MINUTES OF 266th MEETING OF CENTRAL LICENSING BOARD HELD ON 24th OCTOBER, 2018

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266th meeting of the Central Licensing Board (CLB) was held on 24th October , 2018 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-09/4, Islamabad under the Chairmanship of Mr. Ghulam Rasool Dutani, Director Drug Licensing, Drug Regulatory Authority of Pakistan, Islamabad.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1	Dr. Ikram UL Haq, Expert in testing of drugs.	Member
2	Prof. Dr. Abdullah Dayo, Faculty of Pharmacy, University of Sindh, Jamshoro	Member
3	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
4	Prof. Dr. Mohammad Usman, Expert in manufacturing of drugs	Member
5	Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar.	Member
6	Mr. Syed Adnan Rizvi, Chief Drug Inspector, Sindh.	Member
7	Mr. Munawar Hayat, Chief Drug Controller, Primary and Secondary Health Care Department, Govt. of Punjab, Lahore	Member
8	Mr. Zakir Shah, Nominee of Chief Drug Inspector, KPK.	Member
9	Dr. Hafsa Karam Ellahi Representative Director (QA/LT), DRAP, Islamabad	Member
10	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
11	Mr. Nadeem Alamgir, Representative of Pharma Bureau	Observer
12	Mr. Muhammad Arshad & Mr. Saboor Ahmed, Representative of PPMA.	Observer
13	Mr. Kamran Anwar, Representative of PCDA	Observer

The meeting started with the recitation of verses from the Holy Qura'an. The Chairman Central Licensing Board welcomed the honorable members and participants of the meeting. He 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. Mr. Abdul Sattar Sohrani Deputy Director (QC) Mr. Ayyaz Ahmad, Deputy Director (Lic), Dr. Muhammad Yaqoob AD (Lic.), Dr. Muhammad Usman, AD (Lic) and Dr. Zunaira Farayad, Assistant Director (Lic), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 265th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 265th meeting held on 9th & 10th August, 2018.

A. DRUG LICENSING DIVISION

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

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

<table>
<tr><th>S #</th><th>Name of the firm</th><th>Date of Inspection</th><th>Ranking/ Evaluation</th><th>Inspection Panel Members</th></tr>
<tr><td>1.</td><td>M/s Dew-Max Pharmaceuticals (Pvt) Ltd., Plot No. 6, Street No. SS-4, Main Industrial Area, Rawat, Islamabad Formulation.</td><td>16-08-2018</td><td>Good</td><td>1. Prof. Dr. Muhammad Usman, Member, Member Central Licensing Board.
2. Additional Director, Licensing, DRAP, Islamabad.
3. FID-III, DRAP, Islamabad
4. AD Lic-III, DRAP, Islamabad</td></tr>
<tr><td></td><td colspan="4">“Keeping in view the manufacturing and testing facility in place, the panel unanimously <u>recommends</u> M/s Dew-Max Pharmaceuticals (Pvt) Ltd., Plot No. 6, Street No. SS-4, Main Industrial Area, Rawat, Islamabad Formulation. The responsibility lies with the manufacturer to ascertain the regulatory requirements during the validity period of DML. The said premise is being recommended for grant of DML by way of Formulation for the following sections;
1. Tablet Section (General).
2. Capsule Section (General).
3. Oral Liquid Section (General).
<u>Decision of the Central Licensing Board in 266th meeting</u>
The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Dew-Max Pharmaceuticals (Pvt) Ltd., Plot No. 6, Street No. SS-4, Main Industrial Area, Rawat, Islamabad with following sections:

<u>Section (03)</u>
1. Tablet Section (General).
2. Capsule Section (General).
3. Oral Liquid Section (General).</td></tr>
<tr><td>1</td><td>M/s Health Care Pharmaceuticals, 40-Km, Lahore Raod, Multan.</td><td>04-07-2018 & 17-10-2018</td><td></td><td>1. Dr. Ikram-ul-Haq, Member CLB.
2. Mr. Asim Rauf, Additional Director, DRAP, Lahore.
3. Mr. Munawar Hayyat, Chief Drug Controller, Health Department Govt. of Punjab, Lahore.
4. Mr. Abdul Rashid Sheikh, FID, DRAP, Lahore.</td></tr>
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Recommendations of the panel: -

The firm M/s Health Care Pharmaceuticals, 40-Km Lahore Road, Multan has been inspected twice i.e. on 04-07-2018 & 17-10-2018**.** The following shortcomings were pending as pointed out during the course of inspection;

1. HVAC caliberation was required as most of the manometers were non functional also at different places monometers were yet to be installed.
2. Quality Control Laboratory was not fully ready, HPLC, Viscometer, Karal Fisher were non functional and qualifications were yet to be completed on most of the instruments.
3. Auto Clave in Microbiological Lab was non operational.
4. Water treatment plant was not stated yet so, no qualification was available.
5. The caliberations stickers were found pasted, even on non-operational instruments.

Decision of the Central Licensing Board in 266th meeting

The Board considered and did not approve the grant of Drug Manufacturing License on the recommendations of the the panel of experts. The Board further decided to advise the firm to follow Rule 10 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The respective panel of experts for grant of additional sections/amendments 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 Herbion Pharmaceuticals (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad. DML No. 000795 (Formulation) **Section (01)** **1.** Sachet (General).	10-08-2018	**Good**	1. Prof. Dr. Muhammad Usman, Member, Member Central Licensing Board. 2. Additional Director, Licensing Division, DRAP, Islamabad. 3. Mr. Babar Khan, Area FID, DRAP, Islamabad.

Recommendations of the panel: -

"Keeping in view of the above facts on record, the panel unanimously **recommended the approval of new / additional section of Sachet (General)** to M/s Herbion Pharmaceuticals (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad DML No. 000795.

Decision by the Central Licensing Board in 266th meeting

The Board considered and approved the grant of following one additional section in the name

	of M/s Herbion Pharmaceuticals (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad, on the recommendations of the panel of experts:- **Section (01)** Sachet (General).			
2.	M/s Saffron Pharmaceuticals (Pvt) Ltd, 19-Km, Sheikhupura Road, Faisalabad. DML No. 000616 (Formulation) **Section (02)** 1. Soft Gel Capsule. 2. Oral Dry Powder Suspension (General) Section.	11-07-2017	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ahsan Ul Haq Ather, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: - The panel of inspectors recommends the approval /grant of above mentioned sections/facilities in favour of M/s Saffron Pharmaceuticals (Pvt) Ltd, 19-Km, Sheikhupura Road, Faisalabad under DML bearing No. 000616. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the grant of following two additional sections in the name of M/s Saffron Pharmaceuticals (Pvt) Ltd, 19-Km, Sheikhupura Road, Faisalabad, on the recommendations of the panel of experts:- **Section (02)** 1. Soft Gel Capsule. 2. Oral Dry Powder Suspension (General) Section.			
3.	M/s Medipharm (Pvt) Ltd, 108-Kot Lakhpat Industrial Estate, Lahore DML No. 000243 (Formulation) (Improvements in lay out plan).	02-07-2018 & 09-08-2018	---	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Ms. Anam Saeed, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - The amendments in layout of the firm were approved on 20-10-2017 and panel was constituted vide DRAP, Islamabad letter No. F. 1-43/85-Lic (Vol-III) dated 02-05-2018 to verify the amendments. The panel conducted inspection on 09-08-2018 and verified the changes made by the firm and recommended for regularization. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the grant of improvements as per approved layout plan by Licensing Division of M/s Medipharm (Pvt) Ltd, 108-Kot Lakhpat Industrial Estate, Lahore on the recommendations of the panel.			
4	M/s Mylab (Pvt) Ltd, Khanqah Sharif, Bahawalpur DML No. 000747 (Formulation). **Section (07)** 1. Liquid Injectable (Penicillin) Veterinary. 2. Dry Powder Injectable (Penicillin) Veterinary. 3. Oral Powder (Penicillin) Veterinary.	13-09-2018 and 14-09-2018	**V. Good**	1. Dr. Ikram-ul-Haq, Member, Central Licensing Board 2. Dr. Mahmood Ahmad, Member, PQCB, Lahore. 3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, Lahore.

	4. Liquid Injectable (Hormone) Veterinary. 5. Liquid Injectable (Steroid) Veterinary. 6. Oral Liquid (General) Veterinary. 7. Aerosol Veterinary.			
	Recommendations of the panel: - The Panel of inspector also recommends granting permission for production of Mylab (Pvt) Ltd, Khanqah Sharif, Bahawalpur for the above-mentioned additional new sections. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the grant of following seven additional sections in the name of M/s Mylab (Pvt) Ltd, Khanqah Sharif, Bahawalpur on the recommendations of the panel of experts:- **Section (07)** 1. Liquid Injectable (Penicillin) Veterinary. 2. Dry Powder Injectable (Penicillin) Veterinary. 3. Oral Powder (Penicillin) Veterinary. 4. Liquid Injectable (Hormone) Veterinary. 5. Liquid Injectable (Steroid) Veterinary. 6. Oral Liquid (General) Veterinary. 7. Aerosol (Veterinary).			
5.	M/s Hudson Pharma (Pvt) Ltd, Plot No. D-93, North Western Industrail Zone, Port Qasim, Karachi. **Section (01)** 1. Eye/Ear & Nasal Drops (General Section).(Revised)	17-08-2018	**Good**	1. Dr. Abdullah Dayo, Member CLB. 2. Najam-us-Saqib, Additional Director (E&M), DRAP, Karachi.. 3. Dr. Mehwish Tanveer, Area FID, DRAP, Karachi.
	Recommendations of the panel: - Based on the people met, documents reviewed and observations made during inspection including positive intention of the management towards international prequalification and vision for export The panel of inspectors **Recommends** the grant of **Eye/Ear & Nasal Drops (General) Section**. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the grant of following one additional section in the name of M/s Hudson Pharma (Pvt) Ltd,Plot No. D-93, North Western Industrail Zone, Port Qasim, Karachi.on the recommendations of the panel of experts:- **Section (01)** Eye/Ear & Nasal Drops (General Section).(Revised)			
6.	M/s Maxitech Pharma (Pvt) Ltd, Plot No. E/178,S.I.T.E. , Karachi. DML No. 000851 (Formulation). **Section (10)** 1. Dry Powder Injection (Carbapenem)	08-09-2018	**Good**	1. Dr. Ghulam Sarwar, Member DRB, Karachi. 2. Director DTL, Sindh. 3. Mr. Abdul Rasool Sheikh, Federal Inspector

	Section 2. Liquid Ampoule (General) Section 3. Liquid Vial/infusion (General) SVP section 4. Sterile Eye Drop Section(General) 5. Capsule (Cephalosporin) Section 6. Sachet (Cephalosporin) Section 7. Oral Dry Powder Suspension (Cephalosporin) section. 8. Dry Powder vial Injectable(Cephalosporin) section 9. Raw Material (Cephalosporin) section. 10. Finished Good Store (Cephalosporin) Section.			of Drugs, DRAP,Karachi 4. Mrs. Ume Laila, Area Assistant Director, Karachi.
	Recommendations of the panel: - The Panel of inspectors **<u>Recommends</u>** the grant of additional sections under the scope**.** **<u>Decision by the Central Licensing Board in 266th meeting</u>** The Board considered and approved the grant of following ten additional sections in the name of M/s Maxitech Pharma (Pvt) Ltd, Plot No. E/178,S.I.T.E. , Karachi on the recommendations of the panel of experts:- **<u>Section (10)</u>** 1. Dry Powder Injection (Carbapenem) Section 2. Liquid Ampoule (General) Section 3. Liquid Vial/infusion (General) SVP section 4. Sterile Eye Drop Section(General) 5. Capsule (Cephalosporin) Section 6. Sachet (Cephalosporin) Section 7. Oral Dry Powder Suspension (Cephalosporin) section. 8. Dry Powder vial Injectable(Cephalosporin) section 9. Raw Material (Cephalosporin) section. 10. Finished Good Store(Cephalosporin) Section.			
7.	M/s Abbott Laboratories Pakistan Ltd, Plot No. 13, Sector 20, Korangi Industrial Area, Karachi. DML No. 000004 (Formulation) **<u>Facility (01)</u>** 1. Raw Material Store (Amendments)	02-08-2018	**Good**	1. Dr. Abdullah Dayo, Member CLB. 2. Mr. Najam-us-Saqib, Additional Director (E&M), DRAP, Karachi. 3. Ms. Muneeza Khan, Federal Inspector of Drugs, Karachi.
	Recommendations of the panel: - During the course of visit the panel observed the amendments in warehouse as per approved layout pla of DRAP. All areas were found maintained as per cGMP . Therefore, panel of			

	inspectors **Recommends** the grant of amendments in layout as per approval of DRAP. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the following facility in the name of M/s Abbott Laboratories Pakistan Ltd, Plot No. 13, Sector 20, Korangi Industrial Area, Karachi on the recommendations of the panel of experts:- Raw Material Store (Amendments)

8.	M/s OBS Pakistan (Pvt) Ltd, C-14, Mangophir Road, SITE, Karachi. DML No. 000012 (Formulation) **Sections /Facility** 1. Warehouse Hormone(Amendment) 2. Sachet Section Hormone(Amendment) 3. Tablet Section (Hormone) – Amendments. 4. Capsule Hormone Section-Amendments.	01-08-2018	**Good**	1. Mr. Muied Ahmed, Member CLB, Karachi. 2. Mr. Najam-us-Saqib, Additional Director (E&M), DRAP, Karachi 3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - The firm was inspected keeping in view the dedicated sections for hormone ,soft gel and sachet production equipments. QC facilities ,HVAC, stores constructed as per approved layout plan.The panel unanimously **recommends** the amendments in Capsule, tablet, sachet and warehouse. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the amendment of following sections/ facility in the name of M/s OBS Pakistan (Pvt) Ltd, C-14, Mangophir Road, SITE, Karachi on the recommendations of the panel of experts:- **Section/facility** **1.** Warehouse Hormone(Amendment) **2.** Sachet Section Hormone(Amendment) **3.** Tablet Section (Hormone) –Amendments. **4.** Capsule Hormone Section-Amendments			

9.	M/s FAAS Pharmaceuticals (Pvt) Ltd, Plot No. F-748L, S.I.T.E, Karachi DML No. 000767 (Formulation) **Sections / Facilities** 1. Tablet (General) Section (Amendments). 2. Sachet (General) Section (Amendments). 3. Warehouse (Amendments). 4. Finished Goods Store (Amendments).	**03-08-2018**	**Good**	1. Dr. Abdullah Dayo, Member CLB. 2. Najam-us-Saqib, Additional Director(E&M), DRAP, Karachi.. 3. Syed Hakim Masood, Area FID, DRAP, Karachi. 4. Mrs. Ume Laila, Assistant Director, DRAP, Karachi.
	Recommendations of the panel: - Keeping in view the people met, documents reviewed and finding of the inspection and positive intention of the management towards further compliance of DRAP Act,2012 and efforts towards exports to various countries, the panel recommends renewal of the Drug Manufacturing License No. 000767 (Formulation) for **Tablet Section, Capsule and sachet section General** and regularization of layout plan. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the amendments of following sections/ facility in the name of M/s FAAS Pharmaceuticals (Pvt) Ltd, Plot No. F-748L, S.I.T.E, Karachi on the recommendations of the panel of experts:- **Section/facilities** 1. Tablet (General) Section (Amendments). 2. Sachet (General) Section (Amendments). **3.** Warehouse (Amendments). **4.** Finished Goods Store (Amendments).			
10.	M/s Martin Dow Ltd., Plot No.37, Sector 19, Korangi Industrial Area, Karachi. DML No. 000267 (Formulation) **Facility (01)** 1. Research & Development Laboratory (Amendment).	**07-08-2018**	**Very Good**	1. Syed Muied Ahmad, Member CLB. 2. Najam-us-Saqib, Additional Director(E&M), DRAP, Karachi.. 3. Ms. Muneeza Khan, Area FID, DRAP, Karachi.
	Recommendations of the panel: - The panel recommends the grant of amendment/expansion of R&D Lab First Floor as the facility is qualified for manufacturing and testing of stability batches for Martin Dow Group of Companies. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the amendments of following facility in the name of M/s Martin Dow Ltd., Plot No.37, Sector 19, Korangi Industrial Area, Karachi on the recommendations of the panel of experts:- Research & Development Laboratory (Amendment).			
11.	M/s GlaxoSmithKline OTC (Pvt) Ltd., Petaro Road, Jamshoro. DML No. 000010 (Formulation) **Facility (01)**	**10-10-2018**	**Good**	1. Syed Muied Ahmad, Member CLB. 2. Dr. Abdullah Dayo, Member

	1. Two Additional Production Lines in Tablet Section (Vitamin)			CLB. 3. Director DTL, Sindh (**Not Available)** 4. Mr. Sajjad Ahmad, Area FID, DRAP, Karachi.
	Recommendations of the panel: - Keeping in view the people met, documents reviewed and observations made during inspection including the commitment of management towards export, the panel recommends the grant of additional section (Two Additional Production Lines in Tablet Section (Vitamin)). **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the grant of expansion in following section/facility in the name of M/s GlaxoSmithKline OTC (Pvt) Ltd., Petaro Road, Jamshoro on the recommendations of the panel of experts:- **Facility (01)** Two Additional Production Lines in Tablet Section (Vitamin) The board further resolved that word OTC in the title of may creates confusion therefore firm may consider change of title .			
12.	M/s Delta Pharma (Pvt) Ltd., Plot No.09, Nowshera Industrial Estate, (S.I.Z.) Nowshera, Risalpur. **Section (02)** 1. Oral Liquid Section (General). 2. Dry Suspension Section (General)	12-10-2018	**Good**	4. Dr. Jamshaid Ali Khan, Member CLB. 5. Dr. Khalid Javed, Director DTL, Peshawar, KPK. 6. Area FID/AD, DRAP, Peshawar.
	Recommendations of the panel: - In compliance to DRAP Islamabad letter No.F.3-2/96-Lic dated 30-03-2018, M/s Delta Pharma (Pvt) Ltd., Plot No.09, Nowshera Industrial Estate, (S.I.Z.) Nowshera, Risalpur was inspected by the constituted panel. The firm has provided the requisite manufacturing facilities in both the dry powder suspension and oral liquid sections with HVAC facilities installed. An independent Quality Control has been established with all the necessary equipments adequate for tests/analysis. Storage and dispensing areas are also equipped with requisite facilities. As per manufacturing, quality control, environmental facilities provided and the technical staff employed, the panel unanimously recommends the grant of above mentioned two (02) additional sections to M/s Delta Pharma (Pvt) Ltd., Plot No. 09, Nowshera Industrial Estate, (S.I.Z.) Nowshera, Risalpur vide DML No.000446 by way of formulation. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the grant of following two additional sections in the name of M/s Delta Pharma (Pvt) Ltd., Plot No.09, Nowshera Industrial Estate, (S.I.Z.) Nowshera, Risalpur, on the recommendations of the panel of experts:- **Section (02)** 1. Oral Liquid Section (General). 2. Dry Suspension Section (General)			
13.	M/s Fresh Pharmaceutical, Plot	**01-10-2018 &**	**GOOD**	1. Prof. Dr. Muhammad Usman,

	No. 07-S-6, RCCI, Rawat **Section (02)** 1. Topical Lotion (General) 2. Capsule (General-II)	**22-10-2018**		Member Central Licensing Board. 2. Dr. Muhammad Fakhar Uddin Aamir, Additional Director (QA & LT-II), DRAP, Islamabad. 3. Mr. Hasan Afzaal, Federal Inspector of Drugs, DRAP, Islamabad.
	Recommendations of the panel: - Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously recommends M/s Fresh Pharmaceutical, Plot No. 07-S-6, RCCI, Rawat, for the grant of additional section Topical Lotion (General) & Capsule (General-II) **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the grant of following two additional sections in the name of M/s Fresh Pharmaceutical, Plot No. 07-S-6, RCCI, Rawat on the recommendations of the panel of experts:- **Section (02)** 1. Topical Lotion (General) 2. Capsule (General-II)			
14.	M/s Roryan Pharmaceutical Industries (Pvt) Ltd, 85/B, Hayatabad Industrial Estate, Peshawar. **Section (01)** 1. Cream/Ointment Section (General)	**03-10-2018**	**GOOD**	1. Dr. Jamshaid Ali Khan, Member Central Licensing Board. 2. Additional Director (E&M), DRAP, KPK. 3. Federal Inspector of Drugs, DRAP, KPK.
	Recommendations of the panel: - It is an old Pharma unit designed as per approved layout plan. The unit is located in the industrial area and management has tried to maintained overall environment. The Technical staff appointed knows their responsibilities and are technically sound. They have prepared the SOPs for working and also have plane for the development of their facility. They also showed the receipt / invoice for the purchase of FTIR which is essential for the testing. The management informed that it will be installed in coming three month's time. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the grant of following one additional section in the name of M/s Roryan Pharmaceutical Industries (Pvt) Ltd, 85/B, Hayatabad Industrial Estate, Peshawar, on the recommendations of the panel of experts:- **Section (01)** Cream/Ointment Section (General)			

15.	M/s Vision Pharmaceuticals, Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad. **LYOPHILIZED DRUGS** i. Azithromycin Lyophilized Powder for Injection USP. ii. Clarithromycin Lyophilized Powder for Injection USP. iii. Tigecycline Lyophilized Powder for Injection USP. iv. Vancomycin Lyophilized Powder for Injection USP. **PELLETS** i. Linezolid (In house specs) ii. Paracetamol BP. iii. Famotidine BP. iv. Micro Crystalline Cellulose Pellets **MICRO-PELLETS DISPERSION** i. Velpatasvir Disperson (Velpatasvir:Copovidone) (1:1) (In house specs) ii. Elbasvir Dispersion (In house specs). iii. Grazoprevir Dispersion (In house specs). iv. Ledipasvir Dispersion (In house specs). v. Misoprostol Dispersion (In house specs).	**09-07-2018** **&** **19-07-2018**		1. Dr. Ikram ul Haq, 1. QC Expert of Drugs, Lahore. 2. Dr. Muhammad Saeed, Prof of Pharmacy, (could not join the inspection) 3. Additional Director (QALT), DRAP, Islamabad. 4. FID-I, DRAP, Islamabad.
	Recommendations of the panel: - Based on the facilities and the discussion with the management and technical staff, the panel unanimously recommended for the grant of approval of applied products to be manufactured in the semi-basic manufacturing facility in following two sections: **<u>Decision by the Central Licensing Board in 266th meeting</u>** The Board considered and approved the grant of following Additional APIs in the name of M/s Vision Pharmaceuticals, Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad, on the recommendations of the panel of experts:- 1) Pellets / Pelletization 2) Lyophilization **LYOPHILIZED DRUGS** i. Azithromycin Lyophilized Powder for Injection USP. ii. Clarithromycin Lyophilized Powder for Injection USP.			

	iii. Tigecycline Lyophilized Powder for Injection USP. iv. Vancomycin Lyophilized Powder for Injection USP. **PELLETS** i. Linezolid (In house specs) ii. Paracetamol BP. iii. Famotidine BP. iv. Micro Crystalline Cellulose Pellets **MICRO-PELLETS DISPERSION** i. Velpatasvir Disperson (Velpatasvir:Copovidone) (1:1) (In house specs) ii. Elbasvir Dispersion (In house specs). iii. Grazoprevir Dispersion (In house specs). iv. Ledipasvir Dispersion (In house specs). v. Misoprostol Dispersion (In house specs).			
16.	M/s Well & Well Pharma (Pvt) Ltd, Plot No. 7, Street No. S-8, National Industrial Zone, RCCI Rawat, Islamabad. **Section (1)** 1. Dry Powder Vial Injection (Ceph).	**23-10-2018**	**GOOD**	1. Dr. Muhammad Usman, Member CLB. 2. Additional Director (Lic), DRAP, ISB. 3. Federal Inspector of Drugs-III, DRAP, ISB.
	Recommendations of the panel: - Keeping in view of the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously ***Recommended*** M/s Well & Well Pharma (Pvt) Ltd, Plot No. 7, Street No. S-8, National Industrial Zone, RCCI Rawat, Islamabad for the grant of above Additional Section. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the grant of following one additional section in the name of M/s Well & Well Pharma (Pvt) Ltd, Plot No. 7, Street No. S-8, National Industrial Zone, RCCI Rawat, Islamabad, on the recommendations of the panel of experts:- **Section (1)** 1. Dry powder Vial Injection (Ceph).			
17.	M/s Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad. **Section (15)** **First Floor** 1. Sterile Dry Powder Vial (Steroid) Section	**19-09-2018**	**GOOD**	1. Dr. Obaid Ullah, Director (P,E&R). 2. Additional Director (Lic), DRAP, Islamabad. 3. Area FID, DRAP, Islamabad.

	2. Sterile Liquid Ampoule (Steroid) Section 3. Topical (Steroid Section) 4. Eye/Ear/Nasal Drops (Steroid Section) 5. Warehouse (Steroid Section) **Second Floor** 1. Sterile Liquid Vials SVP (General) 2. Liquid Ampoule SVP (General) 3. Ear, Eye Drops (General) 4. Oral Liquid (General) 5. Tablet (General) 6. Capsule (General) 7. Sachet (General) 8. Oral Dry Suspension (General) 9. Cream/Ointment (General) 10. Dry Powder Vials SVP (General)			

Recommendations of the panel: -

Keeping in view of the above facts on record, the panel unanimously **recommends the approval of above (15) new/additional section** to M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad. The panel did not recommend the Gel preparations/products in **Cream/Ointment (General) and Topical (Steroid)** sections since the firm did not possess required machinery and equipments for said purpose.

Decision by the Central Licensing Board in 266th meeting

The Board considered and approved the grant of following fifteen additional sections and did not recommend the Gel preparations/product in **Cream/Ointment (General) and Topical (Steroid)** sections since the firm did not possess required machinery and equipments for said purpose in the name of M/s Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad. on the recommendations of the panel of experts:-

Section (15)

First Floor

1. Sterile Dry Powder Vial (Steroid) Section
2. Sterile Liquid Ampoule (Steroid) Section
3. Topical (Steroid Section)
4. Eye/Ear/Nasal Drops (Steroid Section)
5. Warehouse (Steroid Section)

Second Floor

1. Sterile Liquid Vials SVP (General)
2. Liquid Ampoule SVP (General)
3. Ear, Eye Drops (General)
4. Oral Liquid (General)

	5. Tablet (General) 6. Capsule (General) 7. Sachet (General) 8. Oral Dry Suspension (General) 9. Cream/Ointment (General) 10. Dry Powder Vials SVP (General) However the Central Licensing Board did not approved Gel products in the section of Topical (Steroid Section) and Cream/Ointment (General) on the recommendation of the panel and same shall be conveyed to Drug Registration Board.

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

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad. DML No. 000613 (Formulation) **Period**: 21-03-2017 to 20-03-2022	**8-8-2018**	**Good**	1. Prof. Dr. Muhammad Usman, Member CLB 2. Additional Director (QA &LT-II), DRAP Islamabad. 3. Additional Director Lic, (could not join the panel due to official engagement.) 4. FID-III, DRAP Islamabad

"Keeping in view the manufacturing and testing facility in place, the panel unanimously **recommends** M/s Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad Formulation (Formerly M/s Goodman Laboratories, Plot No. 05, S-5, National Industrial Zone, Rawat) for the renewal of Drug Manufacturing License No. 000613 (Formulation). The responsibility lies with the manufacturer to ascertain the regulatory requirements during the validity period of DML. The said License is being recommended for the following sections namely as under;

1. Tablet Section (General).
2. Capsule Section (General).
3. Oral Liquid Section (General).
4. Dry suspension Section (General).
5. Capsule Section (Ceph).
6. Dry Suspension Section (Ceph).

Decision by the Central Licensing Board in 266th meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000613 (Formulation) in the name of M/s Goodman Laboratories (Pvt) Ltd., Plot No. 05, S-05, National Industrial Zone, Rawat, Islamabad , on the recommendations of the panel of experts for the further period of five years commencing on 21-03-2017 and ending on 20-03-2022.

2.	M/s Pulse Pharmaceuticals (Pvt) Ltd, Mozay Baddoki Raiwind Road (Sua Aasil Road), Lahore. DML No. 000564 (Formulation) **Period**: Commencing on 31-12-2014 ending on 30-12-2019.	**28-08-2018**	**Good**	1. Dr. Mahmood Ahmed, Ex-Dean, University of Bahawalpur. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Mr. Anjum Pervaiz, Health Department, Government of Punjab, Lahore. 4. Mr. Shoaib Ahmed, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - The Panel of inspector recommends the renewal of DML bearing No. 000564 in respect to all approved section, **except liquid infusion section**, which the firm is withdrawing and have also submitted documents in DRAP Islamabad for conversion to ampoule section in future. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000564 (Formulation) , **except liquid infusion section** in the name of M/s Pulse Pharmaceuticals (Pvt) Ltd, Mozay Baddoki Raiwind Road (Sua Aasil Road), Lahore., on the recommendations of the panel of experts for the further period of five years Commencing on 31-12-2014 and ending on 30-12-2019. The liquid infusion section stand withdraw with immediate effect and same shall be communicated to Drug Registration Board .			
3	M/s Mylab (Pvt) Ltd, Khanqah Sharif, Bahawalpur DML No. 000747 (Formulation) **Period**: Commencing on 27-08-2017 ending on 26-08-2022.	13-09-2018 and 14-09-2018	**V. Good**	1. Dr. Ikram-ul-Haq, Member, Central Licensing Board 2. Dr. Mahmood Ahmad, Member, PQCB, Lahore. 3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - The Panel of inspector recommends the renewal of DML bearing No. 000747 in respect to following approved sections: 1. Liquid Injectable (General) Veterinary. 2. Oral Liquid (General) Veterinary. 3. Oral Powder (General) Veterinary. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000747 (Formulation) in the name of M/s Mylab (Pvt) Ltd, Khanqah Sharif, Bahawalpur, on the			

	recommendations of the panel of experts for the further period of five years Commencing on 27-08-2017 and ending on 26-08-2022.			
4	M/s Welmark Pharmaceuticals, Plot No.122, Block B, Phase-V, Industrial Estate, Hattar. DML No. 000614 (Formulation) **Period**: 11-04-2017 to 10-04-2022.	04-9-2018 And 26-9-2018	**Good**	1. Dr. Muhammad Usman, Member CLB. 2. Additonal Director (QA-II), DRAP, Islamabad. 3. Area Federal Inspector of Drugs, DRAP, Peshawar.
	Recommendations of the panel: - In compliance to DRAP Islamabad letter No.F.3-3/2006-Lic (Vol-II) dated 08-08-2018, factory premises of M/s Welmark Pharmaceuticals, Hattar was inspected by the constituted panel. Equipments required for manufacturing of capsules, tablets, dry suspension, dry powder injectables, liquid injectables and sachets are available. HVAC system found installed separately in all sections. Quality Control equipments adequate for analysis. Stores and dispensing area are also equipped with requisite facilities. Keeping in view the available facilities the constituted panel unanimously recommend the grant of renewal of Drug Manufacturing License (DML) No.000614 by way of formulation granted to M/s Welmark Pharmaceuticals, Industrial Estate, Hattar, Khyber Pakhtunkhawa. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000614 (Formulation) in the name of M/s Welmark Pharmaceuticals, Plot No.122, Block B, Phase-V, Industrial Estate, Hattar, on the recommendations of the panel of experts for the further period of five years Commencing on 11-04-2017 and ending on 10-04-2022.			
5	M/s FAAS Pharmaceuticals (Pvt) Ltd, Plot No. F-748L, S.I.T.E, Karachi DML No. 000767 (Formulation) **Period**: 15-02-2018 to 14-02-2023	**03-08-2018**	**Good**	1. Dr. Abdullah Dayo, Member CLB. 2. Najam-us-Saqib, Additional Director(E&M), DRAP, Karachi.. 3. Syed Hakim Masood, Area FID, DRAP, Karachi. 4. Mrs. Ume Laila, Assistant Director, DRAP, Karachi.
	Recommendations of the panel: - Keeping in view the people met, documents reviewed and finding of the inspection and positive intention of the management towards further compliance of DRAP Act,2012 and efforts towards exports to various countries, the panel recommends renewal of the Drug Manufacturing License No. 000767 (Formulation) for **Tablet Section, Capsule and sachet section General** and regularization of layout plan. **Decision by the Central Licensing Board in 266th meeting**			

	The Board considered and approved the renewal of Drug Manufacturing Licence No. 000747 (Formulation) and regularization of layout plan in the name of M/s FAAS Pharmaceuticals (Pvt) Ltd, Plot No. F-748L, S.I.T.E, Karachi, on the recommendations of the panel of experts for the further period of five years Commencing on 15-02-2018 ending on 14-02-2023.			
6.	M/s Epoch Pharmaceuticals, (Pvt). Ltd, Plot No. 83-85, Sector 15, Korangi industrial Area,Karachi. DML No. 000425 (Formulation) **Period**: Commencing on 25-03-2016 ending on 24-03-2021.	**10-09-2018**	**Good**	1. Syed Javed Yousuf Bukhari, QC Expert. 2. Dr. Ghulam Sarwar, Member DRB, Karachi. 3. Ms. Muneeza Khan,Area FID, Karachi. 4. Mr. Krishan Das, Area Assistant Director, DRAP, Karachi.
	Recommendations of the panel: - Keeping in view the existing GMP condition suitability of equipment, capabilities of technical staff panel unanimously **recommends** the grant of Renewal of Drug Manufacturing License 000425 (By way of Formulation) for the next tenure. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000425 (Formulation) in the name of M/s Epoch Pharmaceuticals, (Pvt). Ltd, Plot No. 83-85, Sector 15, Korangi industrial Area, Karachi on the recommendations of the panel of experts for the further period of five years Commencing on 25-03-2016 and ending on 24-03-2021.			
7.	M/s Medimarker's Laboratories (Pvt) Ltd, Plot No.A-104, S.I.T.E, Hyderabad. DML No. 000615 (Formulation) **Period**: 07-04-2017 to 06-04-2022.	**16-10-2018**	**Good**	1. Dr. Abdullah Dayo, Member CLB 2. Mr. Najam-us-Saqib Additonal Director (E&M) DRAP, Karachi. 3. Mr. Sajjad Abbasi Area Federal Inspector of Drugs, DRAP, Karachi. 4. Ms. Umme-Laila Assistant Director, DRAP, Karachi.
	Recommendations of the panel: - The panel reviewed their overall documentation, inspected manufacturing facilities, Quality control laboratory, stores and utilities and met their technical person and higher management. The panel observed that M/s Medimarker Laboratories is constructed as per DRAP approved layout plan. Good level of sanitation, cleanliness and work hygiene was noted. The firm has adequate number of processing and testing equipment in respective departments. Based on the stated observations, the panel recommends renewal of the Drug Manufacturing License No. 000615 (Formulation) for **1. Tablet Section (General),** **2. Ointment Section (General),** **3. Liquid Syrup Section (General),**			

	4. Sachet section (General), **5. Tablet (Psychotropic),** **6. Ear & Eye Drop Section,** **7. Injectable Section (sterile),** **8. Dry Syrup section (Cephalosporin),** **9. Injectable Section (Cephalosporin),** **10.Capsule (Penicillin) section,** **11.Dry Syrup (Penicillin) Section.** The panel further recommends the regularization of the existing layout plan regularization of layout plan. **Decision by the Central Licensing Board in 266th meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000615 (Formulation) in the name of M/s Medimarker's Laboratories (Pvt) Ltd, Plot No.A-104, S.I.T.E, Hyderabad. on the recommendations of the panel of experts for the further period of five years Commencing on 07-04-2017 and ending on 06-04-2022.

Item-V: **MISCELLANEOUS CASES.**

CASE NO. 1. CHANGE OF MANAGEMENT OF M/S PRAYS PHARMACEUTICALS, PLOT NO. 10, STREET SS/4, NATIONAL INDUSTRIAL ZONE, RCCI, RAWAT, ISLAMABAD.

M/s Prays Pharmaceuticals, Plot No. 10, Street SS/4, National Industrial Zone, RCCI, Rawat, Islamabad, under DML No. 000719 by way of Formulation has submitted request for change in management of the firm as per partnership deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management as per partnership deed.	Incoming Management	New Management as per partnership deed.
1. Mr. Basit Abbasi S/o Muhammad Khalil Abbasi CNIC No. 37405-1139012-1. 2. Mr. Sohail Abbasi S/o Muhammad Khalil Abbasi CNIC No. 35202-7627978-7. 3. Mr. Ahmed Bilal Adil S/o Muhammad Aqleen Sheikh CNIC No. 37405-0579211-1.	1. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-248331-5.	1. Mr. Basit Abbasi S/o Muhammad Khalil Abbasi CNIC No. 37405-1139012-1. 2. Mr. Ahmed Bilal Adil S/o Muhammad Aqleen Sheikh CNIC No. 37405-0579211-1. 3. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-248331-5.

Decision by the Central Licensing Board in 266th meeting:

The Board considered and endorsed the change of management of the company M/s Prays Pharmaceuticals, Plot No. 10, Street SS/4, National Industrial Zone, RCCI, Rawat, Islamabad, as per partnership deed as under;

Previous Management as per partnership deed.	Incoming Management	New Management as per partnership deed.
1. Mr. Basit Abbasi S/o Muhammad Khalil Abbasi CNIC No. 37405-1139012-1. 2. Mr. Sohail Abbasi S/o Muhammad Khalil Abbasi CNIC No. 35202-7627978-7. 3. Mr. Ahmed Bilal Adil S/o Muhammad Aqleen Sheikh CNIC No. 37405-0579211-1.	1. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-248331-5.	1. Mr. Basit Abbasi S/o Muhammad Khalil Abbasi CNIC No. 37405-1139012-1. 2. Mr. Ahmed Bilal Adil S/o Muhammad Aqleen Sheikh CNIC No. 37405-0579211-1. 3. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-248331-5.

Case No.2. CHANGE OF MANAGEMENT OF M/S ARSONS PHARMACEUTICAL INDUSTRIES (PVT) LTD, LAHORE.

M/s Arsons Pharmaceutical Industries (Pvt) Ltd, 2.5-Km, Defence Road, Off Multan Road, Lahoreunder DML No. 000514by way of formulationhas submitted request for change in management of the firm as per Form 29& Form-A along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-A	Added Management	Proposed Management as per Form-A & Form-29
1. Mr. Muhammad Shahid S/o Mukhtar Ahmed CNIC No. 35202-0220038-5. 2. Mr. Muhammad Arshad Javaid S/o Mukhtar Ahmed CNIC No. 35202-9650326-9.	1. Mr. Muhammad Ali Arshad S/o Muhammad Arshad Javaid CNIC No.91506-0128861-7.	1. Mr. Muhammad Shahid S/o Mukhtar Ahmed CNIC No. 35202-0220038-5. 2. Mr. Muhammad Arshad Javaid S/o Mukhtar Ahmed CNIC No. 35202-9650326-9. 3. Mr. Muhammad Ali Arshad S/o Muhammad Arshad Javaid CNIC No.91506-0128861-7.

Decision by the Central Licensing Board in 266th meeting:

The Board considered and endorsed the change of management of the M/s Arsons Pharmaceutical Industries (Pvt) Ltd, 2.5-Km, Defence Road, Off Multan Road, Lahore as per Form 29 and Form-A issued by S.E.C.P as under;

Previous Management as per Form-A	Added Management	New Management as per Form-A & Form-29
1. Mr. Muhammad Shahid S/o Mukhtar Ahmed CNIC No. 35202-0220038-5. 2. Mr. Muhammad Arshad Javaid S/o Mukhtar Ahmed CNIC No. 35202-9650326-9.	1. Mr. Muhammad Ali Arshad S/o Muhammad Arshad Javaid CNIC No.91506-0128861-7.	1. Mr. Muhammad Shahid S/o Mukhtar Ahmed CNIC No. 35202-0220038-5. 2. Mr. Muhammad Arshad Javaid S/o Mukhtar Ahmed CNIC No. 35202-9650326-9. 3. Mr. Muhammad Ali Arshad S/o Muhammad Arshad Javaid CNIC No.91506-0128861-7.

Case No.3. CHANGE OF MANAGEMENT OF M/S CHERISHED PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Cherished Pharmaceuticals (Pvt) Ltd, 10-Km, Sunder Raiwind Road, Lahore under DML No. 000596by way of formulation has submitted request for change in management of the firm as per Form 29 along with prescribed Fee Challan of 50,000/- as under:-

Previous Management at the time of renewal of DML as per Form-29	Interim Management as per Form-29	Proposed Management as per Form-29

1. Mr. Muhammad Azam Chaudhary S/o Ch. Muhamad Hafeez CNIC No. 61101-1903673-1. 2. Mrs. Samra Azam W/o Ch. Muhamad Hafeez CNIC No. 61101-1800424-4.	1. Mr. Muhammad Azam Chaudhary S/o Ch. Muhamad Hafeez CNIC No. 61101-1903673-1. 2.Mr. Syed Bahadur Ali Kazmi S/o Syed Safdar Ali Kazmi CNIC No. 35401-7102402-9.	1. Mr. Muhammad Azam Chaudhary S/o Ch. Muhamad Hafeez CNIC No. 61101-1903673-1.

Decision by the Central Licensing Board in 266th meeting:

The Board considered and endorsed the change of management of the company M/s Cherished Pharmaceuticals (Pvt) Ltd, 10-Km, Sunder Raiwind Road, Lahore as per Form 29 issued by S.E.C.P as under;

Previous Management at the time of renewal of DML as per Form-29	**Interim Management as per Form-29**	**New Management as per Form-29**
1. Mr. Muhammad Azam Chaudhary S/o Ch. Muhamad Hafeez CNIC No. 61101-1903673-1. 2. Mrs. Samra Azam W/o Ch. Muhamad Hafeez CNIC No. 61101-1800424-4.	1. Mr. Muhammad Azam Chaudhary S/o Ch. Muhamad Hafeez CNIC No. 61101-1903673-1. 2.Mr. Syed Bahadur Ali Kazmi S/o Syed Safdar Ali Kazmi CNIC No. 35401-7102402-9.	1. Mr. Muhammad Azam Chaudhary S/o Ch. Muhamad Hafeez CNIC No. 61101-1903673-1.

Case No.4. CHANGE OF MANAGEMENT OF M/S A&K PHARMACEUTICAL, FAISALABAD

M/s A&K Pharmaceutical, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad under DML No. 000534by way of formulationhas submitted request for change in management of the firm as per Partnership deed and Form-D along with prescribed Fee Challan of 50,000/- as under:-

Previous management as per Partnership deed	**Retiring Management**	**Proposed management as per Partnership deed and Form-D**
1. Mr. Akhtar Ali S/o Umer Din CNIC No. 331021-788835-3. 2. Mr. Muhammad Mohsin Akhtar S/o Akhtar Ali CNIC No. 33100-5574430-1. 3. Mr. Muhammad Ahsan S/o Akhtar Ali CNIC No. 33102-1788832-1.	1. Mr. Akhtar Ali S/o Umer Din CNIC No. 331021-788835-3. 2. Mr. Muhammad Ahsan S/o Akhtar Ali CNIC No. 33102-	1. Mr. Muhammad Mohsin Akhtar S/o Akhtar Ali CNIC No. 33100-5574430-1. 2. Mr. Arfan-ur-Rehman S/o Akhtar Ali CNIC No. 33100-6743196-1.

4. Mr. Arfan-ur-Rehman S/o Akhtar Ali CNIC No. 33100-6743196-1.	1788832-1.	

Decision by the Central Licensing Board in 266th meeting:

The Board considered and endorsed the change of management of the company M/s A&K Pharmaceutical, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad, as per Partnership deed and Form-D as under;

Previous Management as per Partnership deed	Retiring Management	New Management as per Partnership deed and Form-D
1. Mr. Akhtar Ali S/o Umer Din CNIC No. 331021-788835-3. 2. Mr. Muhammad Mohsin Akhtar S/o Akhtar Ali CNIC No. 33100-5574430-1. 3. Mr. Muhammad Ahsan S/o Akhtar Ali CNIC No. 33102-1788832-1. 4. Mr. Arfan-ur-Rehman S/o Akhtar Ali CNIC No. 33100-6743196-1.	1. Mr. Akhtar Ali S/o Umer Din CNIC No. 331021-788835-3. 2. Mr. Muhammad Ahsan S/o Akhtar Ali CNIC No. 33102-1788832-1.	1. Mr. Muhammad Mohsin Akhtar S/o Akhtar Ali CNIC No. 33100-5574430-1. 2. Mr. Arfan-ur-Rehman S/o Akhtar Ali CNIC No. 33100-6743196-1.

Case No.5. CHANGE OF MANAGEMENT OF M/S ALLMED (PVT) LTD, LAHORE

M/s Allmed (Pvt) Ltd, Plot 590, Sunder Industrial Estate, Lahore under DML No. 000645by way of formulationhas submitted request for change in management of the firm as per Form 29& Form-Aalong with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-29	Retiring Management	Proposed Management as per Form-29 & Form-A
1)Mr. Muhammad Ejaz Mirza S/o Naseem Mirza CNIC No.42201-5932766-1 2)Mr. Muhammad Adil Mirza S/o Naseem Mirza CNIC No.42000-6586101-3 3)Mr. Tariq Mehboob S/o Rashid Mehboob CNIC No. 42101-1868830-5.	1)Mr. Tariq Mehboob S/o Rashid Mehboob CNIC No. 42101-1868830-5.	1)Mr. Muhammad Ejaz Mirza S/o Naseem Mirza CNIC No.42201-5932766-1 2)Mr. Muhammad Adil Mirza S/o Naseem Mirza CNIC No.42000-6586101-3 3)Ms. Sadaf Mirza W/o Muhammad Ejaz Mirza CNIC No. 42201-2885869-6.

Decision by the Central Licensing Board in 266th meeting:

The Board considered and endorsed the change of management of the company M/s Allmed (Pvt) Ltd, Plot 590, Sunder Industrial Estate, Lahore, as per Form 29 and Form-A issued by S.E.C.P as under;

Previous Management as per Form-29	**Retiring Management**	**New Management as per Form-29 & Form-A**
1)Mr. Muhammad Ejaz Mirza S/o Naseem Mirza CNIC No.42201-5932766-1 2)Mr. Muhammad Adil Mirza S/o Naseem Mirza CNIC No.42000-6586101-3 3)Mr. Tariq Mehboob S/o Rashid Mehboob CNIC No. 42101-1868830-5.	1)Mr. Tariq Mehboob S/o Rashid Mehboob CNIC No. 42101-1868830-5.	1) Mr. Muhammad Ejaz Mirza S/o Naseem Mirza CNIC No.42201-5932766-1 2)Mr. Muhammad Adil Mirza S/o Naseem Mirza CNIC No.42000-6586101-3 3)Ms. Sadaf Mirza W/o Muhammad Ejaz Mirza CNIC No. 42201-2885869-6.

CASE NO. 6 <u>CHANGE OF MANAGEMENT OF M/S BAXTER PHARMACEUTICALS, KARACHI</u>

M/s Baxter Pharmaceuticals, A-1/A Scheme No. 33 Phase-I S.I.T.E. Super Highway Karachi under DML No. 000700 by way of Formulation has submitted request for change in management of the firm as per Partnership deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management	**Retiring management**	**Proposed Management as per partnership deed**
1. Mr. Sohail Talib S/oTalib Ali Badayuni CNIC No. 42101-1380821-7 2. Mr. Nazar Talib S/o Talib Ali Badayuni S/o 42101-2663022-1	1. Mr. Nazar Talib S/o Talib Ali Badayuni S/o 42101-2663022-1	1. Mr. Sohail Talib S/oTalib Ali Badayuni CNIC No. 42101-1380821-7. 2. Mr. Muhamad Azhar Sohail S/o Sohail Talib CNIC No. 42101-9641026-5. 3. Mr. Muhammad Ashar Sohail S/o Sohail Talib CNIC No. 42101-9631621-5.

<u>Decision by the Central Licensing Board in 266th meeting:</u>

The Board considered and endorsed the change of management of M/s Baxter Pharmaceuticals, A-1/A Scheme No. 33 Phase-I S.I.T.E. Super Highway Karachi as per partnership deed as under;

Previous management	**Retiring management**	**New Management as per partnership deed**

1. Mr. Sohail Talib S/oTalib Ali Badayuni CNIC No. 42101-1380821-7 3. Mr. Nazar Talib S/o Talib Ali Badayuni S/o 42101-2663022-1	2. Mr. Nazar Talib S/o Talib Ali Badayuni S/o 42101-2663022-1	1. Mr. Sohail Talib S/oTalib Ali Badayuni CNIC No. 42101-1380821-7. 2. Mr. Muhamad Azhar Sohail S/o Sohail Talib CNIC No. 42101-9641026-5. 3. Mr. Muhammad Ashar Sohail S/o Sohail Talib CNIC No. 42101-9631621-5.

Case No. 7 CHANGE OF TITLE/LEGAL STATUS OF M/S MEDIPHARM (PVT) LTD, LAHORE

M/s MediPharm (Pvt) Ltd, 108-Kot Lakhpat Industrial Estate, Lahore under DML No. 000243by way of formulation has submitted request for change of title of the firm as per Certificate of incorporation Form S.E.C.P with prescribed Fee Challan of Rs.50,000/-. The detail is as under:

Previous Title/name of firm as per Form-2	Proposed title of Firm as per letter of S.E.C.P
M/s MediPharm (Pvt) Ltd, Lahore.	M/s Bayer Pakistan (Pvt) Ltd, Lahore.

Decision by the Central Licensing Board in 266th meeting:

The Board considered and endorsed the change of title/ name of the company M/s MediPharm (Pvt) Ltd, 108-Kot Lakhpat Industrial Estate, Lahore as per letter issued by S.E.C.P

Previous Title/name of firm as per Form-2	New title of Firm as per letter of S.E.C.P
M/s MediPharm (Pvt) Ltd, Lahore.	M/s Bayer Pakistan (Pvt) Ltd, Lahore. [Formerly M/s MediPharm (Pvt) Ltd, Lahore]

Case No.8. CHANGE OF MANAGEMENT OF M/S BAYER PAKISTAN (PVT) LTD, LAHORE.

M/s Bayer Pakistan (Pvt) Ltd, [Formerly M/s MediPharm (Pvt) Ltd, Lahore] 108-Kot Lakhpat Industrial Estate, Lahore under DML No. 000243by way of formulationhas submitted request for change in management of the firm as per Form 29& Form-A along with prescribed Fee Challan of 50,000/- as under:-

Previous management as per Form-1A & Form-A	Retiring Management	Proposed management as per Form-A
1. Mr. Amir Iqbal 2. Ms. Andrea Cornelissen	1. Mr. Amir Iqbal 2. Ms. Andrea Cornelissen	1. Mr. Imran Ahmad Khan S/o Anwar Ahmad Khan CNIC No. 35202-0840996-1. 2. Mr. Muhammad Shafiq S/o Muhammad Rafiq Moti CNIC No. 42301-5878799-9.

Decision by the Central Licensing Board in 266th meeting:

The Board considered and endorsed the change of management of M/s Bayer Pakistan (Pvt) Ltd, [Formerly M/s MediPharm (Pvt) Ltd, Lahore] 108-Kot Lakhpat Industrial Estate, Lahore, as per Form-A issued by S.E.C.P as under;

Previous management as per Form-1A & Form-A	Retiring Management	New management as per Form-A
3. Mr. Amir Iqbal 4. Ms. Andrea Cornelissen	3. Mr. Amir Iqbal 4. Ms. Andrea Cornelissen	1. Mr. Imran Ahmad Khan S/o Anwar Ahmad Khan CNIC No. 35202-0840996-1. 2. Mr. Muhammad Shafiq S/o Muhammad Rafiq Moti CNIC No. 42301-5878799-9.

Case No. 9. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S WISE PHARMACEUTICALS, PLOT NO. 3-A, STREET NO. S-1, RCCI, INDUSTRIAL ESTATE, RAWAT, RAWALPINDI.

M/s Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi, had applied for renewal of DML 000625 by way of (Formulation) for the period of 25-09-2017 to 24-09-2022. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13th December, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

Renewal.

i. Form 1-A.
ii. Classes of Drugs.
iii. Dosage forms of drugs.
iv. Name(s) of drugs registered / approved.
v. Change(s) in name of proprietor / directors / partners (if any).
vi. Detail of premises including layout plan.
vii. Section wise detail of machinery for manufacture.
viii. Section wise detail of machinery for Quality Control Lab.
ix. Name and Qualification of Production & Quality Incharge.
x. Nothing due certificate regarding CRF from STO.
xi. Proof of Licensed Section from CLB.
xii. All documents should be duly attested.

Detail of management.

i. Detail of Management at the time of previous renewal and present renewal.
ii. Partnership Deed attested / Sole Proprietor.
iii. All documents duly should be attested.

The firm submitted their reply on 18th January, 2018 After evaluation of the submitted documents, final reminder was issued on 10th April, 2018 to the firm with following shortcomings: -

Renewal.

i. Form 1-A.
ii. Classes of Drugs.
iii. Dosage forms of drugs.
iv. Name(s) of drugs registered / approved.
v. Change(s) in name of proprietor / directors / partners (if any).
vi. Detail of premises including layout plan.
vii. Section wise detail of machinery for manufacture.
viii. Section wise detail of machinery for Quality Control Lab.
ix. Name and Qualification of Production & Quality Incharge.
x. Nothing due certificate regarding CRF from STO.
xi. Proof of Licensed Section from CLB.
xii. All documents should be duly attested.

Detail of management.

i. Detail of Management at the time of previous renewal and present renewal.
ii. Partnership Deed attested / Sole Proprietor.
iii. All documents duly should be attested.

Firm has submited their reply in response to this Division's Final Reminder and following documents are still deficient /short and application for renewal of DML was incomplete:-

Renewal.

i. Attested copy of CNIC of Mr. Sajjad Ahmad, QC Incharge.
ii. Resignation / retirement of earlier QC Incharge.
iii. Undertaking as whole time employee on stamp paper of QC Incharge.
iv. Nothing due certificate regarding CRF from STO.
v. All documents should be duly attested.

Detail of management.

i. There is change in management from previous management following documents are required:-
   a). NOCs from retiring / outgoing management.
   b). CNICs of all directors (Previous & New).
   c). Prescribed fee for change of management.
ii. All documents duly should be attested.

Proceedings and Decision of Central Licensing Board in 266th meeting

- The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi, Drug Manufacturing Licence No 000625 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.
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Case No. 10 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S BASEL PHARMACEUTICAL, MULTAN.

M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, Multan had applied for renewal of DML No. 000726 by way of Formulation for the period of 21-06-2016 to 20-06-2021 on 06-06-2016.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 3rd October, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form 1-A
2. Classes of Drugs
3. Dosage form of Drugs
4. Name (s) of drugs Registered / approved
5. Chang (s) in name of proprietor / director / partner (If any)
6. Detail of premises including layout plan and proof of section form CLB
7. Nothing due certificate regarding CRF from STO.
8. Resignation of earlier Production Incharge & QC Incharge.
9. Resignation of appointee Production Incharge & QC Incharge from Pervious firm.
10. Experience of QC Incharge is less than 10 year.
11. Job Acceptance / joining letter from production Incharge.

No reply was receive from the firm. Final Reminder letter was issued on 10thJanuary, 2017 to the firm for submission of following documents.

1. Form1-A duly signed and stamped.
2. Classes of Drugs.
3. Dosage Forms of Drugs.
4. Name(s) of drugs registered/Approved.
5. Detail of premises including approved master layout plan.
6. Proof of sections approved by CLB.
7. CNIC copies of All Directors/Partners.
8. Nothing due certificate regarding CRF from STO (Updated).
9. Resignation of earlier Production Incharge & QC Incharge.
10. Resignation of appointee Production Incharge & QC Incharge from Pervious firm.
11. Experience certificates of Proposed Production Incharge & QC Incharge(Not less than 10 years in relevant field)
12. Job Acceptance / joining letter from production Incharge.

13. Undertaking as whole time employee on stamp paper of both Production Incharge & QC Incharge.
14. Registration Certificate from pharmacy council of Production Incharge.
15. CNIC copy of Production Incharge.

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

Proceedings and Decision of Central Licensing Board in 265th meeting

- The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, Multan, under Drug Manufacturing Licence No. 000726 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 5th September 2018 was issued to the M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, Multan.

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

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

Proceedings and Decision of Central Licensing Board in 266th meeting

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

Case No. 11 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AVICENNA LABORATORIES (PVT) LTD, DISTRICT SHEIKHUPURA

M/s Avicenna Laboratories (Pvt) Ltd, 14-Km, Sheikhupura Road, Faisalabad Raod, Bhikkhi, District Sheikhupura had applied for renewal of DML No. 000328 by way of formulation for the period of 05-10-2017 to 04-10-2022 on 29-09-2017.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 30thOctober, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Updated Form-29 duly attested by S.E.C.P.

ii. Classes of Drugs
iii. Dosage form of drugs.
iv. Complete set documents of proposed production Incharge Mr. Sajjad Haider as per checklist (attached)
v. Nothing due certificate regarding CRF form STO (R&D), Islamabad. 2016-17 .
vi. Proof of all Licensed Section approved by the CLB
vii. All documents should be duly attested.

The firm submitted their reply on 20thNovember, 2017.After evaluation of the submitted documents, Final reminder was issued on 04thJanuary, 2018 to the firm with following shortcomings: -

i. Nothing due certificate regarding CRF form STO (Updated).
ii. Updated Form-29 duly attested by S.E.C.P.
iii. Classes & Dosage form of Drugs.
iv. CNIC copies of all Directors.
v. Resignation / retirement of earlier Production Incharge
vi. Resignation letter of appointee from previous firm.
vii. All documents should be duly attested.

Firm submitted documents on 05th July, 2018 in reply to Final Reminder but following documents are still deficient /short and application for renewal of DML is still incomplete.

i. Nothing due certificate regarding CRF (Updated).
ii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of proposed Production Incharge (Not less than 10 years).
iii. Resignation of proposed Q.C Incharge from previous firm (Not attested).
iv. All documents should be duly attested.

Proceedings and Decision of Central Licensing Board in 265thmeeting

- The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/sAvicenna Laboratories (Pvt) Ltd, 14-Km, Sheikhupura Road, Faisalabad Raod, Bhikkhi, District Sheikhupura, under Drug Manufacturing Licence No. 000328 by way of formulation

may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 7th September, 2018 was issued to the M/sAvicenna Laboratories (Pvt) Ltd, 14-Km, Sheikhupura Road, Faisalabad Raod, Bhikkhi, District Sheikhupura.

The firm has submitted shortcomings in the application for renewal of DML on 11thSeptember, 2018 and Chairman Central Licensing Board passed orders for revocation of Show Cause notice upon completion of application for renewal of DML.

Proceedings and Decision of Central Licensing Board in 266th meeting

The Central Licensing Board endorsed the decision of Chairman Central Licensing Board regarding revocation of showcuase notices issued to the firm.

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Case No. 12 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDELLA PHARMACEUTICALS (PVT) LTD, LAHORE

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

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

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

1. Duly attested signed and stamped Form-1A.
2. Classes of Drugs.
3. Update Form-29 (Attested by S.E.C.P) if change of management, prescribed fee of Rs. 50,000/- for change of management.
4. CNIC Copies of all Directors.
5. Prescribed fee of Rs. 10,000/- for change of Production Incharge and Quality Control Incharge.
6. Registration Certificate from pharmacy council of Production Incharge.

7. Resignation letter of earlier Production Incharge and Quality Control Incharge.
8. Resignation letter of proposed Production Incharge from previous firm.
9. Undertaking as whole time employee on stamp paper of Production Incharge and Quality Control
10. Copy of CNIC of Production Incharge and Quality Control Incharge..
11. All documents should be duly attested.

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

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

Proceedings and Decision of Central Licensing Board in 263rd meeting

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

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

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

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

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

Proceedings and Decision of Central Licensing Board in 266th meeting

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

Case No. 13 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S UMER USMAN COTTON INDUSTRIES, JHANG.

M/s Umer Usman Cotton Industries, Faisalabad Road, Jhang Saddar had applied for renewal of DML No. 000361 by way of formulation for the period of 18-09-2015 to 17-09-2020 on 10-09-2015.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 26th May, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Name registered drugs approved.
2. Detail of premises including Layout plan.
3. Detail of management / owner / partners on firm letter head alongwith declaration regarding any change in management & copies of CNIC (Attested).
4. Nothing due certificate regarding CRF (Latest).

Firm did not submit the shortcoming documents and a Final Reminder letter was issued on 17th May, 2017 under Rule 5{2A} of Drugs (Licensing, Registering & Advertising) Rules, 1976 of following shortcomings.

1. Name(s) of drugs registered / approved.
2. Detail of premises including Layout plan.
3. Approved Master Layout Plan / Proof of licensed section from CLB.
4. Detail of management / owner / partners on firm letter head along with declaration regarding any change in management & copies of CNIC (Attested).
5. Nothing due certificate regarding CRF (Latest).
6. Documents should be duly attested.

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

1. Name(s) of drugs registered / approved.
2. Detail of premises including Layout plan.
3. Approved Master Layout Plan / Proof of licensed section from CLB.
4. Nothing due certificate regarding CRF (Latest).
5. Detail of management / owner / partners on firm letter head along with declaration regarding any change in management & copies of CNIC (Attested) if change, then prescribe fee of Rs. 50,000/-.

Proceedings and Decision of Central Licensing Board in 259thmeeting

- The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Umer Usman Cotton Industries, Faisalabad Road, Jhang Saddar, Drug Manufacturing Licence No. 000361by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.
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Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause notice dated 27th April, 2018was issued to the M/s Umer Usman Cotton Industries, Faisalabad Road, Jhang Saddar.

The firm has submitted the documents in reply of the show cause notice. Upon evaluation following documents are found to be deficient;

i) Detail of premises including Layout plan.
ii) Prescribe fee of Rs. 50,000/- for change of management along with duly attested copy of revised partnership deed.

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

Proceedings and Decision of Central Licensing Board in 266th meeting

The Central Licensing Board after deliberation decided to refer the case to Medical Devices and Medicated Cosmetics Division DRAP Islamabad for any future correspondence as the subject matter falls under the jurisdiction of Medical Devices &Medicated Cosmetics Division in the light of SRO No. 824(1)2018 Dated 26-06-2018.

Case No.14. WITHDRAWAL OF EXTERNAL PREPARATION SECTION OF M/S HORIZON HEALTHCARE (PVT) LTD, [FORMERLY M/S WELLNESS PHARMACEUTICAL (PVT) LTD], LAHORE

M/s Horizon Healthcare (Pvt) Ltd, [Formerly M/s Wellness Pharmaceutical (Pvt) Ltd] Plot No. 33, Sunder Industrial Estate, Lahore, has applied for withdrawal of Liquid External Preparation Section.

Proceedings and Decision of Central Licensing Board in 266th meeting

The Central Licensing Board considered and acceded the request of the firm

Case No. 15 GRANT OF DRUGS FOR RE-PACKING:

M/s A.H Pharmaceuticals (Pvt) Ltd, Plot No. 865-A, S.I.E, Sargodha Road, Faisalabad, under Drug Manufacturing Licence No. 000630 by way of formulation has submitted

Application for Grant of Re-packing drugs as per Schedule-D. Firm has submitted challan Fee of 5,000/ per product.

Sr.No	Name of drugs for Repacking	Schedule-D
01	Boric Acid.	Yes
02	Castro Oil.	Yes
03	Glycerin.	Yes
04	Kaolin.	Yes
05	Liquid Paraffin.	Yes
06	Magnesium Sulphate.	Yes
07	Sodium Salicylate.	Yes
08	Sodium Bi Carbonate.	Yes

Proceedings and Decision of Central Licensing Board in 266th meeting

The central licesnig board considered and acceded the request of the firm

Case No. 16 GRANT OF DRUGS FOR RE-PACKING:

M/s International Pharma Labs, Raiwind Road, Bhobatian Chowk, Defence Road, 1Km towards Kahna Lahore, under Drug Manufacturing Licence No. 000582 by way of formulation has submitted Application for Grant of Re-packing drugs as per Schedule-D. Firm has submitted challan Fee of 5,000/ per product.

Sr. No.	Drug	Schedule-D
01	Aluminum Hydroxide Gel Dried	Yes
02	Ammonium Chloride	Yes
03	Benzoic Acid	Yes
04	Bismuth subnitrate	Yes
05	Borax	Yes
06	Calamine	Yes
07	Calcium Lactate	Yes
08	Calcium Hydroxide	Yes
09	Cetrimide Powder	Yes
10	Ferrous Sulphate	Yes
11	Gentian Violet	Yes
12	Iodine	Yes
13	Kaolin	Yes
14	Magnesium Carbonate	Yes
15	Magnesium Sulphate	Yes
16	Magnesium Trisilicate	Yes
17	Phenothlazine (B. VET.C)	Yes
18	Potassium Acetate	Yes
19	Potassium Bicarb	Yes
20	Potassium lodine	Yes
21	Pulv Gentian	Yes
22	Salicylic Acid	Yes
23	Sena	Yes

24	Sodium Bicarbonate	Yes
25	Sodium Bromide	Yes
26	Sodium Citrate	Yes
27	Sodium Metabisulphite	Yes
28	Sodium Potassium Tartrate	Yes
29	Sodium Thiosulphate	Yes
30	Sulphonilamide Powder (B. VET.C.)	Yes
31	Sulphur Sublime	Yes
32	Zinc Oxide	Yes
33	Ammonium Bicarbonate	Yes
34	Ammonium Carbonate	Yes
35	Bismuth Carbonate	Yes
36	Boric Acid	Yes
38	Calcium Carbonate	Yes
39	Calcium Gluconate	Yes
40	Castor Oil	Yes
41	Chloral Hydrate	Yes
42	Ferric Ammonium Citrate	Yes
43	Glycerin	Yes
44	Ichthammol	Yes
45	Liquid Paraffin Heavy	Yes
46	Magnesium Hydroxide	Yes
47	Methylene Blue	Yes
48	Methyl Salicylate	Yes
49	Pix Carb	Yes
50	Potassium Bromide	Yes
51	Potassium Citrate	Yes
52	Procaine Hydrochloride	Yes
53	Resorcin	Yes
54	Sentonin	Yes
55	Sodium Benzoate	Yes
56	Sodium Chloride	Yes
57	Sodium Carbonate	Yes
58	Sodium Iodide	Yes
59	Sodium Salicylate	Yes
60	Sodium Sulphate	Yes
61	Soft Yellow Paraffin	Yes
62	Sulphur Precipitated	Yes
63	Tannic Acid	Yes
64	Zinc Sulphate	Yes

Proceedings and Decision of Central Licensing Board in 266th meeting

The Central Licensing Board decided to defer the case till next meeting of the board for further deliberation and justification for all items

Case No. 17 SUSPENSION OF LICENSE M/S IMCO PHARMACEUTICALS LABS (PVT) LTD, 73, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR

A letter No. 51 dated 31st July, 2018 is received from Hon'ble Mr. Mehta Rajesh Nath Kohli, Chairman, Drug Court Quetta, Balochistan wherein he has stated that a case No. 101/2017 is pending against Mr. Imtiaz Khan, Chief Executive of M/s IMCO Pharmaceuticals Labs (Pvt)

Ltd, 73 Industrial Estate, Hayatabad, Peshawar, in which accused namely Mr. Imtiaz Khan has been declared absconder and perpetual warrant of the accused has been issued, despite that the accused intentionally and deliberately avoiding to appear before the Court. It is therefore, necessary to suspend the license of the above mentioned company after fulfilling the requisite requirement as per law and intimate the same to this Court at your earliest.

Proceedings and Decision of Central Licensing Board in 265th 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 suspension of Drug Manufacturing Licence in compliance of the orders of Drug Court, Quetta.

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

The Show Cause notice dated 11th September, 2018 was issued to the M/s IMCO Pharmaceuticals Labs (Pvt) Ltd, 73 Industrial Estate, Hayatabad, Peshawar.

The firm has submitted of the show cause notice which is as under;

> *"1. We know through your showcase notice that there is a case against of our firm in drug court Quetta. So we attend the court in 18/09/2018 and on 19/09/2018, we submitted guaranty of Rs: 3,00,000/- in National Bank Quetta in favor of chairman drug court Quetta. Copy attached.*
> *2. There is no postal sumins record present in the drug court file.*
> *3. The mention name on the written warrant is ICMO Pharmaceutical, which not our firm name. (copy attached)*
> *4. On written warrant the wrote in Urdu سی-ایم-او ای which is not our firm name?*
> *5. There is no warranty invoice of our firm in the record of Drug court.*
> *6. On the basis of the above facts, request you to withdraw case or call me for personal hearing."*

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

Proceedings and Decision of Central Licensing Board in 266th meeting

Mr. Imtiaz Khan CEO of the firm appeared before the Board and informed the Board that he has appeared before hon'ble Chairman, Drug Court Quetta, Balochistan and complied the orders of the Honourable Court. He therefore, stated that Show cause notice may be withdrawn. The Central Licensing Board after hearing representative of the firm decided to intimate the hon'ble Chairman, Drug Court Quetta, Balochistan regarding the statement of Mr. Imtiaz Khan CEO of the firm before the Board.

Case No. 18 **SITE VERIFICATION OF M/S WINMED PHARMACEUTICAL INDUSTRIES, GADOON.**

M/s Winmed Pharmaceutical Industries, Gadoon vide their application dated Nil has forwarded a request for approval of site to establish a pharmaceutical unit located at Plot No.31/13-A, R-2, Gadoon Industrial Estate, Swabi, KPK. Accordingly Area FID, DRAP, Peshawar was directed vide letter dated 11th July, 2018 for verification of site. Area FID, DRAP, Peshawar, after visiting the site has forwarded site verification report of the said firm. The recommendation of the Area FID, DRAP, Peshawar is as under;

> *"As per observations of the FID site is suitable for establishment of a pharmaceutical unit as per requirements laid down under paragraph 1 of section 1 of Schedule B (SRO 470(I)/98 dated 15-05-1998) under Rule 16(a) of Drugs (L, R&A) Rules, 1976."*

Briefing by the Secretary Licensing Board:

The Board was briefed that the procedure of Site Verification regarding Establishment of Pharmaceutical Unit has been changed. Previously, inspection was being carried by the Federal Inspector of Drugs only. Now, procedure has been changed and in future two officer including Additional Director and one Federal Inspector of Drugs or Assistant Director may carry the inspection of the site for establishment of a pharmaceutical unit.

Proceedings and Decision of Central Licensing Board in 266th meeting

The Central Licensing Board approved the inspection report of single member as it was received before the issuance of direction, however in future the inspection will be conducted by the panel.

Case No. 19 **APPROVAL OF MASTER LAYOUT PLAN / AUTHENTICATION / REGULARIZATION OF EXISTING FACILITY, DRUG MANUFACTURING LICENSE NO.000615 (FORMULATION) OF M/S MEDMARKER'S LABORATORIES (PVT) LTD, PLOT NO. A-104, S.I.T.E,AREA, HYDERABAD**

M/s Medimarker's Laboratories (Pvt) Ltd, Plot No. A-104, S.I.T.E, Area Hyderabad DML No. 000615 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

Ground Floor	First Floor
i. Warehouse (RM Store, PM Store, FG store)	vii. Ear and Eye Drop (General) Section
ii. Tablet Section (General)	viii. Injectable Vial Section (Sterile General)

iii.	Liquid Section (General)	ix.	Dry Syrup Section (Cephalosporin)
iv.	Sachet (General) Section	x.	Injectable Section (Cephalosporin)
v.	Ointment (General) Section	xi.	Capsule Section (Penicillin)
vi.	Tablets (Psychotropic) Section	xii.	Dry Syrup (Penicillin) Section

Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1. Dr. Abdullah Dayo, Member CLB
2. Mr. Najam-us-Saqib Additional Director (E&M) DRAP, Karachi.
3. Mr. Sajjad Abbasi Area Federal Inspector of Drugs, DRAP, Karachi.
4. Ms. Umme-Laila Assistant Director, DRAP, Karachi.

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

Recommendations: -

The panel reviewed their overall documentation, inspected manufacturing facilities, Quality control laboratory, stores and utilities and met their technical person and higher management. The panel observed that M/s Medimarker Laboratories is constructed as per DRAP approved layout plan. Good level of sanitation, cleanliness and work hygiene was noted. The firm has adequate number of processing and testing equipment in respective departments. Based on the stated observations, the panel recommends renewal of the Drug Manufacturing License No. 000615 (Formulation) for **Tablet Section (General), Ointment Section (General), Liquid Syrup Section (General), Sachet section (General), Tablet (Psychotropic), Ear & Eye Drop Section, Injectable Section (sterile), Dry Syrup section (Cephalosporin), Injectable Section (Cephalosporin), Capsule (Penicillin) section, Dry Syrup (Penicillin) Section.** The panel further recommends the regularization of the existing layout plan regularization of layout plan.

Proceedings and Decision of Central Licensing Board in 266th meeting

The Board considered the case and approved the regularization of the existing facility(including QC laboratory and warehouse) as per approved Lay out plan on the recommendations of the panel of experts for following sections :

1. Tablet Section (General),
2. Ointment Section (General),
3. Liquid Syrup Section (General),
4. Sachet section (General),
5. Tablet (Psychotropic),
6. Ear & Eye Drop Section,
7. Injectable Section (sterile),
8. Dry Syrup section (Cephalosporin),
9. Injectable Section (Cephalosporin),
10. Capsule (Penicillin) section,
11. Dry Syrup (Penicillin) Section.

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Case No.20. QUERIES OF THE FIRMS REGARDING APPROVED/RECOMMENDED SECTIONS ON THE BASIS OF PREVIOUS INSPECTION REPORTS.

It is submitted that many requests are being made by different firms to Licensing Division in which they request to provide the names of sections mentioned in their previous inspection reports as this information/confirmation shared by Licensing Division is being used for Drug Registration purpose in place of section approval letters issued by Central Licensing Board.

Proceedings and Decision of Central Licensing Board in 266th meeting

The Central Licensing Board deliberated the matter and PPMA and Pharma Bureau volunteered to communicate all firms to get their existing facility regularized at the earliest which shall be verified by the panel of experts /inspectors.

Case No.21. WITHDRAWAL OF BIOTECH (PEG-INTERFERON) M/S GETZ PHARMA (PVT), LTD, KARACHI

M/s Getz Pharma (Pvt), Ltd, Karachi has applied for withdrawal of biotech (peg-interferon) Section.

Proceedings and Decision of Central Licensing Board in 266th meeting

The Central Licensing Board considered and acceded the request of the firm and also decided to inform the Drug Registration Board DRAP Islamabad regarding withdrawal of the section.

Case No 22. **Voluntary cancellation/ surrender of DML No. 000693(Formulation) by M/s UDL Pharmaceuticals Plot No. E-44 & 45, North Western Industrial Zone Port Qasim Authority, Karachi.**

Mr. Shuja Malik (Executive Director) of firm has submitted request for voluntary surrender of valid DML No. 000693 of M/s UDL Pharmaceuticals, Karachi stating that management of the firm has taken the said decision after careful evaluation of the current evaluation of the current internal and external factors faced by our company. The firm has also submitted undertaking that board of directors of firm has no objection in the discontinuation of the pharmaceutical operations. The request of the firm is evaluated and it is found that on Undertakng is signed by the 04 directors namely Mr. Ather Naqvi , Mr. Majid Hasan. Mr. Shuja Malik and Mr. Abdul Rahim Suriya, However, record of the Licensing division reveals that firm actually comprises of following 05 Directors and the Undertaking regarding voluntary Discontinuation is not signed by Mr. Syed Nasir Raza Rizvi.

1. Ather Naqvi S/O Muhammed Din
   CNIC: 42000-4488387-3
   Chief Executive & Director –
2. Shuja Malik S/O Khalid Malik
   CNIC: 42301-1600531-9
   Director of the firm –
3. Syed Nasir Raza Rizvi S/O Syed Farzand Raza Rizvi
   CNIC: 42101-1739755-1
   Director of the firm –
4. Majid Hasan S/O Mahmood Hasan
   CNIC: 42201-0172348-5
   Director of the firm -
5. Abdul Rahim Suriya S/O Muhammed Siddiq
   CNIC : 42201-0757537-5
   Director of the firm

Submitted for consideration of the Board.

Proceedings and Decision of Central Licensing Board in 266th meeting

The Central Licensing Board considered and acceded the request of the firm and also decided to inform the Drug Registration Board DRAP Islamabad regarding withdrawal of the section.

QUALITY CONTROL CASES

Case No.01

Subject: **BUSINESS OF UN-REGISTERED AND SPURIOUS MEDICINES BY CH. MUHAMAMD USMAN OWNER OF M/S EVEREST PHARMACEUTICALS, ISLAMABAD.**
REQUEST FOR PERMISSION FOR PROSECUTION 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.

1. 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:

1. Ch. Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran izhar (owner of M/s Everest pharmaceuticals)
3. Noor Muhammad Mahar (owner of M/s Everest pharmaceuticals)
4. MianIshtiaq Ahmed (QC in charge), M/s Everest Pharmaceuticals

2. 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, along with 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. On the scrutiny of the record from DRAP it transpired that above referred import authorization was never issued from DRAP office, Lahore under the Drug (import & Export Rules 1976. The import authorizations is 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.

04. As the records show that the import authorizations is forged bearing the fake Diary and issue Nos. of DRAP office Lahore and used for the illegal import of pharmaceutical raw material without any requisite Drug Import License hence the management of M/s Everest pharmaceuticals has committed offence under section 420,467,468,471 &472 of Pakistan Panel Code and Clause (I) (e) of the paragraph A of the Schedule-II of the DRAP Act 2012 read with Section 23 (1)(a)(e) of the Drugs Act 1976 which is cognizable offence under para (2)(a) of the schedule-IV to the DRAP Act 2012 read with section 30 (2)(a) of the Drugs Act 1976 and is punishable under clause (1)(c) of the Schedule-III of the DRAP Act 2012 read with section 27 (1)(c) of the drugs 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.

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. It is further submitted 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. It is therefore submitted that all the 39 permissions may be ratified

07. CLB Decided in its 262nd Meeting as under:

The CLB considered the record, reports and invoices of the 39 consignments forwarded by Custom Authorities regarding Pharmaceuticals Raw Materials imported by Everest Pharmaceuticals through forged documents, reply by MsSairaNaeem ADC received through and response of Lahore office vide their letter No. 7014/2018-DRAP(AD-IV) dated 23rd May 2018. The CLB unanimously decided that as per official record available M/s Everest Pharmaceutical prepared forged documents and imported pharmaceutical raw materials without obtaining Drug Import license as required under the Drug Act 1976 and Drugs (Import & Export Rules) 1976. Already permission granted by the Director QA/LT being authorized by the CLB for granting permission registration of FIR against the accused persons mentioned in para 6 of this case was endorsed/ratified by CLB for the registration of 39 FIRs.

08. Decision of the case has been communicated to the concerned FID, Lahore vide No. F. 03-41/2018-QC Dated 13.06.2018.

09. The FID-IV, Lahore has requested the Director, FIA, Lahore that FIRs may kindly be lodged against as under:

1. M/s Everest Pharmaceuticals 86-G, Model Town, Lahore, through its managing director.
2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals).
3. Dr. Kamran Izhar (owner of M/s Everest Pharmaceuticals),
4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals
5. MianIshtiaq Ahmed (QC Incharge), M/s Everest Pharmaceuticals Islamabad

10. The management of M/s Everest Pharmaceurticals, has committed offence under section 420, 467, 468, 471, and 472 of Pakistan Penal Code and clause (1)(e) of the paragraph A of the Schedule II of the DRAP Act, 2012, read with section 23 (1)(e) of the Drugs Act, 1976, which is cognizable offence under para (2) (a) of the Schedule IV to the DRAP Act 2012 read with Section 30 (2) (a) of the Drugs Act 1976, and is punishable under clause (1)(c) of the Schedule III of the DRAP Act, 2012, read with Section 27 (1) (c) of the Drugs Act, 1976.

11. The Federal Inspector of Drugs-IV, Lahore vide letters nos. 6-14/2018 (iv)/c-74, 73, 72, 71, 96, 97/2018 dated: 11th October, 2018 submitted the incomplete challans, reproduced as under, along with relevant record in said seven (07)cases of M/s Everest Pharmaceutical, Islamabad with reference to following FIRs Nos.:

I. C-71/2018, dated 16-5-2018 vide FID letter nos. 6240/2018-AD (I&E) dated 08.05.2018,

II. C-72/2018 dated 16-5-2018 vide FID letter nos. 6277/2018-AD (I&E) dated 08.05.2018,

III. C-73/2018 dated 16-5-2-18 vide FID letter nos. 6273/2018-AD (I&E) dated 08.05.2018,

IV. C-74/2018 dated 16-5-2018 vide FID letter nos. 6250/2018-AD (I&E) dated 08.05.2018,

V. C-75/2018 dated 16-5-2018 vide FID letter nos. 6274/2018-AD (I&E)dated 08.05.2018,

VI. C-96/2018 dated 24-5-2018 vide FID letter nos. 6264/2018-AD (I&E) dated 08.05.2018,

VII. C-97/2018 dated 24-5-2018 vide FID letter nos. 6263/2018-AD (I&E)dated 08.05.2018

to seek orders from Central Licensing Board as to the action to be taken in respect of contravention for further necessary action, information and guidance. Complete challan will be submitted when received from FIA, authorities.

I. Incomplete Challan for FIR No. C-74/2018 dated 16/05/2018:

01. "Brief facts of case are that istighasa received from AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No.6250/2018-DRAP-AD(I&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request for lodging FIR against the Management of M/s Everest Pharmaceuticals for the illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate without any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the honorable Supreme Court of Pakistan in HRC No.5845-G/2018, a raid was conducted on premises of M/s Everest Pharmaceuticals, 124-Industrial 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/Drugs Act, 1976 and rules made thereunder against the following persons, namely:- Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals) Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals) Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. 2. Accordingly, a letter No.F.13-8/2018-QC dated 14.03.2018 was written to the Deputy Collector G-11, MCC Appraisement (West), Karachi, (Annex-I) for providing com0plete import record of pharmaceutical raw materials imported by M/s Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (I&E), DRAP, stamped invoices submitted by the firm. The Custom Collectorate, amongst other, has provided the invoice, detailed below, purportedly signed and stamped by the Assistant Director (I&E), DRAP, Lahore, alongwith Good Declaration-GD-I, of the pharmaceutical raw materials (Annex-II), imported by M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, vide letter SI/Misc/15/2018 Group II, dated 22.03.2018 (Annex-III).

Name of Importer	**Invoice No.**	**Dated**	**Name of raw material**	**Quantity**
M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore	00214835	09.03.2016	Levofloxacin Hemihydrate	500kg

02. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation of Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976. 4. As the records show that the import authorizations is forged, bearing the fake Diary and Issues Nos. of DRAP Office, Lahore and used for the illegal import of pharmaceuticals raw material, without any requisite Drug Import License, hence, the management of M/s Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. 5. The direction to lodge FIR against the responsible accused persons has been received vide letter No.F.13-8/18-QC, dated 17.04.2018, of the DRAP, Islamabad (Annex-IV). 6. It is, therefore, requested to register FIR for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the officer of DRAP, Lahore, in her official capacity:- 1. M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, through its Managing Partner. 2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals). 3. Dr. Kamran Izhar (owner of

M/s Everest Pharmaceuticals). 4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals). 5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. Sd/- AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore. At the Police station: On receipt of istighasa and having permission from Competent Authority vide letter No.DPL/Misc-L/4157/18/18462 case is hereby registered against above said accused persons U/S 420,467,468,471,472 PPC R/W 23(1)(e), 30(2)(a), 27(1)(c) of Drugs Act, 1976 and DRAP Act, 2012. Copies of FIR are being sent to all concerned. Hence the case was registered and investigation is entrusted to the undersigned. During course of investigation the facts of the case have been enquired and discussed with witnesses, the record was taken into custody at the time of raid has also been perused and discussed. Their statements U/s 61 of Cr. P.C have been recorded separately. The nominated accused Ch. Muhammad Usman has been arrested on 30.08.2018. Now he is on judicial remand. Yet no any other accused persons have been arrested. During investigation it is found that the accused Ch. Muhammad Usman has been involved in illegal import of pharmaceutical raw materials through forged import clearance certificate without any drug import license and he was manufacturing of unregistered, spurious and sex inducing drugs at large scale with active connivance of other accused persons. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered.

03. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty. The incomplete challan u/s 173 Cr. P.C is submitted please. It is therefore, requested that accused and witnesses may please be called to start the trial of the case."

04. in the light of investigation of the FID, Lahore and IO, FIA, Lahore, the accused persons have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the following accused persons may be show caused for the offences committed by them as stated herein above in this para:

Decision: The Central Licensing Board considered the facts on record and decided as under:

1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:

- **i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman**
- **ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)**
- **iii. Dr. KamramIzhar (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.**

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.

II. <u>Incomplete Challan for FIR No. C-73/2018 dated 16/05/2018:</u>

01. “Brief facts of case are that istighasa received from AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No.6246/2018-DRAP-AD(I&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request for lodging FIR against the Management of M/s Everest Pharmaceuticals for the illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate without any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the honorable Supreme Court of Pakistan in HRC No.5845-G/2018, a raid was conducted on premises of M/s Everest Pharmaceuticals, 124-Industrial 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/Drugs Act, 1976 and rules made thereunder against the following persons, namely:- Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals) Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals) Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. 2. Accordingly, a letter No.F.13-8/2018-QC dated 14.03.2018 was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (I&E), DRAP, stamped invoices submitted by the firm. The Custom Collectorate, amongst other, has provided the invoice, detailed below, purportedly signed and stamped by the Assistant Director (I&E), DRAP, Lahore, alongwith Good Declaration-GD-I, of the pharmaceutical raw materials (Annex-II), imported by M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, vide letter SI/Misc/15/2018 Group II, dated 22.03.2018 (Annex-III).

Name of Importer	**Invoice No.**	**Dated**	**Name of raw material**	**Quantity**
M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore	JXS170239	03.03.2017	Gabapantin	1000Kg

02. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation of Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976. 4. As the records show that the import authorizations is forged, bearing the fake Diary and Issues Nos. of DRAP Office, Lahore and used for the illegal import of pharmaceuticals raw material, without any requisite Drug Import License, hence, the management of M/s Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. 5. The direction to lodge FIR against the responsible accused persons has been received vide letter No.F.13-8/18-QC, dated 17.04.2018, of the DRAP, Islamabad (Annex-IV). 6. It is, therefore, requested to register FIR for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the officer of DRAP, Lahore, in her official capacity:- 1. M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, through its Managing Partner. 2. Ch.

Muhammad Usman (owner of M/s Everest Pharmaceuticals). 3. Dr. Kamran Izhar (owner of M/s Everest Pharmaceuticals). 4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals). 5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. Sd/- AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore. At the Police station: On receipt of istighasa and having permission from Competent Authority vide letter No.DPL/Misc-L/4177/18/18461 case is hereby registered against above said accused persons U/S 420,467,468,471,472 PPC R/W 23(1)(e), 30(2)(a), 27(1)(c) of Drugs Act, 1976 and DRAP Act, 2012. Copies of FIR are being sent to all concerned. Hence the case was registered and investigation is entrusted to the Haroon Malik, Inspector, FIA/CCC, Lahore. During course of investigation the facts of the case have been enquired and discussed with witnesses, the record was taken into custody at the time of raid has also been perused and discussed. Their statements U/s 161 of Cr. P.C have been recorded separately. The nominated accused Ch. Muhammad Usman has been arrested on 30.08.2018. Now he is on judicial remand. Yet no any other accused persons have been arrested. During investigation it revealed that the accused Ch. Muhammad Usman has been involved in illegal import of pharmaceutical raw materials through forged import clearance certificate without any drug import license and he was manufacturing of unregistered, spurious and sex inducing drugs at large scale with active connivance of other accused persons. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered.

03. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty. The incomplete challan u/s 173 Cr. P.C is submitted please. It is therefore, requested that accused and witnesses may please be called to start the trial of the case."

04. in the light of investigation of the FID, Lahore and IO, FIA, Lahore, the accused persons have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the following accused persons may be show caused for the offences committed by them as stated herein above in this para:

1. M/s Everest Pharmaceuticals, Islamabad through its owners Ch. Muhammad Usman
2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)
3. Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals)
4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)
5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.

Decision: The Central Licensing Board considered the facts on record and decided as under:

1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:

i. **M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman**
ii. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)**
iii. **Dr. KamramIzhar (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.**

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012

read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.

III. Incomplete Challan for FIR No. C-72/2018 dated 16/05/2018:

01. "Brief facts of case are that istighasa received from AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No.6246/2018-DRAP-AD(I&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request for lodging FIR against the Management of M/s Everest Pharmaceuticals for the illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate without any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the honorable Supreme Court of Pakistan in HRC No.5845-G/2018, a raid was conducted on premises of M/s Everest Pharmaceuticals, 124-Industrial 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/Drugs Act, 1976 and rules made thereunder against the following persons, namely:- Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals) Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals) Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. 2. Accordingly, a letter No.F.13-8/2018-QC dated 14.03.2018 was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (I&E), DRAP, stamped invoices submitted by the firm. The Custom Collectorate, amongst other, has provided the invoice, detailed below, purportedly signed and stamped by the Assistant Director (I&E), DRAP, Lahore, alongwith Good Declaration-GD-I, of the pharmaceutical raw materials (Annex-II), imported by M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, vide letter SI/Misc/15/2018 Group II, dated 22.03.2018 (Annex-III).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore	AE073	31.05.2016	Omeprazole	200Kg

02. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation of Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976. 4. As the records show that the import authorizations is forged, bearing the fake Diary and Issues Nos. of DRAP Office, Lahore and used for the illegal import of pharmaceuticals raw material, without any requisite Drug Import License, hence, the management of M/s Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. 5. The direction to lodge FIR against the responsible accused persons has been received vide letter No.F.13-8/18-QC, dated 17.04.2018, of the DRAP, Islamabad (Annex-IV). 6. It is, therefore, requested to register FIR for illegally importing pharmaceutical raw material through forged import

authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the officer of DRAP, Lahore, in her official capacity:- 1. M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, through its Managing Partner. 2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals). 3. Dr. Kamran Izhar (owner of M/s Everest Pharmaceuticals). 4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals). 5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. Sd/- AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore. At the Police station: On receipt of istighasa and having permission from Competent Authority vide letter No.DPL/Misc-L/4145/18/8460 case is hereby registered against above said accused persons U/S 420,467,468,471,472 PPC R/W 23(1)(e), 30(2)(a), 27(1)(c) of Drugs Act, 1976 and DRAP Act, 2012. Copies of FIR are being sent to all concerned. Hence the case was registered and investigation is entrusted to the Nasir Mahmood Awan, Inspector, FIA/CCC, Lahore. During course of investigation the facts of the case have been enquired and discussed with witnesses, the record was taken into custody at the time of raid has also been perused and discussed. Their statements U/s 161 of Cr. P.C have been recorded separately. The nominated accused Ch. Muhammad Usman has been arrested on 30.08.2018. Now he is on judicial remand. Yet no any other accused persons have been arrested. During investigation it revealed that the accused Ch. Muhammad Usman has been involved in illegal import of pharmaceutical raw materials through forged import clearance certificate without any drug import license and he was manufacturing of unregistered, spurious and sex inducing drugs at large scale with active connivance of other accused persons. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered.

03. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty. The incomplete challan u/s 173 Cr. P.C is submitted please. It is therefore, requested that accused and witnesses may please be called to start the trial of the case."

04. in the light of investigation of the FID, Lahore and IO, FIA, Lahore, the accused persons have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the following accused persons may be show caused for the offences committed by them as stated herein above in this para:

1. M/s Everest Pharmaceuticals, Islamabad through its owners Ch. Muhammad Usman
2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)
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Decision: The Central Licensing Board considered the facts on record and decided as under:

1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:

- **i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman**
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- **iv. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)**
- **v. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.**

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.

IV. Incomplete Challan for FIR No. C-71/2018 dated 16/05/2018:

01. "Brief facts of case are that istighasa received from AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No.6246/2018-DRAP-AD(I&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request for lodging FIR against the Management of M/s Everest Pharmaceuticals for the illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate without any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the honorable Supreme Court of Pakistan in HRC No.5845-G/2018, a raid was conducted on premises of M/s Everest Pharmaceuticals, 124-Industrial 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/Drugs Act, 1976 and rules made thereunder against the following persons, namely:- Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals) Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals) Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. 2. Accordingly, a letter No.F.13-8/2018-QC dated 14.03.2018 was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (I&E), DRAP, stamped invoices submitted by the firm. The Custom Collectorate, amongst other, has provided the invoice, detailed below, purportedly signed and stamped by the Assistant Director (I&E), DRAP, Lahore, alongwith Good Declaration-GD-I, of the pharmaceutical raw materials (Annex-II), imported by M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, vide letter SI/Misc/15/2018 Group II, dated 22.03.2018 (Annex-III).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore	ZY2015099037	17.09.2015	Naproxen Sodium	3000Kg

02. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation of Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976. 4. As the records show that the import authorizations is forged, bearing the fake Diary and Issues Nos. of DRAP Office, Lahore and used for the illegal import of pharmaceuticals raw material, without any requisite Drug Import License, hence, the management of M/s Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with

Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. 5. The direction to lodge FIR against the responsible accused persons has been received vide letter No.F.13-8/18-QC, dated 17.04.2018, of the DRAP, Islamabad (Annex-IV). 6. It is, therefore, requested to register FIR for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the officer of DRAP, Lahore, in her official capacity:- 1. M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, through its Managing Partner. 2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals). 3. Dr. Kamran Izhar (owner of M/s Everest Pharmaceuticals). 4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals). 5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. Sd/-AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore. At the Police station: On receipt of istighasa and having permission from Competent Authority vide letter No.DPL/Misc-L/4145/18/8460 case is hereby registered against above said accused persons U/S 420,467,468,471,472 PPC R/W 23(1)(e), 30(2)(a), 27(1)(c) of Drugs Act, 1976 and DRAP Act, 2012. Copies of FIR are being sent to all concerned. Hence the case was registered and investigation is entrusted to the Nasir Mahmood Awan, Inspector, FIA/CCC, Lahore. During course of investigation the facts of the case have been enquired and discussed with witnesses, the record was taken into custody at the time of raid has also been perused and discussed. Their statements U/s 161 of Cr. P.C have been recorded separately. The nominated accused Ch. Muhammad Usman has been arrested on 30.08.2018. Now he is on judicial remand. Yet no any other accused persons have been arrested. During investigation it revealed that the accused Ch. Muhammad Usman has been involved in illegal import of pharmaceutical raw materials through forged import clearance certificate without any drug import license and he was manufacturing of unregistered, spurious and sex inducing drugs at large scale with active connivance of other accused persons. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered.

03. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty. The incomplete challan u/s 173 Cr. P.C is submitted please. It is therefore, requested that accused and witnesses may please be called to start the trial of the case."

04. in the light of investigation of the FID, Lahore and IO, FIA, Lahore, the accused persons have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the following accused persons may be show caused for the offences committed by them as stated herein above in this para:

1. M/s Everest Pharmaceuticals, Islamabad through its owners Ch. Muhammad Usman
2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)
3. Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals)
4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)
5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.

Decision: The Central Licensing Board considered the facts on record and decided as under:

1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:

- **i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman**
- **ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)**

iii. **Dr. KamramIzhar (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.**

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.

V. Incomplete Challan for FIR No. C-96/2018 dated 24/05/2018:

01. "Brief facts of case are that istighasa received from AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No.6246/2018-DRAP-AD(I&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request for lodging FIR against the Management of M/s Everest Pharmaceuticals for the illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate without any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the honorable Supreme Court of Pakistan in HRC No.5845-G/2018, a raid was conducted on premises of M/s Everest Pharmaceuticals, 124-Industrial 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/Drugs Act, 1976 and rules made thereunder against the following persons, namely:- Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals) Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals) Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. 2. Accordingly, a letter No.F.13-8/2018-QC dated 14.03.2018 was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (I&E), DRAP, stamped invoices submitted by the firm. The Custom Collectorate, amongst other, has provided the invoice, detailed below, purportedly signed and stamped by the Assistant Director (I&E), DRAP, Lahore, alongwith Good Declaration-GD-I, of the pharmaceutical raw materials (Annex-II), imported by M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, vide letter SI/Misc/15/2018 Group II, dated 22.03.2018 (Annex-III).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore	ZY201605123	14.07.2016	PVP K-30	350Kg

02. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation of Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976. 4. As the records show that the import authorizations is forged, bearing the fake Diary and Issues Nos. of DRAP Office, Lahore and used for the illegal import of pharmaceuticals raw material, without any requisite Drug Import License, hence, the management of M/s Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the

Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. 5. The direction to lodge FIR against the responsible accused persons has been received vide letter No.F.13-8/18-QC, dated 17.04.2018, of the DRAP, Islamabad (Annex-IV). 6. It is, therefore, requested to register FIR for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the officer of DRAP, Lahore, in her official capacity:- 1. M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, through its Managing Partner. 2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals). 3. Dr. Kamran Izhar (owner of M/s Everest Pharmaceuticals). 4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals). 5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. Sd/- AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore. At the Police station: On receipt of istighasa and having permission from Competent Authority vide letter No.DPL/Misc-L/4168/18/18487 case is hereby registered against above said accused persons U/S 420,467,468,471,472 PPC R/W 23(1)(e), 30(2)(a), 27(1)(c) of Drugs Act, 1976 and DRAP Act, 2012. Copies of FIR are being sent to all concerned. Hence the case was registered and investigation is entrusted to the NaureenRamzan, Inspector, FIA/CCC, Lahore. During course of investigation the facts of the case have been enquired and discussed with witnesses, the record was taken into custody at the time of raid has also been perused and discussed. Their statements U/s 161 of Cr. P.C have been recorded separately. The nominated accused Ch. Muhammad Usman has been arrested on 30.08.2018. Now he is on judicial remand. Yet no any other accused persons have been arrested. During investigation it revealed that the accused Ch. Muhammad Usman has been involved in illegal import of pharmaceutical raw materials through forged import clearance certificate without any drug import license and he was manufacturing of unregistered, spurious and sex inducing drugs at large scale with active connivance of other accused persons. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered.

03. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty. The incomplete challan u/s 173 Cr. P.C is submitted please. It is therefore, requested that accused and witnesses may please be called to start the trial of the case."

04. in the light of investigation of the FID, Lahore and IO, FIA, Lahore, the accused persons have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the following accused persons may be show caused for the offences committed by them as stated herein above in this para:

1. M/s Everest Pharmaceuticals, Islamabad through its owners Ch. Muhammad Usman
2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)
3. Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals)
4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)
5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.

DECISION:

The Central Licensing Board considered the facts on record and decided as under:

1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:

i. **M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman**
ii. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)**
iii. **Dr. KamramIzhar (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.**

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.

VI. Incomplete Challan for FIR No. C-97/2018 dated 24/05/2018:

01. "Brief facts of case are that istighasa received from AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No.6246/2018-DRAP-AD(I&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request for lodging FIR against the Management of M/s Everest Pharmaceuticals for the illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate without any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the honorable Supreme Court of Pakistan in HRC No.5845-G/2018, a raid was conducted on premises of M/s Everest Pharmaceuticals, 124-Industrial 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/Drugs Act, 1976 and rules made thereunder against the following persons, namely:- Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals) Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals) Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. 2. Accordingly, a letter No.F.13-8/2018-QC dated 14.03.2018 was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (I&E), DRAP, stamped invoices submitted by the firm. The Custom Collectorate, amongst other, has provided the invoice, detailed below, purportedly signed and stamped by the Assistant Director (I&E), DRAP, Lahore, alongwith Good Declaration-GD-I, of the pharmaceutical raw materials (Annex-II), imported by M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, vide letter SI/Misc/15/2018 Group II, dated 22.03.2018 (Annex-III).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore	GBSL/109/16-17	25.08.2016	Lidocaine HCl	100Kg

02. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw

material stands illegal in violation of Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976. 4. As the records show that the import authorizations is forged, bearing the fake Diary and Issues Nos. of DRAP Office, Lahore and used for the illegal import of pharmaceuticals raw material, without any requisite Drug Import License, hence, the management of M/s Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. 5. The direction to lodge FIR against the responsible accused persons has been received vide letter No.F.13-8/18-QC, dated 17.04.2018, of the DRAP, Islamabad (Annex-IV). 6. It is, therefore, requested to register FIR for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the officer of DRAP, Lahore, in her official capacity:- 1. M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, through its Managing Partner. 2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals). 3. Dr. Kamran Izhar (owner of M/s Everest Pharmaceuticals). 4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals). 5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. Sd/-AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore. At the Police station: On receipt of istighasa and having permission from Competent Authority vide letter No.DPL/Misc-L/4167/18/18488 case is hereby registered against above said accused persons U/S 420,467,468,471,472 PPC R/W 23(1)(e), 30(2)(a), 27(1)(c) of Drugs Act, 1976 and DRAP Act, 2012. Copies of FIR are being sent to all concerned. Hence the case was registered and investigation is entrusted to the NaureenRamzan, Inspector, FIA/CCC, Lahore. During course of investigation the facts of the case have been enquired and discussed with witnesses, the record was taken into custody at the time of raid has also been perused and discussed. Their statements U/s 161 of Cr. P.C have been recorded separately. The nominated accused Ch. Muhammad Usman has been arrested on 30.08.2018. Now he is on judicial remand. Yet no any other accused persons have been arrested. During investigation it revealed that the accused Ch. Muhammad Usman has been involved in illegal import of pharmaceutical raw materials through forged import clearance certificate without any drug import license and he was manufacturing of unregistered, spurious and sex inducing drugs at large scale with active connivance of other accused persons. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered.

03. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty. The incomplete challan u/s 173 Cr. P.C is submitted please. It is therefore, requested that accused and witnesses may please be called to start the trial of the case."

04. in the light of investigation of the FID, Lahore and IO, FIA, Lahore, the accused persons have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the following accused persons may be show caused for the offences committed by them as stated herein above in this para:

1. M/s Everest Pharmaceuticals, Islamabad through its owners Ch. Muhammad Usman
2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)
3. Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals)
4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)
5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.

Decision: The Central Licensing Board considered the facts on record and decided as under:

1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:

i. **M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman**
ii. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)**
iii. **Dr. KamramIzhar (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.**

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.

VII. Incomplete Challan for FIR No. C-75/2018 dated 16/05/2018:

01. "Brief facts of case are that istighasa received from AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No.6246/2018-DRAP-AD(I&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request for lodging FIR against the Management of M/s Everest Pharmaceuticals for the illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate without any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the honorable Supreme Court of Pakistan in HRC No.5845-G/2018, a raid was conducted on premises of M/s Everest Pharmaceuticals, 124-Industrial 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/Drugs Act, 1976 and rules made thereunder against the following persons, namely:- Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals) Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals) Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. 2. Accordingly, a letter No.F.13-8/2018-QC dated 14.03.2018 was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (I&E), DRAP, stamped invoices submitted by the firm. The Custom Collectorate, amongst other, has provided the invoice, detailed below, purportedly signed and stamped by the Assistant Director (I&E), DRAP, Lahore, alongwith Good Declaration-GD-I, of the pharmaceutical raw materials (Annex-II), imported by M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, vide letter SI/Misc/15/2018 Group II, dated 22.03.2018 (Annex-III).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s Everest Pharmaceuticals, 86-G, Model Town,	MS-EXP165165622582	28.02.2017	Fexofenadine HCl	500Kg

Lahore				

02. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation of Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976. 4. As the records show that the import authorizations is forged, bearing the fake Diary and Issues Nos. of DRAP Office, Lahore and used for the illegal import of pharmaceuticals raw material, without any requisite Drug Import License, hence, the management of M/s Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. 5. The direction to lodge FIR against the responsible accused persons has been received vide letter No.F.13-8/18-QC, dated 17.04.2018, of the DRAP, Islamabad (Annex-IV). 6. It is, therefore, requested to register FIR for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the officer of DRAP, Lahore, in her official capacity:- 1. M/s Everest Pharmaceuticals, 86-G, Model Town, Lahore, through its Managing Partner. 2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals). 3. Dr. Kamran Izhar (owner of M/s Everest Pharmaceuticals). 4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals). 5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals. Sd/- AjmalSohail Asif Federal Inspector of Drugs DRAP Lahore. At the Police station: On receipt of istighasa and having permission from Competent Authority vide letter No.DPL/Misc-L/4178/18/18468 case is hereby registered against above said accused persons U/S 420,467,468,471,472 PPC R/W 23(1)(e), 30(2)(a), 27(1)(c) of Drugs Act, 1976 and DRAP Act, 2012. Copies of FIR are being sent to all concerned. Hence the case was registered and investigation is entrusted to the NaureenRamzan, Inspector, FIA/CCC, Lahore. During course of investigation the facts of the case have been enquired and discussed with witnesses, the record was taken into custody at the time of raid has also been perused and discussed. Their statements U/s 161 of Cr. P.C have been recorded separately. The nominated accused Ch. Muhammad Usman has been arrested on 30.08.2018. Now he is on judicial remand. Yet no any other accused persons have been arrested. During investigation it revealed that the accused Ch. Muhammad Usman has been involved in illegal import of pharmaceutical raw materials through forged import clearance certificate without any drug import license and he was manufacturing of unregistered, spurious and sex inducing drugs at large scale with active connivance of other accused persons. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered.

03. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty. The incomplete challan u/s 173 Cr. P.C is submitted please. It is therefore, requested that accused and witnesses may please be called to start the trial of the case."

04. in the light of investigation of the FID, Lahore and IO, FIA, Lahore, the accused persons have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the following accused persons may be show caused for the offences committed by them as stated herein above in this para:

1. M/s Everest Pharmaceuticals, Islamabad through its owners Ch. Muhammad Usman
2. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)
3. Dr. KamramIzhar (owner of M/s Everest Pharmaceuticals)
4. Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)
5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.

Decision: The Central Licensing Board considered the facts on record and decided as under:

1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:

i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman
ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)
iii. Dr. KamramIzhar (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.

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.

Case No. 02

Subject:- INSPECTION OF MEDICAL STORES/PHARMACIES/ MANUFACTURING UNITS.

Proceedings of 265th meeting CLB.

1. The Federal Inspector of Drugs, Lahore through his correspondence has informed that National Task Force activity for Federal Inspectors plan is provided by QA&LT Division, DRAP Islamabad through WhatsApp Group (National Task Force) and E-mail (ntf_drap@dra.gov.pk) and is monitored and updated regularly on WhatsApp Group (National Task Force).
2. The inspection of Bahawalnagar was planned on **04-07-2018**. The inspection in Bahawalnagar started with DHQ Hospital Central Pharmacy. The next visit was Arif Hospital Pharmacy opposite DHQ Hospital, Bahawalnagar. Next adjacent pharmacy M/s Al Raheem Pharmacy was visited and the copy of license was taken for record. In the same way third M/s New United Medicines Traders was inspected. The Al Hafiz medicine Company was inspected next.
3. During the visit of Bilal Medical Store, members of **Bahawalnagar Chemist Association,** Mr. Malik Riaz (Gen. Secretary) owner of Shaheen Medical Store, Mr. Khalid Hussain (Union cashier) owner of Public Medical Store and Mr. Javed Hussain

Butt (Joint Secretary) owner of Butt Medical Store alongwith three other people interrupted the inspection. They started inquiring the Authority Letter and asking what in what capacity we are doing inspection. They asked us to go with them to CEO Health Office Dr. Abdul Aziz Sheikh (who already left office) to take permission from him, so they telephonically communicated with him and offered me to talk to CEO Health. I attended call with respect and introduced myself as FID DFRAP, he rudely answered and asked that if "I have my Authority Letter and how can I do inspection in his area without informing him". I told him I have my DRAP notification with me and I can send you and we can have a meeting as well. He answered, I am in Chistian and I cannot. He further said that I will talk to CEO DRAP and how can DRAP do inspection without CEO Health permission. The call was disconnected and I contact my senior Dr. Muhammad FakhruddinAamir, he asked me to contact Provincial Drug Inspector but he didn't receive the call. Meanwhile, Mr. Malik Riaz (Gen. Secretary) owner of Shaheen Medical Store and Mr. Javed Hussain Butt (Joint Secretary) owner of Butt Medical Store started taking our photos. They took us in Arif Hospital waiting area and started inquiring about authority letter I tried to show them my DRAP notification by they did not bother to see.Meanwhile, I contacted my cousin's son Mr. MunibShahid who was in Bahawalnagar to reach Arif Hospital. He came there immediately. Mr. Malik Riaz (Gen. Secretary) already knew so he let us go to our car. We left for Lahore. After that Malik Riaz (Gen. Secretary) owner of Shaheen Medical Store started sharing our photos on social medica (WhaAtpp groups) by saying that Team of National Task Force was fraud and are arrested in CEO Health Office. These rumors started spreading on WhatsApp group of various Associations of medicines in Bahawalnagar, Bahawalnagar and Chistian, which is negatively impacting the image of DRAP. I'm writing this report for further necessary action.

4. As report of FID, Lahore that the above accused persons deliberately and intentionally violated para 3 of schedule-III of DRAP Act, 2012 which states as under:-

> (3) ***Obstruction of Inspector*: Whoever obstructs and Inspector in the exercise of any power conferred upon him by or under this Act, or disobeys the lawful authority of any Inspector, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one lakh rupees, or with both.**

5. As per report of the FID,Lahore the act of the accused persons is also offense under Sub-Section 3 of section 27 of Drug Act, 1976 which is punishable under sub-section 4 of section 27 of the Drugs Act, 1976. In view of the above facts, it is evident that above mentioned accused persons obstructed the FID, Lahore in the performance of her official

duties and don't allowed her the inspection of the said pharmacy which is offense as submitted in Para 5/N above.

6. **In the light of the above mentioned facts the case is submitted before CLB for the grant of permission of issuance of show cause notice to following accused persons to seek necessary response before grant of permission of prosecution:**
    a. Owner/Proprietor, M/s Bilal Medical Store, Bahawalnagar,
    b. Mr. Malik Riaz (Gen. Secretary, Bahawalnagar Chemist Association) owner of Shaheen Medical Store, Bahawalnagar,
    c. Mr. Khalid Hussain (Union Cashier, Bahawalnagar Chemist Association) owner of Public Medical Store and
    d. Mr. Javed Hussain Butt (Joint Secretary, Bahawalnagar Chemist Association) owner of Butt Medical Store

Decision of 265th CLB meeting :

7. The Central Licensing Board (CLB) after through deliberations and examination of the record decided as under:
    I. The matter of CEO Health Authority, district Bahawalnagar, shall be referred to the Secretary, Primary and Secondary Healthcare Department, Punjab for appropriate disciplinary proceedings by deliberate intervention in the official duties of the area Federal Inspector of Drugs, Lahore
    II. The Board decided to issue Show cause notice to the following accused persons regarding obstruction of federal inspector of drugs in the exercise of her lawful powers and intentionally and deliberately violated the following provisions of para 3 of Schedule III of DRAP Act, 2012 which stipulates as under:

"(3) ***Obstruction of Inspector*: *Whoever obstructs and Inspector in the exercise of any power conferred upon him by or under this Act, or disobeys the lawful authority of any Inspector, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one lakh rupees, or with both."***

    a. Owner/Proprietor, M/s Bilal Medical Store, Bahawalnagar,
    b. Mr. Malik Riaz (Gen. Secretary, Bahawalnagar Chemist Association) owner of Shaheen Medical Store, Bahawalnagar,
    c. Mr. Khalid Hussain (Union Cashier, Bahawalnagar Chemist Association) owner of Public Medical Store and
    d. Mr. Javed Hussain Butt (Joint Secretary, Bahawalnagar Chemist Association) owner of Butt Medical Store.

8. The decision was communicated to quarters concerned on 4thSeptember, 2018**.**

9. **Reply of defendants**:
In response, letter bearing reply is received from Chemist and Druggist Association Tehsil Bahawalnagar vide reference No. Nil dated 10.09.2018 in response to show cause

issued to persons, who were nominated by concerned area FID Lahore, dated 04.09.2018 wherein Chemist and Druggist Association submitted that the respected FID visited six medicals stores/pharmacies on dated 04.07.2018 in the meantime some office bearers of the chemist association contacted the CEO Health that any checking team/task force etc. checking/inspecting medical stores/pharmacies are and also obtaining photos of signing boards and other accessories, A.C temperature clock meter etc. and the copies of Drug Sale License.

10. The Association added that CEO Health told the office bearers of the association that none of the task force or any other officer of drugs inspection team has informed him (CEO) to inspect the medical stores/pharmacies in District Bahawalnagar and without prior intimation and permission of the CEO Health no inspection team or authority is allowed to check/inspect the medical stores and pharmacies under rules.
11. The Association also added that some bogus agencies were involved in rural area to check the medical stores and clinics in this area. Recently a so called inspection team headed by so called Additional Secretary (Health) are arrested and are behind the bars at Minchinnabad Police Station. Now after conversation with CEO Health the above said office bear of the chemist association requested the respected FID to produce their identity authority but he could produce the same.
12. The Association stated that in this division's letter of show cause it is mentioned that he has showed the Notification of DRAP but we all the stake holders declare that he could not produce any identification or authority. Office bearer of the Chemist Association requested the worthy FID to accompany with them to CEO Health office. He came with the above person in CEO Health office but the CEO was not present in his office. However, CEO health was contacted by a phone call. He (CEO) talked with the respected FID. The CEO Health asked the FID why you have not informed me and prior permission was also not taken for inspection purposes in this District. But FID could not satisfied the CEO.
13. The Association also stated that according to show cause notices contents the respected FID called upon his cousin Mr. MuneebShahid who is also a Pharma Distributor in Bahawalnagar. He approached the site (Arif Hospital) and satisfy the office bearer of the association. He categorically assured that the said FID is his relative and he is responsible of all his word and deed. He also assured that the said FID is not a bogus office he is genuine one. Necessary Notification identity and authority will be provided soon on this assurance of Mr. MuneebShahid. The matter was closed they reconciliated and took tea together. Anyhow after this incident some press reports of electronic and print media viral the matter with negative rumors in the social media.
14. The Association also added that it is also clarified an oath that no office bearers of the Chemist Association or Members of the Union is involved in viral activity of social media. They really and extremely sorry for the inconvenience caused faced to worthy FID during his official duty. It is also submitted that because the matter was solved by the interference his cousin Mr. MuneebShahid. They are of the opinion that the matter was closed and wind up accordingly. But after issuance of said show cause notice and in the prevailing circumstances we feel sorry and beg – pardon for the same and assure you that the said incident occurred was based on misunderstanding and unintentionally.
15. They requested to please forgive us and accept our unintentional apologize. They are really felt shamed on the said incident for the satisfaction of worthy FID. They all the

above stake holder are ready to tender apologize when and where you deem fit and call upon us.

Decision: The Central Licensing Board after deliberations on the facts on record decided to give personal hearing to the accused persons in its forthcoming meeting.

Case No.03

Subject: **MANUFACTURING OF UN-REGISTERED DRUG EI-RAM 10 MG BY M/S ICE BERG PHARMACEUTICALS (PVT) LTD. PLOT NO. 144, NOWSHERA INDUSTRIAL ESTATE RISALPUR.**

FID Peshawar drew sample of Ei-ram 10mg tablet batch number C-108 manufactured by M/s Ice Berg Pharmaceuticals, Risalpur on 27-5-2016 and sent to CDL Karachi for test/ analysis.

2. CDL Karachi declared above drug substandard vide report no. IP.38/2016 dated 29th July, 2016. The result is as under:

Assay for Escitalopram	
Determined amount/ tablet	**8.037mg**
Stated amount/ tablet	**10.0mg**
Percentage	**80.37%**
Limit	**90-110% (does not comply)**

3. In the light of CDL's test report, the FID served an explanation letter dated 24-08-2016 to the firm. In response, the firm did not accept the CDL test report vide their reply dated 06-11-2016 which was received in the office of FID on 08-12-2016. The company has challenged the CDL's test report as per Section 22(4) of the Drugs Act 1976 but the Appeal is time barred and sample cannot be retested.

4. The FID Peshawar directed the firm to provide the names of responsible persons of the firm but till to date no reply received from the firm. However, firm did not provide the names of responsible persons. QA & LT Division DRAP requested Division of Licensing DRAP to provide the names of responsible persons. The Division of Licensing provided the names of responsible persons vide no. 3-8/2005-Lic dated 18-4-2018 as under:

I. Muhammad Tahir S/o Sahib Gul, House No. T3439, DomailGunj, Rehmana, Mardan
II. Muhammad Fayaz S/o Kachkol,MohallahShabi Khel, Charsadda Town,

5. The show cause was served to firm on 25-4-2017. In response to show cause notice, firm submitted its reply.

6. The case was presented before Registration Board in its 274th, 278th and 279th meetings and three opportunities of personal hearing were also given to firm but no person appeared before board. The Registration Board in its 279th meeting held on 28th Feb-2nd March, 2018 decided the case as under:

"Registration Board decided to cancel the registration of drug Ei-Ram 10mg tablets, Registration number 079784 by M/s Ice Berg Pharmaceuticals, Risalpur, KPK under section 42 of Drugs Act, 1976."

7. The Registration Board's decision was conveyed to firm vide no. 3-33/2016-QC dated 3rd May, 2018. FID DRAP Peshawar also conveyed same decision to firm vide no. 11-95/2018-Iceberg-DRAP(P)1933 dated 17th May, 2018. During routine inspection of firm on 2-08-2018, FID DRAP Peshawar found stock (1500packs) of tablet Ei-Ram tablet 10mg, batch no. C-126, mfg dated 7-2018 expiry date, 07-2020 manufactured by M/s Ice berg Pharmaceuticals, Risalpur and ordered to "not to dispose off" on form-I.

8. Meanwhile FID DRAP Peshawar requested Director QA & LT, DRAP, Islamabad to grant extension in "not to dispose off" period for three months under the law. The QC Section conveyed the approval of Director QA & LT, DRAP, as powers are delegated to Director QA & LT, DRAP for extension in "not to dispose off period" for three months on 29th August, 2018.

9. FID DRAP Peshawar further submitted the case on 12th September, 2018 wherein FID DRAP Peshawar has stated that stock of Ei-Ram tablet batch no. C-126, mfg date 7-18, Exp date, 7-20, was found at the premises of M/s Ice berg Pharmaceuticals Risalpur (Registration of the said product has been cancelled by Drug Registration Board in its 279th meeting held on 28th feb-2nd March, 2018). The said decision was conveyed to firm vide letter f. 3-33/2016-QC dated 3rd May, 2018 and subsequently vide letter no. 11-95/2018-Iceberg-DRAP(P) 1933 dated 17th May, 2018 by FID, DRAP, Peshawar.

10. AD/FID stated that QA & LT Division, vide letter no. 4-124/2015-QA dated 28-8-2018 suspended the production activities of the firm and issued show cause notice on account of GMP non-compliance as were reported in the same GMP inspection, suspension orders conveyed and implemented by AD/FID, Peshawar on 31-08-2018 as requested. Moreover, the stock of unregistered drug tab. Ei-ram 10mg batch no. C-126, that was initially on " Not to Dispose Off" was also seized on Form-2 along with the relevant available record.

11. AD/FID further submitted that the firm vide letter nil dated 1-9-2018 has informed about the non-receipt of cancellation orders from Drug Registration Board or the Area Federal Inspector of Drugs and has requested for hearing in person in response to show cause notice served by AD/FID Peshawar.

12. AD/FID also stated that firm has been found involved in manufacturing of the unregistered drug, which is prohibited under section 23(a)(vii) and punishable under section 27(a) of the Drugs Act, 1976, the case may be presented to concerned board for appropriate legal action as per prevailing law against the following and permission may be granted for safe custody of the seized stock till decision of case.

I. M/s Ice Berg Pharmaceuticals, Industrial Estaste, Risalpurr
II. Mr. Haji Muhammad Fayyaz, CEO, M/s Ice Berg Pharmaceutical, Industrial Estate, Risalpur.
III. Mr. Kamran Khan (Production Incharge)
IV. Mr. HaseebUlHaq (Quality Control Incharge).

Decision: The Central Licensing Board (CLB) considered the facts on record of the case decided:

i. to grant the permission to continue the safe custody of the seized stock till the decision of the case

ii. to issue show cause noticeand personal hearing to the accused persons:
- **a) M/s Ice Berg Pharmaceuticals, Industrial Estaste, Risalpurr**
- **b) Mr. Haji Muhammad Fayyaz, CEO, M/s Ice Berg Pharmaceutical, Industrial Estate, Risalpur.**
- **c) Mr. Kamran Khan (Production Incharge)**
- **d) Mr. Haseeb Ul Haq (Quality Control Incharge)**

iii. The accused persons have committed offence of manufacturing un-registered drugs as evidentthrough the following facts:

A. The registration of the said drug (Ei-ram (Escitalopram) 10 mg, Reg. No. 079784) was cancelled by DRB in its 279th Meeting after due process and was conveyed to the firm vide letter No. F. 03-33/2016-QC dated 03/05/2018 and the same information was also conveyed by the area FID, Peshawar vide his letter no. F. 11-95/2018-Iceberg-DRAP(P)1933 dated 17.05.2018.

B. That the area FID, Peshawar inspected the premises of M/s Iceberg Pharmaceuticals, Risalpur on 02/08/2018 and ordered not to dispose of on prescribed FORM-I as he found 5X300 Packs of the said (un-registered/de-registered) drug Batch No. C-126 Manufacturing Date 07/2018 and Expiry Date 07/2020.

C. That after verification/confirmationof cancellation of registration of the said drug the area FID, Peshawar seized the stock on prescribed FORM-2.

D. That it was further revealed after investigations, the firm manufactured the said batch (B# C-126)having batch size =156494/- Tablets after the cancellation of registration and committed offence of manufacturing un-registered drugs.

Case No. 04

Subject: SEIZURE OF STOCK MANUFACTURED BY EVEREST PHARMACUETICALS FROM M/S SERVAID PHARMACY PVT LTD 65 QUAID-E-AZAM INDUSTRIAL ESTATE LAHORE

Proceedings of 261st meeting of CLB

Ms. Uzma Barkat, Additional Director, DRAP, Lahore and DRAP team alongwith Mr. Muhammad Usman, Inspector, FIA, Crim Circle, Lahore visited the premises of M/s Servaid Pharmacy (Pvt) Ltd., 65 Quaid-e-Azam Industrial Estate, KotLakhpat, Lahore on 06-03-2018.

02. The FID further informed that she seized the following drugs on Form-2 under section 18 (1) of the Drugs Act, 1976 & DRAP Act 2012.

Sr. No.	Name of Drug (s)	Batch No.	Mfg. Date	Exp. Date	Mfg. by	Quantity
01.	Everelong 60mg Tablets	374	11-17	11-19	M/s Everest Pharmaceuticals 124-Industrial Triangle,	255 packs x 10 Tablets

					Islamabad	
02.	Dyone Tablets	144	05/17	05/19	-do-	07 packs x 20 Tablets
03.	Sumat-N Tablets	089	03/17	03/19	Do-	04 packs x 10 Tablets
04.	Zitpro Oral Suspension	017L018	11/17	11/19	Do-	10 Pakssx01
05.	Esoval Tablets	365	10/17	10/19	-do-	08 Packs x14 Tablets

03. The FID further informed that the above mentioned drugs were recovered and seized in the presence of Mr. Sajjad, proprietor present (CNIC No.35202-2654857-7) and Ms. Alia Aroosa, Qualified person present (CNIC No.35201-8259479-7). The witnesses were also recorded on the seizure from.

04. Permission for safe custody of the seized stocks of therapeutic goods/drugs was allowed to the FID till the finalization of the case by the CLB.

05. That M/s Servaid Pharmacy supplied invoice warranty of M/s Alqamar distributor 14-A Asharafia Parka Ferozepur Road Lahroe whereas Al qamar distributor Lahore provided inovice warranty for the product Esoval bearing no. TPO/11909 dated 06-01-2018 issued by Everest Pharmaceuticals Islamabad. M/s Paris distributor who supplied sumat-N tabletB.No. 089 provided inovoice warranty No. EPO/618 dated 31-10-2017 supplied by M/s Everest Pharmaceuticals Islamabad. Similarly M/s Paris Pharmaceuticals supplied invoice warranty No. EPO/906 dated 23-02-2018 issued by M/s Everest Pharmaceuticals Islamabad to the Paris distributors. The product zitrpor oral suspension was incorrectly mentioned mfg Everest Pharmaceuticals actely it is manufacture by M/s ARP Pvt Ltd Rawat and is registered products. FID has requested to corrrectteh name of manfuaturerforteh said product. Dyone tablet B.NO. 144 mfg Everest Pharmaceuticals were sold by Saint & Sailor Pharmaceuticals suit No. 13 03rd floor Wahdat Road Lahore vide invoice No. 1759 dated 02-08-2017 to M/s Decent Enterprises Lahore who supplied the same to Servaid Pharmacy. It is pertinent to mentioned that the warranty was signed by Mr. KhuramNaeem who is also warrantor of M/s Everest Pharmaceuticals in a number of cases .

06. That the accused persons given below have violated the provisions of Schedule-II, of DRAP Act 2012 and hence, committed offences as under:-

a. A. (1)(a)(vii) i.e. export, import are manufacture for sale or sell any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceuticals evaluation;

b. A. (1)(a)(x) i.e. export, import are manufacture for sale or sell any therapeutic good in contravention of any of the provision of this Act are rules made thereunder;

c. A. (1)(b), manufacture for sale any therapeutic goods except under and in accordance with the condition of a license issued under this Act and;

d. (1)(e), Import or export any therapeutic goods drugs for the import or export of which a license is required except under , and in accordance with the conditions of such license.

07. The Prohibitions mentioned in para 5 are offences and punishable under schedule III of DRAP Act 2012

a. (1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.

b. (1)(c), Imports without license any therapeutic goods for the import of which a license is required.

c. (2)(b) gives to the purchaser a false warranty in respect of any therapeutic goods sold by him that the therapeutic goods does not is any way contravene the

provisions of schedule II and is not able to prove that, when gave the warranty , he had good and sufficient reason to believe the same to be true.

d. (4) i.e. contravention of rules:- subject to the provisions of clause (1) (2) and (3) whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or any rule shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one lakh rupees or with both.

e. (6), Penalty for violating the prohibitions: whoever himself or by any other person on his behalf violates any prohibitions specified in schedule-II shall be punished with imprisonment for a term upto five years and with fine up to five hundred thousand rupees

08. Permission for Lodging of FIR

The FID Lahore has requested to grant the permission of lodging of FIR of the following accused persons:-

1. M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.
2. Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad
3. Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad
4. Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad
5. Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad
6. MianIshtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad
7. KhuramNaeem warrantor M/s Saint & Sailor who signed and issued above mentioned false warranty on behalf of M/s Saint & Sailor Pharmaceuticals.
8. Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranty on behalf of M/s Everest Pharmaceuticals Islamabad.

09. **Decision of 261st meeting of CLB.**

The CLB considered the record of the case and on the basis of facts decided as under:-

1. That the accused persons have violated the provisions of Schedule-II, of DRAP Act 2012 and hence, committed offences as under:-

a. A. (1)(a)(vii) i.e. export, import are manufacture for sale or sell any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceuticals evaluation;

b. A. (1)(a)(x) i.e. export, import are manufacture for sale or sell any therapeutic good in contravention of any of the provision of this Act are rules made thereunder;

c. A. (1)(b), manufacture for sale any therapeutic goods except under and in accordance with the condition of a license issued under this Act and;

d. (1)(e), Import or export any therapeutic goods drugs for the import or export of which a license is required except under , and in accordance with the conditions of such license.

02. The Prohibitions mentioned in para 5 are offences and punishable under schedule III of DRAP Act 2012

a. (1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.

b. (1)(c), Imports without license any therapeutic goods for the import of which a license is required.

c. (2)(b) gives to the purchaser a false warranty in respect of any therapeutic goods sold by him that the therapeutic goods does not is any way contravene

the provisions of schedule II and is not able to prove that, when gave the warranty , he had good and sufficient reason to believe the same to be true.

d. (4) i.e. contravention of rules:- subject to the provisions of clause (1) (2) and (3) whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or any rule shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one lakh rupees or with both.

e. (6), Penalty for violating the prohibitions: whoever himself or by any other person on his behalf violates any prohibitions specified in schedule-II shall be punished with imprisonment for a term upto five years and with fine up to five hundred thousand rupees

03. <u>Permission for Lodging of FIR</u>

That CLB also granted the permission of lodging of FIR against the following accused persons for above mentioned violations mentioned in para 1 which are punishable under the provisions of schedule III has mentioned in para 2:-

1. **M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.**
2. **Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad**
3. **Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad**
4. **Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad**
5. **Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad**
6. **MianIshtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad**
7. **KhuramNaeem warrantor M/s Saint & Sailor who signed and issued above mentioned false warranty on behalf of M/s Saint & Sailor Pharmaceuticals.**
8. **Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranty on behalf of M/s Everest Pharmaceuticals Islamabad.**

10. The said decision was communicated to quarter concerned vide f. 3-33/2018-QC (261-CLB) dated 24th May, 2018.

11. In the light of decision of CLB, the FID-VII, Lahore has requested the Director, FIA, Lahore vide letter no. 8330/2018-DRAP(L-VII) dated 14-6-2018 that FIR may kindly be lodged against the persons mentioned in decision made by 261st meeting of CLB.

12. In the challan (incomplete) submitted by IO, Assistant Director FIA/CCC/Lhr U/S 173 Cr. P.C in continuation to FIR no. C-149/2018 dated 17.7.2018, the accused person Ch. Muhammad Usman S/o Zaheer Ahmed (owner of M/s Everest Pharmaceuticals, Islamabad is under custody and none of the accused persons are on bail. FIA/ACC Lahore took up the matter on receipt of istighasa received from Anum Saeed, Federal Inspector of Drugs Lahore vide letter no. 8330/2018-DRAP(L-VII) is reproduced as under:

> "Ms. Uzma Barkat, FID DRAP Lahore, Mr. Asim Rauf, Additional Director, DRAP, Lahore; Mr. Ajmal Sohail, FID, Lahore, Mr. Abdul Rashid Shaikh, FID, Lahore along with Mr. Muhammad Usman, Inspector, FIA, Lahore inspected the premises of M/s. Servaid Pharmacy (Pvt.) Ltd., 65-Quaid-e-Azam Industrial Estate. Kot Lakhpat, Lahore on 06-03-2018. The following drugs were seized on Form 2 under Section 18 (1) (f) of the Drugs Act, 1976 & DRAP Act, 2012.

Sr.	Name of	Batch	Mfg.	Exp.	Mfg. by	Quantity

No.	Drug (s)	No.	Date	Date		
01.	EverLong 60 mg Tablets	374	11-17	11-19	M/s. Everest Pharmaceuticals 124-Industrial Tiangle, Islamabad	255 Packs× 10 Tablets
02.	Dyone Tablets	144	05/17	05/19	-do-	07 Packs× 20 Tablets
03.	Sumat-N Tablets	089	03/17	03/19	-do-	04 Packs× 10 Tablets
04.	Esoval Tablets	365	10/17	10/19	-do-	08 Packs× 14 Tablets

With regard to products at sr. no. 1 and 3: Everlong 60mg tablets and Sumat-N tablets, M/s Servaid Pharmacy (pvt), provided invoices/ warranties bearing no. 7351 dated 16-10-17 and no. 836534, dated 23-2-2018, respectively, issued by M/s Paaris Distributors, Lahore. Upon explanation, M/s Paaris Distributors, Lahore provided letter of authentication dated 9-2-2018 and invoice/ warranties bearing no. EPO/618 dated 31-10-2017 and no. EPO/906 dated 23-2-2018, issued by M/s Everest Pharmaceurticals, 124- industrial triangle in their favor. An explanation letter in this regard was sent to the manufacture, M/s Everest Pharmaceuticals, 124, Industrial Triangle, Islamabad vide letter No.5053/2018-DRAP(L-V-VII) dated 12.04.2018. With regard to the product at Sr. No.2, namely Dyone Tablets, M/s Servaid Pharmacy (Pvt) Ltd. Lahore provided invoice/warranty bearing No.00058758 dated 17.08.2017, issued by M/s Decent Enterprises, 1-A/4C, Kanal Park, Gulberg-II, Lahore in their favor. Upon explanation M/s Decent Enterprises, Lahore submitted a copy of the letter of authorization dated 03.02.2016 and invoice/warranty bearing No.17590 dated 02.08.2017 issued by M/s Saint and Sailor Pharmaceuticals Suit No.13 3rd Floor Gohar Center, Wahdat Road, Lahore in their favor. And explanation letter and a reminder thereto were issued to M/s Saint and Sailor Pharmaceuticals vide letter No.5051/2018-DRAP (L-VIII) dated 12.04.2018 and letter No.5789/2018-DRAP(L-VIII) dated 27.04.2018 respectively. 4- With regard to product at Sr. No.4 namely Esoval Tablets, M/s Servaid Pharmacy Pvt. Ltd, Lahore provided invoice/warranty bearing No.1186382 dated 25.01.2018, issued by M/s Al-Qamar Distributor, 14-A, Ashrafia Park, Ferozepur Road, Lahore in their favor. Upon explanation M/s Al-Qamar Distributors submitted a copy of the letter of authorization dated Nil, and invoice/warranty bearing No. TOP/11909 dated 06.01.2018 issued by M/s Everest Pharmaceuticals, Islamabad in their favor. An explanation letter in this regard was send the manufacturer M/s Everest Pharmaceuticals, Islamabad vide letter No.5050/2018-DRAP (L-VIII) dated 12.04.2018. 5- The matter was referred to the Central Licensing Board, and was placed before the Board in its 260th meeting. The Board after evaluation of the facts of the case, granted permission to lodge FIR against the following accused persons vide 2-Chaudhry Muhammad Usman (Owner) M/s Everest Pharmaceuticals, Islamabad. 3- Dr. Kamran Izhar (Partner) M/s Everest Pharmaceuticals, Islamabad. 4- Noor Muhammad Mahar (Partner) M/s Everest Pharmaceuticals, Islamabad. 5- Chaudhry Muhammad Usman, Production Incharge, M/s Everest Pharmaceuticals, Islamabad. 6- MianIshtiaq Ahmed, Quality Control Incharge, M/s Everest Pharmaceuticals, Islamabad. 7- KhurramNaeem, Warrantor on behalf of M/s Saint and Sailor Pharmaceuticals. 8- Mr. Haroon Yousuf, Warrantor for M/s Everest Pharmaceuticals, Islamabad who

signed and issued above mentioned false warranty on behalf of M/s Everest Pharmaceuticals, Islamabad. 6- The above accused persons have committed offense by violating provision of sub-clause (vii) and (x) of clause (a); clause (b) and clause (e) of paragraph (1) of heading A of Schedule-II to the DRAP Act, 2012. All the offenses are cognizable offenses under clause (a) of paragraph (2) of the Schedule-IV to the DRAP Act, 2012, and are punishable under sub-clause (a) and (c) of clause (1); sub-clause (b) of clause (2); clause (4); and clause (6) under of Schedule-III to the DRAP Act, 2012. 7- It is therefore requested that FIR against the aforementioned accused persons may please be lodged accordingly. Sd/- Anam Saeed, Federal Inspector of Drugs, Lahore. At the police station: on receipt of Istigasa and having permission from competent authority vide letter No.DPL/Misc-L/5198/18/23344 dated 26.06.2018 case is hereby registered against above said accused persons u/s 1(a) and (c), 2(b), 4 and 6 of Schedule-III, DRAP Act, 2012 r/w 23/27 Drugs Act, 1976. Investigation is assigned to the Mr. Muhammad Riaz Khan, Assistant Director FIA/CCC, Lahore. Copies of FIR are being sent to all concerned. Later on investigation of instant case is entrusted to Mr. Sajid Amin, Assistant Director FIA/CCC, Lahore. During course of investigation the facts of the case have been enquired and discussed with witnesses, that was taken into custody at the time of raid has also been perused and discussed. Their statements u/s 161 of Cr. P.C have been recorded separately. The nominated accused person Chaudhry Muhammad Usman arrested on 30.08.2018 now he is on judicial remand. Yet no any other accused person has been arrested. During investigation it revealed that the accused Chaudhry Muhammad Usman has been involved in manufacturing and sale of unregistered, spurious and sex inducing drugs at a large scale with active connivance of other accused person. The investigation is in process. In the light of oral as well documentary evidence accused person are found guilty. The incomplete challan u/s 173 Cr. P.C is submitted please. It is therefore requested that the accused and the witnesses may please be called to start the trial of the case".

13. Assistant Director, FIA/CCC/Lahore recorded the statements of witnesses listed under column no. 6:
    i. Anam Saeed Federal Inspector Of Drugs DRAP Lahore.
    ii. UzmaBarkat Federal Inspector Of Drugs DRAP Lahore.
    iii. AjmalSohail Asif Federal Inspector Of Drugs DRAP Lahore.
    iv. Muhammad Usman inspector FIA/CCC/Lahore.
    v. Ali Rizwan Zaidi Paaras Distributor Everest pharmaceutical. 288/A Johar Town Lahore.
    vi. Nauman Raza, Sub Inspector, FIA, CCC, Lahore.
    vii. ShafqatJabbar, FC, FIA,CCC, Lahore.
    viii. Waseem Abbas Steno/Typist FIA/CCC/ Lahore.
    ix. Muhammad Riaz khan Assistant Director FIA/CCC/ Lahore.

14.The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty. The incomplete challan u/s 173 Cr. P.C is submitted please. It is therefore, requested that accused and witnesses may please be called to start the trial of the case.

15. In the light of investigation of the FID, Lahore and IO, FIA, Lahore, the accused persons have been declared guilty u/s 1(a) and (c), 2(b), 4 and 6 of Schedule-III, DRAP Act, 2012 r/w 23/27 Drugs Act, 1976. It is therefore submitted that the following accused persons may be show caused for the offences committed by them as stated herein above in this para:

1. M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.
2. Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad

3. Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad
4. Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad
5. Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad
6. MianIshtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad
7. KhuramNaeem warrantor M/s Saint & Sailor who signed and issued above mentioned false warranty on behalf of M/s Saint & Sailor Pharmaceuticals.
8. Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranty on behalf of M/s Everest Pharmaceuticals Islamabad.

Decision: The Central Licensing Board considered the facts on record and decided as under:

1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:

i. **M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.**
ii. **Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad**
iii. **Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad**
iv. **Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad**
v. **Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad**
vi. **MianIshtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad**
vii. **KhuramNaeem warrantor M/s Saint & Sailor who signed and issued above mentioned false warranty on behalf of M/s Saint & Sailor Pharmaceuticals.**
viii. **Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranty on behalf of M/s Everest Pharmaceuticals Islamabad.**

2. The aforesaid accused persons have been found guilty under sub-clause (vii) and (x) of clause (a); clause (b) and clause (e) of paragraph (1) of heading A of Schedule-II to the DRAP Act, 2012. Offenses are cognizable offenses under clause (a) of paragraph (2) of the Schedule-IV to the DRAP Act, 2012, and are punishable under sub-clause (a) and (c) of clause (1); sub-clause (b) of clause (2); clause (4); and clause (6) under of Schedule-III to the DRAP Act, 2012.

3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.

Case No. 05

Subject: Seizure Of Stock Under Section 18 (1) (f) of the Drugs Act, 1976 From (M/s. Fazal Din & Sons (Pvt.) Ltd., 53-Shahrah-e-Quaid-e-Azam, Lahore) i.e., Tablet Everlong 60 mg Manufactured By M/s. Everest Pharmaceuticals 124-Industrial Triangle, Islamabad.

Proceedings of 261st meeting of CLB.

Mr. Abdul Rashid Sheikh FID Lahore-VI has forwarded the subject mentioned case. The FID Lahore along with Ms. Uzmabarkat, FID Lahore and Ms. NureenRamzan, inspector, FIA Lahore visited the premises of M/s Fazal Din & sons (pvt) Ltd on 06-03-2018.

2. The FID Lahore seized the following unregistered drugs:-

S.No	Name of drug and	Mfg date	Exp date	Mfg by	Quantity

	Batch No..				
1.	Everelong 60mg Tablets	374	11-17	11-19	127 Tablets

3. The Everlong 60mg tablets were recovered and seized in the presence of Syed Asghar Abbas Zaidi, Branch Manager and Ms. SamiaAltaf pharmacist (newly appointed Qualified person). The witnesses were also recorded on the seizure form.

4. The FID referred to the competent authority as required under Drug Act 1976 and Schedule-V to the DRAP Act 2012.

5. The permission for safe custody was already allowed by the CLB in its 259th which is as under:-

"259 Decision of the Case:-

Permission for safe custody of the seized stocks of therapeutic goods/drugs was allowed to the FID till the finalization of the case".

6. That Fazal Din and sons Pvt Ltd submitted invoice warranty duly issued by Paris Distributor Lahore. M/s Paris distributors submitted inovie warranty bearing No. EPO 743 dated 08-01-2018 issued by M/s Everst Pharmaceutical Islamabad. M/s Paris distributors also submitted copies of cheaks to the FID which were given to the manufacturer in return to the price of purchased drugs

7. That the accused persons given below have violated the provisions of Schedule-II, of DRAP Act 2012 and hence, committed offences as under:-

a. A. (1)(a)(vii) i.e. export, import are manufacture for sale or sell any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceuticals evaluation;
b. A. (1)(a)(x) i.e. export, import are manufacture for sale or sell any therapeutic good in contravention of any of the provision of this Act are rules made thereunder;
c. A. (1)(b), manufacture for sale any theraputice goods except under and in accordance with the condition of a license issued under this Act and;
d. (1)(e), Import or export any therapeutic goods drugs for the import or export of which a license is required except under , and in accordance with the conditions of such license.

8. The Prohibitions mentioned in para 5 are offences and punishable under schedule III of DRAP Act 2012

a. (1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.
b. (1)(c), Imports without license any therapeutic goods for the import of which a license is required.
c. (2)(b) gives to the purchaser a false warranty in respect of any therapeutic goods sold by him that the therapeutic goods does not is any way contravene the provisions of schedule II and is not able to prove that, when gave the warranty , he had good and sufficient reason to believe the same to be true.
d. (4) i.e. contravention of rules:- subject to the provisions of clause (1) (2) and (3) whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or any rule shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one lakh rupees or with both.

e. (6), Penalty for violating the prohibitions: whoever himself or by any other person on his behalf violates any prohibitions specified in schedule-II shall be punished with imprisonment for a term upto five years and with fine up to five hundred thousand rupees

9. Permission for Lodging of FIR

The FID Lahore has requested to grant the permission of lodging of FIR of the following accused persons:-

1. *M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.*
2. *Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad*
3. *Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad*
4. *Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad*
5. *Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad*
6. *MianIshtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad*
7. Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranty on behalf of M/s Everest Pharmaceuticals Islamabad.

10. Decision of 261st meeting of CLB.

1. The CLB allowed to the FID for grant the permission for

i. Extension of sealing period of sealed premises for further 90 days

ii. Safe custody of seized drugs was allowed till finalization of the case.

02 The CLB also granted the permission for lodging the registration of FIR against the following accused persons:-

a) ***M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.***

b) ***Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad***

c) ***Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad***

d) ***Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad***

e) ***Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad***

f) ***MianIshtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad***

g) **Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranty on behalf of M/s Everest Pharmaceuticals Islamabad.**

03. That the accused persons mentioned above have violated the provisions of **Schedule-II, of DRAP Act 2012 and hence, committed offences as under:-**

a. A (1)(a)(vii) i.e. export, import are manufacture for sale or sell any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceuticals evaluation;

b. A (1)(a)(x) i.e. export, import are manufacture for sale or sell any therapeutic good in contravention of any of the provision of this Act are rules made thereunder;

c. A (1)(b), manufacture for sale any theraputice goods except under and in accordance with the condition of a license issued under this Act and;

d. (1)(e), Import or export any therapeutic goods drugs for the import or export of which a license is required except under , and in accordance with the conditions of such license.

04. The Prohibitions mentioned in para 3 are offences and punishable under schedule III of DRAP Act 2012 as mentioned below.

a. **(1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.**
b. **(1)(c), Imports without license any therapeutic goods for the import of which a license is required.**
c. **(2)(b) gives to the purchaser a false warranty in respect of any therapeutic goods sold by him that the therapeutic goods does not is any way contravene the provisions of schedule II and is not able to prove that, when gave the warranty , he had good and sufficient reason to believe the same to be true.**
d. **(4) i.e. contravention of rules:- subject to the provisions of clause (1) (2) and (3) whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or any rule shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one lakh rupees or with both.**
e. **(6), Penalty for violating the prohibitions: whoever himself or by any other person on his behalf violates any prohibitions specified in schedule-II shall be punished with imprisonment for a term upto five years and with fine up to five hundred thousand rupees.**

11. The said decision was communicated to quarters concerned vide f. no. 3-33/2018-QC (261-CLB) dated 24th May, 2018.

12. FIR was lodged by Abdul Rashid Shaikh, FID Lahore vide FIR no. C-166/2018 dated 7-8-2018 at FIA/CCC/Lahore. In the challan (incomplete) submitted by IO, Assistant Director FIA/CCC/Lhr U/S 173 Cr. P.C, the accused person Ch. Muhammad Usman S/o Zaheer Ahmed (owner of M/s Everest Pharmaceuticals, Islamabad is under custody and none of the accused persons are on bail. FIA/ACC Lahore took up the matter on receipt of istighasa received from Abdul Rashid Shaikh, FID Lahore vide letter no. 9332/2018-DRAP (L-VI) is reproduced as under:

"Mr. Abdul Rashid Sheikh, FID, Lahore alongwith Ms. UzmaBarkat, FID, DRAP, Lahore and Mst. NoureenRamzan Inspector FIA/CCC/Lahore inspected the premises of M/s Fazal Din & Sons (Pvt) Ltd., 53-Shahrah-e-Quaid-e-Azam, Lahore, on 06.03.2018. 2- The following drug being, unregistered, was seized on Form-2 under Section 18(1)(f) of the Drugs Act, 1976 & DRAP, Act, 2012. Copy of Form-2 attached as Annex-A.

Sr. No.	***Name of Drug (s)***	***Batch No.***	***Mfg. Date***	***Exp. Date***	***Mfg. by***	***Quantity***
01.	*EverLong 60 mg Tablets*	*374*	*11-17*	*11-19*	*M/s. Everest Pharmaceuticals 124-Industrial Tiangle, Islamabad*	*127 Tablets*

3- M/s Fazal Din & Sons (Pvt) Ltd., 53-Shahrah-e-Quaid-e-Azam, Lahore provided the invoice/warranty No.808359, dated 19.01.2018 and No.813501, dated 26.01.2018, issued by M/s Paaris Distributors, Lahore in their favour, as a proof of their purchase. 4- M/s Paaris Distributors, 5-Old FC, of Ferozepur Road, Gulberg, Lahore, in turn provided the invoices/warranty bearing No.EPO/743, dated 08.01.2018 issued by M/s Everest Pharmaceuticals, 124-Industrial Triangle, Islamabad in their favour, vide their letters No.Nil, dated 21.03.2018. 5- Accordingly, a letter was sent to the warrantor/manufacturer, i.e. M/s Everest

Pharmaceuticals, Islamabad, vide this office letter No.3957/2018-DRAP(L-VI) dated 22.03.2018, with the directions to explain their position and submit the requisite information, which is yet to be replied. 6- The matter was placed before Central Licensing Board. The Board after evaluation of the facts of the case inter alia, granted permission vide letter No.F.03-33/2018-QC (Pt-261-CLB) dated 24.05.2018 to lodge FIR against the following accused persons: a) M/s Everest Pharmaceuticals, Islamabad, through owner, Ch. Muhammad Usman. b) Ch. Muhammad Usman (owner), M/s Everest Pharmaceutical, Islamabad. c) Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals, Islamabad. d) Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals, Islamabad. e) Ch. Muhammad Usman, Production Incharge, M/s Everest, Pharmaceuticals, Islamabad. f) MianIshtiaq Ahmed Quality Control Incharge, M/s Everest, Pharmaceuticals, Islamabad. g) Haroon YOusaf, Warrantor M/s Everest, Pharmaceuticals, Islamabad who signed and issued above mentioned false warranty on behalf of M/s Everest, Pharmaceuticals, Islamabad. 7- the above accused persons have committed offence by violating provision of sub-clause (vii) & (x) of clause (a), clause (b) & clause (e) of paragraph (1) of heading A of Schedule-II to the DRAP, Act, 2012, read with Section 23(1)(a)(vii)(x), (b) and € of the Drugs Act, 1976, with the exception of offence under sub-clause (x) of clause (a) of paragraph (1) of the heading A of the Schedule-II to the DRAP Act, 2012, read with Section 23(1)(a)(x) of the Drugs Act, 1976, all the offences are cognizable offences under clause (a) of paragraph (2) of the Schedule-IV to the DRAP Act, 2012, read with Section 30(2)(a) of the Drugs Act, 1976, and are punishable under clause (1)(a) & (e), (2)(b), (4) and (6) of Schedule-III to the DRAP Act, 2012, read with Section 27(1)(a) & (c), (2)(b) and (4) of the Drugs Act, 1976. It is, therefore, requested that FIR against the aforementioned accused persons may please be lodged accordingly. Sd/- Abdul Rashid Shaikh Federal Inspector of Drugs, Lahore. At the police station: On receipt of istighasa and having permission from Competent Authority, case is hereby registered against above said accused persons U/S 1(a)&(e), 2(b), 4&6 of Schedule-III DRAP Act 2012 R/W Section 27(1)(a)&(c), (2)(b) and (4) of the Drugs Act, 1976. Investigaton is assigned to the Muhammad Riaz Khan, Assistant Director FIA/CCC Lahore. Copies of FIR are being sent to all concerned. Later on investigation of instant case is entrusted to undersigned. During course of investigation the facts of the case have been enquired and discussed with witnesses, the record was taken into custody at the time of raid has also been perused and discussed. Their statements u/s 161 of Cr. P.C have been recorded separately. The nominated accused Ch. Muhammad Usman has been arrested on 30.08.2018. Now he is on judicial remand. Yet no any other accused person has been arrested. During investigation it revealed that the accused Ch. Muhammad Usman has been involved in manufacturing and sale of unregistered, spurious and sex inducing drugs at large scale with active connivance of other accused persons. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty. The incomplete challan u/s 173 Cr. P.C is submitted please. It is therefore requested that accused and witnesses may please be called to start the trial of the case.

13. Assistant Director, FIA/CCC/Lahore recorded the statements of witnesses listed under column no. 6:

    a. Abdul Rashid Shaikh, Federal Inspector Of Drugs, DRAP Lahore.
    b. UzmaBarkat, Federal Inspector Of Drugs, DRAP Lahore.
    c. AjmalSohail Asif, Federal Inspector Of Drugs, DRAP Lahore.

d. Ms. NoureenRamzan Inspector FIA/ACC/Lahore.
e. Ali Rizwan Zaidi Paaras Distributor Everest Pharmaceutical, 288/A Johar Town, Lahore.
f. Waseem Abbas Steno/ typist FIA/CCC/Lahore.
g. Nauman Raza, Sub inspector, sub inspector, FIA, CCC, Lahore.
h. ShafqatJabbar, FC, FIA, CCC, Lahore.
i. Muhammad Riaz Khan Assistant Director FIA/CCC/ Lahore.

14. The investigation is in progress. In the light of oral as well as documentary evidence accused persons are found guilty. The incomplete challan u/s 173 Cr. P.C is submitted please. It is therefore, requested that accused and witnesses may please be called to start the trial of the case.

15. In the light of investigation of the FID, Lahore and IO, FIA, Lahore, the accused persons have been declared guilty *U/S 1(a)&(e), 2(b), 4&6 of Schedule-III DRAP Act 2012 R/W Section 27(1)(a)&(c), (2)(b) and (4) of the Drugs Act,* 1976. It is therefore submitted that the following accused persons may be show caused for the offences committed by them as stated herein above in this para:

1. *M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.*
2. *Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad*
3. *Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad*
4. *Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad*
5. *Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad*
6. *MianIshtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad*
7. Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranty on behalf of M/s Everest Pharmaceuticals Islamabad.

Decision: The Central Licensing Board considered the facts on record and decided as under:

1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:

i. **M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.**
ii. **Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad**
iii. **Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad**
iv. **Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad**
v. **Ch. Muhammad Usman Production In charge, M/s Everest Pharmaceuticals Islamabad**
vi. **MianIshtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad**
vii. **Haroon Yousuf Warrantor M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranty on behalf of M/s Everest Pharmaceuticals Islamabad.**

2. The aforesaid accused persons have been found guilty under sub-clause (vii) and (x) of clause (a); clause (b) and clause (e) of paragraph (1) of heading A of Schedule-II to the DRAP Act, 2012. Offenses are cognizable offenses under clause (a) of paragraph (2) of the Schedule-IV to the DRAP Act, 2012, and are punishable under sub-clause (a) and (c) of clause (1); sub-clause (b) of clause (2); clause (4); and clause (6) under of Schedule-III to the DRAP Act, 2012.

3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.

Case No. 06

Subject: ISSUANCE OF LICENSE/ PROVISIONAL CERTIFICATE FOR FIRST PRIVATE DRUG TESTING LABORATORY IN ISLAMABAD

01. The Prime Health (Pvt) Ltd, 30-East, Mezzanine Floor, Royal Plaza, Fazal-e-Haq Road. Blue Area, Islamabad-Pakistan vide letter NIL dated 31.07.2018 has requested issuance of License/Provisional Certificate for First Private Drugs Testing Laboratory in Islamabad, the complete request is reproduced as under:

> *"this is further to our letter, ref:* ***PHPL/DRA/001/17****, & Letter ref: PHPL/DRA/002/18, our request for the issuance of Provisional Certificate to our State of the Art Drug Testing Laboratory located at 30-East, Mezzanine Floor, Royal Plaza, fazal-e-Haq Road. Blue Area, Islamabad-Pakistan.*
>
> *Our GMP compliant laboratory is equipped with latest technology, state of the art German/Italian/American/Japanese equipment fully compliant with 21CFR Part 11. Staff is trained & qualified to perform chemical & microbiological testing on Drug substances & Drug products. The different sections included are wet chemistry, instrument rooms, Microbiological testing laboratory with clean rooms and equipped with double door autoclave, Media preparation area, stability chambers dedicated for accelerated & Long-term stability for zone IV region and 12 situation dissolution test apparatus for conducting comparative/in-vitro studios.*
>
> *We are pleased to inform you that Prime Health (PVT) Ltd is now fully commissioned and ready to go live. All our analytical instruments are in place at their designated locations with their relevant SOPs. Our Laboratory staff has been trained for QMS and is in process for accreditations (ISO 17025)*
>
> *We are in position to offer our services to pharmaceutical and related industries in the area of simple chemical and microbiological testing, stability studies, comparative dissolution, method development and validation, training services and CTDs.*
>
> *In order to offer our service to different pharmaceutical and related industry clients, we need to have approval by Drug Regulatory Authority of Pakistan (DRAP).*
>
> *I request, your help to please arrange for issuance of License/Provisional Certificate for Prime Health (Pvt) Ltd. so that we can offer our professional services to all the pharmaceutical and related industries."*

02. Keeping in view of the request of the M/s Prime Health, Islamabad the Director (QA&LT), DRAP, Islamabad has directed the Additional Director (QA&LT-I), Islamabad on 31.07.2018 to evaluate & inspect the premises of M/s Prime Health (Pvt.) Ltd., Islamabad along with FID-IV, Islamabad and Assistant Director (Import & Export), Islamabad. Subsequently the Assistant Director (QA-IV), DRAP, Islamabad informed the same vide letter no. F. 6-17/18-QA dated 01.08.2018 and requested to submit conclusive report for issuance of License /Provisional certificate within a period of 10 days.

03. In the light of directions, the FID-IV, Islamabad alongwith other panel members visited the premises on 03-08-18 and submitted the inspection report Additional Director (QA&LT-I), Islamabad vide letter no. 3-1/2018-FID-IV(ISD) dated 17.08.2018, reproduced as under:

Name of Establishment	*Prime Health Pvt Ltd*
Physical Address	*Royal Plaza, Mezzanine Floor, 30 East, Fazal-e-Haq Road, Blue Area, Islamabad-Pakistan*
Date of inspection	*03-08-18*
Purpose of inspection	*Objective Panel Inspection:*

	Issuance of provisional certificate/license for testing facility
Name of inspector (s)	1. *DrHafsaKaramElahi, Additional Director QA&LT* 2. *Mahvash Ansari, DD(QC)/FID (ISB)* 3. *Ayesha Saleem, AD(I&E)*
Name of Firm's Representative (s) accompanying during inspection	1. *MrsAmbreen Amir, Chief Operating Officer* 2. *MrShahidShoaib, Chief Finance Officer*

Brief Introduction of Establishment

Firm is Located at Royal Plaza, Mezzanine Floor, 30 East, Fazal-e-Haq Road, Blue Area, Islamabad-Pakistan.It is Quality Control Laboratory to offer customer specific contract analytical services, Product development, Pre-Qualification and Compliance.

Scope of laboratory

- *Pharmaceutical Analytical Services (Drug Substances and Drug Products)*
- *Stability Studies*
- *Comparative Dissolution*
- *Impurity Profiling (HPLC & GC)*
- *Water Testing*

Building

Laboratory is built on the first floor in a commercial plaza. Surrounding of facility has the direction as such that,

- *East* *Geo News Building*
- *West* *Hamdard University*
- *North* *MCB Bank, Metro Bus Stop (Parade Ground)*
- *South* *Afghan Embassy*

Premises consist of mainly two sections:

1. ***Wet chemistry Lab***
2. ***Microbiological lab***

1. ***Wet chemistry Section***

Chemical section consist of change room, instrument lab having HPLC, stability room adjacent to instrument lab, sample preparation area (equipped with fume hoods, refrigerator and working bench), separate area for AAS (atomic absorption spectrophotometer), washing area, and store rooms for glassware and chemicals and retention room.*

2. ***Microbiological Section***

Microbiology section consists of change room, washing area, washing area and sterile area which is provided with 3 buffers.*

**layout plan attached as an Anexxure A*

Equipment

Wet chemistry lab is equipped with GC (GC is not equipped with head spacer and MS hence impurity profiling cannot be done at present), two HPLCs, Atomic Absorption Spectrometer, FTIR, UV/VIS Spectrophotometer, TOC Analyzer, Dissolution Apparatus(8 & 12 vessels), Karl Fisher Apparatus, Disintegration Apparatus, Polarimeter, Fume Hood, Water Distillation Apparatus, Stability Chamber etc. Microbiology section is equipped with particle counter, Biological Safety Cabinet, Air Sampler, Colony Counter, Water Purification Plant, Autoclave etc. Establishment has no facility for testing of biological and sterility of antibiotics(parenteral & powder for injection).

***list along with model attached as an Anexxure B*

Personnel

*Firm has hired QA and QC manager experience of 7.5 and 14 years respectively. Other technical persons include a senior microbiologist and an analyst.****

****list of managerial and technical staff along with qualification and experience attached as an Anexxure C*

Documentation

Establishment has developed organogram along with job description and responsibilities quality manual. SOPs for various procedures as well as equipment are also in place. SOP for disposal of waste material is also been prepared and there is a mechanism (established for the handling and disposal of waste materials. Company has also provided format for contact agreement with customers and a sample test report/CoA.

*****docements attached as Annexure D*

Conclusion

Establishment has necessary equipment and arrangements for compliance to Good laboratory practices. However following areas need improvement/changes etc

Pharmaceutical Analytical Services (Drug Substances and Drug Products), should restrict to testing of pharmaceuticals only as far as approval from CLB is concerned subject to relevant provision of DRAP Act 2012, The Drugs Act 1976 and the rules framed thereunder.

- ***Reason for request of testing should be included in /request for anylysis of products/Contract agreement***
- ***GC should be provided with head spacer and detector(MS etc)***
- ***SOP for disposal of waste should include incineration after treatment.***
  Stringent safety parameters should be adopted as per Good Laboratory Practices.*"*

04. Report was submitted to QA for review, the matter was processed in the light of the decision of 60th meeting of authority.

05. The Deputy Director to CEO vide letter No. F. 5-4/2018-CEO(DRAP) dated 27th July, 2018 forwarded the minutes of 60th Meeting of the Drug Regulatory Authority of Pakistan held on 13th July, 2018 and requested all Directors to take further necessary action on the matters related to their division to implement the decisions/directions of the Authority. The Agenda Item No. IV i.e. "Proposal for new type of licensing in addition to Existing ones" that was presented by Division of Drugs Licensing. The Discussion and Decision of the Authority regarding aforementioned agenda item is reproduced as under:

"Discussion:

> *It was discussion that for such activities like* ***"Licensing for contract pharmaceutical test and analysis"*** *a separate Board is required to be constituted under the Division of QA&LT to deal with this type of activities. Meanwhile, such*

cases may be processed by that Division for provisional approvals and ratification may be obtained from Central Licensing Board till the time a full time Board for such activities is constituted by the QA & LT Division.

Decision:

*The proposed rules for **"Licensing for contract pharmaceutical test and analysis"** were referredto the Division of QA&LT for review. The Division was advised to formulate a proposal for constitution of a Separate Board for such type of activities as specified in DRAP Act, 2012. Meanwhile, such cases shall be processed in the Division of Quality Assurance & Laboratory Testing for provisional approval after verifying available requisite testing facilities with the applicant(s). Such approvals shall be ratified by Central Licensing Board till promulgation of rules and subsequent establishment of a separate Board under the QA&LT Division."*

06. As per authority's decision, Application for provisional approval was processed in QA &LT Division as rules are in process. Following fee was submitted by the applicant as per existing LRA rules.

07. The M/s Prime Health (Pvt.) Ltd., Islamabad has deposited following fee in Allied Bank on 14.09.2018:

	Item Description	Deposit Slip #	Amount Rs.
i.	Drug Manufacturing License Fee	0785903	100,000
ii.	Site Verification and layout	0785904	10,000

*Attached as annex E

08. The M/s Prime Health (Pvt.) Ltd., Islamabad has also deposited following fee for approval of proposed quality control In-charge in Allied Bank on 18.09.2018:

	Item Description	Deposit Slip #	Amount Rs.
i.	Applicant of proposed quality control In-charge	0785404	5,000

*Attached as Annex F

09. In the light of the decision of the authority matter was submitted to CEO/ Director QA& LT for issuance of **Provisional Certificate For Contract Testing And Analysis Of Pharmaceuticals**, for the period of one year which has been issued (copy is attached as *annexure G). The matter is being placed for ratification from Central Licensing Board in the light of above mentioned authority's decision.

DECISION:

The Board deliberated the case in depth and appreciated the step taken by the Authority to provide alternate testing facility in public and private sector. It was emphasized that it is the need of time and is in line with the international practice. Enabling provision of outsource testing will help local manufacturers to use testing facilities of such laboratories which will be adequately equipped and properly qualified for such specialized testing of Pharmaceuticals. Economic burden on the industry will be reduced and save the foreign exchange spent for purchasing of costly equipment by pharmaceutical industry. It will also provide an independent testing facility by third party. The Board advised that before ratification specific rules may be framed by the Authority.

Case No.07

Subject: **SEIZURE OF DRUGS UNDER DRUG ACT, 1976. PERMISSION FOR SAFE CUSTODY OF SEIZED DRUGS UNDER SECTION 19 (5) (A) OF THE DRUGS ACT, 1976 (FIVE STAR PHARMACY)**

Proceedings and Decision of the case in 260th Meeting of CLB

Mr. Khalid Mehmood, FID-II, Islamabad vide letter No. F. 1-3/2018-FID-II (ISD) dated 04th April, 2018.

02. The FID-II, Islamabad informed that he alongwith Mr. Ch. ZeeshanNazir, Deputy Director (QA), Mr. NoumanYousaf, Assistant Director (QA), Mr. Muhammad Awais, Assistant Director (QA), Mr. HanifUllah, Assistant Directro, (QA), Mr,. Zain-ul-Abidin, Assistant Director, (QC), Mr. Hassan Afzaal, FID-III/ Assistant Director, Mrs. RaziyahIkram, FID-VI/ Assistant Director has visited the premises of M/s. **Five Star Pharmacy**, B-210/2, Jahanbad Plaza, ChandniChowk, Rawalpindi and seized the below mentioned drugs under section (18) (1) (f) of the Drugs Act, 1976 read with Schedule-V of the DRAP Act, 2012.

Sr. No.	Name of Drug	Batch No. & Quantity	Manufacturer	Reason of Seizure
01.	Vega 100	SC-132 88 Tabs.	Combitic Global, D-2, Industrial Area, Sonepat, India.	**"Un-registered Drugs"**
02.	Vega-100	SC-135 52 Tabs.	-Do-	**"Un-registered Drugs"**
03.	Viagra 100 mg	20990543A 12 Tabs.	Pfizer USA	**"Un-registered Drugs"**
04.	Viagra 50 mg	19686524AH 12 Tabs.	-Do-	**"Un-registered Drugs"**
05.	Cobra 150 mg	0149 60 Tabs.	Combitic Global, D-2, Industrial Area, Sonepat, India.	**"Un-registered Drugs"**
06.	Cialis 20 mg	0923107560 18 Tabs.	Eli Lilly UK	**"Un-registered Drugs"**
07.	Cialis 20 mg	6TCP2MG 48 Tabs.	-Do-	**"Un-registered Drugs"**
08.	Cialis 20 mg	6TCP2MG 12 Tabs.	-Do-	**"Un-registered Drugs"**
09.	Viagra 100 mg	96P017F 30 Tabs.	Pfizer US Pharma, NY	**"Un-registered Drugs"**
10.	MyDekla 60	8061965 28 Tabs.	Mylan Labs Pharma, India.	**"Un-registered Drugs"**
11.	Vivioptal	2075 30 Caps	Dr. Gerhad Mann, Germany	**"Un-registered Drugs"**
12.	Anafranil 25 mg/ 2 ml	Lot No. 130613/A. 05 Inj.	Biotutura Pharma, Pemeria	**"Un-registered Drugs"**
13.	Cialis Gold 20 mg	95DE 165M	Eli Lilly, UK.	**"Un-registered**

		30 Tabs.		**Drugs"**

03. The said therapeutic goods/drugs were sized on Form-2 under Section 18(1) (f) of the Drug Act 1976. Mr. Muhammad Iftikhar Afzal (Propriotor)/ (Qualified person) was present at the time of visit. As he has violated the section 23(1)(a) (vii) of the Drugs Act1976 read with schedule-II (A)(1)(a)(vii) of the DRAP act 2012 which is punishable under section 27 (1) (a) of the Drugs Act 1976 read with schedule-III (1) (a) of the DRAP Act 2012.

04. An Explanation letter was issued M/s Five Star pharmacy, B-210/2, Jahanabad Plaza ChandniChowk Rawalpindi to explain the position on sale of the said unregistered drugs and further to explain as why the action may not be taken against him under section 27 of the Drugs Act 1976 read with schedule III of the DRAP Act 2012. He was also directed to provide the proof of purchase of above mentioned drugs within 07 working days under the Drugs Act 1976 read with schedule –III of DRAP Act 2012

05. Mr. Muhammad Iftikahr Afzal CNIC 37405-9531410-3 owner/ proprietor of M/s Five stare pharmacy B-2 10/2 jahanabad plaza ChandniShowk Rawalpindi vide his reply/statement No. Nil dated 09-04-2018 submitted as under:-

> ***"My son who was of 17 years old suddenly, diagnosed Blood Cancer due to treatment of him I was unable to give time to pharmacy. I had never purchased and sold any unregistered drugs in my life. These drugs were recovered from my pharmacy, in presence of inspecting team, He further claimed that it is someone propaganda against me and I was not awareof presence of these unregistered sex drugs etc and I swear yoib ALLAH that I don't know about these drugs which were recovered by team. I am giving this statement without anyone pressure and in reference of Explanation letter No. F.1-3/2018-FID-II (ISD) dated 04-04-2018. It is requested that in light of my statement and being professional (Pharmacist) Kindly pardon my mistake."***

06. Mr. Muhammad iftikahr Afzal (proprietor) / (Qualifed person/ pharmacist) has violated the section 23 (1) (a)(vii) of the Drugs Act 1976 read with schedule-II (A) (1)(a)(vii) of the DRAP Act 2012 which is punishable under section 27 (1) (a) of the Drugs Act 1976 read with schedule-III (1) (a) of the DRAP Act 2012

07. FID requested for **grant the permission for keeping the above mentioned seized drugs in safe custody till the decision of the case, under section 19 (5) (a) of the Drugs Act, 1976 or hand over the stock, if any to the provincial Inspector of drugs for further action under the Drugs Act, 1976, Section 19 (5) (a), as deem appropriate, as stock being seized at sales outlet which comes under the purview of Provincial Government under Section 6 of the Drugs Act, 1976.**

08. Keeping in view the above facts and investigation the case is submitted for guidance of the CLB and same may kindly be placed before the forthcoming meeting of CLB for its decision. The CLB is requested to decide the case as deem appropriate with the following proposal/facts on legal grounds

i. **To remand back the case to the Punjab Provincial health Department as sales of drug comes under section 6 of the Drug Act 1976 and same has also been intimated vide letter of even No date 04-04-2018 wherein under section 19(5) (a) of the Drugs Act 1976 the case comes under the purview of Provincial Health authorities which is the most appropriate proposal.**

ii. **<u>Permission may be granted to lodge FIR/prosecute the accused in the Drug Court.</u>**

iii. **To decide the case in the light of submission/statement of the proprietor/owner**

09. The matter of sale of unregistered drugs falls within the jurisdiction of FIDs and could not be referred to the Provincial Inspector under the proviso of sub section (5) of section 19 of Drug Act 1976 and schedule V of DRAP Act 2012. It is therefore submitted that option 2 of the FID is relevant for the grant of permission for registration of **FIR against** the following

i. **M/s Five Star Pharmacy B-210/2, Jahandad Plaza ChandiChowk Rawalpindi through proprietor Mr. Muhammad Iftikhar Afzal s/o Shiekh Muhammad Afzal CNIC No. 37405-9531410-3 .**

ii Mr. Muhammad Iftikhar Afzal s/o Shiekh Muhammad Afzal (proprietor)/ Qualified person

10 That the accused person is involved:-

i. sale of un registered drugs
ii. Sale of drugs without warranty
iii. Sale of smuggled sex medicine.

11. The above offences are prohibited under schedule II and punishable under schedule III of DRAP Act 2012.

12. **<u>DECISION OF THE CASE:</u>**

<u>The Central Licensing Board evaluated the record and decided as under:-</u>

1. **Allowed safe custody to the Federal Inspector of drugs till the finalization of the case.**
2. **Registration of FIR against the following persons**

i. **M/s Five Star Pharmacy B-210/2, Jahandad Plaza ChandiChowk Rawalpindi through proprietor Mr. Muhammad Iftikhar Afzal s/o Shiekh Muhammad Afzal CNIC No. 37405-9531410-3 .**

ii **Mr. Muhammad Iftikhar Afzal s/o Shiekh Muhammad Afzal (proprietor)/ Qualified person**

3. **The accused persons have committed violation of schedule II and schedule III of DRAP Act 2012 as under:-**
   a) **Sale/storage of un registered drugs**
   b) **Sale/storage of drugs without warranty.**
   c) **Sale/storage smuggled drugs/ imported without authorization**

13. In the light of decision of CLB communicated vide letter no. 03-26/2018-QC(260-CLB) dated 10.05.2018, the FID-II, Islamabad has requested the Director, FIA, Islamabad Zone, Islamabad vide letter 1-3/2018-FID-II(ISD) dated 17.05.2018 that an FIR may kindly be lodged against Mr. Muhammad Iftikhar Afzal (Proprietor)/(Qualified Person / Pharmacist) on violation of section 23(1)(a)(vii) of the Drugs Act, 1976 read with Schedule-II (A)(I)(a)(vii) of the DRAP Act, 2012, which is punishable under Section 27(1)(a) of the Drugs Act, 1976 read with Schedule-III(1)(a) of the DRAP Act, 2012 to probe the nexus of this violation and provide full support to the undersigned as per letter No. HQC/GB/M/16/2018/1825-33 dated 29.03.2018, so that spurious and unregistered drugs may be eliminated from the country as per direction of apex court in HRC no. 5845-G of 2018.
14. FIA/ACC Islamabad took up the matter under Enquiry no. 66/2018, and inferred that prima facie a case U/S 23(1)(a)(vii) of the Drugs Act, 1976 against Mr. Muhammad Iftikhar Afzal S/o Mr. Muhammad Afzal r/o House No. F-864 Mohallah Satellite Town, Rawalpindi made out for criminal investigation. Therefore, with the approval of competent authority the case is registered to be investigated by the Syed Ahmed Shah, Inspector, FIA ACC ISB vide **FIR No. 13/2018** dated 16.07.2018.
15. The Federal Inspector of Drugs-II, Islamabad vide letter no. 1-3/2018-FID-II dated 14.09.2018 submitted that in continuation to FIR No. 13/2018 registered with FIA (ACC) dated 16.07.2018. the complete challan received by the FID on 14.09.2018 and forwarded for soliciting approval of prosecution against accused, Mr. Muhammad Iftikhar Afzal S/o Sheikh Muhammad Afzal proprietor/Qualified person of M/s Five Star Pharmacy, ChandniChowk, Rawalpindi by Central Licensing Board.
16. In the complete challan submitted by IO, FIA ACC, Islamabad U/S 173 Cr. PC, the accused person Mr. Muhammad Iftikhar Afzal S/o Sheikh Muhammad Afzal (Proprietor M/s Five Star Pharmacy, B-210/2, Jahandad Plaza, ChandniChowk, Rawalpindi) r/o House No. F-864 Mohallah Satellite Town, Rawalpindi is **under arrest** and placed in Column 3 i.e. "**Name & Address of persons who have been Challaned**"
17. Brief fact of the case mentioned in challan are reproduced as under:

"that Mr. Khalid Mahmood, Federal Inspector of Drugs-II, DRAP along with the raiding team of DRAP's officers (Prosecution witnesses), Ch. ZeeshanNazir, Deputy Director (QA), Mr. NoumanYousaf, Assistant Director (QA) Mr. Muhammad Awais, Assistant Director (QA), Mr. Hanifullah, Assistant Director (QA), Mr. Zain-ul-Abideen, Assistant Director (QC), Mr. Hassan Afzal, Federal Inspector of Drugs-III/Assistant Director, Mrs. RaazeyahIkram, Federal Inspector of Drugs-IV/Assistant Director visited the premises of M/s Five Star Pharmacy B-210/2, Jahandad Plaza, ChandniChowk, Rawalpindi on 4th April, 2018 and seized the below mentioned drugs under Section (18) of the Drugs Act,

1976 [on Form-2] r/w Schedule-V of the DRAP Act, 2012 on violation of the Section 23(1)(a)(vii) of the Drugs Act, 1976 r/w Schedule-II(A)(1)(a)(vii) of the DRAP Act, 2012, which is punishable u/s 27(1)(a) of the Drugs Act, 1976 r/w Schedule-III(1)(a) of the DRAP Act, 2012 in the presence of Mr. Muhammad Iftikhar Afzal (Proprietor):

Sr. No.	***Name of Drug***	***Batch No. & Quantity***	***Manufacturer***	***Reason of Seizure***
01.	*Vega 100*	*SC-132 88 Tabs.*	*Combitic Global, D-2, Industrial Area, Sonepat, India.*	***"Un-registered Drugs"***
02.	*Vega-100*	*SC-135 52 Tabs.*	*-Do-*	***"Un-registered Drugs"***
03.	*Viagra 100 mg*	*20990543A 12 Tabs.*	*Pfizer USA*	***"Un-registered Drugs"***
04.	*Viagra 50 mg*	*19686524AH 12 Tabs.*	*-Do-*	***"Un-registered Drugs"***
05.	*Cobra 150 mg*	*0149 60 Tabs.*	*Combitic Global, D-2, Industrial Area, Sonepat, India.*	***"Un-registered Drugs"***
06.	*Cialis 20 mg*	*0923107560 18 Tabs.*	*Eli Lilly UK*	***"Un-registered Drugs"***
07.	*Cialis 20 mg*	*6TCP2MG 48 Tabs.*	*-Do-*	***"Un-registered Drugs"***
08.	*Cialis 20 mg*	*6TCP2MG 12 Tabs.*	*-Do-*	***"Un-registered Drugs"***
09.	*Viagra 100 mg*	*96P017F 30 Tabs.*	*Pfizer US Pharma, NY*	***"Un-registered Drugs"***
10.	*MyDekla 60*	*8061965 28 Tabs.*	*Mylan Labs Pharma, India.*	***"Un-registered Drugs"***
11.	*Vivioptal*	*2075 30 Caps*	*Dr. Gerhad Mann, Germany*	***"Un-registered Drugs"***
12.	*Anafranil 25 mg/ 2 ml*	*Lot No. 130613/A. 05 Inj.*	*Biotutura Pharma, Pemeria*	***"Un-registered Drugs"***
13.	*Cialis Gold 20 mg*	*95DE 165M 30 Tabs.*	*Eli Lilly, UK.*	***"Un-registered Drugs"***

In light of above mentioned compelling evidence seized and recovered from the premises of Five Star Pharmacy Jahandad Plaza, ChandniChowk, Rawalpindi FIR No. 13/2018 dated 16.07.2018 U/S 23(1)(a)(vii) of Drugs Act 1976 was registered on the complaint of DRAP against Mr. Muhammad Iftikhar Afzal, Proprietor M/s Five Star Pharmacy, B-210/2, Jahandad Plaza, ChandniChowk, Rawalpindi. During the course of investigation the statement of the complainant and the entire raiding team were recorded u/s 161 Cr.PC. The entire team affirmed in positive that the above mentioned unregistered drugs were recovered from the premises of M/s Five Star Pharmacy, B-210/2, Jahandad Plaza, ChandniChowk, Rawalpindi and that the same were kept in contravention of the provisions of Drugs Act, 1976 and DRAP Act, 2012. The accused person after obtaining pre-arrest bail from the Honorable District and Session Judge, Drug Court, Rawalpindi appeared before the undersigned on 30.07.2018. on 31.08.2018 the pre arrest bail of the accused was cancelled by Honorable District and Session Judge, Drug Court, Rawalpindi. Resultantly, the accused was taken into custody. Physical custody of three days was obtained from Senior Civil Judge, Rawalpindi on 01.08.2018. The accused revealed that a general vendor named came from Peshawar and gave him the unregistered drugs and that their estimated cost was around Rs.5000/-. The accused was then sent behind judicial lockup on 04.08.2018. The accused was released on post-arrest bail by the Honorable Chairman Drug Court, Rawalpindi on 30.08.2018. The drugs possessed by the accused gave rise to serious contravention of 23(1)(a)(vii) of Drugs Act, 1976. During investigation the accused person mentioned in column 3 was found guilty of commission of offence u/s 23(1)(a)(vii) of the Drugs Act, 1976.

In view of the above, challan u/s 173 Cr.P.C. against the accused person Muhammad Iftikhar Afzal S/o Sheikh Muhamamd Afzal CNIC No. 37405-9531410-3 is hereby submitted through Federal Inspector of Drugs, DRAP. It is requested that the trial of the accused person may be initiated by summoning the witnesses, please."

18. Keeping in view of the above the area FID, Islamabad has requested that the matter may kindly be placed before upcoming meeting of Central Licensing Board for according approval of the Central Licensing Board, so as to prosecute the accused before the Honorable Drug Court.

DECISION:

The Central Licensing Board considered the facts on record and decided as under:

1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:

i. Mr. Muhammad Iftikhar Afzal S/o Sheikh Muhammad Afzal (Proprietor M/s Five Star Pharmacy, B-210/2, Jahandad Plaza, ChandniChowk, Rawalpindi) r/o House No. F-864 Mohallah Satellite Town, Rawalpindi (CNIC No. 37405-9531410-3)

2. The aforesaid accused persons have been found guilty under sub-clause (vii) of paragraph (1) of heading A of Schedule-II to the DRAP Act, 2012 read with Section 23(1)(a)(vii) of the Drugs Act, 1976. The Offenses are cognizable offenses under clause (a) of paragraph (2) of the Schedule-IV to the DRAP Act, 2012, and are punishable under sub-clause (a) of clause (1) of Schedule-III to the DRAP Act, 2012 read with Section 27(1)(a) of the Drugs Act, 1976.

3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.

Case No. 08

Subject: SPURIOUS AMROPYRON INJECTION (FOR VET ONLY), REG. NO. 022160, BATCH NO. 365, DATE OF MANUFACTURING 09-2017, DATE OF EXPIRY 09-2022, CLAIMED TO BE MANUFACTURED BY M/S AMROS PHARAMCEUTICALS, KARACHI.

1. That the Federal Inspector of Drugs, Karachi vide letter no. SHM-33-34/2018-DRAP(FID/K-IV) dated 20.07.2018 has submitted that he alongwith Dr. Shoaib Ahmed Lohar (FID, DRAP, Karachi) inspected the premises of M/s Silani Traders, situated at Shop No. C-3, Gate No. 2, Madina Centre, Karachi, on 06.04.2018 in compliance to the directions contained in letter of M/s Amros Pharmaceuticals received vide Dy. No. 1098 dated 02.04.2018, , wherein the FID, Karachi recovered following suspected Spurious drug product and draw the samples on prescribed Form-3 alongwith other drug for the purpose of test/analysis. The remaining stock of suspected drugs seized on prescribed Form-2 as per Drugs Act, 1976.

The details of the samples taken on Form-3 for test/analysis purpose:

Serial No.	Name of Drugs	Reg. No.	Batch No.	Mfg. Date	Expiry Date	Manufactured By:
1	Amropyron 500mg/2ml I.M. or Slow I.V.	022160	365	09-2016	09-2022	Amros Pharmaceuticals, A/96, S.I.T.E., Karachi Mfg. Lic. No. 000406
2	Ephassef 250mg	044179	EA068	02-18	02-21	Epharm Laboratories A-40,

	Capsules					Road No.1, S.I.T.E., Super Highway Industrial Area, North Karachi. DML No. 000598

The detail of the sample seized on prescribed Form-2:

Serial No.	Name of Drugs	Reg. No.	Batach No.	Mfg. Date	Expiry Date	Qty	Manufactured By:
1	Amropyron 500mg/2ml I.M. or Slow I.V.	022160	365	09-2016	09-2022	04 Vials of 50ml	M/s AMROS Pharmaceuticals, A/96, S.I.T.E., Karachi Mfg. Lic. No. 000406

2. The area FID-IV, Karachi submitted that he has forwarded portion of sealed sample to Federal Government Analyst, Central Drugs Laboratory, Karachi vide his office memorandum No. SHM-33-34/2018-FID(K-IV) dated 09.04.2018.

3. The FID-IV, Karachi reported that he asked M/s Silani Traders, situated at Shop No. C-3, Gate No. 2, Madina Centre, Karachi to provide bill warranty vide his office letter No. SHM-33-34/2018-FID(K-IV) dated 09.04.2018 through registered post out the same received undelivered.

4. The area FID-IV, Karachi informed that he has forwarded a portion of sealed sample to Chairman, CLB, DRAP, Islamabad vide his office letter No. SHM-33-34/2018-FID(K-IV) dated 09.04.2018.

5. The area FID-IV, Karachi informed that he has requested the Director (QA&LT, DRAP, Islamabad) for permission for safe custody of seize drug vide this office letter No. SHM-33-34/2018-FID(K-IV) dated 09.04.2018.

6. The area FID-IV, Karachi informed that he sent a portion of sealed sample to M/s Amros Pharmaceuticals, A/96, S.I.T.E., Karachi vide his office letter No. SHM-33/2018-FID-IV(K) Market dated 09.04.2018. The firm vide letter no. NIL dated 20.04.2018 acknowledged for the safe receipt of sample and replied that this product containing Dipyron [Metamizole] was banned in 2006 by DRAP. Manufacturing of this product was discontinued since 2006 by Amros Pharmaceuticals. This is **Fake Product and we have already intimated about this to FID Karachi through their letter dated 27.03.2018**

7. FID-IV, Karachi submitted that the Federal Government Analyst, CDL, Karachi vide CDL test/analysis report No. R. KQ. SC. 228/2018 dated 04th May,2018 has declared the subject cited sample as **"Spurious"**Drug Product: under section 3(zb) (i) and 3(zb)(ii) of the Drugs Act 1976.

8. FID-IV, Karachi asked the M/s Silani Traders, situated at Shop No. C-3, Gate No. 2, Madina Centre, Karachi to explain their position vide his office letter No. SHM-33-34/2018-FID(K-IV) dated 14.05.2018 and 31.05.2018 which is received undelivered. The FID-IV, Karachi further informed that **No Reply has been received till to date from M/s SilaniTarders, Karachi.**

9. The Secretary, Central Licensing Board (CLB), DRAP, Islamabad vide their letter no. 03-33/2018-QC (pt-261-CLB) dated 24.05.2018, allowed the safe custody of the Drug Seized on prescribed Form-2 till the finalization of the case

10. In the light of Federal Government Analyst, Central Drugs Laboratory, Karachi test report no. R.KQ.SC.228/2018 dated 04.05.2018, the FID-IV, Karachi found M/s Silani Traders, situated at Shop No. C-3, Gate No. 2, Madina Centre, Karachi involved in selling of spurious drug product **Amropyrone 500mg/2ml I.M. or Slow I.V.** "Batch No. 365 claimed to be manufactured by M/s **Amros Pharmaceuticals, A/96, S.I.T.E., Karachi Mfg.Lic. No. 000406,** violated the section 23(1)(a)(i), & 23(1)(c) which is punishable under section 27(1)(a) of the Drugs Act 1976.

Recommendations of FID: -

In view of the above, Board is accordingly requested to grant permission for prosecution in Drug Court against the following accused person:

(i) HanifShakoor S/o Abdul Shakoorhodling CNIC No. 42101-1695691-0

11. Keeping in view of the above, the accused (HanifShakoor) was show caused in writing to explain his position vide letter no. F. No. 4-52/2018-QC dated 17.09.2018.

12. Muhammad Masood Khan (Barrister at Law) on behalf of Mr. HanifShakoor S/o Abdul Shakoor (accused person) vide letter no. Nil dated 24.09.2018 submitted the reply of Show Cause Notice. The reply is reproduced as under:

"*That on behalf of my client namely Mr. HanifShakoor son of Abdul Shakoor, having business at Karachi in the name and style of M/s Silani Traders, may be please to kept the following point on record as legal objection, and withdrawn the show cause notice dated 17.09.2019.*

LEGAL OBJECTION

1. *That the show cause notice has been issued by your respective authority on the basis of the personal statement of the so-called Inspector and two another un-identified persons (names and further identify now shown to my client, which is questionable in nature, and not any official identity card were tie on their shirt), hence not any written complaint showed to client at the spot nor any detail mentioned in the show cause notice.*
2. *That all the allegations mentioned in the show cause notice were self explanatory in nature, nor any opportunity were given to my client to explain his version of reality, and the show cause is also silent that the notices were sent to my client were why un-delivered, and more shockingly this show cause notice was received on the same address, which create serious doubt on the story and shown the biasness.*
3. *That the so-called product mentioned at the Form-2 name Amropyron 500mg/2ml I.M or Slow I.V, was never recovered at my client shop nor it was available for sale and displayed at the shop shelf's, and not a single proof's contained at the show cause notice which showed that my client were involved at the import, export, manufacture for sale or sell any Spurious drugs or involved in any category mentioned in section. 23(1)(a)(i) and S. 23(1)(c) of the Drugs Act, 1976, hence the show cause having no locus standi.*
4. *That my client was never ever involved in activities which fall in any categories of crime of the state and doing his business in a very transparent manner, and having good reputation in market, and due to the illegal and un-lawful act done by so-called officials were offensive in nature, and posted the fake and frivolous pictures in the social media and website are cause mental torture, agnoy and distress to my client and destroy their reputation in business market, for which my client have sufficient proof's, so therefore, my client reserved the right to file suit for damages for Rupees 100 million.*

5. *That my client also reserved the right of Panel Action against the related so-called officials, and the above said act of black mailing and defamation fall in under section 499 and 500 of Pakistan Panel Code 1860.*

That the allegation levied in the said show cause notice is only based on the self explanatory statement and without logical thoughts and legal backing and reasoning and may be withdrawn immediately, in the larger interest of justice."

13. The accused "HanifShakoor S/o Abdul Shakoor(proprietor), M/s Silani Traders, situated at Shop No. C-3, Gate No. 2, Madina Centre, Karachi hodlingCNIC No. 42101-1695691-0"is guilty of manufacturing and selling of Spurious/Contrabanned item/drug and violated Section 23(1)(a)(i) and 23(1)(c) which is punishable underSeciton 27(1)(a) of the Drugs Act, 1976 read with Schedule-II (A)(1)(a)(i) punishable under Schedule-III(1)(a)of the DRAP Act, 2012.It is therefore requested that permission for registration of FIR may be granted against accused "HanifShakoor S/o Abdul Shakoor (proprietor), M/s Silani Traders, situated at Shop No. C-3, Gate No. 2, Madina Centre, Karachi hodling CNIC No. 42101-1695691-0".

Decision of the case:

The Central Licensing Board considered the facts on record and decided as under:

1. to grant the Permission forlodging FIR against the accused person namely "HanifShakoor S/o Abdul Shakoor(proprietor) of M/s Silani Traders, situated at Shop No. C-3, Gate No. 2, Madina Centre, Karachi holding CNIC No. 42101-1695691-0" for manufacturing without having Drug Manufacturing License,selling/storing of Spurious Drugwithout invoice warranty and contra-banned drug. The accused has committed violations of Schedule-II and III of the DRAP Act, 2012 read with Section 23/27 of the Drugs Act, 1976. The offences of the accused persons are cognizable under schedule IV of the DRAP Act 2012 read with Section 30 of the Drug Act 1976.

2. The FID is directed to file complaint for registration of FIR against the following accused person:

- **i. M/s Silani Traders, situated at Shop No. C-3, Gate No. 2, Madina Centre, Karachi**
- **ii. HanifShakoor S/o Abdul Shakoor (proprietor) of M/s Silani Traders, situated at Shop No. C-3, Gate No. 2, Madina Centre, Karachi holding CNIC No. 42101-1695691-0**

Case No. 09

Subject**:** **MANUFACTURING AND SALE OF UN-REGISTERED RELIEF EXTRA TABLETS REG. NO. NIL BATCH NO. RR-549 MANUFACTURED BY M/S COMBITIC GLOBAL CAPLET (PVT) LTD INDIA.**

1. The Federal Inspector of Drugs-III, DRAP, Karachi has forwarded the subject cited case vide No. F. SHM-24/2018-DRAP(FID/K-III) dated 10.08.2018.
2. The FID has submitted that he alongwith Mr. Ghuam Ali Lakho, Provincial Drug Inspector inspected the premises of M/s NagoriSubhan Medical Store, situated at Plot No. 541, Block D Street No. 5, Sher Shah Karachi holding DSL no. 1512 on 22.03.2018, wherein he recovered following **un-registered** drug product and took the samples on prescribed Fomr-3 for the purpose of test/analysis as per Drugs Act 1976.

   The detail of the sample is as under:-

Serial No.	Name of	Reg. No.	Batch No.	Manfg:	Expiry	Manufactured

	Drugs			Date	Date	By
SHM-24/18	Relief Extra	Nil (Not Mentioned)	RR-549 (Mentioned on strips not on carton/box)	May-2017 (Mentioned on strips only)	Apr-2017 (Mentioned on strips only)	Combitic Global Caplet (Pvt.) Ltd., M-15, D-2, D-3, Ind. Area, Hr., India MfgLic. No. 325-OSP(H)

3. As per report of FID the portion of sealed sample was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi vide this office memorandum NO. SHM 24/2018-FID-(K-III) dated 22.03.2018.
4. FID submitted that M/s NagoriSubhan Medical Store, Plot No. 541, Block D Street No. 5, Sher Shah Karachi was asked to provide bill warranty vide this office letter of even number dated 26.03.2018.
5. FID further submitted that a portion of sealed sample was also sent to Chairman, CLB, DRAP, Islamabad vide letter of even number dated 26.03.2018.
6. FID informed that M/s NagoriSubhan Medical Store Plot No. 541, Block D Street No. 5, Sher Shah Karachi explained his position vide their letter number nil dated 09.04.2018.
7. The FID added that the Federal Government Analyst, Central Drugs Laboratory, Karachi vide their test report NO. R.KQ.193/2018 dated 10.05.2018 declared the sample as **"Un-Registered Drug Product"** under the Drugs Act, 1976.
8. The FID informed that M/s NagoriSubhan Medical Store Plot No. 541, Block D Street No. 5, SherShah Karachi was asked to explain his position vide letter no. SHM-24/2018-DRAP(FID/K-III) dated 21.05.2018 and 01.06.2018. In their response they have taken the plea that this drug (Product Relief Extra) is not meant for sell but it is for personal use as can be evident that a meager quantity of only 50 tablets is found which is not for commercial use.
9. In the light of Federal Government Analyst, Central Drugs Laboratory, Karachi test report No. R.KQ.193/2018 dated 10.05.2018, M/s NagoriSubhan Medical Store, Plot No. 541, Block D Street No. 5, SherShah Karachi holding DSL No. 1512 (By way of retail sale) is in involved in sale of unregistered drug and violated the Seciton 23(1)(a)(vii) of the Drugs Act 1976 and punishable under section 27(1) of the Drugs Act, 1976 and rules framed thereunder.

Recommendations of FID:

In view of above, Board is accordingly requested and recommended as follows:

i. Cancellation of Drug Sale License as per Drugs Act, 1976 and rules framed thereunder.

"OR"

ii. Permission for grant of prosecution in Drug Court against the following accused persons:
   a. Amjad Hussain S/o Hussain Nagori (*License proprietor*)
   b. Ghulam Sarwar S/o Muhammad Hanif (*Proprietor*) CNIC No.: 42401-206974-1
   c. Riaz Ghulam Muhammad S/o Ghulam Muhammad (*Salesman*) CNIC No. 42401-3420490-1

10. It is submitted that that the name of qualified person i.e. Sajjad Ahmed S/o Abdul Qayyum was not mentioned among the names of accused persons as evident from the photocopy of Drug Sale License (DSL No. 1512) provided with the complete case by the

area FID, Karachi. Furthermore, the designations against the names of each of nominated accused person was also missing in the case forwarded by area FID, Karachi. Clarification in this regard was issued to the area FID, Karachi vide letter no. 4-59/2018-QC dated 07.09.2018.

11. The area FID, Karachi Clarified vide letter no. SHM-24/2018-DRAP(FID/K-III) dated 17.09.2018 reproduced as under:

> *"I have the honor to refer DRAP, Islamabad letter no. F. No. 04-59/2018-QC dated 07.09.2018 and continuation of this office letter of even no. dated 10.08.2018 it is submitted that the qualified accused Mr. Sajjad Ahmed S/o Abdul Qayyum mentioned on License no. 1512 dated 08/02/2017 was not available at the time of inspection. Amjad Hussain (License proprietor) was also not available. Their CNIC/copies were also not provided/available. However, Mr. Ghulam Sarwar s/o Muhammad Hanif introduced himself as the proprietor and Riaz Ghulam Muhammad introduced himself as salesman"*

12. The accused persons are guilty of manufacturing/import and selling of Un-registered Drugand violated Section 23(1)(a)(vii)&& 23(1)(c) punishable under Section 27(1)(a) of the Drugs Act, 1976 read with Schedule-II (A)(1)(a)(vii) and (A)(1)(c) punishable under Schedule-III(1)(a) of the DRAP Act, 2012. It is therefore requested that permission for registration of FIR may be granted against the following accused persons:

i. M/s NagoriSubhan Medical Store, Plot No. 541, Block D Street No. 5, SherShah Karachi holding DSL No. 1512 (By way of retail sale) through its proprietor Amjad Hussain S/o Hussain Nagori (*License proprietor*).
ii. Amjad Hussain S/o Hussain Nagori (*License proprietor*)
iii. Ghulam Sarwar S/o Muhammad Hanif (*Proprietor*) CNIC No.: 42401-206974-1
iv. Riaz Ghulam Muhammad S/o Ghulam Muhammad (*Salesman*) CNIC No. 42401-3420490-1

Decision of the case:

The Central Licensing Board considered the facts on record and decided as under:

1. to grant the Permission for Lodging FIR against theaccused persons for illegal import without import authorization and selling/storing of Un-Registered Drugs without product registration and drug import license as required under the law. The accused persons have committed violations of Schedule-II and III of the DRAP Act, 2012 read with Section 23/27 of the Drugs Act, 1976. The offences of the accused persons are cognizable under schedule IV of the DRAP Act 2012 read with Section 30 of the Drug Act 1976.

2. The FID is directed to file complaint for registration of FIR against the accused person and forward complete case for consideration of the CLB:

i. M/s NagoriSubhan Medical Store, Plot No. 541, Block D Street No. 5, SherShah Karachi holding DSL No. 1512 (By way of retail sale) through its proprietor Amjad Hussain S/o Hussain Nagori (License proprietor).
ii. Amjad Hussain S/o Hussain Nagori (License proprietor).
iii. Ghulam Sarwar S/o Muhammad Hanif (Proprietor) CNIC No. 42401-206974-1.
iv. Riaz Ghulam Muhammad S/o Ghulam Muhammad (Salesman) CNIC No. 42401-3420490-1.

<u>Case No. 10</u>

Subject: **PERMISSION FOR SAFE CUSTODY OF THE SEIZED DRUGS (UN-REGISTERED) OF M/S ASHRAF MEDICOS, MAIN MARKET, DAWOOD CHOWRANGI, LANDHI, KARACHI.**

1. The Assistant Director/Federal Inspector of Drugs, Karachi vide letter no. DMT/46/18-FIDVII(K) dated 11.10.2018 has submitted the complete case in reference to letter of even number dated 28.09.2018 wherein it is informed that FID alongwith Mr. AsfandYaarAjab Khan A.D, DRAP Karachi visited /inspected the premises of M/s Ashraf Medicos Main Market, DawoodChowrangiLandhi Karachi on 02.07.2018. During inspection of pharmacy the AD/FID-VII, Karachi recovered the following unregistered drug/medicine and seized on the prescribed Form-2 as per Drugs Act 1976. AD/FID-VII, Karachi also took samples for the purposes of test/analysis on prescribed Form-3.

Details of drugs seized are as under:-

Sr. #	Name of Drug	Batch No.	Reg. No.	Mfg. Date	Exp. Date	Quantity	Mfd. By
1	Tablet Penegra	G705344	Nil	09-2017	08-2020	1X10X4 Tablet	M/s Candila Health Care Limited, India.
2	Tablet Penegra	G705345	Nil	09-2017	08-2020	1X11X4 Tablet	
3	Tablet Penegra	G705348	Nil	09-2017	08-2020	1X10X4 Tablet	

Details of samples taken for the purpose of test/analysis:-

Sr. #	Name of Drug	Batch No.	Reg. No.	Mfg. Date	Exp. Date	Mfd. By
1	Tablet Penegra	G705346	Nil	09-2017	08-2020	M/s Candila Health Care Limited, India.

2. As per report of FID the portion of sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi vide this office memorandum vide letter no. DMT/-R-46/2018-FIDVII(K) dated 03.07.2018**.**
3. FID submitted that a portion of sealed sample was also sent to Chairman, CLB, DRAP, Islamabad vide letter no. DMT/-R-46/2018-FIDVII(K) dated 03.07.2018.
4. FID vide his office letter no. DMT/-R-46/2018-FIDVII(K) dated 05.07.2018 requested DRAP Islamabad to issue permission for safe custody of drugs seized on prescribed Form-2.
5. The FID added that the Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as **"Un-Registered Drug Product"** under the Drugs Act, 1976 and rules framed thereunder vide their test report NO. KQ.501/2018 dated 31.08.2018.
6. FID informed that Toufique Ahmed (proprietor) of M/s Ashraf Medicos Main Market, DawoodChowrangiLandhi Karachi was asked to explained his position and provide bill warranty or any other document regarding purchase/import vide FID's office letter no. DMT-46/2018-FIDVII(K) dated 06.09.2018 with subsequent reminder dated 28.09.2018.
7. The FID reported that DRAP Islamabad vide their letter no. 3-58/2018-QC(265-CLB) dated 04.09.2018 allowed safe custody of drugs seized by the undersigned on prescribed Form-2
8. FID submitted that Toufique Ahmed (proprietor) of M/s Ashraf Medicos Main Market, DawoodChowrangiLandhi Karachi vides their letter no. nil dated nil submitted unsatisfactory reply.
9. FID concluded that Toufique Ahmed (proprietor) CINC # 42201-8368254-7 of M/s Ashraf Medicos Main Market, DawoodChowrangiLandhi Karachi having Drugs Sale License is involved in selling unregistered drug and contravened the Section 23(1)(a)(vii) & 23(1)(c)

of the Drugs Act, 1976 which is punishable under section 27(1)(a) of Drugs Act, 1976 and rules framed thereunder.

10. Recommendations of FID:-

In the light of above it is recommended that M/s Ashraf Medicos Main Market, DawoodChowrangiLandhi Karachi alongwith its proprietor Mr. Toufique Ahmed S/O Abdul Latif may be prosecuted in the Drug Court Karachi.

11. The accused persons are guilty of manufacturing/import and selling of Un-registered Drugsand violated Section 23(1)(a)(vii)&& 23(1)(c) punishable under Section 27(1)(a) of the Drugs Act, 1976 read with Schedule-II (A)(1)(a)(vii)& (A)(1)(c) punishable under Schedule-III(1)(a) of the DRAP Act, 2012. It is therefore requested that permission for registration of FIR may be granted against the following accused "Toufique Ahmed (proprietor) CINC # 42201-8368254-7 of M/s Ashraf Medicos Main Market, DawoodChowrangiLandhi Karachi".

Decision of the case:

The Central Licensing Board considered the facts on record and decided as under:

1. to grant the Permission for Lodging FIR against the accused person namely "Mr. Toufique Ahmed S/O Abdul Latif (proprietor) M/s Ashraf Medicos Main Market, DawoodChowrangiLandhi Karachiholding CINC # 42201-8368254-7" for illegal import without import authorization and selling/storingof Un-Registered Drugswithout product registration and drug import license as required under the law. The accused has committed violations of Schedule-II and III of the DRAP Act, 2012 read with Section 23/27 of the Drugs Act, 1976. The offences of the accused persons are cognizable under schedule IV of the DRAP Act 2012 read with Section 30 of the Drug Act 1976.

The FID is directed to file complaint for registration of FIR against the accused person and forward complete case for consideration of the CLB.

QUALITY ASSURANCE CASES (GMP NON-COMPLIANCE)

Item No. I GMP Non-compliance Cases (Old)

Case No. i: M/S LIBRA PHARMA (PVT) LTD, PESHAWAR

Background:

Muhammad Arif Chaudhary, FID, DRAP, Peshawar conducted inspection of the firm M/s Libra Pharmaceuticals, Peshawar on 24.04.2018, to verify the GMP compliance and production activities.

2. The FID noticed number of observations which need urgent attention and rectification. The observations include:-

General Information

- It is an old Pharma unit and they have failed to show approved layout plan for all existing sections although they have showed the separate layout plan but all the existing sections are not mentioned. HVAC was not working at the time of inspection. The drainage lines also need attention regarding cleanliness as the firm did not have the SOP for cleanliness of drainage and treatment of waste produced by them.

Observations

- They are not monitoring the humidity and temperature and no record found. They have also not maintained the log books of the machine kept in different sections further all the machines are not calibrated since 2016.

Storage Areas

- The firm has one small single dispensing room for the dispensing of all classes of APIs like (General products, Cephalosporin and Hormones) weighing balances are neither calibrated nor placed under the dispensing hood. They are advised to provide HVAC supply to control the humidity and temperature. No record of temperature and humidity was maintained and they are using Methylene Chloride as coating agent for non aqueous solvent and management is strictly directed to immediately stop using this solvent. They are advised to maintain the humidity and temperature before dispensing the raw material. They are also advised to calibrate the dispensing balances and record the QC number of the dispensed materials in the BMR. The raw material testing record was seen randomly but regretted to state the record was not up-to date although QC released tags found placed on all the raw material but the data is not traceable in the QC lab.

Workers entrance

- These areas are required drastic improvements as the toilets are adjacent to the change room and it should be closed from here and may be constructed some other place. The air curtain was not working at entrance. The firm is advised to improve the flooring and placed insecticutor.

Tablet Section General

- The management is advised to validate their tray dryers as apparently, their meters are looking out of order. The log books required to be updated. The management is advised

to upgrade their SOPs and prepare a mechanism for the cleanliness of the drains. The area also needs fresh paint and overhauling of HVAC.

Syrup Section (General)

They are using PET bottles for the syrup filling and failed to provide any approval or stability studies for change of packaging material. Management is advised to get approval of the DRAP for change of primary container system. The volume of syrup Manicol Drops 30 ml was measured and advised to the management to adjust the volume as per pharmacopeia guidelines.

Quality Assurance

- The firm has not set up quality assurance system and a fresh pharmacist with one year experience has appointed for the purpose although he also working as analyst in QC section.

Qualification and Validation

- The firm needs immediately calibration and validate all the equipments in QC and production as per GMP requirements.

Self GMP Inspection and quality audit

- The firm is advised to conduct self GMP inspection and conduct quality audit of the documents and system after every three months.

Training

- They are advised to give technical training to the workers and technical staff on safety, security, personal hygiene, GMP compliance and fire fighting. They are advised to give fire safety guideline to workers against fire.

Quality Control

- The firm has provided the equipment for the testing of their registered products but the record is not maintained. Although they have HPLC but it was not in working condition, it is a very old model and needs to be replaced. The management is also advised to follow official testing methods for the testing of their registered products and should buy recent official books which are mandatory for the development of their QC methods. Although firm has a stability testing chamber but the SOP are not satisfactory the stability chamber was out of order not sufficient for their registered products.
- The HPLC operator also needs training. The management is advised to appoint the full time QA in charge with sufficient experience.
- The management was advised to do the following things immediately.

i. Revalidation of layout plan.
ii. Purchase of FTIR, Karl Fischer apparatus and potentiometer.
iii. Calibration of all the equipment.
iv. Preparation and up gradation of all the SOPs of production and QC.
v. Purchase of official books (latest edition) and preparation of testing method accordingly.
vi. Up gradation of HPLC.
vii. Adaptation of official testing methods.
viii. Training of staff.
ix. Appointment of QA staff as per rules.

The FID further concluded that:-

Overall the cGMP compliance is poor and the management is directed to prepare a plan for the rectification all the deficiencies mentioned at their earliest. They are further directed to immediately got the approval / validation of their layout plan from Licensing Division.

Action taken by DRAP:-

The case was placed for the approval of show cause notice and suspension of production activities on the critical observation noted by the FID. It was advised to place the case before the central licensing board for taking further necessary action in this regard. The case was placed in 265th meeting of CLB. The Central Licensing Board decided as under:-

Decision of the 265th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to serve show cause notice to the firm M/s. Libra Pharmaceuticals, Peshawar on the observations noted by the FID in its inspection conducted on 24.04.2018.

Show Cause Notice:-

As per decision of 265th meeting of CLB held on 10.08.2018, show cause notice was issued to the firm M/s. Libra Pharmaceuticals, Peshawar on 31.08.2018.

Reply of the Firm:-

The firm vide letter dated 11.09.2018 submitted reply of show cause notice and acknowledge the visit of FID. The firm informed that the observations noted by the FID have been corrected.

Proceedings of the 266th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) presented the case before the Board. Mr. Mohabat Khan, Plant Manager of the firm M/s. Libra Pharmaceuticals, Peshawar appeared before the Board.

Decision of the 266th Meeting of CLB

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

i. Conduct GMP inspection of the firm M/s. Libra Pharmaceuticals, Peshawar by following panel of experts:-

a. Prof. Dr. Jamshaid Ali Khan, Member, CLB
b. Additional Director, DRAP, Peshawar
c. Area Federal Inspector of Drugs, Peshawar

ii. Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB.

iii. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 24.04.2018, with clear and candid recommendations.

Case No. ii: - M/s Ali Industries (Pvt) Ltd, Lahore

The case is presented before the Central Licensing Board in compliance to the decision of the 246th meeting of CLB held on 22.02.2016.

Background of the case

Dr. Sheikh Akhter Hussain, Mr. Asim Rauf and Mrs. Sara Mehreen, ADC, DRAP, Lahore conducted inspection of the firm M/s Ali Industries (Pvt) Ltd, Lahore on 10.03.2015, to verify the GMP compliance and production activities. The panel noticed critical observations.

Action Taken by DRAP: - After receiving inspection report, a show cause notice was issued to the firm on 22.12.2015 and corrigendum was issued on 06.01.2016.

Decision of the 246th Meeting of CLB

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

i. Dr. Ikram ul Haq, Member, CLB
ii. Dr. Zaka ur Rehman, Member, CLB
iii. Mr. Asim Rauf, FID, Lahore

The Board further decided to ask the panel to also submit the report in tabulated form identifying the previous observations and the current status of the observations noted by the panel in its inspection conducted on 10.03.2015.

Compliance of Decision of the 246th Meeting of CLB

Decision of the 246th meeting of CLB was conveyed on 05.04.2016 and reminder was sent on 24.11.2017.

Inspection Report of the Firm in compliance to 246th meeting of CLB

The following panel in compliance to decision of 246th meeting of CLB conducted inspection of the firm on 02.07.2018.

i. Dr. Ikram ul Haq, Member, CLB
ii. Dr. Zaka ur Rehman, Member, CLB
iii. Mr. Asim Rauf, Additional Director, Lahore
iv. Ms. Ufaq Tanveer, area FID

The panel recommended as under:-

"The firm was advised to improve the maintenance of machines in production area and to observe GMP compliance for cleanliness and hygiene strictly. Keeping in view the observations and after going through the documentations and facilities like building flow, HVAC Personnel's Quality Control, Quality Assurance and Production Operations, the panel of inspectors was of the opinion that the firm M/s. Ali Industries (Pvt) Ltd., 239-C, Sunder Industrial Estate, Lahore had maintained conformance to GMP compliance in the manufacturing and Quality Control operations on the day of inspection."

Proceedings of the 266th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) placed the case before the Central Licensing Board for appraisal, in compliance to the decision of 246th meeting of CLB and fate of show cause notice.

Decision of the 266th Meeting of CLB

After thorough discussion and deliberations the Board appraised panel inspection report dated 02.07.2018 and decided to seize enforcement of show cause notice with immediate effect.

Case No. iii: - M/s Lahore Chemical and Pharmaceuticals Works, Lahore

Background of the case

Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab vides letter No. PQCB/F-42/2016 dated 08th August 2016 informed that provincial teams of experts/Drug Inspectors conducted GMP inspections of various pharmaceutical manufacturing units and reported the violations found there by Provincial Quality Control Board, Punjab. He added that the Board after due deliberations recommended cancellation/suspension of Drug Manufacturing Licenses of the firms who were involved in violations of Good Manufacturing Practices (GMP), conditions of license and were involved in manufacturing / selling of substandard drugs. It is worth mention here that M/s LCPW was one of the firms whose DML cancellation/suspension was recommended by PQCB, Punjab besides other. Mr. Abid Saeed Baig further requested to look into the matter and direct the concerned authority to take action in the best interest to curb the menace of spurious and substandard drugs.

2. Accordingly the case was placed before the CLB in its 249th meeting held on 29.08.2016.

Decision of the 249th Meeting of CLB

1. After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, the Board considered the recommendations of the Secretary, PQCB, Punjab and observed that laid-down procedure as provided under the rule 5(3) of the Punjab Drugs Rule, 2007 has not been observed. Therefore it has been resolved by the Board that following information / documents / record is required in order to proceed further:-

    i. Copy of the notification of the Provincial Inspector of Drugs under Section 17 of the Drugs Act, 1976
    ii. Copy of the inspection report of the firm
    iii. Copies of the test reports of the samples of the firm (if any)
    iv. Showcause notice issued to the firm.
    v. Reply of the firm.
    vi. Letter of personnel hearing issue to the firm under Section 41 of the Drugs Act, 1976.
    vii. Copy of the minutes of the meeting.
    viii. Copy of the permission for prosecution (if any).
    ix. Copy of the report of the appellate testing Under Section 22 (5) of the Drugs Act, 1976 (if any).
    x. Enquiry report (if any).
    xi. Reason for imposing both penalties including prosecution and recommendation for cancellation / suspension of DML of the firm. Even the Rule 5(3) of the Punjab Drugs Rules, 2007 states that *"The provincial and district Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the rule, issue a showcause notice to the personal and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."*

2. The Board further decided that the representative of the firm shall also be asked to submit the reply on the observations of the PQCB and may be given an opportunity of personnel hearing in the forthcoming meeting of CLB.

3. As per decision of CLB in its 249th meeting, the case was referred to the Secretary, Provincial Quality Control Board, Punjab vide letter dated 03.10.2016, for clarification.

4. The case was placed before the CLB in its 251st meeting held on 18.01.2017 and opportunity of personal hearing was granted on firm's request.

Decision of the 251st Meeting of CLB

A: After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the record submitted by Secretary, PQCB and factual position of the case, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members:-

i. Dr. Ikram ul Haq, Member CLB.
ii. Ch. Zeeshan Nazir, Deputy Director (QA)
iii. Mr. Muhammad Jamil, Provincial Drug Inspector, Lahore
iv. Area FID, Lahore

B: The panel inspection report shall be placed in the next meeting of CLB

5. The case was placed before the CLB in its 255th Meeting held on 17.08.2017.

Decision of the 255th Meeting of CLB

After through discussion / deliberation, the board took serious notice of the observations reported by the panel and therefore, the board decided to:-'

i. Issue show cause notice to the M/s Lahore Chemical & Pharmaceutical Works under section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for cancellation or suspension of the License of M/s Lahore Chemical & Pharmaceutical Works, Lahore based upon findings of panel inspection report dated 12.04.2017 and 17.05.2017 and for manufacturing drugs in Cephalosporin Dry Powder Suspension / Capsule Sections, General Capsule Section and Narcotic / Hormone / Steroid Liquid Injectable Sections despite the panel had directed to stop production in these areas.

ii. Direct the Area FID to ensure the stoppage of production in the sections mentioned by the panel.

Action Taken by DRAP:- As per directions by the CLB, the firm was served show cause notice along with suspension of production orders in Cephalosporin Dry Powder Suspension / Capsule Sections, General Capsule Section and Narcotic / Hormone / Steroid Liquid Injectable sections on 05.10.2017.

Decision of the 256th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view available record and submission of the firm, the Board decided to verify the submission of the representative of the firm through the following panel members, already constituted in 251st meeting of Central Licensing Board:-

i. Dr. Ikram ul Haq, Member CLB.
ii. Ch. Zeeshan Nazir, Deputy Director (QA)
iii. Mr. Muhammad Jamil, Provincial Drug Inspector, Lahore

iv. Area FID, Lahore

ii. The panel inspection report shall be placed before the forthcoming meeting of Central Licensing Board for consideration and further decision.

Inspection Report of the Firm in compliance to 256th meeting of CLB

The following panel in compliance to decision of 256th meeting of CLB held on 10.11.2017conducted inspection of the firm M/s LCPW, Lahore on 26.06.2018.

i. Dr. Ikram ul Haq, Member CLB.
ii. Mr. Sanaullah Saif, area Provincial Drug Inspector, Lahore
iii. Mr. Abdul Rashid Sheikh, area FID, Lahore

The panel recommended as under:-

"The panel visited the premises of M/s. Lahore Chemical & Pharmaceuticals Works (Pvt) Ltd, Lahore, and discussed the matter in hand in detail with the management.

i. The management agreed that the production of Cephalosporin Capsule and dry powder suspension will remain stopped till the development of self contained and segregated facilities, as the management had already submitted the revised layout plan to the DRAP, Islamabad. The management informed that they had not got any quota of narcotic substance for manufacturing of their registered injectable. Hence they agreed that till the development of narcotic injectable area, they will not start the production.

ii. The management also agreed to discontinue the production of steroidal / hormonal injectable drugs, which were registered in their favor, till the development of new steroidal / hormonal injectable areas, as they were in the process of development thereof.

iii. Keeping in view the other proceedings of inspection with regard to the areas inspected, building documentation, testing facilities, sanitation, hygiene of the workers, storage facilities, etc., the panel of inspectors is of the opinion that the firm was operating at the satisfactory level of GMP as per Drug Act, 1976 and rules framed there under."

Proceedings of the 266th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) placed the case before the Central Licensing Board.

Decision of the 266th Meeting of CLB

After thorough discussion and deliberations the Board appraises recommendations of panel and decided to suspend the production for Cephalosporin Capsules, Cephalosporin Suspensions, Narcotic/Psychotropic Injectable, Steroidal/ Hormonal Injectables till development of dedicated facility. However, firm may carry operations of production in other areas as recommended by the panel. The Division of Pharmaceutical Evaluation and Division of Controlled Drugs shall be informed of the decision.

Item No. II GMP Non-compliance Cases (New)

Case No. i **M/s. Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur-KP**

Background of the case:-

Mr. Zia Ullah, AD/FID-III, DRAP, Peshawar conducted inspection of firm M/s. Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur-KP on 02.08.2018.

2. The FID noticed a number of observations, which need urgent attention and rectification. The FID stated that:-

Change Rooms:-

- The air curtains of both the change rooms were non-functional / out of order.
- There was no insectocutor installed.
- SOPs were not available for the workers.
- Due to seepage, the paint has been peeled off at various points on the walls.
- In the changing area, although the step over were in place, but that is too close to the entrance. It is therefore advised to remove the step-over from its current place and placed it more centrally for more appropriate and better changing practices.
- The firm is also advised to increase the number of racks and almirahs in the change room.

Storage areas:-

- Since no proper facility for receiving and de-dusting is provided in the receiving bay. It is therefore advised to provide the de-dusting facility like vacuum cleaner and pallets etc in the receiving bay.
- No racks were available in the raw materials quarantine area. The firm is directed to provide SS racks for the quarantined materials and also to install AC as well, as there was no arrangement for temperature control.
- To provide the requisite facilities in the sampling room for sampling procedure as the sampling room is not in use.
- The racks in the released area need to be cleaned and repainted as green.
- To maintain proper dispensing record for each material.
- The firm is involved in the utilization of "used bottles" for filling of their dry suspension products as stocks of these bottles were found stored in the bottle stores and packing materials stores. The firm was strictly directed to "dispose off" these immediately under intimation to the area FID and use only fresh bottles in future.
- In the finished goods store, stocks of tablet Ei-Ram 10mg Batch No. C-126, Mfg. date 07-2018 was found Ex. Available. The registration of said product has been cancelled by the Drug Registration Board in its 279th meeting held on 28th Feb to 2nd March, 2018 vide letter F. No. 03-33/2016-QC dated 3rd May, 2018. The decision was also communicated to the firm vide letter No. F. 11-95/2018-Iceberg-DRAP (P) 1933 dated 17th May, 2018. Details of Tablet Ei-Ram stock recorded on Form-I and put on "Not to dispose off". The firm was also directed to immediately recall the already marketed stock under intimation to the area FID. The matter will be forwarded to QA & LT Division DRAP, Islamabad for further necessary action.

Tablet (General):-

- Tray dryer is provided that was under maintenance No work was in progress at the time of inspection. Log books of the machines were checked that were not properly maintained. The HVAC system was also not functional in the tablet section.

Capsule (General):-

- Capsule Esamal 20mg Batch No. was under filling. However, the pellets and shells containers were not label. Log books of the machines were also not properly maintained and the hygrometer was not calibrated.

Dry Powder Suspension (General):-

- In the dry suspension section. The firm has provided cone mixer and bottle filling and sealing machines. In the mixing area Cefixime D/S Batch No. D-083 was under mixing process in the filling area. Z-Cin (Azithromycin) 200mg was also under process of filling. On inquiring about processing of cephalosporin product in the general dry suspension section. The firm informed that the mixer in the cephalosporin dry suspension section is out of order. The firm was strictly directed to carry out each process of manufacturing in its designated area.

Cephalosporin area:-

- The air curtains were found installed at the entrances but were of order.
- The firm is advised to provide a dispensing booth in the dispensing area so that dispensing can be done in clean environment under Laminar flow.
- The firm is advised to install AC in the finished goods store for temperature control.
- Log books of the machines were not properly maintained. The general cleanliness of the area was not satisfactory.

Quality Control:-

- All the equipments / instruments need to be calibrated as calibration of the equipments is due.
- To upgrade the testing methods / SOPs for their registered products as per latest pharmacopoeia books.
- To develop log books for the equipments/ instruments and properly maintain them.
- To keep proper record of all the testing / analysis performed for the raw materials and finished goods.
- The batch manufacturing and testing record was found incomplete. Not a single complete batch history was available. It is therefore strictly directed to record complete procedural details of every batch manufactured in organized form (BMR etc).
- The firm has only the production in-charge and a quality control in-charge to look after the production and quality control activities respectively. The firm is therefore advised to appoint more qualified staff both in the production and quality control sections proportionately to the work load.
- The firm is further advised to appoint a quality assurance manager as quality assurance is the backbone of the cGMP.
- To develop SOPs for addressing market complaints and product recall.
- To conduct self GMP inspection at least once a year and implement its outcomes.

The FID further concluded that:-

"The firm's compliance towards the cGMP is poor. Keeping in view overall cGMP compliance of the firm, the firm may be directed to stop the production activities till rectification of the shortcomings and devise / implement a comprehensive plan for bringing itself at par with cGMP as per the Drugs Act, 1976. DRAP Act, 2012 and rules framed there under."

Action taken by DRAP:

The firm M/s Iceberg Pharma, Risalpur was issued Show Cause Notice/ Suspension of production order on 28.08.2018.

Reply of the firm:

The firm M/s Iceberg Pharma, Risalpur vide letter dated 01.09.2018 submitted reply of Show Cause Notice/ Suspension of production. The firm informed that almost all the shortcomings have been rectified.

Proceedings of the 266th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) presented the case before the Central Licensing Board. Mr. Haseeb Ul Haq, Q.C. Manager and Mr. Kamran Khan, Production Manager appeared before the Board and informed that they had completed most of observations has been rectified before issuance of suspension of production orders and now they are ready for inspection.

Decision of the 266th Meeting of CLB

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

i. Constitution of following panel of experts for verification of the observations before resumption of production:-

   a. Prof. Dr. Jamshaid Ali Khan, Member, CLB
   b. Additional Director, DRAP, Peshawar
   c. Area Federal Inspector of Drugs, Peshawar

ii. Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB.

iii. The panel shall submit detailed inspection report to CLB including rectification status of the observations noted by the FID in its report dated 02.08.2018, with clear and candid recommendations.

Case No. ii **M/s Wise Pharmaceuticals, Plot No. 03, Street No. S-1, RCCI, Rawat, Rawalpindi.**

Background of the case:-

Mr. Hasan Afzaal, FID, Islamabad conducted inspection of the firm M/s Wise Pharma, Rawat on 18.09.2017 and noticed number of observations. The firm was directed to submit compliance report vide office letter dated 30.10.2017. The firm submitted compliance report on 13.11.2017.

2. The case was placed before the Director (QA & LT). The Director (QA & LT) constituted following panel of experts to conduct inspection of the firm

i. Mrs. Tahreem Sara (Deputy Director, PE&R)
ii. Dr. Hassan Afzaal FID-III Islamabad.

3. The panel conducted inspection of the firm on 02.08.2018 and concluded as under:

"The panel is of opinion that the production in the sterile area i.e; Sterile Liquid Ampoule (General), Sterile Liquid Infusion (General) and Sterile Dry Powder (Ceph) is in major contravention of GMP guidelines including area maintenance, sanitation, hygiene and pest/insect control and therefore it is recommended that the production may be stopped till the up-gradation of highlighted points."

Action taken by DRAP:

The firm M/s Wise Pharma, Rawat was issued Show Cause Notice/ Suspension of production in Sterile Section order on 16.08.2018.

Reply of the firm:

The firm M/s Wise Pharma, Rawat vide letter dated 06.08.2018 submitted reply of Show Cause Notice/ Suspension of production in Sterile Section. The firm informed that almost all the shortcomings have been rectified and requested for personal hearing.

Proceedings of the 266th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) presented the case before the Central Licensing Board. Dr. Muhammad Abdullah, C.E.O. of the firm appeared before the Board and informed that all shortcomings have been rectified.

Decision of the 266th Meeting of CLB

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

i. Constitution of following panel of experts for verification of the observations before resumption of production in sterile section:-

a. Prof. Dr. Muhammad Usman, Member, CLB
b. Additional Director-I (QA & LT), DRAP, Islamabad
c. Area Federal Inspector of Drugs, Islamabad

ii. Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB.

iii. The panel shall submit detailed inspection report to CLB including rectification status of the observations noted by the panel in their report dated 02.08.2018, with clear and candid recommendations.

Case No. iii **M/s Pharmedic Laboratories, Lahore**

Background:-

Mr. Asim Rauf, Additional Director, Mr. Ajmal Sohail, FID alongwith Ms. Uzma Barkat, Assistant Director, DRAP, Lahore conducted inspection of the firm M/s Pharmedic Laboratories, Lahore on 21.06.2017, for the purpose of verification of the consumption of Buprenorphine HCI and GMP compliance. During inspection the panel noticed critical observations.

Action Taken by DRAP: - Accordingly, Show Cause Notice along-with suspension of production order in Liquid Injectable (General) Section sections was issued to the firm on 18.09.2017.

2. The case was placed in 256th meeting of CLB. Wherein the Board has decided as under:-

Decision of the 256th Meeting of CLB

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

i. Conduct GMP inspection of the firm, on approved Schedule B-II format, by following panel members :-

- Dr. Farzan Chaudhary, UVAS, Lahore
- Mr. Munawar Hayat, CDI, Punjab.
- Area FID, Lahore
- Anjum Parvaiz, Consultant, Govt of Punjab, Lahore

ii. Direct the panel to submit brief report in tabulated form identifying the previous observations and the current status with clear and candid recommendations.

iii. Refer the case to Drug Registration Board for cancellation of the product Buprenorphine HCI injection of the firm M/s Pharmedic Labs, Lahore, as the firm does not have the required facilities for the manufacturing of said product.

iv. Intimated the Controlled Drug Division regarding the decision of 256th Meeting, requesting not to allocate quota of the Buprenorphine HCI injection.

3. Decision of the 256th meeting was conveyed on 03.01.2018. However report of the panel is still awaited.

Inspection of FID on 20.08.2018: -

Ms. Uzma Barkat, area FID along with Mr. Shoaib Ahmed, FID and Ms. Maham Misbah, AD (DRAP), Lahore visited the firm on 20.08.2018 and informed that "she *visited the raw material store and General Injectable Section of the firm and reported that firm was manufacturing Onset (Ondensetron) 4mg and 8mg injections in their General Injectable Section, in violation of show cause / suspension of production orders in Liquid Injectable (General) Section vide letter No. F. 4-49/2004-QA (Vol-III) dated 18.09.2017 and area FID further ordered the firm for not to dispose of the stock of Ondensetron for 28 days on Form-I and requested to grant further extension for three months for not to dispose of the said stock."*

Updated Status: -

The matter of extension in not to dispose of period of seized stock has been taken up by the Quality Control Section. Extension in not to dispose of period of seized stock has been conveyed to the firm, after approval from the Director (QA&LT).

4. The firm M/s. Pharmedic Laboratories (Pvt) Ltd, Lahore has violated the direction of Show Cause Notice / Suspension of production order in General Injectable Section, decision of 256th meeting of CLB and start manufacturing in the General Injectable Section without panel inspection and subsequent approval from the Central Licensing Board.

Proceedings of the 266th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) presented the case before the Board.

Decision of the 266th Meeting of CLB

After thorough discussion and deliberations the Board decided as to issue show cause notice to the firm M/s Pharmedic Laboratories, Lahore under Section 41 for manufacture of drugs during period of suspension of the Injectable Section (General) which is violation of Section 30 read with Section 23 and 27 of the Drugs Act, 1976 and rules framed thereunder.

Case No. iv **M/s Wisdom Pharma, Peshawar**

Background:-

Mr. Muhammad Arif Ch., FID-I, DRAP, Peshawar conducted inspection of the firm M/s. Wisdom Pharmaceutical Peshawar on 28.08.2018.

2. The FID noticed number of critical observations during the inspection.

Raw Material Store:-

- The management is advised to provide sampling booth in quarantine for sampling.
- The temperature and humidity are very high in the store as no facility of AC or De-humidifier is provided for the raw materials.
- No record of dispensing is found.
- No labels are pasted for the status of the materials.
- Person in-charge is advised to prepare SOPs from its working.
- Raw material of Cephalosporin is also stored in general area and management is advised to shift it to Cephalosporin area as per their approved section.
- No record of temperature / humidity is available.

Tablet Section (General):-

- Management is advised to remove the fans from the packing area and provided AC facility in the area.
- Log books are seen and advised them to update.

Q.C Section:-

- Although the firm has provided HPLC for testing but is not in working condition and software needs up-gradation all the equipments need their attention.
- No SOPs for testing are available.

- Management is advised to use officials testing methods.
- They need following equipments for testing of their already registered products. (a) FTIR (b) Karl Fischer apparatus (c) maintenance of Dissolution Apparatus (d) Potentiometer meter (e) Stability Chamber with data logger.
- There is no system of QA they are advised to appoint a senior technical person as QA In-charge.
- The SOPs are not present in the form of hard copies and management is advised to prepare their SOPs according to compendial requirements.

Action taken by DRAP:

The firm M/s. Wisdom Pharmaceuticals, Peshawar was served with Show Cause Notice/ Suspension of production orders on 05.10.2018.

Reply of the firm:

Reply of the firm is still awaited.

Proceedings of the 266th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) presented the case before the Central Licensing Board. Mr. Muhammad Tahir, C.E.O. of the firm Wisdom Pharmaceuticals, Peshawar appeared before the Board and informed that they have rectified all the observations and they are ready for inspection.

Decision of the 266th Meeting of CLB

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

i. Constitute following panel of experts for verification of the observations before resumption of production:-

a. Prof. Dr. Jamshaid Ali Khan, Member, CLB
b. Additional Director, DRAP, Peshawar
c. Area Federal Inspector of Drugs, Peshawar

ii. Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB.

iii. The panel shall submit detailed inspection report to CLB including rectification status of the observations noted by the FID in its report dated 28.08.2018, with clear and candid recommendations.

Case No. v **M/s. Alson Pharmaceuticals, Peshawar**

Background of the Case:-

Mr. Muhammad Arif Ch., FID-I, DRAP, Peshawar conducted inspection of the firm M/s. Alson Pharmaceuticals (Pvt) Ltd, Peshawar on 04.09.2018.

2. The FID during inspection noted following critical observations.

Raw Material Store:-

- Raw material store area is not maintained.
- The hygrometers and balance are not calibrated and management is advised to get them calibrated.
- They are further advised to prepare SOP for daily calibration of their balances.
- The temperature and humidity data is not maintained and management is advised to strengthen their QA system to overcome these shortcomings.
- They are using single dispensing area for dispensing of all cephalosporin along with general materials.

Production Area:-

- They have installed HVAC in every section but it was not working at the time of inspection. The firm has installed split AC and window AC which shows their HVAC is not working the management is directed to immediately remove these ACs and made their HVAC working.
- They are using old bottles for filling the packing area is sealed under section 18 (1) of the Drug Act, 1976 and case will be send to the Chairman CLB for consideration.

Quality Control:-

- They are once again advised to appoint one more technical person for QC testing and one for production department.
- The firm is further advised to upgrade their SOPs according to latest Pharmacopeia's requirements.
- The management is also advised to follow official testing methods for the testing of their registered products and should buy recent official books which are mandatory for the development of their QC Methods.
- The Microbiologist is not present today as during the last visit.
- The firm needs "FTIR, Karl Fischer apparatus and potentiometer for testing of their products.
- No record is maintained and reference samples are not kept and staff informed on inquiry that they has dispose of samples of last year which is a violation of GMP guidelines.

Recommendation:-

- The HPLC operator needs training. The firm is further advised to purchase latest official books.
- The firm is also directed to upgrade their SOPs.
- The record keeping is very poor, which need complete review of the mechanism for record handling.

Overall Directions:-

- Calibration of all the equipment.
- Preparation and up-gradation of all the SOPs of Production and QC.

- Purchase of official books (latest edition) and preparation of testing method accordingly.
- Replacement of Syrup filling line and provision of bottle blowing facility.
- Purchase of Karl Fischer apparatus and up-gradation of HPLC and its software.
- Purchase of Potentiometer.
- Adaptation of official testing method.
- Training of staff.
- Appointment of QC, Production and Q.A staff as per rules.

Action taken by DRAP:

The firm M/s. Alson Pharmaceuticals, Peshawar was served with Show Cause Notice/ Suspension of production orders on 09.10.2018.

Reply of the firm:

The firm vide letter dated 15.10.2018 submitted reply of show cause notice and requested to withdraw the show cause notice, re-inspection of the unit and opportunity of personal hearing.

Proceedings of the 266th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) presented the case before the Central Licensing Board. Mr. Saif Ul Islam, Chief Executive of the firm appeared before the Board and informed that they have rectified all the observations and ready for inspection.

Decision of the 266th Meeting of CLB

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

i. Constitute following panel of experts for verification of the observations before resumption of production:-

a. Prof. Dr. Jamshaid Ali Khan, Member, CLB
b. Additional Director, DRAP, Peshawar
c. Area Federal Inspector of Drugs, Peshawar

ii. Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB.

iii. The panel shall submit detailed inspection report to CLB including rectification status of the observations noted by the FID in its report dated 28.08.2018, with clear and candid recommendations.

Case No. vi **M/s. Heal Pharmaceuticals (Pvt) Ltd, Peshawar**

Background of the Case:-

Mr. Muhammad Arif Ch., FID-I, DRAP, Peshawar conducted inspection of the firm M/s. Heal Pharmaceuticals (Pvt) Ltd, Peshawar on 10.08.2018.

2. The FID during inspection noted the following observations which need attention and rectifications:-

Raw Material Store:-

- The observation regarding insufficient temperature control by AC facility is still unattended which is once again strictly directed them to maintenance of temperature and humidity. The hygrometers are also not calibrated (as advised in last inspection) and management is again advised to get them calibrated alongwith other equipment as per their due date which was August, 2017.

Tablet Section General:-

- Management is advised to validate capacity of their HVAC system which is not sufficiently working at the time of inspection.
- The management is advised to upgrade their SOPs and prepare a mechanism for the cleanliness of the drains. The area also needs overhauling of HVAC.

Quality Control:-

- QA department was not existing (as advised in last inspection).
- The firm is further advised to upgrade their SOPs according to latest Pharmacopeia's requirements.
- The management is also advised to follow official testing methods for the testing of their registered products and should buy recent official books which are mandatory for the development of their QC Methods.
- Although firm has a stability testing chamber but the SOP are still not satisfactory and firm has informed they are under negotiation for higher capacity of the "Stability Chamber" and will replace in couple of week.
- The firm was advised in last inspection for the purchase of "FTIR and Karl Fischer Apparatus" required for testing of APIs but these are under process.

Quality Assurance:-

- The firm has not set up quality assurance system and a fresh Pharmacist with one year experience has appointed for the purpose although he also working as analyst in QC section.

Qualification and validation:-

- The firm needs immediately calibration and validated all the equipment in QC and Production as per GMP requirements.

Action taken by DRAP:

The firm M/s. Heal Pharmaceuticals (Pvt) Ltd, Peshawar was served with Show Cause Notice/ Suspension of production orders on 05.10.2018.

Reply of the firm:

The firm vide letter dated 10.10.2018 submitted reply of the show cause notice and informed that all the shortcomings has been rectified and requested for re-inspection.

Proceedings of the 266th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) presented the case before the Central Licensing Board. Mr. Bashir Khan, Managing Director of the firm M/s. Heal Pharmaceuticals (Pvt) Ltd, Peshawar appeared before the Board and inform that they have rectified all the observations and ready for inspection.

Decision of the 266th Meeting of CLB

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

i. Constitute following panel of experts for verification of the observations before resumption of production:-

   a. Prof. Dr. Jamshaid Ali Khan, Member, CLB
   b. Additional Director, DRAP, Peshawar
   c. Area Federal Inspector of Drugs, Peshawar

ii. Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB.

iii. The panel shall submit detailed inspection report to CLB including rectification status of the observations noted by the FID in its report dated 28.08.2018, with clear and candid recommendations.

Item No. III **CORRIGENDUM ISSUED BY THE PANEL**

Case No. i. **M/S HARMANN PHARMACEUTICAL LABORATORIES (PVT) LIMITED, LAHORE**

Background of the case:

Mr. Ajmal Sohail, FID conducted inspection of firm on 3rd and 4th October, 2013 to check the GMP compliance of the firm. The FID reported that the firm was operating at unsatisfactory level of compliance with GMP guidelines as per the Drugs Act, 1976 and rules framed there under and recommended that the firm may be directed to stop all kinds of manufacturing activities till rectification of the shortcomings and improvement of GMP compliance level. Accordingly, show cause notice was issued to the firm and directed to stop manufacturing of drugs in all sections immediately.

2. The case was placed in 252nd meeting of CLB held on 15.03.2017, wherein the Board decided as under:-

Decision of the 252nd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the Federal Inspector of Drugs in its inspection dated 03 & 04.10.2013, poor compliance of the firm towards GMP compliance and orders of the Honorable Islamabad High Court, Islamabad in its Writ Petition No. 4328/2013 dated 14.02.2017, the Board decided to:-

i. Suspend the Drug Manufacturing License of the firm M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, Lahore for a period of (06) six months, under Section 41 of the Drugs Act, 1976 read with Rule 12 (1) of the Drugs (L, R&A) Rules, 1976, from the date of issuance of decision of the 252nd meeting of CLB.

ii. If the management of the firm wants to continue the manufacturing of registered products, the firm shall submit revised layout plan in accordance with the prevailing law, with respect to the registered products and get approval from the Licensing Division.

iii. Re-inspection shall be conducted after completion of suspension period of DML and approval of revised layout plan from the Licensing Division. The CLB authorized Chairman CLB to constitute panel of experts to verify the rectification status of the observations noted during the inspections dated 03&04.10.2013 and 24.01.2017.

iv. The Panel should submit the report on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976. The panel shall also submit brief report in tabulated form identifying the previous observations and the current status with clear and candid recommendations.

v. The report shall be presented in the meeting of Central Licensing Board for perusal and approval.

3. **Decision of the 147th Meeting of Appellate Board**

i. The firm M/s Harmann Pharma, Lahore files an appeal in the Appellate Board, against decision of the 252nd Meeting of CLB. The Board after hearing arguments of the appellant and defendants decided to remand the appeal back to the CLB and constituted a panel of following experts to inspect the premises of the appellant who shall submit its report within 30 days from communication of this decision :-

a) Dr. Farzana Chaudhary, UVAS, Lahore
b) Mr. Shahid Nasir
c) Mr. Syed Muid Ahmed, member CLB
d) Mr. Asim Rauf, Additional director, Lahore

ii. The report of the panel will be placed before the CLB in its forthcoming meeting. Meanwhile the production of the firm will remain suspended till recommendation by the panel for resumption of production and approval thereof by the CLB.

4. **Panel Inspection:-**

The panel constituted by the Appellate Board conducted inspection of the firm M/s Harmann Pharma, Lahore on 17.10.2017 and 27.03.2018. The panel submitted detailed inspection report including previous observations and updated status and forwarded following conclusion and recommendation:-

"Based on the finding of the inspection, the panel recommends resumption of production of following sections to M/s Harmann Pharmaceutical Labs, Lahore:-

i. Tablet Section (Genera)
ii. Capsule Section (General)
iii. Oral Liquid Section
iv. Cream / Ointment Section
v. Sterile Section II

Sterile I & III were not ready for inspection."

5. The case was placed before the 261st meeting of CLB, wherein CLB decided as under:-

Decision of the 261st Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendation of the panel of experts in its report dated 27.03.2018, the Central Licensing Board decided to:-

I. Revoke the suspension of DML and resume the production activities of the firm M/s Harmann Pharmaceutical Laboratories (Pvt) Limited, Lahore in Tablet Section (General), Capsule Section (General), Oral Liquid Syrup Section, Ointment / Cream Section and Sterile Section II (Steroidal Injection Section).

II. Production of Sterile Section I (General Injections) and Sterile Section III (Hormonal Injections) shall remain suspended till submission of compliance report by the firm, verification by the panel of experts and subsequent approval from the CLB.

6. **Corrigendum issued by the Panel**

The panel comprising of following members issued corrigendum dated 06.09.2018.

a) Dr. Farzana Chaudhary, UVAS, Lahore
b) Mr. Shahid Nasir
c) Mr. Syed Muid Ahmed, member CLB
d) Mr. Asim Rauf, Additional director, Lahore

The panel stated that "*with reference to the inspection of M/s. Harmann Pharmaceutical Laboratories (Pvt) Ltd, Lahore conducted on 17.10.2017 and 27.03.2018 and inspection report forwarded to QA & LT Division wide letter No. 5016/2018-DRAP (L-VIII) dated 12.04.2018, the panel of experts recommended resumption of production in the Sterile Section-II and meanwhile production in Sterile-I and III will remain suspended till submission of compliance report by the firm and re-inspection by the panel of inspectors, subsequently.*

It is further clarified that the panel of inspectors recommended resumption of production in Sterile Section-II for General Injectables. As per previous inspection of area FID conducted on 03.10.2013 and 04.10.2013, it was reported that the firm was manufacturing Steroidal Injections in Sterile Section-II at that time. However, in the inspection conducted on 17.10.2017 and 27.03.2018 the panel of inspectors had recommended resumption of production in Sterile Section-II ***only for General Injectables,*** *as steroidal injection section was converted into general injection section. Therefore the recommendation was for general injection only in sterile section-II.*

Production in the Steroidal and Hormonal Injection will remain suspended as stated above."

7. **Clarification of QA Division**

Claim of the panel in its corrigendum stating that "*the panel of inspectors recommended resumption of production in Sterile Section-II for General Injectables. It is further clarified that the panel of inspectors recommended resumption of production in Sterile Section-II for General Injectables"* is not maintainable as inspection report of the panel dated 04.10.2013, 17.10.2017 & 27.03.2018 was placed before the Board in its 261st meeting. It was clearly mentioned in the report that

i. Sterile area I (claimed to be designated for general products)
ii. Sterile area II (claimed to be designated for steroidal products)
iii. Sterile area III (claimed to be designated for hormonal products)

The Board after detailed discussion and deliberation considered recommendation of the panel and allow resumption of production in sterile section II. Contents of the report show that sterile area II is designated for the steroidal products.
The panel in its corrigendum dated 06.09.2018 stated that "*As per previous inspection of area FID conducted on 03.10.2013 and 04.10.2013, it was reported that the firm was manufacturing Steroidal Injections in Sterile Section-II at that time."* In order to verify statement of the panel, the undersigned also go through the GMP inspection report dated 03.10.2013 & 04.10.2013 conducted by Mr. Ajmal Sohail Asif, area FID, Lahore. The FID in its report dated 03.10.2013 & 04.10.2013 discussed the sections as under:-

i. Sterile area I (claimed to be designated for general products)
ii. Sterile area II (claimed to be designated for steroidal products)
iii. Sterile area III (claimed to be designated for hormonal products)

Proceedings of the 266th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) presented the case before the Central Licensing Board.

Decision of the 266th Meeting of CLB

After thorough discussion/deliberations and the Board decided to refer the copies of reports dated 17.10.2017, 27.03.2018 and corrigendum dated 06.09.2018 of the firm M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, Lahore to members of the panel to review the corrigendum in the light of the inspection reports dated 17.10.2017 and 27.03.2018. Report of the panel members shall be placed before the CLB in its forthcoming meeting.

The meeting ended with the vote of thanks to and by the chair.