MINUTES OF 288th MEETING OF CENTRAL LICENSING BOARD HELD ON 18th OCTOBER, 2022

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288th meeting of the Central Licensing Board (CLB) was held on 18thOctober, 2022 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad. Mr. Muhammad Akhtar Abbas Khan, Chairman Central Licensing Board, Drug Regulatory Authority of Pakistan, Islamabad presided the meeting. Following members attended the meeting: -

S.No	Name & Designation	Status
1.	Dr. Najam-us-Saquib, Addl. Director, Drug Regulatory Authority of Pakistan, Islamabad.	Secretary/ Member
2.	Mr. Azher Jamal Saleemi, Chief Drugs Controller, Government of Punjab, Lahore	Member
3.	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Balochistan, Quetta	Member
4.	Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Bannu Government of Khyber PakhtunKhwa	Member
5.	Mr.Ghulam Ali Lakho, Drug Inspector, Government of Sindh, Karachi	Member
6.	Mr. Ajmal Sohail, Director, Division of Quality Assurance and Lab Testing, Drug Regulatory Authority of Pakistan, Islamabad	Member
7.	Mr. Abid Ali, Law Expert, Ministry of Law & Justice Division, Islamabad	Member
8.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
9.	Mr. Adnan Hirani Representative of PPPMA	Observer
10.	Mr. Khalid Muneer, Representative of PPPMA	Observer
11.	Mr. Kamran Anwar Representative PCDA	Observer

The meeting started with the recitation of Holy verses.The Chairperson stated that all the legal and codal formalities would be taken into account for disposal of cases and respective Divisions shall be responsible for the contents, errors and omissions of agenda and minutes thereof. The Central Licensing Board considered, discussed and decided cases on merit. Secretary Licensing Board presented the agenda before the Board. Ms. Zunaira Faryad, AD (Lic), Mr. Muhammad Yaqoob AD (Lic) Mr. Abdullah Bangash, AD (Lic), Mr. Hassan Afzal, AD (QA) and Ms. Mehwish Tanveer, AD (QA) DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 287TH MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 287th meeting of the Central Licensing Board (CLB) held on 24th June, 2022.

A. DRUG LICENSING DIVISION

Item-II **GRANT OF NEW DRUG MANUFACTURING LICENSE.**

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s S&K Pharmaceuticals, Plot No. 252, Sunder Industrial Estate, Lahore.	11-03-2022 24-06-2022 25-07-2022 (Formulation)	Good	1. Mr. Muhammad Shamoon, Expert Member. 2. Mrs. Majida Mujahid, Additional Director/FID, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

On the basis of the inspection of M/s S&K Pharmaceuticals, Plot No. 252, Sunder Industrial Estate, Lahore conducted on 11-03-2022, 24-06-2022 and 25-07-2022, with reference to DRAP Letter No.F.1-22/2014-Lic, dated 22-06-2021, the personnel met and the equipment and facility seen and the documentation reviewed, the panel of inspectors is of the opinion to recommend the grant of Drug Manufacturing License to M/s S&K Pharmaceuticals, for the following two sections;

i. **Liquid Infusion (General)**
ii. **Liquid Injectable Ampule (General)**

On the basis of high risk of cross-contamination, due to the absence of dedicated facility for production of injectable steroids and the observations given in detail in the report, **the panel does not recommend the grant of Drug Manufacturing License to the firm in Injectable (Steroid)**section till the rectification of deficiencies, pointed out during the course of inspection after approval from the competent authority, where required.

Decision of the Central Licensing Board in 288th meeting

	The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s S&K Pharmaceuticals, Plot No. 252, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the following sections: **Sections (2)** i. Liquid Infusion (General) ii. Liquid Injectable Ampoule (General)			
2	M/s A.J. Mirza Pharma (Pvt) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi	22-08-2022 (Formulation)	Good	1. Dr. Najam-us-Saquib, Additional Director, DRAP, Karachi. 2. Mr. Abdul Rasool Sheikh, Area FID, DRAP, Karachi. 3. Dr. Krishan, Assistant Director, DRAP, Karachi.
	Drug Manufacturing License No. 000234 by way of Formulation was issued to M/s A.J. Mirza Pharma (Pvt) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi and due date of renewal of License was10-07-2020. It is pertinent to mention that Rule 6 of Drug (L, R & A) Rule, 1976 states "if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 7,500/- per day the application is delayed and thereafter until orders are passed on such application". Furthermore, Rule 5(3) states that "If the application for renewal of the license is made after the expiry of the period of the validity of the license, it shall be treated as a fresh application for the grant of a license."Application for renewal of DML for the period 10-07-2020 till 09-07-2025 has not been received with in prescribed period. The case was placed before Central Licensing Board in its 279th meeting held on 18th February,2021 with all details. The Central Licensing Board considered facts and decided to cancel the Drug Manufacturing License No. 000234 (Formulation) of M/s A.J. Mirza Pharma (Pvt) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi as the Drug Manufacturing License No. 0000234 (Formulation) is no more valid as under Rule 5 (6) of Drug (L, R & A) Rule, 1976.Accordingly, letter was issued in light of decision of CLB in above meeting. M/s A.J. Mirza Pharma (Pvt) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi applied afresh application alongwith requisite documents and prescribed fee for grant of afresh DML vide letter No. DRAP/AJM/10197 dated 09-02-2021. After completion of application and other codal formalities, a panel was constituted for inspection of the premises for afresh/re-grant of DML. **Recommendations of the panel:** M/s A.J. Mirza, situated at Plot No.44, Sector 27, Korangi Industrial Area, Karachi was inspected by the panel as constituted vide DRAP Islamabad Letter No.F.2-31/84-Lic (Vol-III) dated 16th August, 2022. Following are the observations:			

	During the detailed inspection it was observed that the firm is equipped with necessary equipment and machinery required for the production and quality control. HVAC system seen installed and observed operational in all the production sections. Management informed that the production activities are no carried out since the acquirement of this factory from the previous management. The current management has made tremendous improvements and upgradations as per approved layout plan. Technical personnel engaged by the management were seen experiment and well conversant with the concept of the GMP/cGMP compliance. QC Lab was found equipped with required equipment including 21 CFR compliant HPLC etc. Climate Chambers were seen available on site. Keeping in view the above stated findings of the inspection and intention of the management towards exports, the Panel unanimously recommends the re-grant of Drug Manufacturing License (by way of formulation) for the below mentioned section: i. Tablet (General) ii. Capsule (General) iii. Liquid Syrup (General) iv. Dry Powder (General) **Decision of the Central Licensing Board in 288th meeting** The Board considered the facts and approved the grant of **a fresh** Drug Manufacturing License by way of Formulation in the name of M/s A.J. Mirza Pharma (Pvt) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi assigning the DML NO 000234 on the recommendations of the panel of experts for the following sections: **Sections (04)** i. Tablet (General) ii. Capsule (General) iii. Liquid Syrup (General) iv. Dry Powder (General) This approval shall not absolve company from its previous/pending liabilities/obligations of what soever nature.			
3	M/s Saturn Pharmaceuticals (Pvt) Ltd., 23-Km, Thokar Raiwind Road, Lahore.	30-06-2022 (Formulation)	Good	1. Dr. Ikram Ul Haq, Expert Member. 2. Federal Inspector Drugs, DRAP, Lahore. 3. Assistant Director, DRAP, Lahore.

Drug Manufacturing License No. 000734 by way of Formulation was issued to **M/s Saturn Pharmaceuticals (Pvt) Ltd, Lahore** and due date of renewal of License was 15-06-2021. It is pertinent to mention that Rule 6 of Drug (L, R & A) Rule, 1976 states "if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 7,500/- per day the application is delayed and thereafter until orders are passed on such application". Furthermore, Rule 5(3) states that "If the application for renewal of the license is made after the expiry of the period of the validity of the license, it shall be treated as a fresh application for the grant of a license. Application for renewal of DML for the period 15-06-2021 to 14-06-2026 has not been received with in prescribed period. The case was placed before Central Licensing Board in its 284th meeting held on 16th December, 2021 with all details. The Central Licensing Board considered facts and decided to cancel the Drug Manufacturing License No. 000734 (Formulation) of M/s Saturn Pharmaceuticals (Pvt) Ltd, Lahore as the Drug Manufacturing License No. 000734 (Formulation) is no more valid as under Rule 5 (6) of Drug (L, R & A) Rule, 1976. The Board further decided that firm may file an application a fresh under Rule 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

M/s Saturn Pharmaceuticals (Pvt) Ltd, Lahore applied afresh application alongwith requisite documents and prescribed fee for grant of afresh DML vide letter No. Nil dated 07/09/2021

Accordingly, after completion of application and other codal formalities, a panel was constituted for inspection of the premises for afresh/re-grant of DML.

The panel submitted its report and recommendation.

Recommendations of the panel:

In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, water treatment system, personnel and documentation e.t.c the panel of inspectors recommends the re-grant of of Drug Manufacturing License to M/s Saturn Pharmaceuticals (Pvt) Ltd., 23-Km, Raiwind Road, Lahore by way of formulation to the following sections only:

i. Liquid Injectable (Vial) (General/Antibiotic) Section
ii. Liquid Injectable (Ampoule) General Section

Decision of the Central Licensing Board in 2888 meeting

The Board considered the facts and approved the grant of **a fresh** Drug Manufacturing License by way of Formulation in the name of M/s Saturn Pharmaceuticals (Pvt) Ltd., 23-Km, Raiwind Road, Lahore assigning DML NO 000734 on the recommendations of the panel of experts for the following sections:

	Sections (02) i. Liquid Injectable (Vial) (General/Antibiotic) Section ii. Liquid Injectable (Ampoule) General Section This approval shall not absolve company from its previous/pending liabilities/obligations of what soever nature.			
4.	M/s. Medevo (Pvt.) Ltd., Plot No. 94, Sunder Industrial Estate, Raiwind Road, Lahore	02-08-2022 (Formulation)	Good	1. Mr. Muhammad Shamoon, Expert Member. 2. Ms. Majida Mujhahid, Additional Director, DRAP, Lahore. 3. Ms. Mehwish Jamil, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: On the basis of the inspection of M/s. Medevo (Pvt.) Ltd., Lahore conducted on 02-082022, with reference to DRAP Letter No. F. 1-15/2015-Lic., dated 22-04-2022, the personnel met and the equipment and facility seen and the documentation reviewed, the panel of inspectors is of the opinion to **recommend** the grant of Drug Manufacturing License to M/s. Medevo (Pvt.) Ltd., Plot No. 94-Sundar Industrial Estate, Lahore for the following two sections: 1. Eye Drops (General) Section 2. Eye Ointment (General) Section **Decision of the Central Licensing Board in 288th meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s. Medevo (Pvt.) Ltd., Plot No. 94, Sunder Industrial Estate, Raiwind Road, Lahore on the recommendations of the panel of experts for the following sections: **Sections (2)** 1. Eye Drops (General) Section 2. Eye Ointment (General) Section			
5.	M/s Meditech Pharmaceuticals, Plot No. 83-A and 83-B, industrial Estate,	30-09-2022 (Formulation)	Good	1. Mr. Muhammad Younas Khattak, CDI, Peshawar. 2. Federal Inspector of Drugs, DRAP, Peshawar.

	Hayatabad, Peshawar; 1. Capsule (General) 2. Oral Dry Powder for Suspension (General) 3. Oral Liquid (General)			3. Mr. Adnan Shahidullah, Assistant Director, DRAP, Peshawar.

Recommendations of the panel:

As per manufacturing / testing equipment installed in the production, quality control & microbiology lab, utilities, engineering as well as the eGMP compliance status of the firm, the panel unanimously recommended the grant/transfer DML No. 000544 by way of formulation to M/s Meditech Pharmaceuticals from its old premises Plot No. 15-D, Hayatabad Industrial Estate, Peshawar to new premises Plot No. 83-A, 83-B, Hayatabad Industrial Estate, Peshawar.

Decision of the Central Licensing Board in 288th meeting

The Board considered the facts and approved the grant of Drug Manufacturing License **(000544)**by way of Formulation in the name of M/s Meditech Pharmaceuticals at new premises No. 83-A, 83-B, Hayatabad Industrial Estate, Peshawar on the recommendations of the panel of experts for the following sections:

Sections (3)

1. Capsule (General)
2. Oral Dry Powder for Suspension (General)
3. Oral Liquid (General

The Drug Manufacturing License at old premises situated at M/s Meditech Pharmaceuticals Plot No. 15-D, Hayatabad Industrial Estate, Peshawar shall stand cancelled from the date of issuance of license at new premises.

This approval shall not absolve company from its previous/pending liabilities/obligations of what soever nature.

6.	M/s SUVAE Pharmaceutical (Pvt) Ltd, Plot No.2C, Value Addition City, Khurianwala Industrial Estate, Faisalabad	30-09-2022 (Formulation)	Good	Accordingly, first panel was constituted for grant of DML; i. Mr. Azahar Jamal Saleemi, Chief Drugs Controller, Punjab. ii. Abdul Rasheed Shiekh,FID, DRAP, Lahore. iii. Mrs. Uzma Barkat, Assistant Director, DRAP, Lahore. Later on, firm has informed that Area FID, DRAP, Lahore has been promoted and the post was vacant. Therefore, following second panel was re-constituted on the request of the firm; 1. Mr. Zaka-ur-Rehman, Expert member. 2. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Assistant Director, DRAP, Lahore. However, inspection was conducted by first constituted panel. Moreover, Mr. Azher Jamal Saleemi, CDC Punjab (Member CLB & Panel) informed that the inspection was conducted as, second letter wasn't received.
	Recommendations of the panel: Keeping in view the manufacturing facility like, building, production, machinery, Equipment in Quality Control and microbiology laboratory, testing facilities, utilities and documentation reviewed, the company was given some advises for further improvement and the panel of inspectors recommends the grant of Drug Manufacturing License by way of formulation for the following sections to M/s. SUAVE Pharmaceuticals (Pvt.) Ltd., Plot No. 2C, Value Addition City, Khuraianwala Industrial Estate, Faisalabad 1. Oral Liquid (General & antibiotic) (Veterinary)			

2. Oral Powder (General & Antibiotic) (Veterinary)
3. Liquid Injection (General & Antibiotic) (Veterinary)
4. Oral Powder Penicillin (Veterinary)

Decision of the Central Licensing Board in 288th meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s SUVAE Pharmaceutical (Pvt) Ltd, Plot No.2C, Value Addition City, Khurianwala Industrial Estate, Faisalabad on the recommendations of the panel of experts for the following sections:

Sections (4)

1. Oral Liquid (General/ antibiotic) (Veterinary)
2. Oral Powder (General/Antibiotic) (Veterinary)
3. Liquid Injection (General/ Antibiotic) (Veterinary)
4. Oral Powder (Penicillin) (Veterinary)

7	M/s Neutro Pharma (Pvt) Ltd, Khewat No. 50, Khatooni No. 278, Khaki Kot Abdul Malik, Tehsil Ferozewala District Sheikhupura.	14-10-2022 & 17-10-2022 (Semi-Basic Manufacturing)	Good	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

Keeping in view the facility is for semi-basic manufacturing (palletization) and in view of the building, HVAC, production equipment, personnel met, documentation and the commitment of the management of the firm, the panel of inspectors **recommends** the grant of Drug Manufacturing License by way of semi-basic manufacturing (palletization) to M/s Neutro Pharma (Pvt) Ltd, situated at Khewat No. 50, Khatooni No.278, Khaki Kot Abdul Malik, Tehsil Ferozewala District Sheikhupura for semi-basic manufacturing (palletization) only.

Decision of the Central Licensing Board in 288th meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Semi Basic Manufacturing in the name of M/s Neutro Pharma (Pvt) Ltd, Khewat No. 50, Khatooni No. 278, Khaki Kot Abdul Malik, Tehsil Ferozewala District Sheikhupura on the recommendations of the panel of experts for the following facility:

1. Palletization

	The Drug Manufacturing License at old premises situated atM/s Neutro Pharma (Pvt) Ltd, 9.5-Km Sheikhupura Road, Lahoreshall stand cancelled from the date of issuance of Licence at new premises. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature.

Item- III: **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 Helix Pharma(Pvt) Ltd, Plot No. A-56, S.I.T.E, Karachi **Sections (02):** i. Liquid Ampoule SVP (General) Section – Revised ii. Quality Control (as shifted to 2nd floor from 1st floor)	**04-07-2022**	**Good**	1. Prof. Dr. Rafique Alam, Expert member. 2. Dr. Hira Bhutto, Area Federal Inspector of Drugs, DRAP, Karachi. 3. Dr. Krishan, Assistant Director, DRAP, Karachi.
	Recommendations of the panel: "The firm M/s Helix Pharma (Pvt) Ltd was visited by panel in compliance to DRAP Islamabad Letter No. F.2-20/84-Lic (Vol-V) dated 23rd June, 2022 for grant of amendment in facilities, the panel visited the facility as per the approved layout plan which were found in good condition all relevant change control documents and SOP's were reviewed at the time of inspection which were found complaint. The area has HVAC system installed. In general, Firm has adequate number of technical staff. Keeping in view of, Peoples met, documents reviewed and observations made during inspection, the panel **recommends** the Authentication of new/amended in facilities, DML No. 000030 By Way of Formulation of M/s Helix Pharmaceutical (Pvt) Ltd., Plot No. A-56,layout S.I.T.E for following sections. i. Liquid Ampoule SVP (General) Section – Revised			

	ii. Quality Control (as shifted to 2nd floor from 1st floor) **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of following Revised/Relocated sections 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 recommendations of the panel of experts. **Section / facility (2):** i. Liquid Ampoule SVP (General) Section – Revised ii. Quality Control laboratory relocated from 1st floor to 2nd floor.			
2	M/s AGP Limited, B-23, S.I.T.E, Karachi DML No. 000348 **Sections (04):** i. Tablet (General) ii. Stores (General) iii. Sachet (General) iv. Dry Powder Suspension (General)	**14-09-2022**	**Good**	1. Additional Director (E&M), DRAP, Karachi 2. Area FID, DRAP, Karachi 3. Sidra Yasmeen, AD, CDL, Karachi
	Recommendations of the panel: "With Reference to the DRAP Islamabad Letter No. F.2-3/92-Lic (Vol-III) Dated: 7th September, 2022 the constituted panel inspected the premises in detail on 14th September, 2022 to verify the facilities modified/upgraded/newly built by the firm as per approved design. Syed Muhammad Imran Plant Head of the firm and their technical team assisted during the course of inspection. As per the scope of inspection the panel inspected in detail their newly built areas like Oral Dry Powder & Sachet Sections, newly built Granulation Suite, two Dispensing booth areas and interim finished goods areas are provided at ground floor. All the inspected area, facilities were seen built as per approved design and were provided with required necessary machines, equipment, utilities and amenities. During initial meeting HVAC design, approved layout design, installation qualification of equipment with respective documents			

	were checked in detail however, practical demonstration of the same were also seen during ground checks. Overall the facilities were seen suitably & purposefully constructed with the aim to enhance their capacities and to attain a better GMP compliance level. During the onsite inspection the firm has also provided all relevant documents of area and machine qualification record. All required SOPs are in place with training records. All inspected sections were found well maintained. Keeping in view the stated facts, people met, documents reviewed and considering the attitude of the management towards continuous improvements, the panel is of the opinion to **recommend** the grant of additional section of Oral Dry Powder Suspension section and also recommends the entire changes/modifications/up-gradation made in their Sachet section, Tablet Granulations and stores, be regularized for better regulatory compliance **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of following additional sections in the name of M/s AGP Limited, B-23, S.I.T.E, Karachi under DML No.000348 (Formulation)on the recommendations of the panel of experts. **Section / facility (4):** i. Tablet (General)Revised ii. Stores (General) Revised iii. Sachet (General) Revised iv. Dry Powder Suspension (General) Additional			
3	M/s Ras Pharmaceuticals (Pvt) Ltd., 25-Km, Lahore Road, District Multan DML No. 000821 (Formulation) **Sections (01):** i. Injectable (Hormones) Section Veterinary ii. Topical Spray Section – Veterinary	**01-06-2022 and 03-08-2022**	**Good**	1. Director, DTL, Multan. 2. FID, DRAP, Lahore. 3. Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control and Microbiology Laboratory, testing			

	facilities, technical personnel met and documentation reviewed, the panel of inspectors recommend the grant of following additional sections to M/s Ras Pharmaceuticals 25-Km Lahore Road, Multan i. Injectable (Hormones) -Veterinary ii. Topical Spray Section – Veterinary **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of following additional sections in the name of M/s Ras Pharmaceuticals (Pvt) Ltd., 25-Km, Lahore Road, District Multan, under DML No. 000821 (Formulation)on the recommendations of the panel of experts. **Section / facility (2):** i. Injectable (Hormones)- Veterinary ii. Topical Spray (General) – Veterinary			
4	M/s Pakheim International (Pvt) Ltd., 28-Km, Ferozepur Road, Lahore **Sections (02):** i. Tablet Steroid Section (New) ii. Sachet (General) Section (New)	**08-06-2022**	**Good**	1. Director, DTL, Multan. 2. FID, DRAP, Lahore. 3. Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "In view of above inspection proceedings and facilities verified, such as company profile, building, production , in-process controls, quality control testing, machinery/equipment, material, management, air handling, water treatment system, personnel and documentation e.t.c the panel **recommends** the renewal / regularization of Drug Manufacturing License and **grant of new sections** to M/s Pakheim International (Pvt) Ltd., 28-Km, Ferozepur Road, Lahore by way of formulation to the following sections only: i. Tablet Steroid Section (New) ii. Sachet (General) Section (New) **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of following additional sections in the name of M/s Pakheim International (Pvt) Ltd., 28-Km, Ferozepur Road, Lahore under DML			

	No.00492 (Formulation)on the recommendations of the panel of experts. **Section / facility (2):** i. Tablet (Steroid) ii. Sachet (General)			
5	M/s Abbott Laboratories (Pakistan) Ltd. Opposite Radio Pakistan Transmission Centre Hyderabad Road Landhi Karachi.	**30-06-2022**	**V. Good**	Mr Sajjad Ahmad Abbasi, DD, CDL, Karachi FID, DRAP, Lahore. Mr. Krishan, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: Based on the people met, areas visited and commitment of the Firm's management for continuous improvement of personnel, processes and facilities, the panel is of the view to recommend: Grant of Amendments in Facilities under Drug Manufacturing License (By way of Formulation) No. 000001 to the firm M/s. Abbott Laboratories Pakistan Ltd. situated Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi. Karachi, holding Drug Whole Sale License no. 065/2021 dated 30/11/2021(copy enclosed) for following section: Finished Goods Warehouse for New Proposed Cold Room **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of amendments in following additional facility in the name of M/s Abbott Laboratories (Pakistan) Ltd. under DML No.000001 (Formulation)on the recommendations of the panel of experts. **Section / facility (1):** Finished Goods Warehouse for New Proposed Cold Room			
6	M/s Elite Pharma (Pvt) Ltd, 9.5-km, Sheikhupura Road, Lahore. **Sections (03):** i. Dry Powder Suspension (General) (New) ii. Capsule (General) (New). iii. Sachet (General) (New).	06-10-2022	Good	1. Mr. Muhammad Shamoon, Expert Member. 2. Me. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.

	Recommendations of the panel: Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and review of the production facilities, building, equipment, quality control and quality assurance, the panel is of the opinion to **recommend** the renewal of Drug Manufacturing License No. 000455, by way of formulation to M/s Elite Pharma (Pvt) Ltd 9.5-km, Sheikhupura Road, Lahore for the following eight sections: i. Liquid Injectable (General). ii. Liquid Infusion (General) iii. Ointment & Creams (Steroidal & non-steroidal) (Skin and ophthalmic/Gel) iv. Capsule (Penicillin) v. Dry Powder for Suspension (Penicillin). vi. Dry Powder for Suspension (Cephalosporin) vii. Capsules (Cephalosporin) viii. Dry Powder for Injection (Cephalosporin) The firm also **recommends** the grant of following three additional section: i. Dry Powder Suspension (General) (New) ii. Capsule (General) (New). iii. Sachet (General) (New). **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of following additional sections in the name of M/s Elite Pharma (Pvt) Ltd, 9.5-km, Sheikhupura Road, Lahore under DML No.000455 (Formulation)on the recommendations of the panel of experts. **Section / facility (03):** i. Dry Powder Suspension (General) (New) ii. Capsule (General) (New). iii. Sachet (General) (New).			
7.	M/s Amson Vaccines & Pharma (Pvt) Ltd., Plot No. 154, Industrial Triangele, Kahuta Road, Islamabad. DML No. 000393 (Formulation) **Section (01):** i. Tablet (Psychotropic) Section.	**15-09-2022**	**Good**	i. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. ii. Sadia Mahwish, Area Federal Inspector of Drugs, DRAP, Islamabad. iii. Mr. Mubashir Iqbal,

				Assistant Director (CD), DRAP, Islamabad.

Recommendations:-

"Keeping in view the above facts on record and the people met, documents reviewed during the visit, the panel unanimously recommended the grant of following addition section to M/s Amson Vaccines & Pharma (Pvt) Ltd., Plot No. 154, Industrial Triangle, Kahuta Road, Islamabad :-

1. Tablet Section (Psychotropic).

Decision of the Central Licensing Board in 288th meeting

The Board observed that mandate was given for the regularization of Tablet (Psychotropic) Section but as per inspection report, the recommendations were given by the panel for grant of the additional section Tablet (Psychotropic) Section.

The Board while considering the facts on record approved the Regularization of following section in the name of M/s Amson Vaccines & Pharma (Pvt) Ltd., Plot No. 154, Industrial Triangele, Kahuta Road, Islamabad under DML No.000393 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020.

Section / facility (01):

1. Tablet Section (Psychotropic)- Regularization

8.	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar. DML No. 000725 (formulation) **Section (02):** i. Oral Liquid (General) Veterinary. ii. Oral Dry Powder (General) Veterinary.	**12-10-2022**	**Good**	i. Mr. Khalid Khan, Expert Member, Peshawar. ii. Mr. Faisal Shahzad, Area Federal Inspector of Drugs, DRAP, Peshawar. iii. Mr. Adnan Shahidullah, Assistant Director, DRAP, Peshawar.

Recommendation of the Panel

Base on documentation reviewed, technical / management people met, materials / processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab and allied facilities, the panel is of the view that the firm is operating at satisfactory level of GMP compliance and unanimously recommends grant of two new additional section for veterinary products in accordance with DRAP Islamabad letter No. F.3-7/2007-Lic (Vol-I) dated 04-03-2022 as below:-

i. Oral Liquid (General) Veterinary.

	ii. Oral Dry Powder (General) Veterinary. **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of following additional sections in the name of M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar underDML No.000725 (Formulation)on the recommendations of the panel of experts. **Section / facility (2):** i. Oral Liquid (General) Veterinary. ii. Oral Dry Powder (General) Veterinary.			
9	M/s Seraph PharmaceuticalPlot# 210, Industrial Triangle Kahuta Road Islamabad. DML# 000860	11-07-2019	Good	i. Additional Director, (Field), QA/LT, DRAP Islamabad ii. FID, DRAP, Islamabad iii. Mr. Abdullah AD, DRAP, Islamabad
	Recommendations: Keeping in view the above facts on record, documents reviewed people met during the visit & compliance of the firm to the directions of inspection team, the panel unanimously **recommended** following sections of M/s Seraph Pharmaceutical, Plot# 210, Industrial Triangle Kahuta Road. DML# 000860: **i.** Grant of Additional sections & Revised sections **1.** Liquid Injectable Ampoule (General) (Additional Section) **2.** R&D Lab (Additional Section) **3.** Warehouse (FGS&PMS) (from ground to first floor-relocation) **4.** Raw Material Store-Ground Floor Revised **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of following additional sections in the name of M/s Seraph Pharmaceutical Plot# 210, Industrial Triangle Kahuta Road Islamabadunder DML No.000860 (Formulation)on the recommendations of the panel of experts. **Section / facility (4):** 1. Liquid Injectable Ampoule (General) (Additional Section) 2. R&D Facility 3. Warehouse (FGS&PMS) (from ground to first floor-relocation) 4. Raw Material Store-Ground Floor- Revised			

10	M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad. DML No.000340 (Formulation). **Sections (05)** i. Oral Dry Suspension (General)-**Additional Section** ii. Sachet (General)-**Revised** iii. Tablet (Effervescent-General)-**New section in place of withdrawn Aerosol Section** iv. Packing Material Store-**Revised** v. Raw Material Store-**Revised**	05th 11th and 12th August, 2022	Very Good	1. Dr. Hafsa Karam Elahi, Additional Director, QA&LT, DRAP, Islamabad. 2. Malik Muhammad Asad, Deputy Director (Lic), DRAP, Islamabad. 3. Mr. Adil Saeed, Assistant Director, DRAP, Islamabad.

Recommendations:

"Keeping in view the facts observed during inspection, the panel unanimously recommends renewal of DML by way of formulation to M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad (DML No.000340) along with following sections and revisions;

i. Oral Dry Suspension (General)-**Additional Section**
ii. Sachet (General)-**Revised**
iii. Tablet (Effervescent-General)-**New section in place of withdrawn Aerosol Section**
iv. Packing Material Store-**Revised**
v. Raw Material Store-**Revised**

*Note: The firm has agreed to convert the segregated Cephalosporin Dry Powder Section and Penicillin Dry Powder Section into dedicated at the earliest not later than date of next renewal inspection."

Decision of the Central Licensing Board in 288th meeting

	The Board considered and approved the grant of following additional sections in the name of M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad under DML No.000340 (Formulation)on the recommendations of the panel of experts. **Sections (05)** 1. Oral Dry Suspension (General)-**Additional Section** 2. Sachet (General)-**Revised** 3. Tablet (Effervescent-General)-**New section in place of withdrawn Aerosol Section** 4. Packing Material Store-**Revised** 5. Raw Material Store-**Revised**			
11	M/s Athan Pharmaceuticals, Plot No, 84/1, Block –B, Phase-V Industrial Estate, Hattar. DML No.000900 (Formulation). **Sections (03)** i. Oral Powder (General-Vet) ii. Liquid Injectable-Vial (General-Vet) iii. Oral Syrup (General-Vet)	10-10-2022	Good	1. Mr. Muhammad Younas Khattak, Chief Drug Inspector, Peshawar. 2. Mr. Faisal Shahzad, FID, DRAP, Peshawar. 3. Syed Adnan Ali Shah, Assistant Director, DRAP, Peshawar.
	Recommendations: "Based on documentation reviewed, technical/ management people met, materials/ processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab and allied facilities, the panel is of the view that the firm has provided necessary facilitates for the following mentioned new section in accordance with DRAP, Islamabad letter No.F.1-16/2013-Lic dated 18.02.2022 and unanimously recommends grant of new additional section namely; **S.No.** | **Name of Section** 1. | Oral Powder (General-Vet) 2. | Liquid InjectableVial (General-Vet) 3. | Oral Syrup (General-Vet)			

	Decision of the Central Licensing Board in 288th meeting The Board considered and approved the grant of following additional sections in the name of M/s Athan Pharmaceuticals, Plot No, 84/1, Block –B, Phase-V Industrial Estate, Hattar under DML No.000900 (Formulation)on the recommendations of the panel of experts. **Sections (03)** 1. Oral Powder (General-Vet) 2. Liquid Injectable-Vial (General-Vet) 3. Oral Syrup (General-Vet)

Item-IV: **GRANT OF RENEWAL / REGULARIZATION OF LOP OF DRUG MANUFACTURING LICENSES.**

Following cases have been forwarded by the respective panel of experts for grant of Renewal of Drug Manufacturing Licenses and regularization. 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 Decent Pharma, Plot No.30, Street No. SS-3, National Industrial Zone (RCCI), Rawat. DML No.000766 (Formulation) **Period:** Commencing on 12-03-2018 & ending on 11-03-2023.	**10-03-2022 & 21-04-2022 & 09-05-2022**	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad 2. Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad. 3. Mr. Malik Muhammad Asad, Deputy Director (Licensing), DRAP, Islamabad
	Recommendations of the panel: Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the approval of DML by way of formulation to of M/s Decent Pharma, Plot No.30 Street No.SS-3, National Industrial Zone (RCCI), Rawat with the following sections: i. Oral Liquid Syrup (General). ii. Oral Dry Powder (General). iii. Oral Powder (General). iv. Oral Liquid (General).			

	v. Oral Powder (Penicillin). vi. Liquid Injectable (General). **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of renewal of DML No. 000766 by way of Formulation in the name of M/s Decent Pharma, Plot No.30, Street No. SS-3, National Industrial Zone (RCCI), Rawat. on the recommendations of the panel of experts for the period commencing on12-03-2018 & ending on 11-03-2023for the following section: - i. Oral Liquid Syrup (General). ii. Oral Dry Powder (General). iii. Oral Powder (General). iv. Oral Liquid (General). v. Oral Powder (Penicillin). vi. Liquid Injectable (General).			
2	M/s Fresh Pharmaceutical, Plot No.7, Street S-6, National Industrial Zone, RCCI, Rawat. DML No. 000827 (Formulation) **Period:** Commencing on 07.10.2020 & ending on 06.10.2025	**31-05-2022**	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad 2. Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad. 3. Ms. Zunaira Faryad, Assistant Director (Licensing), DRAP, Islamabad
	Recommendations of the panel: Keeping in view the above facts on record and the people met during the visit the panel unanimously **recommended** the renewal of DML by way of Formulation to M/s Fresh Pharmaceutical, Plot No.7, Street S-6, National Industrial Zone, RCCI, Rawat with following sections: i. Tablet Section (General) ii. Capsule Section-I (General) iii. Capsule Section-II(General) iv. Cream/Ointment/Gel Section (General) v. Lotion Section (General). **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of renewal of DML No. 000827 by way of Formulation in the name of M/s Fresh Pharmaceutical, Plot No.7, Street S-6, National			

	Industrial Zone, RCCI, Rawat on the recommendations of the panel of experts for the period Commencing on07.10.2020 & ending on 06.10.2025 for the following section: - i. Tablet Section (General) ii. Capsule Section-I (General) iii. Capsule Section-II(General) iv. Cream/Ointment/Gel Section (General) v. Lotion Section (General).			
3	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Lutafabad Bosan Road, Multan. DML No. 000427 (Formulation) Period: : Commencing on 01-04-2021 & ending on 31-03-2026.	**21-02-2022 & 22-02-2022 & 04-08-2022**	**Good**	1. Mr. Mouqadus-Un-Nisa, Director, Drugs Testing Laboratory, Multan. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore.
	<u>Recommendations of the panel:</u> Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and review of the production facilities, building, equipment, quality control and quality Assurance, the panel is of the opinion to **recommend** the renewal of Drug Manufacturing License No. 000427, by way of formulation to M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Lutafabad Bosan Road, Multan for the following sections: i. Tablet Section (General & Antibiotic). ii. Capsule Section (General & Antibiotic). iii. Dry Powder Suspension (General and Antibiotic) iv. Oral Liquid Section. (General & Antibiotic) v. Liquid Injection (Ampoule & Vials) (General & Antibiotics) vi. Sachet Section (General) vii. Ointment/ Cream/Gel Section viii. Capsule Section (Cephalosporin) ix. Dry Powder Suspension (Cephalosporin). x. Dry Powder for Injection (Cephalosporin). xi. Dry Powder for Suspension (Penicillin). xii. (Oral) Capsule Section (Penicillin). xiii. Tablet Section (Penicillin). As per available record of Licensing Division, the detail of sections is as under: i. Tablet Section (General Antibiotic). ii. Capsule Section (General Antibiotic). iii. Dry Powder (General Antibiotic)			

	iv. Liquid Section. (Antibiotic) v. Liquid Injection (Ampoule/Vial) (General & General Antibiotics) vi. Sachet Section (Non Antibiotic) vii. Ointment/ Cream/Gel Section (General) viii. Capsule Section (Cephalosporin) ix. Dry Powder (Cephalosporin). x. Dry Powder for Injection (Cephalosporin). xi. Dry Powder (Penicillin). xii. Capsule Section (Penicillin). xiii. Tablet Section (Penicillin). **Decision of the Central Licensing Board in 288th meeting** Mr. Azher Jamal Saleemi, Member CLB, informed the board that M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Lutafabad Bosan Road, Multan, DML No. 000427 (Formulation)has been found involved in manufacturing of Citalem 10mg Tab (Escitalopram) Batch No. 46201 adulterated with other drug i-e Sildenafil. He also shared a copy of case report (Annexed). The board decided to defer the renewal application and referred the case to QA & LT division for further investigation in the instant matter and to submit the report to the CLB.			
4	M/s Arreta Pharmaceuticals (Pvt) Ltd, Plot No.13, Street No. N-5, RCCI, Industrial Estate, Rawat. DML No. 000846 (Formulation) **Period**: Commencing on 25-10-2021 & ending on 24-10-2026	**11-08-2022**	**Good**	1. Dr. Hafsa Karam Elahi, Addl. Director (QALT), DRAP, Islamabad. 2. Mr. Khalid Mahmood, Federal Inspector of Drugs-II, DRAP, Islamabad. 3. Hafiz Muhammad Umair, Assistant Director (I&E), 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 Arreta Pharmaceuticals (Pvt) Ltd, Plot No.13, Street No. N-5, RCCI, Industrial Estate, Rawat for the renewal of Drug Manufacturing License No. 000846 (formulations) for the following section only. i. Tablet (General) ii. Capsule (General) iii. Oral Liquid (General) iv. Tablet (Psychotropic) v. Capsule (Cephalosporin) vi. Dry Powder for Suspension (Cephalosporin) vii. Sterile Dry Powder for Injection (Cephalosporin).			

	Decision of the Central Licensing Board in 288th meeting The Board considered and approved the grant of renewal of DML No. 000846 by way of Formulation in the name of M/s Arreta Pharmaceuticals (Pvt) Ltd, Plot No.13, Street No. N-5, RCCI, Industrial Estate, Rawat on the recommendations of the panel of experts for the period commencing on25-10-2021 & ending on 24-10-2026 for the following section subject to submission of NOC for Psychotropic Section 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: - i. Tablet (General) ii. Capsule (General) iii. Oral Liquid (General) iv. Tablet (Psychotropic) v. Capsule (Cephalosporin) vi. Dry Powder for Suspension (Cephalosporin) vii. Sterile Dry Powder for Injection (Cephalosporin).			
5	M/s Elko Organization (Pvt) Ltd., Plot No.27&28, Sector 12B, North Karachi Industrial Area, Karachi. DML No.000245 (Formulation) Tenure: Commencing on 27-04-2020& ending on 26-04-2025	**22-08-2022**	**Good**	1. Dr. Najam-us-Saquib, Additional Director, DRAP, Karachi. 2. Mr. Abdul Rasool Sheikh, Area FID, DRAP, Karachi. 3. Mr. Asfand Yar, Assistant Director CDL, DRAP, Karachi.
	Recommendations of the panel: "Based on the stated facts and keeping in view the attitude of the management towards continuous improvements the Panel unanimously recommends the grant of renewal of DML 000245 (Formulation) for the next five years for following sections and also recommends the regularization of existing layout plan. Tablet (General), Capsule (General), Cream/Ointment/Lotion (G/Steroid), Liquid Syrup (General), Sterile Eye/Ear/Nasal Drops, Sterile Liquid Injection Ampoule/Vial (General) Veterinary, Sterile Liquid Injection Vial/Infusion (Steroid) Veterinary, Liquid Injection Ampoule/Vial (Hormones) Veterinary, Infusion LVP (General) Veterinary, Tablet/Bolus Vet, Oral Powder (General) Vet and Oral Liquid (General) Vet. **Decision of the Central Licensing Board in 288th meeting**			

	The Board considered and approved the grant of renewal of DML No. 000245 by way of Formulation and Regularization of Layout plan in the name of M/s Elko Organization (Pvt) Ltd., Plot No.27&28, Sector 12B, North Karachi Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 27-04-2020& ending on 26-04-2025for the following section: - Tablet (General) Capsule (General) Cream/Ointment (General) Liquid Syrup (General) Eye Drops (General) Liquid Injection Ampoule/Vial (General) Sterile Liquid Injection Vial/Infusion (Steroid) Veterinary, Liquid Injection Ampoule/Vial (Hormones) Veterinary, Infusion LVP (General)- Veterinary, Tablet/Bolus Vet, Oral Powder (General)-Vet, Oral Liquid (General)-Vet. The panel did not give recommendations for cephalosporin sections. The Board decided to stop the production in the cephalosporin area, if any.			
6	M/s Platinum Pharmaceuticals (Pvt) Ltd., Plot No.A-20, NWIZ, Port Qasim, Karachi DML No.000415 (Formulation) Tenure: Commencing on 07-08-2020 & ending on 06-08-2025	**06-07-2022**	**Very Good**	1. Mr. Sajjad Ahmed, DD CDL, Karachi. 2. Mr. Ghulam Ali, Senior Drug Inspector, Govt. of Sindh, Karachi. 3. Area FID, DRAP, Karachi.
	<u>Recommendations of the panel:</u> The panel inspected the premises of Ms. Platinum Pharmaceutical (Pvt) Ltd., A-20, NWIZ, Bin Qasim, in compliance to DRAP, Islamabad F.2-3/94-Lic (Vol-III) dated 21st June, 2022. (Annexure-A) and recommends as follows: i. Based on the people met, areas visited and commitment of the management for continuous improvement and up-gradation, the panel is of the view to **recommend** the Renewal of Drugs Manufacturing License # 000415 (By way of Formulation) to the firm M/s Platinum Pharmaceutical (Pvt) Ltd., for following sections namely:			

Tablet (General)	Oral Liquid (General)	Capsule (General)	Mouth wash(General)
Cream/ Ointment/Gel/Tooth	Sachet (General)	Dry Powder suspension (General)	Tablet (H)

paste (General)				
Capsule (H)	Tablet (Ceph)	Capsule (Ceph)	Dry Powder suspension (Ceph)	
Inhaler / Aerosol				

ii. The panel does not recommend grant of Cream (Hormone) and Nasal spray (Hormone) sections due to non-availability of the section as per the already approved layout plan.

Decision of the Central Licensing Board in 288th meeting

The Board while considering the facts on record approved the grant of renewal of DML No. 000415 by way of Formulation in the name of M/s Platinum Pharmaceuticals (Pvt) Ltd., Plot No.A-20, NWIZ, Port Qasim, Karachion the recommendations of the panel of experts for the period Commencing on 07/08/2020 & ending on 06/08/2025 for the following section: -

1. Tablet (General)
2. Oral Liquid (General)
3. Capsule (General)
4. Mouth wash (General)
5. Cream/ Ointment/Gel/Tooth paste (General)
6. Sachet (General)
7. Dry Powder suspension (General)
8. Tablet (Hormone)
9. Capsule (Hormone)
10. Tablet (Cephalosporin)
11. Capsule (Cephalosporin)
12. Dry Powder suspension (Cephalosporin)
13. Inhaler / Aerosol

The Board did not grant renewal of following sections under the DML No. 000415 on recommendation of the panel:

1. Cream (Hormone)
2. Nasal spray (Hormone) sections

7	M/s Maxitech Pharma (Pvt) Ltd., Plot No.E-178, S.I.T.E. Phase II, Super Highway, Karachi. DML No.000851 (Formulation)	**23rd , 24th June and 04th July 2022**	**Good**	1. Dr. Saif-ur-Rehman Khattak, Additional Director, CDL, Karachi. 2. Mr. Abdul Rasool, Area FID, DRAP, Karachi.

	Tenure: Commencing on 25-11-2021 & ending on 24-11-2026.			3. Dr. Kirshan, Assistant Director, DRAP, Karachi.

Recommendations of the panel:

Based on the stated facts and keeping in view the attitude of the management towards continuous improvements the panel unanimously recommends the grant of renewal of DML 000851 (Formulation) for the next five years for following sections and regularization of Sterile Dry Powder Injection Section (Carbapenem).

Tablet (General), Capsule (General), Sachet (General), Dry Powder Suspension (General), Cream/Ointment/Lotion (G/Steroid), Liquid Syrup, Sterile Dry Powder Injection (Carbapenem), Capsule (Soft Gelatin), Sterile E/E/Nasal Drops, Sterile Liquid injection ampoule (General), Sterile Liquid Injection Vial/Infusion (General) and Dedicated Sections for Cephalosporin Containing Products including (Capsule, Dry Powder Suspension, Sachet & Sterile Dry Powder Injection).

Decision of the Central Licensing Board in 288th meeting

The Board considered and approved the grant of renewal of DML No. 000851 by way of Formulation and regularization of Layout Plan in the name ofM/s Maxitech Pharma (Pvt) Ltd., Plot No.E-178, S.I.T.E. Phase II, Super Highway, Karachion the recommendations of the panel of experts for the period Commencing on 25-11-2021 & ending on 24-11-2026 for the following section: -

1. Sterile Dry Powder Injection Section (Carbapenem)
2. Tablet (General),
3. Capsule (General),
4. Sachet (General),
5. Dry Powder Suspension (General),
6. Cream/Ointment/Lotion (General),
7. Liquid Syrup (General),
8. Dry Powder Injection (Carbapenem) Section
9. Capsule (Soft Gelatin)
10. Sterile Eye, Ear &Nasal Drops (General)
11. Liquid injection ampoule (General)
12. Liquid Vial/Infusion (General) SVP Section
13. Capsule (Cephalosporin) Section

	14. Sachet (Cephalosporin) Section 15. Oral Dry Powder Suspension (Cephalosporin) Section 16. Dry Powder Vial Injection (Cephalosporin) Section			
8	M/s MBL Pharma, Plot No.B-77/A, Hub Industrial and Trading Estate, Hub. DML No.000495 (Formulation) Tenure: Commencing on 03-03-2022 & ending on 02-03-2027.	**22-07-2022**	**Good**	1. Dr. Shoaib Ahmed, FID, DRAP, Quetta 2. Mr. Muhammad Salik, CDI,Govt of Baluchistan 3. Mr. Asfand Yar, Assistant Director, CDL, Karachi

Recommendations of the panel:

"M/s MBL Pharma, Plot No.B-77/A, H.I.T.E, Baluchistan, Pakistan was visited and inspected in detail on 22-07-2022 in compliance to the directions contained in DRAP, Islamabad Letter No. F.4-2/2001-Lic (Vol-I) dated 04 July 2022 in connection with renewal of DML. The panel inspected all the manufacturing sections, store and QC Lab and found the facility as per approved layout plan. The facility has been provided with necessary utilities, machineries and equipment as required under guidelines.

Necessary documents relating to QC, QA, installation qualification of machines, HVAC and other utilities were also verified under scope and noted good level of compliance.

Based on the people met, documents reviewed, the panel recommends the grant of renewal of Drug Manufacturing License No.000495 by way of formulation for following section and regularization of layout plan of section mentioned below;

Sr	Name of Section	Sr	Name of Section
i.	Ware House(General)	ii.	Tablet (General)
iii.	Capsule (General)	iv.	Dry Powder Suspension (General)
v.	Liquid Syrup (General)	vi.	Tablet (Psychotropic)
vii.	Tablet (Steroid)	viii.	Capsule (Penicillin)

ix.	Dry Powder Suspension (Penicillin)	x.	Capsule (Cephalosporin)
xi.	Dry Powder Suspension (Cephalosporin)	xii.	Dry Powder Injection (Cephalosporin)
xiii.	Cream / Ointment / Gel (General)	xiv.	Liquid Injectable Ampoule (General)
xv.	Eye Drops (General)	xvi.	QC Laboratory
xvii.	Ware House (General)	xviii.	Ware House (Penicillin)
xix.	Ware House(Cephalosporin)	xx.	**********

Decision of the Central Licensing Board in 288th meeting

The Board considered and approved the grant of renewal of DML No. 000495 by way of Formulation and regularization of Layout Plan in the name of M/s MBL Pharma, Plot No.B-77/A, Hub Industrial and Trading Estate Hub, on the recommendations of the panel of experts subject to submission of NOC for Psychotropic Section from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for the period commencing on 03-03-2022 & ending on 02-03-2027 for the following section: -

1. Ware House (General)
2. Tablet (General)
3. Capsule (General)
4. Dry Powder Suspension (General)
5. Liquid Syrup (General)
6. Tablet (Psychotropic)
7. Tablet (Steroid)
8. Capsule (Penicillin)
9. Dry Powder Suspension (Penicillin)
10. Capsule (Cephalosporin)
11. Dry Powder Suspension (Cephalosporin)
12. Dry Powder Injection (Cephalosporin)

	13. Cream / Ointment / Gel (General) 14. Liquid Injectable Ampoule (General) 15. Eye Drops (General) 16. QC Laboratory 17. Ware House (General) 18. Ware House (Penicillin) 19. Ware House (Cephalosporin)			
9.	M/s Seatle (Pvt) Ltd., 45-Km, Multan Road, District Kasur. DML No.000481 (Formulation) Tenure: Commencing on 29-09-2020& ending on 28-09-2025.	**30-06-2022**	**Good**	1. Mr. Azahar Jamal Saleemi, Chief Drugs Controller, Punjab. 2. Dr. Syed Zia Husnain, FID, DRAP, Lahore. 3. Ms. Anam Saeed, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

Panel inspected the unit thoroughly and evaluated various documents revealed by the firm management in connection with Quality assurance, Quality Control and Production operations. Different technical aspects were also discussed with firm management at length. Panel observed that firm has not yet established the Lotion and Solution (General Topical) section as per revised layout for regularization. Moreover, as observed by the panel and submitted by the firm (duly signed submission of the firm is attached herewith), firm has not yet installed the machinery in the Capsule (psychotropic) section. Therefore, panel has **deferred** the renewal of Capsule (Psychotropic)section and the regularization of Lotion & Solution section at this stage under the explained circumstances mentioned above.

Based on the physical inspection of the unit, evaluation of the documents revealed by the firm management and discussion with the technical staff, panel was of the opinion **to recommend** the renewal of Drug Manufacturing License No.000481 (Formulation) of M/s Seatle (Pvt) Ltd., 45-Km, Multan Road, Kasur for the following sections.

i. Tablet (General, Cephalosporin, Psychotropic) Sections
ii. Capsule (General, Cephalosporin) Sections
iii. Cream/Ointment/Gel (General Topical) Section

	iv. Cream/Ointment/Gel (Steroidal Topical) Section v. Dry Powder suspension (Cephalosporin) Section **<u>Decision of the Central Licensing Board in 288th meeting</u>** The Board considered and approved the grant of renewal of DML No. 000481 by way of Formulation in the name of M/s Seatle (Pvt) Ltd., 45-Km, Multan Road, District Kasuron the recommendations of the panel of experts subject to submission of NOC for Psychotropic Section from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for the period Commencing on29-09-2020 & ending on 28-09-2025 for the following section: - i. Tablet (General) Section ii. Tablet (Cephalosporin) Section iii. Tablet (Psychotropic) Section iv. Capsule (General) Section v. Capsule (Cephalosporin) Section vi. Cream/Ointment/Gel (General) Section vii. Cream/Ointment/Gel (Steroidal) Section viii. Dry Powder suspension (Cephalosporin) Section The Board did not grant renewal of following sections under the DML No. 000481 on recommendation of the panel: 1. Capsule (Psychotropic)-Renewal, 2. Lotion & Solution (General)-Regularization			
10	M/s Sarco Chemical Industries, 17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan. DML No.000203 (Formulation) Tenure: Commencing on 20-09-2019 & ending on	**01-06-2022**	**Good**	1. Mr. Muhammad Shamoon, Expert Member. 2. FID, DRAP, Lahore. 3. Assistant Director, DRAP, Lahore.

	19-09-2024.			
	Recommendations of the panel: Keeping in view the manufacturing facility like building, HVAC System, sanitation, production Machinery, Equipment in Quality Control Laboratory, Testing Facilities, Technical Personnel met and documentation, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of formulation to M/s Sarco Chemical Industry, 17-Km, Peerwala Morr, Qadir Pur Ban, Khanewala Road, District Multan for the following sections: i. Powder Section Re-Packing ii. External Preparation section iii. Liquid Section Re-Packing **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of renewal of DML No. 000203 by way of Formulation in the name of M/s Sarco Chemical Industries, 17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan.on the recommendations of the panel of experts for the period Commencing on 20-09-2019 & ending on 19-09-2024 for the following sections: - 1. Powder Section Re-Packing 2. External Preparation section 3. Liquid Section Re-Packing			
11	M/s Pakheim International (Pvt) Ltd., 28-Km, Ferozepur Road, Lahore DML No.000492 (Formulation) Tenure: Commencing on 02-01-2022& ending on 01-01-2027.	**08-06-2022**	**Good**	1. Director, DTL, Multan. 2. FID, DRAP, Lahore. 3. Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "In view of above inspection proceedings and facilities verified, such as company profile,			

	building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, water treatment system, personnel and documentation e.t.c the panel **recommends** the **renewal / regularization of Drug Manufacturing License** and grant of new sections to M/s Pakheim International (Pvt) Ltd., 28-Km, Ferozepur Road, Lahore by way of formulation to the following sections only: i. Tablet (General) Section ii. Capsule Section (General) iii. Capsule Cephalosporin Section iv. Dry Powder Cephalosporin Section v. Oral Liquid (General) Section vi. Cream/Ointment/Gel/Lotion (General) Section **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of renewal of DML No. 000492 by way of Formulation and regularization of Layout Plan in the name of M/s Pakheim International (Pvt) Ltd., 28-Km, Ferozepur Road, Lahore on the recommendations of the panel of experts for the period Commencing on 02-01-2022& ending on 01-01-2027 for the following section:- i. Tablet (General) Section ii. Capsule Section (General) iii. Capsule Cephalosporin Section iv. Dry Powder Cephalosporin Section v. Liquid Syrup (General) Section vi. Cream/Ointment/Gel/ (General) Section			
12	M/s. PharmEvo (Pvt.) Ltd. situated at A-29. N.W.I.Z.. Karachi DML No. 0000504(formulation) Tenure: Commencing on 05-10-2022 and ending on 04-10-2027	**29/09/2022**	**Good**	1. Dr. Abdul Rasool Sheikh, Additional Director, DRAP, Karachi. 2. Syed Hakim Masood, Area FID, DRAP, Karachi. 3. Mrs. Sanam Kausar, Assistant Director, DRAP, Karachi.

	Recommendations of the panel: Based on the people met, areas visited and commitment of the management for continuous improvement. the panel is of the view to recommend the Renewal of Drug Manufacturing License no. 000504 (By way of Formulation) as per DRAP. Islamabad letter of even no. dated 14 September 2022 to the firm M/s. PharmEvo (Pvt.) Ltd. situated at A-29. N.W.I.Z.. Karachi for following sections w.e.f 5th Oct 2022: 1. Tablet (General) 2. Capsule (General) 3. Dry Powder Inhaler Capsule (General) 4. Sachet (General) 5. Oral Liquid (General) 6. Tablet (Cephalosporin) 7. Capsule (Cephalosporin) 8. Sterile Dry Powder Injectable (Cephalosporin) 9. Oral Dry Powder Suspension (Cephalosporin) **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of renewal of DML No. 000504 by way of Formulation in the name of M/s. PharmEvo (Pvt.) Ltd. situated at A-29. N.W.I.Z.. Karachi on the recommendations of the panel of experts for the period Commencing on05-10-2022 and ending on 04-10-2027for the following section: - 1. Tablet (General) 2. Capsule (General) 3. Dry Powder Inhaler Capsule (General) 4. Sachet (General) 5. Oral Liquid (General) 6. Tablet (Cephalosporin) 7. Capsule (Cephalosporin) 8. Sterile Dry Powder Injectable (Cephalosporin) 9. Oral Dry Powder Suspension (Cephalosporin)			
13	M/s Wilson's Pharmaceuticals, Islamabad. DML No.000239 (Formulation). Period: Commencing on 30-09-2019 ending on 29-09-2024.	28-07-2022	Very Good	1. Dr. Hafsa Karam Elahi, Additional Director, QA&LT, DRAP, Islamabad. 2. Mr. Abdullah, Assistant Director (Lic), DRAP, Islamabad.

				3. Mr. Adil Saeed, Assistant Director, DRAP, Islamabad.

Recommendations:

"Keeping in view the facts observed during inspection, the panel unanimously recommends renewal of DML by way of formulation to M/s Wilson's Pharmaceuticals, Plot No. 387-388 & 366, Sector I-9, Industrial Area, Islamabad (DML No.000239) with following sections;

i. Tablet (General)
ii. Capsule (General)
iii. Oral Dry Powder for Suspension (General)
iv. Oral Liquid (General)
v. Sachet (General)
vi. `Ointment / Cream / Gel (General)
vii. Tablet (Psychotropic)
viii. Dry Powder Inhaler Capsule (Steroidal)
ix. Soft Gel Capsule (General)
x. R&D Laboratory – Additional section"

Decision of the Central Licensing Board in 288th meeting

The Board considered and approved the grant of renewal of DML No. 000239 by way of Formulation in the name of M/s Wilson's Pharmaceuticals, Islamabad on the recommendations of the panel of experts subject to submission of NOC for Psychotropic Section from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for the period Commencing on 30-09-2019 ending on 29-09-2024 for the following sections : -

i. Tablet (General)
ii. Capsule (General)
iii. Oral Dry Powder for Suspension (General)
iv. Oral Liquid (General)
v. Sachet (General)
vi. Ointment / Cream / Gel (General)
vii. Tablet (Psychotropic)

	viii. Dry Powder Inhaler Capsule (Steroidal) ix. Soft Gel Capsule (General) x. R & D Facility			
14	M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad. DML No.000340 (Formulation). Period: Commencing on 16-10-2019 ending on 15-10-2024.	05th 11th and 12th August, 2022	Very Good	4. Dr. Hafsa Karam Elahi, Additional Director, QA&LT, DRAP, Islamabad. 5. Malik Muhammad Asad, Deputy Director (Lic), DRAP, Islamabad. 6. Mr. Adil Saeed, Assistant Director, DRAP, Islamabad.
	Recommendations: "Keeping in view the facts observed during inspection, the panel unanimously recommends renewal of DML by way of formulation to M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad (DML No.000340) along with following sections and revisions; vi. Soft Gel Section (Hormone) vii. Dry Powder Inhaler viii. Tablet (General) ix. Capsule (General) x. Dry Powder for Suspension (Cephalosporin)* xi. Capsule (Penicillin) xii. Dry Powder for Suspension (Penicillin)* xiii. Oral Liquid (General) xiv. Cream/Ointment (General) xv. Sachet Powder (General) xvi. R&D Laboratory xvii. Oral Dry Suspension (General)-**Additional Section** xviii. Sachet (General)-**Revised**			

	xix. Tablet (Effervescent-General)-**New section in place of withdrawn Aerosol Section** xx. Packing Material Store-**Revised** xxi. Raw Material Store-**Revised** *Note: The firm has agreed to convert the segregated Cephalosporin Dry Powder Section and Penicillin Dry Powder Section into dedicated at the earliest not later than date of next renewal inspection." **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of renewal of DML No. 000340 by way of Formulation in the name of M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad on the recommendations of the panel of experts subject to submission of NOC for Psychotropic Section from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for the period Commencing on 16-10-2019 ending on 15-10-2024 for the following section: - i. Soft Gel Capsule (Hormone) Section ii. Dry Powder Inhaler iii. Tablet (General) iv. Capsule (General) v. Oral Liquid (General) vi. Cream/Ointment (General) vii. Sachet Powder (General) viii. Tablet (Psychotropic) ix. Capsule (Psychotropic) x. Capsule (Penicillin) xi. R&D Facility The Board further decided to defer the following section till dedication of the facility as required under the Drugs (Licensing, registering and advertising) Rules -1976: i. Dry Powder for Suspension (Cephalosporin) ii. Dry Powder for Suspension (Penicillin)			
15	M/s SAAAF Pharmaceutical	23-05-2022	Good	1. Dr. Jamshed Ali

	Industries, 15-Nowshera Industrial Estate, (SIZ), Risalpur. DML No.000637 (Formulation). Period: Commencing on 19-06-2018 ending on 18-06-2023.			Khan, Expert Member. 2. Mr. Younas Khattak, Chief Drug Inspector, KPK. 3. Faisal Shahzad, Area Federal Inspector of Drugs, DRAP, Peshawar.

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

Sr. No	***Name of Section***	***Sr. No***	***Name of Section***
1.	*Tablet (General)*	*3.*	*Dry Powder Suspension (General)*
2.	*Capsule (General)*	*4.*	*Liquid Section (General)*

Decision of the Central Licensing Board in 288th meeting

The Board considered and approved the grant of renewal of DML No. 000637 by way of Formulation in the name of M/s SAAAF Pharmaceutical Industries, 15-Nowshera Industrial Estate, (SIZ), Risalpur on the recommendations of the panel of experts for the period Commencing on 19-06-2018 ending on 18-06-2023 for the following section: -

1. Tablet (General)
2. Capsule (General)
3. Dry Powder Suspension (General)
4. Liquid Section (General)

16	M/s S.N.B Pharma (Pvt) Ltd,	02-12-2021	Good	1. Mr. Zahid Khan, Chief

	Hayatabad, Peshawar DML No.000759 (Formulation). Period: Commencing on 20-09-2017 ending on 19-09-2022.			Drug Inspector, Peshawar. 2. Mr. Zia Ullah, Assistant Director, DRAP, Peshawar. 3. Mr. Atiq Ul Bari, Area FID, DRAP, Peshawar.
	Based on the areas inspected, the people met, documents reviewed, the intension towards further improvements and the corrective and preventive action taken, the firm was considered to be operating at good level of compliance with cGMP guide lines as per drug act, 1976 and rules framed there under and the panel **recommended** the grant of renewal of DML No. 000759 by way of formulation to M/s S.N.B Pharma (Pvt) Ltd, Hayatabad, Peshawar. **Decision of the Central Licensing Board in 288th meeting** The Board considered and acknowledged the renewal application and recommendations of the panel for the tenure commencing on 20-09-2017 ending on 19-09-2022 that has already been expired. The firm has already applied for the renewal of DML for further five years. The decision shall be taken in the light of report of panel for further period.			
17	M/s Zeta Pharmaceuticals, Plot No. 494-A, Sunder Industrial Estate, Lahore. DML No.000818 (Formulation). Period: Commencing on 23-06-2020 ending on 22-06-2025.	03-06-2022	Good	1. Mr. Muhammad Shamoon, Expert Member. 2. Ms. Majida Mujahid, Additional Director, / FID, DRAP, Lahore. 3. Ms. Mehwish Jamil Butt, Assistant Director, DRAP, Lahore.
	Keeping in view the facilities like building, HVAC System, Equipment, Instrument, Machinery, Personnel, the panel of inspectors is of the opinion to recommend the Renewal of Drugs Manufacturing License to M/s Zeta Pharmaceuticals, Plot No. 494/A, Sunder Industrial Estate, Raiwind Road, Lahore Bearing License No. 000818 and regularization of the			

	following approved sections: - i. Tablet Section (General). ii. Capsule Section (General). iii. Sachet Section (General). **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of renewal of DML No. 000818 by way of Formulation and regularization of Layout Plan in the name of M/s Zeta Pharmaceuticals, Plot No. 494-A, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the period Commencing on23-06-2020 ending on 22-06-2025 for the following section: - i. Tablet Section (General). ii. Capsule Section (General). iii. Sachet Section (General).			
18	M/s Elite Pharma (Pvt) Ltd 9.5-km, Sheikhupura Road, Lahore. DML No.000455 (Formulation) Tenure: Commencing on 01-08-2020 & ending on 31-07-2025.	**06-10-2022**	**Good**	1. Mr. Muhammad Shamoon, Expert Member. 2. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and review of the production facilities, building, equipments, quality control and quality assurance, the panel is of the opinion to **recommend** the renewal of Drug Manufacturing License No. 000455, by way of formulation to M/s Elite Pharma (Pvt) Ltd 9.5-km, Sheikhupura Road, Lahore for the following eight sections: i. Liquid Injectable (General). ii. Liquid Infusion (General) iii. Ointment & Creams **(Steroidal & non-steroidal)** (Skin and ophthalmic/Gel)			

	iv. Capsule (Penicillin) v. Dry Powder for Suspension (Penicillin). vi. Dry Powder for Suspension (Cephalosporin) vii. Capsules (Cephalosporin) viii. Dry Powder for Injection (Cephalosporin) The firm also **recommends** the grant of following three additional section: i. Dry Powder Suspension (General) (New) ii. Capsule (General) (New). iii. Sachet (General) (New). **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of renewal of DML No. 000455 by way of Formulation in the name of Elite Pharma (Pvt) Ltd 9.5-km, Sheikhupura Road, Lahoreon the recommendations of the panel of experts for the period Commencing on01-08-2020 & ending on 31-07-2025 for the following section: - i. Liquid Injectable infusion (100ml) ii. Liquid Infusion (General) iii. Ointment &Creams (Skin and ophthalmic) iv. Capsule (Penicillin) v. Dry Powder for Suspension (Penicillin). vi. Dry Powder for Suspension (Cephalosporin) vii. Capsules (Cephalosporin) viii. Dry Powder for Injection (Cephalosporin)			
19	M/s Saydon Pharmaceutical Industries (Pvt) Ltd, 77-A, Hayatabad Industrial Estate, Peshawar. DML No.000420 (Formulation). Period: Commencing on 07-11-2020 ending on 06-11-2025.	**10-10-2022**	**Good**	1. Dr. Jamshed Ali Khan, Faculty of Pharmacy, University of Peshawar. 2. Faisal Shahzad, Additional Director, DRAP, Peshawar. 3. Mr. Atiq Ul Bari, Area FID, DRAP, Peshawar.
	"As per manufacturing / testing equipment installed in the production, quality control & microbiology lab, utilities, engineering as well as the cGMP compliance status of the firm, the panel unanimously recommended the grant of renewal of DML No. 000420 by way of formulation". **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of renewal of DML No. 000420 by way of Formulation in the name of M/s Saydon Pharmaceutical Industries (Pvt) Ltd, 77-A, Hayatabad Industrial Estate, Peshawaron the recommendations of the panel of experts for the period			

	Commencing on 07-11-2020 ending on 06-11-2025 for the following section: - 1. Injectable Dry Powder (Cephalosporin) 2. Liquid Injectable (Psychotropic) 3. Injectable Liquid (General) 4. Infusion Small Volume (General) 5. Tablet (Psychotropic)			
20	M/s Servier Research and Pharmaceuticals (Pakistan) (Pvt) Ltd, 9-KM, Sheikhupura Road, Lahore. DML No.000472 (Formulation). Period: Commencing on 02-03-2020 ending on 01-03-2025.	**03-10-2022**	**Good**	1. Mr. Muhammad Shamoon Ch, Expert Member. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore..
	"Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and review of the production facilities, building, equipment, quality control and Quality Assurance, the panel is of the opinion to recommend the renewal of Drug Manufacturing License No. 000472, by way of the formulation and regularization of layout plan to M/s Servier Research and Pharmaceuticals (Pakistan) (Pvt) Ltd, 9-KM, Sheikhupura Road, Lahore for the Tablet Section (General) only". **<u>Decision of the Central Licensing Board in 288th meeting</u>** The Board considered and approved the grant of renewal and DML No. 000472 by way of Formulation and regularization of Layout Plan in the name of M/s Servier Research and Pharmaceuticals (Pakistan) (Pvt) Ltd, 9-KM, Sheikhupura Road, Lahoreon the recommendations of the panel of experts for the period Commencing on 02-03-2020 ending on 01-03-2025 for the following section: - i. Tablet (General)			
21	M/s Newton Health Care (Pvt) Ltd., Plot No.N-8&9, HITE, Hub, Balochistan. DML No.000870 (Formulation). Period: Commencing on 13-09-	**14-10-2022**	**Good**	1. Dr. Abdul Rasool Sheikh, Additional Director, DRAP, Karachi. 2. Dr. Kirshan, Area FID, DRAP, Quetta. 3. Mst. Hira Bhutto, Assistant Director, DRAP,

	2022 ending on 12-08-2027.			Karachi.
	"Based on the stated facts and observations, production facilities, QA System, QC Lab, Stores, Utiliites, people met and documents reviewed during the course of inspection, the panel unanimously recommends the grant of renewal of DML No.000870 (Formulation) for the next five years for the following sections: - i. Tablet (General) ii. Capsule (General) iii. Oral Dry Powder (General) iv. Oral Liquid (General)" **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of renewal of DML No. 000870 by way of Formulation in the name of M/s Newton Health Care (Pvt) Ltd., Plot No.N-8&9, HITE, Hub, Balochistanon the recommendations of the panel of experts for the period Commencing on13-09-2022 ending on 12-08-2027for the following section: - i. Tablet (General) ii. Capsule (General) iii. Oral Dry Powder (General) iv. Oral Liquid (General)"			
22	M/s Seraph Pharmaceutical Plot# 210, Industrial Triangle Kahuta Road, Islamabad. DML No.000860 (Formulation). Period: Commencing on 11-06-2022 ending on 10-06-2027.	11-07-2019	Good	1. Additional Director, (Field), QA/LT, DRAP Islamabad 2. FID, DRAP, Islamabad 3. Mr. Abdullah AD, DRAP, Islamabad
	Recommendations: Keeping in view the above facts on record, documents reviewed people met during the visit & compliance of the firm to the directions of inspection team, the panel unanimously **recommended** following sections of M/s Seraph Pharmaceutical, Plot# 210, Industrial Triangle Kahuta Road. DML# 000860: **i. Renewal of Drug Manufacturing License by way of Formulation** **1.** Tablet I (General) **2.** Tablet II (General) **3.** Capsule (General) **4.** Topical (Cream/Ointment/Lotion/Gel) (General) **5.** Capsule (Cephalosporin) **6.** Dry Powder (Cephalosporin)			

	7. Dry Powder for Injectable Vial (Cephalosporin) **Decision of the Central Licensing Board in 288th meeting** The Board considered and approved the grant of renewal of DML No. 000860 by way of Formulation in the name of M/s Seraph Pharmaceutical Plot# 210, Industrial Triangle Kahuta Road, Islamabadon the recommendations of the panel of experts for the period Commencing 11-06-2022 ending on 10-06-2027 onfor the following sections: - **1.** Tablet I (General) **2.** Tablet II (General) **3.** Capsule (General) **4.** Topical (Cream/Ointment/Lotion/Gel) (General) **5.** Capsule (Cephalosporin) **6.** Dry Powder (Cephalosporin) **7.** Dry Powder for Injectable Vial (Cephalosporin)			
23	M/s Shazal'sPharmaceuticals, Plot No.41/1-A-1, Phase-I, Industrial Estate, Hattar. DML No.000592 (Formulation). Period: Commencing on 15-10-2019 ending on 14-10-2024.	**13-10-2022**	**Satisfactory/ Average**	1. Mr. Muhammad Younas Khattak, Chief Drug Inspector, Bannu. 2. Federal Inspector of Drugs, DRAP, Peshawar. 3. Assistant Director, DRAP, Peshawar.
	Based on documentation reviewed, technical/ management people met, materials/ processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab and allied facilities, the panel is of the view that the firm is operating at satisfactory level of GMP compliance and recommends grant of renewal of Drug Manufacturing License to the firm from 09.09.2020 for following mentioned nine sections; Tablet (General) Capsule (General) Capsule (Cephalosporin) Dry Powder Suspension (Cephalosporin) **Decision of the Central Licensing Board in 288th meeting** The Board considered and decided to re-inspect the premises, for which the following panel was constituted: 1. Mr. Muhammad Younas Khattak, Chief Drug Inspector, Peshawar. 2.FID, DRAP, Peshawar			
24	M/s Alliance Pharmaceuticals (Pvt)	02-09-2022	Good	2. Mr. Muhammad

	Ltd, 112-A, Industrial Estate, Hayatabad, Peshawar. DML No.000594 (Formulation). Period: Commencing on 13-06-2021 ending on 12-06-2026.	And 03-10-2022		Younas Khattak, Chief Drug Inspector, Peshawar. 3. FID, DRAP, Peshawar, 4. Mr. Adnan Shahidullah, Assistant Director, DRAP, Peshawar.

Recommendations:

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

As per manufacturing / testing equipment installed in the production, quality control & microbiology lab, utilities, engineering as well as the cGMP compliance status of the firm, the panel unanimously recommended the grant of renewal of DML No.000594 by way of formulation.

Decision of the Central Licensing Board in 288th meeting

The Board considered and approved the grant of renewal of DML No. 000594 by way of Formulation in the name of M/s Alliance Pharmaceuticals (Pvt) Ltd, 112-A, Industrial Estate, Hayatabad, Peshawaron the recommendations of the panel of experts for the period Commencing on13-06-2021 ending on 12-06-2026for the following sections: -

1. Tablet (General)
2. Oral Dry Suspension (General)
3. Capsule (General)
4. Tablet (Antibiotic)
5. Sachet (General)
6. Capsule (Cephalosporin)
7. Oral Dry Suspension (Cephalosporin)
8. Syrup (General)

ITEM-IV: MISC. CASES

Case No. 1 **CHANGE OF MANAGEMENT OF M/S NIMRALL LABORATORIES, PLOT NO.24, STREET NO.SS-3, RAWAT INDUSTRIAL ESTATE, RAWAT UNDER DML NO 000611 (FORMULATION).**

AD-I

M/s Nimrall Laboratories, Plot No.24, Street No. SS-3, Rawat Industrial Estate, Rawat submitted the documents for change in management. The firm has deposited fee of Rs.75,000/- for change of management. The detail is as under;

Previous Management	Current management as per Partnership Deed
1. Shahzad Saeed S/o Saeed Ahmed Khan, CNIC No.37405-5119440-7.	1. Mr. Shahzad Saeed S/o Saeed Ahmed Khan CNIC No.37405-5119440-7. 2. Mr. Muhammad Kashif S/o Muhammad Parvaiz Akhtar CNIC No.37405-0325311-9. 3. Mr. Muhammad Badar Jamil S/o Muhammad Ismail CNIC No.33100-8275652-9. 4. Mr. Aftab Saeed S/o Saeed Ahmed Khan CNIC No. 37405-8861347-5. 5. Ms. Kalsoom Mubashir W/o Mubashir Raza Chohan CNIC No. 37405-6497899-2. 6. Mr. Hassan Bin Mubashir S/o Mubashir Raza Chohan. 7. Mr. Shahyan Bin Mubashir S/o Mubashir Raza Chohan.

Decision of the Central Licensing Board in 288th meeting:

The Board considered and accepted for record the change of management of, M/s Nimrall Laboratories, Plot No.24, Street No. SS-3, Rawat Industrial Estate, Rawat DML No.000611(By way of Formulation) as under;

Previous Management	Current management as per Partnership Deed
2. Shahzad Saeed S/o Saeed Ahmed Khan, CNIC No.37405-5119440-7.	8. Mr. Shahzad Saeed S/o Saeed Ahmed Khan CNIC No.37405-5119440-7. 9. Mr. Muhammad Kashif S/o Muhammad Parvaiz Akhtar CNIC No.37405-0325311-9. 10. Mr. Muhammad Badar Jamil S/o Muhammad Ismail CNIC No.33100-8275652-9. 11. Mr. Aftab Saeed S/o Saeed Ahmed Khan

	CNIC No. 37405-8861347-5. 12. Ms. Kalsoom Mubashir W/o Mubashir Raza Chohan CNIC No. 37405-6497899-2. 13. Mr. Hassan Bin Mubashir S/o Mubashir Raza Chohan. 37405-7406636-3 14. Mr. Shahyan Bin Mubashir S/o Mubashir Raza Chohan. 37405-7501636-3

Case No. 2 **CHANGE OF MANAGEMENT M/S RAZEE THERAPEUTICS (PVT) LTD, 48-KM, LAHORE KASUR ROAD, KASUR**

AD-III

The firm, M/s Razee Therapeutics (Pvt) Ltd, 48-KM, Lahore Kasur Road, Kasur, wherein the firm has submitted application for change of management under Drug Manufacturing License No. 000437 by way of (Formulation) with relevant fee of Rs. 75,000/. The detail of management is as under;

Existing management	**New management As per Form-A** Issuing date 28-10-2021
1. Mr. Muhammad Hassan Razzee S/o Kh. M. Arif CNIC No. 35201-3926312-3. 2. Kh. Muhammad Asif Razee S/o Kh. M. Arif CNI No. 35201-2703742-1. 3. Mr. Muhammad GhalibRazzee S/o Muhammad Arif CNIC No. 35201-5586575-5. 4. Mrs. Misbah Arif.	1. Kh. MuhammadAsifRazee S/o Kh. M. Arif CNI No. 35201-2703742-1. 2. Mr. Muhammad GhalibRazzee S/o Muhammad Arif CNIC No. 35201-5586575-5. 3. Mr. Muhammad Hassan Razzee S/o Kh. M. Arif CNIC No. 35201-3926312-3. 4. Mr. HameedaBanoRaazee S/o Muhammad Arif CNIC No. 35201-9891933-2.

Decision of the Central Licensing Board in 288th meeting:

The Board observed that the details of the directors (ceasing of officer/retirement/resignation) is not mentioned in Form-29. The case is deferred for clarification by the firm.

Case No. 3 **CHANGE OF MANAGEMENT M/S STAR LABORATORIES (PVT) LTD, 23-KM, MULATAN ROAD, LAHORE**

AD-III

The firm, M/s Star Laboratories (Pvt) Ltd, 23-KM, Multan Road, Lahore, wherein the firm has submitted application for change of management with relevant fee of Rs.75,000/. The detail of management is as under;

Previous Management as per Form-IA	**Current Management as per Form-29**
1. Ch.Rehmat Ullah S/o Muhammad Bashir CNIC No. 35202-3035965-92. 2. Mr. Muhammad Asrar H. Malik S/o Iqbal Malik CNIC No.35202-2257887-3. 3. Mr. Muhammad Ashar H. Malik S/o Iqbal H Malik CNIC No. 35202-2766524-7.	1. Mr. Muhammad Asrar Hussain Malik S/o Iqbal Malik CNIC No.35202-2257887-3. 2. Mr. Muhammad Ashar Hussain Malik S/o Iqbal H Malik CNIC No. 35202-2766524-7. 3. Mr. Iqbal Hussain Malik S/o Jaml Din CNIC No. 35202- 8890175-3.

Decision of the Central Licensing Board in 288th meeting:

The Board observed that the details of the directors (ceasing of officer/retirement/resignation) is not mentioned in Form-29. The case is deferred for clarification by the firm.

Case No 4 **CHANGE OF MANAGEMENT M/S SYMANS PHARMACEUTICALS (PVT) LTD, 10-KM, SHEIKHUPURA ROAD, LAHORE.**

AD-III

The firm, M/s Symans Pharmaceuticals (Pvt) Ltd, 10-KM, Sheikhupura Road, Lahore, submitted application for change of management under Drug Manufacturing Licence No. 000323. The firm also submitted fee Rs 75000/= for change of management detail as under;

Previous Management as per Form-IA	**Current Management as per Form-A**
i. Syed Salem Haider, ii. Sven Javed Armed, iii. Dr .SyedaTabassam Sajjad, iv. Dr. Syed Muhammad Naeem	i. Dr. Syed Sajjad Haider S/O Syed Muhammad Anwer, CNIC No. 35201-1548934-1 ii. Dr. Syed Saleem Haider, S/O Syed Muhammad Anwer, CNIC No. 35201-1548929-9 iii. Syed Javed Ahmed S/O Syed Muhammad Anwer, CNIC No.35201-1548924-1 iv. Syed Muhammad Naeem S/O Syed Muhammad Anwer, CNIC No.35201-1548902-3

Decision of the Central Licensing Board in 288th meeting:

The Board observed that firm has not provided the Form-29 mentioning the details of all directors. The case is deferred for provision of an updated Form-29.

Case No.5 **CHANGE OF MANAGEMENT OF M/S HIGHNOON LABORATORIES, LTD, 17.5 KM MULTAN ROAD, LAHORE UNDER DML NO 000155 (FORMULATION).**

AD-I

M/s Highnoon Laboratories Ltd, 17.5 Km Multan Road, Lahore under DML No. 000155 (Formulation) submitted the documents for change in management. The firm has deposited fee of Rs. 75,000/- for change of management. The detail of management is as under;

Previous Management	New Management as per Form-29
1. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1. 2. Mr. Ghulam Hussain Khan S/o Haji Abdul Jalil Khan CNIC No. 35201-3787935-7. 3. Mr. Shazib Masud S/o Syed Mehmood Masud CNIC No. 35202-0873913-7. 4. Mr. Taufiq Ahmed Khan S/o Jawaid Tariq Khan CNIC No. 35201-9273258-3. 5. Ms. Zainab Abbas W/o Tausif Ahmad Khan CNIC No. 35202-2649546-6. 6. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7. 7. Mr. Romesh Alexander Iddamalgoda Elapata S/o Samuel Alexander Iddamalgoda Elapata Passport No. 538661630.	1. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1. 2. Mr. Ghulam Hussain Khan S/o Haji Abdul Jalil Khan CNIC No. 35201-3787935-7. 3. Ms. Nael Najam W/o Syed Najam Rafiq CNIC No. 61101-7901490-4. 4. Mr. Taufiq Ahmed Khan S/o Jawaid Tariq Khan CNIC No. 35201-9273258-3. 5. Ms. Zainab Abbas W/o Tausif Ahmad Khan CNIC No. 35202-2649546-6. 6. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7. 7. Mr. Romesh Alexander Iddamalgoda Elapata S/o Samuel Alexander Iddamalgoda Elapata Passport No. 538661630.

Decision of the Central Licensing Board in 288th meeting:

The Board considered and accepted for record the change of management of M/s Highnoon Laboratories Ltd, 17.5 Km Multan Road, Lahore, DML No.000155(By way of Formulation) as under.

Previous Management	New Management as per Form-29
8. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1. 9. Mr. Ghulam Hussain Khan S/o Haji Abdul Jalil Khan CNIC No. 35201-3787935-7. 10. Mr. Shazib Masud S/o Syed Mehmood Masud CNIC No. 35202-0873913-7. 11. Mr. Taufiq Ahmed Khan S/o Jawaid Tariq Khan CNIC No. 35201-9273258-3. 12. Ms. Zainab Abbas W/o Tausif Ahmad Khan CNIC No. 35202-2649546-6. 13. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7. 14. Mr. Romesh Alexander Iddamalgoda Elapata S/o Samuel Alexander Iddamalgoda Elapata Passport No. 538661630.	8. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1. 9. Mr. Ghulam Hussain Khan S/o Haji Abdul Jalil Khan CNIC No. 35201-3787935-7. 10. Ms. Nael Najam W/o Syed Najam Rafiq CNIC No. 61101-7901490-4. 11. Mr. Taufiq Ahmed Khan S/o Jawaid Tariq Khan CNIC No. 35201-9273258-3. 12. Ms. Zainab Abbas W/o Tausif Ahmad Khan CNIC No. 35202-2649546-6. 13. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7. 14. Mr. Romesh Alexander Iddamalgoda Elapata S/o Samuel Alexander Iddamalgoda Elapata Passport No. 538661630.

Case No.6 CHANGE OF MANAGEMENT OF M/S ZETA PHARMACEUTICALS, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000818 BY WAY OF (FORMULATION).

M/s Zeta Pharmaceuticals, Plot No. 494-A, Sunder Industrial Estate, Lahore, DML No.000818 by way of formulation has submitted request for change in management of the firm along with partnership deed (reconstituted) and fee Rs. 75000/-. The detail of management of the firm is as under:-

Previous Management	Current Management
i. Mr. Attaullah Aziz S/o Abdul Aziz Bhatti CNIC No. 36601-9882210-9. ii. Mr. AtiqQamar S/o Ch. Qamar Uddin Ahmed CNIC No. 35200-1424093-5, iii. Mr. Zahid Masood Nasir S/o Basharat Ali CNIC No. 35202-5632630-7,	i. Mr. Attaullah Aziz S/o Abdul Aziz Bhatti CNIC No. 36601-9882210-9. ii. Mr. AtiqQamar S/o Ch. Qamar Uddin Ahmed CNIC No. 35200-1424093-5,

Decision of the Central Licensing Board in 288th meeting:

The Board observed that firm has not provided Form-D and the copy of the partnership deed is not readable. Hence the case is deferred for submission of original certified true copies.

Case No. 7 **CHANGE OF MANAGEMENT OF M/S ALEN PHARMACEUTICALS (PVT) LTD, RISALPUR UNDER DRUG MANUFACTURING LICENSE NO. 000435 BY WAY OF (FORMULATION).**

AD-IV

M/s Alen Pharmaceuticals (Pvt) Ltd, Risalpur, DML No.000435 by way of formulation has submitted request for change in management of the firm as per partnership deed with prescribed fee. The detail of management of the firm is as under:-

Previous Management	Current Management as per Form-29 & Form-A.
i. Muhammad Ali Khan S/o Muhammad Umar Khan, CNIC No.16101-5065473-1. ii. Mrs. Nusrat Ali W/o Muhammad Ali, CNIC No.16101-1073976-8. iii. Mr. Shaukat Ali S/o Muhammad Ali, CNIC No.16101-4235301-3.	i. Mrs. Nusrat Ali W/o Muhammad Ali, CNIC No.16101-1073976-8. ii. Mr. Shaukat Ali S/o Muhammad Ali, CNIC No.16101-4235301-3.

Decision of the Central Licensing Board in 288th meeting:

The Board observed that the firm did not submit the Form-29 and the application is incomplete hence case is deferred for completion of application.

Case No. 8 **CHANGE OF MANAGEMENT OF M/S MEDIMARKER'S LABORATORIES (PVT) LTD., PLOT NO.A-104, S.I.T.E, HYDERABAD UNDER DRUG MANUFACTURING LICENSE NO.000615 (FORMULATION).**

AD-III

M/s Medimarker's Laboratories (Pvt) Ltd., Hyderabad, DML No.000615 by way of formulation has submitted request for change in management of the firm as per Form-A with prescribed fee. The detail of management of the firm is as under:-

Previous Management	**Current Management as per Form-A.**
i. Mrs. Ayesha Abdullah W/o Abdullah Sheikh, CNIC No.42301-7863442-6.	i. Mrs. Ayesha Abdullah W/o Abdullah Sheikh, CNIC No.42301-7863442-6. ii. Mr. Jai Paldas S/o Parcho Mal, CNIC No.42201-0299960-9.

Decision of the Central Licensing Board in 288th meeting:

The Board considered and accepted for record the change of management of M/s Medimarker's Laboratories (Pvt) Ltd., Hyderabad, DML No.000615 by way of formulation as under:

Previous Management	**Current Management as per Form-A.**
ii. Mrs. Ayesha Abdullah W/o Abdullah Sheikh, CNIC No.42301-7863442-6.	iii. Mrs. Ayesha Abdullah W/o Abdullah Sheikh, CNIC No.42301-7863442-6. iv. Mr. Jai Paldas S/o Parcho Mal, CNIC No.42201-0299960-9.

Case No. 9 **CHANGE OF MANAGEMENT M/S ICE BERG PHARMACEUTICALS (PVT) LTD., PLOT NO/ 144, NOWSHERA INDUSTRIAL ESTATE, RISALPUR**

AD-IV

M/s Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No/ 144, Nowshera Industrial Estate, Risalpur has submitted application for change of management under Drug Manufacturing License No. 000816 by way of (Formulation) with relevant fee of Rs. 75,000/. The detail of management is as under;

Previous management	New management As per Form-29
1. Mr. Muhammad Fayaz S/o Kachkol CNIC No. 17101-7193842-7. 2. Mr. Najeeb Ullah S/o Habib Ullah CNIC No. 17301-8989720-9. 3. Mr. Muhammad Tahir S/o Sahib Gul CNIC No. 16101-9356882-3.	1. Mr. Kamran Anjum S/o Ihsan Ullah CNIC No. 17301-8270898-1. 2. Mr. Hasnain Ali Gulfam S/o Gulfam Hussain CNIC No. 17301-0101205-7.

Decision of the Central Licensing Board in 288th meeting:

The Board observed that certified true copy of the Form-29 is not provided by the firm hence case is deferred.

Case No. 10 **CHANGE OF MANAGEMENT M/S PCP LABORATORIES, 98-KM, AKHTARABAD, DISTRICT OKARA**

AD-III

M/s PCP Laboratories, 98-Km, Akhtarabad, District Okarahas submitted application for change of management under Drug Manufacturing License No. 000814 by way of (Formulation) with relevant fee of Rs. 75,000/. The detail of management is as under;

Previous management	New management As per partnership deed
1. 1. Dr. Mehmood Ahmad Mirza S/o Chaudry Barkat Ali. 2. 2. Dr. Noor Ahmad Noor S/o Haji Barkat Ali. 3. 3. Dr. Saeed Ahmad S/o Faqir Muhammad. 4. 4. Dr. Muhammad Ali Bukhari S/o Syed Khursheed 5. Hussan. 6. 5. Dr. Abdu Salam Arshad S/o	1. Salman Hassan S/o Muhammad Hassan CNIC No. 91509-0173536-9. 2. Mst. Amber Saeed W/o Salman Hassan CNIC No. 91509- 0245525-6.

Muhammad Rafiq. 7. 6. Doctor Khan S/o Behram Khan. 8. 7. Mr. Rehan Manzoor S/o Manzoor Afshar. 9. 8. Dr. Muhammad Yousuf S/o Abdul Rehman Sodager. 10. 9. Dr. Tariq Rasheed S/o Rasheed Ahmed. 11. 10. Dr. Muhammad Aslam S/o Muhabat Ali. 12. 11. Dr. Naqshab Ahmed S/o Atta Ahmed. 13. 12. Dr. Tarin Nadeem S/o Syed Karamat Ali Shah. 14. 13. Mrs. SafiaBano w/o Taj Muhammad Zahid. 15. 14. Mr. Muhammad Shahzad Ilyas S/o Muhammad Ilyas 16. Sajid. 17. 15. Dr. Zulfagar Ali S/o Allah Rakha. 18. 16. Dr. Muhammad Faisal Javed S/o Abdul Qadeer Javed. 19. 17. Mr. Muhammad Manzoor S/o Muhammad Hussain. 20. 18. Syed Mir Zaman Ali Shah S/o Abdul Hameed Shah.	

Decision of the Central Licensing Board in 288th meeting:

The Board observed that the partnership deed dated 4-02-2022 and partnership deed 20-08-2015 does not match the details of the partners. The Board deferred the case for clarification.

Case No. **CHANGE OF MANAGEMENT M/S NEWTON HEALTH CARE (PVT) LTD., PLOT NO. N-8&9, HITE, HUB, BALOCHISTAN**

AD-III

M/s Newton Health Care (Pvt) Ltd., Plot No. N-8 & 9, HITE, Hub, Balochistan has submitted application for change of management under Drug Manufacturing License No. 000870 by way of (Formulation) with relevant fee of Rs. 75,000/. The detail of management is as under;

Previous management	New management As per Form-29

1. Shazia Zeb W/o Farooq Ahmed Qazi CNIC No.43203-5513610-4 2. Jawaid Ahmed Qureshi S/o Abdul Majeed Qureshi CNIC No.43203-8926177-1. 3. Muhammad Khalid Qazi S/o Abdul Ghafoor CNIC No.43203-1568676-5. 4. Qadeer Ahmed S/o Ghulam Rasool Somroo CNIC No.42301-3103594-1. 5. Muhammad Tariq Qazi S/o Abdul Ghafoor Qazi CNIC No.43203-5129028-1.	1. Shafaq Sultana S/o Farooq Ahmed Qazi CNIC No.43203-7952187-0. 2. Farooq Ahmed Qazi S/o Abdul Ghafoor CNIC No.43203-9496796-7 3. Jawaid Ahmed Qureshi S/o Abdul Majeed Qureshi CNIC No.43203-8926177-1. 4. Muhammad Khalid Qazi S/o Abdul Ghafoor CNIC No.43203-1568676-5. 5. Qadeer Ahmed S/o Ghulam Rasool Somroo CNIC No.42301-3103594-1. 6. Muhammad Tariq Qazi S/o Abdul Ghafoor Qazi CNIC No.43203-5129028-1.

Decision of the Central Licensing Board in 288th meeting:

The Board observed that the details of the directors (ceasing of officer/retirement/resignation) is not mentioned in Form-29. The case is deferred for clarification by the firm.

Case No. 11 **GRANT OF RE-PACKING PRODUCTS TO M/S SARCO CHEMICAL INDUSTRIES, 17-KM, PEERWALA MORR, QADER PUR BAN, KHANEWAL ROAD, DISTRICT MULTAN.**

AD-III

M/s Sarco Chemical Industries, 17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan., under Drug Manufacturing Licence No. 000203 by way of formulation has submitted application for Grant of Re-packing drug as per Schedule-D. Firm has submitted challan Fee of 7,500/ per product.

S#	Drug	Schedule-D
1.	Ammonium Bicarbonate	Yes
2.	Ammonium chloride.	Yes
3.	Kaolin.	Yes
4.	Zinc Oxide.	Yes
5.	Salicylic Acid.	Yes
6.	Potassium Bromide.	Yes
7.	Soda Bicarb.	Yes
8.	Sodium Salicylate.	Yes
9.	Soft Paraffin.	Yes
10.	Chloral Hydrate.	Yes
11.	Mag. Sulphate.	Yes
12.	Boric Acid.	Yes

13.	Caffeine Citrate.	Yes
14.	Castor Oil.	Yes
15.	Glycerin.	Yes
16.	Liquid Paraffin.	Yes

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board considering the case and decided to approve following drugs by way of repacking except caffein citrate in the name of M/s Sarco Chemical Industries, 17-Km, Peerwala Morr, Qader Pur Ban, Khanewal Road, District Multan., under Drug Manufacturing License No. 000203 by way of formulation:

S#	Drugs for Re-Packing
1.	Ammonium Bicarbonate
2.	Ammonium chloride
3.	Kaolin
4.	Zinc Oxide
5.	Salicylic Acid
6.	Potassium Bromide
7.	Sodium Bicarbonate (Soda Bicarb)
8.	Sodium Salicylate
9.	Soft Paraffin (Yellow)
10.	Chloral Hydrate
11.	MagnesiumSulphate
12.	Boric Acid
13.	Castor Oil
14.	Glycerin
15.	Liquid Paraffin (Heavy)

The Board desired to provide further details regarding the source of import of Caffeine Citrate and its sale by the firm.

CASE NO.12 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000814 OF M/S PCP LABORATORIES, 98-KM, AKHTARABAD, DISTRICT OKARA.

AD-III

M/s PCP Laboratories, 98-Km, Akhtarabad, District Okara had applied for renewal of DML No. 000814 by way of formulation for the period of 23-06-2015 to 22-06-2020. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 5th October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

For Renewal of DML.

i. Detail of management at the time of previous renewal and at present, if any change apply for change of management.
ii. Partnership deed alongwith CNIC's of all partners.
iii. Detail of premises including layout plan.
iv. Proof of licensed sections from CLB.
v. Approval letter of Quality Control Incharge in case of change than submit required documents as per check list.
vi. Form 1A as per prescribed format.
vii. Up-to-date nothing due certificate regarding CRF from STO.

All documents should be duly attested.

For Production Incharge (Mr. Rehmat Jamil)

i. Copy of appointment letter of appointee.
ii. Copy of job acceptance letter by the appointee.
iii. Readable copy of registration certificate from pharmacy council.
iv. Copy of resignation letter of earlier Production Incharge.
v. Copy of resignation letter of appointee from previous firm.
vi. Undertaking as whole-time employee on stamp paper signed by both appointee & management.

All documents should be duly attested.

The firm submitted their reply after evaluation of the submitted documents, final reminder was issued on 3rd March, 2021 to the firm with following shortcomings: -

For Renewal of DML.

i. Detail of management at the time of previous renewal and at present, in case of any change apply for change of management.
ii. Partnership deed alongwith copies of CNIC of all partners.
iii. Detail of premises including layout plan.
iv. Proof of licensed sections from CLB.
v. Approval letter of Quality Control Incharge, in case of change, submit required documents as per check list.
vi. Form 1A as per prescribed format.
vii. Up-to-date nothing due certificate regarding CRF from STO.

All documents should be duly attested.

No reply is received from the firm as of today and the application for renewal of DML No. 000814 (Formulation) is still deficient of above-mentioned documents.

The case was placed before the Central Licensing Board in its 282nd meeting of Central Licensing Board held on 31st August, 2021. The Board decided that:-

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

"The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising)

Rules, 1976 as to why Drug Manufacturing License No 000814 (by way of formulation) of M/s PCP Laboratories, 98-Km, Akhtarabad, District Okara may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976".

In response to Show Cause Notice dated 28th September, 2021 firm has submitted their reply. The Firm also submitted for change of management. However following shortcoming is not rectified so for;

i. Compete Legal Documents for management are not provided.

A letter of personal hearing was served to the firm for 283rd meeting of Central Licensing Board schedule held on 28th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

Mr. Adeel Shahzad, IR & Compliance Manager and Ms. Aden Naseem Khan, HOD Regulatory, of the firm appeared before the board. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000814 by way of Formulation of M/s PCP Laboratories, 98-Km, Akhtarabad, District Okara till fulfillment of codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the board for ratification.

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

In light of above decision of the Board, letter of suspension of DMLNo 000814 by way of Formulation of M/s PCP Laboratories, 98-Km, Akhtarabad, District Okara on10/12/2021.

The firm completed all codal formalities and application for renewal of DML was complete. in light of decision of the Board, Secretary CLB issued ceasing of DML suspension order on14/06/2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board while considering the facts on the record ratified the decision/action of Secretary, Central Licensing Board.

Case No. 13 **APPROVAL OF TECHNICAL PERSON I.E., PRODUCTION INCHARGE OF M/S PHARMACARE LABORATORIES (PVT) LTD, 129/1, INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000225 (BY WAY FORMULATION)**

AD-III

The firm M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, KotLakhpat, Lahore, submitted application for approval of technical person, production incharge, on 10-01-2020.

The application was evaluated as per the Drug (Liceisng, registering &advertising)Rule 1976 and found following shortcomings which were asked from the firm to rectify on 12-03-2020:

i. Appointment letter of appointee.
ii. Job acceptance letter by the appointee.
iii. Copy of CNIC of appointee.
iv. Copy of academic degrees, as under Drugs (Licensing, Registering & Advertising) Rules, 1976.
v. Registration certificate from Pharmacy Council (in case of Pharmacist).
vi. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
vii. Resignation / retirement of earlier Production Manager.
viii. Resignation / termination letter of appointee from previous firm.
ix. Undertaking as whole time employee on stamp paper.
x. Fee of approval of Production Incharge Rs.5000/- in DRAP account.
xi. All documents duly should be attested.

As the firm did not submit any reposed to this Office's letter dated 12-03-2020, a final reminder was issued on 14th January, 2022to the firm to rectify above said shortcomings**.**

The case was placed before the Central Licensing Board in its 285th meeting held on 17thand 18th March, 2022 and Board decided as under:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000225 by way of formulation of M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore, may not be suspended or cancelled by Central Licensing Board.

Accordingly, Show Cause Notice to the firm was issued on 23/05/20222.

The firm completed all codal formalities and application for approval of production inchargeis complete now.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Since, the firm has completed the application for the approval of production incharge, the Board while considering the facts on the record decided to cease the operation of Show Cause Notice for the further period issued in the name of M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore

Case No. **14** **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000037 OF M/S REKO PHARMACEUTICAL (PVT) LTD, 13-KM, MULTAN ROAD, LAHORE.**

AD-III

M/s Reko Pharmaceutical (Pvt) Ltd, 13-KM, Multan Road, Lahore had applied for renewal of DML No. 000037 by way of formulation for the period of 30-04-2020 to 29-04-2025. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 22nd October, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Detail of previous management and current management is required.
ii. Certified as "true copy" of Form-29 by SECP (in original) is required.
iii. Approval letter of technical persons are not provided.
iv. Updated NOC (CRF) from STO, DRAP is not provided.

The firm submitted their reply on 15th November, 2021. After evaluation of the submitted documents, reminder was issued on 11th March, 2022 to the firm with following shortcomings:-

i. Complete Form-29 attested as "true copy" by SECP (In original).

Firm did not submit their reply in response to this Division's reminder till to date. The application of Renewal of Drug Manufacturing License is still deficient for following documents: -

i. Form-29 attested as "true copy" by SECP (In original).

The case was placed before the Central Licensing Board in its 286th meeting held on 11th May, 2022 and the Board decided as under;

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, 5and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000037 by way of formulation of M/s Reko Pharmaceutical (Pvt) Ltd, 13-KM, Multan Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Accordingly, Show Cause Notice to the firm was issued.

The firm completed all codal formalities and application for renewal is complete now.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Since, the firm has completed the application for the Renewal of DML No. 000037, the Board while considering the facts on the record decided to cease the operation of Show Cause Notice

for the further period issued in the name of M/s Reko Pharmaceutical (Pvt) Ltd, 13-KM, Multan Road, Lahore.

Case No. 15 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S CAYLEX PHARMACEUTICALS (PVT) LTD, LAHORE.**

AD-I

M/s Caylex Pharmaceuticals (Pvt) Ltd, 10-Km, Main Raiwind Road, Lahore had applied for renewal of DML No. 000451 by way of Formulation for the period of 01-08-2020 to 31-07-2025 on 30-07-2020.

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 24-08-2020 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 letter of sections approved by CLB, if not available, apply for regularization of layout plan.
vii. Duly attested resignation of earlier production Incharge.
viii. Duly attested resignation of proposed production Incharge from previous firm.

The firm then filed application for approval of Production Incharge and Quality Control Incharge. Reminder letter was issued on 16-11-2021 to the firm for completion of application for renewal of DML and approval of technical staff:

i. Properly filled, signed and stamped Form-1 A (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 true copy of Form-29 duly attested by SECP (original).
v. Duly attested CNIC copies of all directors.
vi. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
vii. Complete set of duly attested documents (as per checklist) of proposed Production Incharge & Quality Control Incharge.

The firm replied on 08-12-2021 but application is still deficient of following documents:

i. Properly filled, signed and stamped Form-1 A (as per format).
i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management, if any change, apply for change of management.
iii. Latest true copy of Form-29 duly attested by SECP (original).
iv. Duly attested CNIC copies of all directors.

v. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
vi. Complete set of duly attested documents (as per checklist) of proposed Production Incharge & Quality Control Incharge.

Decision of the Central Licensing Board in 288th meeting

The Board while considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No000451 by way of formulation of M/s Caylex Pharmaceuticals (Pvt) Ltd, 10-Km, Main Raiwind Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 16 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MIRACLE PHARMACEUTICALS (PVT) LTD, RAWAT.**

AD-I

M/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 8, Street S-5, National Industrial Zone, Rawat had applied for renewal of DML No. 000593 by way of Formulation for the period of 29-06-2021 to 28-06-2026 on 28-06-2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 02-08-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing due certificate regarding CRF from STO.
iii. Detail of management, if any change, apply for change of management.
iv. Duly attested CNIC copies of Directors.
v. Latest certified true copy of Form-A or Form-29 duly attested by SECP (Original).
vi. Section approval letters approved by CLB, if not available, apply for regularization of layout plan.
vii. Approval letters of technical staff.

The firmdid not reply and reminder letter was issued on 18-10-2021 to the firm for completion of application for renewal of DML:

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing due certificate regarding CRF from STO.

iii. Application for change of management along with prescribed fee of Rs. 75,000/-.
iv. Duly attested CNIC copies of Directors.
v. Latest certified true copy of Form-A or Form-29 duly attested by SECP (Original).
vi. Section approval letters approved by CLB, if not available, apply for regularization of layout plan.
vii. Approval letters of technical staff.

The firm has not yet reply and application for renewal of DML is not complete.

Decision of the Central Licensing Board in 288th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No000593 by way of formulation ofM/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 8, Street S-5, National Industrial Zone, Rawat, 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. 17 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S LAHORE PHARMA, LAHORE.**

AD-I

M/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore had applied for renewal of DML No. 000084 by way of Formulation for the period of 26-03-2021 to 31-25-03-2026 on 22-03-2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 01-07-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated Nothing Due Certificate (CRF) from STO, DRAP.
ii. Detail of premises including layout plan.
iii. Section approval letters, if not approved by CLB, submit layout plan for regularization,
iv. Proper application along with prescribed fee of Rs. 75,000/- for change in management of the firm.
v. Duly attested CNIC copies of partners, revised partnership deed & Form-D.

The firm did not reply and Reminder letter was issued on 11-10-2021 to the firm for completion of application for renewal of DML:

i. Updated Nothing Due Certificate (CRF) from STO, DRAP.
ii. Detail of premises including layout plan.
iii. Section approval letters, if not approved by CLB, submit layout plan for regularization,
iv. Proper application along with prescribed fee of Rs. 75,000/- for change in management of the firm.
v. Duly attested CNIC copies of partners, revised partnership deed & Form-D.

In the meanwhile, Production Incharge of the firm has resigned and letter was issued on 02-08-2022 for appointment and approval of Production Incharge. The firm did not reply and application for renewal of DML and Production Incharge is still incomplete.

Decision of the Central Licensing Board in 288th 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No000084 by way of formulation ofM/s Lahore Pharma, 9-Km Sheikhupura Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 18 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MUNAWAR PHARMA (PVT) LTD, LAHORE.**

AD-I

M/s Munawar Pharma (Pvt) Ltd, 31-Km Ferozepur Road, Lahore had applied for renewal of DML No. 000379 by way of Formulation for the period of 12-01-2019 to 11-01-2024 on 19-12-2018.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 15-02-2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Nothing due certificate regarding CRF from STO (Updated).

ii. Properly filled, signed and stamped Form-1A (as per format)

iii. Duly attested CNIC copies of all Directors.

The firm did not reply and Reminder letter was issued on 15-09-2020 to the firm for completion of application for renewal of DML.

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

i. Nothing due certificate regarding CRF from STO (Updated).

ii. Properly filled, signed and stamped Form-1A (as per format)

iii. Duly attested CNIC copies of all Directors.

Decision of the Central Licensing Board in 288th 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No.000379by way of formulation ofM/s Munawar Pharma (Pvt) Ltd, 31-Km Ferozepur Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 19 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S IDEAL PHARMACEUTICAL INDUSTRIES, LAHORE.**

AD-I

M/s Ideal Pharmaceutical Industries, 18-Km Ferozepur Road, Lahore had applied for renewal of DML No. 000146 by way of Formulation for the period of 30-10-2019 to 29-10-2024 on 28-10-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 18-02-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Update NDC regarding CRF from STO (R&D) DRAP, Islamabad.

ii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.

iii. Duly attested Form-C, partnership deed & CNIC Copies of all Directors.

iv. Section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm did not reply and Reminder letter was issued on 15-09-2020 to the firm for completion of application for renewal of DML.

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

i. Update NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iii. Duly attested Form-C, partnership deed & CNIC Copies of all Directors.
iv. Section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

Decision of the Central Licensing Board in 288th 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No000146by way of formulation ofM/s Ideal Pharmaceutical Industries, 18-Km Ferozepur Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 20 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDICEENA PHARMA (PVT) LTD, LAHORE.**

AD-I

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 28th September, 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 19th October, 2020 but application for renewal of DML is still incomplete with following documents being deficient.

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

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

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

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

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

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

i. Latest certified true copy of Form-29 duly attested by SECP without stamp that SECP does not take responsibility of contents of Form. (original).

ii. Section approval letters of all sections approved by Central Licensing Board, if not available, apply for regularization of Layout Plan.
iii. Properly filled, signed & stamped Form-1A (as per format).

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

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

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

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

A letter was issued to Deputy Registrar of Companies (SECP), Lahore for clarity of disclaimer of SECP on Form.

Deputy Registrar of Companies (SECP) clarified that reason for posting such stamp (qualification stamp) is that this office has not accepted the documents as filed by the company as yet due to possibility of any mistakes/errors in the company documents. This is a usual practice to issue certified copies with qualification stamp when companies apply for certified copies early and the documents are not yet scrutinized by the concerned dealing registrar. However, in order to get certified true copies without qualification stamp, the company needs to take up the matter with the concerned registrar to resolve any issues in the company documents so that they are accepted and certified true copies can be issued without qualification.

Decision of the Central Licensing Board in 288th meeting

The Board while considering the facts on the record and after thread bare deliberation decided that the firm shall submit updated Form-29 attested as true copy (in original) without disclaimer/qualification stamp within 15days. The case shall be placed before the Board in its upcoming meeting for decision.

Case No.**21. RENEWAL OF DRUG MANUFACTURING LICENCE OF CHERISHED PHARMACEUTICALS, LAHORE.**

AD-I

M/s Cherished Pharmaceuticals, 10-Km, Sunder Raiwind Road, Lahore had applied for renewal of DML No. 000596 by way of Formulation for the period of 11-07-2021 to 10-07-2026 on 04-08-2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 24-09-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Late fee surcharge of Rs. 187,500/- (7500/day *25 days).
ii. Updated Nothing Due Certificate (CRF) from STO, DRAP.
iii. Detail of management, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 or Form-A duly attested by SECP (Original).

The firm replied to this letter on 26-10-2021 and reminder letter was issued on 23-11-2021 to the firm for completion of application:

i. Late fee surcharge of Rs. 187,500/- (7500/day *25 days).

The firm did not reply and application for renewal of DML is still incomplete.

Decision of the Central Licensing Board in 285th 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 000596 by way of formulation of M/s Cherished Pharmaceuticals, 10-Km, Sunder Raiwind Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause Notice was issued to M/s Cherished Pharmaceuticals, 10-Km, Sunder Raiwind Road, Lahore on 4th June, 2022.

The firm has replied and now application for renewal of DML is complete.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board while considering the facts on the record decided to cease the operation of Show Cause Notice for the further period issued in the name of M/s Cherished Pharmaceuticals, 10-Km, Sunder Raiwind Road, Lahore.

Case No. 22 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ANEEB PHARMACEUTICALS (PVT) LTD, LAHORE.**

AD-I

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

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

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

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

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

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

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

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

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

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

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

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

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 duly attested by SECP (original)

iii. Section approval letters, if not available, apply for regularization of Layout Plan of Cream / Ointment, Sachet & Dry Powder Syrup Sections.
iv. Nothing due certificate regarding CRF from STO (Updated).

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

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

Mr. AtifSahrief, Managing Director of the Company appeared before the Board. He contended that he had submitted documents and taken up the matter with Budget and Accounts for issuance of nothing due certificate. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000555 by way of formulation of M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till completion of codal formalities/submission of required documents. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

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

The firm has submitted all the deficient and application for renewal of DML is complete.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board observed that the case was inadvertently included in agenda of 288th Meeting of CLB , while the board has already taken the decision in 287th meeting of CLB.

Case No. 23 **CHANGE OF ADDRESS OF M/S LIVEN PHARMACEUTICALS (PVT) LTD, DISTRICT KASUR.**

AD-I

M/s Liven Pharmaceuticals (Pvt) Ltd, Sray Road, 49-Km Multan road, Phool Nagar, District Kasur had applied for verification of site for establishment of pharmaceutical unit at 49-Km, Multan Road, Lahore. Address of the site as per fard was Khewat No.42/43, Khatooni No.114-116, Tehsil Pattoki District Kasur. FID conducted the inspection and forwarded report that proposed site i.e. Sray Road, 49-Km, Multan Road, Phool Nagar, District Kasur is suitable for establishing a pharmaceutical unit (PageNo.56-57, F.No.1-27/2015-Lic) and same was approved. Drug Manufacturing License was issued on the same address. The firm, then filed application for

change of their address to 49-Km, Multan Road, Lahore and submitted undertaking that this address is same as Sray Road, 49-Km, Multan Road, Phool Nagar, District Kasur. Request of the firm was forwarded to Area FID, DRAP, Lahore for comments on the subject matter. The comments of FID are reproduced as under:

"It is to inform you that the address of the firm under reference as per DRAP letter No. F. 1-27/2015-Lic dated 11-04-2018 regarding grant of Drug Manufacturing License is "M/s. Liven Pharmaceuticals (Pvt.) Ltd., Sray Road, 49-K.M. Multan Road, Phool Nagar, District, Kasur). The time to time correspondence done by the DRAP was at the same address.

It is also clarified that the land documents (Fard) as per available record of DRAP Lahore submitted by the firm at the time of the site verification has been issued from Tehsil Pattoki District Kasur (Copy is enclosed for verification from record of Licensing Division of DRAP, Islamabad).

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board considering the facts on the record and decided not to accede the request of the firm, M/s Liven Pharmaceuticals (Pvt) Ltd, Sray Road, 49-Km Multan road, Phool Nagar, District Kasur.

Case No. 24 **VOLUNTARY DISCONTINUING PRODUCTION ACTIVITIES FRO MAINTENANCE & REVAMPING OF M/S CORTEX PHARMACEUTICALS, RAWAT.**

AD-I

M/s Cortex Pharmaceuticals (Pvt) Ltd, Plot No. 16-A, Road SS-4, National Industrial Zone, Rawat under DML No. 000826 (Formulation) has intimated that they are voluntarily stopping all manufacturing activities in their premises from 14th March, 2022 as they are planning to change machinery, equipment and addition of some new sections to follow latest GMP practices.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board while considering the facts on the record decided that FID, DRAP, Islamabad shall inspect the licensed premises for updated status of the production and submit report thereof.

Case No. 25 **CORRECTION IN THE ADDRESS OF M/S CARAWAY PHARMACEUTICALS, RAWAT.**

AD-I

A. GRANT OF ADDITIONAL SECTIONS/ REVISION/AMENDMENTS ETC.

	M/s Caraway Pharmaceuticals, Plot No. 12, Street No. S-4, National Industrial Zone, Rawat, Rawalpindi DML No. 000629 (Formulation). **Section (02):** 1. Liquid Syrup (General) First floor. 2. Tablet Section (Psychotropic) Ground floor.)	**22-02-2022 & 17-05-2022**	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad 2. Mr. Khalid Mahmood, Federal Inspector of Drugs, DRAP, Islamabad. 3. Hafiz Muhammad Umair, Assistant Director, 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 Caraway Pharmaceuticals, Plot No. 12, Street No. S-4, National Industrial Zone, Rawat, Rawalpindi for the renewal of Drug Manufacturing License No. 000629 (formulations) for the following twelve (12) sections and grant of following newly developed section. except sachet.

Renewal of DML No. 000629 for following twelve sections:

1. Tablet Section (General)
2. Tablet Section (Antibiotic)
3. Capsule Section (General)
4. Semisolids Cream/Ointment/gel Section (General)
5. Semisolids Cream/Ointment/gel Section (Steroidal)
6. Liquid Vial Section (Infusion) Changed into syrup on first floor
7. Capsule Section (Cephalosporin)
8. Oral Dry Powder for Suspension Section (Cephalosporin)
9. Dry Powder for Injection Section (Cephalosporin)
10. X. Liquid Ampoule Section (Injectable)
11. Lotion/shampoo (Medicated)
12. Oral Dry Powder Suspension (General)

Newly developed three Sections:

13. Liquid Syrup (General) First floor.
14. Tablet Section (Psychotropic) Ground floor.)
15. Sachet Section (General) is not ready **(Not recommended)".**

Decision of the Central Licensing Board in 287th meeting:

The Board considered and approved the grant of following section in the name of M/s

	Caraway Pharmaceuticals, Plot No. 12, Street No. S-4, National Industrial Zone, RawatunderDML No.000629 (Formulation) on the recommendations of the panel of experts subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020: **Section (02):** 1. Liquid Syrup (General) First floor. 2. Tablet Section (Psychotropic) Ground floor.) The Board did not approve the following section on the recommendation of panel of experts. The applicant is required to comply Rule 10 of the Drugs (Licensing, Registering and Advertising) Rules,1976. 1. Sachet Section (General) In the agenda and in the minutes the address of the firm due to typographical mistakewas mentioned as M/s Caraway Pharmaceuticals, Plot No. 12, Street No. S-4, National Industrial Zone, Rawatinstead of M/s Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone, Rawat.

B. **GRANT OF RENEWAL / REGULARIZATION OF LOP OF DRUG MANUFACTURING LICENSES.**

	M/s Caraway Pharmaceuticals, Plot No. 12, Street No. S-4, National Industrial Zone, Rawat, Rawalpindi DML No. 000629 (Formulation). Period: Commencing on 19-06-2018 ending on 18-06-2023.	**22-02-2022 & 17-05-2022**	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad 2. Mr. Khalid Mahmood, Federal Inspector of Drugs, DRAP, Islamabad. 3. Hafiz Muhammad Umair, Assistant Director, 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 Caraway			

Pharmaceuticals, Plot No. 12, Street No. S-4, National Industrial Zone, Rawat, Rawalpindi for the renewal of Drug Manufacturing License No. 000629 (formulations) for the following twelve (12) sections and grant of following newly developed section except Sachet.

Renewal of DML No. 000629 for following twelve sections:

1. Tablet Section (General)
2. Tablet Section (Antibiotic)
3. Capsule Section (General)
4. Semisolids Cream/Ointment/gel Section (General)
5. Semisolids Cream/Ointment/gel Section (Steroidal)
6. Liquid Vial Section (Infusion) Changed into syrup on first floor
7. Capsule Section (Cephalosporin)
8. Oral Dry Powder for Suspension Section (Cephalosporin)
9. Dry Powder for Injection Section (Cephalosporin)
10. Liquid Ampoule Section (Injectable)
11. Lotion (Medicated)
12. Oral Dry Powder Suspension (General)

Newly developed three Sections:

13. Liquid Syrup (General) First floor.
14. Tablet Section (Psychotropic) Ground floor.)
15. Sachet Section (General) is not ready **(Not recommended)".**

Decision of the Central Licensing Board in 287th meeting:

The Board considered and approved the grant of renewal of DML No. 000629 by way of Formulation in the name of M/s Caraway Pharmaceuticals, Plot No. 12, Street No. S-4, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period commencing on 19-06-2018 ending on 18-06-2023 for the following section: -

1. Tablet Section (General)
2. Tablet Section (Antibiotic)
3. Capsule Section (General)
4. Semisolids Cream/Ointment/gel Section (General)
5. Semisolids Cream/Ointment/gel Section (Steroidal)
6. Liquid Vial Section (Infusion) Changed into syrup on first floor
7. Capsule Section (Cephalosporin)
8. Oral Dry Powder for Suspension Section (Cephalosporin)
9. Dry Powder for Injection Section (Cephalosporin)
10. X. Liquid Ampoule Section (Injectable)
11. Lotion (Medicated)
12. Oral Dry Powder Suspension (General)

In the agenda and in the minutes the address of the firm due to typographical mistakewas mentioned as M/s Caraway Pharmaceuticals, Plot No. 12, Street No. S-4, National Industrial Zone, Rawatinstead of M/s Caraway Pharmaceuticals, Plot No.

	12, Street No. N-3, National Industrial Zone, Rawat.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board while considering the facts on the record approved the correction in the Address of M/s Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone, Rawatunder DML No. 000629 (Formulation) as under

M/s Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone, Rawat

CASE NO. 26 CORRECTION IN NAME/TITLE OF M/S M/S BIOGEN PHARMA, RAWALPINDI.

AD-I

A) RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000639 (FORMULATION) OF M/S BIOGEN PHARMACEUTICALS, RAWALPINDI.

M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Khan Road, Rawat, Rawalpindi. DML No. 000639 (Formulation) **Period**: Commencing on 19-06-2018 &ending 18-06-2023.	**25-11-2019**	**Good**	1. Dr. Muhammad Usman, Member, CLB. 2. Mr. Abdul SattarSohrani, Deputy Director (QC-I), DRAP, Islamabad. 3. Mr. Khalid Mahmood, FID-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 **Recommended** M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Road, Rawat, Rawalpindi for the grant of Drug Manufacturing License No. 000639 (Formulations) w.e.f. 19th June, 2018.

Decision by the Central Licensing Board in 273rdmeeting

The Board considered and approved the renewal of Drug Manufacturing License 000639 (Formulation) in the name of M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Khan Road, Rawat, Rawalpindi on the recommendations of the panel of experts for the further period of five years Commencing on 19-06-2018 ending 18-06-2023 for following sections: -

i. Oral Liquid (General) veterinary

ii.	Oral Powder (General) Veterinary
iii.	Liquid Injection (Vial) (General) Section veterinary
iv.	Tablet (General) Section (Human)
v.	Cream/Ointment/Gel (General) Human

It is submitted that before issuance of DML to the firm, Dr. Masud ur Rehman got transferred. As per opinion/remarks of Legal Affair Division, DRAP Division, Rule 18(8) of the Drugs (Licensing Registering & Advertising) Rules 1976 prescribe that in case of absence of the Chairman, the Board may elect one of the members to preside over the meeting. Therefore, in case of absence of the Chairman, the Presiding member of the CLB may sign the Drug Manufacturing License Now, the post of Director (Licensing) is vacant, therefore, case of the firm is placed before the CLB for the orders of the Board regarding issuance of the renewal of DML of the firm.

Decision of Central Licensing Board in 282nd meeting.

The Board considering the facts on the record, after thread bare deliberation and in the light of opinion/remarks of Legal Affair Division, DRAP allowed the Presiding Member of the 282nd meeting of the CLB to sign the Drug Manufacturing License in absence of the Chairman CLB.

It is submitted that title of the firm was inadvertently types as "Biogen Pharmaceuticals" instead of correct title i. e, "Biogen Pharma" in minutes of 282nd meeting of Central Licensing Board.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board while considering the facts on the record approved the correction in the title of the firm asM/s Biogen Pharma, 8-KM, ChakbeliRoad, Rawat, Rawalpindiunder DML No. 000639 (Formulation).

Case No**. 27** **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FARMIGEA PAKISTAN (PVT) LTD, LAHORE.**

AD-I

M/s Farmigea Pakistan (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahore had applied for renewal of DML No. 000471 by way of Formulation for the period of 02-03-2020 to 01-03-2025 on 24-02-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 1st September, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Duly attested CNIC copies of all Directors.
iv. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letter of Production Incharge.

The firm did not reply and reminder letter was issued on 3rd February,2021 to the firm for completion of application.

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

i. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Duly attested CNIC copies of all Directors.
iv. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letter of Production Incharge.

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

The Board while 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 Rule5 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000471 (by way of formulation) of M/s Farmigea Pakistan (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause Notice was issued to M/s Farmigea Pakistan (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahore on 28th September, 2021.

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

i. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Duly attested CNIC copies of all Directors.
iv. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letter of Production Incharge.

A letter of Personal hearing has been issued on 20th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

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

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

The firm replied to Show Cause Notice 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) without the stamp that SECP does not take responsibility of contents of Form.
ii. Duly attested CNIC copies of all Directors.
iii. Deposit prescribed fee of Rs.7,500/- per section/facility for regularization of layout plan.
iv. Two (02) legible copies of proposed layout plan.

A letter of personal hearing was issued to the firm on 7th March, 2022.

Furthermore, the firm had filed application of Mr. Muhammad Riaz Lodhi for approval as Quality Control Incharge on 25th June,2018. Application was incomplete which were conveyed to the firm vide letter dated 2nd August, 2018, however, no reply was received from the firm.

The firm then filed new application of Mr. Rashid Mehmood as Quality Control Incharge on 15th Janaury,2019. A letter of following shortcomings was issued on 15th February, 2019:

1. Resignation or termination letter of appointee from the previous firm promotion letter / transfer letter from the same firm.
2. Undertaking as whole-time employee on stamp paper duly signed by management and appointee.

Documents should be duly attested.

The firm did not reply and reminder dated 14th January,2022 was issued and reply was not received.

Decision of the Central Licensing Board in 285th meeting

The Board after perusal of record and facts decided to suspend Drug Manufacturing License No 000471 (by way of formulation) of M/s Farmigea Pakistan (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahoretill fulfillment of codal formalities/submission of required documents under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Secretary CLB may take decision on completion of codal formalities and case may be placed before the board for ratification.

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

Letter of suspension of Drug Manufacturing License No. 000471 (Formulation) was issued to M/s Farmigea Pakistan (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahore on 26th May, 20222.

The firm replied on 23-06-2022 and completed application for renewal of DML. Secretary CLB issued ceasing of DML suspension order on 24th August, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board considering the facts on the record ratified the decision of Secretary, Central Licensing Board**.**

CASE NO. 28 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ALI INDUSTRIES, LAHORE.

AD-I

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

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

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

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

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

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

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

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

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision

of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000222 by way of formulation of M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

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

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

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

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

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

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

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

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

A letter of Personal hearing has been issued on 20th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

Mr. Aif Siddique, CEO of the firm appeared before the Board. He contended that he has not got registry of the property in his name due to his personal reasons which he could not disclose to the Board. He further contended that he may be given one-month time for submission of required documents. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000222by way of Formulation M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore till fulfillment of codal formalities/submission of required documents under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5 (2A), Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the board for ratification.

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

DML suspension letter was issued on 8th December, 2021 to M/s M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore.

Now, the firm has replied and submitted copies of Acknowledgement/Undertaking and sale deed.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board while considering the facts on the record decided to cease the operation of suspension for the further period in the name of M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore.

Case No. 29 **SITE INSPECTION /SITE VERIFICATION OF M/S VETLINE PHARMA (PVT) LTD, Plot No. 761, SUNDAR INDUSTRIAL ESTATE, RAIWIND ROAD, LAHORE.**

AD-IV

M/s Vet Line Pharma (Pvt) Ltd, **Plot No. 761, Sundar Industrial Estate, Raiwind Road, Lahore** submitted application for site verification of proposed plot. After application was completed by the firm, area FID was requested to conduct site inspection of proposed plot and submit report regarding suitability of plot for establishment of pharmaceutical unit.

The FID submitted inspection report which is reproduced below :

1. On the front side of the said site there was 80 feet wide road and on the front side across the raod, there was a vacant plot. On the right side there was also 40 feet wide road. On the left side there was a motor cycle manufacturing chain factory namely M/s Nice Chain Factory (Pvt) Ltd. At the time of inspection this factory was producing pollution in the form of smoke and oil spreading in wall of factory. This factory is main cause of pollution. Undersigned asked the firm about it. They informed that Sundar Industrial Estate had already issued a show cause notice to them. On the back side of the site there was a Generator Godam.

   *"The observations led to the conclusion that the site of M/s Vet Line Pharma (Pvt) Ltd, Plot No. 761, Sundar Industrial Estate – Raiwind Road, Lahore,**is not suitable for the establishment of a pharmaceutical unit**due to a Nice Chain Factory which was located on the left side of the site as of today, as per requirement laid down under paragraph 1 of section-1 of the Schedule "B" (SRO, 470 (1)/98), dated 15-05-1998, under rule 18 of the Drugs (Licensing, Registering and Advertising) Rules, 1976)"*

The firm is called for personal hearing.

Decision of the Central Licensing Board in 286th meeting

DrMohsinDirector andAamir Bashir Director Technical of the firm appeared before the Board. They contended that Nice Chain Factory has taken measures on their request and matter of smoke has improved. They also contended that they have carried study from Private Environment consultant and annexing to the report. Impact of smoke would not be there in the presence of HVAC installation. The Board considering the facts on the record and deliberations made by representative of the firm, decided to inspect the site by following two members panel on the basis of new facts;

i. Ms. MajidaMujahid Federal Inspector of Drugs, DRRAP, Lahore.
ii. Mr. AjmalSuhail, Federal Inspector of Drugs, DRRAP, Lahore.

In the light of Board decision a panel was constituted on 23rd May, 2022 for site verification. In response to our letter panel inspected the site on 6th June, 2022 and recommends the site as "suitable for establishment of a pharmaceutical unit". Accordingly, site approval letter was issued to the firm.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board considered and acknowledged the report.

Case No. 30 **CORRECTION IN BLOCK NAME OF M/S FARM AID GROUP, PLOT NO. 3/2, PHASE I&II, HATTAR INDUSTRIAL ESTATE, HARIPUR.**

AD-IV

The Central Licensing Board in its 286th meeting held on 11th May, 2022 considered and approved the grant of renewal of M/s Farm Aid Group, Plot No. 3/2, Phase-I&II, Hattar Industrial Estate, Haripur under DML No. 000298 (Formulation) and decided as under:-

Decision of the Central Licensing Board in 286th meeting:

During the meeting, secretary CLB apprised that as per approved and existing layout plan, following sections exit. The Board considered and approved the grant of renewal of DML No. 000298 by way of Formulation in the name of M/s. Farm Aid Group, Plot No.3/2, Phase-I&II, Hattar Industrial Estate, Haripur**,** on the recommendations of the panel of experts for the period Commencing on 25-10-2020 ending 24-10-2025for the following section: -

Block-A			
1	Tablet (Human-General)	2	Capsule (Human-General)
Block C			
1	Micro Laboratory	2	Quality Control Laboratory
3	Oral Penicillin Powder (Penicillin Veterinary)		

The secretariat of the Board informed that mandate for renewal of following section was inadvertently missed and subsequently panel of expert did not give any recommendation regarding renewal.The Board after consideration of the facts and perusal of record decided to not approve the grant of renewal of DML No. 000298 by way of Formulation in the name of M/s. Farm Aid Group, Plot No.3/2, Phase-I&II, Hattar Industrial Estate, Haripur, for following sections. The Board further decided to ask the firm for further utilization of the following sections. The production in following sections shall remain suspended till decision by the Board.

Block C	
Oral Powder-I (General-Veterinary-)	Oral Liquid-I (General-Veterinary)

Oral Bolus -I (General-Veterinary)

It is submitted that the decision conveyed to the firm on 7th June, 2022 wherein word is mentioned as "Block-A" instead of "Block-B" for 1Tablet (Human-General) and Capsule (Human-General).

In the light of above, it is proposed that name of Block may be corrected as Block-B instead of Block-A.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board while considered the facts on the record and approved the correction in the block of section of M/s Farm Aid Group, Plot No. 3/2, Phase-I&II, Hattar Industrial Estate, Haripur DML No. 000298 (Formulation) as under:

Block-B			
1	Tablet (Human-General)	2	Capsule (Human-General)

Case No. 31 **GRANT OF DRUG MANUFACTURING LICENSE OF M/S GLIMS PHARMACEUTICAL (PVT) LTD., RISALPUR**

AD-IV

M/s Glims Pharmaceutical (Pvt) Ltd., Risalpur through Mr. MoinudDin submitted that they have purchased the said firm in the year 2014. It is further requested for the issuance of Drug Manufacturing License.

The case of M/s Glims Pharmaceutical (Pvt) Ltd., Risalpur is summarized as under;

a. The firm M/s Glims Pharmaceutical (Pvt) Ltd., applied for site verification for establishment of Pharmaceutical Unit situated at Plot No 12 Industrial Estate, Resalpur. Management of the firm was as under;
    i. Mr. Arbab Muhammad Iqbal
    ii. Syed Farrukh Mahmood Gilani
    iii. Haji Shib Gul
    iv. MrMushtaq Ahmed
    v. Haji Noor Gul

b. The said site and LOP for said Unit at said plot was approved, accordingly

c. The firm applied for the grant of DML as per Form-1 and panel of experts/inspectors was constituted for the said purpose.
d. The constituted panel conducted the inspection of said firm and a panel inspection report was submitted and the case was placed in 225th meeting of CLB held on 22-10-2010**.** The case presented in 225th meeting **"Grant of Drug Manufacturing License of M/s Glims Pharmaceuticals - Not Recommended** is reproduced as under;

The inspection of M/s Glims Pharmaceuticals, Risalpur was conducted by a panel comprising Prof. Dr. Zafar Iqbal, Member CLB, Dr. Tariq Siddique, FID Peshawar and Mr. Nematullah Khan, ADC Peshawar for grant of drug manufacturing license. The panel has reported as under:

i) Civil work is incomplete which includes installation of aluminum doors, windows, glass walls, concealment of electrical ducts and electrical points.
ii) Connection of electricity has not been acquired. Most of the equipment in quality control laboratory were not available. Requisite tools in raw material store and dispensing area were not provided.
iii) Documentation and SOPs has not been prepared.

The panel has reported that the FIR was launched against all the directors of the firm for their involvement in manufacturing of spurious drugs and the case is under investigation by the police. However, Dr. Azam Khan introduced himself as one of the new owners of the unit and informed that all the previous management has been changed.

Keeping in view the above facts, panel has decided to re-inspect the facility after completion of requisite civil work, installation of equipments / machinery appointment of technical personnel and an uptodate Form-29 issued by Securities and Exchange Commission of Pakistan with the approval of Sarhad Development Authority regarding confirmation of change in management.

The Board discussed the case in detail and decided to pend it.

Moreover, Mr. Moinud Din, claims that he is the Chief Executive/Director of M/s Glims Pharmaceutical (Pvt) Ltd., Risalpur and requested for withdrawal of documents. He has requested which is reproduced as under;

"It is stated that due to some unfavorable circumstances we are not in a position to process our case, therefore all members of the company decided to withdraw the documents. In this regard a resolution of the meeting of the board of directors is enclosed herewith for your perusal and necessary action, please."

Meanwhile another request was received from Mr. Moinud Din of M/s Glims Pharmaceutical (Pvt) Ltd., Risalpur wherein he has submitted request for legalization of premises and stated as under;

"That with the great reverence and veneration it is submitted that the pharmaceutical request for regularization and clearance of the premises whereby the Pharmaceutical is caring its business activity but in response, the application was not acceded to, for the simple reason, that case has been registered against the directors of the company thereafter the company waited for the result / fate of the said criminal case. The case was finally decided by the competent court vide judgment dated 09/10/2018 and culminated in the acquittal of the accused nominated therein.
That the judgment if the acquittal had gain finality as no appeal etc. was filed by the state and hence the acquittal tantamount to certificate of innocence (Copy of the judgment dates 09/10/2018 is attached)
That in the present scenario the company has the honor to ask for regularization, legalization and clearance of its premises.
It is therefore most humbly requested that this application be considered sympathetically and the needful be done and will be highly obliged."

Mr. Moinud Din requested for the further processing in the matter and issuance of Drug Manufacturing License.

In light of above, Area FID, DRAP Peshawar was requested to obtain certified true copy of the decision(s) of the Honorable Drug Court, Peshawar about instant case.

Additional Director/FID-I, DRAP Peshawar in response to this office letter, submitted certified true copy of the decision(s) of the Honorable Drug Court, Peshawar about instant case vide letter No. 10-46/2009-Glims-DRAP-342 dated 26/01/2022.

Decision of Honorable Drug Court, Peshawar passed on 09/10/2018 is reproduce as under;

"Accused Haji Sahib Gul, Mushtaq Ahmad and Haji Noor Gul with their counsel present while rest of the Iram Rehman, Imran Khan and Naveed Iqbal are absconding. PP for State present. Arguments heard and case file/record perused.
Vide separate judgment (placed on file), the prosecution has not been able to prove its case/charge against the accused, hence, accused Haji Sahib Gul, Mushtaq Ahmad and Haji Noor Gul are acquitted of the charges leveled against them on the grounds mentioned in the judgment. Their bonds shall stand discharged. Prima facie case exists against the absconding accused Iram Rehman, Imran Khan and Naveed Iqbal, therefore, they are declared proclaimed offenders. Perpetual NBWs of arrest be issued against them with directions to DPO concerned to include their names in the register of Pos. Case property be dealt with by the prosecution according to law.
File be consigned to record room after its completion."

In light of above, the firm was asked to submit application from grant of DML on prescribed Form-1A duly signed and stamped by the management of the firm along with requisite documents/annexures dully attested/notarized and prescribed fee Rs 150,000/=

Decision of the Central Licensing Board in 285th meeting

The Board, after deliberation, considered the facts and decided that FID, DRAP, Peshawar may be asked to provide Memo of recovery and copy of case file for consideration of the Board.

In light of above decision of the Board, the FID, DRAP, Peshawar submitted Memo of recovery and copy of case file.

Decision of the Central Licensing Board in 288th meeting

The Board observed that a decision had already been taken in 225th meeting of CLB held on 22-10-2010.The Board while considering the facts on the record decided to refer the case to QA& LT Division, DRAP, Islamabad for further processing in the matter. The Board further decided that QA& LT, Division, DRAP, Islamabad will seek legal opinion from Legal Affair Division, DRAP on the instant matter and place the case before the Board in its upcoming meeting.

CASE NO. 32 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000496 OF M/S VALOR PHARMACEUTICALS, PLOT NO. 124/A, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

AD-IV

M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad wherein the firm has application renewal of Drug Manufacturing License No. 000496 (Formulation). The application was received on 27-07-2022 after validity of the DML as the validity of License is 28-03-2022. The firm has deposited a fee of Rs. 75,000/-. Therefore, DML No. 000496 (Formulation) M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad, is no more valid.

It pertinent to mention that as per Rule 5 (6) of Drug (L, R & A) Rule, 1976 "if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 7,500/- per day the application is delayed and thereafter until orders are passed on such application". Furthermore, Rule 5(3) states that "If the application for renewal of the license is made after the expiry of the period of the validity of the license, it shall be treated as a fresh application for the grant of a license."

Decision of the Central Licensing Board in 288th meeting

The Board while considering the facts on the record 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000496by way of formulation of M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case. No. 33 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000572 OF MEDIZAN LABORATORIES (PVT) LTD, PLOT NO. 313, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad had applied for renewal of DML No. 000572 by way of (formulation) on 8th May, 2020 for the period of 13-05-2020 to 12-05-2025. On scrutiny of application for renewal following observations have been observed:-

i. Proof of Licensed Section from CLB.
ii. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.

A shortcoming letter was issued to the firm on 31st August, 2020 for rectification of above-mentioned shortcoming.

Firm has not rectified shortcoming and final reminder was issued on 26the February, 2021.

In response to this Division's final reminder firm has submitted their reply on 18th March, 2021. On scrutiny of submitted documents for renewal of Drug Manufacturing License is still deficient / short and application for renewal of Drug Manufacturing License is still incomplete for following documents: -

i. Up to date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.

Decision of the Central Licensing Board in 288th meeting

The Board while considering the facts on the record 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No000572by way of formulation ofM/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad, may not be suspended or cancelled

by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 34 **M/S CONVELL LABORATORIES, SAIDU SHARIF, SWAT UNDER DRUG MANUFACTURING LICENSE NO. 000509 BY WAY OF FORMULATION.**

AD-IV

M/s Convell Laboratories, is licensed firm under Drug Manufacturing License No. 000509 by way of Formulation situated at Saidu Sharif, Swat. The Central Licensing Board in its 270th meeting held on 23rd May, 2019 has considered and approved the renewal of Drug Manufacturing License w.e.f. 26-02-2018.

2. An unfortunate incident was occurred in the premises. The Federal Inspector of Drug-I, Peshawar, DRAP vide letter No. 11-58/2005-Convell-DRAP(P) dated 18/05/2022 wherein the FID submitted inspection report and recommendation regarding said incident of M/s Convell Laboratories, Saidu Sharif, Swat which is reproduced as under;

"Please refer to the subject cited above and to say that it was learnt from media and reliable sources that building of M/s. Convell Laboratories, Saidu Sharif Swat, having Drug Manufacturing License (DML) No. 000509, granted under the Drugs (Licensing, Registering and Advertising Rules, 1976, has collapsed on 14.05.2022 afternoon. Under the said rules, it is the responsibility of the manufacturer to maintain/ensure/comply with all the conditions required for DML.

2. In order to assess the factual position, the firm was visited on 17.05.2022. The firm's production manager Mr. FazalMabood was available at the firm's premises who informed about the collapse of the building. During the site visit, it was observed that

;

i. Major building part of the firm including tablet general, capsule general, liquid syrup general, dry suspension general, tablet psychotropic, ware house, finished goods and section of H&OTC vide E.No.00121 (Tablet, Capsule, Oral Liquid syrup, Sachet) have been totally collapsed.

ii. *Some remaining tilted walls/ major slabs are also being demolished by the firm.*

iii. *Small portion of the building having Ceph section and QC is intact, however, due to major collapse, dirt/ dust, building scrap, this area is also totally nonoperational.*

iv. *The approved management of the firm was involved in legal matters as informed by technical person and not available at the site. Inspection book was also not available at the time of visit.*

3. In the light of above mentioned position, it is submitted that the conditions under which DML No. 000509 was granted in accordance with the Drugs (L.R.&A), Rules 1976 of the Drugs Act 1976/ DRAP Act, 2012 no more exist. Hence, the DML No. 000509 of M/s. Convell Laboratories, Saidu Sharif, Swat may be cancelled as per laid down procedure under the DRAP, Act, 2012."

Proceedings and Decision by the Central Licensing Board in 287th meeting:

Mr. Abid Hameed Puri Advocate and Ikram ul Haq Managing Director appeared before the Board and contended that Unit was consist of two blocks. One block consist of Ceph section and QC and other block consist of tablet general, capsule general, liquid syrup general, dry suspension general, tablet psychotropic, ware house, finished goods. Block consist of Ceph section and QC is intact while other block is demolished due to blast. They further contended that minimum requirements for holding a license exists therefore, licence may not be cancelled. The further contended that there is no production activity carried out and they may be allowed to carry production activity in Ceph block. The Board after hearing the arguments decided to get the unit inspected by the panel of following officers before taking any conclusive decision.

1. Mr. Muhammad Younas Khattak, CDI, Peshawar.
2. Federal Inspector of Drugs, DRAP, Peshawar.
3. Assistant Director, DRAP, Peshawar

In response to this Division's letter dated 4th July, 2022 inspection report is submitted by Mr. Atiq Ul Bari, FID / Additional Director, DRAP, Peshawar of M/s Convell Laboratories, Saidu Sharif, Swat in the light of decision of Central Licensing Board in its 287th meeting held on 24th June, 2022. The inspection was carried out on 29-07-2022. The recommendations of the panel are as under:-

"Based on the unit inspected (Cephalosporin section and Quality Control Lab) and considering the findings of inspection, the panel verified the claim of the firm that heir above part of unit is intact and may carry production activities as per GMP guidelines described in Drugs Act, 1976 and rules framed thereunder."

Decision of the Central Licensing Board in 288th meeting

The Board observed that the case requires complete investigation on the matter before further proceeding. The board further decided to refer the case to areaFID Peshawar for complete investigation in the light of the case filed by the local Government, police inquiry, building fitness certificate by the concerned government department and nature of incidence, etc.

Case No. 35 **RENEWAL OF DRUG MANUFACTURING LICENCE 000456 BY WAY OF FORMULATION) OF M/S CROWN PHARMACEUTICALS, PLOT NO. 286, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

AD-IV

M/s Crown Pharmaceuticals, Plot No. 286, Industrial Triangle, Kahuta Road, Islamabad, applied for renewal of DML No. 000456 by way of formulation for the period of **11-06-2021** to 10-06-2026.

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 01st October, 2020under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form-1A duly signed and stamped by CEO/Owner of the firm.
2. Readable copy of approved layout plan.
3. Undertaking on stamp paper as "Sole Proprietor" or "Partnership deed" alongwith CNICs of all partners.
4. Updated Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 12th August, 2021 to the firm with following shortcomings: -

i. Form-1A duly signed and stamped by CEO/owner of the firm.
ii. Updated Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.

Decision of the Central Licensing Board in 285th 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000456 by way of formulation of M/s Crown Pharmaceuticals, Plot No. 286, Industrial Triangle, Kahuta Road, Islamabad, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

M/s Crown Pharmaceuticals, Plot No. 286, Industrial Triangle, Kahuta Road, Islamabad has submitted required documents in response to this Division's Show Cause Notice 26th May, 2022 for renewal of Drug Manufacturing License. The application for renewal of Drug Manufacturing License No. 000456 for the period from 11-06-2021 to 10-06-2026 is now complete.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board while considering the facts on the record decided to cease the operation of Show Cause Notice for the further period issued in the name of M/s Crown Pharmaceuticals, Plot No. 286, Industrial Triangle, Kahuta Road, Islamabad.

Case No. 36 RENEWAL OF DML OF M/S MEDICON PHARMACEUTICAL INDUSTRIES (PVT) LTD., B-1/11, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR

AD-IV

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

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

a. With reference to above letter, it is mentioned that as per available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. The Licensing Division issued final reminder on for completion of application of renewal of DML to the firm for information / documents as under;

i. To submit renewal of Drug Manufacturing License application on prescribed Form-1A (copy enclosed).

ii. To submit detail of management / owners with attested copies of CNIC's and Form-29 (previous and current).

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

Decision of CLB in its 253rd meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar DML No. 000440 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

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

c. Reply of Firm to Show Cause Notice

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

i. Application for renewal of DML on prescribed Form-1A

ii. Detail of management /owners with attested CNICs and Form-29, previous and current along with Challan for Rs. 50,000/- being fee of Change of management.

d. The firm has fulfilled rest of the codal formalities for renewal of Drug Manufacturing Licensee excluding proof of approved sections.

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

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

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

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

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

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

i. The firm has deposited fee of Rs. 50000/- only whereas there are eleven sections in LOP under discussion and remaining fee of Rs. 5000/- needs to be deposited.
ii. Door for entry from male change room to general production corridor has not been given.
iii. The area for storage of non active material in raw material store (general) needs to be segregated.
iv. Sachet Section (General) needs to be divided into mixing and filling areas.
v. Man and material flow in Syrup Section (General) is not in order i.e. the entry is through packing hall and manufacturing area is away from filling area.
vi. Granulation and drying area has not been provided in Tablet Section (Psychotropic).

vii. Solution preparation area has not been provided with coating area in Tablet Section (Psychotropic).

viii. Door for entering to change room of penicillin area has not been given.

ix. Step over bench has not been shown in change room of penicillin area.

x. Transfer window needs to be installed between bottle blowing and Dry Powder Suspension filling area of Dry Powder Suspension Section (Penicillin).

xi. Sampling and dispensing areas has not been provided with raw material store of penicillin area.

xii. Entry of raw and packing material to the cephalosporin area is not in order.

xiii. Transfer window needs to be installed between bottle blowing and Dry Powder Suspension filling area of Dry Powder Suspension Section (Cephalosporin).

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

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

i. To follow up their application for renewal of DML and remove deficiencies if any pending on the part of firm.

ii. To shift their penicillin sections to separate block.

iii. To regularize their layout plan with consultation of Licensing Division of DRAP Islamabad.

iv. To improve their Microbiology Lab.

v. To purchase primary reference standards initially for three top selling products and then gradually for remaining products.

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

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision

of Rule, 5(2A), Rule 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar DML No. 000215 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

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

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

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

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

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

The firm completed all codal formalities and application for renewal of DML was complete. in light of decision of the Board, Secretary CLB issued ceasing of DML suspension order.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board while considering the facts on the record ratified the decision of Secretary, Central Licensing Board

Case No. 37 **RENEWAL OF DRUG MANUFACTURING LICENCE 000511 BY WAY OF FORMULATION) OF M/S CSH PHARMACEUTICALS-NORTH (PVT) LTD., 38-A, INDUSTRIAL ESTATE, HAYATABAD PESHAWAR. AD-IV**

M/s CSH Pharmaceuticals-North (Pvt) Ltd., 38-A, Industrial Estate, Hayatabad Peshawar, applied for renewal of DML No. 000511 by way of formulation for the period of 19-06-2018 to 18-06-2023.

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 31st October, 2018. under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Late fee of Rs.45,000/- @ 5,000/- per day additional surcharge as per Rule 6 of Drugs (Licensing, Registering & Advertising) Rules, 1976
ii. Form-1A alongwith enclosures/flags.
iii. Class (es) of Drugs.
iv. Dosage forms of drugs.
v. Name(s) of registered drug(s).
vi. Detail of management at the time of previous renewal and present renewal.
vii. CNIC's of all directors/owner.
viii. Approved building layout plan.
ix. Proof of licensed sections from Central Licensing Board.
x. Section wise detail of machinery for manufacture and QC Lab.

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 25th October, 2021 to the firm with following shortcomings: -

i. Late fee of Rs. 22500/= (differential fee) as per Rule 6 of Drugs (Licensing, Registering & Advertising) Rules, 1976.
ii. Form-1A signed and stamped by the management.
iii. Proof of licensed sections from Central Licensing Board.
iv. Documents are not certified/notarized as "True Copy"

All documents should be duly attested/notarized.

The firm submitted their reply to Final Reminder and following documents are still deficient /short and application for renewal of DML is still incomplete;

i. Form-1A signed and stamped by the management.
ii. Proof of licensed sections from Central Licensing Board not provided.

Decision of the Central Licensing Board in 285th 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 000511 by way of formulation of M/s CSH Pharmaceuticals-North (Pvt) Ltd., 38-A, Industrial Estate, Hayatabad Peshawar, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

In light of decisions of the Board, Show CauseNotice was issued to the firm.

The firm has submitted all deficient documents and application for renewal of Drug Manufacturing License is now complete.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board while considering the facts on the record decided to cease the operation of Show Cause Notice for the further period issued in the name of M/s CSH Pharmaceuticals-North (Pvt) Ltd., 38-A, Industrial Estate, Hayatabad Peshawar.

Case No. 38 **RENEWAL OF DRUG MANUFACTURING LICENCE 000357 BY WAY OF FORMULATION) OF M/S HASSAN PHARMACEUTICALS HAYATABAD PESHAWAR.**

AD-IV

M/s Hassan Pharmaceuticals Hayatabad Peshawar has submitted application for renewal of DML No. 000357. The application was received on 16-09-2020 which is well on time as validity of License is 17-09-2020.

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 8th April, 2021under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Proof of sections approval from CLB including approved Layout Plan not provided.
ii. Updated "Nothing Due Certificate (CRF)" up to 31-12-2021 from STO, DRAP is not provided.

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 5th April, 2022 to the firm with following shortcomings: -

i. Proof of section approval from CLB including approved Layout Plan not provided.
ii. Updated "Nothing Due Certificate (CRF)" up to 31-12-2021 from STO, DRAP is not provided.

The 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;

i. Proof of section approval from CLB including approved Layout Plan not provided.

ii. Updated "Nothing Due Certificate (CRF)" up to 31-12-2021 from STO, DRAP is not provided.

Decision of the Central Licensing Board in 286th 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000357 by way of formulation of M/s Hassan Pharmaceuticals Hayatabad Peshawar, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In light of decisions of the Board show cause Notice was issued to the firm.

The firm has submitted all deficient documents and application for renewal of Drug Manufacturing License is now complete.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board considering the facts on the record decided to cease the operation of Show Cause Notice for the further period issued in the name ofM/s Hassan Pharmaceuticals Hayatabad Peshawar.

Case No. 39 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S LEAMA CHEMI PHARMA (PVT) LTD., INDUSTRIAL ESATATE, JAMRUD ROAD, PESHAWAR.

AD-IV

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 (Licensing, 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: -

2. Application for renewal is received one day late. Fee Rs. 5000/day is required,
3. Updated Form-29 attested as True Copy by SECP along with attested copy of CNIC of all Directors, not provided,
4. Attested copy of list of registered products (brand) along with registration No and Drug (s) not attached,
5. Updated nothing Due Certificate (CRF) upto 31-12-2020 from STO, DRAP, Islamabad.
6. 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

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 Board Drugs (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..

In light of decisions of the Board show cause Notice was issued to the firm.

The firm has submitted all deficient documents and application for renewal of Drug Manufacturing License is now complete.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board while considering the facts on the record decided to cease the operation of Show Cause Notice for the further period issued in the name of M/s Leama Chemi Pharma (Pvt) Ltd., Industrial Esatate, Jamrud Road, Peshawar

Case No. 40 **CORRECTION IN SECTION NAME OF M/S WAHABSONS PHARMA (PVT) LTD., 4-KM, BUNNER ROAD, BARIKOT, SWAT.**

AD-IV

The Central Licensing Board in its 285th meeting held on 17th& 18th March, 2022 considered and approved the grant of renewal of M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swatunder DML No. 000533 (Formulation) and decided as under:-

Decision of the Central Licensing Board in 285th meeting:

"The Board considered and approved the regularization of lay out plan and grant of renewal of DML No. 000533 by way of Formulation in the name of M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat on the recommendations of the panel of experts for the period Commencing on 27-01-2019 & ending on 26-01-2024for the following sections: -

1. Oral Liquid Section (General) **Regularization**
2. Capsule Section (General) **Regularization**
3. Warehouse **Regularization**
4. Quality Control Lab and microbiology **Regularization"**

It is submitted that the following sections have been written inadvertently in the letter of inspection, inspection report and minutes and same is conveyed to the firm:-

1. Capsule Section (General) **Regularization.**

In light of above, it is proposed that name of section may be corrected as Capsule Section (General) **Additional**instead of Capsule Section (General) **Regularization**.

Proceedings and Decision by the Central Licensing Board in 287th meeting:

The Board while considering the facts on the record and approved the correction in the name/title of section of the firmM/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swatunder DML No. 000533(Formulation) as under;

i. Capsule (General) **Additional**

Case No. 41 **CANCELLATION OF LICENSE OF M/S ALKEMY PHARMACEUTICAL LAB (PVT) LTD P/9, S.I.T.E. HYDERABAD**

AD-III

A letter is received from Honorable Chairman Drug Court of Bahawalpur, Bahawalpur which is re-produced as under;

"Reference this office letter No.225/DCB/Dated 0l/08/2022 addressed to your office on the subject noted above

It is once again stated that the case –ludl/09/DCB/2019, State Vs. M/S Alkemy Pharmaceutical Lab (PVT) Ltd P/9, S.I.T.E. Hyderabad through its Chief Executive Officer Faraz Ahmed etc. is pending in this Court for attendance of accused persons. Summons,/ non-bailable warrant of arrest against the following accused persons were issued but they are rot appearing deliberating before this court.

1. *Mr. Faraz Ahme4 (Chief Executive Officer) of Alkemy Pharmaceutical Lab (PVT) Ltd P/9, S.I.T.E. Hyderabad*
2. *Miss Kishwar, (Production Manager) of Alkemy Pharmaceutical Lab (PVT) Ltd P/9, S.I.T.E. Hyderabad*
3. *Mr. Asif Najeeb, (Quality Control Incharge) of Alkemy Pharmaceutical Lab (PVT) Ltd P/9, S.I.T.E. Hyderabad*
4. *ShabanaYousaf, (Warantor) of Alkemy Pharmaceutical Lab (PVT) Ltd P/9, S.I.T.E. Hyderabad*

To procurement of the attendance of the accused persons, in the above title case, you were directed to cancel the drug manufacturing license of the accused person's company M/s Alkemy Pharmaceutical Lab (PVT) Ltd P/9, S.[.T.E. Hyderabad

and submit compliance report in this regard on 26.09.2022, which is still awaited from your side. You are now directed to appear in person before this court on 31.10.2022, alongwithcompliance report regarding to procurement of the attendance of above mentioned accused persons, in the above title case to proceed further, otherwise stern legal action shall be taken against you. Given udder the seal of this court on 26.09.2022."

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board after taking opinion of the Mr. Abid Ali, Law Expert, Ministry of Law & Justice Division, Islamabad on the letter No. 7263 dated 28-09-22 decided to forward the said letter of the Chairman, Drug Court Bhawalpur to area FID Hyderabad forimmediate compliance under intimation to the Board.

Case No 42 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000712 OF M/S SUNRISE PHARMA (PVT) LTD, LAHORE.**

AD-III

Case Background:

M/s Sunrise Pharma (Pvt) Ltd, 594-A, Sunder Industrial Estate, Raiwind Road, Lahore had applied for renewal of DML No. 000712 by way of formulation for the period of 20-06-2021 to 19-06-2026. 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 October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Detail of management at the time of previous renewal and at present renewal, if any change apply for change of management.
ii. Section approval letter by Central License Board.
iii. Certified true copy of Form-II or Form-29 by SECP.
iv. No Objection Certificate regarding CRF from STO.

For QC Incharge.

i. Experience certificate as per Drugs Licensing, Registering and Advertising Rules, it should not be less than 10 years.

All documents should be duly attested.

The firm submitted their reply on 29thSeptember, 2021. After evaluation of the submitted documents, a letter was issued on 13th December, 2021 to the firm with following shortcomings:-

For Renewal of DML.

i. Apply for change of management alongwith Form-29 attested by SECP alongwith prescribed fee.

For QC Incharge.

i. Experience certificate as per Drugs Licensing, Registering and Advertising Rules, it should not be less than 10 years.
All documents should be duly attested.

The application of Renewal of Drug Manufacturing License and Quality Control Incharge is still deficient for following documents: -

1.

For Renewal of DML.

i. Apply for change of management alongwith Form-29 attested by SECP alongwith prescribed fee.

For QC Incharge.

i. Experience certificate as per Drugs Licensing, Registering and Advertising Rules, it should not be less than 10 years.
All documents should be duly attested.

The case was placed before the Central Licensing Board in its285th meeting held on 17thand 18th March, 2022 and the Board decided as under

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000712by way of formulation of M/s Sunrise Pharma (Pvt) Ltd, 594-A, Sunder Industrial Estate, Raiwind Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

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

Accordingly, showcause notice was issued to the firm on 21/05/2022.

In response to Show Couse Notice the firm submitted their response. However, the firm did not rectify following shortcoming;

i. Form -29 certified true copy by SECP (in original) is required.

Moreover, the photocopy of Form-29submitted by firm bears the stamp of the Security and Exchange Commission of the Pakistan (SECP) as under: -

"certified true copy of the document filed by the company However, this office accepts no responsibility to the details given in the documents"

A letter of personal hearing has been issued to the applicant on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Muhammad Asim Aslam GM and Qazi Ahmed of the firm appeared before the Board. They contended that they will provide/submit updated Form-29 attested as true copy (in original) without disclaimer/qualification stamp with in 15days. The Board decided to accept request of the firm for provision of Form-29 within 15days and the case be placed before the Board in its upcoming meeting for its consideration.

Case No. 43 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000459 OF M/S P.D.H PHARMACEUTICALS (PVT) LTD, 19-KM, FEROZEPUR ROAD, LAHORE.**

AD-III

M/s P.D.H Pharmaceutical (Pvt) Ltd, 19-KM, Ferozepur Road, Lahore had applied for renewal of DML No. 000459 by way of formulation for the period of 22-09-2020 to 21-09-2025. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13th October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
ii. Latest Certified true copy of Form-29 (Attestation by SECP).
iii. Attested CNIC's copies of all Directors.
iv. Detail of premises including layout plan.
v. Proof of licensed sections from CLB.
vi. Approval letter of Production / QC Incharge in case of change than submit required documents as per check list.
vii. Up-to-date nothing due certificate regarding CRF from STO.

All documents should be duly attested.

The firm submitted their reply on 24th September, 2020. After evaluation of the submitted documents, a letter was issued on 30th December, 2020 to the firm with following shortcomings: -

i. Latest Form-29 duly attested from SECP.
ii. Legible copies of CNICs of previous & current management / directors.
iii. Copy of Nothing Due Certificate regarding CRF from STO (Latest).

The firm submitted their reply on 12th January, 2021. After evaluation of the submitted documents, a Final Reminder was issued on 20th October, 2021 to the firm with following shortcomings: -

i. Latest Form-29 duly attested from SECP.
ii. Legible copies of CNICs of previous & current management / directors.
iii. All documents should be duly attested.

The application of Renewal of Drug Manufacturing License and Quality Control Incharge is still deficient for following documents: -

i. Latest Form-29 duly attested from SECP.
ii. Legible copies of CNICs of previous & current management / directors.

For Quality Control Incharge.

1. Attested copy of appointment and job acceptance letter.
2. Attested copy of CNIC of appointee.
3. Attested copy of academic degrees, as required under Drugs (Licensing, Registering and Advertising) Rules, 1976.
4. Attested copies of Experience Certificate as required under Drugs (Licensing, Registering & Advertising Rules), 1976.
5. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
6. Undertaking as whole time employee on stamp paper as per check list.
   All documents should be duly attested.

The case was placed before the Central Licensing Board in its in 285th meeting held on 17thand 18th March, 2022 and the Board decided as under

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000459 by way of formulation of M/s P.D.H Pharmaceutical (Pvt) Ltd, 19-KM, Ferozepur Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

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

Accordingly, showcause notice was issued to the firm on 21/05/2022. However, the firm did not rectify above mentioned shortcoming.

A letter of personal hearing has been issued to the applicant on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mrs. Fatima Bajwa representative of the firm appeared before the Board. They contended that they will provide/submit all requisite documents at earliest. The Board decided that the firm will complete all the codal formalities within 15days within 15days and the case be placed before the Board in its upcoming meeting for its consideration.

Case No 44 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000228 OF M/S PHARMEDIC LABORATORIES (PVT) LTD, 16-KM, MULTAN ROAD, LAHORE.**

AD-III

M/s Pharmedic Laboratories (Pvt) Ltd, 16-KM, Multan Road, Lahore had applied for renewal of DML No. 000228 by way of formulation for the period of 07-04-2020 to 06-04-2025. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 29th October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form 1A as per prescribed format.
ii. Classes of drugs & dosage form of drugs.
iii. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
iv. Latest Certified true copy of Form-29 (Attestation by SECP).
v. Attested CNIC's copies of all Directors.
vi. Detail of premises including layout plan.
All documents should be duly attested.

The firm submitted their reply on 24th December, 2020. After evaluation of the submitted documents, final reminder was issued on 5th April, 2021 to the firm with following shortcomings:-

For Renewal of DML.

ii. Form 1A as per prescribed format.
iii. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
iv. Latest Certified true copy of Form-29 (Attestation by SECP).
v. Attested CNIC copies of all Directors.
vi. Detail of premises including layout plan.
All documents shall be duly attested.

However, the application of Renewal of Drug Manufacturing License is still deficient for following documents: -

i. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
ii. Latest Certified true copy of Form-29 (Attestation by SECP).

The case was placed before the Central Licensing Board in its in 285th meeting held on 17thand 18th March, 2022 and the Board decided as under

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 000228 by way of formulation of M/s Pharmedic Laboratories (Pvt) Ltd, 16-KM, Multan Road, Lahore, may not be suspended or cancelled by

Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

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

Accordingly, showcause notice was issued to the firm on 26/05/2022.

The firm replied in response of Show Cause Notice which is reproduced as under

> *"In regard to the decision of CLB in its 285th meeting to serve show cause notice to M/s Pharmedic Laboratories as to why its DML should not be suspended or cancelled, we hereby state that we have tried to submit attested copy of Form-29 but the DRAP has refused to accept the copy as SECP has stated on the attestation the following words: "Certified to be true copy. however, this office accepts no responsibility as to the correctness of the details given in the document". We have been told by officials at DRAP that the stamp should just contain the words: "Certified To Be True Copy".*
>
> *The board may kindly note that as per the version of the SECP, the department uses these words in such a case where the company has a litigation pending in any court of law. Currently their is no outstanding litigation against the company or involving any of its directors however since the litigation has just recently ended the SECP, as we have been informed, shall only revert back to the standard attestation after the filing of the next Form-29 by the company.*
>
> *We are engaged with the SECP in efforts to obtain the document as is required by DRAP. In case the SECP refuses to entertain our request we shall submit the same after the next filing of the Form-29. The company accepts full responsibility to the correctness of the Form-29."*

The firm submitted from-29 Form-29 bears the stamp of the Security and Exchange Commission of the Pakistan (SECP) as under: -

> "certified true copy of the document filed by the company However, this office accepts no responsibility to the details given in the documents"

However, the firm did not rectify above mentioned shortcoming.

A letter of personal hearing has been issued to the applicant on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Shahid Iqabl and Mr. Hassan Javid representative of the firm appeared before the Board. They contended that the case was under litigation at SECP and the case has been resolved/decided. They further contended that they will provide/submit updated Form-29 attested as true copy (in original) without disclaimer/qualification within a week. The Board decided to accept firm's request and decided that the firm shall submit Form 29 within 15days and the case be placed before the Board in its upcoming meeting for its consideration.

CASE NO. 45 RENEWAL OF DRUG NUFACTURING LICENCE (000370 BY WAY OF FORMULATION) OF M/S IPP, 34, INDUSTRIAL TRIANGLE, KAHUTA RAOD, ISLAMABAD.

AD-IV

M/s IPP, 34, Industrial Triangle, Kahuta Road, Islamabad, applied for renewal of DML No. 000370 by way of formulation for the period of 17-11-2020 to 16-11-2025.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 3rd January, 2022 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Proof of section approval from Central Licensing Boar is required.
ii. Detail of premises including layout plan
iii. Detail of management at the time of previous renewal and current renewal is required along with legal documents are not provided,
iv. Detail an approval letters of technical staff are not provided,
v. Updated nothing due certificate regarding CRF valid till 31-12-2021 from STO is not provided,

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 25th January, 2022 to the firm with following shortcomings: -

i. Proof of section approval from Central Licensing Board.
ii. Detail of premises including layout plan.
iii. Detail of management at the time of previous renewal and current renewal is required along with legal documents.
iv. Detail of approval letters for technical staff are not provided.
v. Updated nothing due certificate regarding CRF valid till 31-12-2021 from STO.

Decision of the Central Licensing Board in 285th 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 000370 by way of formulation of M/s IPP, 34, Industrial Triangle, Kahuta Road, Islamabad, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

A Show Cause Notice was issued on 26th May, 2022 in the light of decision of 285th meeting of Central Licensing Board held on 17th& 18th March, 2022 and firm has not rectified shortcomings till to date.

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mrs. Rukhsana Javeed and Mr. Nadeedm Javeed Directors of the firm appeared before the Board. They contended that they will submit all requisite documents at earliest. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration.

CASE NO. 46 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000605 OF M/S SPL PHARMACEUTICALS (PVT) LTD, PLOT NO. 04, PHASE-III, HATTAR INDUSTRIAL ESTATE, HATTAR.

AD-IV

M/s SPL Pharmaceuticals (Pvt) Ltd, Plot No. 04, Phase-III, Hattar Industrial Estate, Hattar had applied for renewal of DML No. 000605 by way of formulation for the period of 19-02-2022 to 18-02-2027. 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 14th January, 2022 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Classes of drugs not provided.
ii. Dosage form of drugs not provided.
iii. Names of drugs registered/approved not provided.
iv. Detail of management at the time of previous renewal and current renewal not provided.
v. Copy of approved layout plan not provided.
vi. Section(s) approval letter(s) from Central Licensing Board not provided.
vii. Name and qualification of technical staff not provided.

The firm submitted their reply after evaluation of the submitted documents, final reminder was issued on 15th February, 2022 to the firm with following shortcomings: -

i. Detail of management at the time of previous renewal and current renewal.
ii. Form-29 attested as true copy (in original) by S.E.C.P.

Decision of Central Licensing Board in its 285th 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 000605 by way of formulation of M/s SPL Pharmaceuticals (Pvt) Ltd., Plot No.04, Phase-III, Hattar Industrial Estate, Hattar,, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976."

In response to Show Cause Notice dated 30th May, 2022 firm has submitted Form-29 attested as true copy by SECP (in original), however they said Form is stamped as under:-

"Certified to be true copy of the document filed by the company however this office accepts no responsibility as to the correctness of the details given in the document company registration office Lahore."

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Abdul Aziz CEO of the firm appeared before the Board. They contended that the High Court desposed off the case and they will provide/submit updated Form-29 attested as true copy (in original) without disclaimer/qualification with in 15days. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration.

Case No. 47 **RENEWAL OF DRUG MANUFACTURING LICENCE 000244 BY WAY OF FORMULATION) OF M/S IPP (PVT) LTD, VALLEY ROAD, GULKADA NO.III, SAIDU SHARIF, SWAT**.

AD-IV

M/s IPP (Pvt) Ltd, Valley Road, Gulkada No. III, Saidu Sharif, applied for renewal of DML No. 000244 by way of formulation for the period of 11-11-2019 to 10-11-2024.

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 26th December, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form-1A dully signed and stamped by CEO of the firm.
ii. Classes of drugs.
iii. Dosage form of drugs.
iv. Name of registered drugs.
v. Detail of management at the time of previous renewal and present renewal.
vi. 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).
vii. Proof of Licensed section (s) from Central Licensing Board.
viii. Detail of the section wise equipments and machinery for manufacture.
ix. Up-to-date nothing due certificate (CRF) from STO, DRAP, Islamabad.

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 01st February, 2022 to the firm with following shortcomings: -

i. Form-1A dully signed and stamped by CEO of the firm.
ii. List of classes of drugs.
iii. List of dosage form of drugs.
iv. List of registered drugs.

v. Detail of management at the time of previous renewal and present renewal.

vi. 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).

vii. Proof of Licensed section (s) from Central Licensing Board.

viii. Detail of the section wise equipment and machinery for manufacture.

The firm submitted their reply to Final Reminder and following documents are still deficient /short and application for renewal of DML is still incomplete;

i. Detail of management at the time of previous renewal and current renewal is required along with legal documents are not provided,

ii. Latest original certified true copy of Form-29 and Form-21 issued by S.E.C.P. along with CNICs' copies of all director(s).

Decision of the Central Licensing Board in 285th 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 000244 by way of formulation of M/s IPP (Pvt) Ltd, Valley Road, Gulkada No. III, Saidu Sharif, 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"

A Show Cause Notice issued on 26th May, 2022 in the light of decision of 285th meeting of Central Licensing Board held on 17th& 18th March, 2022 and firm has not rectified shortcomings till to date.

In response to this Division's show cause notice dated 26-05-2022 the firm has submitted reply to the show cause notice which is re-produced as under;

"In continuation of your letter No.F.3-10/2011-Lic dated 26 May 2022, which we have received on 7th June 2022 Respected sir, it is to brought into your kind notice that letter No.F.3-10/2011-Lic dated 1/02/22.which was received to our firm. On 6/2/2022. and our firm had replied and submitted all the required documents duly attested in our letter No IPPL/02/2022. and deposited R&I on 10th Feb 2022. Now once again Photocopy of the reply with received stamp of R&I on 10-02-2022, we are submitting to your kind consideration and fruther action

Kindly inform us in case of any deficiency regarding your requirement.

Thanking you and assuring you best of our co-operation at all time."

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. WaseemJaveed, MD of the firm appeared before the Board. He contended that he will submit all requisite document/informationwithin 2-3 weeks. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before the Board in its upcoming meeting for its consideration

Case No. 48 **RENEWAL OF DRUG MANUFACTURING LICENCE 000369 BY WAY OF FORMULATION) OF M/S LIBRA (PVT) LTD., 77- INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR**.

AD-IV

M/s Libra (Pvt) Ltd., 77- Industrial Estate, Hayatabad, Peshawar, applied for renewal of DML No. 000369 by way of formulation for the period of **17-10-2020** to 16-10-2025.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 02nd November, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

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.
iii. Detail of management at the time of previous renewal and current renewal.
iv. Updated Form-29 certified as true copy by S.E.C.P.
v. CNIC copies of all Directors/Partners.
vi. Up-to-date Nothing Due Certificate (CRF) valid upto 31-12-2020 from STO, DRAP, Islamabad

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 26th February, 2021 to the firm with following shortcomings: -

Renewal of DML

i. Complete Form-29 and certified as "True Copy" by S.E.C.P is not provided.

Regularization of Layout plan.

i. Provision of dimensions in sachet filling area and quarantine not mentioned.
ii. Purpose of liquid raw material store either volatile or non volatile materials is not clarified.
iii. Dimension in compression (I, II & III) and coating area of tablet section is not mentioned.
iv. Entry of raw and packing material to the hormone tablet and capsule sections are not in order.
v. Provision of dosage form of psychotropic section, in case of psychotropic tablet area is less than as required.
vi. Man and material flow of cephalosporin is not in order.
vii. Sterility room and media preparation of microbiology are not provided.

Decision of the Central Licensing Board in 285th 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 000369 by way of formulation of M/s Libra (Pvt) Ltd., 77- Industrial Estate, Hayatabad, Peshawar, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

A Show Cause Notice issued on 26th May, 2022 in the light of decision of 285th meeting of Central Licensing Board held on 17th& 18th March, 2022 and firm has not rectified shortcomings till to date.

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Muhabbat Khan QC Incharge and Mr. Shah Nawaz, Manager Regulatory of the firm appeared before the Board. They contended that they will submit all requisite document/information. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration.

Case No. 49 **APPROVAL OF TECHNICAL PERSON, QC INCHARGE OF M/S ALEN PHARMACEUTICALS (PVT) LTD, RISALPUR, UNDER DRUG MANUFACTURING LICENSE NO. 000435 (BY WAY FORMULATION) AD-IV**

M/s Alen Pharmaceuticals (Pvt) Ltd, Risalpur Drug Manufacturing License No.000435 (by way of formulation) has submitted the application for approval of proposed QC Incharge Mr. Naveed Muhammad S/o Yar Muhammad (Pharm-D) CNIC No.16102-9220966-9

The application was evaluated as per the Drug (Licensing, Registering & Advertising) Rules, 1976 and found following shortcomings which were asked from the firm to rectify on 20th October, 2021;

i. Resignation of previous Quality Control Incharge is not provided.
ii. Resignation letter of appointee from previous firm is not provided.

As the firm did not submit any response to above quoted letter, a final reminder was issued on 5thApril, 2022 to the firm to rectify above said shortcomings**.**

The firm did not submit their reply to Final Reminder and has not rectified above mentioned shortcomings/deficiencies.

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000435 by way of formulation of M/s Alen Pharmaceuticals (Pvt) Ltd, Risalpur, may not be suspended or cancelled by Central Licensing Board.

A Show Cause Notice was issued on 2nd June, 2022 in the light of decision of 285th meeting of Central Licensing Board held on 17th& 18th March, 2022 and firm has not rectified shortcomings till to date.

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Shoukat Ali CEO and Abdul Rasheed Production Incharge firm appeared before the Board. They contended that they will submit all requisite document/information. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration. The Board further decided that Area FID, DRAP, Peshawar will submit report regarding verification of the proposed technical persons.

Case No. 50 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S GILLMAN PHARMACEUTICALS, HATTAR (DML# 000683)**

AD-IV

M/s Gillman Pharmaceuticals, Hattar submitted application for renewal of Drug Manufacturing No. 000683 (by way of Formulation). The application was received on 11/02/2020which is well on time as validity of License is 15/02/2020.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 27th July, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976;

i. Form-1A as per format (attached) duly signed and stamped by the CEO/Owner of the firm.
ii. Classes of Drugs.
iii. Proof of approved sections from Central Licensing Board.
iv. Photocopies of documents submitted are not attested / notarized.

The firm submitted their reply to above mentioned letter and same was evaluated and following shortcoming were observed for which final reminder issued to the firm on 05th April, 2022;

i. Form-1A as per format (attached) duly signed and stamped by the CEO/Owner of the firm.

ii. Classes of Drugs.

iii. Proof of approved sections from Central Licensing Board.

iv. Photocopies of documents submitted are not attested/notarized.

It is pertinent to mention that application for renewal of Drug Manufacturing License for the period of 11/02/2020 to 10-02-2025 is still deficient due to above mentioned shortcomings;

Meanwhile, Mr. Faisal Shahzad, FID-I, DRAP, Peshawar submitted vide letter No.11-75/2010—Gillman DRAP (P)/708 dated 04/03/2022 which is re-produced as under;

> *"Please refer to the subject cited above and to inform you that the firm M/s Gillman Pharmaceuticals, Plot No.41/A, Phase I&II, Industrial Area, Hattar was inspected on 02.03.2022 for the purpose of routine GMP compliance. However, the firm was found non-operational and no technical/ non-technical staff was available at the time of inspection. Further, no production activity was observed during visit and it was noticed that civil work is under progress. Matter is submitted for information and further necessary action (if any).*

Proceedings and Decision by the Central Licensing Board in 287th 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 Rule, 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000683(by way of formulation) of M/s Gillman Pharmaceuticals, Hattar may not be suspended 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."

A Show Cause Notice was issued on 4th July, 2022 in the light of decision of 287th meeting of Central Licensing Board held on 24th June, 2022 and firm has not rectified shortcomings till to date.

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Hussain Ahmed CEO and Mr. SuhrabQC Incharge firm appeared before the Board. They contended that he will submit all requisite document/information. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration. The Board further decided that Area FID, DRAP, KPK will inspect the firm and will submit report there of.

Case No. 51 RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S LOTUSPHARMACEUTICALS (PVT) LTD., ISLAMABAD

AD-IV

The firm, M/s Lotus Pharmaceuticals (Pvt) Ltd., Islamabad, has submitted application for renewal of Drug Manufacturing License No. 000661 (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 along with CNIC(s) copies of all directors.
x. Proof of licensed section(s) from Central Licensing Board.
xi. Detail of machinery for QC lab and section wise.

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

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

Show-Cause Notice to the firm was issued on 08-01-2021.

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

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

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

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

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

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

A letter of personal hearing was served on 06.10.2022 to the said firm for 288th meeting of Central Licensing Board schedule to be held on 18th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Umair CEO and Mr. Arsalan Ex-Finance Manager firm appeared before the Board. They contended that he will submit all requisite document/information. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration.

Case No. 52 SITE VERIFICATION OF M/S ORGANO CHEMTECH, SHEIKHUPURA. AD-I

M/s Organo Chemtech, **Khewat No. 28, Khatooni No. 39-74, Tehsil Ferozewala, District Sheikhupura** applied for site verification of proposed plot. After application was completed by the firm, FID was requested to conduct site inspection of proposed site and submit report regarding suitability of plot for establishment of pharmaceutical unit.

The inspection was conducted by Mr. Ajmal Sohail Asif, FID, DRAP, Lahore and the recommendations of the inspection report are as under: -

2. **Location** **:** The proposed site was located at Khewat No. 28, Khatooni No. 39-74, Tehsil Ferozewala, District Sheikhupura. **It was a congested area within the locality of town Kot Abdul Malik. As per surroundings observed; the area was a mix of residential and commercial activities. There were shops and residential homes around the proposed site. Access to proposed site was a small road / street having homes around**.

Location map of the proposed site is attached, taken from the google maps at the time of visit, showing geographical coordinates (31.631213, 74.227502) for reference.

3. **Surrounding** **:**
   - On the north side of the proposed site was vacant plot.
   - On the west north side of the proposed site was vacant land and some industry.
   - On the south side of the proposed site was a veterinary hospital.
   - On the east side of the proposed site was a street / road having residential homes.

4. **Size** **:** Total size of the plot was 4 kanals as per documents provided.

5. **Recommendations** **:** The director of the firm Dr. AssharUz Zaman accompanied during the site visit, he informed that they intend to establish a pharmaceutical unit for basic manufacturing of APIs. In the light of physical verification of site, the proposed site was **Not Suitable** on the grounds mentioned in para 2 above for establishment of an API manufacturing unit.

Decision of the Central Licensing Board in 285th meeting

The Board considered the case and decided to afford personal hearing to the company in the next meeting of the Board.

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

A letter of personal hearing has been issued to the applicant on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

No Director/Owner/Representative of the firm appeared before the Board. The Board considering the facts on record and after thread bare deliberation decided to reject the site for pharmaceutical establishment on the recommendation of the FID, DRAP, Lahore

Case No. 53 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/s DIVINE PHARMACEUTICALS, LAHORE.**

AD-I

M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore had applied for renewal of DML No. 000850 by way of Formulation for the period of 25-11-2021 to 24-11-2026 on 14-12-2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 11-01-2022 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Deposit late fee surcharge of Rs. 142, 500/ (19 days * 7500/day).
ii. Properly filled, signed and stamped Form-1A (as per format) along with signed annexures of names, classes and dosage forms of drugs manufactured.
iii. Detail of management, if any change, apply for change of management.
iv. Duly attested CNIC copies of all partners.

The firm replied to this letter on 14-02-2022 and reminder letter was issued on 14-03-2022 to the firm for completion of application:

i. Deposit late fee surcharge of Rs. 142,500/-.
ii. Properly filled, signed and stamped Form-1A (as per prescribed format).
iii. Duly attested revised partnership deed issued by registrar of firms & CNIC copies of all partners.

The firm replied to this letter on 08-04-2022 but application for renewal of DML is still incomplete.

i. Deposit late fee surcharge of Rs. 142,500/-.
ii. Properly filled, signed and stamped Form-1A (as per prescribed format).

Moreover, the firm has requested to waive off fine. The request of the firm is reproduced as under:

"Sir with due respect, late fee surcharge is not due to our fault because first time when we came at DRAP office for submitting all these renewals related documents on 23rd November, 2021 your reception desk (R &I) staff refused to receive the file saying that the licensing applications are now applied by online portal and they asked us to submit these documents online. After that we tried a lot to upload all documents online but your website was not responding due to some technical fault in your online system. Then again, we visited your office for this issue and the I.T staff also tried to upload and apply online yet failed. Then they suggested us to submit these documents manually in DRAP Office and upon request of I.T Dept. the file was received by R&I desk. Hence, you are requested to waive off all late fee surcharge as the fee was submitted in due time and file submission got delayed due to some I.T issues."

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000850 by way of formulation of M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore, may not be cancelled by Central Licensing Board.

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

The Show Cause Notice was issued to M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore on 9th June, 2022.

The firm has replied and requested to waive off late fee surcharge. Application for renewal of DML is deficient of late fee surcharge of Rs. 142,500/-.

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Amin Farooq GM of the firm appeared before the Board. The Board while considering the facts on record did not accede to the request of the firm and directed to pay late fee/surcharge for renewal of DML, without delay.

Case No. 54 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000607 (FORMULATION) OF M/S ENVOY PHARMACEUTICALS (PVT) LTD, LAHORE.**

AD-I

M/s Envoy Pharmaceuticals (Pvt) Ltd, Lahore is licensed firm having DML # 000607 by way of Formulation with validity of 20-03-2022. However, as per available record, application for renewal of DML # 000607 by way of Formulation, for the period 21-03-2022 to 20-03-2027 of M/s Envoy Pharmaceuticals (Pvt) Ltd, Lahore has not been received in Licensing Division.

It pertinent to mention that as per Rule 5 (6) of Drug (L, R & A) Rule, 1976 "if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs.

5,000/- per day the application is delayed and thereafter until orders are passed on such application". Furthermore, Rule 5(3) states that "If the application for renewal of the Licence is made after the expiry of the period of the validity of the Licence, it shall be treated as a fresh application for the grant of a License."

In light of above, DML No. 000607 by way of formulation, M/s Envoy Pharmaceuticals (Pvt) Ltd, Lahore is no more valid.

Proceedings and Decision by the Central Licensing Board in 287th 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 as to why Drug Manufacturing License No 000613 (by way of formulation) of M/s Envoy Pharmaceuticals (Pvt) Ltd, Lahore may not be declared cancelled by the Central Licensing Board as application for renewal of Drug Manufacturing Licence is not filed under Rule 5 and Rule 6 of Drug (Licensing, Registering and Advertising) Rule, 1976.

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

The Show Cause Notice was issued to M/s Envoy Pharmaceuticals (Pvt) Ltd, Lahore on 4th July, 2022.

The firm has not replied and application for renewal of DML is incomplete.

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

No person appeared on behalf of the firm.The Board while considering the facts on record and after thread bare deliberation decided to cancel the Drug Manufacturing License No. 000653 (Formulation) of M/s Envoy Pharmaceuticals (Pvt) Ltd, Lahoreas the Drug Manufacturing License No. 000607 (Formulation) is no more valid as under Rule Rule 5 (6) of Drug (L, R & A) Rule, 1976.

Case No. 55 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000231 (FORMULATION) OFHIMONT PHARMACEUTICALS (PVT.) LTD, 17-KM, FEROZEPUR ROAD, LAHORE**

AD-I

M/s. Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, Lahore DML No.000231 (Formulation) Period: Commencing on 27-09-2020 ending on 26-09-2025	**24-03-2022** **&** **07-04-2022**	**Good**	1. Dr. Ikram Ul Haq, Member, Central Licensing Board 2. Ms. Aisha Irfan, FID, DRAP, Lahore, 3. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, water treatment system, personnel and documentation etc. the panel **recommends** the renewal of Drug Manufacturing License, to M/s. Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, Lahore by way of formulation to the following sections only:

1. Tablet (General) Section.
2. Tablet (Psychotropic) Section.
3. Capsule (General) Section.
4. Dry Powder Suspension
5. Sachet (General) Section.
6. Oral Liquid (General) Section.
7. Liquid injectable (SVP) (General) Section.
8. Capsule (Cephalosporin) Section
9. Dry Powder Suspension (Cephalosporin) Section.
10. Dry Powder Injectable (Cephalosporin) Section.

The panel observed that the firm has not made changes/regularization as per new approved layout plan and informed that it would take 2-3 years' time period, to implement new layout plan, hence the renewal of DML is recommended as per old layout plan respectively.

Decision of the Central Licensing Board in 287th meeting:

The Board considered the case and decided to defer the case till next Board meeting. The Board also decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000231 by

way of Formulation of M/s. Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, Lahoremay not be suspended or cancelled by the Central Licensing Board.

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

The Show Cause Notice was issued to M/s Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, Lahore on 24th August, 2022.

The firm has replied that they have applied for renewal of DML and regularization of sections vide letter dated 17th September, 2020. Meanwhile, the management decided to upgrade the facility and submitted revised layout plan but after the pandemic, the economy and business were so badly affected and they could not go for the project. Due to this reason, the management requested the panel to renew their DML on the basis of previously approved layout plan.

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Maqsood Ahmed Technical Director of the firm appeared before the Board. They contended that the regularization and extension of sections will take 2-3 years. The Board while considering the facts on record and after thread bare deliberation decided to defer the renewal application of DML. The firm shall first withdraw the LOP approved on 28th November 2018 (F.1-14/84-Licensing-Vol-6) because they have not made any development/changes for regularization. The firm shall apply for the regularization of existing lay out plan.

Case No. 56 **RENEWAL OF DRUG MANUFACTURING LICENCE OF LAHORE CHEMICAL & PHARMACEUTICALS WORKS (PVT) LTD, LAHORE.**

AD-I

M/s Lahore Chemical & Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulana Jalal-Ud-Din Roomi, Lahore had applied for renewal of DML No. 000064 by way of Formulation for the period of 31-12-2021 to 30-12-2026.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 29-10-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Prescribed fee of Rs.75000/- as there is change in management of firm.
ii. Latest certified true copy of Form-29 or Form-A duly attested by SECP (Original).
iii. Duly attested CNIC copies of all Directors.

The firm replied to this letter on 16-12-2021 and reminder letter was issued on 14-01-2022 to the firm for completion of application:

i. Prescribed fee of Rs.75,000/- as there is change in management of the firm.

ii. Latest certified true copy of Form-A or Form-29 duly attested by SECP (Original) without stamp that "SECP does not take responsibility of content of Form".

The firm replied that due to sudden death of Managing Director of the firm, issuance of Form-A & Form-29 is in process and application for renewal of DML is still incomplete.

Decision of the Central Licensing Board in 285th 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 000064 by way of formulation of M/s Lahore Chemical &Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulana Jalal-Ud-Din Roomi, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause Notice was issued to M/s Lahore Chemical & Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulana Jalal-Ud-Din Roomi, Lahore on 4th June, 2022.

The firm has replied but application for renewal of DML is deficient of latest certified true copy of Form-A or Form-29 duly attested by SECP (Original) without stamp that "SECP does not take responsibility of contents of Form.

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Ijaz Hussain Regulatory Manager of the firm appeared before the Board. He contended that they will provide/submit all requisite documents and prescribed fee. The Board decided that the firm will complete all codal formalities such from within 15days and the case be placed before Board in its upcoming meeting for its consideration

Case No. 57 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HUMAYUN INTERNATIONAL PHARMA (PVT) LTD, FAISALABAD.**

AD-I

M/s Humayun International Pharma (Pvt) Ltd, 20-KM, Satiana Road, Faisalabad had applied for renewal of DML No. 000443 by way of Formulation for the period of 26-11-2019 to 25-11-2024.

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 19-02-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Classes of drugs.
iii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).
v. Duly attested CNIC copies of all Directors.
vi. Approval letters of Production Incharge & Quality Control Incharge, if not approved, submit application to this office for approval.
vii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.
viii. Nothing due certificate regarding CRF from STO (Updated).

The firm did not reply to this letter and reminder letter was issued on 21-09-2020 to the firm for completion of application:

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Classes of drugs.
iii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).
v. Duly attested CNIC copies of all Directors.
vi. Approval letters of Production Incharge & Quality Control Incharge, if not approved, submit application to this office for approval.
vii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.
viii. Nothing due certificate regarding CRF from STO (Updated).

The firm did not reply and application for renewal of DML is still incomplete.

Moreover, FID, DRAP has intimated that firm has informed about closing of their factory due to financial crisis.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000443 by way of formulation of M/s Humayun International Pharma (Pvt) Ltd, 20-KM, Satiana Road, Faisalabad may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause Notice was issued to M/s Humayun International Pharma (Pvt) Ltd, 20-KM, Satiana Road, Faisalabad on 9th June, 2022.

The firm has not replied and application for renewal of DML is incomplete.

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Tahir CEO of the firm appeared before the Board. He contended that the firm is closed and under renovation. He further contended that he will complete all requisitedocuments/information within 2-3 months. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000443 (by way of formulation) of M/s Humayun International Pharma (Pvt) Ltd, 20-KM, Satiana Road, Faisalabad, till fulfillment of the codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 58 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000156 OF M/S OVAL PHARMACEUTICALS, 112/11, QUAID-E-AZAM INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE.**

AD-I

M/s Oval Pharmaceuticals, 112/11, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore had applied for renewal of DML No. 000156 by way of formulation for the period of 21-07-2019 to 20-07-2024. 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 2nd October, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

For Renewal of DML.

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP, Islamabad.
iii. Detail of management at the time of previous renewal, and at present, if any change, apply for change of management.
iv. Duly attested copy of partnership deed and CNIC copies of all partners.

The firm did not submit their reply in response to this Division's letter dated 2nd October, 2019 and Final reminder was issued to the firm on 9th November, 2021 with following shortcomings: -

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP, Islamabad.
iii. Detail of management at the time of previous renewal, and at present, if any change, apply for change of management.
iv. Duly attested copy of partnership deed and CNIC copies of all partners.

The firm has submitted their reply on 15th January, 2022 in response to this Division's Final Reminder. However, application of Renewal of Drug Manufacturing License is still deficient of following documents:

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP, Islamabad.
iii. Prescribed fee of Rs.75,00/- for change in management of firm.
iv. Duly attested CNIC copies of all partners.
v. Duly attested Form D from Registrar of firms.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000156 by way of formulation of M/s Oval Pharmaceuticals, 112/11, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause Notice was issued to M/s Oval Pharmaceuticals, 112/11, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore on 26th May, 2022.

The firm has not replied and application for renewal of DML is incomplete.

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

Mr. Tahir CEO and Mr. Naseem Haider, QC Incharge of the firm appeared before the Board. They contended that they will provide/submit all requisite documents at the earliest. The Board decided that the firm will complete all codal formalities within 15days and the case be placed before Board in its upcoming meeting for its consideration.

Case No. 59 **RENEWAL OF DRUG MANUFACTURING LICENCE OF MOON PHARMACEUTICALS, RAWAT.**

AD-I

M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, RCCI, Rawat had applied for renewal of DML No. 000833 by way of Formulation for the period of 23-08-2021 to 22-08-2026.

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 10-09-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed & stamped Form-1A (as per format),
ii. Updated Nothing Due Certificate (CRF) from STO, DRAP.
iii. Detail of management, if any change, apply for change of management.
iv. Duly attested partnership deed & CNIC copies of all partners.
v. Approval letters of Production Incharge & Quality Control Incharge, if not approved, submit application along with prescribed fee.
vi. Approval letter of sections approved by CLB.

The firm replied to this letter on 18-10-2021 and reminder letter was issued on 23-11-2021 to the firm for completion of application:

i. Prescribed fee of Rs.75,000/- for change of management.
ii. Duly attested revised partnership deed & CNIC copies of all partners & Form-D.
iii. Complete set of duly attested documents (as per checklist) along with prescribed fee of Rs.7500/- of proposed Quality Control Incharge.
iv. Duly attested CNIC and undertaking on stamp paper of proposed Production Incharge.
v. Duly attested resignation of earlier Production Incharge.

The firm replied on 13-12-2021 and requested for some extra time for submission of deficient documents.Application for renewal of DML is still incomplete.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 Rule 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000833 by way of formulation of M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, RCCI, Rawat, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause Notice was issued to M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, RCCI, Rawat on 4th June, 2022.

The firm has replied to Show Cause Notice but application for renewal of DML is still deficient of following documents:

i. Complete set of duly attested documents (as per checklist) of proposed Quality Control Incharge.
ii. Submit original fee challan of Rs.7500/-of proposed Quality Control Incharge.
iii. Duly attested CNIC and undertaking on stamp paper of proposed Production Incharge.
iv. Duly attested resignation of earlier Production Incharge.

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

No one on behalf of the firm appeared before the Board. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000443 (by way of formulation) of M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, RCCI, Rawat, till fulfillment of the codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 60 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000613 (FORMULATION) OF M/S GOODMAN LABORATORIES (PVT) LTD, RAWAT.**

AD-I

M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat is licensed firm having DML No. 000613 by way of Formulation with validity of 20-03-2022. However, it is submitted that as per available record, application for renewal of DML No. 000613 by way of Formulation for the period 21-03-2022 to 20-03-2027 of M/s Goodman Laboratories (Pvt) Ltd, Rawat has not been received in Licensing Division.

It pertinent to mention that as per Rule 5 (6) of Drug (L, R & A) Rule, 1976 "if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application". Furthermore, Rule 5(3) states that "If the application for renewal of the Licence is made after the expiry of the period of the validity of the Licence, it shall be treated as a fresh application for the grant of a Licence."

In light of above, DML No. 000613 by way of formulation, M/s Goodman Laboratories (Pvt) Ltd, Rawat is no more valid.

Proceedings and Decision by the Central Licensing Board in 287th 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 as to why Drug Manufacturing License No 000613(by way of formulation) of M/s Goodman Laboratories (Pvt) Ltd, Rawatmay not be declared cancelled by the Central Licensing Board as application for renewal of Drug Manufacturing Licence is not filed under Rule 5 and Rule 6 of Drug (Licensing, Registering and Advertising) Rule, 1976.

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

The Show Cause Notice was issued to M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat on 4thJuly, 2022.

The firm has replied that they have paid DML renewal fee of Rs.75,000/- within due date on 18-03-2022 and submitted In-Process data through PIRIMS and still waiting for approval.

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

No person appeared on behalf of the firm.The Board considering the facts on record and after thread bare deliberation decided to cancel the Drug Manufacturing License No. 000613 (Formulation) of M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat as the Drug Manufacturing License No. 000613 (Formulation) is no more valid as under Rule 5 (6) of Drug (L, R & A) Rule, 1976.

Case No. 61 **M/S MEDISYNTH PHARMACEUTICALS, RAWAT.**

AD-I

A legal notice received from Malik Khalid Mahmood, Advocate Supreme Court of Pakistan addressed to Chief Executive Officer **M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-05, Industrial Estate, Rawat.** The detail of legal notice is reproduced as under: -

1. That my client entered into a written Rent Deed Agreement No. 17 dated 16-06-2010 ("agreement") on 14th May 2010 for the Plot No. 55 (Ground Floor inclusive of roof for HVAC System with temporary MS Sheet covering only) street No. S-05, Industrial Estate, Rawat, Rawalpindi (hereinafter" plot") registered in Court of learned Special Judge Rent, Rawalpindi on 10-06-2010. The premises specification has been mentioned in the agreement, Pursuant to the agreement, the relationship of Landlord and tenant was established between my client and you.

2. That my client is the sole owner of the plot. It has been written in the agreement that Rent Deed / Agreement shall be valid between both the parties (my client & you) for the maximum period of 12 years ending on 13th May, 2022. It has also been settled / written in the agreement that it is discretionary right of my client to extend or not extend the period after its expiry.

3. That it is stated the agreement is going to be expired on 13th May 2022 having discretion of my client to extend it or otherwise. My client does not intend to extend the agreement anymore and do not want to have Rent Deed Agreement with you for further period in respect of the plot.

4. That it is pertinent to mention here that during the subsistence of agreement my client has always abided by the terms and conditions of the instant agreement. Nothing is outstanding against him.

5. That my client has verbally requested you that he is no more interested to extend the agreement and therefore, requested you to vacate the premises mentioned above after expiry of agreement but you are not ready to hear anything reasonable.

6. That through this legal notice to evict you are advised to vacate the said plot after expiry of agreement, otherwise, my client has positively instructed me to file a suit for eviction against you in the Court of Law oat your risk and costs.

It is submitted for information that M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-05, Industrial Estate, Rawat under DML NO. 000718 (by Way of Formulation) has applied for renewal of DML for the period of 14-06-2021 to 13-06-2026 and panel of experts/inspector has been constituted, accordingly.

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000000by way of formulation of M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-05, Industrial Estate, Rawat, may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause Notice was issued to M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-05, Industrial Estate, Rawat on 9th June, 2022.

The firm has replied which is reproduced as under:

"In fact the owner of the plot has concealed material facts from his counsel which led to misconception on the part of DRAP and resultantly issuance of the instant show Cause Notice.

In this regard, it is submitted that Mr. Ishtiaq Ahmed Khan S/o Abdul Ghafoor Khan plot owner entered into the agreement with the then owner of Medisynth Pharmaceuticals encompassing different obligations on the part of the owner and tenant. That vide article 2, the purpose of the agreement was to construct two independent Human and Veterinary Units. It was mutually agreed that Mr. Ishtiaq Ahmad owner of the plot will be liable to construct an independent unit of Veterinary Medicines on the first floor on the said premises/plot (Article 8). That Mr. Arshad Hussain will construct a Quality Control Laboratory, which will be used by Mr. Ishtiaq Ahmed Khan for its veterinary medicines as well. That Mr. Arshad Hussain has thus raised a QC Laboratory with the state of the art technology so as to meet the requirement of the Pharmaceuticals and Veterinary section of the Mr. Ishtiaq Ahmed Khan.

However, Mr. Ishtiaq Ahmad lingered on the matter where after Mr. Arshad Hussain couldn't sustain the continuous loss and as such offered the sale of its pharmaceutical to some third party.

In the circumstances, Mr. Arshad Hussain in the presence of Mr. Ishtiaq Ahmed Khan strike down an agreement of sale of firm with us. Mr. Ishtiaq Ahmed Khan assured us that he will extend the lease agreement for another 5 years after the expiry of the current agreement and will also construct the Veterinary Section so as to divide the rent and other expenditures on the two units as per provision of the clause 8 of the agreement.

As such in good faith and his personal assurance that this issue of liability will be adjusted in the extended period (14th May, 2027) of agreement, we kept on paying the total rent with 10% annual increase from 2010 till date. As per our calculation an over payment of Rs.9,565,455/- is outstanding against him.

The malafide intention of the Land Owner is further evident from the fact that he has not served any prior notice of one year as required in the registered rent agreement. For your kind perusal the relevant clause i.e Clause 7 is reproduced as under;

"After the initial 5 year & within expiry period of this agreement, either party willing to terminate the agreement will serve a notice of one year and liable to pay the penalty/compensation of rupees Two million to the other party."

Neither the land owner Mr. Ishtiaq Ahmed Khan has given any notice as required above nor has compensated the penalty provided in the said clause of the agreement. The said notice has placed our firm in a very embarrassing situation and as such on the receipt of the legal notice we had no alternative but to seek legal remedy against this illegal blackmailing and

nefarious design. Thus we filed a suit with Special Judge (Rent)/Civil Judge 15 Class, Rawalpindi.

The matter was fixed before the court on 14.06.2022, which has passed the following orders

"Till the next date of hearing subject to notice, the respondent is restrained from interfering into the peaceful possession of applicant illegally; unlawfully, otherwise, due course of law"

In view of the situation explained above, the notice of the legal Counsel is misleading, unlawful and tantamount to blackmailing, embarrassing and maligning of the goodwill of our firm and is therefore is requested to file the same."

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

No one appeared on behalf of the firm before the Board. The Board while considering the facts on the record decided to offer final opportunity to the firm. The Board further decided that Area FID shall submit updated status of the firm to the Board in its upcoming meeting.

Case No. 62 **DRAFT GUIDLINES ON ESTABLISHMENT OF PHARMACEUTICAL UNIT& POST LICENSE CHANGES**

This document is applicable to any applicant/firm/company who intends to establish a New Pharmaceutical Unit and for approval/endorsement of post license changes. The details is on Annex-I.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

The Board recommended the draft guidelines, with minor revision, to the DRAP Authority for its approval.

CASES OF QA & LT DIVISION

Item No. I **PERSONAL HEARING IN COMPLIANCE TO DECISION OF 237th MEETING OF CLB**

Case No. I:- **M/S. HASSAN PHARMACEUTICALS, 99-A, HAYATABAD INDUSTRIAL ESTATE, PESHAWAR.**

QA received letter No. F. 11-15/2010-Hassan-DRAP/1267 dated 04.07.2022 from Mr. Atiq-ul-Bari, FID, DRAP, Peshawar. Wherein he enclosed GMP inspection report of the firm M/s. Hassan Pharmaceuticals, Plot No. 99-A, Hayatabad Industrial Estate, Peshawar. The inspection

report was conducted on 28.06.2022. to check GMP compliance and reconciliation of Substandard Pantopep Tablets Batch No. 911.

1. Background

Inspection report of M/s Hassan Pharmaceuticals, 99-A, Hayatabad Industrial Estate, Peshawar. The FID Mr. Atiq-ul-Bari has informed that in last renewal inspection the panel had recommended the grant of renewal of M/s Hassan Pharmaceuticals, Hayatabad, Peshawar for following sections only.

i. Tablet Section (General)
ii. Tablet Section (Quinolones)
iii. Capsule Section (General)
iv. Oral liquid Section (General)

The panel had also recommended that the following sections may be suspended till approval of revised / new layout plan and its subsequent approval from Central Licensing Board.

i. Capsule Section (Cephalosporin)
ii. Dry Suspension Section (Cephalosporin)
iii. Capsule Section (Penicillin)
iv. Dry Suspension Section (Penicillin)

The Central Licensing Board has not approved these sections yet. The FID has made the following Observations: -

Change rooms

There were no shoe covers available for visitors. Workers shoes were lying in a disordered manner. Lockers are not available for workers. They were advised to shift water basins from change room to outside of change rooms.

Storage area/ware houses:

The air curtains on raw material entry and packaging material entry were out of order. The Receiving bay, Quarantine, sampling, raw material store, dispensing area, packaging material store were not maintained. Cleaning was not satisfactory as cobwebs were seen in the store. The air conditioner and light in raw material store were out of order. Dispensing booth and sampling booth were not available. Drums of Solvents and cartons of empty glass bottles were lying outside unapproved area. They were also directed to use new bottles only in manufacturing of their products. Finished products store has been shifted from area proposed for new penicillin sections to a block proposed for Neutracutical Sections without proper arrangement for control of temperature and humidity.

Production area:

The approved production In-Charge and even no production pharmacist were available at the time of inspection. Later on the management of the firm informed that their approved production In-Charged has resigned from their firm. Manufacturing order and dispensing of Zencet Syrup 60ml Batch No. 265 were processed without approval of production In-Charge. HVAC system was not running in the Production area at the time of inspection. Ceiling fans were installed in Oral liquid

section. Logbooks of machine, temperature humidity and cleaning log sheets were not properly maintained. The silicon pipe in liquid section was broken and closed with plastic adhesive tape while some pipes for transfer of products in oral liquid section were simple collapsible plastic/rubber pipes where liquid product could not be easily drained/washed out where microbiological growth can occur. No proper tags indicating status of equipment in production sections were displayed. External preparation product Scab Lotion has been prepared in Oral Liquid Section (General). The product was put on "not to dispose of" for clarification from DRAP. The spare parts of blistering machine were not properly stored and need buffing and oiling. Printed Aluminium foil of Zolopep Capsule and PVC were still mounted on blistering machine in capsule section although the firm claimed that they had not produced any batch in capsule section in the year 2022. There were cracks in walls near pump and RO plant of water system. The layout plan of Penicillin sections has been approved in a separate block but only walls of the building have been constructed yet. They were directed to stop production in all sections until removal of all deficiencies in GMP and verification by DRAP.

Quality Control

QC laboratory was not satisfactory. Reference standards were lying in desiccator without any temperature control. Although they have provided basic QC equipment in the lab like HPLC, Spectrophotometer, FTIR, 02 stability chambers, Autoclave, incubator, laminar flow hood etc. but no microbiologist and other technical staff except one QC In-Charge was available. Stability Chambers were empty and off at the time of inspection. The testing methods need up gradation to latest pharmacopoeia.

Quality Assurance

The firm has no Quality Assurance In-Charge although they claimed that Mr. Qamer Abbas (who is also among the owners of the firm and chemist by qualification) was looking after the Quality Assurance. The firm was directed to comply with the S.R.O. 1460(I)/2019 dated 27th November, 2019 and DRAP Islamabad letter No. F. 313-DRB/2021 (PE&R) dated 29th December 2021 in true letter & spirit.

The FID has reported that the firm has a block of proposed Neutraceutical Sections and in its basement the firm has established a printing press. According to the firm they only print their own labels, unit cartons etc. in the printing press. Irrelevant machinery was lying in the proposed neutraceutical block although they are not interested in development of neutraceutical sections now and in near future. They were directed to remove the irrelevant machinery from this block and keep proper record of their printing press.

The FID has further reported that Stock put on "not to dispose of": the firm had recalled stock of substandard Pantopep Tablets Batch No. 911 which was put on "not to dispose of" for onward destruction as per directions of QA & LT Division of DRAP Islamabad. Available stock of following product was also put on "not to dispose of" for further clarification (Copy of Form 1 attached for intimation and request for extension of not to dispose period beyond 28 days by Drug Registration Board).

i. Scab Lotion, an external preparation product being manufactured in oral liquid section (General)
ii. previous stock of Betacef powder for oral suspension, a Cephalosporin containing product without approved dedicated section

The FID has concluded that Based on the observations made during the inspection the firm may be considered operating at poor level of GMP compliance and following are recommendations:-

i. *The firm should rectify not only the observations mentioned in the inspection report but they should perform a self-inspection on Schedule B-II Performa or other cGMP Code approved by the DRAP and rectify all the observations as soon as possible.*
ii. *They firm should stop production in all sections until removal of all deficiencies in GMP, verification by a panel constituted by QA & LT Division and subsequent approval for resumption of production.*
iii. *The registration of Penicillin and Cephalosporin containing products may be suspended till approval of dedicated sections for these products.*

2. Action Taken by QA&LT Division: -

The firm was issued Show Cause Notice / Suspension of Production in all Sections vide QA letter No. F. 4-3/96-QA dated 09.09.2022.

3. Reply of the Firm:-

The firm replied vide Letter No. Nil dated 23.09.2022, wherein it is stated that we have regularized our entire layout plan and got our approval letter on 27.07.2022 and we have started work on that approved layout immediately as a proof visual picture are attached we have completed our work in cephalosporin section currently working in liquid section is going on we agrees with report of area FID the shortcoming he mentioned in report and schedule B-II. Also our production in-charge resigned just a day before visit of FID and in a span of 2 days we hired new production in-charge and his document will be submitted in PIRIMS once we get our grant of license on PIRIMS we waiting for that as we get our license in PIRIMS we will immediately submits his documents as we have arranged all the required documents required for approval of technical staff. Also we have stopped our production since area FID visits,

We request the Central Licensing Board to give us 2 month time so we can overcome all the shortcomings mentioned in report after that your panel can visit us to see the progress.

4. Evaluation of the Reply submitted by the Firm:-

Based on the evaluation of the reply of the firm it is evident that the firm had not provided the requisite information i.e. pertaining to the registration status of Penicillin and Cephalosporin containing products. Furthermore, the reply submitted by the firm is superficial and does not address the issues related to violation of GMP in light of Schedule B-II of the Drugs (LR&A) Rules, 1976; Showing lack of intent and capacity to comply with the prevalent GMP guidelines as per Drugs Act, 1976 and DRAP Act, 2012.

Representative of the firm M/s. Hassan Pharmaceutical, Peshawar has been called upon for personal hearing in compliance to decision of 237th meeting of CLB.

FIRM REPRESENTATION:-

On Behalf of firm following representatives attended the meeting:-

I. Hassan Nawaz, MD,
II. Hamid Hussain, Quality Control Manager

DECISION OF 288TH MEETING OF CLB: -

The board after considering the statement of firm's representative and deliberating on the facts of the matter, decided as under;

i. ***Since the CAPA report was not satisfactory, the orders passed vide letter No. F. 4-3/96-QA dated 09.09.2022 for Suspension of Production in all Sections shall remain intact.***
ii. ***The firm is directed to re-submit its CAPA report. The Division of QA&LT will evaluate the CAPA and then proceed as per delegation of powers by CLB after verification of rectifications of observations through a follow up inspection.***

Case No. II **M/S. USAWA PHARMACEUTICALS, PLOT NO. 146-SPECIAL INDUSTRIAL ZONE, (EXPORT PROCESSING ZONE), RISALPUR-PAKISTAN.**

1. Background

QA received letter No. F. 11-50/2021-Usawa-DRAP/1527 dated 06.09.2022 from Mr. Faisal Shahzad, FID-I, DRAP, Peshawar. Wherein he enclosed panel inspection report of the firm M/s. Usawa Pharmaceuticals, Plot No. 146-Special Industrial Zone, (Export Processing Zone), Risalpur-Pakistan. The inspection was conducted by following panel on 02.09.2022.

i. Mr. Faisal Shahzad, FID, DRAP, Peshawar
ii. Mr. Adnan Shahidullah, Area AD, DRAP, Peshawar

2. Focus of the Inspection:-

Panel inspection of the firm against DRAP, Islamabad letter No. F. 4-29/2001-QA dated 21.04.2021 for conducting thorough cGMP inspection of the firm and improvements made by the firm for inspection of area FID dated 04.02.2021.

The firm's management along with above mentioned technical persons were available at the time of inspection. The firm management was asked to provide report of compliance against inspection dated 04.02.2021 but the firm management informed that they have not yet prepared any such report. Further, no CAPA is prepared / implemented yet. Additionally, no implementation plan was available for compliance to DRAP Islamabad letter No. F. 313-DRB/2021 (PE&R) dated 29.12.2021.

The panel concluded that, despite more than sufficient time has lapsed, the firm has failed to upgrade their facility in line with cGMP guidelines i.e., Schedule B-II of the Drugs (L.R.A.) Rules, 1976 of the Drugs Act, 1976 / DRAP Act, 2012 and to comply with observations of last inspection report dated 04.02.2021.

3. Action Taken by QA&LT Division: -

The firm was issued Show Cause Notice / Suspension of Production in all Sections vide QA letter No. F. 4-29/2001-QA dated 21.09.2022.

4. Reply of the Firm:-

The firm replied vide Letter No. Nil dated 30.09.2022, wherein it is stated that we have already submitted compliance report on 15.09.2022. in light of your show cause notice on 21.09.2022, we are re-submitting our compliance report CAPA format. Kindly review and accept it. It is therefore requested to withdraw the suspension of production activities.

5. Evaluation of the Reply submitted by the Firm:-

Based on the evaluation of the reply of the firm; the information provided in the compliance report in point # 1.3 does not match the annexure-III, Annexure-IV reported to be conforming with point # 1.4 is not attached. Reference 2.2 the annexure claims to have in voice of equipment purchase however in reality it is not provided. Furthermore, the reply submitted by the firm partially addresses the issues related to violation of GMP in light of Schedule B-II of the Drugs (LR&A) Rules, 1976 as the details regarding procedures and their controls is not attached; pointing out to the fact that the firm requires to upgrade its capacity to comply with the prevalent GMP guidelines as per Drugs Act, 1976 and DRAP Act, 2012.

Representative of the firm M/s. Usawa Pharmaceuticals, Risalpur has been called upon for personal hearing in compliance to decision of 237th meeting of CLB.

FIRM'sREPRESENTATION:-

On Behalf of firm following representatives attended the meeting:-

I. Muhammad Usama Khan, Director.
II. Hameed ur RehmanHamid Hussain, Production In-charge.

DECISION OF 288TH MEETING OF CLB: -

The board after considering the statement of firm's representative and deliberating on the facts of the matter, decided as under;

i. Since the CAPA report was not satisfactory, the orders passed vide letter F. 4-29/2001-QA dated 21.09.2022 for Suspension of Production in all Sections shall remain intact.
ii. The firm is directed to re-submit its CAPA report. The Division of QA&LT will evaluate the CAPA and then proceed as per delegation of powers by CLB after verification of rectifications of observations through a follow up inspection.

Case No. III **M/S. AAA HEALTH PHARMA LABORATORIES, PLOT # 9-A, STREET NO. N-5, RCCI INDUSTRIAL ESTATE RAWAT, RAWALPINDI. (DML NO. 000871).**

Mr. Khalid Mahmood, FID-II DRAP Islamabad, inspected the firm M/s AAA Health Pharma Laboratories, Plot # 9-A, Street No. N-5, RCCI Industrial Estate Rawat, Rawalpindi. (DML No. 000871) on 28.07.2022 to check the GMP compliance.

2. The FID reported following observations;

Production Areas:-

i. Gaps and cracks found in door of the production areas which can cause cross contamination.
ii. Hygrometers and Manometers were not found present in the production area.
iii. Insect and flies seen in the production areas.
iv. Some Wiring needs to be concealed in the production areas.
v. The firm does not have the pharmaceutical grade colors as per requirement of E. Numbers under BNF along with other official books.
vi. The humidity and temperature control devices with legible charts needs to be mounted on the walls.
vii. The firm is required to furnish the list of all registered products being manufactured along with their manufacturing record to the office of FID-II Islamabad.
viii. The firm has registration of approx.50 products and not manufacturing all products.
ix. The GAP analysis found regarding evaluation of GMP as per SOPs given by the registration Board vide letter No. 313-DRB-2021(PER) dated 21-09-2021 is required to be implemented by the firm in letter& spirit.

Stores:-

i. No vendor qualification for purchase of APIs could be seen.
ii. The firm needs to have a record of thermal mapping in their stores FGS, PMS and RMS.
iii. The temperature mapping have never been performed by the firm compliance is advised.
iv. Validation of Humidity measuring and control devices needs to be done.

Microbiology Lab:-

i. There is no active Microbiology lab with microbiologist. Who can assess the microbiological testing and growth.
ii. The firm does not have any record of Bio-burden of the area.
iii. No active Micro Biology lab established in the unit. The firm has been advised to establish microbiology and appoint microbiologist.

Quality Assurance:-

i. There is no QA Manager and No QA section with R&D Lab established as per requirements of GMP protocols laid down by the Registration Board in its 313-DRB meeting held on 29.12.2021.

Quality Control:-

i. The firm's QC Lab is also devoid of essential technical personnel meant for performing the testing duties. Fungal growth found seen in QC.
ii. No reference standards and development of analytical method as per ICH Guidelines found observed.
iii. The firm is advised to purchase F.T.I.R., TOC. TDS, Gradient HPLC with CFR 21 compliant as required under the DRAP and ICH guidelines.

HVAC System:-

i. The OQ,PQ has not been found. There is no working HVAC in the unit. Calibration from and ISO certified company has not been found observed.
ii. The firm does not possess the manometers to observe the pressure differential of HVAC in all sections and corridor.

Water Distillation Plant:

i. The firm has a defective/out of order distillation assembly which needs to be replaced with immediate effect with other sections which require distilled water also& buffing.

R &D:

i. There is no product development area seen as per requirement for approval by CLB.
ii. The firm does not have proper product development area and requisite QA trained officers and did not even endorsed from CLB the performance qualification and operational qualification of the installed equipment with the in premises have not been calibrated /validated from ISO certified firm with in the latest addition of relevant official pharmacopoeia.
iii. No Stability chambers found in working condition.

Premises / Building:-

iii. The firm is not working with good compliance of GMP as per attached photographs as in number of places the fungal growth and the cracks in the walls and the removed paint seen.
iv. The firm is full of dirt/dust with fungal growth on the walls were seen which may amount to destroy/ adulterate the medicines. The public at large is at stake as the firm has not improved.
v. The entire unit including the raw material store of the unit is under maintenance due to heavy rain and seepage, fungus, cobwebs etc seen in the area.
vi. Fire extinguishers found expired, no sticker pasted regarding refill or expire date and hanging without displaying any SOP for use.
vii. All the section required maintenance, seepage and dust/rust found in the area.
viii. The air curtains needs to be made functional in some areas. Some air curtains are out of order and needs immediate repair, only box of air curtain is hanging with birds nest.
ix. No First Aid box was found seen.

Personnel:-

i. The firm is working without the presence of any technical staff mandatory under section 16 of the Drugs (LRA) Rules, 1976.
ii. There is no authorized person appointed as per Rules 1 of Drugs (LRA) Rules, 1976
iii. The production and Quality Control In-charge have been given the duties as envisaged under the schedule B of the Drug Act 1976.

iv. The firm also has not notified the authorized person under rule 1 of Drug (LRA) rules Drug Act 1976.

Regulatory:-

i. The firm also have not the proper warranty as per form 2-A under the drugs Act 1976.
ii. The firm is required to submit the price increase data to the undersigned as well as to the Division of Costing and Pricing, DRAP Islamabad along with Registration letters.
iii. The firm needs to provide the quarterly production record to the Chairman Registration Board under rule 30 (6) of the Drug (LRA) rules Drug Act 1976.

Conclusion:-

*The firm is in the process of changing the management, the production & QC In-charge also given an undertaking **(Copy attached)** to improve as per above points within a period of 02 months. No production activity will be carried out during this renovation time. The whole report warrants immediate necessary actions keeping in view public health at large stake. **The current cGMP is not good and graded as poor, which may pose great threat to public health**. The report is submitted under section 19 (7) of the Drugs Act, 1976 with pictorial images.*

3. Keeping in view the above stated observations and conclusion by the FID, the firm was issued **Show Cause and directed to Suspend the Production Activities** vide this office letter No. F.4-103/2014-QA dated 11th August, 2022**.**

4. M/s AAA Health Pharma Laboratories, Plot # 9-A, Street No. N-5, RCCI Industrial Estate Rawat, Rawalpindi vide letter DRAP/FID/001 dated 18-08-2022 submitted plan for rectification of the observations which were observed in GMP inspection of their firm conducted on 28.07.2022 by Mr. Khalid Mahmood, FID-II, DRAP, Islamabad.

5. In addition the firm also submitted that:

*"That the AAA Health Pharmaceutical Laboratories Islamabad (the Company) is in transition of change of Managemant" That the change of Management is under process with Rite Biosciences (Pvt) Ltd., Karachi. This matter was already discussed with the Area FID during Inspection and he also mentioned in conclusion remarks as **"The firm is in the process of changing the management"** and the requisite fee is already in process and this challan is already paid."*

"As the company is under the sale transition period, so there were no regular production activities going on the floor."

"New management has stringent intention towards cGMP compliance and their mission to intent regarding DRAP regulations. In this regard, already made immediate action plan during sale agreement to overcome the shortcomings regarding machines equipment and R&D / Product Development."

6. The central licensing board has delegated power of Suspensions of Production (in case of GMP and Quality Control matters) to the Director QA&LT, under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) rules, 1976, in its 273rd meeting. The power was further delegated to the Additional Director QA&LT in 278th meeting of CLB in case of vacancy of post of the Director QA&LT.

7. The firm **M/s AAA Health Pharma Laboratories, Plot # 9-A, Street No. N-5, RCCI Industrial Estate Rawat, Rawalpindi** ordered by the QA &LT Division to stop production activities vide letter No. F.4-103/2014-QA dated 11th August, 2022due to non-compliance of the Schedule B-II of the Drugs (Licensing, Registering and advertising) Rules 1976.

8. A license holder is bound under rule 19(1) & (7) of the Drugs (Licensing, Registering and advertising) Rules 1976 to comply with the provision of the act, the rules and further requirements. Under rule 12 of the Drugs (Licensing, Registering and Advertising) Rules 1976 if the licensee does not comply with any of the conditions of a license or violates any of the provisions of the Ordinance or the rules, the Central Licensing Board may, by an order in writing stating the reasons thereof cancel a license or suspend it for such period as it thinks fit either wholly or in respect of some of the drugs to which it relates. Moreover Contravention of Rules is an offence punishable under Clause 4 of Schedule-III of the DRAP Act 2012 with imprisonment for a term which may extend to five years, or with fine which may extend to one lakh rupees, or with both. The penalty of same under subsection 4 of section 27 of the Drugs Act 1976 is imprisonment for a term which may extend to five years, or with fine which may extend to fifty thousand rupees, or with both.

9. As per detailed report of the FID, the firm **M/s AAA Health Pharma Laboratories, Plot # 9-A, Street No. N-5, RCCI Industrial Estate Rawat, Rawalpindi. (DML No. 000871)** through its responsible persons, is found to be contravening rule 19(1) & (7) of the Drugs (Licensing, Registering and advertising) Rules 1976 which is an offence punishable under Clause 4 of Schedule-III of the DRAP Act 2012 and section 27 subsection 4 of the Drugs Act 1976 whereas Under rule 12 of the Drugs (Licensing, Registering and advertising) Rules 1976 the license of the firm may please be cancelled upon violation of the rule 19(1) & (7) as the firm was asked for any opportunity of personal hearing vide this above mentioned letter F.4-103/2014-QA dated 11th August, 2022 but no such request has made by them so it is desirable to proceed the matter accordingly.

The matter of poor GMP condition, changing the management and carrying the renovation without any intimation to the area FID / CLB along with pictorial images as evidence is placed before the Central Licensing Board for consideration please.

DECISION OF 288TH MEETING OF CLB: -

The board after considering the reply of firm and deliberating on the facts of the matter, decided as under;

i. ***Since the CAPA report was not satisfactory, the orders passed vide letter No. F.4-103/2014-QA dated 11th August, 2022 for Suspension of Production in all Sections shall remain intact.***
ii. ***The firm is directed to re-submit its CAPA report. The Division of QA&LT will evaluate the CAPA and then proceed as per delegation of powers by CLB after verification of rectifications of observations through a follow up inspection.***
iii. ***Additional Director Field office Islamabad shall be directed to ensure the compliance of suspension of production orders through area Federal Inspector of Drugs, Islamabad.***

Item No. III RESUMPTION OF PRODUCTION

Case No. I: M/S. PHARMIX LABORATORIES (PRIVATE) LIMITED, LAHORE.

Background:

F.R is the panel cGMP inspection report of M/s. Pharmix Laboratories (Pvt.) Ltd, 21-KM, Ferozepur Road, Lahore, wherein the inspection was conducted by following panel on 26.05.2021 & 07.07.2021, for verification of cGMP compliance of the firm and issuance of cGMP certificate.

i. Ms. Aisha Irfan, FID, DRAP, Lahore
ii. Mr. Shahrukh Ali, AD, DRAP, Lahore

2. During evaluation of the report, it is noted that the panel has given *Grade "A" (Good Compliance) to total of one hundred forty three (143)* conditions and give *Grade "B" (Fair Compliance) to total of forty five (45)* conditions: -

3. The panel recommendations / desired action *"In view of above inspection proceedings and facilities verified such as company profile, building, production, in-process control, quality control testing, machinery / equipment, material management, air handling, water treatment system personnel and documents, the firm is operating at satisfactory level of GMP compliance. Moreover, it was observed that the firm did not have approved segregated psychotropic / narcotic tablet section in the layout plan. Separate store, and dispensing area for psychotropic drugs were provided, however a mixing room and a compression cabin in the general tablet area were designated for psychotropic tablet with common HVAC system operating in all the rooms. The packing area was also common.* ***The psychotropic section was not provided in the approved layout plan submitted by the firm and was not approved in the letter No. F. 1-28/93-Lic dated 30.06.2020 issued for renewal of DML. Hence the firm was advised to develop proper segregated psychotropic section, stop the production of psychotropic tablet without approved section and regularize the layout plan in this regard. As the firm has registration of psychotropic drug Anxnil Tablet 0.5mg without approved section, hence the matter may be referred to Drug Registration Board for further necessary action under the prescribed rules.***

Therefore, the panel recommends the firm for GMP certificate of following sections only.

1. *Tablet (General)*
2. *Oral Liquid (General)*
3. *Dry Suspension (General Antibiotic)*
4. *Capsule (General Antibiotic)*
5. *Tablet (Hormone)*
6. *Capsule (General)"*

4. Keeping in view the fact that the Panel has concluded that **"*The psychotropic section was not provided in the approved layout plan submitted by the firm and was not approved in the letter No. F. 1-28/93-Lic dated 30.06.2020 issued for renewal of DML. Hence the firm was advised to develop proper segregated psychotropic section, stop the production of psychotropic tablet without approved section and regularize the layout plan in this regard. As the firm has registration of psychotropic drug Anxnil Tablet 0.5mg without approved section, hence the matter may be referred to Drug Registration Board***

for further necessary action under the prescribed rules."It is therefore, proposed that the we may ask the quarter concerned to comment on the status of Psychotropic Section of the firm and as recommended by the panel the firm may be directed to **Suspend the Production in the Psychotropic Section in light of the conclusion of the report, with immediate effect**. The CLB in its 278th meeting has delegated the powers of "Show Cause Notices regarding contravention of any of the provision of Drugs Act, 1976 and rules framed there under (in case of GMP and Quality Control matters" to Addl. Director (QA&LT) in the absence of Director (QA&LT).

Action taken by DRAP:

The firm M/s. Pharmix Laboratories (Private) Limited, Lahore directed to immediately stop the production of Psychotropic Tablet without approval of Section and served Suspension of Production orders in Psychotropic Tablet Section vide letter No. F. 4-12/95-QA (Vol-I) dated 15.09.2021.

Reply of the Firm:-

The firm replied vide Letter No. Nil dated 28.07.2021 with the subject title *"Please Grant Approval for Continuation of Manufacturing Anxnil 0.5mg Tablet"*, wherein it is stated that with reference to the subject request letter we are manufacturing Anxnil 0.5mg (Alprazolam) Registration Number 017546 since 1996 in General Tablet Section. Sir, we manufacture ONE PRODUCT having only ONE POTENCY on campaign basis. In the current GMP inspection dated 07.07.2021 the Respected FID has asked to stop production until we are having a separate section for this product

Sir, we have:-

- Dedicated locked storage area (with restricted entry) with HEPA fitted dispensing booth in raw material warehouse.
- Dedicated mixing area with dedicated cube mixer.
- Dedicated compression machine.
- Dedicated dust collector with Tablet polisher.

Along with request letter please find following documents

1. Current inspection report
2. SOP for campaign basis
3. List of machinery hormonal section

Sir, as this is Anti-Psychotic Product and Patients are psychologically not comfortable to switch the brand. We request you to please allow us the production of Anxnil 0.5 tablets in General Section for 2 years meanwhile we will build our separate section as per DRAP advice.

Furthermore, The firm again replied vide Letter No. Nil dated 31.08.2022 with the subject title *"Suspension of Production Orders of Psychotropic Tablets"*, wherein it is stated that with reference to subject, we have received letter No. F. 4-12/95-QA (Vol-I) dated 15.09.2021 and have advised us to Stop Production of Anxnil (Alprazolam 0.5mg) Tablets Registration Number 017546 due to Non Availability of Psychotropic Segregated Section.

Sir, as now respected Licensing Board of Drugs Regulatory Authority Pakistan has given decision regarding segregated Psychotropic Section in 287th CLB Meeting and allowed to manufacture Psychotropic tablets in General Tablet Section so after that Decision we can manufacture Anxnil (Alprazolam 0.5mg) tablets registration number 017546 in General Tablet Section to serve the ailing humanity.

The Board therefore, decide that segregated requirement of psychotropic section is dispensed with in public interest to ensure availability of medicines for ailing patients.

Sir, we have sent you request letter on 20.07.2022 (Copy is attached) we request you to please allow for production as per Board decision.

The case is placed before the CLB in compliance to the decision of 287th meeting of CLB for resumption of production of Psychotropic Tablet in General Tablet Section subject to compliance of precautionary measures as advised by the Central Licensing Board.

DECISION OF 288TH MEETING OF CLB: -

The board after thorough deliberation on the facts of the matter; decided that the request of the firm to allow the resumption of production of Psychotropic Tablets in General Tablet Section cannot be acceded to, and is being linked with the decision of the CAQCS, Ministry of Narcotic Control, Pakistan.

Item No. IV **RATIFICATION OF DECISION OF 287TH MEETING OF CLB**

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

QA received vide letter No. 9448/2022-DRAP (L-V) dated 17.08.2022 with the subject title "Decision of Central Licensing Board in its 287th Meeting M/s. Dosaco Laboratories, 9.5-KM, Sheikhupura Road, Lahore (DML No. 000094)" from Additional Director (DRAP), Lahore. Wherein she enclosed inspection report of M/s. Dosaco Laboratories, 9.5-KM, Sheikhupura Road, Lahore with reference to DRAP, Islamabad letter No. F. 8-3/2022-QA (M-287-CLB) dated 07.07.2022. The inspection was conducted by following panel of inspectors on 27.07.2022, to check improvements made by the firm.

2. the panel concluded as under: -

Conclusion of Panel: -

"No production activity was being carried out at the time of inspection. Three areas were ready for inspection. The firm's management had made several improvements, section were revamped completely and most of the shortcomings had been rectified. Based on the findings of the inspection, review of documents and the personnel met, the panel of inspectors recommends the resumption of production of M/s. Dosaco Laboratories, 9.5-KM, Sheikhupura Road, Lahore in the following three sections only:

i. Liquid Injectable I (General)
ii. Liquid Injectable II (General)
iii. Oral Liquid Section (General)"

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 27.07.2022. Accordingly, resumption of production was allowed vide letter No. F. 4-50/89-QA (Vol-I) dated 22.08.2022.

The Case is placed before the board in compliance to decision of 287th& 278th meeting of CLB for ratification, please

DECISION OF 288TH MEETING OF CLB: -

The board endorsed/ratified the decision to resume the production activities in the specified sections of M/s Dosaco Laboratories, Lahore by the then Additional Director (QA&LT) in light of the decision of CLB from its 278th and 287th meeting.

DRAFT GUIDLINES ON ESTABLISHMENT OF PHARMACEUTICAL UNIT& POST LICENSE CHANGES

This document is applicable to any applicant/firm/company who intends to establish a New Pharmaceutical Unit and for approval/endorsement of post license changes. The details is on Annex-I.

ESTABLISHMENT OF PHARMACEUTICAL UNIT& POST LICENSE CHANGES

Guidelines Draft

Document Number: DLIC/GL/LC/001

Document History: 1st Edition

Effective Date: DD-MM-YYYY

Drug Regulatory Authority of Pakistan
Islamabad-Pakistan

HISTORY

This is the first edition of this document.

APPLICATION -

This document is applicable to any applicant/firm/company who intends to establish a New Pharmaceutical Unit and for approval/endorsement of post license changes.

PURPOSE

3.1. This document is aimed: -

3.1.1. To provide comprehensive information on the regulatory procedures for applicants/firms who are willing to apply for Grant, renewal of Drug Manufacturing License and other post license variations.

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INTRODUCTION

Division of Drug Licensing has been setup under Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) which is responsible for the licensing of the drugs manufacturing facilities and to perform other functions connected therewith.

DEFINITIONS& ACCRONYMS:

5.1 Site: Area/location being selected for establishment of Pharmaceutical unit**.**

5.2 Drug Manufacturing License:

Drug Manufacturing License is a license to manufacture drugs. There are five types of the Drug Manufacturing License which are as follow:

Types of Drug Manufacturing License:

i) By way of Formulation

ii) By way of Basic Manufacturing

iii) By way of Semi-Basic Manufacturing

iv) By way of Re-packing

v) For Experimental purpose.

5.3 Technical staff: The production activities in any pharmaceutical unit are carried out in the presence of approved Production Incharge& Quality control Incharge.

5.4 Active Pharmaceutical Ingredient (API's): means a substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a pharmacologically active compound (ingredient).

5.5 Inspection Book: Inspection Book is the document/ book issued at the time of Grant of Drug Manufacturing License.

5.6 Repacking Products/Drugs: The products/drugs which are enlisted in Schedule-D of Drugs (Licensing, Registration &Advertising) rules, 1976.

5.7 Central Licensing Board: Central Licensing Board is a statutory body for licensing of drug manufacturing facilities. CLB has been setup under section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with Clause (1) of Section 5 and Section 43 of the Drugs Act, 1976 (XXXI of 1976).

GUIDELINES FOR ESTABLISHMENT OF PHARMACEUTICA UNIT:

6.1 Guidelines for Site Verification:

6.1.1. The site/premises for establishment of pharmaceutical unit shall be located preferably in an industrial area and not in any residential or commercial area and size of the plot shall not be less than 2000 Sq Yards. The applicant submits the application along with documents as per check list attached as **Annexure-I** through PIRIMS (In case of any technical problem submission of documents on PIRIMS, hard form of the application shall be accepted in R & I of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

6.1.2. In case of shortcomings in the above said required documents the applicant is informed in writing for doing the needful.

6.1.3. On completion of the application, the field officers (Additional Director (E&M)/FID/Assistant Director) is asked for site verification with a copy of the letter to the firm for coordination with the concerned officers of the DRAP

6.1.4. The field officer (Additional Director (E&M)/FID/Assistant Director) inspects the site of the proposed pharmaceutical unit to check / verify the requirements for suitability of site as laid down under the Drugs Act, 1976 and Schedule B of the Drugs (L, R & A) Rules 1976 framed under the Drugs Act,1976.

6.1.5. The field officer then sends the report to Licensing Division, in either case (positive or negative report) in the light of provision of schedule B of the Drugs (Licensing, Registering and Advertising) Rules, 1976 either recommending or not recommending the site for establishment of Pharmaceutical Manufacturing Unit.

6.1.6. At present the Competent Authority for granting approval of Site for the establishment of a pharmaceutical unit is Chairman, Central Licensing Board as per delegation of powers approved by CLB under the Rules.

6.1.7. In case field officer recommends the site for establishment of Pharmaceutical Unit, the case/file is initiated / processed by the desk Officer for approval of Chairman CLB and same is communicated to the applicant/person/company.

6.1.8. In case of adverse report by the field officer the proposed site is rejected by the competent authority and communicated to the applicant/person/company accordingly.

6.1.9. In case of approval of the site, the firm is advised to submit the layout plan of the proposed pharmaceutical unit.

6.1.10. The firm is informed accordingly in either case as applicant may file an appeal before Appellate Board under the Law against the decision of CLB.

6.2. <u>Guidelines for Approval of the building layout plan</u>:

6.2.1. An applicant must get approval of building layout plan before construction from the Central Licensing Board.

6.2.2. Applicant submits application along with two copies of proposed layout plan through PIRIMS, in case of technical problem hard form of the application shall be accepted in R & I of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

6.2.3. The requirements for building layout plan are attached as **Annexure-II.**

6.2.4. The layout plan is scrutinized by the scrutiny committee as constituted by the Central Licensing Board. The Chairman of the Central Licensing Board also performs function of Chairman of the scrutiny committee for layout plan. The Layout Plan is approved by the committee in case it is found compliant to the requirement of Schedule-B of Drugs (Licensing, Registering& Advertising) rules, 1976 as per facilities being constructed and drawn on the proposed layout plan.

6.2.5 In case of major shortcomings in the layout plan, the observations are communicated to the applicant or a technical expert or representative of the firm is asked to discuss the layout plan with the licensing directorate. However, the minor shortcomings are rectified by the licensing directorate in the joint meeting.

6.2.6. After approval, the duly signed and stamped layout plan is sent to the firm for construction of the unit as per approved layout plan and further

necessary action. However, if approval is granted, the applicant is informed/advised to construct proper building structure with proper provision of safety exits under intimation / seek approval of the relevant building control authorities too.

6.3 <u>Guidelines for Grant of Drug Manufacturing License</u>:

6.3.1 After construction of the building, the firm submits application for grant of Drug Manufacturing License through PIRIMS, in case of technical problem hard form of the application shall be accepted in R & I of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing) on prescribed Form 1(**Annexure-III)**, after completion of construction of the unit as per approved layout plan, installation of machinery, equipment, HVAC system, engagement of the required technical personnel and completing other requirements as per the Drugs Act, 1976 and Rules framed there under.

6.3.2. The application is scrutinized by the licensing division and if found same in order, it is processed further and as per delegation of powers, a panel of experts is constituted by the Chairman, Central Licensing Board for inspection of the unit and evaluation of the provided facilities as required under the rules.

6.3.3. The field officer (Additional Director (E&M)/FID) is advised for coordinating with the other members of the panel and the firm's representative and conduct the panel inspection of the firm as per checklist / evaluation form and submit the report of inspection thereof.

6.3.4. If there is any shortcoming in the application, the same is communicated to the applicant for doing the needful in the light of observation made by the concerned officer (s) as per requirement of Rules. As the required information / documents are provided the case is processed as stated above.

6.3.5. The panel of experts / inspectors inspects the proposed pharmaceutical unit and carries out detailed evaluation of the requirements as laid down as per criteria/checklist under the Drugs Act, 1976, rules framed there under and practice in vogue.

6.3.6. In case of having all the required facilities made available and in order, the panel recommends the grant of Drug Manufacturing License for its approval by the Central Licensing Board and vice versa.

6.3.7. The field officer then sends the report to Licensing Division, in either case and same is placed before the Central Licensing Board for Grant of Drug Manufacturing License then the DML on Form-2 and inspection book with covering letter is issued to the firm.

7. GUIDELINES FOR POST LICENSURE CHANGES

7.1. Guidelines for Renewal of Drug Manufacturing License:

7.1.1. The Licensed firm before expiry of tenure submits application for the grant of renewal of Drug Manufacturing License on prescribed Form 1A, as per attached (**Annexure-IV**) through PIRIMS, in case of any technical problem hard form of the application shall be accepted in R & I of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

7.1.2. The application is scrutinized by the licensing division and if found same in order, it is processed further and as per delegation of powers, a panel of experts is constituted by the Chairman, Central Licensing Board for inspection of the unit and evaluation of the provided facilities as required under the rules.

7.1.3. The field officer (Additional Director (E&M)/FID) is advised for coordinating with the other members of the panel and the firm's representative and conduct the panel inspection of the firm as per checklist / evaluation form and submit the report of inspection thereof.

7.1.4. If there is any shortcoming in the application, the same is communicated to the applicant for doing the needful in the light of observation made by the concerned officer (s) as per requirement of Rules. As the required information / documents are provided the case is processed as stated above.

7.1.5. The panel of experts / inspectors inspects the proposed pharmaceutical unit and carries out detailed evaluation of the requirements as laid down as

per criteria/checklist under the Drugs Act, 1976, rules framed there under and practice in vogue.

7.1.6. In case of having all the required facilities made available and in order, the panel recommends the renewal of Drug Manufacturing License for its approval by the Central Licensing Board and vice versa.

7.1.7. The field officer then sends the report to Licensing Division, in either case and same is placed before the Central Licensing Board for Grant of renewal of Drug Manufacturing License then the DML on Form-2 with covering letter is issued to the firm.

7.1.8. Provided that if directed by the Central Licensing Board, the licensee shall rectify the observations made during the inspection within the period which shall not be less than one (01) month and more than three (03) months from the date of receipt of orders in this regard and during this period the manufacturing in that particular area or the premises, as the case may be, shall remain suspended and until after re-inspection the Board grants the renewal of license or otherwise reject the application and inform the licensee accordingly.

7.2 <u>Guidelines for Change of Qualified Staff (Production Incharge & Quality Control Incharge)</u>:

7.2.1. As per Rule 15 & 16 of Drugs (Licensing, Registering & Advertising) rules, 1976, the manufacture of Drugs shall be conducted under active directions and personal supervisions of qualified staff. The firm submits application for the approval of qualified staff (Production Incharge/Quality Control Incharge) in case, already approved qualified staff resign or terminated by the firm as per attached (**Annexure-V**) through PIRIMS, in case of technical problem hard form of the application shall be accepted in R & I of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

7.2.2. The Central Licensing Board has delegated the power to Secretary, Central Licensing Board for approval of qualified staff. In case the application is complete, approval letter is issued to the firm and if there is any shortcoming in the application, the same is communicated to the applicant for doing the needful.

7.3. Guidelines for Grant of Active Pharmaceutical Ingredient(s) (APIs):

7.3.1. A pharmaceutical firm having Drug Manufacturing License by way of Basic manufacture or Semi Basic Manufacture intends to manufacture active pharmaceutical ingredient (s) submits application for the grant of Active Pharmaceutical Ingredient (s) (APIs)as per attached **Annexure-VI** through PIRIMS, in case of technical problem hard form of the application shall be accepted in R & I of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

7.3.2. The application is scrutinized by the licensing division and if found same in order, it is processed further and as per delegation of powers, a panel of experts is constituted by the Chairman, Central Licensing Board for inspection of the unit.

7.3.3. If there is any shortcoming in the application, the same is communicated to the applicant for doing the needful in the light of observation made by the concerned officer (s) as per requirement of Rules. As the required information / documents are provided the case is processed as stated above

7.3.4. The field officer (Additional Director (E&M)/FID) is advised for coordinating with the other members of the panel and the firm's representative and conduct the panel inspection of the firm as per checklist / evaluation form and submit the report of inspection thereof.

7.3.5. The panel of experts / inspectors inspects the proposed pharmaceutical unit and carries out detailed evaluation of the requirements as laid down as per criteria/checklist under the Drugs Act, 1976, rules framed there under and practice in vogue.

7.3.6. The field officer then sends the report to Licensing Division, and same is placed before the Central Licensing Board for approval of Grant Active Pharmaceutical Ingredient (APIs) then approval letter is issued to firm.

7.4. Guidelines for Grant of additional /Revised/Regularized Section's:

7.4.1. A licensed pharmaceutical firm intends to develop new sections or amend the already approved sections or regularize their existing facility submits application for Grant of additional /Revised/Regularized Section (s) as per attached **Annexure-VII** through PIRIMS, in case of technical problem hard form of the application shall be accepted in R & I of DRAP,

Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

7.4.2. The application/ layout plan is scrutinized by the scrutiny committee as per requirements of Schedule-B of Drugs (Licensing, Registering& Advertising) rules, 1976. The Chairman of the Central Licensing Board also performs function of Chairman of the scrutiny committee for layout plan. The Layout Plan is approved by the committee in case it is found compliant to the requirement of Schedule-B of Drugs (Licensing, Registering& Advertising) rules, 1976 as per facilities being constructed and drawn on the proposed layout plan.

7.4.3. In case of shortcomings in the layout plan, the observations are communicated to the applicant or a technical expert or representative of the firm is asked to discuss the layout plan with the licensing directorate.

7.4.4. After approval, the duly signed and stamped layout plan is sent to the firm for construction of the unit as per approved layout plan and further necessary action. However, if approval is granted, the applicant is informed/advised to construct proper building structure with proper provision of safety exits under intimation / seek approval of the relevant building control authorities too.

7.4.5. The panel of experts / inspectors inspects the proposed pharmaceutical unit/facility and carries out detailed evaluation of the requirements as laid down as per criteria/checklist under the Drugs Act, 1976, rules framed there under and practice in vogue.

7.4.6. The field officer then sends the report to Licensing Division, and same is placed before the Central Licensing Board for approval of Grant of additional /Revised/Regularized Section's by the panel then approval letter is issued to firm.

7.5. <u>Guidelines for issuance of Inspection Book</u>:

7.5.1. A licensed Pharmaceutical firm submits application for the issuance of inspection book as per attached (**Annexure-VIII**) through PIRIMS, in case of technical problem hard form of the application shall be accepted in R & I of DRAP, Islamabad only after verification by Director (Licensing)/

Additional Director (Licensing). in case the already issued inspection book is lost or damaged or finished.

7.5.2. The Central Licensing Board has delegated the power to Secretary, Central Licensing Board for approval of issuance of inspection book. In case the application is complete, inspection book is issued to the firm and if there is any shortcoming in the application, the same is communicated to the applicant for doing the needful.

7.5.3. **Guidelines for Change of Management/ Title of Firm:**

7.5.4. A licensed pharmaceutical firm submits application for the change of management/title of the firm (APIs) as per attached **Annexure-IX** through PIRIMS, in case of technical problem hard form of the application shall be accepted in R & I of DRAP, Islamabad only after verification by Director (Licensing)/ Additional Director (Licensing).

7.5.5. If the application is complete, case is placed is placed before the Central Licensing Board and letter is issued to the firm afterwards. If there is any shortcoming in the application, the same is communicated to the applicant for doing the needful.

8. REFERENCES:

8.1 The Drugs Act, 1976.

8.2 The Drugs (Licensing, Registering & Advertising) Rules, 1976.

8.3 The DRAP Act, 2012.

ANNEXURE -I

DOCUMENTS / INFORMATION REQUIRED FOR SITE VERIFICATION FOR ESTABLISHMENT OF A PHARMACEUTICAL UNIT

Following listed documents / information's required for processing the request / application;

i. Proper application on covering letter on letter head.

ii. Prescribed fee of Rs.75,00/- for site verification.

iii. Disclosure of status of firm: proprietorship, partnership, public limited or private limited etc.

iv. Copy of Partnership deed duly executed in the court of competent jurisdiction/registrar of the firms & Copy of Certificate of Registration (Form-C) with Registrar of firms in case of partnership.

v. Copy (s) of CNIC of Chief Executive Officer / Managing Director /Directors/ Partners.

vi. Declaration of firm on stamp paper, In case of Sole Proprietorship Company.

vii. Complete documents of proposed land / plot in the name of firm or its all Directors/partners (purchase document of land/plot, allotment letter, transfer letter/ possession letter, Fard, copy of site map or Aks Shajrah etc.)

viii. In case if firm is Private Limited, the Certificate of Incorporation with SECP, Memorandum and Article of Association, Form-A, Form-21 and Form-29 should also be furnished. (Attested by SECP)

ix. All documents submitted should be duly attested by Notary Public /SECP/Registrar of firms, office as the case may be.

*As per requirement of paragraph 1.1 of Schedule B under the Drugs (Licensing, Registering and Advertising) Rules 1976, the proposed site shall be located preferably in Industrial area and in any case not in any Residential or commercial area and as per paragraph 1.3 of schedule 'B' the size of plot shall not be less than 2000 Sq. Yards.

ANNEXURE -II

DOCUMENTS / INFORMATION REQUIRED FOR APPROVAL OF BUILDING LAYOUT PLAN.

1. Proper application on covering letter on letter head.
2. Prescribed fee of Rs.75,00/- each section/facility.
3. Two (02) copies of proposed layout plan.
4. Highlight the proposed amendments on copy of approved master layout plan.

REQUIREMENTS OF AREA ACCORDING TO SCHEDULE B-1

S. No	Section	Minimum Area	Remarks
1	External Appliances or Suspension	200 Sq. ft.	
2	Syrups, Elixirs & Solutions	300 Sq. ft.	
3	Compressed Tablets	900 Sq. ft.	Should be divided into three distinct subsections situated in different rooms (Granulation, Compression, Coating) Hypodermic Tablets in aseptic & separate room
5	Hard Gelatin Capsules	200 Sq. ft.	
7	Eye ointments, Eye drops, Eye lotions and other use	250 Sq. ft.	Manufacture and filling shall be in aseptic conditions
8	Pessaries and Suppositories	200 Sq. ft.	If compression is involved, a separate room with min. 300 Sq. ft
9	Inhaler and Vitrallae	200 Sq. ft.	
10	Repacking	300 Sq. ft.	
12	Hypodermic Disposable Syringes	900 Sq. ft.	
13	Hypodermic Disposable needles	600 Sq. ft.	
14	Infusion Set	900 Sq. ft.	
	Sterilization	400. ft./unit of sterilizer	

5. Dedicated and self -contained facilities for the production of particular drugs shall be provided in addition to the general facilities such as highly sensitizing materials (e.g. penicillin) or biological preparations (e.g. live microorganisms) or cytotoxic substances or radiopharmaceutical or veterinary immunological preparations or sterile products or for that matter such other highly active pharmaceutical products, antibiotics, hormones, as may be identified by the Central Licensing Board at any stage.
6. Men and material flow maybe intimated in different colored arrows.

ANNEXURE -III

DOCUMENTS / INFORMATION REQUIRED FOR GRANT OF DRUG MANUFACTURING LICENSE

"FORM-1

[See rule 5(1)]

APPLICATION FORM FOR GRANT OF A LICENSE TO MANUFACTURE DRUGS BY WAY OF FORMULATION/BASIC MANUFACTURE/ SEMI-BASIC MANUFACTURE/RE-PACKING.

I/We _____ of _____ hereby apply for the grant of a license to manufacture by way of _____ on premises situated at _____.

2. The drug (s) or class (es) of drugs intended to be manufactured: -

   (I) Class (es) of drugs

   (II) Dosage form(s) of drugs.

   (III) Name of drug (s).

3. I enclose: -

   (i) Particulars regarding legal status of the applicant (i.e. in case of proprietorship the name(s) of proprietors and their address(es), in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).

   (ii) Details of the premises including layout plan of the factory.

   (iii) Details of the section-wise equipment and machinery for manufacture and quality control.

   (iv) Names and qualifications of the Production Incharge and Quality Control Incharge for supervising manufacturing processes and Quality Control Department, and other technical staff working in these departments.

4. The premises and plant will be ready for inspection on …….. or are ready for inspection.

Date…….. Signed……..

Place ……. Name, designation and address of the signatory..... ……..

ANNEXURE -IV

DOCUMENTS / INFORMATION REQUIRED FOR GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE

FORM-1A

I/We _____ of _____ hereby apply for the renewal of a license to manufacture by way of _____ on premises situated at _____.

1. The drug (s) or class (es) of drugs intended to be manufactured: -
   - (I) Class (es) of drugs
   - (II) Dosage form(s) of drugs.
   - (III) Name of drug (s).
2. There have been / have not been any change in respect of: -I enclose: -
   - **i.** Name of the proprietor (s) / directors (s)/ partner (s).
   - **ii.** Details of the premises including layout plan of the factory.
   - **iii.** Details of the section-wise equipment and machinery for manufacture and quality control.
   - **iv.** Names and qualifications of the Production In-charge and Quality Control In-charge for supervising manufacturing processes and Quality Control Department, and other technical staff working in these departments.
3. Statement of the Central Research Fund.

   Following statement, as per audited accounts/ based on Income Tax Return for the last five years:-

Year	Investment	Turn-over***	CRF due	C.R.F. ** paid as per Col.4.
1	2	3	4	5

*If there is any change it should be furnished.

**(Original Challan attached).

***Central Research Fund at the rate of 1% of gross profit before deduction of income tax.

(a) Attested copies of the last two income tax assessment order of the Income Tax Department attached.

Dated…… Signed……

Place …… Name Designation & Address……..

ii). Copy of Challan of Fee original duly retained by Statistical Officer DRAP as per following schedule, to be deposited under the following head of account:

A/C No. 0010008463-700018 Allied Bank Limited

1) Fee of Rs. 50,000/- for renewal of DML by way of Formulation.
2) Fee of Rs. 15,000/- for renewal of DML by way of Basic and Semi Basic Formulation.
3) Fee of Rs. 30,000/- for renewal of DML by way of Repacking.
4) Fee of Rs. 5,000/- per Drugs specified in Schedule D for repacking.

iii). **All documents submitted should be duly attested.**

DOCUMENTS / INFORMATION REQUIRED FOR CHNAGE OF QUALIFIED STAFF (PRODUCTION INCHARGE/QUALITY CONTROL INCHARGE)

1. Proper application on covering letter on letter head.
2. Prescribe fee of Rs. 75,00/- for proposed Production or Q.C Incharge.
3. Appointment letter.
4. Job acceptance letter by the appointee.
5. Copy of CNIC of appointee.
6. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
7. Registration certificate from Pharmacy Council (in case of Production Incharge).
8. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
9. Resignation / retirement of earlier Production Incharge / QC Incharge.
10. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
11. Undertaking as whole time employee on stamp paper.

LETTER OF UNDERTAKING FOR PRODUCTION INCHARGE

I ----------, S/O ---------- CNIC No. ---------- and Managing Director ---------- CNIC No. ---------- For the management of ---------- ---------- do here by agree that proposed Production Incharge ---------- is whole time employee of the firm and not working anywhere else. We hereby confirm that the information / documents provided for academic qualification and experience as per Rule 16-c of Drugs (Licensing, Registering & Advertising) Rules, 1976 are correct and up-to-date.

Management signature / Date **Production Incharge signature / date**

LETTER OF UNDERTAKING FOR QUALITY CONTROL INCHARGE

I ----------, S/O ---------- CNIC No. ---------- And Managing Director ---------- CNIC No. ---------- For the management of ---------- ---------- do here by agree that proposed Quality Control Incharge ---------- is whole time employee of the firm and not working anywhere else. We hereby confirm that the information / documents provided for academic qualification and experience as per Rule 16-e of Drugs (Licensing, Registering & Advertising) Rules, 1976 are correct and up-to-date.

Management signature **Q.C Incharge Signature**

13.All documents should be attested by gazette officer or Notary Public.

DOCUMENTS / INFORMATION REQUIRED FOR GRANT OF ACTIVE PHARMACEUTICAL INGREDIENT(S)

1. Proper application on covering letter on letter head.
2. Prescribed fee of Rs. 75,00/- per API.
3. Names and quantities of chemicals to be used in manufacturing.
4. Names and quantities of chemicals to recycled in manufacturing.
5. Manufacturing process steps and flow chart.
6. Theoretical yield of manufacturing process.
7. Trial batches record and stability data along with validation (if available).
8. Reference monograph and Testing method
9. List of Testing equipments
10. Shelf life of API
11. Material safety data sheet
12. **All documents should be duly attested/verified by approved technical staff along with Company stamp.**

DOCUMENTS / INFORMATION REQUIRED FOR APPROVAL OF ADDITIONAL/REVISED/REGULARIZED SECTION(S)

7. Proper application on covering letter on letter head.
8. Prescribed fee of Rs.75,00/- each section/facility.

9. Two (02) copies of proposed layout plan.
10. Highlight the proposed amendments on copy of approved master layout plan.

REQUIREMENTS OF AREA ACCORDING TO SCHEDULE B-1

S. No	Section	Minimum Area	Remarks
1	External Appliances or Suspension	200 Sq. ft	
2	Syrups, Elixirs & Solutions	300 Sq. ft	
3	Compressed Tablets	900 Sq. ft	Should be divided into three distinct subsections situated in different rooms (Granulation, Compression, Coating) Hypodermic Tablets in aseptic & separate room
5	Hard Gelatin Capsules	200 Sq. ft	
7	Eye ointments, Eye drops, Eye lotions and other use	250 Sq. ft	Manufacture and filling shall be in aseptic conditions
8	Pessaries and Suppositories	200 Sq. ft	If compression is involved, a separate room with min. 300 Sq. ft
9	Inhaler and Vitrallae	200 Sq. ft	
10	Repacking	300 Sq. ft	
12	Hypodermic Disposable Syringes	900 Sq. ft	
13	Hypodermic Disposable needles	600 Sq. ft	
14	Infusion Set	900 Sq. ft	
	Sterilization	401. ft/unit of sterilizer	

11. Dedicated and self contained facilities for the production of particular drugs shall be provided in addition to the general facilities such as highly sensitizing materials (e.g. penicillin) or biological preparations (e.g. live microorganisms) or cytotoxic substances or radiopharmaceutical or veterinary immunological preparations or sterile products or for that matter such other highly active pharmaceutical products, antibiotics, hormones, as may be identified by the Central Licensing Board at any stage.
12. Men and material flow maybe intimated in different colored arrows.

ANNEXURE -VIII

DOCUMENTS / INFORMATION REQUIRED FOR ISSUANCE OF INSPECTION BOOK

i). Proper application on covering letter on letter head.

ii). Prescribed fee of Rs.75, 00/- for Issuance of Inspection Book.

iii). Copy of last three pages of previous inspection book.

iv). Copy of FIR and Advertisement in National News Paper (in case of lost / damaged inspection book).

v). All documents should be attested by gazetted officer or Notary Public.

ANNEXURE -IX

DOCUMENTS / INFORMATION REQUIRED FOR CHANGE OF MANGEMENT/TITLE OF FIRM

1. Proper application on covering letter on letter head.

2. A Fee equivalent to fee for renewal of DML.

3. Copy of revised partnership deed, Agreement of Sale and Transfer of Share/ Transfer Deeds and NOC from Previous Owners on Stamp Paper (In Case of Partnership firm).

4. Undertaking as sole proprietor on stamp paper and NOC from Previous Owner on Stamp Paper (In Case Of sole proprietor firm).

5. Latest certified true copy of Form-29 or Form-A duly attested from S.E.C.P (In Case of Private Limited)

6. Copies of CNIC'S (Previous and New Management).

7. All documents should be attested by gazetted officer or Notary Public.