MINUTES OF 285th MEETING OF CENTRAL LICENSING BOARD HELD ON 17thAND 18TH MARCH, 2022

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285th meeting of the Central Licensing Board (CLB) was held on 17thand 18th March, 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. Azhar Jamal Saleemi, Chief Drug Controller, Primary and Secondary Health Department, Government of Punjab, Lahore	Member
2	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Balochistan, Quetta	Member
3	Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Peshawar Government of Khyber Pahtunkwa	Member
4	Mr Ghulam Ali Lakho, Sr. Inspector of Drugs, Government of Sindh	Member
5	Dr Hafsa Karam Ellahi, Representative Division of Quality Assurance and Laboratory Testing Division	Member
6	Mr. Manzoor Ali Bozdar, Addl Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
7	Ms Maria Rizvi, Representative of PPPMA	Observer
8	Mr Khalid Muneer, Representative of PPPMA	Observer
9	Mr.Ammad Zafar, Representative of Pharma Bureau.	Observer
10	Mr Kamran Anwar, Representative of PCDA	Observer

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

Item-I **CONFIRMATION OF THE MINUTES OF 284th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 284th meeting of the Central Licensing Board (CLB) held on 16th December, 2021.

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

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s May & Baker (Pvt) Ltd, 45-Km Dina Nath, Multan Road, Lahore.	16-02-2022 (Formulation)	Good	1. Dr. Mahmood Ahmed, Expert Member. 2. Mrs. Majida Mujahid, Area Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Ufaq Tanveer Butt, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

On the basis of the inspection of the firm M/s May & Baker (Pvt.) Ltd, Quality Control Equipment, HVAC and all necessary requisites, the panel of inspectors **recommends** the Grant of New Drug Manufacturing License to M/s May & Baker (Pvt.) Ltd, for the following sections:

1. Injectable Section (General).
2. Capsule Section (General).
3. Dry Powder Suspension Section (General).
4. Sachet Section (General).
5. Dry Powder Vial Section (General).

It is pertinent to mention that mandate was given to panel for inspection of Injectable (Ampoule) (General) section rather than Injectable Section (General).

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

Decision of the Central Licensing Board in 285th meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s May & Baker (Pvt) Ltd, 45-Km Dina Nath, Multan Road, Lahoreon the recommendations of the panel of experts for the following sections:

1. Injectable Ampule Section (General).

	2. Capsule Section (General). 3. Dry Powder Suspension Section (General). 4. Sachet Section (General). 5. Dry Powder Vial Section (General).			
2	M/S Fast Pharmaceuticals (Pvt.) Ltd. Plot No.55, Street No. S-4, National Industrial Zone, Rawat.	**01-02-2022 & 28-02-2022**	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Lahore. 2. Mr. Babar Khan, Federal Inspector of Drugs-III, DRAP, Islamabad. 3. Mr. Muhammad Usman Assistant Director, 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 Fast Pharmaceuticals (Pvt.) Ltd, Plot No. 55, Street No. S-4, National Industrial Zone, Rawat with the following sections: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointment/Gel (General) 4. Cream/Ointment/Gel (Steroid) 5. Sterile Dry Powder Vial Injection (Cephalosporin) 6. Capsule section (Cephalosporin) 7. Dry Powder Suspension (Cephalosporin) 8. Quality Control. 9. Warehouse. The case is hereby submitted for consideration and orders of the Board, please. **Decision of the Central Licensing Board in 285th meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Fast Pharmaceuticals (Pvt.) Ltd, Plot No. 55, Street No. S-4, National Industrial Zone, Rawat on the recommendations of the panel of experts for the following sections: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointment/Gel (General) 4. Cream/Ointment/Gel (Steroid) 5. Sterile Dry Powder Vial Injection (Cephalosporin) 6. Capsule section (Cephalosporin) 7. Dry Powder Suspension (Cephalosporin)			
3	M/s TriVista Pharmaceuticals, 8-Km,	10-03-2022 (Formulation)	Good	1. Mr. Younas Khattak, Chief Drug Inspector, Peshawar.

	Taxila Khanpur Road, District Haripur, Khyber Pakhtunkhwa			2. Area Federal Inspector of Drugs, DRAP, Peshawar. 3. Assistant Director, DRAP, Peshawar
	RECOMMENDATIONS: Based on documentation reviewed, technical/management people met, personnel / materials / processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab and allied facilities including HVAC system, the panel is of the view that the firm has established satisfactory facility in accordance with GMP guidelines and unanimously recommended grant of Drug Manufacturing License to the firm from for following mentioned two sections namely; i. Tablet (General) ii. Capsule (General) The case is hereby submitted for consideration and orders of the Board, please. **<u>Decision of the Central Licensing Board in 285th meeting:</u>** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s TriVista Pharmaceuticals, 8-Km, Taxila Khanpur Road, District Haripur, Khyber Pakhtunkhwa on the recommendations of the panel of experts for the following sections: i. Tablet (General) ii. Capsule (General)			
4	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat. **<u>Sections (03):</u>** i. Tablet (General) ii. Capsule (General) iii. Cream / Ointment (General)	27-01-2022 (Formulation)	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QALT), DRAP, Islamabad. 2. Mr. Babar Khan, FID, DRAP, Islamabad. 3. Ms. Mahwish Tanveer, AD, Islamabad.
	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 Pine Pharmaceuticals Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat**, with following sections of: i. Tablet (General) Section. ii. Capsule (General) Section.			

	iii. Cream / Ointment (General) Section. The case is hereby submitted for consideration and orders of the Board, please. **Decision of the Central Licensing Board in 285th meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of **M/s Pine Pharmaceuticals Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat**on the recommendations of the panel of experts for the following sections: i. Tablet (General) Section. ii. Capsule (General) Section. iii. Cream / Ointment (General) Section.			
5	M/s Biological Research Centre, DESTO, Karachi.	03-03-2022 (For Experimental Purpose)	Good	1) Dr. Noor-us-Saba, Director Biological , DRAP, Islamabad. 2) Mr. Najam-us-Saquib , FID/Additional Director (E&M), DRAP, Karachi
	Recommendations of the panel: Based on the people met, documents reviewed and considering the finding of the inspection including facilities, infrastructure and research activities in national interest, panel recommends the grant of license of experimental purpose. **Decision of the Central Licensing Board in 285th meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Experimental in the name of M/s Biological Research Centre, DESTO, Karachi on the recommendations of the panel of experts for the manufacture of Covid-19 Vaccine.			
6	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura.	**26-08-2021**	**Unsatisfactory**	1. Dr. Zaka Ur Rehman, COO, PDTRC. 2. Mr Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Akbar Ali, Assistant Director,

			DRAP, Lahore.

Recommendations of the panel:

"The panel of Inspectors **does not recommend** the grant of Drug Manufacturing License by way of Formulation to M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura.

Decision of the Central Licensing Board in 283rd meeting

The Board considered the facts and decided to re-inspect the firm as provided under the rules.

Proceedings of Licensing Division in compliance of decision of Central Licensing Board:

Licensing Division Issued letter for panel **re-inspection** on 22-11-2021.

Panel inspection was conducted on 15-02-2022 and recommendations is as under:

"Based on the areas inspected, the technical staff met and the documents reviewed, and considering the findings of Inspection and improvements made with respect to observation of previous inspection, the panel was of the opinion that the firm possess facility for manufacturing and quality control of products for following manufacturing sections.

1. Tablet (General).
2. Oral Dry Powder suspension (General).
3. Capsule (General).
4. Sachet (General).

Recommendations of the Panel:

The panel of inspectors **recommends** the grant of Drug Manufacturing License by way of formulation to M/s ICU Pharmaceutical, situated at Khewat No. 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, district Sheikhupura."

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

Decision of the Central Licensing Board in 285th meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s ICU Pharmaceutical, situated at Khewat No. 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, district Sheikhupura on the recommendations of the panel of experts for the following sections:

1. Tablet (General).
2. Oral Dry Powder suspension (General).
3. Capsule (General).
4. Sachet (General).

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

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

S #	Name of the firm	Date of Inspection /	Ranking/ Evaluation	Inspection Panel Members
1	M/s Neutro Pharma (Pvt) Ltd, 9.5KM, Sheikhupura Road, Lahore. DML No. 000576 (Formulation) **Section (03):** i. Liquid Injectable (Ampoule) (General) Section. ii. Tablet (General) Section. iii. Capsule (General) Section.	**02-10-2019 & 17-12-2021**	**Good**	1. Dr. Farzana Chowdhary, Member. 2. Syed Shahid Nasir, Member. 3. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore.

Recommendations of the panel:

"Keeping in view the building, HVAC system, machinery & equipment, personnel, documentation and quality control testing facilities the panel of inspectors is of the opinion to **recommend** the grant of following additional sections to M/s Neutro Pharma (Pvt) Ltd, situated at 9.5-KM, Sheikhupura Road, Lahore:

i. Liquid Injectable (Ampoule General) Section (First Floor).
ii. Tablet (General) Section (Second Floor).
iii. Capsule (General) Section (Second Floor).

Decision of the Central Licensing Board in 285th meeting:

The Board considered and approved the grant of following sections in the name of M/s Neutro Pharma (Pvt) Ltd, 9.5KM, Sheikhupura Road, Lahore under DML No.000576 (Formulation) on the recommendations of the panel of experts:

Section (03):

i. Liquid Injectable (Ampoule General) Section (First Floor).
ii. Tablet (General) Section (Second Floor).
iii. Capsule (General) Section (Second Floor).

2	M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga Off Raiwind Road, Lahore. DML No.000493 (Formulation). **Section (01):** i. Liquid Injectable Section	**09-12-2021**		1. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Government of Punjab, Lahore. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "The panel of inspector **recommends** the renewal of DML bearing No. 000493 issued in favour of M/s Nawabsons Laboratories (Pvt) Ltd, in respect of Oral Dry Powder Section, Capsule Section, Sachet Section and Cream / Ointment Section. The panel of inspectors **Does Not Recommend** the grant of new section i.e Liquid Injectable Section. **Decision of the Central Licensing Board in 285th meeting:** The Board considered and **did not approve** grant of new section i.e Liquid Injectable Section in the name of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga Off Raiwind Road,, Lahore under DML No.000493 (Formulation) on the recommendations of the panel of experts.			
3	M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat. DML No.000533 (Formulation). **Sections (01):** i. Dry Powder Suspension (General) **Additional**	**09-03-2022**	**Good**	1. Director, Drug testing Laboratory, Peshawar. 2. Federal Inspector of Drugs, DRAP, Peshawar. 3. Mr. Adnan Shahidullah, 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 and regularization of sections for Drug Manufacturing License to the firm from 27.01.2019 for following mentioned five sections; 1. Dry Powder Suspension (General) **Additional** **Decision of the Central Licensing Board in 285th meeting:**			

	The Board considered and approved the grant of following sections in the name of M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, SwatunderDML No.000533 (Formulation) on the recommendations of the panel of experts: **Section (01):** 1. Dry Powder Suspension (General) **Additional**			
4	M/s Leads Pharma (Pvt) Ltd., Plot No.81, Street No.6, I-10/3, Industrial Area, Islamabad **Sections (03):** i. Oral Powder Section I&II (General) into Oral Powder (General-Vet) – First Floor ii. Finished Goods Store (FGS) (First Floor) Additional iii. Quality Assurance Lab (First Floor)	**17-02-2022**	**Good**	1. Additional Director (QA/LT), DRAP, Islamabad, 2. FID, DRAP, Islamabad, 3. Mr. Muneeb Ahmad, Assistant Director, DRAP, Islamabad.
	Recommendations of the panel: "In view of the above condition the panel is of the view to recommend the Oral Powder Section I&II (General) into Oral Powder (General-Vet) First Floor, Finished Goods Store (FGS) (First floor) Additional, Quality Assurance Laboratory (First floor) for the approval of Licensing Board. **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of following sections in the name of M/s Leads Pharma (Pvt) Ltd., Plot No.81, Street No.6, I-10/3, Industrial Area, Islamabad under DML No.000392 (Formulation) on the recommendations of the panel of experts: **Section (03):** i. Oral Powder Section I&II (General) into Oral Powder (General-Vet) – First Floor ii. Finished Goods Store (FGS) (First Floor) Additional iii. Quality Assurance Lab (First Floor)			
5	M/s PDH Laboratories (Pvt) Ltd, 9.5-KM Sheikhupura Road,	**03-01-2022** **&**	**Good**	1. Mrs. Majida Mujahid, Additional Director (E&M), DRAP, Lahore.

	Lahore. DML No.000039 (Formulation). **Sections (01).** 1. Oral Liquid Section (General) (New).	**04-01-2022**		2. Mr. Muhammad Arif Chaudhary, Additional Director (CD), DRAP, Islamabad. 3. Ms. Abdul Rashid Shaikh, FID, DRAP, Lahore.
	"In view of above inspection proceedings and facilities verified, building, material management, production, in-process controls, quality control testing, machinery / equipment, air handling, water treatment system, personnel and documentation e.t.**the panel recommends the renewal of Drug Manufacturing License (by way of formulation), Regularization of Layout Plan and Grant of Additional Section** to M/s PDH Laboratories (Pvt) Ltd, 9.5-KM Sheikhupura Road, Lahore:- 1. Oral Liquid Section (General) (New). **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of following sections in the name of M/s PDH Laboratories (Pvt) Ltd, 9.5-KM Sheikhupura Road, Lahore under DML No.000039 (Formulation) on the recommendations of the panel of experts: **Section (01):** 1. Oral Liquid Section (General) (New).			
6	M/s City Pharmaceutical Laboratories, 12-A, I-5, Sector 5, New Survey No. 276, Korangi Industrial Area, Karachi. DML No.000723 (Formulation) Section (01): 1. Quality Control Laboratory– **Revised/Relocated.**	**29-12-2021**	**Good**	1) Prof. Abdullah Dayo, Expert Member 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, Assistant Director, DRAP, Karachi

Recommendations of panel :

"Based on the stated facts and observations, production facilities, QA System, QC Lab Stores, Utilities and people met during the inspection, the panel unanimously recommends as follows:

S#	***Name of Section (s)***	***S#***	***Name of Section (s)***
1	*Liquid Injection Sterile (General)*	*2*	*Tablet (General)*
3	*Capsule (General)*	*4*	*Sterile Dry Powder for Injection (Cephalosporin)*
5	*Capsule (Cephalosporin)*	*6*	*Dry Powder Suspension (Cephalosporin)*
7	*Sterile Dry Powder for Injection (Penicillin)*	*8*	*Capsule (Penicillin)*
9	*Dry Powder Suspension (Penicillin)*		**********

The panel also recommends the grant of relocation and regularization of the same under DML No. 000723 (Formulation)

Decision of the Central Licensing Board in 285th meeting:

The Board considered and approved the grant of following sections in the name of M/s City Pharmaceutical Laboratories, 12-A, I-5, Sector 5, New Survey No. 276, Korangi Industrial Area, Karachi under DML No.000723 (Formulation) on the recommendations of the panel of experts:

Section (09):

1. *Liquid Injection Sterile (General)*
2. *Capsule (General)*
3. *Capsule (Cephalosporin)*
4. *Sterile Dry Powder for Injection (Penicillin)*
5. *Dry Powder Suspension (Penicillin)*
6. *Tablet (General)*
7. *Sterile Dry Powder for Injection (Cephalosporin)*
8. *Dry Powder Suspension (Cephalosporin)*
9. *Capsule (Penicillin)*

7	M/s Pharm Evo (Pvt) Ltd, A-29, North Western Industrial Zone Port Qasim, Karachi. DML No.000504 (Formulation) **Section (01):** 1. Dry Powder Inhaler Capsule (General) - **New**	**17-02-2022**	**Good**	1) Additional Director (E&M), DRAP, Karachi. 2) Federal Inspector of Drugs, DRAP, Islamabad. 3) Mr. Sajjad Ahmed, DD, CDL, Karachi.
	Recommendations of panel : "Based on the people met, areas visited and commitment of the management for continuous improvement, the panel is of the view to **recommend the grant of additional section namely DPI Capsule (General)-New** as per DRAP Islamabad letter of even no. dated 17th January, 2022 to the firm M/s PharmEvo (Pvt) Ltd, situated at Plot No. A-29, N.W.I.Z, Karachi, under License No. 000504." **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 Pharm Evo (Pvt) Ltd, A-29, North Western Industrial Zone Port Qasim, Karachi under DML No.000504 (Formulation) on the recommendations of the panel of experts: **Section (01):** Dry Powder Inhaler Capsule (General) - **New**			
8	M/s Zenith Chemical Industries (Pvt) Ltd, MozaDonday, Jia Baga, Raiwind Road, Lahore. DML No. 000733 (Semi-Basic Manufacture) **API's (01):** 1. Diazepam (USP) – **New** 2. Alprazolam(USP) – **New** 3. Caffeine (USP) – **New**	**20-12-2021**	**Good**	1) Mr. Muhammad Shamoon – Expert Member 2) FID, DRAP, Lahore. 3) Ms. MahamMibah, DRAP, Lahore
	Recommendations of panel : *"The panel of inspectors **Recommends** the renewal of DML bearing No. 000733 issued in favor of M/s Zenith Chemical Industries, 6 Km, off Raiwind Road, Jia Baga, MozaDondey and grant of additional API's as mentioned above"* **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of following API in the name of M/s Zenith Chemical Industries (Pvt) Ltd, MozaDonday, Jia Baga, Raiwind Road, LahoreunderDML No.000733 (Semi-Basic Manufacture)on the recommendations of the panel of expertssubject to			

<table>
<tr><td></td><td colspan="4">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. Diazepam (USP) – New
2. Alprazolam(USP) – New
3. Caffeine (USP) – New</td></tr>
<tr><td>9</td><td>M/s Mission Pharmaceuticals, Plot No. A-94, S.I.T.E. Super Highway, Karachi

DML No.000809 (Formulation).

Section (01) :

1. Dry Powder Injection (Cephalosporin)</td><td>04-11-2021</td><td>Good</td><td>1. Additional Director (E&M), DRAP, Karachi.
2. Federal Inspector of Drugs-II, DRAP, Islamabad.
3. Ms. SanamKausar, Assistant Director, DRAP, Karachi.</td></tr>
<tr><td></td><td colspan="4">Recommendations:
"Based on the stated facts and observations and people met during the inspection, the panel unanimously recommends as follows:

<table>
<tr><th>S#</th><th>Name of Section (s)</th><th>S#</th><th>Name of Section (s)</th></tr>
<tr><td>1</td><td>Tablet (General)</td><td>2</td><td>Capsule (General)</td></tr>
<tr><td>3</td><td>Capsule (Cephalosporin)</td><td>4</td><td>Dry Powder Suspension (Cephalosporin)</td></tr>
<tr><td>5</td><td>Liquid Syrup (General)</td><td>6</td><td>Dry Powder Suspension (General)</td></tr>
<tr><td>7</td><td>Capsule (General Antibiotic)</td><td>8</td><td>Sterile Liquid Injection Ampoule/Vials (SVP)</td></tr>
<tr><td>9</td><td>Liquid Solution for Dialysis</td><td>10</td><td>Powder for Dialysis</td></tr>
</table>
The panel also recommends the grant of additional section of Sterile Dry Powder Injection (Cephalosporin).

<u>Decision of the Central Licensing Board in 285th meeting:</u>

The Board considered and approved the grant of following section in the name of M/s Mission Pharmaceuticals, Plot No. A-94, S.I.T.E. Super Highway, Karachi under DML No.000809 (Formulation) on the recommendations of the panel of experts:

<u>Section (01):</u>

1. Dry Powder Injection (Cephalosporin)</td></tr>
<tr><td>10</td><td>M/s Titlis Pharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore.</td><td>01-03-2022</td><td>Good</td><td>1. Dr. Zakaur Rehman, COO, PDTRC, Lahore.
2. Federal Inspector of Drugs-II, DRAP, Lahore</td></tr>
</table>

	DML No. 000779 (Formulation) Sections (03) : 1. Tablet (General) II- **New** 2. Dry Powder Suspension - **New** 3. Dry Powder Sachet (General) - **New**			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**

<u>Decision of the Central Licensing Board in 285th meeting:</u>

The Board considered and approved the grant of following section in the name of M/s Titlis Pharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore under DML No.000779 (Formulation) on the recommendations of the panel of experts:

<u>Section (03):</u>

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

11	M/s Allmed (Pvt.) Ltd., Plot No. 590, Sunder Industrial Estate, Lahore. DML No. 000645 (Formulation)	**03-03-2022**	**Good**	1. Dr. Farzana Chaudhary, Expert Member. 2. Mrs. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Ufaq Tanveer Butt, Assistant Director, DRAP, Lahore.

	Recommendations of the panel: In light of inspection conducted by the panel and based on the findings, the panel of inspectors **recommends** the grant of following Additional / Revised sections to M/s. Allmed (Pvt.) Ltd., Plot No. 590, Sunder Industrial Estate, Lahore. i. Liquid Solution for Inhalation (General) Section (New). ii. Injectable (Ampoule) (General) Section (Revised). iii. Injectable (Vial) (SVP/LVP) (General) Section (Revised). iv. Syrup (General) Section (Revised). v. Tablet (General) Section (Revised.) vi. Capsule (General) Section (Revised) **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. Allmed (Pvt.) Ltd., Plot No. 590, Sunder Industrial Estate, Lahore under DML No.000645 (Formulation) on the recommendations of the panel of experts: **Section (06):** 1. Liquid Solution for Inhalation (General) Section (New). 2. Injectable (Ampoule) (General) Section (Revised). 3. Injectable (Vial) (SVP/LVP) (General) Section (Revised). 4. Syrup (General) Section (Revised). 5. Tablet (General) Section (Revised.) 6. Capsule (General) Section (Revised)			
12	M/s Fedro Pharmaceutical Labs (Pvt) Ltd, 149-Industrial Estate, Hayatabad, Peshawar. DML No.000238 (Formulation)	**09-12-2021** **03-02-2022**	**Good**	1. Dr. Jamshaid Ali Khan, Expert Member. 2. FID, DRAP, Peshawar. 3. Syed Adnan Ali Shah, Assistant Director, DRAP, Peshawar.
	Recommendations of the panel: "In compliance to Licensing Division letter No.F.3-6/85-Lic (Vol-I) dated 22-09-2021, the firm M/s Fedro Pharmaceutical Labs (Pvt) Ltd., Peshawar was inspected by the nominated panel for renewal of Drug manufacturing license (DML# 000238-Formulation) and grant of additional section. Accordingly, the firm was inspected in detail on prescribed evaluation form and the panel unanimously recommends the grant of renewal of DML and **grant of additional section (Dry Suspension Section-General).** Detailed evaluation form (singed & stamped) will be forwarded to Licensing Division, DRAP, Islamabad in due course of time. **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 Fedro Pharmaceutical Labs (Pvt) Ltd, 149-Industrial Estate, Hayatabad, Peshawar under DML			

	No.000238 (Formulation) on the recommendations of the panel of experts: **Section (01):** 1. Dry Suspension Section-General).			
13	M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle Kahuta road Islamabad. DML No.000711 (Formulation)	06-12-2021 & 26-01-2022	**Good**	1. Additional Director (QA/LT), DRAP, Islamabad. 2. Federal Inspector of Drugs, DRAP, Islamabad. 3. Mr. Muhammad Usman, Assistant Director (Licensing), DRAP, Islamabad.
	Recommendations of the panel: **Recommendations:** Keeping in view the above facts on record and the people met during the visit, the panel unanimously recommendedfollowing sections ofSiam Pharmaceutical, Plot # 217, Industrial Triangle Kahuta Road Islamabad. **i) grant of additional sections** 1. **Sachet (General) Section** 2. **Finished Goods Store** **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of following section in the name of Siam Pharmaceutical, Plot # 217, Industrial Triangle Kahuta Road Islamabad under DML No.000711 (Formulation) on the recommendations of the panel of experts: **Section (02):** 1. Sachet (General) Section 2. Finished Goods Store (Revised)			
14	M/s JHK Pharma (Pvt) Ltd, Khushal Khan Khattak Mazar Road, AkoraKhattak, District Nowshera DML No.000946 (Formulation)	11-03-2022 (Formulation)	Good	1. Mr. Muhammad Younas Khattak, Chief Drug Inspector, Peshawar. 2. Additional Director (E&M), DRAP, Peshawar. 3. Area Federal Inspector of Drugs, DRAP, Peshawar.
	RECOMMENDATIONS: Based on documentation reviewed, technical/management people met, personnel / materials /			

	processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiological lab, distil water system with continuous loop system, and allied facilities including HVAC system, the panel is of the view that the firm has established good facility in accordance with GMP guidelines and unanimously **recommended** grant of following mentioned two sections of the firm; i. Intravenous Ampoule-SVP (General) ii. Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/Antibiotic) **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 JHK Pharma (Pvt) Ltd, Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera under DML No.000946 (Formulation) on the recommendations of the panel of experts: **Section (02):** i. Intravenous Ampoule-SVP (General) ii. Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/Antibiotic) The Drug Registration Board shall be informed regarding withdrawal of Intravenous Infusion-LVP (General/Antibiotic) by the firm. Drug Registration Board may take necessary action accordingly.

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

Following cases have been forwarded by the respective panel of experts for grant of Renewal of Drug Manufacturing Licenses. 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 Ambrosia Pharmaceuticals, Plot No.18 St. No. 09, National Industrial Zone, Rawat. DML No.000561 (Formulation). Period: Commencing on 08-12-2019& ending on 07-12-2024.	**27-12-2021 & 28-12-2021**	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad. 2. Mr. Babar Khan, Federal Inspector of Drugs-III, DRAP, Islamabad. 3. Mr. Adil Saeed, Assistant Director (QA), 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 renewal of DML No. 000561 by way of Formulation to M/s Ambrosia Pharmaceuticals, Plot No.18 St: No. 09 National Industrial Zone Rawat with following sections: 1. Tablet (General) 2. Capsule (General) 3. Cream/Ointment (General) 4. Liquid Syrup (General) **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of renewal of DML No. 000561 by way of Formulation in the name of M/s Ambrosia Pharmaceuticals, Plot No.18 St. No. 09, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period Commencing on 08-12-2019& ending on 07-12-2024 for the following section: - 1. Tablet (General) 2. Capsule (General) 3. Cream/Ointment (General) 4. Liquid Syrup (General)			
2	M/s Horizon Healthcare (Pvt.) Ltd, Plot No 33, Sunder Industrial Estate, Lahore. DML No.000782 (Formulation). Period: Commencing on 03-02-2019 & ending on 02-02-2024.	**14-10-2021**	**Good**	1. Dr. Farzana Chaudhry, Expert Member. 2. Mr. Shaheen Iqbal, Secretary, PQCB. 3. Mrs. Majida Mujahid, Area Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the Panel: Keeping in view the manufacturing facilities like building, functional HVAC system, installed Production Machinery in the respective sections & availability of Quality Control equipments, instruments, Technical & experienced personnel, having adequate documentation, regarding production, QA, quality control, microbiology lab and purified water production and testing facilities. Panel thoroughly observed their revised lay out plan approved by DRAP, Islamabad (copy is attached). The panel of inspectors **recommends** the grant of Renewal of DML& Grant of Amendments/Expansion in layout to M/s Horizon Healthcare (Pvt.) Ltd, Plot No 33, Sunder Industrial Estate, Lahore bearing Lic No. 000782 in respect of its approved following three Sections: 1. Tablet (General) 2. Capsule (General) 3. Oral Liquid (General) **Decision of the Central Licensing Board in 285th meeting:**			

	The Board considered and approved the grant of renewal of DML No. 000782 by way of Formulation in the name of M/s Horizon Healthcare (Pvt.) Ltd, Plot No 33,Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the period Commencing on 03-02-2019 & ending on 02-02-2024 for the following section: - 1. Tablet (General) 2. Capsule (General) 3. Oral Liquid (General)			
3	M/s Al-Fazal Pharma Industries (Pvt) Ltd., 16 Km, Sheikhupura Road, Lahore. DML No.000803 (Formulation). Period: Commencing on 19-09-2019& ending on 18-09-2024.	**29-01-2022**	**Good**	1. Mr. Muhammad Shamoon Chaudhry, Expert Member. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
	<u>Recommendations of the Panel:</u> Based on the areas inspected, the technical people met and the documents reviewed, and considering the findings of the inspection the panel verified a satisfactorily maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per Drug (Licensing, Registering and Advertising) Rules, 1976 and capacity & capability of the firm in respect of manufacturing and quality control of all the registered products as per following sections: 1. Oral Liquid (General) 2. Capsule General) 3. Cream/Ointment/Gel (General) The panel of inspectors **recommends** the renewal of DML bearing No. 000803 issued in favour M/s Al-Fazal Pharma Industries (Pvt) Ltd., 16 Km, Lahore-Sheikhupura Road, Lahore. The case is hereby submitted for consideration and orders of the Board, please. **<u>Decision of the Central Licensing Board in 285th meeting:</u>** The Board considered and approved the grant of renewal of DML No. 000803 by way of Formulation in the name of M/s Al-Fazal Pharma Industries (Pvt) Ltd., 16 Km, Sheikhupura Road, Lahore on the recommendations of the panel of experts for the period Commencing on 19-09-2019& ending on 18-09-2024 for the following sections: - 1. Oral Liquid (General) 2. Capsule General) 3. Cream/Ointment/Gel (General)			
4	M/s Murfy Pharmaceuticals (Pvt) Ltd, 8- Km Raiwind Road, Lahore. DML No.000543 (Formulation).	**22-12-2021**	**Good**	1. Dr. Farzana Chaudhry, Expert Member. 2. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Government of Punjab,

	Period: Commencing on 25-07-2019& ending on 24-07-2024. **Section (04):** 1.Tablet (General/Antibiotic). 2.Capsule (General/Antibiotic). 3.Cream/Ointment/Gel (General/Antibiotic). 4.Liquid Injectable Ampoule (General/Antibiotic).			Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the Panel: "Based on the areas inspected, the people met and considering the findings of inspection, the panel was of the opinion that at the time of inspection, the firm was complying with the requirements and conditions for renewal of Drug Manufacturing License as required under Rule 16, 19 & 20 of the Drug (Licensing, Registering and Advertising) Rules, 1976 with reference to all approved manufacturing sections. The panel of inspectors **recommends** the renewal of DML bearing No. 000543 issued in favour of M/s Murfy Pharmaceuticals (Pvt) Ltd. situated at 8 Km Raiwind Road, Lahore." **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of renewal of DML No. 000543 by way of Formulation in the name of M/s Murfy Pharmaceuticals (Pvt) Ltd. situated at 8 Km Raiwind Road, Lahore on the recommendations of the panel of experts for the period Commencing on 25-07-2019& ending on 24-07-2024 for the following sections: - 1. Tablet (General) 2. Capsule (General) 3. Cream/Ointment/Gel (General) 4. Liquid Injectable Ampoule (General)			
5	M/s Next Pharmaceutical Products (Pvt) Ltd, Plot No. 44 A&B, Sundar Industrial Estate, Lahore. DML No.000847 (Formulation). Period: Commencing on 25-10-2021 ending on 24-10-2026.	**18-02-2022**	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab 2. Mrs. Majida Mujahid, FID, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
	Recommendations of the Panel: "Keeping in view the facilities like building, HVAC, equipment, instruments, personnel, documentation, Quality Control and testing facilities, the panel recommends the renewal of DML of M/s Next Pharmaceutical Products (Pvt) Ltd, Plot No. 44 A&B, Sundar Industrial Estate, Lahore for a period of 5 years for following four sections: -			

	1. Tablet Section (General). 2. Capsule Section (General). 3. Cream / Ointment Section (General). 4. Oral Liquid Section (General). As per available record of Licensing Division, the firm possesses section namely **Cream / Ointment /Gel (General)**. **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of renewal of DML No. 000847 by way of Formulation in the name of M/s Next Pharmaceutical Products (Pvt) Ltd, Plot No. 44 A&B, Sundar Industrial Estate, Lahore on the recommendations of the panel of experts for the period Commencing on 25-10-2021 ending on 24-10-2026 for the following sections: - 1. Tablet (General). 2. Capsule (General). 3. Cream/Ointment/Gel (General). 4. Oral Liquid Section (General).			
6	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road,1-Km, towards Kahna, Lahore. DML No.000582 (Formulation). Period: Commencing on 02-09-2020 & ending on 01-09-2025.	**13-01-2022**	**Good**	4. Dr. Farzana Chaudhry, Expert Member. 5. Mrs. Majida Mujahid, Area Federal Inspector of Drugs, DRAP, Lahore. 6. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
	Recommendations of the Panel: Based on the sections and areas inspected, the personnel interacted with, discussion held during the course of inspection, the documents reviewed, andconsidering the findings of the inspection, the panel **recommends** the renewal of DML to M/s. International Labs, Raiwind Road, Bhobtian Chowk 1, Km Defence Road, toward Kahna, Lahore for the following sections namely: **Veterinary:** i. Syrup (General) ii. Liquid Injectable (General) iii. Bolus iv. Dry Powder (General) v. Penicillin Liquid Injectable vi. Penicillin Powder Injectable vii. Penicillin Powder Oral viii. Hormone Injectable ix. Liquid Injectable steroid **Human:** i. Liquid Repacking section ii. Powder Repacking section			

	iii. Sachet (General) section iv. External preparation / application/aerosol section. Panel was given mandate for inspection of **Aerosol (Human) section** but panel has recommended this section with the title of External preparation / application/aerosol section. **The case is hereby submitted for consideration and orders of the Board, please.** **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of renewal of DML No. 000582 by way of Formulation in the name of M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road,1-Km, towards Kahna, Lahore on the recommendations of the panel of experts for the period Commencing on 02-09-2020 & ending on 01-09-2025 for the following sections: - **Veterinary:** 1. Syrup (General) 2. Liquid Injectable (General) 3. Bolus 4. Dry Powder (General) 5. Penicillin Liquid Injectable 6. Penicillin Powder Injectable 7. Penicillin Powder Oral 8. Hormone Injectable 9. Liquid Injectable steroid **Human:** 1. Liquid Repacking section i. Powder Repacking section ii. Sachet (General) section iii. Aerosol Section.			
7	M/s A'raf (Pvt) Ltd., 23-Km, Raiwind Road, Lahore. DML No.000685 (Formulation). Period: Commencing on 10-05-2020 & ending on 09-05-2025.	**24-01-2022**	**Good**	1. Dr. Farzana Chaudhary, Member. 2. Ms. Aisha Irfan, Federal Inspector of Drugs, 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, controls, quality control testing, building, material management, production, in-process machinery/equipment, air handling, water treatment system, personnel and documentation etc, the panel **recommends** the renewal of Drug Manufacturing License to M/s A'raf (Pvt.) Ltd., 23-km, Raiwind Road, Lahore by way of formulation for the following sections only: 1. Tablet Section (General). 2. Capsule Section (General). 3. External Preparation Section (General). **Decision of the Central Licensing Board in 285th meeting:**			

	The Board considered and approved the grant of renewal of DML No. 000685 by way of Formulation in the name of M/s A'raf (Pvt) Ltd., 23-Km, Raiwind Road, Lahore on the recommendations of the panel of experts for the period Commencing 10-05-2020 & ending on 09-05-2025 for the following sections: - 1. Tablet Section (General). 2. Capsule Section (General). 3. External Preparation Section (General).			
8	M/s City Pharmaceutical Laboratories, 12-A, I-5, Sector 5, New Survey No. 276, Korangi Industrial Area, Karachi. DML No.000723 (Formulation) Period: Commencing on 15-06-2020 & Ending 14-06-2025	**29-12-2021**	**Good**	4) Prof. Abdullah Dayo, Expert Member 5) Federal Inspector of Drugs, DRAP, Karachi. 6) Mr. Krishan Das, Assistant Director, DRAP, Karachi 1.

Recommendations of panel :

"Based on the stated facts and observations, production facilities, QA System, QC Lab Stores, Utilities and people met during the inspection, the panel unanimously recommends as follows:

S#	***Name of Section (s)***	***S#***	***Name of Section (s)***
1	*Liquid Injection Sterile (General) SVP/LVP*	*2*	*Tablet (General)*
3	*Capsule (General)*	*4*	*Sterile Dry Powder for Injection vial (Cephalosporin)*
5	*Capsule (Cephalosporin)*	*6*	*Dry Powder Suspension (Cephalosporin)*
7	*Sterile Dry Powder for Injection (Penicillin)*	*8*	*Capsule (Penicillin)*
9	*Dry Powder Suspension (Penicillin)*		**********

The panel also recommends the grant of relocation and regularization of the same under DML No. 000723 (Formulation)

Decision of the Central Licensing Board in 285th meeting:

	The Board considered and approved the grant of renewal of DML No. 000723 by way of Formulation in the name of M/s City Pharmaceutical Laboratories, 12-A, I-5, Sector 5, New Survey No. 276, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 15-06-2020 & Ending 14-06-2025for the following sections: - 1. Liquid Injection Sterile (General) SVP/LVP 2. Capsule (General) 3. Capsule (Cephalosporin) 4. Sterile Dry Powder for Injection (Penicillin) 5. Dry Powder Suspension (Penicillin) 6. Tablet (General) 7. Sterile Dry Powder for Injection vial (Cephalosporin) 8. Dry Powder Suspension (Cephalosporin) 9. Capsule (Penicillin)			
9	M/s Zenith Chemical Industries (Pvt) Ltd, MozaDonday, Jia Baga, Raiwind Road, Lahore. DML No. 000733 (Semi-Basic Manufacture) **Period: Commencing on 15-06-2021 & Ending 14-06-2026**	**20-12-2021**	**Good**	4) Mr. Muhammad Shamoon – Expert Member 5) FID, DRAP, Lahore. Ms. MahamMibah, DRAP, Lahore
	Recommendation of panel : *"The panel of inspectors **Recommends** the renewal of DML bearing No. 000733 issued in favour of M/s Zenith Chemical Industries, 6 Km, off Raiwind Road, Jia Baga, MozaDondey and grant of additional API's as mentioned above"* **<u>Decision of the Central Licensing Board in 285th meeting:</u>** The Board considered and approved the grant of renewal of DML No. 000733 by way of Semi-Basic Manufacture in the name of M/s Zenith Chemical Industries (Pvt) Ltd, MozaDonday, Jia Baga, Raiwind Road, Lahore on the recommendations of the panel of experts for the period Commencing on 15-06-2021 & Ending 14-06-202.			
10	M/s Sanofi Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, Karachi. Drug Manufacturing License No. 000007 (Formulation) Period: Commencing on 31-03-	**10-11-2021**	**Good**	1. Dr. Abdullah Day, Expert Member. 2. Federal Inspector of Drugs, DRAP, Karachi. 3. Mr. Affan Ali, Assistant

	2015 & Ending 30-03-2020			Director, CDL, Karachi.

Recommendations of panel :

"Based on the people met, document reviewed and observations made during the inspection, panel recommend the ***renewal of DML and regularization of manufacturing facility*** *for the following sections* ***except Dry Powder Suspension (General) for which management should be asked for the unauthorized conversion of the section without approval of the concerned authorities:***

Sr. No	***Name of Sections***	***Sr.No***	***Name of Sections***
i.	*Tablet (General)*	*vii.*	*Dry Powder Sachet (General)*
ii.	*Oral Liquid Syrup (General)*	*viii.*	*Capsule (General)*
iii.	*Ointment/Cream (General)*	*ix.*	*Injectable Liquid Section ampoule SVP (General)*
iv.	*Injectable Liquid Section vial SVP (General)*	*x.*	*Quality Control Laboratory*
v.	*Ware House (General)*	*xi.*	*Dry Powder Injectable (Cephalosporin)*
vi.	*Raw Material Store (Cephalosporin)*	*xii.*	**********

Decision of the Central Licensing Board in 285th meeting:

The Board considered and approved the grant of renewal of DML No. 000007 by way of Formulation in the name of M/s Sanofi Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 31-03-2015 & Ending 30-03-2020 for the following except Dry Powder Suspension (General) sections: -

1. *Tablet (General)*
2. *Oral Liquid Syrup (General)*
3. *Ointment/Cream (General)*
4. *Injectable Liquid Section vial SVP (General)*
5. *Ware House (General)*
6. *Raw Material Store (Cephalosporin)*
7. *Dry Powder Sachet (General)*
8. *Capsule (General)*
9. *Injectable Liquid Section ampoule SVP (General)*
10. *Quality Control Laboratory*
11. *Dry Powder Injectable (Cephalosporin)*

The Board further advised that firm may be advised to submit revised Lay out plan within 15 days for approval of Dry Powder Suspension (General). Moreover, production shall remain suspended in the section till approval by the Central Licensing Board after fulfillment of codal formalities.

11	M/s Mission Pharmaceuticals, Plot No. A-94, S.I.T.E. Super Highway, Karachi DML No.000809 (Formulation). Period: Commencing on 25-02-2020 & ending on 24-02-2025.	**04-11-2021**	**Good**	1. Additional Director (E&M), DRAP, Karachi. 2. Federal Inspector of Drugs-II, DRAP, Islamabad. 3. Ms. SanamKausar, Assistant Director, DRAP, Karachi.

Recommendations of panel :

"Based on the stated facts and observations and people met during the inspection, the panel unanimously recommends as follows:

S#	***Name of Section (s)***	***S#***	***Name of Section (s)***
1	*Tablet (General)*	*2*	*Capsule (General)*
3	*Capsule (Cephalosporin)*	*4*	*Dry Powder Suspension (Cephalosporin)*
5	*Liquid Syrup (General)*	*6*	*Dry Powder Suspension (General)*
7	*Capsule (General Antibiotic)*	*8*	*Sterile Liquid Injection Ampoule/Vials (SVP)*
9	*Liquid Solution for Dialysis*	*10*	*Powder for Dialysis*

The panel also recommends the grant of additional section of Sterile Dry Powder Injection (Cephalosporin).

Decision of the Central Licensing Board in 285th meeting:

The Board considered and approved the grant of renewal of DML No. 000809 by way of Formulation in the name of M/s Mission Pharmaceuticals, Plot No. A-94, S.I.T.E. Super Highway, Karachi on the recommendations of the panel of experts for the period Commencing on 25-02-2020 & ending on 24-02-2025 for the following sections: -

1. *Tablet (General)*
2. *Capsule (Cephalosporin)*
3. *Liquid Syrup (General)*
4. *Capsule (General Antibiotic)*
5. *Capsule (General)*

	6. *Dry Powder Suspension (Cephalosporin)* 7. *Dry Powder Suspension (General)* 8. *Sterile Liquid Injection Ampoule/Vials (SVP)* The Board also decided to refer following sections to MDMC, Division DRAP for taking necessary action at their end as subject matter comes under their domain.; 9. *Liquid Solution for Dialysis* **10.** *Powder for Dialysis*			
11	M/s Xenon Pharmaceuticals (Pvt) Ltd, 9.5 km, Sheikhupura Road, Lahore. DML No. 000077 (Formulation) Period: Commencing on 30-09-2020 & ending on 29-09-2025.	**11-02-2022**	**Good**	1. Mr. Shoaib Hakeem, Expert Member. 2. FID, DRAP, Lahore. 3. Ms.Uzma Barkat, AD, DRAP, Lahore.
	Recommendations of panel : *"In view of above inspection proceeding and facilities verified, building, material management, production, in-process controls, quality control testing, machinery / equipment, air handling, water treatment system, personnel and documentation e.t.c**the panel recommends the renewal of Drug Manufacturing License** to M/s. Xenon Pharmaceuticals (Pvt) Ltd, 9.5 Km, Sheikhupura Road, Lahore by way of formulation and **regularization for the following sections** only:-* 1. *Tablet (General) Section.* 2. *Capsule (General) Section.* 3. *Dry Powder Suspension (General) Section.* 4. *Ointment / Cream (General) Section.* 5. *Oral Liquid / Syrup (Steroids) Section.* 6. *Oral Liquid / Syrup (General) Section.* 7. *Oral Liquid / Syrup (Psychotropic) Section.* 8. *Tablet (Psychotropic) Section.* 9. *Nasal Drop Section.* 10. *Sachet (General) Section.* **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of renewal of DML No. 000077 by way of Formulation in the name of M/s Xenon Pharmaceuticals (Pvt) Ltd, 9.5 km, Sheikhupura Road, Lahoreon the recommendations of the panel of experts for the period Commencing 30-09-2020 and ending on 29-09-2025for the following sections: - 1. *Tablet (General) Section.* 2. *Capsule (General) Section.* 3. *Dry Powder Suspension (General) Section.* 4. *Ointment / Cream (General) Section.*			

	5. *Oral Liquid / Syrup (Steroids) Section.* 6. *Oral Liquid / Syrup (General) Section.* 7. *Oral Liquid / Syrup (Psychotropic) Section.* 8. *Tablet (Psychotropic) Section.* 9. *Nasal Drop Section.* 10. *Sachet (General) Section.*			

12	M/s Ahsons Drug Company, T/1, S.I.T.E. Tando Adam, Sindh. DML No.000138 (Formulation) Period: Commencing on 17-02-2019 & ending on 16-02-2024.	**29-12-2021**	**Good**	1) Additional Director (E&M), DRAP, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, Assistant Director, DRAP, Karachi

Recommendations of panel :

Based on the people met, areas visited and commitment of the management for continuous improvement and advises of the panel members, the panel of the view to recommend as follows:

(i) Renewal of Drug Manufacturing License No. 000138 (By way of formulation) to the firm M/s Ahson Drug Company situated at Plot No. T/1, S.I.T.E, Tando Adam, Sindh for following sections namely:

S#	***Name of Section (s)***	***S#***	***Name of Section (s)***
1	*Liquid/Syrup (General)*	*2*	*Tablet (General)*
3	*Cream/Ointment (General)*	*4*	*Eye Ointment (Sterile General)*
5	*Eye Drops (Sterile General)*	*6*	*Liquid Ampoule SVP (General)*
7	*Liquid Vial SVP (General)*	*8*	*Dry Powder Suspension (Penicillin)*
9	*Dry Powder Injection (Cephalosporin)*		**********

ii. **Regularization and capsule (Penicillin) section not recommended till completion of renovation/maintenance work.**

Decision of the Central Licensing Board in 285th meeting:

The Board considered and approved the grant of renewal of DML No. 000138 by way of Formulation in the name of M/s Ahsons Drug Company, T/1, S.I.T.E. Tando Adam, Sindh on the recommendations of the panel of experts for the period Commencing on 17-02-2019 & ending on 16-02-2024 for the following sections: -

1. *Liquid/Syrup (General)*
2. *Cream/Ointment (General)*
3. *Eye Drops (Sterile General)*
4. *Liquid Vial SVP (General)*
5. *Dry Powder Injection (Cephalosporin)*
6. *Tablet (General)*
7. *Eye Ointment (Sterile General)*
8. *Liquid Ampoule SVP (General)*
9. *Dry Powder Suspension (Penicillin)*

The Board did not approve renewal and regularization of Capsule (Penicillin) on the recommendation of panel of expert till renovation by the firm. The production shall remain suspended till completion of renovation work and subsequent inspection by the panel to be constituted. Drug Registration Board shall be informed for taking necessary action at their end.

13	M/s E-Pharm Laboratories, Plot No. A-40, Road No. 1, SITE, Super DML No.000598 (Formulation). Period: Commencing on 25-02-2020 & ending on 24-02-2025.	**30-12-2021**	**Good**	1) Additional Director(E&M), DRAP, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, Assistant Director, DRAP, Karachi

Recommendations of panel :

"Based on the stated facts and observations, production facilities, QA System, QC Lab, Stores, Utilities, People met during the inspection, the panel unanimously recommends as follows: Grant of renewal for DML No. 000598 (Formulation) for the next five years for the following sections:

S#	***Name of Section (s)***	***S#***	***Name of Section (s)***
1	*Tablet (General)*	*2*	*Capsule (General)*
3	*Liquid Syrup (General)*	*4*	*Capsule (Cephalosporin)*
5	*Dry Powder Suspension (Cephalosporin)*	*6*	*Sterile Dry Powder Injectable (Cephalosporin)*
7	*Cream/Ointment/Gel*	*8*	*ENT/Sterile Ophthalmic Drops (General)*
9	*SterileLiquid Injection (Ampoules/Vials)*		**********

Decision of the Central Licensing Board in 285th meeting:

The Board considered and approved the grant of renewal of DML No. 000598 by way of Formulation in the name of M/s E-Pharm Laboratories, Plot No. A-40, Road No. 1, SITE, Super on the recommendations of the panel of experts for the period Commencing on 25-02-2020 & ending on 24-02-2025. for the following sections: -

1. *Tablet (General)*
2. *Liquid Syrup (General)*
3. *Dry Powder Suspension (Cephalosporin)*
4. *Cream/Ointment/Gel*
5. *Sterile Liquid Injection (Ampoules/Vials)*
6. *Capsule (General)*
7. *Capsule (Cephalosporin)*
8. *Sterile Dry Powder Injectable (Cephalosporin)*
9. *ENT/Sterile Ophthalmic Drops (General)*

<table>
<tr><td>14</td><td>M/s Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshera Industrial Estate, Risalpur.

DML No.000816 (Formulation)

Period commencing on 22-06-2020& ending on 21-06-2025</td><td>11-01-2022</td><td>Good</td><td>1. Mr. Zahid Khan, Chief Drug Inspector, Peshawar.
2. Federal Inspector of Drugs, DRAP, Peshawar.
3. Mr. Adnan Shahidullah, AD, DRAP, Peshawar.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>

“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 23.06.2020 for following mentioned five sections;

<table>
<tr><th>Ser</th><th>Name of Section</th><th>Ser</th><th>Name of Section</th></tr>
<tr><td>1.</td><td>Tablet (General)</td><td>4.</td><td>Capsule (Cephalosporin)</td></tr>
<tr><td>2.</td><td>Capsule (General)</td><td>5.</td><td>Dry Powder Suspension (Cephalosporin)</td></tr>
<tr><td>3.</td><td>Dry Powder Suspension (General)</td><td colspan="2">----------</td></tr>
</table>

<u>Decision of the Central Licensing Board in 285th meeting:</u>

The Board considered and approved the grant of renewal of DML No. 000816 by way of Formulation in the name of M/s Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No. 144, Nowshera Industrial Estate, Risalpur on the recommendations of the panel of experts for the period Commencing on 22-06-2020& ending on 21-06-2025 for the following sections: -
1. Tablet (General)
2. Capsule (General)
3. Dry Powder Suspension (General)
4. Capsule (Cephalosporin)
5. Dry Powder Suspension (Cephalosporin)</td></tr>
<tr><td>15</td><td>M/s Rakaposhi Pharmaceutical (Pvt) Ltd., 97-KM, Hayatabad Industrial Estate, Peshawar

DML No.000386 (Formulation)

Tenure: Commencing on 30-07-</td><td>01-12-2021 & 21-01-2022</td><td>Good</td><td>1. Dr. Muhammad Saeed, Expert Member
2. Federal Inspector of Drugs, DRAP, Peshawar.
3. Syed Adnan Ali Shah, AD, DRAP, Peshawar.</td></tr>
</table>

	2020& ending on 29-07-2025 **Sections** 1. Tablet (General) 2. Dry Powder for Suspension (General) 3. Capsule (General) 4. Tablet (Psychotropic) 5. Capsule (Cephalosporin) 6. Dry Powder for Suspension (Cephalosporin) 7. Oral Liquid (General)			
	<u>Recommendations of the panel:</u> Renewal of DML is recommended by the panel except for **ORAL LIQUID SECTION(GENERAL).** **<u>Decision of the Central Licensing Board in 285th meeting:</u>** The Board considered and approved the grant of renewal of DML No. 00000 by way of Formulation in the name of M/s Rakaposhi Pharmaceutical (Pvt) Ltd., 97-KM, Hayatabad Industrial Estate, Peshawar on the recommendations of the panel of experts for the period Commencing on 30-07-2020& ending on 29-07-2025 for the following sectionssubject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for Tablet (Psychotropic) section: - 1. Tablet (General) 2. Dry Powder for Suspension (General) 3. Capsule (General) 4. Tablet (Psychotropic) 5. Capsule (Cephalosporin) 6. Dry Powder for Suspension (Cephalosporin) The Board did not approve renewal and regularization of Oral Liquid Section (General) on the recommendation of panel of expert till rectification of observations by the firm. The production shall remain suspended till completion of rectification of observations and subsequent inspection by the panel to be constituted. Drug Registration Board shall be informed for taking necessary action at their end.			
16	M/s Roryan Pharmaceutical Industries (Pvt) Ltd., 85/B, Hayatabad Industrial Estate, Peshawar. DML No.000566 (Formulation)	**13-01-2022**	**Good**	1. Prof. Dr. Jamshed Ali Khan, Expert member 2. Chief Drug Inspector, Peshawar. 3. Area FID, DRAP, Peshawar.

	Tenure: Commencing on 31-12-2019& ending on 30-12-2024. Sections 1. Tablet (General). 2. Capsule (General). 3. Tablet (Psychotropic). 4. Capsule (Cephalosporin). 5. Dry Powder Suspension (Cephalosporin). 6. Dry Powder Suspension (General). 7. Oral Liquid (General). 8. Dry Powder Sachet (General) 9. Cream/ointment (General)			
	Recommendations of the panel: "Keeping in view the above, the panel unanimously recommends the grant of renewal of DML No.000566 by way of formulation to M/s Roryan Pharmaceutical Industries (Pvt) Ltd., 85/B, Hayatabad Industrial Estate, Peshawar." **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of renewal of DML No. 000566 by way of Formulation in the name of M/s Roryan Pharmaceutical Industries (Pvt) Ltd., 85/B, Hayatabad Industrial Estate, Peshawar on the recommendations of the panel of experts for the period Commencing on 31-12-2019& ending on 30-12-2024 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for Tablet (Psychotropic) section: -: 1. Tablet (General). 2. Capsule (General). 3. Tablet (Psychotropic). 4. Capsule (Cephalosporin). 5. Dry Powder Suspension (Cephalosporin). 6. Dry Powder Suspension (General). 7. Oral Liquid (General). 8. Dry Powder Sachet (General) 9. Cream/ointment (General)			
17	M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat.	**09-03-2022**	**Good**	1. Director, Drug testing Laboratory, Peshawar. 2. Federal Inspector of Drugs, DRAP, Peshawar.

<table>
<tr><td></td><td>DML No.000533 (Formulation)

Tenure: Commencing on 27-01-2019& ending on 26-01-2024.</td><td></td><td></td><td>3. Mr. Adnan Shahidullah, Assistant Director, DRAP, Peshawar</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>

“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 and regularization of sections for Drug Manufacturing License to the firm from 27.01.2019 for following mentioned five sections;

<table>
<tr><th>Ser</th><th>Name of Section</th><th>Ser</th><th>Name of Section</th></tr>
<tr><td>1.</td><td>Oral Liquid Section (General) Regularization</td><td>4.</td><td>Quality Control Lab and microbiology Regularization</td></tr>
<tr><td>2.</td><td>Capsule Section (General) Regularization</td><td>5.</td><td>Dry Powder Suspension (General) Additional</td></tr>
<tr><td>3.</td><td>Warehouse Regularization</td><td colspan="2">----------</td></tr>
</table>

<u>Decision of the Central Licensing Board in 285th meeting:</u>

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

1. Oral Liquid Section (General) Regularization
2. Capsule Section (General) Regularization
3. Warehouse Regularization
4. Quality Control Lab and microbiology Regularization</td></tr>
<tr><td>18</td><td>M/s Regal Pharmaceuticals, Plot No. A2, Street No. S-5, National Industrial Zone, Rawat.

DML No.000839 (Formulation).

Period: Commencing on 01-06-2021 ending on 30-05-2026.</td><td>17-12-2021

&

19-01-2022</td><td>Good</td><td>1. Dr. Hafsa Karam Elahi, Additional Director (QALT), DRAP, Islamabad.
2. Mr. Babar Khan, Federal Inspector of Drugs, DRAP-III, Islamabad.
3. Ms. Haleema Sharif, Assistant Director, DRAP, Islamabad.</td></tr>
<tr><td></td><td colspan="4">“Keeping in view the above facts on record and the people met during the visit, the panel unanimously recommended the approval of renewal of (DML # 000687 by way of Formulation)</td></tr>
</table>

	of M/s Regal Pharmaceuticals, Plot No. 2A, Street No. S-5, National Industrial Zone, Rawat, Islamabad (DML No. 000839 by way of Formulation) with following approved sections: The detailed report is attached herewith) 1. Tablet (General). 2. Capsule (General). 3. Dry Powder Suspension (General). 4. Oral Liquid (General). 5. Liquid Ampoule (General). 6. Liquid Vial Injectable (General). 7. Capsule (Cephalosporin). 8. Dry Powder Suspension (Cephalosporin). 9. Dry Powder Vial Injection (Cephalosporin). **<u>Decision of the Central Licensing Board in 285th meeting:</u>** The Board considered and approved the grant of renewal of DML No. 000839 by way of Formulation in the name of M/s Regal Pharmaceuticals, Plot No. A2, Street No. S-5, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period Commencing on 01-06-2021 ending on 30-05-2026 for the following sections: - 1. Tablet (General). 2. Capsule (General). 3. Dry Powder Suspension (General). 4. Oral Liquid (General). 5. Liquid Ampoule (General). 6. Liquid Vial Injectable (General). 7. Capsule (Cephalosporin). 8. Dry Powder Suspension (Cephalosporin). 9. Dry Powder Vial Injection (Cephalosporin).			
19	M/s PDH Laboratories (Pvt) Ltd, 9.5-KM Sheikhupura Road, Lahore. DML No.000039 (Formulation). Period: Commencing on 30-04-2020 ending on 29-04-2025.	**03-01-2022** **&** **04-01-2022**	**Good**	4. Mrs. Majida Mujahid, Additional Director (E&M), DRAP, Lahore. 5. Mr. Muhammad Arif Chaudhary, Additional Director (CD), DRAP, Islamabad. 6. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore.
	"In view of above inspection proceedings and facilities verified, building, material management, production, in-process controls, quality control testing, machinery / equipment, air handling, water treatment system, personnel and documentation e.t.c **the panel recommends the renewal of Drug Manufacturing License (by way of formulation), Regularization of Layout Plan and Grant of Additional Section** to M/s PDH Laboratories (Pvt) Ltd, 9.5-KM Sheikhupura Road, Lahore: - 1. Dry Powder Injectable (Penicillin).			

	2. Liquid Injectable Section (Narcotic). 3. Dry Powder Injectable Section (Cephalosporin). 4. Liquid Injectable Section (General). 5. Oral Liquid Section (General) (New). **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of renewal of DML No. 000039 by way of Formulation in the name of M/s PDH Laboratories (Pvt) Ltd, 9.5-KM Sheikhupura Road, Lahore on the recommendations of the panel of experts for the period Commencing on 30-04-2020 ending on 29-04-2025 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for Liquid Injectable Section (Psychotropic): - 1. Dry Powder Injectable (Penicillin). 2. Liquid Injectable Section (Psychotropic). 3. Dry Powder Injectable Section (Cephalosporin). 4. Liquid Injectable Section (General). 5. Oral Liquid Section (General) (New).			
20	M/s MTI Medical (Pvt) Ltd, Plot No. 586-587, Sunder Industrial Estate, Raiwind Road, Lahore. DML No. 000801 (Formulation). Period: Commencing on 19-09-2019 & ending on 18-09-2024.	**09-02-2022**	**Good**	1. Dr. Ikram ul Haq, Expert Member. 2. Mrs. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: Keeping in view the facilities like building, HVAC system, equipment, Instrument, Machinery, Personnel, Documentation, Quality Assurance department, Quality Control and testing facilities, the panel of Inspectors **recommend** the grant of following new section to M/s MTI Medical (Pvt) Ltd, Plot No. 586-587, Sunder Industrial Estate, Raiwind Road, Lahore. i. Injectable (Vial) Liquid & Lyophilized Section (General) (New). Panel also **recommend** the renewal of Grant of Drug Manufacturing License for the following sections: 1. Lyophilized Vials Injectable (General) (already existing section) 2. Dry Powder Injectable (Cephalosporin) 3. Oral Liquid 4. Tablet (General) 5. Capsule (General) 6. Dry Suspension (General) 7. Liquid Vial Injectable (General) (SVP). It is pertinent to mention here that as per available record of Licensing Division, Injectable (Vial) Liquid & Lyophilized Section (General), Lyophilized Vials Injectable (General) and			

	Liquid Vial Injectable (General) (SVP) are same licensed section and revised layout plan of this section is approved with the title "Injectable (Vial) (Liquid & Lyophilized) (General) Section. **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of renewal of DML No. 000801 by way of Formulation in the name of M/s MTI Medical (Pvt) Ltd, Plot No. 586-587, Sunder Industrial Estate, Raiwind Road, Lahore on the recommendations of the panel of experts for the period Commencing on 19-09-2019 & ending on 18-09-2024 for the following sections: - 1. Injectable (Vial) (Liquid & Lyophilized) (General) Section 2. Dry Powder Injectable (Cephalosporin) 3. Oral Liquid 4. Tablet (General) 5. Capsule (General) 6. Dry Suspension (General)			
21	M/s Lowitt Pharma (Pvt) Ltd., Plot No.24, Industrial Estate, Hayatabad, Peshawar DML No.000568 (Formulation) Tenure: Commencing on 27-01-2019& ending on 26-01-2024. **Sections** 1. Tablet Section (General) 2. Dry Powder for suspension (General) 3. Capsule Section (General) 4. Syrup Section (General) 5. Tablet Section (Psychotropic) 6. Capsule Section (ceph) 7. Dry Powder For Injection (ceph) 8. Dry Powder for Suspension (ceph) 9. Dry Powder for suspension (Penicillin) 10. Capsule Section (Penicillin)	**24-02-2022**	**Good**	1. Prof. Jamshaid Bangash, University of Peshawar, Peshawar. 2. Federal Inspector of Drugs, DRAP, Peshawar. 3. Mr. Adnan Shahidullah, AD, DRAP, Peshawar.
	Recommendations of the panel: "Based on the areas inspected, the people met, documents reviewed the intension towards further			

	improvements and the corrective and preventive action taken, the firm is considered to be operating at good level of compliance with cGMP guide lines as per drug act, 1976 and rules framed there under. As per manufacturing / testing equipment installed in the production, quality control & microbiology lab, utilities, engineering as well as the cGMP compliance status of the firm, the panel unanimously recommended the grant of renewal of DML No.000568 by way of formulation. The panel also verified the revised layout plan of the firm approved by the Licensing Division of DRAP. **The case is hereby submitted for consideration and orders of the Board, please.** **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the grant of renewal of DML No. 000568 by way of Formulation in the name of M/s Lowitt Pharma (Pvt) Ltd., Plot No.24, Industrial Estate, Hayatabad, Peshawaron the recommendations of the panel of experts for the period Commencing on 27-01-2019& ending on 26-01-2024 for the following sectionssubject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for Tablet Section (Psychotropic) 1. Tablet Section (General) 2. Dry Powder for suspension (General) 3. Capsule Section (General) 4. Syrup Section (General) 5. Tablet Section (Psychotropic) 6. Capsule Section (Cephalosporin) 7. Dry Powder For Injection (Cephalosporin) 8. Dry Powder for Suspension (Cephalosporin) 9. Dry Powder for suspension (Penicillin) 10. Capsule Section (Penicillin)			
22	M/s Fedro Pharmaceutical Labs (Pvt) Ltd, 149-Industrial Estate, Hayatabad, Peshawar. DML No.000238 (Formulation) Tenure: Commencing on 09-02-2021 & ending on 08-02-2026.	**09-12-2021** **03-02-2022**	**Good**	4. Dr. Jamshaid Ali Khan, Expert Member. 5. FID, DRAP, Peshawar. 6. Syed Adnan Ali Shah, Assistant Director, DRAP, Peshawar.
	Recommendations of the panel: "In compliance to Licensing Division letter No.F.3-6/85-Lic (Vol-I) dated 22-09-2021, the firm M/s Fedro Pharmaceutical Labs (Pvt) Ltd., Peshawar was inspected by the nominated panel for			

	renewal of Drug manufacturing license (DML# 000238-Formulation) and grant of additional section. Accordingly, the firm was inspected in detail on prescribed evaluation form and the panel unanimously recommends the grant of renewal of DML and grant of additional section (Dry Suspension Section-General). Detailed evaluation form (singed & stamped) will be forwarded to Licensing Division, DRAP, Islamabad in due course of time. **Decision of the Central Licensing Board in 285th meeting:** The Board considered and approved the regularization of lay out plan grant of renewal of DML No. 000238 by way of Formulation in the name of M/s Fedro Pharmaceutical Labs (Pvt) Ltd, 149-Industrial Estate, Hayatabad, Peshawar on the recommendations of the panel of experts for the period Commencingon 09-02-2021 & ending on 08-02-2026for the following sections: - 1. Tablet Section (General) 2. Dry Powder for suspension (Ceph) 3. Capsule Section (General) 4. Oral Liquid Section (General) 5. Capsule Section (Ceph) 6. Capsule Section (Penicillin) 7. Dry Powder for suspension (Penicillin)			
23	M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle Kahuta road Islamabad. DML No.000711 (Formulation) Tenure: Commencing on 09-02-2021 & ending on 08-02-2026.	06-12-2021 & 26-01-2022	**Good**	4. Additional Director (QA/LT), DRAP, Islamabad. 5. Federal Inspector of Drugs, DRAP, Islamabad. 6. Mr. Muhammad Usman, Assistant Director (Licensing), DRAP, Islamabad.
	Recommendations of the panel: **Recommendations:** Keeping in view the above facts on record and the people met during the visit, the panel unanimously recommendedfollowing sections ofSiam Pharmaceutical, Plot # 217, Industrial Triangle Kahuta Road Islamabad. **ii) the renewal of Drug Manufacturing License by way of Formulation** **1. Tablet (General) Section** **2. Capsule (General) Section** **iii) grant of additional sections** 1. Sachet (General) Section 2. Finished Goods Store			

Decision of the Central Licensing Board in 285th meeting:

The Board considered and approved the grant of renewal of DML No. 000711 by way of Formulation in the name of M/s Siam Pharmaceutical, Plot # 217, Industrial Triangle Kahuta Road,Islamabad on the recommendations of the panel of experts for the period Commencing on 09-02-2021 & ending on 08-02-2026 for the following sections: -

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

24	M/s Ethical Laboratories (Pvt) Ltd, 14-Km, Thokar Niaz Baig, Multan Road, Lahore. DML No.000100 (Formulation). Period: Commencing on 14-05-2019 & ending on 13-05-2024.	**08-03-2022**	**Good**	1. Mr. Muhammad Shamoon Chaudhary, Expert Member. 2. Mrs. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Mehwish Jamil Butt, Assistant Director, DRAP, Lahore.

Recommendations of the Panel:

"Based on the areas inspected, technical people met and the documents reviewed and considering the findings of inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per Drug (Licensing, Registering and Advertising) Rules, 1976 and capacity & capability of the firm in respect of manufacturing and quality control of registered products in respect to following sections:

i. Tablet Section (General)
ii. Tablet Section (Steroid)
iii. Eye Drops Section (Non-Steroidal)
iv. Eye Drops Section (Steroidal)
v. Capsule (General)
vi. Oral Liquid (General)

Recommendation:

The panel of inspectors **recommends** the renewal of DML bearing No 000100 issued in favour of M/s Ethical Laboratories (Pvt) Ltd, Lahore in respect to above mentioned sections along with regularization of Layout plan.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and approved the grant of renewal of DML No. 000100 by way of

	Formulation in the name of M/s Ethical Laboratories (Pvt) Ltd, 14-Km, Thokar Niaz Baig, Multan Road, Lahore on the recommendations of the panel of experts for the period Commencing on on 14-05-2019 & ending on 13-05-2024 for the following sections: i. Tablet Section (General) ii. Tablet Section (Steroid) iii. Eye Drops Section (Non-Steroidal) iv. Eye Drops Section (Steroidal) v. Capsule (General) vi. Oral Liquid (General)

ITEM-V MISCELLANEOUS CASES

Case No-1 **CHANGE OF TITLE M/S ONYX PHARMACEUTICALS, 30-A, SMALL INDUSTRIAL ESTATE, MANSEHRA, UNDER DRUG MANUFACTURING LICENSE NO. 000440 BY WAY OF (FORMULATION).**

M/s Onyx Pharmaceuticals, 30-A, Small Industrial Estate, Mansehra, DML No.000440 by way of formulation has submitted request for change of title/name of the firm/business detailed as under;

Previous Title/Name	Current Title/Name
M/s "Onyx Pharmaceuticals"	M/s "Onyx Pharmaceuticals (Pvt) Ltd"

Decision of the Central Licensing Board in 285th meeting:

The Board considered and approved change of title/name of the firm/business in the light of Form-29 as under;

Previous Title/Name	Current Title/Name
M/s "Onyx Pharmaceuticals"	M/s "Onyx Pharmaceuticals (Pvt) Ltd"

Case No-2 **CHANGE OF MANAGEMENT OF M/S SHAZEB PHARMACEUTICALS INDUSTRIES LTD, HAZARA TRUNK ROAD, SARAI GADAEE, HARIPUR, UNDER DRUG MANUFACTURING LICENSE NO. 000380 BY WAY OF (FORMULATION).**

M/s Shazeb Pharmaceuticals Industries Ltd, Hazara Trunk Road, Sarai Gadaee, Haripur, DML No.000380 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under;

Previous Management as per Form-29	Current management as per Form-29
i. Riaz-ul-Hasnain CNIC No. 35201-5095551-1	i. Ashfaq Safdar CNIC No. 35202-9065126-5
ii. Qaiser Zulfiqar CNIC No. 35201-3751074-0	ii. Uzam Aftab CNIC No. 57858-6153246-2
iii. Zulqar Hussain CNIC No. 35201-5391685-5	iii. Qaiser Zulfiqar CNIC No. 35201-3751074-0
iv. Ashfaq Safdar CNIC No. 35202-9065126-5	iv. Ejaz Ahmad CNIC No. 57858-6830311-1
v. Naheed Ashfaq CNIC No. 35201-1028628-0	v. Riaz-ul-Hasnain CNIC No. 35201-5095551-1
vi. Ejaz Ahmad CNIC No. 57858-6830311-1	vi. Zulqar Hussain CNIC No. 35201-5391685-5

	vii. Naheed Ashfaq CNIC No. 35201-1028628-0

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Shazeb Pharmaceuticals Industries Ltd, Hazara Trunk Road, Sarai Gadaee, Haripur, DML No.000380 by way of formulation as per Form-29 as under:

Previous Management as per Form-29	Current management as per Form-29
i. Riaz-ul-Hasnain CNIC No. 35201-5095551-1 ii. Qaiser Zulfiqar CNIC No. 35201-3751074-0 iii. Zulqar Hussain CNIC No. 35201-5391685-5 iv. Ashfaq Safdar CNIC No. 35202-9065126-5 v. Naheed Ashfaq CNIC No. 35201-1028628-0 vi. Ejaz Ahmad CNIC No. 57858-6830311-1	i. Ashfaq Safdar CNIC No. 35202-9065126-5 ii. Uzam Aftab CNIC No. 57858-6153246-2 iii. Qaiser Zulfiqar CNIC No. 35201-3751074-0 iv. Ejaz Ahmad CNIC No. 57858-6830311-1 v. Riaz-ul-Hasnain CNIC No. 35201-5095551-1 vi. Zulqar Hussain CNIC No. 35201-5391685-5 vii. Naheed Ashfaq CNIC No. 35201-1028628-0

Case No-3 **CHANGE OF MANAGEMENT OF M/S RAKAPOSHI PHARMACEUTICAL (PVT) LTD., 97-KM, HAYATABAD INDUSTRIAL ESTATE, PESHAWAR, UNDER DRUG MANUFACTURING LICENSE NO. 000386 BY WAY OF (FORMULATION).**

M/s Rakaposhi Pharmaceutical (Pvt) Ltd., 97-KM, Hayatabad Industrial Estate, Peshawar, DML No.000386 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under;

Previous Management as per Form-29	Current management as per Form-29

i. Mr. Ambareed Zahid ii. Salma Baseer	i. Jehan Zeb S/o Shehzada CNIC 17301-2535004-7 **(C.E.O)** ii. Mr. Saad Khan Zahid S/o. Mr. Zahid Arif CNIC # 17301-8405234-5 iii. Mrs. Ambreen Zahid w/o Mr. Zahid Arif CNIC No. 17301-1255849-4

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Rakaposhi Pharmaceutical (Pvt) Ltd., 97-KM, Hayatabad Industrial Estate, Peshawar, DML No.000386 by way of formulation as per Form-29 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 10/11/2020;

Previous Management as per Form-29	**Current management as per Form-29**
i. Mr. Ambareed Zahid ii. Salma Baseer	i. Jehan Zeb S/o Shehzada CNIC 17301-2535004-7 **(C.E.O)** ii. Mr. Saad Khan Zahid S/o. Mr. Zahid Arif CNIC # 17301-8405234-5 iii. Mrs. Ambreen Zahid w/o Mr. Zahid Arif CNIC No. 17301-1255849-4

Case No-4 **CHANGE OF MANAGEMENT OF M/S PAKISTAN INSTITUTE OF NUCLEAR SCIENCE AND TECHNOLOGY (PINSTECH), ISLAMABAD, UNDER DRUG MANUFACTURING LICENSE NO. 000930 BY WAY OF (FORMULATION).**

M/s Pakistan Institute of Nuclear Science and Technology (PINSTECH), Islamabad, DML No.000930 by way of formulation has submitted request for change in management of the firm with prescribed fee. The detail of management of the firm is as under;

Previous Management	**New Management**
1. Dr. Ammad Hussain Qureshi	1. Dr. Qamar-ul-Haque

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Pakistan Institute of Nuclear Science and Technology (PINSTECH), Islamabad, DML No.000930by way of formulationas under;

Previous Management	New Management
1. Dr. Ammad Hussain Qureshi	1. Dr. Qamar-ul-Haque

Case No-5 **CHANGE OF MANAGEMENT OF M/S WERRICK PHARMACEUTICALS, PLOTNO. 216-217, I/10-3, INDUSTRIAL AREA, ISLAMABAD, UNDER DRUG MANUFACTURING LICENSE NO. 000489 BY WAY OF (SEMI BASIC MANUFACTURING).**

M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad, DML No.000489 by way of Semi Basic Manufacturing has submitted request for change in management as per partnership deed of the firm with prescribed fee. The detail of management of the firm is as under;

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

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad, DML No.000489 by way of Semi Basic Manufacturing as per Partnershi deed as under;

Previous management per Partnership deed	New management as per revised Partnership deed

i. Mr, Muhammad Awais S/o Muhammad Shafi ii. Mr. Ali Amin S/o Noor ul Amin iii. Mr, Muhammad Bilal S/o Tahir Hamid iv. Mr, Muhammad Umair S/o Tahir Hamid v. Mr. Farooq Owais S/o Muhammad Awais	i. Mr. Ali Amin S/o Noor ul Amin CNIC No.61101-0909202-7. ii. Mr, Muhammad Bilal S/o Tahir Hamid, CNIC No.61101-1856273-3. iii. Mr, Muhammad Umair S/o Tahir Hamid, CNIC No.61101-7964040-9. iv. Mr. Farooq Owais S/o Muhammad Awais, CNIC No.61101-1929057-5.

Case No-6 **CHANGE OF MANAGEMENT OF M/S PRIX PHARMACEUTICA (PVT) LTD, PLOT NO. 05, PHARMA CITY, 30-KM, MULTAN ROAD, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000587 BY WAY OF (FORMULATION).**

M/s Prix Pharmaceutica (Pvt) Ltd, Plot No. 05, Pharma City, 30-KM, Multan Road, Lahore, DML No.000587 by way of formulation has submitted request for change in management of the firm as per Form-29with prescribed fee. The detail of management of the firm is as under:-

Existing management	New management as per Form-29
1. Dr. Syed Abid Abbas S/o Syed Abbas Ali CNIC No. 35201-1295910-1. 2. Syed Baqar Abbas Naqvi S/o Syed Abbas Ali Shah CNIC No. 35201-1556328-7. 3. Syed Hassan Mehdi S/o Syed Saadat Hussain CNIC No. 35202-2476986-3.	1. Dr. Syed Abid Abbas S/o Syed Abbas Ali CNIC No. 35201-1295910-1. 2. Syed Baqar Abbas Naqvi S/o Syed Abbas Ali Shah CNIC No. 35201-1556328-7.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Prix Pharmaceutica (Pvt) Ltd, Plot No. 05, Pharma City, 30-KM, Multan Road, Lahore, DML No.000587 by way of formulation as per Form-29 as under;

Existing management	New management
1. Dr. Syed Abid Abbas S/o Syed Abbas Ali CNIC No. 35201-1295910-1. 2. Syed Baqar Abbas Naqvi S/o Syed Abbas Ali Shah CNIC No. 35201-1556328-7. 3. Syed Hassan Mehdi S/o Syed Saadat Hussain CNIC No. 35202-2476986-3.	1. Dr. Syed Abid Abbas S/o Syed Abbas Ali CNIC No. 35201-1295910-1. 2. Syed Baqar Abbas Naqvi S/o Syed Abbas Ali Shah CNIC No. 35201-1556328-7.

Case No-7 **CHANGE OF MANAGEMENT OF M/S SERVIER RESEARCH AND PHARMACEUTICALS (PAKISTAN (PVT) LTD, 9-KM SHEIKHUPURA ROAD, LAHORE UNDER DML NO. 000472.**

M/s Servier Research and Pharmaceuticals (Pakistan (Pvt) Ltd, 9-Km Sheikhupura Road, Lahore under DML No. 000472 has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under:-

Existing management As per Form-29.	**New management As per Form-29.**
1. Mr. Christian Henri Bazantay S/o Henri Jean Bazantay Passport No. 11A18632. 2. Mr. Patrice Lucien Jacques Courtois S/o Lucien Courtois Passport No.11CV31661.	1. Mr. Patrick Genissel S/o Bernard Genissel Passport No.11AR35254. 2. Mr. Nicolas Charles Marie Joseph Bouts S/o Thierry Bouts Passport No. 12CT38704.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Servier Research and Pharmaceuticals (Pakistan (Pvt) Ltd, 9-Km Sheikhupura Road, Lahore under DML No. 000472 by way of formulation as under;

Existing management As per Form-29.	**New management As per Form-29.**
1. Mr. Christian Henri Bazantay S/o Henri Jean Bazantay Passport No. 11A18632. 2. Mr. Patrice Lucien Jacques Courtois S/o Lucien Courtois Passport No.11CV31661.	1. Mr. Patrick Genissel S/o Bernard Genissel Passport No.11AR35254. 2. Mr. Nicolas Charles Marie Joseph Bouts S/o Thierry Bouts Passport No. 12CT38704.

Case No-8 **CHANGE OF MANAGEMENT OF M/S NICHOLAS PHARMACEUTICALS, PLOT NO. 34, STREET NO. SS-2, NATIONAL INDUSTRIAL ZONE, RAWAT, UNDER DRUG MANUFACTURING LICENSE NO. 000886 (FORMULATION).**

M/s Nicholas Pharmaceuticals, Plot No. 34, Street No. SS-2, National Industrial Zone, Rawat under DML No. 000886 by way of Formulation has submitted request for change in management of the firm as per partnership deed with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-1A.	**New Management as per Partnership deed dated 26-07-2021**

1. Mr. Amjid Ali Zeb S/o Muhammad Aurangzeb, CNIC No. 42201-3056252-3. 2. Mr. Muhammad Azmat Ali S/o Fazal Manan CNIC No. 17301-3861340-1.	1. Mr. Muhammad Azmat Ali S/o Fazal Manan CNIC No. 17301-3861340-1. 2. Mr. Amjid Ali Zeb S/o Muhammad Aurangzeb, CNIC No. 42201-3056252-3. 3. Mr. Asif Salam S/o Abdul Salam CNIC No. 17301-4062838-9. 4. Mr. Naveed Salam S/o Haji Abdul Salam CNIC No. 17301-1325807-9.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Nicholas Pharmaceuticals, Plot No. 34, Street No. SS-2, National Industrial Zone, Rawat under DML No. 000886 by way of Formulation as per Form-29 as under: -

Previous Management as per Form-1A.	New Management as per Partnership deed dated 26-07-2021
1. Mr. Amjid Ali Zeb S/o Muhammad Aurangzeb, CNIC No. 42201-3056252-3. 2. Mr. Muhammad Azmat Ali S/o Fazal Manan CNIC No. 17301-3861340-1.	1. Mr. Muhammad Azmat Ali S/o Fazal Manan CNIC No. 17301-3861340-1. 2. Mr. Amjid Ali Zeb S/o Muhammad Aurangzeb, CNIC No. 42201-3056252-3. 3. Mr. Asif Salam S/o Abdul Salam CNIC No. 17301-4062838-9. 4. Mr. Naveed Salam S/o Haji Abdul Salam CNIC No. 17301-1325807-9.

Case No-9 **CHANGE OF MANAGEMENT OF M/S NEXT PHARMACEUTICAL PRODUCTS (PVT) LTD, PLOT NO. 44 A&B, SUNDAR INDUSTRIAL ESTATE, LAHORE UNDER DML NO. 000847.**

M/s Next Pharmaceutical Products (Pvt) Ltd, Plot No. 44 A&B, Sundar Industrial Estate, Lahore under DML No. 000847 by way of Formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under: -

Previous Management	New management

1. Mrs. Saleha But W/o Salman Khalid Butt CNIC No. 90601-0100195-4. 2. Mr. Rizwan Khalid Butt S/o Khalid Masood Butt CNIC No. 35201-7000395-3. 3. Mr. Tabassum Khan S/o Abdul Jabbar Khan CNIC No. 35201-5079875-7.	1. Mr. Nauman Khalid Butt S/o Khalid Masud Butt CNIC No. 35201-1548802-9. 2. Mrs. Saleha But W/o Salman Khalid Butt CNIC No. 90601-0100195-4. 3. Mr. Rizwan Khalid Butt S/o Khalid Masood Butt CNIC No. 35201-7000395-3. 4. Mr. Tabassum Khan S/o Abdul Jabbar Khan CNIC No. 35201-5079875-7. 5. Mr. Asif Majeed Shaikh S/o Abdul Majeed Shaikh CNIC No. 37406-1628708-7.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Next Pharmaceutical Products (Pvt) Ltd, Plot No. 44 A&B, Sundar Industrial Estate, Lahore under DML No. 000847 by way of Formulationas per Form-29 as under: -

Previous Management	New management
1. Mrs. Saleha But W/o Salman Khalid Butt CNIC No. 90601-0100195-4. 2. Mr. Rizwan Khalid Butt S/o Khalid Masood Butt CNIC No. 35201-7000395-3. 3. Mr. Tabassum Khan S/o Abdul Jabbar Khan CNIC No. 35201-5079875-7.	1. Mr. Nauman Khalid Butt S/o Khalid Masud Butt CNIC No. 35201-1548802-9. 2. Mrs. Saleha But W/o Salman Khalid Butt CNIC No. 90601-0100195-4. 3. Mr. Rizwan Khalid Butt S/o Khalid Masood Butt CNIC No. 35201-7000395-3. 4. Mr. Tabassum Khan S/o Abdul Jabbar Khan CNIC No. 35201-5079875-7. 5. Mr. Asif Majeed Shaikh S/o Abdul Majeed Shaikh CNIC No. 37406-1628708-7.

Case No-10 **CHANGE OF MANAGEMENT OF M/S PHARM EVO (PVT) LTD, KARACHI**

M/s. Pharm Evo (Pvt) Ltd, Plot No. DML No. 000 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee as under: -

Current Management	New Management as per Form-29 & Form-A of SECP (Year 2021)
1. Mr. Derek AlenEvans, S/o William Baden Passport No. 016319260 2. Mr. Mohammad Haroon Qassim, S/o Ebrahim Qassim CNIC No. 42201-5924502-1	1. Mr. Mohammad Haroon Qassim S/o Ebrahim Qassim CNIC No. 42201-5924502-1 2. Mr. Mohammad Bilal Qassim S/o Muhammad Jamil Khan

3. Mr. ZamiruddinAhmed, S/o Amiruddin Ahmed CNIC No. 42201-0567744-1	CNIC No. 42201-3473943-9

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of **M/s. Pharm Evo (Pvt) Ltd, Plot No.** DML No. 000 by way of formulation as per Form-29 as under: -

Current Management	**New Management as per Form-29 & Form-A of SECP (Year 2021)**
1. Mr. Derek AlenEvans, S/o William Baden Passport No. 016319260 2. Mr. Mohammad Haroon Qassim, S/o Ebrahim Qassim CNIC No. 42201-5924502-1 3. Mr. ZamiruddinAhmed, S/o Amiruddin Ahmed CNIC No. 42201-0567744-1	1. Mr. Mohammad Haroon Qassim S/o Ebrahim Qassim CNIC No. 42201-5924502-1 2. Mr. Mohammad Bilal Qassim S/o Muhammad Jamil Khan CNIC No. 42201-3473943-9

Case No-11 **CHANGE OF MANAGEMENT OF M/S ELKO ORGANIZATION (PVT) LTD, KARACHI**

M/s. Elko Organization (Pvt) Ltd, Plot No. 27 & 28, Sector 12/B, North Karachi DML No. 000 245 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee as under: -

Existing Management Last Renewal Year 2015	**New Management** Form- 29 Year 2021
1. Mr. Nadeem Ahmed Chandna S/o S.M. Ahmed (Late) CNIC No. 42201-5369040-3. 2. Mr. Shakeel Ahmed Chandna S/o S.M. Ahmed (Late) CNIC No. 42201-1366087-7.	1. Mr. Nadeem Ahmed Chandna S/o S.M. Ahmed (Late) CNIC No. 42201-5369040-3. 2. Mr. Shakeel Ahmed Chandna S/o S.M. Ahmed (Late) CNIC No. 42201-1366087-7.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s. Elko Organization (Pvt) Ltd, Plot No. 27 & 28, Sector 12/B, North Karachi DML No. 000245 by way of formulationas per Form-29 as under: -

Existing Management Last Renewal Year 2015	**Interim Management** Form- 29 Year 2020	**New Management** Form- 29 Year 2021
1. Mr. Nadeem Ahmed Chandna S/o S.M. Ahmed (Late) CNIC No. 42201-5369040-3. 2. Mr. Shakeel Ahmed Chandna S/o S.M. Ahmed (Late) CNIC No. 42201-1366087-7.	1. Mr. Nadeem Ahmed Chandna S/o S.M. Ahmed (Late) CNIC No. 42201-5369040-3. 2. Mr. Shakeel Ahmed Chandna S/o S.M. Ahmed (Late) CNIC No. 42201-1366087-7. 3. Ms. Shamima Khatoon W/o S.M. Ahmed (Late) CNIC No. 42000-3202652-6	1. Mr. Nadeem Ahmed Chandna S/o S.M. Ahmed (Late) CNIC No. 42201-5369040-3. 2. Mr. Shakeel Ahmed Chandna S/o S.M. Ahmed (Late) CNIC No. 42201-1366087-7.

Case No-12 **CHANGE OF MANAGEMENT OF M/S MAXITECH PHARMA (PVT) LTD, KARACHI**

M/s. MaxitechPharma (Pvt) Ltd, Plot No. E-178, S.I.T.E. Super Highway, Karachi DML No. 000851 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee as under: -

Current Management Form-1A	**New Management as per Form-29 & Form-A**
i. Mr. Zeeshan Hasan Khan Chaudry S/o Nadir Hassan Khan CNIC No. 42101-4241083-5 i. Mrs. Shaista Nadir S/o Nadir Hassan Khan CNIC No. 42101-06008340.	ii. Mr. Zeeshan Hasan Khan Chaudry S/o Nadir Hassan Khan CNIC No. 42101-4241083-5 ii. Mr. Nadir Hassan Khan S/o Manzoor Hassan Khan CNIC No. 42101-6265138-9

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of **M/s. MaxitechPharma (Pvt) Ltd, Plot No. E-178, S.I.T.E. Super Highway, Karachi** DML No. 000851 by way of formulation as per Form-29 as under: -

Current Management Form-1A	**New Management as per Form-29 & Form-A**
i. Mr. Zeeshan Hasan Khan Chaudry S/o Nadir Hassan Khan CNIC No. 42101-4241083-5 iii. Mrs. Shaista Nadir S/o Nadir Hassan Khan CNIC No. 42101-06008340.	i. Mr. Zeeshan Hasan Khan Chaudry S/o Nadir Hassan KhanCNIC No. 42101-4241083-5 ii. Mr. Nadir Hassan Khan S/o Manzoor Hassan Khan CNIC No. 42101-6265138-9

Case No- 13 **CHANGE OF MANAGEMENT OF M/S GLAXO SMITH KLINE PAKSITAN LTD, JAMSHORO**

M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd, Petaro Road, Jamshoro under DML No. 000010 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee as under: -

Existing management	**New Management**
1. Mr. Syed Azeem Abbas Naqvi S/o Syed Takreem Hussain Naqvi CNIC: 35202-2835969-1. 2. Mr. Sohail Ahmed S/o Mohammad Matin CNIC: 42000-9133745-7. 3. Mr. Husain Lawai S/o Haji Moosa CNIC: 914000-140464-5. 4. Ms. EmineTasci Kaya D/o YildizTasci Passport No: U00287385. 5. Ms. Annelize Roberts D/o David William Roberts Passport No: 510602988. 6. Mr. Syed Anwar Mahmood S/o Syed Mahmood CNIC: 61101-7697428-9. 7. Mr. Talal Javed Ahmed S/o Javed Ahmed	1. Mr. DilawarMeghani S/o Muhammad Sadiq Meghani CNIC No. 42201-1497576-1 2. Mr. Syed Anwar Mahmood S/o Syed Mahmood CNIC: 61101-7697428-9. 3. Ms. Ayesha Aziz W/o Mr. Tahir Aziz CNIC No. 42301-6741819-6. 4. Mr. Farhan Muhammad Haroon S/o Muhammad Haroon CNIC No. 42201-0271246-9. 5. Mr. Oussama Abbas S/o Hassan Abbas Passport No. 19FH69224 6. Mr. Muhammad ZindahMoinMohajir S/o Muhammad Abdullah Mohajir CNIC No. 42301-8664878-1. 7. Ms. Erum Shakir D/o Mr. Muhammad Shakkir Rahim

CNIC: 42201-8932528-1. 8. Mr. Muhmmad ZindahMoinMohajirS/o Muhmmad Abdullah Mohajir CNIC: 42301-8664878-1.	CNIC No. 42101-7411745-0.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd, Petaro Road, Jamshoro under DML No. 000010 by way of formulation as per Form-29 as under: -

Existing management	New Management (Form-29
1. Mr. Syed Azeem Abbas Naqvi S/o Syed Takreem Hussain Naqvi CNIC: 35202-2835969-1. 2. Mr. Sohail Ahmed S/o Mohammad Matin CNIC: 42000-9133745-7. 3. Mr. Husain Lawai S/o Haji Moosa CNIC: 914000-140464-5. 4. Ms. EmineTasci Kaya D/o YildizTasci Passport No: U00287385. 5. Ms. Annelize Roberts D/o David William Roberts Passport No: 510602988. 6. Mr. Syed Anwar Mahmood S/o Syed Mahmood CNIC: 61101-7697428-9. 7. Mr. Talal Javed Ahmed S/o Javed Ahmed CNIC: 42201-8932528-1. 8. Mr. Muhmmad ZindahMoinMohajir S/o Muhmmad Abdullah Mohajir CNIC: 42301-8664878-1.	1. Mr. DilawarMeghani S/o Muhammad Sadiq Meghani CNIC No. 42201-1497576-1 2. Mr. Syed Anwar Mahmood S/o Syed Mahmood CNIC: 61101-7697428-9. 3. Ms. Ayesha Aziz W/o Mr. Tahir Aziz CNIC No. 42301-6741819-6. 4. Mr. Farhan Muhammad Haroon S/o Muhammad Haroon CNIC No. 42201-0271246-9. 5. Mr. Oussama Abbas S/o Hassan Abbas Passport No. 19FH69224 6. Mr. Muhammad ZindahMoinMohajir S/o Muhammad Abdullah Mohajir CNIC No. 42301-8664878-1. 7. Ms. Erum Shakir D/o Mr. Muhammad Shakkir Rahim CNIC No. 42101-7411745-0.

Case No. 14 CHANGE OF MANAGEMENT OF M/S JINNAH PHARMACEUTICALS (PVT) LTD, 13-KM, LAHORE ROAD, MULTAN UNDER DRUG MANUFACTURING LICENSE NO. 000578 (FORMULATION).

M/s Jinnah Pharmaceuticals (Pvt) Ltd, 13-Km, Lahore Road, Multan Under Drug Manufacturing License No. 000578 (Formulation) has submitted request for change in

management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under: -

Previous Management as Form-29	New Management as per Form-29
1. Mr. Taimoor Fazil S/o Muhammad Fazil CNIC No. 36302-0507065-9 2. Mr. Malik Manzoor Ahmad S/o Mahmood Khan CNIC No.37405-8480043-3 3. Mr. Abdul Hameed S/o Muhammad Ramzan CNIC No.32102-4616584-3	1. Mr. Taimoor Fazil S/o Muhammad Fazil CNIC No. 36302-0507065-9 2. Mr. Abdul Hameed S/o Muhammad Ramzan CNIC No.32302-4616584-3. 3. Mr. Ghulam Sarwar Chohan S/o Ghulam Muhammad CNIC No.35200-1426720-1. 4. Mr. Muhammad Akhtar S/o Malik Naseer Bukhsh CNIC No.36302-0238753-9.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Jinnah Pharmaceuticals (Pvt) Ltd, 13-Km, Lahore Road, Multan Under Drug Manufacturing License No. 000578 (Formulation) as per Form-29 as under: -

Previous Management as Form-29	New Management as per Form-29
1. Mr. TaimoorFazil S/o Muhammad Fazil CNIC No. 36302-0507065-9 2. Mr. Malik Manzoor Ahmad S/o Mahmood Khan CNIC No.37405-8480043-3 3. Mr. Abdul Hameed S/o Muhammad Ramzan CNIC No.32102-4616584-3	1. Mr. TaimoorFazil S/o Muhammad Fazil CNIC No. 36302-0507065-9 2. Mr. Abdul Hameed S/o Muhammad Ramzan CNIC No.32302-4616584-3. 3. Mr. Ghulam Sarwar Chohan S/o Ghulam Muhammad CNIC No.35200-1426720-1. 4. Mr. Muhammad Akhtar S/o Malik Naseer Bukhsh CNIC No.36302-0238753-9.

Case No. 15 **CHANGE OF MANAGEMENT OF M/S IPRAM INTERNATIONAL, PLOT NO. 26, SS-3, NATIONAL INDUSTRIAL ZONE, RAWAT UNDER DRUG MANUFACTURING LICENSE NO. 000551 (FORMULATION).**

M/s Ipram International, Plot No. 26, Ss-3, National Industrial Zone, Rawat Under Drug Manufacturing License No. 000551 (Formulation) has submitted request for change in management of the firm as per Undertaking with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Partnership Deed	New Management as per Undertaking
1. Pervaiz Ahmed Waraich S/o Rehmat Khan. 2. Mrs. Shehnaz Pervaiz W/o Pervaiz Ahmed.	1. Pervaiz Ahmed Warraich S/o Rehmat Khan CNIC No.37405-6402588-1.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Ipram International, Plot No. 26, Ss-3, National Industrial Zone, Rawat Under Drug Manufacturing License No. 000551 (Formulation) as under: -

Previous Management as per Partnership Deed	New Management as per Undertaking
1. Pervaiz Ahmed Waraich S/o Rehmat Khan. 2. Mrs. Shehnaz Pervaiz W/o Pervaiz Ahmed.	1. Pervaiz Ahmed Warraich S/o Rehmat Khan CNIC No.37405-6402588-1.

Case No. 16 **CHANGE OF MANAGEMENT OF M/S ARRETA PHARMACEUTICALS (PVT) LTD, PLOT NO. 13, STREET NO. N-5, RCCI INDUSTRIAL ESTATE, RAWAT UNDER DRUG MANUFACTURING LICENSE NO. 000846 (FORMULATION).**

M/s Arreta Pharmaceuticals (Pvt) Ltd, Plot No. 13, Street No. N-5, RCCI Industrial Estate, Rawat Under Drug Manufacturing License No. 000846 (Formulation) has submitted request for change in management of the firm as per Form-A with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-A	New Management as per Form-A.
1. Mr. Sajjad Hussain S/o Pir	1. Mr. Haroon Sajjad S/o Sajjad Hussain

Bakhsh CNIC No.17301-2138068-7. 2. Mr. Taimur Sajjad S/o Sajjad Hussain CNIC No.17301-4648381-7.	CNIC No.17301-7396211-5. 2. Mr. Taimur Sajjad S/o Sajjad Hussain CNIC No.17301-4648381-7. 3. Mr. Sajjad Hussain S/o Pir Bakhsh CNIC No.17301-2138068-7.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Arreta Pharmaceuticals (Pvt) Ltd, Plot No. 13, Street No. N-5, RCCI Industrial Estate, Rawat Under Drug Manufacturing License No. 000846 (Formulation) as under: -

Previous Management as per Form-A	New Management as per Form-A.
1. Mr. Sajjad Hussain S/o Pir Bakhsh CNIC No.17301-2138068-7. 2. Mr. Taimur Sajjad S/o Sajjad Hussain CNIC No.17301-4648381-7.	1. Mr. Haroon Sajjad S/o Sajjad Hussain CNIC No.17301-7396211-5. 2. Mr. Taimur Sajjad S/o Sajjad Hussain CNIC No.17301-4648381-7. 3. Mr. Sajjad Hussain S/o Pir Bakhsh CNIC No.17301-2138068-7.

Case No. 17 CHANGE OF MANAGEMENT OF M/S MEDIPAK LIMITED, PLOT NO. 554, SUNDER INDUSTRIAL ESTATE, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000841 (FORMULATION).

M/s Medipak Limited, Plot No. 554, Sunder Industrial Estate, Lahore Under Drug Manufacturing License No. 000841 (Formulation) has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-A	New Management as per Form-29.
1. Dr. Muhammad Khalid Javaid Chowdhry S/o Muhammad Din Chowdhry CNIC No. 35201-9666380-3. 2. Mr. Naveed Khalid Chowdhry S/o Muhammad Khalid Javaid Chowdhry CNIC No. 35201-1301165-3. 3. Mr. Nasir Javaid Chowdhry S/o Muhammad Din Chowdhry CNIC No.35202-2509124-1. 4. Dr. KhalidaJavaid w/o Muhammad Khalid Javaid Chowdhry CNIC No.35201-1561600-6.	1. Dr. Muhammad Khalid Javaid Chowdhry S/o Muhammad Din Chowdhry CNIC No. 35201-9666380-3. 2. Mr. Naveed Khalid Chowdhry S/o Muhammad Khalid Javaid Chowdhry CNIC No. 35201-1301165-3. 3. Mr. Nasir Javaid Chowdhry S/o Muhammad Din Chowdhry CNIC No.35202-2509124-1. 4. Dr. KhalidaJavaid W/o Muhammad Khalid Javaid Chowdhry CNIC

5. Nosheen Khalid D/o Muhammad Khalid Javaid Chowdhry CNIC No.35201-2319990-8. 6. Naureen Khalid D/o Muhammad Khalid Javaid Chowdhry CNIC No.35201-1379008-0. 7. Mr. Muhammad Tariq Javaid S/o Muhammad din Chowdhry.	No.35201-1561600-6. 5. Ms. Nosheen Khalid D/o Muhammad Khalid Javaid Chowdhry CNIC No.35201-2319990-8. 6. Mr. Naureen Khalid D/o Muhammad Khalid Javaid Chowdhry CNIC No.35201-1379008-0.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Medipak Limited, Plot No. 554, Sunder Industrial Estate, Lahore Under Drug Manufacturing License No. 000841 (Formulation) as under: -

Previous Management as per Form-A	New Management as per Form-29.
1. Dr. Muhammad Khalid JavaidChowdhry S/o Muhammad Din Chowdhry CNIC No. 35201-9666380-3. 2. Mr. Naveed Khalid Chowdhry S/o Muhammad Khalid JavaidChowdhry CNIC No. 35201-1301165-3. 3. Mr. Nasir JavaidChowdhry S/o Muhammad Din Chowdhry CNIC No.35202-2509124-1. 4. Dr. KhalidaJavaid w/o Muhammad Khalid JavaidChowdhry CNIC No.35201-1561600-6. 5. Nosheen Khalid D/o Muhammad Khalid JavaidChowdhry CNIC No.35201-2319990-8. 6. Naureen Khalid D/o Muhammad Khalid JavaidChowdhry CNIC No.35201-1379008-0. 7. Mr. Muhammad Tariq Javaid S/o Muhammad din Chowdhry.	1. Dr. Muhammad Khalid JavaidChowdhry S/o Muhammad Din Chowdhry CNIC No. 35201-9666380-3. 2. Mr. Naveed Khalid Chowdhry S/o Muhammad Khalid JavaidChowdhry CNIC No. 35201-1301165-3. 3. Mr. Nasir JavaidChowdhry S/o Muhammad Din Chowdhry CNIC No.35202-2509124-1. 4. Dr. KhalidaJavaid W/o Muhammad Khalid JavaidChowdhry CNIC No.35201-1561600-6. 5. Ms. Nosheen Khalid D/o Muhammad Khalid JavaidChowdhry CNIC No.35201-2319990-8. 6. Mr. Naureen Khalid D/o Muhammad Khalid JavaidChowdhry CNIC No.35201-1379008-0.

Case No.18 **CHANGE OF MANAGEMENT OF M/S DEMONT RESEARCH LABORATORIES (PVT) LTD, 20-KM, LAHORE SHARIKPUR ROAD, SHEIKHUPURA UNDER DRUG MANUFACTURING LICENSE NO. 000844 (FORMULATION).**

M/S Demont Research Laboratories (Pvt) Ltd, 20-Km, Lahore Sharikpur Road, Sheikhupura Under Drug Manufacturing License No. 000844 (Formulation) has submitted request for change in management of the firm as per Form-A with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-A	New Management as per Form-A.
1. Mr. Muhammad Abbas S/o Muhammad Yousaf CNIC No. 34102-7100357-3. 2. Mr. Ali Sarwar Sheikh Muhammad Sarwar CNIC No.54400-8325570-9. 3. Mr. Bilal Ajmal S/o Ajmal Rauf Kahlon CNIC No. 35201-6261490-5. 4. Mr. Mahmood Ahmed Virk S/o Muhammad Younas CNIC No. 352010-499026-7. 5. Mr. Maqsood Ali S/o Muhammad Sharif CNIC No.35201-135699-3.	1. Mr. Maqsood Ali S/o Muhammad Sharif CNIC No.35201-135699-3. 2. Mr. Taimoor Mahmood Ahmad CNIC No.35201-4502364-7. 3. Mr. Bilal Ajmal S/o Ajmal Rauf Kahlon CNIC No. 35201-6261490-5. 4. Mr. Ali Sarwar S/o Sheikh Muhammad Sarwar CNIC No.54400-8325570-9. 5. Mr. Muhammad Abbas S/o Muhammad Yousaf CNIC No. 34102-7100357-3.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/S Demont Research Laboratories (Pvt) Ltd, 20-Km, Lahore Sharikpur Road, Sheikhupura Under Drug Manufacturing License No. 000844 (Formulation) as under: -

Previous Management as per Form-A	New Management as per Form-A.
1. Mr. Muhammad Abbas S/o Muhammad Yousaf CNIC No. 34102-7100357-3. 2. Mr. Ali Sarwar Sheikh Muhammad Sarwar CNIC No.54400-8325570-9. 3. Mr. Bilal Ajmal S/o Ajmal Rauf Kahlon CNIC No. 35201-6261490-5. 4. Mr. Mahmood Ahmed Virk S/o Muhammad Younas CNIC No. 352010-499026-7. 5. Mr. Maqsood Ali S/o Muhammad Sharif CNIC No.35201-135699-3.	1. Mr. Maqsood Ali S/o Muhammad Sharif CNIC No.35201-135699-3. 2. Mr. Taimoor Mahmood Ahmad CNIC No.35201-4502364-7. 3. Mr. Bilal Ajmal S/o Ajmal Rauf Kahlon CNIC No. 35201-6261490-5. 4. Mr. Ali Sarwar S/o Sheikh Muhammad Sarwar CNIC No.54400-8325570-9. 5. Mr. Muhammad Abbas S/o Muhammad Yousaf CNIC No. 34102-7100357-3.

Case No. 19 **CHANGE OF TITLE OF M/S GREATER PHARMA, PLOT NO. 35, SS-3, NATIONAL INDUSTRIAL ZONE, RAWAT UNDER DRUG MANUFACTURING LICENSE NO. 000896 (FORMULATION).**

M/s Greater Pharma, Plot No. 35, SS-3, National Industrial Zone, Rawat Under Drug Manufacturing License No. 000896 (Formulation) has submitted request for change in Title of the firm as per Certificate of Incorporation with SECP with prescribed fee. The detail is as under: -

Previous Title	New Title
M/s Greater Pharma, Plot No. 35, SS-3, National Industrial Zone, Rawat.	**Greater Pharmaceuticals (Pvt) Ltd**, Plot No. 35, SS-3, National Industrial Zone, Rawat

Decision of the Central Licensing Board in 285th meeting:

The Board considered and approved change in Title of the firm Under Drug Manufacturing License No. 000896 (Formulation) as under;

Previous Title	New Title
M/s Greater Pharma, Plot No. 35, SS-3, National Industrial Zone, Rawat.	**Greater Pharmaceuticals (Pvt) Ltd**, Plot No. 35, SS-3, National Industrial Zone, Rawat

Case No. 20 **CHANGE OF MANAGEMENT OF M/S GREATER PHARMA, PLOT NO. 35, SS-3, NATIONAL INDUSTRIAL ZONE, RAWAT UNDER DRUG MANUFACTURING LICENSE NO. 000896 (FORMULATION).**

M/s Greater Pharma, Plot No. 35, SS-3, National Industrial Zone, Rawat Under Drug Manufacturing License No. 000896 (Formulation) has submitted request for change in management of the firm as per Form-II with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Undertaking	New Management as per Form-II
1. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-2468331-5.	1. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-2468331-5. 2. Mr. Muhammad Masood S/o

	Muhammad Dawood CNIC No. 54401-3218968-3. 3. Mr. Khalid Ahmed S/o Muhammad Dawood CNIC No.37405-3033798-7.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of M/s Greater Pharma, Plot No. 35, SS-3, National Industrial Zone, Rawat Under Drug Manufacturing License No. 000896 (Formulation) has submitted request for change in management of the firm as per Form-II with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Undertaking	New Management as per Form-II
1. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-2468331-5.	1. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-2468331-5. 2. Mr. Muhammad Masood S/o Muhammad Dawood CNIC No. 54401-3218968-3. 3. Mr. Khalid Ahmed S/o Muhammad Dawood CNIC No.37405-3033798-7.

Case No. 21 CHANGE OF MANAGEMENT OF M/S. PFIZER PAKISTAN LTD, PLOT NO. B-2, S.I.T.E. KARACHI UNDER DML NO. 000025

M/s. Pfizer Pakistan Ltd, Plot No. B-2, S.I.T.E. Karachi under DML No. 000025 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee as under: -

Existing Management as per Form-29	Interim Management as per Form-29	Current Management as per Form-29 Year 2021
1. Mr. Farid Khan S/o Nasir Khan CNIC No. 42301-1048442-7. 2.Mr. S.M. Wajeehuddin S/o Muhammad Fashuddin CNIC No. 42201-4564592-3. 3.Mr. Syed Zakwan Ahmed S/o Syed Sultan Ahmed CNIC No. 42201-6338339-5.	1. Mr. S.M. Wajeehuddin S/o Muhammad Fashuddin CNIC No. 42201-4564592-3. 2. Mr. Kashif Shafi S/oMuhammadShafi Siddique CNIC No. 42301-15754802-7 3. Mr. Rashid Mohammad Khan S/o Faiyaz Khan CNIC No. 42401-9462658-5.	1. Mr. S.M. Wajeehuddin S/o Muhammad Fashuddin CNIC No. 42201-4564592-3. 2. Mr. Tafazull Khan S/o Habibullah CNIC No. 42201-878585-1 3. Mr. Rashid Mohammad Khan S/o Faiyaz Khan CNIC No. 42401-9462658-5.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of **M/s. Pfizer Pakistan Ltd, Plot No. B-2, S.I.T.E. Karachi under** DML No. 000025 by way of formulation as under: -

Existing Management as per Form-29	Current Management as per Form-29 Year 2021
1. Mr. Farid Khan S/o Nasir Khan CNIC No. 42301-1048442-7. 2.Mr. S.M. Wajeehuddin S/o Muhammad Fashuddin CNIC No. 42201-4564592-3. 3.Mr. Syed Zakwan Ahmed S/o Syed Sultan Ahmed CNIC No. 42201-6338339-5.	1. Mr. S.M. Wajeehuddin S/o Muhammad Fashuddin CNIC No. 42201-4564592-3. 2. Mr. Tafazull Khan S/o Habibullah CNIC No. 42201-878585-1 3. Mr. Rashid Mohammad Khan S/o Faiyaz Khan CNIC No. 42401-9462658-5.

Case No-22 **CORRECTION IN SECTION NAME ON RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000513 (FORMULATION) TO M/S ZAFA PHARMACEUTICAL LABORAOTIRES (PVT) LTD KARACHI.**

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1	M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, Plot No. L-1B, Block 22, Federal B Industrial Area, Karachi. DML No. 000513 (Formulation) Period: Commencing on 22-06-2018 & Ending on 21-06-2023	**21-10-2021**	**Good**	1. Dr. Abdullah Dayo, Expert Member. 2. FID, DRAP, Karachi. 3. Mr. Krishan Das, AD, DRAP, Karachi.

Recommendation of panel :

Based on the above stated observations the panel unanimously recommends the grant of renewal of DML No. 000513 by way of formulation for the next five years for following sections:

Sr #	*Name of Section*	*Sr. #*	*Name of Section*
1.	*Tablet (General)*	*2.*	*Capsule (General)*
3.	Eye Ointment (Sterile)	*4.*	*Liquid Syrup (General)*

5.	Dry Powder Suspension (General)	*6.*	*Liquid Injection (Biotech)*
7.	Cream Ointment (General)	*8.*	*Sterile Liquid Injection (Biotech)*
9.	Sterile Dry Powder Injection (General)	*10.*	*Sterile Ampoule LDPE (BFS)*

The panel was given mandated for inspection of the firm for renewal of DML No. 000513 (Formulation) and regularization in the light of approved layout plan , however, panel has only recommended the grant of renewal of DML and the recommendation of the panel regarding regularization of facility are not mentioned.

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000513 by way of formulation in the name of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, Plot No. L-1B, Block 22, Federal B Industrial Area, Karachi the recommendations of the panel of experts for the period commencing on 22-06-2018 & Ending on 21-06-2023for the following section:

Section (10)

1. Tablet (General)
2. Capsule (General)
3. Eye Ointment (Sterile)
4. Liquid Syrup (General)
5. Dry Powder Suspension (General)
6. Liquid Injection (Biotech)
7. Cream Ointment (General)
8. Sterile Liquid Injection (Biotech)
9. Sterile Dry Powder Injection (General)
10. Sterile Ampoule LDPE (BFS)

Accordingly, the decision/DML was issued/renewed.

However, it is observed that the panel of experts was given mandate for inspection of following sections for renewal and regularization :

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Tablet (General)*	*2.*	*Capsule (General)*
3.	Eye Ointment (Sterile)	*4.*	*Liquid Syrup (General)*
5.	Dry Powder Suspension (General)	*6.*	*Liquid vial/ampoule SVP (Biotech)*
7.	Cream Ointment (General)	*8.*	*Ware House (General)*
9.	Sterile Dry Powder Injection (General)	*10.*	*Q C Laboratory*

	However in the panel inspection report the panel recommended the grant of renewal of following sections : **Sr # / Name of Section / Sr. # / Name of Section** 1. *Tablet (General)* — 2. *Capsule (General)* 3. Eye Ointment (Sterile) — 4. *Liquid Syrup (General)* 5. Dry Powder Suspension (General) — 6. *Liquid Injection (Biotech)* 7. Cream Ointment (General) — 8. ***Sterile Liquid Injection (Biotech)*** 9. Sterile Dry Powder Injection (General) — 10. ***Sterile Ampoule LDPE (BFS)*** And same was granted by the CLB and the DML was issued accordingly.

Proceedings and Decision by the Central Licensing Board in 285th meeting:

The Board considering the facts on the record and approved the renewal of Drug Manufacturing License for following sections;

Sr #	Name of Section	Sr. #	Name of Section
1.	*Tablet (General)*	2.	*Capsule (General)*
3.	Eye Ointment (Sterile)	4.	*Liquid Syrup (General)*
5.	Dry Powder Suspension (General)	6.	*Liquid vial/ampoule SVP (General)*
7.	Cream Ointment (General)	8.	*Ware House (General)*
9.	Sterile Dry Powder Injection (General)	10.	*Q C Laboratory*

Case No-23 **CORRECTION IN THE NAME/TITLE OF API's OF M/S SAAKH PHARMA (PVT) LTD, KARACHI UNDER DML NO. 000588 (FORMULATION)**

M/s Saakh Pharma (Pvt) Ltd, Plot No. C-7/1, North Western Industrial Zone, Port Qasim Authority Karachi DML No. 000588 (Formulation) **Facility (s) :** 1. Penicillin Facility – **Revised.** 2. Quality Control Laboratory – **Revised**	**16-09-2021**	**Good**	1) Dir. Abdullah Dayo, Expert Member. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Ms. Krishan Das, AD DRAP, Karachi.

API(s)/Pallets (19): 1. Aceclofenac Pallets – **In House Specs** 2. Clopidogrel Pallets – **In House Specs –** 3. Cyclobenzaprine HCL Pallets **In House Specs** 4. Domperidone Pallets **In House Specs** 5. Doxycycline Pallets **In House Specs** 6. Ferrous Sulphate Pallets **In House Specs** 7. Fexofenadine HCL Pallets **In House Specs** 8. Folic Acid Pallets **In House Specs** 9. Itopride Pallets **In House Specs** 10. Ketoprofen Pallets **In House Specs** 11. Memantine Pallets **In House Specs** 12. Naproxen Pallets **In House Specs** 13. Nitroglycerine Pallets **In House Specs** 14. Rabeprazole Sodium Pallets **In House Specs** 15. Tizanidine Pallets **In House Specs** 16. Venlafaxine HCL Pallets **In House Specs** 17. Secnidazole Taste Masked Granules **In House Specs** 18. Additional Process flow for manufacturing of Cefixime Trihydrate 19. Cephalexin USP.			

Recommendations of the panel:

"M/S. Saakh Pharma (Pvt.) Ltd. Situated at Plot No. C-7/1, North Western Industrial Zone Port Qasim Bin Qasim Town, Karachi inspected is by the panel on 16th Sep 2021 in compliance to the directions contained in DRAP, Islamabad Letter No. F.2-5/2001-Lic. (Vol-IV) dated 2nd April, 9th and 17th August 2021in connection with renewal of Drug Manufacturing License No. 000588 (By of Semi Basic). Following are the observation:

1. The panel inspected the firm in detail including al the manufacturing sections, stores and

QC lab and found the facility as per approved layout plan. The facility has been provided with necessary utilities, machineries and equipment required for the production and test/analysis of the products being manufactured. Necessary documents relating to QC, QA and HVAC and other utilities were also seen in place.

2. Based on the people met, documents reviewed and observations made during the inspections, the panel recommends the grant of renewal of Drug manufacturing License No. 000588 (By way of Semi Basic), grant of additional API and regularization/amendments of Master Layout plan as per DRAP, Islamabad Letter No.F.2-5/2001-Lic (Vol-IV) dated 2" April, 9'" August and 17" August 2021; for following sections:

S.No.	*Name of Section*
1.	*Penicillin*
2.	*Cephalosporins*
3.	*General*
4.	*TasteMasking&Pelletization*

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of following revised facilities & additional API's in the name of M/s Saakh Pharma (Pvt) Ltd, Plot No. C-7/1, North Western Industrial Zone, Port Qasim Authority Karachi under DML No.000588 (Semi-Basic Manufacture) on the recommendations of the panel of experts

Section / facility (04):

S. No.	*Name of Section*
1.	*Penicillin (revised)*
2.	*Cephalosporins*
3.	*General*
4.	*Taste Masking& Palletization*
5.	*Quality Control (Revised)*

1. Aceclofenac Pallets – **In House Specs**
2. Clopidogrel Pallets – **In House Specs –**
3. Cyclobenzaprine HCL Pallets **In House Specs**
4. Domperidone Pallets **In House Specs**
5. Doxycycline Pallets **In House Specs**
6. Ferrous Sulphate Pallets **In House Specs**
7. Fexofenadine HCL Pallets **In House Specs**
8. Folic Acid Pallets **In House Specs**
9. Itopride Pallets **In House Specs**

10. Ketoprofen Pallets **In House Specs**
11. Memantine Pallets **In House Specs**
12. Naproxen Pallets **In House Specs**
13. Nitroglycerine Pallets **In House Specs**
14. Rabeprazole Sodium Pallets **In House Specs**
15. Tizanidine Pallets **In House Specs**
16. Venlafaxine HCL Pallets **In House Specs**
17. Secnidazole Taste Masked Granules **In House Specs**
18. Additional Process flow for manufacturing of Cefixime Trihydrate
19. Cephalexin USP.

M/s Saakh Pharma (Pvt) Ltd, Karachi submitted request for grant of Pallets by the title mentioned in column1 of the following table and after evaluation the panel of experts was constituted for inspection of the firm . However, in the said panel letter and then in the agenda and subsequently in the minutes the title/names of the said API's (Pallets) were inadvertently mentioned below :

S.No.	***Applied Product Name (APIs)***	***Written on letter 30th November, 2021***
1	*Doxycycline Hyclate Pellets*	*"Hyclate" missing*
2	*Itropride HCI Pellets*	*"HCI" missing*
3	*Tizanidine HCI Pellets*	*"HCI missing*
4	*Venlafaxine HCI Pellets*	*Spelling "e" instead of "a" i.e Venlafaxine HCI*

Proceedings and Decision by the Central Licensing Board in 285thmeeting:

The Board considering the facts on the record and approved correction in the name/title of API's of M/s Saakh Pharma (Pvt) Ltd, Karachi under Drug Manufacturing License No. 000588 (By of Semi Basic) as under;

S.No.	***Correct Product Name (APIs)***
1	*Doxycycline Hyclate Pellets*
2	*Itropride HCI Pellets*
3	*Tizanidine HCI Pellets*
4	*Venlafaxine HCI Pellets*

Case No- 24 **CHANGE OF LICENSED SECTION TITLE /NAME BYM/S VEGA PHARMAEUTICALS (PVT) LTD , 30-KM, MULTAN ROAD, LAHORE UNDER DML NO. 000542 BY WAY OF FORMULATION.**

M/s Vega Pharmaceuticals (Pvt) Ltd, 30-km, , Multan Road, Lahore under DML No. 000542 by way of Formulation has submitted request for change of licensed section title as under :

Sr.No.	Existing Section Title	New Section Title
01.	Eye Drops (General)	Eye/Ear Drops & Nasal Spray (General)
02.	Eye Drops (Steriod)	Eye/Ear Drops & Nasal Spray (Steroid)
03.	Ointment/Cream/Gel (General)	Ointment/Cream/Gel (General)
04.	Ointment/Cream/Gel (Steriod)	Ophthalmic Ointment/Cream/Gel (Steroid)

Proceedings and Decision by the Central Licensing Board in 285th meeting:

The Board considering the facts on the record and approved correction name of existing sections with correct name of M/s Vega Pharmaceuticals (Pvt) Ltd, 30-km, , Multan Road, Lahore under DML No. 000542 by way of Formulation asunder;

Sr.No.	Existing Section Title	New Section Title
01.	Eye Drops (General)	Eye/Ear Drops & Nasal Spray (General)
02.	Eye Drops (Steriod)	Eye/Ear Drops & Nasal Spray (Steroid)
03.	Ointment/Cream/Gel (General)	Ointment/Cream/Gel (General)
04.	Ointment/Cream/Gel (Steriod)	Ophthalmic Ointment/Cream/Gel (Steroid)

Case No-25 **CORRECTION IN CHANGE OF MANAGEMENT OF M/S CITI PARMA (PVT) LTD, DISTRICT KASUR.**

M/s Citi Parma (Pvt) Ltd. 3.5 km, Head Balloki Road, Bhai Pheru Distt. Kasur under DML No. 000512 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management as per Form-29	Retiring Management	Proposed Management
1. Mr. Muhammad Naeem S/o Shar Muhammad CNIC No. 35202-2835907-9. 2. Mr. Naveed Amjad S/o Shar Muhammad CNIC No.	1. Mr. Muhammad Naeem S/o Shar Muhammad CNIC No. 35202-2835907-9.	2. Mr. Naveed Amjad S/o Shar Muhammad CNIC No. 352025-060989-7. 3. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-

35202-2835402-7. 3. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5.		6462958-5.

Decision by the Central Licensing Board in 261st meeting:

The Board considered and endorsed the change of management from old to new management of M/s Citi Parma (Pvt) Ltd. 3.5 km, Head Balloki Road, Bhai Pheru Distt. Kasur, under DML No. 000512by way of formulation as per Form-29 as under;

Previous Management as per Form-29	**Retiring Management**	**Proposed Management**
1. Mr. Muhammad Naeem S/o Shar Muhammad CNIC No. 35202-2835907-9. 2. Mr. Naveed Amjad S/o Shar Muhammad CNIC No. 35202-2835402-7. 3. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5.	1. Mr. Muhammad Naeem S/o Shar Muhammad CNIC No. 35202-2835907-9.	1. Mr. Naveed Amjad S/o Shar Muhammad CNIC No. 352025-060989-7. 2. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5.

It is submitted that name of Mr. Naveed Amjad was inadvertently typed instead of Mr. Nadeem Amjad.

Proceedings and Decision by the Central Licensing Board in 285th meeting:

The Board considering the facts on the record and approved correction in the name of management of the firm M/s Citi Parma (Pvt) Ltd. 3.5 km, Head Balloki Road, Bhai Pheru Distt. Kasur, under DML No. 000512by way of formulation. The name of Mr Mr. Naveed Amjad S/o Shar Muhammad CNIC No. 352025-060989-7 may be read as Mr. Nadeem Amjad S/o Shar Muhammad CNIC No. 352025-060989-7.

Case No-26 **CORRECTION IN NAME OF LICENSED SECTION OF M/S PULSE PHARMACEUTICALS (PVT) LTD, MOZAY BADOKE, RAIWIND ROAD (SUA AASIL ROAD), LAHORE DML NO.000564 (FORMULATION)**

M/s Pulse Pharmaceuticals (Pvt) Ltd, MozayBadoke, Raiwind Road (SuaAasil Road), Lahore No.000564 (Formulation), has requested for correction in the name of Liquid Ampoule (Genral)-Revised section.

It is submitted for information that renewal of M/s Pulse Pharmaceuticals (Pvt) Ltd, MozayBadoke, Raiwind Road (SuaAasil Road), Lahore,DML No.000564 (Formulation) 31-12-2019 ending on 30-12-2024. was presented and approved in 283rd meeting of CLB held on 28h-Oct, 2021 for following sections, accordingly;

1. Tablet (General) Section.
2. Tablet (Quinolone) Section.
3. Oral Dry Powder Suspension (Cephalosporin).
4. Tablet (Psychotropic) Section.
5. Capsule (Cephalosporin) Section.
6. Capsule (General) Section.
7. Dry Powder Injection (Cephalosporin) Section.
8. Liquid Injection Ampoule.
9. Injectable Ampoule (General) Section **(Revised).**
10. Warehouse (Revised).

It is further submitted that;

i. CLB granted Liquid Infusion section (General) to the firm in its 227th meeting held on 1st-2nd June, 20011.
ii. As per request of the firm the, said section i.e., Liquid Infusion section (General) was withdrawn in 266th meeting held on 24th October, 2018.
iii. LOP for Liquid Ampoule (General) was approved by LOP committee.
iv. However, panel for inspection was constituted with Liquid Ampoule (General)-Revised section. Reference para 15/N, the said panel also submitted its recommendation with Liquid Ampoule (General)-Revised. Same was reflected in agenda and minutes of 283rd meeting of CLB held on 28th October, 2021

In light of above, it is proposed that name of section may be corrected as Liquid Ampoule-II (General) - Additional instead of Liquid Ampoule (General)-Revised.

Proceedings and Decision by the Central Licensing Board in 285th meeting:

The Board considering the facts on the record and approved correction in the name of section M/s Pulse Pharmaceuticals (Pvt) Ltd, MozayBadoke, Raiwind Road (SuaAasil Road), Lahore No.000564 (Formulation) as Liquid Ampoule-II (General) - Additional instead of Liquid Ampoule (General)-Revised.

Case No-.27 VOLUNTARY SURRENDER OF LICENSED SECTION OF M/S. HYGEIA PHARMACEUTICALS, PLOT NO.295, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD

The firm, M/s. Hygeia Pharmaceuticals, Plot No.295, Industrial Triangle, Kahuta Road, Islamabad submitted request for surrender of their licensed section;

i. Injectable-(Steroidal/Hormone).

It is submitted for information that the said section was granted by CLB in its 227th meeting held on 1st& 2nd June, 2011.

Proceedings and Decision by the Central Licensing Board in 285th meeting:

The Board considering the facts on the record and after threadbare deliberation acceded the request of the firm. The Board also decided to inform Drug Registration Board, DRAP for necessary action at their end.

Case No.28 **WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTIONS BY M/S PHARMEVO (PVT) LTD , PLOT NO. A-29, NWIZ, PORT QASIM KARACHI UNDER DML NO. 000504 BY WAY OF FORMULATION.**

M/s Pharm Evo (Pvt) Ltd, A-29, North Western Industrial Zone Port Qasim, Karachi under DML No. 000504 by way of Formulation has submitted request for withdrawal of following licensed section namely:

i. Ointment/cream (General).

Proceedings and Decision by the Central Licensing Board in 285th meeting:

The Board considering the facts on the record and after threadbare deliberation acceded the request of the firm. The Board also decided to inform Drug Registration Board, DRAP for necessary action at their end.

Case No- 29. **GRANT OF DRUG MANUFACTURING LICENSE OF M/S GLIMS PHARMACEUTICAL (PVT) LTD., RISALPUR**

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

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

a. The firm M/s Glims Pharmaceutical (Pvt) Ltd., applied for site verification for establishment of Pharmaceutical Unit situated at Plot No 12 Industrial Estate, Resalpur. Management of the firm was as under; (Page 5/Corr)
    i. Mr. Arbab Muhammad Iqbal
    ii. Syed Farrukh Mahmood Gilani
    iii. Haji Shib Gul
    iv. Mr Mushtaq Ahmed
    v. Haji Noor Gul

b. The said site (Page 32/Corr F/A) and LOP for said Unit at said plot was approved, accordingly (Pages 49-50/Corr & 55-56/Corr F/Bi F/Bii).

c. The firm applied for the grant of DML as per Form-1 (Pages 63-115/Corr) and panel of experts/inspectors was constituted for the said purpose (para 45/N refers).
d. The constituted panel conducted the inspection of said firm and a panel inspection report was submitted vide para 47/N and the case was placed in 225th meeting of CLB held on 22-10-2010**.** The case presented in 225th meeting **"Grant of Drug Manufacturing License of M/s Glims Pharmaceuticals - Not Recommended** is reproduced as under;

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

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

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

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

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

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

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

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

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

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

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

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

Decision of Honorable Drug Court, Peshawar passed on 09/10/2018 is reproduce as under (For detail pages 210-216/Corr refer);

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

In light of above, the firm was asked to submit application from grant of DML on prescribed Form-1A duly signed and stamped by the management of the firm along with requisite documents/annexures dully attested/notarized and prescribed fee Rs 1,50,000/=

Decision of the Central Licensing Board in 285th meeting

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

Case No.30 **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.

Case No-31 **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 PharmaceuticalsPlot 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.

Case No-32 **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.

Case No-33 **RENEWAL OF DRUG MANUFACTURING LICENCE 000511 BY WAY OF FORMULATION) OF M/S CSH PHARMACEUTICALS-NORTH (PVT) LTD., 38-A, INDUSTRIAL ESTATE, HAYATABAD PESHAWAR.**

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

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 31st October, 2018. under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

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

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

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

All documents should be duly attested/notarized.

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

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

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000511 by way of formulation of M/s CSH Pharmaceuticals-North (Pvt) Ltd., 38-A, Industrial Estate, Hayatabad Peshawar, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-34 **RENEWAL OF DRUG MANUFACTURING LICENCE 000371 BY WAY OF FORMULATION) OF M/S YOUSAF ALI SHAH CHEMICAL INDUSTRIES (PVT) LTD., PLOT NO.191/1, STREET L-10, GADOON AMAZAI, SWABI.**

M/s Yousaf Ali Shah Chemical Industries (Pvt) Ltd., Plot No.191/1, Street L-10, GadoonAmazai, Swabi, applied for renewal of DML No. 000371 by way of formulation for the period of 31-03-2021 30-030-2026.

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 24th June, 2021under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form-1A is not signed and stamped by management.
ii. Detail of management at the time of previous renewal and current renewal is not provided.
iii. Proof of section(s) approval from Central Licensing Board is required.
iv. Names of registered drugs are not provided.
v. Approved master layout plan is not provided.

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 14th October, 2021 to the firm with following shortcomings: -

i. Section approval letter from Central Licensing Board (not provided).
ii. Notarized copy of partnership deed (not provided).

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

i. Section approval letter from Central Licensing Board (not provided).

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000371 by way of formulation of M/s Yousaf Ali Shah Chemical Industries (Pvt) Ltd., Plot No.191/1, Street L-10, GadoonAmazai, Swabi, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-35 **RENEWAL OF DRUG MANUFACTURING LICENCE 000369 BY WAY OF FORMULATION) OF M/S LIBRA (PVT) LTD., 77- INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR**.

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

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

i. Form-IA as per prescribed format duly signed and stamped by CEO/Owner of the firm.
ii. Section approval letter/proof of approval of sections from Central Licensing Board.
iii. Detail of management at the time of previous renewal and current renewal.
iv. Updated Form-29 certified as true copy by S.E.C.P.
v. CNIC copies of all Directors/Partners.
vi. Up-to-date Nothing Due Certificate (CRF) valid upto 31-12-2020 from STO, DRAP, Islamabad

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

Renewal of DML

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

Regularization of Layout plan.

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

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

Case No-36 **RENEWAL OF DRUG MANUFACTURING LICENCE 000605 BY WAY OF FORMULATION) OF M/S SPL PHARMACEUTICALS (PVT) LTD., PLOT NO.04, PHASE-III, HATTAR INDUSTRIAL ESTATE, HATTAR.**

M/s SPL Pharmaceuticals (Pvt) Ltd., Plot No.04, Phase-III, Hattar Industrial Estate, Hattar, applied for renewal of DML No. 000605 by way of formulation for the period of 17-09-2020 to 16-09-2025.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 14th January, 2022under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

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

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 15th February, 2022 to the firm with following shortcomings: -

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

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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000605 by way of formulation of M/s SPL Pharmaceuticals (Pvt) Ltd., Plot No.04, Phase-III, Hattar Industrial Estate, Hattar,, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-37 **RENEWAL OF DRUG MANUFACTURING LICENCE 000456 BY WAY OF FORMULATION) OF M/S CROWN PHARMACEUTICALS, PLOT NO. 286, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

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

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

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

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

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

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000456 by way of formulation of M/s Crown Pharmaceuticals, Plot No. 286, Industrial Triangle, Kahuta Road, Islamabad, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-38 **RENEWAL OF DRUG MANUFACTURING LICENCE (000370 BY WAY OF FORMULATION) OF M/S IPP, 34, INDUSTRIAL TRIANGLE, KAHUTA RAOD, ISLAMABAD.**

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

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

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

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

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

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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000370 by way of formulation of M/s IPP, 34, Industrial Triangle, Kahuta Road, Islamabad, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-39 **RENEWAL OF DRUG MANUFACTURING LICENCE 000244 BY WAY OF FORMULATION) OF M/S IPP (PVT) LTD, VALLEY ROAD, GULKADA NO.III, SAIDU SHARIF, SWAT**.

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

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 26th December, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form-1A dully signed and stamped by CEO of the firm.
ii. Classes of drugs.
iii. Dosage form of drugs.
iv. Name of registered drugs.
v. Detail of management at the time of previous renewal and present renewal.
vi. Latest original certified true copy of Form-29 and Form-21 issued by S.E.C.P. alongwith CNIC's copies of all director(s).
vii. Proof of Licensed section (s) from Central Licensing Board.
viii. Detail of the section wise equipments and machinery for manufacture.
ix. Up-to-date nothing due certificate (CRF) from STO, DRAP, Islamabad.

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

i. Form-1A dully signed and stamped by CEO of the firm.
ii. List of classes of drugs.
iii. List of dosage form of drugs.
iv. List of registered drugs.
v. Detail of management at the time of previous renewal and present renewal.
vi. Latest original certified true copy of Form-29 and Form-21 issued by S.E.C.P. alongwith CNIC's copies of all director(s).
vii. Proof of Licensed section (s) from Central Licensing Board.
viii. Detail of the section wise equipment and machinery for manufacture.

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

i. Detail of management at the time of previous renewal and current renewal is required along with legal documents are not provided,
ii. Latest original certified true copy of Form-29 and Form-21 issued by S.E.C.P. alongwith CNIC's copies of all director(s).

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000244 by way of formulation of M/s IPP (Pvt) Ltd, Valley Road, GulkadaNo.III, Saidu Sharif, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-41 **RENEWAL OF DRUG MANUFACTURING LICENCE NO.000440 BY WAY OF FORMULATION) OF M/S ONYX PHARMACEUTICALS, 30-A, SMALL INDUSTRIAL ESTATE, MANSEHRA.**

M/s Onyx Pharmaceuticals, 30-A, Small Industrial Estate, Mansehra, applied for renewal of DML No. 000440 by way of formulation for the period of 15-06-2021 to 14-06-20226.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 3rd August, 2021under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form-1A is not provided,

ii. Detail of current management and management at the time of previous renewal on letter head is required,
iii. Updated Form-29 issued and Certified "True Copy" by SECP (in original) along with CNIC copies of all director are required,
iv. Proof of section approval from Central Licensing Board is not provided,
v. Class(es) of Drugs, Dosage form(s) of drugs and Name of drug (s) registered / approved are not provided.
vi. Updated nothing due certificate (CRF) up to 31-12-2020 from STO, DRAP is not provided,

The firm submitted their reply in response to above shortcoming letter. After evaluation of the submitted documents, a final reminder was issued on 10th February, 2022 to the firm with following shortcomings: -

i. Submit application for change of management as per SOP along with prescribed fee as change in previous management is observed in the application for renewal of DML.
ii. Proof of section(s) approval from Central Licensing Board is not provided.
iii. Updated nothing due certificate (CRF) up to 31-12-2020 from STO, DRAP.

However, as of today, the firm did not rectify above mentioned shortcomings.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000440 by way of formulation of M/s Onyx Pharmaceuticals, 30-A, Small Industrial Estate, Mansehra, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-.42. **NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S PHARMEDIC PHARMACEUTICAL INDUSTIES, LAHORE (DML NO.000853).**

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

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

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

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

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

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

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

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

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

The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000853(by way of formulation) of M/s Pharmedic Pharmaceuticals Industries (Pvt) Ltd., 17KM, Multan Road, Lahore under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

The firm fulfilled coda formality *i.e.,* submitted updated CRF. However, inadvertently, in light of decision of CLB in its 282nd meeting, revocation of suspension order was not issued.

The case was placed before CLB in its 284th meeting held on 16-12-2021 and Board decided to cease the Showcause Notice issued to the firm. However, revocation of suspension order/decision was not reflected in the agenda and subsequently in the minute of 284th meeting.

In light decision of CLB in its 282ndmeeting revocation of suspension order was issued14/01/2022.

In light of above, the case is submitted for ratification of the decision of Secretary Central Licensing Board revocation of suspension of Drug Manufacturing Licence.

Decision of the Central Licensing Board in 285th meeting

The Board considered the facts on the record and ratified the decision of Secretary CLB for revocation of suspension of Drug Manufacturing Licence.

Case no. 43 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000116(FORMULATION) OF M/S ZUMARS PHARMA FTY (PVT) LTD, 02-MALIR INDUSTRIAL AREA, KARACHI**

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

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

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

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

v. Updated NOC of CRF issued from statistical officer DRAP.

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

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

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

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

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

i. Updated (Original) Certified True Copy of Form-29 & Form-A issued from SECP.
ii. Updated NDC of CRF issued from statistical officer, DRAP
iii. Details of all licensed sections as per dosage form on firm's letter head.
iv. Relevant experience certificates of Proposed QC Incharge Mr. Liaqat Mugheri.
v. Resignation of previous QC In charge.
vi. Prescribed fee for change of Production In charge Mr. Altaf Hussain.
vii. Attested documents of proposed Production In charge including notarized
viii. Undertaking signed by the appointee and the management of the firm.

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

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

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

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

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

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

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

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

The suspension orders dated 27th September 2021 were issued.
Later on, the firm has submitted the required documents for completion of application for renewal of DML No. 000116 (Formulation) [Original Form-29 & Form-A , QC In charge approved , layout plan is regularized] and the application is now complete as per Form-1A.

Accordingly, orders of revocation of suspension/resumption of production dated 16th March 2022 are issued .

Decision of the Central Licensing Board in 285th meeting

The Board considered the facts on the record and ratified the decision of Secretary CLB for revocation of suspension/resumption of production.

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

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

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

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

For Renewal of DML.

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

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

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

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 000228 by way of formulation of M/s Pharmedic

Laboratories (Pvt) Ltd, 16-KM, Multan Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-45 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000520 OF M/S QINTAR PHARMACEUTICALS (PVT) LTD, 14-A, PUNJAB SMALL INDUSTRIAL ESTATE, LAHORE ROAD, SARGODHA.**

M/s Qintar Pharmaceuticals (Pvt) Ltd, 14-A, Punjab Small Industrial Estate, Lahore Road, Sargodha had applied for renewal of DML No. 000520 by way of formulation for the period of 19-06-2018 to 19-06-2023. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 10th July, 2018 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Proof of all approved section issued by CLB.
ii. Duly attested CNIC copies of partners.

The firm submitted their reply on 10th August, 2018. After evaluation of the submitted documents, final reminder was issued on 5th September, 2018 to the firm with following shortcomings:-

i. Approval letters of sections issued by the Central Licensing Board and if not available then submit master layout plan for regularization of manufacturing facility.

The application of Renewal of Drug Manufacturing License is still deficient for following documents: -

i. Approval letters of sections issued by the Central Licensing Board and if not available then submit master layout plan for regularization of manufacturing facility.

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 000520 by way of formulation of M/s Qintar Pharmaceuticals (Pvt) Ltd, 14-A, Punjab Small Industrial Estate, Lahore Road, Sargodha may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-46 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000459 OF M/S P.D.H PHARMACEUTICALS (PVT) LTD, 19-KM, FEROZEPUR ROAD, LAHORE.**

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

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

All documents should be duly attested.

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

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

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

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

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

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

For Quality Control Incharge.

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

Decision of the Central Licensing Board in 285th meeting

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

Case No-47 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000712 OF M/S SUNRISE PHARMA (PVT) LTD, LAHORE.**

Case Background:

M/s Sunrise Pharma (Pvt) Ltd, 594-A, Sunder Industrial Estate, Raiwind Road, Lahore had applied for renewal of DML No. 000712 by way of formulation for the period of 20-06-2021 to 19-06-2026. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 22nd October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

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

For QC Incharge.

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

All documents should be duly attested.

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

For Renewal of DML.

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

For QC Incharge.

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

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

1.

For Renewal of DML.

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

For QC Incharge.

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

Decision of the Central Licensing Board in 285th meeting

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

Case No-48. **APPROVAL OF TECHNICAL PERSON I.E., PRODUCTION INCHARGE OF M/S PHARMACARE LABORATORIES (PVT) LTD, 129/1, INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000225 (BY WAY FORMULATION)**

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

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

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

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

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, 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000225 by way of formulation of M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore, may not be suspended or cancelled by Central Licensing Board.

Case No-49 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000259 OF M/S SIZA INTERNATIONAL (PVT) LTD, 18-KM, MAIN FEROZEPUR ROAD, LAHORE.**

M/s Siza International (Pvt) Ltd, 18-KM, Main Ferozepur Road, Lahore had applied for renewal of DML No. 000259 by way of formulation for the period of 26-10-2019 to 25-10-2024. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13th October, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form 1A alongwith enclosure / annexure / flags.
ii. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
iii. Attested CNIC's copies of all Directors.
iv. Latest Certified true copy of Form-29 (Attestation by SECP).

v. Detail of premises including layout plan.
vi. Proof of licensed sections from CLB.
vii. Approval letter of Production / QC Incharge in case of change than submit required documents as per check list.
viii. Up-to-date nothing due certificate regarding CRF from STO.
All documents should be duly attested.

The firm did not submit their reply in response to this Division's letter dated 23th October, 2021. The application is found still deficient and Final reminder was issued to the firm on 4th February, 2022 with following shortcomings:-

i. Form 1A alongwith enclosure / annexure / flags.
ii. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
iii. Attested CNIC's copies of all Directors.
iv. Latest Certified true copy of Form-29 (Attestation by SECP).
v. Detail of premises including layout plan.
vi. Proof of licensed sections from CLB.
vii. Approval letter of Production / QC Incharge in case of change than submit required documents as per check list.
viii. Up-to-date nothing due certificate regarding CRF from STO.
All documents should be duly attested.

Firm did not submit their reply till to date and application of Renewal of Drug Manufacturing License is still deficient.

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 16and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000259 by way of formulation of M/s Siza International (Pvt) Ltd, 18-KM, Main Ferozepur Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-50 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HUMAYUN INTERNATIONAL PHARMA (PVT) LTD, FAISALABAD.**

M/s Humayun International Pharma (Pvt) Ltd, 20-KM, Satiana Road, Faisalabad had applied for renewal of DML No. 000443 by way of Formulation for the period of 26-11-2019 to 25-11-2024.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 19-02-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Classes of drugs.
iii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).
v. Duly attested CNIC copies of all Directors.
vi. Approval letters of Production Incharge & Quality Control Incharge, if not approved, submit application to this office for approval.
vii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.
viii. Nothing due certificate regarding CRF from STO (Updated).

The firm did not reply to this letter and reminder letter was issued on 21-09-2020 to the firm for completion of application:

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Classes of drugs.
iii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).
v. Duly attested CNIC copies of all Directors.
vi. Approval letters of Production Incharge & Quality Control Incharge, if not approved, submit application to this office for approval.
vii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.
viii. Nothing due certificate regarding CRF from STO (Updated).

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

Moreover, FID, DRAP has intimated that firm has informed about closing of their factory due to financial crisis.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000443 by way of formulation of M/s Humayun International Pharma (Pvt) Ltd, 20-KM, Satiana Road, Faisalabad may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-51 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S A.Z PHARMACEUTICALS CO. LTD, DISTRICT KASUR.**

M/s A.Z Pharmaceuticals Co. Ltd, 4-Km, Manga Road, Raiwind, District Kasur had applied for renewal of DML No. 000338 by way of Formulation for the period of 18-07-2019 to 17-07-2024.

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 22nd August, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Proper filled, signed & stamped For1A (as per format)
ii. Names, classes & dosage form of drugs.
iii. Section wise detail of Production and Quality control machinery.
iv. Name & qualification of staff working in Production and Quality control departments.
v. Detail of management, if any change, apply for change of management.
vi. Latest certified true copy of Form-29 (Attestation by SECP).
vii. Approval letters of Production Incharge and Quality Control Incharge, if not available, apply for approval.
viii. Duly attested CNIC copies of all Directors.

The firm replied to this letter on 4th September, 2019 but application was incomplete with following shortcomings and reminder letter was issued on 21st October, 2019 to the firm for completion of application:

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

The firm submitted documents on 04thNovember, 2019 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest Certified true copy of Form-29 without the stamp/phrase that SECP does not take any responsibility of correctness of contents of Form.

In the meanwhile, the firm has intimated that according to Companies Act, 2017 SECP do not issue true copies to the companies which are having Court cases, they only issue the Forms bearing stamps that the company is under litigation.
It is pertinent to mention here that as per available record of Licensing Division, Mr. Iftikhar Ahmad had filed the application for renewal of DML as Managing Director on June 2014.Then Mr. Iftikhar Ahmad filed new application for renewal of DML as CEO on 16-07-2019. Then the firm submitted copy of court case and In Suit of 2013, case was filed by AZ pharmaceutical through its CEO, Mrs. Musarrat Maqsood but Mr. Iftikhar Ahmad submitted undertaking on stamp paper as CEO that the firm will submit certified true copy of Form-29 once issued from SECP after closure of court cases. Then opinion was sought from Division of Legal Affairs of DRAP which is as under:

"It is submitted that as per available record in file, the application for renewal of DML was filed by Mr. Iftikhar Ahmad as Managing Director in 2014. Then Mr. Iftikhar Ahmad filed new application for renewal of DML as CEO on 16-07-2019. The firm was asked to submit latest certified true copy of Form-29 attested by SECP but the firm replied that according to Companies Act, 2017 SECP do not issue true copies to the firm which is under litigation. The firm also submitted details and copies of its court cases. In the light of above facts and record available in this regard, this Division is of opinion that the renewal application of the firm may not be processed till submission of certified copies of the Form-29 by SECP so that the status of management of the firm is clear."

Now, Dr. Syed Zia Husnain, FID, DRAP, Lahore has informed that he intended to visit M/s A. Z Pharmaceuticals Co. Ltd on 17-11-2021 for routine GMP verification. Persons present at the gate were reluctant to get inspected, they informed that firm is closed. After about 25 minutes, main gate was opened, however, it was informed that keys were not available to open the production and QC areas, only water treatment was shown which was not well maintained. Subsequently, firm vide letter dated 22-11-2021 received on 29-11-2021 informed that due to COVId-19 pandemic, their production operations are temporarily halted. Firm also informed that litigation is going on between Directors of the firm which also made them to cease the Production. He has requested to constitute a panel for inspection of the firm to safe guard the public health as there is potential of misuse.

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 000338 by way of formulation of M/s A.Z Pharmaceuticals Co. Ltd, 4-Km, Manga Road, Raiwind, District Kasur may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-52 **RENEWAL OF DRUG MANUFACTURING LICENCE OF LAHORE CHEMICAL & PHARMACEUTICALS WORKS (PVT) LTD, LAHORE.**

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

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

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

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

i. Prescribed fee of Rs.75,000/- as there is change in management of the firm.
ii. Latest certified true copy of Form-A or Form-29 duly attested by SECP (Original) without stamp that "SECP does not take responsibility of content of Form".

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

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000064 by way of formulation of M/s Lahore Chemical & Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulana Jalal-Ud-Din Roomi, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-53 **RENEWAL OF DRUG MANUFACTURING LICENCE OF CHERISHED PHARMACEUTICALS, LAHORE.**

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

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

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

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

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

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

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000596 by way of formulation of M/s Cherished Pharmaceuticals, 10-Km, Sunder Raiwind Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-54 **RENEWAL OF DRUG MANUFACTURING LICENCE OF MOON PHARMACEUTICALS, RAWAT.**

M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, RCCI, Rawat had applied for renewal of DML No. 000833 by way of Formulation for the period of 23-08-2021 to 22-08-2026.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 10-09-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed & stamped Form-1A (as per format),
ii. Updated Nothing Due Certificate (CRF) from STO, DRAP.
iii. Detail of management, if any change, apply for change of management.
iv. Duly attested partnership deed & CNIC copies of all partners.
v. Approval letters of Production Incharge & Quality Control Incharge, if not approved, submit application along with prescribed fee.
vi. Approval letter of sections approved by CLB.

The firm replied to this letter on 18-10-2021 and reminder letter was issued on 23-11-2021 to the firm for completion of application:

i. Prescribed fee of Rs.75,000/- for change of management.
ii. Duly attested revised partnership deed & CNIC copies of all partners & Form-D.
iii. Complete set of duly attested documents (as per checklist) along with prescribed fee of Rs.7500/- of proposed Quality Control Incharge.
iv. Duly attested CNIC and undertaking on stamp paper of proposed Production Incharge.
v. Duly attested resignation of earlier Production Incharge.

The firm replied on 13-12-2021 and requested for some extra time for submission of deficient documents.Application for renewal of DML is still incomplete.

Decision of the Central Licensing Board in 285th meeting

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

1976 as to why Drug Manufacturing License No 000833 by way of formulation of M/s Moon Pharmaceuticals, Plot No. 5, Street No. SS-4, National Industrial Zone, RCCI, Rawat, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-55 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDISAVE PHARMACEUTICALS, LAHORE.**

M/s Medisave Pharmaceuticals. Plot No. 578,579 Sunder Industrial Estate, Lahore had applied for renewal of DML No. 000681 by way of Formulation for the period of 26-01-2020 to 25-01-2025 on 17-01-2019.

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

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Duly attested CNIC Copies of all partners.
iii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm replied to this letter on 03rd March, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 27th April, 2020 to the firm for completion of application:

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

The firm submitted documents on 04th June, 2020 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

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

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

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medisave Pharmaceuticals. Plot No. 578,579 Sunder Industrial Estate, Lahore Drug Manufacturing License No. 000681 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

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

The show Cause Notice dated 25th September, 2020 was issued to M/s Medisave Pharmaceuticals. Plot No. 578,579 Sunder Industrial Estate, Lahore.

The firm has not replied to show Cause Notice and application for renewal of DML is incomplete.

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

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

Mr. Imtiaz Ahmed, Chief Executive of the firm appeared before the Board and contended that he has submitted lay out plan for regularization a day before personal hearing. Therefore, all codal formalities has been complied. Hence, Show cause notice may be withdrawn. The Board after hearing the representative of the firm decided to defer the case till next meeting of the Board.

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

Layout plan of the firm was regularized and application for renewal of DML is now complete.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice.

Case No-56 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000493 OF M/S NAWABSONS LABORATORIES (PVT) LTD, JIA BAGGA OFF RAIWIND ROAD, LAHORE.**

M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore. DML No. 000493(Formulation) **Period**: Commencing on27-02-2017ending on26-02-2022	**12-06-2019**	**Satisfactory / Average** (w.r.t. Liquid repacking and external preparation sections) **Un-satisfactory (**w.r.t all other sections**)**	1. Dr. Ikram-ul-Haq, Member CLB. 2. Mr. Jamil Anwar, Secretary PQCB, Punjab, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 4. Dr. Akbar Ali, Assistant Director, DRAP, Lahore.
Case Background: - Panel Inspection report dated 26-11-2018 was received from DRAP, Lahore for renewal of Drug			

Manufacturing License with following recommendations of the panel.

Recommendations of the panel: -
The Panel of inspectors **does Not Recommend** the renewal of DML bearing No. 000493 issued in favour of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore.

Decision by the Central Licensing Board in 267th meeting
The Board considered the case and decided to issue showcause notice under section 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause notice dated 29th January, 2019 was issued to M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore.

The firm has replied to show cause notice and the firm has requested to provide sufficient time to explain their position in writing.

A letter of Personal hearing has been issued on 19-02-2019

Decision by the Central Licensing Board in 269th meeting
Mr. ArjumandBhutta, Director of the company appeared before the Board and contended that almost most of the shortcomings have been rectified as advised during the panel inspection and report received with Showcause Notice. He further contended that period of one month is required to rectify rest of the shortcomings as reported in the report. The Board after hearing the representative of the firm decided to give one-month period to the firm. The company shall submit request for re-inspection of the unit once rectification are made and accordingly a panel would be constituted to conduct inspection for consideration of the Board. Meanwhile License of the company shall remain suspended.

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

The Licensing Division issued Drug Manufacturing License suspension letter dated 13-03-2019. The firm submitted compliance report and request for re-inspection. Following panel of experts were constituted dated 06-05-2019.

1. Dr. Ikram-ul-Haq, Member CLB.
2. Mr. Jamil Anwar, Secretary PQCB, Punjab, Lahore.
3. Area Federal Inspector of Drugs, DRAP, Lahore.
4. Area Assistant Director, DRAP, Lahore.

Inspection report has been received from DRAP, Lahore with following recommendations of the panel.

Recommendations of the panel: -

The Panel of Inspectors **Recommends** the renewal of DML bearing No. 000493 issued in favour of

M/s Nawabsons Laboratories (Pvt) Ltd in respect of Liquid repacking and external preparation sections only. The Panel of Inspectors **does not recommend** the renewal in respect of all other sections. The Panel further recommends suspension of production in all the section which are not recommended for renewal till the rectification of shortcoming and GMP compliance.

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

In the meanwhile, the firm has informed that they improved of working of HVAC system as per instruction by Panel of inspectors which conducted firms inspection on 12-06-2019. The firm has requested for re-inspection.

Decision by the Central Licensing Board in 271st meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000493 (Formulation) in the name of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore on the recommendations of the panel of experts for the further period of five years commencing on 27-02-2017 and ending on 26-02-2022for following sections:

Sections

1. Liquid Repacking
2. External Preparation Sections

Moreover, the Board did not approve rest of sections on the recommendation of the panel of experts.

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

The Licensing Division issued Drug Manufacturing License to the firm for Liquid Repacking and External Preparation Sections 04-10-2019. The firm requested for re-inspection. Following panel of experts were constituted dated 07-11-2019.

1. Dr. Ikram-ul-Haq, Member CLB.
2. Secretary PQCB, Punjab, Lahore.
3. Area Federal Inspector of Drugs, DRAP, Lahore.
4. Area Assistant Director, DRAP, Lahore.

Ms. Majida Mujahid was nominated in place of Dr. Ikram-ul-Haq, Member CLB as he has gone aboard due to his personal commitments vide letter dated 20-12-2019.

Inspection report has been received from DRAP, Lahore with following recommendations of the panel.

> "The panel of Inspectors **Recommends** the renewal of Drug manufacturing License bearing No.000493 issued in favor of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga off Rawind Road, Lahore in respect of Oral Liquid section and Tablet (General) section only, The panel of inspectors **Does not Recommend** the renewal in respect of all the sections situated at first floor i,e Tablet (Antibiotic),Capsule, cream/ointment and oral dry powder suspension sections, which are not recommended for renewal till the rectification of shortcomings and GMP compliance".

Decision by the Central Licensing Board in 273rd meeting

1. The Board considered and approved the renewal of Drug Manufacturing Licence No. 000493 (Formulation) in the name of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore on the recommendations of the panel of experts for the further following

sections:

i. Oral liquid Section (General)

ii. Tablet section (General)

2. The Board did not approve the renewal of Sections namely Tablet (Antibiotic), Capsule, cream/ointment and oral dry powder suspension sections, on the recommendation of panel of Experts / Inspector till the rectification of shortcomings and GMP compliance the production shall remain suspended till rectification made and verified by the panel constituted by the Board.
3. The Board also decided to advise the firm for regularization of layout plan for better GMP compliance.

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

Licensing Division issued letter in compliance to decision of CLB on 17th February, 2020.

Inspection report for grant of renewal of DML for remaining sections is as under:

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
2.	M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga Off Raiwind Road, Lahore. DML No.000493 (Formulation). Period: Commencing on 27-02-2017 ending on 26-02-2022.	**09-12-2021**	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Government of Punjab, Lahore. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
	"The panel of inspector **recommends** the renewal of DML bearing No. 000493 issued in favour of M/s Nawabsons Laboratories (Pvt) Ltd, in respect of Oral Dry Powder Section, Capsule Section, Sachet Section and Cream / Ointment Section. The panel of inspectors **Does Not Recommend** the grant of new section i.e Liquid Injectable Section.			

Decision of the Central Licensing Board in 285th meeting

The case is placed befor the Board for information as tenure i.e., Commencing on 27-02-2017 ending on 26-02-2022. Is already expired

Case No-57 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000156 OF M/S OVAL PHARMACEUTICALS, 112/11, QUAID-E-AZAM INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE.**

Case Background:

M/s Oval Pharmaceuticals, 112/11, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore had applied for renewal of DML No. 000156 by way of formulation for the period of 21-07-2019 to 20-07-2024. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 2nd October, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP, Islamabad.
iii. Detail of management at the time of previous renewal, and at present, if any change, apply for change of management.
iv. Duly attested copy of partnership deed and CNIC copies of all partners.

The firm did not submit their reply in response to this Division's letter dated 2nd October, 2019 and Final reminder was issued to the firm on 9th November, 2021 with following shortcomings: -

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP, Islamabad.
iii. Detail of management at the time of previous renewal, and at present, if any change, apply for change of management.
iv. Duly attested copy of partnership deed and CNIC copies of all partners.

The firm has submitted their reply on 15th January, 2022 in response to this Division's Final Reminder. However, application of Renewal of Drug Manufacturing License is still deficient of following documents:

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP, Islamabad.
iii. Prescribed fee of Rs.75,00/- for change in management of firm.
iv. Duly attested CNIC copies of all partners.
v. Duly attested Form D from Registrar of firms.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000156 by way of formulation of M/s Oval

Pharmaceuticals, 112/11, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-58 **GRANT OF REPACKING DRUGS TO M/S OVAL PHARMACEUTICALS, 112/11, QUAID-E-AZAM INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE.**

M/s Oval Pharmaceuticals, 112/11, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore had applied for grant of re-packing of following drugs under Drug Manufacturing License No. 000156 by way of Formulation: -

1. Glycerin.
2. Magnesium Sulphate.
3. Calcium Gluconate.
4. Boric Acid.
5. Calcium Lactate.
6. Castor Oil.
7. Sodium Salicylate.
8. Salicylic Acid.
9. Potassium Bromide.
10. Sodium Bicarbonate.
11. Kaolin Powder.
12. Soft Yellow Paraffin.
13. Liquid Paraffin.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to defer the case for inspection of the premises.

Case No-59 **GRANT OF REPACKING DRUGS TO M/S BRITISH PHARMACEUTICALS, 23-KM, SHEIKHUPURA ROAD, LAHORE.**

M/s British Pharmaceuticals, 23-Km Sheikhupura Road, Lahore had applied for grant of re-packing of following drugs under Drug Manufacturing License No. 000729 by way of Formulation: -

1. Calamine Powder.
2. Kaolin Powder.
3. Magnesium Sulphate Powder.
4. Sodium Bicarbonate Powder.

5. Sulphur Sublime Powder.
6. Zinc Oxide Powder.
7. Boric Acid Powder.
8. Castor Oil.
9. Glycerin.
10. Ichthammol **Glycerin.**
11. Liquid Paraffin Heavy.
12. Gentian Violet.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation, approved grant of re-packing of following drugs under Drug Manufacturing License No. 000729 by way of Formulation;

1. Calamine Powder.
2. Kaolin Powder.
3. Magnesium Sulphate Powder.
4. Sodium Bicarbonate Powder.
5. Sulphur Sublime Powder.
6. Zinc Oxide Powder.
7. Boric Acid Powder.
8. Castor Oil.
9. Glycerin.
10. Ichthammol **Glycerin.**
11. Liquid Paraffin Heavy.
12. Gentian Violet.

Case No-60 **SITE VERIFICATION OF M/S ORGANO CHEMTECH, SHEIKHUPURA.**

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

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

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

Location map of the proposed site is attached, taken from the

google maps at the time of visit, showing geographical coordinates (31.631213, 74.227502) for reference.

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

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

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

Decision of the Central Licensing Board in 285th meeting

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

Case No-61. **APPROVAL OF TECHNICAL STAFF PRODUCTION AND QUALITY CONTROL INCHARGE OF M/S ORTA LABORATORIES (PVT) LTD, 24-KM, MULTAN ROAD, OFF DEFENCE ROAD, MOHALANWAL, NEAR BAHRIA TOWN BRIDGE, LAHORE.**

The firm, M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohalanwal, Near Bahria Town Bridge, Lahore has submitted application for approval of proposed Production and Quality Control Incharge. The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found some deficiencies and shortcomings has conveyed to firm. Firm has submitted their reply, after evaluation of the submitted documents, final reminder was issued on 10th February, 2021 to the firm with following shortcomings: -

For Production Incharge (Mr. Atta Ur Rehman).

1. Job acceptance letter by appointee.
2. Resignation letter of appointee from previous firm and also mention name of firm.

For Quality Control Incharge (Mr. Muhammad Ziaqat).

1. Resignation letter of earlier QC Incharge.

2. Resignation letter of appointee from previous firm.

All documents should be duly attested.

Meanwhile the firm has submitted application for approval of another QC Incharge Omer Mahmood instead of Mr. Muhammad Ziaqat. Upon evaluation of application for approval of proposed QC Incharge per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

For QC Incharge (Omer Mahmood).

i. Readable copy of CNIC.
ii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 not less than six years.
iii. Undertaking of whole-time employee on stamp paper signed by both Management & QC Incharge (Notarized).

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

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

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000075 (by way of formulation) of M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohalanwal, Near Bahria Town Bridge, Lahoremay not be suspended or cancelled by 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 28th September, 2021.

The firm replied to Show Cause Notice and filed new application for approval of Ms. Bushra Karamat as Production Incharge but application is still short of following documents:

For Production Incharge (Ms. Bushra Karamat):

i. Valid registration certificate from Pharmacy Council.
ii. Undertaking as Whole-time employee.
iii. Resignation of earlier Production Incharge.
iv. Copy of CNIC

Documents should be duly attested.

For QC Incharge (Omer Mahmood):

i. Readable copy of CNIC.
ii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 not less than six years.

Documents should be duly attested.

A letter of personal hearing was issued to the firm on 28th October, 2021.

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

Mr. Omer Mehmood, Quality Control Manager, Mr. Muneeb Nawaz and Mr. Maqsood Ahmad, HOD Accounts of the firm appeared before the board. The documents presented before the Board were not readable which were communicated to the persons appeared on behalf of the firm. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000075by way of Formulation M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohalanwal, Near Bahria Town Bridge, 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 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

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

Letter for Suspension of DML was issued to the firm on 19th November, 2021.

The firm replied and submitted all deficient documents in the application. Accordingly, Secretary CLB issued letter for ceasing of Suspension orders on 30th November, 2021.

Decision of the Central Licensing Board in 285th meeting

The Board considered the facts on the record and ratified the decision of Secretary CLB for revocation of Suspension orders.

Case No-62. **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDI-VET (PVT) LTD, LAHORE.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Letter for Suspension of DML was issued to the firm on 22nd October, 2021.

The firm replied and submitted all deficient documents in the application. Accordingly, Secretary CLB issued letter for ceasing of Suspension orders on 7th March, 2022.

Decision of the Central Licensing Board in 285th meeting

The Board considered the facts on the record and ratified the decision of Secretary CLB for revocation of Suspension orders

Case No-63 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDELLA PHARMACEUTICALS (PVT) LTD, LAHORE.**

M/s Medella Pharmaceuticals (Pvt) Ltd, Plot No. 569/570, Sunder Industrial Estate, Raiwind Road, Lahore had applied for renewal of DML No. 000749 by way of formulation for the period of 31-08-2017 to 30-08-2022 on 25-08-2017.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13thDecember, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Complete application on prescribed Form-1A for renewal of DML as per checklist.
2. Documents should be duly attested.

The firm submitted their reply on 10th January, 2018 After evaluation of the submitted documents, final reminder was issued on 22ndFebruary, 2018 to the firm with following shortcomings: -

1. Duly attested signed and stamped Form-1A.
2. Classes of Drugs.
3. Update Form-29 (Attested by S.E.C.P) if change of management, prescribed fee of Rs. 50,000/- for change of management.
4. CNIC Copies of all Directors.
5. Prescribed fee of Rs. 10,000/- for change of Production Incharge and Quality Control Incharge.
6. Registration Certificate from pharmacy council of Production Incharge.
7. Resignation letter of earlier Production Incharge and Quality Control Incharge.
8. Resignation letter of proposed Production Incharge from previous firm.
9. Undertaking as whole-time employee on stamp paper of Production Incharge and Quality Control
10. Copy of CNIC of Production Incharge and Quality Control Incharge.
11. All documents should be duly attested.

The firm submitted documents on 15th May, 2018 in reply to Final Reminder. Upon Evaluation following shortcoming has been observed and application for renewal of DML is **still incomplete.**

i. Duly signed & stamped Form-1A.
ii. Classes of Drugs.
iii. Latest certified true copy of Form-29 (Attested by SECP), if any change in management, prescribe fee of Rs.50, 000/- for change of management.
iv. Duly attested CNIC copies of all Directors.
v. Duly attested resignation/retirement of earlier proposed Production Incharge and Quality Control Incharge.

Proceedings and Decision of Central Licensing Board in 263rdmeeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medella Pharmaceuticals (Pvt) Ltd, Plot No. 569/570, Sunder Industrial Estate, Raiwind Road, Lahore under DML No. 000749 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 8thAugust, 2018 was issued to the M/s Medella Pharmaceuticals (Pvt) Ltd, Plot No. 569/570, Sunder Industrial Estate, Raiwind Road, Lahore.

The firm did not reply the show cause notice and the application for renewal of DML is incomplete till date.

A letter of Personal hearing has been issued on 18th October, 2018.

Proceedings and Decision of Central Licensing Board in 266th meeting

No person on the behalf of the firm appeared before the Board, therefore, the Central Licensing Board decided to serve the show cause notices to the firm through Additional Director (E&M) DRAP Lahore.

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

A letter of copy of show cause notice was issued on 12th December, 2018 to Additional Director (E&M) DRAP Lahore to ensure delivery and receiving of letter to the firm and submit compliance.

The firm replied the show cause notice but following documents are still deficient in the application.

1. Prescribe fee of Rs.50, 000/- for change of management.
2. Latest certified true copy of Form-29 (Attested by SECP).
3. Duly attested resignation/retirement of earlier Production Incharge.

A letter of Personal hearing has been issued on 24thDecember, 2018.

Proceedings and Decision of Central Licensing Board in 267thmeeting

Mr. Imran Ahmed Khan appeared before the Board and contended that currently no production activity is carried out at premises. During his presence, following shortcomings were still not addressed in completion of application for renewal of DML.

1. Prescribe fee of Rs.50, 000/- for change of management.
2. Duly attested resignation/retirement of earlier Production Incharge.

The Board after hearing the representative of the firm and considering the facts on the record and after thread bare deliberation decided to suspend the Drug Manufacturing Licence No. 000749by way of formulation issued in the name of M/s Medella Pharmaceuticals (Pvt) Ltd, Plot No. 569/570, Sunder Industrial Estate, Raiwind Road, Lahore till settlement of codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 , Rule 19, Rule, 5(6) and Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. If the firm completes the codal formalities, the Chairman Central Licensing Board shall pass an order for revocation of suspension. However, case would be brought before Central Licensing Board in forthcoming meeting for endorsement of decision taken by the Chairman.

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

Letter for Suspension of DML was issued to the firm on 25th January, 2019.

The firm replied on 13-12-2021 and submitted all deficient documents in the application. Accordingly, Secretary CLB issued letter for ceasing of Suspension orders on 31st December, 2021.

Decision of the Central Licensing Board in 285th meeting

The Board considered the facts on the record and ratified the decision of Secretary CLB for revocation of Suspension orders

Case No-64 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDICEENA PHARMA (PVT) LTD, LAHORE.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Letter dated 8th October, 2021 was issued to SECP for seeking clarification.

Reply of Deputy Registrar, SECP, Companies Registration Office, Lahore is as under:

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

Decision of the Central Licensing Board in 285th meeting

The Board deliberated the case and decided to afford final opportunity for personal hearing to the firm in the next meeting of the Central Licensing Board before taking decision.

Case No-65 **APPROVAL OF PRODUCTION INCHARGE OF M/S IQRA PHARMACEUTICALS, RAWAT.**

M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, RCCI Industrial Estate, Rawat filed application of Mr. Arif Ullah Khan for approval as Production Incharge on 01-10-2020.

The application was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13-10-2020 under Rule 16 of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Deposit Prescribed fee of Rs. 5000/- and original fee challan must be retained by STO, DRAP.
ii. CNIC copy of appointee.
iii. Registration certificate from Pharmacy Council.
iv. Resignation/ retirement of earlier Production Incharge.
v. Documents should be duly attested.

The firm did not reply to this letter and filed new application of Mr. Jamshaid Ali as Production Incharge on 05-07-2021. Application was evaluated and following deficient documents in the application were conveyed to the firm via reminder dated 10-08-2021:

i. Duly attested resignation of earlier Production Incharge and proposed Production Incharge from previous firm.

Reply to reminder was received on 01-09-2021 but application was still incomplete with following documents being deficient:

i. Duly attested resignation of earlier Production Incharge and proposed Production Incharge from previous firm.

Final Reminder dated 28-09-2021 was issued to the firm for completion of application. However, the firm has not replied and application is incomplete with following documents being deficient:

i. Duly attested resignation of earlier Production Incharge and proposed Production Incharge from previous firm.

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

The Show Cause Notice was issued to M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, RCCI Industrial Estate, Rawat on 22nd November, 2021.

The firm replied to Show Cause Notice and submitted all deficient documents. Now, application for approval of Production Incharge is complete.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice

Case No-66 **APPROVAL OF QUALITY CONTROL INCHARGE OF M/S BIO MARK PHARMACEUTICALS, LAHORE.**

M/s Bio Mark Pharmaceuticals, Plot No. 527, Sunder IndustrialEstate, Lahore filed application for approval of Quality Control Incharge on 17-05-2021.

The application was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 11-06-2021 under Rule 16 of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Duly attested appointment letter, job acceptance letter & resignation of proposed Q.C Incharge from previous firm.
ii. Duly attested resignation of earlier Q.C Incharge.
iii. Duly notarized undertaking as whole-time employee on stamp paper duly signed by appointee & management.

The firm did not reply to this letter and filed new application of Ms. Rehana Kausar on 07-07-2021. Application was evaluated and following deficient documents in the application were conveyed to the firm via reminder dated 10-08-2021:

i. Complete set of duly attested documents (as per checklist, except undertaking) of proposed Q.C Incharge.

Reply to reminder was received on 13-09-2021 but application is still incomplete with following documents being deficient:

i. Appointment letter.
ii. Job acceptance letter.
iii. Resignation of earlier Q.C Incharge.

Documents should be duly attested.

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

The Show Cause Notice was issued to M/s Bio Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore on 22nd November, 2021.

The firm replied to Show Cause Notice and submitted all deficient documents. Now, application for approval of Quality Control Incharge is complete.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice

Case. No- 67. **CHANGE OF LICENSED SECTION TITLE /NAME BYM/S FORTUNE PHARMAEUTICALS , PLOT NO. K/201, SITE, SUPER HIGHWAY KARACHI UNDER DML NO. 000924 BY WAY OF FORMULATION.**

M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E Super Highway Karachi under DML No. 000924 by way of Formulation has submitted request for change of licensed section title as under :

Existing Section Title	New Section Title
Liquid Injection vial (General)	Liquid Injection vial SVP (General)

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation approved change in name of section of M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E Super Highway Karachi under DML No. 000924 by way of Formulation as under :

Existing Section Title	New Section Title
Liquid Injection vial (General)	Liquid Injection vial SVP (General)

Case No.67 **RENEWAL OF DRUG MANUFACTURING LICENCE No. 000074 (FORMULATION) BY M/S KARACHI PHARMACEUTICAL LABORATORTIES, PLOT NO. S/54, HAWKES BAY ROAD, KARACHI.**

M/s Karachi Pharmaceutical Laboratories, Plot No. S/54, Hawkes Bay Road, Karachi, has applied for renewal of DML No. 000074 by way of formulation for the period of 30-09-2020 to 29-09-2025 on 30th July 2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 27th January, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Detail of all sections of firm on firm's letter head along with approval letters of all sections issued from CLB of if not available then submit layout plan for regularization.
(ii) Undertaking on stamp paper regarding sole proprietor ship along with attested CNIC copy of Sole Proprietor.
(iii) Updated NDC of CRF.
(iv) Complete set of attested documents (as per checklist) for approval of QC In charge.

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

(i) Submit layout plan for regularization of manufacturing facility along with Prescribed fee as the firm does not possess the approval letters of licensed sections issued from the CLB.
(ii) Complete set of attested documents (as per checklist) for approval of QC In charge who fulfills the requirement of Rule 16 (e) of the Drugs (L,R&A) Rules, 1976 as the proposed QC In charge Ms. Seema Ashqeen possess the degree in B.SC Chemistry and does not fulfil the requirement of Rule 16 (e) of the Drugs (L,R&A) Rules, 1976 in terms of required qualification.
(iii) Updated NDC of CRF.

The firm has submitted their reply which is evaluated and application for renewal of DML is still found deficient of following shortcomings / deficiencies: -

i. Updated NDC of CRF issued from the statistical officer, DRAP, Islamabad.
ii. Complete set of attested documents **(as per checklist)** for approval of Mrs. Amna Mehboob as Proposed Production in charge along with prescribed fee.
iii. Proof of sections/approval letters of all sections issued by the Central Licensing Board or if not available then submit layout plan for regularization of manufacturing facility.
iv. Prescribed fee for change of QC In charge for approval of new proposed QC In charge Mr. Hasan Adil.

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

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000074 (by way of formulation) M/s Karachi Pharmaceutical Laboratories, Plot No. S/54, Hawkes Bay Road, Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In compliance to the decision of the CLB, show cause notice dated 30th September 2021 was issued. The reply/documents of the firm are submitted by the firm in response to the show cause notice which are evaluated and the application for renewal of DML No. 000074 (Formulation) is still found deficient of following documents:

i. Updated NDC of CRF issued from the statistical officer, DRAP, Islamabad.
ii. Complete set of attested documents **(as per checklist)** for approval of Mrs. Amna Mehboob as Proposed Production in charge along with prescribed fee.
iii. Prescribed fee for change of QC In charge for approval of new proposed QC In charge Mr. Hasan Adil.

The firm is also called for Personal Hearing vide letter dated 22nd October 2021.

Managing Director of the Company forwarded prescription of the Doctor regarding his ailing condition and chest X- ray . The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

In the meanwhile the firm submitted the required documents and got approval of Production In charge and QC In charge and also submitted updated NDC of CRF and the application for renewal of DML is now complete.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice

Case No-68 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000053 (FORMULATION) OF M/s RISMA LABORAOTIRES KARACHI.**

M/s Risma Laboratories , Plot No. A-2B, S.I.T.E has applied for renewal of DML No. 000053 by way of formulation for the period commencing on 01-06-2020 to 31-05-2025.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 6th October 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Dully attested annexure/enclosures of Form-1A .

(ii) Additional Prescribed fee of Rs. 15,000 for late submission (03 days) of application for renewal of DML.

(iii) Updated NDC of CRF from STO DRAP.

No reply was received from the firm and a Reminder dated 10th February 2021 was issued to the firm to submit documents mentioned above for completion of the application for renewal of DML.

No reply of the Final Reminder is received as of today.

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 000053 by way of formulation of M/s Risma Laboratories , Plot No. A-2B, S.I.T.E, Karachi, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-69. **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000245 (FORMULATION) OF M/S ELKO ORGANIZATION (PVT) LTD, PLOT No. 27 & 28, SECTOR 12/B, NORTH KARACHI INDUSTRIAL AREA, KARACHI**

M/s Elko Organization (Pvt) Ltd, Plot No. 27 & 28, Sector 12/B, North Karachi Industrial Area, Karachi has filled/submitted application for renewal of DML No. 000245 (Formulation) for the period commencing on 27-04-2020 and ending on 26-04-2025.. The application for the renewal of DML of the firm was evaluated and a letter dated 08th August 2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Application on Prescribed From-1A along with duly attested enclosures.
ii. Original certified true copy of Form-29 & From-A for year 2020 issued from SECP along with attested CNIC copies of all directors.
iii. Detail/names of all licensed sections on firm's letter head along with approval letters of all sections issued from CLB. Or if not available then submit layout plan for regularization of manufacturing facility.
iv. Name and approval letter of QC In charge or if not available then submit complete set of attested documents (as per checklist) for approval.
v. Prescribed fee for change of management (as the management is changed from the last renewal of DML).

In reply firm submitted the shortcoming documents which were evaluated and following documents were still found deficient for which a Reminder dated 19thNovember 2020 was issued to the firm :

i. Application on Prescribed From-1A.
ii. Original & Updated certified true copy of Form-29 & From-A for year 2020 issued from SECP along with attested CNIC copies of all directors.
iii. Status of sections whether they are ready for inspection in the light of approved layout plan for regularization dated 06th September 2010.
iv. Name and approval letter of QC In charge or if not available then submit complete set of attested documents (as per checklist) for approval.
v. Prescribed fee for change of management (as the management is changed from the last renewal of DML).

The firm submitted reply/shortcoming documents which are evaluated and the application for renewal of DML is still deficient of following documents :

i. Prescribed fee for change of management (as the management is changed from the last renewal of DML).
ii. Complete set of attested documents (as per checklist) for approval of QC In charge Mr. AyyazBaig.
iii. Submit revised layout plan for regularization of existing manufacturing facility after rectification of observations already communicated and for which reply is awaited.

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

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000245 (by way of formulation) of M/s Elko Organization (Pvt) Ltd, Plot No. 27 & 28, Sector 12/B, North Karachi Industrial Area, Karachi, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In compliance show cause notice dated 28th September 2021 was issued to the firm.

Later on , the firm submitted documents (layout for regularization of existing manufacturing facility , documents along with Prescribed fee for change of management and documents for approval of QC In charge) and the application for renewal of DML No. 000245(Formulation) is now complete.

Decision of the Central Licensing Board in 285th meeting

The Board considered the facts on the record and ratified the decision of Secretary CLB for revocation of Show Cause Notice.

Case No.70 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000033(FORMULATION) OF M/s DELUX CHEMICAL INDUSTRIES KARACHI.**

M/s Delux Chemical Industries Karachi, Plot No. LT-26/A-1, Landhi Industrial Area, Karachi, has applied for renewal of DML No. 000033 by way of formulation for the period of 09-01-2021 to 08-01-2026.

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 29th January, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Detail/Names of all licensed sections on firm's letter head along with approval letters of all sections issued from the CLB or if not available then submit layout plan for regularization of manufacturing facility.
(ii) Undertaking on stamp paper regarding sole proprietorship along with attested CNIC copy of Sole Proprietor Mr. Nazeef Ch.
(iii) Approval letter of Production in charge Mr. Amir or if not available then submit complete set of attested documents (as per checklist) for approval of production in charge.
(iv) Updated NDC of CRF.

Later on firm submitted reply / documents which were evaluated and a reminder letter was issued on 13th April 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

(i) Detail/Names of all licensed sections on firm's letter head along with approval letters of all sections issued from the CLB or if not available then submit layout plan for regularization of manufacturing facility.
(ii) Duly signed Undertaking on stamp of sole proprietorship by Sole Proprietor Mr. Nazeef Ch.
(iii) Clarification regarding name of Production in charge whether (mentioned as production in charge on Form-1A) or Mr. Aftab (which is approved Production in charge) on DML No.00033(Formulation) is currently working as production in charge
(iv) Updated NDC of CRF.

The firm has submitted their reply along with layout plan for regularization which is evaluated and application for renewal of DML is still found deficient of following document:

i. The firm does not possess approval letter of licensed sections and has submitted layout plan for regularization without Prescribed fee and in the layout plan neither the sections are demarcated / specified nor the man & material flow is mentioned with separate colored arrows.

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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000033 by way of formulation of M/s Delux Chemical Industries Karachi, Plot No. LT-26/A-1, Landhi Industrial Area, Karachi may not be suspended or cancelled by the Central Licensing Board.

The show cause notice dated 30th November 2021 was issued to the firm.

In response the firm submitted the layout plan for regularization of existing manufacturing facility which after subsequent discussion in LOP committee was approved vide letter dated 3rd February 2022 and the application for renewal of DML No. 000033 (Formulation) is now complete.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice

Case No-71. **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000554(FORMULATION) OF M/s FARMACEUTICS INTERNATIONAL KARACHI.**

M/s Farmaceutics International, F-1 A-3, S.I.T.E. Karachi, has applied for renewal of DML No. 000554 by way of formulation for the period of 03-11-2019 to 02-11-2024.

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

(i) Application on Prescribed Form-1A.
(ii) Fee Challan of Additional surcharge fee of Rs. 40,000 for late submission of application for renewal of DML.
(iii) Attested CNIC copy of Sole Proprietor along with Undertaking on stamp paper regarding sole proprietorship.
(iv) Updated NDC of CRF issued by the STO, DRAP, Islamabad.
(v) Complete set of attested documents (as per checklist) for approval of proposed Production in charge Ms. Shehla Khanum.
(vi) Attested CNIC copy of Proposed QC In charge Ms. Rakhshanda Parveen.
(vii) Resignation of earlier appointed QC In charge.

Later on firm submitted reply / documents which were evaluated and a reminder letter was issued on 13th April 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

(i) Updated NDC of CRF issued by the STO, DRAP, Islamabad.
(ii) Prescribed fee of Rs. 7500 for approval of Production in charge.
(iii) Dully notarized Undertaking on stamp paper regarding Sole Proprietorship.
(iv) Dully notarized Undertaking on stamp paper regarding whole time employment of Production in charge & QC In charge.

The firm has submitted their reply is evaluated and application for renewal of DML is still found deficient of following document:

(i) Dully notarized Undertaking on stamp paper regarding Sole Proprietorship.
(ii) Dully notarized Undertaking on stamp paper regarding whole time employment of Production in charge & QC In charge signed by both technical staff and the management of the firm respectively.

Decision of the Central Licensing Board in 285th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000554 by way of formulation of M/s Farmaceutics International, F-1 A-3, S.I.T.E. Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No-72 **CHANGE OF MANAGEMENT OF M/S AHSONS DRUG COMPANY SINDH**

M/s. Ahsons Drug Company, T/1, SITE, Tando Adam Sindh DML No. 000138 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee as under: -

Current Management Form-1A	**New Management as per Form-29 & Form-A of SECP (Year 2021)**
i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1. ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5. iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1. iv. Mr. Abdul Saleem S/o Abdul Hakeem CNIC No. 44206-0143901-1. v. Mst. Shakooran Begum Wd/o Late Abdul Hakeem	i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1. ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5. iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1.

Decision of the Central Licensing Board in 284th meeting:

The Board considered and accepted for record the change of management of M/s **Ahsons Drug Company, T/1, SITE, Tando Adam Sindh** DML No. 000138 (By way of Formulation) as under:-

Current Management Form-1A	**New Management as per Form-29 & Form-A of SECP (Year 2021)**
i. Mr. Abdul Wahab S/o Abdul Hakeem	i. Mr. Abdul Wahab S/o Abdul Hakeem

CNIC No. 44206-4077486-1. ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5. iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1. iv. Mr. Abdul Saleem S/o Abdul Hakeem CNIC No. 44206-0143901-1. v. Mst. Shakooran Begum Wd/o Late Abdul Hakeem	CNIC No. 44206-4077486-1. ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5. iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1.

Requests are received from Mr. Abdul Saleem (previous partner of the firm), Ms. Khairunsia and legal heirs of MstZaineb claiming that that their mother was also a share holder of the firm and they have requested to suspend the DML of the firm and **add their names in the license of M/s Ahsons DC, Tando Adam Sindh.**

Meanwhile, a representation from Dr Abdul Saleem Ansari FRCS and others are received which are reproduced as under:

> "The AHSONS DRUG CO was granted the Drug Manufacturing license in 1962. You will be pleased to know that the undersigned is Surgeon (Urologist) by Profession and the lawful Partner of AHSONS DRUG CO plot no T-1 at SITE Area, Tehsil Tando Adam District Sanghar Sindh.
>
> After the death of three basic legal partners, my Mother, Zainab Bibi and Two Brothers, (Abdul Razzaq and Abdul Hameed), I am the only alive basic partner.
>
> Now after the death of my previous partners, their legal heirs entered in the firm. As I a Legal Partner My visits in the firm are essential to check the affairs of the Company relating to Machines, Building and Land, but the legal heirs of my previous partners are not giving me excess to the account books and some time they even stopped me to enter in the factory.
>
> As you know that the valuable rights of the applicant are involved in this firm but the hurdles created by the legal heirs of my previous partners are against the law And natural justice as well.
>
> As per facts mentioned above you are requested to suspend the manufacturing License of firm Ahsons Drug Co, Tehsil Tando Adam District Sanghar, Sindh As soon as possible till the resolution of our disputes.
>
> **Anticipating a quick and positive response from you side.**
>
> Dr Abdul Saleem Ansari FRCS

Partner of Ahsons Drug Co Tehsil Tando Adam

District Sanghar, Sindh

SUB: APPLICATION FOR CANCELLATION OF MANUFACTURING LICENSE OF THE AHSONS DRUG CO TANDO ADAM SINDH.

Respected sir,

The AHSONS DRUG CO was granted the Drug Manufacturing license in 1962. That the undersigned is lawful partner of AHSONS DRUG CO plot no T-1 (1.00 Acre) tehsil Tando Adam District Sanghar which was leased through Sindh Industrial Estate Limited.

After the death of three basic legal partners, (My Mother, Zainab Bibi and Two brothers, Abdul Razzaq and Abdul Hameed), undersigned was the only alive basic partner and then Addenda deed was made by undersigned along with the legal heirs of my previous partners in September 2006.

After that an agreement/settlement deed was made between the partners on 9th September 2015 regarding all affairs and shares of the company. Annex-D.

Now the partners are not complying that agreement and they are not giving me the excess to check the building, equipment and plant which is clear violation of agreement/settlement deed dated 9th September 2015. So the undersigned do not allow to work on this leased plot mentioned above.

As per facts mentioned above the undersigned is not interested to continue the manufacturing process through the Drug Manufacturing license.

You are requested to cancel the manufacturing License of Ahsons Drug Co. Tehsil Tando Adam District Sanghar, Sindh in the interest of Justice.

Anticipating a quick and positive response from your side.

Dr Abdul Saleem Ansari FRCS
Partner of Ahsons Drug Co Tehsil Tando Adam
District Sanghar, Sindh"

"2. Letter is received from Ms. Khairunisa D/o Late Abdul Hameed, CNIC 35201-0214701-6, wherein she has requested that her father Abdul Hameed was the registered executive partner of Ahsons Drug Co, expired in 2005 and I am the legal heir of Abdul Hameed. I therefore requested please add my name in the license of Ahsons Drug Co.

3. Letter is received from Mst. Kulsoom D/o Late Abdul Hakeem, District Sanghar, wherein she has requested to please add a name in the license of Ahsons Drug Company, Tando Adam.

4. Letter is received from **(i)**Mst, Badar Un Nisa D/o Mst Zainab, **(ii)** Ms. Zahida Khatoon D/o Mst Zainab, **(iii)** Ms. Bilquees Khalid D/o Mst Zainab, Dist,

Sanghar, Sindh, wherein they are requested to please add a name in the license No. 000138 of Ahsons Drug Company, Tando Adam."

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 Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000138 by way of formulation of M/s. Ahsons Drug Company, T/1, SITE, Tando Adam Sindh may not be suspended or cancelled by Central Licensing Board.

Case No-73 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 Mumahhad 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.

Case No-74. **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. Usman Enterprise, Plot No, A 116 Site (SHW), Phase-1, Karachi (DML No: 000656)*	*Submitted*	*ELM-0013* *9-12-2019*
2.	*M/s. Silver Surgical Complex (Pvt) Ltd, C-40/41 Scheme 33, S.I.T.E Super Highway, Industrial Area, Karachi (DML No: 000674)*	*Submitted*	*ELM-0007* *18-02-2020*
3.	*M/s. BSN Medical (Pvt) Ltd, A-69, SITE Mangopir Road, Karachi (DML No: 000085)*	*Submitted*	*ELM-0008* *09-10-2019*
4.	*M/s. IDCOT Pharmaceuticals, Plot No. 6/A, Pharmaceutical Zone, M-3 Industrial, City, Faisalabad (DML No: 000852)*	*Submitted*	*ELM-0003* *29-10-2018*
5.	*M/s. Cotton Craft (Pvt) Ltd. Plot No. 407-4-8- Sunder Industrial Estate, Raiwind Road, Lahore (DML No: 000227)*	*Submitted*	*ELM-0015* *21-02-2020*
6.	*M/s Karim Industries, 12 Km Lahore Raiwind Road, Onside Roohi, Nala Near, Petrol Pump Raiwind Distt. Lahore (DML No: 000254)*	*Submitted*	*ELM-0014* *13-02-2020*
7.	*M/s. Vikor Healthcare (Pvt) Ltd. Plot No. C-126 to C-135, LIEDA. Hub District LasbellaBalochistan (DML No: 000834)*	*Submitted*	*ELM-0006* *07-12-2018*
8.	*M/s. Vikor Healthcare (Pvt) Ltd. Plot No. C-126 to C. 135, LIEDA, Hub District Lasbella, Balochistan (DML No: 000835)*	*Submitted*	*ELM-0006* *07-12-2018*

9.	*M/s. Asian Fiber, Plot No. 41 &42, Sector-25, Korangi Industrial Area. Karachi (DML No: 000668)*	*Submitted*	*ELM-0031* *29-10-2020*
10.	*M/s. Rehman Rainbow (Pvt) Ltd., 82, Industrial Estate, KotLakhpat, Lahore (DML No: 000510)*	*Submitted*	*ELM-0045* *15-11-2021*
11.	*M/s. Fintex Cotton Industry, Near DeraSahi Singh, Site-3 KM d G.T Road, Kamonke, Disst. Gujranwala (DML No: 000741)*	*Submitted*	*ELM-0027* *12-10-2020*
12.	*M/s. General Pharma, Farm Road, 3-Km, GT Road, Manhas (KotliWagha) Kamonke, Gujranwala (DML No: 000689)*	*Submitted*	*ELM-0027* *12-10-2020*
13.	*M/s. Renacon Pharma (Pvt) Ltd, 18-Km, Ferozepur Road, Opp, Nishtar Colony Lahore (DML No: 000458)*	*Submitted*	*ELM-0038* *28-06-2021*
14.	***M/s. Frontier Pharmaceutical (Pvt) Ltd., W-10, Industrial Estate, Jamrud Road, Peshawar.(DML No: 000706)***	***Submitted***	***ELM-0024*** ***01-10-2019***
15.	***M/s. Crespak Medical Industries, Lahore, 8th KM Manga Raiwind Road, Lahore (DML No: 000709).***	***Submitted***	***ELM-0004*** ***31-10-2018***

The case was placed before the MDB in its 41st meeting held 23rd November, 2021and decided to refer the above companies/firms to Central Licensing Baord (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.

Oraginal DML of above mentioned firms are enclosed herewith for further necessary action at your end please.

M/s. Frontier Pharmaceutical (Pvt) Ltd., W-10, Industrial Estate, Jamrud Road, Peshawar. (DML No: 000706) and M/s. Crespak Medical Industries, Lahore, 8th KM Manga Raiwind Road, Lahore (DML No: 000709) original DMLs are not received.

Case is submitted for consideration of the board.

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***
1	*M/s. Usman Enterprise, Plot No, A 116 Site (SHW), Phase-1, Karachi (DML No: 000656)*
2	*M/s. Silver Surgical Complex (Pvt) Ltd, C-40/41 Scheme 33, S.I.T.E Super Highway, Industrial Area, Karachi (DML No: 000674)*
3	*M/s. BSN Medical (Pvt) Ltd, A-69, SITE Mangopir Road, Karachi (DML No: 000085)*
4	*M/s. IDCOT Pharmaceuticals, Plot No. 6/A, Pharmaceutical Zone, M-3 Industrial, City, Faisalabad (DML No: 000852)*
5	*M/s. Cotton Craft (Pvt) Ltd. Plot No. 407-4-8- Sunder Industrial Estate, Raiwind Road, Lahore (DML No: 000227)*
6	*M/s Karim Industries, 12 Km Lahore Raiwind Road, Onside Roohi, Nala Near, Petrol Pump Raiwind Distt. Lahore (DML No: 000254)*
7	*M/s. Vikor Healthcare (Pvt) Ltd. Plot No. C-126 to C-135, LIEDA. Hub District LasbellaBalochistan (DML No: 000834)*
8	*M/s. Vikor Healthcare (Pvt) Ltd. Plot No. C-126 to C. 135, LIEDA, Hub District Lasbella, Balochistan (DML No: 000835)*
9	*M/s. Asian Fiber, Plot No. 41 &42, Sector-25, Korangi Industrial Area. Karachi (DML No: 000668)*
10	*M/s. Rehman Rainbow (Pvt) Ltd., 82, Industrial Estate, KotLakhpat, Lahore (DML No: 000510)*
11	*M/s. Fintex Cotton Industry, Near DeraSahi Singh, Site-3 KM d G.T Road, Kamonke, Disst. Gujranwala (DML No: 000741)*
12	*M/s. General Pharma, Farm Road, 3-Km, GT Road, Manhas (KotliWagha) Kamonke, Gujranwala (DML No: 000689)*

13	*M/s. Renacon Pharma (Pvt) Ltd, 18-Km, Ferozepur Road, Opp, Nishtar Colony Lahore (DML No: 000458)*
14	***M/s. Frontier Pharmaceutical (Pvt) Ltd., W-10, Industrial Estate, Jamrud Road, Peshawar.(DML No: 000706)***
15	***M/s. Crespak Medical Industries, Lahore, 8th KM Manga Raiwind Road, Lahore (DML No: 000709).***

Case No-75 **CHANGE OF MANAGEMENT OF M/S GREATER PHARMA, RAWAT.**

The Central Licensing Board in its 279th Meeting held on 18th February, 2021 considered and endorsed the change of management of M/s Greater Pharma, Plot No. 35, Street No. SS-3, National Industrial Zone, RCCI, Rawat under DML No. 000896 by way of Formulation as under:

Previous Management	New Management as per Affidavit
2. Mr. Abdul Wadood Khan S/o Masood Khan CNIC No. 17301-0355625-1.	4. Mr. Muhammad Dawood S/o Haji Momeen CNIC No. 54201-2468331-5.

Accordingly**,** Decision of the Board was conveyed to the firm on 30th March, 2021.

Then, letters/complaints received from **Mr. Abdul Wadood Khan** which are reproduced as under:

"I am a sole owner of the factory "Greater Pharma" situated at Plot No.35, Street SS-3, Industrial Zone, Rawat Islamabad and a license has been issued by your worthy Office (copy Attached). Sir unluckily I was suffering from serious injuries and mental disability and was also in comma for long period due to road accident on 14-08-2020. When I came to normal life, surprisingly it reveals that my factory has been fraudantly transferred to Mr M. Dawood via fake Deed Dated 15-01-2021 by my nearest relative namely Sajid Masood S/o Manzoor and they have illegally occupied my suste factory and it's all machinery and items. Sir Mr. M. Dawood has been manufacturing the medicines/items without having any authority which is highly illegal and it may damage the public at large, thus it required attention of your worthy office. Furthermore, I did not attend any board meeting which is essential for granting permission or authority for manufacturing. It is therefore, requested, that stern action may kindly be taken against Muhammad Dawood or any other person if involved and manufacturing may discontinue in the interest of public at large."

&

"I have an accident on motorway 14th August 2020 along with wife, after accident I was admitted in RMI and North West hospital Hayatabad Peshawar. I was suffering, in comma

disease and mentally abnormal. That time I was treated with Prof Tariq hashim and Khalid mufti. All hospital evidence records with me in hospital.

1. *1 have submitted complaint in DRAP Islamabad two weeks ago. But I am waiting reply from DRAP.*
2. *I have already submitted complaint in Chairman NAB Islamabad for legal action.*
3. *My factory was rented to Mr. Daud through fraud agreement.*
4. *The Meezan Bank Hayatabad Peshawar through evidence Mr. Sajid masood received all payment, ID CARD copy attaches in bank record.*
5. *The DRAP has taken decision without my presence, I have no physical visit to DRAP Islamabad, according to 1976 Rule regulation agreement is against rules, regulation and Director (Licencing) according to DRAP Rule and regulation agreement was not follow through DRAP Rules and regulation."*

Complaint of Mr. Abdul Wadood Khan was forwarded to the firm for their comments. **Reply of the firm** is as under:

"With ref of your letter dated 10/sep/2021, subjected justification and comments on complain of Mr. Abdul wadood. We here by justify the complaint as follows. I Muhammad Dawood CNIC NO 54201-2468331-5 (CEO) Greater pharmaceuticals Pvt Ltd plot 35, Street SS-3 Rawat Industrial zone Islamabd,

COMMENTS OF C.E.O

Abdul Wadood's complain is based on absolutely fake statement, he was in his own senses as per described with evidences as follow, his fake allegations are only based on malicious, he is just miss guiding the DRAP and doing a fraud complain and as well damaging the time and goodwill of DRAP,we have submitted all the required documents in DRAP, after the NOC of Abdul Wadood and many more documents DRAP have issued the change of management letter, on the bases of DRAP's said letter we applied for new sections approval, after the receiving of new approved map from DRAP we started construction, we have invested a huge amount on new sections construction, machinery HVAC system, equipments, market and many more, According to his statement majorly he have dispute with his own family and he is mixing up the dispute with our deal and confusing the DRAP,

FURTHER JUSTIFICATIONS WITH EVIDENCES AND WITNESSES

Mr. Abdul Wadood's accident and discharging date. According to his statement he had accident on 17 Aug 2020 as per his hospital reports, he was hospitalized for 15 days only, from dated 17 Aug 2020 to 2 Sep 2020 and he was discharged on 2 September 2020, he was ok and his own senses.

SALE AND PURCHASE

After 6 months of his accident Mr Abdul Wodood visited the Greater pharma to us, he was absolutely in his senses, then we matured the deal (agreement attached) and Agreement was signed personally by Mr Abdul. Wadood (pictures are attached for evidence) in the presence of following witnesses. Personal appearance of all following witnesses is absolutely possible if DRAP required.

1. Mr. Naeem shah (Ex owner of Goodman Lab rawat)
2. Mr. Masood khan (Father of Abdul Wodood khan)
3. Mr. Waheedullah (Brother of Abdul Wadood)
4. Mr. Sajid masood s/o Manzoor khan
5. Mr. Huzaifawodood (son of Abdul wadood khan)
6. Mr. Masood s/o (M. Dawood)

Payments to Mr. Abdul wadood

We have paid the payment as per attached agreement to Mr. Abdul wadood by cheqs (cheq copies are attached) and Mr. Wodood personally received all the cheq (signed receipts are available) with his named title (Abdul wodood khan) and he collected all the payment from banks. (Bank record is attached).

We are requesting to DRAP kindly do not entertain such kind of nonsense complains which have no legal documents, proofs and any evidences. And this is only based on malicious."

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 give personal hearing both parties in next meeting of the Board.

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

Letter received from Mr. Abdul Wadood Khan which is reproduced as under:

"I HAVE GREATER PHARMA ON MY NAME. THE DRAP ISLAMABAD ISSUED LICENSE ON 05-93-2019. THEREFORE, REQUEST TO DRAP ISLAMABAD TO STOP GREATER PHARMA FACTORY PRODUCTION AND RAW MATERAIL PROCESS THE GREATER PHARMA HAS BEEN MANUFACTURE PRODUCTS SINCE JANUARY 2021. TIE DAWOOD AND HIS SON MASOOD GOT ILLEGALLY PERMISSION FROM DRAP ISLAMABAD. I HAVE DONE ACCIDENT ON MOTERWAY ADMITTED IN NORTH WEST HOSPITAL HAYATABAD NOW I HAVE GOOD HEALTH AND MENTELY GOOD HU CONDITION FROM BRAIN FIT FOR BUSINESS THROUGH DOCTORS CERTIFICATE, THE DAWOOD BELONG TO AFGHANISTAN MADE FAKE PAKISTAN JID FROM PASHEEN QUETTA. (ID Card of Pakistan :) THEREFORE KINDLY TAKE ACTION AGAINT DAWOOD AND HIS WSON MASOOD THROUGH DRAP RULES THROUGH I'IA ISLAMABAD AND STOP BANK ACCOUNT FROM FBR PAKISTAN ISLAMABAD. AFTER THIS LETTER I AM NOT RESPONSIBLE FOR DAWOOD AND MASOOD PRODUCTS IN BUSINESS MARKET."

Request for change of title also received from Mr. Abdul Wadood Khan which is reproduced as under:

Previous Title	New Title
M/s Greater Pharmaceutical, Plot No.35, Street SS-3, National Industrial Zone, Rawat, Islamabad.	**M/s Al Wadood Pharmaceutical,** Plot No.35, Street SS-3, National Industrial Zone, Rawat, Islamabad.

Letters of Personal hearing has been issued on 7th March, 2022 to the firm and Mr. Abdul Wadood Khan.

Proceedings and Decision by the Central Licensing Board in 285th meeting:

Mr. Masood Khan, managing Director appeared on behalf of the firm. He contended that all transactions have carried in the presence of witnesses which includes his brother and son. He

further stated that his written reply may be considered as his statement. He prayed that his representation may be dropped as same are based on malafide.

The complainant Mr. Abdul Wadood Khan did not appear before the Board. The Board considering the facts observed that matter pertains to private transactions between two parties. Therefore, there is nothing to intervene. However, aggrieved party may approach court of competent jurisdiction for redressal of his grievance.

Case No-76 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FARMIGEA PAKISTAN (PVT) LTD, LAHORE.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

i. Latest certified true copy of Form-29 duly attested by SECP (original) without the stamp that SECP does not take responsibility of contents of Form.
ii. Duly attested CNIC copies of all Directors.
iii. Deposit prescribed fee of Rs.7,500/- per section/facility for regularization of layout plan.
iv. Two (02) legible copies of proposed layout plan.

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

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

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

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

Documents should be duly attested.

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

Decision of the Central Licensing Board in 285th meeting

The Board after perusal of record and facts decided to suspend Drug Manufacturing License No 000471 (by way of formulation) of M/s Farmigea Pakistan (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahoretill fulfillment of codal formalities/submission of required documents under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision ofRule, 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.

Case No-77 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, 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) 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.

Case No-78 **GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000065 OF M/S UNEXO LABS PVT) LTD, LAHORE.**

Case Background:

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

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

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

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

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

Submitted for consideration and orders of the Board.

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

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000065 (by way of formulation) of M/s Unexo Labs (Pvt) Ltd, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976..

The show cause notice dated 30th December 2020 was issued to the firm.

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

i. Updated Original Form-29 & Form-A of SECP.
ii. Prescribed fee for change of management.
iii. Attested CNIC copies of all directors.
iv. Detail/names of sections on firm's letter head as per dosage form.

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

Decision of the Central Licensing Board in 285th meeting

Mian Ahmad Riaz GM and Mr. Ramzan Manager of the firm appeared before the board and contended that. The Board after perusal of record and facts decided to suspend Drug Manufacturing License No 000065 (by way of formulation) of M/s Unexo Labs (Pvt) Ltd, 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.

Case No-79**CHANGE OF MANAGEMENT UNDER DRUG MANUFACTURING LICENSE NO. 000529 (FORMULATION) OF M/s TRISON RESEARCH LABORATORIES (PVT) LTD, PLOT NO. 27-A, PUNJAB SMALL INDUSTRIAL ESTATE, SARGODHA**

M/s. Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, Punjab Small Industrial Estate, SargodhaDML No. 000529 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee as under: -

Current/Existing Management	**New Management as per Form-29 & Form-A of SECP Year 2021**
1. Mr.MubasharJaved 2. Mrs. ShaziaMubashar 3. Mr. M. Waqas Butt	1. Mr. MubasharJaved CNIC No. 35201-1514163-3 2. Mr. Irfan Gulzar Anjum S/o CNIC No. 38403-2956767-5.

Decision of the Central Licensing Board in 285th meeting:

The Board considered and accepted for record the change of management of **M/s.** Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, Punjab Small Industrial Estate, SargodhaDML No. 000529 by way of formulation as under: -

Current/Existing Management	**New Management as per Form-29 & Form-A of SECP Year 2021**

1. Mr.MubasharJave d 2. Mrs. ShaziaMubashar 3. Mr. M. Waqas Butt	1. Mr. MubasharJaved CNIC No. 35201-1514163-3 2. Mr. Irfan Gulzar Anjum S/o CNIC No. 38403-2956767-5.

Case No.80 **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 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).	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 (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).	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

Case No- 81 **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 Incharge 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

Case No-82. **APPROVAL OF PRODUCTION INCHARGE& RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000342 (FORMULATION) OF M/s TRIGON PHARMACEUTICALS (PVT) LTD, LAHORE.**

M/s Trigon Pharmaceuticals (Pvt) Ltd , 8-km, Thokar Raiwind Road, Lahore had applied for renewal of DML No. 000342 by way of formulation for the period of commencing on 16-10-2019 & ending on 15-10-2024.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 6th October 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Form-1A along with enclosure/annexure.
(ii) Classes of Drugs attested.
(iii) Dosage Form of Drugs attested.
(iv) Name (s) of drugs registered / approved.

(v) Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
(vi) Attested CNIC's of all directors.
(vii) Latest Certified True copy of From-29 issued by SECP.
(viii) Detail/of premises including layout plan.
(ix) Proof of sections from the CLB.
(x) Section wise detail of machinery for manufacture.
(xi) Section wise detail of machinery for Quality Control Laboratory.
(xii) Approval letters of Production/QC In charge or if not available then submit complete documents as per check list.
(xiii) Updated NDC of CRF from STO DRAP.

No reply was received from the firm and a Reminder dated 8th January 2021 was issued to the firm to submit documents mentioned above for completion of the application for renewal of DML.

No reply is received from the firm and the application for renewal of DML No. 000342 (Formulation) is still incomplete .

The firm also applied for approval of Production In charge Mr. Imran Mehmood which were evaluated and a letter dated 8th May 2020 was issued to the firm to submit following documents :

i. Experience certificates as under the Prescribed Rules.
ii. Resignation of earlier Production In charge.
iii. Resignation letter of appointee from previous firm.
iv. Documents should be dully attested.

The reply/documents submitted by the firm were evaluated and later on a Reminder dated 7th January 2021 was issued to the firm to submit the documents following documents :

i. Experience certificates as under the Prescribed Rules, it should be not less than six years and if not available then submit documents of another person.

In reply, the firm has submitted **un attested** and **incomplete (Undertaking on stamp paper, resignation of previous production in charge & Resignation of appointee from previous firm)** documents for approval of **new Proposed Production in charge Mr. Hafiz Muhammad Naseem** Sarwar and the complete attested documents as per checklist are still to be provided by the firm.

Decision of the 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. 000342 by way of formulation of M/s Trigon

Pharmaceuticals (Pvt) Ltd , 8-km, Thokar Raiwind Road, Lahore 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 10th January 2022 was issued to the firm.

The reply of the firm was received and the documents submitted are evaluated and the applications are still found deficient of following documents :

(i) Application for renewal of DML on Prescribed Form-1A along with dully attested annexure/enclosures.
(ii) Original &Updated legible certified true copy of Form-29 & From-A issued from SECP along with attested CNIC copies of all directors.
(iii) Approval letter of QC In charge Mr. Muhammad Umer or if not available then submit complete set of attested documents (as per checklist) for approval.
(iv) complete set of attested documents (as per checklist) for approval of new proposed Production in charge Mr. Naeem Sarwar along with Prescribed fee.

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

Decision of the Central Licensing Board in 285th meeting

Mr. Muhammad Safdar Chief executive of the firm appeared before the board and contended that they were willing to submit required documents. He further contended that they may be given some time to submit documents. . The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No. 000342 by way of formulation of M/s Trigon Pharmaceuticals (Pvt) Ltd , 8-km, Thokar Raiwind 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) 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

Case No.83 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000277 (FORMULATION) OF M/s KAILGON AGRO INDUSTRIES (PVT) LTD, HITE BALOCHISTAN.**

M/s KailgonAgro Industries (Pvt) Ltd, 849PAthra Road, Hub Chowky Road, Lasbella Baluchistan had applied for renewal of DML No. 000277 by way of formulation for the period of commencing on 13-10-2021 & ending on 12-10-2026.

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 21st April 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(v) Dully retained fee challan by AD (Revenue) DRAP, Islamabad.

(vi) Updated Form-29 and Form-A issued by SECP.

(vii) Attested CNIC copies of all directors.

(viii) Updated NDC of CRF.

Later on firm submitted reply / documents which were evaluated and a reminder letter was issued on 13th April 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

(v) Detail/Names of all licensed sections on firm's letter head along with approval letters of all sections issued from the CLB or if not available then submit layout plan for regularization of manufacturing facility.

(vi) Duly signed Undertaking on stamp of sole proprietorship by Sole Proprietor Mr. Nazeef Ch.

(vii) Complete set of documents of new proposed production In charge Mr. Mushtaq Ahmed Khan.

(viii) Updated NDC of CRF.

(ix) Attested section wise detail of machinery for manufacture.

(x) Attested section wise detail of machinery for QC Laboratory.

(xi) Detail of all licensed sections along with approval letter.

No response was received from the firm and a Reminder dated 25th June 2021 was issued to the firm to provide the said documents.

No response / documents are received from the firm regarding completion of application for renewal of DML .

In the meanwhile a letter is received from the firm , in which the firm has intimated that the firm intends to stop the production operations.

The firm is also called for personal hearing vide letter dated 07th December 2021.

Decision of the Central Licensing Board in 284th meeting

No one appeared before the Board on behalf of the firm and the board decided to give Final Opportunity of Personal Hearing to the firm in next meeting of the Board.

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

Decision of the Central Licensing Board in 285th meeting

No representative if the firm was appeared before the Board . The Board after perusal of record and facts decided to cancel the Drug Manufacturing License No. 000277 by way of formulation of M/s KailgonAgro Industries (Pvt) Ltd, 849 Pathra Road, Hub Chowky Road, Lasbella

Baluchistan under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

QUALITY ASSUARNCE CASES

Item No. I.: M/s Wahabsons Pharma (Pvt.) Ltd. Plot No. 402, 4 KM Bunir Road Barikot, Swat. (DML No. 000533)

Mr. Zia Ullah, FID, Peshawar on 25.10.2018 conducted inspection of the firm M/s. Wahabsons Pharma (Pvt) Ltd, Plot No.402, 4 Km, Bunir Road, Bairkot Swat.

2. The FID noticed number of critical observations.

Action taken by DRAP:

3. The firm M/s. Wahabsons Pharma (Pvt) Ltd, Swat was served Show Cause Notice and suspension of production orders in Dry Powder for Suspension Section (Cephalosporin) on 13.12.2018.

4. The Case was placed before the 267th meeting of CLB. Wherein the Board decided as under: -

Decision of the 267thMeeting of CLB

After thorough discussion / deliberations, the Central Licensing Board decided to suspend the Drug Manufacturing License of the firm M/s. Wahabsons Pharma (Pvt) Ltd, Swat under section 41 of the Drug Act, 1976 read with Rule 12 of the Drugs (LRA) Rules, 1976 till rectification of the observations noted by the FID in its report dated 25.10.2018.

5. The firm vide letter dated 22.10.2020 submitted compliance report and requested for verifications of GMP compliance and rectification status.

Proceedings of 279thMeeting of CLB

6. Division of QA&LT presented the case before the CLB. The Board discussed the CAPA submitted by the firm M/s. Wahabsons Pharma (Pvt) Ltd, Plot No.402, 4 Km, Bunir Road, Bairkot Swat.

Decision of 279thMeeting of CLB

7. After thorough discussion / deliberations, considering all the pros and cons of the case, keeping in view CAPA submitted by the firm, the Central Licensing Board decided to: -

i. Constitute following panel of experts for verification of rectification status of the observations noted by the FID in its report dated 25.10.2018: -

   a) Prof. Dr. Jamshaid Ali Khan, Member, CLB.
   b) The Area FID, DRAP, Peshawar
   c) Mr. Adnan Shahidullah, AD, DRAP, Peshawar

ii. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 25.10.2018, with clear and candid recommendations.

Current status

8. The decision of 279th meeting of CLB was communicated on 21.04.2021. The panel inspection report is still pending and a reminder was also issued on 01.02.2022.

9. The firm M/s Wahabsons Pharma Pvt. Ltd 4KM Buner Road Barikot Swat has informed vide letter No. nil dated 08.02.2022 that following panel has been constituted for their renewal vide Licensing Division's letter No. 3-5/99-Lic (Vol-I) dated 14.12.2021;

i. Director, Drug Testing Laboratory, Peshawar.
ii. Federal Inspector of Drugs, DRAP, Peshawar.
iii. Mr. Adnan Shahidullah, Assistant Director, DRAP, Peshawar.

10. The firm has requested that same panel may be given mandate to verify firm's compliance against observations noted during inspection dated 25.10.2018.

Decision of 285th meeting of the Board:

11. Keeping in view the fact that the inspection report for renewal of the firm has already been received in the Licensing Division, the board decided that the panel constituted in 279th meeting of Central Licensing Board shall proceed as per their mandate.

QUALITY CONTROL CASES

Case No. 01: **GRANT OF PERMISSION OF FIR AGAINST MR. ZEESHAN AND OTHER FOR MANUFACTURE AND SALE OF SUSPECTED FAKE, SPURIOUS AND COUNTERFEIT DRUGS**

Ms. Hira Bhutto, FID-III/AD-XII, DRAP, Karachi received an information from FIA Office, Corporate Crime Circle, Karachi that Muhammad Zeeshan of M/s. Hoorain Impex Lassani Arcade Mezzanine floor, Neckless Street Ramswami, Ranchore line, Karachi is involved in manufacturing of fake/spurious medicines in the name of different Pharmaceutical Industries.

FID-III along with FIA team including Inspector Asfandyar Khan, Sub inspector Muhammad Tahir Gujjar, and Sub Inspector Miss Mehvish Iftikhar raided said premises on 18-01-2022.At the time of visit Muhammad Zeeshan was found available and huge stock of following suspected spurious/ fake/ counterfeit medicine were recovered which were taken in custody by FIA officials.

S.No.	*Name of medicine*
01	*Disprin Tablet*
02	*Aldactone atbelet*
03	*Cefixime Suspension*
4	*Cefim Suspension*
5	*Ventoline expectorant*
6	*Inocef injection*
7	*Cefim DS suspension*
8	*Kinz Injection*
9	*Water for injection*
10	*Norvasc Tablet*

FID submitted that Mr. Muhammad Zeeshan of M/s. Hoorain Impex Lassani Arcade Mezzanine floor, Neck lass Street Ramswami, Ranchore line, Karachi and others found involved in manufacturing in unlicensed premises, labelling & repacking of suspected fake/spurious drug and violated the Section 23 & 27 of Drugs Act, 1976 and rules framed thereunder.

RECOMMENDATION of FID:-

Grant permission to register FIR against following accused:-

	e of Accused	C No.	RESS
	Hoorain Impex		Lassani Arcade Mezzanine floor, Neckeass Street Ramswami, Ranchore line, Karachi.
	mmad Zeeshan S/O Muhammad Haroon Memon	**-7632141-7**	No.601, Madina Corner Nakcless Street, NashtarRoad,Ranchoe line, Karachi.
	mmad Adnan S/o Muhammad Haroon Memon	**-4370766-9**	No. 501, SafaMarwa Tower RanchorlineArba Arcade Karachi.
	dar Abdul Aziz S/o Abdul Aziz		No. 08, Seema Manzil, Meethadar Karachi.
	Ahmed S/o Iftikhar Ahmed	**-5352131-7**	e No. ROW-7, Street 1, C-1 Area LiaquatabadDakhkhana Karachi
	Nadeem Baig S/o Mirza Abdul Salam		House No. B-11/75, Bismillah Hotel Asif Colony, Manghopir Road Karachi

Secretary, Central Licensing Board, DRAP, Islamabad approved the grant of permission of FIR as being authorized by the Central Licensing Board in its 281st Meeting held on 25-08-2021 to grant the permission to lodge FIR. Permission of FIR has been communicated to FID dated 28-01-2022.

Reports have been received from Federal Government Analyst, details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	CDL Remarks
Cefim Suspension	M/s. Hilton Pharma (Pvt.) Ltd., Karachi	029082	141865	01-2022	01-2024	Sub-Standard and Spurious
Cefim DS Suspension	-do-	022108	134774	05-2021	05-2023	Sub-Standard and Spurious
Disprin tablet	M/s. Reckitt Benckiser Pakistan Ltd., Karachi.	000152	2BN1080	Nil	March-2024	Sub-Standard

Permission has been placed before the Central Licensing Board for ratificationof the decision please.

PROCEEDINGS AND DECISION OF THE 285TH MEETING OF THE BOARD.

The case has been discussed and after thorough deliberations; the Board has granted ratification of the decision i.e. grant of permission of FIR.

Case No. 02 **REQUEST FOR LODGING FIR AGAINST THE MANAGEMENT OF M/S EVEREST PHARMACEUTICALS FOR THE ILLEGAL IMPORT OF PHARMACEUTICAL RAW MATERIAL THROUGH FORGED IMPORT CLEARANCE CERTIFICATE WITHOUT ANY DRUG IMPORT LICENSE.**

DRAP team conducted the raid on 06-03-2018 at the premises of M/s Everest Pharmaceuticals 124-industiral Triangle Kahuta Road Islamabad. The firm was found in manufacturing of unregistered spurious and sex inducing drugs on large scale. A large quantity of raw materials which were being used in manufacturing of these drugs was also recovered. Accordingly, the premises was sealed and FIR No. 05/2018 was registered in FIA/ACC Islamabad for contravention of the DRAP Act 2012/Drug Act 1976 and rules made thereunder against the following persons namely:

i. Ch. Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
ii. Dr. Kamran izhar (owner of M/s Everest pharmaceuticals)
iii. Noor Muhammad Mahar (owner of M/s Everest pharmaceuticals)
iv. Mian Ishtiaq Ahmed (QC incharge), M/s Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-08/2018-QC dated 14-03-2018 was written to the Deputy Collector G- II MCC Appraisement (West) Karachi for providing complete import record of pharmaceuticals raw materials imported by the M/s Everest Pharmaceuticals during the last three years along with copies of Assistant Director (I&E) DRAP, stamped invoices submitted by the firm. The Customs Collectorate, amongst other has provided the invoice detailed below purportedly signed and stamped by the assistant Director (I&E), DRAP, Lahore, alongwith goods declaration-GD-I of the pharmaceutical raw material imported by M/s Everest Pharmaceuticals 86-G, Model Town Lahore vide letter SI/Misc/15/2018 Group II dated 22-03-2018

03. The details of consignments is given below:-

SR.NO	NAME OF INDUSTRY/ SUPPLIER	INVOIC E NO.	INVOIC E DATE	RAW MATERIAL	QUANTITY	PERPORTED LY RELEASED BY
1	M/S ARSHINE PHARMACEUTI CAL CO,LIMITED	ZY201509 037	17.09.2015	NAPROXEN SODIUM	500KG	SAIRA NAEEM
2	M/S HAZHOU CITY LINGHU XINWANG CHEMICALS, LTD. CHINA	XW150701	01.07.2015	MAGNESIUM STEARATE	1000KG	SAIRA NAEEM
3	M/S LA PALMA HOLLAND BV, HOLAND	4182-01	31.05.2015	LACTOSE MONOHYDR ATE	2.60KG	SAIRA NAEEM

4	M/S AFINE CHEMICALS LIMITED, CHINA	HF15089	04.05.2015	TRIS (HYDROXYMETHYL) AMINO METHANE	300KG	SAIRA NAEEM
5	M/S MINGTAI CHEMICAL CO, LTD TAIWAN	MT-1505115	07.05.2015	MICROCRYSTALLINE CELLULOSE	2000KG	SAIRA NAEEM
6	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15003	02.04.2015	XANTHAN GUM OHARMA GRADE 200MESH	25KG	SAIRA NAEEM
7	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15 001	02.04.2015	XANTHAN GUM OHARMA GRADE 200MESH	25KG	SAIRA NAEEM
8	M/S NINGBO FREE TRADE ZONE MEDICIN PHARMACEUTICAL CO, LTD.	FS02E0118	04.03.2015	CLOTRIMAZOLE	100KG	SAIRA NAEEM
9	M/S IMPERIAL CHEM, INCORPORATION, INDIA	CJ/E/141	16.12.2014	IRON III HYDROXIDE POLYMALTOSE COMPLEX	500KG	SAIRA NAEEM
10	M/S DEPEW FINE CHEMICAL CO, LTD. CHINA	DE14W004	31.12.2014	CLOTRIMAZOLE	100KG	SAIRA NAEEM
11	M/S ZHEJIANG APELOA KANGYU PHARMACEUTICAL CO,LTD. CHINA	214835	09.03.2016	LEVOFLOXACIN	500KG	SAIRA NAEEM
12	M/S HAZHOU CITY LINGHU XINWANG CHEMICALS, LTD. CHINA	XW160121	21.01.2016	MICROCRYSTALLINE CELLULOSE	3000KG	SAIRA NAEEM
13	M/S 366 PHARMA (NANJING) CO, LTD. CHINA	36616021 7B2	17.02.2016	ASPARTAME	100KG	SAIRA NAEEM

14	M/S HANGZHOU MAYTIME BIO TECH CO,LTD.	CMT160305	10.03.2016	PIROXICAM BCD	500KG	SAIRA NAEEM
15	M/S BAKUL PHARMA PRIVATE LIMITED, INDIA	BPPL/EXP/42/15-16	31.08.2015	DOXOFYLLINE	200KG	SAIRA NAEEM
16	M/S INAVIR PHARMA TECH PVT LTD. INDIA	EXP/PPL/24/15-16	29.06.2015	GABAPANTIN	300KG	SAIRA NAEEM
17	M/S INFOARK CO,LTD. CHINA	2151010290	27.07.2015	GLUCOSAMINE SULFATE	500KG	SAIRA NAEEM
18	M/S SINOCHEM QINGDAO CO,LTD. CHINA	N15AD23387	15.06.2015	PHLOROGLUCINNOL DIHYDRATE TRIMETHY	100KG, 100KG	SAIRA NAEEM
19	M/S INFOARK CO,LTD. CHINA	2151020300	03.08.2015	PIROXICAM BCD	510KG	SAIRA NAEEM
20	M/S NINGBO FREE TRADE ZONE MEDICIN PHARMACEUTICAL CO, LTD. CHINA	FS10E0503	15.06.2015	CLOTRIMAZOLE	100KG	SAIRA NAEEM
21	M/S BAKUL PHARMA PRIVATE LIMITED, INDIA	BPPL/EXP/32/16-17	10.08.2016	DOXOFYLLINE	200KG	SAIRA NAEEM
22	M/S JIANGXI TIANXIN PHARMACEUTICAL CO,LTD. CHINA	16JXTXI-0842	21.06.2016	VITAMIN B6 HCL	100KG	SAIRA NAEEM
23	M/S INFOARK CO,LTD. CHINA	2161010493	20.10.2016	PIROXICAM BCD	1005KG	SAIRA NAEEM
24	M/S ARSHINE PHARMACEUTICAL CO,LIMITED	ZY201605123	14.06.2016	PVP K-30	350KG	SAIRA NAEEM
25	M/S GLUFIC BIOSCIENCES LIMITED, INDIA	GBSL/109/16-17	25.08.2016	LIDOCAINE HCL	100KG	SAIRA NAEEM

26	M/S SHANDONG HEAD CO LTD CHINA	16HD6103	14.06.2016	METHYL CELLULOSE	400KG	SAIRA NAEEM
27	M/S SHANGHAI WELLTONE MATERIAL TECHNOLOGY CO,LTD. CHINA	16WT190613	13.06.2016	CROSPOVID ONE USP26	400KG	SAIRA NAEEM
28	**M/S LOHITHA LIFESCIENCES PVT, LTD. INDIA**	**11**	**24.02.2016**	**DOMPERID ONE BASE, DOMPERID ONE MALEATE**	**200KG, 25KG**	**ATIQ UL BARI**
29	M/S INFOARK CO,LTD. CHINA	2151010442	10.10.2015	CLOTRIMAZOLE	150KG	SAIRA NAEEM
30	M/S ARSHINE PHARMACEUTI CAL CO,LIMITED	ZY201603134	08.04.2016	PVP K-30	300KG	SAIRA NAEEM
31	M/S ZHEJIANG TIANXIN PHARMACEUTI CAL CO, LTD. CHINA	17TXI-996	01.04.2017	NAPROXEN SODIUM	1000KG	SAIRA NAEEM
32	M/S JAINGXI SYNERGY PHARMACEUTI CAL, IMPORT AND EXPORT CO,LTD. CHINA	JXS170827	21.09.2017	ACECLOFEN AC EP4	500KG	SAIRA NAEEM
33	M/S ZHEJIANG JIANFENG INTERNATION AL TRADE CO ,LTD. CHINA	ZC17003	06.02.2017	CLOTRIMAZ OLE	21KG	SAIRA NAEEM
34	M/S METROCHEM API PRIVATE LTD, INDIA	AE293	23.11.2016	ESOMEPRAZ OLE MAGNESIUM TRIHYDRAT E	300KG	SAIRA NAEEM
35	M/S JIANGXI TIANXIN PHARMACEUTI CAL CO,LTD. CHINA	JXS170239	03.03.2017	GABAPANTIN	1000KG	SAIRA NAEEM

36	M/S MALLADI DRUGS & PHARMACEUTICALS LIMITED, INDIA	MS-EXP16516522582	28.02.2017	FEXOFENADINE HCL	500KG	SAIRA NAEEM
37	M/S METROCHEM API PRIVATE	AE303	29.11.2016	PANTOPERAZOLE SODIUM	300KG	SAIRA NAEEM
38	M/S SINOCHEM QINGDAO CO LTD. CHINA	N16AD59521	27.10.2016	PHLOROGLUCINNOL DIHYDRATE	500KG	SAIRA NAEEM
39	M/S METROCHEM API PRIVATE LTD, INDIA	AE073	31.05.2016	OMEPRAZOLE	200KG	SAIRA NAEEM
40	M/S 366 PHARMA (NANJING) CO, LTD. CHINA	36616110 4B1	04.11.2016	ASPARTAME	200KG	SAIRA NAEEM

03. On the scrutiny of the record from DRAP it transpired that above referred import authorizations(other than mentioned on Sr. No. 28) were never issued from DRAP office, Lahore under the Drug (import & Export Rules 1976. The import authorizationsare forged; hence the import of such pharmaceuticals raw materials stands illegal in violation of Drug (import &Export) Rules, 1976 framed under the Drug Act 1976.

05. The permission to lodge FIR against the responsible accused persons was given vide letter No. F.13-8/18-QC dated 17-04-2018 of the DRAP Islamabad by Director QA/LT DRAP, Islamabad against the following persons:

i. M/s Everest Pharmaceuticals 86-G Model Town Lahore through its Managing partner
ii. Ch. Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
iii. Dr. Kamran izhar (owner of M/s Everest pharmaceuticals)
iv. Noor Muhammad Mahar (owner of M/s Everest pharmaceuticals)
v. Mian IshtiaqAhmed(QC incharge), M/s Everest Pharmaceuticals

Proceedings of 262nd meeting of CLB.

06. The case was submitted for consideration of the CLB for ratification/endorsement of the order issued by the Director QA&LT, DRAP Islamabad being authorized by the CLB to grant permission for registration of FIR against the accused persons. Furthermore, it was informed that there are 39 consignments of pharmaceuticals raw materials which were released by the Custom authorities on the submission of forged documents by M/s Everest Pharmaceuticals without obtaining import license under the Drugs (Import & Export) rules 1976. This is also cognizable offence under the Drug Act 1976/DRAP Act 2012.

07. The Board endorsed the permission granted by the Director QA/LT being authorized by the CLB for granting permission registration of FIR against the accused persons.

08. The complete challan for the above-mentioned cases were presented in various meetings of the Board where the Board granted permission to prosecute the accused for the violations of the Drugs Act 1976 and the rules framed thereunder. Details of cases are given as under:

S#	Name of RM	FIR No. and Date	Status
1	Xanthan Gum Pharma Grade 200Mesh	FIR No. C-69/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting.
2	Xanthan Gum Pharma Grade 200Mesh	FIR No. C-70/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting
3	Naproxen Sodium	FIR No. C-71/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
4	Omeprazole	FIR No. C-72/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
5	Gabapentin	FIR No. C-73/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
6	Levofloxacin Hemihydrate	FIR No. C-74/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
7	Fexofenadine HCL	FIR No. C-75/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
8	PVP K-30	FIR No. C-76/2018 Dated 17-05-2018	No Challan received yet
9	Clotrimazole	FIR No. C-77/2018 Dated 17-05-2018	No Challan received yet
10	Gabapentine	FIR No. C-78/2018 Dated 17-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
11	Magnesium Citrate	FIR No. C-79/2018 Dated 17-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
12	Clotrimazole	FIR No. C-81/2018 Dated 17-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting.
13	Clotrimazole	FIR No. C-83/2018 Dated 23-05-2018	No Challan received yet
14	Esomeprazole Magnesium Trihydrate	FIR No. C-84/2018 Dated 23-05-2018	No Challan received yet
15	Microcrystalline Cellulose	FIR No. C-85/2018 Dated 23-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting.
16	Lactose Monohydrate	FIR No. C-86/2018	Incomplete challan was received and case sent to CLB. Prosecution

		Dated 23-05-2018	was granted in 276th meeting.
17	Doxofylline	FIR No. C-87/2018 Dated 24-05-2018	No Challan received yet
18	Glucosomine Sulfate	FIR No. C-88/2018 Dated 24-05-2018	No Challan received yet
19	Piroxicam BCD	FIR No. C-89/2018 Dated 24-05-2018	No Challan received yet
20	Clotrimazole	FIR No. C-90/2018 Dated 24-05-2018	No Challan received yet
21	Crosspovidone USP 26	FIR No. C-91/2018 Dated 24-05-2018	No Challan received yet
22	Phloroglucinol Dihydrate	FIR No. C-92/2018 Dated 24-05-2018	No Challan received yet
23	Pentoprazole Sodium	FIR No. C-93/2018 Dated 24-05-2018	No Challan received yet
24	Iron (III) Hydroxide Polymaltose complex	FIR No. C-94/2018 Dated 24-05-2018	No Challan received yet
25	Aspartamine	FIR No. C-95/2018 Dated 24-05-2018	No Challan received yet
26	PVP K-30	FIR No. C-96/2018 Dated 24-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
27	Lidocaine HCL	FIR No. C-97/2018 Dated 24-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
28	Methyl Cellulose	FIR No. C-98/2018 Dated 24-05-2018	No Challan received yet
29	Piroxicam BCD	FIR No. C-99/2018 Dated 24-05-2018	No Challan received yet
30	Vitamin B6 HCl	FIR No. C-100/2018 Dated 24-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting.
31	Tris (Hydroxymethyl) Amino Methane	FIR No. C-105/2018 Dated 29-05-2018	No Challan received yet
32	Microcrystalline Cellulose	FIR No. C-106/2018 Dated 29-05-2018	No Challan received yet
33	Phloroglucinol Dihydrate Phloroglucinol Trimethyle	FIR No. C-107/2018 Dated 30-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting.
34	Clotrimazole	FIR No. C-108/2018 Dated 30-05-2018	No Challan received yet

35	Aspatamine	FIR No. C-109/2018 Dated 30-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
36	Naproxen Sodium	FIR No. C-110/2018 Dated 31-05-2018	No Challan received yet
37	Piroxicam BCD	FIR No. C-111/2018 Dated 31-05-2018	No Challan received yet
38	Aceclofenac EP4	FIR No. C-112/2018 Dated 31-05-2018	No Challan received yet
39	Doxyfylline	FIR No. C-113/2018 Dated 31-05-2018	No Challan received yet

Current status of the case:

09. Federal Inspector of Drugs-IV Lahore vide letter No. 3247/2022-DRAP (L-III) dated 15-03-2022 wherein FID-III submitted as under:

> *"Reference is made to DRAP Islamabad's letter No. 13-8/18-QC dated 17.04.2018. Wherein, undersigned was directed to lodge 39 individual FIRs against M/s Everest Pharmaceuticals for importing different raw materials through 39 Take and forged documents/invoices. Accordingly, 39 individual applications for lodging FIRs against management of M/s Everest Pharmaceuticals were submitted in the office of the Director, FIA Lahore.*

2. Details of the fake/forged document, application for lodging FIR, FIR Number and status of the inquiry is given below:

Sr.#	Invoice No.	Name of RM	Letter No. and Date	FIR No. and Date	Status
1.	SPKGC15001	Xanthan Gum Pharma Grade 200 Mesh	6246/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-69/ 2018 dated 16-05-2018	In complete challan was received and case sent to CLB. Prosecution was received
2.	SPKGC15003	Xanthan Gum Pharma Grade 200 Mesh	6245/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-70/2018 dated 16-05-2018	In complete challan was received and case sent to CLB Prosecution was received
3.	ZY2015099037	Naproxen Sodium	6240/2018-DRAP-AD (I&E) 08.05.2018	FIR No C-71/2018 dated 16-05-2018	In complete challan was received and case sent to CLB. Prosecution was received.
4.	AE073	Omeprazole	62772018-DRAP-AD (I&E) 08.05.2018	FIR No. C-72/2018 dated 16-05-2018	In complete challan was received and case sent to CLB Prosecution was received
5.	JXS170239	Gabapantine	6273/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-73/2018 dated 16-05-2018	In complete challan was received and case sent to CLB Prosecution was received
6.	00214835	Levofloxacin Hemihydrate	6250/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-74/2018 dated 16-05-2018	In complete challan was received and case sent to CLB. Prosecution was received.

7.	MS-EXP16516522582	Fexofinadine HCL	6274/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-75/2018 dated 16-05-2018	In complete challan was received and case sent to CLB. Prosecution was received.
8.	ZY201603134	PVP K-30	6268/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-76/2018 dated 17-05-2018	No challan received yet
9.	2151010442	Clotrimazole	6267/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-77/2018 dated 17-05-2018	No challan received yet
10.	EXP/PPL/24/15-16	Gabapantine	6252/2018-DRAP-AD (I&E) 08.05.2018	FIR No C-78/2018 dated 17-05-2018	In complete challan was received and case sent to CLB
11.	XW150701	Magnesium citrate	6242/2018-DRAP-AD (I&E) 08.05.2018	FIR No C-79/2018 dated 17-05-2018	In complete challan was received and case sent to CLB.
12.	BE14W004	Clotrimazole	6249/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-81/2018 dated 17-05-2018	In complete challan was received and case sent to CLB. Prosecution was received.
13.	ZC17003	Clotrimazole	6271/2018-DRAP-AD (I&E) 08.05.2018	FIR No C-83/2018 dated 23-05-2018	No challan received yet
14.	AE293	Esomeprazole Magnesium Trihydrate	6272/2018-DRAP-AD (I&E) 08.05.2018	FIR No C-84/2018 dated 23-05-2018	No challan received yet
15.	MT-1505115	Microcrystalline Cellulose	6244/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-85/2018 dated 23-05-2018	In complete challan was received and case sent to CLB. Prosecution was received.
16.	4182-01	Lactose Monohydrate	6241/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-86/2018 dated 23-05-2018	In complete challan was received and case sent to CLB. Prosecution was received.
17.	BPPL/EXP/42/15-16	Doxofylline	6255/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-87/2018 dated 24-05-2018	No challan received yet
18.	2151010290	Glucosomine Sulfate	6257/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-88/2018 dated 24-05-2018	No challan received yet
19.	2161010493	Piroxicam BCD	6262/2018-DRAP-AD (I&E) 08.05.2018	FIR No C-89/2018 dated 24-05-2018	No challan received yet
20.	FS10E0503	Clotrimazole	6259/2018-DRAP-AD (I&E) 08.05.2018	FIR No C-90/2018 dated 24-05-2018	No challan received yet
21.	16WT190613	Crospovidone USP 26	6266/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-91/2018 dated 24-05-2018	No challan received yet
22.	N16AD59521	Phloroglucinol Dihydrate	6276/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-92/2018 dated 24-05-2018	No challan received yet
23.	AE303	Pentoprazole sodium	6275/2018-DRAP-AD (I&E) 08.05.2018	FIR No C-93/2018 dated 24-05-2018	No challan received yet
24.	CIU/141	Iron (III) Hydroxide Polymaltose complex	6248/2018-DRAP-AD (I&E) 08.05.2018	FIR No C-94/2018 dated 24-05-2018	No challan received yet
25.	366160217B2	Aspartamine	6254/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-95/2018 dated 24-05-2018	No challan received yet
26.	ZY201603123	PVP K-30	6264/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-96/2018 dated 24-05-2018	In complete challan was received and case sent to CLB. Prosecution was received
27.	GVSL/109/16-17	Lidocaine HCL	6263/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-97/2018 dated 24-05-2018	In complete challan was received and case sent to CLB. Prosecution was received.
28.	16HD6103	Methyl Cellulose	6265/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-98/2018 dated 24-05-2018	No challan received yet
29.	CMT160305	Piroxicam BCD	6253/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-99/2018 dated 24-05-2018	No challan received yet
30.	16JXTXI-0812	Vitamin B6 HCL	6261/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-100/2018 dated 24-05-2018	In complete challan was received and case sent to CLB. Prosecution was received.

31.	HF15088	Tris (Hydroxymethyl) Amino Methane	6243/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-105/2018 dated 29-05-2018	No challan received yet
32.	XW160121	Microcrystallin cellulose	6251/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-106/2018 dated 29-05-2018	No challan received yet
33.	N15AD23387	Phloroglucinol Dihydrate Phloroglucinol Trimethyle	6256/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-107/2018 dated 30-05-2018	In complete challan was received and case sent to CLB Prosecution was received.
34.	FS02E0118	Clotrimazole	6247/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-108/2018 dated 30-05-2018	No challan received yet
35.	366161104D1	Aspatamine	6278/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-109/2018 dated 30-05-2018	In complete challan was received and case sent to CLB.
36.	17TXI-096	Naproxen Sodium	6269/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-110/2018 dated 31-05-2018	No challan received yet
37.	2151020300	Piroxicam BCD	6258/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-111/2018 dated 31-05-2018	No challan received yet
38.	JXS170827	Aceclofenac EP4	6270/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-112/2018 dated 31-05-2018	No challan received yet
39.	BPPL/ESP/32/16-17	Doxyfylline	6260/2018-DRAP-AD (I&E) 08.05.2018	FIR No. C-113/2018 dated 31-05-2018	No challan received yet

3. FIA Corporate Crime Circle, Lahore registered 39 FIRs as per above table against following accused:

i. M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, through its Managing Partner.

ii. Ch. Muhammad Usman (Owner of M/s Everest Pharmaceuticals).

iii. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals).

iv. Noor Muhammad Mahar (Owner of M/s Everest Pharmaceuticals).

v. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.

4. Out of 39 FIRs, in-complete challans of only 17 FIRs were submitted by FIA Corporate Crime Circle, Lahore as given in above table.

5. FIA Corporate Crime Circle, Lahore was requested to provide final investigation reports/complete challans in respect to above FIRs vide (his office letter No. 2935/2022-FID (L-II1) dated 08.03.2022. but no response is received yet.

6. However, today, Mr. Hafiz Bilal Bin Akbar, AD Legal communicated a FIRs cancellation report submitted by FIA in the Court of Senior Civil Judge (Criminal Division) Lahore with respect to above FIRs. Wherein FIA has submitted that "Registration of 39 FIRs for alleged fake authorization of DRAP amount to double jeopardy as Pakistan Customs has already taken cognizance of the matter on the complaint of DRAP and has registered its FIR No. 14/2018 on 21.04.2018 under relevant provision of the Custom Act 1969 and the Import and Export (Control) Act 1950 prior to registration of FIRs on similar charges in FIA CCC Lahore. Therefore, in all such FIRs of FIA CCC Lahore, proprietor and/or management of the firm should be discharged and cancellation report should be submitted under section 173 Cr. Pc".

7. Therefore keeping in view the facts that accused persons mentioned at para 3 have committed offence of illegal import of pharmaceutical raw materials through forged documents, and the stance of FIA as mentioned in para 6. above mentioned cases are being referred to Central Licensing Board as required under Schedule-V of the DRAP Act 2012 to see further orders as to the action to be taken in respect of contraventions of the Act as mentioned above,

8. Submitted for further necessary action and directions, please."

10. In the light of challan of FIA and request of area FID Lahore, the matter is submitted for the opinion/orders of the Board.

PROCEEDINGS AND DECISION OF THE 285TH MEETING OF THE BOARD:

11. The Central Licensing Board in light of the aforementioned facts undertook a detailed discussion of the FIRs and their current status of investigation. Hafiz Bilal Bin Akbar, Assistant Director (Legal Affairs) DRAP assisted the Board. The Board noted that the status of investigation in the above discussed FIRs can be divided into following two categories:

    a. FIRs in which incomplete Investigation Reports were provided by the Investigation Officers of FIA to the concerned Federal Inspector of Drugs, following which the Board decided to issue permission to institute prosecution after following the process prescribed under the law. Details of these cases are given as under;

S#	Name of RM	FIR No. and Date	Status
1	Xanthan Gum Pharma Grade 200Mesh	FIR No. C-69/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting.
2	Xanthan Gum Pharma Grade 200Mesh	FIR No. C-70/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting
3	Naproxen Sodium	FIR No. C-71/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
4	Omeprazole	FIR No. C-72/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
5	Gabapentin	FIR No. C-73/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
6	Levofloxacin Hemihydrate	FIR No. C-74/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
7	Fexofenadine HCL	FIR No. C-75/2018 Dated 16-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
8	Gabapentine	FIR No. C-78/2018	Incomplete challan was received and case sent to CLB. Prosecution

		Dated 17-05-2018	was granted in 269th meeting.
9	Magnesium Citrate	FIR No. C-79/2018 Dated 17-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
10	Clotrimazole	FIR No. C-81/2018 Dated 17-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting.
11	Microcrystalline Cellulose	FIR No. C-85/2018 Dated 23-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting.
12	Lactose Monohydrate	FIR No. C-86/2018 Dated 23-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting.
13	PVP K-30	FIR No. C-96/2018 Dated 24-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
14	Lidocaine HCL	FIR No. C-97/2018 Dated 24-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.
15	Vitamin B6 HCl	FIR No. C-100/2018 Dated 24-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting.
16	Phloroglucinol Dihydrate Phloroglucinol Trimethyle	FIR No. C-107/2018 Dated 30-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 276th meeting.
17	Aspatamine	FIR No. C-109/2018 Dated 30-05-2018	Incomplete challan was received and case sent to CLB. Prosecution was granted in 269th meeting.

b. FIRs in which no Investigation Reports have been provided by the Investigation Officers of FIA to the concerned Federal Inspector of Drugs. Details of the cases are given as under:

S#	Name of RM	FIR No. and Date	Status
1	PVP K-30	FIR No. C-76/2018 Dated 17-05-2018	No Challan received yet
2	Clotrimazole	FIR No. C-77/2018 Dated 17-05-2018	No Challan received yet
3	Clotrimazole	FIR No. C-83/2018 Dated 23-05-2018	No Challan received yet
4	Esomeprazole Magnesium Trihydrate	FIR No. C-84/2018 Dated 23-05-2018	No Challan received yet
5	Doxofylline	FIR No. C-87/2018 Dated 24-05-2018	No Challan received yet
6	Glucosomine Sulfate	FIR No. C-88/2018 Dated 24-05-2018	No Challan received yet
7	Piroxicam BCD	FIR No. C-89/2018	No Challan received yet

		Dated 24-05-2018	
8	Clotrimazole	FIR No. C-90/2018 Dated 24-05-2018	No Challan received yet
9	Crosspovidone USP 26	FIR No. C-91/2018 Dated 24-05-2018	No Challan received yet
10	Phloroglucinol Dihydrate	FIR No. C-92/2018 Dated 24-05-2018	No Challan received yet
11	Pentoprazole Sodium	FIR No. C-93/2018 Dated 24-05-2018	No Challan received yet
12	Iron (III) Hydroxide Polymaltose complex	FIR No. C-94/2018 Dated 24-05-2018	No Challan received yet
13	Aspartamine	FIR No. C-95/2018 Dated 24-05-2018	No Challan received yet
14	Methyl Cellulose	FIR No. C-98/2018 Dated 24-05-2018	No Challan received yet
15	Piroxicam BCD	FIR No. C-99/2018 Dated 24-05-2018	No Challan received yet
16	Tris (Hydroxymethyl) Amino Methane	FIR No. C-105/2018 Dated 29-05-2018	No Challan received yet
17	Microcrystalline Cellulose	FIR No. C-106/2018 Dated 29-05-2018	No Challan received yet
18	Clotrimazole	FIR No. C-108/2018 Dated 30-05-2018	No Challan received yet
19	Naproxen Sodium	FIR No. C-110/2018 Dated 31-05-2018	No Challan received yet
20	Piroxicam BCD	FIR No. C-111/2018 Dated 31-05-2018	No Challan received yet
21	Aceclofenac EP4	FIR No. C-112/2018 Dated 31-05-2018	No Challan received yet
22	Doxyfylline	FIR No. C-113/2018 Dated 31-05-2018	No Challan received yet

12. The Board has been informed that the Investigating Officer of FIA have compiled complete investigation reports under Section 173 of the Code of Criminal Procedure, 1898 ('**Cr.P.C.**'), and instead of handing them over to the area Federal Inspector of Drugs ('**FID**'), have submitted them before the learned Judicial Magistrate Section-30, District Courts, Lahore. In

all the said complete investigation reports recommendations have been made for cancellation of FIRs against all the nominated accused.

13. The concerned FID requested for copies of the complete Investigation Report through letter bearing reference no. No. 2935/2022-FID (L-II1) dated 08.03.2022, but received no reply to it. The area FID after obtaining the complete Investigation Reports, have placed the same before the Board by the area FID through letter No. 3247/2022-DRAP (L-III) dated 15-03-2022.

14. The Board at the outset noted that the scheme of the drug laws provide that the FID undertakes investigation of offenses under the drug laws and FIA merely assists the concerned FID in undertaking investigation. After conclusion of investigations, the FID forwards the Investigation Report to the Central Licensing Board; the Investigation Report by FIA forms a part of the report by the FID. However, in the instant matter, the investigating officers not only refused to hand over their investigation reports to the FID but also presented the same first before the learned Drugs Court, Lahore and then before the learned Judicial Magistrate under Section 30 Cr.P.C., Lahore, which are not only against the law but also caused unnecessary delay in the matter which is of public importance.

15. After perusal of the complete Investigation Reports suggesting cancellation of FIRs, the Board noted that the same had been compiled in pursuance of findings of a report titled 'Inquiry Committee Report' bearing No. Misc/FIA/CCC/L/Report/Everest Pharmaceutical Case/1282 dated 10-08-2020 ('**Inquiry Report**'). It is to be emphasized that the said Inquiry Committee neither associated the complainant FID nor took into consideration the evidence provided by him or his investigation. It was also noted that the FID remained unable to apprise the Inquiry Committee with his version and investigation as he was never informed about the constitution or meeting of the committee, which undoubtedly cast a mark on its functioning and the conclusions drawn by it. It has been concluded by the Hon'ble Court that judicious and transparent investigation is cornerstone of fair trial, therefore, dishonest and biased investigation is violative of constitutionally ensured right to fair trial.

16. The complete text of the Inquiry Report has been reproduced verbatim in the Investigation Report, wherein recommendation has been made for cancellation of the FIRs related to the illegal import of drugs for the following reason:

> "[…]10. It is pertinent to mention here that Pakistan Customs had also registered an FIR No. 14/ 2018 on 21.04.2018 on the complaint of DRAP against M/s Everest Pharma for clearance of consignments through above mentioned fake authorizations of DRAP under section 16, 32, 32(A) & 79 of the Customs Act, 1969 and section 3 (1) of the Import and Export (Control) Act, 1950 punishable under clause 9, 14, 14A & 466 of section 156 (1) of the Custom Act, 1969.
>
> 11. The question is when cognizance had already been taken by Customs Department under Customs Act, 1969 what would be the fate of FIR registered by FIA as no public servant is nominated in these FIRs. It is a clear case of Double Jeopardy."

17. It has to be noted at the outset that determination as to if double jeopardy applies to a particular set of facts, is a judicial function which cannot be usurped by any investigating agency. The law has by now been settled that the investigating agencies have to merely collect facts regarding an offence without expressing any opinion regarding them. A perusal of both the Inquiry Report as well as the Investigation Reports show that it has not been denied that the offence complained of have been committed by the nominated accused; both the said Reports have not collected any facts which would show that the nominated accused have no role in the commission of offences. Therefore, both the Inquiry Report as well as the Investigation Report are strongly disagreed with as they have usurped the judicial function by diluting the trichotomy of powers to determine the FIRs as violating the doctrine of protection from double jeopardy.

18. Even otherwise, both the Inquiry Report as well as the Investigation Report have wrongly applied the doctrine of protection against double jeopardy. A perusal of both the FIRs evinces that the same were lodged under different enactments of law having different procedure and forum for initiating proceedings thereunder, although both the sets of offences have been committed by the petitioners in one go that is to say that the accused acted in such a manner which constituted offences punishable under two separate and distinct enactments i.e. one under the Customs Act and the other under the Pakistan Penal Code along with the drug laws. Both are different and distinct pieces of legislation,

therefore, acts and omissions of the accused committed by them cannot be said to be same offences.

19. The Inquiry Report also made reference to alleged personal agenda of unnamed 'higher-ups of DRAP' in order to malign the functioning of DRAP in the following words:

> "27. In the Report of three member Committee headed by the ADG Immigration tasked to look into cases of M/s Everest Pharma, detail of bitter rivalry between higher-ups of DRAP and the alleged persons of these FIRs is exhaustively documented, which prima facie points to vexatious, vendetta-driven and motivated nature of these FIRs registered in the complaints of DRAP."

20. The reference to anonymous higher ups and un-detailed documented 'bitter rivalry' again lacks any concrete evidence. Even otherwise, as discussed above, the offences are evident from the record and any purported bitter rivalry cannot be made the ground for maligning proceedings undertaken against the accused under the law. It is to be noted that most of the accused challenged the instant and other proceedings in a litany of cases before the Hon'ble Lahore High Court as well as Hon'ble Islamabad High Court, but no relief whatsoever were granted in the same; the Hon'ble Courts despite pleadings of the accused did not question lawfulness of the proceedings undertaken by DRAP in pursuance of orders by the Hon'ble Supreme Court.

21. It merits discussion here that the accused Business Concern after Orders by the Hon'ble Supreme Court, tried to obtain relief before the Hon'ble Islamabad High Court, Islamabad. However, the Hon'ble High Court through Order dated 22-07-2020 in W.P. No. 2982 of 2019 was pleased to dismiss the same by holding that granting of any relief to the instant Plaintiff would "amount to interfere with the above order of the August Supreme Court".

22. The Inquiry Report also discharged two of the accused namely Mr. Noor Muhammad Mahr and Mr. Kamran Izhar in Para. No. 27. With regards to Mr. Kamran Izhar, the contention recorded by the Inquiry Report is against the facts and based on complete misrepresentation. FIA through its two replies submitted before the Hon'ble Lahore High Court, Lahore in W.P. No. 207678 of 2018 through Diary No. 13992 dated 01-10-2018 as well as Diary No. 467

dated 10-01-2019, provided a complete list of evidence linking Kamran Izhar to Everest Pharmaceuticals. Even otherwise, piercing/ lifting of corporate veil has been endorsed by the Hon'ble Supreme Court so that Courts can look behind the corporate attire to identify real person who is exercising and managing the control and the affairs of such body corporate or firm or any combination thereof that is under scrutiny. There is ample evidence linking Mr. Kamran Izhar to the Everest Pharmaceuticals provided in the very reply by FIA filed before the Hon'ble High Court, which has perhaps been ignored by the Inquiry Report. Besides, there is ample evidence available which has been provided to the Investigating Officer linking Mr. Kamran Izhar to the ownership of Everest Pharmaceuticals.

23. With regards to Mr. Noor Muhammad Mahar, he has already been absconder by the learned Drug Court, Islamabad through Order dated: 12-11-2018 in FIR No. 5 of 2018. Perpetual warrants for his arrest have been issued but the same is evading them and is a fugitive from the law. Even FIA through Challan dated 31-12-2018 submitted before the aforementioned Court has held that Mr. Noor Muhammad Mahar is a fugitive from the law and hiding to evade arrest. He has admitted in W.P. No. 517/18 his association with Everest Pharmaceuticals, which prima facie evinces his role.

24. The Board for the aforementioned reasons strongly disagreed with the findings/conclusions by both the Inquiry Report and the Investigation Report and decided the following:
    a. For the cases in which permission for prosecution has already been granted, the concerned FID is directed to file prosecution against the accused within 15 days with intimation to the Board;
    b. For the cases in which permission for prosecution has not been granted, show cause notice be promptly issued through all means including through registered posts/courier service, Special Messengers/ Dispatch Riders and E-mails and WhatsApp for the accused persons whose IDs are available. Furthermore, show cause notices should be published in prominent Print Media in the reputable English & Urdu Newspapers. The published notices shall be pasted by area FID in front of residence of accused person and relevant Drug Courts.

Case No. 03: **SEIZURE OF STOCK UNDER SECTION 18 (1) (F) OF THE DRUGS ACT, 1976 FROM (M/S. FAZAL DIN & SONS (PVT.) LTD., 53-SHAHRAH-E-QUAID-E-AZAM, LAHORE) I.E., TABLET EVERLONG 60 MG MANUFACTURED BY M/S. EVEREST PHARMACEUTICALS 124-INDUSTRIAL TRIANGLE, ISLAMABAD (C-166).**

Proceedings of 259th meeting of CLB.

Mr. Abdul Rashid Sheikh FID Lahore-VI in 259th meeting of the Board informed regarding the visit of M/s Fazal Din &Sons (Pvt.) Ltd., Lahore on 06-03-2018 along with Ms. Uzma barkat, FID Lahore and Ms. Nureen Ramzan, inspector, FIA Lahore wherein following products were seized:-

S.No	Name of drug and Batch No..	Mfg date	Exp date	Mfg by	Quantity
1.	Everelong 60mg Tablets	374	11-17	11-19	127 Tablets

02. The Board granted Permission for safe custody of the seized stocks of therapeutic goods/drugs was allowed to the FID by the Board in the said meeting.

Proceedings of 261st meeting of CLB

03. Area FID Lahore, submitted investigation report for the consideration of the Board and requested to grant permission for lodging of FIR against the following accused persons:-

i. M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.
ii. Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad
iii. Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad
iv. Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad
v. Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad
vi. Mian Ishtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad
vii. Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranty on behalf of M/s Everest Pharmaceuticals Islamabad.

04. Moreover, The CLB allowed to the FID for grant the permission for extension of sealing period of sealed premises for further 90 days and safe custody of seized drugs was allowed till finalization of the case.

05. The said decision was communicated to FID vide F. No. 3-33/2018-QC (261-CLB) dated 24th May, 2018. In compliance to the above-said decision of the Board, FIR was lodged by Abdul Rashid Shaikh, FID Lahore vide FIR No. C-166/2018 dated 7-8-2018 at FIA/CCC/Lahore.

06. I/O i.e. Assistant Director FIA/CCC/LHR submitted incomplete challan of the casewherein he submitted that the nominated accused Ch. Muhammad Usman has been arrested on 30.08.2018. Now he is on judicial remand. Yet no any other accused person has been arrested. During investigation it revealed that the accused Ch. Muhammad Usman has been involved in manufacturing and sale of unregistered, spurious and sex inducing drugs at large scale with active connivance of other accused persons. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty and requested that accused and witnesses may please be called to start the trial of the case.

Proceedings of 266th meeting of CLB

07. In the light of the incomplete challan submitted by I/O FIA, the Board decided to issue show cause notice and call the accused for a chance of personal hearing in the forthcoming meeting.

08. In the light of decision of the Central Licensing Board taken in 266th Meeting dated 24.10.2018, Show Cause Notices for prosecution were issued to the accused through routine procedure as well as through area FID vide letter no. 03-77/2018-QC (266-CLB) dated 07.12.2018and Personal Hearing letters were issued to the accused persons vide letter No. 03-77/2018-QC (266-CLB) dated 21.12.2018.

Proceedings of 267th meeting of CLB

09. Central Licensing Board (CLB) was apprised that Show Cause Notice & Personal Hearing were forwarded through M&P Courier/Urgent Mail Service/Dispatch Rider however, show cause and personal hearing notices of only M/s. Everest Pharmaceuticals Islamabad and Muhammad Usman s/o Zaheer Ahmad (Owner of M/s. Everest Pharmaceuticals Islamabad) were delivered. Rest of the notices returned back undelivered.

10. Keeping in view the above facts, the Board was of the view that the accused persons are reluctant to receive the show cause notice and personal hearing letters. It was therefore unanimously decided that all the available means in addition to given below at a time should be adopted in this regard to meet the ends of justice and to avoid delays:

i. Through registered posts/courier service
ii. Through Special Messengers/ Dispatch Riders
iii. Through E-mails and WhatsApp for the accused persons whose IDs are available.
iv. By publishing show cause notices & personal hearing letters in the prominent Print Media in the reputable English & Urdu Newspapers
v. The published notices shall be pasted by area FID in front of residence of accused person and relevant Drug Courts.

11. The Board considered the records and reports regarding the case and granted permission for prosecution to the area Federal Inspector of Drugs, Lahore for launching the case in the court of competent jurisdiction against the following:

i. M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch.

Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore

ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore

Proceedings of 269th meeting of CLB

12. Central Licensing Board (CLB) was apprised that Show Cause Notice & Personal Hearing letters were served to the accused as mentioned in agenda through Courier/Urgent Mail Service. Dr. Kamran Izhar appeared before the CLB in person and provided his written reply to the showcause notice whereas Advocate Abubakar Gondal appeared before the Board on behalf of Noor Muhammad Mahar. No council appeared before CLB on behalf of MuhamamdIshtiaq (QC Manager),Khuram Naeem warrantor of M/s Saint & Sailor Pharmaceuticals, Lahoreand Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad neither did they responded to the showcause notice served.

13. The Central Licensing Board after hearing the above mentioned accused and examining the available records with various divisions at DRAP headquarters, Islamabad and facts presented by the secretariat granted permission for prosecution to the area Federal Inspector of Drugs, Lahore for launching the case in the court of competent jurisdiction against the following accused persons:

i. Dr. Kamram Izhar (owner of M/s Everest Pharmaceuticals) R/o Address: House 397-D, Phase V, Defense Housing Authority, Lahore
CNIC: 35202-2713085-5

ii. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)
CNIC: 54400-0553619-3;
Cell No.: 03009673869, 03224453577, 03224453578 R/o Basti Khair Muhammad Meher, Near Aar C.A. Factory, Sadiqabad, Wahid BakashMeher, Rahim Yar Khan / Block No. 2, Sector C-1, Township, Lahore / Flat No. 17, 2nd Floor, Abrar Centre, Wahdat Road, Lahore.

iii. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. R/o Manki Mohalla-A, Tehsil Lahore, District Sawabi.

iv. Khuram Naeem warrantor of M/s Saint & Sailor Pharmaceuticals, Lahore R/o 18-G Hajvery Complex, 2-Mozang Road, Lahore.

v. Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad R/o Johar Town, Lahore.

Current status of the case:

14. Federal Inspector of Drugs-IV Lahore vide letter No. 2345/2022-DRAP (L-IV) dated 15-03-2022 wherein FID-IV submitted as under:

> *"Reference is made to DRAP Islamabad's letter No. F.03-33/2018-QC (261-CLB) dated 24-05-2018. Wherein, undersigned was directed to lodge FIR against M/s Everest Pharmaceuticals Accordingly, the application for lodging FIR against management of M/s Everest Pharmaceuticals was submitted in the office of the Director, FIA Lahore.*

2. Details of the application for lodging FIR. FIR Number and status of the inquiry' is given below:

Sr.#	Letter No. and Date	FIR No. and Date	Status
1.	9332/2018-DRAP-(L-VI) 11.07.2018	FIR No. C-166/ 2018 dated 07-08-2018	In complete challan was sent to CLB vide this office letter No. 13210/2018-DRAP (L-VI) dated 12-10-18. Permission for prosecution received.

3. FIA Corporate Crime Circle, Lahore registered FIR as per above table against following accused:

a) M/s. Everest Pharmaceuticals. Islamabad, through owner. Ch. Muhammad Usman.
b) Ch. Muhammad Usman (owner), M/s. Everest Pharmaceuticals, Islamabad.
c) Dr. Kamran Izhar (Partner), M/s. Everest Pharmaceuticals. Islamabad.
d) Noor Muhammad Mehar (Partner), M/s. Everest Pharmaceuticals. Islamabad.
e) Ch. Muhammad Usman. Production Incharge. M/s. Everest Pharmaceuticals. Islamabad.
f) Mian Isthiaq Ahmed. Quality Control Incharge. M/s. Everest Pharmaceuticals, Islamabad.
g) Haroon Yousaf. Warrantor M/s. Everest Pharmaceuticals. Islamabad who signed and issued above mentioned false warranty on behalf of M/s. Everest Pharmaceuticals. Islamabad.

4. In-complete challan of FIR No. C-166/2018, was submitted by FIA Corporate Crime Circle, Lahore which was sent to CLB, DRAP, Islamabad vide this office letter No. 13210/2018-DRAP (L-VI) dated 12-10-18.

5. FIA Corporate Crime Circle, Lahore was requested to provide final investigation reports/complete challans in respect to above FIR vide this office letter No. 3153/2022- DRAP (L-V) dated 14.03.2022, but no response is received yet.

6. However, today, Mr. Hafiz Bilal Bin Akbar, AD Legal communicated a FIRs cancellation report submitted by FIA in the Court of Senior Civil Judge (Criminal Division) Lahore with respect to FIRs. Therefore, in all such FIRs of FIA CCC Lahore submitted report that proprietor and/or management of the firm should be discharged and cancellation report should be submitted under section 173 Cr.Pc".

7. Therefore keeping in view the facts that accused persons nominated as earlier have committed offence of manufacturing and sale of un-registered drugs and the stance of FIA in above mentioned case is being referred to Central Licensing Board as required under Schedule-V of the DRAP Act 2012

to seek further orders as to the action to be taken in respect of contraventions of the Act as mentioned above.

8. Submitted for further necessary action and directions, please."

15. Reference to para 6 of FIDs letter, the mentioned complete challan is placed as Annex-A.

16. In the light of challan of FIA and request of area FID Lahore, the matter is submitted for the opinion/orders of the Board.

PROCEEDINGS AND DECISION OF THE 285TH MEETING OF THE BOARD:

16. The Central Licensing Board in light of the aforementioned facts undertook a detailed discussion of the FIR and their current status of investigation. Hafiz Bilal bin Akbar, Assistant Director (Legal Affairs) DRAP assisted the Board. The Board noted that incomplete Investigation Reports were provided by the Investigation Officers of FIA to the concerned Federal Inspector of Drugs, following which the Board decided to issue permission to institute prosecution after following the process prescribed under the law.

17. The Board has been informed that the Investigating Officer of FIA have compiled complete investigation reports under Section 173 of the Code of Criminal Procedure, 1898 ('**Cr.P.C.**'), and instead of handing them over to the area Federal Inspector of Drugs ('**FID**'), have submitted them before the learned Judicial Magistrate Section-30, District Courts, Lahore. In all the said complete investigation reports, recommendations have been made for cancellation of FIRs against all the nominated accused.

18. The concerned FID requested for copies of the complete Investigation Report through letter bearing reference no. No. 2935/2022-FID (L-II1) dated 08.03.2022, but received no reply to it. The area FID after obtaining the complete Investigation Reports, have placed the same before the Board by the area FID through letter No. 3153/2022- DRAP (L-V) dated 14.03.2022 in Case No. 3, letter No. 3210/2022- DRAP (L-V) dated 15.03.2022 in Case No. 4 and through letter No. 13955/2018-DRAP (VIII) dated, 30-10-2018 in Case No. 5.

19. The Board at the outset noted that the scheme of the drug laws provide that the FID undertakes investigation of offenses under the drug laws and FIA merely assists the concerned FID in undertaking investigation. After conclusion of investigations, the FID

forwards the Investigation Report to the Central Licensing Board; the Investigation Report by FIA forms a part of the report by the FID. However, in the instant matter, the investigating officers not only refused to hand over their investigation reports to the FID but also presented the same first before the learned Drugs Court, Lahore and then before the learned Judicial Magistrate under Section 30 Cr.P.C., Lahore, which are not only against the law but also caused unnecessary delay in the matter which is of public importance.

20. After perusal of the complete Investigation Reports suggesting cancellation of FIRs, the Board noted that the same had been compiled in pursuance of findings of a report titled 'Inquiry Committee Report' bearing No. Misc/FIA/CCC/L/Report/Everest Pharmaceutical Case/1282 dated 10-08-2020 ('**Inquiry Report**'). It is to be emphasized that the said Inquiry Committee neither associated the complainant FID nor took into consideration the evidence provided by him or his investigation. It was also noted that the FID remained unable to apprise the Inquiry Committee with his version and investigation as he was never informed about the constitution or meeting of the committee, which undoubtedly cast a mark on its functioning and the conclusions drawn by it. It has been concluded by the Hon'ble Court that judicious and transparent investigation is cornerstone of fair trial, therefore, dishonest and biased investigation is violative of constitutionally ensured right to fair trial.

21. The complete text of the Inquiry Report has been reproduced verbatim in the Investigation Report, wherein recommendation has been made for cancellation of the FIRs related to the illegal import of drugs for the following reason:

"[…]23. Moreover, the registration of 12 FIRs in respect of drug Everlong in the intervening period, when Honorable Lahore High Court Lahore had upheld Everlong's registration and subsequent stay order by Honorable Supreme Court on the same, is not legally tenable and justified. DRAP illegally lodged complaints for registration of these FIRs despite being aware of the factual position regarding the drug Everlong.

24. In the similar vein, registration of remaining 02 FIRs in respect of alleged unregistered/deregistered drugs, it has been observed that in most FIRs, registration numbers of alleged unregistered drugs are also mentioned. If a drug is alleged to be unregistered or deregistered, it is cannot have a registration number. DRAP has so far failed to substantiate this factum stated in these FIRs. The same has been discussed at length in the Report of three member Committee headed by

the ADG Immigration tasked to look into the matter. The report of the said committee highlights glaring loopholes in the Drug Registration record of DRAP and its assertions in respect of Drugs alleged as unregistered/deregistered in these FIRs.

25. It is relevant to mention that allegation of manufacturing of unregistered drugs was also subject matter of primary FIR registered at FIA Anti-Corruption Circle, Islamabad. ”

22. It is to be noted at the outset that the Hon’ble Supreme Court through Order dated 10-10-2018 in Civil Petition No. 1158 of 2018 titled ‘FoP *Vs.* Everest Pharmaceuticals’ has already held that Everlongis unregistered and was never registered. It comes as shock and surprise to the Board that the Inquiry Report in Para. No. 18 has gone to the extent of denying the existence of such an Order in the following words:

“18 […] The August Supreme Court had never passed any such order”

It is trite law that only the Hon’ble Courts have the jurisdiction and powers to interpret its judgments and decrees. The Inquiry Report instead of obtaining any clarification or interpretation from the Hon’ble Supreme Court, chose to give its self-serving and wrongful interpretation to the aforementioned Judgment which is not warranted under the law. The above mentioned judgment by the Hon’ble Supreme Court is quite clear and is binding on all under Article 189 of the Constitution of the Islamic Republic of Pakistan, 1973.

23. The complainant FIDs while lodging the FIRs mentioned the drug registration numbers which the nominated accused had been wrongly using to falsely claim that their drugs were registered. The Inquiry Report at no point positively referred to any evidence that the drugs manufactured and sold by the accused were registered under the law. However, the Inquiry Report still makes a confusing claim discrediting the complaint by the FID that unregistered drugs were being sold by the nominated accused by mentioning false registration numbers.
24. It is also surprising that the Inquiry Report has not highlighted even a single step taken by Inquiry Committee for collecting evidence, facts and data regarding the purported

registration of Everlong and other unregistered drugs being manufactured and sold by the accused persons, including investigation of Registration Board's records, which has the statutorily prescribed duty of registering drugs and medicines.

25. The Inquiry Report has also noted that since the offence of manufacturing and sale of unregistered drugs has been lodged through primary FIR registered at FIA, Islamabad, therefore no FIR could be lodged for the manufacturing and sale of such unregistered drugs anywhere else in Pakistan. The determination as to whether FIR can be lodged or not is a judicial function which cannot be usurped by any investigating agency. The law has by now been settled that the investigating agencies have to merely collect facts regarding an offence without expressing any opinion regarding them. However, the Inquiry Report has been compiled in violation of the settled law and instead of collecting facts regarding the offence, interpreted and gave opinion which were not backed by any concrete facts.

26. Every act/event of sale at a separate point of sale has been intended by the legislature under the drug laws to be an independent criminal act/ different and separate offence/occurrence. Therefore, separate FIRs were lodged against the accused for every act/event of sale at a separate point of sale. One of the accused Ch. M. Usman also raised the argument identical to the one adopted by the Inquiry Committee in Para. No. 15, reproduced above, before the Hon'ble Lahore High Court, Lahore, while seeking quashment of the FIRs in question. However, the Hon'ble Court did not agree with it and the Petitioners were withdrawn after arguments at length; FIA was a party to the said proceedings. Subsequent to the proceedings before the Hon'ble Court, the Inquiry Report lacked any legal jurisdiction and power to arrive at conclusions which would assume judicial functions without any proper investigation of facts or discovery of any concrete evidence.

27. The Inquiry Report also made reference to alleged personal agenda of unnamed 'higher-ups of DRAP' in order to malign the functioning of DRAP in the following words:

"27. In the Report of three member Committee headed by the ADG Immigration tasked to look into cases of M/s Everest Pharma, detail of bitter rivalry between higher-

ups of DRAP and the alleged persons of these FIRs is exhaustively documented, which prima facie points to vexatious, vendetta-driven and motivated nature of these FIRs registered in the complaints of DRAP."

28. The reference to anonymous higher ups and un-detailed documented 'bitter rivalry' again lacks any concrete evidence. Even otherwise, as discussed above, the offences are evident from the record and any purported bitter rivalry cannot be made the ground for maligning proceedings undertaken against the accused under the law. It is to be noted that most of the accused challenged the instant and other proceedings in a litany of cases before the Hon'ble Lahore High Court as well as Hon'ble Islamabad High Court, but no relief whatsoever were granted in the same; the Hon'ble Courts despite pleadings of the accused did not question lawfulness of the proceedings undertaken by DRAP in pursuance of orders by the Hon'ble Supreme Court.

29. It merits discussion here that the accused Business Concern after Orders by the Hon'ble Supreme Court, tried to obtain relief before the Hon'ble Islamabad High Court, Islamabad. However, the Hon'ble High Court through Order dated 22-07-2020 in W.P. No. 2982 of 2019 was pleased to dismiss the same by holding that granting of any relief to the instant Plaintiff would "amount to interfere with the above order of the August Supreme Court".

30. The Inquiry Report also discharged two of the accused namely Mr. Noor Muhammad Mahr and Mr. Kamran Izhar in Para. No. 27.With regards to Mr. Kamran Izhar, the contention recorded by the Inquiry Report is against the facts and based on complete misrepresentation. FIA through its two replies submitted before the Hon'ble Lahore High Court, Lahore in W.P. No. 207678 of 2018 through Diary No. 13992 dated 01-10-2018 as well as Diary No. 467 dated 10-01-2019, provided a complete list of evidence linking Kamran Izhar to Everest Pharmaceuticals. Even otherwise, piercing/ lifting of corporate veil has been endorsed by the Hon'ble Supreme Court so that Courts can look behind the corporate attire to identify real person who is exercising and managing the control and the affairs of such body corporate or firm or any combination thereof that is under scrutiny. There is ample evidence linking Mr. Kamran Izhar to the Everest Pharmaceuticals

provided in the very reply by FIA filed before the Hon'ble High Court, which has perhaps been ignored by the Inquiry Report. Besides, there is ample evidence available which has been provided to the Investigating Officer linking Mr. Kamran Izhar to the ownership of Everest Pharmaceuticals.

31. With regards to Mr. Noor Muhammad Mahar, he has already been absconder by the learned Drug Court, Islamabad through Order dated: 12-11-2018 in FIR No. 5 of 2018. Perpetual warrants for his arrest have been issued but the same is evading them and is a fugitive from the law. Even FIA through Challan dated 31-12-2018 submitted before the aforementioned Court has held that Mr. Noor Muhammad Mahar is a fugitive from the law and hiding to evade arrest. He has admitted in W.P. No. 517/18 his association with Everest Pharmaceuticals, which prima facie evinces his role.

32. The Board for the aforementioned reasons strongly disagreed with the findings/conclusions by both the Inquiry Report and the Investigation Report and decided that since permission for prosecution has already been granted in the titled matters, the concerned FID is directed to file prosecution against the accused within 15 days with intimation to the Board.

Case No. 04: **SEIZURE OF STOCK MANUFACTURED BY EVEREST PHARMACUETICALS FROM M/S SERVAID PHARMACY PVT LTD 65 QUAID-E-AZAM INDUSTRIAL ESTATE LAHORE (C-149/2018).**

Proceedings of 259th meeting of CLB.

Ms. Uzma Barkat area FID Lahore in 259th meeting of the Board informed regarding the visit of M/s Servaid Pharmacy (Pvt.) Ltd., 65-Quaid-e-Azam Industrial Estate. Kot Lakhpat, Lahore on 06-03-2018 along with Additional Director DRAP Lahore, DRAP Lahore team andMr. Muhammad Usman, Inspector, FIA, Crime Circle, Lahore wherein following products were seized:-

Sr. No.	Name of Drug (s)	Batch No.	Mfg. Date	Exp. Date	Mfg. by	Quantity
01.	Everelong 60mg Tablets	374	11-17	11-19	M/s Everest Pharmaceuticals 124-Industrial Triangle, Islamabad	255 packs x 10 Tablets
02.	Dyone Tablets	144	05/17	05/19	-do-	07 packs x 20 Tablets
03.	Sumat-N Tablets	089	03/17	03/19	Do-	04 packs x 10 Tablets
04.	Zitpro Oral Suspension	017L018	11/17	11/19	Do-	10 Pakssx01
05.	Esoval Tablets	365	10/17	10/19	-do-	08 Packs x14 Tablets

02. The Board granted Permission for safe custody of the seized stocks of therapeutic goods/drugs was allowed to the FID by the Board in the said meeting.

Proceedings of 261st meeting of CLB

03. Area FID Lahore, submitted investigation report for the consideration of the Board and requested to grant permission for lodging of FIR against the following accused persons:-

i. M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.
ii. Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad
iii. Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad
iv. Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad
v. Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad
vi. Mian Ishtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad
vii. Khuram Naeem warrantor M/s Saint & Sailor who signed and issued above mentioned false warranty on behalf of M/s Saint & Sailor Pharmaceuticals.
viii. Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranty on behalf of M/s Everest Pharmaceuticals Islamabad.

04. The said decision was communicated to FID vide F. No. 3-33/2018-QC (261-CLB) dated 24th May, 2018. In compliance to the above-said decision of the Board, FIR was lodged by Abdul Rashid Shaikh, FID Lahore vide FIR No. C-166/2018 dated 7-8-2018 at FIA/CCC/Lahore.

05. I/O FIA/CCC/LHR submitted incomplete challan of the casewherein he submitted that the nominated accused Ch. Muhammad Usman has been arrested on 30.08.2018. Now he is on judicial remand. Yet no any other accused person has been arrested. During investigation it revealed that the accused Ch. Muhammad Usman has been involved in manufacturing and sale of unregistered, spurious and sex inducing drugs at large scale with active connivance of other accused persons. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty and requested that accused and witnesses may please be called to start the trial of the case.

Proceedings of 266th meeting of CLB

06. In the light of the incomplete challan submitted by I/O FIA, the Board decided to issue show cause notice and call the accused mentioned in para 05 for a chance of personal hearing in the forthcoming meeting.

07. In the light of decision of the Central Licensing Board taken in 266th Meeting dated 24.10.2018, Show Cause Notices for prosecution were issued to the accused persons mentioned in para 05 through routine procedure as well as through area FID vide letter no. 03-77/2018-QC (266-CLB) dated 24.10.2018and Personal Hearing letters were issued to the accused persons vide letter No. 03-77/2018-QC (266-CLB) dated 21.12.2018.

Proceedings of 267th meeting of CLB

08. Central Licensing Board (CLB) was apprised that Show Cause Notice & Personal Hearing were forwarded through M&P Courier/Urgent Mail Service/Dispatch Rider however, show cause and personal hearing notices of only M/s. Everest Pharmaceuticals Islamabad and Muhammad Usman s/o Zaheer Ahmad (Owner of M/s. Everest Pharmaceuticals Islamabad) were delivered. Rest of the notices returned back undelivered.

09. Keeping in view the above facts, the Board was of the view that the accused persons are reluctant to receive the show cause notice and personal hearing letters. It was therefore unanimously decided that all the available means in addition to given below at a time should be adopted in this regard to meet the ends of justice and to avoid delays:

i. Through registered posts/courier service
ii. Through Special Messengers/ Dispatch Riders
iii. Through E-mails and WhatsApp for the accused persons whose IDs are available.
iv. By publishing show cause notices & personal hearing letters in the prominent Print Media in the reputable English & Urdu Newspapers
v. The published notices shall be pasted by area FID in front of residence of accused person and relevant Drug Courts.

10. The Board considered the records and reports regarding the case and granted permission for prosecution to the area Federal Inspector of Drugs, Lahore for launching the case in the court of competent jurisdiction against the following:

i. M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore
ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore

Proceedings of 269th meeting of CLB

12. Central Licensing Board (CLB) was apprised that Show Cause Notice & Personal Hearing letters were served to the accused as mentioned in agenda through Courier/Urgent Mail Service. Dr. Kamran Izhar appeared before the CLB in person and provided his written reply to the showcause notice whereas Advocate Abubakar Gondal appeared before the Board on behalf of Noor Muhammad Mahar. No council appeared before CLB on behalf of MuhamamdIshtiaq (QC Manager),Khuram Naeem warrantor of M/s Saint & Sailor Pharmaceuticals, Lahoreand Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad neither did they responded to the showcause notice served.

13. The Central Licensing Board after hearing the above mentioned accused and examining the available records with various divisions at DRAP headquarters, Islamabad and facts presented by the secretariat granted permission for prosecution to the area Federal Inspector of Drugs, Lahore for launching the case in the court of competent jurisdiction against the following accused persons:

i. Dr. Kamram Izhar (owner of M/s Everest Pharmaceuticals) R/o Address: House 397-D, Phase V, Defense Housing Authority, Lahore
CNIC: 35202-2713085-5
ii. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)
CNIC: 54400-0553619-3;
Cell No.: 03009673869, 03224453577, 03224453578 R/o Basti Khair Muhammad Meher, Near Aar C.A. Factory, Sadiqabad, Wahid BakashMeher, Rahim Yar Khan / Block No. 2, Sector C-1, Township, Lahore / Flat No. 17, 2nd Floor, Abrar Centre, Wahdat Road, Lahore.
iii. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. R/o Manki Mohalla-A, Tehsil Lahore, District Sawabi.
iv. Khuram Naeem warrantor of M/s Saint & Sailor Pharmaceuticals, Lahore R/o 18-G Hajvery Complex, 2-Mozang Road, Lahore.
v. Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad R/o Johar Town, Lahore.

Current progress of the case:

11. Federal Inspector of Drugs-V Lahore vide letter No. 3253/2022-DRAP (L-V) dated 16-03-2022 wherein FID-V submitted as under:

"Reference is made to DRAP Islamabad's letter No. F.03-91/2018-QC (267-CLB) dated 22-03-2018, wherein, the then FID, Ms. Anam Saeed, was directed to lodge FIR against M/s Everest Pharmaceuticals Accordingly, the application for lodging FIR against management of M/s Everest Pharmaceuticals was submitted in the office of the Director, FIA Lahore.

2. Details of the application for lodging FIR, FIR Number and status of the inquiry is given below:

Sr.#	Letter No. and Date	FIR No. and Date	Status
1.	8330/2018-DRAP-(L-VII) 14.06.2018	FIR No. C-149/ 2018 dated 17-07-2018	In complete challan was sent to CLB vide this office letter No. 13171/2018-DRAP (L-VII) dated 12-10-18. Permission for prosecution received.

3. FIA Corporate Crime Circle, Lahore registered FIR as per above table against following accused:

1) M/s. Everest Pharmaceuticals, Islamabad. Through owner, Ch. Muhammad Usman.
2) Ch. Muhammad Usman (owner), M/s. Everest Pharmaceuticals, Islamabad.
3) Dr. Kamran Izhar (Partner), M/s. Everest Pharmaceuticals, Islamabad.
4) Noor Muhammad Mehar (Partner), M/s. Everest Pharmaceuticals, Islamabad.
5) Ch. Muhammad Usman, Production Incharge, M/s. Everest Pharmaceuticals, Islamabad.
6) Mian Ishtiaq Ahmed, Quality Control Incharge, M/s. Everest Pharmaceuticals, Islamabad.
7) Khuram Naeem warrantor on behalf of M/s. Saint & Sailor Pharmaceuticals.
8) Mr. Haroon Yousaf warrantor for M/s. Everest Pharmaceuticals, Islamabad who signed and issued above mentioned false warranty on behalf of M/s. Everest Pharmaceuticals, Islamabad.

4. In-complete challan of FIR No. C-149/2018, was submitted by FIA Corporate Crime Circle, Lahore which was sent to CLB, DRAP, Islamabad vide this office letter No. 13171/2018-DRAP (L-VII) dated 12-10-18.

FIA Corporate Crime Circle, Lahore was requested to provide final investigation reports/complete challans in respect to above FIR vide this office letter No. 3210/2022- DRAP (L-V) dated 15.03.2022.

6. However, Mr. Hafiz Bilal Bin Akbar, AD Legal communicated on 15-03-2022 vide WhatsApp, FIRs discharge report submitted by FIA in the Court of Senior Civil Judge (Criminal Division) Lahore with respect to FIRs. Therefore, in all such FIRs of FIA CCC Lahore submitted report that proprietor and/or management of the firm should be discharged and cancellation report should be submitted under section 173 Cr.Pc.

7. Therefore keeping in view the facts that accused persons nominated as earlier have committed offence of manufacturing and sale of un-registered drugs and the stance of FIA in above mentioned case is being referred to Central Licensing Board as required under Schedule-

V of the DRAP Act 2012 to seek further orders as to the action to be taken in respect of contraventions of the Act as mentioned above.

Submitted for further necessary action and directions, please."

12. Reference to para 6 of FIDs letter, the mentioned complete challan is placed as Annex-A.

13. In the light of challan of FIA and request of area FID Lahore, the matter is submitted for the opinion/orders of the Board.

PROCEEDINGS AND DECISION OF THE 285TH MEETING OF THE BOARD:

14. The Central Licensing Board in light of the aforementioned facts undertook a detailed discussion of the FIRs and their current status of investigation. Hafiz Bilal bin Akbar, Assistant Director (Legal Affairs) DRAP assisted the Board. The Board noted that incomplete Investigation Reports were provided by the Investigation Officers of FIA to the concerned Federal Inspector of Drugs, following which the Board decided to issue permission to institute prosecution after following the process prescribed under the law.

15. The Board has been informed that the Investigating Officer of FIA have compiled complete investigation reports under Section 173 of the Code of Criminal Procedure, 1898 ('**Cr.P.C.**'), and instead of handing them over to the area Federal Inspector of Drugs ('**FID**'), have submitted them before the learned Judicial Magistrate Section-30, District Courts, Lahore. In all the said complete investigation reports, recommendations have been made for cancellation of FIRs against all the nominated accused.

16. The concerned FID requested for copies of the complete Investigation Report through letter bearing reference no. No. 2935/2022-FID (L-II1) dated 08.03.2022, but received no reply to it. The area FID after obtaining the complete Investigation Reports, have placed the same before the Board by the area FID through letter No. 3153/2022- DRAP (L-V) dated 14.03.2022 in Case No. 3, letter No. 3210/2022- DRAP (L-V) dated 15.03.2022 in Case No. 4 and through letter No. 13955/2018-DRAP (VIII) dated, 30-10-2018 in Case No. 5.

17. The Board at the outset noted that the scheme of the drug laws provide that the FID undertakes investigation of offenses under the drug laws and FIA merely assists the concerned FID in undertaking investigation. After conclusion of investigations, the FID

forwards the Investigation Report to the Central Licensing Board; the Investigation Report by FIA forms a part of the report by the FID. However, in the instant matter, the investigating officers not only refused to hand over their investigation reports to the FID but also presented the same first before the learned Drugs Court, Lahore and then before the learned Judicial Magistrate under Section 30 Cr.P.C., Lahore, which are not only against the law but also caused unnecessary delay in the matter which is of public importance.

18. After perusal of the complete Investigation Reports suggesting cancellation of FIRs, the Board noted that the same had been compiled in pursuance of findings of a report titled 'Inquiry Committee Report' bearing No. Misc/FIA/CCC/L/Report/Everest Pharmaceutical Case/1282 dated 10-08-2020 ('**Inquiry Report**'). It is to be emphasized that the said Inquiry Committee neither associated the complainant FID nor took into consideration the evidence provided by him or his investigation. It was also noted that the FID remained unable to apprise the Inquiry Committee with his version and investigation as he was never informed about the constitution or meeting of the committee, which undoubtedly cast a mark on its functioning and the conclusions drawn by it. It has been concluded by the Hon'ble Court that judicious and transparent investigation is cornerstone of fair trial, therefore, dishonest and biased investigation is violative of constitutionally ensured right to fair trial.

19. The complete text of the Inquiry Report has been reproduced verbatim in the Investigation Report, wherein recommendation has been made for cancellation of the FIRs related to the illegal import of drugs for the following reason:

"[…]23. Moreover, the registration of 12 FIRs in respect of drug Everlong in the intervening period, when Honorable Lahore High Court Lahore had upheld Everlong's registration and subsequent stay order by Honorable Supreme Court on the same, is not legally tenable and justified. DRAP illegally lodged complaints for registration of these FIRs despite being aware of the factual position regarding the drug Everlong.

24. In the similar vein, registration of remaining 02 FIRs in respect of alleged unregistered/deregistered drugs, it has been observed that in most FIRs, registration numbers of alleged unregistered drugs are also mentioned. If a drug is alleged to be unregistered or deregistered, it is cannot have a registration number. DRAP has so far failed to substantiate this factum stated in these FIRs. The same has been discussed at length in the Report of three member Committee headed by

the ADG Immigration tasked to look into the matter. The report of the said committee highlights glaring loopholes in the Drug Registration record of DRAP and its assertions in respect of Drugs alleged as unregistered/deregistered in these FIRs.

25. It is relevant to mention that allegation of manufacturing of unregistered drugs was also subject matter of primary FIR registered at FIA Anti-Corruption Circle, Islamabad. ”

20. It is to be noted at the outset that the Hon’ble Supreme Court through Order dated 10-10-2018 in Civil Petition No. 1158 of 2018 titled ‘FoP *Vs.* Everest Pharmaceuticals’ has already held that Everlongis unregistered and was never registered. It comes as shock and surprise to the Board that the Inquiry Report in Para. No. 18 has gone to the extent of denying the existence of such an Order in the following words:

“18 […] The August Supreme Court had never passed any such order”

It is trite law that only the Hon’ble Courts have the jurisdiction and powers to interpret its judgments and decrees. The Inquiry Report instead of obtaining any clarification or interpretation from the Hon’ble Supreme Court, chose to give its self-serving and wrongful interpretation to the aforementioned Judgment which is not warranted under the law. The above mentioned judgment by the Hon’ble Supreme Court is quite clear and is binding on all under Article 189 of the Constitution of the Islamic Republic of Pakistan, 1973.

21. The complainant FIDs while lodging the FIRs mentioned the drug registration numbers which the nominated accused had been wrongly using to falsely claim that their drugs were registered. The Inquiry Report at no point positively referred to any evidence that the drugs manufactured and sold by the accused were registered under the law. However, the Inquiry Report still makes a confusing claim discrediting the complaint by the FID that unregistered drugs were being sold by the nominated accused by mentioning false registration numbers.
22. It is also surprising that the Inquiry Report has not highlighted even a single step taken by Inquiry Committee for collecting evidence, facts and data regarding the purported

registration of Everlong and other unregistered drugs being manufactured and sold by the accused persons, including investigation of Registration Board's records, which has the statutorily prescribed duty of registering drugs and medicines. Furthermore, FIR No. C-149/2018 dated 7-8-2018 lodged at FIA/CCC/Lahore is regarding the recovery of drugs Everlong Tablet, Dyone tablets, Sumat-N tablets, Zitpro oral suspention and Esoval tablets manufactured and sold by the accused persons, all of which were unregistered. However, both the Inquiry Report and the Investigation Reports (Challan) are silent regarding the aforementioned drugs except Everlong tablet which goes at length to show the limitations marring the investigation.

23. The Inquiry Report has also noted that since the offence of manufacturing and sale of unregistered drugs has been lodged through primary FIR registered at FIA, Islamabad, therefore no FIR could be lodged for the manufacturing and sale of such unregistered drugs anywhere else in Pakistan. The determination as to whether FIR can be lodged or not is a judicial function which cannot be usurped by any investigating agency. The law has by now been settled that the investigating agencies have to merely collect facts regarding an offence without expressing any opinion regarding them. However, the Inquiry Report has been compiled in violation of the settled law and instead of collecting facts regarding the offence, interpreted and gave opinion which were not backed by any concrete facts.

24. Every act/event of sale at a separate point of sale has been intended by the legislature under the drug laws to be an independent criminal act/ different and separate offence/occurrence. Therefore, separate FIRs were lodged against the accused for every act/event of sale at a separate point of sale. One of the accused Ch. M. Usman also raised the argument identical to the one adopted by the Inquiry Committee in Para. No. 15, reproduced above, before the Hon'ble Lahore High Court, Lahore, while seeking quashment of the FIRs in question. However, the Hon'ble Court did not agree with it and the Petitioners were withdrawn after arguments at length; FIA was a party to the said proceedings. Subsequent to the proceedings before the Hon'ble Court, the Inquiry Report lacked any legal jurisdiction and power to arrive at conclusions which would assume

judicial functions without any proper investigation of facts or discovery of any concrete evidence.

25. The Inquiry Report also made reference to alleged personal agenda of unnamed 'higher-ups of DRAP' in order to malign the functioning of DRAP in the following words:

> "27. In the Report of three member Committee headed by the ADG Immigration tasked to look into cases of M/s Everest Pharma, detail of bitter rivalry between higher-ups of DRAP and the alleged persons of these FIRs is exhaustively documented, which prima facie points to vexatious, vendetta-driven and motivated nature of these FIRs registered in the complaints of DRAP."

26. The reference to anonymous higher ups and un-detailed documented 'bitter rivalry' again lacks any concrete evidence. Even otherwise, as discussed above, the offences are evident from the record and any purported bitter rivalry cannot be made the ground for maligning proceedings undertaken against the accused under the law. It is to be noted that most of the accused challenged the instant and other proceedings in a litany of cases before the Hon'ble Lahore High Court as well as Hon'ble Islamabad High Court, but no relief whatsoever were granted in the same; the Hon'ble Courts despite pleadings of the accused did not question lawfulness of the proceedings undertaken by DRAP in pursuance of orders by the Hon'ble Supreme Court.

27. It merits discussion here that the accused Business Concern after Orders by the Hon'ble Supreme Court, tried to obtain relief before the Hon'ble Islamabad High Court, Islamabad. However, the Hon'ble High Court through Order dated 22-07-2020 in W.P. No. 2982 of 2019 was pleased to dismiss the same by holding that granting of any relief to the instant Plaintiff would "amount to interfere with the above order of the August Supreme Court".

28. The Inquiry Report also discharged two of the accused namely Mr. Noor Muhammad Mahr and Mr. Kamran Izhar in Para. No. 27.With regards to Mr. Kamran Izhar, the contention recorded by the Inquiry Report is against the facts and based on complete misrepresentation. FIA through its two replies submitted before the Hon'ble Lahore High

Court, Lahore in W.P. No. 207678 of 2018 through Diary No. 13992 dated 01-10-2018 as well as Diary No. 467 dated 10-01-2019, provided a complete list of evidence linking Kamran Izhar to Everest Pharmaceuticals. Even otherwise, piercing/ lifting of corporate veil has been endorsed by the Hon'ble Supreme Court so that Courts can look behind the corporate attire to identify real person who is exercising and managing the control and the affairs of such body corporate or firm or any combination thereof that is under scrutiny. There is ample evidence linking Mr. Kamran Izhar to the Everest Pharmaceuticals provided in the very reply by FIA filed before the Hon'ble High Court, which has perhaps been ignored by the Inquiry Report. Besides, there is ample evidence available which has been provided to the Investigating Officer linking Mr. Kamran Izhar to the ownership of Everest Pharmaceuticals.

29. With regards to Mr. Noor Muhammad Mahar, he has already been absconder by the learned Drug Court, Islamabad through Order dated: 12-11-2018 in FIR No. 5 of 2018. Perpetual warrants for his arrest have been issued but the same is evading them and is a fugitive from the law. Even FIA through Challan dated 31-12-2018 submitted before the aforementioned Court has held that Mr. Noor Muhammad Mahar is a fugitive from the law and hiding to evade arrest. He has admitted in W.P. No. 517/18 his association with Everest Pharmaceuticals, which prima facie evinces his role.

30. The Board for the aforementioned reasons strongly disagreed with the findings/conclusions by both the Inquiry Report and the Investigation Report and decided that since permission for prosecution has already been granted in the titled matters, the concerned FIDis directed to file prosecution against the accused within 15 days with intimation to the Board.

Case No. 05: **PERMISSION FOR PROSECUTION W.R.T. SEIZURE OF STOCK UNDER SECTION 18 (F) OF THE DRUGS ACT, 1976 FROM (M/S. CLINIX CENTRAL PHARMACY FRANCHISE OF CLINIX, MULTAN ROAD, NEAR SHAHNOOR STUDIOS, LAHORE (C-151/2018).**

Proceedings of 259th meeting of CLB.

Ms. Uzma Barkat area FID Lahore in 259th meeting of the Board informed regarding the visit of M/s. Clinix Plus Pharmacy Franchise of Clinix, Multan Road, Near Shahnoor Studios, Lahore on 06-03-2018 along with Additional Director DRAP Lahore, DRAP Lahore team and Mr. Ijaz Ahmed, Assistant Director, FIA, Crime Circle, Lahorewherein following products were seized:-

Sr. No.	Name of Drug (s)	Batch No.	Mfg. Date	Exp. Date	Mfg. by	Quantity
01.	EverLong 60 mg Tablets	374	11-17	11-19	M/s. Everest Pharmaceuticals 124-Industrial Triangle, Islamabad	(72 Tablets) 07Packs× 10 Tablets + 02 Tablets loose
	-do-	131	05-17	05-19		(20 Tablets) 02 Packs× 10 Tablets (20 Tablets) 02 Packs× 10 Tablets
02.	Chill Tablets	269	08-17	08-19	-do-	(70 Tablets) 07 Packs× 10′s
	-do-	001	01-18	01-20	-do-	(84 Tablets) 08 Packs× 10 Tablets + 04 Tablets loose

02. The Board granted Permission for safe custody of the seized stocks of therapeutic goods/drugs was allowed to the FID by the Board in the said meeting.

Proceedings of 260th meeting of CLB

03. Area FID Lahore, submitted investigation report for the consideration of the Board and requested to grant permission for lodging of FIR against the following accused persons:-

i. M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.
ii. Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad
iii. Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad
iv. Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad
v. Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad
vi. Mian Ishtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad
vii. Mr Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranties on behalf of M/s Everest Pharmaceuticals Islamabad.
viii. Ghiasul Haq warrantor Shaffi Pharma 257-J I, Johar Town Lahore for failure to provide the invoice warranty of Chill tablets Batch no 269 and batch no 001 as source of their purchase. They also issued false warranties.

04. The said decision was communicated to FID vide F. No. 03-26/2018-QC260-CLB dated 10.05.2018.

Proceedings of 267th meeting of CLB

05. I/O FIA/CCC/LHR submitted incomplete challan of the casewherein he submitted that the nominated accused Ch. Muhammad Usman has been arrested on 30.08.2018. Now he is on judicial remand. Yet no any other accused person has been arrested. During investigation it revealed that the accused Ch. Muhammad Usman has been involved in manufacturing and sale of unregistered, spurious and sex inducing drugs at large scale with active connivance of other accused persons. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty and requested that accused and witnesses may please be called to start the trial of the case.

06. In the light of the incomplete challan submitted by I/O FIA, the Board decided to issue show cause notice and call the accused mentioned in para 05 for a chance of personal hearing in the forthcoming meeting.

07. In the light of decision of the Central Licensing Board taken in 266th Meeting dated 24.10.2018, Show Cause Notices for prosecution were issued to the accused persons mentioned in para 05 through routine procedure as well as through area FID vide letter no. 03-77/2018-QC (266-CLB) dated 24.10.2018and Personal Hearing letters were issued to the accused persons vide letter No. 03-77/2018-QC (266-CLB) dated 21.12.2018.

08. Central Licensing Board (CLB) was apprised that Show Cause Notice & Personal Hearing were forwarded through M&P Courier/Urgent Mail Service/Dispatch Rider however, show cause and personal hearing notices of only M/s. Everest Pharmaceuticals Islamabad and Muhammad Usman s/o Zaheer Ahmad (Owner of M/s. Everest Pharmaceuticals Islamabad) were delivered. Rest of the notices returned back undelivered.

09. Keeping in view the above facts, the Board was of the view that the accused persons are reluctant to receive the show cause notice and personal hearing letters. It was therefore unanimously decided that all the available means in addition to given below at a time should be adopted in this regard to meet the ends of justice and to avoid delays:

i. Through registered posts/courier service

ii. Through Special Messengers/ Dispatch Riders
iii. Through E-mails and WhatsApp for the accused persons whose IDs are available.
iv. By publishing show cause notices & personal hearing letters in the prominent Print Media in the reputable English & Urdu Newspapers
v. The published notices shall be pasted by area FID in front of residence of accused person and relevant Drug Courts.

10. The Board considered the records and reports regarding the case and granted permission for prosecution to the area Federal Inspector of Drugs, Lahore for launching the case in the court of competent jurisdiction against the following:

i. M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore
ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore

Proceedings of 269th meeting of CLB

12. Central Licensing Board (CLB) was apprised that Show Cause Notice & Personal Hearing letters were served to the accused as mentioned in agenda through Courier/Urgent Mail Service. Dr. Kamran Izhar appeared before the CLB in person and provided his written reply to the showcause notice whereas Advocate Abubakar Gondal appeared before the Board on behalf of Noor Muhammad Mahar. No council appeared before CLB on behalf of MuhamamdIshtiaq (QC Manager),Khuram Naeem warrantor of M/s Saint & Sailor Pharmaceuticals, Lahoreand Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad neither did they responded to the showcause notice served.

13. The Central Licensing Board after hearing the above mentioned accused and examining the available records with various divisions at DRAP headquarters, Islamabad and facts presented by the secretariat granted permission for prosecution to the area Federal Inspector of Drugs, Lahore for launching the case in the court of competent jurisdiction against the following accused persons:

i. Dr. Kamram Izhar (owner of M/s Everest Pharmaceuticals) R/o Address: House 397-D, Phase V, Defense Housing Authority, Lahore
CNIC: 35202-2713085-5
ii. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)
CNIC: 54400-0553619-3;
Cell No.: 03009673869, 03224453577, 03224453578 R/o Basti Khair Muhammad Meher, Near Aar C.A. Factory, Sadiqabad, Wahid BakashMeher, Rahim Yar Khan / Block No. 2, Sector C-1, Township, Lahore / Flat No. 17, 2nd Floor, Abrar Centre, Wahdat Road, Lahore.
iii. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. R/o Manki Mohalla-A, Tehsil Lahore, District Sawabi.

iv. Khuram Naeem warrantor of M/s Saint & Sailor Pharmaceuticals, Lahore R/o 18-G Hajvery Complex, 2-Mozang Road, Lahore.
v. Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad R/o Johar Town, Lahore.

Current progress of the case:

11. Federal Inspector of Drugs-V Lahore vide letter No. 3253/2022-DRAP (L-V) dated 16-03-2022 wherein FID-V submitted as under:

"Reference is made to DRAP Islamabad's letter No. F.03-26/2018-QC (260-CLB) dated 10-05-2018. Wherein, FID was directed to lodge FIR against M/s Everest Pharmaceuticals Accordingly, the application for lodging FIR against management of M/s Everest Pharmaceuticals was submitted in the office of the Director, FIA Lahore.

2. Details of the application for lodging FIR, FIR Number and status of the inquiry is given below:

Sr.#	Letter No. and Date	FIR No. and Date	Status
1.	8039/2018-DRAP-(L-VIII) 08.06.2018	FIR No. C-151/2018 dated 17-07-2018	In complete challan sent to CLB vide this office letter No. 13955/2018-DRAP (L-VIII) dated 30-10-18

3. FIA Corporate Crime Circle, Lahore registered FIR as per above table against following accused:

a) M/s. Everest Pharmaceuticals, Islamabad, through owner, Ch. Muhammad Usman.
b) Ch. Muhammad Usman (owner), M/s. Everest Pharmaceuticals, Islamabad.
c) Dr. Kamran Izhar (Partner), M/s. Everest Pharmaceuticals, Islamabad.
d) Noor Muhammad Mchar (Partner), M/s. Everest Pharmaceuticals, Islamabad.
e) Ch. Muhammad Usman, Production Incharge, M/s. Everest Pharmaceuticals, Islamabad.
f) Mian Ishtiaq Ahmed, Quality Control Incharge, M/s. Everest Pharmaceuticals, Islamabad.
g) Mr. Haroon Yousaf, warrantor M/s. Everest Pharmaceuticals, Islamabad who signed and issued above mentioned false warranties on behalf of M/s. Everest Pharmaceuticals, Islamabad.
h) Ghiasul Haq, Warrantor, Shaffi Pharm 257-Johar Town, Lahore for failure to provide the invoice warranty for chill tables Batch No, 269 and 001 as a source of their purchase.

4. In-complete challan of FIR No C-151/2018, was sent to CLB, DRAP, Islamabad vide this office letter No. 13955/2018-DRAP (VIII) dated, 30-10-2018.

6. However, today, Mr, Hafiz Bilal Bin Akbar, AD Legal communicated a FIRs cancellation report submitted by FIA in the Court of Senior Civil Judge (Criminal Division) Lahore with respect to above FIR among others. In the report, FIA CCC Lahore submitted that proprietor and/or management of (he firm should be discharged and FIRs cancellation report should be submitted under section 173 Cr.Pc".

7. Therefore, keeping in view, the facts that accused persons nominated as earlier have committed offence of manufacturing and sale of un-registered drugs and the stance of FIA in the report mentioned in para 6, instant case is being referred to Central Licensing Board as required under Schedule-V of the DRAP Act 2012 to seek further orders as to the action to be taken in respect of contraventions of the Act as mentioned above.

8. Submitted for further necessary action and directions, please."

12. Reference to para 6 of FIDs letter, the mentioned complete challan is placed as Annex-A.

13. In the light of challan of FIA and request of area FID Lahore, the matter is submitted for the opinion/orders of the Board.

PROCEEDINGS AND DECISION OF THE 285TH MEETING OF THE BOARD:

14. The Central Licensing Board in light of the aforementioned facts undertook a detailed discussion of the FIRs and their current status of investigation. Hafiz Bilal bin Akbar, Assistant Director (Legal Affairs) DRAP assisted the Board. The Board noted that incomplete Investigation Reports were provided by the Investigation Officers of FIA to the concerned Federal Inspector of Drugs, following which the Board decided to issue permission to institute prosecution after following the process prescribed under the law.

15. The Board has been informed that the Investigating Officer of FIA have compiled complete investigation reports under Section 173 of the Code of Criminal Procedure, 1898 ('**Cr.P.C.**'), and instead of handing them over to the area Federal Inspector of Drugs ('**FID**'), have submitted them before the learned Judicial Magistrate Section-30, District Courts, Lahore. In all the said complete investigation reports, recommendations have been made for cancellation of FIRs against all the nominated accused.

16. The concerned FID requested for copies of the complete Investigation Report through letter bearing reference no. No. 2935/2022-FID (L-II1) dated 08.03.2022, but received no reply to it. The area FID after obtaining the complete Investigation Reports, have placed the same before the Board by the area FID through letter No. 3153/2022- DRAP (L-V) dated 14.03.2022 in Case No. 3, letter No. 3210/2022- DRAP (L-V) dated 15.03.2022 in Case No. 4 and through letter No. 13955/2018-DRAP (VIII) dated, 30-10-2018 in Case No. 5.

17. The Board at the outset noted that the scheme of the drug laws provide that the FID undertakes investigation of offenses under the drug laws and FIA merely assists the concerned FID in undertaking investigation. After conclusion of investigations, the FID forwards the Investigation Report to the Central Licensing Board; the Investigation Report by FIA forms a part of the report by the FID. However, in the instant matter, the investigating officers not only refused to hand over their investigation reports to the FID but also presented the same first before the learned Drugs Court, Lahore and then before the learned Judicial Magistrate under Section 30 Cr.P.C., Lahore, which are not only against the law but also caused unnecessary delay in the matter which is of public importance.

18. After perusal of the complete Investigation Reports suggesting cancellation of FIRs, the Board noted that the same had been compiled in pursuance of findings of a report titled 'Inquiry Committee Report' bearing No. Misc/FIA/CCC/L/Report/Everest Pharmaceutical Case/1282 dated 10-08-2020 ('**Inquiry Report**'). It is to be emphasized that the said Inquiry Committee neither associated the complainant FID nor took into consideration the evidence provided by him or his investigation. It was also noted that the FID remained unable to apprise the Inquiry Committee with his version and investigation as he was never informed about the constitution or meeting of the committee, which undoubtedly cast a mark on its functioning and the conclusions drawn by it. It has been concluded by the Hon'ble Court that judicious and transparent investigation is cornerstone of fair trial, therefore, dishonest and biased investigation is violative of constitutionally ensured right to fair trial.

19. The complete text of the Inquiry Report has been reproduced verbatim in the Investigation Report, wherein recommendation has been made for cancellation of the FIRs related to the illegal import of drugs for the following reason:

> "[…]23. Moreover, the registration of 12 FIRs in respect of drug Everlong in the intervening period, when Honorable Lahore High Court Lahore had upheld Everlong's registration and subsequent stay order by Honorable Supreme Court on the same, is not legally tenable and justified. DRAP illegally lodged complaints for registration of these FIRs despite being aware of the factual position regarding the drug Everlong.

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25. It is relevant to mention that allegation of manufacturing of unregistered drugs was also subject matter of primary FIR registered at FIA Anti-Corruption Circle, Islamabad. ”

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It is trite law that only the Hon’ble Courts have the jurisdiction and powers to interpret its judgments and decrees. The Inquiry Report instead of obtaining any clarification or interpretation from the Hon’ble Supreme Court, chose to give its self-serving and wrongful interpretation to the aforementioned Judgment which is not warranted under the law. The above mentioned judgment by the Hon’ble Supreme Court is quite clear and is binding on all under Article 189 of the Constitution of the Islamic Republic of Pakistan, 1973.

21. The complainant FIDs while lodging the FIRs mentioned the drug registration numbers which the nominated accused had been wrongly using to falsely claim that their drugs were registered. The Inquiry Report at no point positively referred to any evidence that the drugs manufactured and sold by the accused were registered under the law. However, the Inquiry Report still makes a confusing claim discrediting the complaint by the FID

that unregistered drugs were being sold by the nominated accused by mentioning false registration numbers.

22. It is also surprising that the Inquiry Report has not highlighted even a single step taken by Inquiry Committee for collecting evidence, facts and data regarding the purported registration of Everlong and other unregistered drugs being manufactured and sold by the accused persons, including investigation of Registration Board's records, which has the statutorily prescribed duty of registering drugs and medicines. Furthermore, FIR No. C-151/2018 dated 17-07-2018 is regarding recovery of unregistered "Everlong tablet" and 'Chill Tablets'. However, both the Inquiry Report and the Investigation Reports (Challan) are silent regarding the aforementioned drugs except Everlong tablet which goes at length to show the limitations marring the investigation.

23. The Inquiry Report has also noted that since the offence of manufacturing and sale of unregistered drugs has been lodged through primary FIR registered at FIA, Islamabad, therefore no FIR could be lodged for the manufacturing and sale of such unregistered drugs anywhere else in Pakistan. The determination as to whether FIR can be lodged or not is a judicial function which cannot be usurped by any investigating agency. The law has by now been settled that the investigating agencies have to merely collect facts regarding an offence without expressing any opinion regarding them. However, the Inquiry Report has been compiled in violation of the settled law and instead of collecting facts regarding the offence, interpreted and gave opinion which were not backed by any concrete facts.

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lacked any legal jurisdiction and power to arrive at conclusions which would assume judicial functions without any proper investigation of facts or discovery of any concrete evidence.

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26. The reference to anonymous higher ups and un-detailed documented 'bitter rivalry' again lacks any concrete evidence. Even otherwise, as discussed above, the offences are evident from the record and any purported bitter rivalry cannot be made the ground for maligning proceedings undertaken against the accused under the law. It is to be noted that most of the accused challenged the instant and other proceedings in a litany of cases before the Hon'ble Lahore High Court as well as Hon'ble Islamabad High Court, but no relief whatsoever were granted in the same; the Hon'ble Courts despite pleadings of the accused did not question lawfulness of the proceedings undertaken by DRAP in pursuance of orders by the Hon'ble Supreme Court.

27. It merits discussion here that the accused Business Concern after Orders by the Hon'ble Supreme Court, tried to obtain relief before the Hon'ble Islamabad High Court, Islamabad. However, the Hon'ble High Court through Order dated 22-07-2020 in W.P. No. 2982 of 2019 was pleased to dismiss the same by holding that granting of any relief to the instant Plaintiff would "amount to interfere with the above order of the August Supreme Court".

28. The Inquiry Report also discharged two of the accused namely Mr. Noor Muhammad Mahr and Mr. Kamran Izhar in Para. No. 27.With regards to Mr. Kamran Izhar, the contention recorded by the Inquiry Report is against the facts and based on complete

misrepresentation. FIA through its two replies submitted before the Hon'ble Lahore High Court, Lahore in W.P. No. 207678 of 2018 through Diary No. 13992 dated 01-10-2018 as well as Diary No. 467 dated 10-01-2019, provided a complete list of evidence linking Kamran Izhar to Everest Pharmaceuticals. Even otherwise, piercing/ lifting of corporate veil has been endorsed by the Hon'ble Supreme Court so that Courts can look behind the corporate attire to identify real person who is exercising and managing the control and the affairs of such body corporate or firm or any combination thereof that is under scrutiny. There is ample evidence linking Mr. Kamran Izhar to the Everest Pharmaceuticals provided in the very reply by FIA filed before the Hon'ble High Court, which has perhaps been ignored by the Inquiry Report. Besides, there is ample evidence available which has been provided to the Investigating Officer linking Mr. Kamran Izhar to the ownership of Everest Pharmaceuticals.

29. With regards to Mr. Noor Muhammad Mahar, he has already been absconder by the learned Drug Court, Islamabad through Order dated: 12-11-2018 in FIR No. 5 of 2018. Perpetual warrants for his arrest have been issued but the same is evading them and is a fugitive from the law. Even FIA through Challan dated 31-12-2018 submitted before the aforementioned Court has held that Mr. Noor Muhammad Mahar is a fugitive from the law and hiding to evade arrest. He has admitted in W.P. No. 517/18 his association with Everest Pharmaceuticals, which prima facie evinces his role.

30. The Board for the aforementioned reasons strongly disagreed with the findings/conclusions by both the Inquiry Report and the Investigation Report and decided that since permission for prosecution has already been granted in the titled matters, the concerned FID is directed to file prosecution against the accused within 15 days with intimation to the Board.

Case No. 06: **SEIZURE OF STOCK UNDER SECTION 18 (1) (F) OF THE DRUGS ACT, 1976 FROM (M/S. HUDABIA INTERNATIONAL SHOP NO. 11-12, JALAL CENTRE, OPP. OPD GATE, SIR GANGA RAM HOSPITAL AND GODOWN, ROOM NO. 07, 2ND FLOOR JALAL CENTRE, OPP. OPD GATE, SIR GANGA RAM HOSPITAL, LAHORE (C-139/2018).**

Proceedings of 260th meeting of CLB.

Mr. Abdul Rashid Shaikh FID-IV Lahore 260th meeting of the Board informed regarding the visit of M/s Hudabia International, Shop No. 11-12, Jalal Center, Opp. Gate Sir Ganga Ram Hospital and Godown room No. 07, 02nd floor, Jalal Center, Opp. OPD gate Sir Ganga Ram Hospital Lahore along with Mr. Ajmal Sohail Asif, FID Lahore, Hafiz Jawad Ali, Assistant Director, DRAP Lahore and Dr. Akbar Ali, Assistant Director, DRAP, Lahore, wherein following products were seized:-

Sr. No.	Name of Drug (s)	Batch No.	Mfg. Date	Exp. Date	Mfg. by	Quantity
01.	Reap Capsules Reg. No. 068804	367	10-17	04-19	M/s. Everest Pharmaceuticals 124-Industrial Tiangle, Islamabad	30 Capsules
02.	Vasocath Cannula (Un-registered)	-	-	-	-	16

02. The Board granted Permission for safe custody of the seized stocks of therapeutic goods/drugs was allowed to the FID by the Board in the said meeting moreover, the Board also granted permission for registration of FIR to area FID Lahore against the following accused persons:

i. M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.
ii. Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad
iii. Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad
iv. Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad
v. Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad
vi. Mian Ishtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad
vii. Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranties on behalf of M/s Everest Pharmaceuticals Islamabad

Current progress of the case:

03. Federal Inspector of Drugs-IV Lahore vide letter No. 3246/2022-DRAP (L-IV) dated 15-03-2022 wherein FID-IV submitted as under:

"Reference is made to DRAP Islamabad's letter No. F.03-26/2018-QC (260-CLB) dated 10-05-2018. Wherein, undersigned was directed to lodge FIR against M/s Everest Pharmaceuticals Accordingly, the application for lodging FIR against management of M/s Everest Pharmaceuticals was submitted in the office of the Director, FIA Lahore.

2. Details of the application for lodging FIR, FIR Number and status of the inquiry is given below:

Sr.#	Letter No. and Date	FIR No. and Date	Status
1.	7250/201 S-DRAP-(L-VI) 25.05.2018	FIR No. C-139/2018 dated 29-06-2018	Complete case sent to CLB vide this office letter No. 3878/2018-DRAP (L-VI) dated 21-03-18

3. FIA Corporate Crime Circle, Lahore registered FIR as per above table against following accused:

a) M/s. Everest Pharmaceuticals, Islamabad, through owner, Ch. Muhammad Usman.
b) Ch. Muhammad Usman (owner), M/s. Everest Pharmaceuticals, Islamabad.
c) Dr. Kamran Izhar (Partner), M/s. Everest Pharmaceuticals, Islamabad.
d) Noor Muhammad Mehar (Partner), M/s. Everest Pharmaceuticals, Islamabad.
e) Ch. Muhammad Usman, Production Incharge, M/s. Everest Pharmaceuticals, Islamabad.
f) Mian Ishtiaq Ahmed, Quality Control Incharge, M/s. Everest Pharmaceuticals, Islamabad.
g) Warrantor M/s. Everest Pharmaceuticals, Islamabad who signed and issued above mentioned false warranties on behalf of M/s. Everest Pharmaceuticals, Islamabad.

4. The complete case was sent to CLB, DRAP, Islamabad vide this office letter No. 3878/2018-DRAP (L-VI) dated, 21-03-2018.

5. FIA Corporate Crime Circle, Lahore was requested to provide final investigation reports/complete challans in respect to above FIR vide this office letter No. 3153/2022- DRAP (L-V) dated 14.03.2022, but no response is received yet.

6. However, today, Mr. Hafiz Bilal Bin Akbar, AD Legal communicated a FIRs cancellation report submitted by FIA in the Court of Senior Civil Judge (Criminal Division) Lahore with respect to FIRs. Therefore, in all such FIRs of FIA CCC Lahore submitted report that proprietor and/or management of the firm should be discharged and cancellation report should be submitted under section 173 Cr.Pc".

7. Therefore keeping in view the facts that accused persons nominated as earlier have committed offence of manufacturing and sale of un-registered drugs and the stance of FIA in above mentioned case is being referred to Central Licensing Board as required under Schedule-V of the DRAP Act 2012 to seek further orders as to the action to be taken in respect of contraventions of the Act as mentioned above.

8. Submitted for further necessary action and directions, please."

12. Reference to para 6 of FIDs letter, the mentioned complete challan is placed as Annex-A.

13. In the light of challan of FIA and request of area FID Lahore, the matter is submitted for the opinion/orders of the Board.

PROCEEDINGS AND DECISION OF THE 285TH MEETING OF THE BOARD:

14. The Central Licensing Board in light of the aforementioned facts undertook a detailed discussion of the FIRs and their current status of investigation. Hafiz Bilal bin Akbar, Assistant Director (Legal Affairs) DRAP assisted the Board. The Board noted that incomplete Investigation Reports were provided by the Investigation Officers of FIA to the concerned Federal Inspector of Drugs, following which the Board decided to issue permission to institute prosecution after following the process prescribed under the law.

15. The Board has been informed that the Investigating Officer of FIA have compiled complete investigation reports under Section 173 of the Code of Criminal Procedure, 1898 ('**Cr.P.C.**'), and instead of handing them over to the area Federal Inspector of Drugs ('**FID**'), have submitted them before the learned Judicial Magistrate Section-30, District Courts, Lahore. In all the said complete investigation reports, recommendations have been made for cancellation of FIRs against all the nominated accused.

16. The concerned FID requested for copies of the complete Investigation Report through letter bearing reference no. No. 2935/2022-FID (L-II1) dated 08.03.2022, but received no reply to it. The area FID after obtaining the complete Investigation Reports, have placed the same before the Board by the area FID through letter No. 3153/2022- DRAP (L-V) dated 14.03.2022 in Case No. 3, letter No. 3210/2022- DRAP (L-V) dated 15.03.2022 in Case No. 4 and through letter No. 13955/2018-DRAP (VIII) dated, 30-10-2018 in Case No. 5.

17. The Board at the outset noted that the scheme of the drug laws provide that the FID undertakes investigation of offenses under the drug laws and FIA merely assists the concerned FID in undertaking investigation. After conclusion of investigations, the FID forwards the Investigation Report to the Central Licensing Board; the Investigation Report by FIA forms a part of the report by the FID. However, in the instant matter, the

investigating officers not only refused to hand over their investigation reports to the FID but also presented the same first before the learned Drugs Court, Lahore and then before the learned Judicial Magistrate under Section 30 Cr.P.C., Lahore, which are not only against the law but also caused unnecessary delay in the matter which is of public importance.

18. After perusal of the complete Investigation Reports suggesting cancellation of FIRs, the Board noted that the same had been compiled in pursuance of findings of a report titled 'Inquiry Committee Report' bearing No. Misc/FIA/CCC/L/Report/Everest Pharmaceutical Case/1282 dated 10-08-2020 ('**Inquiry Report**'). It is to be emphasized that the said Inquiry Committee neither associated the complainant FID nor took into consideration the evidence provided by him or his investigation. It was also noted that the FID remained unable to apprise the Inquiry Committee with his version and investigation as he was never informed about the constitution or meeting of the committee, which undoubtedly cast a mark on its functioning and the conclusions drawn by it. It has been concluded by the Hon'ble Court that judicious and transparent investigation is cornerstone of fair trial, therefore, dishonest and biased investigation is violative of constitutionally ensured right to fair trial.

19. The complete text of the Inquiry Report has been reproduced verbatim in the Investigation Report, wherein recommendation has been made for cancellation of the FIRs related to the illegal import of drugs for the following reason:

> "[…]23. Moreover, the registration of 12 FIRs in respect of drug Everlong in the intervening period, when Honorable Lahore High Court Lahore had upheld Everlong's registration and subsequent stay order by Honorable Supreme Court on the same, is not legally tenable and justified. DRAP illegally lodged complaints for registration of these FIRs despite being aware of the factual position regarding the drug Everlong.
>
> 24. In the similar vein, registration of remaining 02 FIRs in respect of alleged unregistered/deregistered drugs, it has been observed that in most FIRs, registration numbers of alleged unregistered drugs are also mentioned. If a drug is alleged to be unregistered or deregistered, it is cannot have a registration number. DRAP has so far failed to substantiate this factum stated in these FIRs. The same has been discussed at length in the Report of three member Committee headed by the ADG Immigration tasked to look into the matter. The report of the said committee highlights glaring loopholes in the Drug Registration record of DRAP

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The meeting ended with the vote of thanks to and by the chair.