MINUTES OF 278th MEETING OF CENTRAL LICENSING BOARD HELD ON DECEMBER 10-11, 2020

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278th meeting of the Central Licensing Board (CLB) was held on December 10-11, 2020 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad. Dr. Ikram U Haq, 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	Dr Ikram Ul Haq, Quality Control Expert	Member
2	Prof. Dr. Abdullah Dayo, Dean Faculty of Pharmacy, University of Sindh, Jamshoro	Member
3	Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar.	Member
4	Mr. Abid Ali, Law Expert, Ministry of Law & Justice Division, Islamabad	Member
5	Mr. Azhar Jamal Saleemi, Chief Drug Controller, Primary and Secondary Health Department, Government of Punjab, Lahore	Member
6	Mr Saleem Shah, Chief Inspector of Drugs, Government of Balochistan, Quetta	Member
7	Mr Shoaib Ahmed Ansari, Chief Inspector of Drugs, Government of Sindh, Karachi	Member
9	Dr. Hafsa Karam Ellahi, Additional Director Representative Director (QA/LT), DRAP, Islamabad	Member
10	Mr. Manzoor Ali Bozdar, Addl Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
11	Mr. Saboor Ahmad, Representative of PPMA.	Observer
12	Mr. Tipu Sultan Akram, Representative of PPMA.	Observer
13	Ms. Binish Alam, Representative, PCDA	Observer
14	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 discussed and decided that initial draft minutes of the meeting would be prepared by concerned sections of Divisions and counter verified by the Secretary, Central Licensing Board before submitting to the members of the Board for perusal and concurrence. Secretary Licensing Board presented the agenda before the Board. Mr. Zeeshan Nazir, Deputy Director (QA), 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) and Mr. Muhammad Ashfaq, AD (QC)DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

DRUG LICENSING DIVISION

Item-I CONFIRMATION OF THE MINUTES OF 277thMEETING

The Central Licensing Board (CLB) formally confirmed the minutes of its 277th meeting of the Central Licensing Board (CLB) which was held on 15-16 October, 2020.

Item-II: GRANT OF NEW DRUG MANUFACTURING LICENSES.

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1.	M/s. Fortune Pharmaceuticals, Plot No. K/201, SITE, Super Highway, Phase – II, Karachi. **Sections:** 1. Tablet (General) 2. Capsule(General) 3. LiquidSyrup (General) 4. Sachet Powder (General) 5. Cream/Ointment (General) 6. Liquid Ampoule (General) 7. Liquid Vial (General) 8. Tablet (Psychotropic) 9. Capsule (Psychotropic) 10. Liquid Ampoule (Psychotropic)	27-10-2020	Good	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director (E&M),DRAP, Karachi. 3. Area FID, DRAP, Karachi.
	Recommendation. *"Ms. Fortune Pharmaceuticals is newly and purposefully built industry and found built as per approved layout plan. The firm has provided facilities as per approved design for following sections* *1. Tablet (G)*			

	2. *Capsule (G)* 3. *Liquid Syrup (G)* 4. *Sachet Powder (G)* 5. *Cream/Ointment (G)* 6. *Sterile Liquid Injection (Ampoules)General* 7. *Liquid Injection (Vials) General* 8. *Sterile Liquid Injection (Ampoules) Psychotropic* 9. *Tablet Psychotropic* 10. *Capsule Psychotropic* *Based on the above stated facts, personnel met, documents reviewed and keeping in view the attitude of the management towards constant improvements the panel unanimously recommends the grant of Drug Manufacturing License (Formulation) for the above sections in the name of M/s. Fortune Pharmaceuticals, Karachi."* **Decision of the Central Licensing Board in 278th meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s. Fortune Pharmaceuticals, Plot No. K/201, SITE, Super Highway, Phase – II, Karachi(By way of Formulation) on the recommendations of the panel of experts for the following sections: **Sections (10)** 1. *Tablet (General)* 2. *Capsule (General)* 3. *Liquid Syrup (General)* 4. *Sachet Powder (General)* 5. *Cream/Ointment (General)* 6. *Sterile Liquid Injection (Ampoules) SVP General* 7. *Liquid Injection (Vials) General* 8. *Sterile Liquid Injection Ampoules Psychotropic* 9. *Tablet (Psychotropic)* 10. *Capsule (Psychotropic)*			
2	M/s. Eterna Pharma (Pvt) Ltd, Plot No. 99, 100, 101 &198-C, Sector D1, Old Industrial Estate, Mirpur AJ&K Sections (03) :- *1. Oral Powder Section*	10-10-2020	Good	1. Dr. Masud Ur Rehman, Director (Licensing), DRAP, Islamabad 2. Dr. Raja Hanif, Chief Drug Inspector, AJ&K. 3. Area FID, DRAP, Islamabad.

	(Veterinary) General). 2. *Oral Liquid Section (Veterinary) General.* 3. *Liquid Injection Section (Veterinary) General."*			
	Recommendation. *"Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously* ***Recommended*** *M/s. Eterna Pharma (Pvt) Ltd,Plot No.99,100,101&198-C, Sector D1, Old industrial Estate, Mirpur AJ&K for the Grant of Drug Manufacturing License for the following sections namely:* i. Oral Powder Section (Veterinary) Genera). ii. Oral Liquid Section (Veterinary) General. iii. Liquid Injection Section (Veterinary) General." **Decision of the Central Licensing Board in 278th meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s. Eterna Pharma (Pvt) Ltd, Plot No. 99, 100, 101 &198-C, Sector D1, Old Industrial Estate, Mirpur AJ&K(By way of Formulation) on the recommendations of the panel of experts for the following sections: **Sections (3)** *i. Oral Powder Section) General(Veterinary.* *ii. Oral Liquid Section) General(Veterinary.* *iii. Liquid Injection Section General(Veterinary."*			
3	M/s Carer Pharmaceuticals Industries, Plot No. 27, Main Road, Rawat Industrial Estate. Rawat. **Sections (05)** i. Tablet(General) ii. Capsule (General) iii. Dry Powder Suspension (General). iv. Sachet (General). v. Ampoule (General).	11-11-2020 & 19-11-2020	**Good**	1. Prof. Dr. Gul Majeed, Head & Dean faculty of Pharmacy, Quaid-e-Azam University Islamabad. 2. Mr. Abdullah, Additional Director (PE&R), DRAP, Islamabad. 3. Mr. Khalid Mahmood, Federal Inspector of Drugs-II, 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 **Recommends**M/s Carer Pharmaceuticals Industries, Plot No. 27, Main Road, Rawat Industrial Estate. Rawat for grant of Drug manufacturing License by way of Formulation as of today as per mandate given videletter No.F.1-32/2016-Lic dated 30th October, 2020 for following sections as per Lay Out Plan as of today. 1. Tablet (General) Section. 2. Capsule section (General) Section. 3. Dry Powder Suspension (General) Section. 4. Sachet (General Section).			

	5. Ampoule (General Section). 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 278th meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Carer Pharmaceuticals Industries, Plot No. 27, Main Road, Rawat Industrial Estate. Rawat.(By way of Formulation) on the recommendations of the panel of experts for the following sections: **Sections (5)** 1. Capsule section (General) Section. 2. Dry Powder Suspension (General) Section. 3. Sachet (General) Section. 4. Ampoule (General) Section. 5. Tablet (General) Section.			
4	M/s Krypton Pharma (Pvt) Ltd, Plot No. 52, Pharmaceutical Zone, M-3 Industrial City, Faisalabad. **Sections (04):** 1. Oral Liquid (General) (Veterinary). 2. Oral Liquid (Antibiotic) (Veterinary). 3. Oral Powder (General) (Veterinary). 4. Oral Powder (Antibiotics) section (Veterinary).	**12-10-2020**	Good (W.r.t Oral Liquid, Oral Powder General & Antibiotics) Unsatisfactory (w.r.t Penicillin)	1. Dr. Farzana Chaudhary, 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 DML in favour of M/s Krypton Pharma (Pvt) Ltd, Plot No. 52, M3 Industrial City, Sahianwala, Faisalabad in respect of Oral Liquid (General), Oral Liquid (Antibiotic), Oral Powder (General) and Oral Powder (Antibiotics) sections only. The panel of inspectors **does not recommend** the grant of DML in respect of Oral Powder (Penicillin) section. **Decision of the Central Licensing Board in 278th meeting**			

	The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Krypton Pharma (Pvt) Ltd, Plot No. 52, Pharmaceutical Zone, M-3 Industrial City, Faisalabadon the recommendations of the panel of experts for the following sections: **<u>Sections (04)</u>** 1. Oral Liquid (General) (Veterinary). 2. Oral Liquid (Antibiotic) (Veterinary). 3. Oral Powder (General) (Veterinary). 4. Oral Powder (Antibiotics) section (Veterinary). The Board did not approve Oral Powder (Penicillin) on the recommendations of the panel of experts.			
5.	M/s Nagarsons Pharmaceuticals (Pvt) Ltd, Plot No. 34, Street No. NS-2, National Industrial Zone, Rawat.	**11-11-2020 & 30-11-2020**	**Good**	1. Prof. Dr. Gul Majeed, Member, CLB, Quaid-e-Azam University, Islamabad. 2. Mr. Ayyaz Ahmad,Additional Director (H&OTC), DRAP, Islamabad. 3. Khalid Mahmood, FID, DRAP, Islamabad
	"Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously Recommended M/s Nagarsons Pharmaceuticals (Pvt) Ltd, Plot No. 34, Street No. NS-2, National Industrial Zone, Rawat for the grant of Drug Manufacturing License (Formulation) for the following four sections namely; 1. Tablet (General). 2. Tablet (Psychotropic). 3. Capsule (General). 4. Cream / Ointment / Lotion / Gel (General). **Disclaimer:-** *The report is limited to verification of manufacturing and quality control facility as per above mentioned sections for manufacturing of Drugs under Act 1976 & Rules framed there under. Quality of Products of Individual Batches remains the responsibility of the technical staff and manufacturer. 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 & Building Control Authorities (BCA). Certification is advised to be sought from BCA.* **<u>Decision of the Central Licensing Board in 278th meeting</u>** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Nagarsons Pharmaceuticals (Pvt) Ltd, Plot No. 34, Street No. NS-2, National Industrial Zone, Rawat (By way of Formulation) on the recommendations			

	of the panel of experts for the following sections: **Sections (04)** 1. Tablet (General). 2. Tablet (Psychotropic). 3. Capsule (General). 4. Cream / Ointment / Lotion / Gel (General).

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

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1.	M/s City Pharmaceutical Laboratories, Plot No. 12-A, I-5 Sector 5, New Survey No. 276,Korangi Industrial Area, Karachi **Section (03)** **1.** Sterile Dry Powder Injection (Penicillin) - **New** **2.** Capsule (Penicillin)- **New** **3.** Dry Powder for suspension (Penicillin) - **New**	**23-10-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director (E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi.
	Recommendation. *"Based on the stated facts and keeping in view the attitude of the management towards constant improvements the panel unanimously recommends the grant of additional sections of sterile Dry Powder Injection (Penicillin), Capsule (Penicillin) and Dry Powder for suspension (Penicillin) under DML No. 000723 (Formulation) ."* **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of additional sections in the name of M/s City Pharmaceutical Laboratories, Plot No. 12-A, I-5 Sector 5, New Survey No. 276,Korangi Industrial Area, Karachiunder DML No. 000723 (Formulation); **Section (3)** **1.** Sterile Dry Powder Injection (Penicillin) - **New** **2.** Capsule (Penicillin)- **New** **3.** Dry Powder for suspension (Penicillin) - **New**			

2.	M/s Platinum Pharmaceuticals (Pvt) Ltd., Plot no. A-20, North Western Industrial Zone, Port Qasim, Karachi. DML No. 000415(By way of Formulation) **Facility(01)** i. Ware House (Cephalosporin)- **Revised.**	11-11-2020	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Director CDL, Karachi. 3. Area FID, DRAP, Karachi.

Recommendation.

During the inspection, panel observed that the above Said areas were as per approved layout plan and dispensing booth installed as approved layout. HVAC system installed in Cephalosporin (Warehouse) section as well as dispensing area and observed in operational conditional.
Findings based on the area inspected, panel recommends the grant of amendments of Warehouse (Cephalosporin).

Decision of the Central Licensing Board in 278th meeting

The Board considered and approved the grant of revised facility in the name of M/s Platinum Pharmaceuticals (Pvt) Ltd., Plot no. A-20, North Western Industrial Zone, Port Qasim, Karachi. under DML No. 000415 (Formulation);

Facility (01)

1. Ware House (Cephalosporin)- **Revised.**

3.	M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachi. DML No. 000746 (Formulation) **Sections :** **1.** Cream/Ointment (General) - **New**	**16-09-2020**	**Good**	1. Dr. Abdullah Dayo, Member CLB. 2. Additional Director (E & M) DRAP, Karachi. 3. Area FID, DRAP, Karachi.

"***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 additional section in the name M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachi.

under DML No. 000746 (Formulation);

Section (01)

1. Cream/Ointment (General) –**New**

4.	M/s Islam Pharmaceuticals, 7-KM, Pasrur Road, Sialkot. DML No. 000885 (Formulation) **Section (01)** i. Liquid Ampoule (SVP) (General) (New).	18-09-2020	**Very Good**	1. Dr. Farzana Chaudary, Expert Member. 2. Mrs. Majida Mujahid, FID, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

In view of the above observations, the members of the panel **recommend** the grant of new additional Section Liquid Ampoule (SVP) (General) (New) only to M/s Islam Pharmaceuticals, 7-KM, Pasrur Road, Sialkot as per lay out plan approved by DRAP.

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

Decision of the Central Licensing Board in 278th meeting

The Board considered and approved the grant of additional section in the name M/s Islam Pharmaceuticals, 7-KM, Pasrur Road, Sialkot.under DML No. 000885 (Formulation);

Section (01)

i. Liquid Ampoule(SVP) (General) (New).

5.	M/s Citi Pharma (Pvt) Ltd, 3-Km, HeadBaloki Road, Phool Nagar, Kasur. DML No. 000429 (Semi-Basic	**29-10-2020**	**Good**	1. Mr. Azher Jamal Saleemi, Chief Drugs Controller, Punjab. 2. Mr Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.

	Manufacture) **API (04)** i. Ascorbic Acid (Ph.Eur). ii. Chloroquine Phosphate (USP) iii. Hydroxychloroquine Sulphate (USP) iv. Azithromycin (USP).			3. Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore
	Recommendations of the panel: M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Baloki Road, Phool Nagar Kasur has Drug Manufacturing License No. 000429 by way of Semi Basic Manufacturing. Panel has thoroughly inspected the unit, evaluated the documents revealed by the firm and discussed various technical aspects at length. Panel is of the view that firm must manufacturer pilot batches for trial before start of commercial manufacturing of above-mentioned new APIs upon its formal approval of Central Licensing Board, as per law Manufacturing process, process flow chart, list of material intended to used. undertaking by the firm to ensure the authorize use of all material with proper records, detail of equipment of production and quality control departmental list of technical staff duly signed by the firm / panel members are attached with this report for perusal of Central Licensing Board. Based on the description mentioned above, documentations revealed and submitted by the firm, physical inspection of the unit, Panel has **recommended** the facility for grant of following four new APIs by the way of semi-basic manufacturing method. i. Ascorbic Acid (Ph.Eur). ii. Chloroquine Phosphate (USP) iii. Hydroxychloroquine Sulphate (USP) iv. Azithromycin (USP). **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of additional API's in the M/s Citi Pharma (Pvt) Ltd, 3-Km, HeadBaloki Road, Phool Nagar, Kasurunder DML No. 000429 (Semi-Basic Manufacture); **API's(04)** 1. Ascorbic Acid (Ph.Eur). 2. Chloroquine Phosphate (USP) 3. Hydroxychloroquine Sulphate (USP) 4. Azithromycin (USP).			
6.	M/s Moringa Pharmaceuticals (Pvt) Ltd, 35-A, Sunder Industrial Estate, Raiwind Road, Lahore. DML No.000769 (Formulation).	**07-10-2020**	**Good**	1. Dr. Farzana Chaudhary, Expert Member. 2. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP,

	Section/Facility (01) i. Stability Section			Lahore.
	Recommendations of the panel: Keeping in view the facilities provided by the firm for stability Suite (Real Time Studies) the panel is of the opinion to **recommend** the grant of following additional Section to the firm. i. Stability Section. **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of additional section/facility in the name of M/s Moringa Pharmaceuticals (Pvt) Ltd, 35-A, Sunder Industrial Estate, Raiwind ~~Road,Lahore.under~~Road, Lahore.under DML No. 000769 (Formulation); **Section/Facility (01)** **1.** Stability Section.			
7	M/s Alpha Chemicals (Pvt) Ltd, 65-Km, Lahore, Multan National Highway Industrial Zone, Chunian, Distt Kasur. DML No. 000373(Basic Manufacture) **API(03)** **i.** Phenylephrine Hydrochloride(Ph.Eur) **ii.** Trimethoprim(Ph.Eur) . **iii.** Fexofenadine Hydrochloride (USP)	19-10-2020	Good	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 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: - Firm M/s M/s Alpha Chemicals (Pvt) Ltd, 65-Km, Lahore, Multan National Highway Industrial Zone, Chunian, Distt Kasur has Drug Manufacturing License No. 000373 by way of Basic Manufacturing. Firm has presently established the facility for conversion of i] Phenylephrine base to phenylephrine Hydrochloride (ii) Trimethoprim technical to Trimethoprim and iii) Fexofenadine base to Fexofenadine Hydrochloride by way of semi Basic Manufacturing process. Firm claimed that under Drug Manufacturing License, Registrationand Advertising Rules 1976, they can manufacture APIs by way **of semi basic manufacturing under the license of basic manufacturing (copy of rules signed by the firm is attached for perusal)**. Form also informed that they have also already got approval of Central Licensing Board in its 238th meeting on 19-11-2014 vide DRAP letter No.F1-3/94-Lc (Vol-I) dated 02-12-2014 to manufacture pseudoephedrine HCI by way of Semi Basic Manufacture methodform intermediate i.e.(+)-(IS,2S)-2Methylamino-I phenylpropan-I-OL base (i.e. Pseudoephedrine base) (Copy of approval letter attached with the report for perusal).Panel is of the view that firm must manufacture pilot batches for trial and stability studies before start of commercial manufacturing of above mentioned APIs upon its formal approval of Central Licensing Board as per law. Firm			

	must have calculation and recording of theoratical and practical yield for every batch along with complete record of all the materials used and keep these records as part of BMR as well as in consolidated and tabulated form. Manufacturing process, process flow chart, list of material intended to be used, undertaking by the firm to ensure the authorize use of all material with proper records, details of equipment's of production and quality control departmental list of technical staff duly signed by the firm / panel members are attached with this report for perusal of Central Licensing Board. Based on the description mentioned above, documentations revealed and submitted by the firm, physical inspection of the unit and previous approval of Central Licensing Board to manufacture a product as cited above by way of semi basic manufacturing methods panel has **recommended** the facility for grant of three new APIs i.e, PhenylephrineHydrochloride, Trimethoprim and Fexofenadine Hydrochloride by way of semi basic manufacturing method methods following four new APIs by the way of semi-basic manufacturing method. **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of additional API's in the name of M/s Alpha Chemicals (Pvt) Ltd, 65-Km, Lahore, Multan National Highway Industrial Zone, Chunian, Distt Kasur.under DML No. 000373 (Basic Manufacture) on the recommendation of panel of experts to be manufactured by way of semi basic manufacture; **API's (03)** **i.** Phenylephrine Hydrochloride(Ph.Eur) **ii.** Trimethoprim(Ph.Eur) . **iii.** Fexofenadine Hydrochloride (USP)			
8.	M/s Univet Pharmaceuticals, 14-KM, Adyala Road, Rawalpindi. DML No. 000424 (Formulation). **Section (01).** 1. Liquid Injection Vial (Veterinary) (New).	**01-12-2020**	Good	1. Khalid Mahmood, FID, DRAP, Islamabad.
	"Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the undersigned unanimously recommends M/s Univet Pharmaceuticals, 14-KM, Adyala Road, Rawalpindi for approval of Liquid Injection Section Vial (General Veterinary) / Regularization under Drug Manufacturing License No. 000424 as per given mandate. **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 from relevant Building Control Authorities (BCA) as per prevailing laws and ensure proper emergency exists alongwith firefighting equipments in the premises. The quality of individual batches of registered procedures and their safety shall remain the responsibility of the manufacturer as envisaged under the Drugs Act, 1976 read with DRAP Act, 2012.			

	Decision of the Central Licensing Board in 278th meeting The Board considered and approved the grant of additional section in the name of M/s Univet Pharmaceuticals, 14-KM, Adyala Road, Rawalpindi under DML No. 000424 (Formulation); **Section (01)** 1.Liquid Injection Section Vial (Veterinary) (New).			
9.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, Phase S1, Industrial Estate, Rawat. DML No. 000882 (Formulation). **Section (04).** 1. Tablet (General). 2. Capsule(General). 3. Sachet (General). 4. Ointment/Cream/ Gel (General).	**03-12-2020 & 04-12-2020**	Good	1. Dr. Kashif Iqbal, Head of Department of Pharmacy, University of Lahore, Islamabad Campus. 2. Mr. Manzoor Ali Bozdar, Additional Director (Licensing), DRAP, Islamabad. 3. Mr. Hasan Afzaal, Area FID-III, DRAP, Islamabad.
	"Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously recommended M/s Wezen Pharmaceuticals, Plot No. 23 & 24, Phase S1, Industrial Estate, Rawat for the grant of Additional Section namely; 1. Tablet (General). 2. Capsule (General). 3. Sachet (General). 4. Ointment / Cream / Gel (General). **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of additional section in the name of M/s Wezen Pharmaceuticals, Plot No. 23 & 24, Phase S1, Industrial Estate, Rawatunder DML No. 000822 (Formulation); **Section (04)** 1. Tablet (General). 2. Capsule (General). 3. Sachet (General). 4. Ointment / Cream / Gel (General).			
10.	M/s Hawk Bio (Pvt) Ltd, Plot No. 10, Street No. S-6, National industrial Estate, RCCI, Rawat. DML No. 000798 (Formulation) **Sections /Facility (02)** i. Packing Material Store	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.

	(Expansion) (Ground Floor Veterinary) ii. Expansion of Quality Control Laboratory.			3. Mr. Hassan Afzaal, Federal Inspector of Drugs, DRAP, Islamabad.
	<u>Recommendations of the panel:</u> 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 renewal 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. **<u>Decision of the Central Licensing Board in 278th meeting</u>** The Board considered and approved the grant of additional section/facility in the name of M/s Hawk Bio (Pvt) Ltd, Plot No. 10, Street No. S-6, National industrial Estate, RCCI, Rawat.under DML No. 000798 (Formulation); **<u>Section/Facility (02)</u>** i. Packing Material Store (Expansion) (Ground Floor Veterinary) ii. Expansion of Quality Control Laboratory.			
11.	M/s Curatech Pharma (Pvt) Ltd,35 km Multan Road, Lahore. DML No. 000619 (Formulation) **<u>Sections /Facility (04)</u>** i. Syrup/Suspension (General) Section (Revised New) ii. Capsule (Cephalosporin) Section (New) iii. Dry Powder for Suspension (Cephalosporin) Section (New) iv. Dry Powder for Injection (Cephalosporin) Section (New)	02-10-2020	Good	1. Dr. Farzana Chowdhary, Expert Member. 2. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab 3. Ms. Uzma Barkat, Federal Inspector of Drugs, DRAP, Lahore

	Recommendations of the panel: In the light of the inspection conducted by the panel and based on the findings, the panel of inspectors **recommends** the grant of following sections to M/s Curatech Pharma Pvt. Ltd., 35 km Multan Road, Lahore, *except the Tablet (Psychotropic) Section (New).* i. Syrup/Suspension (General) Section (Revised New) ii. Capsule (Cephalosporin) Section (New) iii. Dry Powder for Suspension (Cephalosporin) Section (New) iv. Dry Powder for Injection (Cephalosporin) Section (New) The panel also directed the firm to get the layout plan of Psychotropic tablet section revised and approved by the concerned division of DRAP as it was noted during the inspection that the Psychotropic section was not constructed as per the approved layout plan rather the firm had established an additional area for manufacturing of Psychotropic capsules within that approved layout. The facility will be re-inspected accordingly. **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of additional section/facility in the name of M/s Curatech Pharma (Pvt) Ltd,35 km Multan Road, Lahoreunder DML No. 000619 (Formulation); **Section/Facility (04)** 1. Syrup/Suspension (General) Section (Revised New) 2. Capsule (Cephalosporin) Section (New) 3. Dry Powder for Suspension (Cephalosporin) Section (New) 4. Dry Powder for Injection (Cephalosporin) Section (New) The Board also decided to pursue the firm for approval of Layout plan for Tablet (Psychotropic) as per advice of panel of inspectors.			
12.	M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat. DML No. 000680 (Formulation) **Sections /Facility (02)** i. Liquid Injection Vial (Steroid) Veterinary. ii. Liquid Injection Vial (General) Veterinary (Revised).	08-10-2020	Good	1. Prof. Dr. Gul Majeed, Head & Dean faculty of Pharmacy, Quaid-e-Azam University Islamabad. 2. Dr. Hafsa Karam Elahi, Additional Director (QA &LT), DRAP, Islamabad. 3. Mr. Khalid Mahmood, Federal Inspector of Drugs-II, 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 **Recommends**M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawatfor the grant of additional sections under Drug Manufacturing License No. 000680 (Formulation) as of today as per mandate given vide letter No. F.1-36/2006-Lic (Vol-II) dated14th September, 2020 for following sections as per approved layout plan. i. Liquid Injection Vial (Steroid) Veterinary. ii. Liquid Injection Vial (General) Veterinary (Revised). ***Disclaimer:-*** *The report is limited to verification of manufacturing and quality control facility as per above mentioned sections for manufacturing of Drugs under Act 1976 & Rules framed there under. Quality of Products of Individual Batches remains the responsibility of the technical staff and manufacturer. 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 & Building Control Authorities (BCA). Certification is advised to be sought from BCA.* **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of additional & revised sections in the name M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat. under DML No. 000680 (Formulation); **Sections (02)** i. Liquid Injection Vial (Steroid) Veterinary- New **ii.** Liquid Injection Vial (General) Veterinary (Revised).			
13	M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad DML No. 000340 (Formulation) **Name of Sections (02).** 1. Soft Gel Capsule(Hormone). 2. Dry Powder Inhaler	**20-11-2020**	**Very Good**	i. Dr. Hafsa Karam Elahi, Additional Director (QA/LT), DRAP, Islamabad, ii. Ms. Mahvash Ansari, Area FID, DRAP, Islamabad, iii. Mr. Malik Muhammad Asad, Deputy Director (Licensing), DRAP, Islamabad.

	Recommendation. *"Keeping in view the premises inspected of facility and documents reviewed, the panel unanimously* ***recommended*** *the approval of following additional section;* *i. Soft Gel Encapsulation Hormonal Section.* *ii. Dry Powder Inhaler Section* **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of additional sections in the name M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad under DML No. 000340 (Formulation); **Sections (01)** 1. Soft Gel Capsule (Hormone) - New 2. Dry Powder Inhaler - New			
14	M/s National Institute of Health, Chak Shahzad, Islamabad . DML No. 000092 (Formulation) **Name of Section (01).** 1) Sera Section / Laboratory (dedicated facility)	**30-11-2020**	**Very Good**	1. Additional Director (Biological), DRAP, Islamabad. 2. Additional Director (Licensing), DRAP, Islamabad. 3. Area Federal Inspector of Drugs, DRAP, Islamabad.
	Recommendations of the panel: - *Keeping in view the premises visited, facilities verified, people met and documents reviewed panel unanimously recommend the approval of newly built facility for Sera Processing Laboratory, Biological Production Division, National Institute of Health, Chak Shahzad, Islamabad.* **The case is hereby submitted for consideration and orders of the Board, please.** **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of additional facility in the name M/s National Institute of Health, Chak Shahzad, Islamabadunder DML No. 000092(Formulation) and Drug Manufacturing License No. 000092 (Basic Manufacture) ; **Sections (01)** i. Sera Section /Laboratory (dedicated facility) - New			

Item-III: **GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE.**

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 Sigma Pharma International (Pvt) Ltd, Plot No. E-50, North Western Industrial Zone, Port Qasim, Karachi DML No. 000804 (Formulation) **Period**. Commencing on 15-10-2019and ending on14-10-2024 Sections : 1. Capsule (General) 2. Oral Dry Powder Suspension (General) 3. Cream/Ointment/Gel (General) 4. Tablet (General) 5. Sachet (General)	**12-08-2020** **&** **12-11-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Director CDL, Karachi. 3. Area FID, DRAP, Karachi.

Recommendations of the panel: -

M/s. Sigma Pharma (Pvt) Ltd, has been build as per approved layout plan. Necessary equipment's& procedures are available to manufacture and test their registered products. All the sections including QC Laboratory provided with dedicated HVAC units. The areas are properly classified, maintained & Qualified. Appropriate numbers of personnel with adequate knowledge expertise are available. The panel recommends the Renewal of License by way of Formulation.

Decision of the Central Licensing Board in 278th meeting

The Board considered and approved the grant of renewal of (DML No. 000804) by way of formulation in the name of M/s Sigma Pharma International (Pvt) Ltd, Plot No. E-50, North Western Industrial Zone, Port Qasim, Karachion the recommendations of the panel of experts for the period commencing on **15-10-2019**and ending on **14-10-2024**for the following sections:-

SECTIONS (05)

1. Capsule (General)
2. Oral Dry Powder Suspension (General)

	3. Cream/Ointment/Gel (General) 4. Tablet (General) 5. Sachet (General)			
2.	M/s Helix Pharma (Pvt) Ltd, Plot No. A-56, S.I.T.E, Karachi DML No. 000030 (Formulation) **Period**. Commencing on 24-04-2020 and ending on 23-04-2025	**29-10-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Director DTL, Karachi. 3. Area FID, DRAP, Karachi.

Recommendation.

"Keeping in view overall GMP compliance and positive intention towards improvements, panel unanimously recommend regularization of layout and recommends the renewal of DML No. 000030 of M/s. Helix Pharma (Pvt) Ltd, Plot No. A-56, S.I.T.E, Karachi as per following sections

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Capsule (General)
iii.	Dry Powder Suspension (General)	iv.	Oral Liquid Syrup (General)
v.	Eye/Ear Drops (General)	vi.	Liquid Injectable (General)
vii.	Warehouse (General)	viii.	Quality Control Laboratory

Decision of the Central Licensing Board in 278th meeting

The Board considered and approved the grant of renewal of DML No. 000030 by way of formulation in the name of M/s Helix Pharma (Pvt) Ltd, Plot No. A-56, S.I.T.E, Karachion the recommendations of the panel of experts for the period commencing on **24-04-2020**and ending on **23-04-2025 for** the following sections:-

SECTIONS (05)

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Capsule (General)
iii.	Dry Powder Suspension (General)	iv.	Oral /Liquid Syrup (General)
v.	Eye/Ear Drops (General)	vi.	Liquid Injectable (General)

<table>
<tr><td>3.</td><td>M/s Winthrox Laboratories (Pvt) Ltd, Plot No. K-219/A, Phase-II SITE Super Highway, Karachi

DML No. 000807 (Formulation)

Period.Commencing on 23-09-2020 and ending on 22-09-2025</td><td>19-11-2020</td><td>Good</td><td>1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Additional Director, DRAP, Karachi.
3. Area FID, DRAP, Karachi.</td></tr>
<tr><td>4.</td><td colspan="3">Recommendations of the panel: -

Based on the people met, documents reviewed and positive intentions of the ,management towards constant improvements, the panel recommends the grant of renewal of DML No. 000807 (Formulation) for the sections namely Tablet (G), Capsule (G), Sachet (G), Oral Dry Powder Suspension (G), Liquid Syrup (G), Sterile Eye Drops (G),Sterile Dry Powder Injection (Cephalosporin), Capsule (Cephalosporin), Dry Powder Suspension (cephalosporin) and Liquid Injectable (General) SVP (Ampoule/vials).

<u>Decision of the Central Licensing Board in 278th meeting</u>

The Board considered and approved the grant of renewal of (DML No. 000807) by way of formulation in the name of M/s Winthrox Laboratories (Pvt) Ltd, Plot No. K-219/A, Phase-II SITE Super Highway, Karachi on the recommendations of the panel of experts for the period commencing on 23-09-2020 and ending on 22-09-2025 for the following sections:

<u>Sections (10) :</u>

1. Tablet (General),
2. Capsule (General),
3. Sachet (General),
4. Oral Dry Powder Suspension (G),
5. Liquid Syrup (General),
6. Sterile Eye Drops (General)
7. Sterile Dry Powder Injection (Cephalosporin),
8. Capsule (Cephalosporin),
9. Dry Powder Suspension (cephalosporin)
10. Liquid Injectable (General) SVP (Ampoule/vials).</td></tr>
<tr><td>4.</td><td>M/s Barrett Hodgson Pakistan (Pvt) Ltd, Plot No. F/423, SITE Karachi

DML No. 000457 (Formulation)

Period.Commencing 23-09-2020 and ending on 22-09-2025</td><td>19-11-2020</td><td>Good</td><td>1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Additional Director, DRAP, Karachi.
3. Area FID, DRAP, Karachi.</td></tr>
</table>

4.	**Recommendations of the panel: -** M/s Barrett Hodgson Pakistan (Pvt) Ltd, Plot No. F/423, SITE Karachi was inspected by the panel members in connection with the renewal of Drug Manufacturing License No. 000457 (formulation) vide DRAP's Letter No. F. 2-4/97-Lic (Vol-IV0 dated 02nd November, 2020. The panel reviewed their overall documentation, inspected Manufacturing Facility, Quality Control Lab and Stores and met with their technical person's and management. The observed as follows: 1. The premises/sections have been constructed as per DRAP's authority approved Layout plan. 2. An appropriate level of sanitation, cleanliness &workers hygiene was noted. 3. The firm has adequate number of processing & testing equipments in respective departments, based on requirements of products. 4. The HVAC system was seen installed and observed in operational condition. 5. Quality control lab also observed equipped with necessary equipments, analytical methods and other relevant accessories required for testing of their registered drugs. 6. Separate storage areas were noted and noticed organized and well maintained. 7. Personnel met during inspection, observed well conversant with necessary qualification and experienced. Based on the sated observation, the panel recommends the Renewal of following sections:- 1. Tablet (General) 2. Capsule (General) 3. Sachet (General) 4. Liquid syrup/Suspension (General) 5. Ointment (General) 6. Dry Powder Suspension (General) 7. Ophthalmic /Ear Drops 8. Liquid Injection 9. Dry Powder Injectable (Cephalosporin) 10. Capsule (Cephalosporin) 11. Dry Powder Suspension (cephalosporin). **<u>Decision of the Central Licensing Board in 278th meeting</u>** The Board considered and approved the grant of renewal of (DML No. 000457) by way of formulation in the name of M/s Barrett Hodgson Pakistan (Pvt) Ltd, Plot No. F/423, SITE Karachion the recommendations of the panel of experts for the period commencing **23-09-2020**

	and ending on **22-09-2025** for the following sections:- **<u>SECTIONS (11)</u>** 1. Tablet (General) 2. Capsule (General) 3. Sachet (General) 4. Liquid syrup/Suspension (General) 5. Ointment (General) 6. Dry Powder Suspension (General) 7. Ophthalmic /Ear Drops (General) 8. Liquid Injection (General) 9. Dry Powder Injectable (Cephalosporin) 10. Capsule (Cephalosporin) 11. Dry Powder Suspension (cephalosporin).			
5.	M/s Zafa Pharmaceuticals Laboratories (Pvt) Ltd, Plot No. A-79, SITE Super Highway, Karachi DML No. 000516 (Formulation) **Period**. Commencing on **19-06-2018** and ending on **18-06-2023** Section : 1. Soft Gelatin Capsule (General)	**01-10-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director, DRAP, Karachi. 3. Area FID, DRAP, Karachi.
4.	**Recommendations of the panel: -** Based on the above stated facts and keeping in view the attitude of the management of the firm, the panel unanimously recommends the grant of renewal of DML No. 000516 for the next five years and panel also recommends the regularization of the current facility which is according to approved design. **<u>Decision of the Central Licensing Board in 278th meeting</u>** The Board considered and approved the grant of renewal of (DML No. 000516) by way of formulation in the name of M/s Zafa Pharmaceuticals Laboratories (Pvt) Ltd, Plot No. A-79, SITE Super Highway, Karachion the recommendations of the panel of experts for the period			

	commencing on **19-06-2018** and ending on **18-06-2023** for the following sections:- **SECTIONS (01)** 1. Soft Gelatin Capsule (General)			
6	M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad DML No. 000806 (Semi-Basic Manufacture) **Period**: Commencing **02-12-2019**and ending on **01-12-2024**	23-06-2020	**Good**	1. Prof. Dr. Gul Majeed Khan, Quaid-e-Azam University, Islamabad. 2. Additional Director (Lic), DRAP, Islamabad. 3. Area Federal Inspector of Drugs, DRAP, Islamabad.
1.	**Proceedings in 276th meeting of the Central Licensing Board** Panel of three members was constituted accordingly. However, panel inspection was conducted by following two members, 1. Dr. Muhammad Usman, Member CLB. 2. Area Federal Inspector of Drugs, DRAP, Islamabad. **The Recommendations of the above panel was place before CLB in its 276th meeting** "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended the renewal of DML by The Way of Semi Basic (000806)** of Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahtua Road, Islamabad-Pakistan" **Decision of the Central Licensing Board in 276th meeting** " *The Board considered and deferred the grant of renewal of Drug manufacturing License by Way of **Semi Basic Manufacture** in the name of Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahtua Road, Islamabad-Pakistan as inspection was carried out by two members instead of three (full) member of the constituted panel. The Board decided to re-inspect the premises and panel to be constituted by the Chairman Central Licensing Board"* In light of decision of CLB in its 276the meeting, panel was constituted by Chairman of the CLB and letter was issued, accordingly. **Recommendations of the panel:** *"Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended the renewal of DML by The Way of Semi Basic (000806)** of Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahtua Road, Islamabad-Pakistan."* **The case is hereby submitted for consideration and orders of the Board, please**			

	Decision of the Central Licensing Board in 278th meeting The Board considered and approved the grant of renewal of (DML No. 000806) by way of Semi-Basic Manufacture inthe name of M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabadon the recommendations of the panel of experts for the period commencing **02-12-2019**and ending on 01**-12-2024**.			
7	M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad DML No. 000517 (Formulation) **Period**: 01-04-2019 to 31-03-2024 Sections i) Tablet (General) ii) Capsule General iii) Sachet (General) iv) Oral Dry powder Suspension (General) v) Sterile Dry Powder Injectable Vial (General) vi) Small Volume Parenteral (Blow Fill Seal Technology) vii) Liquid Ampoule (General) viii) Liquid Vial (SVP) (General) ix) Steroidal Power injection (Steroid)	22-06-2020	**Good**	i. Dr. Hafsa Karam Elahi, Additional Director (QA), DRAP, Islamabad. ii. Area Federal Inspector of Drugs, DRAP, Islamabad. iii. Sardar Shabbir, Senior Inspector of Drugs, Islamabad.
1.	**Proceedings in 276th meeting of the Central Licensing Board** Panel of three members was constituted accordingly. However, panel inspection was conducted by following members, 3. Dr. Muhammad Usman, Member CLB. 4. Area Federal Inspector of Drugs, DRAP, Islamabad. The Recommendations of the above panel was place before CLB in its 27th meeting. Keeping in view the above facts on record and the people met during the visit, the panel unanimously recommended the renewal of DML by The Way of Formulation (000517) of			

	Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahtua Road, Islamabad-Pakistan. **Decision of the Central Licensing Board in 276th meeting** *"The Board considered and deferred the grant of renewal of Drug manufacturing License by Way of Formulation in the name of Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahtua Road, Islamabad-Pakistan as inspection was carried out by two members instead of three (full) member of the constituted panel. The Board decided to re-inspect the premises and panel to be constituted by the Chairman Central Licensing Board."* In light of decision of CLB in its 276the meeting, panel was constituted by Chairman of the CLB and letter was issued, accordingly. **Recommendations of the panel:** *"Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended the renewal of DML by The Way of Formulation (000517)** of Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahtua Road, Islamabad-Pakistan."* **The case is hereby submitted for consideration and orders of the Board, please** **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of renewal of (DML No. 000517) by way of formulation in the name of M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabadon the recommendations of the panel of experts for the period commencing **01-04-2019**and ending on **31-03-2024**for the following sections:- **SECTIONS (09)** i) Tablet (General) ii) Capsule General iii) Sachet (General) iv) Oral Dry powder Suspension (General) v) Sterile Dry Powder Injectable Vial (General) vi) Liquid Infusion (SVP) (Blow Fill Seal Technology) vii) Liquid Ampoule (General) viii) Liquid Injectable Vial SVP (General) ix) Dry Power injection (Steroid)			
8	M/s ICI Pakistan Ltd., (Formerly M/s Cirin Pharmaceuticals (Pvt) Ltd.), 32/2A, Phase-III, Industrial Estate, Hattar DML No. 000363 (Formulation)	23-06-2020	**Good**	1. Prof. Dr. Jamshed Ali Khan, Member CLB. 2. Chief Inspector of Drugs, Khyber Pakhtunkhwa, Peshawar. 3. Area Federal Inspector of

	Period: Commencing **18-09-2020** and ending on **17-09-2025**			Drugs, DRAP, Peshawar.

Recommendations of the panel: -

"The firm has maintained all the record/documents required as per cGMP. They have calibrated and validated all the operating equipment in QC and production. The technical staff in QC, QA, Micro, R&D and production is professional, well qualified and experienced. They have maintained the cGMP compliance as per DRAP and WHO guide lines.

Based on the findings of the inspection M/s ICI Pakistan Limited (32/32A, Phase-III, Hattar Industrial Estate, Haripur") was considered to be operating at a good level of compliance with cGMP guidelines as per drug act 1976 and rules framed there under and the panel unanimously recommended the grant of renewal of DML to the firm."

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

Decision of the Central Licensing Board in 278th meeting

The Board considered and approved the grant of renewal of (DML No. 000363) by way of formulation in the name M/s ICI Pakistan Ltd., (Formerly M/s Cirin Pharmaceuticals (Pvt) Ltd.), 32/2A, Phase-III, Industrial Estate, Hattaron the recommendations of the panel of experts for the period commencing on **18-09-2020** and ending on **17-09-2025** for the following sections:-

SECTIONS (15)

1. Tablet Section (General)
2. Sachet Section (General)
3. Capsule Section (General)
4. Dry Powder Suspension (General)
5. Liquid Injectable (General) Ampoule
6. Capsule Section (Cephalosporin)
7. Dry Powder Suspension Section (Cephalosporin)
8. Dry Powder Injection Section (Cephalosporin)
9. Capsule Section (Penicillin)
10. Tablet Section (Penicillin)
11. Dry Powder Suspension Section (Penicillin)
12. Dry Powder Injection (Vial) Section (Penicillin)
13. Tablet Section (Psychotropic)
14. Dry Powder Injection (Steroid)
15. Injectable Vial (Carbapenem)

9	M/s Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta	**11-11-2020**	**Good**	1. Prof. Dr. Gul Majeed Khan, Quaid-e-Azam

	Road, Islamabad DML No. 000439 (Formulation) **Period**: Commencing on **04-10-2019** and ending on 0**3-10-2024** **<u>Sections (06):-</u>** 1. Oral Dry powder Suspension (General) 2. Tablet (Cephalosporin) 3. Capsule (General) 4. Capsule (Cephalosporin) 5. Oral Liquid (General) 6. Oral Dry powder Suspension (Cephalosporin)			University, Islamabad. 2. Dr. Mehwish, Deputy Director (QC-II), DRAP, Islamabad. 3. Area Federal Inspector of Drugs, DRAP, Islamabad.

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

*"*Keeping in view the above facts on record and the people met during the visit, the panel unanimously **<u>recommended the renewal of DML by</u>** of M/s Paramount Pharmaceuticals, plot #36, Industrial Triangle, Kahuta Road, Islamabad."

<u>The case is hereby submitted for consideration and orders of the Board, please.</u>

<u>Decision of the Central Licensing Board in 278th meeting</u>

The Board considered and approved the grant of renewal of DML No. 000439 By way of formulation in the name M/s Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road, Islamabadon the recommendations of the panel of experts for the period commencing on **04-10-2019** and ending on 0**3-10-2024** for the following sections:-

<u>SECTIONS (06)</u>

1. Oral Dry powder Suspension (General)
2. Tablet (Cephalosporin)
3. Capsule (General)
4. Capsule (Cephalosporin)
5. Oral Liquid (General)
6. Oral Dry powder Suspension (Cephalosporin)

10.	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**	1. Dr. Ikram Ul Haq, Member Central Licensing Board, 2. Mr. Azher Jamaal Saleemi, Chief Drugs Controller, Punjab 3. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.
	<u>Recommendations of the panel:</u> 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. — xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx **<u>Decision of the Central Licensing Board in 278th meeting</u>** 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, Lahore.on 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. — xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx			
11.	M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Indsutrial Estate, KotLakhpat, Lahore. DML No.000052(Formulation) Tenure 21-07-2020 to 20-07-2025.	**14-09-2020 &** **15-09-2020 &** **21-10-2020**	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board, 2. Dr. Arif Chaudhry, Deputy Director DRAP, Islamabad. 3. Ms. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore.
	<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's, material,management, air handling, water treatment system, personnel and documentatione,t,c, the panel **recommends** the renewal of Drug Manufacturing License to M/s CCL Pharmaceuticals (Pvt) Ltd, by way of Formulation to the following sections only, 1. Liquid Injectable (General).			

	2. Tablet (General). 3. Capsule (General). 4. Dry Powder(Suspension) . 5. Capsule (Steroid). 6. Oral Liquid Section. **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of renewal of (DML No. 000052) by way of formulation in the name M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Indsutrial Estate, KotLakhpat, Lahore.on the recommendations of the panel of experts for the period commencing **21-07-2020** and ending on **20-07-2025**for the following sections:- **SECTIONS (06)** 1. Liquid Injectable (General). 2. Tablet (General). 3. Capsule (General). 4. Dry Powder (Suspension) . 5. Capsule (Steroid). 6. Oral Liquid Section.			
12.	M/s Aurik Pharmaceuticals, Plot No. 6 & 7, Street No. S-9, National Industrial Zone, RCCI, Rawat. DML No.000802(Formulation) Period: Commencing on **19-09-2019** and ending on **18-09-2024**	**18-09-2020 &** **19-11-2020**	**Good**	1. Prof. Dr. Gul Majeed, Quaid-e-Azam University, Islamabad, Member Central Licensing Board, 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 **Recommends**M/s Aurik Pharmaceuticals Plot No. 6 & 7, Street No. S-9, National Industrial Zone, RCCI, Rawat under DML No. 000802 (Formulation). For the following sections namely. i. Tablet Section (General). ii. Capsule Section (General). **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of renewal of DML No. 000802 by way of formulation in the name M/s Aurik Pharmaceuticals, Plot No. 6 & 7, Street No. S-9, National Industrial Zone, RCCI, Rawat.on the recommendations of the panel of experts for the period commencing on **19-09-2019**and ending on **18-09-2024**for the following sections:-			

	Sections (02) 1. Tablet (General) Section. 2. Capsule (General) Section.			
13.	M/s Medipak Ltd, 132, Industrial Estate, KotLakhpat, Lahore. DML No.000257(Formulation) Period : Commencing on **25-07-2019** and ending on **24-07-2024**	**16-07-2020** **&** **18-11-2020** **&** **19-11-2020**	**Good**	1. Dr. Farzana Chaudhary, Expert Member. 2. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab 3. Ms. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: In view of above inspection proceeding and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery / equipment's, material, management, air handling, water treatment system, personnel and documentations e,t,c, the panel **recommends** the renewal of Drug Manufacturing License to M/s Medipak Ltd, 132, Industrial Estate, KotLakhpat, Lahore by way of Formulation to the following sections only, i. Eye Drop Section (General). ii. Liquid (LVP) Infusion. iii. Hemodialysis Solution Section. iv. Irrigation Solution Section. v. Medical Devises (Disposable IV Sets) vi. Tablet Section (General). vii. Capsule (General) Section. **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of renewal of (DML No. 000257) by way of formulation in the name M/s Medipak Ltd, 132, Industrial Estate, Kot Lakhpat, Lahore..on the recommendations of the panel of experts for the period commencing on **25-07-2019** and ending on **24-07-2024** for the following sections:- **Sections (06)** i. Eye Drop Section (General). ii. Liquid (LVP) Infusion. iii. Capsule Section(General). iv. Irrigation solution Section. v. Tablet Section (General). The Board also decided to refer the case for renewal of Hemodialysis Solution Section and Medical Devises (Disposable IV Sets) to the Medical Device and Medicated Cosmetics Division, DRAP, Islamabad.			
14.	M/s ICI Pakistan Limited Life Sciences, 45-Km, Off Multan Road,	**10-11-2020**	**Good**	i. Ms. Majida Mujahid, Federal Inspector of

	Lahore. DML No. 000811(Formulation) Period : Commencing on **02-04-2020** and ending on **01-04-2025**.			Drugs, DRAP, Lahore.. ii. Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore.
	<u>Recommendations of the panel:</u> 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. **<u>Decision of the Central Licensing Board in 278th meeting</u>** 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, Lahore...on the recommendations of the panel of experts for the period commencing **02-04-2020** and ending on **01-04-2025** for the following sections:- **<u>SECTIONS (03)</u>** 1. Liquid Injectable Section (SVP) (Veterinary) Section. 2. Oral Dry Powder (General) (Veterinary) Section. 3. Oral Liquid (General) (Veterinary) Section			
15	M/s Cherished Pharmaceuticals, 10-Km, Sunder Raiwind Road, Lahore. DML No. 000596 (Formulation) **Period**: Commencing on **11-07-2016** and ending on **10-07-2021**	25-09-2020	**Good**	i. Dr. Farzana Chaudhry, Member. ii. Dr, Zaka-Ur – Rehman, Government of Punjab. iii. Dr. Mehmood Ahmad, Ex Dean, University of Bahawalpur. iv. Ms. Ufaq Tanveer, Federal Inspector Drugs, DRAP, Lahore
	<u>Recommendations of the panel:</u> Keeping in view the facilities like building, HVAC system, Purified Water, Other Utilities, Production Machinery & Equipment's, Personnel, Documentation, Quality Control Instruments and Testing facilities the panel of Inspectors was of the opinion to **<u>Recommends</u>** renewal of M/s Cherished Pharmaceuticals, 10-Km, Sunder Raiwind Road, Lahore under DML No.00596 (Formulation)for following sections. i. Oral Liquid Section. (Veterinary) ii. Oral Powder Section (Veterinary)			

	iii. Liquid Injectable (Veterinary) **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of renewal of (DML No. 000596) by way of formulation in the name M/s Cherished Pharmaceuticals, 10-Km, Sunder Raiwind Road, Lahoreon the recommendations of the panel of experts for the period commencing on **11-07-2016** and ending on **10-07-2021** for the following sections:- **Sections (03)** i. Oral Liquid Section. (Veterinary) ii. Oral Powder Section (Veterinary) iii. Liquid Injectable (Veterinary)			
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).			
17	M/s Univet Pharmaceuticals, 14-KM, Adyala Road, Rawalpindi. DML No. 000424 (Formulation). **Period**: Commencing on **11-05-2020** and ending on **10-05-2025**	**01-12-2020**	Good	4. Prof. Dr. Gul Majeed, Quaid-e-Azam University, Islamabad. 5. Ms. Mahvash Ansari, DD (QC-II), DRAP, Islamabad. 6. Khalid Mahmood, FID, DRAP, Islamabad
	"Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the undersigned unanimously **Recommended** M/s Univet Pharmaceuticals, 14-KM, Adyala Road, Rawalpindi for renewal of Drug Manufacturing License No. 000424 for following sections. The Additional Section Liquid Vial (General) Veterinary may also been inspected which is to be approved and separate report as per letter as being sent pl:- 1. Oral Liquids General (Veterinary). 2. Oral Powder Section (Veterinary). 3. Liquid Vial Injection (Veterinary) (General). **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 from relevant Building Control Authorities (BCA) as per prevailing laws and ensure proper emergency exists alongwith firefighting equipments in the premises. The quality of individual batches of registered procedures and their safety shall remain the responsibility of the manufacturer as envisaged under the Drugs Act, 1976 read with DRAP Act, 2012. **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of renewal of (DML No. 000424) by way of formulation in the name M/s Univet Pharmaceuticals, 14-KM, Adyala Road, Rawalpindi.on the recommendations of the panel of experts for the period commencing on **11-05-2020**and ending on **10-05-2025**for the following sections:-			

	SECTIONS (03) 1. Oral Liquids General (Veterinary). 2. Oral Powder Section General (Veterinary). 3. Liquid Vial Injection General (Veterinary)			
18.	M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, DML No. 000600 (Formulation). **Period**: Commencing on 15-09-2016 and ending on 14-09-2021	**01-12-2020**	**Good**	1. Prof. Dr. Gul Majeed, Member, CLB, Quaid-e-Azam University, Islamabad. 2. Ms. Mahvash Ansari, DD (QC-II), DRAP, Islamabad. 3. Mr. Hasan Afzaal, FID-III, DRAP, Islamabad
	"Keeping in view the above facts, detailed visit of facility considering the improvements made from last inspection the panel unanimously has rated the firm to be operating at Good Level of GMP compliance and **Recommends** M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad for the Renewal of Drug Manufacturing License No. 000600 (Formulation) for the following sections namely; 1. Tablet Section (General). 2. Capsule-I Section (General). 3. Capsule-II Section (General). 4. Tablet Section (Psychotropic). 5. Cream / Ointment Section (General). 6. Dry Suspension Section (General). 7. Sachet Section (General). 8. Sterile Ophthalmic (General). The panel has also verified the amendments in the Layout of the following sections; 9. Capsule (Ceph). 10. Dry Powder for Suspension (Ceph). **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of renewal of (DML No. 000600) by way of formulation in the name M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, on the recommendations of the panel of experts for the period commencing on **15-09-2016** and ending on **14-09-2021**for the following sections:- **SECTIONS (08)** 1. Tablet Section (General). 2. Capsule-I Section (General). 3. Capsule-II Section (General). 4. Tablet Section (Psychotropic). 5. Cream / Ointment Section (General). 6. Dry Suspension Section (General).			

	7. Sachet Section (General). 8. Sterile Ophthalmic (General).			
19.	M/s Vega Pharmaceuticals (Pvt) Ltd, Pharma city, 30-KM Multan Road, Lahore, DML No. 000542 (Formulation). **Period**: 16-07-2019to 15-07-2024	**28-09-2020** **15-10-2020** **10-11-2020**	**Good**	1.Dr. Farzana Choudhary, Expert , Member, Lahore. 2.Mr.Azhar Jamal Saleemi, Chief Drugs Controller, Punjab. 3.Ms. Uzma Barkat, FID, DRAP, Islamabad
	a. Some discrepancy was noted in the section names mentioned in DRAP Islamabad letter No.F. 1-22/2001-Lic (Vol-II) dated 09-10-2020. The sections inspected physically for which the firm has already registered products and that were previously granted drug manufacturing license renewal w.e.f. 16-07-2014 also are enlisted below accordingly based on dosage form. b. The firm was directed to get the existing layout plan for facility and the sections approved / regularized from DRAP, Islamabad without fail. c. In the light of the inspection conducted by the panel and based on the findings and registered products of the firm, the panel of inspectors recommends grant of renewal of drug manufacturing license y way of formulation of M/s Vega Pharmaceuticals (Pvt) Ltd, Pharma city, 30-KM Multan Road, Lahore, for the following sections and some changes in the nomenclature of existing sections are also suggested* as given below; i. Tablet Section (General). ii. Capsule Section (General). ii. Eye, Ear Drops & Nasal Section (General) (Eye / Ear Drops, Nasal Spray)* v. Eye, Ear Drops & Nasal Section (Steroid) (Eye / Ear Drops, Nasal Spray)* v. Capsules (Cephalosporin). i. Oral Dry Powder for Suspension (Cephalosporin). ii. Dry Powder for Injection (Cephalosporin). d. The panel of inspectors recommends grant of renewal of DML of previously approved **Semisolid (Ointment / Cream / Gel) (Steroid) Section** on first floor for manufacturing of **Ophthalmic Semisolid (Ointment / Cream / Gel) Steroid and General*** preparations only with campaign manufacturing and ensuring cleaning validation studies as per DRAP policy. e. The panel of inspectors recommends grant of renewal of DML of previously approved **Semisolid (Ointment / Cream / Gel) (General) Section** on ground fllor for manufacturing of **External Semisolid (Ointment / Cream / Gel) Steroid and General*** preparations for topical administration only **(and not for Ophthalmic preparations)** with campaign manufacturing and ensuring cleaning validation studies as per DRAP policy. **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of renewal of (DML No. 000542) by way of formulation in the name M/s Vega Pharmaceuticals (Pvt) Ltd, Pharma city, 30-KM Multan Road, Lahore, on the recommendations of the panel of experts for the period commencing **16-07-2019** and ending on **15-07-2024**for the following sections:- **SECTIONS (09)** 1. Tablet Section (General).			

	2. Capsule Section (General). 3. Eye Drops Section(General). 4. Eye Drops Section (Steroid). 5. Capsule (Cephalosporin). 6. Dry Suspension Section (Cephalosporin). 7. Dry Powder Injectable (Cephalosporin). 8. Ointment / Cream / Gel) (Steroid Section 9. Ointment / Cream / Gel) (General Section The Board also decided to advise the firm to submit Lay Out Plan for regularization as recommended by the panel of experts.			
20	M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore. DML No. 000537 (Formulation) Period :Commencing on **17-04-2019** and ending on **16-04-2024**.	04-11-2020	**Good**	1. Dr. Farzana Chaudhry, Expert Member. 2. Dr. Ikram Ul Haq, Member Central Licensing Board. 3. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.
	<u>Recommendations of the panel:</u> Keeping in view the improvements made by the firm and commitment for future improvement, the members of the panel are of opinion to **recommend** the grant of renewal of Drug Manufacturing License (000537) by way of formulation. i. Tablet (General) Section. ii. Capsule (General) Section. iii. Oral Dry Powder Suspension (Antibiotic) Section. iv. Tablet (Antibiotic) Section. v. Oral Dry Powder Suspension (Cephalosporin) Section. vi. Capsule (Cephalosporin) Section. **<u>Decision of the Central Licensing Board in 278th meeting</u>** The Board considered and approved the grant of renewal of (DML No. 000537) by way of formulation in the name M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahoreon the recommendations of the panel of experts for the period commencing on **17-04-2019** and ending on **16-04-2024**for the following sections:- **<u>Sections (06)</u>** i. Tablet (General) Section. ii. Capsule (General) Section. iii. Oral Dry Powder Suspension (Antibiotic) Section.			

	iv. Tablet (Antibiotic) Section. v. Oral Dry Powder Suspension (Cephalosporin) Section. vi. Capsule (Cephalosporin) Section.			
21	M/s Dyson Research Laboratories (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore. DML No. 000559 (Formulation) Tenure 09-12-2019 to 08-12-2024.	**13-07-2020**	**Good**	1. Dr. Farzana Chaudhary, Expert Member. 2. Dr. Ikram ul Haq, Member, CLB. 3. Mr. Shoaib Ahmad, Federal Inspector of Drugs, DRAP, Lahore
	Recommendations of the panel: The panel of inspectors **recommends** the renewal of Drug Manufacturing License of M/s Dyson Research Laboratories (Pvt) Ltd, Located at 28-Km, Ferozepur Road, Lahore (bearing DML No. 000559 by way of Formulation of following approved sections). i. Tablet (General) Section. ii. Tablet (Hormonal) section. iii. Liquid syrup (General). iv. Oral Dry Powder Suspension (General). v. Capsule (General) section. **Decision of the Central Licensing Board in 278th meeting** The Board considered and approved the grant of renewal of (DML No. 000559) by way of formulation in the M/s Dyson Research Laboratories (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore on the recommendations of the panel of experts for the period commencing **09-12-2019** and ending on **08-12-2024**for the following sections:- **Sections (05)** i. Tablet (General) Section. ii. Tablet (Hormonal) section. iii. Liquid syrup (General). iv. Oral Dry Powder Suspension (General). v. Capsule (General) section.			
22	M/s Hawk Bio (Pvt) Ltd, Plot No. 10, Street No. S-6, National industrial Estate, RCCI, Rawat. DML No. 000798 (Formulation)	19-11-2020	Good	4. Dr. Hafsa Karam Elahi, Additional Director (QA &LT),DRAP, Islamabad. 5. Mr. Manzoor Ali Bozdar Additional Director, (Licensing Division) DRAP,

	Period: Commencing on **03-07-2019** and ending on **02-07-2024**.			Islamabad. 6. 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;

iii. Packing Material Store (Expansion) (Ground Floor Veterinary)
iv. 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, Rawaton 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)

ITEM – IV MISC CASES

Case No. 01 NOC FROM MINISTRY OF NARCOTICS CONTROL.

Ministry of Narcotic Control, Islamabad vide letter No. 5-8/2012-Ppoilic-I dated 06/11/2020 along with letter from Anti Narcotics Force, Rawalpindi Letter No. 37(1) ANF/I&E/2020 dated 02/11/2020 have forwarded decision of Committee of Allocation Quota of Controlled Substance in its 71st Meeting held on 14/10/2020. Content of the letter is reproduced as under.

"During 71st Meeting of CAQCS it has been observed that NOCs for allocation of controlled / narcotic / psychotropics substances have issued to persons allegedly involved in illegal activities in the past. In order to avoid recurrence of such incidents/cases in future, it is suggested that MCNC should take up the case with Central Licensing Board to issue licenses to pharmaceutical firms that are manufacturing / importing / exporting / using controlled, narcotic and psychotropic substances subject to NOC from ANF. Same shall also be applied to applicants who apply for change of ownership during business."

Similarly, Division of Controlled Drugs, DRAP vide letter no. 5-4/2020-CD date 10/11/2020 also forwarded decision of Committee of Allocation Quota of Controlled Substance in its 71st Meeting held on 14/10/2020 which is reproduced as under;

"Please refer to the subject citied above and to the Headquarters Anti Narcotics Force's letter Case No.37(1)ANF/I&E/2020 dated 14th October, 2020 on the subject cited above regarding the share holding of Mr. Ansar Farooq S/o Muzammil Hussain in M/s Medizan Laboratories (Pvt.) Ltd. Islamabad, who happens to be a prime accused in Case FIR No.40/2011 PS ANF Rawalpindi with the allegation to get huge quantity of chemical precursor i.e. Ephedrine and its diversion/sale to smugglers.

A. After confirmation of the shareholding of Mr. Ansar Farooq s/o Muzammil Hussain in the management of M/s Medizan Laboratories (Pvt.) Ltd. Islamabad, from Drugs Licensing Division of DRAP, as per recommendation of ANF, the matter of cancellation of import permits/authorizations granted to the company in the light of decisions of the 70th meeting of the Committee for Allocation of Quota of Controlled Substances (CAQCS) held on 20-08-2020 was placed before the CAQCS in its 71st meeting held on 28th October, 2020. The meeting was Chaired by the Secretary, Ministry of Narcotics Control, Islamabad. ***The Committee discussed the matter in detail and decided as follows****:*

(i) The ANF shall conduct ground check inspection of the premises of M/s Medizan Laboratories (Pvt.) Ltd. Islamabad and Area Federal Inspector of Drugs may be co-opted for the said purpose, if required for technical input during the inspection.

(ii) The ANF shall prepare reference to be forwarded to the Law and Justice Division for legal opinion regarding the quota allocation of controlled substance to the pharmaceutical firm (s) / individuals involved in Ephedrine Scam that took place in the year 2012.

(iii) The Drug Licensing and PE&R Division of the DRAP shall also oversee their policy for grant of Psychotropic Section and the registration of products containing controlled substances to the firms. The Psychotropic Section and the registration of products containing controlled substances to the firms shall be given to the applicant firms after issuance of NOC from Ministry of Narcotics Control. The cases of the firms already possessing the Psychotropic Sections and registrations of the products containing controlled substances should be forwarded to MNC for seeking the NOC to regularize the procedure.

B. It is therefore requested that the above said decision of the competent forum i.e. Committee for Allocation of Quota of Controlled Substances (CAQCS) shall be complied with in letter and spirit."

The case is hereby submitted for consideration and orders of the Board, please

Decision of the Central Licensing Board in 278th meeting

The Board considered and decided to inform Pharma Bureau and Pakistan Pharmaceutical Manufacturing Association (PPMA) for compliance of the decision of Committee of Allocation Quota of Controlled Substance (CAQCS) and letter of Ministry of narcotics Control.

Case No. 02 SUSPENSION OF LICENSE OF M/S ONYX PHARMACEUTICALS, 30-A, SMALL INDUSTRIAL ESTATE, MANSEHRA, PAKISTAN.

A letter No. 269 dated 10th May, 2019 is received from Hon'ble Mr. Mehta Rajesh Nath Kohli, Chairman, Drug Court Quetta, Balochistan wherein he has stated that a case No. 49/2017 is pending against Hafiz Muhammad Arif and Maaz Mehmood owners of M/s Onyx Pharmaceuticals, 30-A, Small Industrial Estate, Mansehra, Pakistan in which accused namely Mr. Maaz Mehmood being the owner has been charged with the commission of the offence and he is intentionally and deliberately avoiding to appear before this Court. It is therefore directed to suspend the license of the above mentioned company after fulfilling the requisite requirement as per law and intimate the same to this Court at your earliest.

Decision by the Central Licensing Board in 270th meeting:

The Board in compliance to orders of Hon'ble Chairman, Drug Court Quetta, Balochistan 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 suspension of Drug Manufacturing Licence.

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

The firm was issued show cause notice as per decision of Central Licensing Board on 03rd July, 2019.

Reply of the firm.

The firm has replied vide their letter dated 19-07-2019, wherein the firm has forwarded copy of court orders of High Court of Balochistan, Quetta. The detail of Court order is as under;

"In the meanwhile, the implementation of the impugned order dated 18th June, 2019 and the impugned Murasla dated 10th May, 2019, passed by the Chairman Drug Court, Balochistan, Quetta are hereby suspended till the next date of hearing."

Proceedings and Decision of the Central Licensing Board in 271st meeting

The Board after perusal of facts on record decided to seek further confirmation of stay order as mentioned in the Order of the Hnourable High Court dated 18th June, 2019 from the firm as well as area Federal Inspector of Drugs and deferred the case till next date of meeting.

Now an Order is received from the High Court of Balochistan, Quetta, which is re-produced as under;

"Mr. Manzoor Ali Bozdar, Additional Director, DRAP/Secretary Central Licensing Board Islamabad entered appearance and state that details have already been submitted before the Court and though the Federal Inspector of Drugs ('FID') are being posted by the Chief Executive Officer (CEO). However, powers with regard to registration of criminal cases, raids, sealing and seizure cannot be delegated without requisite notification by the Federal Government. He also submitted the copies of correspondence between DRAP and the Ministry of National Health Services, Islamabad.

2. In the instant case, the order passed by the Drug Court could not be implemented initially due to non-issuance of requisite notification and subsequently the ati-interim suspension order passed by this Court. However, we are dismayed to observe that the present Federal Inspector of Drugs was posted in January, 2020, but the Ministry has not taken any serious notice with regard to issuance of notification, while earlier charge was assigned to FID of Karachi Region, and we are unable to comprehend that for inspection of Pharmaceutical factories in Balochistan the charge was given to an FID of Karachi, which is a serious violation of Constitution of Pakistan and against the Provincial Autonomy.

Be that as it may, office to issue notice to CEO Drugs and Federal Secretary Ministry of Health Services Government of Pakistan, which shall accompany the copy of this order with direction either to ensure the issuance of requisite notification for the Province of Balochistan, and, in case of failure, to appear in person and submit a report in a personal capacity.

3. As far as the case of Onyx Pharma is concerned, since it relates to Provincial Quality Control Board. Therefore, the Secretary Provincial Quality Control Board is directed to proceed strictly in accordance with law and submit a report in this behalf. The officials present in court are directed to furnish the requisite details before the court on next date hearing.

To come up on 07.12.2020.

s/d MUHAMMAD KAMRAN KHAN MULAKHAIL
JUDGE
s/d ROZI KHAN BARRECH
JUDGE"

Accordingly a letter for personel hearing is issued to the firm vide letter No.F.3-4/90-Lic (Vol-I) dated 01-12-2020.

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

Decision of the Central Licensing Board in 278th meeting

Mr. Zahid Shafique, Director and Mr. Kamran Makhdoom General Manager Admin appeared on behalf of the firm . They contended that they were new management while drug was manufactured during the period of previous management.The Board after hearing the

representatives of the firm and consideringthe Order of the High Court of Balochistan, Quetta decided to suspend the Drug Manufacturing License No. 000440(by way of Formulation) of M/s Onyx Pharmaceuticals, 30-A, Small Industrial Estate, Mansehra, in the light of the Orders of the Drug Court of Balochistan, Quetta dated 10th May, 2019 till further orders.

Case No. 03. **REQUEST/APPLICATION FOR RETAINNG A SUBSTANTIAL PORTION OF CRF FOR THE YEAR 2017 BY M/S. GETZ PHARMA (PVT) LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000284(FORMULATION)**

M/s Getz Pharma (Pvt) Limited Karachi has submitted request for retaining substantial portion of CRF and has stated as under;

1. At the outset, we would like to state that Sub-Rule 14 of Rule 19 of the Licensing, Registering and Advertising Rules, 1976 (LR&A Rule), requires a pharmaceutical company to contribute one percent of its gross profit before deduction of income tax towards the Central Research Fund to be maintained by the Federal Government.
2. However; under the proviso to this Sub-Rule 14 of Rule 19, the Central Licensing Board may allow a portion of such contribution to be spent by the Firm/Pharmaceutical Company itself for research and development of new drugs or for establishing research laboratories, when it is satisfied that such expenditure is being utilized for the said purpose effectively and properly.
3. To keep the record straight, we would like to submit that Getz Pharma has been paying CRF to DRAP since 1995. The total amount of CRF paid as of today in the last 21 years is Rs. 295.73 million [from 1995-2016].
4. We note with great regret that billions of rupees are lying unutilized in the Central Research Fund for which the pharma companies including Getz Pharma has contributed one percent profit to the CRF under the Rule LR&A Rules.
5. It is submitted that the total one percent CRF contribution of Getz Pharma for the year, 2017, comes to Rs. 86.49 million. However, the sums of investments

made towards research and development of new drugs and/or for establishing research laboratories in the year, 2017, are Rs. 232 million. As it is obvious, the amount of investments and expenditure incurred by Getz Pharma in the year, 2017, it almost three times more than the annual CRF contribution of Getz Pharma for the year, 2017.

6. Therefore, in view of the forgoing provisions and submissions, we would like to make our requests as follows:

    i. **In accordance with Sub-Rule (14) of Rule 19 of the LR & A Rules, Getz Pharma may kindly be allowed to retain a substantial portion out of one percent CRF annual contribution on the grounds that it has already made substantial investment towards development of new drugs and establishing research laboratories/facilities, in the year, 2016, which investments exceed the prescribed limit of one percent. A summary of investments and audit reports are enclosed herewith (which can be substantiated with documentary proof as and when so required). We would also like to note that Getz Pharma is continuously making, and will be making, investments towards the development of new drugs and establishing research laboratories/facilities and we are willing to provide details of such continuous and future investments, as and when required (subject to requirements of business and trade confidentiality).**

    ii. **We should be informed as to the quantum of the CRF contribution which can be retained by Getz Pharma.**

    iii. As you are already aware, and as is our legal right, the contribution to CRF is subject to intimation by DRAP regarding the quantum of the contribution which can retained by the company. Therefore, once you have informed us as to how much of the contribution can be retained by Gets Pharma

and what the balance reminder amount is, the balance remainder amount will be deposited by Getz Pharma.

iv. In the meantime, no adverse or coercive action, including but not limited to suspension of Getz Pharma's routine work concerning pending or new registration applications, should be taken by DRAP. Please note that in relation to CR amount, we have filed a Constitution Petition No. 3896 of 2016, which is pending before the Honorable High Court of Sindh, and through Order dated 01-07-2016, the Honorable High Court has been pleased to restrain DRAP from takingany adverse or coercive action against us. Therefore, if any adverse or coercive action, including but not limited to suspension of Getz Pharma's routine work concerning the pending new registration applications is taken against Getz Pharma by DRAP, We reserve the right to institute contempt proceedings against you and other relevant officials. Similarly, another Const. Petition No. D-5820 of 2017 is also pending before the Honorable Sindh High Court in relation to CRF amounts for the year, 2016, and the Honorable Sindh High Court was pleased; vide Order dated 11-4-2018, to restrain, inter-alia, DRAP from taking any adverse/coercive action against Getz Pharma.

Budget & Accounts Division, DRAP, Islamabad has also 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. Getz Pharma (pvt) Ltd, Karachi having DML no. 000284 has submitted CRF till year 2014. 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.

Decision by the Central Licensing Board in 269th meeting:

The Board considered and deferred the case till decision by the Court on the matter since the matter is *sub- judice*.

Now request submitted by M/s Getz Pharma (Pvt) Ltd, Karachi for retaining a substantial portion of CRF for the year 2019 was considered by the DRAP Authority in its 91st meeting of the Authority wherein following decision has been made :

> ''The Authority endorsed the proposal of Legal Affairs Division to forward the case of utilization of portion of CRF by the firm to Secretary CLB for placing the same before the Central Licensing Board under proviso of rule 19(14) of the Drugs (L,R&A) Rules, 1976 along with legal interpretation made by Division of Legal Affairs.''

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

The Board has been apprised that there are three petitions pending before High Court of Sindh and there is some injunction order of the said Court restraining the respondents to take adverse action against the petitioner firm/ company. The petitioner firm/ company has sought relief in accordance with Sub-rule (14) of the Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 having enabling provision under Section 12 of the Drug Regulatory Authority of Pakistan Act, 2012 for the purpose of utilizing certain portion of Central Research

Fund (CRF) due ~~to~~ from him since long without approval of the authorities in respect of research and development of new drugs or for establishing research laboratories. Perusal of the record placed before the Board shows that the petitioner firm has not so far provided a plan in accordance with the aforesaid provisions of law on the basis of which it seeks approval of the Board for utilization of certain part of its outstanding CRF for the purpose of research and development of new drugs or for establishing research laboratories, if any, which new drugs or laboratories, it is responsibility of the firm, to identify. In these circumstances the Board unanimously decided that, without prejudice to any existing order of the said Court and any other court and also subject to ultimate decision of the said Court and any other court and judicial forums, in the first instance the three petitions should be vigorously pursued in the Court with due care and also for vacation of injunction order, if any. Simultaneously the petitioner firm may be advised to make application as per applicable law, statutory rules and procedure by submitting a plan for making research on a new drug to be identified in the said application or, as the case may be, for establishing research laboratories, similarly to be identified in the said application . Thereafter, his request will be considered in accordance with applicable provisions of law, statutory rules and procedures as well as in accordance of orders of the said Court and all other courts and judicial fora in this regard.

Compliance of the Decision of the Board :

In the light of decision of the Central Licensing Board a letter Dated : 04-11-2020 was issued to the firm M/s. Getz Pharma (Pvt) Ltd, Karachi wherein firm was asked to file proper application in the light of the decision of the Central Licensing Board for further processing the matter. Letter was also issued to Deputy Director (Legal Affairs, Division) DRAP to vigorously pursue the writ petitions of the firm in the court with due care for vacation of injunction order/stay at the earliest.

Order of the Honorable High Court of Sindh at Karachi :

In the meanwhile, a letter was received from M/s. Getz Pharma (Pvt) Ltd, Karachi wherein firm forwarded/enclosed the order of Honorable High Court of Sindh, Karachi dated : 12-11-2020 in the Constitutional petitions No. D-3896/2016, 5820/2017 & 4579/2019 filed by M/s. Getz Pharma (Pvt) Ltd, Karachi. Detailed order of the Honorable High Court of Sindh, Karachi is as under :

"Mr. M. Akbar Awan. Advocate has filed vakalatanama for the DRAP in C.P. No. D-4579/2019. Basically, in this petition and connected constitution petition No. D-3896/2012 and 5820/2017 the basic question is with regard to the application and interpretation of Rule 19(14) of Drug (Licensing, Registration and Advertising) Rules, 1976 and the said rule is also reproduced in the petition. The counsel for the petitioners argued that in terms of the proviso attached to the said rule they have already applied to DRAP so that some portion of contribution may be allowed to be spent by the petitioners for research and development of new drugs and for establishment of research laboratories but the applications are pending for last many years without any action by the DRAP. At this juncture, the learned counsel for the DRAP submits that all the applications of the petitioners will be decided within a period of thirty days. **We order that competent authority, before passing order on the applications of the petitioners, shall provide opportunity of hearing to the representative of the petitioners so that they may produce all relevant documents in support of their applications thereafter speaking orders shall be passed and communicated to the petitioners.** Under the first portion of the said rule it is obligatory on the license to contribute 1% of gross profit before deduction of income tax towards the central research fund to be maintained by the Federal Government and utilized in accordance with the Drugs (Research) Rules, 1978. Counsel for the petitioners argued that though they are collecting the contribution for last several years but no research center has been established by the Federal Government in terms of Drugs (Research) Rules, 1978 but this contribution has not been utilized for the purpose of research and development. The counsel for the DRAP will also come up with progress report on this aspect as to whether this amount is being consumed on the research and development or not. By consent adjourned to 15.12.2020.

Interim order passed earlier to continue till next date in the matters it is already in force.

Office is directed to place copy of this order in the connected petitions listed above."

Letter of Personal Hearing :

In compliance of the orders of Honorable High Court Sindh at Karachi, the firm has been called in person in 278th meeting of the Central Licensing Board scheduled to be held on 10th& 11th December 2020. Accordingly, letter has been issued on 27th November 2020 through UMS and conveyed to representative of the company through Whats App as well.

Submitted for consideration of the Board, please.

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

Mr. Malik Ayub, Director Corporate Affairs, Mr. M. Zeeshan, Director Business development and R&D, Ms. Aisha Zaman, Senior manager Costing, Ms. Marrium Malik, Legal Counsel and Mr. Shahid Memon, Director Legal appeared on behalf of M/s. Getz Pharma (Pvt) Ltd, Karachi. They made a powerpoint presentation and submitted written applications for retaining portion of CRF from 2015 to 2019 and referred to the Order of the Honourable High Court Sindh at Karachi dated 12-11-2020. They stated that they were not aware about the procedure for getting portion of CRF from Central Licensing Board. They further stated if they had made contribution as provided in Rule 19 (14) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 they might not be able to get portion from Central Licensing Board due to lack of clarity of procedure before them therefore, they submitted application with Central Licensing Board and approached Honourable High Court Sindh, Karachi for relief.

They stated that they had made huge investment in development of drugs and establishment of laboratories and expenditure incurred is more than CRF due to them, therefore, their applications may be considered in their favour and they may be allowed to retain CRF due to them.

The Board made specific questions from the persons appeared on behalf of M/s. Getz Pharma (Pvt) Ltd, Karachi as under:-

Q 1. Could you mention the names of new drugs developed by M/s. Getz Pharma (Pvt) Ltd, Karachi?

Ans. Our research is in generic development and we have done bioequivalence studies. We have also got WHO accreditation. Our growth rate is evidence of quality of our drugs. They failed to provide any specific details of new drugs and remained silent.

Q2. Whether your applications are for retaining portion of CRF for development of new drug or establishment of laboratories?

Ans. Our application is for both.

Sub-rule 14 of the Rule 19 was read proviso before the Board in the presence of persons appearing on behalf of the M/s. Getz Pharma (Pvt) Ltd, Karachi which is also reproduced as under:

"(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.

Provided that Central Licensing Board may allow a portion of such contribution to be spent by the firm itself for research and development of new drugsorfor establishing research laboratories when it is fully satisfied that such expenditure will be utilized for the said purpose effectively and properly."

The Board observed that enquired from the persons appearing on behalf of the M/s. Getz Pharma (Pvt) Ltd, Karachi that they were aware of the procedure for submission of Central Research fund previously with Federal government through Budget and Accounts Division which realizes the actual amount due to the company and said Division is competent to scrutinize the documents submitted by the company including but not limited to the documents for Audit and Accounts for ascertaining actual amount of CRF due to a company as provided in sub-rules (14), (14-A) and (15) of rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Mr. Shahid Memon appearing on behalf of the M/s. Getz Pharma (Pvt) Ltd, Karachi reiterated that they had doubt if they had made contribution they might not be able to get portion of the CRF therefore they preferred to approach Honourable High Court Sindh, Karachi.

The Board also observed that law should be complied in its letter and spirit rather than on presumptions. The Board further observed, without prejudice to any order of the Court, that M/s. Getz Pharma (Pvt) Ltd, Karachi has not be able to submit any evidence in support of development of new drug rather their research pertains to generic development. The board also observed that their application is not in accordance of law as proviso of Rule 19 (14) of the Drugs (Licenisng, Registering and advertising) Rules, 1976 provides for separate application for development of new drugs and establishment of laboratories. The Board also observed that reliance could only be made for allowing portion of contribution of CRF after actual realization of amount of CRF due to company and in absence of any realization and submission of contribution as provided under the rules would be real impediment to adjucate.

The Board therefore decided that petitioner may be asked to make contribution as provided under Rule 19 (14), (14-A) and (15) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

and then file application for allowing portion of such contribution as provided in the said rules. The Board also reiterated its earlier decision that petitioner firm may be advised to make application as per applicable law, statutory rules and procedure by submitting a plan for making research on a new drug to be identified in the said application or, as the case may be, for establishing research laboratories, similarly to be identified in the said application . Thereafter, his request will be considered in accordance with applicable provisions of law, statutory rules and procedures as well as in accordance of orders of the said Court and all other courts and judicial fora in this regard.

Case No. 04. <u>CHANGE OF MANAGEMENT OF M/S. VETZ PHARMACEUTICAL (PVT) LTD, KOTRI SINDH.</u>

M/s. Vetz Pharmaceutical (Pvt) Ltd, Q-1, SITE Kotri Sindhunder DML No. 000813 (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 50,000/-. The detail of management is as under:-

Current Management as per Form-29 Year 2013	New Management as per Form-29 Year 2020
1. Mr. Mohammad IshaqueMemon S/O Ghulam Akbar Memon CNIC NO. 41306-9730657-3. 2. Miss. NazmaMemon W/O Mohammad IshaqueMemon CNIC NO. 41306-7851813-8 3. Mr. Salman Khan S/O Ghulam Akbar Memon CNIC No. 41306-5853437-5	1. Mr. Mohammad IshaqueMemon S/O Ghulam Akbar Memon CNIC NO. 41306-9730657-3. 2. Miss. NazmaMemon W/O Mohammad IshaqueMemon CNIC NO. 41306-7851813-8

Submitted for consideration of the board, please.

<u>Decision of the Central Licensing Board in 278th meeting:</u>

The Board considered and endorsed the change of management M/s. Vetz Pharmaceutical (Pvt) Ltd, Q-1, SITE Kotri Sindhunder DML No. 000813 (By way of formulation) (By way of Formulation) as under ;

Current Management as per Form-29 Year 2013	New Management as per Form-29 Year 2020
1. Mr. Mohammad IshaqueMemon S/O Ghulam Akbar Memon CNIC NO.	1. Mr. Mohammad IshaqueMemon S/O Ghulam Akbar Memon CNIC NO.

41306-9730657-3. 2. Miss. NazmaMemon W/O Mohammad IshaqueMemon CNIC NO. 41306-7851813-8 3. Mr. Salman Khan S/O Ghulam Akbar Memon CNIC No. 41306-5853437-5	41306-9730657-3. 2. Miss. NazmaMemon W/O Mohammad IshaqueMemon CNIC NO. 41306-7851813-8

Case No. 05. <u>CHANGE OF MANAGEMENT OF M/S. BROOKES PHARMA PRIVATE LTD, KARACHI.</u>

M/s. Brookes Pharma (Pvt) Ltd, Plot No. 58-59 Sector 15 Korangi Industrial Area Karachi under DML No. 000275 (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 50,000/-. The detail of management is as under:-

Current Management as per Form-29 Year 2019	New Management as per Form-29 Year 2020
1. Mr. Abdul Haseeb Khan S/O Abdul Hafeez Khan CNIC NO. 42201-7147924-1 2. Mr. Saleem Khan S/o Abdul Haseeb Khan CNIC No. 42201-7251474-1. 3. Mr. Nadeem Khan S/O Abdul Haseeb Khan CNIC NO. 42201-3511776-7. 4. Mr. Waseem Iqbal Khan S/o Haseeb Khan CNIC No. 42201-537677-3	1. Mr. Abdul Haseeb Khan S/O Abdul Hafeez Khan CNIC NO. 42201-7147924-1 2. Mr. Nadeem Khan S/O Abdul Haseeb Khan CNIC NO. 42201-3511776-7. 3. Mr. Saleem Khan S/o Abdul Haseeb Khan CNIC No. 42201-7251474-1. 4. Mr. Omar Khan S/o Nadeem Khan CNIC No. 42201-4683581-5.

<u>Decision of the Central Licensing Board in 278th meeting:</u>

The Board considered and endorsed the change of management M/s. Brookes Pharma (Pvt) Ltd, Plot No. 58-59 Sector 15 Korangi Industrial Area Karachi under DML No. 000275 (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 as per Form-29 Year 2019	New Management as per Form-29 Year 2020
1. Mr. Abdul Haseeb Khan S/O Abdul Hafeez Khan CNIC NO. 42201-7147924-1	1. Mr. Abdul Haseeb Khan S/O Abdul Hafeez Khan CNIC NO. 42201-7147924-1

2. Mr. Saleem Khan S/o Abdul Haseeb Khan CNIC No. 42201-7251474-1. 3. Mr. Nadeem Khan S/O Abdul Haseeb Khan CNIC NO. 42201-3511776-7. 4. Mr. Waseem Iqbal Khan S/o Haseeb Khan CNIC No. 42201-537677-3	2. Mr. Nadeem Khan S/O Abdul Haseeb Khan CNIC NO. 42201-3511776-7. 3. Mr. Saleem Khan S/o Abdul Haseeb Khan CNIC No. 42201-7251474-1. 4. Mr. Omar Khan S/o Nadeem Khan CNIC No. 42201-4683581-5.

Case No. 06. <u>CHANGE OF MANAGEMENT OF M/S. SAMI PHARMACEUTICALS (PVT) LTD, KARACHI.</u>

M/s. Sami Pharmaceuticals (Pvt) Ltd, F-95, Off. Hub River Road, S.I.T.E Karachi under DML No. 000072 (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 50,000/-. The detail of management is as under:-

Previous Management as per Form-29 from SECP[Year 2017]	Current Management as per Form-29 from SECP [Year 2020]
1. Mr. Shamim Ahmed S/o S.M. Rafi CNIC No. 42201-0709868-7. 2. Mr. Muhammad Yasin Malik S/o Hameed Eid Muhammad CNIC No. 42301-0668555-7. 3. Ovais Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-5. 4. Mr. Zubair Shamim S/o Shamim Ahmed CNIC No. 42201-0709872-3. 5. Mr. Shoaib Shamim S/o Shamim Ahmed CNIC No. 42201-0709871-7. 6. Mr. Junaid Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3. 7. Mr. Abdul Salam S/o Zik-ur-Rehman CNIC No. 42201-6555398-5.	1. Mr. Shamim Ahmed S/o S.M. Rafi CNIC No. 42201-0709868-7. 2. Mr. Muhammad Yasin Malik S/o Hameed Eid Muhammad CNIC No. 42301-0668555-7. 3. Mr. Ovais Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-5. 4. Mr. Zubair Shamim S/o Shamim Ahmed CNIC No. 42201-0709872-3. 5. Mr. Junaid Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3. 6. Mr. Abdul Salam S/o Zik-ur-Rehman CNIC No. 42201-6555398-5.

<u>Decision of the Central Licensing Board in 278th meeting:</u>

The Board considered and endorsed the change of management M/s. Sami Pharmaceuticals (Pvt) Ltd, F-95, Off. Hub River Road, S.I.T.E Karachi under DML No. 000072 (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 from SECP[Year 2017]	Current Management as per Form-29 from SECP [Year 2020]
1. Mr. Shamim Ahmed S/o S.M. Rafi CNIC No. 42201-0709868-7. 2. Mr. Muhammad Yasin Malik S/o Hameed Eid Muhammad CNIC No. 42301-0668555-7. 3. Ovais Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-5. 4. Mr. Zubair Shamim S/o Shamim Ahmed CNIC No. 42201-0709872-3. 5. Mr. Shoaib Shamim S/o Shamim Ahmed CNIC No. 42201-0709871-7. 6. Mr. Junaid Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3. 7. Mr. Abdul Salam S/o Zik-ur-Rehman CNIC No. 42201-6555398-5.	1. Mr. Shamim Ahmed S/o S.M. Rafi CNIC No. 42201-0709868-7. 2. Mr. Muhammad Yasin Malik S/o Hameed Eid Muhammad CNIC No. 42301-0668555-7. 3. Mr. Ovais Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-5. 4. Mr. Zubair Shamim S/o Shamim Ahmed CNIC No. 42201-0709872-3. 5. Mr. Junaid Shamim S/o Shamim Ahmed CNIC No. 42201-0709876-3. 6. Mr. Abdul Salam S/o Zik-ur-Rehman CNIC No. 42201-6555398-5.

Case No. 07. <u>CHANGE OF MANAGEMENT OF M/S. GELCAPS PAKISTAN LTD, KARACHI.</u>

M/s. Gelcaps Pakistan Ltd, Karachi Plot No. B-43, H.I.T.E District Lasbela , Balochistan under DML No. 000282 (By way of Semi-Basic Manufacture) has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 15,000. The detail of management is as under:-

Sr. No	Existing Management	New Management
1.	Mr. Sadruddin Hashwani	Mr. Muhammad Fahad Qureshi S/o Muhammad Akhtar Qureshi CNIC No. 42301-6367632-1
2.	Mr. Murtaza Hashwani	Mr. Muhammad Akhtar Qureshi S/o Abdul Ghaffar Qureshi CNIC No. 42301-8949502-3
3.	Ms. Sara Hashwani	Miss Ghazala Naz W/o Muhammad Akhtar Qureshi CNIC No. 42301-8815728-0
4.	Mr. Asad Ali Shah	Miss Eman Syed W/o Muhammad Fahad Qureshi CNIC No. 42201-2960348-8
	**********	Miss SamreenNaz Qureshi D/o Muhammad Akhtar Qureshi CNIC No. 42301-8031586-2

	**********	Miss FariyalAfreen Qureshi D/o Muhammad Akhtar Qureshi CNIC No. 42301-2441978-2
	**********	Mr. Karim S/o Rajab Ali CNIC No. 42101-1775690-1

Submitted for consideration of the board, please.

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of management of M/s. Gelcaps Pakistan Ltd, Plot No. B-43, H.I.T.E District Lasbela , Balochistan under DML No. 000282 (By way of Semi-Basic Manufacture) as under ;

Sr. No	Existing Management	New Management
1.	Mr. Sadruddin Hashwani	Mr. Muhammad Fahad Qureshi S/o Muhammad Akhtar Qureshi CNIC No. 42301-6367632-1
2.	Mr. Murtaza Hashwani	Mr. Muhammad Akhtar Qureshi S/o Abdul Ghaffar Qureshi CNIC No. 42301-8949502-3
3.	Ms. Sara Hashwani	Miss Ghazala Naz W/o Muhammad Akhtar Qureshi CNIC No. 42301-8815728-0
4.	Mr. Asad Ali Shah	Miss Eman Syed W/o Muhammad Fahad Qureshi CNIC No. 42201-2960348-8
	**********	Miss SamreenNaz Qureshi D/o Muhammad Akhtar Qureshi CNIC No. 42301-8031586-2
	**********	Miss FariyalAfreen Qureshi D/o Muhammad Akhtar Qureshi CNIC No. 42301-2441978-2
	**********	Mr. Karim S/o Rajab Ali CNIC No. 42101-1775690-1

Case No. 08. CHANGE OF MANAGEMENT OF M/S. CIBA PHARMACEUTICALS (PVT) LTD, KARACHI.

M/s. Ciba Pharmaceuticals (Pvt) Ltd, A-371 Nooriabad S.I.T.E Karachi Hyderabad Super Highway, DistrictJamshoro under DML No. 000825 (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 50,000/-. The detail of management is as under:-

Sr. No	Existing Management as	New Management as per Form A (year 2019)

1.	Mr. Naveed Shakeel CNIC No. 42000-0477217-5	Mr. Imran Idris S/o Aslam Idris CNIC No. 42501-2091018-1
2.	Ms. Shamim Akhtar CNIC No. 42101-3914189-7	Mr. Abdul Jabbar Saya S/o Haji Abdul Ghani CNIC No. 42000-08684288-1
3.	**********	Mr. Muhammad Saleh S/o TayabAlam CNIC No. 42201-4648276-7
4.	**********	Mr. Muhammad Ashraf Zeb S/o Abu Bakar Ishaq CNIC No. 42301-10836941-7

Submitted for consideration of the board, please.

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Ciba Pharmaceuticals (Pvt) Ltd, A-371 Nooriabad S.I.T.E Karachi Hyderabad Super Highway, DistrictJamshoro under DML No. 000825 (By way of Formulation) as under ;

Sr. No	Existing Management as	New Management as per Form A (year 2019)
1.	Mr. Naveed Shakeel CNIC No. 42000-0477217-5	Mr. Imran Idris S/o Aslam Idris CNIC No. 42501-2091018-1
2.	Ms. Shamim Akhtar CNIC No. 42101-3914189-7	Mr. Abdul Jabbar Saya S/o Haji Abdul Ghani CNIC No. 42000-08684288-1
3.	**********	Mr. Muhammad Saleh S/o TayabAlam CNIC No. 42201-4648276-7
4.	**********	Mr. Muhammad Ashraf Zeb S/o Abu Bakar Ishaq CNIC No. 42301-10836941-7

Case No. 09. CHANGE OF MANAGEMENT OF M/S. BARRET HODGSON PAKISTAN (PVT) LTD, KARACHI.

M/s Barret Hodgson Pakistan (Pvt) Ltd, F/423, SITE, Karachi, under DML No. 000457 (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 50,000/-. The detail of management is as under:-

Current Management as per Form-29 Year	New Management as per Form-29 Year

2015	2020
1. Mr. Muhammad Feroz Alam S/o Muhammad Shafiq CNIC No. 42201-0360806-1 2. Mr. Muhammad Abbas S/o Muhammad Taufiq CNIC No. 42201-0807980-5. 3. Mr. M.S. Habib S/o Choudhary Wali Muhammad CNIC No. 42301-0862904-5 4. Ms. Iram Afaq W/o Shaikh Afaq Ahmed CNIC No. 42101-3890213-6 5. Mr. Hasan Tharani S/o Ismail CNIC No. 42101-6039308-9.	1. Mr. Hasan Tharani S/o Ismail CNIC No. 42101-6039308-9. 2. Ms. Iram Afaq W/o Shaikh Afaq Ahmed CNIC No. 42101-3890213-6 3. Mr. M.S. Habib S/o Choudhary Wali Muhammad CNIC No. 42301-0862904-5. 4. Mr. Muhammad Abbas S/o Muhammad Taufiq CNIC No. 42201-0807980-5. 5. Mr. Muhammad Feroz Alam S/o Muhammad Shafiq CNIC No. 42201-0360806-1 6. Mr. Saleem Ishrat Hashmi S/o Ishrat Ali Hashmi CNIC No. 42201-4986773-1. 7. Mr. Zubair S/o Ahmed Sulemani CNIC No. 42201-0249790-7

Submitted for consideration of the board, please.

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Barret Hodgson Pakistan (Pvt) Ltd, F/423, SITE, Karachi, under DML No. 000457 (By way of Formulation) as under ;

Current Management as per Form-29 Year 2015	New Management as per Form-29 Year 2020
1. Mr. Muhammad Feroz Alam S/o Muhammad Shafiq CNIC No. 42201-0360806-1 2. Mr. Muhammad Abbas S/o Muhammad Taufiq CNIC No. 42201-0807980-5. 3. Mr. M.S. Habib S/o Choudhary Wali Muhammad CNIC No. 42301-0862904-5 4. Ms. Iram Afaq W/o Shaikh Afaq Ahmed CNIC No. 42101-3890213-6 5. Mr. Hasan Tharani S/o Ismail CNIC	1. Mr. Hasan Tharani S/o Ismail CNIC No. 42101-6039308-9. 2. Ms. Iram Afaq W/o Shaikh Afaq Ahmed CNIC No. 42101-3890213-6 3. Mr. M.S. Habib S/o Choudhary Wali Muhammad CNIC No. 42301-0862904-5. 4. Mr. Muhammad Abbas S/o Muhammad Taufiq CNIC No. 42201-0807980-5. 5. Mr. Muhammad Feroz Alam S/o Muhammad Shafiq CNIC No. 42201-

No. 42101-6039308-9.	0360806-1 6. Mr. Saleem Ishrat Hashmi S/o Ishrat Ali Hashmi CNIC No. 42201-4986773-1. 7. Mr. Zubair S/o Ahmed Sulemani CNIC No. 42201-0249790-7

CaseNo. 10 **CHANGE OF NAME / TITLE AND MANAGEMENT OF M M/S INVENTOR PHARMA, PLOT NO. PLOT NO. K/196, S.I.T.E (SHW) PHASE II. KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000866 (FORMULATION).**

M/s Inventor Pharma, Plot No. Plot No. K/196, S.I.T.E (SHW) Phase II. Karachi, has submitted request for Change of Name / Title with fee of Rs.1,00,000/-. The pre-requisite documents of the change of name / title and management are as under: -

i. Change of Name/Title.

Current Title	New Title as per Form-29 Year 2020
M/s Inventor Pharma, Plot No. K/196, S.I.T.E (SHW) Phase II, Karachi.	M/s Inventor Pharma (Private) Ltd, Plot No. K/196, S.I.T.E (SHW) Phase II, Karachi.

ii. Change of Management.

Current Management as Partnership Deed	New Management as per Form-29 Year 2020
1. Mr. Imtiaz Ahmad Khan S/o Haji Muhammad CNIC No. 44103-3035579-5. 2. Mr. Muhammad Jameel Jokhio S/o Muhammad Sharif CNIC No. 42501-2678780-5	1. Mr. Imtiaz Ahmed Khan S/o Haji Muhammad CNIC No. 44103-3035579-5. 2. Mr. Bilal Khan S/o Abdul Sattar CNIC No. 44103-4798386-1

Submitted for consideration of the board, please.

Decision of the Central Licensing Board in 278th meeting:

The Board considered, approved that change of title and endorsed the change of management of M/s Inventor Pharma, Plot No. Plot No. K/196, S.I.T.E (SHW) Phase II. Karachiunder DML No. 000866 by way of formulation as under:-

i. Change of Name/Title.

Current Title	New Title as per Form-29 Year 2020

M/s Inventor Pharma, Plot No. K/196, S.I.T.E (SHW) Phase II, Karachi.	M/s Inventor Pharma (Private) Ltd, Plot No. K/196, S.I.T.E (SHW) Phase II, Karachi.

ii. Change of Management.

Current Management as Partnership Deed	New Management as per Form-29 Year 2020
1. Mr. Imtiaz Ahmad Khan S/o Haji Muhammad CNIC No. 44103-3035579-5. 2. Mr. Muhammad Jameel Jokhio S/o Muhammad Sharif CNIC No. 42501-2678780-5	1. Mr. Imtiaz Ahmed Khan S/o Haji Muhammad CNIC No. 44103-3035579-5. 2. Mr. Bilal Khan S/o Abdul Sattar CNIC No. 44103-4798386-1

Case No. 11. CHANGE OF MANAGEMENT OFM/S BOSCH PHARMACEUTICALS (PVT) LTD, PLOT NO 209, SECTOR 23, KORANGI INDUSTRIAL AREA KARACHI

M/s Bosch Pharmaceuticals (Pvt) Limited, Plot No. 209, Sector 23, Korangi Industrial Area, Karachi under Drug Manufacturing License No. 000707 (By way formulation)) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Sr. No	Existing Management	New Management
1.	Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7	1. Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7
2.	Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1	2. Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1
3.	Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddinchawla CNIC NO. 42201-2175782-3	3. Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddinchawla CNIC NO. 42201-2175782-3
4.	Mr. ZakrariaNasib S/O Mr. Ahmed Nasib CNIC NO. 42201-2340655-3	4. Mr. ZakrariaNasib S/O Mr. Ahmed Nasib CNIC NO. 42201-2340655-3
	********	5. Mr. AmbiaNasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Bosch Pharmaceuticals (Pvt) Limited, Plot No. 209, Sector 23, Korangi Industrial Area, Karachi under Drug Manufacturing License No. 000707 (By way of Formulation) as under ;

Sr. No	Existing Management	New Management
1.	Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7	1. Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7
2.	Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1	2. Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1
3.	Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddinchawla CNIC NO. 42201-2175782-3	3. Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddinchawla CNIC NO. 42201-2175782-3
4.	Mr. ZakrariaNasib S/O Mr. Ahmed Nasib CNIC NO. 42201-2340655-3	4. Mr. ZakrariaNasib S/O Mr. Ahmed Nasib CNIC NO. 42201-2340655-3
	********	5. Mr. AmbiaNasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3

CaseNo.12 **CHANGE OF NAME / TITLE AND MANAGEMENT OF M/S D-MAARSON PHARMACEUTICALS, PLOT NO. 17, SS-2. RCCI, RAWAT UNDER DRUG MANUFACTURING LICENSE NO. 000744(FORMULATION).**

M/s D-Maarson Pharmaceuticals, Plot No. 17, SS-2. RCCI, Rawat Under Drug Manufacturing License No. 000744(Formulation) has submitted request for Change of Name / Title with fee of Rs.1,00,000/-. The pre-requisite documents of the change of name / title and management are as under: -

i. Change of Name/Title.

Current Title as per Form-D	Current Title as per Form-D
M/s D-Maarson Pharmaceuticals, Plot No. 17, SS-2. RCCI, Industrial Estate Rawat.	M/s Newland Laboratories, Plot No. 17, SS-2. RCCI, Industrial Estate Rawat.

ii. Change of Management.

Current Management as per Partnership Deed	New Management as per Partnership Deed
1. Mr. Daulat Khan S/o Haji Naushad Khan CNIC No. 17201-5897787-1. 2. Mr. Ayaz Hussain Qureshi S/o Fiaz Hussain Qureshi CNIC No.37301-2242519-7. 3. Mr. Raja Shoaib Mehmood S/o Raja Mehmood Ahmed CNIC No. 37405-7946539-3.	1. Mr. Daulat Khan S/o Haji Naushad Khan CNIC No. 17201-5897787-1. 2. Mr. Ayaz Hussain Qureshi S/o Fiaz Hussain Qureshi CNIC No.37301-2242519-7. 3. Mr. Raja Shoaib Mehmood S/o Raja Mehmood Ahmed CNIC No. 37405-7946539-3. 4. Mr. Raja Muhammad Rizwan S/o Raja Muhammad Khan CNIC No. 37202-4137003-9.

4. Mr. Zaheer Ahmad S/o Mubashir Ahmad CNIC No. 34202-4190698-1.	5. Mr. Aamir Mubashir S/o Mubashir Ahmed CNIC No. 34202-0827130-1.

Decision of the Central Licensing Board in 278th meeting:

The Board considered, approved that change of title and endorsed the change of management of M/s D-Maarson Pharmaceuticals, Plot No. 17, SS-2. RCCI, Rawat Under Drug Manufacturing License No. 000744(Formulation)as under:-

i. Change of Name/Title.

Current Title as per Form-D	New Title as per Form-D
M/s D-Maarson Pharmaceuticals, Plot No. 17, SS-2. RCCI, Industrial Estate Rawat.	M/s Newland Laboratories, Plot No. 17, SS-2. RCCI, Industrial Estate Rawat.

ii. Change of Management.

Current Management as per Partnership Deed	New Management as per Partnership Deed
1. Mr. Daulat Khan S/o Haji Naushad Khan CNIC No. 17201-5897787-1. 2. Mr. Ayaz Hussain Qureshi S/o Fiaz Hussain Qureshi CNIC No.37301-2242519-7. 3. Mr. Raja Shoaib Mehmood S/o Raja Mehmood Ahmed CNIC No. 37405-7946539-3. 4. Mr. Zaheer Ahmad S/o Mubashir Ahmad CNIC No. 34202-4190698-1.	1. Mr. Daulat Khan S/o Haji Naushad Khan CNIC No. 17201-5897787-1. 2. Mr. Ayaz Hussain Qureshi S/o Fiaz Hussain Qureshi CNIC No.37301-2242519-7. 3. Mr. Raja Shoaib Mehmood S/o Raja Mehmood Ahmed CNIC No. 37405-7946539-3. 4. Mr. Raja Muhammad Rizwan S/o Raja Muhammad Khan CNIC No. 37202-4137003-9. 5. Mr. Aamir Mubashir S/o Mubashir Ahmed CNIC No. 34202-0827130-1.

CASE NO.13CHANGE OF MANAGEMENT OF M/S HOOVER PHARMACEUTICALS(PVT.)LTD, LAHORE.

M/s Hoover Pharmaceuticals(Pvt.) Ltd, Plot # 16 Zain Park,Industrial Area Saggian By Pass Road, Lahoreunder DML No.000676 by way of Formulation has submitted request for change in management of the firm as per Form-Awith prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	Current Management as per Form-A
1. Mr. Mir Anjum IshaqS/o Mir Muhammad Ishaq CNIC No. 35202-	1. Mr. Mir Anjum Ishaque S/o Mir Muhammad Ishaq CNIC No. 35202-

9968914-1. 2. Mrs. Sumera Ahmed W/o Imtiaz Abdullah CNIC No. 35202-4322091-6. 3. Mr. Azhar Mahmood S/o Abdul Majeed CNIC No. 35202-2187045-5. 4. Mr. Muhammad Inamullah S/o Muhammad Yousaf CNIC No. 35202-830177-5.	9968914-1. 2. Mrs. Sumera Ahmed W/o Imtiaz Abdullah CNIC No. 35202-4322091-6. 3. Mr. Azhar Mahmood S/o Abdul Majeed CNIC No. 35202-2187045-5.

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Hoover Pharmaceuticals(Pvt.) Ltd, Plot # 16 Zain Park,Industrial Area Saggian By Pass Road, Lahoreunder DML No.000676 (By way of Formulation) as under ;

Previous Management	New Management as per Form-A
1. Mr. Mir Anjum IshaqS/o Mir Muhammad Ishaq CNIC No. 35202-9968914-1. 2. Mrs. Sumera Ahmed W/o Imtiaz Abdullah CNIC No. 35202-4322091-6. 3. Mr. Azhar Mahmood S/o Abdul Majeed CNIC No. 35202-2187045-5. 4. Mr. Muhammad Inamullah S/o Muhammad Yousaf CNIC No. 35202-830177-5.	1. Mr. Mir Anjum Ishaque S/o Mir Muhammad Ishaq CNIC No. 35202-9968914-1. 2. Mrs. Sumera Ahmed W/o Imtiaz Abdullah CNIC No. 35202-4322091-6. 3. Mr. Azhar Mahmood S/o Abdul Majeed CNIC No. 35202-2187045-5.

CASE NO.14CHANGE OF MANAGEMENT OF M/S JAWA PHARMACEUTICALS (PVT) LTD,LAHORE.

M/s Jawa Pharmaceuticals(Pvt.) Ltd, 112/10,Quaid-e-Azam Industrial Area KotLakhpat Lahoreunder DML No. 000150 by way of Formulation has submitted request for change in management of the firm as per Form-Awith prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	Current Management as per Form-A
1. Mr. Muhammad BaqirJawa CNIC No.35202-6006551-5. 2. Mr. Muhammad Raza Jawa CNIC No.35202-3053233-7. 3. Mr. Sajid Ali Jawa CNIC No. 35202-9826417-1. 4. Ms. Saeeda Fatima CNIC No. 35202-5879406-2.	1. Mr. Muhammad BaqirJawa S/o Sajid Ali Jawa CNIC No.35202-6006551-5. 2. Mr. Muhammad Raza Jawa S/o Sajid Ali CNIC No.35202-3053233-7.

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Jawa Pharmaceuticals (Pvt.) Ltd, 112/10,Quaid-e-Azam Industrial Area KotLakhpat Lahore under DML No. 000150 (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 Form-A
1. Mr. Muhammad BaqirJawa CNIC No.35202-6006551-5. 2. Mr. Muhammad Raza Jawa CNIC No.35202-3053233-7. 3. Mr. Sajid Ali Jawa CNIC No. 35202-9826417-1. 4. Ms. Saeeda Fatima CNIC No. 35202-5879406-2.	1. Mr. Muhammad BaqirJawa S/o Sajid Ali Jawa CNIC No.35202-6006551-5. 2. Mr. Muhammad Raza Jawa S/o Sajid Ali CNIC No.35202-3053233-7.

CASE NO.15 CHANGE OF MANAGEMENT OF M/S APTCURE (PVT) LTD, LAHORE.

M/s Aptcure (Pvt.) Ltd, 8- Pharma city, 30-Km, Multan Road, Lahore under DML No. 000648 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	Current Management as per Form-29
1. Mr. Wajahat Ali Khan S/o Aftikhar Ali Khan CNIC No.42201-3849129-7. 2. Mr. Shazar Khan, S/o Wajahat Ali Khan CNIC No.42201-6833188-5.	1. Mr. Farooq Ahmad, S/o Jan Muhammad CNIC No.35202-0279828-5. 2. Ms. Shazia Farooq w/o Farooq Ahmad CNIC No.35202-2727487-2

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Aptcure (Pvt.) Ltd, 8- Pharma city, 30-Km, Multan Road, Lahore under DML No. 000648 (By way of Formulation) as under ;

Previous Management	New Management as per Form-29
1. Mr. Wajahat Ali Khan S/o Aftikhar Ali Khan CNIC No.42201-3849129-7. 2. Mr. Shazar Khan, S/o Wajahat Ali Khan CNIC No.42201-6833188-5.	1. Mr. Farooq Ahmad, S/o Jan Muhammad CNIC No.35202-0279828-5. 2. Ms. Shazia Farooq w/o Farooq Ahmad CNIC No.35202-2727487-2

CASE NO. 16CHANGE OF MANAGEMENT OF M/S CORTEX PHARMACETICALS, RAWAT

M/s Cortex Pharmaceuticals, Plot No.16-A, SS-4, National Industrial Zone, Rawat under DML No. 000826 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	Current Management as per Partnership Deed
1. Mr. Muhammad Nazir S/o Muhammad Ramzan CNIC No.34101-1767462-7.	1. Mr. Muhammad Nazir S/o Muhammad Ramzan CNIC No.34101-1767462-7. 2. Ms. RiffatTahira W/o Muhammad Nazir CNIC No.34101-5087864-2

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Cortex Pharmaceuticals, Plot No.16-A, SS-4, National Industrial Zone, Rawat under DML No. 000826 (By way of Formulation) as under;

Previous Management	New Management as per Partnership Deed
1. Mr. Muhammad Nazir S/o Muhammad Ramzan CNIC No.34101-1767462-7.	1. Mr. Muhammad Nazir S/o Muhammad Ramzan CNIC No.34101-1767462-7. 2. Ms. RiffatTahira W/o Muhammad Nazir CNIC No.34101-5087864-2

CASE NO. 17CHANGE OF MANAGEMENT OF M/S CARE PHARMACETICALS, LAHORE

M/s Care Pharmaceuticals, 8-Km, Thokar, Raiwind Road, Lahore under DML No. 000563 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	Current Management as per Partnership Deed
1. Mr. Zulfiqar Ahmad S/o Sheikh Munawar Din CNIC No. 35202-7758313-1 2. Mr. Aamir Zulfiqar Ahmed S/o Zulfiqar Ahmed Sheikh 35202-2185828-7. 3. Mr. Imran Zulfiqar S/o Zulfiqar Ahmed Sheikh CNIC No.35202-0805691-1.	1. Mr. Aamir Zulfiqar Ahmed S/o Zulfiqar Ahmed Sheikh 35202-2185828-7. 2. Mr. Imran Zulfiqar S/o Zulfiqar Ahmed Sheikh CNIC No.35202-0805691-1.

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Care Pharmaceuticals, 8-Km, Thokar, Raiwind Road, Lahore under DML No. 000563 (By way of Formulation) as under ;

Previous Management	New Management as per Partnership Deed
1. Mr. Zulfiqar Ahmad S/o Sheikh Munawar Din CNIC No. 35202-7758313-1 2. Mr. Aamir Zulfiqar Ahmed S/o Zulfiqar Ahmed Sheikh 35202-2185828-7. 3. Mr. Imran Zulfiqar S/o Zulfiqar Ahmed Sheikh CNIC No.35202-0805691-1.	1. Mr. Aamir Zulfiqar Ahmed S/o Zulfiqar Ahmed Sheikh 35202-2185828-7. 2. Mr. Imran Zulfiqar S/o Zulfiqar Ahmed Sheikh CNIC No.35202-0805691-1.

CASE NO.18 CHANGE OF MANAGEMENT OF M/S JENNER PHARMACETICALS, (PVT) LTD, SHEIKHUPURA.

M/s Jenner Pharmaceuticals (Pvt) Ltd, Plot No. 3, M-2, Pharmazone, 26th Km Lahore Sharqpur Road, District Sheikhupura under DML No. 000823 by way of Formulation has submitted request for change in management of the firm as per Form-A with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	Current Management as per Form-A

1. Mr. Zafar Mustafa S/o Ghulam Mustafa CNIC No. 35202-1546650-7. 2. Mr. Muhammad Umer Farooq S/o Ghulam Mustafa 34101-1182020-5	1. Mr. Shahzad Sahfique S/o SahfiqueAhmad CNIC No.35202-3030292-5. 2. Ms. Tahira Khatoon W/o Mian Muhammad Sharif CNIC No. 35202-2574072-0. 3. Mr. Zafar Mustafa S/o Ghulam Mustafa CNIC No.35202-1546650-7. 4. Mr. Muhammad Umer Farooq S/o Ghulam Mustafa 34101-1182020-5

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Jenner Pharmaceuticals (Pvt) Ltd, Plot No. 3, M-2, Pharmazone, 26th Km Lahore Sharqpur Road, District Sheikhupura under DML No. 000823 (By way of Formulation) as under ;

Previous Management	New Management as per Form-A
1. Mr. Zafar Mustafa S/o Ghulam Mustafa CNIC No. 35202-1546650-7. 2. Mr. Muhammad Umer Farooq S/o Ghulam Mustafa 34101-1182020-5	1. Mr. Shahzad Sahfique S/o SahfiqueAhmad CNIC No.35202-3030292-5. 2. Ms. Tahira Khatoon W/o Mian Muhammad Sharif CNIC No. 35202-2574072-0. 3. Mr. Zafar Mustafa S/o Ghulam Mustafa CNIC No.35202-1546650-7. 4. Mr. Muhammad Umer Farooq S/o Ghulam Mustafa 34101-1182020-5

CASE NO. 19 CHANGE OF MANAGEMENT OF M/S AMAAN PHARMA, LAHORE.

M/s Amaan Pharma, 30-Km, Sheikhupura Road, Lahore under DML No. 000808 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	Current Management as per Partnership Deed
1. Mr. Kamran Butt S/o Khushnood Hassan Butt CNIC No. CNIC No.35202-2551523-5.	1. Mr. Kamran Butt S/o Khushnood Hassan Butt CNIC No. CNIC No.35202-2551523-5 2. Mr. Mustajab Butt S/o Maqsood Hassan Butt CNIC No. 35202-8895252-7. 3. Mr. Muhammad Nouman Butt S/o

	Khushnood Hassan Butt CNIC No. 35202-2698486-1

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Amaan Pharma, 30-Km, Sheikhupura Road, Lahore under DML No. 000808 by way of Formulation as under ;

Previous Management	New Management as per Partnership Deed
1. Mr. Kamran Butt S/o Khushnood Hassan Butt CNIC No. CNIC No.35202-2551523-5.	1. Mr. Kamran Butt S/o Khushnood Hassan Butt CNIC No. CNIC No.35202-2551523-5 2. Mr. Mustajab Butt S/o Maqsood Hassan Butt CNIC No. 35202-8895252-7. 3. Mr. Muhammad Nouman Butt S/o Khushnood Hassan Butt CNIC No. 35202-2698486-1

CASE NO. 20CHANGE OF MANAGEMENT OF M/S MEDICRAFT PHARMACEUTICALS (PVT) LTD., 126-B, HAYATABAD INDUSTRIAL ESTATE, PESHAWAR.

M/s Medicraft Pharmaceuticals (Pvt) Ltd., 126-B, Hayatabad Industrial Estate, Peshawar under DML No. 000390 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 SECP	Retiring Management	Current Management as per Form-A and Form-29 SECP
1. Mr. Ishtiaq Ahmad S/o Mushtaq Ahmad, CNIC No.17301-1513111-4. 2. Mr. Imtiaz Ahmad S/o Mushtaq Ahmad, CNIC No.17301-1674179-9. 3. Mr. Ashfaq Ahmad S/o Mushtaq Ahmad CNIC No.17301-1523177-9. 4. Abida Aftab D/o Ahmad Jan, CNIC No.35200-6654328-0.	1. Mr. Ishtiaq Ahmad S/o Mushtaq Ahmad, CNIC No.17301-1513111-4. 2. Mr. Ashfaq Ahmad S/o Mushtaq Ahmad CNIC No.17301-1523177-9. 3. Abida Aftab D/o Ahmad Jan, CNIC No.35200-6654328-0.	1. Mr. Imtiaz Ahmad S/o Mushtaq Ahmad, CNIC No.17301-1674179-9. 2. Mr. Muhammad Shayan S/o Imtiaz Ahmad, CNIC No. 17301-6530661-5.

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Medicraft Pharmaceuticals (Pvt) Ltd., 126-B, Hayatabad Industrial Estate, Peshawar under DML No. 000390 (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 SECP	New Management as per Form-A and Form-29 SECP
1. Mr. Ishtiaq Ahmad S/o Mushtaq Ahmad, CNIC No.17301-1513111-4. 2. Mr. Imtiaz Ahmad S/o Mushtaq Ahmad, CNIC No.17301-1674179-9. 3. Mr. Ashfaq Ahmad S/o Mushtaq Ahmad CNIC No.17301-1523177-9. 4. Abida Aftab D/o Ahmad Jan, CNIC No.35200-6654328-0.	1. Mr. Imtiaz Ahmad S/o Mushtaq Ahmad, CNIC No.17301-1674179-9. 2. Mr. Muhammad Shayan S/o Imtiaz Ahmad, CNIC No. 17301-6530661-5.

CASE NO.21 CHANGE OF MANAGEMENT OF M/S NORTECH PHARMACEUTICALS (PVT) LTD., PLOT NO.203, SIHALA INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

M/s Nortech Pharmaceuticals (Pvt) Ltd.), Plot No.203, Sihala Industrial Triangle, Kahuta Road, Islamabad under DML No. 000307 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 as per Form-A SECP dated 10-06-2019 (Pages 275-279/Corr)	Current Management per Form-A SECP dated 26-10-2019 (Pages 340-344/Corr)
1. Mr. Nadeem Ahmed Khan, CNIC No.61101-1395940-1. 2. Mr. Saad Ullah Khan S/o Naseer Malik, CNIC No.61101-2619795-7. 3. Mr. Naeem Ahmed Khan CNIC No.35202-6923307-3.	1. Mrs. Mehreen Nadeem W/o Nadeem Ahmed Khan, CNIC No.61101-1169317-0. 2. Mr. Saad Ullah Khan S/o Naseer Malik, CNIC No. 61101-2619795-7. 3. Mr. Asif Javed S/o Muhammad Mukhtar, CNIC No.61101-1151409-3.

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Nortech Pharmaceuticals (Pvt) Ltd.), Plot No.203, Sihala Industrial Triangle, Kahuta Road, Islamabad under DML No. 000307 (By way of Formulation) as under ;

Previous Management as per Form-A SECP dated 10-06-2019	Current Management per Form-A SECP dated 26-10-2019
1. Mr. Nadeem Ahmed Khan, CNIC No.61101-1395940-1. 2. Mr. Saad Ullah Khan S/o Naseer Malik, CNIC No.61101-2619795-7 3. Mr. Naeem Ahmed Khan CNIC No.35202-6923307-3.	1. Mrs. Mehreen Nadeem W/o Nadeem Ahmed Khan, CNIC No.61101-1169317-0. 2. Mr. Saad Ullah Khan S/o Naseer Malik, CNIC No. 61101-2619795-7. 3. Mr. Asif Javed S/o Muhammad Mukhtar, CNIC No.61101-1151409-3.

CASE NO. 22 CHANGE OF MANAGEMENT OF M/S MEDIFINE LABORATORIES (PVT) LTD., PLOT NO. A-11, NEW INDUSTRIAL AREA, MIRPUR, AZAD KASHMIR.

M/s Medifine Laboratories (Pvt) Ltd., Plot No. A-11, New Industrial Area, Mirpur, Azad Kashmir wherein the firm has submitted the documents for approval of change of management. The firm has deposited fee of Rs.50,000/- (Page-114/Corr) for change of management. The detail is as under;

Previous Management as per Form-29	Previous Management as per Form-A SECP dated 12-02-2020
1. Mr. Mumtaz Rasool Mir S/o. Mr. Ghulam Rasool Mir CNIC No. 81302-8966810-9, 2. Mr. Sabir Hussain Shah S/o Mr Syed Maqbool Hussain Shah CNIC No. 81302-4743881-5 3. Mr. Shahid Naeem S/o Mr. Muhammad Hussain CNIC No. 81302-3484330-3 4. Mr. Umer Amin S/o Mr. Muhammad Amin CNIC No. 81302-8528223-3 5. Mr. Saeed Ahmed S/o Mr. Rashid Ahmad CNIC No. 35202-9582577-1	1. Mr. Mumtaz Rasool Mir S/o. Mr. Ghulam Rasool Mir CNIC No. 81302-8966810-9, 2. Mr. Sabir Hussain Shah S/o Mr Syed Maqbool Hussain Shah CNIC No. 81302-4743881-5 3. Mr. Shahid Naeem S/o Mr. Muhammad Hussain CNIC No. 81302-3484330-3 4. Mr. Bashrit Mahmood S/o Mr. Muhammad Hussain CNIC No. 81302-6859904-3 5. Mr. Saeed Ahmed S/o Mr. Rashid Ahmad CNIC No. 35202-9582577-1

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the change of M/s. Medifine Laboratories (Pvt) Ltd., Plot No. A-11, New Industrial Area, Mirpur, Azad Kashmirunder DML No. 000672 (By way ofFormulation) 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'sLetter No.5-4/2020-CD date 10/11/2020;

Previous Management as per Form-29	Previous Management as per Form-A SECP dated 12-02-2020
1. Mr. Mumtaz Rasool Mir S/o. Mr. Ghulam Rasool Mir CNIC No. 81302-8966810-9, 2. Mr. Sabir Hussain Shah S/o Mr Syed Maqbool Hussain Shah CNIC No. 81302-4743881-5 3. Mr. Shahid Naeem S/o Mr. Muhammad Hussain CNIC No. 81302-3484330-3 4. Mr. Umer Amin S/o Mr. Muhammad Amin CNIC No. 81302-8528223-3 5. Mr. Saeed Ahmed S/o Mr. Rashid Ahmad CNIC No. 35202-9582577-1	1. Mr. Mumtaz Rasool Mir S/o. Mr. Ghulam Rasool Mir CNIC No. 81302-8966810-9, 2. Mr. Sabir Hussain Shah S/o Mr Syed Maqbool Hussain Shah CNIC No. 81302-4743881-5 3. Mr. Shahid Naeem S/o Mr. Muhammad Hussain CNIC No. 81302-3484330-3 4. Mr. Bashrit Mahmood S/o Mr. Muhammad Hussain CNIC No. 81302-6859904-3 5. Mr. Saeed Ahmed S/o Mr. Rashid Ahmad CNIC No. 35202-9582577-1

CaseNo. 23 CORRECTION IN THE NAME OF MANAGEMENT OF M/S MEDITECH, PESHAWAR.

The case was presented before LCB in 273rdmeeting held on, however the name of Mr. Nadeem Shahzad S/o Haji Abdul Rasheed CNIC No.17301-9554612-3 was inadvertently written/mentioned in agenda and minutes (Decision of CLB) as Mr. Nadeem Shahzad Nawaz S/o Haji Abdul Rasheed CNIC No.17301-9554612-3. Accordingly decision was conveyed to the firm. M/s Meditech, Peshawar, under DML No. 000544 By way of Formulation has submitted request for change in management of the firm as per Form-1A along with prescribed Fee Challan of 50,000/- as under:-

Current Management as per Sole proprietor	Incoming management as per Partnership Deed	New Management as per Form-H & Partnership Deed
1. Mr. Nadeem Shahzad Nawaz S/o Haji Abdul Rasheed CNIC No.17301-	1. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-	1. Mr. Nadeem Shahzad S/o Haji Abdul Rasheed CNIC No.17301-9554612-3

9554612-3.	276733-5	2. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-276733-5

The case is hereby submitted for consideration and orders of the Board, please

Decision of the Central Licensing Board in 278th meeting:

The Board considered and endorsed the correction in change of management of M/s Meditech, Peshawar, under DML No. 000544 By way of Formulationunder DML No. 000544 (By way of Formulation) as under ;

Current Management as per Sole proprietor	Incoming management as per Partnership Deed	New Management as per Form-H & Partnership Deed
2. Mr. Nadeem Shahzad Nawaz S/o Haji Abdul Rasheed CNIC No.17301-9554612-3.	3. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-276733-5	1. Mr. Nadeem Shahzad S/o Haji Abdul Rasheed CNIC No.17301-9554612-3 4. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-276733-5

CaseNo. 24 CORRECTION IN THE NAME AND ADDRESS OF M/S AMSON VACCINES & PHARMA (PVT) LTD., 154-INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD

The firm, M/s Amson Vaccines & Pharma (Pvt) Ltd.,154-Industrial Triangle, Kahuta Road, Islamabad has requested for correction in the name and address of their firm mentioned on Drug Manufacturing License (Form-2) and further requested to issue revised DML (Form-2) with correct name.

The name of the firm is M/s Amson Vaccines & Pharma (Pvt) Ltd., 154-Industrial Triangle, Kahuta Road, Islamabad (Form-2 pages 210/Cor, form-29 253/Cor). However, the name and address of the firm was inadvertently written/mentioned as M/s Amson Vaccine & Pharma (Pvt) Ltd., Plot No.154, Industrial Triangle, Kahuta Road, Islamabad in agenda and minutes of 275thCentral Licensing Boardmeeting held on 25th June, 2020 instead of M/s Amson Vaccines & Pharma (Pvt) Ltd., 154-Industrial Triangle, Kahuta Road, Islamabad. Accordingly, Form-2 was issued with same name as mentioned in minutes of 275th CLB meeting.

The case is hereby 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 approvecorrection in name/title of M/s Amson Vaccines & Pharma (Pvt) Ltd., 154-Industrial Triangle, Kahuta Road, Islamabad as proposed.

CaseNo. 25 **CORRECTION IN THE NAME OF SECTION OF M/S ARIES PHARMACEUTICALS (PVT) LTD, 1-W, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR**

The firm M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar has requested for correction in the name of their already approved section "Dry Powder Suspension (Cephalosporine).

The name of section was mentioned as Dry Powder Suspension (Cephalosporine) in inspection report submitted by Mr. Atiq Ul Bari, FID, DRAP, Peshawar of M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar for the purpose of grant of renewal of DML No.000565 (Formulation) vide letter No. 11-42-/2020-Aries-DRAP 3721, dated 30/09/2020 (Page 270/Corr). However, the name of section was inadvertently written as Dry Powder Suspension (General). In agenda and subsequently minutes of 277th meeting of Central Licensing Board held on 15-16 October, 2020. Accordingly, a letter was issued where name of the section is mentioned as Dry Powder Suspension (General). It is proposed that the case may be placed before CLB in its upcoming meeting for corrigendum.

The case is hereby 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 approve the change in name/title of licensed section "Dry Powder Suspension (Cephalosporin)M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawarunder Drug Manufacturing License No. 000565(Formulation) as proposed.

Case No. 26. **REGULARIZATION OF LAYOUT PLAN OF M/S HELIX PHARMA (PVT) LTD, PLOT NO. A-56, S.I.T.E, KARACHI**

M/s Helix Pharma (Pvt) Ltd, Plot No. A-56, S.I.T.E, Karachi under DML No. 000030 (Formulation), had applied for regularization of layout plan of facility for their existing following sections;

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Capsule (General)

iii.	Dry Powder Suspension (General)	iv.	Oral Solution/Liquid Syrup (General)
v.	Eye/Ear Drops (General)	vi.	Liquid Injectable (General)
vii.	Warehouse (General)	viii.	Quality Control Laboratory

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. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Director DTL, Karachi.
3. Area FID, DRAP, Karachi

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

Recommendations of the panel: -

"Keeping in view overall GMP compliance and positive intention towards improvements, panel unanimously recommend regularization of layout and recommends the renewal of DML No. 000030 of M/s. Helix Pharma (Pvt) Ltd, Plot No. A-56, S.I.T.E, Karachi as per following sections

Sr. No	**Name of Sections**	**Sr. No**	**Name of Sections**
i.	Tablet (General)	ii.	Capsule (General)
iii.	Dry Powder Suspension (General)	iv.	Oral Solution/Liquid Syrup (General)
v.	Eye/Ear Drops (General)	vi.	Liquid Injectable (General)
vii.	Warehouse (General)	viii.	Quality Control Laboratory

Submitted for consideration of the board, please.

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

The Board considering the case and approved the regularization of lay out plan in the name of M/s Helix Pharma (Pvt) Ltd, Plot No. A-56, S.I.T.E, Karachi under DML No. 000030 (Formulation) on the recommendation of panel of experts for the following sections:-

SECTIONS / FACILITIES :

Sr. No	**Name of Sections**	**Sr. No**	**Name of Sections**
i.	Tablet (General)	ii.	Capsule (General)
iii.	Dry Powder Suspension (General)	iv.	Oral Solution/Liquid Syrup (General)

v.	Eye/Ear Drops (General)	vi.	Liquid Injectable (General)
vii.	Warehouse (General)	viii.	Quality Control Laboratory

Case No. 27. <u>GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S. APEX PHARMACEUTICALS (PVT) LTD, KARACHI</u>

	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**	4. Dr. Abdullah Dayo, Member CLB. 5. Additional Director (E & M) DRAP, Karachi.. 6. 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.

<u>Conclusion.</u> 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.

<u>Decision by the Central Licensing Board in 267th meeting</u>

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 accordinglyone month time may be given.

The Board after hearing the representative of thefirm 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)

Case No. 28. REGULARIZATION OF LAYOUT PLAN OF M/S. APEX PHARMACEUTICALS (PVT) LTD, KARACHI PLOT NO. A-56, S.I.T.E, KARACHI

M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachi.

under DML No. 000746 (Formulation), had applied for regularization of layout plan of facility for their existing following sections;

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Capsule (General)
iii.	Capsule (Cephalosporin)	iv.	Dry Powder Suspension (Cephalosporin)

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. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Additional Director (E & M) ,DRAP, Karachi.
3. Area FID, DRAP, Karachi.

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

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. 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)

Submitted for consideration of the board, please.

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

The Board considering the case and approved the regularization of lay out plan in the name M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachi. under DML No. 000746(Formulation) on the recommendation of panel of experts for the following sections:-

SECTIONS / FACILITIES :

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Capsule (General)
iii.	Capsule (Cephalosporin)	iv.	Dry Powder Suspension (Cephalosporin)

Case No. 29. REGULARIZATION OF LAYOUT PLAN OF M/S. ZAFA PHARMACEUTICALS LABORATORIES (PVT) LTD, PLOT NO. A-79, SITE SUPER HIGHWAY, KARACHI

M/s Zafa Pharmaceuticals Laboratories (Pvt) Ltd, Plot No. A-79, SITE Super Highway, Karachi under DML No. 000516 (Formulation), had applied for regularization of layout plan of facility for their existing following sections;

1. Soft Gelatin Capsule (General)

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. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Additional Director (E & M) ,DRAP, Karachi.
3. Area FID, DRAP, Karachi.

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

Recommendations of the panel: -

Based on the above stated facts and keeping in view the attitude of the management of the firm, the panel unanimously recommends the grant of renewal of DML No. 000516 for the next five years and panel also recommends the regularization of the current facility which is according to approved design.

Submitted for consideration of the board, please.

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

The Board considering the case and approved the regularization of lay out plan in the name of M/s Zafa Pharmaceuticals Laboratories (Pvt) Ltd, Plot No. A-79, SITE Super Highway, Karachi under DML No. 000516 (Formulation) on the recommendation of panel of experts for the following sections:-

SECTIONS / FACILITIES :

1. Soft Gelatin Capsule (General) Section.

Case No. 30 RENEWAL OF M/S LOWITT PHARMA (PVT) LTD., PLOT NO.24, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR

The firm M/s Lowitt Pharma (Pvt) Ltd., Plot No.24, Industrial Estate, Hayatabad, Peshawar, wherein the firm has submitted the application for renewal of Drug Manufacturing No. 000568 (Formulation). The application was received on 12-05-2020 which is well on time as due date of License is 12-05-2020. The firm has submitted a fee of Rs. 50,000 . The application was evaluated as per Drugs (Licesning, Registering and advertising) Rules 1976 and found following shortcoming for which shortcoming letter No.03-3/2002-Lic (Vol-I) dated 01/09/2020 was issued to the firm;

i. Detail of management at the time of previous and current renewal.
ii. Updated copy of Form-29 issued and certified true copy by S.E.C.P.
iii. Proof of section(s) approval from Central Licensing Board and copy of approved layout plan.
iv. Up-to-date nothing due certificate (Central Research Fund) from STO, DRAP, Islamabad upto 31-12-2020.

In response to above quoted letter the firm has submitted their reply but did not rectified following shortcoming. Subsequently final reminder vide letter No.3-3/2002-Lic (Vol-I) dated 04/11/2020 was issued to rectify following shortcomings

i. Updated copy of Form-29 issued and certified true copy by S.E.C.P.
ii. Proof of section(s) approval from Central Licensing Board and copy of approved layout plan.

In response to above final reminder the firm has submitted their reply but as of today the firm did not rectified following shortcoming;

i. Updated copy of Form-29 issued and certified true copy by S.E.C.P.
ii. Proof of section(s) approval from Central Licensing Board and copy of approved layout plan.

Submitted for consideration 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(2A) & Rule 16 and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000568 (by way of formulation) of M/s Lowitt Pharma (Pvt) Ltd., Plot No.24, Industrial Estate, Hayatabad, Peshawar may not be suspended or cancelled by Central Licensing Board or application for renewal of DML under Rule 5(2A) may not be rejected.

CASE NO. 31. RENEWAL OF DRUG MANUFACTURING LICENCE UNDER DML NO. 000255 OF M/S PHARMACARE LABORATORIES (PVT) LTD, PLOT NO. 129/1, INDUSTRIAL ESTATE, KOTLAKHPAT, LAHORE.

Case background. The Central Licensing Board in its 276th meeting held on 3rd September, 2020 has considered the facts on the record and decided to suspend the Drug Manufacturing Licensing No. 000255 (Formulation) for three months 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, 19 and Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 of M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore. The Board also observed that application for renewal of Drug Manufacturing License for the period commencing on 13-06-2019 and ending 12-06-2024 was short of the following documents despite of letter dated 18th July, 2019 and reminder dated 14th October, 2019 were issued to the company for completing the application for renewal of Drug Manufacturing License:-

i. Nothing Due Certificate regarding CRF from STO (updated).
ii. Latest certified true copy of Form-29 (Attestation by SECP without the phrase of (SECP) to not take responsibility of contents of form.
iii. Section approval letter of all sections approved by Central Licensing Board, if not available, apply for regularization of layout plan.

M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore has submitted their reply in response to this Division's letter dated 15th July, 2020 with following submissions:-

S. #.	Points raised by Panel.	Reply of the firm.
1.	i. The Building was not as per approved layout Plan. Several changes were made without approval.	i. Layout plan was approved. ii. Key box and hammer has installed with emergency exit door.

	ii. Proper emergency exits required. iii. Smoke detectors / fire alarm were not installed. iv. The firm had registration of cephalosporin Dry Powder suspension / capsule however dedicated section for cephalosporin products was not provided. v. The flooring of the facility required improvements, cracks were as open dirty lights were seen. vi. Certificate from building control Authority was also required.	iii. Smoke detector / Fire Alarm has been installed. iv. Section was dedicated and segregated but separate entrance is under planning. v. The flooring of facility has improved as per requirement of GMP. vi. Structure certificate for building is available but new is inprocess.
2.	i. In change area wash basins were installed before executive entry. It was advised to remove wash basins to avoid spillage of water. Coats were placed haphazardly cabinet. Factory slippers were placed on floor. It was advised to provide proper cabinet for factory shoes. ii. The workers entries required improvements with respect to cleanliness and implementation of changing SOPs for workers.	i. In changing area of executive entry wash basin has removed. ii. The worker entries have improved with respect to cleanness and implementation of changing sop's for worker.
3.	i. In the raw material store, de-dusting was not provided. The quarantine area was also not proper. ii. The flooring of the store required improvements, as cracks on the floors were accumulating dust particles. iii. Segregated dispensing area for psychotropic / narcotics drugs was not available. iv. Labeling on raw material was not proper, as quarantine and sampled slips were not posted on materials. v. Temperature mapping of store was not being conducted. The firm was advised to computerize data of store.	i. In process. ii. The flooring of store has repaired. iii. Segregated dispensing hood order has been generated and come within few days. iv. Quarantine and sampled slips has pasted on material. v. Complied.
4.	The Inactive materials were purchased from local market. It was advised to conduct vender qualification for all the raw materials. No separate area under lock and key was provided for rejected materials.	Complied.

5.	Narcotic material was stored in a cabinet under lock and key the temperature humidity of which was not monitored.	The temperature / humidity record of narcotic material is being monitored.
6.	The finished goods store was located out the main building No proper dispatch area provided. Cleanliness in the store was not satisfactory.	Complied.
7.	In tablet section, the silverson mixer for wet granulation and fluidized bed dryer were installed in the same congested room, hence chances of cross contamination increased, if both were being used at the same time.	Silver mixer does not exist in factory and machinery of section is installed in segregated areas hence there are no chances for cross contamination. Single product is being processed in granulation section.
8.	The machinery was not properly cleaned, powder from previous batch was seen in the fluidized bed dryer, no filter was installed in the dryer. The edges of dry granulator were very sharp, hence the worker safely could be compromised.	a-Pre-filters were installed at the time of inspection in fluid bed dryer. b-Dry granulator has modified with smooth edges from safety point of view.
9.	i. In the granulation room a partition of glass and aluminum was provided which was not smooth and clean. Firm was advised to remove that partition and provide smooth partition if required. ii. HVAC system was not functioned as no negative pressure was observed. iii. Three rooms for compression of tablets were provided. The compression machines were not GMP compliant. iv. The return ducts of HVAC system was not provided, Dust collectors were installed above the compression machines, which were full of powder of previous batches. The firm was advised to remove all dust collectors. Install proper HVAC return ducts in the area, and maintained negative pressure.	i. Complied. ii. Calibration is due. iii. 2 compression machines were GMP complied but 2 compression machine is under planning for GMP complied. iv. The return ducts of HVAC system has installed in compression section.
10.	It was observed that tablet cores Pharmic Tablet date of manufacturing 05/19 batch	In process delay time testing SOP has

	No. 0603 and MYZA Tablet Batch No. 0597 Date of Manufacturing 07/03/2019 were placed in the in-process quarantine area for the last 10-11 months, without blistering. No temperature / humidity was maintained in the area. The management was unable to explain such delays in packing. There was no concept of in-process delay time testing before packing.	developed. Temperature / humidity was maintained in the area at the time of inspection.
11.	i. In Psychotropic / Narcotics Tablet Section The tray dryer did not have thermal probes for temperature monitoring. Thermanal mapping of dryer required. The granulator had dangerous edges, cone mixer was without safety rod. ii. In the compression room, double door transfer hatch was required instead of single door hatch. iii. The HVAC system did not have pre bag fitters at the return air vents, only grills were installed without filters, the system was not installed properly hence was not functional.	i. Safety rod has installed with Cone mixer. ii. Under planning. iii. The pre-filters has installed at the return air vents.
12.	Cephalosporin Capsule and Dry Powder Suspension Section. Dedicated area with separate entries in the section were not provided. Separate raw material store / dispensing area for cephalosporin was also not available.	Under planning.
13.	It was advised to deregister cephalosporin products, as proper area for the manufacturing of cephalosporin products was not available.	Area was dedicated but separate entrance is required which is in-process.

14.	i. In Quality Control Laboratory. It was observed that HPLC was not working properly. ii. Very old dissolution apparatus was installed. ii. No sampler was available. The quality control Incharge was not aware, how to perform dissolution test as the procedure of testing sample from dissolution apparatus was not explained when asked by the panel. v. Reference standards were not available. Raw materials were used as working standards which were not even placed in any dessicator. v. Only one stability chamber was installed without any data logger and backup supply. vi. The firm was advised to upgrade quality control equipment, purchase reference standards and perform tests as per pharmacopeial requirements. Microbiology Laboratory was also not developed.	i. Complied. ii. Sampler has purchased. iii. Apparatus was old but working properly as per pharmacopial specs. iv. Working standards were available but USP/BP standards are in planning. Working standards has placed in desicator. Purchase of second Stability Chamber is in process. Data logger is required for stability chamber. Backup supply was available at the time of inspection. Tests are performed as per pharmacopeial methods or by validated methods.
15.	The Documentation and record with respect to manufacturing SOP, BMRs and testing procedures required improvement. No annual product quality review, deviation in processes etc were being preformed, and recorded.	i. Manufacturing procedure SOP and BMR has revised and updated. ii. All testing procedures are as per pharmacopoeia.
16.	No self-inspection / audit was being conducted. The quality assurance department was not fully developed.	Previous inspection
17.	No personal training of technical staff was being conducted, on GMP, HVAC system etc.	Training of technical staff has been conducted and record is available.
18.	The water treatment plant was not functional at the time of inspection. The washing of equipment and paste making was being done through a tap water.	Complied.
19.	The HVAC system was not properly functioning. Number of air changes, pressure difference and other controls were	a. In compression area of general tablet section return ducts has installed with prefilters. b. HVAC previous validation has been

	not as per requirement. In compression area of general tablet section return ducts were not installed. Ducts were without filters. Hence HVAC system required proper installation and validation.	available and new validation is in planning.

M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore has submitted the CAPA report and deficient documents in the application for the renewal of DML for the period commencing on 13-06-2019 and ending 12-06-2024.

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 for re-inspection of the firm for resumption of production of M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore under DML No. 000255 (Formulation) by the same panel.

Case No. 32 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.

Case No. 33 APPROVAL OF QUALITY CONTROL (QC) INCHARGE OF M/S WARAFANA PHARMACEUTICALS, ISLAMABAD

The firm, M/s Warafana Pharmaceuticals, Islamabad has submitted application for approval of proposed Quality Control (QC) Incharge Mr. Shakeel Badshah S/o Amir Bad Shah (M.Sc Chemistry) CNIC.16101-1231406-7. The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Resignation/retirement of earlier Quality Control Incharge is not provided.

Accordingly a shortcoming letter No.F.1-40/2003-Lic Dated 27-03-2018was issued to the firm to rectify above mentioned shortcoming.

Meanwhile the firm has submitted application for approval of proposed QC Incharge Mr. Majid Riaz S/o Muhammad Riaz (M.Sc Chemistry) CNIC.13101-0757707-3. The firm has deposited the fee of Rs.5,000/. Upon evaluation of application for approval of proposed QC incharge per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Appointment letter not attached.

ii. Job acceptance letter not attached.
iii. Copy of CNIC is not attested.
iv. Copies of academic degrees are not attested.
v. Copy of M.Sc Degree is not readable.
vi. Copies of experience certificates are not attested.
vii. Resignation of already approved QC Incharge not attached.
viii. Resignation letter of appointee from previous firm not attached.
ix. Undertaking as whole time employee on stamp paper not attached.

The firm was advised vide letter No.F.1-40/2003-Lic dated 23-04-2020to rectify above mentioned shortcoming (Complete set of documents as per checklist)

In response to aforementioned letter, the firm has submitted their reply, however the firm has not rectified following shortcoming;

i. Undertaking as whole-time employee on stamp paper signed and stamped by both appointee and the manager (duly notarized).

Accordingly, a final reminder vide letter No.F.1-40/2003-Lic dated 18-08-2020 was issued to the firm. Till date the firm has not rectified fowling shortcoming;

i. Undertaking as whole-time employee on stamp paper signed and stamped by both appointee and the manager (duly notarized).

The case is hereby 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, 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000720(by way of formulation) of M/s Warafana Pharmaceuticals, Islamabad may not be suspended or cancelled by Central Licensing Board.

Case No. 34 RENEWAL OF DRUG MANUFACTURING LICENCE OFM/S NOBLE PHARMA, PLOT NO. B-1, OLD INDUSTRIAL AREA, MIRPUR, AJK

The firm, M/s Noble Pharma, Plot No. B-1, Old Industrial Area, Mirpur, AJK, has submitted application for renewal of Drug Manufacturing License No. 000652 (by way Formulation). The application was received on 08-01-2019 and due date of renewal of DML 30-01-2019. 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. Detail of management at the time of previous renewal and present renewal.
ii. Declaration of firm on stamp paper in case of sole proprietorship alongwith CNIC of Director.
iii. Proof of licensed section from CLB.
iv. Nothing Due Certificate regarding CRF from STO, DRAP up-to-date.

Accordingly, shortcoming letter vide letter No.F.5-2/2007-Lic dated 08-05-2019was issued to the firm to rectify above mentioned shortcomings.

In response to this office shortcoming letter, the firm submitted their reply and same was evaluated but the firm has not rectified following shortcoming. Subsequently a final reminder vide letter No. F.5-2/2007-Lic dated 18-08-2020 was issued to the firm to rectify following shortcoming;

i. Up to date nothing due certificate from STO, DRAP, Islamabad.

Till date the firm has not rectified above mentioned shortcoming.

The case is hereby 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 and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000652(by way of formulation) of M/s Noble Pharma, Plot No. B-1, Old Industrial Area, Mirpur, AJK, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML under Rule 5(2A) may not be rejected.

Case No. 35 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.

The case is hereby 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 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., Islamabadmay 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. 36 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 fountfollowing shortcoming for which final reminder vide letter No. 3-4/91-Lic (Vol-II) dated04/11/2020 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.

The case is hereby 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 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.

Case No. 37 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S S.N.B. PHARMACEUTICALS (PVT) LTD., PESHAWAR

The firm, M/s S.N.B. Pharmaceuticals (Pvt) Ltd., Peshawar wherein the firm has submitted the application for renewal of DML No. 000759 (Formulation) for the period of **20-09-2017** to **19-09-2022**. The application was received on **19-09-2017** which is well on time as validity of License is **19-09-2017**. The firm has submitted a fee of **Rs. 50,000** . The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Attested copy of up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad, has not been attached.
ii. Copy of approved layout plan, has not been attached.
iii. Approval letter(s) of CLB for all approved section(s), has not been attached.
iv. Fee Challan of Rs.50,000/- for change of management has not been attached.
v. Attested copy of Form-29 and Form-A of SECP showing current management has not been attached.
vi. The title of the firm mentioned on Form-29 is M/s S.N.B. Pharmaceuticals (Pvt) Ltd., whereas the title mentioned on Form-1A and letter head is M/s S.N.B. Pharma (Pvt) Ltd.

Proposed Production Incharge (Mr. SahibzadaWali Ullah Khan).

vii. Fee challan of Rs.5,000/- for change of Production Incharge has not been attached.
viii. Attested copy of registration certificate from Pharmacy Council, has not been attached.
ix. Attested copies resignation letter of proposed Production Incharge as well as previous Production Incharge, have not been attached.
x. Undertaking on stamp paper as whole time employee, has not been attached.

Proposed QC Incharge (Mr. Muhammad Saleem).

xi. Fee challan of Rs.5,000/- for change of QC Incharge has not been attached.

xii. Attested copies resignation letter of proposed QC Incharge as well as previous QC Incharge, have not been attached.
xiii. Undertaking on stamp paper as whole time employee, has not been attached.

Accordingly, shortcoming letter No. 3-1/2005-Lic dated10/10/2017was issued to rectify above mentioned shortcomings.

In response to above quoted letter the firm has submitted their response however, the firm has not rectified following shortcoming; subsequently final reminder vide letter No. 3-1/2005-Lic dated 06/11/2018 was issued to the firm;

i. Attested copy of up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.
ii. Copy of approved layout plan.
iii. Approval letter(s) of CLB for all approved section(s).
iv. Fee Challan of Rs.50,000/- for change of management.
v. Attested copy of Form-29 and Form-A of SECP showing current management.
vi. The title of the firm mentioned on Form-29 is M/s S.N.B. Pharmaceuticals (Pvt) Ltd., whereas the title mentioned on Form-1A and letter head is M/s S.N.B. Pharma (Pvt) Ltd.

Proposed Production Incharge (Mr. SahibzadaWali Ullah Khan).

i. Job acceptance letter of proposed Production Incharge.
ii. Undertaking as whole time employee of Production Incharge does not hold the signature of management.

Proposed QC Incharge (Mr. Muhammad Saleem).

i. Job acceptance letter of proposed QC Incharge.
ii. Copies of academic degrees of proposed QC Incharge.
iii. Undertaking as whole time employee of QC Incharge does not hold the signature of management.

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

i. Attested copy of up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad, has not been attached.
ii. Copy of approved layout plan, has not been attached.
iii. Approval letter(s) of CLB for all approved section(s), has not been attached.
iv. Fee Challan of Rs.50,000/- for change of management has not been attached.
v. Attested copy of Form-29 and Form-A of SECP showing current management has not been attached.

Proposed Production Incharge (Mr. SahibzadaWali Ullah Khan).

i. Fee challan of Rs.5,000/- for change of Production Incharge has not been attached.
ii. Attested copy of registration certificate from Pharmacy Council, has not been attached.

iii. Attested copies resignation letter of proposed Production Incharge as well as previous Production Incharge, have not been attached.
iv. Undertaking on stamp paper as whole time employee, has not been attached.

Proposed QC Incharge (Mr. Muhammad Saleem).

i. Fee challan of Rs.5,000/- for change of QC Incharge has not been attached.
ii. Attested copies resignation letter of proposed QC Incharge as well as previous QC Incharge, have not been attached.
iii. Undertaking on stamp paper as whole time employee, has not been attached.

The case is hereby 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 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000759(by way of formulation) of M/s S.N.B. Pharmaceuticals (Pvt) Ltd., 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. 38 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S LEAMA CHEMI PHARMA (PVT) LTD., INDUSTRIAL ESATATE, JAMRUD ROAD, PESHAWAR.

M/s Leama Chemi Pharma (Pvt) Ltd., Industrial Esatate, Jamrud Road, Peshawar had applied for renewal of DML No. 000533 by way of formulation for the period from 03-04-2020 to 02-04-2025 on 03-04-2020.
The application for the renewal of DML of the firm was evaluated Drugs (Licesning, Registering and advertising) Rules 1976 and a letter for following shortcomings / deficiencies was issued to the firm on 01st October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Application for renewal is received one day late. Fee Rs. 5000/day is required,
2. Updated Form-29 attested as True Copy by SECP along with attested copy of CNIC of all Directors, not provided,

3. Attested copy of list of registered products (brand) along with registration No and Drug (s) not attached,
4. Updated nothing Due Certificate (CRF) upto 31-12-2020 from STO, DRAP, Islamabad.
5. Proof of section(s) approval from Central Licensing Board along with approved LOP is required.

The firm submitted their reply on 12th October, 2020. After evaluation of the submitted documents, a final reminder was issued on 03rd November, 2020 to the firm with following shortcomings: -

1. Application for renewal is received one day late. Fee Rs. 5000/day is required,
2. Updated Form-29 attested as True Copy by SECP along with attested copy of CNIC of all Directors, not provided,
3. Attested copy of list of registered products (brand) along with registration No and Drug (s) not attached,
4. Updated nothing Due Certificate (CRF) upto 31-12-2020 from STO, DRAP, Islamabad.
5. Proof of section(s) approval from Central Licensing Board along with approved LOP is required.

The firm has not submitted their reply to Final Reminder

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, Rule 16 and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000533(by way of formulation) of M/s Leama Chemi Pharma (Pvt) Ltd., Industrial Esatate, Jamrud Road, Peshawar may not be suspended or cancelled by Central Licensing BoardDrugs (Licensing, Registering and Advertising) Rules, 1976or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976..

Case No. 39 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.

Case No. 40 RENEWAL OF DRUG MANUFACTURING LICENCE M/S TREAT PHARMACEUTICAL INDUSTRY (PVT) LTD, A-37, SMALL INDUSTRIAL ESTATE, TOWNSHIP, KOHAT ROAD, BANNU

The firm M/s Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township, Kohat Road, Bannu has submitted application for renewal of DML No.000352 by way of Formulation. The application was received on 14-02-2020 which was Nine (09) days late as the validity of License is 05-02-2020. The firm has not submitted Form-1A and supported documents and only deposited fee of Rs.50,000/ for renewal of DML.

A shortcoming letter was issued to the firm to rectify following **shortcoming** vide letter No.F.3-4/93-Lic (Vol-II) dated 01-09-2020 as per Drug (LR&A) Rules 1976;

i. Form-1A on prescribed format duly singed and stamped by CEO/Owner of the firm alongwith late fee of Rs.40,000/- @5000/day as the application is 08 days late and complete set of documents/annexures.

In response to s**hortcoming** letter the firm did not submitted their reply and **subsequently** a reminder vide letter No.F.3-4/93-Lic (Vol-II) dated 14-10-2020 was issued to the **firm** to **rectif**y above mentioned shortcoming.

In response to final reminder the firm has submitted their reply. The firm also **submitteddocument**s for change of **management**. The reply was evaluated as per Drugs (L,R&A) Rules 1976 and did not **rectified** following **shortcomings**;

i. Nothing due certificate (Central Research Fund) from STO, DRAP up to 31-12-2020 is not provided,
ii. Updated Form-29 issued and certified as "True Copy" by SECP is not provided.

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 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000352 (by way of formulation) of M/s Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township, Kohat Road, Bannumay 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. 41 RENEWAL OF DRUG MANUFACTURING LICENCE OF VETCON PHARMACEUTICALS (PVT) LTD., PLOT NO.7-10B, INDUSTRIAL ESTATE, BHIMBER, AZAD KASHMIR.

M/s Vetcon Pharmaceuticals (Pvt) Ltd., Plot No.7-10B, Industrial Estate, Bhimber, Azad Kashmir had applied for renewal of DML No. 000307 by way of formulation for the period of 29-06-2020 on 28-06-2024.

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 17th March, 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 Present renewal.
ii. Latest original certified true copy of Form-29 & Form-21 issued by S.E.C.P. alongwith CNIC copies of all directors.
iii. Update Nothing due certificate regarding CRF from STO, DRAP, Islamabad.

For Quality Control Incharge.

i. Appointment letter and job acceptance letter.
ii. Copy of CNIC of appointee.
iii. Copies academic degrees.
iv. Experience certificate(s).
v. Resignation earlier Quality Control Incharge.
vi. Resignation of appointee from previous firm.
vii. Undertaking as whole time employee on stamp paper as per format of checklist (attached).

The firm submitted their reply on 21st April, 2020. After evaluation of the submitted documents, a final reminder was issued on 24th August, 2020 to the firm with following shortcomings: -

For Renewal of DML.

i. Proof of sections approved from Central Licensing Board (Approval letters).
ii. Detail and approval letter of Production Incharge
iii. Update Nothing due certificate regarding CRF from STO, DRAP, Islamabad.

For Quality Control Incharge.

i. Relevant experience certificate(s) (As per prescribed rules).
ii. Registration certificate from Pharmacy Council.
iii. Academic degrees where date of result is clearly mentioned.
iv. Submitted documents are not attested/notarized.

The firm submitted their reply to Final Reminder on 15th July, 2019 and following documents are still deficient /short and application for renewal of DML is still incomplete.

1. Form-1A dully signed and attested by the management of firm alongwith all enclosures.
2. Form-29 and Form-A for year 2019 (certified true copy) issued by S.E.C.P. alongwith prescribed fee for change of management (if management is changed).
3. Approval letter(s) of all sections issued from CLB.

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 16 and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000307 (by way of formulation) of M/s Vetcon Pharmaceuticals (Pvt) Ltd., Plot No.7-10B, Industrial Estate, Bhimber, Azad Kashmir 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..

Case No. 42 **M/S BREEZE PHARMA (PVT) LTD, PLOT NO. 125-126-127A, KAHUTA ROAD,ISLAMABAD.**

The firm, M/s Breeze Pharma (Pvt) Ltd, Plot No. 125-126-127A, Kahuta Road, Islamabad has submitted application renewal of Drug Manufacturing License No. 000659 (by way Formulation). The application was received on 15-03-2019 and due date of renewal of DML 21/03/2019. The firm has submitted a fee of Rs. 50,000. Upon evaluation of application as per Drugs (Licensing, Registering and advertising) Rules 1976, following shortcomings were observed which were convey to the firm vide letter No No. F. 1-36/2003-Lic(Vol-III) dated 17/03/2020.

i. Change(s) in name of proprietor / directors / partners (if any).
ii. Detail of management at the time of previous renewal and Present renewal.
iii. Updated Nothing due certificate regarding CRF from STO.
iv. Latest updated Form-29 & Form-21 issued by S.E.C.P. along with CNIC copies of all directors.

For Production Incharge (Malik Majid Irfan).

i. Copy of CNIC of appointee.
ii. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
iii. Registration certificate from Pharmacy Council (in case of Pharmacist).
iv. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
v. Resignation / retirement of earlier Production Incharge.
vi. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

For Quality Control Incharge (Mr. Qaiser Iqbal).

i. Copy of CNIC of appointee.
ii. Resignation / retirement of earlier approved Quality Control Incharge.

The firm has not submitted their reply to the shortcoming letter and subsequently final reminder was issued to the firm vide letter No 1-36/2003-Lic(Vol-III) dated 18/09/2020. However, till date the firm has rectified above mentioned shortcoming.

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 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000659 (by way of formulation) of M/s Breeze Pharma (Pvt) Ltd, Plot No. 125-126-127A, Kahuta Road, Islamabadmay 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. 43 SURRENDERING OF ALREADY APPROVED HUMAN SECTIONSOF M/S LEADS PHARMA (PVT) LTD, ISLAMABAD

The firm, M/s Leads Pharma (Pvt) Ltd, Islamabad firm has submitted request for surrendering of following Human sections vide letter No Nil dated 15/10/2010. Following section were approve by Central Licensing Board in its 212th meeting held on 26/05/2008.

i. Dry Injection Section (Cephalosporin)
ii. Dry Suspension Section (Cephalosporin)
iii. Capsule Section (Cephalosporin)
iv. Tablet Section (General)
v. Capsule Section (General)
vi. Tablet Section (Psychotropic)

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

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

The Board considered and acceded the request fo the firm for withdrawal of following licensed sections of firm :

i. Dry Injection Section (Cephalosporin)
ii. Dry Suspension Section (Cephalosporin)
iii. Capsule Section (Cephalosporin)
iv. Tablet Section (General)
v. Capsule Section (General)
vi. Tablet Section (Psychotropic)

CASE NO. 44 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AHAD INTERNATIONAL PHARMACEUTICAL, 13-KM MULTAN ROAD, DERA ISMAIL KHAN.

The firm M/s Ahad International Pharmaceutical, Dera Ismail Khan has submitted application for renewal of Drug Manufacturing No. 000433 (Formulation). The application was received on **18-06-2019** which is well on time as validity of License is **23-07-2019** (Page-217/Corr)**.** The firm has submitted a fee of **Rs. 50,000**. The application for renewal of DML was evaluated as per Drugs (LR&A) Rules 1976 and found following shortcomings which were conveyed to the firm vide letter No. F.3-8/92-Lic (Vol-I) dated 18-10-2019;

i. Detail of management at the time of previous renewal and present renewal.
ii. Certified true copy of Form-29 and Form-21 issued by S.E.C.P. alongwith CNIC's copies of all director(s).
iii. Proof of Licensed section (s) from Central Licensing Board.

In response to this Division Shortcoming letter the firm has submitted their reply, however the firm has not rectified following shortcomings and subsequently a reminder was issued vide letter No.F.3-8/92-Lic (Vol-) dated 16-01-2020.

i. Latest original certified true copy of Form-29 issued by S.E.C.P. showing complete detail of directors.

In response to final reminder the firm has submitted notarized copy of Form-29 issued by SECP (Not certified as true Copy by SECP). However, from the notarized copy of Form-29 it was observed that the firm management has been changed from previous management and firm was informed accordingly vide letter no.F.3-8/92-Lic (Vol-I) dated 18-08-2020. Till date, the firm has not rectified following shortcomings;

i. Certified true copy of Form-29 and Form-21 issued by S.E.C.P. alongwith CNIC's copies of all director(s).
ii. Application for change of management as per Drug (Licensing, registering & advertising) Rules 1976 is not submitted by firm.

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 000433(by way of formulation) of M/s Ahad International Pharmaceutical, Dera Ismail Khan 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. 45 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..

Case No. 46 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S DRUGPHARM (PVT) LTD, LAHORE

M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore had applied for renewal of DML No. 000366 by way of formulation for the period of 24-04-2016 to 23-04-2021 on 15-04-2016.

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 23th August, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Classes of Drugs.
2. Dosage forms of drugs.
3. Change (s) in name of proprietor / directors / partners.
4. Detail of premises including approved layout plan of the factory / proof of section from CLB.
5. Copy of approval production and QC Incharge
6. Noting due certificate regarding CRF from STO.
7. Form-29 from S.E.C.P and CNIC of partners

The firm submitted their reply on 8th September, 2016 After evaluation of the submitted documents, a letter was issued on 30th January, 2017 to the firm with following shortcomings: -

1. Attested Form-29 from S.E.C.P along with copies of CNIC of all directors.
2. Any change in directors from last renewal along with Form-29 at previous renewal.
3. N.O.C for C.R.F (attested up to 2015).
4. Approved copy of Layout Plan.
5. Approved of technical staff or application / documents.
6. All documents should be duly attested.

The firm submitted their reply on 23th February, 2017 After evaluation of the submitted documents, Final Reminder was issued on 19th June, 2017 to the firm with following shortcomings: -

1. Attested Form-29 from S.E.C.P along with copies of CNIC of all directors.
2. Any change in directors from last renewal along with Form-29 at previous renewal.
3. N.O.C for C.R.F (attested up to 2016).
4. Approved copy of Layout Plan.
5. Approved of technical staff or application / documents.
6. All documents should be duly attested.

Firm did not submit their reply to Final Reminder and following documents are still deficient /short and application for renewal of DML is still incomplete.

1. Attested Form-29 from S.E.C.P along with copies of CNIC of all directors.
2. Any change in directors from last renewal along with Form-29 at previous renewal.

3. N.O.C for C.R.F (attested up to 2016).
4. Approved copy of Layout Plan.
5. Approved of technical staff or application / documents.
6. All documents should be duly attested.

Moreover, The Hon'ble Chairman, Drug Court, Balochistan Quetta has passed an order whereby it is stated that a case No. 37/17 is filed before Hon'ble Drug Court, Quetta in respect of M/s DrugPharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore. Accused are not appearing before the Court despite issuance of Non bailable warrants repeatedly. Therefore, Chairman Drug Court, Balochistan, Quetta has ordered to cancel the Drug Manufacturing Licence of said firm and report in this regard may be forwarded to Chairman Drug Court, Balochistan, Quetta.

Proceedings and Decision of Central Licensing Board in 256th 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 Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore Drug Manufacturing Licence No. 000366 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 Central Licensing Board.

The Show Cause notice dated 05th January, 2018 was issued to the M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore

A letter of Personal hearing has been issued on 17th January,2018.

Proceedings and Decision of Central Licensing Board in 257th meeting

No representative of the of the firm appeared before the Board. The Board considering the facts on the record and after thread bare deliberation decided to cancel Drug Manufacturing License No. 000366 by way of formulation issued in the name of M/s Drugpharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahoreon the orders of the Court 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.

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

The Central Licensing Board in its 257th meeting held on 24-25th January, 2018 cancelled the Drug Manufacturing Licence No. 000366 (Formulation)M/s Drugpharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore and the same decision was conveyed to the firm vide letter dated 20th March, 2018.

The firm filed appeal in Appellate Board against the decision of CLB. Appellate Board in its 151st sitting held on 16th January, 2019" considered the appeal of the firm and decided as under:-

> *"The Board, after hearing arguments and perusing record if the case, decided to remand the case back to the Central Licensing Board with direction to decide a fresh the*

application for renewal of DML No. 000336 submitted by M/s DrugPharm (Pvt) Ltd, Lahore in forthcoming meeting.

The Licensing Division shall constitute panel for inspection of the firm to be carried out after two months of the communication of this decision. Dr. Farzana Chaudhary and Mr. Shahid Nasir (Member, Appellate Board) are to be included in the Panel. The panel so constituted may allow production if the firm is complying with Good Manufacturing Practices (GMP) guidelines".

Licensing Division then afresh evaluate the application of the firm and following shortcoming in the application were conveyed to the firm vide letter dated 3rdJuly 2019.

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of 50,000/-.
iii. Latest certified true copy of Form-29 (duly attested by S.E.C.P).
iv. Duly attested CNIC copies of all directors.
v. Section approval letters of all sections issued by Central Licensing Board, if not available, apply for regularization of layout plan.
vi. Complete set of duly attested documents of proposed Production Incharge and Quality Control Incharge (as per checklist) along with prescribed fee of Rs. 10,000/-.

Firm did not submit their reply till date and application for renewal of DML is still incomplete. File forwarded to Legal Affairs Division, DRAP for legal opinion whether the Drug Manufacturing Licence of the firm is valid or the decision of Central Licensing Board is intact.

Reply of the Legal Affair Division

Appellate Board in its 151stmeeting held on 16th January, 2019 decided to remand back the case to Central Licensing Board with direction to decide afresh the application of renewal of DML No. 000336 submitted by M/s Drugpharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore in its forthcoming meeting. The Licensing division the afresh evaluate the renewal application of the firm and shortcoming were conveyed to firm but the firm did not reply yet. In the light of above available facts, Legal Affairs Division is opined that the decision of the Appellate Board is still intact and Central Licensing Board may finally decide the renewal application of the firm according to its procedure.

Proceedings and Decision by the Central Licensing Board in 275th 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), 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore Drug Manufacturing Licence No. 000366 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 Central Licensing Board.

The show cause notice dated 06thJuly, 2020 was issued to M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore.

The firm has replied to show cause notice on 24-8-2020 but following documents are still deficient in the application

1. Prescribed fee of Rs. 50,000/- (change of management).
2. Prescribed fee of Rs. 5,000/- (Quality Control Incharge).
3. Prescribed fee of Rs. 5,000/- (Production Incharge).
4. Prescribed fee of Rs. 35,000/- (Regularization of Layout plan).
5. Updated Nothing due certificate regarding CRF from STO.
6. Duly attested legible copies of CNIC of all Directors.
7. Duly attested legible copies of CNIC of Quality Control Incharge.
8. Registration certificate from Pharmacy Council of Production Incharge.

A letter of Personal Hearing was issued to the firm on 28th August, 2020.

Decision by the Central Licensing Board in 276th meeting

Mr. Shoaib Butt CEO and Mr. Waqas Butt Director HR of the company appeared before the Board and contended that almost most of the shortcomings have been rectified. 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 Licence No. 000366 by way of formulation for three (03) months issued in the name of M/s Drugpharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahoreunder 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.

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

Letter for suspension of Drug Manufacturing License was issued on 24th September, 2020. Now, the firm has replied and submitted all deficient documents in the application for renewal of DML.

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 constitute a panel comprising of following members for inspection of the firm for renewal of DML & resumption of production ofM/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore under DML No. 000366 (Formulation).

1. Dr. Farzana Chaudhry, Expert Member.
2. Dr. Ikram -ul-Haq, Member CLB.
3. Area Federal Inspector of Drugs, Lahore.

Case No. 47 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, Lahoremay 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. 48 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/SHONIG PHARMACEUTICAL LABORATORIES, RAWALPINDI.

M/s Honig Pharmaceutical Laboratories, 14-Km, Adyala Road, Rawalpindihad applied for renewal of DML No. 000550 by way of Formulation for the period of 28-08-2019 to 27-08-2024on 19-07-2019.

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 6th January, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Partnership deed alongwithCNIC copies of all Directors.
ii. Proof of licensed section from CLB.
iii. All documents should be duly attested.

The firm did replied to this letter on 17th January,2020 and reminder letter was issued on 26th February, 2020 to the firm for completion of application:

i. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

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

i. 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 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 16of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000550 (by way of formulation) of M/s Honig Pharmaceutical Laboratories, 14-Km, Adyala Road, Rawalpindihadmay 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 ALBRO PHARMACEUTICALS (PVT) LTD, 340-S, QUAID-E-AZAM INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE.

Background of the case

Mr. Abdul Rashid Shaikh, FID and Mrs. Saira Naeem, area ADC, Lahore conducted inspection of the firm M/s Albro Pharmaceutical, Lahore on 12.06.2015, to verify the GMP compliance and production activities. Following critical observations were noticed by the panel during their visit:-

General Information

- Land of the firm does not fulfill the requirements of SRO. 470 (1)/98 dated 15.05.1998 Schedule-B to the Drugs (Licensing, Registration & Advertisement) Rules, 1976. It is advised to shift the manufacturing facility to appropriate area to fulfill the requirement of above said SRO till then; the management is directed to strictly maintain the cGMP requirements for the manufacturing of registered drugs.

Workers Entrance:

- It is advised to improve the workers entrance.

Oral Liquid Section:

- The firm was advised to replace the drains with GMP drains in the section.
- The firm was advised to replace the cooking vessel for the syrup manufacturing.
- The firm was advised to conceal the lights of areas.

Raw Material Store:

- The firm was advised to ensure the availability of closed trolleys for the transportation of dispensed materials from store to production floor.
- The firm was advised to affix the proper labeling with relevant colours on the quarantine materials released or rejected
- The firm was advised to improve the storage condition of liquid materials by keeping in view the safety measures.
- The firm was advised to review and upgrade the dispensing SOPs.

Tablet Section:

- The firm was directed to ensure availability of the Double Cone Mixer.
- The firm was directed to ensure the availability of separate bags for each product for Fluid-bed dryer.
- The firm was directed to review the manufacturing SOPs as far as batch size is concerned.
- The firm was directed to ensure the batch size as per available manufacturing capacity.

Quality Control Laboratory:

- The firm was advised to ensure the FTIR, KARL Fischer and Automatic Polarimeter.
- The firm was advised to upgrade the SOPs for testing methods as per current pharmacopoeia requirements.
- The firm was advised to develop separate and independent Quality Assurance Department under the supervision of senior technical person without fail.

- The firm was advised to get internal and external audit and then its CAPA, and the report be submitted to the office of FID.
- The firm was advised to ensure to make the stability chamber functional, conduct stability of the products and maintain their record as per guidance of stability study.

The FID further directed the management to:-

- Remove the shortcomings at the earliest. The re-inspection will be conducted accordingly.

Action Taken by DRAP:- After receiving inspection report, a show cause notice was issued to the firm on 10.11.2015.

Reply of the firm:- In response of the show cause notice, the firm vide letter No. Nil dated 23.11.2015 informed that many of the observations has been resolved and improved.

Proceedings of the 246th Meeting of CLB

Mr. Waseem Ahmad Bari, Director and Mr. Sibtul Hassan Abaas, Production Manager of the firm M/s Albro Pharma, Lahore appeared before the Board for personnel hearing. Mr. Waseem Ahmad Bari informed to the Board that the existing plot is about 2.5 Kanal and assured that he will purchase the new plot of 4 kanal (size) in next six months. He has submitted an undertaking stating that the facility will be developed in four years. He further informed that all the observations identified by FID have been rectified and are ready for inspection for verification of the rectification.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and request of Director of the firm M/s Albro Pharma, Lahore, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members.

i. Dr. Zakaur Rehman, Member, CLB
ii. Mr. Abdul Rashid Sheikh, FID, Lahore
iii. Mr. Zia Husnain, FID, Lahore

The Board further decided to ask the panel to also submit the report in tabulated form identifying the previous observations and the current status of the observations noted by the panel in its inspection conducted on 12.06.2015.

To purchase the plot of 4 kanals in 06 months and complete the facility within a period of 2 years

Proceedings and Decision of Central Licensing Board in 257th meeting

The Board considered the case and decided to defer the renewal of DML till next meeting of the Board for want of personal hearing regarding update from the licensee on the decision of the Central Licensing Board for purchase of plot and completion of facility.

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

A letter of Personal hearing has been issued on 20th March, 2018.

Proceedings and Decision of Central Licensing Board in 259th meeting

Mr. Waseem Bari, Owner of the firm appeared before the Board. He contested that firm possess three sections, land at new site has been purchased and application for site verification has already been filed. He further contended that considerable time may be allowed to shift to new premises. The Board after hearing the representative of the firm and considering the facts on the record and after thread bare deliberation decided to defer the case for the sake of shifting of the premises to new site within a period of one years. The firm shall get site approval within one month and lay out approval within one month and will apply for grant of license within a period of one year. The firm shall also submit progress report quarterly. If firm fails to comply at any stage the Central Licensing Board shall start proceedings as per law.

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

Decision of the Board was conveyed to the firm vide letter dated 6th June, 2018. The firm filed application for site verification at new premises and site approval letter was issued to the firm on 6th March, 2019. Then the firm submitted layout plan which was approved on 14th November, 2019.

The firm applied for renewal of DML No. 000175 by way of Formulation for the period of 14-06-2020 to 13-06-2025 on 20-05-2020.

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 18th August, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed and stamped Form-1A (as per format)
ii. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
iii. Detail of management, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 duly attested by SECP (original).
v. Duly attested CNIC copies of all Directors.
vi. Approval letters of Production Incharge and Quality Control Incharge, if not already approved, submit their complete application alongwith prescribed fee & pre-requisites.
vii. Comply the minimum area requirement of 2000 square yards as under Schedule-B of Drugs (Licensing, Registering and Advertising) Rule, 1976.

The firm did repliedto this letter on 18th September, 2020 and reminder letter was issued on 12thOctober, 2020 to the firm for completion of application:

i. Comply the minimum area requirement of 2000 square yards as under Schedule-B of Drugs (Licensing, Registering and Advertising) Rule, 1976.
ii. Prescribed fee of 50,000/- for change in management, as there is change in management of the firm.
iii. Documents should be duly attested.

The firm replied to reminder on 29thOctober, 2020 but failed to Comply the minimum area requirement of 2000 square yards as under Schedule-B of Drugs (Licensing, Registering and

Advertising) Rule, 1976. The firm has submitted Undertaking for shifting to new site after construction which is under process.

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 19 , Schedule B under Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000175 (by way of formulation) of M/S Albro Pharmaceuticals (Pvt) Ltd, 340-S, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahoremay not be suspended or cancelled by Central Licensing Board.

Case No. 50. WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTION BY M/S HORIZON HAELTHCARE (PVT) LTD, TAXILA UNDER DRUG MANUFACTURING LICENSE NO. 000856 (FORMULATION)

M/s Horizon Healthcare (Pvt) Ltd, Plot No. 35-A, Small Industrial Estate, Taxila under DML No. 000856 By way of Formulationhas submitted request for withdrawal of following licensed sections namely:

i. Tablet (Hormone) Section.
ii. Dry Powder Injection (Hormone) Section.
iii. Liquid Injection (Hormone) Section.

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

The Board considered and acceded the request of the firm for withdrawal of following licensed sections of the firm :

i. Tablet (Hormone) Section.
ii. Dry Powder Injection (Hormone) Section.
iii. Liquid Injection (Hormone) Section.

CASE NO. 51. GRANT OF NOC FOR METHYLENE CHLORIDE TO M/S PHARMAGEN (PVT) LTD, LAHORE.

Case Background:

. Assistant Director (I&E), DRAP, Lahore, has informed vide his letter dated 24th June, 2020 that M/s Pharmagen Ltd., uses Methylene Chloride as solvent in the manufacturing of APIs Amoxycillin, Ampicillin, Cephradine, Cephalexin, Cephadroxil, Cefaclor, Omeprazole, Betamethasone Sodium Phosphate, Betamethasone Valerate and Betamethasone Dipropionate.

. Assistant Director (I&E), DRAP, Lahore further informed that Drug Registration Board on its 286th meeting has decided as "Prohibit the use of Methylene Chloride and Sodium Cyclamate in the formulation of pharmaceutical products on the basis of ban imposed by USFDA.

. Meanwhile M/s. Pharmagen has submitted a document referring to ICH Q3C guideline stating that methylene chloride is a class II solvent whose use should be limited.

Working of Licensing Division:
According to ICH Q3C guideline Organic solvents are divided into four groups:

Class 1 solvents: Solvents to be avoided
The first group (Class 1) contains known human carcinogens, compounds strongly suspected of being human carcinogens, and environmental hazards. These solvents should be avoided, unless strongly justified.

Class 2 solvents: Solvents to be limited
Use of Class 2 solvents ought to be limited because they are non-genotoxic, animal carcinogens, possible causative agents of irreversible toxicity, such as neurotoxicity or teratogenicity. They are also suspected of other significant, reversible toxicities.

It is submitted that methylene chloride falls under category of Class II solvents with Permissible Daily Exposure of 6 mg per day.

Solvent	PDE (mg/day)	Concentration limit (ppm)
Dichloromethane (Methylene Chloride)	6.0	600

Class 3 solvents: Solvents with low toxic potential
They are less toxic in acute or short-term studies, and negative in genotoxicity studies. There is no solvent recognized as a human health hazard at levels normally accepted in pharmaceuticals in this group.

Class 4 solvents: Solvents for which no adequate toxicological data was found
For this group there is no adequate toxicological data enabling formulation of acceptable limits. If manufacturers want to use Class 4 solvents, they should supply justification for residual levels of these class solvents in a pharmaceutical product

Organization for Economic Co-Operation and Development Conducted a Survey & Published Its Report in 1994 in Paris,

According to the report the methylene chloride is mainly used :

1. As a component of paint and varnish strippers, and of adhesive formulations;
2. As a solvent in aerosol formulations;
3. **As an extractant solvent and as a process solvent in the food and pharmaceutical**
4. **industries;**
5. As an extractant of fats and paraffin.
6. As a process solvent in cellulose ester production, fiber and film forming, and
7. polycarbonate production.
8. As a blowing agent in the production of flexible polyurethane foam.
9. in plastics processing, and metal and textile treatment.
10. As a vapour degreasing solvent in the metalworking industries.

Use of methylene chloride in the pharmaceutical industry:

Main use of methylene chloride in the pharmaceutical industry are as under:

1. Reaction solvent and Extraction medium during manufacturing of APIs including a wide range of antibiotics. This solvent is used as it gives very specific extraction of the desired product with high yields. Due to its low boiling point, methylene chloride is readily removed without causing thermal degradation of the extract.
2. Methylene chloride, or blends with other solvents such as methanol or ethanol, are used in applying coatings to pills and tablets.

Reaction of world to the use of methylene chloride in the pharmaceutical industry according to OECD report:

. In the pharmaceutical industry in Sweden, intensive efforts are under way to find substitutes for methylene chloride. In the production of pharmaceutical substances, methylene chloride will mainly be replaced by other non-halogenated organic solvents. In the coating of tablets, water- or alcohol-based systems will be used.

Alternative Chemicals to Methylene Chloride in Pharmaceutical Industry according to OECD report:

• Non-halogenated solvents
• Water-based solutions

Cases discussed in 277th meeting of CLB with two different chemicals for synthesis of same molecule "Moxifloxacin hydrochloride".

. For synthesis of Moxifloxacin hydrochloride M/s Unichem Pharmaceuticals Pakistan (Pvt) Ltd., Islamabad is using methylene chloride in the process & M/s. Zenith Cheimcal Industries is using Methanol & Ethyle acetate in the process as an alternative solvent to methylene chloride both cases were discussed in 277th meeting of CLB.

Submitted for consideration and orders of the Board.

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

The Board considered and decided as under :

i. Firms may be allowed to use Methylene Chloride till final decision by the Central Licensing Board.

ii. API manufacturers may be asked to submit concrete proposal for alternate of methylene chloride as solvent in API to avoid unforeseen shortage of drugs .

iii. Personal hearing shall be accorded to all Pharmaceutical firms manufacturing APIs and they shall be heard before taking final decision.

CASE NO. 52. **GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000065 OF M/S UNEXO LABS PVT) LTD, LAHORE.**

Case Background:

M/s Unexo Labs (Pvt) Ltd, Lahore had applied for renewal of DML No. 000065 by way of formulation for the period of 13-06-2019 to 11-06-2024 on 16-04-2019. 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 22nd August, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

2. Nothing due certificate regarding CRF from STO, DRAP (Updated).
3. Detail of management at the time of previous renewal and at present, if any change apply for change of management.
4. Latest Certified true copy of Form-29 (Attestation by SECP).
5. Duly attested CNIC copies of all Directors.
6. Proof of all sections approved by CLB.

The firm submitted their reply on 24th September, 2019. After evaluation of the submitted documents, final reminder was issued on 20th July, 2020 to the firm with following shortcomings: -

1. Detail of management at the time of previous renewal and at present, if any change apply for change of management.
2. Attested copies of CNICs of all the Directors.

The firm did not submitted their reply in response to this Division's Final Reminder dated 20th July, 2020.

Submitted for consideration and orders of the Board.

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 000065 (by way of formulation) of M/s Unexo Labs (Pvt) Ltd, 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. 53. CHANGE IN ROUTE OF SYNTHESIS OF ESOMEPRAZOLE MAGNESIUM TRIHYDRATE PELLETS (MANUFACTURER SPECS) AND OMEPRAZOLE PELLETS (MANUFACTURER SPECS) M/S PHARMAGEN (PVT) LTD, LAHORE.

Case Background:

The Board considered the case in its 275th meeting of Central Licensing Board held on 25th June and decide to seek clarification from the panel of experts for not making recommendations as requested and mentioned in letter for inspection for Esomeprazole Magnesium Trihydrate Pellets (Manufacturer Specs) and Omeprazole Pellets (Manufacturer Specs).

Accordingly a letter was issued and now Mr. Ajmal Sohail Asif, FID, DRAP, Lahore in response to this Division's letter dated 28th August, 2020, has submitted stocks status of chemicals Omeprazole Sulphide, Omerprazole Powder and Esomeprazole Powder in the record of the firm as under:

Omeprazole Sulphide ; 1000kgs
Omerprazole Powder;1093.33kgs
Esomeprazole Powder; Nil

Submitted for consideration and orders of the Board.

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

The Board considering the facts on the record and after thread bare deliberation approved/allowed manufacture of esomeprazole pallets from API and the Board also approved manufacture of omeprazole pallets from API. However, firm will switch over to manufacture as approved after consumption of remaining raw material lying in stores as reported by the Federal Inspector of Drugs.

Case No. 54 CHANGE OF TECHNICAL STAFF UNDER DRUG MANUFACTURING LICENCE NO.000657 (FORMULATION) OF M/S WELBORNE PHARMACHEM & BIOLOGICALS, PLOT NO.51/1,52/2, PHASE I&II, INDSUTRIAL ESTATE, HATTAR.

The firm M/s Welborne Pharmachem & Biologicals, Plot No.51/1, 52/2, Phase I&II, Industrial Estate, Hattar has submitted the application for approval of proposed Production Incharge Mr. Shoukat Zaman S/o Sardar Gul Zaman (B-Pharm) CNIC No.13101-0993556-7. The firm has submitted a fee of **Rs. 5,000** . The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Attested copy of resignation letter of appointee from previous firm, has not been attached.

Accordingly, shortcoming letter No.F.3-4/2007-Lic (Vol-I) dated 27-07-2018was issued to rectify above mentioned shortcomings.

In response to above quoted letter the firm has submitted documents of new proposed Production Incahrge Mr. Shahbaz Khan S/o Haji Muhammad Anwar Khan (B-Pharm) CNIC No.13503-6846957-5 and proposed QC Incahrge Mr. Shah Alija Baig Mughal S/o Shah Taimur Baig Mughal alongwith Fee Challans of Rs.10,000/- . The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Resignation letter of previous Production Incharge.
ii. Attested copy of CNIC of proposed QC Incharge.
iii. Resignation letter of previous QC Incharge.
iv. Resignation letter of proposed QC Incharge from previous firm.
v. The proposed QC Incharge does not fulfill the requirements of Rule 16 (e) of (Licensing, Registering & Advertising) Rules, 1976 in terms of relevant experience in testing of drugs.

In response to above quoted letter the firm has submitted documents of new proposed QC Incahrge Mr. Nadeem Ilyas S/o Noor Khan ud Din alongwith Fee Challans of Rs.5,000/-. The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Copy of CNIC.
ii. Copy of academic degree(s).
iii. Experience certificate(s) not less than ten (10) years.
iv. Resignation letter of earlier QC Incharge.
v. Resignation letter of appointee from previous firm.
vi. Undertaking as whole time employee on stamp paper as per format of check list (attached).

Accordingly, shortcoming letter No.F.3-4/2007-Lic (Vol-I) dated 28-02-2019was issued to rectify above mentioned shortcomings.

In response to above quoted letter the firm has not submitted any response and a final reminder issued to the firm on 22-05-2019 with following shortcomings;

Proposed Production Incharge (Mr. Shahbaz Khan)

i. Resignation letter of previous Production Incharge.

Proposed QC Incharge (Mr. Nadeem Ilyas)

i. Copy of CNIC.
ii. Copy of academic degree(s).
iii. Experience certificate(s) not less than ten (10) years.
iv. Resignation letter of earlier QC Incharge.
v. Resignation letter of appointee from previous firm.
vi. Undertaking as whole time employee on stamp paper as per format of check list (attached).

Meanwhile, the firm has submitted another application for approval of proposed Production Incharge Mr. Muhammad Zubair S/o Musa Khan (Pharm-D) CNIC No. 12103-4437883-7 and proposed QC Incahrge Mr. Rehmat Zaman S/o Haider Zaman (M.Sc Chemistry) CNIC No.37406-1607037-7 alongwith fee challans of Rs.10,000/-. The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

Proposed Production Incharge (Mr. Muhammad Zubair)

i. Job acceptance letter
ii. Registration Certificate from Pharmacy Council.
iii. Resignation letter of previous Production Incharge.

Proposed QC Incharge (Mr. Rehmat Zaman)

i. Resignation letter of appointee from previous firm.

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, 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000657 (by way of formulation) of M/s Welborne Pharmachem & Biologicals, Plot No.51/1, 52/2, Phase I&II, Industrial Estate, Hattar, may not be suspended or cancelled by Central Licensing Board.

Case No. 55 CORRECTION IN THE NAME OF M/S JENNERPHARMACEUTICALS (PVT) LTD, DISTT. SHEIKHUPURA.

The firm, M/s Jenner Pharmaceuticals (Pvt) Ltd, Plot No. 3, M-2, Pharmazone, 26th Km Lahore Sharqpur Road, District Sheikhupurahas requested for correction in the name /title of the firm. The name/title of the firm is M/s Jenner Pharmaceuticals (Pvt) Ltd, Plot No. 3, M-2, Pharmazone, 26th Km Lahore Sharqpur Road, District Sheikhupura However, the name/title of the firm was inadvertently written/mentioned (Typho-eror) as M/s Jenner Research Laboratories, Plot No. 3, M-2, Pharmazone, 26th Km Lahore Sharqpur Road, District Sheikhupura in agenda and minutes of 277th meeting held on October 15-16, 2020 instead of M/s Jenner Pharmaceuticals (Pvt) Ltd, Plot No. 3, M-2, Pharmazone, 26th Km Lahore Sharqpur Road, District Sheikhupura.

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 approve correction in name/title of M/s Jenner Pharmaceuticals (Pvt) Ltd from M/s Jenner Research Laboratories under Drug Manufacturing License No. 000823 as proposed.

Case No. 56 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AGROR PHARMA (PVT) LTD, RAWAT, ISLAMABAD.**

M/s Agror Pharma(Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat, Islamabad had applied for renewal of DML No. 000791 by way of Formulation for the period of 03-02-2019 to 02-02-2024 on 23-01-2019.

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 29th May, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

1. Detail of management at the time of previous renewal and present renewal.
2. Attested Form 29 from SECP alongwith CNICs of all Directors.
3. Proof of sections approved by the Central Licensing Board.
4. Nothing due certificate regarding CRF from STO DRAP updated.

For Production Incharge (Mr. Abid Maqsood).

i. Appointment letter and job acceptance letter
ii. Resignation of the earlier production Incharge.
iii. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

For Quality Control Incharge (Mr. Salah ud Din).

i. Appointment letter and job acceptance letter
ii. Resignation of the earlier Quality Control Incharge
iii. Resignation / retirement of earlier approved QC Incharge.
iv. All documents should be duly attested.

The firm filed new application for approval of new Production Incharge on 24th May, 2019 but application was incomplete with following shortcomings and reminder letter was issued on 8th November, 2019 to the firm for completion of application:

For Renewal of DML.

1. Detail of management at the time of previous renewal and present renewal.
2. Attested Form 29 from SECP alongwith CNICs of all Directors.
3. Proof of sections approved by the Central Licensing Board.

For Quality Control Incharge (Mr. Salah ud Din).

1. Appointment letter and job acceptance letter of appointee.
2. Resignation / retirement of earlier approved QC Incharge.
3. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
4. All documents should be duly attested.

For Production Incharge (Khalid Rehman Khattak).

1. Appointment letter.
2. Job acceptance letter by the appointee.
3. Copy of CNIC of appointee.
4. Resignation / retirement of earlier approved Production Incharge.
5. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
6. All documents should be duly attested.

The firm submitted documents on 18th December, 2019 in reply to final reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Prescribed fee of Rs. 50,000/- for change of management as there is change in management of the firm.
ii. Latest certified true copy of Form-29 duly attested by SECP mentioning detail / name of all Directors / CEO.
iii. Duly attested CNIC copies of all Directors.
iv. Duly attested CNIC copy of proposed Production Incharge.

Proceedings and Decision by the Central Licensing Board in 275th 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), 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Agror Pharma(Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat Drug Manufacturing Licence No. 000791 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 Central Licensing Board.

The show cause notice dated 06thJuly, 2020 was issued to M/s Agror Pharma(Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat, Islamabad.
The firm has replied to show cause notice on22-07-2020 and submitted all documents except certified true copy of form-29.

A letter of Personal Hearing was issued to the firm on 28th August, 2020.

Decision by the Central Licensing Board in 276th meeting
Mr. Asad ullah, Chief Executive and Mr. Khalil Rehman Khattak respresenatative of the company appeared before the Board and contended that almost most of the shortcomings have been rectified. The Board after hearing the representative of the firm and considering the facts that some shortcomings still exists on the record and after thread bare deliberation decided to suspend the Drug Manufacturing Licence No. 000791 by way of formulation for three (03) months issued in the name of M/s Agror Pharma(Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat, 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 19 and 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.

Letter for suspension of Drug Manufacturing License was issued on 24th September, 2020. Now, the firm has replied and submitted all deficient documents in the application for renewal of DML.

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 cease the orders of suspension of Drug Manufacturing License No. 000791 (By way of Formulation)of M/s Agror Pharma(Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat, Islamabad for further period and allowed the firm to resume the production.

Case No. 56 DELEGATION OF POWERS UNDER RULE 8 (10) OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976.

The Rule 8 (10) empowers the Central Licensing Board to authorize Chairperson or any of its member for performing any specific functions of the Board including the disposal of day to day business of the Board through Secretary of the Central Licensing Board or any authorized officer. According, following proposal and are made for the consideration of the Central Licensing Board.

S#.	Powers	Powder to be Delegated to
	Delegation of Power related to Division of Drug Licensing	
1.	Show Cause Notice regarding contravention of any of the provision of the Drugs Act, 1976 and rules framed there under.	Chairman CLB
2.	Issuance of Inspection Book	Secretary CLB
3.	Approval of layout plan and constitution of committee for evaluation of layout plan.	Chairman CLB

	(The committee shall be constituted for the purpose of evaluation / assessment and analysis of the layout plan and shall furnish its recommendations accordingly to the Chairman CLB for approval).	
4.	Approval of change of name of a firm for licensed units/unlicensed units (after the site approval).	Chairman CLB
5.	Enlistment of drugs / APIs (Molecules) for basic, and semi basic manufacturing. (The inspections shall be made mandatory before grant of any item(s) / drugs/ APIs under respective Schedule etc.)	Chairman CLB
6.	Implementation of decisions of Appellate Board related to Division of Drug Licensing	Chairman CLB
7.	Approval of Repacking items under Schedule D of Drugs Act 1976 and Rules framed there under. (The inspections shall be made mandatory before grant of any item(s) / drugs/ APIs under respective Schedule etc.)	Chairman CLB
8.	Constitution / amendments in constitution of panel for inspection for grant/renewal of Drug Manufacturing License, Grant of Additional Sections and Verification / Checking of conditions of License etc of firms.	Chairman CLB
9.	Extension in Sealing period of Licensed manufacturers where Contraventions(s) is / are of Conditions of DMLs only.	Chairman CLB
10.	Correction of typographical error in recording of agenda and minutes of the CLB.	Chairman CLB
11.	Approval of change of management / Director / Owner etc of licensed firm after verification of relevant legal documents.	Chairman CLB
12.	Approval of Technical Staff and communication / Issuance of decisions of Central Licensing Board.	Secretary CLB
13.	Site approval for establishment of pharmaceutical units.	Secretary CLB
14.	Approval of change of name of an unlicensed firm / unit (before the approval of site).	Secretary CLB

Decision by the Central Licensing Board in 273rd meeting

The Central Licensing Board approved and delegated its functions/powers related to Division of Drug Licensing to its Chairman and Secretary under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 in order to facilitate timely disposal of routine and day to day business of Central Licensing Board as under:

S#.	Powers	Powder to be Delegated to
1.	Issuance of Inspection Book	Secretary CLB
2.	Approval of layout plan and constitution of committee for evaluation of layout plan. (The committee shall be constituted for the purpose of evaluation / assessment and analysis of the layout plan and shall furnish its recommendations accordingly to the Chairman CLB for approval).	Chairman CLB
3.	Approval of change of name/management of a firm for unlicensed units (after the site approval).	Chairman CLB
4.	Constitution / amendments in constitution of panel for inspection for grant/renewal of Drug Manufacturing License, Grant of Additional Sections and Verification / Checking of conditions of License etc of firms.	Chairman CLB
5.	Correction of typographical error in recording of agenda and minutes of the CLB.	Chairman CLB
6.	Approval of Technical Staff	Secretary CLB
7.	Site approval for establishment of pharmaceutical units.	Chairman CLB

The delegation of power accorded in any of the previous meetings shall stand superceeded with immediate effect.

Current position:-

At present post of Director (Licensing) is vacant. Numbers of cases are pending due to non-availability of Director (Licensing), which results in delay in disposal of day to day work. Submitted for consideration of the board appropriate decision to address the matter.

The case is placed before the CLB for consideration, please.

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

The Board discussed and deliberated that powers delegated to Director(Licensing)) in its 273rd meeting of Central Licensing Board shall be exercised by Additional Director (Licensing) in case of occurrence of vacancy on the post of Director (Licensing) or leave for the period more than ten (10) days.

QUALITY ASSURANCE CASES

Item No. I DELEGATION OF POWERS

Case No. i: POWER DELEGATION.

As per decision of 273rd meeting of CLB, the powers delegated to Director QA&LT and other officers of QA&LT in 237th meeting of CLB are given below;

"The Central Licensing Board approved and delegated its powers retrospectively with certain modifications to Director Quality Assurance and Laboratory Testing under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) rules, 1976 in order to facilitate timely disposal of routine and day to day business of Central Licensing Board.

S No.	Functions / Powers	Function / Powder Delegated to
Delegation of Functions / Powers related to the Division of Quality Assurance & Laboratory Testing		
1.	Show Cause Notice regarding contravention of any of the provision of Drugs Act, 1976 and rules framed there under (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
2.	Advisory letters, explanation letters or any other action as deems fit for the purpose of improvement (in case of GMP matters)	Director Quality Assurance and Laboratory Testing
3.	Suspensions of Production (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
4.	Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members	Director Quality Assurance and Laboratory Testing
5.	Permission to Lodge FIR	Director Quality Assurance and Laboratory Testing
6.	Panel Constitution (GMP Inspections and related issues etc)	Director Quality Assurance and Laboratory Testing
7.	Constitution/ amendments in constitution of panel for inspection for GMP compliance and quality control matters.	Director Quality Assurance and Laboratory Testing
8.	To continue the period of "not to dispose-of stocks orders passed by FID" for three months or till the finalization of the case (in case of un-registered/Spurious Drugs).	Director Quality Assurance and Laboratory Testing
9.	To continue custody of the seized stocks by the FID till decision of the case (in case of un-registered/Spurious Drugs).	Director Quality Assurance and Laboratory Testing
10	To grant approval for sending Board's portion of drug samples to the Appellate Laboratory (in case of un-	Director Quality Assurance and Laboratory Testing

	registered/Spurious Drugs).	
11	Grant of extension in the time of testing to Federal Government Analyst (in case of un-registered/Spurious Drugs).	Director Quality Assurance and Laboratory Testing
12	Issue of Show Cause Notices/Personal hearing letters/Circulars/Communication of Minutes/Decisions/Directions of the Board to the Concerned quarters regarding GMP and Quality Control matters on behalf of Secretary Board.	Assistant Director (QA&LT) / Deputy Director (QA&LT)

At present post of Director (QA&LT) is vacant. Number of cases are pending due to non-availability of Director (QA&LT), which results in delay in disposal of day to day work.

Proceedings & decision of 278th meeting: -

The Board discussed and deliberated that power delegated to Director (QA&LT) in its 273rd meeting of Central Licensing Board shall be exercised by Additional Director (QA&LT), in case of occurrence of vacancy on the post of Director (QA&LT) or leave for the period more than ten (10) days.

Item No. II PERSONAL HEARING IN COMPLIANCE TO DECISION OF 277TH MEETING OF CLB

Case No. I:- M/s Welwink Pharmaceutical. Gujranwala.

Background

The GMP inspection of the firm M/s. Welwink Pharmaceuticals, G.T. Road, Industrial Estate, Gujranwala Cantt, Gujranwala was conducted by following *panel on 11.10.2019* to check the GMP compliance.

i. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore
ii. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore
iii. Ms. Maham Misbah, AD, DRAP, Lahore

2. The panel during inspection noticed following observations which need urgent attention and rectifications:-

Change Rooms:-

i. Improve the cleanliness of workers change rooms.

Storage Areas:-

i. Firm has not provided exterior solvent storage area and drums of solvents i.e. IPA were placed in receiving bay.
ii. HVAC was not provided in RM dispensing room.
iii. Sampling booth was not provided.

Production Areas

Tablet Section:-

i. Differential pressures of rooms were not proper, manometers in drying room were not working and glass of windows was broken at some places.

Capsule Section:-

i. Differential pressure of filling room was not appropriate.

Sachet Section:-

i. Differential pressure of filling room was not appropriate.

Liquid Injectable Section:-

i. Ampoule / vial washing room was having a door directly opening in water treatment system room (Uncontrolled area) without any buffer.
ii. Epoxy flooring was damaged at various places.
iii. In filling room pressure gradient was not appropriate as per manometers. HVAC ducting was not appropriate both air supply and air return ducts were in the ceiling, suggesting inadequate air flow and supply in the filling room.
iv. Doors and windows were made of aluminum and glass, were not smooth / flushed, not being closed properly, gaskets were broken / damaged at many places having edges and recesses for accumulation of dirt and dust. Such doors and windows were not appropriate for sterile manufacturing area.
v. Buffers at entrance were not appropriate, pressure differentials were not adequate, doors were not being closed properly.
vi. There was no provision for supply of purified water for manufacturing, management informed that they carry purified / WFI form water purification system in buckets.

Dry Powder Injectable Section:-

i. Ampoule / vial washing room was having a door directly opening in water treatment system room (Uncontrolled area) without any buffer.
ii. Epoxy flooring was damaged at various places.
iii. In filling room pressure gradient was not appropriate as per manometers. HVAC ducting was not appropriate both air supply and air return ducts were in the ceiling, suggesting inadequate air flow and supply in the filling room.
iv. Doors and windows were made of aluminum and glass, were not smooth / flushed, not being closed properly, gaskets were broken / damaged at many places having edges and recesses for accumulation of dirt and dust. Such doors and windows were not appropriate for sterile manufacturing area.
v. Buffers at entrance were not appropriate, pressure differentials were not adequate, doors were not being closed properly.

Sanitation and Hygiene:-

i. Improve the general cleanliness of RM store, receiving bay and workers change rooms.

Qualification and Validation:-

i. Process and cleaning validations were not being carried out as per SOPs and no record for cleaning validation was provided.
ii. Media fill test for aseptic filling processes was not performed.

Complaints:-

i. No records were maintained and shown.

Product Recalls:-

i. The firm has not developed a proper SOP for product recall only a very rudimentary procedure was available. The firm was advised to upgrade the SOP and perform a mock recall to evaluate the effectiveness of the recall system.

Personnel:-

i. The firm has not hired adequate number of qualified persons. In addition to production manager, in production department there was only one Pharmacist despite the fact that firm has 5 manufacturing sections.
ii. Strengthen the production and QA sections by hiring adequate technical staff.

Equipment & Machinery:-

i. At the time of inspection FTIR was not present, the management informed that it was out of order and sent for maintenance.
ii. Karl Fischer was not available.
iii. Dissolution and Disintegration apparatuses required upgradation as their glass has become hazy / blurred.
iv. Digital Polarimeter was not provided.

Materials:-

i. Improve the material management system.
ii. The labels were not having complete information of the product as required to be.
iii. Maintain the storage conditions of stores as at the time of inspection, temperature and humidity of the PM store, where aluminum foils etc. were placed, was found out of specification.

Documentation:-

i. It was noted that BMRs in tablet section were not being filled appropriately with real time entries.
ii. Log books for QC instruments were not maintained.
iii. Log books for production machinery were not maintained.

Good Practices in Production:-

i. Workers were seen wandering outside the production area in uniform.
ii. In in-process quarantine of the tablet section a number of different products in different manufacturing stages were placed in poly bags / empty and dirty drums of raw materials without proper labelling and storage conditions.
iii. Real time entries of manufacturing procedure were not being made in BMR.

Good Practices in Quality Control:-

i. It was found that the log books were not being maintained properly. The SOPs were not being implemented in true letter and spirit. Deviations from standard procedures were observed.

ii. For most of the products firm was using in-house testing procedures (which were even not validated) in spite the fact that these products were included in official monographs of compendial books.
iii. The firm was using in house working standards for testing and was advised to purchase reference standards.
iv. No microbial cultures were available in microbiology lab. Firm was not performing growth promotion test for media.

Utilities

Water Purification System;-

i. It was noted with grave concern that the firm has not provided loop system for supplying the purified water to manufacturing sections even no water transfer pipes were provided. Firm was carrying purified water to manufacturing section, even in sterile manufacturing areas, through buckets. It was also noted that firm was many times asked to install loop system for transferring purified water but no avail.

ii. *Fir has not validated its water purification system. The firm has not developed procedure for sanitization of water purification system.*

HVAC System;-

i. *It seemed to be in adequate in injectable sections as both air supply and return ducts were in ceiling, suggesting it to be incapable to provide class A/B for aseptic processing area. Manometers were not installed in some areas. In oral solid dosage sections pressure differentials needed to be adjusted properly as pressure gradients were not appropriate in different sections.*

ii. *It was also noted that there was no electricity generator as a backup in electricity shut down, this also put the manufacturing process in high risk especially the aseptic and sterile manufacturing processes.*

Conclusion:-

"Based on the areas inspected, the people met and considering the findings of inspection, the panel was of the opinion that at the time of inspection, the firm was:

i. ***Not complying*** *with the GMP requirements as required under the Drug (Licensing, Registering and Advertising) Rules, 1976 with reference to* ***Liquid Injectable and Dry Powder Injectable Sections.***

ii. Operating at a satisfactory level of compliance with the GMP requirements as required under the Drug (Licensing, Registering and Advertising) Rules, 1976 with reference to Tablet, Capsule and Sachet sections."

Recommendations:-

"In the light of conclusion, the panel recommends that the firm may be directed to stop production in liquid injectable and dry powder injectable sections. Rectify the deficiencies and submit CAPA."

3. However the firm M/s. Welwink Pharmaceuticals, G.T. Road, Industrial Estate, Gujranwala Cantt, Gujranwala *disagreed with the above report vide Letter No. Nil dated 06.01.2020. Management of the firm requested for re-inspection with other panel of inspectors*.

4. Following panel conducted *re-inspection of M/s Welwink Pharmaceuticals, G.T. Road Industrial Estate Gujranwala Cantt, Gujranwala on 25-02-2020*.

i. Mr. Abdul Rashid Sheikh FID, DRAP Lahore.
ii. Mr. Shoaib Ahmed FID DRAP Lahore.
iii. Ms. Anam Saeed AD, DRAP Lahore.

5. The panel reported following observations: -

i. Change Rooms

a. The firm was advised to install hand sanitizer and provide lockers for the workers to keep their belongings.

ii. Storage Area:

a. Provide exterior solvent storage area to store solvents/liquids.
b. Provide HVAC ducting in dispensing room.
c. Ensure availability of sampling booth.
d. Provide separate rejected area.
e. Monitor temperature humidity of store because capsule shells were found stored inside Raw Material Store where humidity was 92% at the time of visit.
f. Provide separate recalled / returned area.
g. Improve labels.

iii. Tablet Section:

a. It was noted that differential pressures of rooms were not proper, manometer was not installed in mixing room. It was advised to maintain the differential pressure and install manometers in all rooms.

iv. Capsule Section:

a. Differential pressure of filling room was not appropriate. It was advised to adjust the differential pressures.

v. Sachet Section:

a. Differential pressure of filling room was not appropriate and humidity was found 65% at the time of visit.

vi. Injectable Section:

a. The firm was having a single autoclave which was used for sterilization of filled liquid vials as well as for sterilization of uniforms and utensils.
b. One side of autoclave was opened in vial washing room and other side was in cooling room (between liquid injectable filling room and dry powder injection filling room).
c. Ampoule / vial washing room was having a door directly opening in water treatment system (uncontrolled area) without any buffer. The firm informed that the door is not in use but it was advised to close it permanently.
d. Firm was advised to validate HVAC system as differential pressures were not proper in many areas.
e. HVAC ducting in some rooms were not appropriate as both air supply and air return ducts were in the ceiling, suggesting

inadequate air flow and supply in those areas. It was advised to make proper ducting.

f. Firm was advised to make doors and windows smooth/flushed with proper door closures.
g. Firm was advised to install air supply and air return ducts in all buffers as returns were not provided in some buffers and air supply ducts were missing in some buffers.
h. It was advised to provide proper loop system because a paste cooking vessel was modified as a storage tank of WFI in water treatment as well as for supply of WFI in manufacturing areas which was not found appropriate.
i. It was advised to provide cooling trolley with HEPA filter in the cooling zone.
j. It was advised to provide supply of RO water in solution preparation room.
k. It was advised to arrange separate autoclave for sterilization of uniform and utensils.
l. It was advised to calibrate temperature and pressure gauges of the solution preparation tanks and install heat exchanger in solution preparation room.
m. It was advised to replace screens of optical checking and ensure availability of Lux meter.
n. It was advised to perform media fill trial.

vii. <u>Quality Control</u>

a. HVAC ducting was not appropriate in microbiology laboratory and its buffers.
b. Improve LFC in sterility room as it was not working properly at the time of inspection.
c. Ensure the availability of air sampler and improve area monitoring reports as advised.
d. Purchase reference standards
e. Perform media fill trial.
f. Ensure the availability of FTIR, Karl Fischer and Digital Polarimeter.
g. Upgrade Dissolution and Disintegration apparatus.
h. Ensure the availability of cultures in microbiological laboratory.
i. Perform growth promotion test for media.

viii. <u>Personnel:</u>

a. Only 1 pharmacist in addition to production pharmacist was working despite the fact that firm had 5 manufacturing sections. The firm had one QC Manager who was M.Sc. Chemistry and one pharmacist who was working as microbiologist. In QA there was only one pharmacist who

was a fresh graduate. The firm was advised to strengthen the Production and Quality Assurance Departments.

ix. <u>Water Purification System:</u>

a. The system was not functional at the time of visit and also found inappropriate. Firm had also not validated its water purification

system and not developed procedure for sanitization of water purification system.

b. Provide proper storage tank for WFI with a proper loop system.
c. Validate water purification system.
d. Develop procedure for sanitization of water purification system.

x. <u>HVAC System:</u>

a. Both air supply and return ducts were found in ceiling, inside some areas of injectable sections, suggesting it to be incapable to provide class A/B for aseptic processing, areas. Manometers were not installed in some areas. Differentials pressures required adjustments as pressure gradient were not appropriate in different sections. Firm was asked to provide HVAC validation data but the firm could not provide the same to the panel.
b. It was also noted that there was no electricity generator as a backup in electricity shut down, this also put the manufacturing process in high risk especially the aseptic and sterile manufacturing processes.

6. The Conclusion of report is reproduced below;

> *"Based on the areas inspected, the people met and considering the findings of inspection, the panel is of the opinion that the firm was operating at satisfactory level of GMP compliance for all sections* ***except Liquid Injectable Section*** *because of absence of proper loop system and others observations pointed out above in the different areas as well, As the improvements of the system is a continuous process."*

7. Since the panel had reported critical points yet concluded that the firm was operating at satisfactory level of GMP compliance, the competent authority advised to ask the panel for clarification on the critical points.

8. Consequently, the panel submitted the following reply;

> *"As GMP is ongoing improvement process, whereas the firm also addressed some points which were already mentioned. However, as there were no such critical observations in the recommended sections as per the view of the panel. The panel did not recommend the "<u>liquid injectable section</u>" of the firm. Since there were no critical observations in the remaining sections other than liquid injectable section. So, the panel keeping in view the major and minor observations, recommends their other approved sections, except* ***liquid injectable section.*** *The panel is of the opinion that firm was operating at satisfactory level of GMP at the time of inspection."*

9. In light of above the firm was advised to rectify the observations of liquid injectable section and submit compliance report. It was communicated vide letter No.F.4-169/2016-QA dated 07.09.2020 that the ***<u>production in liquid injectable section shall remain suspended till submission of compliance report</u>****;* it was further informed that the

verification shall be done by the panel and subsequent approval from competent authority as panel did not recommend the liquid injectable section.

10. In response to the above the firm submitted letter with the subject title ***"Challenging GMP Inspection Report"***. Wherein the firm M/s. Welwink Pharmaceuticals, Gujranwala challenged this office letter of even No. dated 07.09.2020, recommending not to resume the production activities in Liquid Injectable Section. Furthermore, they have stated that *"they disagree with the recommendation in the report regarding* ***Liquid Injectable Section*** *and overall recommendations."* and they have requested to reconstitute new panel for inspection of their premises.

11. The case was placed before the 277th meeting of CLB. Wherein the Board decided as under:-

Decision of 277th meeting of CLB:

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendation of panel in its report dated 11.10.2019 & 25.02.2020 and reply of the firm dated 06.01.2020 & 22.09.2020, the Central Licensing Board decided to: -

i. Direct the firm to submit compliance report on the observations noted in panel inspection reports dated 11.10.2019 & 25.02.2020.

ii. Production in ***Sterile Area (Liquid Injectable)*** of the firm M/s Welwink Pharmaceuticals, GT Road, Gujranwala shall remain suspended.

12. Decision of 277th meeting of CLB was conveyed to the firm vide letter dated 28.10.2020.

Proceedings of 278thMeeting of CLB

Mr. Arshad Mehmood, Managing Director of the firm M/s. Welwink Pharmaceuticals, GT Road, Gujranwala appeared before the Board.

Decision of 278thMeeting of CLB

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

i. Direct the firm M/s. Welwink Pharmaceuticals, GT Road, Gujranwalato submit CAPA on the observations noted in panel inspection reports dated 11.10.2019 & 25.02.2020.

ii. Additional Director (QA&LT) shall decide the matter accordingly.

Item No. III **RESUMPTION OF PRODUCTION**

Case No. I: **M/S. RAAZEE THERAPUTICS (PVT.) LTD, KASUR.**

Background:

Inspection of the firm M/s. Raazee Therapeutics (Pvt.) Ltd., 48-KM, Lahore-Kasur Road, Kasur was conducted in compliance to letter No. F. 03-41/2019-QC (291-RB) dated 19.09.2019. The following panel conducted inspection on 03.10.2019.

i. Mr. AjmalSohail Asif, FID, DRAP, Lahore
ii. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore
iii. Ms. MahamMisbah, AD, DRAP, Lahore

Action taken by DRAP:

2. The firm M/s. Raazee Therapeutics (Pvt.) Ltd, Kasur was served Show Cause Notice /Suspension of Production activities in Liquid Injectable Section order No.F.4-17/2002-QA (Vol-I) on 05.12.2019.

3. The case was placed before 273rd meeting of Central Licensing Board. Wherein the Board decided as under:-

Decision of 273rd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view available record and submission of the firm, the Board decided to :-

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

- Dr. Munawar Hayat, CDI, Punjab.
- Mr. AjmalSohail Asif, FID, Lahore
- Area FID, Lahore

ii. Direct the panel to submit detailed report with clear and candid recommendations.

iii. Production in the Liquid Injectable Section shall remain suspended till verification by panel of experts and subsequent approval by the Central Licensing Board.

iv. Refer the case to Drug Registration Board for necessary action at their end regarding manufacturing and sale of substandard Narobe Infusion, Batch No. 104092.

4. The decision was conveyed to the quarter concerned vide letter dated 06.02.2020 and reminder was issued on 13.05.2020.

Request of FID

5. Dr. Syed Zia Husnain, FID, DRAP, Lahore vide letter dated 04.08.2020 informed that Dr. Munawar Hayat, CDI Punjab has been transferred from the post of CDI, Punjab. He requested for reconstitution of panel of experts to carry out the said inspection.

6. Request of the FID was placed before the 276th meeting of CLB, wherein Board decided as under: -

Decision of 276th Meeting of CLB

The Board considered the proposal and decided to replace Dr. Munawar Hayat, Chief Drug Controller, Punjab with Chief Drug Controller Punjab in panel already constituted in 273rd meeting of CLB.

Panel Inspection

7. Panel comprising of Mr. Azhar Jamal Saleemi, CDC, Punjab, Mr. Ajmal Sohail Asif, FID, Lahore and Dr. Syed Zia Husnain, FID, Lahore in compliance to the decision of 276th meeting of CLB conducted inspection of the firm M/s. Raazee Therapeutics (Pvt.) Ltd, Kasur on 27.10.2020 and concluded as under: -

"panel thoroughly inspected the liquid injectable section and other respective areas of the unit. Panel also evaluated various documents in detail. Panel is of the view that the firm has complied advises already given during previous panel inspections and made the improvements and upgradations as per GMP requirements as already advised. Therefore, panel recommended resumption of production of liquid injectable section of M/s Therapeutics (pvt) Ltd, Kasur".

Proceedings of 278thmeeting: -

Quality Assurance Division presented the panel inspection report of the firm M/s. Raazee Therapeutics (Pvt.) Ltd, Kasur dated 27.10.2020 in compliance to decision of 273rd and 276thmeeting of CLB.

Decision of the 278thMeeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case and panel inspection report dated 27.10.2020 constituted in 276thmeeting of CLB, the Central Licensing Board decided to allow resumption of production activitiesin *liquid injectable section*of the firm M/s Raazee Therapeutics (pvt) Ltd, Kasur, as per recommendation of panel, from the date of issuance of decision of 278thmeeting of CLB.

Item No. IV **RATIFICATION OF DECISION OF 277TH DECISION OF CLB**

Case No. I:- **M/s ATCO LABORATORIES LIMITED KARACHI**

Mr. Awais Ahmed FID DRAP Karachi conducted GMP inspection of M/s Atco laboratories Limited Karachi on 21.08.2020 and 02.09.2020.

2. FID noticed number of observations. The FID concluded as under: -

Conclusion of FID: -

"Keeping in view above mentioned major and critical observations, violation of Schedule B-II of LRA rules 1976 and approved Layout, non-compliance of the directions issued for suspension of production area for lotion manufacturing in unauthorized area, firm was considered to be operating at unsatisfactory compliance level of GMP in Old unit, and firm has already been ***directed to suspend their production activities in Sterile Area (Liquid Injectable Ear/Eye/Nasal Drops), Lotion and Enema*** *vide letter No.NO.F.03-03 /2 019 AD / FID-I X (K) dated 09.10.2020 and submit compliance letter and CAPA to QA&L T division for above mentioned observations for onward consideration at earliest."*

3. The Case was placed before the 277th meeting of CLB. Wherein the Board decided as under: -

Decision of 277th meeting of CLB:

After thorough discussion/deliberations, considering all the pros and cons of the case and recommendations of FID in his reports dated 21.08.2020, 02.09.2020 & 01.10.2020 and CAPA submitted by the firm, the Central Licensing Board decided as follows;

i. In order to verify CAPA submitted by the firm following panel has been constituted by the board;

   a. Dr. Abdullah Dayo, Member Central Licensing Board.
   b. Mr. Sajjad Ahmed Abbasi, FID DRAP Karachi.
   c. Area FID, DRAP Karachi

ii. The board authorized Chairman CLB/Additional Director QA&LT to pass orders on the recommendations of the panel of experts, accordingly.

4. The panel conducted inspection of the firm M/s Atco laboratories Limited Karachi on 06.11.2020. The panel concluded as under: -

> ***"firm may be allowed to resume their production activities in Sterile Area (Liquid Injectable, Ear/Eye/Nasal Drops), till shifting to new area or for the period six months, which-ever is the earlier or any other decision, Honorable board may deems fit. However Liquid and Enema section was already in operational condition, which was allowed by area FID on dated 01st Oct 2020, is also hereby endorsed by the panel. Firm unanimously verified the changes as per layout approval, issued vide Letter No. F .2-5/85-Lic (Vol-vi), dated 30th Sep 2020."***

5. It is pertinent to mention here that Dr. Abdullah Dayo, Member CLB gave note as under: -

> *"it was unanimously decided by the panel to allow one year shifting period to firm. Period of six months mentioned was note unanimous decision of panel"*

6. Keeping in view decision of CLB, the report was referred to the Additional Director (QA&LT). The Additional Director (QA&LT) endorsed recommendations of Panel report dated 06.11.2020. Accordingly, resumption of production was allowed vide letter dated 19.11.2020 for a period of Six Months.

Proceedings of 278thmeeting: -

Quality Assurance Division presented the panel inspection report of the firm M/s Atco laboratories Limited Karachi dated 06.11.2020 in compliance to decision of 277thmeeting of CLB. It was apprised to the Board that resumption of production was allowed vide letter dated 19.11.2020 for a period of six months. Dr. Abdullah Dayo, Member, CLB added that during inspection it was decided by the panel to allow one-year time to firm for shifting to new premises/building.

Decision of the 278thMeeting of CLB

After thorough discussion/deliberations, the board considered recommendations of Dr. Abdullah Dayo, Member CLB and allow one-year time period for shifting of the firm M/s Atco laboratories Limited Karachi to new premises/buildingfrom the date of inspection dated 06.11.2020. In case of failure, Board will proceed as per law.

Meeting ended with the vote of thanks to and by the Chair.