MINUTES OF 287th MEETING OF CENTRAL LICENSING BOARD HELD ON 24thJUNE, 2022

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287th meeting of the Central Licensing Board (CLB) was held on 24th June, 2022 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad. Mr. Abid Ali, Law Expert, Ministry of Law & Justice Division, Islamabad/Member Central Licensing Board, Drug Regulatory Authority of Pakistan, Islamabad presided the meeting in the absence of Chairman as provided under Rule 8(8) of the Drugs (Licensing, Registering &Advertising) Rules, 1976. Following members attended the meeting:-

S.No	Name & Designation	Status
1	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Balochistan, Quetta	Member
2	Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Bannu Government of Khyber Pahtunkwa	Member
3	Mr.Ghulam Ali Lakho, Drug Inspector, Government of Sindh, Karachi	Member
4	Dr. Hafsa Karam Ellahi, Addl Director, Representative, Division of Quality Assurance and Lab Testing, Drug Regulatory Authority of Pakistan, Islamabad	Member
4	Mr. Manzoor Ali Bozdar, Addl Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
5	Mr Khalid Muneer, Representative of PPPMA	Observer
6	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
7	Mr Kamran Anwar, Representative of Pharma Bureau.	Observer

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

Item-I **CONFIRMATION OF THE MINUTES OF 286TH MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 286th meeting of the Central Licensing Board (CLB) held on 11th May, 2022 with incorporating correction of Drug manufacturing number of M/s Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore.

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 /	Ranking/ Evaluation	Inspection Panel Members
1	M/s Oncogen Pharma (Pvt) Ltd., Plot No. WH-26&27/A3, Korangi Creek Industrial Park, Karachi. Sections (02): i. Tablet Section (Oncology). ii. Capsule Section (Oncology).	08-06-2022	Good	1. Dr. Abdullah Dayo, Expert Member. 2. Mr. Najam-us-Saqib,FID, DRAP, Karachi. 3. Dr. Sanam Kausar, AD, DRAP, Karachi.
	"Based on the people met, the documents reviewed and considering the findings of the inspection M/s Oncogen Pharma (Pvt) Ltd, Plots No. WH-26 & 27-A3, Korangi Creek Industrial Park Karachi is considered to be designed and established at an acceptable level of compliance of GMP requirements. Therefore, the panel recommends approval for grant of new DML (By way of Formulation) . **Decision of the Central Licensing Board in 287th meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Oncogen Pharma (Pvt) Ltd, Plots No. WH-26 & 27-A3, Korangi Creek Industrial Park Karachi on the recommendations of the panel of experts for the following sections: **Sections (02):** 1. Tablet Section (Oncology). 2. Capsule Section (Oncology).			
2	M/s Anthro API-Gen (Pvt) Ltd., Plot No.04. Street No. N-4, RCCI Industrial Estate, Rawat, Islamabad. **(By way of Semi Basic Manufacturing)**	13-06-2022 & 14-06-2022	**GOOD**	1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad 2. Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad. 3. Malik Muhammad Asad, Deputy Director (Licensing), DRAP, Islamabad

Recommendations of the panel:

"Keeping in view the manufacturing and testing facility in place, the panel unanimously **recommended** the approval of drug manufacturing license by way of **semi-basic manufacturing** to M/s Anthro API-Gen (Pvt) Ltd., Plot No.04. Street No. N-4, RCCI Industrial Estate, Rawat, Islamabad, for manufacturing of following 14 active pharmaceutical ingredients for Semi basic manufacturing. The responsibility lies with the manufacturer to ascertain the regulatory requirements during the validity period of DML.

Multi-Purpose Non-Sterile

1. Montelukast sodium (BP-2022)
2. Esomeprazole (BP-2022)
3. Omeprazole (BP-2022)
4. Paracetamol (BP)
5. Moxifloxacin hydrochloride (BP)
6. Ciprofloxacin Base (BP)
7. Itraconazole (JP)
8. Levitericetam (USP)
9. Clarithromycin (BP)
10. Azithromycin (BP)
11. Ciprofloxacin hydrochloride (BP)
12. Drotaverine hydrochloride (In House Anthro Specifications)
13. Levofloxacin hemihydrate (BP)
14. Dexlansoprazole (In house Anthro Specifications)"

Decision of the Central Licensing Board in 287th meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of **semi-basic manufacturing** to M/s Anthro API-Gen (Pvt) Ltd., Plot No.04. Street No. N-4, RCCI Industrial Estate, Rawat on the recommendations of the panel of experts for the following facility and APIs:

Multi-Purpose Non-Sterile

1. Montelukast sodium (BP-2022)
2. Esomeprazole (BP-2022)
3. Omeprazole (BP-2022)
4. Paracetamol (BP)
5. Moxifloxacin hydrochloride (BP)
6. Ciprofloxacin Base (BP)
7. Itraconazole (JP)
8. Levitericetam (USP)
9. Clarithromycin (BP)
10. Azithromycin (BP)
11. Ciprofloxacin hydrochloride (BP)
12. Drotaverine hydrochloride (In House Anthro Specifications)
13. Levofloxacin hemihydrate (BP)
14. Dexlansoprazole (In house Anthro Specifications)"

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1	M/s Standpharm Pakistan (Pvt) Ltd, 20-KM, Ferozepur Road, Lahore DML No.000051 (Formulation).	12-04-2022	**Good**	1. Dr. Farzana Chowdhary, Member. 2. Aisha Irfan, FID DRAP, Lahore 3. Anam Saeed, Assistant Director, DRAP Lahore.
	Recommendations of the panel: - In view of above inspection proceedings and facilities verified, such as company profile, building, material management, production, in-process controls, Quality Control testing, machinery / equipment, air handling, water treatment system, personnel and documentation etc, the panel of inspectors recommends the grant of additional sections to M/s. Standpharm Pakistan (Pt) Ltd, 20-Km, Ferozepur Road, Lahore by way of formulation to the following sections only:- 1. Liquid Injectable Ampoule (General) Section (New) **2.** 2. Liquid Injectable Vial LVP (General) Section (New) **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. Standpharm Pakistan (Pt) Ltd, 20-Km, Ferozepur Road, Lahore under DML No.000051 (Formulation) on the recommendations of the panel of experts: **Section (02):** 1. Liquid Injectable Ampoule (General) Section (New) **2.** Liquid Injectable Vial LVP (General) Section (New)			
2	M/s. Neutro Pharma (Pvt.) Ltd., situated at 9.5-km, Sheikhupura Road, Lahore DML No.000576 (Formulation) **Section (01):** Liquid Injectable (Ampoule) (General) Section (New).	**13-04-2022 & 14-04-2022**	**Good**	i. Dr. Ikram Ul Haq, Expert Member ii. Majida Mujahid, Additional Director, DRAP, Lahore. iii. Abdul Rashid Sheikh, FID, DRAP, Lahore. iv. Anam Saeed, 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, the panel of inspectors **recommends** the renewal of Drug Manufacturing License by way of formulation along with regularization of M/s. Neutro Pharma (Pvt.) Ltd., Lahore. layout plan to M/s.			

	Neutro Pharma (Pvt.) Ltd., situated at 9.5-km, Sheikhupura Road, Lahore for the following sections: 1. Tablet (General) Section. 2. Capsule (General) Section. 3. Tablet (General) Antibiotic Section. 4. Oral Liquid General Section. 5. Dry Powder for Suspension Section. 6. Cream/Ointment (General) Section. 7. Liquid Injection Ampoule/vial (General) Section. 8. Lyophilization Section. 9. LVP Section (Blow, Fill, Seal). 10. SVP Section (Blow, Fill, Seal). 11. Tablet (Psychotropic) Section. 12. Capsule (Psychotropic) Section. 13. Liquid Injection Psychotropic Section. 14. Capsule (Cephalosporin) Section. 15. Dry Powder Suspension (Cephalosporin) Section. 16. Dry Powder Injection (Cephalosporin) Section. The panel of inspectors also **recommends** grant of following additional section to M/s. Neutro Pharma (Pvt.) Ltd., situated at 9.5-km, Sheikhupura Road, Lahore: 1. Liquid Injectable (Ampoule) (General) Section (New). **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. Neutro Pharma (Pvt.) Ltd., situated at 9.5-km, Sheikhupura Road, LahoreunderDML No.000576 (Formulation) on the recommendations of the panel of experts: **Section (01):** 1. Liquid Injectable Ampoule (General) Section (New)			
3	M/s Filix Pharmaceuticals (Pvt) Ltd, Plot No. 4-A, Main Road, RRCI, Rawat. DML No. 000779 (Formulation). **Section (02):** 1. Capsule Section (Cephalosporin). 2. Dry Powder for Suspension Section (Cephalosporin).	**18-01-2022 & 19-01-2022**	**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, the panel unanimously **recommended** for the grant of Renewal of Drug Manufacturing License No. 000779 (by way of formulation) w.e.f. 30.08.2018 to 29.08.2023 and Additional Section to M/s Filix Pharmaceuticals, Plot No. 4-A, Main Road, NIZ, Rawat, Rawalpindi for following sections namely as of			

	today: Renewal: 1. Tablet Section (Gen) 2. Capsule Section (Gen). Additional Section: - 1. Capsule Section (Cephalosporin) 2. Dry Powder for Suspension Section (Cephalosporin) NOTE: Scope of the inspection was limited to the verification of compliance in terms of manufacturing and testing facilities, as committed in approved layout plan, which was found satisfactory under the best knowledge and belief. The panel could not guarantee the strength of building and safety of installed electric panels. The verification of strength of building and safety of installed electric panels is a technical job and pertains to civil and electrical engineers." **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 Filix Pharmaceuticals (Pvt) Ltd, Plot No. 4-A, Main Road, RRCI, RawatunderDML No.000779 (Formulation) on the recommendations of the panel of experts: **Section (02):** 1. Capsule Section (Cephalosporin) 2. Dry Powder for Suspension Section (Cephalosporin) However, Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad who was present in the meting who disowned the note by Federal Inspector of Drugs and contended that it personal opinion of the Federal Inspector of Drugs and should not be considered as opinion of the panel.			
4	M/s. Sami Pharmaceuticals (Pvt) Ltd, Plot No.F-95, Off Hub River Road, Karachi.p DML No.000072 (Formulation) 1. Sterile Dry Powder Injection (General) in place of Liquid Injection (General) -II – **Second Floor** 2. Research & Development Laboratory – Expansion in place of Tablet (Hormone) Section – **Ground Floor** 3. Microbiology Laboratory in	**16th, 17th,20th, 23rd& 24th May 2022**	**Good**	1. Dr. Saif -ur-Rehman Khttak, CDL, DRAP, Karachi. 2. FID, DRAP, Karachi 3. Mrs. Sanam Kausar, Assistant Director, DRAP, Karachi.

	place of Quality Assurance Department – Second Floor. 4. R & D Laboratory (Oncology) – **Second Floor**			

Recommendations of the panel:

Following sections were also inspected and found satisfactory as per approved layout plan accordingly panel recommends the following sections :

1. Sterile Dry Powder Injection (General) in place of Liquid Injection (General) -II – **Second Floor**
2. Research & Development Laboratory – Expansion in place of Tablet (Hormone) Section – **Ground Floor**
3. Microbiology Laboratory in place of Quality Assurance Department – Second Floor.
4. R & D Laboratory (Oncology) – **Second Floor**

A compact raw material and packaging material storage area has also been provided with appropriate HVAC system and other control arrangement at F-95 site.

Moreover, another facility situated at walking distance on Plot No. F-140/A has been granted DML No. 000938(Formulation) by DRAP. This facility has been authorized to share for materials belonging to DML No. 000072 also. Hence, DML No. 000938(Formulation) is housing manufacturing areas for spansules and dedicated large three storeys areas for raw material, packaging material and finished goods store. The storage areas are provided with arrangements such as HVAC system, dedicated staff and other control and monitoring system.

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. Sami Pharmaceuticals (Pvt) Ltd, Plot No.F-95, Off Hub River Road, Karachi under DML No.000072 (Formulation) on the recommendations of the panel of experts:

Section (04):

1. Sterile Dry Powder Injection (General) in place of Liquid Injection (General) -II – **Second Floor**
2. Research & Development Laboratory – Expansion in place of Tablet (Hormone) Section – **Ground Floor**
3. Microbiology Laboratory in place of Quality Assurance Department – Second Floor.
4. R & D Laboratory (Oncology) – **Second Floor**

The Board did not accept the remarks/ recommendations of the panel regarding keeping raw material of one licenced facility at an other as such activity is not in accordance with law. The Board therefore advised that manufacturer should avoid and

	remove such material without delay. The Federal Inspector of Drugs is advised to ensure compliance of the decision of the Board without delay and report.			
5	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:

i. 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, Rawat under DML 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)			
6	M/s Selmore Pharmaceuticals (Pvt) Ltd, 36-KM, Multan Road, Lahore, DML No. 000507 (Formulation)	**14/03/2022**	**Good**	1. Dr. Farzana Chowdhary, Member. 2. Mr. Ajmal Sohail Asif, FID (F) DRAP, Lahore 3. Ms. Maham Misbah, Assistant Director, DRAP Lahore.
	Recommendations of the panel: Based on the areas inspected, the technical people met and the documents reviewed, and considering the findings of the inspection the panel verified that the firm has developed the following manufacturing facilities as per approved layout plan: 1. Liquid Injectable Cephalosporin (Veterinary). 2. Dry Powder Injectable Cephalosporin (Veterinary). 3. Liquid Injectable Vial-I General (Veterinary). 4. Liquid Injectable Vial-II General (Veterinary). 5. External Liquid Preparation (Veterinary). 6. External Powder Preparation (Veterinary). **RECOMMENDATION:** The panel of inspectors Recommends the approval/grant of above-mentioned new/additional manufacturing sections in favour of M/s Selmore Pharmaceuticals (Pvt) Ltd., 36 Km, Multan Road, Lahore under DML bearing No. 000507. **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 Selmore Pharmaceuticals (Pvt) Ltd., 36 Km, Multan Road, Lahore under DML			

	No.000507 (Formulation) on the recommendations of the panel of experts: **Section (06):** 1. Liquid Injectable Cephalosporin (Veterinary). 2. Dry Powder Injectable Cephalosporin (Veterinary). 3. Liquid Injectable Vial-I General (Veterinary)-Revised 4. Liquid Injectable Vial-II General (Veterinary) **in place of** Injectable steroid (Veterinary) 5. External Liquid Preparation (Veterinary) **in place of** pesticide/insecticide/disinfectant Liquid preparation (Veterinary) 6. External Powder Preparation (Veterinary) **in place of** pesticide/insecticide/disinfectant powder preparation (Veterinary)			
7	M/s ICI Pakistan., S-33, Hawkes Bay Road, Karachi. DML No. 000006 (Formulation) Sections (03) : 1. Tablet(General) -Revised 2. Capsule (General) – New 3. Liquid Syrup(General) - Revised	**04-06-2022**	**Good**	1. Dr. Abdullah Dayo, Expert Member. 2. FID, DRAP, Karachi 3. Dr. Sidra Yasmeen, Assistant Director, DRAP, Karachi
	Recommendations of the panel: "Keeping in view of the facts and positive intention of the firm the panel unanimously recommends the following sections in DML No. 000006(Formulation) of the firm: 1. Tablet(General) -Revised 2. Capsule (General) – New 3. Liquid Syrup(General) - Revised **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 ICI Pakistan., S-33, Hawkes Bay Road, KarachiunderDML No.000006 (Formulation) on the recommendations of the panel of experts: **Section (03):** 1. Tablet(General) -Revised 2. Capsule (General) – New 3. Liquid Syrup(General) - Revised			
8	M/s Rotex Pharma (Pvt) Ltd, Plot No.206 & 207, Industrial Triangle, Kahuta Road, **Islamabad**. DML No. 000651 (by way	26-01-2022	**Good**	i. Dr. Hafsa Karam Ellahie, Additional Director, QA&LT Division, DRAP, Islamabad ii. Mr. Ch. Zeeshan

	Formulation).			Nazir, Additional Director, Biological Division DRAP, Islamabad iii. Saadia Mahwish, Area FID, DRAP, Islamabad

Recommendations of the panel: -

M/s Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad has requested for correction in the following licensed Sections;

S.No	Name of Licensed Section	Corrigendum Required
1.	Biotech rDNA Vial Section. (filling and sealing)	Biotech rDNA Vial Section.
2.	Biological – Non-rDNA Vial Section. (filling and sealing)	Biological – Non-rDNA Vial Section.
3.	Biological – Vaccines Ampoule Filling & Sealing (Ready to Fill Form).	Biological – Vaccines Ampoule Filling & Sealing (Ready to Fill Form).
4.	Restructuring/Extension of QC as per approved layout.	Restructuring/Extension of QC as per approved layout.

It is pertinent to mentioned that the Central Licensing Board in its 274th meeting held on 07th April, 2020 has considered and approved the grant of following four additional section to the firm M/s Rotex Pharma (Pvt) Ltd, Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad (Drug Manufacturing License No. 000651 (Formulation), accordingly;

1. Biotech rDNA Vial Section. (filling and sealing)
2. Biological – Non-rDNA Vial Section. (filling and sealing)
3. Biological – Vaccines Ampoule Filling & Sealing (Ready to Fill Form
4. Restructuring/Extension of QC as per approved layout.

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

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to the firm in next meeting of Central Licensing Board.

A letter of personal hearing is served to the firm to appear personally before the Board.

Decision of the Central Licensing Board in 284th meeting:

Mr. Umer Farooq Director of the firm appeared before the Board along with Mr. Shoaib Manager Biological on behalf of the firm . The Board decided to verify the facility by the following panel of experts for the said purpose :

1. Additional Director (QA/LT), DRAP, Islamabad.
2. Additional Director (Biological), DRAP, Islamabad.

	3. Area FID, DRAP, Islamabad. **Proceedings of the Central Licensing Board in 287th meeting:** The panel constituted in light of Decision of the CLB inspected the premises and submitted its report. **Recommendations of the panel: -** Keeping in view the above facts on record, people met during the visit, and the reports relating to re-calibration of clean class status of identified areas, the panel unanimously **recommended the approval**offollowing additional (new) sections ofRotex Pharma (PVT) Ltd. Plot #206 -207, Industrial triangle, Kahuta road, Islamabad. 1. Biotech rDNA Vial Section (Formulation, Filling & Sealing) 2. Biological – Non-rDNA Vial Section (Formulation, Filling & Sealing) 3. Biological – Vaccines Ampoule Filling & Sealing (Ready to Fill Form) 4. Restructuring / Extension of QC as per approved layout **Decision of the Central Licensing Board in 287th meeting:** During the meeting, secretariat of CLB apprised that as request and deliberation of the Board in its previous meeting, the request of the frim was correction in the name of section as mentioned above. Therefore, the Board after considering the facts and perusal of the record, approved the correctio in the name of section as us under; 1. Biotech rDNA Vial Section (Formulation, Filling & Sealing) 2. Biological – Non-rDNA Vial Section (Formulation, Filling & Sealing) 3. Biological – Vaccines Ampoule Filling & Sealing (Ready to Fill Form) 4. Restructuring / Extension of QC (Revised)			
9	M/s. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo town, 20-km, Ferozepur Road, Lahore. DML No. 000736 (Formulation) Sections (02): i. Powder Injectable (Penicillin) Section (New) ii. Oral Powder (Penicillin) Section (New).	**11-03-2022**	**Good**	i. Dr. Zaka Ur Rehman COO, PDTRC, Lahore ii. Ms. Aisha Irfan, FID, DRAP, Lahore, iii. Ms. Ufaq Tanveer, 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 of inspectors **recommends** to grant following additional sections to M/s. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo town, 20-km, Ferozepur Road, Lahore: i. Powder Injectable (Penicillin) Section (New) ii. Oral Powder (Penicillin) Section (New). **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. Evergreen Pharmaceuticals, 69-70/B, Main Glaxo town, 20-km, Ferozepur Road, Lahore under DML No.000736 (Formulation) on the recommendations of the panel of experts for the following sections: iii. Powder Injectable (Penicillin) Section (New) iv. Oral Powder (Penicillin) Section (New).

Item-III: **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 Welwrd Pharmaceuticals, Plot No.3, Block A, Phase-I & II, Industrial Estate, Hattar. DML No.000574 Period: Commencing on 20-05-2020 & ending on 19-05-2025.	**30-03-2022**	**Good**	1. Prof. Dr. Jamshed Ali Khan, Expert Member, 2. Area Federal Inspector of Drugs, DRAP, Peshawar, 3. Area Assistant Director, DRAP, Peshawar.
	Recommendations of the panel: Based on documentation reviewed, technical / management people met, materials/ processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab 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 from 20.05.2020 for following sections as per DRAP letter No. F/3-9/2004-Lic			

(Vol-I) dated 18.02.2021.

Sr. No	Name of Section	Sr. No	Name of Section
1.	Tablet (General)	5.	Injection Vial (Cephalospori
2.	Capsule (General)	6.	Injection dry powder vial (G
3.	Dry Powder Suspension (General)	7.	Sachet (General)
4.	Injection ampoule/vial (General)	8.	**Injection Ampoule (Psycho**

Decision of the Central Licensing Board in 287th meeting:

The Board considered and approved the grant of renewal of DML No. 000574 by way of Formulation in the name of M/s Welwrd Pharmaceuticals, Plot No.3, Block A, Phase-I & II, Industrial Estate, Hattar on the recommendations of the panel of experts for the period commencing on 20-05-2020 & ending on 19-05-2025 for the following section subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020: -

1. Tablet (General)
2. Capsule (General)
3. Dry Powder Suspension (General)
4. Injection Ampoule / Vial (General)
5. Injection Vial (Cephalosporin)
6. Injection dry powder vial (General)
7. Sachet (General)
8. Injection Ampoule (Psychotropic)

2	M/s Wellborne Pharmachem & Biologicals, Plot No.51/1, 52/2, Phase I&II, Industrial Estate, Hattar DML No. 000657 (Formulation) Period: Commencing on 28.01.2019 & ending on 27.01.2024	**15-03-2022**	**Good**	1) Mr. Muhammad Younas Khattak, Chief Drug Inspector, Peshawar 2) Federal Inspector of Drugs, DRAP, Peshawar. 3) Assistant Director, DRAP, Peshawar.

Recommendations of the panel:

"*Based on documentation reviewed, technical / management people met, materials/ processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab and allied facilities, the panel is of the view that the firm is operating at satisfactory level of GMP compliance and unanimously recommends grant of renewal of Drug Manufacturing License to the firm from 28.01.2019 for following sections;*

Sr. No	Name of Section	Sr. No	Name of Section
1.	Tablet (General)	5.	Dry Powder for Injection (General)
2.	Capsule (General)	6.	Liquid Injectable Ampoule (General)
3.	Capsule (Cephalosporin)	7.	Dry Powder Injection (Cephalosporin)
4.	Dry Suspension Section (Cephalosporin)	XXXXXXXXXXXXXXXXXXXXX	

Decision of the Central Licensing Board in 287th meeting:

The Board considered and approved the grant of renewal of DML No. 000657 by way of Formulation in the name of M/s Wellborne Pharmachem & Biologicals, Plot No.51/1, 52/2, Phase I&II, Industrial Estate, Hattaron the recommendations of the panel of experts for the period commencing on 28.01.2019 & ending on 27.01.2024 for the following section: -

1. Tablet (General)
2. Capsule (General)
3. *Capsule (Cephalosporin)*
4. *Dry Suspension Section (Cephalosporin)*
5. *Dry Powder for Injection (General)*
6. *Liquid Injectable Ampoule (General)*
7. *Dry Powder Injection (Cephalosporin)*

3	M/s Shazeb Pharmaceuticals Industries Ltd, Hazara Trunk Road, Sarai Gadaee, Haripur, DML No. 000380 (Formulation) Period: : Commencing on **21-02-2021 & ending on 20-02-2026**	**30-03-2022**	**Good**	i. Mr. Younas Khattak, Chief Drug Inspector, Peshawar. ii. FID, DRAP, Peshawar, iii. Mr. Abdullah Bangash, Assistant Director, DRAP, Islamabad

Recommendations of the panel:

Based on documentation reviewed, technical / management people met, materials/processes flow and detailed physical inspection of the stores, section wise visit of manufacturing facilities, quality control lab, microbiology lab and allied facilities, the panel is of the view that the firm is operating at good level of GMP compliance and unanimously **recommended** grant of renewal of Drug Manufacturing License to the firm from 21.02.2021 for following sections as detailed in DRAP, Islamabad letter No. F/3-6/92-Lic (Vol-III) dated 01.02.2021.

S.#	Name of Section	S.#	Name of Section
1.	Liquid Injectable LVP (General)	3.	Liquid Injectable SVP (General)

	2. Quality Control Laboratory		4. Warehouses	

Decision of the Central Licensing Board in 287th meeting:

The Board considered and approved the grant of renewal of DML No. 000380 by way of Formulation in the name of M/s Shazeb Pharmaceuticals Industries Ltd, Hazara Trunk Road, Sarai Gadaee, Haripuron the recommendations of the panel of experts for the period Commencing on **21-02-2021 & ending on 20-02-2026**for the following section: -

1. Liquid Injectable LVP (General)
2. Liquid Injectable SVP (General)

4	Reliance Pharma, Plot No. 8, Street No. S-8, RCCI Industrial Estate, Rawat. DML No. 000724 (Formulation) **Period**. 20-06-2021 till 19-06-2026	**02-06-2022**	**Good**	1. Dr. Hafsa Karam Elahi, Addl. Director (QALT), DRAP, Islamabad. 2. Mr. Babar Khan, Federal Inspector of Drugs-III, DRAP, Islamabad. 3. Mr. Abdullah, Assistant Director (Lic), DRAP, Islamabad.

Recommendations of the panel: -

Keeping in view the above facts on record and the people met during the visit, the panel unanimously recommended the approval of DML by way of formulation to M/s. Reliance Pharma, Plot No. 8, Street No. S-8, RCCI Industrial Estate, Rawat, with following sections of:-

1. Tablet Section (General)
2. Capsule Section (General)
3. Ointment/Cream Section (General)
4. Gel Section (General)

Decision of the Central Licensing Board in 287th meeting:

The Board considered and approved the grant of renewal of DML No. 000724 by way of Formulation in the name of M/s Reliance Pharma, Plot No. 8, Street No. S-8, RCCI Industrial Estate, Rawaton the recommendations of the panel of experts for the period commencing on 20-06-2021 and ending on 19-06-2026 for the following section: -

1. Tablet Section (General)
2. Capsule Section (General)
3. Ointment/Cream Section (General)
4. Gel Section (General)

5	M/s. Sami Pharmaceuticals (Pvt) Ltd, Plot No.F-95, Off Hub River Road, Karachi. DML No.000072 (Formulation) Period: commencing on 21-08-2020 and ending 20-08-2025	**16th, 17th,20th,23rd& 24th May 2022**	**Good**	1. Dr. Saif -ur-Rehman Khattak, Addl. Director, CDL, DRAP, Karachi. 2. FID, DRAP, Karachi 3. Mrs. Sanam Kausar, Assistant Director, DRAP, Karachi.

Recommendations of the panel:

RECOMMENDATIONS:

Overall facilities, system, processes were reviewed in detail and found in compliance to applicable regulations and procedures. The Management and technical staff is highly commited for continuous improvement. Hence based on inspection, the panel recommends renewal of DMl No. 000072(Formulation) of M/s Sami Pharmaceuticals (Pvt) Ltd, with reference to DRAP Islamabad , sections detail is as under :

Sr. No	Name of Section	Sr. No	Name of Section
	Block-A		
1	Raw Material Store- **Basement**	14	Cream/Ointment/Gel (General) – **First Floor**
3	Oral Liquid (Syrup/Suspension/Drop) General **-Ground Floor**	15.	Quality Control Laboratory – Firs Floor
5	Liquid Injectable LVP (General) - **Ground Floor**	16.	Capsule (Psychotropic) – Second Floor
7	Packaging Material Store - **Ground Floor**	17.	Liquid Injection SVP (Psychotrop – Second Floor
9	R & D Laboratory **-Ground Floor**	18.	Tablet (General) – Second Floor
10.	Tablet (General) – **First Floor**	19.	Sachet (General) – Second Floor
11.	Capsule (General) – **First Floor**	20.	Dry Powder Suspension (General) Second Floor
12.	Sachet (General) – **First Floor**	21.	Liquid Injection SVP (General) – Second Floor
13.	Liquid/Freeze Dried Injectable (General) – **First Floor**	22	Tablet (Psychotropic) – Second F
	BLOCK-B		
1	Packaging Material Store - Basement	4.	Biological Products (Human vacc killed/concentrate & Antisera) – F Floor
2.	FG Store - Basement	5.	Q C Laboratory – Second Floor
3.	Biological Products (rDNA, Protein Products, Heparins, Monoclonal Antibodies) –	6.	Research & Development Laborat (Formulation)

	Ground Floor			

Decision of the Central Licensing Board in 287th meeting:

The Board considered and approved the grant of renewal of DML No. 000072 by way of Formulation in the name of M/s. Sami Pharmaceuticals (Pvt) Ltd, Plot No.F-95, Off Hub River Road, Karachi on the recommendations of the panel of experts for the period commencing on 21-08-2020 and ending 20-08-2025 for the following section subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020: -

Sr. No	Name of Section	Sr. No	Name of Section
	Block-A		
1	Raw Material Store- **Basement**	14	Cream/Ointment/Gel (General) – **First Floor**
3	Oral Liquid (Syrup/Suspension/Drop) General -**Ground Floor**	15.	Quality Control Laboratory – Firs Floor
5	Liquid Injectable LVP (General) - **Ground Floor**	16.	Capsule (Psychotropic) – Second Floor
7	Packaging Material Store - **Ground Floor**	17.	Liquid Injection SVP (Psychotrop – Second Floor
9	R & D Laboratory -**Ground Floor**	18.	Tablet (General) – Second Floor
10.	Tablet (General) – **First Floor**	19.	Sachet (General) – Second Floor
11.	Capsule (General) – **First Floor**	20. .	Dry Powder Suspension (General) Second Floor
12.	Sachet (General) – **First Floor**	21.	Liquid Injection SVP (General) – Second Floor
13.	Liquid/Freeze Dried Injectable (General) – **First Floor**		Tablet (Psychotropic) – Second F
	BLOCK-B		
1	Packaging Material Store - Basement	4.	Biological Products (Human vacc killed/concentrate & Antisera) – F Floor
2.	FG Store - Basement	5.	Q C Laboratory – Second Floor
3.	Biological Products (rDNA, Protein Products, Heparins, Monoclonal Antibodies) – Ground Floor	6.	Research & Development Laborat (Formulation)

6	M/s. Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, LahoreDML 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 e.t.c 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.

7	M/s. Neutro Pharma	**13-04-2022**	**Good**	1. Dr. Ikram Ul Haq, Expert

	(Pvt.) Ltd., situated at 9.5-km, Sheikhupura Road, Lahore DML No.000576 (Formulation) Period: Commencing on 10-05-2020 ending on 09-05-2025	**&14-04-2022**		Member 2. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Abdul Rashid Sheikh, FID, DRAP, Lahore. 4. Anam Saeed, 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, the panel of inspectors **recommends** the renewal of Drug Manufacturing License by way of formulation along with regularization of M/s. Neutro Pharma (Pvt.) Ltd., Lahore. layout plan to M/s. Neutro Pharma (Pvt.) Ltd., situated at 9.5-km, Sheikhupura Road, Lahore for the following sections:

1.Tablet (General) Section.
2.Capsule (General) Section.
3.Tablet (General) Antibiotic Section.
4.Oral Liquid General Section.
5.Dry Powder for Suspension Section.
6.Cream/Ointment (General) Section.
7.Liquid Injection Ampoule/vial (General) Section.
8.Lyophilization Section.
9.LVP Section (Blow, Fill, Seal).
10. SVP Section (Blow, Fill, Seal).
11. Tablet (Psychotropic) Section.
12. Capsule (Psychotropic) Section.
13. Liquid Injection Psychotropic Section.
14. Capsule (Cephalosporin) Section.
15. Dry Powder Suspension (Cephalosporin) Section.
16. Dry Powder Injection (Cephalosporin) Section.

The panel of inspectors also **recommends** grant of following additional section to M/s. Neutro Pharma (Pvt.) Ltd., situated at 9.5-km, Sheikhupura Road, Lahore:

i. Liquid Injectable (Ampoule) (General) Section (New).

Decision of the Central Licensing Board in 287th meeting:

The Board considered and approved the grant of renewal of DML No. 000576 by way of Formulation in the name of M/s. Neutro Pharma (Pvt.) Ltd., situated at 9.5-km, Sheikhupura Road, Lahoreon the recommendations of the panel of experts for the period commencing on 10-05-2020 ending on 09-05-2025 for the following section subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division: -

1. Tablet (General) Section.
2. Capsule (General) Section.

	3. Tablet (General) Antibiotic Section. 4. Oral Liquid General Section. 5. Dry Powder for Suspension Section. 6. Cream/Ointment (General) Section. 7. Liquid Injection Ampoule/vial (General) Section. 8. Lyophilization Section. 9. LVP Section (Blow, Fill, Seal). 10. SVP Section (Blow, Fill, Seal). 11. Tablet (Psychotropic) Section. 12. Capsule (Psychotropic) Section. 13. Liquid Injection Psychotropic Section. 14. Capsule (Cephalosporin) Section. 15. Dry Powder Suspension (Cephalosporin) Section. 16. Dry Powder Injection (Cephalosporin) Section.

8	M/s Filix Pharmaceuticals (Pvt) Ltd, Plot No. 4-A, Main Road, RRCI, Rawat. DML No. 000779 (Formulation). Period: Commencing on 30-08-2018 & ending on 29-08-2023.	**18-01-2022 & 19-01-2022**	**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, the panel unanimously **recommended** for the grant of Renewal of Drug Manufacturing License No. 000779 (by way of formulation) w.e.f. 30.08.2018 to 29.08.2023 and Additional Section to M/s Filix Pharmaceuticals, Plot No. 4-A, Main Road, NIZ, Rawat, Rawalpindi for following sections namely as of today:

Renewal:

1. Tablet Section (Gen)
2. Capsule Section (Gen).

Additional Section: -

1. Capsule Section (Cephalosporin)
2. Dry Powder for Suspension Section (Cephalosporin)

NOTE: Scope of the inspection was limited to the verification of compliance in terms of manufacturing and testing facilities, as committed in approved layout plan, which was found satisfactory under the best knowledge and belief. The panel could not guarantee the strength of building and safety of installed electric panels. The verification of strength of building and safety of installed electric panels is a technical job and pertains to civil and electrical engineers."

Decision of the Central Licensing Board in 287th meeting:

The Board considered and approved the grant of renewal of DML No. 000779 by way of Formulation in the name of M/s Filix Pharmaceuticals (Pvt) Ltd, Plot No. 4-A, Main Road, RRCI, Rawat on the recommendations of the panel of experts for the period commencing on 30-08-2018 & ending on 29-08-2023 for the following section: -

1. Tablet Section (Gen)
2. Capsule Section (Gen).

However, Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad who was present in the meting who disowned the note by Federal Inspector of Drugs and contended that it personal opinion of the Federal Inspector of Drugs and should not be considered as opinion of the panel.

9	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)			
10	M/s. GMP Pharmaceuticals, 28-Km Sheikhupura Road, Lahore. DML No.000815 (Formulation) Period: Commencing on 23-06-2020 ending on 22-06-2025.	**09-03-2022**	**Good**	i. Dr. Zaka ur Rehman, CEO, PDTRC, Lahore ii. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore. iii. Ms. Ufaq Tanvir, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: *"The panel of inspectors **Recommends** the renewal of DML bearing No.000815 issued in favour of M/s GMP Pharmaceuticals in respect to all approved sections."* **Sections (05):** 1. Capsule (Cephalosporin) 2. Oral Dry Powder Suspension (Cephalosporin) 3. Dry Powder Injection (Vial) (Cephalosporin) 4. Liquid Injection (Ampoule) (General) *5.* Liquid Injectable (Vial) (General)			

	Decision of the Central Licensing Board in 287th meeting: The Board considered and approved the grant of renewal of DML No. 000815 by way of Formulation in the name of M/s. GMP Pharmaceuticals, 28-Km Sheikhupura Road, Lahoreon the recommendations of the panel of experts for the period commencing on 23-06-2020 and ending on 22-06-2025 for the following section : - 1. Capsule (Cephalosporin) 2. Oral Dry Powder Suspension (Cephalosporin) 3. Dry Powder Injection (Vial) (Cephalosporin) 4. Liquid Injection (Ampoule) (General) *5.* Liquid Injectable (Vial) (General)

ITEM-V MISCELLANEOUS CASES

Case No. 1 **CHANGE OF MANAGEMENT OF M/S M/S PAKHEIM INTERNATIONAL PHARMA (PVT) LTD. 28 KM FEROZEPUR ROAD LAHORE DML NO 000492 (BY WAY OF FORMULATION)**

M/s Pakheim International Pharma (Pvt) Ltd. 28 Km Ferozepur Road Lahore submitted the documents for change in management. The firm has deposited fee of Rs.75,000/- for change of management Detail is as under;

Previous Management as per Form-29	Current management as per Form 29
1. Dr Muhammad Ijaz Nasir S/o Mr. Muhammad Sharif CNIC No. 35201-1521450-7 2. Dr. Farida Ijaz W/o Dr Muhammad Ijaz Nasir CNIC No. 35201-1271008-4	1. Mr. Muhammad Mustafiz-ur-Rehman S/o Mr. Mian Muhammad Naim-Ur-Rehman CNIC No. 34603-8137022-1 2. Mr. Arif Ahmed Khawaja S/o Mr. Muhammad Anwar CNIC No. 34603-2183307-5

Decision of the Central Licensing Board in 287th meeting:

The Board considered and accepted for record the change of management of M/s Pakheim International Pharma (Pvt) Ltd. 28 Km Ferozepur Road Lahore, DML No.000492(By way of Formulation) as under:-

Previous Management as per Form-29	Current management as per Form 29
3. Dr Muhammad Ijaz Nasir S/o Mr. Muhammad Sharif CNIC No. 35201-1521450-7 4. Dr. Farida Ijaz W/o Dr Muhammad Ijaz Nasir CNIC No. 35201-1271008-4	3. Mr. Muhammad Mustafiz-ur-Rehman S/o Mr. Mian Muhammad Naim-Ur-Rehman CNIC No. 34603-8137022-1 4. Mr. Arif Ahmed Khawaja S/o Mr. Muhammad Anwar CNIC No. 34603-2183307-5

Case No. 2 **CHANGE OF MANAGEMENT OF M/S USAWA PHARMACEUTICALS, 146-SPECIAL INDUSTRIAL ZONE (EXPORT PROCESSING ZONE), RISALPUR DML NO 000491 (BY WAY OF FORMULATION)**

M/s Usawa Pharmaceuticals, 146-Special Industrial Zone (Export Processing Zone), Risalpur submitted the documents for change in management. The firm has deposited fee of Rs.75,000/- for change of management Detail is as under;

Previous Management as per Partnership Deed	Current Management as per Partnership Deed
i. Dr. Mohammad Farooq ii. Dr. Rizwana Khan iii. Mohammad Waqas Khan iv. Mohammad Usama Khan	i. Mrs. Rizwana Khan W/o Muhammad Farooq Khan CNIC No. 16101-1076868-2. ii. Mr. Muhammad Waqas Khan S/o Muhammad Farooq Khan CNIC No.16101-1226387-3. iii. Mr. Muhammad Usama Khan S/o Muhammad Farooq Khan CNIC No.16101-9472733-7.

Decision of the Central Licensing Board in 287th meeting:

The Board considered and accepted for record the change of management of M/s Usawa Pharmaceuticals, 146-Special Industrial Zone (Export Processing Zone), Risalpur, DML No.000491(By way of Formulation) as undersubject 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 10/11/2020as under:-

Previous Management as per Partnership Deed	Current Management as per Partnership Deed
1. Dr. Mohammad Farooq 2. Dr. Rizwana Khan 3. Mohammad Waqas Khan 4. Mohammad Usama Khan	1. Mrs. Rizwana Khan W/o Muhammad Farooq Khan CNIC No. 16101-1076868-2. 2. Mr. Muhammad Waqas Khan S/o Muhammad Farooq Khan CNIC No.16101-1226387-3. 3. Mr. Muhammad Usama Khan S/o Muhammad Farooq Khan CNIC No.16101-9472733-7.

Case No- 3 **CHANGE OF MANAGEMENT OF M/S CUREXA HEALTH (PVT) LTD, LAHORE UNDER DML NO 000864 (BY WAY OF FORMULATION)**

M/s Curexa Health (Pvt) Ltd, Plot No. 517, Sunder Industrial Estate, Lahore under DML No. 000864 (Formulation)submitted the documents for change in management. The firm has deposited fee of Rs.75,000/- for change of management. Detail is as under;

Previous Management	Current Management as per Form-29 & Form-A

i. Mr. Taufiq Ahmad Khan S/o Mr. Jawaid Tariq Khan, CNIC No. 35201-9273258-3 ii. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1 iii. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7 iv. Mr. Anees Ahmad Khan S/o Ishfaq Ahmad Khan CNIC No. 35202-2392890-5	i. Mr. Taufiq Ahmad Khan S/o Mr. Jawaid Tariq Khan, CNIC No. 35201-9273258-3 ii. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1 iii. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7

Decision of the Central Licensing Board in 287th meeting:

The Board considered and accepted for record the change of management of M/s Curexa Health (Pvt) Ltd, Plot No. 517, Sunder Industrial Estate, Lahore under DML No. 000864 (Formulation) as under:-

Previous Management	Current Management as per Form-29 & Form-A
1. Mr. Taufiq Ahmad Khan S/o Mr. Jawaid Tariq Khan, CNIC No. 35201-9273258-3 2. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1 3. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7 4. Mr. Anees Ahmad Khan S/o Ishfaq Ahmad Khan CNIC No. 35202-2392890-5	1. Mr. Taufiq Ahmad Khan S/o Mr. Jawaid Tariq Khan, CNIC No. 35201-9273258-3 2. Mr. Adeel Abbas Haideri S/o Zaigham Abbas Hydrie CNIC No. 35201-9490548-1 3. Mr. Tausif Ahmad Khan S/o Jawaid Tariq Khan CNIC No. 35202-5478882-7

Case No- 4 **CHANGE OF MANAGEMENT OF M/S MOON PHARMACEUTICAL RAWAT, ISLAMABAD UNDER DML NO 000833 (BY WAY OF FORMULATION)**

M/s Moon Pharmaceutical,Plot No. 5, Street SS-4, National Industrial Zone Rawat Islamabad submitted the documents for change in management. The firm has deposited fee of Rs.75,000/- for change of management. Detail is as under;

Previous Management	Current Management as per Form-D
1. Mr. Arshad Ali khan S/o khurshid Ali, CNIC No. 15402-5317176-1 2. Muhammad nabi S/o rahimjan CNIC No. 17301-0597727-5 3. Mr. Sawat khan S/o olasmir CNIC No. 14101-0791677-9 4. Ms. rozina Wahab W/o naveed khan CNIC No. 15402-6694400-0 5. Mr. Muhammad Nawaz S/o Fazal Rahim CNIC No. 15307-373210-5	1. Mr. AAMIR IQBAL S/o Mr. MUHAMMAD IQBAL CNIC No. 42301-8632235-1 2. Ms. Asma W/o AAMIR IQBAL CNIC No. 42301-2581984-2

Decision of the Central Licensing Board in 287th meeting:

The Board considered and accepted for record the change of management of M/s Moon Pharmaceutical,Plot No. 5, Street SS-4, National Industrial Zone Rawat, DML No.000833 (By way of Formulation) as under:-

Previous Management	Current Management as per Form-D
1. Mr. Arshad Ali khan S/o khurshid Ali, CNIC No. 15402-5317176-1 2. Muhammad nabi S/o rahimjan CNIC No. 17301-0597727-5 3. Mr. Sawat khan S/o olasmir CNIC No. 14101-0791677-9 4. Ms. rozina Wahab W/o naveed khan CNIC No. 15402-6694400-0 5. Mr. Muhammad Nawaz S/o Fazal Rahim CNIC No. 15307-373210-5	1. Mr. AAMIR IQBAL S/o Mr. MUHAMMAD IQBAL CNIC No. 42301-8632235-1 2. Ms. Asma W/o AAMIR IQBAL CNIC No. 42301-2581984-2

Case No. 5 **REQUEST OF M/S WILSON'S PHARMACEUTICALS, ISLAMABAD FOR CONTRACT TESTING /ANALYSIS OF IMPURITY (NDMA & NDEA) PROFILING OF ARBS (ANGIOTENSIN RECEPTOR BLOCKERS) THROUGH GCMS WITH M/S WERRICK PHARMACEUTICALS, ISLAMABAD**

M/s Wilson's Pharmaceuticals, Islamabad informed that they had ben made an agreement for contract testing /analysis of Impurity (NDMA & NDEA) Profiling of ARBs (Angiotensin Receptor Blockers) through GCMS with M/s Werrick Pharmaceuticals, Islamabad, which has dedicated approved GCMS facility. The firm also submitted copy of the agreement for contract testing and Inspection report of M/s Werrick Pharmaceuticals, Islamabad for verification of GCMS facility. The firm , M/s Wilson's Pharmaceuticals, Islamabad requested for authorize contract testing/analysis with M/s Werrick Pharmaceuticals, Islamabad

2. It is pertinent to mentioned that it is mentioned in the Inspection report of with M/s Werrick Pharmaceuticals, Islamabad) conducted by Area FID, DRAP Islamabad on 18/07/2019 that Equipment was installed and fully functional. Installation documents of system including installation qualification report was verified (Annex A). Testing Reports of two batches were verified as per FDA method of testing of NDMA and NDEA (Annex B). Firm has also maintained impurities standards of NDMA and NDEA.

3. It is further submitted that Rule 20(C0 of Drugs (Licensing, Registering and Advertising) Rules, 1976 stated that

> *"The licensee shall either in his own laboratory or, where so authorized under the proviso to clause (e) of rule 16, in any other laboratory approved by the Central Licensing Board, test each batch of the raw materials used by him for the manufacture of drugs and also each batch of the final drug, shall maintain records showing the particulars in respect of such tests as specified in Schedule B-III and shall retain such records, in the case of a substance for which expiry*

date is fixed for a period of two years from the expiry of such date and, in the case of other substances, for a period of five years from the date of manufacture."

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

Decision of the Central Licensing Board in 287th meeting:

The Board considered the case and decided to authorize M/s Wilson's Pharmaceuticals Plot No.387-388, & 366 Sector I-9, Industrial Area, Islamabad for the testing of impurity profiling of raw material namely Valsartan from Werrick Pharmaceuticals 216-217, I-10/3, Industrial Area Islamabad for the period of 5 years and further authorization shall be linked with renewal of Drug manufacturing Licence of M/s Wilson's Pharmaceuticals, Islamabad subject to mutual agreement between the parties.

Case No 7 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S PACIFIC PHARMACEUTICALS LTD, PLOT NO. 30-KM, MULTAN ROAD, LAHORE (DML# 000295)**

M/s Pacific Pharmaceuticals Ltd, Plot No. 30-KM, Multan Road, Lahore, submitted application for for renewal of Drug Manufacturing License No. 000295 (by way of Formulation) for the period 22-07-2020 to 21-07-2025. The application was received on 13-07-2020 and due date of renewal of DML 22-07-2020.

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 29th December, 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. Partnership Deed alongwith CNIC's of all partners.
iii. Detail of premises including layout plan
iv. Proof of licensed sections from CLB.
v. Name and Qualification of Quality Control Incharge.
vi. Up-to-date nothing due certificate regarding CRF from STO.

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 18th June, 2021;

i. Latest certified true copy of form-29.
ii. Proof of licensed sections from CLB.
iii. Up-to-date nothing due certificate regarding CRF from STO.

In repose to final reminder the firm submitted their reply which is summarized as under;

a. Trust this letter finds you safe and in the best of health. I hope there will be no need to reintroduce Pacific Pharmaceuticals Ltd to your good self. We are being the MHRA certified company always tried our level best to represent Pakistan globally in the best possible way. Pacific Pharmaceuticals Ltd is the

company, which is always strictly following the rules and regulations set by DRAP and other international regulatory bodies. Sir, I am writing this letter for the need of your kind support and attention to the subject matter. The brief detail is provided below for your kind attention.

b. Dear Sir, Pacific Pharmaceuticals applied for the renewal of Drug Manufacturing License (DML) in 13-07-2020 (copy enclosed) but inspection is still pending what we have been told by Licensing Division due to pending CRF NOC. I would like to bring it into your kind notice that we applied for NOC against CRF for the year 2019-2020 on 8-9-2020 (copy enclosed). We received letter from B&A Division on 4-11-2020 for payment of differential amount (copy enclosed). The differential amount was paid and response was submitted on 12-02-2021 received at DRAP on 19-2-2021 (copy enclosed). We have been telephonically advised by B&A Division to submit auditor's attested financial statements which were submitted on 3-8-2021 (copy enclosed). However we received another query on 6-8-2021 and demanded huge amount which was not calculated according to the original financial statements. We were told by B&A Division that two types of financial statements were submitted by Pacific and they have considered the highest values.
c. Dear Sir, it took us four months to probe this issue because it really hit our integrity. We have reached to the culprits and found out that elevated financial statements were submitted to DRAP but those statements are incorrect. We are in contact with B&A Division to justify our case with solid evidences of auditor's attested financial statements. We are willing to pay any sort of amount provided, it is justified with the financial statements. We have always tried to work through and proper channels.
d. Dear Sir, keeping in view the above provided background, I request your competent authority to look into this matter and advised Licensing Division not to take further action until the matter is amicably resolved. You have always been kind enough to support Pacific Pharmaceuticals not for the uplift of pharmaceutical industry but also for the prestige of Pakistan globally.

In light of above, Division of Budget and Account, DAP was requested to submit updated status of the firm regarding nothing due certificate (CRF). Division of Budget and Account, DAP informed that the CRF certificate valid up to 31-12/2017 was issued to the firm.

It is pertinent to mention that application for renewal of Drug Manufacturing License for the period of 22-07-2020 to 21-07-2025 is still deficient due non availability of up to date nothing due certificate (CRF)

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

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, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000295 (by way of formulation) of M/s Pacific Pharmaceuticals Ltd, Plot No. 30-KM, Multan Road, Lahoremay 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.

Case No 8 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S GILLMAN PHARMACEUTICALS, HATTAR (DML# 000683)**

M/s Gillman Pharmaceuticals, Hattar submitted application for renewal of Drug Manufacturing No. 000683 (by way of Formulation). The application was received on **11/02/2020** which 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 Pacific Pharmaceuticals Ltd, Plot No. 30-KM, Multan Road, Lahore 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.

Case No. 9 **RENEWAL OF DRUG MANUFACTURING LICENCE 000720 BY WAY OF FORMULATION) OF M/S WARAFANA PHARMACEUTICALSPLOT NO. 125-126-127, INDUSTRIAL TRIANGLE, KAHUTTA ROAD, ISLAMABAD**

M/s Warafana Pharmaceuticals Plot No. 125-126-127, Industrial Triangle, Kahutta Road, Islamabad, applied for renewal of DML No. 000720 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 03rd January, 2022under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

to submit application on prescribed Form-1A duly signed and stamped by the management of the firm along with following requisite documents/annexures dully attested/notarized and late fee of Rs.45,000/- @7,500/day as per SOP;

i. Proper Application
ii. Form 1-A
iii. Classes of Drugs
iv. Dosage forms of drugs
v. Name(s) of drugs registered / approved
vi. Change(s) in name of proprietor / directors / partners (if any).
vii. Detail of premises including layout plan
viii. Detail of the section-wise equipment and machinery for manufacture and quality control.
ix. Name and Qualification of Production Incharge
x. Name and Qualification of QC Incharge.
xi. Nothing due certificate regarding CRF from STO.

As the firm did not submitted any reposed to this Office's letter of even number dated 03-01-2022, a final reminder was issued on 11th February, 2022to the firm to rectify above said shortcomings**.**

As of today, the firm has not rectified above mentioned shortcomings/deficiencies

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 000720 by way of formulation of M/s Warafana Pharmaceuticals Plot No. 125-126-127, Industrial Triangle, Kahutta 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.

Accordingly, a show cause notice was issued to the firm on 26th May, 2022. But no reply of the firm received so far.

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

> *"As we received this letter (whose copy is attached herewith), few days before on 08-06-2022. The said time was very short to comply it due to closure of our unit as per your orders of suspension of our DML. So we humbly, hereby request to give us more time to comply it."*

Now a personnel hearing letter is issued to the firm on 16-06-20222.

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

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

Mr. Iftikhar Ahmad, Director of the company and Malik Rab Nawaz, Production Incharge appeared before the Board. They contended that unit is non operational since two months. They further contended that they need further period of three months for making unit operational. The Board considering the facts on record decided to suspend the Drug Manufacturing License No 000147 by way of Formulation M/s Warafana Pharmaceuticals Plot No. 125-126-127, Industrial Triangle, Kahutta Road, Islamabad 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 12, Rule 16, Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Chairman or Secretary CLB may take decision and case may be placed before the Board for ratification.

Case No. 10 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000653 (SEMI BASIC MANUFACTURING) OF M/S WELBORNE PHARMACHEM AND BIOLOGICALS, HATTAR.**

It is submitted that as per available record, application for renewal of DML # 000653 by way of Semi Basic Manufacturing, for the period 28-01-2019 to 27-01-2024 of M/s Welborne Pharmachem and Biologicals, Hattar 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. 000653 by way of Semi Basic Manufacturing, M/s Welborne Pharmachem and Biologicals, Hattar is no more valid.

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. 000653 by way of Semi Basic Manufacturing of M/s Welborne Pharmachem and Biologicals, Hattar, may not be declared cancelled by Central Licensing Board.

Accordingly, a show cause notice was issued to the firm on 26th May, 2022. The firm has submitted reply to the show cause notice on 10.06.2022 which is re produced as under;

> *"Kindly refer to your letter # F-3/2008-Lic dated 26th May 2022 received in our premises on dated June 6, 2022 regarding the captioned matter. (copy of letter attached).*
> *We have no resources to hold our drug manufacturing license No.000653 by way of semi basic manufacturing of M/S Wellborne Pharmachem & Biologicals, Plot #51/1,52/2, PhaseI&II industrial estate Hattar.*
> *We surrender at all and further excuse to our mistake for not answering yours letter in time.*
> *We request you to guide us for cancellation procedure of License.*
> *With excuse kindly correct the typing mistake in 3rd paragraph (highlight at attached letter) i.e. by way of Semi Basic Manufacturing instead of by way of formulation."*

Now a personnel hearing letter is issued to the firm on 16-06-2022.

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

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

No person appeared on behalf of the firm. Keeping in view, reply of the firm the Board decided to cancel the Drug Manufacturing License No. 000653 (Semi Basic Manufacture) of M/s Welborne Pharmachem and Biologicals, Hattar as the Drug Manufacturing License No. 000653 (Formulation) is no more valid as under Rule 5 (6) of Drug (L, R & A) Rule, 1976.

Case No. 11 **M/S CONVELL LABORATORIES, SAIDU SHARIF, SWAT UNDER DRUG MANUFACTURING LICENSE NO. 000509 BY WAY OF FORMULATION.**

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.

Recently, 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. Fazal Mabood 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."*

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

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 licence 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**

Case No. 12 **RENEWAL OF DRUG MANUFACTURING LICENCE (000546 BY WAY OF FORMULATION) OF M/S WELMED PHARMACEUTICAL INDUSTRIES (PVT) LTD., GADOON AMAZAI.**

M/s Welmed Pharmaceutical Industries (Pvt) Ltd., GadoonAmazai, applied for renewal of DML No. 000546 by way of formulation for the period of 16-07-2019 to 15-07-2024.

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 07th November, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1) Form-1A duly signed and stamped by CEO of the firm.
2) Proof of Licensed section(s) from Central Licensing Board.
3) There is change in management of the firm, following documents are required;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).
4) Previous Form-29 (attested) alongwith CNIC's copies of all directors.
5) Fee challan i.e. Rs.50,000/- retained by 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 25th December, 2021to the firm with following shortcomings: -

i. Form-1A as per the Drug (Licensing, Registering & Advertising) Rules, 1976.
ii. Updated Nothing Due Certificate (CRF) from STO, DRAP.
iii. Approved layout plan.

However, as of today, above shortcoming has not been rectified by the firm

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 000546 by way of formulation of M/s Welmed Pharmaceutical Industries (Pvt) Ltd., GadoonAmazai,, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In light of Decision of the Central Licensing Board held on Show Cause Notice was issued to the firm on 26/05/2022.

The firm M/s Welmed Pharmaceutical Industries (Pvt) Ltd., GadoonAmazai has rectified above mentioned shortcomings.

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

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 cease the operation of Show Cause Notice for the further period issued in the name of M/s Welmed Pharmaceutical Industries (Pvt) Ltd., Gadoon Amazai

Case No. 13 **RENEWAL OF DRUG MANUFACTURING LICENCE (000491 BY WAY OF FORMULATION) OF M/S USAWA PHARMACEUTICALS, RISALPUR.**

M/s Usawa Pharmaceuticals, 146-Special Industrial Zone (Export Processing Zone), Risalpur submitted application for renewal of DML No.000491 (Formulation). The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 14th January, 2022 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Submit application for change of management as per SOP alongwith prescribed fee.
ii. Up-to-date Nothing Due Certificate from STO, DRAP, Islamabad.

The firm did not reply to above quoted letter and final reminder was issued to the firm on April, 2022 for ratification of said shortcomings.

The firm did not reply to the final reminder and application for renewal of DML is still incomplete due to following shortcomings;

i. Submit application for change of management as per SOP alongwith prescribed fee.
ii. Up-to-date Nothing Due Certificate from STO, DRAP, Islamabad is not provided.

As of today, the firm 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, 5, Rule 12and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000491 by way of formulation of M/s Usawa Pharmaceuticals, 146-Special Industrial Zone (Export Processing Zone), Risalpur, 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.

The firm M/s Usawa Pharmaceuticals, 146-Special Industrial Zone (Export Processing Zone), Risalpur has rectified above mentioned shortcomings.

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

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 cease the operation of Show Cause Notice for the further period issued in the name of M/s Usawa Pharmaceuticals, 146-Special Industrial Zone (Export Processing Zone), Risalpur.

Case No. 14 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S CHERWEL PHARMACEUTICALS (PVT) LTD., PLOT NO.20, PHASE-IV, HATTAR INDUSTRIAL ESTATE, HATTAR (DML# 000606)**

M/s Cherwel Pharmaceuticals (Pvt) Ltd., Plot No.20, Phase-IV, Hattar Industrial Estate, Hattar wherein the firm has submitted documents of the application for renewal of DML No.000606 (Formulation). The application was received on 16-12-2021 which was well on time as the validity of the license is 30-12-2020.

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 14th January, 2022 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Form-1A dully singed and stamped by the CEO/Director of the firm not provided.
ii. Classes of drugs not provided.
iii. Dosage form of drugs not provided.
iv. Name of registered drugs not provided.
v. Detail of management at the time of previous renewal and current renewal not provided.
vi. All submitted photocopies are not attested/notarized/certified as true copy.

The firm did not reply to above quoted letter and final reminder was issued to the firm on 14thApril, 2022 for ratification of said shortcomings.

The firm did not reply to the final reminder and application for renewal of DML is still incomplete due to following shortcomings;

i. Form-1A dully singed and stamped by the CEO/Director of the firm not provided.
ii. Classes of drugs not provided.
iii. Dosage form of drugs not provided.
iv. Name of registered drugs not provided.
v. Detail of management at the time of previous renewal and current renewal not provided.
vi. All submitted photocopies are not attested/notarized/certified as true copy.

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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000606 by way of formulation of M/s Cherwel Pharmaceuticals (Pvt) Ltd., Plot No.20, Phase-IV, 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.

The firm M/s Cherwel Pharmaceuticals (Pvt) Ltd., Plot No.20, Phase-IV, Hattar Industrial Estate, Hattar has rectified above mentioned shortcomings.

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 cease the operation of Show Cause Notice for the further period issued in the name of M/s Cherwel Pharmaceuticals (Pvt) Ltd., Plot No.20, Phase-IV, Hattar Industrial Estate, Hattar

Case No. 15 **RENEWAL OF DRUG MANUFACTURING LICENCE 000644 BY WAY OF FORMULATION) OF M/S WEATHER FOLDS PHARMACEUTICALS, HATTAR.**

M/s Weather Folds Pharmaceuticals, Hattar wherein the firm has submitted the application for renewal of Drug Manufacturing No. 000644 (Formulation). The application was received on **19-09-2018** which is well on time as validity of License is **26-09-2018**

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 11-09-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad upto 31-12-2020.

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 11th March, 2022 to the firm with following shortcomings: -

i. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad upto 31-12-2020.

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. Updated/amended/addendum partnership 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 and Rule 12of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000644 by way of formulation of M/s Weather Folds 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.

The firm M/s Weather Folds Pharmaceuticals, Hattar has rectified above mentioned shortcomings.

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 cease the operation of Show Cause Notice for the further period issued in the name of M/s Weather Folds Pharmaceuticals Plot No. 62/2 Phase-II Industrial Estate Hattar.

Case No. 16 **RENEWAL OF DRUG MANUFACTURING LICENCE 000843BY WAY OF RE-PACKING) OF M/S SIMAX CHEMICAL, PLOT NO. 188-A, INDUSTRIAL ESTATE HAYATABAD, PESHAWAR.**

M/s Simax Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Peshawar wherein the firm has submitted application for renewal of DML No. 000843. The application was received on 31-08-2021 which was 07 days late as the validity of the license was 24-08-2021.

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 9th Nov, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. advised to submit application on prescribed Form-1A duly signed and stamped by the management of the firm along with following documents/annexures dully attested/notarized and a late fee of Rs.52,500/- @7,500/day as per SOP;
   i. Proper Application
   ii. Form 1-A
   iii. Classes of Drugs
   iv. Dosage forms of drugs
   v. Name(s) of drugs registered / approved
   vi. Change(s) in name of proprietor / directors / partners (if any).
   vii. Detail of premises including layout plan
   viii. Detail of the section-wise equipment and machinery for manufacture and quality control.
   ix. Name and Qualification of Production Incharge
   x. Name and Qualification of QC Incharge.
   xi. Nothing due certificate regarding CRF from STO.

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 7thApril, 2022 to the firm with following shortcomings: -

2. advised to submit application on prescribed Form-1A duly signed and stamped by the management of the firm along with following documents/annexures dully attested/notarized;
   i. Proper Application
   ii. Form 1-A
   iii. Classes of Drugs
   iv. Dosage forms of drugs
   v. Name(s) of drugs registered / approved
   vi. Change(s) in name of proprietor / directors / partners (if any).
   vii. Detail of premises including layout plan
   viii. Detail of the section-wise equipment and machinery for manufacture and quality control.
   ix. Name and Qualification of Production Incharge
   x. Name and Qualification of QC Incharge.
   xi. Nothing due certificate regarding CRF from STO.

The firm did not submit their reply to Final Reminder and above mentioned documents are still deficient /short and application for renewal of DML is still incomplete;

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, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000843 by way of re-packing of M/s Simax Chemical, Plot No. 188-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.

The firm M/s Simax Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Peshawar has rectified above mentioned shortcomings.

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 cease the operation of Show Cause Notice for the further period issued in the name of M/s Simax Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Peshawar

Case No. 17 **GRANT OF RE-PACKING PRODUCTS TO M/S SIMAX CHEMICAL, PLOT NO. 188-A, INDUSTRIAL ESTATE HAYATABAD, PESHAWAR UNDER DML NO. 000843 BY WAY OF RE-PACKING.**

M/s Simax Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Peshawar, under Drug Manufacturing Licence No. 000843 by way of re-packing 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
01	Ichthammol	Yes
02.	Gentian Violet	Yes
03.	Caster Oil	Yes
04.	Liquid Parafin	Yes
05.	Glycerin	Yes

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

The Board considering the case and decided to approve following drugs by way of repacking in the name of M/s Simax Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Peshawar.

S#	Drug
01	Ichthammol
02.	Gentian Violet
03.	Caster Oil
04.	Liquid Parafin
05.	Glycerin

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. Atif Sahrief, Managing Director of the Company appeared before the Board. He contended that he had submitted documents and taken up the matter with Budget and Accounts for issuance of nothing due certificate. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000555 by way of formulation of M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahoreunder Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 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 fulfilled all the codal formalities before issuance of Suspension Order.

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 cease the operation of suspension of Drug Manufacturing Licence for the further period in the name of M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore.

Case No. 19 **WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTIONS BY M/S SCOTMAN PHARMACEUTICALS, PLOT NO. 5-D, SECTOR I-10/3 ISLAMABAD, UNDER DML NO. 000498 BY WAY OF FORMULATION.**

M/s Scotman Pharmaceuticals, Plot No. 5-D, Sector I-10/3 Islamabad under DML No. 000498 by way of Formulation has submitted request for withdrawal of following licensed section namely:

1. Bio-Tech Antiviral vaccine (Vials)
2. Bio-Tech Interferon **(**Vials/Ampoule/Pre-filled syringes)

It is submitted for information that the Central Licensing Board (CLB) in its 239th meeting held on 22nd January, 2015 has approved grant of above additional sections.

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 accept the request of M/s Scotman Pharmaceuticals, Plot No. 5-D, Sector I-10/3 Islamabad under DML No. 000498 by way of Formulation for withdrawl of following sections;-

1. Bio-Tech Antiviral vaccine (Vials)
2. Bio-Tech Interferon **(**Vials/Ampoule/Pre-filled syringes)

The Board also decided to seek further utilization of the area from the firm.

Case No. 20 **WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTION BY M/S SAMI PHARMACEUTICALS (PVT) LTD , PLOT NO. F-95, OFF HUB RIVER ROAD KARACHI UNDER DML NO. 000072 BY WAY OF FORMULATION.**

M/s Sami Pharmaceuticals (Pvt) Ltd, F-95, Off Hub River Road Karachi under DML No. 000072 by way of Formulation has submitted request for withdrawal of following licensed section namely:

1.Tablet (Hormone).

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 accept the request of M/s Sami Pharmaceuticals (Pvt) Ltd, F-95, Off Hub River Road Karachi under DML No. 000072 by way of Formulation for withdrawl of following sections;-

1.Tablet (Hormone).

The Board also decided to seek further utilization of the area from the firm.

Case No. 21 **WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTION BY M/S EPOCH PHARMACEUTICALS , UNDER DML NO. 000425 BY WAY OF FORMULATION.**

M/s Epoch Pharmaceuticals, Plot No 83-85 Sector 15 Korangi Industrial Area Karachi. under DML No. 000425 by way of Formulation has submitted request for withdrawal of following licensed section namely:

i. Tablet (Cephalosporin).

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 accept the request of M/s Epoch Pharmaceuticals, Plot No 83-85 Sector 15 Korangi Industrial Area Karachi. under DML No. 000425 by way of Formulation for withdrawl of following sections;-

1. Tablet (Cephalosporin).

The Board also decided to seek further utilization of the area from the firm.

Case No. 22 **GRANT OF RE-PACKING PRODUCTS TO M/S WELCARE PHARMACEUTICALS, SARGODHA UNDER DML NO. 000465 BY WAY OF FORMULATION.**

M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha, under Drug Manufacturing Licence No. 000465 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
01	Calamine	Yes
02.	Ichthammol	Yes
03.	Gentian Violet	Yes

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

The Board considering the case and decided to approve following drugs by way of repacking in the name of M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha, under Drug Manufacturing Licence No. 000465 by way of formulation.

S#	Drug
01	Calamine
02.	Ichthammol
03.	Gentian Violet

Case No**23** **SUSPENSION OF LICENSE OF M/S EPHARM LABORAOTORIES A-40 ROAD NO.01, SITE, SUPER HIGHWAY INDUSTRIAL AREA NORTH KARACHI**

A Marasla is received from Honorable Chairman Drug Court of Balochistan, Quetta wherein it is stated that a case No. 35/2021 is pending against Muhammad Ilyas Nanitalwala , Atif Ilyas Nanitalwala, ASad Ilyas MD, Ch. Yawar Ashfaq QCI and Ahmed Nadeem PI of M/s EPharm Laboratories North Karachi and accused persons have not been appearing before this court since despite issuance of non bailable warrants and deliberately avoiding to appear before the court.

It is, therefore, necessary to suspend the license of the above mentioned company after fulfilling the requisite requirement as per law under intimation to this court, at your earliest.

Submitted for consideration of the Board.

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

The Board considering the case and observed that there is no express provision undr the Drugs Act, 1976 and rules framed there under to suspend the Drug Manufacturing Licence of M/S EpharmLaboraotories A-40 Road No.01, Site, Super Highway Industrial Area North Karachi on the basis of Marasla of the Chairman, Drug Court Balochistan, Quetta. The Board further observed that Drug Court Balochistan, Quetta may seek attendance of the accused through Law Enforcement Departments. The Board therefore decided to forward Marasla of the Chairman, Drug Court Balochistan, Quetta to of M/S EpharmLaboratories A-40 Road No.01, Site, Super Highway Industrial Area North Karachi for compliance under intimation to the Board.

Case No**24** **SUSPENSION OF LICENSE OF M/S PLIVA PAKSITAN(PVT) LTD PLOT NO.B-77, H.I.T.E ,HUB BALOCHISTAN**

A Marasla is received from Honorable Chairman Drug Court of Baluchistan, Quetta wherein it is stated that a case No. 39/2021 is pending against Mr. Imran Usman Director, Mr. Santoosh Kumar QCI, Mr. Farzana Mugheri PI of M/s PlivaPaksitanPvtLtd B-77, HITE, Balochsitan and accused persons have not been appearing before this court since despite issuance of non bailable warrants and deliberately avoiding to appear before the court.

It is, therefore, necessary to suspend the license of the above mentioned company after fulfilling the requisite requirement as per law under intimation to this court, at your earliest.

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

The Board considering the case and observed that there is no express provision undr the Drugs Act, 1976 and rules framed there under to suspend the Drug Manufacturing Licence of M/s PlivaPakistan Pvt Ltd B-77, HITE, Balochsitanon the basis of Marasla of the Chairman, Drug Court Balochistan, Quetta. The Board further observed that Drug Court Balochistan, Quetta may seek attendance of the accused through Law Enforcement Departments. The Board therefore decided to forward Marasla of the Chairman, Drug Court Balochistan, Quetta to of M/s PlivaPaksitan Pvt Ltd B-77, HITE, Balochsitan for compliance under intimation to the Board.

Case No. 25 **RENEWAL OF DRUG MANUFACTURING LICENCE No. 000425(FORMULATION) & APPROVAL OF QC INCHARGE BY M/S EPOCH PHARMACEUTICALS, KARACHI.**

M/s Epoch Pharmaceutical, Plot No. 83-85, Sector 15, Korangi Industrial Area, Karachi, has applied for renewal of DML No. 000425 by way of formulation for the period of 25-3-2021 to 24-03-2026 on 1st March 2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 7th May , 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Name / detail of directors/partners on letter head along with attested CNIC copies of all partners.
(ii) Dully attested annexure/enclosure of Form-1A.
(iii) Dully attested updated partnership deed.
(iv) Detail of all sections of firm on firm's letter head along with approval letters of all sections issued from CLB of if not available then submit layout plan for regularization.
(v) Updated NDC of CRF.

Later on firm submitted reply / documents which were evaluated and a reminder letter was issued on 2nd July 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

(i) Detail of all sections of firm on firm's letter head along with approval letters of all sections issued from CLB of if not available then submit layout plan for regularization.
(ii) Attested documents regarding management including attested CNIC copies of partners.

The firm has submitted their reply received on 15th July 2021 which is evaluated and application for renewal of DML is still found following shortcomings / deficiencies:-

i. Approval letters of all licensed sections issued from the CLB or submit layout plan for regularization of manufacturing facility in the light of approved layout plan as the firm only **possess approval letters of only four (04) sections** namely Human Liquid Injection amp & vial (General) , Ophthalmic Drop (General) , Liquid Injection Vet (Gen antibiotic), Oral Veterinary.

The firm also submitted layout plan for regularization of existing manufacturing facility which was not legible and the firm is advised to submit legible copy of layout plan and also depute technical person to discuss the layout plan.

The firm also applied for approval of QC In charge Mr. Ahmed Saeed which were evaluated and a letter dated 23rd August 2021 was issued to the firm to submit following documents :

i. Copy of Detail Marks sheet (M.Sc Chemistry).
ii. Relevant Experience certificates as under the Prescribed Rules.
iii. Dully notarized Undertaking on stamp paper regarding whole time employment.
iv. Resignation letter of appointee from previous firm.

The reply/documents submitted by the firm were evaluated and later on a Reminder dated 18th October 2021 was issued to the firm to submit the documents following documents :

i. Dully attested copy of Detail Marks sheet (M.Sc Chemistry).
ii. Dully attested Relevant Experience certificates as under the Prescribed Rules.

iii. Dully notarized Undertaking on stamp paper regarding whole time employment.

iv. Attested Resignation letter of appointee from previous firm.

No reply/documents are submitted by the firm in response to Final Reminder.

Decision of Central Licensing Board in 284th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000425 by way of formulation of M/s Epoch Pharmaceutical, Plot No. 83-85, Sector 15, Korangi Industrial Area, Karachi may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

The show cause notice dated 4th January 2022 was issued to the firm.

In response/reply to show cause notice the firm has submitted layout plan for regularization of existing manufacturing facility along with documents for approval of QC In charge which are evaluated .

The firm is issued a letter for rectifications of shortcomings in the layout plan for regularization after being discussed in the LOP committee.

The application for renewal of DML No. 000425 (Formulation) & for approval of QC In charge are still deficient of following documents :

i. Submit revised layout plan for regularization in the light of observations conveyed vide letter dated 16th February 2022.
ii. Dully attested copy of Detail Marks sheet (M.Sc Chemistry) on which the date of declaration of result is mentioned.
iii. Dully attested Relevant Experience certificates as under the Prescribed Rules.
iv. Dully notarized Undertaking on stamp paper regarding whole time employment.
v. Attested Resignation letter of appointee from previous firm.

The firm is called for **Personal Hearing** vide letter dated 7th March 2022.

Decision of the Central Licensing Board in 285th meeting

Mr. Muhammad Saleem managing partner and Mr. Salman assistant of the firm appeared before the Board and contended that they had submitted all required documents as and when asked. They further argued that they are willing to submit documents as required. When confronted with the question they admitted that at present there is no Quality Control In charge in their factory. The person whose documents had been submitted for approval has left before approval. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No. 000425 by way of formulation of M/s Epoch Pharmaceutical, Plot

No. 83-85, Sector 15, Korangi Industrial Area, Karachi 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) 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

Before the issuance of suspension orders/decision of the CLB, the firm submitted the required documents and the application of renewal of DML No. 000425(Formulation) was complete , therefore, the suspension orders were not issued.

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 cease the operation of suspension for the further period issued in the name of M/s Epoch Pharmaceutical, Plot No. 83-85, Sector 15, Korangi Industrial Area, Karachi

Case No. 26 **APPROVAL OF TECHNICAL STAFF PRODUCTION AND QUALITY CONTROL INCHARGE UNDER DRUG MANUFACTURING LICENSE NO. 000529 OF M/S TRISON RESEARCH LABORATORIES (PVT) LTD, PLOT NO. 27-A, PUNJAB SMALL INDUSTRIAL ESTATE, SARGODHA.**

Case Background:

M/s Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, Punjab Small Industrial Estate, Sargodha had applied for change of technical staff's application under DML No. 000529 by way of formulation. The application for the change of technical staff was evaluated and a letter for shortcomings / deficiencies was issued to the firm on 18th November, 2019 and final reminder was issued on 8th December, 2020 for following shortcomings:-

For QC Incharge Ms. Fatima Akbar.

1. Resignation / retirement documents of previous QC Incharge.

For Production Incharge Khalil Ahmed.

1. Resignation / retirement documents of previous Production Incharge.
2. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

The firm submitted their reply on 26th March, 2021 and submitted fresh documents for change of technical staff instead of above mentioned technical staff. After evaluation of the submitted documents following shortcomings has been still observed: -

For Pro. Incharge (Mr. Khalid Saleem).	For QC Incharge (Qurat Ul Ain Shahid).
1. Appointment letter (Not provided). 2. Job acceptance letter by the appointee (Not Provided). 3. Copy of CNIC of appointee (Not provided). 4. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not Attested). 5. Registration certificate from Pharmacy	1.Appointment letter (Not provided). 2.Job acceptance letter by the appointee Appointment letter (Not provided). 3.Copy of CNIC of appointee (Not provided). 4.Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not Attested). 5.Registration certificate from Pharmacy Council

Council (in case of Production Incharge) (Not Attested). 6. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not Attested). 7. Resignation / retirement of earlier Production Incharge (Not provided). 8. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Not Provided). 9. Undertaking as whole time employee (Not provided).	(in case of Production Incharge) (Not Attested). 6.Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not Attested). 7.Resignation / retirement of earlier Production Incharge (Not provided). 8.Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Not Provided). 9.Undertaking as whole time employee (Not provided).

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000529 (by way of formulation) of M/s Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, Punjab Small Industrial Estate, Sargodha may not be suspended or cancelled by the Central Licensing Board.

The show cause notice dated 28th May 2021 was issued to the firm.

In response/reply the **un attested** documents submitted by the firm are evaluated and the following documents are still deficient :

i. Attested Appointment & Job Acceptance letter of both Production in charge and QC In charge.
ii. Duly notarized undertaking regarding whole time employment of production and QC In charge signed by both appointee and management of the firm.
iii. Relevant experience certificates in testing of drugs as required under Rule 16 (e) of the Drugs (L,R&A) Rules, 1976 of Proposed QC In charge Ms. Qurat ul Ain as she posses experience in regulatory affairs and production as per documents submitted by the firm, or if not available, then submit documents of new proposed QC In charge along with Prescribed fee.
iv. Resignation of previously appointed QC In charge.

The firm is called for Personal Hearing vide letter dated 7th March 2022.

Decision of the Central Licensing Board in 285th meeting

Mr. Irfan Gulzar, Director of the firm appeared before the board and contended that he had submitted documents multiple time and gain willing to submit. When confronted with the requirement of documents he agrred to submit correct documents with in day or two. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000529

(by way of formulation) of M/s Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, Punjab Small Industrial Estate, Sargodhatill 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

Before the issuance of suspension orders/decision of the CLB, the firm submitted the required documents and the application of renewal of DML No. 000529 (Formulation) was complete , therefore, the suspension orders were not issued.

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 cease the operation of suspension of Drug Manufacturing Licence of for the further period issued in the name of M/s Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, Punjab Small Industrial Estate, Sargodha

Case No. 27 **CORRECTION IN THE TITLE AND DRUG MANUFACTURING LICENSE NO. OF M/S TITLIS PHARMACEUTICALS (VT) LTD, FAISLABAD**

M/s Titlis Pharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore. DML No. 000779 (Formulation) Sections (03) : 1. Tablet (General) II- **New** 2. Dry Powder Suspension - **New** 3. Dry Powder Sachet (General) - **New**	**01-03-2022**	**Good**	1. Dr. Zakaur Rehman, COO, PDTRC, Lahore. 2. Federal Inspector of Drugs-II, DRAP, Lahore 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.

Recommendations of panel :

Keeping in view the facilities like building, HVAC system, equipment, instruments, personnel, documentation, SOPs availability, quality control and testing facilities; the ***panel of inspectors recommends the grant of approval of additional sections of M/s. Titlis Pharma (pvt) Ltd, Lahore for the following three sections****:-*

1. *Tablet Section II (General)* **New**
2. *Dry Powder Suspension Section.* **New**
3. *Dry Powder Sachet Section (General).* **New**

Decision of the Central Licensing Board in 285th meeting:

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

TitlisPharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore under DML No.000779 (Formulation) on the recommendations of the panel of experts:

Section (03):

1. *Tablet Section II (General)* **New**
2. *Dry Powder Suspension Section.* **New**
3. *Dry Powder Sachet Section (General).* **New**

In the agenda and in the minutes the title of the firm was in advertently mentioned as M/s Titlis Pharma, instead of M/s Titlis Pharma (Pvt) Ltd, Lahore and the DML No. 000799 (Formulation) was mentioned instead of DML No. 000779(Formulation).

Case is placed before the Board for consideration, please.

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

The Board considered the facts on the record and approved the correction in the title and DML No. of the firm asM/s Titlis Pharma (Pvt) Ltd, Lahore under DML No. 000799(Formulation).

Case No. 28 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000613 (FORMULATION) OF M/S GOODMAN LABORATORIES (PVT) LTD, RAWAT.**

M/s Goodman Laboratories (Pvt) Ltd, Rawat is licensed firm having DML # 000613 by way of Formulation with validity of 20-03-2022. However, is submitted that as per available record, application for renewal of DML # 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,

Rawatmaynot 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.

Case No. 29 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000607 (FORMULATION) OF M/S ENVOY PHARMACEUTICALS (PVT) LTD, LAHORE.**

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 licence."

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.

Case No. 30 **LICENSED PHARMACEUTICAL UNITS BEING ISSUED THE ENLISTMENT CERTIFCIATES BY THE DIVISION OF MD&MC, DRAP, ISLAMABAD**

A letter is received from Dr. Ghazanfar Ali Khan, Additional Director (MDMC), (Secretary MDB), DRAP, Islamabad wherein he has stated as under:
"I am directed to refer to the subject noted above and to say that below mentioned firms have been issued Establishment License to Manufacture Medical Devices (ELM) under the policy of Drug Regulatory Authority of Pakistan as mentioned against each:

Sr. No.	Name, Address and DML Number of Manufacturer	Status	ELM Number & Date
1.	M/s. Jaash Pharma, 19 km, Ferozpur Road, Lahore	Submitted	ELM-0037 28-06-2021
2.	M/s. Lasani Health Care, KPK. (DML No. 000788)	Submitted	ELM-0036 26-05-202
3.	M/s. Uniferoz Karachi. (DML No.000 515)	Submitted	ELM-0011 28-11-2019
4.	M/s. Injection System, Godon Amazai DML No. 000695(Formulation)	Submitted	ELM-0034 18-05-2021
5.	M/s Al Badar Manufacturing (Pvt) Ltd, District Swabi. (DML No: 000705)	Submitted	ELM-0029 19-10-2020
6.	M/s. National Absorbant Cotton Mills, Karachi (DML No: 000137)	Submitted	ELM-0009 11-11-2019
7.	M/s Amsons Vaccines & Pharma (Pvt) Ltd, Islamabad		ELM-0005 16-11-2018
8.	M/s. Faisal Pharmaceutical Industries, Faisalabad	Submitted	ELM-0019 06-04-2020
9.	M/s. Dr. Sethi Pharma Industries, Chichawatni.	Submitted	ELM-0023 20-07--2020
10.	M/s. Paktex Industries, Kamoke	Submitted	ELM-0025 23-10-2020
11.	M/s. 3N Lifemed Pharmaceuitcals, Sargodha	Submitted	ELM-0026 09-10-2020
12.	M/s. Surg Plast, Gadoon Amazai, KPK	Submitted	ELM-0030 29-10-2020
13.	M/s. Medicare Disposable Industries, Lahore.	Submitted	ELM-0043 16-09-2021
14.	**M/s. Armoz Pharma (Pvt) Ltd, Lahore**	**Submitted**	**ELM-0047 13-01-2022**

The case was placed before the MDB in its 41st meeting held 23rd November, 2021 & in 46th meeting held on 28th Feb, 2022 and decided to refer the above companies/firms to Central Licensing Board (CLB) for cancellation of DML from the date they were granted Establishment License to manufacturing medical devices as mentioned in the last column in the above table.

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

The Board was apprised that DRAP Authority has approved the guidelines for Drug Manufacturing Licence holders which were previously manufacturing products which have been notified and defined as Medical Devices. In the pursuance to the decision of the Authority, the Medical Device and Medicated Cosmetics (MDMC) Division had issued a notification 26th May, 2021 which is reproduced as under:-

"*all those DML holders under the Drugs (Licensing, Registering & Advertising) Rules, 1976, who are only manufacturing medical devices will be converted to the Establishment License to Manufacture Medical Devices (ELM) under Medical Devices Rules-2007 and MDB will grant ELM for remaining period of validity of DML issued by*

the Central Licensing Board (CLB) and subsequently, the CLB will cancel these licenses under intimation to MDB."

The Board considering the facts decided to cancel the Drug Manufacturing Licenses of following firms:-

Sr. No.	Name, Address and DML Number of Manufacturer	Status	ELM Number & Date
1	M/s. Jaash Pharma, 19 km, Ferozpur Road, Lahore	Submitted	ELM-0037 228-06-2021
2	M/s. Lasani Health Care, KPK. (DML No. 000788)	Submitted	E3LM-0036 264-05-202
3	M/s. Uniferoz Karachi. (DML No.000 515)	Submitted	EL5M-0011 28-11-2019
4	M/s. Injection System, Godon Amazai DML No. 000695(Formulation)	Submitted	ELM-0034 18-05-2021
5	M/s Al Badar Manufacturing (Pvt) Ltd, District Swabi. (DML No: 000705)	Submitted	ELM-0029 19-10-2020
6	M/s. National Absorbant Cotton Mills, Karachi (DML No: 000137)	Submitted	ELM-0009 11-11-2019
7	M/s. Faisal Pharmaceutical Industries, Faisalabad	Submitted	ELM-0019 06-04-2020
8	M/s. Dr. Sethi Pharma Industries, Chichawatni.	Submitted	ELM-0023 20-07--2020
9	M/s. Paktex Industries, Kamoke	Submitted	ELM-0025 23-10-2020
10	M/s. 3N Lifemed Pharmaceuitcals, Sargodha	Submitted	ELM-0026 09-10-2020
11	M/s. Surg Plast, Gadoon Amazai, KPK	Submitted	ELM-0030 29-10-2020
12	M/s. Medicare Disposable Industries, Lahore.	Submitted	ELM-0043 16-09-2021
13	**M/s. Armoz Pharma (Pvt) Ltd, Lahore**	**Submitted**	**ELM-0047 13-01-2022**

The Board also decided to cancel the section of M/s Amsons Vaccines & Pharma (Pvt) Ltd, Islamabad which was licensed under the domain of formulation and now has come under MDMC.

Case No 31 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S BASEL PHARMACEUTICALS, MULTAN.

M/s Basel Pharmaceuticals, 227- Phase-II, Multan Industrial Estate, Multan had applied for renewal of DML No. 000726 by way of Formulation for the period of 21-06-2021 to 20-06-2026 on 16-06-2021.

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 08-07-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management.
iii. Legal status of the firm, if sole proprietor submit undertaking as whole proprietor on stamp paper.
iv. Duly attested CNIC of owner.
v. Section approval letters approved by CLB, if not available, submit layout plan apply for regularization.
vi. Name, class and dosage form of drugs being manufactured.
vii. Name and qualification of technical staff.
viii. Approval letters of Production Incharge and Quality Control Incharge.

The firm did not reply and reminder was issued on 28-09-2021 to the firm for submission of following documents:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management.
iii. Legal status of the firm, if sole proprietor, submit undertaking as whole proprietor on stamp paper.
iv. Duly attested CNIC of owner.
v. Section approval letters approved by CLB, if not available, submit layout plan apply for regularization.
vi. Name, class and dosage form of drugs being manufactured.
vii. Name and qualification of technical staff.
viii. Approval letters of Production Incharge and Quality Control Incharge.

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

In the meanwhile, Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore has reported that he visited the premises of the firm on 30-09-2021 to check status of the firm on second time. Firm was found closed, no any activity was observed since long. Presently also found the premises closed and the building seems non-functional and closed since long and was in deplorable condition, no any person was present. In these conditions, it is not possible to maintain the conditions of manufacturing of Pharmaceuticals products (conditions of DML). So, he has suggested that personal hearing may be given to the management of the firm in this regard and then the DML may be cancel after codal formalities as per Drugs Act, 1976 and DRAP Act, 2012.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5 (2A), Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000726 by way of Formulation of M/s Basel Pharmaceuticals, 227- Phase-II, Multan Industrial Estate, Multan may not be suspended or cancelled by the Central Licensing Board.

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

Show Cause Notice was issued to the firm on 22nd November,2021.

The firm replied to Show Cause Notice but application for renewal of DML is still incomplete with following documents being deficient:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Duly attested valid Registration Certificate from Pharmacy Council and experience certificates of proposed Quality Control Incharge.

A letter of personal hearing was issued to the firm on 8th March, 2022.

Decision of the Central Licensing Board in 285th meeting

Mr. Khalid Muhammad Managing Director and Syed Muhammad Raza GM of the firm appeared before the board and contended that they were new management and wanted to make company operational. He further contended that they have taken up matter of CRF with Budget and Accounts and would be resolved soon. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No. 000726 by way of Formulation of M/s Basel Pharmaceuticals, 227- Phase-II, Multan Industrial Estate, Multan 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) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Secretary CLB may take decision in case codal formalities are submitted and case may be placed before the board for ratification in forthcoming meeting.

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

The firm has fulfilled all the codal formalities before issuance of Suspension Order.

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 cease the operation of suspension for the further period in the name of M/s Basel Pharmaceuticals, 227- Phase-II, Multan Industrial Estate, Multan.

Case No-32 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HARMANN PHARMACEUTICAL LABORATORIES (PVT) LTD, LAHORE.

M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, 16-Km, Multan Road, Lahore had applied for renewal of DML No. 000145 by way of Formulation for the period of 09-01-2021 to 08-01-2026 on 07-12-2020.

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 15-01-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management.
iii. Latest certified true copy of Form-29 duly attested by SECP (Original).
iv. Duly attested CNIC copies of all Directors.
v. Status of regularized sections/facility whether the firm is ready for inspection or otherwise.

The firm did not reply to this letter and reminder letter was issued on 08-07-2021 to the firm for completion of application:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management.

iii. Latest certified true copy of Form-29 duly attested by SECP (Original).
iv. Duly attested CNIC copies of all Directors.
v. Status of regularized sections/facility whether the firm is ready for inspection or otherwise.

The firm replied to reminder on 12-08-2021 and intimated that their two Directors died due to Covid and they are in process of finalization of succession certificates from Court however, application for renewal of DML is still incomplete with following documents being deficient:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Prescribed fee of Rs.75,000/- and apply for change of management.
iii. Latest certified true copy of Form-29 duly attested by SECP (Original).
iv. Duly attested CNIC copies of all Directors.
v. Status of regularized sections/facility whether the firm is ready for inspection or otherwise.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5 (2A), Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000145 by way of formulation of M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, 16-Km, Multan Road, Lahore may not be suspended or cancelled by the Central Licensing Board.

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

A Show Cause Notice was issued to the firm on 22nd November, 2021.

The firm replied to Show Cause Notice and but application for renewal of DML is still deficient of following documents:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Latest certified true copy of Form-29 duly attested by SECP (Original).
iii. Status of regularized sections/facility whether the firm is ready for inspection or otherwise.

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

Decision of the Central Licensing Board in 285th meeting

Mr. Haseeb Khan CEO of the firm appeared before the board and contended that he had taken up the matter with Budget and Accounts and would get nothing due certificate soon. He also reiterated that he was ready for the inspection of regularized sections. He also added that Form-29 from SECP would be issued in day or one. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000145 by way of formulation of M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, 16-Km, Multan 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.

The firm has fulfilled all the codal formalities before issuance of Suspension Order.

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 cease the operation of suspension for the further period in the name of M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, 16-Km, Multan Road, Lahore.

CASE NO.33 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FERROZA INTERNATIONAL PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur Road, Lahore had applied for renewal of DML No. 000389 by way of Formulation for the period of 26-06-2021 to 25-06-2026 on 23-06-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 01-09-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management at the time of previous renewal, if any change, apply for change of management with proper application and prescribed fee.
iii. Duly attested CNIC copies of all Directors.
iv. Sections approval letters approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letters of Production Incharge and Quality Control Incharge.

The firm did not reply and reminder was issued on 08-10-2020 to the firm for submission of following documents:

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management at the time of previous renewal, if any change, apply for change of management with proper application and prescribed fee.
iii. Duly attested CNIC copies of all Directors.
iv. Sections approval letters approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letters of Production Incharge and Quality Control Incharge.
vi. Documents should be duly attested.

The firm replied to reminder on 27-10-2020 but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest certified true copy of Form-29 duly attested by SECP (Original).
ii. Sections approval letters approved by CLB, if not available, apply for regularization of layout plan.
iii. Complete set of duly attested documents (as per checklist except CNIC & experience certificates) of proposed Production Incharge and Quality Control Incharge along with prescribed fee.
iv. Documents should be duly attested.

Moreover, it is pertinent to mention here that the firm has been carrying out production activities without approved Quality Control Incharge since 2015 and without approved Production Incharge since 2013 as reflected in certificates submitted by the firm.

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

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000389 (by way of formulation) of M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur Road, Lahore may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause Notice was issued to M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur Road, Lahore on 30th September, 2021.

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

i. Latest certified true copy of Form-29 duly attested by SECP (Original).
ii. Sections approval letters approved by CLB, if not available, apply for regularization of layout plan.
iii. Complete set of duly attested documents (as per checklist except CNIC & experience certificates) of proposed Production Incharge and Quality Control Incharge along with prescribed fee.
iv. Documents should be duly attested.

Moreover, it is pertinent to mention here that the firm has been carrying out production activities without approved Quality Control Incharge since 2015 and without approved Production Incharge since 2013 as reflected in certificates submitted by the firm.

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

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

Mr. Usman Khalid, Director of the firm appeared before the board. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000389 by way of Formulation M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur Road, 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.

The firm has completed all the codal formalities.

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

DML Suspension order was issued to the firm on 27th December, 2021. Later on, the firm fulfilled all the codal formalities and in the light of decision of CLB, Secretary, CLB has revoked the suspension order on 12th January, 2022.

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

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

Case No. 34 **REQUIREMENT OF PSYCHOTROPIC SECTION FOR MANUAFCTURE OF DRUGS.**

CASE BACKGROUND

The Drugs Act, 1976 and rules framed thereunder regulates the manufacture, import, export and sale of drugs including Psychotropic/ narcotic drugs. The Psychotropic/ narcotic drugs were manufactured by the pharmaceutical manufacturers in the General Area/Sections along with general class of drugs since enactment of the Drugs Act 1976 and rules framed there under.

Later on, an issue of misuse of quota allocation of "Ephedrine" which is a precursor chemical arose and a number of applications for quota applications increased. To manage the thrust of applicants, the CLB in its 220th meeting held on 5th November 2009 devised a policy for conversion/establishment of segregated section for the manufacturing of Psychotropic drugs. The policy points are represented as below :

i. Approval of layout plan with proper segregation of the section (900 square feet as per Schedule B), its raw material store and dispensing area.
ii. HVAC system should be mandatory requirement along with cleaning validation system.
iii. Establishment and maintenance of lock and key for proper storage of Narcotic/Psychotropic raw materials and finished goods would also be an essential requirement prior grant of additional section / conversion.
iv. Inspection would be a pre-requisite and subsequently the case

PPMA made a representation to Chairman Policy Board and the Policy Board. The Policy Board in its 4th meeting held on 23rd October, 2013 discussed the instant matter and the Board decided as under; (extract attached)

> *a. The Board regretted the request of the PPMA to allow the contract manufacturing permission for the controlled drugs keeping in view the issue of related to allocation and consumption of quota of the controlled Drugs,*
> *b. The Board advised the Director Licensing/Chairman Central licensing Board to resolve the issue of dedicated facility for the manufacturing of Psychotropic Drugs, on priority and if that was not express requirement of respective rules then the CLB should considered allowing campaign manufacturing as per international practice.*

The DRAP Policy Board again considered the matter and in its 5th meeting held on 16-01-2014 discussed and it was decided as under;

> *"The Board after hearing the view point of stakeholders and DRAP decided to authorize its Chairman to constitute a Committee to make its recommendations to the Policy Board for decision in the forthcoming meeting. The Committee shall make its recommendations keeping in view the international best practice as well as the local regulatory requirements. In the meanwhile, the practice as decided by the Central Licensing Board shall continue."*

It is submitted that no committee has been constituted yet to resolve the matter. Now Chairman, Policy Board/ Secretary, Ministry of National Health Services and Regulation and Coordination has directed that it is purely technical issue and needs to be resolved/ dealt at appropriate forum i. e. Central Licensing Board.

FACTS.

It is submitted that International narcotics Board (INCB) monitors the import, export and sale of controlled substances which includes:-

a. Precursor chemicals
b. Psychotropic Substances
c. Narcotics Drugs

Sr. #	Name of controlled substance	Controlled Substances (Class)
1	Diphenoxylate	Narcotics
2	Fentanyl	
3	Morphine	
4	Pholcodine	
5	Pethidine	
6	Remifentanil	
7	Oxycodone	
8	Ergotamine	Pre-Cursor Chemical
9	Ephedrine	
10	Pseudoephedrine	
11	Ergometrine	
12	Diazepam	Psychotropic
13	Estazolam	
14	Lorazepam	
15	Lormetazepam	
16	Methylphenidate	
17	Midazolam	
18	Nitrazepam	
19	Pentazocine	
20	Phenobarbitone	
21	Temazepam	
22	Zolpidem	
23	Fludiazepam	
24	Meprobamate	
25	Medazepam	
26	Nimetazepam	
27	Oxazepam	
28	Pinazepam	
29	Prazepam	
30	Triazolam	
31	Alprazolam	
32	Bromazepam	
33	Buprenorphine	
34	Chlordiazepoxide	
35	Clobazam	
36	Clorazepate	

37	Clonazepam	

The INCB also allocates on the request of member country for increase or decrease of legitimate requirement of the controlled substance.

It is also submitted that case of mis-appropriation of the quota of "Ephedrine" which is a precursor chemical surfaced and one of the measures was requirement of Psychotropic Section was decided in 220th meeting of the Central Licensing Board in pursuance of the paragraph 5.2 of the Schdeule "B" notified under Rule, 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. It is also submitted that Ephedrine is a precursor chemical but not a psychotropic drug and as of today Ephedrine containing drugs are also manufactured in "General Section" on the pretext that it is not a "psychotropic drug". It is also submitted that internationally under PICs Guidelines or WHO Guidelines there is no requirement of segregate section for psychotropic drugs. Moreover, a draft amendment has also been proposed which is lying with the Federal Government for adaptation of PICs Guidelines and Schedule "B" under the under Rule, 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 will be substituted.

In view of the above, it is submitted that Central Licensing Board may deliberate the matter in public interest.

Decision of the Central Licensing Board in 286thmeeting:

The Board after deliberation in length decided to seek detail presentation from PPMA and Pharma Bureau to present their point of view before the CLB in upcoming meeting. The Board also decided to refer the case to PE&R Division and Controlled Drugs Division DRAP for their comments/views on the matter.

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

In light of above decision of the board, PE&R Division and Controlled Drugs Division DRAP were requested to their comments/views on the matter.

PE&R Division, DRAP submitted their comment/view which is reproduce as under;

"The Matter may be reviewed in light of Schedule B-II of Drugs (LR&A), 1976. Moreover, it has been observed that after separate section requirement, influx of such applications have been increased due to investment in establishment of such facilities."

Meanwhile , an applicant firm, M/s. The Schazoo Pharmaceutical Laboratories(Pvt) Ltd, Lahore requested which is reproduced under

> *"We are pleased to invite your kind invitation towards a continuing delay by the concerned authorities in releasing our annual quota of Medazolam for the calendar year 2022.*

It is to inform you that we had applied for issuance of our annual quota of Medazolam 6.7971Kgs. for the year 2022 on 4th January 2022, release of which is still awaited.

In this context it is submitted that we had participated in various tenders throughout Pakistan and till today have received confirmed orders from 19 different government institutions for supply of Medazolam Injections amounting to about One Hundred Thousand ampoules. In addition to this order from other government institutions are also expected.

In case the said quota is not released at the earliest we will not be able to undertake implementation of these orders due to which there is going to be an acute shortage of these injections and the institutions will be facing a hard time without these injections (list of institutions along with their required quantities is attached with this letter.

It is therefore requested that kindly take personal interest in getting our requested quota released as soon as possible."

Furthermore, the Federal Cabinet in its meeting held on 24th February, 2022 has approved Minimum Area Requirement of Pharmaceutical Units and Adoption of Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guidelines for Good Manufacturing Practices (GMP) vide Cabinet decision No.CCLC-29/02/2022 dated 24' February, 2022. The said draft amendment has been notified Vide S.R.O 778(I)/2022 and available on DRAP official Website.

Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
*****

Islamabad, the 10th June, 2022.

NOTIFICATION

S.R.O. 778 **(I)/2022.**— The following draft of further amendments in the Drugs (Licensing, Registering and Advertising) Rules, 1976, which is proposed to be made by the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, in exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with clause (a) of section 7 thereof and section 43 of the Drugs Act, 1976 (XXXI of 1976), is hereby published for the information of all persons likely to be affected thereby and, as required by sub-section (3) of section 43 of the said Act (XXXI of 1976), notice is hereby given that objections or suggestions thereon, if any, may, for consideration of the Federal Government, be sent within fourteen days of the publication of this Notification in the official Gazette.

Any objections or suggestions which may be received from any person in respect of the said draft before expiry of the aforesaid period shall be taken into consideration by the Federal Government, namely:-

DRAFT AMENDMENTS

In the aforesaid Rules,--

(1) in rule 16.—

(i) in clause (a), for the expression "Schedule B", the expression "Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, as updated from time to time" shall be substituted;

(ii) in clause (b), for the expression "Schedule B-I", the expression "Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, as updated from time to time" shall be substituted;

(iii) in clause (bb), for the expression "in addition to the conditions specified in Schedule B and Schedule B-1 comply with the conditions specified in Schedule B-IA", the expression "comply with the conditions specified in Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, as updated from time to time" shall be substituted; and

(iv) after clause (bb), amended as aforesaid, the following two provisos shall be inserted, namely:-

"Provided that the amendments in clause (a), (b) and (bb) shall take effect from the 1st July, 2022:

Provided further that the matters not explicitly covered in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, the guidelines of the World Health Organization shall be followed.";

(2) in rule 20.—

(i) in clauses (a) and (c), for the expression "Schedule B-III", the expression "Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, as updated from time to time" shall be substituted;

(ii) in clause (b), for the expression "Schedule B-III", the expression "in a manner as specified in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, as updated from time to time" shall be substituted; and

(iii) in clause (c), for full stop at the end, a colon shall be substituted and thereafter the following provisos shall be inserted, namely:-

"Provided that the amendments in clause (a), (b) and (c) shall take effect from the 1st July, 2022:

Provided further that the matters not explicitly covered in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP guidelines, the guidelines of the World Health Organization shall be followed.";

(3) in Schedule-B, clause 1.3 shall be omitted; and

(4) Schedule B, B-1, and B-1A, B-II and B-III shall be omitted with effect from the 1st July, 2022.".

[No. F.10-9/2021-Lic/DRAP]

AAMAR LATIF,
Deputy Director (Legal Affairs).

The Manager,
Printing Corporation of Pakistan Press,
Islamabad.

Mr. Asad Shuja made a presentation on behalf of the PPMA and focused on following points.

1. **Previous practice of section and quota allocation.**

   He argued when SRO. 470/98 was notified in 1998, which envisages requirement for segregated and dedicated facilities for manufacturing of drugs. It does not contain segregated facilities for Psychotropic drugs. He further argued that SOP framed for allocation of quota for controlled substances also does not require for segregated section. It only requires copy of drug Manufacturing Licence and Registration of Drug. This years scrutiny has been made and extended to section approval for psychotropic section. Resultantly, quota allocation has not been

made to certain critically required drugs which may cause shortage of drugs in the market and unavailability for needy patients.

2. **No example of dedicated section in stringent countries**
   He argued that no example of segregated section is available in Stringent Regulatory Authority (SRA) countries. While DRAP is following SRA countries as bench mark in registration of drugs therefore same analogy may be applied for controlled substances as well. He further argued that making huge investment for establishment of independent section for one product does make it viable and resultantly companies urge for more registration. This trend does not promote healthy competition for controlled substances.

3. **Already very strong check and control of quota allocation by DRAP and Ministry of Narcotic control and ANF.**
   He argued that there are strong checks on utilization of quota and inspection by panel from DRAP and Ministry of Narcotics Control and ANF for verification of legitimate utilization. In the presence these stringent requirements there is no logic for having separate section which may be deterrence to misappropriation. Inspection by DRAP and ANF cause enough deterrence.

4. **Present status and problem created.**
   He argues that this year section requirement has been asked and thereby quota has not been allocated to some critically available drugs. He further argues that Pics also do not require segregated section while draft notification has also been published for repealing of Schedule B and implementation of PICs.

5. **Way forward to create further complications.**
   He argues that since PICs is being implemented it would be appropriate to follow SRA countries and requirement of segregated section, which was self-created, be dispensed with and let the Drug Registration Board to decide for the requirement for registration of drugs containing controlled substances.

The Board after seeking detailed deliberation observed that segregated section forpsychotropic section has not served the purpose for which it was meant. It has been observed that after separate section requirement, influx of registration applications have been increased due to investment in establishment of such facilities. Meanwhile, stringent requirements framed in SOP for allocation of quota of controlled substances effectively regulates legitimate utilization of the

controlled substances. Moreover, Requirement of segregated section, after repealing of schedule B and implementation of PICs guidelines, will be in fructus. The Board therefore, decide that segregated requirement of psychotropic section is dispensed with in public interest to ensure availability of medicines for ailing patients. However, those companies who intend to continue with segregated section are at liberty to continue with the nomenclature of said section.

QUALITY ASSURANCE (QA) CASES

Item No. I.: **M/s Alen Pharmaceutical (Pvt.) Ltd. Plot No. 138-A, Nowshera Industrial Estate Risalpur, KP. (DML No. 000435) [Personal Hearing].**

Mr. Zia Ullah FID-III DRAP Peshawar inspected the firm M/s. Alen Pharmaceuticals (Pvt) Ltd., 138, Nowshera Industrial Estate, Risalpur (DML No. 000435) on 23.12.2019 to check the GMP compliance.

2. The FID reported following observations;

Change Rooms:-

i. Replace air curtains at entrances of the change rooms as the existing air curtains are inefficient.
ii. Make arrangement for placements of overhauls, shoes etc in the executive change rooms.
iii. Provide almirahs / cupboards for placement of uniforms / clothes and stainless steel racks for shoes. Cleaning of the change rooms should be monitored and its record should be maintained properly.
iv. Blind the glass partitions and to properly seal the gaps towards the upper part of these partitions to ensure complete segregation.
v. Apart from this the other small gaps present in these partitions also need to be sealed completely.
vi. Provide a separate liquid materials store for such materials.
vii. Arrange and install a suitable dispensing booth at the earliest and to provide HVAC system with HEPA filters in the dispensing room as required for the dispensing operations.
viii. Facilities for keeping the relevant record of the raw materials store such as stocks ledgers, bin cards, sampling request slips, manufacturing orders forms etc. should also be provided.

Tablet Section (General):-

i. Arrange a separate double cone mixer for the tablet section and install in the designated room as per approved layout plan.
ii. For the drying purpose, there is an old tray dryer provided, which lacks appropriate facilities of uniform drying. It is recommended to replace tray dryer with a more efficient and GMP compliant dryer.
iii. Installed HVAC system in the section; however the wet mixing and drying room lack the HVAC system. The firm directed to install HVAC system in these rooms.

Blistering / Packing Hall:-

i. Segregate the blistering area and the blister machine by installing a partition, so that the blistering and packing operations can be performed in separate areas.

Cephalosporin Sections:-

i. Provide a laminar flow dispensing booth as well.

Quality Control:-

i. Arrange another stability chamber for the real time and accelerated stability studies with data loggers and backup power supply.
ii. Stability studies protocols need to be developed and followed.
iii. Purchase recent editions of official books and official testing methods should be adopted for the products manufactured by the firm.

HVAC System:-

i. HVAC system for tablet section needs to be properly validated for its various parameters.
ii. The HVAC system in this section lacks the bag filters.

iii. Pressure monitoring gauges were also not functioning, which need to be refilled.

Premises / Building:-

i. Seepage was observed in multiple areas, which need urgent treatment.
ii. The walls in certain areas also need to be painted afresh as it appeared that the building has not been given due attention over the course of time.

Personnel:-

i. Appoint quality assurance personnel.

Conclusion:-

"As per preceding observations made during inspection including but not limited to absence of HVAC system in tablet wet mixing and drying areas, a suitable GMP compliant dryer in tablet section, lack of dry mixing facility in tablet section, a properly and completely functioning validated HVAC system in the tablet section, the firm is directed to immediately stop the production activities in tablet section and rectify all the shortcomings at the earliest."

3. Keeping in view the observations and conclusion by the FID, the firm was directed to **Suspend Production Activities in Tablet Section** vide this office letter No. 4-22/2002-QA dated 15.01.2020.

4. M/s. Alen Pharmaceutical (Pvt) Ltd, Plot No. 138-A, Nowshera Industrial Estate, Risalpur, KPK-Pakistan vide letter Ref. No: - DRAP/QA-001 dated 15.03.2021 submitted plan for rectification of the observations which were observed in GMP inspection of their firm conducted on 23.12.2019 by Mr. Zia Ullah, FID, DRAP, Peshawar.

5. While response of the firm was being processed, an inspection, report of the same firm was received from Mr. Faisal Shahzad, FID-I, DRAP, Peshawar dated 19.04.2021. The report is reproduced below;

"The firm M/s Alen Pharmaceuticals (Pvt.) Ltd. 138, Nowshera Industrial Estate, Risalpur was visited to observe compliance DRAP letter No. F. 4-22/2002-QA dated 15.01.2020 wherein production activities in Tablet Section were suspended. During the visit, no production activities of tablet section were observed, however, the following product was recovered from the tablet section;

1- Dolint 7.5mg tablet, Mfg. date 01/2021, Exp. Date 12/2023, 62 packs Reg. No. (031016) claimed to be manufactured by the firm M/s. Alen Pharmaceuticals (Pvt) Ltd., Risalpur.

Accordingly, the product was seized on Form-2. Case will be processed as per the DRAP Act, 2012 / Drug Act, 1976."

5. The firm was issued show cause notice vide No. 4-22/2002-QA dated 07.05.2021 on illegal/unauthorized manufacturing, to which the firm submitted following reply vide letter No. No. 02/QAI/QC/02 dated 28.05.2021;

"Referring to your letter (Show Cause Notice-Copy Attached) No. F.4-22/2002-QA dated 07th May, 2021 and received on 24th May 2021, it is to inform you that our tablet section has been closed by area FID on 23rd December 2019 on behalf of some shortcomings.
Sir, it took reasonably long time to complete these shortcomings and the reasons of this delay was nothing but Covid 19. Meanwhile due to non-production activity because of tablet section closing and Covid 19, the firm becomes unable to pay the pending salaries of the staff. Remember that during this critical time, we have not fired even a single worker of the firm.
It was the beginning of the Holy Ramadan and Eid ul Fitr was ahead. Keeping all these factors in mind, we decided to manufacture a batch of tablet (it should be noted that our 92% production belongs to tablet section only) and to relieve the workers on this special occasion of Holy Ramadan and Eid ul Fitr.
We decide it purely on the intension and humanity basis and the aim was clear…..to facilitate the worker financially ahead of Eid ul Fitr.

Sir, we know that we have contravened the law but we have done it with good intensions and that it is to relieve the staff. We hope that you will spare our mistake and will consider our THIS application sympathetically."

6. The Additional Director/FID DRAP Peshawar was requested vide letter No. 4-22/2002-QA dated 28.09.2021 to investigate the matter of unauthorized manufacturing of Dolint 7.5mg Tablet and provide names of the responsible persons. Till date no response has been received from the field office in this regard.

7. The firm M/s Alen Pharmaceutical Pvt. Ltd Risalpur has submitted another letter dated 15.12.2021 wherein they have stated that their 92% percent production is mainly concerned to tablet section and they are facing loses. The firm has requested to constitute a panel to visit the firm and resume the tablet section.

Decision of 284th meeting of CLB

8. The board decided that the area FID shall be directed to submit complete case along with names of responsible persons for presenting the case in next meeting of Central Licensing Board.

9. In compliance of decision of the 284th meeting of Central Licensing Board, the area FID was directed to provide complete case along with names of the responsible persons vide letter dated 30.12.21. The FID vide letter No. 3-20/2021-Alen-DRAP (P) 362 dated 25.01.2022 provided following details;

i. Details of seized stocks of Dolint 7.5mg Tablets manufactured in January 2021.
ii. Copy of BMR of Dolint 7.5mg tablets Batch No. 247 indicating manufacturing of this batch was done from 15.01.2021 to 19.01.2021.
iii. Undertaking by Mr. Abdur Rasheed Production Manager Alen Pharm (Pvt) Ltd Risalpur dated 23.08.2021 having following content;

"I, Mr. Abdur Rasheed (Production Manager- Alen Pharma (Pvt.) Ltd. Risalpur, Nowshera, KPK) hereby confirm that this product (Tablet Dolint 7.5mg) was recovered from us and was held by the area Federal Inspector of Drug (Faisal Shahzad) on 19.04.2021 during a routine inspection to Alen Pharma. The area inspector himself will decide the fate of this stock later on. This stock will remain with us till next order.

Further information about this product has already been handed over to honourable Inspector's Office.

Some necessary particulars / information about this product are given below;

Product Name: Tablet Dolint 7.5mg

Batch No. 247

Batch Size: 6535 Packs

Pack Size: 10 Tablets per pack

Mfg Date: 01-2021

Exp. Date: 12-2023

Total Quantity: 6197 Packs (Present at the time of inspection)"

iv. The FID has given following names of the responsible persons;

a. Mr. Shaukat Ali S/o Muhammad Ali
Chief Executive Officer
M/s Alen Pharmaceutical (pvt.) Ltd 138-A, Nowshera Industrial Estate Risalpur.

CNIC No. :16101-4235301-3

b. Mr. Abdul Rasheed S/o Abdul Raheem
Production Manager
M/s Alen Pharmaceutical (pvt.) Ltd 138-A, Nowshera Industrial Estate Risalpur.
CNIC No. :17101-4472890-3

c. Mr. Muhammad Noshad Ali
Quality Control Manager
M/s Alen Pharmaceutical (pvt.) Ltd 138-A, Nowshera Industrial Estate Risalpur.
CNIC No. :17301-8613319-3

10. The FID has further stated that in light of fore mentioned position and confession statement of the firm, it is established that firm has violated the suspension of production orders passed by the DRAP, Islamabad conveyed vide letter No. F.4-22/2002-QA dated 15.01.2020. The FID has further stated that the firm was visited for case investigation on 16.08.2021 and 06.12.2021 but the firm was never found ready for inspection on one pretext or the other while no manufacturing activity in tablet section was noted. No substantial improvements were observed during visits despite lapse of a long period of almost 2 years.

11. The FID had requested that a three-member panel inspection of the firm may be conducted for detailed evaluation of adherence to GMP compliance and complete case of GMP compliance level along with violations committed by the firm may be considered by the CLB for a decision in the matter.

12. On request of FID following panel of experts was constituted for detailed inspection of the firm;

i. Additional Director DRAP Peshawar.
ii. Area FID, DRAP Peshawar.
iii. Area AD DRAP Peshawar.

13. The panel inspected the firm M/s Alen Pharmaceuticals (Pvt.) Ltd. Plot No. 138-A, Road No. 2 Nowshera Industrial Estate, Risalpur on 14.04.2022. The panel has reported that all observations are satisfactorily addressed and has concluded the report as under;

"Based on the observations of improvement and commitment of the firm to further upgrade their unit in accordance with the latest guidelines issued by DRAP, Islamabad the panel recommends to revoke suspension of production order in tablet (general) section of the firm, if otherwise in accordance with the Drugs Act 1976/ DRAP Act 2012."

14. 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.

15. The firm M/s Alen Pharmaceutical (Pvt.) Ltd. Plot No. 138-A, Nowshera Industrial Estate Risalpur was order by the QA &LT Division to stop production activities in tablet section vide letter No. 4-22/2002-QA dated 15.01.2020 due to non-compliance of the Schedule B-II of the Drugs (Licensing, Registering and advertising) Rules 1976, which they violated by manufacturing Dolint 7.5mg tablet batch No. 247.

16. 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. 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.

17. As per detailed report of the FID, the firm M/s. Alen Pharmaceuticals (Pvt) Ltd., 138, Nowshera Industrial Estate, Risalpur (DML No. 000435), 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.

Proceedings of the 286th Meeting of the Central Licensing Board:

18. The board inquired whether the firm was issued show caused notice or otherwise. The board was apprised that the firm was issued show cause notice vide letter No. 4-22/2002-QA dated 07.05.2021 by QA&LT Division. The violation of the Rule 19 leads to prosecution of the firm and its responsible persons, for this the show cause notice is to be issued by the Central Licensing Board. The board also considered that opportunity for personal hearing shall be given to the firm.

Decision of 286th meeting of the Central Licensing Board:

19. After deliberating and considering all the facts, the board decided as under;

i. The suspension of production in tablet section shall be maintained. The board will decide about the matter after giving personal hearing to the firm M/s Alen Pharmaceuticals (Pvt) Ltd., 138, Nowshera Industrial Estate, Risalpur (DML No. 000435) through its representatives.

ii. The firm M/s Alen Pharmaceuticals (Pvt) Ltd., 138, Nowshera Industrial Estate, Risalpur (DML No. 000435) through its CEO and its following responsible persons shall be called for personal hearing in next meeting of the board.

   a. Mr. Shaukat Ali S/o Muhammad Ali
   Chief Executive Officer
   M/s Alen Pharmaceutical (pvt.) Ltd 138-A, Nowshera Industrial Estate Risalpur.
   CNIC No. :16101-4235301-3

   b. Mr. Abdul Rasheed S/o Abdul Raheem
   Production Manager
   M/s Alen Pharmaceutical (pvt.) Ltd 138-A, Nowshera Industrial Estate Risalpur.
   CNIC No. :17101-4472890-3

   c. Mr. Muhammad Noshad Ali
   Quality Control Manager
   M/s Alen Pharmaceutical (pvt.) Ltd 138-A, Nowshera Industrial Estate Risalpur.
   CNIC No. :17301-8613319-3

The firm's representatives are called upon before the board for personal hearing in compliance to decision of 286th meeting of the CLB.

Proceedings of 287th Meeting of Central Licensing Board:

20. Mr. Shaukat Ali CEO M/s Alen Pharmaceuticals (pvt.) Ltd 138-A, Nowshera Industrial Estate Risalpur and Mr. Inayatullah marketing incharge M/s Alen Pharmaceuticals (pvt.) Ltd 138-A, Nowshera Industrial Estate Risalpurappeared before the Board, made admission and reiterated same statement which they have submitted before in writing vide letter No. No. 02/QAI/QC/02 dated 28.05.2021.

Decision of 287th meeting of Central Licensing Board:

21. After thorough deliberation, considering the panel inspection report dated 14.04.2022 and all the facts, the board decided as under;

i. Allowed Federal Inspector of Drugs, Peshawar for filling prosecution in the Drug Court for contravention of 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 against following;

a. M/s Alen Pharmaceuticals (Pvt) Ltd. (DML No. 000435),
138, Nowshera Industrial Estate,
Risalpur

b. Mr. Shaukat Ali S/o Muhammad Ali
Chief Executive Officer
M/s Alen Pharmaceutical (pvt.) Ltd 138-A, Nowshera Industrial Estate Risalpur.
CNIC No. :16101-4235301-3

c. Mr. Abdul Rasheed S/o Abdul Raheem
Production Manager
M/s Alen Pharmaceutical (pvt.) Ltd 138-A, Nowshera Industrial Estate Risalpur.
CNIC No. :17101-4472890-3

d. Mr. Muhammad Noshad Ali
Quality Control Manager
M/s Alen Pharmaceutical (pvt.) Ltd 138-A, Nowshera Industrial Estate Risalpur.
CNIC No. :17301-8613319-3

ii. Allowed resumption of production activities in tablet section with effect from date of communication of decision of the Central Licensing Board.

Item No. II.: M/s Dosaco Laboratories, 9.5 KM Sheikhupura Road, Lahore (DML No. 000094).

Background:

GMP inspection of the firm M/s. Dosaco Laboratories, 9.5-KM, Sheikhupura Road, Lahore was conducted by following panel on 18.06.2019 to check the GMP compliance.

i. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore
ii. Ms. Uzma Barkat, AD, DRAP, Lahore

2. The panel noticed following observations:-

Executive Entrance:-

i. To improve the executive entrance by providing a complete step over bench.
ii. Improve cleanliness.
iii. To install mirror and display pictorial SOP for change over.
iv. To provide hand sanitizer.

Workers Entrance:-

i. Male & female worker change rooms were in poor condition with reference to cleanliness, maintenance and changeover facilities.
ii. To improve the male and female worker entries by providing fresh air into the areas, proper changeover facilities and maintain the area.

Raw Material Store:-

i. Firm had provided a common entry for workers and raw material receiving.
ii. No proper sampling booth was provided.
iii. Firm was advised that store must be with proper and well equipped receiving bay, de-dusting area, quarantine area sampling area, released area, dispensing area, staging / post-dispensing area.
iv. To remove ceiling fans and open lights from all areas.
v. To review and improve the newly developed raw material store. Also advised to get the approval of revised layout plan from DRAP, Islamabad.
vi. To immediately remove wooden fixtures and furniture from the facility.
vii. To install printers with dispensing and analytical balances.
viii. To review and improve SOPs for dispensing.
ix. To import their raw material and export finish drugs as per Import and Export Rules of Drugs Act, 1976 without fail.

Finished Goods Store:-

i. It was an empty hall with no AC and temperature maintenance mechanism.
ii. To improve and maintain the area and provide proper storage conditions.

Quality Control Laboratory:-

i. To properly install Liquid Particle Counter and all others as per requirements and also develop log books for all major equipment and machines.
ii. To ensure availability of FTIR for testing of raw materials.
iii. Stability testing was not being done advised to provide stability chambers, develop SOPs & protocols and perform stability studies as per recommended guidelines.
iv. Advised to strengthen the quality control department.

v. To ensure one additional HPLC and appoint more technical staff in QC Department and in other sections as per requirement of Drugs Act and make all the equipment functional.

Microbiological Laboratory:-

The Microbiological Laboratory was under completion at the day of visit. It was advised;

i. To ensure the availability of cool incubator.
ii. To replace LFC cabinet in Microbiology Laboratory with a proper biosafety cabinet.

Quality Assurance Department:-

i. To develop independent Quality Assurance Department in the supervision of senior technical person without fail increase the strength of QA officers.

Liquid Injectable Area 1 (General):-

Ampoule Washing:-

i. To ensure the availability of loop system in their injectable areas by maintaining temperature of the water and also ensure distilled water for final rinse during washing.
ii. To get calibration of dry heat sterilizer.

Solution Preparation Room:-

i. To ensure the availability of loop system by maintaining the temperature of distilled water.
ii. To remove slab in the solution preparation room.
iii. To re-do epoxy in the all sterile areas and improve the areas.

Filling Room:-

i. To ensure a complete Laminar flow hood over filling machine and provide strip curtains.
ii. To ensure availability of cooling bay / trolley with laminar flow hood.
iii. To remove all recesses in the area and provide flushed doors and windows in sterile areas.
iv. Perform water treatment and HVAC qualification and submit report.

Autoclave Room:-

i. To get calibration of autoclave as well for all gauges.
ii. To improve the health and safety parameters in the area.
iii. No HVAC was given in corridor outside sterile areas. Advised to provide HVAC system in corridor also.
iv. In the basement, firm had provided a quarantine area. Firm was advised to provide AC and concealed lights in this area.

Optical Checking Areas:-

i. To ensure the availability of lux meter and comply with the standard requirements.
ii. To install air conditioner in the optical checking area and also improve false ceiling.

Liquid Injectable Section 2 (Psychotropic) observations similar to Liquid Injectable Section were seen:-

i. To upgrade this area in a similar way as Liquid Injectable Section 1.

Oral Liquid Section:-

i. To improve flow and condition of the area by ensuring HVAC and air conditioner where required and also get approval of layout plan by competent authority.
ii. To immediately close the open heating system (Burner) and ensure steam jacketed vessel for solution preparation.
iii. To provide machinery / capacity according to batch size.

Tablet Section:-

i. Remove AC from the area and provide functional HVAC system.
ii. To revise coating formulations and not use, methylene chloride in any formulation.

Documentation:-

v. To review and upgrade documentation and record keeping as per current requirement.
vi. To review and upgrade testing and production SOPs and methods & BMRs as per current requirement.
vii. To review and implement in process checks in all sections.
viii. No record / results of sterility testing was present in BMR seen. No terminal sterilization record present in BMR seen. Firm was advised to follow standard testing protocols for sterile products and maintain proper record.
ix. Advised to review and revise Job Descriptions of all technical heads and officers.

Conclusions:-

"No production activity was being carried on in the premises at the time of visit. The management informed that all Liquid Injectable Sections & Oral Liquid Section are closed for renovation and up-gradation and will inform the competent authority on completion. Firm was advised to rectify the shortcomings noted during inspection, submit compliance and inform the competent authority for re-inspection. Meanwhile, it is recommended that the production may be stopped in all liquid injectable sections and oral liquid section till compliance by the firm and re-inspection."

Action taken by DRAP:

3. The firm M/s. Dosaco Laboratories, Lahore was served Show Cause Notice /Suspension of Production activities order No.F.4-50/89-QA (Vol-I)on12.11.2019.

Reply of the firm:

4. The firm M/s. Dosaco Laboratories, Lahore vide letter dated 27.11.2019 submitted reply of Show Cause Notice and requested for one-month time to do the needful.

Proceedings of 273rd Meeting of CLB

5. Division of QA&LT presented the case before CLB. Mr. Hasan Raza Butt, Brother of Director and Mr. Yasir Khan, Production Pharmacist of the firm M/s. Dosaco Laboratories, 9.5-KM, Sheikhupura Road, Lahore appeared before the Board. Mr. Hasan Raza Butt submitted that owner of the firm Mr. Nadeem Firdous is not well. He presented copies of prescription and Lab reports. Mr. Hasan Raza Butt added that they need further two-month time for the rectification of the observations noted by the Panel in its report dated 18.06.2019. He added that they will be ready for inspection by the end of March, 2020.

Decision of 273rdMeeting of CLB

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

i. suspend production of the firm M/s. Dosaco Laboratories, 9.5-KM, Sheikhupura Road, Lahore till completion of the work, request submitted by the firm to Licensing Board for inspection, panel inspection of the firm and subsequent approval by the Central Licensing Board.

ii. Direct FID to ensure compliance of orders of CLB and submit report on monthly basis.

7. The decision of the 273rd meeting of board was communicated vide letter No. 8-5/2019-QA (M-273-CLB) dated 06.02.2020.

Current Status

8. The firm M/s Dosaco Laboratories Lahore vide letter No. DL/DRAP/22/003 dated 23.05.2022 has submitted a detailed CAPA report and has requested for resumption of production activities.

The matter is placed before the board with request to constitute a panel of experts for GMP inspection of the firm M/s Dosaco Laboratories, 9.2KM Sheikhupura Road Lahore (DML No. 000094)

Decision of 287th Meeting of the Central Licensing Board:

9. After considering all the facts and request of the firm, the board constituted following panel of experts for GMP inspection of the firm M/s Dosaco Laboratories, 9.5 KM Sheikhupura Road, Lahore (DML No. 000094);

a. The Additional Director DRAP Lahore.
b. Area FID DRAP Lahore.
c. Area Assistant Director I&E DRAP Lahore.

QUALITY CONTROL (QC) CASE

MANUFACTURE AND SALE OF UNREGISTERED NRUFEN SUSPENSION BY M/S. PERFECT PHARMA (Pvt.) Ltd., LAHORE.

A complaint was received from M/s. Abbott Laboratories Pakistan regarding manufacture and sale of product namely "Nrufen suspension" by M/s. Perfect Pharma (Pvt.) Ltd., Lahore, name and packaging desing of which is similar to registered product of M/s. Abbott Laboratories Karachi namely "Brufen Suspension".

02. A letter vide F. No. 13-196/2019-QC (Vol-I) dated 27-04-2021 was issued to area FID Lahore for investigation of the matter. Area FID Lahore submitted a report of inspection conducted on 08-06-2021 for verification of the said complaint. The report is reproduced as under:

*"**Purpose of inspection:***

With reference to DRAP Islamabad's Letter No.F.No. 13-196/2019-QC (Vol- I) dated 27-04-2021 on the subject, "Manufacturing/ Sale of Unregistered Drugs by M's Perfect Pharma (Pvt) Ltd,5km Manga Road, Raiwind, Lahore", a panel comprising of Mrs. Majida Mujahid (Area Federal Inspector of Drugs) and Ms. Maham Misbah (Assistant Director, DRAP, Lahore) conducted a surprise visit of M/s Perfect Pharma (DML No. 00469) located at 5km Manga Raiwind Road, Lahore an 08-06-2021.

Firm's representatives present during the inspection:

The representatives of the firm who were present at the time of inspection included Mr. Salman Shafi (CEO), Mr, M. Yamin (Production Incharge), Mr. M. Nasir (Quality Control Manger) and Mr. Ashfaq Ahmad (Manager), among others. Proceedings of the inspection dated 08-06-2021:

The firm was asked about the production of its purported product Nrufen Suspension. The firm's management responded that they had recently taken over the firm from the previous management. The Central Licensing Board in its 273rd meeting held on 15-01-2020 had endorsed the change of management and the decision had been communicated vide DRAP, Islamabad letter No. F.l-15/98-Lic (Vol-III) dated 10-06-2020. (Letter of change of management attached, Annex 1). The CEO of the firm informed the panel that his firm had not manufactured Nrufen Suspension (Ibuprofen Suspension) since the change of management

neither had they received any record of production (BMR) of Nrufen Suspension from the previous management, at the time of change of management. He further stated that his team did not receive any registration letter of Nrufen Suspension from the previous management, therefore, the same could not be produced before the panel.

Nrufen Suspension was not included in the Section-wise registered product list of the firm, as shown to the panel. No Ibuprofen API, unit carton or label of Nrufen suspension was found in the premises at the time of inspection. Further, no production record of Nrufen Suspension, testing record of Ibuprofen API, testing record of finished Nrufen suspension or any retained samples of Nrufen Suspension were found in the premises at the time of inspection.

However, the panel conducted an Inspection to check the firm's conformance to cGMP on 08-06-2021 and concluded as follows:

"Overall, the sanitaryandhygenic conditions of the firm were poor at the time of inspection. The civic work, working of HVAC and condition of equipment was found unsatisfactory at the time of inspection. Firm did not comply with the current GMP requirements as per Schedule B-II of the Drugs (Licensing, Registraton and Advertisement) Rules, 1976."

Accordingly, the report was forwarded to Additional Director (QC), DRAP, Islamabad vide Ref No.8485 dated 10-06-2021 for further necessary action (Copy of report attached Annex 2). Subsequently, the firm was directed vide DRAP, Islamabad letter No. F.4-43/98-QA (Pt) dated 08-07-2021 to "Not to resume production prior to the approval of this Directorate, subject to relevant proceeding as deemed necessary by the Competent Authority and to show cause in writing within 15 days of issuance ofthis notice".

Subsequently, the Central Licensing Board in its 282nd meeting after thorough deliberation, considering compliance report ofthe firm and personal hearing of the firm's representative decided to constitute the following panel to verify the rectification of observations reported by the FID in her report dated 08-06-2021, as communicated vide DRAP, Islamabad letter No.F.8-8/2021-QA (M-282-CLB) dated 14-09-2021:

a. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab.

b. Area FID, DRAP, Lahore.

c. Ms. Maham Misbah, Assistant Director, DRAP. Lahore

Proceedings of the inspection dated 22-09-2021

The above panel, along with Ms. Uzma Barkat, Assistant Director. DRAP, Lahore, on the directions of Additional Director, DRAP. Lahore, conducted the inspection of M/s Perfect Pharma on 22-09-2021 to verify the rectification status of the firm. Accordingly, report shall be forwarded to the Additional Director QA&LT for further necessary action. The representatives ofthe firm who were present at the time of inspection included Mr. Salman Shafi (CEO), Mr. Shehzad Ali Shah (Patter), Mr. M Yamin (Production In-charge), Mr. M. Nasir (Quality Control Manger), Mr. Waqas bin Aftab (Quality Assurance Manager) and Mr. Ashfaq Ahmad (Manager), among others.

The matter of complaint was once again investigated by the panel on 22-09-2021 and the same observations were noted as on 08-06-2021, in the instant matter. Meanwhile, this office's record of import of Ibuprofen API by M/s Perfect Pharma was also scrutinized. As per available office record of DRAP, Lahore office, the firm had applied for import clearance of 1000kg Ibuprofen raw material vide letter Ref No. 220/PPL/202I dated 18-03-2021 (Diary No. 4544 dated 22-03-2021) for purported use in the manufacturing ofNrufen Suspension (Drug Registration No. 093957), as stated in application by the firm. The firm had got clearance certificate for import vide Dispatch No. 4739/2021-DRAP dated 30-03-2021. Further, the firm had submitted undertaking with their application that they will submit the original documents later on but till date they have not provided original documents.

Accordingly, the firm was directed to clarify its position vide this office's letter No. 14339/2021-DRAP-AD dated 23-09-2021 regarding the manufacturing of unregistered drug and importing material based on mis-declaration made in its application submitted in this office for clearance certificate of Ibuprofen API for purported use in the manufacturing of Nrufen Suspension, having Drug Registration No. 093957 (as mentioned in the firm's application). (Copy of letter attached, Annex 3.)

The firm submitted its response vide letter No. REF: 322/PPU2021 dated 24-09-2021 (Diary No. 14115 dated 27-09-2021) wherein they have stated the following:

"Please refer to your letter: 14339/2021-DRAP-AD dated 23-09-2021 regarding the afore mentioned subject. Ever since we have taken over the factory from the previous management, as per DRAP Islamabad Letter No. F.l-15/98-Lic (Vol-Ill) dated 10-06-2020, we have never manufactured the product Nrufen Suspension.

Our stance regarding the manufacturing of the said product has been extremely straightforward. Our commitment has been assured since the day of the surprise visit of FID Lahore on 08-06-2021 and on personal hearing in front of the Central Licensing Board, in its 282nd meeting held on 31-08-2021. Furthermore, it was also evidentfrom the report of FID send to DRAP Islamabad, mentioned in the Letter No: F.8-8/2021-QA (M-282-CLB) of DRAP, Islamabad dated 14th September 2021. The product was also not included in the registered product list of the firm, as shown to the FID.

After acquisition, the previous management informed us that the product has been registered in 284th meeting of Registration Board held on 31 July to 1 August 2018 and that they will provide us with the necessary registration letters. Due to certain notable factors, C0VID-I9, primarily, and base of operations of new management in Karachi, no communication could be established with the previous management for over a year.

In the interim, we applied for the import of raw material of Ibuprofen based on the previous management's claim of possession of the required registration letter. After the raw material was acquired, we demanded for the registration letters, however, the previous management failed to deliver on this promise. After repeated notifications there was no response from them. In the interim, the previous owner passed away.

The absence of the registration letter for the said product came as an immediate shock for us and signaled lack of professionalism on their part. Currently, we possess the entirety of the raw material and the relevant documentation. This affirms our Integrity and work ethic to not allow unethical business activity. We hope that this letter clarifies the issue at hand." (Reply attached at Annex 4)."

Submitted again for further necessary action, please."

03. In the light of information provided by area FID Lahore in the above-mentioned report, names of both nrw and old management of M/s. Perfect Parma Lahore were obtained from the division of Drugs Licensing DRAP which are given as under:

Old management	Aijaz Ahmad S/o Malik Muhammad Hussain Asad Aijaz Malik S/o Aijaz Ahmad Azhar Aijaz S/o Aijaz Ahmad.
New management	Salman Shafi S/o Muhammad Jameel, CEO M/s. Perfect Pharma (Pvt.) Ltd., Lahore Farhan Jawed S/o Jawed Iqbal

04. Show-cause notice vide letter F. No. 04-04/2021-QC dated 14-03-2022 was also issued to both old and new management of M/s. Perfect Pharma Lahore. Replies of both are given as under:

Reply of old management:

"Dear Sir,

Please refer to you Lettet No: F.04-04/2021-QC dated 14th March, 2022 regarding above mentioned subject. It is stated that we have absolutely no knowledge of the above mentioned case as we have already sold our factory on 17-04-2019.

It is also for your information that the Chief Executive at that time Mr. Aijaz Ahmad has passed away on 16-02-2021. It is therefore requested that above refer notice be recalled."

Reply of new management:

"In light of the show cause notice issued on grounds of manufacturing and sale of Nrufen suspension please acknowledge our response below. As per inspection conducted on 8th June 2021, by Mrs. Majida Mujahid - Area FID and Ms. Maham Misbah - AD DRAP, the following was quoted by the inspectors in relation to our response submitted under F.88/2021-QA (M-282-CLB) of DRAP, Islamabad, dated 14th Sep 2021:

"Nrufen Suspension was not included m the Section-wise registered product list of the firm, as shown to the panel. No Ibuprofen API, unit carton or label of Nrufen suspension was found in the premises at the time of inspection. Further, no production record of Nrufen suspension, testing record of Ibuprofen API, testing record of finished, Nrufen suspension or any retained samples of Nrufen suspension were found in the premises at the time of inspection."

In view of all above submissions we have clarified our position that we have not manufactured Ibuprofen Suspension (Nrufen)

However we are also willing to appear personally before the relevant authority or board for further clarification, if required.

It is therefore requested that SHOW CAUSE Notice under reply dated March 14th 2022 be recalled."

05. The representatives of the firm are called before personal hearing.

Submitted for the consideration of the Board.

Proceedings and decision of Central Licensing Board in 287 meeting

Mr. Sarfraz Advocate and Mr. Salman Shafi, CEO of the firm appeared before the Board. They contended that though they had imported raw material but same has not been utilized and is lying at following Address:-

House No. 25, HajiFaqeer Dad Village (Goth),
Liaqat Abad, Karachi

They further stated that their application for registration of drugs is pending with the Drug Registration Board and registration has not yet been granted.

The considering the arguments of the firm decide to call certified photocopy of the set of documents submitted with DRAP, Lahore for clearance of raw material. Moreover, DRAP Karachi would be requested in the light of documents received from DRAP, Lahore office to verify lying of the said material at given address in Karachi. The Board also decided to seek surveillance of the market in Karachi and Lahore for existence of product under investigation. The Drug Registration Board may be requested to provide detail of filling of registration application and proposed name of the drug.

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

i. Tablet Section (Gen)
ii. Capsule Section (Gen).
iii. Capsule Section (Cephalosporin)
iv. Dry Powder for Suspension Section (Cephalosporin)