing areas needed improvement, with respect to implementation of SOPs
iv. Open gutterwas seen outside the main executive entry.

c. Material Management

i. Storage conditions were not maintained as AC was off and the humidity was 73% in stores.
ii. Store In charge with appropriate degree was not hired. Mr. Allah Ditta, qualification FA, Quality Control assistant was performing store duties in addition to his own duty in QC.
iii. It was observed that in the quarantine area 20 drums of diclofenac sodium were placed and the QC assistant informed that only 04 drums were sampled and labeled for "sampled" was not pasted on any drum. Upon query he was unable to identify which drums were sampled. The record of testing of samples was also not available in QC.
iv. In the receiving bay banned and hazardous material Methylene Chloride 01drum were stored.
v. In the sampling hood pressure gauge on hood, and weighing balance was not provided.
vi. Sampling log book was also not available.
vii. In the release area, light was not sufficient.
viii. In the dispensing area, dispensing hood was installed, however pressure gauge was required.
ix. Standard weights and dispensing log book were not available.
x. Closed trollies for dispensed raw.
xi. material was also not provided. No software for data handling was installed.
xii. No bin cards or raw material register was provided, for raw materials, at the time of inspection.
xiii. No SOP for sampling was being followed such as AP/ starting material was not 100%
xiv. For inactive the formulas square root n+1 was not used.
xv. In the finished goods store humidity was not maintained as AC was off and RH was 76%.
xvi. In the packaging material store, used and unused Alu foils were placed openly on racks without outer

d. **General Tablet Section**

i. Diclofenac sodium tablet Batch No. DROl was in the blistering machine. However, when asked about BMR of the product the production in charge could not produce the BMRs of diclofenac sodium tablet and the optic 40mg filled seen in raw material store.
ii. Thermal mapping of dryer was not conducted
iii. Flooring in the granulation area required improvement
iv. The drains in the section were not proper.
v. In the coating area methylene chloride was being used in coating which is banned item.
vi. Moreover, the blower of coating was very rusted and chances of shedding of rusted particles in to the pan existed.
vii. Manometers were not functional
viii. Number of air changes, differential pressures were not being monitored.

e. **General Capsule Section**

i. Temperature /humidity monitoring was not being done as thermometer / hygrometer was not functional.
ii. Manometer of HVAC system were out of order.
iii. Differential pressures could not be checked.

f. Laboratory Controls

i. It was noticed that the QC equipment was not properly being used for test/analysis: As per history of FTIR it was last used on 02-06-2019, after that it was not used. Dissolution apparatus required proper sample and QC In-charge was not aware about the full function of dissolution apparatus. He did not even know the procedure of taking sample from the apparatus. Similarly, he did not know how to operate HPLC and stated that he did not know how to operate QC equipment, the owner was also present and confirmed his statement. The QC in charge informed that an analyst performed test and he was not present at the time of inspection.
ii. Certificates of analysis of products were not provided.
iii. Log books for instruments were not available.
iv. Reference Standards were not available.
v. Microbiology Lab was developed but no microbiological water/environment testing was being performed as no microbiologist was hired.

e.Documentation and Records

i. Documentation with respect to material management, BMR, test analysis report etc. were not provided, during inspection proceedings.
ii. Log books of sampling / dispensing hoods / QC equipment were not available. Log books of some machinery ere not filled properly and wrongly filled.
iii. Records were not properly maintained.

g.Quality Management & Self Inspection.

i. No system for quality management was established.
ii. QA department was not functional as there was no person in Quality Assurance.
iii. New Quality Assurance

h. Personnel.

i. Only production and QC In-Charge were present.
ii. No Store In-Charge, QA In-Charge and Production Pharmacist were hired.
iii. The medical record of staff was not available.

i. Water treatment.

i. Cleaning and Validation of R.O plant was required.

j. <u>HAVC System.</u>

i. No concept of internal validation prevailed.

<u>Conclusion /Recommendation.</u>

"In view of above inspection proceedings and facilities verified such as building, production, in process controls, QC testing, material management, machinery /equipment, personnel & documentation etc. it was noticed that the firm had basic facilities such as building, machinery/ equipment to manufacture general tablet/capsule, however the GMP practices were not being followed properly in line with GMP guidelines. ***<u>Hence the firm was not operating at a satisfactory level of GMP compliance."</u>***

2. The matter was placed before the board in its 280th meeting and the board decided to serve show cause notice to the firm M/s. Effort Pharmaceutical (Pvt) Ltd., 28 Km Ferozepur Road, Lahore, on violations of Schedule B-II and not complying with additional conductions of License as mentioned in Rule 20 of the Drugs (LR&A) Rules 1976. In compliance to decision of the CLB, a show cause notice vide No. 8-7/2021-QA (M-280-CLB) dated 07.05.2021 was served to the firm.

3. The firm M/s. Effort Pharmaceuticals (Pvt.) Ltd., 28-KM, Ferozepur Road, Lahore-Pakistan vide letter Ref. No. EP/V-1/DRAP/02/2021 dated 03.06.2021 has replied to this office show cause notice and have stated that all the shortcomings have been rectified.

<u>Proceedings of the 282nd meeting of the Central Licensing Board.</u>

4. Mr. Haroon Javed, CEO and Ms. Nabila Arif, QC In-charge of the firm M/s. Effort Pharmaceutical (Pvt) Ltd., 28 Km Ferozepur Road, Lahore appeared before the board and informed that they have rectified all the observations noted by the FID during her inspection dated 13.03.2021 and are ready for re-inspection.

<u>Decision of 282nd meeting of the Central Licensing Board.</u>

5. After thorough deliberation, considering compliance report of the firm and personal hearing of the firm's representatives, the Board decided as under;

i. Following panel of experts is constituted for inspection of the firm M/s. Effort Pharmaceutical (Pvt) Ltd., 28 Km Ferozepur Road, Lahore to verify of rectification of observations reported by the FID in her report dated 08.06.2021;
    a. Mr. Azhar Jamal Saleemi, Chief Drug Controller Punjab.
    b. Area FID DRAP Lahore.
    c. Ms. Maham Misbah, Assistant Director, DRAP Lahore.

Case No. III:- M/s. Farm Aid Group, Hattar.

An inspection report of the firm M/s. Farm Aid Group, Plot No. 3/2, Phase I & II, Industrial Area, Hattar, conducted on 19.03.2021 by Mr. Faisal Shahzad, FID-I, DRAP, Peshawar was received in this office .

2. During inspection the FID has noticed the following observations in the Human Division and Veterinary Division of the firm**.**

Human Division:-

Change Rooms:-

- Overall maintenance of change rooms is required w.r.t. floors, walls, ceiling. New cupboards to be installed.
- Doors need proper sealing to avoid dust/dirt from outside.
- It was also observed that implementation of SOPs pertaining to change rooms entry/exit are not being followed in letter and spirit.
- Training and implementation are required to avoid contamination.

Storage Areas:-

- Proper receiving bay with necessary equipment to remove dust/dirt from the incoming materials outer packing.
- Proper sampling booth as well as dispensing both for raw material sampling/dispensing with LFH to avoid any contamination.
- Sampling/dispensing tools must be properly cleaned and subsequently properly packed/stored with their status identification to avoid cross contamination.
- Light flux needs to be improved in ware houses.
- Storage conditions of primary packing materials need to be improved i.e., properly packed to avoid dust/dirt/moisture and properly labeled.
- Temperature/humidity requirements needs to be complied with, and proper equipment/record keeping needs to be ensured.
- Re-organize quarantine area with effective SOPs for incoming materials proper placement, storage and prominent identification.

Tablet (General Section):-

- Over all maintenance of the section is required with reference to floor s, walls, ceiling, machinery/equipment for better cleanliness in the area.
- Tools of compression machines needs to be placed in SS boxes with proper cleaning procedure.
- Cleaning SOPs needs to be revised with defined timelines for equipment to be cleaned and re-cleaning time if the cleaned equipment is not used for several days.
- Wet mixer cleaning SOP needs proper review/implementation as the Joint s of mixer parts were observed with sticky materials, posing risk of cross contamination.
- Dry Mixer also needs buffing / cleaning.
- Compression machine tools especially punches cleaning SOPs needs to be reviewed for proper cleaning, removal of cleaning agents and proper storage in SS containers using standard cleaning cloth.
- Drain cleaning / proper sealing in the compression room was also advised.

- Tablet coating equipment nee d to be improved with reference to cleaning.
- Staging of equipment needs to be provided in equipment washing area.
- Proper temperature/ humidity and storage is required for IPQ area.
- At least, RO water must be used for washing of all the equipment in the tablet sect ion.
- Com pressed air used in coat in g sect ion must be through appropriate filters to avoid contamination.
- HVAC system needs to be of class D with proper pressure differentials. Overall HVAC system validation is required.

Capsule (General Section):-

- General maintenance of the area for smooth surfaces, electric panels and proper storage of filled capsules in SS containers.
- Materials staging area, weighing balance for weight variation needs to be provided.
- Proper storage of parts/tools of capsule filling machine is required.

Veterinary Division:-

The firm has established production facilities in separate building for, the dry powder, tablet/bolus and liquid sections for the general veterinary products on the first floor and the veterinary dry powder penicillin products on ground floor. For the general veterinary sections, the firm has provided separate raw materials store, packing materials store and finished goods store with racks and AC facilities. A separate dispensing room has also been provided with HVAC supply. Large scale balance and other dispensing tools were available. The firm has provided a separate store for the packing materials and finished products with racks. The duly labeled stock of the packing materials and finished products was stacked in proper manner. In the dry powder section, the firm has provided 02 double cone mixers, grinding / Fritz mill and sealing machine. Log books were found available. Filling is performed manually in sachets and after sealing packed in jars. The firm recently developed and approved a veterinary dry powder penicillin section in place of the old vaccine section. Separate raw materials, packing materials and finished goods store have been provided. Further, the firm has developed quarantine, dispensing area and released area in the raw materials store. A separate in-process quarantine and a packing hall also been provided. For powder mixing and filling, the firm has provided a double cone mixer and filling sealing machine in separate rooms with HVAC facilities. The FID noticed that;

- Veterinary drugs division except Penicillin, section is an old building and GMP compliance is not at satisfactory level due to lack of space, poor maintenance, no proper flow of personnel as well as materials, very limited HVAC system and no provision of necessary allied facilities for smoothly' performing production operations.
- Improvement in the existing area will be of very limited scope and no noticeable improvement will be possible in the said area.
- The firm also informed that they have already planned new building for the veterinary drugs.

Quality Control:-

- The firm has operational HPLC but testing methods of registered products have not been shifted on HPLC method provided in latest pharmacopeia(s). The firm is advised to immediately act for shifting their testing method s to latest pharmacopeia methods.
- Stability studies are being performed but protocol for study design in not properly prepared. Stability studies protocol needs to be devised in light of ICH guidelines and according studies should be conducted for the reliability of data.
- Separate electricity backup must be provided for all the sensitive equipment in QC along with UPS backup.
- Step wise purchase of Reference Standards from authentic source is also recommended.
- Authenticity of data must be ensured through data loggers/software-based systems.

Quality Assurance:-

The firm has appointed one QA personnel working in the QC department. The firm is advised to;

- Establish separate QA department independent of QC.
- Strengthen QA department with well experienced staff to develop proper Quality Management system and qualification/validation of machinery/equipment/processes *etc.*
- QA department must be assigned the task of master validation plan.
- Cleaning validation and validation of HVAC system needs to be started immediately to avoid contamination/cross contamination of Pharmaceutical products.
- System of self-inspection needs to be strengthened.

Personnel:-

- The firm has hired necessary staff for production/QC department with defined roles and responsibilities. However, further training of staff needs to be done for better understanding of cGMP guidelines.
- Trainings on firefighting system/emergency situation may also be performed.

FID has made the following conclusion:-

"Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities the firm is maintaining compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under for Human Division, ***however, veterinary drug division is not operating at satisfactory level for which the firm may be directed to establish new facility within minimum possible time i.e., within 3 months.*** *It is further added that Panel inspection of the firm vide letter No. F. 4-23/91-QA dated 19.12.2018 was due but panel member Dr. Zafar Iqbal have been retired from University of Peshawar. It is also recommended to constitute fresh panel for inspection or revalidate earlier letter with fresh designation/ member of panel."*

3. Keeping in view the observations noticed, conclusion and recommendations by the FID, a show cause notice vide No. 4-23/91-QA dated 03.05.2021 was served to the firm along with directions to stop production activities in Veterinary Section, except Penicillin Section.

4. The firm replied to this office show cause notice vide letter Ref. No. 21052101 dated 21.05.2021 wherein they stated that they have complied most of the observations. Furthermore, they requested to resume their production activities in veterinary General Section on basis of following grounds.

a) The Veterinary General Section is built on dedicated floor and no contamination is possible with other sections.
b) Veterinary General Section is old one but approved one, and no objection being raised by any authority previously.
c) They have got approval of new layout plan from DRAP and speedy construction is under process.
d) In Existing Veterinary Section they are maintaining area well. Class D area provided, HVAC in production area is well working.
e) FID has not suspended their production and recommended small possible maintenance with the instruction to complete new block as soon as possible.

5. Since most of the observations pertain to the licensing division hence comments were sought from the quarter concerned. The Licensing division has informed regarding the above stated points a, b and c that the central licensing board in its 253rd meeting held on 15th and 16th May, 2017 has considered and approved the renewal of DML on recommendations of panel of experts and also granted additional sections. Furthermore, the licensing division has informed that the LOP for firm in question was approved by committee on Lay out plan in its meeting held on 5th April, 2021.

6. Another letter dated 05.07.2021 was received from the firm wherein they had requested to allow them to resume their production activities for short term to address their financial issues and further requested that area FID may visit them to verify progress of work. The matter was placed before the competent authority and the area Fid was directed to provide current status to apprise the Central Licensing Board.

7. In compliance of the orders of competent authority, the FID inspected the premises of M/s. Farm Aid Group Hattar on 12.08.2021. The updated status reported by the FID along with conclusion is reproduced below;

"Existing Veterinary Division changes	
mprovements Informed by firm	***Observations***
i. We have increased HVAC capacity in the area, and cooling capacity in the stores increased as per instructions.	*The firm has three sections in their veterinary block i.e., Powder section, Liquid section and Bolus section on an 4000 sq. feet area. The building is constructed in L shape. Liquid section is constructed at one corner of the building while powder section is constructed at the other end of the building. Bolus section is designed in the middle of the L- shaped facility. The firm informed that to solve the space issue of facility, they will close the Bolus section which is in the middle of two other sections. Resultantly, the congestion/ space problem of the facility will be addressed and while separating two section, problem of mix-ups/*

	cross contamination shall be reduced and HVAC capacity, also increased will be better utilized.
ii. Sampling booth, dispensing booth, pallets, SS containers replaced with new ones.	*Sampling booth as well as dispensing booth has been provided by the firm in the veterinary division. The firm has provided SS Pallets and SS Containers in all sections. Light flux has increased by the addition of 40w new lights. SS dispensing trolley has also provided for smooth and safe transfer of materials from dispensing room to mixing area.* *The firm has provided separate change room for entry and exit of personnel with material movement management up to limited extent due to building constraints. However, necessary arrangement is made for proper step over benches, uniform and shoe change procedure before entry to the production area. Further, door opening on one side of the L-shaped building directly to roof has been locked and shall be used only as emergency exit, avoiding entry of contamination to production areas. The firm has purchased new Sampling and dispensing booth and they are kept in the proper area.*
iii. Provided new Cupboard and installed one more Cupboard in the change rooms.	*Separately provided by the firm for street clothes and clean uniforms.*
iv. Flooring, ceiling and light flux overall cleaning improved through out the sections.	*The firm has done maintenance work in the in the facility. During inspection it was observed that maintenance has been done in all areas of the veterinary block including Liquid section, Powder section, Bolus section, and storage areas, dispensing room, receiving bays, material transfer areas, change rooms, galleries and corridors. The firm has increased the light flux in all areas after the advice of the QA department by installing 12 more new 40W lights in veterinary block. The visibility in the area is better and working environment is suitable for production. The firm has buffed all machinery in the production.*
v. Training of the staff completed. Cleaning and other SOPs provided	*Documents provided by the firm indicate that training of the staff has been performed. SOPs*

with proper guidelines.	*provided. However, strict implementation of SOPs need to be ensured and properly monitored.*

The firm has made improvements to carry out production activities, though limited due to old building constraints, however the improvements can be considered for allowing production activities for limited period.

Construction status of new Veterinary Block

The firm also informed that they have planned new building for the veterinary drugs. The firm informed speedy constructing new building for veterinary drugs. During physical inspection, it was noticed that the construction work is under process at good pace. Foundations and basic structure have been raised. Technical slab has been laid while main slab of the building is expected to be laid within one week time as per observations at spot. After a month HVAC installation will be started and other electric and civil works will be carried out in parallel. The whole procedure will be completed within 4 months' time period.

In light of above mentioned position, improvements submitted by the firm and with request to operate only two sections in the veterinary division, it is recommended that the firm may be allowed production for four months and meanwhile new facility may be got ready for inspection by the firm."

Proceeding of the 282nd meeting of the Central Licensing Board.

8. Mr. Abdur Razzaq, Director of the firm M/s. Farm Aid Group, Plot No. 3/2, Phase I & II, Industrial Area, Hattar appeared before the Board and requested for resumption of production activities in Veterinary Powder and Veterinary liquid section for 4 months. He further stated that in 4 months their new facility will be ready for inspection.

Decision of 282nd meeting of Central Licensing Board.

9. After thorough deliberation, hearing the plea of firm's representative and considering the report of FID dated 12.08.2021 the Board decided as under;

i. The Board acceded to the recommendations of the FID and allowed the firm M/s. Farm Aid Group, Plot No. 3/2, Phase I & II, Industrial Area, Hattar to resume production activities in Veterinary Powder and Veterinary liquid sections for 4 months. The production activities in veterinary Bolus Section shall remain suspended.
ii. The FID shall submit monthly report on progress of establishment of new facility by the firm.

QUALITY CONTROL CASES

[F. No. 04-64/2018-QC]

Case No. 01: SALE OF "UN-REGISTERED DRUG PRODUCTS" BY M/S. ASHRAF MEDICOS, DAWOOD CHORANGI, LANDHI, KARACHI.

The Assistant Director/Federal Inspector of Drugs, Karachi vide letter no. DMT/46/18 FIDVII(K) dated 11.10.2018 has submitted the complete case in reference to letter of even number dated 28.09.2018 wherein it is informed that FID alongwith Mr. Asfand Yaar Ajab Khan A.D, DRAP Karachi visited /inspected the premises of M/s Ashraf Medicos Main Market, DawoodChowrangiLandhi Karachi on 02.07.2018. During inspection of pharmacy the AD/FID-VII, Karachi recovered the following unregistered drug/medicine and seized on the prescribed Form-2 as per Drugs Act 1976. AD/FID-VII, Karachi also took samples for the purposes of test/analysis on prescribed Form-3.

Details of products seized:

Sr.	Name of drug	Batch No.	Reg. No.	Mfg. date	Exp. Date	Qt.	Mfg. by
1	Tab Penegra	G705344	Nil.	09-2017	08-2020	1x10x4	M/s. Candila Health care Ltd, India.
2	-do-	G705345	Nil.	-do-	-do-	1x11x4	-do-
3	-do-	G705348	Nil.	-do-	-do-	1x10x4	-do-

Details of samples taken for the purpose of test/analysis:

Sr.	Name of drug	Batch No.	Reg. No.	Mfg. date	Exp. Date	Mfg. by
1	Tab Penegra	G705346	Nil	09-2017	08-2020	M/s. Candila Health care Ltd, India.

02. As per report of FID the portion of sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi vide this office memorandum vide letter no. DMT/-R-46/2018-FIDVII(K) dated 03.07.2018. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Un-Registered Drug Product" under the Drugs Act, 1976 and rules framed thereunder vide their test report NO. KQ.501/2018 dated 31.08.2018

03. Area FID informed that Toufique Ahmed (proprietor) of M/s Ashraf Medicos Main Market, Dawood Chowrangi, Landhi Karachi was asked to explained his position and provide

bill warranty or any other document regarding purchase/import vide FID's office letter no. DMT-46/2018-FIDVII(K) dated 06.09.2018 with subsequent reminder dated 28.09.2018. FID submitted that Toufique Ahmed (proprietor) of M/s Ashraf Medicos Main Market, Dawood Chowrangi Landhi Karachi vides their letter no. nil dated nil submitted unsatisfactory reply.

04. Area FID concluded that Toufique Ahmed (proprietor) CINC # 42201-8368254-7 of M/s Ashraf Medicos Main Market, Dawood Chowrangi Landhi, Karachi is involved in selling unregistered drug and contravened the Section 23(1)(a)(vii) & 23(1)(c) of the Drugs Act, 1976 which is punishable under section 27(1)(a) of Drugs Act, 1976 and rules framed thereunder and recommended that M/s Ashraf Medicos Main Market, Dawood Chowrangi Landhi, Karachi alongwith its proprietor Mr. Toufique Ahmed S/O Abdul Latif may be prosecuted in the Drug Court Karachi. Moreover, area FID Karachi requested that permission for registration of FIR may be granted against the following accused "Toufique Ahmed (proprietor) CINC # 42201-8368254-7 of M/s Ashraf Medicos Main Market, Dawood Chowrangi Landhi, Karachi.

05. The case was presented before the Central Licensing Board in its 266th meeting wherein the Board decided as under:

> *"1. to grant the Permission for Lodging FIR against the accused person namely "Mr. Toufique Ahmed S/O Abdul Latif (proprietor) M/s Ashraf Medicos Main Market, Dawood Chowrangi Landhi Karachi holding CINC # 42201-8368254-7" for illegal import without import authorization and selling/storingof Un-Registered Drugswithout product registration and drug import license as required under the law. The accused has committed violations of Schedule-II and III of the DRAP Act, 2012 read with Section 23/27 of the Drugs Act, 1976. The offences of the accused persons are cognizable under schedule IV of the DRAP Act 2012 read with Section 30 of the Drug Act 1976. The FID is directed to file complaint for registration of FIR against the accused person and forward complete case for consideration of the CLB."*

06. Area FID Karachi vide letter No. DMT-46/18-FID-VII (DRAP) (K) dated 13-04-2021 submitted the complete investigation report of the case (FIR No. 14/2020) forwarded by Acting Deputy Director FIA wherein I.O/Inspector FIA, Karachi concluded the report as under;

> *"CONCLUSION/RECOMMENDATION:*
>
> *From the investigation conducted and evidence(s) available on reored, it has been established that accused Taufique Ahmed S/O Abdul Latif holder of CNIC # 42201-8368254-7 Proprietor of M/s Ashraf Medicos, situated at Main Market Daqqood Chowrangi, Landhi, Karachi committed the offences under section 23 (1)(a)(vii) & 23 (1)(c) punishable U/S 27 (1)(a) of Drugs Act-1976, ibid and rules framed there under, for which he is liable to be prosecuted before the Honorable Drug Court of Sindh at Karachi by way of filing a*

complaint for taking cognizance as per law against accused Taufiq Ahmed S/O Abdul Latif.

As such the investigation of the case has been completed, hence under the orders of Competent Authority this Final Investigation Report is submitted accordingly for favour of kind perusal and onward transmission to the Drug Regulatory Authority of Pakistan, Ministry of National Health Services, Regulation & Coordnation, Karachi for submission of proper complaint under the relevant provision of Drugs Acts, before the Honorable Drug Court of Sindh at Karachi through Federal Inspector of Drug Dr. Mehwish Tanveer, Assistant Director/Federal Inspector of Drugs-VII, Karachi (Complainant of above case).

The Final Investigation Report is submitted accordingly, for favour of kind perusal and further necessary action please."

Procedings and decision of 280th meeting of CLB:

07. The Board after thorough deliberations, considering the facts of the case and the Final Investigation report submitted by the I.O FIA Karachi decided to issue show-cause notice for prosecution to the following accused for contraventions of section 23(1)(a)(vii) and 23(1)(c) of the Drugs Act, 1976 and the rules framed thereunder:

i. M/s. Ashraf Medicos, Main Market, Dawood Chowrangi, Landhi, Karachi through its Proprietor Taufique Ahmed S/o Abdul Latif

ii. Taufique Ahmed S/O Abdul Latif (Proprietor) M/s. Ashraf Medicos, R/o House No. R-357, Green park city near Abbott Laboratories, Karachi.

08. In compliance of the decision of 280th meeting of the Board, the accused were issued show cause notices vide letter F.No.03-11/2021-QC(Pt-I) dated 24-05-2021 to which the accused have replied as under:

"With reference to above noted Show Cause Notice, served by your honour, I have to state in my defence as follow:

1. Your honour, it is pertinent to mention here that I was running my medical store according to law and was only selling registered drugs at my store, which is evident from my record, because no any such type of complaint was ever received against me, this case is ever first, however said unregistered drug was in very minimum quantity and does not belongs to me.

2. Your honour, at the very outset, I have to state that alleged unregistered drug does not belongs to my medicos, same belongs to a patient/visitor, who unfortunately missed at our store, which were purchased by him from

anonymous place, therefore being his personal property, same were kept in our store for returning him, but meanwhile a surprise visit happened by your authority.

3. Your honour, a FIR has already been lodged in this matter and I was incarcerated more than 10 days in jail, while I have already joined trial, and case is already pending. My license is ceased and store is seized, due to which 1 have already gone through financial crises, therefore, question to serve referred notice does not raise.

Keeping in view of foregoing omission may kindly regretted and applicant may please be acquitted on issuing of warning, otherwise, please give me a chance of personal appearances before your honourable authorities for my defence."

09. The accused are called before the Board for personal hearing.

PROCEDINGS AND DECISION OF THE 282ND MEETING OF THE CLB:

10. The accused, Taufique Ahmed S/O Abdul Latif (Proprietor) M/s. Ashraf Medicos, Main Market, Dawood Chowrangi, Landhi, Karachi appeared before the Board and agreed to the allegations made against them by the Federal Inspector of Drugs. The Board considered the facts of the case, stance of the accused and Final Investigation report submitted by I/O FIA, granted permission to the area Federal Inspector of Drugs, Karachi for prosecution of case in the court of competent jurisdiction against the following:

i. M/s. Ashraf Medicos, Main Market, Dawood Chowrangi, Landhi, Karachi through its Proprietor Taufique Ahmed S/o Abdul Latif

ii. Taufique Ahmed S/O Abdul Latif (Proprietor) M/s. Ashraf Medicos, R/o House No. R-357, Green park city near Abbott Laboratories, Karachi

Case No. 02: <u>MANUFACTURING AND SALE OF UN-REGISTERED RELIEF EXTRA TABLETS REG. NO. NIL BATCH NO. RR-549 MANUFACTURED BY M/S COMBITIC GLOBAL CAPLET (PVT) LTD INDIA.</u>

01. The Federal Inspector of Drugs-III, DRAP, Karachi has forwarded the subject cited case vide No. F. SHM-24/2018-DRAP(FID/K-III) dated 10.08.2018.

02. The FID has submitted that he alongwith Mr. Ghuam Ali Lakho, Provincial Drug Inspector inspected the premises of M/s Nagori Subhan Medical Store, situated at Plot No. 541, Block D Street No. 5, Sher Shah Karachi holding DSL no. 1512 on 22.03.2018, wherein he recovered following **un-registered** drug product and took the samples on prescribed Fomr-3 for the purpose of test/analysis as per Drugs Act 1976.

The detail of the sample is as under:-

Serial No.	Name of Drugs	Reg. No.	Batch No.	Manfg: Date	Expiry Date	Manufactured By
SHM-24/18	Relief Extra	Nil (Not Mentioned)	RR-549 (Mentioned on strips not on carton/box)	May-2017 (Mentioned on strips only)	Apr-2017 (Mentioned on strips only)	Combitic Global Caplet (Pvt.) Ltd., M-15, D-2, D-3, Ind. Area, Hr., India Mfg Lic. No. 325-OSP(H)

03. As per report of FID the portion of sealed sample was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi vide this office memorandum NO. SHM 24/2018-FID-(K-III) dated 22.03.2018.

04. FID submitted that M/s Nagori Subhan Medical Store, Plot No. 541, Block D Street No. 5, Sher Shah Karachi was asked to provide bill warranty vide this office letter of even number dated 26.03.2018.

05. FID further submitted that a portion of sealed sample was also sent to Chairman, CLB, DRAP, Islamabad vide letter of even number dated 26.03.2018.

06. FID informed that M/s Nagori Subhan Medical Store Plot No. 541, Block D Street No. 5, Sher Shah Karachi explained his position vide their letter number nil dated 09.04.2018.

07. The FID added that the Federal Government Analyst, Central Drugs Laboratory, Karachi vide their test report NO. R.KQ.193/2018 dated 10.05.2018 declared the sample as **"Un-Registered Drug Product"** under the Drugs Act, 1976.

08. The FID informed that M/s Nagori Subhan Medical Store Plot No. 541, Block D Street No. 5, SherShah Karachi was asked to explain his position vide letter no. SHM-24/2018-DRAP(FID/K-III) dated 21.05.2018 and 01.06.2018. In their response they have taken the plea that this drug (Product Relief Extra) is not meant for sell but it is for personal use as can be evident that a meager quantity of only 50 tablets is found which is not for commercial use.

09. In the light of Federal Government Analyst, Central Drugs Laboratory, Karachi test report No. R.KQ.193/2018 dated 10.05.2018, M/s Nagori Subhan Medical Store, Plot No. 541, Block D Street No. 5, SherShah Karachi holding DSL No. 1512 (By way of retail sale) is in involved in sale of unregistered drug and violated the Seciton 23(1)(a)(vii) of the Drugs Act 1976 and punishable under section 27(1) of the Drugs Act, 1976 and rules framed thereunder.

Recommendations of FID:

In view of above, Board is accordingly requested and recommended as follows:

i. Cancellation of Drug Sale License as per Drugs Act, 1976 and rules framed thereunder.

"OR"

ii. Permission for grant of prosecution in Drug Court against the following accused persons:
   a. Amjad Hussain S/o Hussain Nagori (*License proprietor*)
   b. Ghulam Sarwar S/o Muhammad Hanif (*Proprietor*) CNIC No.: 42401-206974-1
   c. Riaz Ghulam Muhammad S/o Ghulam Muhammad (*Salesman*) CNIC No. 42401-3420490-1

10. It is submitted that that the name of qualified person i.e. Sajjad Ahmed S/o Abdul Qayyum was not mentioned among the names of accused persons as evident from the photocopy of Drug Sale License (DSL No. 1512) provided with the complete case by the area FID, Karachi. Furthermore, the designations against the names of each of nominated accused person was also missing in the case forwarded by area FID, Karachi. Clarification in this regard was issued to the area FID, Karachi vide letter no. 4-59/2018-QC dated 07.09.2018.

11. The area FID, Karachi Clarified vide letter no. SHM-24/2018-DRAP(FID/K-III) dated 17.09.2018 reproduced as under:

> *"I have the honor to refer DRAP, Islamabad letter no. F. No. 04-59/2018-QC dated 07.09.2018 and continuation of this office letter of even no. dated 10.08.2018 it is submitted that the qualified accused Mr. Sajjad Ahmed S/o Abdul Qayyum mentioned on License no. 1512 dated 08/02/2017 was not available at the time of inspection. Amjad Hussain (License proprietor) was also not available. Their CNIC/copies were also not provided/available.*

However, Mr. Ghulam Sarwar s/o Muhammad Hanif introduced himself as the proprietor and Riaz Ghulam Muhammad introduced himself as salesman"

12. The accused persons are guilty of manufacturing/import and selling of Un-registered Drug and violated Section 23(1)(a)(vii) & & 23(1)(c) punishable under Section 27(1)(a) of the Drugs Act, 1976 read with Schedule-II (A)(1)(a)(vii) and (A)(1)(c) punishable under Schedule-III(1)(a) of the DRAP Act, 2012. It is therefore requested that permission for registration of FIR may be granted against the following accused persons:

i. M/s Nagori Subhan Medical Store, Plot No. 541, Block D Street No. 5, SherShah Karachi holding DSL No. 1512 (By way of retail sale) through its proprietor Amjad Hussain S/o Hussain Nagori (*License proprietor*).
ii. Amjad Hussain S/o Hussain Nagori (*License proprietor*)
iii. Ghulam Sarwar S/o Muhammad Hanif (*Proprietor*) CNIC No.: 42401-206974-1
iv. Riaz Ghulam Muhammad S/o Ghulam Muhammad (*Salesman*) CNIC No. 42401-3420490-1

Decision of the Board:

13. The CLB examined record of the case including test report and granted the Permission for Lodging FIR against the accused persons for illegal import without import authorization and selling/storing of Un-Registered Drugs without product registration and drug import license as required under the law. The accused persons have committed violations of Schedule-II and III of the DRAP Act, 2012 read with Section 23/27 of the Drugs Act, 1976. The offences of the accused persons are cognizable under schedule IV of the DRAP Act 2012 read with Section 30 of the Drug Act 1976.

14. Moreover, the FID was directed to file complaint for registration of FIR against the accused person and forward complete case for consideration of the CLB:

i. M/s Nagori Subhan Medical Store, Plot No. 541, Block D Street No. 5, SherShah Karachi holding DSL No. 1512 (By way of retail sale) through its proprietor Amjad Hussain S/o Hussain Nagori (License proprietor).
ii. Amjad Hussain S/o Hussain Nagori (License proprietor).
iii. Ghulam Sarwar S/o Muhammad Hanif (Proprietor) CNIC No. 42401-206974-1.
iv. Riaz Ghulam Muhammad S/o Ghulam Muhammad (Salesman) CNIC No. 42401-3420490-1.

15. Area Federal Inspector of Drugs vide letter No. F. SHM-24/2018-DRAP(FID/K-III) dated 09-06-2021 submitted Final Investigation Report in case FIR No. 07/2021 of FIA ACC, Karachi forwarded by Acting Deputy Director FIA, Karachi to Additional Director, DRAP, Karachi.

16. In the final investigation report, I.O/Inspector, FIA, ACC, Karachi has made following recommendations:

"From the investigation conducted and evidence(s) available on record, it has been established that accused persons namely, (1) Amjad Hussain S/O Ghulam Hussain Nagori (2) Riaz Ghulam Muhammad S/O Ghulam Muhammad and (3) Ghulam Sarwar S/O Muhammad Hanif committed the offences under section 23 (1)(a)(vii) & 23 (1)(c) punishable U/S. 27 (1)(a) of Drug Act-1976, ibid and rules framed thereunder, for which they are liable to be prosecuted before the Honorable court f Drug Sindh at Karachi.

As such the investigation o the case has been completes, hence under the orders of Competent Authority this Final Investigation Repost is submitted accordingly for favour of kind perusal and onward transmission to the Drug Regulatory Authority of Pakistan, Ministry of National Health Services, Regulation & Coordination, Karachi for submission of proper complaint under the relevant provision of Drugs Act, before the Honorable Drug Court of Sindh at Karachi through Federal inspector of Drug Syed Hakim Masood Federal Inspector of Drugs-VII, DRAP Karachi (Complainant of the above case).[…]"

17. On recipt of the Final Investigation Report from I/O FIA Karachi, the accsued were served a show-cause notice vide letter No. 04-59/2018-(QC) dated 02-07-2021 to which no reply has been received till date.

18. The accused are called before the Board for personal hearing.

PROCEDINGS AND DECISION OF THE 282ND MEETING OF THE CLB:

19. The accused neither by themselves, nor through any counsel appeared before the Board therefore the Board after considering the facts of the case and Final Investigation report submitted bu I/O FIA, granted permission to the area Federal Inspector of Drugs, Karachi for prosecution of case in the court of competent jurisdiction against the following:

i. M/s Nagori Subhan Medical Store, Plot No. 541, Block D Street No. 5, SherShah Karachi holding DSL No. 1512 (By way of retail sale) through its proprietor Amjad Hussain S/o Hussain Nagori (License proprietor).
ii. Amjad Hussain S/o Hussain Nagori (License proprietor).
iii. Ghulam Sarwar S/o Muhammad Hanif (Proprietor) CNIC No. 42401-206974-1.
iv. Riaz Ghulam Muhammad S/o Ghulam Muhammad (Salesman) CNIC No. 42401-3420490-1.

Case No. 03: <u>MANUFACTURE AND SALE OF UNREGISTERED DRUG PRODUCTS BY M/S. ROYAL HERBAL ENTERPRISES CO., KARACHI.</u>

01. Mr. Syed Hakim Masood, FID-III & IV, Karachi vide No. F. SHM-NTF-35-40/2018-DRAP(K) dated 18.05.2018 has informed with reference to his visit alognwith officers and officials of DRaP, Karachi on 10.04.2018, where in FID-III&IV, Karachi took following samples for the purpose of test/analysis on prescribed Form-3 also seized on prescribed Form-2 and order "Made not to dispose off" on prescribed Form-I under the Drugs Act 1976/DRAP Act 2012.

Sr. No.	Name of product	Reg. No.	Batch No.	Mfg. date	Exp. Date	Mfg. by
01	Knight Rider Extra Powder Tester Delay Capsule	Nil	Nil	12-16	12-20	M/s. Royal Herbal Ent., Co., Plot No. 1730, Near Office Baldia town No. 3, Karachi.
02	Knight Rider Tester Delay Tester	Nil	Nil	02-12-16	01-12-20	-do-
03	Tiger Balm	Nil	Nil	01-11-16	01-11-21	-do-
04	Knight Rider Herbal Delay Cream	Nil	Nil	09-14	10-17	-do-
05	Unlabelled Filled capsule	Nil	Nil	Nil	Nil	-do-
06	Unlabelled Off white powder	Nil	Nil	Nil	Nil	-do-

02. FID submitted that the above samples were sent to the Federal Government Analyst, Central Drugs Laboratory, Karachi, for the purpose of test/analysis on prescribed Fomr-4. The sealed portion of the products was also send to the Chairman CLB vide this office letter of even no. dated 10th April, 2018

03. The Federal Government Analyst, CDL, Karachi, has declared the following 06 samples as "Un-registered". Details are as under

Serial No.	Name of Drug	Name of Allopathic ingredient identified	Batch No.	Manfg. Date	Expiry Date	Manufactured By	Result
1	Knight Rider Extra Powder Tester Delay Capsule	Sildenafil citrate	Nil	12-2016	12-2020	M/s Royal Herbal Ent.. Co., Plot No. 1730, Near Office, Baldia Town No. 3,	**Un-Registered Drug Product** vide test report No.

						Karachi-Pakistan	KQ.SC. 242/2018 Dated 30.04.2018
2	Knight Rider Tester Delay Tester	Lidocaine	Nil	02-12-2016	01-12-2020	-do-	**Un-Registered Drug Product** vide test report No. KQ.SC. 243/2018 Dated 30.04.2018
3	Tiger Balm	Methyl Salicylate	Nil	01-11-2016	01-11-2021	-do-	**Un-Registered Drug Product** vide test report No. KQ.SC. 244/2018 Dated 30.04.2018
4	Knight Rider Herbal Delay Cream	Lidocaine	Nil	Nov. 2014	Oct. 2017	-do-	**Un-Registered Drug Product** vide test report No. KQ.SC. 245/2018 Dated 30.04.2018
5	Unlabelled Filled Capsule	Sildenafil citrate	Nil	Nil	Nil	Nil	**Un-Registered Drug Product** vide test report No. KQ.SC. 246/2018 Dated 30.04.2018
6	Unlabelled Off White	Sildenafil citrate	Nil	Nil	Nil	Nil	**Un-Registered**

	Powder						**Drug Product** vide test report No. KQ.SC. 247/2018 Dated 30.04.2018

04. FID-III&IV, Karachi informed that he has directed the firm to explain their position that why action may not be taken against them under the Drugs Act 1976 & DRAP Act 2012

05. The reply of the firm was un-satisfactory as reported by the FID-III&IV, Karachi which he has received vide Dy. No. 1432 dated 14.05.2018 alongwith enclosures

06. Findings of FID-III & IV, Karachi:

"as per above said Federal Government Analyst, CDL, Karachi test reports M/s Royal Herbal Ent. Co. situated at Plot No. 1730/121, Near Office, Baldia Town No. 3, Karachi is involved in manufacturing and selling of Un-registered Drugs which is in violation of Section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b) and 23(1)(e) of the Drug Act 1976 enacted with DRAP Act 2012.

07. That the accused persons given below have violated the provisions of Schedule-II, of DRAP Act 2012 and hence, committed offences as under:-

a) A (1)(a)(vii) i.e. export, import are manufacture for sale or sell any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceuticals evaluation;

b) A (1)(a)(x) i.e. export, import are manufacture for sale or sell any therapeutic good in contravention of any of the provision of this Act are rules made thereunder;

c) A (1)(b), manufacture for sale any therapeutic goods except under and in accordance with the condition of a license issued under this Act and;

d) A (1)(e), Import or export any therapeutic goods drugs for the import or export of which a license is required except under , and in accordance with the conditions of such license.

e) A (1)(i) sell any therapeutic good without having warranty in the prescribed form bearing the name and batch number of the therapeutic good issued

08. The Prohibitions mentioned above are offences and punishable under schedule III of DRAP Act 2012:

a) (1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.

b) (1)(b) Manufactures for sale any therapeutic good without a license.

c) (1)(c), Imports without license any therapeutic goods for the import of which a license is required.

d) (4) i.e. contravention of rules:- subject to the provisions of clause (1) (2) and (3) whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or any rule shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one lakh rupees or with both.

e) (6), Penalty for violating the prohibitions: whoever himself or by any other person on his behalf violates any prohibitions specified in schedule-II shall be punished with imprisonment for a term upto five years and with fine up to five hundred thousand rupees.

09. FID III&IV, Karachi has requested that permission of lodging of FIR may be grant against the following accused persons:

"in the light of above, permission for FIR against the following accused persons may kindly granted at the earliest:

1. *M/s Royal Herbal Enterprises company (Pvt) (Ltd), 1730/121 Gujrat Colony Baldia Town Karachi.*
2. *Muhammad Rafiq s/o Muhammad Mustafa CNIC No. 42401-1720339-1*
3. *Muhammad Siddiq s/o Muhammad Mustafa CNIC No. 424013-961859-1"*

10. Decision of the Board:

The Central Licensing Board in its 263rd meeting considered the report of Federal Inspector of Drugs Karachi, test reports and relevant record of the case and decided to allow FID, Karachi to lodge FIR against the following accused persons for violations mentioned above:

i. M/s Royal Herbal Enterprises company (Pvt) (Ltd), 1730/121 Gujrat Colony Baldia Town Karachi.

ii. Muhammad Rafiq s/o Muhammad Mustafa CNIC No. 42401-1720339-1

iii. Muhammad Siddiq s/o Muhammad Mustafa CNIC No. 424013-961859-1

11. Syed Hakim Masood, the then Area FID Karachi vide letter No. F. SHM-NTF-35-40/2018-DRAP(K-III) dated 08-03-2021 forwarded the copy of Final Investigation Report in case FIR No. 10/2018 of FIA. Conclusion of the said report is given as under:

"[…] From the investigation conducted and evidences collected so far on record, it has been established that M/s Royal Herbal Enterprises Company (Pvt) Ltd and its Director / shareholder, as per record of CRO, SECP, Karachi, namely Muhammad Siddiq S/o Muhammad Mustafa, as well as his brother namely Muhammad Raiq S/o Muhammad Mustafa have committed the offences U/s 23 Drugs Act 1976 punishable U/s 27 ibid and rules framed thereunder, for which they are liable to be prosecuted before the Hon'ble Drug Court Sindh at Karachi by way of filling a complaint by the Federal Inspector of Drugs.[…]"

12. Moreover, Syed Hakim Masood informed that the matter is now in area of jurisdiction of Mrs. Hira Bhutto (FID-III Karachi) and final recommendations on the matter will be submmited by Mrs. Hira Bhutto accordingly.

13. Mrs. Hira Bhutto (FID-III Karachi) was requested vide letter No. F. 04-53/2018-QC 22-04-2021 to complete the investigation and and provide clear and candid recommendations regarding the case matter for submission to the Board.

14. FID-III Karachi, vide letter No. SHM-NTF-35-40/2018-DRAP(K-IV) dated 04-08-2021 has submitted the complete case as under:

"I have the honour to refer to DRAP Islamabad letter No. 04-53/2018-QC dated 22nd April 2021 on the subject captioned above and to submit that Syed Hakim Masood the than Federal Inspector of Drugs Karachi along with the team of Officers & Officials and Muhammad Aslam. S HO Police Station Baldia Town, Karachi inspected the Premises of M/s Royal Herbal Enterprises Company Pvt Limited. 1730/121. Gujrat Colony, Baldia Town. Karachi on 10-04-2018.

- *That complete inspection detail was sent to Director (H&OTC), DRAP Islamabad vide this office letter of even number dated 11th July 2018 (Annexure-A)*
- *That DRAP Islamabad vide their letter No.4-53/2018-QC(263-CLB) dated 14th June 2018 communicated the decision of Central Licensing Board. DRAP Islamabad that file complaint for registration of FIR against the following accused persons.(Anncxure-B)*
- ***Name of Accused persons:-***

  1. *M/s Royal Herbal Enterprises Company (pvt) Ltd: 1730 121 Gujrat Colony Baldia Town. Karachi.*
  2. *Muhammad Rafiq S/O Muhammad Mustafa CNIC No.42401-1720339-1*
  3. *Muhammad Siddiq S/O Muhammad Mustafa CNIC No.424013*

- *That Syed Hakim Masood the than FID DRAP Karachi vide their letter of even number dated 24th July 2018. requested Director FIA. Karachi for registration of HR against the accused persons. (Annexure-C)*
- *That the Additional Director. FIA. ACC. Karachi vide their letter No. FIA/ACCK/FIR-10-2018/2021/330-31 dated 22nd February 2021 provided the Final Investigation report to this office (Annexure-D)*
- *That Syed Hakim Masood the than FID DRAP Karachi vide their letter of even number dated 08th March 2021 forwarded the Final Investigation report of FIA. ACC, Karach. to DRAP Islamabad for further necessary action.(Annexurc-E)*

In view of above it is clariy that following accused persons are found involved in manufacturing & selling of unregistered Drugs and violated the Section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(e), 23(1)(i) under the provision of Drugs Act 1976 and rules framed thereunder, which is punishable under section 27(1)(a), 27(1)(b), 27(1)(c) & 27(4), under the Drugs Act, 1976. It is therefore requested that permission for prosecution in the Drug Court Sindh Karachi against the following accused persons may kindly be accorded.

NAME OF ACCUSED PERSONS:-

1. ***M/s Royal Herbal Enterprises Company (pvt) Ltd: 1730/121 Gujrat Colony Baldia Town, Karachi***
2. ***Muhammad Rafiq S/O Muhammad Mustafa CNIC No. 42401-1720339-1 1730/121 Gujrat Colony Baldia Town, Karachi***
3. ***Muhammad Siddiq S/O Muhammad Mustafa CNIC No. 424013-961859-1 1730/121 Gujrat Colony Baldia Town, Karachi."***

PROCEDINGS AND DECISION OF THE 282ND MEETING OF THE CLB:

15. The Board considered the facts of the case and the Final Investigation report submitted by I/O FIA, decided to issue Show cause notice for prosecution against the following:

i. M/s Royal Herbal Enterprises Company (pvt) Ltd: 1730/121 Gujrat Colony Baldia Town, Karachi

ii. Muhammad Rafiq S/O Muhammad Mustafa CNIC No. 42401-1720339-1 1730/121 Gujrat Colony Baldia Town, Karachi

iii. Muhammad Siddiq S/O Muhammad Mustafa CNIC No. 424013-961859-1 1730/121 Gujrat Colony Baldia Town, Karachi.

16. The accused will be called before the Voard for a chance of personal heaing in the forthcmming meeting of the Board.

Case No. 04: <u>SEIZURE OF UN REGISTERED DRUGS UNDER SECTION 18(1) OF THE DRUG ACT 1976. RAID ON M/S MAHMOOD PHARMACY S-77-R/85/C, JAIL ROAD, OPPOSITE SERVICES HOSPITAL LAHORE.</u>

01. The FID Lahore Mr. Syed Zia Husnain visited the premises of M/s Mahmood Pharmacy S-77-R/85/C, Jail Road, opposite Services Hospital Lahore on 26th August, 2016. The FID forwarded the case to the Director, QA&LT, DRAP, Islamabad vide letter No.12406/2016-DRAP (L-V) dated 29th August, 2016.

02. At the time of raid Mr. Sana ullah S/o Muhammad Suleman R/o H. No.05 St. No.05, mohallah Amin park Ravi road Lahore who is manger was present. Mr. Atif Ejaz S/o Ejaz pervaz R/o 67/C Punjab Co-operative housing Society, defense Lahore (Qualified person as per drug sale license) was gone for jumma prayer as informed by the manager Mr. Daud Tareen s/o Muhammad Aslam Tareen R/o B-42, GOR-III Shadman, Lahore (Proprietor) was absent.

03. The FID Lahore seized the following drugs on form-2 under section 18 (1) (f) of Drug Act, 1976:

S. No.	Name Of Product(s)	Batch/Lot No.	Mfg Data	Exp. Date	Manufactured by	Quantity
01.	Marevan 5mg Tablets	A520518	11-15	05-18	Mfd By. GSK (Detail address not mentioned in English)	(13) Thirteen jars
02.	Marevan 5mg Tablets	A521058	03-16	09-16	-do-	(11) Eleven jars
03.	Marevan 5mg Tablets	A520917	02-16	08-18	-do-	(04) Four jars
04.	Marevan 5mg Tablets	A520916	02-16	08-18	-do-	(15) Fifteen jars
05.	Marevan 5mg Tablets	A520917	02-16	08-18	-do-	(03) Three jars
06.	Centrum Silver	M25939	-	Sep-17	Marked by. Pfizer Madison, NJ07940 USA 2015 Pfizer Inc Made in Canada	(03) Three Packs
07.	Centrum Silver	M87735	-	Dec-17	2014 Pfizer Inc Made in Canada	(02) Two Packs

08.	Centrum Silver	N43989	-	01-18	2014 Pfizer Inc marked by M/s Pfizer Madison, NJ07940	(02) Two Jars
09.	Colomycin Injection	11393	10-2014	10-2017	M/s Forest Laboratories UK, Ltd, Whiddon Valley, Branstaple, North Devon Ex 32 8NS, United Kingdom.	02 Packs×10 Vials
10.	Viagra 100mg Tablets	MALL 19990544G	Dec-2013	01-Apr-2018	Mfd by. Brooklyn, Ne Packed by: Pfizer Ply Ltd, Australia	(03) Three Packs× 06 Tablets
11.	Cialis 20mg Tablets	Control No. 0674654099	-	April-04/2018	Made in USA	(02) Two Packs× 03 Tablets
12.	Centrum Tablets	M877733	-	Dec-17	Mfd. Pfizer Inc. Canada	(02) Packs
13.	Neurobion Injection	213371	12-2015	112017	Mfd. Merck kGaA, Darmstadt, Germany	(03) Three Packs
14.	Pirfenex 200mg Tablets	BA60218	Dec-15	Nov-17	Mfd. Cipla Malpur, Solan 173205 India	(01) One Pack

04. The FID seized these unregistered drugs in contravention to section 23 of Drugs Act, 1976 and also contravention to DRAP Act, 2012 and the room was locked and sealed under section 18 (i) (h) of Drugs Act, 1976.

05. Samples of drugs which were available in sufficient quantities were also sent to Federal Government Analyst for test/ analysis.

06. The details of test/analysis results of said drugs by Federal Government Analyst, Central Drug Laboratory are as under:-

S.No.	Test Report No.& date	Name of Drug with batch No.	Mfg by	Remarks of CDL
1.	Test Report No. R.LHR.403/2016 dated 01-11-2016	Marevan 5mg Tablets Batch No.A521058	M/s GSK	Declared **Unregistered** report no.R.LHR.403/2016 dated 01-11-2016
2.	Test Report No. R.LHR.404/2016 dated 01-11-2016	Centrum Sliver Batch No.M30477	M/s Pfizer Inch, Canada	Declared **Unregistered** report no.R.LHR.404/2016 dated 01-11-2016
3.	Test Report No. R.LHR.405/2016 dated 02-11-2016	Cialis 20mg Batch No.0674654099	M/s GSK	Declared **Unregistered** test report no. R.LHR.405/2016 dated 02-11-2016
4.	Test Report No. R.LHR.406/2016 dated 02-11-2016	Pirfenex Tablets Batch No.BA60218	M/s Cipla Ltd India	Drug is not included in any Pharmacopoeia, test report no. R.LHR.406/2016, dated 02-11-2016

07. The FID requested to allow to keep the safe custody of the seized drugs mentioned on Form-2 under Section 19(5) of the Drug Act 1976 as the firm is involved in illegal and unregistered manufacturing of drugs.

08. Permission of safe custody of the stock was granted to the FID on 16th September 2016. Meanwhile M/s Mehmood Pharmacy S-77-R/85/C, Jail Road Opposite Services Hospital Lahore filed application in the **Drug Court**, Lahore in connection with case under reference. On the order of Drug Court Lahore, premises (room) under reference was de-sealed on 17-11-2016.

Findings:-

Since the sale and stock of un registered drugs in prohibited under section 23 (1) and section A(1) (a)(vii) of schedule II of Drugs Regulatory Authority of Pakistan Act 2012 which is punishable under section 27(1) (A) of the Drug Act 1976 and schedule III of DRAP Act 2012. Sale of un-registered drug is cognizable offence under section 30(2) of the Drug Act 1976 and schedule IV(1) (a) of Drug regulatory authority of Pakistan Act 2012. As pharmacy is not explaining its position in response to the letters of FID. The FID further informed that all four reports of Federal Government Analyst have also been received, therefore under the explained

circumstances mentioned above case is being forwarded under section 19(7) of Drugs Act, 1976 and section 7 of schedule V of Drugs Regulatory Authority of Pakistan Act 2012 to seek further orders of central licensing Board as to action to be taken against the following accused persons in respect of contravention of Drug Act 1976 and Drug Regulatory Authority of Pakistan Act 2012.

09. The Show cause notice was issued to the following accused persons on 25th January 2017.

M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital, Lahore through its proprietor Mr. Daud Khan Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore	**Mr. Sana Ullah** S/O M Suleman House No. 05, Street No.05 Mohellah Amin Park Ravi Road, Lahore
Mr. Atif Ejaz S/O Ejaz Perves R/O67/C Punjab Co-Operative Housing Society Defense Lahore.	**Mr. Daud Tareen** S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore (Proprietor).

10. *Permission For FIR against the following accused persons may be granted to the FID Lahore For selling un registered drugs in violation to the Drug Act 1976 and DRAP Act 2012*:-

i. Mr. Sana Ullah S/O M Suleman
House No. 05, Street No.05

Mohellah Amin Park Ravi Road, Lahore.

ii. Mr. Atif Ejaz S/O Ejaz Perves R/O67/C
Punjab Co-Operative Housing Society Defense,
Lahore.

iii. Mr. Daud Tareen S/O M Aslam Tareen R/O
B-42, GOR-III, Shadman, Lahore (Proprietor).

11. **Decision of 259th meeting of the Board:-**

A. The Central Licensing Board examined/evaluated the facts of the case in the light of investigations conducted by the FIDs and Quality Assurance Division and decided to grant permission for registration of FIR against the following accused persons:-

M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital, Lahore through its proprietor Mr. Daud Khan Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore	Mr. Sana Ullah S/O M Suleman House No. 05, Street No.05 Mohellah Amin Park Ravi Road, Lahore
Mr. Atif Ejaz S/O Ejaz Perves R/O67/C Punjab Co-Operative Housing Society Defense Lahore.	Mr. Daud Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore (Proprietor).

B. The accused persons are involved in contraventions of the provision of schedule-II and schedule-III of the DRAP Act 2012 as under:-

i. Sale of un registered drugs
ii. Sale of drugs without warranty.
iii. Manufacturing/import without authorization from the DRAP.

The offence is punishable under section 1 (a) and para (4) (contraventions of rules) of schedule-III of DRAP Act 2012.

12. In compliance to the decision of 259th meeting of Central Licensing Board, Permision for registration of FIR was issued to area FID vide letter F. No. 3-21/2018-QC/pt/(259-CLB) dated 20-04-2018.

13. Federal Inspector of Drugs-IV Lahore vide letter No. 4080/2021-DRAP(L-IV) dated 17-03-2021 has submitted complete challan of M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital Lahore with reference to FIR No. C163/2018 wherein Assistant Director FIA/CCC Lahore has submitted that following accused were found guilty of violating the provisions of the Drugs Act 1976 and rules made thereunder;

i. M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital, Lahore through its proprietor Daud Khan Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore.
ii. Daud Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore (Proprietor).
iii. Sana Ullah S/O M Suleman, House No. 05, Street No.05 Mohellah Amin Park Ravi Road, Lahore.
iv. Atif Ejaz S/O Ejaz Perves R/O67/C Punjab Co-Operative Housing Society Defense Lahore.

PROCEDINGS AND DECISION OF THE 282ND MEETING OF THE CLB:

14. The Board considered the facts of the case and the Final Investigation report submitted by I/O FIA, decided to issue Show cause notice for prosecution against the following:

i. M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital, Lahore through its proprietor Daud Khan Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore.
ii. Daud Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore (Proprietor).

iii. Sana Ullah S/O M Suleman, House No. 05, Street No.05 Mohellah Amin Park Ravi Road, Lahore.

iv. Atif Ejaz S/O Ejaz Perves R/O67/C Punjab Co-Operative Housing Society Defense Lahore

15. The accused will be called before the Board for a chance of personal heaing in the forthcmming meeting of the Board.

Meeting ended with the vote of thanks to and by the Chair.