MINUTES OF 286th MEETING OF CENTRAL LICENSING BOARD HELD ON 11th May, 2022.

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286th meeting of the Central Licensing Board (CLB) was held on 11th May, 2022 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad. Mr. Abid Ali, Law Expert, Ministry of Law & Justice Division, Islamabad /Member Central Licensing Board, Drug Regulatory Authority of Pakistan, Islamabad presided the meeting in the absence of Chairman as provided under Rule 8(8) of the Drugs (Licensing, Registering &Advertising) Rules, 1976. Following members attended the meeting:-

S.No	Name & Designation	Status
1.	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Balochistan, Quetta	Member
2.	Mr. Mohammad YunasKhattak, Chief Inspector of Drugs, Peshawar Government of Khyber Pahtunkwa	Member
3.	Mr Ali Raza, Drug Controller, Primary and Secondary Health Department, Government of Punjab,	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.	Mr Khalid Muneer, Representative of PPPMA	Observer
8.	Mr.Nadeem Alamgir, Representative of Pharma Bureau.	Observer
9.	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) 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 285th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 285th meeting of the Central Licensing Board (CLB) held on 17th and 18th March, 2022.

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

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

S #	Name of the firm	Date of Inspection /	Ranking/ Evaluation	Inspection Panel Members
1	M/s Pharman Pharmaceuticals (Pvt) Ltd., Khewat No. 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala. Sections (03): i. Tablet Section (General). ii. Capsule Section (General). iii. Oral Liquid Section (General).	11-04-2022	Good	Prof. Dr. Mehmood Ahmad, Expert Member. Ch. M. Shamoon, Expert Member. Aisha Irfan, FID, DRAP, Lahore.
	"In view of above inspection proceedings and facilities verified, such as company profile, building, material management, production, in-process controls, Quality Control testing, machinery / equipment, air handling, water treatment system, personnel and documentation etc, thepanel recommend the new Drug Manufacturing License to M/s Pharman Pharmaceuticals (Pvt) Ltd., Khewat No. 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala by way of formulation for the following sections only:- 1. Tablet Section (General). 2. Capsule Section (General). 3. Oral Liquid Section (General). **Decision of the Central Licensing Board in 286th meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Pharman Pharmaceuticals (Pvt) Ltd., Khewat No. 59, Khatooni No. 114-120, Tehsil Wazirabad, District Gujranwala on the recommendations of the panel of experts for the following sections: 1. Tablet Section (General). 2. Capsule Section (General). 3. Oral Liquid Section (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 D-Haans Pharma (Pvt) Ltd., Plot No. 9/A, Industrial Estate, Bhimber, AJK**,** DML No. 000912 (Formulation)	**29-03-2022**	**Good**	i. Additional Director (PE&R), DRAP, Islamabad, ii. FID, DRAP, Islamabad, iii. Mr. Muhammad Yaqoob Kakar, Assistant Director, DRAP, Islamabad.
	Recommendations of the panel: "Keeping in view the facts n record and people met during the visit, the panel unanimously recommended the approval of following two additional sections by way of formulation to M/s D-Haans Pharma (Pvt) Ltd., Plot No. 9/A, Industrial Estate, Bhimber, AJK **(DML No. 000912 by way of formulation);** i. Oral Powder Section (Penicillin) - Veterinary. ii. Liquid Injection (Veterinary) **Decision of the Central Licensing Board in 286th meeting:** The Board considered and approved the grant of following additional sections in the name of M/s D-Haans Pharma (Pvt) Ltd., Plot No. 9/A, Industrial Estate, Bhimber, AJK (DML No. 000912 by way of formulation) on the recommendations of the panel of experts: i. Oral Powder Section (Penicillin) - Veterinary. ii. Liquid Injection (Veterinary)			
2	M/s. Farm Aid Group, Plot No.3/2, Phase-I&II, Hattar Industrial Estate, Haripur**,** DML No.000298 (Formulation)	**15-04-2022**	**Good**	i. Additional Director (PE&R), DRAP, Peshawar, ii. FID, DRAP, Peshawar, iii. 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, Microbiology Lab and allied facilities, the panel is of the view that the firm is operating at Good Leve of cGMP compliance and unanimously recommended grant or renewal of Drug Manufacturing License from 25.1032020 to the firm from for following already approved section as well as **additional section&** revised section as per DRAP Islamabad letter No. F. 3-9/91-Lic (Vol-II) dated 01.02.2022;

Sr. No	Name of Section	Sr. No	Name of Section
1	Oral Powder (General-Veterinary-)-**Revised**	2	Oral Liquid section (General-Veterinary) - **Revised**
3	Oral Bolus Section (General-Veterinary)- **Revised**	4	Steroid Injection (Veterinary)-**Additional'**
5	Oral Powder Section-II (General-Veterinary) - **Additional**	6	Liquid Injection Section (General-Veterinary)- **Additional**

Decision of the Central Licensing Board in 286th meeting:

During the meeting, secretariat of CLB apprised that as per approved and existing layout plan, following additional section was approved in new block-B of the premises. However, inadvertently names of the said section were mentioned as "Revised" instead of "additional" section in Layout plan approval letter. Same was reflected in the panel of expert and inspection report thereof.Therefore, the Board after considering the facts and perusal of the record, approved the grant following six (6) additional sections in the of name M/s. Farm Aid Group, Plot No.3/2, Phase-I&II, Hattar Industrial Estate, Haripur, DML No.000298 (Formulation) on the recommendations of the panel of experts:

Block-B			
Sr. No	**Name of Section**	**Sr. No**	**Name of Section**
1	Oral Powder-II (General-Veterinary-)- **Additional**	2	Oral Powder Section-III (General-Veterinary) - **Additional**
3	Oral Liquid -II (General-Veterinary) - **Additional**	4	Steroid Injection (Veterinary)-**Additional'**
5	Oral Bolus -II (General-Veterinary)- **Additional**	6	Liquid Injection Section (General-Veterinary)- **Additional**

3	M/s Pharma Lord (Pvt) Ltd., 12-KM Lahore Road Layyah. DML No. 000774 (Formulation) **Section (01):** i. Capsule (Oncology)	**24-03-2022**	**Good**	2. Mrs. Majida Mujahid, Additional Director (E&M), DRAP, Lahore. 3. Mr. Ajmal Sohail, Asif, FID, DRAP, Lahore. 4. Ms. Mehwish Jamil, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "The panel of inspectors recommends the grant of additional section as mentioned below under Drug Manufacturing License bearing No. 000774 issued in favour of M/s Pharma Lord (Pvt) Ltd., 12-KM Lahore Road Layyah:- 1. Capsule (Oncology. **Decision of the Central Licensing Board in 286th meeting:** The Board considered and approved the grant of following sections in the name M/s Pharma Lord (Pvt) Ltd., 12-KM Lahore Road Layyah**,** DML No.000774 (Formulation) on the recommendations of the panel of experts: 1. Capsule (Oncology)			
4	M/s Indus Pharma (Pvt) Ltd, Plot No. 26-27, 63-67, Sector 27, Korangi Industrial Area, Karachi. DML No.000124 (Formulation) Section (03): 1. Tablet (General) – Revised 2. Tablet (Psychotropic) – Regularization 3. Liquid Ampoule SVP (Psychotropic) – Regularization	**28-3-2022**	**Good**	1) Additional Director (E&M)/FID, DRAP, Karachi 2) Ms. SanamKausar, Assistant Director, DRAP, Karachi
	Recommendations of panel : "M/S Indus Pharma (Pvt.) Ltd. Plots No. 26, 27, 63, 64, 65, 66 & 67, Sector-27, Korangi Industrial Area, Karachi was inspected by the panel in connection with the Revised/Regularized Section of Tablet (General) Section - Revised, Tablet (Psychotropic) – Regularized Liquid Ampoule SVP (Psychotropic) - Regularized Under manufacturing License No. 000124 (Formulation) as per direction DRAP Islamabad Letter no: F.213/85-Lic (Vo-V) dated 25th March 2022. Following are the			

	observations/comments: Panel inspected the firm in detail and observe that the firm was observed maintained as per the layout plan approved by the DRAP Authorities vide letter No. F.2-13/85-Lic (Vol-V) dated 15th March 2022 (Annex-E). Manufacturing and quality control facilities were observed well equipped required for the production and test/analysis of the products registered in the name of firm. Adequate resources interms of qualified persons was seen available on site. HVAC system seen installed and operational in all the sections. Based on the people met, document reviewed and observations made during the inspection, panel recommends grant of revised/regularized sections as mentioned below:: 1. Tablet (General) Section-Revised 2. Tablet (Psychotropic)-Regularized 3. Liquid Ampoule SVP (Psychotropic)-Regularized **Decision of the Central Licensing Board in 286th meeting:** The Board considered and approved the grant of following sections in the name M/s Indus Pharma (Pvt) Ltd, Plot No. 26-27, 63-67, Sector 27, Korangi Industrial Area, Karachi**,** DML No. 000124 (Formulation) on the recommendations of the panel of expertssubject 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: i. Tablet (General) Section-Revised ii. Tablet (Psychotropic)-Regularized iii. Liquid Ampoule SVP (Psychotropic)-Regularized			
5	M/s Atco Laboratories Ltd, B-18, S.I.T.E. Karachi DML No.000188 (Formulation) **Section (05):** 1. Liquid Injection-General(Second Floor **(New)** 2. Eye/Ear/Nasal Drops and Nebulizers/Inhalation Solution-General (Second Floor)-**New** 3. Quality Control Laboratory (Third and Fourth Floor) New 4. R&D Laboratory-Fifth Floor **(New)** 5. Quality Assurance	**22-3-22**	**Good**	1) Prof. Dr Abdullah Dayo -Expert Member. 2) Federal Inspector of Drugs, DRAP, Islamabad. 3) Mr. Affan Ali, AD, CDL, Karachi.

	Laboratory and Stability Chamber Area(6th Floor-**New)**			

Recommendations of panel :

"Panel unanimously recommend the regularization of the layout plan, renewal of DML No. 000118 by way of Formulation and addition of new sections to the firm M/s Atco Laboratories Ltd B-18, S.I.T.E, Karachi for following sections:

S#	Name of Section (s)	S#	Name of Section (s)
Unit-I			
1	Raw Material Store (Ground Floor)	2	Packing Material Store (Ground Floor)
3	Enema General (First Floor)	4	Liquid Injection-General (First Floor)
5	Eye/Ear/Nasal Drops-General (First Floor)	6	Quality Control Lab (First Floor)
7	R&d Laboratory (First Floor)	8	Finished Good Store (Ground Floor)
Unit-II			
1	Oral Liquid Section General (Ground Floor)	2	Cream/Ointment-General (Ground Floor)
3	Gel-General (Ground Floor)	4	Tablet Section-General (First Floor)
5	Capsule Section-General (First Floor)	6	Dry Powder Suspension-General(First Floor)
7	Dry Powder Sachet-General(First Floor)	8	Cream/Ointment-General(Second Floor)
9	Liquid Injection-General(Second Floor (New)	10	Eye/Ear/Nasal Drops and Nebulizers/Inhalation Solution-Genera (Second Floor)-New
11	Packaging Section (Second Floor)	12	Raw Material Store (Ground Floor)
Unit-III			
1	Quality Control Laboratory (Third and Fourth Floor) New	2	R&D Laboratory-Fifth Floor (New)

	3	Quality Assurance Laboratory and Stability Chamber Area(6th Floor-New)		******** **********	

Decision of the Central Licensing Board in 286th meeting:

The Board considered and approved the grant of following additional sections in the name M/s Atco Laboratories Ltd, B-18, S.I.T.E. KarachiDML No. 000188 (Formulation) on the recommendations of the panel of experts:

1. Liquid Injection-General(Second Floor **(New)**
2. Eye/Ear/Nasal Drops and Nebulizers/Inhalation Solution-General (Second Floor)-**New**
3. Quality Control Laboratory (Third and Fourth Floor) New
4. R&D Laboratory-Fifth Floor **(New)**
5. Quality Assurance Laboratory and Stability Chamber Area(6th Floor-**New)**

6	M/s Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore DML No. 000783 (Formulation) **Sections (07):** 1. Capsule (Cephalosporin) – **New** 2. Dry Powder Suspension (Cephalosporin) – **New** 3. Dry Powder Injection (Cephalosporin) – **New** 4. Cream/Ointment/Lotion/Gel (General)- New 5. Drench (General) New-Vet 6. Dry Powder (General) – Veterinary- New 7. Bolus (General) – Vet-New	**21-03-2022**	**Good**	1) Dr. Ikram ul Haq – Expert Member 2) Dr. Mehmood Ahmad- Ex Dean IUB 3) FID, DRAP, Lahore. 4) Ms. Mehwish Jameel, DRAP, Lahore

Recommendations of panel :

"Based on the section and areas inspected, the personnel interacted with, discussion held during the course of inspection the documents reviewed and, considering the findings of the inspection the panel recommends the renewal of DML and grant of additional sections of M/s Wimits Pharmaceutical, Plot No. 129, Sunder Industrial Estate, Lahore for following sections namely:

Renewal Sections:

Sr. No	*Human Sections*	*Sr. No*	*Veterinary Sections*	
1.	*Liquid Injectable (General) Ampoule*	*5.*	*Drench (General)*	
2.	*Oral Liquid (General)*	*6.*	*Liquid Injectable (General)*	
3.	*Tablet (General)*	*7.*	*Bolus (General)*	
4.	*Capsule (General)*	*8.*	*Oral Dry Powder (General)*	

Additional Section:

Sr. #	***Cephalosporin (Human)***
1.	*Capsule (Cephalosporin)*
2.	*Dry Powder Injectable (Cephalosporin)*
3.	*Dry Powder Suspension (Cephalosporin)*
	Topical
4.	*Semi-Solid (Cream/Ointment/Lotion/Gel)*
	Veterinary
5.	*Drench (General)*
6.	*Dry Powder (General)*
7.	*Bolus (General)*

Decision of the Central Licensing Board in 286th meeting:

The Board considered and approved the grant of following sections in the name M/s WimitsPharmaceuticals, Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore**,** DML No.000783 (Formulation) on the recommendations of the panel of experts:

1. Capsule (Cephalosporin) – **New**
2. Dry Powder Suspension (Cephalosporin) – **New**
3. Dry Powder Injection (Cephalosporin) – **New**
4. Cream/Ointment/Lotion/Gel (General)- New
5. Drench (General)-IIVet-New
6. Dry Powder (General)-II – Veterinary- New
7. Bolus (General)-II – Vet-New

The panel was also given mandate for inspection of the firm for renewal of Aerosol (General)-Veterinary section however, recommendations of the panel regarding renewal of said section are not mentioned.

	The production is said section shall remain suspended till clarification from company and the panel.

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. Farm Aid Group, Plot No.3/2, Phase-I&II, Hattar Industrial Estate, Haripur**,** DML No.000298 (Formulation) Period: Commencing on 25-10-2020 ending 24-10-2025	**15-04-2022**	**Good**	i. Additional Director (PE&R), DRAP, Peshawar, ii. FID, DRAP, Peshawar, iii. Mr. Adnan Shahidullah, Assistant Director, DRAP, Peshawar.

Recommendations of the panel:

RECOMMENDATIONS:

Based on documentation reviewed, technical/management people met, materials / processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, Microbiology Lab and allied facilities, the panel is of the view that the firm is operating at Good Leve of cGMP compliance and unanimously recommended grant or renewal of Drug Manufacturing License from 25.1032020 to the firm from for following already approved section as well as additional section & revised section as per DRAP Islamabad letter No. F. 3-9/91-Lic (Vol-II) dated 01.02.2022;

Sr. No	Name of Section	Sr. No	Name of Section
1	Oral Powder (General-Veterinary-)-**Revised**	2	Oral Penicillin Powder Section (Penicillin Veterinary)-**Revised**
3	Oral Liquid section (General-Veterinary) - **Revised**	4	Quality Control Laboratory - **Revised**
5	Oral Bolus Section (General-Veterinary)- **Revised**	6	Micro Laboratory- **Revised**
7	Oral Powder Section-II (General-Veterinary) - **Additional**	8	Steroid Injection (Veterinary)- **Additional'**

	9	Tablet (Human-General)- **Renewal**	10	Capsule (Human-General)- **Renewal**
	11	Liquid Injection Section (General-Veterinary)- **Additional**		

Decision of the Central Licensing Board in 286th meeting:

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

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

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

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

2	M/s Nawan Laboratories (Pvt) Ltd, 136, Sector 15, Korangi Industrial rea, Karachi. DML No.000442 (Formulation) **Period: Commencing on 28-06-2021 & Ending 27-06-2026**	**31-03-2022**	**Good**	3) Prof. Abdullah Dayo, Expert Member 4) Federal Inspector of Drugs, DRAP, Karachi. 5) Mr. Krishan Das, Assistant Director, DRAP, Karachi 1.

Recommendations of panel :

"Based on the stated facts and keeping in view the attitude of the of the management towards continuous improvements the panel unanimously recommends the grant of renewal of DML 000442(Formulation) for the next five years for following sections:

S#	Name of Section (s)	S#	Name of Section (s)
1	Tablet (General)	2	Capsule (General)
3	Dry Powder Suspension (Cephalosporin)	4	Sachet (General)
5	Oral Liquid (General)	6	Capsule (Cephalosporin)
7	Dry Powder Suspension (Cephalosporin)	8	Sterile Dry Powder Injection (Cephalosporin)
9	Sterile Liquid Injection (Cephalosporin)Vet	10	Dry Powder Injection (Penicillin) Vet
11	Sterile Liquid Injection (Penicillin) Vet	12	Dry Powder Sachet (Penicillin) Vet
13	Liquid Injection (Vet)	14	Oral Liquid Syrup sachet (Vet)
15	Dry Powder Sachet (Vet)	16	Tablet Bolus (Vet)

Decision of the Central Licensing Board in 286th meeting:

The Board considered and approved the grant of renewal of DML No. 000442 by way of Formulation in the name of M/s Nawan Laboratories (Pvt) Ltd, 136, Sector 15, Korangi Industrial rea, Karachi**,** on the recommendations of the panel of experts for the period Commencing on 28-06-2021 & Ending 27-06-2026for the following section: -

S#	Name of Section (s)	S#	Name of Section (s)
1	Tablet (General)	2	Capsule (General)
3	Dry Powder Suspension (Cephalosporin)	4	Sachet (General)
5	Oral Liquid (General)	6	Capsule (Cephalosporin)
7	Dry Powder Suspension (Cephalosporin)	8	Sterile Dry Powder Injection (Cephalosporin)
9	Sterile Liquid Injection (Cephalosporin)Vet	10	Dry Powder Injection (Penicillin) Vet
11	Sterile Liquid Injection (Penicillin) Vet	12	Dry Powder Sachet (Penicillin) Vet
13	Liquid Injection (Vet)	14	Oral Liquid Syrup sachet (Vet)
15	Dry Powder Sachet (Vet)	16	Tablet Bolus (Vet)

3	M/s Ophth Pharma (Pvt) Ltd, Plot No. 241, Sector 24, Korangi Industrial Area, Karachi.	**24-03-2022**	**Good**	1) Mr. Qaiser Muhammad, Expert Member

<table>
<tr><td></td><td>DML No. 000488 (Formulation)

Period: Commencing on 05-05-2021 & Ending 04-05-2026</td><td></td><td></td><td>2) Federal Inspector of Drugs, DRAP, Karachi.
3) Mr. Krishan Das, Assistant Director, DRAP, Karachi</td></tr>
<tr><td></td><td colspan="4">Recommendation of panel :

“Based on the people met, documents reviewed and considering the finding of the physical inspection, panel recommends the grant of renewal of Drug manufacturing License (Formulation) and regularization of layout plan of the following sections:

<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>Eye/Ear Drops (General)</td><td>2</td><td>Sterile Eye Ointment/ Topical Cream (General)</td></tr>
<tr><td>3</td><td>Liquid Injection (General)</td><td>4</td><td>Injection (Steroid)</td></tr>
<tr><td>5</td><td>Eye/Ear Drops (Steroid)</td><td>6</td><td>Eye Ointment/ Topical Cream (Steroid)</td></tr>
</table>

<u>Decision of the Central Licensing Board in 286th meeting:</u>

The Board considered and approved the grant of renewal of DML No. 000488 by way of Formulation in the name of M/s Ophth Pharma (Pvt) Ltd, Plot No. 241, Sector 24, Korangi Industrial Area, Karachi, on the recommendations of the panel of experts for the period Commencing 05-05-2021 & Ending 04-05-2026 for the following section: -

<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>Eye/Ear Drops (General)</td><td>2</td><td>Sterile Eye Ointment/ Topical Cream (General)</td></tr>
<tr><td>3</td><td>Liquid Injection (General)</td><td>4</td><td>Injection (Steroid)</td></tr>
<tr><td>5</td><td>Eye/Ear Drops (Steroid)</td><td>6</td><td>Eye Ointment/ Topical Cream (Steroid)</td></tr>
</table>
</td></tr>
<tr><td>4</td><td>M/s Atco Laboratories Ltd, B-18, S.I.T.E. Karachi

DML No.000188 (Formulation)

Period: s</td><td>22-3-22</td><td>Good</td><td>4) Prof. Dr Abdullah Dayo - Expert Member.
5) Federal Inspector of Drugs, DRAP, Islamabad.
Mr. Affan Ali, AD, CDL, Karachi.</td></tr>
</table>

Recommendations of panel :

"Panel unanimously recommend the regularization of the layout plan, renewal of DML No. 000118 by way of Formulation and addition of new sections to the firm M/s Atco Laboratories Ltd B-18, S.I.T.E, Karachi for following sections:

S#	Name of Section (s)	S#	Name of Section (s)
Unit-I			
1	Raw Material Store (Ground Floor)	2	Packing Material Store (Ground Floor)
3	Enema General (First Floor)	4	Liquid Injection-General (First Floor)
5	Eye/Ear/Nasal Drops-General (First Floor)	6	Quality Control Lab (First Floor)
7	R&d Laboratory (First Floor)	8	Finished Good Store (Ground Floor)
Unit-II			
1	Oral Liquid Section General (Ground Floor)	2	Cream/Ointment-General (Ground Floor)
3	Gel-General (Ground Floor)	4	Tablet Section-General (First Floor)
5	Capsule Section-General (First Floor)	6	Dry Powder Suspension-General(First Floor)
7	Dry Powder Sachet-General(First Floor)	8	Cream/Ointment-General(Second Floor)
9	Liquid Injection-General(Second Floor (New)	10	Eye/Ear/Nasal Drops and Nebulizers/Inhalation Solution-General (Second Floor)-New
11	Packaging Section (Second Floor)	12	Raw Material Store (Ground Floor)
Unit-III			
1	Quality Control Laboratory (Third and Fourth Floor) New	2	R&D Laboratory-Fifth Floor (New)
3	Quality Assurance Laboratory and Stability Chamber Area(6th Floor-New)		**********

<u>Decision of the Central Licensing Board in 286th meeting:</u>

The Board considered and approved the grant of renewal of DML No. 000188 by way of Formulation in the name of M/s Atco Laboratories Ltd, B-18, S.I.T.E. Karachi on the recommendations of the panel of experts for the period Commencing on 11-04-2021 & Ending

	10-04-2026 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 10/11/2020for the following sections :: -			

S#	Name of Section (s)	S#	Name of Section (s)
	Unit-I		
1	Raw Material Store (Ground Floor)	2	Packing Material Store (Ground Floor)
3	Enema General (First Floor)	4	Liquid Injection-General (First Floor)
5	Eye/Ear/Nasal Drops-General (First Floor)	6	Quality Control Lab (First Floor)
7	R&d Laboratory (First Floor)	8	Finished Good Store (Ground Floor)
	Unit-II		
1	Oral Liquid Section General (Ground Floor)	2	Cream/Ointment-General (Ground Floor)
3	Gel-General (Ground Floor)	4	Tablet Section-General (First Floor)
5	Capsule Section-General (First Floor)	6	Dry Powder Suspension-General(First Floor)
7	Dry Powder Sachet-General(First Floor)	8	Cream/Ointment-General(Second Floor)
9	Liquid Injection-General(Second Floor (New)	10	Eye/Ear/Nasal Drops and Nebulizers/Inhalation Solution-General (Second Floor)-New
11	Packaging Section (Second Floor)	12	Raw Material Store (Ground Floor)
	Unit-III		
1	Quality Control Laboratory (Third and Fourth Floor) New	2	R&D Laboratory-Fifth Floor (New)
3	Quality Assurance Laboratory and Stability Chamber Area(6th Floor-New)		**********

5	M/s Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore DML No. 000783 (Formulation) **Period: Commencing on 03-02-2019 & Ending 02-02-2024**	**21-03-2022**	**Good**	5) Dr. Ikram ul Haq – Expert Member 6) Dr. Mehmood Ahmad-Ex Dean IUB 7) FID, DRAP, Lahore. 1. Ms. Mehwish Jameel, DRAP, Lahore

Recommendations of panel :

"Based on the section and areas inspected, the personnel interacted with, discussion held during the course of inspection the documents reviewed and, considering the findings of the inspection the panel recommends the renewal of DML and grant of additional sections of M/s Wimits Pharmaceutical, Plot No. 129, Sunder Industrial Estate, Lahore for following sections namely:

Renewal Sections:

Sr. No	***Human Sections***	***Sr. No***	***Veterinary Sections***
5.	*Liquid Injectable (General) Ampoule*	*9.*	*Drench (General)*
6.	*Oral Liquid (General)*	*10.*	*Liquid Injectable (General)*
7.	*Tablet (General)*	*11.*	*Bolus (General)*
8.	*Capsule (General)*	*12.*	*Oral Dry Powder (General)*

Additional Section:

Sr. #	***Cephalosporin (Human)***
8.	*Capsule (Cephalosporin)*
9.	*Dry Powder Injectable (Cephalosporin)*
10.	*Dry Powder Suspension (Cephalosporin)*
	Topical
11.	*Semi-Solid (Cream/Ointment/Lotion/Gel)*
	Veterinary
12.	*Drench (General)*
13.	*Dry Powder (General)*
14.	*Bolus (General)*

Decision of the Central Licensing Board in 286th meeting:

The Board considered and approved the grant of renewal of DML No. 000783 by way of Formulation in the name of M/s Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore**,** on the recommendations of the panel of experts for the period Commencing **on 03-02-2019 & Ending 02-02-2024** for the following sections: -

Sr. No	***Human Sections***	***Sr. No***	***Veterinary Sections***
1	*Liquid Injectable (General) Ampoule*	*1*	*Drench (General)*

		2	*Oral Liquid (General)*	*2*	*Liquid Injectable (General)*
		3	*Tablet (General)*	*3*	*Bolus (General)*
		4	*Capsule (General)*	*4*	*Oral Dry Powder (General)*

6	M/s Magns Pharmaceuticals, Plot No. 7-B, Value Addition City, Sahianwala Road, Khurrainwala, Faisalabad. DML No.000849 (Formulation). Period: Commencing on 25-11-2021 & ending on 24-11-2026.	**11-03-2022**	**Good**	2. Mr. Nadeem Iqbal, Expert Member. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 4. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore.
	<u>Recommendations of the Panel:</u> "The panel of inspectors **recommends** the renewal of DML bearing No. 000849 issued in favour of M/s MAGNS Pharmaceuticals, Plot No. 7-B, Value Addition City, Sahianwala Road, Khurrainwala, Faisalabad for following sections: - i. Tablet Section (General). ii. Capsule Section (General). iii. Dry Powder Suspension Section (General). **<u>Decision of the Central Licensing Board in 286th meeting:</u>** The Board considered and approved the grant of renewal of DML No. 000849 by way of Formulation in the name of M/s MAGNS Pharmaceuticals, Plot No. 7-B, Value Addition City, Sahianwala Road, Khurrainwala, Faisalabadon the recommendations of the panel of experts for the period Commencing on 25-11-2021 & ending on 24-11-2026 for the following sections: - i. Tablet Section (General). ii. Capsule Section (General). iii. Dry Powder Suspension Section (General).			
7	M/s Genetics Pharmaceuticals (Pvt) Ltd, Plot No. 539-A, Sunder Industrial Estate, Lahore. DML No.000845 (Formulation). Period: Commencing on 25-08-2021 & ending on 24-08-2026.	**25-03-2022**	**Good**	1. Mr. Muhammad Shamoon, Expert Member. 2. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Ufaq Tanveer Butt, Assistant Director, DRAP, Lahore.
	<u>Recommendations of the Panel:</u> **"**Keeping in view the facilities i.e, building, equipment, HVAC, Quality Control, Quality Assurance, Personnel etc., the panel of inspectors **recommend** the Renewal of Drug Manufacturing License to manufacture the drugs by way of formulation to M/s Genetics			

	Pharmaceuticals (Pvt) Ltd, Plot No. 539-A, Sunder Industrial Estate, Lahore with respect to the following sections: - i. Tablet (General). ii. Capsule (General). **Decision of the Central Licensing Board in 286th meeting:** The Board considered and approved the grant of renewal of DML No. 000845 by way of Formulation in the name of M/s Genetics Pharmaceuticals (Pvt) Ltd, Plot No. 539-A, Sunder Industrial Estate, Lahoreon the recommendations of the panel of experts for the period Commencing on 25-08-2021 & ending on 24-08-2026. for the following sections: - i. Tablet Section (General). ii. Capsule Section (General).			
8	M/s Moreno Iglisias Research Laboratories (Pvt) Ltd, 21-Km, Ferozepur Road, Lahore. DML No.000478 (Formulation). Period: Commencing on 02-09-2020 & ending on 01-09-2025.	**31-03-2022**	**Good**	1. Ms. Majida Mujahid, Additional Director (E&M), DRAP, Lahore. 2. Ms. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Anam Saeed, Assistant Director, DRAP, Lahore.
	Recommendations of the Panel: "In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery / equipment, material, management, air handling, water treatment system, personnel and documentation etc, **the panel of inspectors recommends the renewal of Drug Manufacturing License** and regularization of layout plan to M/s Moreno Iglisias Research Laboratories (Pvt) Ltd, 21-Km Ferozepur Road, Lahore by way of Formulation for the following sections:- 1. Dry Powder (General) (Veterinary) (Renewal) Section. 2. Dry Powder (General Antibiotic) (Veterinary) (Renewal) Section. 3. Oral Liquid (General) (Veterinary) (Renewal & Regularization Section. 4. Oral Liquid (Antibiotic) (Veterinary) (Renewal & Regularization) Section. **Decision of the Central Licensing Board in 286th meeting:** The Board considered and approved the grant of renewal of DML No. 000478 by way of Formulation in the name of M/s Moreno Iglisias Research Laboratories (Pvt) Ltd, 21-Km Ferozepur Road, Lahoreon the recommendations of the panel of experts for the period Commencing on 02-09-2020 & ending on 01-09-2025. for the following sections: - 1. Dry Powder (General) (Veterinary) (Renewal) Section. 2. Dry Powder (General Antibiotic) (Veterinary) (Renewal) Section. 3. Oral Liquid (General) (Veterinary) (Renewal & Regularization Section. 4. Oral Liquid (Antibiotic) (Veterinary) (Renewal & Regularization) Section.			
9	M/s Nawal Pharmaceuticals, Plot	**11-04-2022**	**Good**	1. Mr. Abdullah, Additional Director (PE&R), DRAP,

	No. 11-A, Punjab Small Industrial Estate, Taxila. DML No.000735 (Formulation). Period: Commencing on 14-06-2021 & ending on 13-06-2026.			Islamabad. 2. Mrs. Tehreem Sara, Area FID-IV, DRAP, Islamabad. 3. Mr. Abdullah Bangash, Assistant Director, DRAP, Islamabad.

Recommendations of the Panel:

"Based on the improvement made by the firm and the people met, the panel is of the opinion to recommend the renewal of Drug Manufacturing License (000735) by way of formulation for Veterinary drugs at present only: -

i. Oral Liquid Syrup (General) Veterinary.
ii. Oral Dry Powder (General) Veterinary.
iii. Liquid Injection (General) Veterinary.

Decision of the Central Licensing Board in 286th meeting:

The Board considered and approved the grant of renewal of DML No. 000735 by way of Formulation in the name of M/s Nawal Pharmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate, Taxila**,** on the recommendations of the panel of experts for the period Commencing on 14-06-2021 & ending on 13-06-2026 for the following sections: -

i. Oral Liquid Syrup (General) Veterinary.
ii. Oral Dry Powder (General) Veterinary.
iii. Liquid Injection (General) Veterinary.

ITEM-V MISCELLANEOUS CASES

Case No- 1 **CHANGE OF MANAGEMENT OF M/S ALEN PHARMACEUTICALS (PVT) LTD, RISALPUR UNDER DML NO 000435 (BY WAY OF FORMULATION)**

M/s Alen Pharmaceuticals (Pvt) Ltd, Risalpur submitted the documents for change in management. The firm has deposited fee of Rs.50,000/- for change of management. Detail is as under;

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

Decision of the Central Licensing Board in 286th meeting:

The Board considered and accepted for record the change of management of M/s Alen Pharmaceuticals (Pvt) Ltd, Risalpur DML No.000435 by way of formulation as per Form-29 as under:

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

Case No- 2 **REQUIREMENT OF PSYCHOTROPIC SECTION FOR MANUAFCTURE OF DRUGS.**

CASE BACKGROUND

The Drugs Act, 1976 and rules framed thereunder regulates the manufacture, import, export and sale of drugs including Psychotropic/ narcotic drugs. The Psychotropic/ narcotic drugs were manufactured by the pharmaceutical manufacturers in the General Area/Sections

along with general class of drugs since enactment of the Drugs Act 1976 and rules framed there under.

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

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

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

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

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

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

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

FACTS.

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

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

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

31	Triazolam	
32	Alprazolam	
33	Bromazepam	
34	Buprenorphine	
35	Chlordiazepoxide	
36	Clobazam	
37	Clorazepate	
38	Clonazepam	

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

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

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

Decision of the Central Licensing Board in 286th meeting:

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

Case No-3 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S CHERWEL PHARMACEUTICALS (PVT) LTD., PLOT NO.20, PHASE-IV, HATTAR INDUSTRIAL ESTATE, HATTAR (DML# 000606)**

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

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

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

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

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

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

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000606 by way of formulation of M/s Cherwel Pharmaceuticals (Pvt) Ltd., Plot No.20, Phase-IV, Hattar Industrial Estate, Hattar, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No-4 **RENEWAL OF DRUG MANUFACTURING LICENCE (000491 BY WAY OF FORMULATION) OF M/S USAWA PHARMACEUTICALS, RISALPUR.**

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

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

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

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

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

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

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000491 by way of formulation of M/s Usawa Pharmaceuticals, 146-Special Industrial Zone (Export Processing Zone), Risalpur, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No-5 **RENEWAL OF DRUG MANUFACTURING LICENCE 000644 BY WAY OF FORMULATION) OF M/S WEATHER FOLDS PHARMACEUTICALS, HATTAR.**

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

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 11-09-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

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

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

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

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

i. Updated/amended/addendum partnership not provided.

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 12of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000644 by way of formulation of M/s Weather Folds Pharmaceuticals, Hattar, may not be suspended by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No-6 **RENEWAL OF DRUG MANUFACTURING LICENCE 000426 BY WAY OF FORMULATION) OF M/S SB PHARMA PLOT NO. 5-E, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD.**

M/s, SB Pharma Plot No. 5-E, Industrial Triangle Kahuta Road, Islamabad submitted application for renewal of Drug Manufacturing License No. 000426 (by way Formulation).

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 14/08/2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated/amended/addendum partnership 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 11th April, 2022 to the firm with following shortcomings: -

i. Updated/amended/addendum partnership not provided.

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

ii. Updated/amended/addendum partnership not provided.

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and Rule 12of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000426 by way of formulation of M/s, SB Pharma Plot No. 5-E, Industrial Triangle Kahuta Road, Islamabad, may not be suspended by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No-7 **RENEWAL OF DRUG MANUFACTURING LICENCE 000357 BY WAY OF FORMULATION) OF M/S HASSAN PHARMACEUTICALS HAYATABAD PESHAWAR.**

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

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 8th April, 2021under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

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

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

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

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

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

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000357 by way of formulation of M/s Hassan Pharmaceuticals Hayatabad Peshawar, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No-8 **RENEWAL OF DRUG MANUFACTURING LICENCE 000843BY WAY OF RE-PACKING) OF M/S SIMAX CHEMICAL, PLOT NO. 188-A, INDUSTRIAL ESTATE HAYATABAD, PESHAWAR.**

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

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 9th Nov, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

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

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

ii. advised to submit application on prescribed Form-1A duly signed and stamped by the management of the firm along with following documents/annexures dully attested/notarized;
    a. Proper Application
    b. Form 1-A
    c. Classes of Drugs
    d. Dosage forms of drugs
    e. Name(s) of drugs registered / approved
    f. Change(s) in name of proprietor / directors / partners (if any).
    g. Detail of premises including layout plan
    h. Detail of the section-wise equipment and machinery for manufacture and quality control.
    i. Name and Qualification of Production Incharge

j. Name and Qualification of QC Incharge.
k. Nothing due certificate regarding CRF from STO.

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

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000843 by way of re-packing of M/s Simax Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Peshawar, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No-9 **APPROVAL OF TECHNICAL PERSON, QC INCHARGE OF M/S ALEN PHARMACEUTICALS (PVT) LTD, RISALPUR, UNDER DRUG MANUFACTURING LICENSE NO. 000435 (BY WAY FORMULATION)**

M/s Alen Pharmaceuticals (Pvt) Ltd, Risalpur Drug Manufacturing License No.000435 (by way of formulation) wherein the firm has submitted the application for approval of proposed QC Incharge Mr. Naveed Muhammad S/o Yar Muhammad (Pharm-D) CNIC No.16102-9220966-9 The application was evaluated as per the Drug (Liceisng, registering & advertising) Rule 1976 and found following shortcomings which were asked from the firm to rectify on 20th October, 2021;

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

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

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

Decision of the Central Licensing Board in 286th meeting

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

Case No-10 **RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000683 (BY WAY OF FORMULATION). OF M/S GILLMAN PHARMACEUTICALS, HATTAR.**

M/s Gillman Pharmaceuticals, Hattar submitted the application for renewal of Drug Manufacturing No. 000683 (by way of Formulation). The application was received on 11/02/2020 which is well on time as validity of License is 15/02/2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 17th August, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

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

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

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

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

Furthermore, Mr. Faisal Shahzad, FID-I, DRAP, Peshawar submitted which is re-produced as under;

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

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000683 by way of formulation of M/s Gillman Pharmaceuticals, 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-11. **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000037 OF M/S REKO PHARMACEUTICAL (PVT) LTD, 13-KM, MULTAN ROAD, LAHORE.**

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

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

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

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

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

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

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000037 by way of formulation of M/s Reko Pharmaceutical (Pvt) Ltd, 13-KM, Multan Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No-12. **SITE INSPECTION /SITE VERIFICATION OF M/S VETLINE PHARMA (PVT) LTD, Plot No. 761, SUNDAR INDUSTRIAL ESTATE, RAIWIND ROAD, LAHORE**

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

The FID submitted inspection report which is reproduced below :

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

*"The observations led to the conclusion that the site of M/s Vet Line Pharma (Pvt) Ltd, Plot No. 761, Sundar Industrial Estate – Raiwind Road, Lahore,**is not suitable for the*

establishment of a pharmaceutical unit*due to a Nice Chain Factory which was located on the left side of the site as of today, as per requirement laid down under paragraph 1 of section-1 of the Schedule "B" (SRO, 470 (1)/98), dated 15-05-1998, under rule 18 of the Drugs (Licensing, Registering and Advertising) Rules, 1976)"*

The firm is called for personal hearing.

Decision of the Central Licensing Board in 286th meeting

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

i. Ms. Majida Mujahid Federal Inspector of Drugs, DRRAP, Lahore,
ii. Mr. Ajmal Suhail, Federal Inspector of Drugs, DRRAP, Lahore

Case No-13 **CHANGE OF TITLE OF LICENSED SECTION OF M/S MEDIFLOW PHARMACEUITCALS (PVT) LTD, KARACHI UNDER DML NO. 000822 (FORMULATION)**

M/s Mediflow Pharmaceuticals (Pvt) Ltd, Plot No. ID-100, Sector 30, Korangi Industrial Area, Karachiapplied for change of title of licensed section namely **Liquid Injection SVP (General) to Liquid Injection LVP/SVP (General).**

A panel of experts comprising of following members was constituted to inspect the firm for the purpose of verification of machines installed along with cleared functions:

1. FID, DRAP, Karachi.
2. Mr. Sajjad Abbasi, DD,CDL,Karachi.

The panel inspection report is received and is reproduced as below:

"M/s Mediflow Pharmaceutical (Pvt.) Limited, Plot ID-100, Korangi Industrial Area Karachi was inspected as per instructions contained in DRAP, Islamabad letter Plot No. ID-100, Sector 30, Korangi Industrial Area, Karachi. dated, 14th February, 2022 in connection with Change of title/name of Licensed section **(Verification of function/capacity of manufacturing of LVP & SVP)**. During the inspection, panel observed that the firm has constructed as per layout plan approved by the DRAP authorities (Annex-C).

During the inspection it was confirmed that the firm has installed Injection Stretch Blow Mold (ISBM) filling line with Euro cap seen that has capacity or manufacture/filling of 50ml to 1000 ml.

Moreover, Firm observed maintained at a good level of cleanliness and well equipped with necessary production and quality control machinery/equipment required for manufacturing and test/analysis of the products registered. Adequate technical personnel also seen onsite that were observed well conversant with the GMP requirements.

Decision of the Central Licensing Board in 286th meeting:

The Board considering the facts on the record and approved change in the name of section M/S Mediflow Pharmaceutical (Pvt.) Limited, Plot ID-100, Korangi Industrial Area Karachi DML No.000822 (Formulation) from **Liquid Injection SVP (General) to Liquid Injection LVP/SVP (General).**;

Case No-14 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000415 (FORMULATION) OF M/S PLATINUM PHARMACEUTICALS (PVT) LTD, PLOT No. A-20, NORTH WESTERN INDUSTRIAL ZONE,PORT QASIM KARACHI**

M/s Platinum Pharmaceuticals (Pvt) Ltd, Karachihas filled application for renewal of DML No. 000415 (Formulation) for the period commencing on 07-08-2020 and ending on 06-08-2025. The application was received on 06-04-2020. The application for the renewal of DML of the firm was evaluated and a letter dated 22-06-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. All attested annexure/enclosures of Prescribed Form-1A .
ii. Detail of all licensed sections on firm's letter head.
iii. Updated original certified true copy of Form-29 & Form-A issued by SECP (original).

The reply of the firm was received on 27-7-2020 and the documents submitted by the firm were evaluated and a Reminder dated 06-10-2020 was issued to the firm to submit following documents :

i. Updated original certified true copy of Form-29 & Form-A issued by SECP.

In response to this Division's Reminder dated 06thOctober 2020 the firm has not submitted the required documents and instead has stated that firm has applied to SECP for issuance of updated Form-29 & Form-A and will submit the same as soon as received and the application is still found deficient of following documents:

i. Updated original certified true copy of Form-29 & Form-A issued by SECP.

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

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000415 (by way of formulation) of M/s Platinum Pharmaceuticals (Pvt) Ltd, Plot No. A-20, North Western Industrial Zone,PortQasimKarachimay not be suspended or cancelled by the Central Licensing Board.

The show cause notice was issued to the firm in compliance to decision of the CLB. The reply received from the firm is reproduced as below :

> *Updated Certified True Copy of Form 29 & Form A has been sought from the SECP but due to departmental coordination between two or three government departments we have not yet received the certified true copy.*
> *Please also note that Platinum Pharmaceuticals have completed all the requirements of SECP for issuance of the said document which your good office may verify from the SECP.*
> *To explain the situation in a better way we would request your good office for a personal hearing.*

The application for renewal of DML No. 000415 (Formulation) is still found deficient of following documents :

i. Updated (Original) Form- 29 & Form-A issued by the SECP containing the names of current directors of the firm.

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

Submitted for consideration of the Board, please.

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

Mr. Faheem Lakhani Plant Manager appeared before the board and contended that firm is persuiting the SECP for issuance of Form-29 . The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000415 (by way of formulation) of M/s Platinum Pharmaceuticals (Pvt) Ltd, Plot No. A-20, North Western Industrial Zone,PortQasimKarachi till clarification from the SECP or submission of Form-29 by 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) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and later on, case may be placed before the board for ratification.

The decision of the CLB was communicated vide letter dated 31st May 2021.

The firm filed an appeal before the Drug Appellate Board against the said decision of the CLB and the Drug Appellate Board in its 156th meeting held on 9th June 2021 decided to set aside the

suspension of DML of the appellant by the CLB and allowed resumption of production accordingly. The Drug Appellate Board also decided to give three months time to the appellant for submission of afresh Form-29 without any observation. After submission of Form-29 the CLB shall proceed in accordance with law.

Now the firm has submitted the Updated Form-29 of SECP and the application for renewal of DML No. 000415 (Formulation) is now complete.

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

The Board perused the case.

Case No-15. **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/s DIVINE PHARMACEUTICALS, LAHORE.**

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

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

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

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

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

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

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

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

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

Decision of the Central Licensing Board in 286th meeting

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

Case No-16 **M/S MEDISYNTH PHARMACEUTICALS, RAWAT.**

A legal notice received from Malik Khalid Mahmood, Advocate Supreme Court of Pakistan addressed to Chief Executive Officer **M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-05, Industrial Estate, Rawat.** The detail of legal notice is reproduced as under: -

1. That my client entered into a written Rent Deed agreement No. 17 dated 16-06-2010 ("agreement") on 14th May 2010 for the Plot No. 55 (Ground Floor inclusive of roof for HVAC System with temporary MS Sheet covering only) street No. S-05, Industrial Estate, Rawat, Rawalpindi (hereinafter" plot") registered in Court of learned Special Judge Rent, Rawalpindi on 10-06-2010.

The premises specification has been mentioned in the agreement, Pursuant to the agreement, the relationship of Landlord and tenant was established between my client and you.

2. That my client is the sole owner of the plot. It has been written in the agreement that Rent Deed / Agreement shall be valid between both the parties (my client & you) for the maximum period of 12 years ending on 13th May, 2022. It has also been settled / written in the agreement that it is discretionary right of my client to extend or not extend the period after its expiry.

3. That it is stated the agreement is going to be expired on 13th May 2022 having discretion of my client to extend it or otherwise. My client does not intend to extend the agreement anymore and do not want to have Rent Deed Agreement with you for further period in respect of the plot.

4. That it is pertinent to mention here that during the subsistence of agreement my client has always abided by the terms and conditions of the instant agreement. Nothing is outstanding against him.

5. That my client has verbally requested you that he is no more interested to extend the agreement and therefore, requested you to vacate the premises mentioned above after expiry of agreement but you are not ready to hear anything reasonable.

6. That through this legal notice to evict you are advised to vacate the said plot after expiry of agreement, otherwise, my client has positively instructed me to file a suit for eviction against you in the Court of Law oat your risk and costs.

It is submitted for information that M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-05, Industrial Estate, Rawat under DML NO. 000718 (by Way of Formulation) has applied for renewal of DML for the period of 14-06-2021 to 13-06-2026 and panel of experts/inspector has been constituted, accordingly.

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000000by way of formulation of M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-05, Industrial Estate, Rawat, may not be suspended or cancelled by Central Licensing Board.

Case No-17 **RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000486 (BY WAY OF FORMULATION). OF M/S AKSON PHARMACEUTICAL (PVT) LTD, PLOT NO. 9-B/1&2, STREET NO. D-1, OLD INDUSTRIAL ESTATE, MIRPUR, AZAD KASHMIR.**

M/s. Akson Pharmaceutical (Pvt) Ltd, Plot No. 9-B/1&2, Street No. D-1, Old Industrial Estate, Mirpur, Azad Kashmir submitted the application for renewal of Drug Manufacturing No. 000486 (by way of Formulation). The application was received on 02-04-2021 which is well on time as validity of License is 12/04/2021.

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 04th August, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Proof of Table (General), Table (Antibiotic), Capsule (General), Liquid Syrup/Suspension(General) sections approval from Central Licensing Board is not provided,
ii. Updated Form-29 issued and certified as "True Copy" by SECP (in original) along with CNIC copies of all director are required,
iii. Updated (up to 31-12-2020) nothing due certificate (CRF) 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 20th October, 2021 to the firm with following shortcomings: -

i. Proof of section approval from Central Licensing Board.

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

Decision of the Central Licensing Board in 286th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000486 by way of formulation of M/s. Akson Pharmaceutical (Pvt) Ltd, Plot No. 9-B/1&2, Street No. D-1, Old Industrial Estate, Mirpur, Azad Kashmir, 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.

QUALITY ASSURANCE (QA) CASES

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

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

2. The FID reported following observations;

Change Rooms:-

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

Tablet Section (General):-

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

Blistering / Packing Hall:-

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

Cephalosporin Sections:-

i. Provide a laminar flow dispensing booth as well.

Quality Control:-

i. Arrange another stability chamber for the real time and accelerated stability studies with data loggers and backup power supply.
ii. Stability studies protocols need to be developed and followed.

iii. Purchase recent editions of official books and official testing methods should be adopted for the products manufactured by the firm.

HVAC System:-

i. HVAC system for tablet section needs to be properly validated for its various parameters.
ii. The HVAC system in this section lacks the bag filters.
iii. Pressure monitoring gauges were also not functioning, which need to be refilled.

Premises / Building:-

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

Personnel:-

i. Appoint quality assurance personnel.

Conclusion:-

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

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

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

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

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

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

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

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

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

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

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

Decision of 284th meeting of CLB

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

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

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

"I, Mr. Abdur Rasheed (Production Manager- Alen Pharma (Pvt.) Ltd. Risalpur, Nowshera, KPK) hereby confirm that this product (Tablet Dolint 7.5mg) was recovered from us and was held by the area Federal Inspector of Drug (Faisal Shahzad) on 19.04.2021 during a routine inspection to Alen Pharma. The area

inspector himself will decide the fate of this stock later on. This stock will remain with us till next order.

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

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

Product Name: *Tablet Dolint 7.5mg*

Batch No. *247*

Batch Size: *6535 Packs*

Pack Size: *10 Tablets per pack*

Mfg Date: *01-2021*

Exp. Date: *12-2023*

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

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

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

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

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

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

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

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

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

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

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

14. The central licensing board has delegated power of Suspensions of Production (in case of GMP and Quality Control matters) to the Director QA&LT, under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) rules, 1976, in its 273rd meeting. The power was further delegated to the Additional Director QA&LT in 278th meeting of CLB in case of vacancy of post of the Director QA&LT.

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

16. A license holder is bound under rule 19(1) & (7) of the Drugs (Licensing, Registering and advertising) Rules 1976 to comply with the provision of the act, the rules and further requirements. Contravention of Rules is an offence punishable under Clause 4 of Schedule-III of the DRAP Act 2012 with imprisonment for a term which may extend to five years, or with fine which may extend to one lakh rupees, or with both. The penalty of same under subsection 4 of section 27 of the Drugs Act 1976 is imprisonment for a term which may extend to five years, or with fine which may extend to fifty thousand rupees, or with both.

17. As per detailed report of the FID, the firm M/s. Alen Pharmaceuticals (Pvt) Ltd., 138, Nowshera Industrial Estate, Risalpur (DML No. 000435), through its responsible persons, is found to be contravening rule 19(1) & (7) of the Drugs (Licensing, Registering and advertising) Rules 1976 which is an offence punishable under Clause 4 of Schedule-III of the DRAP Act 2012 and section 27 subsection 4 of the Drugs Act 1976.

The matter of revoking suspension of production order in tablet (general) section of the firm in light of inspection dated 14.04.2022 and matter of unauthorized manufacturing of Dolint 7.5mg tablet batch No. 247 is placed before the Central Licensing Board for consideration please.

Proceedings of the 286thMeeting of the Central Licensing Board:

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

Decision of 286th meeting of the Central Licensing Board:

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

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

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

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

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

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

QUALITY CONTROL CASES

Case No. 01 **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. MianIshtiaq 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	INVOICE NO.	INVOICE DATE	RAW MATERIAL	QUANTITY	PERPORTEDLY RELEASED BY
1	M/S ARSHINE PHARMACEUTICAL CO,LIMITED	ZY201509037	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 MONOHYDRATE	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-EXP1651652258 2	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. MianIshtiaq Ahmed(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-0842	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.

Show Cause notices were served and published in newspapers in light of decision of 285th meeting of CLB held on 17th and 18th March 2022.

A. *The firm replied show cause notice vide reference No. RNK/L.N/2022/40 dated 07th May 2022 wherein firm has informed which is reproduce as under:-*

"The firm informed that aforementioned FIRs have been cancelled vide order dated 24-01-2022 passed in this regard by Judicial Magistrate Lahore without prejudice to any other ground that may be available regarding the legality of the subject show cause notice it is submitted that our clients are not in position to challenge and defend this show cause notice unless and until the following documents are provided:-

i. ***All import authorization with Diary and Issue No. of DRAP Lahore (Which are allegedly to be as per DRAP)***

ii. ***Copy of the Minutes of 285th meeting of CLB held on 17th& 18th March 2022.***

iii. ***Letter No.13-8/2018-QC dated 14-03-2018 written to the Deputy collector G-II MCC Appraisement (West) Karachi.***

iv ***All import authorizations/record of Everest Pharmaceutical***

v ***Copy of license and licensing record of Everest Pharmaceutical.***

The provision of these documents is without prejudice to other documents that may be required by our client in order to defend the illegal an unlawful show cause notice that has been issued.

The Factory and office of our client till to date remains in the illegal custody of DRAP and he has not assess to any documents or record. The provision of aforementioned documents is requirement of law particularly Article 10-A and 19-A of the Constitution of Pakistan.

B. *Dr. Kamran Izhar replied show cause notice vide reference No. NIL, dated 10th May 2022 which is reproduce as under:-*

It is humbly submitted as follows: —

That the titled Show Cause Notice (SCN) alleges that M/s Everest Pharmaceuticals has forged import authorizations for the use of illegal import of pharmaceutical raw materials without the requisite drug import licenses. The management of Everest Pharmaceuticals is hence held as being culpable for the same. The undersigned (Dr. Kamran 'Aar) is falsely deemed to be the "owner of M/s Everest Pharmaceuticals" and therefore erroneously required to show cause for the company's alleged illegal actions. However, contrary to the SCN, the undersigned is not the owner of Everest Pharmaceuticals. In fact the undersigned has no relation with Everest Pharmaceuticals, either in a professional capacity or otherwise. Therefore, the titled SC \ inapplicable to the undersigned, as no one can be made answerable for the actions of another. An identical stance was taken in an

Application under section 265-K of the Criminal Procedure Code dated 29/06/2018, in which the following was elucidated mutatis mutandis:

FACTS:—

1. That the Undersigned has been arrayed as an Accused in the FIR. , however, was given the benefit of post arrest bail by the Honorable Islamabad high Court vide Order dated 06-194- 2018, where after, he is presently facing trial before the Learned Drug Court and the flutter is fixed for hearing before the Learned Court today for cross-examination on the Prosecution Witnesses by the Co-Accused namely, Ch Muhammad Usman, since, the undersigned has conducted cross on all prosecution witnesses, as well as, the Court Witnesses and to his extent the trial stands concluded and the entire prosecution evidence stands recorded and closed.

2. That concisely, permission was obtained vide letter dated 06-03-2018 liar lodging of the FIR against the Undersigned and other accused person, in pursuance to an inspection conducted at M/S Everest Pharmaceuticals by a team of Drug Regulatory Authority of Pakistan ("DIZAP-") along with FIA and NAB teams on the directions of the August Apex Court in HRC No. 6845/2018.

3. That the interim Challan against the principal accused namely, Ch. Muhammad Usman was forwarded by the Investigating Officer on 16-04-2018 and the same was filed before this Learned Court on 23-05-2018, where after the same was delivered to the said Accused person on 05-06-2018 by this Learned Court, in compliance with the provisions of Section 265-C Cr.p.c.

4. That it is imperative to mention here that in the said Challan filed before the Learned Drug Court, the Undersigned was placed in Column No. 4, however, the Challan was only tiled to the extent of principal accused namely Ch. Muhammad Usman. Another factor of pivotal importance is that as per the permission obtained by the Investigation Officer for registration of case, the Undersigned was referred to as 'Owner' of M/S Everest Pharmaceuticals (erroneously) and the same fact also finds a passing mention in the interim Challan filed only to the extent of the principal accused and not the Applicant.

5. The said interim Challan filed to the extent of the principal accused namely, Ch. Muhammad Usman contained a list of total 09 witnesses.

6. That subsequent to the filing of the interim Challan against the principal accused, the Complainant preferred a Complaint against the Undersigned and other accused persons, however, it is pertinent to mention here that the same was filed in pursuance to a show, cause notice issued to the Undersigned and Others, yet the

Undersigned has not been referred to either as a partner or as a Director / Owner of MIS Everest Pharmaceuticals. The said complaint was taken on the file of the Learned Drug Court on 29-06-2018 and it was delivered to the Undersigned and other accused persons on 18-07-2018 under Section 265-C Cr.p.c. Total of 10 witnesses have been cited in the said Complaint.

7. That the Undersigned took the stance of Challan having not been filed before the Learned Drug Court to his extent in Writ Petition No. 3330/2018 pending adjudication before the honorable Islamabad High Court on 15-11-2018,

8. That, however, the I.earned Prosecutors took the plea that the same had been filed before the Learned Drug Court where after, the attested copy or the order ▶%as applied, which revealed that the matter was fixed for framing of charge, however , on 20.1 1-21)18. theUndersigned requested that the copies of the Challan filed against him had not been delivered to him under Section 265-C Cr.p.c, where after the Learned Drug Court was graciously pleased to allow the said request and delivered the copies of the fresh Challan to the Undersigned and fixed the matter for 28-11-2018 for framing of Charge.

9. That the perusal of the record and the copy of the Challan revealed that the same was forwarded by the I.O. on 05-07-2018 and was filed before the Learned Drug Court on 1309-2018, however, copies of the same under Section 265-C Cr.p.c were delivered to the Undersigned and other accused namely Ch. Muhammad Usman on 20-11-2018.

10. That it transpires from a bare perusal of the Challan filed by the prosecution that the Undersigned has been placed under Column 2 of the Challan and the Prosecution itself has taken a categorical stance, which has been stipulated in the body of the Challan that the Undersigned is 'not' the owner of M/S Everest Pharmaceuticals. Though the Undersigned has been mentioned as one of the director / partners in Form 1-A for renewal of drug manufacturing license, however, the prosecution itself has candidly admitted that the same has not been signed by the Applicant, rather by one namely, Mst. UzmaUnis, who has expired, as such the same is rendered of no value or legal sanctity in determining any connection of the Undersigned with M/S Everest Pharmaceuticals. Importantly, the said Form 1-A was never acted upon since the license was never renewed because of the fact that the documentation required was not provided by the Principal Accused namely, Ch. Muhammad Usman. Even otherwise, the said Form 1-A bears no stamp of the company and the lady that put her signatures under the designation of General Manager is nowhere mentioned in the records of the SECP or the Registrar of Firms.

11. That the prosecution itself has stated that the Learned Drug Court may decide the fate of the Applicant. The first Challan submitted was only to the extent of principal accused Ch. Muhammad Usman and the Complaint was also filed in pursuance to the same, however, the supplementary Challan succeeds both, wherein, the prosecution itself admits that the Undersigned is neither owner nor partner of M/S Everest Pharmaceuticals.

12. That the Undersigned having been placed in Column No. 2 of the Challan can no longer be treated as an accused nor is he an accused and the Learned Drug Court never summoned the Undersigned to face trial and be charged, in the captioned FIR, in lieu of the submission of Challan. In terms of Section 173 (3) Cr.p.c, the Undersigned has been placed under Column No. 2, as such he liable to be discharged or the Learned Drug Court was to express reasonable grounds for refusal to accord such discharge, us such the Undersigned filed an Application seeking discharge in the captioned FIR and Complaint before the Learned Drug Court on 28-11-2018.

13. That the Learned Drug Court vide its order dated 05-12-2018 dismissed the Application preferred by the Undersigned on the ground that *"From the perusal of the complaint interim report under Section 173 Cr.p. c and documents available on record reveal. it reveals that the undersigned / accused person Dr. Kamran Izhar Qureshi, is well nominated in FIR/ complaint with specific role and allegedly the un-registered drugs e.tc were recovered from the premises of M/S Everest Pharmaceuticals (juristic person). The accused is also one of the directors of M/S Everest Pharmaceuticals (juristic person), as per documents submitted by the Complainant".* These findings of the Learned Drug Court being completely and utterly contrary to the record and the report submitted by the Prosecution, itself under Section 173 Cr.p.c, whereby the Undersigned has been placed in Column No. 02 and it has been stipulated that the Undersigned is not owner of M/S Everest Pharmaceutical, as such, the Undersigned invoked the jurisdiction of this honorable Court. vide Cr1. Misc. No. 924 of 2018 before the Honorable Islamabad High Court.

14. That the Honorable Islamabad High Court vide order dated 31-01-2019 was graciously pleased to allow the Petition and remanded the matter back to the Learned Drug Court for decision afresh, setting aside the order dated 05-12-2018.

15. That upon remand of the matter, the Learned Drug Court decided the matter afresh, however, yet again dismissed the discharge application, despite clearly noting in its order dated 26-03-2019, at Paragraph No. 9 that *"Although the record of M/s Everest Pharmaceutical with SECP or Registrar o Firms does not reflect the Undersigned accused as a Director or Partner of M/s Everest Pharmaceutical,*

*prima facia, the documental incriminating material which established association between the Undersigned / accused, M/S Everest Pharmaceutical and accused Ch. Muhammad Uvmanis available...",*which is not only contrary to the directions issued in Paragraph No. 6 of the Honorable Court's order dated 31-01-2019 but are also a complete shift from the case of the prosecution itself that is proceeding against M/s Everest Pharmaceutical and had lodged FIR, filed private complaint and submitted Challan, solely nominating Undersigned as owner, thereby being aggrieved and dissatisfied with the order dated 26-03-2019, the Undersigned again assailed the same, inter alia, on the grounds stipulated therein, vide Cr.l. Misc No. 203/2019, which came up for hearing before the Honorable Islamabad High Court on 01-04-2019, wherein, the same was dismissed.

16. That post dismissal, charge against the Undersigned and Co-Accused namely, Ch. Muhammad Usman was framed on 30-04-2019, wherein, both the Undersigned and the Co-Accused namely, Ch. Muhammad Usman pleaded not guilty and claimed trial.

17. That post framing of charge, evidence of the prosecution / complainant was called, however, the same was delayed on account of various exigencies, however, post direction issued by the Honorable Islamabad High Court, the matter was expedited and the Complainant / Prosecution examined in total five witnesses, including the Complainant and thereafter closed prosecution evidence, where after, with the consent of both the Parties, the Investigating Officers of both the Challans, were summoned as Court Witnesses. All the Complainant / Prosecution Witnesses including the Court Witnesses have been duly cross examined by the Undersigned and to his extent the trial stands concluded, whereas, the Co-Accused has not yet cross examined a single witness,

GROUNDS: -

A. That the undisputed fact clearly transpires that the Investigating Officer of the Challan after all his investigation decided to place the Undersigned in Column No. 2 of the Challan and has taken a categorical stance to the effect that the Undersigned *"Dr. Kamran lzhar Qureshi, is not owner affirm MS Everest Pharma".* The Order dated 26-03-2019 clearly notes, at Paragraph No. 9 that *"Although the record of M/s Everest Pharmaceutical with SECP or Registrar of Firms does not reflect the Undersigned / accused as a Director or Partner of M/s Everest Pharmaceutical, prima facie, the documental incriminating material which established association between the Undersigned / accused M/s Everest Pharmaceutical and accused Ch. Muhammad Usman is available...".*

Nothing is left thereafter for attributing any relationship between the undersigned and the company.

B. That the entire record of the Company M/S Everest Pharma was obtained from the relevant quarters i.e. SECP and Registrar of Firms, and the said record has also been made a part of the Challan, which has further cleared the air surrounding the issue and is a categorical supplement to the stance of the Undersigned that he has no relationship in capacity of owner / director / partner / shareholder with the Company i.e. M/S Everest Pharmaceutical.

C. That Form 1-A dated 28-03-2014 for renewal of license of M/S Everest Pharmaceuticals which mentions the Undersigned as one of the directors / partners of the Company, hem ever, as clarified in the Challan and mentioned earlier, the same has no bearing since it nowhere bears the signatures of the undersigned and the individual that had signed and submitted the same, has expired, whereas, as far as the second witness is concerned i.e. Raja Muhammad Zahoor, his testimony is to the effect that an agreement to sell was entered into for the Plot between him and the Undersigned and after Raja Muhammad Zahoor received theentire amount of the sale, he was directed by the Undersigned to transfer the Plot in the name of Ch. Muhammad Usman, which was so done, as per him. Even if (for the sake of argument-without conceding) the statement of the said witness is believed to be true it does nothing for the prosecution which is evident from the contents of the Challan, itself, since the Plot was never in the name of the Undersigned and even otherwise the entering of the Agreement to Sell has absolutely nothing to do with the ownership of M/S Everest Pharmaceutical or with the allegations leveled in the FIR and the Complaint.

D. That the only document now left for consideration in framing an opinion is the infamous one pager which has recorded the presence of the participants of the meeting and wherein. the presence of the Undersigned stands recorded as a Director.

E. That without even going into whether the same is in fact the Undersigned's writing or signature, let us assume for the sake of argument (without conceding in any manner) that the Undersigned did in fact put his name and signature, does the same make the Undersigned a Director of M/S Everest Pharmaceutical. The answer is an emphatic no. By merely signing or writing the designation as a Director does not make one a Director. Even otherwise, it has not been mentioned that the Undersigned has written that he is a Director of M/S Everest Pharmaceutical. The word written is only Director and nothing else. Lastly, it is interesting to note that DRAP has itself contradicted its own position with respect to this letter because in the letter written for obtaining permission to prosecute the Applicant, it is mentioned that the Undersigned appeared as a Consultant.

F. That except for what has been mentioned above, nothing is existent on the record and the prosecution has found absolutely no evidence, against the Undersigned that he is in any manner involved with the Company i.e. M/S Everest Pharmaceutical.

G. That it has become clear from the relevant record appended with the Challan presented by the Prosecution that the proprietorship is solely owned and controlled by Ch. Muhammad Usman. Furthermore, the record of the registrar of Firms, unambiguously reveals that there are three partners (i) Mr. Sajjad Munir, (ii) Mr. Muhammad Usman and (iii) Mr. Hassan Ahmed and lastly, the record produced by SECP has also stamped that not only was the Company i.e. M/S Everest Pharmaceuticals deregistered in the year 2014 but also that the Undersigned was never associated with the said Company in any capacity, whether as Director, Shareholder or even as an employee.

H. That the record has made it abundantly clear that **no license** was either ever procured for M/S Everest Pharmaceuticals by the Undersigned or renewal sought of the same. "1 he Property also does not stand in the ownership of the undersigned, nor is there an iota of evidence presented by the prosecution to suggest that any monetary gains or the Undersigned for and on behalf of MIS Everest Pharmaceuticals acquired benefits.

I. That the Undersigned admittedly is the CEO of a drug distribution company by the name and style of Maark Pharmaceuticals (Private) Limited and the said Company in an arms length contractual relationship used to distribute sonic of the drugs manufactured by MIS Everest Pharmaceuticals, which it is extremely important to state were duly approved by the DRAP.

J. That the Undersigned holds an MBBS degree from the renowned King Edwards Medical College, Lahore. He also holds postgraduate qualifications in Policy Making from the London School of Economics, United Kingdom and Clinical Research at the University of Surrey, United Kingdom. The Undersigned is thus a highly qualified medical doctor (Aesthetic Physician) and is the first Pakistani to possess the said qualification to conduct various Phase 3 and Phase 4 clinical trials in Pakistan.

K. That the Learned Customs Court in Karachi has primarily acquitted the Undersigned from the case registered before it, on the sole ground that the Undersigned has absolutely no relation of any nature, whatsoever, with M/S Everest Pharmaceuticals, hence, said fact recorded in a judicial order also lends strength to the case of the Applicant.

L. That all the evidence of the Prosecution leads to an irresistible conclusion that the Undersigned is entirely innocent having no connection of any nature, whatsoever, with the alleged offence or the affairs of M/S Everest Pharmaceuticals and has not derived any benefit from the same or being associated with the same. **All** the documentary evidence collected by an independent investigative agency from the relevant Government quarters. reflects that the Undersigned is neither owner, nor Shareholder, Director or Partner of M/S Everest Pharmaceuticals.

Proceedings of the 286th meeting of CLB

Noor Muhammad Mahar and Dr. Kamran Izhar were appeared before the Board and submitted the Affidavits which are reproduce as under:-

a) I Dr. Noor Muhammad Mahar R/o Rais Muhammad Khan R/o 53 D-1 NASPAK Society Township Lahore hereby declare and affirm as under:-

1 That I have no concern of any nature whatsoever with M/s Everest Pharmaceutical 124 Industrial Triangle Kahuta Road Islamabad in any capacity such as partner/owner/Director/employee/manager.

2 That I warrant that I have no concern with the affairs of M/s Everest Pharmaceutical 124 Industrial Triangle Kahuta Road Islamabad and as such I am not responsible or answerable for the action of the said company or its management.

3 That I have been cleared of this allegation in all investigation carried out by FIA across the country police and Customs.

4 That I have been acquitted of the same allegation by the honorable judge Custom Court Karachi

5 That I am a respectable citizen of this country and a medical doctor by profession.

6 That I have not concern with the contents of the paragraph No. 2 and 3 of writ petition Number 517/2018 filed before the honorable Islamabad high court and the same have been amended through CM No. 3206/2018 and I have no concern with the ownership of the M/s Everest Pharmaceutical, 124-Industrial Triangle Kahuta Road Islamabad.

That my above statement is true and correct to the best of my knowledge and belief and nothing has been concealed therein.

b) I Dr. Kamran Izhar Qureshi S/o Izhar Ul Haq Qureshi R/o 134-C, Phase 5, DHA, Lahore hereby declare and affirm as under:-

1. That I have no concern of any nature whatsoever with M/s Everest Pharmaceutical 124 Industrial Triangle Kahuta Road Islamabad in any capacity such as partner/owner/Director/employee/manager.
2. That I warrant that I have no concern with the affairs of M/s Everest Pharmaceutical 124 Industrial Triangle Kahuta Road Islamabad and as such I am not responsible or answerable for the action of the said company or its management.
3. That I have been cleared of this allegation in all investigation carried out by FIA across the country police and Customs.
4. That I have been acquitted of the same allegation by the honorable judge Custom Court Karachi

5. That I am a respectable citizen of this country and a medical doctor by profession.
6. That I have never mingled or harmed any sate institution in particular DRAP Pakistan
7. That I undertake that I will not cause any harm to respect DRAP.

That my above statement is true and correct to the best of my knowledge and belief and nothing has been concealed therein.

Decision of 286th meeting of CLB:-

Board deliberated the case in detail and considering the facts, previous proceeding, reply of the show cause served to the accused, statements, of the accused, who appeared in person before the Board, decided to grant permission for prosecution for remaining 22 cases out of total 39, on the similar grounds as in previous 17 casesagainst:

i. M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, through its Managing Partner

ii. Ch. Muhammad Usman (Owner of M/s Everest Pharmaceuticals),

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