MINUTES OF 265th MEETING OF CENTRAL LICENSING BOARD HELD ON 9th & 10th AUGUST, 2018

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265th meeting of the Central Licensing Board (CLB) was held on 9th & 10th August, 2018 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, 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	Prof. Dr. Abdullah Dayo, Faculty of Pharmacy, University of Sindh, Jamshoro	Member
2	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
3	Prof. Dr. Mohammad Usman, Expert in manufacturing of drugs	Member
4	Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar.	Member
5	Mr. Munawar Hayat, Chief Drug Controller, Primary and Secondary Health Care Department, Govt. of Punjab, Lahore	Member
6	Syed Saleem Shah, Chief Drug Inspector, Department of Health, Govt. of Balochistan, Quetta.	Member
7	Mr. Muhammad Israr Additional Draftsman/Joint Secretary (Ex-officio), Ministry of Law and Justice, Islamabad.	Member
8	Dr. Hafsa Karam Ellahi Representative Director (QA/LT), DRAP, Islamabad	Member
9	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
10	Mr. Nadeem Alamgir, Representative of Pharma Bureau	Observer
11	Mr.Muhammad Arshad Khan & Mr. Nawaaz Ahmad , Representative of PPMA.	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. 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 264th MEETING

The Central Licensing Board (CLB) formally confirmed the minutes of its 264th meeting held on 9th July, 2018.

A. DRUG LICENSING DIVISION

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

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s Islam Pharmaceuticals, 7-Km, Pasrur Road, Sialkot **Sections 04** 1. Tablet (General) Section 2. Capsule (General) Section 3. Sachet (General) Section. 4. Dry Suspension (General) Section.	25-06-2018	**Good**	1. Dr. Ikram ul Haq, Member Central Licensing Board. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Mr. Anjum Pervaiz, Provincial Drugs Inspector, Lahore. 4. Ms. Majida Mujahid, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - Keeping in the view the manufacturing facilities present in the unit the members of the panel recommends the grant of New Drug Manufacturing License to M/s Islam Pharmaceuticals, 7-Km, Pasrur Road, Sialkot as per layout plan approved by DRAP for the above mentioned sections by way of formulation. **Decision of the Central Licensing Board in 265th meeting** The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Islam Pharmaceuticals, 7-Km, Pasrur Road, Sialkot with following sections: **Section (04)** 1. Tablet (General) Section 2. Capsule (General) Section 3. Sachet (General) Section. 4. Dry Suspension (General) Section.			
2	M/s Nicholas Pharmaceuticals, Plot No. 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad . **Sections 04** 1. Capsule Section (Ceph). 2. Dry Suspension Section (Ceph). 3. Dry Powder Injectable Section (Ceph).	03-08-2018	**Good**	1. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad. 2. Dr. Gul Majeed Khan, Prof. of Pharmacy, Quaid-e-Azam University, Islamabad. 3. Dr. Hafsa Karam Elahi, Additional Director (QA&LT-I), DRAP, Islamabad. 4. Mr. Hassan Afzaal, Area Federal Inspector of Drugs-III, DRAP, Islamabad.

	4. Dry Powder Injectable Section (Carbapenems).			
	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 **Recommends** M/s Nicholas Pharmaceuticals, Plot No. 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad for the grant of Drug Manufacturing License (Formulation) for above mentioned sections. **Decision of the Central Licensing Board in 265th meeting** The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Nicholas Pharmaceuticals, Plot No. 34, Street No. SS-2, National Industrial Zone, Rawat, Islamabad with following sections: **Section (04)** 1. Capsule Section (Ceph). 2. Dry Suspension Section (Ceph). 3. Dry Powder Injectable Section (Ceph). 4. Dry Powder Injectable Section (Carbapenems).			
3	M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. **Sections 05** 1. Oral Liquid (General) (Veterinary) Section. 2. Oral Liquid (General Antibiotic) (Veterinary) Section. 3. Oral Powder (General) (Veterinary) Section. 4. Oral Powder (General Antibiotic) (Veterinary) Section. 5. Oral Powder (Penicillin) (Veterinary) Section.	06-08-2018	**Good**	1. Dr. Farzana Chaudhary, Director, UVAS, Lahore. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Mr. Zaka Ur Rehman, Secretary Pharmacy Council Punjab. (Could not join due to official engagements). 4. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - The panel of inspectors **Recommends** the grant of Drug Manufacturing License by way of Formulation (Vet) in respect of above mentioned sections to M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad. **Decision of the Central Licensing Board in 265th meeting** The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Aptly Pharmaceuticals, 5-Km, Sargodha Road Bypass, Faisalabad with following sections: **Sections 05** 1. Oral Liquid (General) (Veterinary) Section. 2. Oral Liquid (General Antibiotic) (Veterinary) Section. 3. Oral Powder (General) (Veterinary) Section. 4. Oral Powder (General Antibiotic) (Veterinary) Section. 5. Oral Powder (Penicillin) (Veterinary) Section.			

4	M/s Trillium Pharmaceuticals (Pvt) Ltd., C-3 & C-4, Value Addition City, Khurrianwala, Faisalabad. **Sections 05** 1. Tablet (General) Section. 2. Capsule (General) Section. 3. Sachet (General) Section. 4. Oral Liquid (General) Section. 5. Cream/Ointment (General **&** Steroid) Section.	03-07-2018	**Good**	1. Dr. Ikram ul Haq, Member Central Licensing Board. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Mr. Anjum Pervaiz, Consultant Licensing and Registration PDCU, Health Department, Punjab. 4. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, Lahore. 5. Mr. Rana Ahsan Ul Haq Ather, Assistant Director, DRAP, Lahore.

Recommendations of the panel: -

The panel of inspectors **recommends** the grant of Drug Manufacturing License by way of Formulation in respect of above mentioned sections to M/s Trillium Pharmaceuticals (Pvt) Ltd., C-3 & C-4, Value Addition City, Khurrianwala, Faisalabad.

At the time of filling application at time of grant of DML, firm applied for (General Section), therefore, Ointment / Cream (General) Section.

Decision of the Central Licensing Board in 265th meeting

The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Trillium Pharmaceuticals (Pvt) Ltd., C-3 & C-4, Value Addition City, Khurrianwala, Faisalabad with following sections:

Sections 05

1. Tablet (General) Section.
2. Capsule (General) Section.
3. Sachet (General) Section.
4. Oral Liquid (General) Section.
5. Cream/Ointment (General) Section.

The board considered and decided that cream \ ointment (steroid) is not allowed as it was neither approved during lay out plan approval nor panel was given mandate for the same.

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

Following cases have been forwarded by the respective panel of experts for grant of additional sections. 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 Raazee Therapeutics (Pvt) Ltd, 48-Km, Lahore-Kasur Road, Kasur. DML No. 000437 (Formulation) **Section (03)** 1. Dry Powder Injectable (Vial) (Cephalosporin) Section. 2. Dry Powder suspension (Cephalosporin) Section. 3. Capsule (Cephalosporin) Section.	14-12-2017 & 15-03-2018	**Good**	1. Dr. Farzana Chaudhary, Director, UVAS, Lahore. 2. Dr. Ikram Ul Haq, Member Central Licensing Board. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - The panel of inspectors **Recommends** the grant of additional sections under DML No. 000437 to firm M/s Raazee Therapeutics (Pvt) Ltd, situated 48-Km, Lahore-Kasur Road, Kasur to manufacture cephalosporin products as per above mentioned sections. **Decision by the Central Licensing Board in 265th meeting** The Board considered and approved the grant of following three additional sections in the name of M/s Raazee Therapeutics (Pvt) Ltd, 48-Km, Lahore-Kasur Road, Kasur on the recommendations of the panel of experts:- **Section (03)** 1. Dry Powder Injectable (Vial) (Cephalosporin) Section. 2. Dry Powder suspension (Cephalosporin) Section. 3. Capsule (Cephalosporin) Section.			
2.	M/s Ethical Laboratories (Pvt) Ltd, 14-Km, Thokar Niaz Baig, Multan Road, Lahore DML No. 000100 (Formulation) **Section (01)** 1. Tablet (Steroid) Section	25-05-2018	**Good**	1. Dr. Farzana Chaudhary, Director, UVAS, Lahore. 2. Dr. Ikram Ul Haq, Member Central Licensing Board. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - The Panel of inspectors **Recommends** the grant of Tablet Section (Steroid) under DML bearing No. 000100 issued in favour of M/s Ethical Laboratories (Pvt) Ltd. However, the panel of inspectors **did not recommend the grant of Capsule (General)(Revised) section at present.**			

	Decision by the Central Licensing Board in 265th meeting The Board considered and approved the grant of following one additional section in the name of Ethical Laboratories (Pvt) Ltd, 14-Km, Thokar Niaz Baig, Multan Road, Lahore on the recommendations of the panel of experts:- **Section (01)** 1. Tablet (Steroid) Section However, The Board **did not approve** the grant of Capsule (General)(Revised) section. The production shall remain suspended in the section till rectification are made and approved by the Central Licensing Board.			
3.	M/s Izfaar Pharmaceuticals (Pvt) Ltd, 542-A&B, Sunder Industrial Estate, Lahore. DML No. 000800 (Formulation) **Section (02)** 1. Veterinary Oral Liquid (General & General Antibiotics) 2. Veterinary Powder (General & General Antibiotics)	21-06-2018	**Good**	1. Dr. Ikram ul Haq, Member Central Licensing Board. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, Lahore. 4. Mr. Shahrukh Ali, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: - Keeping in view the facilities like building HVAC system, machinery and equipment, personnel, documentation and Quality Control Testing facilities the panel of inspectors is of the opinion to **recommend** the grant the grant of aforesaid additional sections to M/s Izfaar Pharmaceuticals (Pvt) Ltd, 542-A&B, Sunder Industrial Estate, Lahore. **Decision by the Central Licensing Board in 265th meeting** The Board considered and approved the grant of following two additional sections in the name of M/s Izfaar Pharmaceuticals (Pvt) Ltd, 542-A&B, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts:- **Section (02)** 1. Veterinary Oral Liquid (General & General Antibiotics) 2. Veterinary Powder (General & General Antibiotics)			

4.	M/s Wilshire Laboratories (Pvt) Ltd, 124/1, Industrial Estate, Kot Lakhpat, Lahore. DML No. 000232 (Formulation) **Section (01)** Warehouse	01-08-2018	**Good**	1. Dr. Farzana Chaudhary, Director, UVAS, Lahore. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - In the light of the inspection conducted by the panel and based on the findings, the panel of inspectors recommend the approval of new warehouse for storage of material to M/s Wilshire Laboratories (Pvt) Ltd, 124/1, Industrial Estate, Kot Lakhpat, Lahore. **Decision by the Central Licensing Board in 265th meeting** The Board considered and approved the grant of following facility in the name of M/s Wilshire Laboratories (Pvt) Ltd, 124/1, Industrial Estate, Kot Lakhpat, Lahore on the recommendations of the panel of experts:- **Section (01)** Warehouse			
5.	M/s Berlex Lab International, 10-Km, Nangshah Chowk, Karachi Road, Multan. DML No. 000678 (Formulation) **Section (04)** 1. Injectable (Psychotropic) Section (New). 2. Injectable (General) Section (SVP) (New). 3. Infusion (General) Section. (New) 4. Tablet (Psychotropic) Section (Revised).	05-07-2018	**Good**	1.Dr. Ikram ul Haq, Member Central Licensing Board. 2.Prof. Dr. Mahmood Ahmed, Ex Dean Bahawalpur University. 3.Mr. Mouqadus-un-Nisa, Director Drugs Testing Laboratory, Multan. 4.Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - Keeping in view the manufacturing facility like building HVAC system, production machinery, Equipment Quality Control and Microbiology Laboratory, Water Treatment System, Testing facilities, Technical Personnels met, documentation, the panel of inspectors **recommend** the			

	aforesaid additional sections to M/s Berlex Lab International, 10-Km, Nangshah Chowk, Karachi Road, Multan with reference to DRAP, Islamabad letter No. F.1-5/2008-Lic (Pt) dated 30-01-2018 and even number dated 09-04-2018. **Decision by the Central Licensing Board in 265th meeting** The Board considered and approved the grant of following four additional sections in the name of M/s Berlex Lab International, 10-Km, Nangshah Chowk, Karachi Road, Multan on the recommendations of the panel of experts:- **Section (04)** 1. Injectable (Psychotropic) Section (New). 2. Injectable (General) Section (SVP) (New). 3. Infusion (General) Section. (New) 4. Tablet (Psychotropic) Section (Revised).			
6.	M/s Lotus Pharmaceuticals (Pvt) Ltd., DML No. 000661, Plot No. 118-A, Street No. 8, I-10/3, Islamabad. DML No. 000661 (Formulation).	27-06-2018	**Un Satisfactory**	1. Mr. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad. 2. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad. 3. Ms. Mahvash Ansari, Federal Inspector of Drugs-IV, DRAP, Islamabad.
	Recommendations of the panel: - "Keeping in view of the above facts on record, documents reviewed and facility inspected, the panel unanimously **do not recommended for the approval of new section as of today namely Dry Powder Injectable Cephalosporin** to M/s Lotus Pharmaceuticals (Pvt) Ltd., DML No. 000661, Plot No. 118-A, Street No. 8, I-10/3, Islamabad. **Decision by the Central Licensing Board in 265th meeting** The Board considered and **did not approve** the grant of following one additional section in the name of Lotus Pharmaceuticals (Pvt) Ltd., DML No. 000661, Plot No. 118-A, Street No. 8, I-10/3, Islamabad on the recommendations of the panel of experts:- **Section (01)** 1.Dry Powder Injectable (Cephalosporin)			
7.	M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad DML No. 000489 (By Way of Semi Basic).	29-06-2018		1.Mr. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad. 2.Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad. 3.Mahvash Ansari, Federal Inspector of Drugs-IV, DRAP, Islamabad.

	Recommendations of the panel: - "Establishment has basic manufacturing facility, trained personnel and required equipment for production and testing of Amlodipine Chemsylate both raw material and finished products. Although firm was asked to get impurity profiling for random batches to ensure the safety of API from batch to batch. Based upon the facility visited, people met and documents (including raw data / meta data), panel unanimously recommend the approval of manufacturing of Amlodipine Chemsylate by way of Semi-Basic Manufacturing. **<u>Decision by the Central Licensing Board in 265th meeting</u>** The Board considered and approved the grant of following one additional API in the name of M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad on the recommendations of the panel of experts:- **<u>API (01)</u>** 1. Amlodipine Chemsylate			
8.	M/s Shaheen Pharmaceuticals, 3-KM, Murghzar Road, Saidu Sharif, Swat. DML No. 000562 (Formulation) **<u>Section (01)</u>** 1. Psychotropic Tablet Section in place of Quinolone tablet section and shifting of Quinolone tablet section to tablet general section.	13-07-2018	**Good**	1. Prof. Dr. Jamshid Ali Khan, Member CLB. 2. Dr. Abbas Khan, Chief Drug Inspector, KP. 3. Area Federal Inspector of Drugs-III, DRAP, Peshawar.
	Recommendations of the panel: - In compliance to DRAP Islamabad letter No.F.3-4/2000-Lic (Vol-I) dated 09-05-2018, M/s. Shaheen Pharmaceuticals, 3-KM, Murghazar Road, Saidu Sharif, Swat was inspected by the above mentioned panel on 13-07-2018 for approval of additional section (Psychotropic tablet section) in place of Quinolone tablet section and shifting of quinolone tablet section to tablet general section. The firm all the required equipments and facilities in both the tablet sections (quinolone and general). The sections have been provided with HVAC facilities. SOPs have been provided. The firm has also separate storage areas for the raw materials, packing materials and finished goods with proper racks and pallets. An independent quality control sections with the required instruments / equipments have been provided. The firm has appointed qualified staff both in production and quality control to look after and perform the manufacturing and testing procedures. Based upon these observations, the panel unanimously **<u>recommend</u>** the approval of additional section (psychotropic tablet section) in place of Quinolone tablet section and shifting of quinolone tablet section to tablet general section. **<u>Decision by the Central Licensing Board in 265th meeting</u>** The Board considered and approved the grant of following facility in the name of M/s Shaheen Pharmaceuticals,3-KM, Murghzar Road, Saidu Sharif, Swat.on the recommendations of the panel of experts:- **<u>Section (01)</u>**			

	1. Psychotropic Tablet Section in place of Quinolone tablet section and shifting of Quinolone tablet section to tablet general section.			
9.	M/s Fynk Pharmaceuticals, 19-Km, G.T. Road, Kala Sha Kaku, Lahore. DML No. 000494 (Formulation) **Section (01)** 1. Additional Bulk Raw Material Store.	29-06-2018	**Good**	1. Dr. Ikram ul Haq, Member Central Licensing Board. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Ms. Majida Mujahid, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - Panel has thoroughly evaluated the various documents in connection with Additional Bulk Raw Material Store. Panel also evaluated the approved layout plan and building construction of Additional Bulk Raw Material Store. Panel also inspected the Additional Bulk Raw Material Store and discussed various technical aspects at length with the management of the firm. After thorough evaluation of documents and inspection of the Additional Bulk Raw Material Store, panel decided to **recommend** the extension / amendment of Additional Bulk Raw Material Store of M/s Fynk Pharmaceuticals, 19-Km, G.T. Road, Kala Sha Kaku, Lahore. **Decision by the Central Licensing Board in 265th meeting** The Board considered and approved the grant of following facility in the name of M/s Fynk Pharmaceuticals, 19-Km, G.T. Road, Kala Sha Kaku, Lahore on the recommendations of the panel of experts:- **Section (01)** Additional Bulk Raw Material Store.			
10.	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, 1-Km, Defence Road towards Kahna, Lahore. DML No. 000582 (Formulation) **Section (07)** 1. Liquid Re-packing (Human) Section. 2. Powder Re-packing (Human) Section. 3. Sachet (General) (Human) Section. 4. External Preparation / Application / Aerosol (Human) Section. 5. Liquid Injectable (Steroid) (Vet) Section. 6. Oral Powder (Penicillin) (Vet)	19-12-2017 & 02-03-2018	**Good**	1. Dr. Ikram ul Haq, Member Central Licensing Board. 2. Dr. Farzana Chaudhary, Director, UVAS, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 4. Ms. Mehwish Jamil Butt Assistant Director, DRAP, Lahore.

	Section. 7. Quality Control Lab (Amendments).			

Recommendations of the panel: -

The panel of inspectors recommends the grant of above mentioned additional sections in favour of M/s International Pharma Labs, Lahore.

Decision by the Central Licensing Board in 265th meeting

The Board considered and approved the grant of following seven sections in the name of M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, 1-Km, Defence Road towards Kahna, Lahore on the recommendations of the panel of experts:-

Section (07)

1. Liquid Re-packing (Human) Section.
2. Powder Re-packing (Human) Section.
3. Sachet (General) (Human) Section.
4. External Preparation / Application / Aerosol (Human) Section.
5. Liquid Injectable (Steroid) (Vet) Section.
6. Oral Powder (Penicillin) (Vet) Section.
7. Quality Control Lab (Amendments).

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.No	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Efroze Chemical Industries (Pvt) Ltd, Plot No. 146/23, Korangi Industrial Area, Karachi DML No. 000151 (Formulation) **Period**: 08-04-2015 to 07-04-2020	**19-03-2018**	**Good**	1. Syed Muied Ahmad, Member CLB. 2. Syed Muzafar Jafri, Director DTL, Sindh. 3. Najam-us-Saqib, FID, DRAP, Karachi. 4. Dr. Waqar Ahmed, Assistant Director, DRAP, Karachi.
	Recommendations of the panel: - Based on the areas inspected, people met and documents reviewed the manufacturing, quality control and storage facility of M/s. Efroze Chemicals (Pvt) Ltd was observed well maintained and equipped with relevant equipment and machinery required for the production and testing of pharmaceutical raw materials, packaging materials and finished drugs. The firm is also exporting the products to around 15 countries of the world including Kenya, Vietnam, Cambodia, Bangladesh, Afghanistan and Sudan etc. Keeping in view the finding of the inspection as listed in this inspection report, the **panel recommends the grant of renewal of the Drug Manufacturing License by way of formulation.** Firm is further advised to follow the application submitted for the regularization of the complete layout plan from the Directorate of Licensing, DRAP, Islamabad. **Decision by the Central Licensing Board in 265th meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000151 (Formulation) in the name of M/s Efroze Chemical Industries (Pvt) Ltd, Plot No. 146/23, Korangi Industrial Area, Karachi, on the recommendations of the panel of experts for the further period of five years commencing on 08-04-2015 and ending on 07-04-2020.			
2	M/s Schazoo Zaka (Pvt). Ltd, 20-Km, Lahore Jaranwala Road, District Sheikhupura. DML No. 000636 (Formulation)	**26-06-2018** **&** **27-06-2018**	**Very Good**	1. Dr. Ikram ul Haq, Member Central Licensing Board. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Dr. Zaka ur Rehman, Secretary Punjab Pharmacy Council, Lahore.

	Period: Commencing on 19-06-2018 ending on 18-06-2023.			4. Ms. Majida Mujahid, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - Keeping in view the above improvements made by the firm, the members of the panel are of the opinion to **recommend** the grant of Renewal of Drug Manufacturing License (000636) Formulation of M/s Schazoo Zaka Pvt Ltd, 20-Km, Lahore Jaranwala Road, District Sheikhupura by the way of formulation. **Decision by the Central Licensing Board in 265th meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000636 (Formulation) in the name of M/s Schazoo Zaka (Pvt). Ltd, 20-Km, Lahore Jaranwala Road, District Sheikhupura on the recommendations of the panel of experts for the further period of five years commencing on 19-06-2018 and ending on 18-06-2023.			
3.	M/s Berlex Lab International, 10-Km, Nangshah Chowk, Karachi Road, Multan. DML No. 000678 (Formulation) **Period**: Commencing on 18-12-2014 ending on 17-12-2019.	05-07-2018	**Good**	1. Dr. Ikram ul Haq, Member Central Licensing Board. 2. Prof. Dr. Mahmood Ahmed, Ex Dean Bahawalpur University. 3. Mr. Mouqadus-un-Nisa, Director Drugs Testing Laboratory, Multan. 4. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - Keeping in view the manufacturing facility like building HVAC system, production machinery, Equipment Quality Control and Microbiology Laboratory, Water Treatment System, Testing facilities, Technical Personnels met, documentation, the panel of inspectors is of the opinion to recommend the renewal of Drug Manufacturing License by way of formulation for following sections. **1. Table Section (General)** **2. Capsule Section (General)** **Decision by the Central Licensing Board in 265th meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000678 (Formulation) in the name of M/s Berlex Lab International, 10-Km, Nangshah Chowk, Karachi Road, Multan on the recommendations of the panel of experts for the further period of five years commencing on 18-12-2014 and ending on 17-12-2019 for following two sections: **1. Tablet Section (General)** 2. **Capsule Section (General)**			

4.	M/s Nimral Laboratories, Plot No. 24, Street No. SS-3, Rawat Industrial Estate, Rawat. DML No. 000611 (Formulation). **Period**: Commencing on 21-03-2017 ending on 20-03-2022.	**19-02-2018**	**Good**	1. Mr. Ghulam Rasool Dotani, Director (Lic), DRAP, Islamabad. 2. Dr. Muhammad Tanveer Alam, Addl. Dir (PS), DRAP, Islamabad. 3. Dr. Hasan Afzaal, Federal Inspector of Drugs-III, DRAP, Islamabad. 4. Dr. Muhammad Yaqoob, Assistant Director (Lic), DRAP, Islamabad.

Recommendations of the panel: -

"Keeping in view the above facts, detailed visit of facility as of today and review of documents the panel unanimously **Recommends** M/s Nimral Laboratories, Plot No. 24, SS-3, RCCI, Rawat, Rawalpindi for the renewal of Drug Manufacturing License No. 000611 (Formulation) for the following sections namely:-

1. Tablet Section (General).
2. Capsule Section (General).
3. Cream / Ointment Section (General).
4. Oral Liquid Section (General).
5. Dry Suspension Section (General).
6. Sterile Ampoule (General).
7. Sterile Infusion (General).
8. Sterile Ophthalmic (General).
9. Capsule (Ceph).
10. Dry Powder for Suspension (Ceph).

Decision by the Central Licensing Board in 265th meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000611 (Formulation) in the name of M/s Nimral Laboratories, Plot No. 24, Street No. SS-3, Rawat Industrial Estate, Rawat.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 for following sections:

1. Tablet Section (General).
2. Capsule Section (General).
3. Cream / Ointment Section (General).
4. Oral Liquid Section (General).
5. Dry Suspension Section (General).
6. Sterile Ampoule (General).
7. Sterile Infusion (General).
8. Sterile Ophthalmic (General).
9. Capsule (Ceph).
10. Dry Powder for Suspension (Ceph).

5.	M/s Swat Pharmaceuticals, Saidu Sharif, Amankot, Swat. DML No. 000035 (Formulation) **Period**: Commencing on 30-04-2015 ending on 29-04-2020.	**09-03-2018** **&** **13-07-2018**	**Good**	1. Dr. M. Saeed, Dean Faculty of Pharmacy, Peshawar University, Peshawar. 2. Chief Drug Inspector, KPK, Peshawar. 3. Area Federal Inspector of Drugs, DRAP, Peshawar.
	Recommendations of the panel: - Keeping in view the overall GMP compliance status of the firm the panel unanimously recommends the renewal of Drug Manufacturing License No. 000035 by way of Formulation granted to M/s Swat Pharmaceuticals, Saidu Sharif Road, Amankot, Swat, Khyber Pakhtunkhawa. **Decision by the Central Licensing Board in 265th meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000035 (Formulation) in the name of M/s Swat Pharmaceuticals, Saidu Sharif, Amankot, Swat on the recommendations of the panel of experts for the further period of five years commencing on 30-04-2015 and ending on 29-04-2020.			
6.	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, 1-Km, Defence Road towards Kahna, Lahore. DML No. 000582 (Formulation) **Period**: Commencing on 02-09-2015 ending on 01-09-2020.	19-12-2017 & 02-03-2018	**Good**	1. Dr. Ikram ul Haq, Member Central Licensing Board. 2. Dr. Farzana Chaudhary, Director, UVAS, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 4. Ms. Mehwish Jamil Butt Assistant Director, DRAP, Lahore.
	Recommendations of the panel: - The panel of inspectors recommends the renewal of Drug Manufacturing License in favour of M/s International Pharma Labs, Lahore. **Decision by the Central Licensing Board in 265th meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000582 (Formulation) in the name of M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, 1-Km, Defence Road towards Kahna, Lahore on the recommendations of the panel of experts for the further period of five years commencing on 02-09-2015 and ending on 01-09-2020.			
7.	M/s News Pharma, 42-Sunder Industrial Estate, Lahore	**26-04-2018**	**Nil**	1. Dr. Ikram-ul-Haq, Member CLB. 2. Mr. Asim Rauf, Additional Director,

	DML No. 000775 (Formulation) **Period**: Commencing on 18-02-2018 ending on 17-02-2023			DRAP, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs.

Recommendations of the panel: -

Keeping in view the facilities like building, HVAC system, machinery, equipment, personnel, documentation, and Quality Control microbiology lab, water treatment and testing facilities, panel of inspectors recommends the renewal of Drug Manufacturing License of the following sections to M/s News Pharma, 42-Sunder Industrial Estate, Lahore

i. Liquid Injection (General).
ii. Dry Powder Injection (Cephalosporin).

Meanwhile a letter is received from Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab wherein he has informed that Provincial Quality Control Board has suspended the Drug Manufacturing License of M/s News Pharma, for 15 days vide ordered dated 31st May, 2018 based on the inspection report (i.e. Inspection conducted on dated 24th May, 2018)submitted by Provincial Inspector of Drugs, Sunder Industrial Estate, & Multan Road, Lahore.

Orders of the Provincial Quality Control Board, Punjab marked as Annex-I.

Decision by the Central Licensing Board in 263rd meeting

The Board considered and deliberated the case in the light of orders of the PQCB, Punjab and legal provisions. The Board decided to defer the renewal of the firm subject to submission of CAPA and further orders of the PQCB, Punjab on the matter.

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

A letter was issued on 03-08-2018 to Secretary PQCB to provide updated status of case of M/s News Pharma, Lahore.

The Secretary PQCB replied on 08-08-2018 that the PQCB in its 187th meeting held on 31-05-2018 decided to suspend the DML for 15 days and constituted one member committee comprising of CDC Punjab for evaluation of CAPA. Upon submission of CAPA submitted by the firm the CDC Punjab inspected the firm on 26-06-2018 and report of inspection was considered in 188th meeting held on 28-06-2018. The Board allow the M/s News Pharma, Lahore to resume production activity in accordance with law. The Board further decided to constitute panel for follow-up inspection within 90 days.

	Decision by the Central Licensing Board in 265th meeting The Board endorsed the report of PQCB Punjab and approved the renewal of Drug Manufacturing Licence No. 000775 (Formulation) in the name of M/s News Pharma, 42-Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the further period of five years commencing on 18-02-2018 and ending on 17-02-2023.			
8	M/s Curatech Pharma (Pvt) Ltd, 35-Km, Multan Road, Lahore DML No. 000619 (Formulation) **Period**: 17-07-2017 to 16-07-2022	**16-03-2018**	**Good**	1. Dr. Farzana Chowdhary, Director, IPS, UVAS, Lahore. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Ms. Nusrat Rehman, Provincial Drugs Inspector for industries, Punjab, Lahore. 4. Ms. Uzma Barkat, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendation In the light of the inspection conducted by the panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Curatech Pharma (Pvt) Ltd, 35-Km, Multan Road, Lahore for the following sections: 1. Tablet (General) Section. 2. Capsule (General) Section. **Decision by the Central Licensing Board in 265th meeting** The Board approved the renewal of Drug Manufacturing Licence No. 000619 (Formulation) in the name of M/s Curatech Pharma (Pvt) Ltd, 35-Km, Multan Road, Lahore on the recommendations of the panel of experts for the further period of five years commencing on 17-07-2017 and ending on 16-07-2022 for following two sections: 1. Tablet (General) Section. 2. Capsule (General) Section.			

Item-V: **MISCELLANEOUS CASES**

Case No. 1 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S EROS PHARMA, KARACHI**

M/s Eros Pharma, Plot No. 94-95, Sector 23, Korangi Industrial Area, Karachi, had applied for renewal of DML No. 000147 by way of formulation for the period of 21-08-2015 to 20-08-2020 on 03-08-2015. 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 5th June, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form-29 along with Form-A duly attested from S.E.C.P (Updated year 2017).
2. Form-29 duly attested from S.E.C.P (for year 2010).
3. Detail of management at the time of pervious renewal of DML and present renewal of DML along with CNIC copies of all directors.
4. Approved Master Layout Plan / Proof of licensed section from CLB.
5. Nothing due certificate regarding CRF from STO (Updated).
6. Prescribed fee of Rs. 50,000/- for change of management / directors.
7. Prescribe fee of Rs. 10,000/- for change of proposed Production Incharge and Quality Control Incharge.
8. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not less than 10 years for proposed Production Incharge and Quality Control).
9. Resignation / retirement of earlier Production Incharge and Quality Control Incharge.
10. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Production Incharge and Quality Control Incharge).
11. All documents should be duly attested.

The firm submitted their reply on 12th October, 2017. After evaluation of the submitted documents, final reminder was issued on 5th December, 2017 to the firm with following shortcomings: -

1. Form-29 along with Form-A duly attested from S.E.C.P (Updated year 2017).
2. Form-29 duly attested from S.E.C.P (for year 2010).
3. Attested CNIC copies of all directors at present renewal and at last renewal.
4. Approval letters of sections issued by the Central Licensing Board or if not available then submit master layout plan for Regularization.
5. Section wise detail of machinery for manufacture.
6. Section wise detail of machinery for Quality Control Lab.
7. Nothing due certificate regarding CRF from STO (Updated).
8. Prescribed fee of Rs. 50,000/- for change of management / directors.
9. Prescribe fee of Rs. 5,000/- (original challan retained by STO (R&D)) for change of proposed Quality Control Incharge alongwith complete set of attested documents of Mr. Ahmed Raza.
10. **All documents should be duly attested.**

Firm submitted documents on 6th February, 2018 in reply to Final Reminder but following documents are still deficient /short and application for renewal of DML is still incomplete.

1. Form-29 along with Form-A duly attested from S.E.C.P (Updated year 2017).
2. Form-29 duly attested from S.E.C.P (for year 2010).
3. Prescribed fee of Rs. 50,000/- for change of management / directors if the management is changed.
4. Attested CNIC copies of all directors at present renewal and at last renewal.
5. Approval letters of sections issued by the Central Licensing Board or if not available then submit master layout plan for Regularization.
6. Nothing due certificate regarding CRF from STO (Updated).
7. **All documents should be duly attested.**

Proceedings and Decision of Central Licensing Board in 259th 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 Eros Pharma, Plot No. 94-95, Sector 23, Korangi Industrial Area, Karachi, Drug Manufacturing Licence No. 000147 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

The show cause notice Dated: 27-04-2018 was issued to the firm and in response firm submitted documents on 28-05-2018 which are evaluated and following documents are evaluated and application for renewal of DML is still deficient of following documents.

1. Form-29 along with Form-A duly attested from S.E.C.P (Updated year 2017) & Form-29 duly attested from S.E.C.P (for year 2010) are not submitted due to which management status of the firm is still not clear as if the management is changed then firm has to submit Prescribed fee of Rs. 50,000/- for change of management / .
2. Attested CNIC copies of all directors at present renewal and at last renewal.
3. Approval letters of sections issued by the Central Licensing Board are not provided and instead firm has submitted approval letter of expansion of layout plan.
4. Nothing due certificate regarding CRF from STO (Updated).

The firm is called for personal hearing vide letter Dated : 31-07-2018.

Proceedings and Decision of Central Licensing Board in 265th meeting

Mr. Asif, (Director) and Mr. Ahsan (Regulatory Affairs Officer) of the firm appeared before the Central Licensing Board and presented documents which were considered and found complete. He also contended that requirements has been completed and show cuase issued to him may be recalled. The Borad after hearing the representative of the firm decided to revoke the show cause notice with the warning to the firm to be careful in future for compliance of Law.

Case No. 2 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDICURE LABORATORIES, KARACHI**

M/s Medicure Laboratories, F/109, S.I.T.E, Hub River Road, Karachi, had applied for renewal of DML No. 000034 by way of formulation for the period of 30-04-2015 to 29-04-2020 on 05-05-2015.

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 23rd February, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i) To submit late fee for submission of DML renewal application i.e. Rs.5,000/- per day for 06 days = Rs.5,000x6=Rs.30,000/-.

ii) No objection certificate for Central Research Fund (CRF) by Statistical Officer DRAP, Islamabad

iii) Legal status of the firm along with details of ownership, attested copies of CNIC's.

iv) List of total section of the firm and their letters of grant which were approved in meetings of Central Licensing Board.

v) Complete documents of technical persons i.e QC Incharge and Production Incharge according to Performa (enclosed).

The firm submitted their reply on 4th March, 2016. After evaluation of the submitted documents, Final reminder was issued on 7th December, 2017 to the firm with following shortcomings: -

1. Prescribed fee of Rs. 50,000/- for change of management / directors.
2. Detail of all partners / Directors of firm's letter head alongwith CNIC copies.
3. Approval / Grant letters of all repacking drugs for which renewal of DML is applied alongwith fee of Rs, 5,000/- per drug / product.
4. Complete set of duly attested documents for Proposed Production Incharge and Quality Control Incharge (as per check list).
5. Nothing due certificate regarding CRF from STO (Updated).
6. Approval letters of sections issued by the Central Licensing Board and if not available then submit master layout plan for Regularization of manufacturing facility.
7. **All documents should be duly attested.**

Firm submitted documents on 22nd December, 2017 in reply to Final Reminder but following documents are still deficient /short and application for renewal of DML is still incomplete.

1. Nothing due certificate regarding CRF from STO (Updated).
2. Approval letters alongwith prescribe fee of Rs. 5,000/- per product for re-packing item / Products.
3. Complete set of duly attested documents for Proposed Production Incharge Ms. Zubia Kawal as her total post qualification experience is less than 10 years which does not

fulfill the requirements of Rule 16 of Drugs (Licensing, Registering and Advertising) Rules 1976 in term of relevant experience.

4. Resignation / retirement of earlier Quality Control Incharge.
5. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Quality Control Incharge).
6. Job acceptance letter by the appointee (Quality Control Incharge).
7. Undertaking as whole time employee on stamp paper (Quality Control Incharge).
8. Prescribed fee of 10,000/- for Production Incharge and Quality Control Incharge.

Proceedings and Decision of Central Licensing Board in 259th 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 Medicure Laboratories, F/109, S.I.T.E, Hub River Road, Karachi, Drug Manufacturing Licence No000034 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

In response to show cause notice Dated: 08-05-2018 firm has submitted documents which are evaluated and renewal application is still found to be deficient of following documents :

1. Nothing due certificate regarding CRF from STO (Updated).
2. Approval letters for re-packing item / Products are not provided. Firm has submitted fee of Rs.20000/-(challan forms not retained by STO (DRAP) for renewal of four (04) repacking items namely Methly salicylate, sodium bicarbonate, Zinc Oxide and sodium citrate but at the time of application for renewal of DML firm claimed that it possess 16 repacking items.
3. Clarify status regarding approval of QC incharge as Previously firm submitted documents of Miss. Shaista Bano as Proposed QC Incharge and firm was advised to submit documents for approval of QC Incharge. In response firm has now claimed that Mr.Sohail Pervez is appointed as a QC incharge since Januaury 1970 and is still continuing his said role/position.The firm has also submitted Undertaking in this regard. Neither approval letter nor the complete set of attested documents of Mr. Sohail Pervez are submitted. Prescribed fee for change of QC incharge is also not submitted.
4. Complete set of duly attested documents for new Production Incharge as Ms. Zubia Kawal (Proposed Production Incharge) has total post qualification experience less than 10 years which does not fulfill the requirements of Rule 16 of Drugs (Licensing, Registering and Advertising) Rules 1976 in term of relevant experience

The firm is called for personal hearing vide letter dated 31st July, 2018.

Proceedings and Decision of Central Licensing Board in 265th meeting

Mr. Ahmed Hassan (General Manager) and Shabbir Hussain Shah (Managing Partner) of the firm appeared before the Central Licensing Board and presented documents and requested for giving one month time for submission of documents. However, the Board after scrutiny of the documents

directed the firm to submit certified copies of the same at the earliest. The Board after hearing the representative of the firm decided to defer the case till next meeting of Central Licensing Board.

Case No. 3 **APPLICATION FOR APPROVAL OF PRODUCTION INCHARGE & QUALITY CONTROL INCHARGE OF M/S AVANT PHARMACEUTICAL (PVT) LTD, BALOCHISTAN.**

M/s Avant Pharmaceutical (Pvt) Ltd, Plot No. M-28, Hub Industrial Estate, Balochistan had applied on 1th September, 2017 for approval of Mr. Gul Muhammad Jamali as Production Incharge and Mr. IqrarHussain as Quality Control Incharge after resignation of earlier Production Incharge w.e.f 11-01-2017.

Application was evaluated and letter of following shortcomings was issued to the firm on 10th October, 2017.

1. Prescribe fee of Rs. 10,000/- for change of proposed Production Incharge and Quality Control Incharge.
2. Job acceptance letter by the appointee (Production Incharge).
3. Resignation / retirement of earlier Production Incharge and Quality Control Incharge.
4. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Production Incharge and Quality Control Incharge).
5. Undertaking as whole time employee on stamp paper (Production Incharge and Quality Control Incharge).
6. **All documents should be duly attested.**

Meanwhile, copy of resignation letter of Mr. Gul Muhammad Jamali was received on 24th October, 2017.The firm replied to aforementioned letter of shortcomings on 11th November, 2017 and submitted deficient documents of Quality Control Incharge and filed new application for approval of Mr. Muhammad Arif Khan as Production Incharge. Again a letter of following shortcomings was issued to the firm on 24th November, 2017 for completion of application:

1. Complete set of duly attested documents for Proposed Production Incharge (as per check list).
2. Appointment letter (Quality Control Incharge).
3. Job acceptance letter by the appointee (Quality Control Incharge).
4. Resignation / retirement of earlier QC Incharge.
5. Undertaking as whole time employee on stamp paper (Production Incharge and Quality Control Incharge).
6. **All documents should be duly attested.**

The firm submitted documents on 26th December, 2017 in reply to Licensing Division's letter and submitted deficient documents of Quality Control Incharge and new application of Mr. Muhammad Aslam. Upon evaluation, the following shortcomings were observed in the application and firm was served with Final Reminder dated 2nd February, 2018:

1. Complete set of duly attested documents for Proposed Production Incharge and Quality Control Incharge (as per check list).
2. Resignation / retirement of earlier QC Incharge and Production Incharge.
3. Undertaking as whole time employee on stamp paper (Production Incharge and Quality Control Incharge).
4. **All documents should be duly attested.**

The firm replied to Final Reminder but application for approval of technical staff is still incomplete with following shortcomings.

1. Complete set of duly attested documents for Proposed Production Incharge and Quality Control Incharge (as per check list).
2. Resignation / retirement of earlier QC Incharge and Production Incharge.
3. Undertaking as whole time employee on stamp paper (Production Incharge and Quality Control Incharge).
4. **All documents should be duly attested.**

Proceedings and Decision of Central Licensing Board in 261st meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000786 by way of Formulation in the name of M/s Avant Pharmaceutical (Pvt) Ltd, Plot No. M-28, Hub Industrial Estate, Balochistan may not be suspended or cancelled by Central Licensing Board.

The show cause notice Dated : 08-06-2018 was issued to the firm and in reply to showcause notice firm submitted complete documents Dated ; 12-06-2018 for approval of Proposed Production Incharge Mr. Muhammad Aslam and QC incharge Mr. Iqrar Hussain which were evaluated and both proposed technical persons fullfied the requirements of Rule 16 of Drugs((Licensing, Registering and Advertising) Rules, 1976. Therefore, said technical persons were approved.

The firm is called for personal hearing vide letter dated 31st July, 2018

Proceedings and Decision of Central Licensing Board in 265th meeting

Mr. Faraz, Director of the firm appeared before the Central Licensing Board. He contended that requirements has been completed and show cuase issued to him may be recalled. The Board after hearing the representative of the firm decided to revoke the show cause notice with the warning to the firm to be careful in future for compliance of Law.

Case No. 4 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S BAXTER PHARMACEUTICALS, KARACHI**

M/s Baxter Pharmaceuticals, A-1/A, Scheme No. 33, Phase-II, S.I.T.E, Super Highway, Karachi had applied for renewal of DML No. 000700 by way of formulation on 28-01-2016 for the period of 25-02-2016 to 24-02-2021.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 07-11-2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form 1-A.
ii. Class(es) of Drugs.
iii. Dosage form(s) of Drugs.
iv. Name of Drug(s) registered.
v. Name of Proprietor/Director alongwith attested CNIC copies.
vi. Detail of Premises including approved L.O.P.
vii. Detail of Section-wise equipments/machinery.
viii. Detail of Technical Staff.
ix. Latest N.O.C. of C.R.F.

The firm did not submit their reply. A Reminder-I was issued on 24-04-2017 to the firm with following shortcomings: -

1. Form 1-A,
2. Class(es) of Drugs.
3. Dosage form(s) of Drugs.
4. Name of Drug(s) registered.
5. Name of Proprietor / Director along with CNIC copies
6. Detail of premises including approved layout plan / Proof of Sections from CLB.
7. Detail of Section-wise equipments/machinery.
8. Nothing due certificate regarding CRF from STO (Updated).
9. Provide name of approved Quality Control Incharge and Production Incharge. In case of new nominees, provide complete set of documents for Proposed Quality Control Incharge and Production Incharge with names as (per check list) along with prescribe fee.
10. All documents should be duly attested.

The firm did not submit their reply. Final Reminder was issued on 19-06-2017 to the firm for above mentioned documents.

The firm has submitted the requisite documents. Upon evaluation, following documents are still found to be short and application for renewal of DML is **still incomplete;**

1. Prescribed fee for change of management.
2. NOC from previous management.

Proceedings and Decision of Central Licensing Board in 257thmeeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000700by way of formulation of M/s Baxter Pharmaceuticals, A-1/A, Scheme No. 33, Phase-II, S.I.T.E, Super Highway, Karachimay not be

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

The show cause notice Dated : 27-02-2018 was issued to the firm. In response to the show cause notice firm has submitted Prescribed fee of Rs. 50,000 for change of management however management status of the firm is still unclear as the following required/necessary documents are still not submitted.

1. N.O.C from previous partner Mr. Nazar Talib along with document regarding dissolution of old partnership deed although firm has submitted document issued from SITE in which the current/new 03 partners of firm are also mentioned.

The firm is called for personal hearing vide letter dated 31st July, 2018.

Proceedings and Decision of Central Licensing Board in 265th meeting

No person on behalf of the firm appeared before the Board. However, The firm submitted the required documents via postal services. The Board considering the facts on record decided to revoke the Showcause Notice issued to the firm and also issue warning to the firm to be careful in future for compliance of the law.

Case No. 5 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S GLAXOSMITHKLINE PAKISTAN LTD, KARACHI

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s GlaxoSmithKline Pakistan Ltd,35, Dockyard Road, West Wharf, Karachi DML No. 000017 (Formulation) **Period**: Commencing on 31-03-2015 ending on 30-03-2020.	**20-03-2018**	**Good**	4. Mr. Syed Muid Ahmed, Member Central Licensing Board. 5. D. Abdullah Dayo, Member Central Licensing Board. 6. DR. Saifur Rehman Khattak, Director CDL, DRAP, Karachi. 7. Syed Hakim Masood, Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - 1. It is an old factory, however, maintained very well by the management. The infrastructure, human resource and other manufacturing and Quality Control facility are well established. The panel recommends the renewal of DML No. 000017 (Formulation) for the approved sections. 2. **The renewal of section for manufacturing Aerosol (HFA based MDI's) may not be considered as per request of the firm.** 3. The transfer of registrations of Liquid Injectable products from West Wharf side to Korangi Site be expedited.			

	4. The firm may also be directed to establish dedicated section for Eye Ointment manufacturing as per revised layout plan. 5. **Authentication/regularization of the master layout plan may kindly be made after successful changes in the layout as proposed by the panel and completion by the same.** **Decision of the Central Licensing Board in 264th meeting** The Central Licensing Board considered and deferred the case for personal hearing in next meeting of the Board for seeking clarification on the observations of the members of the panel of experts.

The firm is called for personal hearing vide letter dated 31st July, 2018.

Proceedings and Decision of Central Licensing Board in 265th meeting

Dr. Gohar Nayyab (Director Regualtory Affairs) and Mr. Gohar Siddique of the firm appeared before the Board. The Board considering the facts on record decided to defer the case for renewal of DML till compliance of the recommendations of the panel of experts.. Furthermore, the Board did not acceded the request of the firm regarding withdrawal of section for manufacturing Aerosol (HFA based MDI's).

Case No. 6 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ALFALAH PHARMA (PVT) LTD, 12-KM, SHEIKHUPURA ROAD, LAHORE

M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore had applied for renewal of DML No. 000461 by way of formulation on 30-08-2017 for the period of 05-08-2017 to 04-08-2022.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 19th October, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Due date of renewal application is 04-08-2017 and renewal application was received on 30-08-2017 which is 26 days late. According to Rule 6 of drugs (L, R&A) rule 1976 the additional surcharge 5,000/- each day and total Rs. 130,000/- = (26x5000) should be deposited.
2. Nothing due certificate regarding CRF from STO (Updated).
3. Approved Master layout plan.
4. Approval letters of all sections issued by the Central Licensing Board.
5. Complete set of documents for Proposed Production Incharge and Quality Control Incharge as (per check list) alongwith prescribe fee of Rs. 10,000/- for change of technical staff.
6. Duly attested copy of shares transfer deed.
7. Duly attested CNIC copies of previous directors.
8. Duly attested NOC from previous management.
9. **All documents should be duly attested.**

The firm submitted documents on 07th November, 2017 but following documents were still deficient /short and Final Reminder was issued on 12th January, 2018 to the firm with following shortcomings: -

1. Nothing due certificate regarding CRF form STO (Updated).
2. Form-29 for year 2017 duly attested by S.E.C.P.
3. CNIC copies of all Directors.
4. CNIC copies of Proposed Production Incharge and Quality Control Incharge.
5. Resignation/ retirement letters of earlier Production Incharge and Quality Control Incharge.
6. Undertaking as whole time employee on Stamp Paper.
7. All documents should be duly attested.

The firm submitted documents on 26th January, 2018 in reply to Final Reminder. Upon Evaluation following shortcoming has been observed and application for renewal of DML is **still incomplete**

1. Nothing due certificate regarding CRF form STO (Updated).
2. Updated Form-29 for year 2017 duly attested by S.E.C.P.
3. Undertaking as whole time employee on Stamp Paper of proposed Production Incharge and Quality Control Incharge.

Proceedings and Decision of Central Licensing Board in 259th 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 Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore, Drug Manufacturing Licence No. 000461 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 27th April, 2018 was issued to the M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore.

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

i) Updated Nothing due certificate regarding CRF from STO**.**
ii) Updated Form-29 for year 2017 duly attested by S.E.C.P.

A letter of Personal hearing has been issued on 02nd August, 2018.

Proceedings and Decision of Central Licensing Board in 265th meeting

Mr. Yasir Gulzar (Quality Assurance Manager), Mr. Bilal Zamir (Quality Control Manager) and Haji Abdul Rashid (CEO) of the firm appeared before the Central Licensing Board and presented

documents which were considered and found complete. He also contended that requirements has been completed and show cuase issued to him may be recalled. The Board after hearing the representative of the firm decided to revoke the show cause notice with the warning to the firm to be careful in future for compliance of Law.

Case No. 7 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S RUKHA PHARMACEUTICAL LABORATOIRES (PVT) LTD, LAHORE**

M/s Rukha Pharmaceutical Laboratories (Pvt) Ltd, Plot No. 537-D&E, Sunder Industrial Estate, Raiwind Road, Lahore had applied for renewal of DML No. 000753 by way of formulation for the period of 12-09-2017 to 11-09-2022 on 30-08-2017.

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 3rd October, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form-29 duly attested from S.E.C.P (Updated)
2. Detail of management at the time of previous renewal of DML and at present Renewal alongwith copies of CNIC of all Directors.
3. Nothing due certificate regarding CRF from STO (Updated).
4. All documents should be duly attested.

The firm submitted their reply on 17th October, 2017.After evaluation of the submitted documents, Final reminder was issued on 08th November, 2017 to the firm with following shortcomings: -

1. Prescribed fee of Rs. 50,000/- for change of management / directors as it seems management is changed from last renewal till at present renewal.
2. Form-29 duly attested from S.E.C.P (Updated) alongwith CNIC copies of all Director.
3. Nothing due certificate regarding CRF from STO (Updated).
4. **All documents should be duly attested.**

Firm submitted documents on 21st November, 2017 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 from STO (Updated).
ii. Form-29 duly attested from S.E.C.P for year 2017 alongwith CNIC copies of all Director.
iii. Copy of CNIC of appointee (Production Incharge).
iv. Undertaking as whole time employee on stamp paper (Production Incharge).
v. All documents should be duly attested.

Proceedings and Decision of Central Licensing Board in 259th 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 Rukha Pharmaceutical Laboratories (Pvt) Ltd, Plot No. 537-D&E, Sunder Industrial Estate, Raiwind Road, Drug Manufacturing Licence No. 000753 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 27th April, 2018 was issued to the M/s Rukha Pharmaceutical Laboratories (Pvt) Ltd, Plot No. 537-D&E, Sunder Industrial Estate, Raiwind Road, Lahore.

The firm has submitted the documents in reply of the show cause notice. Application for renewal of DML is complete however, Form-29 issued by SECP is not certified true copy due to a pending Court case and only issued on the request of the firm and the matter of change of management is sub-judice and pending in SECP.

A letter of Personal hearing has been issued on 02nd August, 2018.

Proceedings and Decision of Central Licensing Board in 265th meeting

Mr. Abdul Sattar Bajwa (Production Incharge) and Mrs. Rukha Rafique (Director) of the firm appeared before the Central Licensing Board and presented documents and requested for giving one month time for submission of documents. However, the Board after scrutiny of the documents directed the firm to submit certified copies of the same at the earliest. The Board after hearing the representative of the firm decided to defer the case till next meeting of Central Licensing Board.

Case No. 8 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S OVAL PHARMACEUTICALS , LAHORE.

M/s Oval Pharmaceuticals, 112/111, Quaid-e-Azam Industrial Estate, Town Ship, Lahore had applied for renewal of DML No. 000156 by way of Formulation for the period of 21-07-2014 to 20-07-2019 on 22-07-2014.

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 17thOctober, 2014 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Your application for renewal of Drug Manufacturing License was received in this office on 25-07-2014 and copy of challan receipt of prescribed fee for renewal has been retained by STO, DRAP, Islamabad on 22-07-2014, hence date of receiving of your application in this Division is 22-07-2014. Therefore, under Rule 6 of Drugs (licensing, Registering & Advertising) Rules, 1976, you are required to deposit additional surcharge of Rs. 10,000/- for submitting renewal application delayed by two days from due date of renewal i.e. 20-07-2014.

2. To enlist the re-packing products and to deposit prescribed fee of Rs. 5,000/- for each product of re-packing for purpose of renewal.
3. Documents of production Incharge Mr. Ifthikhaar Hussain and Q.C Incharge Mr. Shoaib Hussain as per checklist enclosed herewith. **All documents / information should be attested by gazette officer / notary public and also signed and stamp by authorized Director / Owner of the firm.**
4. Nothing Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of Central Research Fund up to 31-12-2014.

The firm replied to this letter on 26th November2014 but application was incomplete with following shortcomings and reminder letter was issued on 14th June, 2017 to the firm for completion of application:

1. Form C/D from registrar of firm for any change partnership / management of firm along with details of previous and new management along with requisite fee for change of management if any (attested).
2. N.O.C for CRF Attested.
3. Proof of all licensed/approved sections (Attested).

The firm submitted documents on 27th July, 2017 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Updated Nothing due certificate for CRF.
ii. Copy of approved master layout plan.
iii. Proof of CLB approved sections.
iv. Detail of management at the time of previous renewal and at present & if any change, prescribe fee of Rs. 50,000/- along with proper application for change of management.
v. Duly attested copy of Partnership deed along with CNIC copies of all partners.

Proceedings and Decision of Central Licensing Board in 262nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Oval Pharmaceuticals, 112/111, Quaid-e-Azam Industrial Estate, Town Ship, Lahore under DML No. 000156 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 21st June, 2018 was issued to the M/s Oval Pharmaceuticals, 112/111, Quaid-e-Azam Industrial Estate, Town Ship, Lahore.

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

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

ii) CNIC copy of Ch. Muhammad Iqbal.

A letter of Personal hearing has been issued on 02nd August, 2018.

Proceedings and Decision of Central Licensing Board in 265th meeting

Mr. Muhammad Mazhar (Quality Control Incharge) and Mr. Tahir Mehmood (CEO) of the firm appeared before the Central Licensing Board and presented documents and requested for giving one month time for submission of documents. However, the Board after scrutiny of the documents directed the firm to submit certified copies of the same at the earliest. The Board after hearing the representative of the firm decided to defer the case till next meeting of Central Licensing Board.

Case No. 9 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HANSEL PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Hansel Pharmaceuticals (Pvt) Ltd, Plot No. 2, Pharma City, 30-Km, Multan Road, Lahore had applied for renewal of DML No. 000581 by way of Formulation for the period of 24-06-2015 to 23-06-2020 on 19-05-2015.

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 9thNovember, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Details of premises including L.O.P.
2. Form – 29 from S.E.C.P along with attested copies of CNIC and affidavit regarding any change from previous renewal.
3. Approval letter of Q.C & Production manager or documents for approval.

The firm replied to this letter on 19th December 2016. Meanwhile, the firm had filed application for approval of Quality Control Incharge. Final Reminder letter was issued on 16th March, 2018 to the firm for submission of following documents.

1. Detail of management at the time of previous renewal and at present renewal, if any change, prescribed fee of Rs.50, 000/- for change in management.
2. Updated Form-29 duly attested from S.E.C.P.
3. Nothing due certificate regarding CRF from STO (updated).
4. Proof of all sections issued by Central Licensing Board.
5. Approval letter of Production Incharge, if and change then complete set of duly attested documents for Proposed Production Incharge (as per checklist).
6. Experience Certificate ofQuality Control Incharge from Hoover Pharmaceutical.
7. Copy of CNIC of proposed Quality Control Incharge.
8. **All documents should be duly attested.**

The firm submitted documents on 16th April, 2018 in reply to Final Reminder but following application for renewal of DML is still incomplete with following documents being deficient.

i. Submitted documents of Production Incharge are not duly attested.
ii. Resignation / retirement of earlier Production Incharge is not provided.
iii. Form-29 not attested from S.E.C.P.

Proceedings and Decision of Central Licensing Board in 262nd 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 Hansel Pharmaceuticals (Pvt) Ltd, Plot NO. 2, Pharma City, 30-Km, Multan Road, Lahore under DML No. 000581 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 21st June, 2018 was issued to the M/s Hansel Pharmaceuticals (Pvt) Ltd, Plot No. 2, Pharma City, 30-Km, Multan Road, Lahore

The firm has submitted the documents in reply of the show cause notice. Application for renewal of DML is complete now.

A letter of Personal hearing has been issued on 02nd August, 2018.

Proceedings and Decision of Central Licensing Board in 265th meeting

Ch. Liaqat Ali appeared before the Central Licensing Board. They contended that requirements has been completed and show cause issued to the firm may be recalled. The Borad after hearing the representatives of the firm decided to revoke the show cause notice with the warning to the firm to be careful in future for compliance of Law.

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 received from the firm. Final Reminder letter was issued on 10th January, 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 /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.

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 30th October, 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 20th November, 2017.After evaluation of the submitted documents, Final reminder was issued on 04th January, 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 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 Avicenna 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.

Case No. 12 M/s Mediways International, Lahore

Background:-

M/s Mediways International, Multan Road, Lahore was inspected on 09.02.2015 by Mr. Ajmal Sohail Asif, FID Lahore to see/verify the GMP compliance. During inspection the FID pointed out a number of serious shortcomings and gross violations including the following:-

Change Rooms:

- Air curtains were installed but were not functional at the time of inspection.
- No Separate change room was provided for visitors or executives.
- Change rooms were very small and need to be reorganized in respect of outside doors.
- The firm was also advised to provide cabinets in the change rooms for keeping the workers belongings etc.
- It was also noticed that at the time of inspection the change rooms were not maintained and were not neat and clean.

Storage Areas:

- Quarantine area not properly demarcated and separated from the de-dusting area.
- The firm has provided a dispensing hood which was placed in the raw material store for recipients. But it seemed not to be in use, since there were no accessories like balance, scoops etc inside the dispensing booth.
- Balances and other accessories for dispensing were available on one of the racks of raw materials.
- No separate facility for sampling of the materials was available; the firm was advised to provide proper sampling facility.
- The firm was also advised to rearrange the placement of dispensing hood providing separate cabin and proper flow of pre and post dispensed materials
- However packing material store was congested the firm was advised to expand the storage area for packing materials.

Production Areas:

- HVAC was not functional at the time of inspection due to load shedding as informed by management of the firm.
- The firm was advised to partition this room for separation of de-cartooning and bottle blowing functions.
- It was also noticed that all the doors in production area were wooden and the firm was advised to replace all the wooden doors.

Quality Control Laboratory:

- It was noticed that QC lab was accessed through the de-dusting/ quarantine area of raw material store; the firm was advised to provide some other entrance to QC laboratory in order to avoid unnecessary movements QC of staff in stores.

Quality Assurance:

- During the last inspection the firm has presented a QA officer but at the time of this inspection no QA personnel was present.
- From ware houses to production and quality control no prevalence/involvement of quality assurance was observed.
- The management of the firm was also advised during previous inspection to strengthen the QA department but no improvement was seen in this department.
- Due to lack of QA system, deviations from SOPs, GMP, GSP etc, were observed in stores, manufacturing areas and quality control.
- Non existence of an independent check and balance system may result in compromises, by manufacturing and QC personnel, for routine deviations from practices and procedures. Such a situation may pose a great potential of compromises on overall quality of the products being manufactured.

Sanitation and Hygiene:

- The equipments in QA laboratory and different gauges, matters and equipment in manufacturing areas were not calibrated.
- There was no system for qualification and validation of machines, procedures and practices.
- The firm has no procedures for cleaning validation and was advised to develop.

Products Recalls:

- The firm was advised to assign a separate area for recall products and demark it well

Self Inspection and Quality Audit:

- No record was available for any audit.

Personnel:

- However, there was no technical person to look after the QA.
- The firm was advised to establish proper QA department and to hire appropriate personnel to strengthen the QA

Training:

- However, It was not being implemented as no record was available

Equipment & Machinery:

- However, the firm was advised to upgrade the syrup filling machine.
- The machines/equipments were not properly labeled regarding the status.
- However, the firm was advised to purchase the FTIR on priority basis.

Materials:

- The firm was advised to purchase the materials from manufacturers or authorized suppliers.

- The firm was also advised to conduct vendor qualification.
- The firm has not developed a proper material management system.
- The materials were not properly labeled.
- The firm was advised to affix the label on each and every container / bag of a lot of material.
- The firm was also advised to develop and implement the procedures for safety and security of the workers/personnel handling the materials in stores and also to mark the racks and allocate locations of the materials.
- In packing materials store the firm was advised for safe storage of printed materials and unit cartons under lock and key.

Documentation:

- It was found that some of the SOPs and BMRs needed review, improvement and updating regarding the actual practices.
- The log books for QC equipment were not maintained.
- The firm was advised to prepare procedure for OOS, cleaning validation etc.

Good Practices in Production:

- In general the practices were observed not to be in accordance with the prescribed procedures.
- The firm was asked to present the BMR for the last batch of a product namely "Antizile Syrup" but the management failed to produce any documentation.

Good Practices in Quality Control:

- There were procedures for QC analysis but they needed to be updated.
- The log books for instruments and equipments were not maintained.
- In general the practices were observed not to be in accordance with the prescribed procedures.

Utilities

Water Purification System:

- The firm was advised to install transfer pipes for supply of purified water to manufacturing area to minimize the exposure to external environment during manual transfer.

HVAC System:

- The firm was advised to repair the manometer so that the pressure gradients in buffer and manufacturing areas may be checked.

The FID further concluded that: The non compliant behavior of the firm towards advises made during previous panel inspection; the firm was considered to be operating at unsatisfactory level of the compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under.

Action Taken by DRAP: - Accordingly, a show cause notice and suspension of production order in all section was issued to the firm on 20.03.2015 with immediate effect.

Reply of the firm: - In response to show cause notice the firm vide letter No. Nil dated 15.06.2015 submitted their reply and requested to verify the shortcomings through area FID.

Proceedings of 245th meeting of CLB held on 30.12.2015

Mr. Jamil Ahmad, CEO of the firm appears before the Board. He informed that the observations given by the FID were given attention and most of the observations have been rectified and compliance report was also submitted. The firm is ready for inspection.

Decision of 245th meeting of CLB held on 30.12.2015

The case was placed before the Central Licensing Board for consideration. The Board after thorough discussion, keeping in view the available record, compliance report and request from CEO of the firm, decided to conduct panel cGMP inspection of the firm, on approved Schedule B-II cGMP format and panel will also submit report in tabulated form identifying the previous observations and the current status, by the following members:-

i. Dr. Ikram ul Haq, Member, CLB
ii. Dr. Zaka ur Rehman, Member, CLB
iii. Mr. Ajmal Sohail Asif, Area FID.

Accordingly decision of 245th meeting of CLB was conveyed to the firm on 10.02.2016

Letter of Secretary PQCB, Lahore:-

Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab informed that Deputy Drug Controller Allama Iqbal Town Lahore alongwith other members inspected the premises on 16.06.2016. The team observed that:-

i. Manufacturing of Drugs was being carried out under unhygienic conditions.
ii. Improper storage of drugs (at 40 degree Centigrade).
iii. Illegal or unauthorized import of raw materials without label (misbranded).

The case was placed in 249th meeting of CLB held on 29.08.2016.

Proceedings of the 249th meeting of CLB

The Board was informed that Mr. Ajmal Sohail Asif, FID conducted inspection of the firm on 09.02.2015. The firm was issued order for suspension of production activities and issued showcause notice / Suspension of production order No.F.4-4/2001-QA on 20.03.2015. Accordingly, the case was discussed in 245th Meeting of CLB, wherein the CLB had constituted following panel of experts to verify the improvements:-

a. Dr. Ikram ul Haq
b. Dr. Zaka ur Rehman
c. Mr. Ajmal Sohail Asif

Inspection report of the firm is still awaited. The Board also discussed and evaluated the reports / cases forwarded by the Secretary, PQCB, Punjab, Lahore and Chief Drug Controller, Punjab for cancellation / suspension of DML of the firm M/s Mediways, Lahore. The Board also consider sub Rule 3 of Rule 5 of Punjab Drugs Rules, 2007 which categorically stated 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."

Decision of the 249th Meeting of CLB

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 took a serious notice on illegal / unauthorized manufacturing and violation of the orders of the DRAP's letter No. No.F.4-4/2001-QA dated 20.03.2015. The Board decided to issue a showcause notice to the firm M/s Mediways, Lahore on illegal / unauthorized production activities and disobeying the orders of DRAP.

Accordingly showcause notice was issued to the firm on 03.10.2016.

Proceedings of the 250th Meeting of CLB

Mr. Jamil Ahmed, Chief Executive of the firm M/s Mediways International, Lahore appeared before the Board for personal hearing. He informed that the production is suspended since March, 2015, as per direction of the Division of QA&LT. The provincial government during the raid sealed the premises, which was later on de-sealed on the order of the Drug Court, Lahore. He also informed that inspection book is also in the custody of provincial drug inspector, which has not been handed over to him till date, despite number of requests. Dr. Ikram ul Haq, Member CLB informed the Board that he along-with other members of the panel visited the firm, in compliance to decision of 245th Meeting of CLB, but the firm was found closed and the inspection could not be carried out.

Decision of the 250th Meeting of CLB

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

i. Suspend the Drug Manufacturing License of the firm M/s Mediways International, Lahore for a period of six months under Section 41 of the Drugs Act, 1976 read with Rule 12 (1) of the Drugs (LR&A) Rules, 1976.
ii. Direct the area FID to visit the firm on alternate months to verify the suspension of production and submit report.
iii. Resumption of production shall only be allowed after completion of suspension of DML period, verification by the panel of experts and subsequent approval from the Competent Authority.

Updated status:-

The panel constituted by the Director QA&LT conducted inspection of the firm on 26.12.2017 (received on 17.04.2018). The panel submitted detailed inspection report including previous observations and updated status on Schedule B-II format and recommended as under:-

"Based on the areas inspected, the people met and the documents reviewed, and considering the finding of the inspection in comparison with the observations of the previous inspection, the panel of inspectors does not consider the firm to be at a satisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under. The plot size is smaller than the prescribed requirement. However, CLB in its 241st meeting held on 15.5.2015 decide "to allow two years time for shifting of unit / enhancement of plot size according to rules"; and that two years period. Therefore, the panel of inspectors does not recommend M/s Mediways International, 16KM Multan Road, Lahore, for resumption of production. The report is forwarded herewith for further consideration and necessary action".

Proceedings of the 261st meeting of the CLB

The case was placed before the board for appraisal in the light of recommendations of the panel of experts in its report dated 26.12.2017.

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 26.12.2017, the Central Licensing Board decided to:-

i. Further extend Suspension of DML period for next six months from the date of issuance of decision of 261st meeting of CLB.
ii. The Licensing Division Shall place the case in forthcoming meeting of CLB in the light of decision of 241st meeting of CLB.

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

The Central Licensing Board in its 241st meeting held on 15th May, 2015 has considered the case of M/S Mediways International, Lahore and decided as under:

- *"To allow two years time for shifting of unit / enhancement of plot size according to the rules.*
- *To scrutinize the application of the renewal of DML of the firm for the period 09-02-2015 to 09-02-2020 and inform the applicant the status of the application according to Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rules 1976 and conduct inspection of the firm after completion of application of renewal of DML."*

The same decision was conveyed to the firm vide letter issued on 24th August, 2015 but till date no application is received from the firm for shifting of their existing facility and application for renewal of DML No. 000468 (Formulation) for period of 09-02-2015 to 08-02-2020 is incomplete with following documents being deficient:

i. Nothing due certificate regarding CRF (Updated).

ii. Approval letters of Production Incharge and Quality Control Incharge, if not approved, complete set of duly attested documents (as per checklist) of qualified staff alongwith prescribed fee of Rs.10,000/-
iii. Detail of management at the time of previous renewal and at present renewal, if any change, prescribed fee of Rs.50, 000/- for change in management.
iv. CNIC copies of owner/partners.
v. Proof of CLB approved sections.
vi. Legal status of the firm.

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, Schedule B-II and Rule 20 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Mediways International, Multan Road, Lahore, under Drug Manufacturing Licence No. 000468 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

CASE NO.13 CHANGE OF TITLE / NAME / LEGAL STATUS M/S TAYYAB LABORATORIES (PVT) LTD, RAWALPINDI.

M/s Tayyab Laboratories (Pvt) Ltd., Plot No. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi under DML No. 000846 by way of (Formulation) has submitted request for change of title / name / legal status of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Title / name / legal status of firm	**Proposed title / name / legal status of Firm as per Certificate of incorporation of S.E.C.P**
M/s Tayyab Laboratories (Pvt) Ltd., Plot No. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi.	M/s Arreta Pharmaceuticals (Pvt) Ltd., Plot No. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi

Proceedings and Decision of Central Licensing Board in 265th meeting

The Board considered and approved the change of title of M/s Tayyab Laboratories (Pvt) Ltd, Plot No. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi under Drug Manufacturing License No. 000846 by way of Formulation as per **Certificate of incorporation of S.E.C.P** as under:

Previous Title / name / legal status of firm	**New title / name / legal status of Firm as per Certificate of incorporation of S.E.C.P**
M/s Tayyab Laboratories (Pvt) Ltd., Plot No. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi.	M/s Arreta Pharmaceuticals (Pvt) Ltd., Plot No. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi

Case No.14 WITHDRAWAL OF TABLET (HORMONE) SECTION OF M/S WEATHER FOLDS PHARMACEUTICALS, HATTAR.

M/s Weather Folds Pharmaceuticals, 69/2, Phase-II, Industrial Area, Hattar, has applied for withdrawal of Tablet (Hormone) Section which was approved in 255th meeting of CLB held on 16th-17th August, 2017.

Proceedings and Decision of Central Licensing Board in 265th meeting

The Board considered and acceded the request of M/s Weather Folds Pharmaceuticals, 69/2, Phase-II, Industrial Area, Hattar. The Board also desired that Drug Registration Board may also be informed.

Case No. 15 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FRIENDS PHARMA (PVT) LTD, LAHORE

M/s Friends Pharma (Pvt) Ltd, 31-Km, Ferozepur Road, Lahore had applied for renewal of DML No. 000531 by way of formulation for the period of 27-01-2014 to 26-01-2019 on 30-01-2014.

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 28th May, 2014 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

I. Your application for renewal of DML was received in this office on 30-01-2014 and the challan of prescribed fee for renewal was also retained from STO, DRAP on 30-01-2014.Therefore, your application is delayed by 04 days from the due date for renewal i.e 26-01-2014.Therefore, you are now required to submit additional surcharge of Rs. 20,000/- according to Rule 6 of Drugs (L,R&A) rules, 1976 for Rs.5000/- for each day application is delayed.

II. Updated copy of Nothing due certificate issued by STO, DRAP, regarding deposition of CRF up to 31-12-2014.

III. Attested photocopy of latest Form-29 issued by S.E.C.P within CNIC copies of all Directors as per Form-29.

IV. To provide names of qualified experts to be nominated on DML of your firm and also submit approval letters of qualified staff(if approved) otherwise to submit documents as per checklist enclosed herewith for the purpose of approval of proposed technical experts to be mentioned on DML of your firm.

The firm submitted their reply on 12th June, 2014. After evaluation of the submitted documents, again a letter was issued on 29th July, 2015 to the firm with following shortcomings: -

i. The proposed Production Incharge of the firm Mr. Muhammad Ashfaq does not fulfill the requirement of minimum 10 years of experience after academic qualification in the manufacturing of drugs as he completed B. Pharm in year 2008.Therefore, firm is required to appoint Production Incharge who shall possess minimum 10 years of experience in the relevant field after academic qualification as per Rule 16 of Drugs (L,R&A) rules, 1976.

ii. Following documents are required for completion of approval of proposed Q.C Incharge:

    i. Resignation letter/transfer letter/promotion letter of previous approved Q.C Incharge of the firm.

    ii. Undertaking signed by new appointed Q.C Incharge and owner of the firm stating that Mr. Meheryab is whole time employee of the firm and not working anywhere else.

iii. CNIC photocopies of Directors of the firm.

iv. Copy of master layout plan approved by the competent authority.

v. Letters of grant of all sections from Central Licensing Board.

vi. Status of production of registered psychotropic products.

The firm submitted their reply on 29th November, 2016. Meanwhile the firm filled an application for approval of Quality Control Incharge and Production Incharge. After evaluation of the submitted documents, a letter was issued on 04th December, 2017 to the firm with following shortcomings: -

i. Complete set of documents for proposed Quality Control Incharge (as per Checklist) along with prescribed fee Rs.5000/- for change of technical staff.

ii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of Production Incharge.

iii. Resignation / retirement of earlier Production Incharge.

iv. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm of Production Incharge.

v. Undertaking as whole time employee on Judiciary Paper of Production Incharge.

vi. All documents should be duly attested.

The firm submitted their reply on 28th December, 2017. After evaluation of the submitted documents, Final reminder was issued on 20th March, 2018 to the firm with following shortcomings: -

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

ii. Updated Form-29 duly attested from S.E.C.P.

iii. Detail of management at the time of previous renewal and at present renewal, if any change, prescribed fee of Rs.50, 000/- for change in management.

iv. CNIC copies of all Directors.

v. Experience certificates as under Drugs (Licensing, Registering and Advertising) rules, 1976 of Quality Control Incharge (Not less than 10 years)

vi. Copy of CNIC of proposed Quality Control Incharge.

vii. Resignation/retirement of earlier Quality Control Incharge and Production Incharge.

viii. Undertaking as whole time employee on stamp paper of proposed Production Incharge and Quality Control Incharge.

ix. All documents should be duly attested.

Firm submitted documents on 24th April, 2018 in reply to Final Reminder but following documents are still deficient /short and application for renewal of DML is still incomplete.

i. Updated Form-29 duly attested from S.E.C.P.
ii. Detail of management at the time of previous renewal and at present renewal, if any change, prescribed fee of Rs.50, 000/- for change in management.
iii. Experience certificates as under Drugs (L, R&A) rules, 1976 (Not less than 10 years) for proposed Quality Control Incharge.
iv. Legible/readable Copy of CNIC of proposed Quality Control Incharge.
v. Resignation/retirement of earlier Production Incharge.
vi. Undertaking as whole time employee on stamp paper of proposed Production Incharge and Quality Control Incharge duly signed by appointee and management.
vii. All documents should be duly attested.

In the meanwhile, the firm has submitted promotion letter of new proposed Production Incharge Ms. Shabana but the remaining documents for approval have not been provided by the firm. The firm has also stated that their proposed Q.C Incharge possess more than ten years experience but as per experience certificates available in Licensing Division, proposed Q.C Incharge has approximately 8years and 7 months experience and same was conveyed to the firm vide letter dated 20th March, 2018. The firm was asked vide letter dated 26th July,2018 to apply for approval of new Production Incharge and submit her complete set of duly attested documents (as per checklist).

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 Friends Pharma (Pvt) Ltd, 31-Km, Ferozepur Road, Lahore, under Drug Manufacturing Licence No. 000531 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 16 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.

Case No. 17. CHANGE OF MANAGEMENT OF M/S MEDICURE LABORATORIES, KARACHI

The Central Licensing Board in its 259th meeting held on 29th & 30th March, 2018, has considered and endorsed the change of management from old to new management of M/s Medicure Laboratories, F/109, S.I.T.E, Hub River Road, Karachi, DML No. 000034 by way of (Formulation) as per partnership deed as under:-

Previous management	Retiring Management	New Management
1. Mr. Shah Mir Hussain S/o Qalandar Shah CNIC No. 42201-0988780-5. 2. Mr. Shabbir Hussain Shah S/o Shah Mir Hussain CNIC No. 42201-5104958-5. 3. Ms. Naushaba Qaisar W/o Qaisar Kamal CNIC No. 42101-2230486-0.	1. Mr. Shah Mir Hussain S/o Qalandar Shah CNIC No. 42201-0988780-5.	1. Mr. Shabbir Hussain Shah S/o Shah Mir Hussain CNIC No. 42201-5104958-5. 2. Ms. Naushaba Qaisar W/o Qaisar Kamal CNIC No. 42101-2230486-0.

In the mean while a letter dated 26-07-2018 is received from Ms. Sana Shahmir pertaining to be the daughter of Mr. Shahmir Hussain (previous partner) in which she has stated that her step brother Mr. Shabbir Hussain Shah has illegally occupied M/s. Medicure Laboratories F/109, S.I.T.E. Karachi and she has also requested that factory must be closed till the decision of the court but the copy of any court order in this regard is not attached.

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 advise Ms. Sana Shahmir to approach Court of competent Jurisdiction for redressal of grievances.

Case No. 18. <u>CONSIDERATION OF BIOCHEMISTS FOR APPROVAL AS QUALITY CONTROL INCHARGE.</u>

<u>Case Background</u>

Mr. Jehangir Alam was proposed as Quality Control Incharge by the M/s Pak Risen Pharmaceuticals, Hattar but application was rejected by the Licensing Division on the basis that he does not fulfill the requirement of Rule 16(e) of Drugs (L,R&A) Rules, 1976 in terms of qualification as he holds the degree of BS (Hons) in Biochemistry.

Now, Mr. Jehangir Alam, Assistant Quality Control Manager, M/s Pak Risen Pharmaceuticals, Hattar has requested to consider Biochemists for approval as Quality Control Incharge as under;

> *"It is stated with great concern that I am a Biochemist and I am associated with Pharmaceutical Industry for about 10 years. I have worked as Quality Control Incharge (DRA approved) for about 04 years. Recently I have applied for the post of Quality Control Incharge from PakRisen Pharmaceuticals but my case was declared rejected as I was found deficient on Rule 16(e) of Drug Act 1976 (i.e degree of Biochemistry was not considered as a branch of chemistry).*
>
> *I have discussed this matter with honorable Dr. Manzoor Bozdar Sahib and Shaikh Faqeer Muhammad Sahib and they both respectable dignities directed me to consult HEC for a clarification note on Biochemistry as a branch of chemistry So, I did accordingly and submitted my application to HEC.*
>
> *The panel of curriculum board immediately responded in positive and declared Bio-chemistry a one of the main five branches of chemistry and more over they (HEC) enquired my need for this clarification so I wrote about the rules of DRAP 16(e). They had gone through my case in detail and released a detail clarification note on **"Biochemistry as one of the main branch of chemistry"**. (Copy of Declaration note attached)*
>
> *Honorable sir, I am working as assistant quality control manger despite of all my experience of pharmaceutical laboratory. Our biochemist friends of India and Philippines are working as quality control Incharge without any objection in their respective authorities.*
>
> *We request honorable DRAP to consider (Biochemists) for Quality Control Incharge. The course outline of biochemistry suggests that it is the most closest and appropriate branch of chemistry for pharmaceutical laboratory."*
>
> **<u>CLARIFICATION BY HEC</u>**

"It is hereby to inform you that your case was forwarded to our expert for comments/reply. The reply from expert is reproduced below;

i. *Biochemistry is one of the five branches of Chemistry.*
ii. *Pharmacology is the branch of Biochemistry.*
iii. *Physical Chemistry and two subjects of organic Chemistry were taught compulsory in BS Biochemistry and are evident from the mark sheet of applicant.*
iv. *Subject of analytical techniques was taught in the degree under heading Biochemical Techniques in which Homogenization, Centrifugation, Spectrophotometry, Chromatography, Gas Chromatography, HPLC, IR, Atomic Absorption, Electrophoresis and other chemical techniques are extensively studies using chemical, pharmaceutical and biological samples.*
v. *Other techniques like density, viscosity, pH and titrations and drug quantity determinations are the part of studies in the degree.*
vi. ***That BS Biochemistry fulfill the requirement of Rule 16(e) of Drugs (Licensing, Registering and Advertising) Rules, 1976 in terms of qualification.***

Therefore, based on the above observations, it is to informed that Biochemistry is a branch of Chemistry and falls in domain of Chemistry under Drugs Rule 1976."

Proceedings and Decision of Central Licensing Board in 257th meeting

Deferred for detailed working regarding the subject being taught in different Universities.

Proceedings and Decision of Central Licensing Board in 265th meeting

The Board deliberated on the matter in detail and observed that there are some Universities imparting education in Biochemistry under the faculty of Chemistry while some are imparting under Biological Sciences. Therefore, the Board decided to continue granting approval for those candidates/ application who have education from faculty of Chemistry. Moreover, it was also advised that proposal for amendments in the rules be made to cater growing specialities in fields and scope of Pharmacy.

Case No.19 RESTRUCTURING OF LICENSED PREMISES WITHOUT PRIOR APPROVAL FROM DRAP OF M/S LISKO PAKISTAN (PVT) LTD, KARACHI

A copy of letter is received from Mr. Kirshan, Assistant Director / Federal Inspector of Drugs, Karachi addressed to the Director M/s Lisko Pakistan (Pvt) Ltd, Karachi, wherein he has stated that as follow:-

"I am directed to inform you that the undersigned visited the premises (Lisko Pakistan (Private) Limited, L-10/D, Block-21, Federal "B" Industrial Area) on dated 26-10-2017 regarding the subject matter and as per telephonic discussion with you that the construction work for bottle store was undergoing on the first floor of the building without approval intimation to Area FID.

2. As per your statement, during the course of construction work, the roof of the floor fallen down due to overload on dated 24-10-2017 and eventually one of the labors died and the four injured.

3. During the visit the undersigned found the factory premises were sealed by Sindh Building Control Authority (SBCA) (annexure attached).

4. You are hereby directed to explain that why the permission was not taken from DRAP.

5. You are further directed that explain your position within 7 days of receipt of this office letter and intimate the DRAP for approval before resuming the activities in factory premises".

Proceedings and Decision of Central Licensing Board in 256th 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, 19 and Rule 20 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug Manufacturing Licence No. 000520 of M/s Qintar Pharmaceuticals (Pvt) Ltd, 14-A, Punjab Small Industrial Estate, Lahore Road, Sargodha by way of formulation may not be suspended or cancelled by Central Licensing Board.

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

In the aforesaid minutes of Central Licensing Board the name of the firm was inadvertently typed as M/s Qintar Pharmaceuticals (Pvt) Ltd, 14-A, Punjab Small Industrial Estate, Lahore Road, Sargodha under Drug Manufacturing Licence No. 000520 by way of formulation Instead of M/s Lisko Pakistan (Pvt) Ltd, L-10/D, Block-21, Federal "B" Industrial Area, Karachi under Drug Manufacturing Licence No. 000110 by way of formulation.

Proceedings and Decision of Central Licensing Board in 257th meeting

The Board approved the correction in decision of the 256th meeting of the Central Licensing Board and decision may be read as under:

"*The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 19 and Rule 20 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug Manufacturing Licence No. 000110, M/s Lisko Pakistan (Pvt) Ltd, L-10/D, Block-21, Federal "B" Industrial Area, Karachi by way of formulation 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 27th February, 2018 was issued to the M/s Lisko Pakistan (Pvt) Ltd, L-10/D, Block-21, Federal "B" Industrial Area, Karachi.

No reply of the show cause notice is received from the firm till date.

A letter of Personal hearing has been issued on 20th March, 2018.

Proceedings and Decision of Central Licensing Board in 259th meeting

Mr. Nazar Talib, Managing Director of the company appeared before the Board. He contended that lay out plan was approved by the Division of Licensing for first floor accordingly construction was being done. Roof of the newly built room was collapsed and incident happened. He argued that there was no un-authorised construction as reported by the Federal Inspector of Drugs. He also submitted approval letter from Licensing Division for layout plan approval for said section. He also argued that Sindh Building Control Authority has initially sealed the premises and de-sealed it after investigations. He also informed that production is also carried out on the ground floor. The Board after hearing the representative of the firm and facts on record decided to revoke the show cause notice issued to the firm. The Board directed area federal Inspector of firm to submit updated report on premises with status as per Lay Out Plan.

The orders in light of said decision of the Central Licensing Board were issued vide letter Dated : 27-04-2018 regarding revoking of the said show cause notice along with the direction to area FID, Karachi to submit updated report on premises with status as per layout plan.

The Area FID, Karachi Mr. Sajjad Ahmed Abbasi has submitted updated report received on 20-06-2018. The report is reproduced as under :

a. The firm did present the copy of letter no.F.2-15/85-Lic (Vol-VI) dated 11th September, 2015 (approval of revised layout plan for expansion).

b. The construction work in first floor was started as per approved layout plan for expansion.

c. During time of visit, there was no any construction work in progress and the firm informed that the construction work has been stopped for time being.

d. The firm was advised to take additional safety measures for workers of the firm by organizing the material placed in first floor and pasting the necessary instructions / precautionary statements, for safety of workers.

Decision of the Central Licensing Board in 265th meeting

The Board considered and endorsed the report of area FID,Karachi.

Case No.20 M/s TRIGON PHARMACEUTICALS (PVT) LTD, LAHORE.

A copy of letter is received from Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab wherein he has informed that Provincial Quality Control Board has suspended the

Drug Manufacturing License of M/s Trigon Pharmaceuticals (Pvt) Ltd, Lahore, for 15 days vide ordered dated 31st May, 2018 based on the inspection report (i.e. Inspection conducted on dated 23rdMay, 2018) submitted by Drug inspector Industries, Ferozepur Road & Raiwind Road, Lahore. The Board further decided to re-inspect the factory premises after 15 days by Chief Drug Controller to evaluate CAPA and remedial measures taken by the firm for further necessary action.

Orders of the Provincial Quality Control Board, Punjab marked as **Annex-I**.

Decision of the Central Licensing Board in 265th meeting

The Board considered and deliberated the case in the light of orders of the PQCB, Punjab and legal provisions. The Board decided to seek updated report from PQCB.

Case No.21 REVOCATION OF SHOWCAUSE NOTICE

The Board considered and approved delegation of its power to Chairman, central Licensing Board for revocation of Show Cause Notice on completion of codal formalities on case to case basis and case shall be submitted before the Board for its concurrence and information.

Case No.22 APPROVAL OF TECNICAL STAFF

The Board considered and delegated the power for approval of technical staff to the Secretary, Central Licensing Board. During any leave period of the Secretary, Central Licensing Board any officer authorise by the Chairman, Central Licensing Board shall approve the technical staff.

QAUALITY ASSURANCE CASES

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

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.

Proceedings of the 265th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) presented the case before the Board in the light of the approval of competent Authority to place the case before the Board for taking decision.

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.

Case No. ii: M/S HIZAT PHARMA, PESHAWAR

Background of the case:

Mr. Muhammad Arif Chaudhary, FID, Peshawar on 26.04.2018 conducted inspection of M/s Hizat Pharmaceuticals, Peshawar to verify the GMP compliance and production activities.

The FID noticed following critical observations, which need urgent attention and rectification.

Observations

- No record of the humidity and temperature monitoring was found. They have not maintained the log books of the machine kept in different sections.

Storage Area

- The firm was advised to provide HVAC supply to control the humidity and temperature. No record of temperature and humidity was maintained. 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 the record was not up to date although QC released tags found placed on all the raw material but the date is not traceable in the QC lab.

Workers entrance

- The firm has set up separate change room for male and female workers but these areas required drastic improvements as no supply of air handling etc provided in change rooms of all sections.
- The firm is advised to improve the flooring and place 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 planning for using pet bottles for the syrup filling and they are directed to not change the primary packing without the approval of DRAP. The volume of Syrup

Mefudol B.No.737 was measured and advised to the management to adjacent 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 validated all the equipment in QC and production as per GMP requirements.

Self GMP inspection and quality audit

- The firm is advised to give technical training to the workers and technical staff on safety, security, personal hygiene, GMP compliance and firefighting. They are advised to give fire safety guideline to the 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 the firm has a stability testing chamber but the SOP are not satisfactory the stability chamber was out of order and it was not sufficient for their already registered products.
- The HPLC operator also needs training. The management is advised to appoint full time QA In-charge with sufficient experience.
- The management is advised to do the following things immediately:-
  i. Use of new bottles for syrup filling.
  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. Adaption of official testing methods.
  viii. Training of staff
  ix. Appointment of QA staff as per rules.

The FID further concluded that

The overall cGMP compliance is not satisfactory and the firm is directed to prepare a plan for the rectification of all the deficiencies mentioned at the earliest. They are further directed to immediately get the approval / validation of their layout plan from Licensing Division.

Action taken by DRAP:

Accordingly show cause notice / suspension of production activities was issued to the firm on 24.07.2018.

Reply by the firm: The firm submitted letter vide letter No. DRP/LIC/07/01 dated 31.07.2018 wherein they have informed that all the shortcomings have been rectified and requested to re-inspect the firm and wants to be heard in person.

Proceedings of the 265th meeting of the CLB

Dr. Hafsa Karam Elahi, Additional Director (QA-I) presented the case before the Board. Mr. Muhammad Tahir, Director of the firm M/s. Hizat Pharmaceuticals (Pvt) Ltd, Peshawar appeared before the Board.

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

i. Re-inspect the firm M/s. Hizat Pharmaceuticals (Pvt) Ltd, Peshawar by following panel of experts:-

   a. Dr. Jamshaid Ali Khan, Member CLB
   b. Additional Director, DRAP, Peshawar
   c. Area FID, Peshawar

ii. The panel shall submit the detailed inspection report on the prescribed schedule B-II format alongwith rectification status of the observations noted in the inspection conducted on 26.04.2018.

iii. The production shall remain suspended till recommendation of panel for the resumption of production and subsequent approval by the Central Licensing Board.

QUALITY CONTROL CASES

Case No. 01:-

Subject: **Requests for permission for prosecution in FIR No. 05/2018 at Police Station FIA, ACC, Islamabad**

The challan submitted by the I.O stated as under:

01. In continuation of already submitted incomplete challan dated 16.04.2018, it is reported that subject case are that Dr. Hafsa Karam Elahi, Additional Director (QA&LT-I), DRAP, Islamabad submitted a complaint vide letter No.F.14-14/2015-QC dated 06.03.2018 alleging there in that DRAP Inspection team alongwith FIA, Assistant Commissioner, Islamabad and NAB teams reached in front of M/s Everest Pharma, Plot No.124, Industrial Triangle, Kahuta Road, Islamabad at 11:00 a.m on the direction of Supreme Court of Pakistan in HRC case No.5845-G/2018, but the factory was found closed and main door was locked. DRAP team comprising of following DRAP officers (1) Dr. Hafsa Karam Elahi, Additional Director, QA&LT-I, Islamabad (2) Dr. Obaid Ullah, Director, PE&R, DRAP, Islamabad (3) Dr. Muhammad Fakhruddin Aamir, Additional Director, QA&LT-II, Islamabad (4) Mr. Abdul Sattar Sohrani, Deputy Director QC, Islamabad (5) Ch. Zeeshan Nazir, Deputy Director, QA, Islamabad (6) Dr. Ghazanfar Ali, Deputy Director, DRAP, Islamabad (7) Mr. Abdullah, Deputy Director, DRAP, Islamabad (8) Mr. Akhtar Abbas Khan, Deputy Director, Islamabad (9) Dr. Arslan, FID, Islamabad (10) Mr. Hassan Afzaal, FID, Islamabad. Accused Ch. Muhammad Usman asked someone to bring keys. Unknown person brought keys and opened the doors at 11:40 am. Detailed inspection of the manufacturing units was conducted. A large number of drugs were seized on Form-2 and some of the samples were also taken on Form-3 for test/analysis. During inspection following contraventions were identified and recorded on prescribed form and accused persons are involved in:- (a) Manufacturing and selling of unregistered drugs. (b) Manufacturing of Drugs with raw material smuggled/imported without approval of DRAP and without having import license. (c) Violation of GMP as prescribed under the rules. (d) Manufacturing of government property drugs without valid purchase orders. (e) The firm was manufacturing drugs in unhygienic conditions. Violating the conditions of license. (f) Manufacturing/storage of drugs without identifiable labels. (g) Unidentifiable raw material. (h) Expired raw materials. (i) Without master production record/batch manufacturing record. (j) Manufacturing of Drugs without approved technical persons responsible for manufacturing and testing of drugs. (k) Without Quality Control record and release certificates. All the recovered un-registered drugs, labels of unregistered and government property drugs, therapeutic goods and available records were listed and inventory was prepared and all these recoveries were witnessed by DRAP Officers mentioned above.

02. The owner Ch. Muhammad Usman and other persons have committed offence under Schedule II A (1) (a) (vii), A (1)(b) & A (1) (e) of DRAP Act, 2012 which is punishable under schedule III 1(a), 1 (c) & 2 (d) of the DRAP, Act, 2012. Manufacturing and selling of unregistered drugs and import of drugs without valid drug import license are cognizable offences under schedule IV of the DRAP, Act, 2012. Permission for registration of FIR against the accused persons have been granted by the Director Quality Assurance & Laboratory Testing, Drug Regulatory Authority of Pakistan (DRAP), Islamabad under the powers delegated by the Central Licensing Board established under the Drugs Act, 1976 vide letter No.F.14-14/2015-QC dated 06.03.2018. It was requested that FIR be registered against Ch. Muhammad Usman, Dr. Kamram Izhaar & Noor Muhammad Mahar, owner as well as Ch. Muhammad Usman, Production In-charge and Muhammad Ishtiaq, QC In-charge of M/s Everest Pharma, Plot No.124, Kahuta Road, Industrial Triangle, Islamabad for manufacturing and selling of unregistered drugs and import/smuggling of active pharmaceutical ingredients without import license and clearance from DRAP as required under DRAP Act, 2012 and rules framed thereunder and as per law. Resultantly after approval of competent authority case was registered against Ch. Muhammad Usman, Production In-charge/owner Dr. Kamran Izhaar owner, Noor Muhammad Mahar owner, and Muhammad Ishtiaq, QC Incharge of M/s Everest Pharma, Plot No.124, Kahuta Road, Industrial Triangle, Islamabad and others u/s 109 PPC r/w 23/27 Drug Act 1976.

03. The accused Dr. Kamran Izhar was arrested on 04.05.2018 in subject case and was sent to judicial custody on 07.05.2018. The other accused Noor Muhammad Mehar scored pre arrest bail on 08.05.2018 from Federal Drug Court Islamabad, joined investigation on 11.05.2018. The Court cancelled his pre arrest bail due to non appearance of Noor Muhammad Mehar in the Court. The complainant of the instant case nominated Dr. Kamran Izhar in subject case on the basis of form 1-A for renewal of Drugs manufacturing license (DML) of M/s Everest Pharmaceuticals submitted to DRAP, in this form Uzma Unis, the then (25.03.2014) GM of M/s Everest Pharmaceuticals entered name of Dr. Kamran Izhar as Proprietor/Director/Partner of this firm.

04. As regards the nomination of Noor Muhammad Mehar in the subject case, the complainant of this case has relied upon Writ Petition No.517/2018 filed by Dr. Noor Muhammad Mehar in Honorable Islamabad High Court, Islamabad. In this Writ Petition Dr. Noor Muhammad Mehar mentioned in Para 2 that “the petitioner is an eminent drug manufacturer in Pakistan carrying on business under the name and style Everest Pharmaceuticals and its place of business and factory is located at 124, Industrial Triangle, Kahuta Road, Islamabad. The drugs manufactured by the petitioner are duly registered with DRAP under a valid license issued by DRAP and drugs manufactured and are marked throughout Pakistan and are also exported to many foreign countries”.

05. After this on 17.05.2018 Babar Khan Federal Inspector of Drugs (FID), DRAP Islamabad produced certified copy of 256th minutes of registration board meeting of DRAP, according to these minutes Dr. Kamran Izhar attended this meeting as Director of M/s Everest Pharmaceuticals.

06. During course of investigation Director Licensing DRAP, member Estate CDA, Registrar of Companies SECP Islamabad, Registrar of Firms (ICT) Islamabad and Joint Sub-Registrar/Tehsildar Islamabad were requested to provide the details of ownership/partnership of M/s Everest Pharma, Plot No.124, Industrial Triangle, Kahuta Road, Islamabad as well as ownership of this property in the name of Ch. Muhammad Usman, Noor Muhammad Mehar and Dr. Kamran Izhaar Qureshi. In response to these requests, Deputy Registrar of Companies SECP Lahore vide letter No.ARL/1630 dated 25.04.2018 informed that "M/s Everest Pharmaceuticals (Private) Limited was incorporated with this office on 31 March 2009, Copies of Memorandum and Articles of Association alongwith Forms A for the years 2009, 2010 and 2011 with details of shareholding and directorship are available on record. The Company applied for being struck off under Section 439 of the Companies Ordinance, 1984 and was struck off on 09.10.2013."

07. The Deputy Director-II of Estate Management Directorate-II, CDA, Islamabad vide letter No.CDA/EM-40(262)/IM/93/1290 dated 09.05.2018 informed that *"as per record, Raja Muhammad Zahoor, Lessee of Plot No.124, Industrial Triangle Kahuta Road, Islamabad requested for issuance of NOC for transfter of lease-hold right in favor of Ch. Muhammad Usman s/o Zaheer Ahmed CNIC No.61101-7023927-7 issued on 17.07.2014* ***subject to provision of documents, but no documents received in this office up till now for change of title"***.

08. Raja Muhammad Zahoor, lessee of Plot No.124, Industrial Triangle Kahuta Road, Islamabad joined investigation and stated that "he was owner of plot No.124, Industrial Triangle, Kahuta Road, Islamabad which was transferred on his name on 17.06.2003.

09. Then Raja Muhammad Zahoor signed an agreement to sell with Dr. Kamran Izhaar Qureshi s/o Izhaar ul Haq Qureshi r/o House No.397-D Phase-V DHA, Lahore CNIC No.35202-2713085-5 vide agreement No.2432 dated 27.06.2013 for which they got NOC from CDA vide letter CDA/DEM-40(262)/IM/93-2307 dated 17.07.2014 after receiving all the amount, Dr. Kamran Izhaar Qureshi requested to transfer the ownership of the plot 124 Kahuta Triangle on the name of Ch. Muhammad Usman s/o Zaheer Ahmed on 08.08.2014. **Resultantly the ownership of plot 124 was transferred in the name of Ch. Muhammad Usman s/o Zaheer Ahmed on 08.08.2014 in Registrar Office Islamabad".**

10. Amir Naveed Industrial Development Officer, Directorate of Industries and Labour, ICT Islamabad joined the investigation and stated that

i. "according to partnership deed of the firm M/s Everest Pharma, Plot No.124, Industrial Triangle, Kahuta Road, Islamabad this firm is registered vide certificate of registration of firms No.RF/ICT/6685 of 2005 under Partnership Act 1932 in the name of

1) Sajjad Munir s/o Muhammad Munir r/o House No.26/197, Street Malik Sardar Ali Mohallah Tabbia Kakaziana, Sialkot.

2) Ch. Muhammad Usman s/o Zaheer Ahmed Ch. r/o 47 School Road F-6/2, Islamabad (Permanent r/o 86-G, Model Town Lahore).

3) Hassan Ahmed s/o S.A Ahmed r/o House No.248 Street No.84, G-11/3 Islamabad".

11. Mr. Manzoor Ali Bozdar Deputy Director Licensing DRAP joined the investigation and stated that "M/s Everest Pharma, Plot No.124, Industrial Triangle, Kahuta Road, Islamabad was granted manufacturing license No.000535 on 01.04.2004 and same was renewed on 01.04.2009. The firm could not provide latest attested copy of partnership deed for directors/partners which was also one of the reasons for their incomplete application and cancellation of Drug Manufacturing License (DML) of M/s Everest Pharma. Moreover, un-attested copies of previous partnership deed dated 12.08.2004 is available in the record. **Dr. Kamran Izhar Qureshi was mentioned as one of Directors/partners on form I-A (application for renewal of DML).**

12. However, as per record available with Licensing Division (DRAP) name of Mr. Noor Muhammad is not mentioned on any partnership deed or Form I-A. DRAP has nominated Dr. Kamran Izhar in subject case on the basis of Form I-A (application for renewal of DML) signed by Uzma Unis (the then General Manager of M/s Everest Pharma) in 2014 and attendance of Dr. Kamran Izhar as Director of M/s Everest Pharma in 256th Registration Board Meeting of DRAP.

13. Keeping in view above mentioned facts, as per record of Directorate of Industries and Labour, ICT Islamabad and other authorities discussed above, **Dr. Kamran Izhar Qureshi is not owner of firm M/s Everest Pharma, Plot No.124, Kahuta Road, Industrial Triangle, Islamabad** but he is mentioned as one of the directors/partners in form I-A (application for renewal of DML) signed by Uzma Unis (the then General Manager of M/s Everest Pharma) in 2014 and attendance of Dr. kamran Izhar as Director of M/s Everest Pharma in 256th Registration Board Meeting of DRAP.

Hence fate of Dr. Kamran Izhar Qureshi be decided by the competent court. Investigation is in progress. Interim Challan/Report U/S 173 Cr. P.C is submitted in competent court through Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan Islamabad to start prosecution of the instant case".

EVALUATION OF THE INCOMPLETE CHALLAN SUBMITTED BY IO, FIA, ISLAMABAD

The findings of the IO in the FIR no. 05/2018 u/s 173 Cr.P.C are not fair and just. He has placed Dr. Kamran Izhar Qurshi in column 2 of 173 Cr.P.C report which pertains to the

"name and address of person who have not been challaned/proclaimed offenders"

The findings of the IO, FIA are based on

i. **old certificate of registration of the firm in 2005, and**
ii. **SECP incorporation certificate of which was issued on 31-3-2009.**
iii. **The company applied for being struck off u/s 439 of the companies act, 1984 and was struck off on 9-10-2013.**
iv. **As per information provided by the Deputy Director-II of Estate Management Directorate-II, CDA, Islamabad vide letter No.CDA/EM-40(262)/IM/93/1290 dated 09.05.2018 wherein he has informed that *"as per record, Raja Muhammad Zahoor, Lessee of Plot No.124, Industrial Triangle Kahuta Road, Islamabad requested for issuance of NOC for transfter of lease-hold right in favor of Ch. Muhammad Usman s/o Zaheer Ahmed CNIC No.61101-7023927-7 issued on 17.07.2014*subject to provision of documents, but no documents received in this office up till now for change of title".**

The facts of the case already deliberated and finalized by the CLB has been overlooked/ignored by the IO, FIA which are as under:

1. The facts narrated by the IO in 173 Cr.P.C. report are old and are not relevant with the instant case registered on 06th March, 2018 vide FIR No. 05/2018. Both firm registration and company incorporation with SECP have been expired and not valid.
2. It is also pertinent to mention thataccused Dr. Kamran Izhar Qureshi is associated with M/s Everest Pharmaceuticals, Islamabad as partner before 27th June, 2013 wherein he made agreement to purchase the land from Raja Muhammad Zahoor lessee of CDA industrial plot number 124, Kahuta Triangle, Islamabad along with Chaudary Muhammad Usman.
3. The matter was already deliberated by the CLB in its 261st Meeting held on 02-05-2018 and decision is reproduced as underL:

"As per available records Dr. Kamran Izhar Qureshi has being involved in the offences committed by M/s Everest pharmaceuticals Islamabad. The record of the firm available with DRAP confirms that he is Director/partner of the firm on the basis of following grounds:-

a. **He has been nominated as Director/partner in the renewal application for the grant of license filed by M/s Everest pharmaceuticals Islamabad on prescribed Form-I.**
b. **Dr. Kamran Izhar Qureshi along with Ch. Usman principal accused appeared before the DRB as Director regarding the registration of ledisovir (Sofosbuvir 400mg and ledisovir 90mg) about observations of panel of inspection conducted on 09th December 2015 to verify to geniuses of stability data for Product registration.**
c. **Lease agreement submitted by M/s Everest Pharmaceuticasl Islamabad with the land lord of the property also confirms the partnership of the Dr. Kamran Izhar Qureshi as its partner/ Director.**
d. **Correspondence of Ch Muhammad Usman also confirmed the partnership of Kamran Izhar Qureshi in M/s Everest Pharmaceuticals Islamabad."**

4. That the Dr. Kamran Izhar Qureshi was present during the inspection of M/s Everest Pharmaceuticals, Islamabad on 14-03-2016 regarding verification of availability of un-registered drugs, wherein he has introduced himself as partner of the firm. The inspection was conducted by the following panel of inspectors, copy of inspection report is Annexed:
    i) Dr. Abdur Rashid, Deputy Director General (E&M), Islamabad/Chairman Quality Control, DRAP;
    ii) Dr. Muhamamd Fakhruddin Aamir, Federal Inspector of Drugs-I, Islamabad;
    iii) Mr. Atiq ul Bari, Assistant Drugs Controller, Islamabad.
5. The FID, Islamabad has requested as under:

"Considering the findings of the Investigation Officer (IO), there are some facts which are required to bring into the notice of the CLB.

Keeping in view the above mentioned facts/evidence available so far, the accused Dr. kamran Izhar Qureshi, one of the owner of M/s Everest Pharmaceuticals, Islamabad in connivance with other have been found guilty of offences under section 109 PPC, r/w Section 23, 27 of Drugs Act, 1976. Investigation is in progress.

It is therefore requested that the case may please be placed in forthcoming meeting of Central Licensing Board and permission for prosecution against the accused persons Dr. Kamran Izhar Qureshi may kindly be granted after fulfillment of codal formalities, who committed offence under **Schedule II A (1)(a)(vii), A(1)(b) & A(1)(e)of DRAP Act, 2012read with Section 23 of Drugs Act, 1976** which is punishable under **Schedule III(1)(c),(2)(d) & (4) of the DRAP Act, 2012 read with section 27 of the Drugs Act, 1976** and manufacturing/ selling of unregistered drugs and import of drugs without valid drug import license which is cognizable under schedule IV of DRAP Act, 2012. If approve interim challan/report u/s 173 Cr.PC may be submitted in competent court through Federal Inspector of Drugs, Islamabad/Public Prosecutor to start prosecution of the instant case."

6. The matter is submitted for consideration of the Central LIcensibg Board for the grant of permission for prosecution and to start with the trial of Dr. Kamran Izhar Qureshi as accused person in the Court of Competent jurisdiction.

Decision

The Central Licensing Board (CLB) considered the challan filed by the IO, FIA to the FID, Islamabad, complaint forwarded by the area FID, relevant records and evaluation report of the QA&LT Division and decided as under:

The Central Licensing Board (CLB) has already granted the permission for prosecution in its 261st Meeting held on 02-05-2018 against Dr. Kamran Izhar Queshi (Director/partner, M/s Everest Pharmaceuticals, Plot No.124, Industrial Triangle, Kahuta Road, Islamabad) in the court of competent jurisdiction and directed that Federal Inspector of Drugs may further proceed as per law.

Case No. 02

Subject: PERMISSION FOR SAFE CUSTODY OF STOCK (UN-REGISTERED DRUG) SEIZED ON PRESCRIBED FORM-2 AND PERMISSION FOR PROSECUTION IN DRUG COURT- M/S EHSAN MEDICOS & GENERAL STORE, SURVEY NO. 287, BUKHARI COLONY, MANGOPIR ROAD, ORANGI TOWN, KARACHI.

The federal inspector of Drugs, Karachi-IX vide letter no. 1-1/2018-FID-IX(K)MKT dated 23.05.2018 has informed that he alongwith Dr. Kirshan Das, AD DRAP, Khi; conducted the market survey at Orangi Town Medicine Market, Karachi. As per report submitted by FID, he recovered suspected/un-registered stocks of following drugs during visit at the premises of M/s Ehsan Medicos & General Store, Survey No. 287, Bukhari Colony, Mangopir Road, Orangi Town, Karachi and seized on prescribed form-2 and samples taken for the purpose of test/analysis on prescribed form-3 on date 21.05.2018 under the DRAP Act, 2012:

Detail of seized drugs are as under:-

S.NO.	Name of Drug	Batch No.	MNFG Date	EXP DATE	QTY	MNFD; BY
1	Dona (Capsule)				12casp x 19's	Faazli Homeo Pharma, Karachi
2	Bella (Capsule)				12x26's	Pure Homeo Pharma, Mir Pur, Azad Kashmir
3	Relief-Extra (Tabs)				10x359's	Indian (Un-registered)
4	Cafcol Plus (Tabs)				250x17's +100tabs	-Do-
5	Gurucid (Caps)				10x356's	-Do-
6	Piapadaol CF (Tabs)				100x3's	-Do-

7	Zentec (Tabs)				30x5's	-Do-
8	Ceten 10mg (tabs)				100x6's	-Do-
9	Vega-100(tabs)				4x172's	-Do-
10	Diclocin Forte (tabs)				20x18's	-Do-
11	Knight Rider Tester				22Packs	-Do-
12	Moov Rapid Relief				25x4's	-Do-

Detail of samples taken for the purpose of test/analysis are as under:-

S.NO.	**Name of Drug**	**Batch No.**	**MNFG Date**	**EXP DATE**	**MNFD; BY**
1	Dona (Capsule)	-	-	-	Faazli Homeo Pharma, Karachi
2	Bella (Capsule)	-	-	-	Pure Homeo Pharma, Mir Pur, Azad Kashmir
3	Relief-Extra (Tabs)	-	-	-	Indian (Un-registered)
4	Cafcol Plus (Tabs)	-	-	-	-Do-
5	Gurucid (Caps)	-	-	-	-Do-
6	Piapadaol CF (Tabs)	-	-	-	-Do-
7	Zentec (Tabs)	-	-	-	-Do-
8	Ceten 10mg (tabs)	-	-	-	-Do-
9	Vega-100(tabs)	-	-	-	-Do-
10	Diclocin Forte (tabs)	-	-	-	-Do-

2. In the light of above the FID has requested that permission for safe custody of above seized drugs and permission for prosecution of following accused in Drug Court Sindh at Karachi may kindly be granted at your earliest in the light of section 23(i)(a)(vii) of DRAP Act 1976.

1. M/s Ehsan Medicos & General Store, Survey No. 287, Bukhari Colony, Mangopir Road, Orangi Town, Karachi

2. Muhammad Hussain S/o Muhammad Rehman (Proprieter), residing at House No. A-74, Pir Abad Colony 06, Mangopir Road, Orangi Town, Karachi CNIC No. 42401-1893938-1

3 The accused persons have committed offences under **Schedule II A (1)(a)(vii),of DRAP Act, 2012read with Section 23 of Drugs Act, 1976** which is punishable under **Schedule III(1)(c) of the DRAP Act, 2012 read with section 27 of the Drugs Act, 1976 for** manufacturing/Importing and selling of unregistered drugs. In the light of above mentioned facts the matter is submitted for safe custody of seized drugs and prosecution/ registration of FIR against the following accused persons:

1. M/s Ehsan Medicos & General Store, Survey No. 287, Bukhari Colony, Mangopir Road, Orangi Town, Karachi

2. Muhammad Hussain S/o Muhammad Rehman (Proprieter), residing at House No. A-74, Pir Abad Colony 06, Mangopir Road, Orangi Town, Karachi CNIC No. 42401-1893938-1

Decision of the case:

The Central Licensing Board (CLB) after through deliberations and examination of the record decided as under:

1. Allowed the safe custody to the Federal Inspector of Drugs till the finalization of the case.
2. The Board decided to issue Show Cause Notice for registration of FIR/ permission for prosecution against the following accused persons:
   i. M/s Ehsan Medicos & General Store, Survey No. 287, Bukhari Colony, Mangopir Road, Orangi Town, Karachi
   ii. Muhammad Hussain S/o Muhammad Rehman (Proprieter), residing at House No. A-74, Pir Abad Colony 06, Mangopir Road, Orangi Town, Karachi CNIC No. 42401-1893938-1.

Case No. 03:-

Subject: SEIZED UNREGISTERED DRUGS ON PRESCRIBED FORM-2 UNDER DRUGS ACT 1976 –M/S ASHRAF MEDICOS, LANDHI, KARACHI.

The Assistant Director/Federal Inspector of Drugs, Karachi vide letter no. DMT/46-49/18-FIDVII(K) dated 05.07.2018 has submitted that she alongwoth Mr. Asfand Yaar Ajab Khan A.D, DRAP Karachi visited /inspected the premises of M/s Ashraf Medicos Mian Market, Dawood Chowrangi Landhi Karachi on 02.07.2018. During inspection of pharmacy the FID, Karachi recovered the following unregistered drug and seized on the prescribed form-2 under the Drugs Act 1076. She also took samples for the purposes of test/analysis on prescribed Form-3.

2. Details of drugs seized are as under:-

Sr. #	Name of Drug	Batch No.	Registration No.	Mfg. Date	Exp. Date	Quantity	Mfd. By
1	Tablet Penegra	6705344	Nil	09-2017	08-2020	1X10X4 Tablet	M/s Candila Health Care Limited, India.
2	Tablet Penegra	6705345	Nil	09-2017	08-2020	1X11X4 Tablet	
3	Tablet Penegra	6705348	Nil	09-2017	08-2020	1X11X4 Tablet	

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

Sr. #	Name of Drug	Batch No.	Registration No.	Mfg. Date	Exp. Date	Mfd. By
1	Tablet Penegra	6705346	Nil	09-2017	08-2020	M/s Candila

						Health Care Limited, India.

4. Keeping in view of the above, the FID/AD, Karachi has requested the permission for safe custody of seized drugs as per Drugs Act, 1976 and rules framed thereunder.

5. The case is under investigation and it is therefore submitted for grant of permission for safe custody of seized custody.

Decision of the case:

The Central Licensing Board (CLB) after through deliberations and examination of the record decided as under:

1. **Allowed the safe custody to the Federal Inspector of drugs till the finalization of the case.**
2. **It was also decided that FID should complete the investigations as soon as possible and submit complete case for consideration of this Board.**

Case No. 04:-

Subject: **Seizure of un registered Drugs under Section 18(1) of the Drug Act 1976. Raid on M/s. Mehmood Pharmacy, Metro habib Cash and Carry, Multan Road, Lahore.**

Proceeding of 259th Meeting of CLB

01. That Mr. Ajmal Sohail Asif, FID-Lahore, raided and inspected M/s. Mehmood Pharmacy, Metro habib Cash and Carry, Multan road, Lahore on 03.01.2017 at about 11:00 am along with FID Miss Ayesha Irfan, FID Mr. Zia Husnain and FID Mr. Abdul Rashid Sheikh.

02. That At the time of raid, Proprietor of the pharmacy namely Muhammad Zeeshan S/o Muhammad Arjumand Mehmood and Qualified Person namely Ms. Amna Riaz D/o Muhammad Riaz were absent. However, a person namely Haseeb Ahmed was present, who told to be the employee of the pharmacy.

03. That During inspection huge quantity of un-registered (smuggled/ unwarranted) drugs including different brands of sexual drugs and many other branded drugs were found at the pharmacy. Some of the quantities of these drugs were seized on form-2, under section 18 (1) (f) of the Drugs Act, 1976 as per following detail:

Sr.#	Names of therapeutic goods	Quantity
1.	Levitra 20mg tablets, Mfd. By Bayer AG Germany	06 packs × 04 tablets
2.	Viagra tablets 100mg, Mfd. By Pfizer France	01 pack × 04 tablets
3.	Cialis 20mg tablets, Mfd. By EliLilly UK	15 packs × 02 tablets
4.	Penegra tablets 100mg, Mfd. By Cadila Healthcare India	05 packs × 04 tablets
5.	Eltroxin tablets 50 mg, Mfd. By GSK Germany	18 packs
6.	Eltroxin tablets 100 mg, Mfd. By GSK Germany	06 packs
7.	Amaryl 03 mg tablets, Mfd. By Sanofi	07 packs × 30 tablets
8.	Amaryl 02 mg tablets, Mfd. By Sanofi	09 packs × 30 tablets

9.	Furolin tablets 30 mg, MFD. BY IASIS Pharma Cyprus	02 packs × 30 tablets
10.	Lipitor 20mg tablets, Mfd. By Pfizer, Istanbul, Turkey	02 packs × 30 tablets
11.	Lipitor 10mg tablets, Mfd. By Pfizer, Istanbul, Turkey	13 packs × 30 tablets
12.	Plaquenil 200 mg tablets, Mfd. By Sanofi Istanbul, Turkey	02 packs × 30 tablets
13.	Roaccutane capsule 20mg, Mfd. By Roche	01 pack × 30 tablets
14.	CellCept 500 mg capsule, Mfd. By Roche	01 pack × 50 capsules
15.	Emla Cream 5%, Mfd. By AstraZeneca UK	03 packs × 5 gm
16.	Centrum Silver tablets (Men), Mfd. By Pfizer Canada	05 packs
17.	Centrum Silver tablets (Adults), Mfd. By Pfizer USA	06 packs
18.	Centrum Silver tablets (Women), Mfd. By Pfizer USA	04 packs
19.	Centrum vlaue tablets (Adults), Mfd. By Pfizer USA	04 packs
20.	One A Day tablets (Men), Mfd. By Bayer USA	01 packs
21.	Infacol Oral Suspension, Mfd/Mktd. By Forest Labs UK	10 packs

04. That All of the above drugs were recovered and seized on Form-2 in the presence of Haseeb Ahmed, employee of the Pharmacy (Person present), Mr. Zia husnain FID, Mr. Abdul Rashid Sheikh FID and Mr. Faraz, Floor manager of Metro-Habib Cash & Carry. The witnesses were recorded on Form-2.

05. That After the seizure of above said drugs the premises comprising a room was sealed under section 18(1) (h) in front of above mentioned witnesses. The Copy of Form-2 along with sealed keys was handed over to Mr. Haseeb Ahmed S/o Tanvir Ahmed (Person present, employee of pharmacy).

06. That the Person present was asked to provide the invoices/warranties of above mentioned drugs or to explain their position by FID that why they were selling these drugs in violation of provisions of the DRAP Act, 2012.But he did not provide any document (invoices/ warranties) and said that owner may have the requisite documents.

07. That Accused persons were served a show cause notice vide office letter No. 6-9/2016-FID (F) dated 06-01-2017 and were directed to provide the invoices/ warranties of seized drugs if any and to explain their position that why they were stocking & selling un-registered drugs. They were also directed to attend the office of the FID for recording of statement regarding the case on 13-01-2017, but neither they did not submit any invoice / warranty regarding the seized drugs nor they attended the office of the FID. Two reminders were sent by FID dated 23-02-2017 and 28-03-2017 but no reply has been received.

08. That the FID requested to grant permission for safe custody of seized drugs and to keep the premises sealed till the decision of the case. Permission of safe custody of the stock and to keep the premises sealed till decision of the case was granted to the FID on 17th February, 2017. Meanwhile the accused filed a petition in the Honorable Drug Court for de-sealing of the premises. The Honorable Court ordered to de-seal the premises on 11-01-2017, which was accordingly de-sealed on 17-01-2017.`

09. Findings:

The FID Lahore requested that either the permission for prosecution of the accused person may be granted or if Honorable Board requires further investigation in the case permission for lodging FIR against the accused persons may be granted as the accused persons have nothing to say in their defense and were involved in the stocking and selling of unregistered/ unwarranted drugs. Since sale and storage of Un- registered/ Unwarranted drugs is prohibited under Section A(1) (a) & A (1) (i) of Schedule-II of the DRAP Act, 2012 read with Section 23 of the Drug Act, 1976 punishable under Schedule-III of the DRAP Act 2012 read with section 27 of the Drug Act, 1976 and is cognizable offence under Section (1)(a) of Schedule-IV of the DRAP Act, 2012 read with

Section 30(1)(a) of the Drug Act, 1976 as to the action to be taken in respect of contraventions of the Act as mentioned above.

10. Permission For FIR against the following accused persons may be granted to the FID Lahore For selling un registered drugs in violation to the Drug Act 1976 and DRAP Act 2012:-

i M/s Mehmood Pharmacy, through Mr. Muhammad Zeeshan (Proprietor) S/o Muhammad Arjumand Mahmood, M/s. Mehmood Pharmacy, Inside Metro Habib Cash and Carry, Thokar Niaz Baig, Multan road, Lahore. Resident of house No.92 army Housing Scheme Defence, Lahore.

ii. Mr. Muhammad Zeeshan (Proprietor) S/o Muhammad Arjumand Mahmood, M/s. Mehmood Pharmacy, Inside Metro Habib Cash and Carry, Thokar Niaz Baig, Multan road, Lahore. Resident of house No.92 army Housing Scheme Defence, Lahore.

ii. Mr. Matee Ur Rehman (Salesman) S/o Tanvir Ahmed, Resident of House No. 254-C, Sabza Zar Scheme, Lahore.

iii. Mr. Haseeb Ahmed (person present at the time of raid) S/o Tanvir Ahmed. Resident of House No. 254-C, Sabza Zar Scheme, Lahore.

11. "Decision of the Case in 259th Meeting of CLB:-

The Central Licensing Board examined/evaluated the facts of the case in the light of investigations conducted by the FIDs and Quality Assurance Division and decided to grant permission for registration of FIR against the following accused persons:-

A. M/s Mehmood Pharmacy, through Mr. Muhammad Zeeshan (Proprietor) S/o Muhammad Arjumand Mahmood, M/s. Mehmood Pharmacy, Inside Metro Habib Cash and Carry, Thokar Niaz Baig, Multan road, Lahore. Resident of house No.92 army Housing Scheme Defence, Lahore.

B. Mr. Muhammad Zeeshan (Proprietor) S/o Muhammad Arjumand Mahmood, M/s. Mehmood Pharmacy, Inside Metro Habib Cash and Carry, Thokar Niaz Baig, Multan road, Lahore. Resident of house No.92 army Housing Scheme Defence, Lahore.

C. Mr. Matee Ur Rehman (Salesman) S/o Tanvir Ahmed, Resident of House No. 254-C, Sabza Zar Scheme, Lahore.

D. Mr. Haseeb Ahmed (person present at the time of raid) S/o Tanvir Ahmed. Resident of House No. 254-C, Sabza Zar Scheme, Lahore.

The accused persons are involved in contraventions of the provision of schedule-II and schedule-III of the DRAP Act 2012 as under:-

i. Sale of un registered drugs
ii. Sale of drugs without warranty.
iii. Manufacturing/import without authorization from the DRAP.

The offence is punishable under section 1 (a) and para (4) (contraventions of rules) of schedule-III of DRAP Act 2012.

Proceeding of 264th Meeting of CLB

12. The accused Mr. Muhammad Zeeshan (Proprietor) etc, filed a writ petition no. 211268 of 2018 in the Lahore High Court, Lahore.

13. The FID Lahore (L-VI) has submitted the Honorable Lahore High Court, Lahore orders dated 11.06.2018 passed in writ petitions 211268-18 + 211763-18 reproduced as under:

" This constitutional petition calls into question the letter dated 24-04-2018 whereby Secretary, Central Licensing Board Respondent No. 2 has requested the Federal Inspector of Drugs to file complaint for registration of FIR against the present petitioner.

2. The grouse of petitioner is that the said letter has been issued without affording opportunity of hearing to them. It is, therefore, requested that buy setting aside the letter dated 24-04-2018 Respondent No. 2 be directed to afford opportunity of hearing to the petitioner and thereafter pass a fresh order in accordance with law.

3. The above noted request is not opposed by the Assistant Director (Legal Affairs), DRAP

4. in view of above, letter dated 24-04-2018 is hereby set aside and consequently the matter shall be deemed to be pending before respondent no. 2, who shall decide the same afresh strictly in accordance with law, after affording opportunity of hearing to the petitioners; and through a well-reasoned speaking order.

5. Disposed of."

14. In compliance to the orders of the Honorable Court, the accused have called for personal hearing in the meeting.

15. **Decision of the case in 264th meeting of CLB:-**

Mr. Waqar Ahmad Warraich, Authorized Attorney appeared before the CLB on behalf of the accused persons Mr. Arjumand Maqsood & Mr. Muhammad Zeeshan. He submitted request for adjournment of the cases because of the reason that his clients (Mr. Arjumand Maqsood & Mr. Muhammad Zeeshan) are abroad since 9th& 12th June, 2018, respectively. He also submitted photocopies of passports and tickets of the accused persons. He further stated that he has been telephonically informed that the accused will return on 21st& 28th July, 2018. The CLB after considering he request his request and evaluation of tickets & passports unanimously decided to adjourn the case till upcoming meeting of CLB after 28th July, 2018.

Proceeding and Decision of 265th Meeting of CLB

Mr. Muhammad Zeeshan (Proprietor, M/s Mehmood Pharmacy, Metro Habib, Cash Carry, Lahore alongwith his counsel Waqar Ahmed Warraich; Matee-Ur-Rehman (Salesman) and Haseeb (person present at the time of raid) appeared before the Central Licensing Board in its 265th Meeting. Mr. Muhammad Zeeshan has admitted before the board that he is the owner of the pharmacy. Mate-Ur-Rehman (Salesman) has stated that he was not present at the time of raid. However, the stock of un-registered drugs belongs to him and M/s Mehmood Pharmacy, Metro Habib, Cash Carry, Lahore was not aware of this stock of un-registered drugs, but he failed to identify the place and person from whom he purchased. The accused

persons were given two opportunities of hearing in 264th and 265th Meetings of CLB but they failed to provide invoice warranty for the purchase of un-registered medicines and prove their innocence. The Board after hearing the counsel of the accused person and statement of accused person (Mate-Ur-Rehman, Salesman), decided to uphold the decision of the CLB taken in its 259th Meeting and directed area FID to proceed for the registration of FIR against the accused persons involved in the sale of un-registered drugs.

Case No. 05:-

Subject: **Illegal/ Unauthorized Sale of Un-registered/ Alternative Medicine Raid on M/s. Mehmood Pharmacy, Property No. S-36-R-2(D),/2, Chowk Mayo Hospital, Lahore.**

Proceeding of 259th Meeting of CLB

FID Lahore-V, Mrs. Aisha Irfan visited the premises of M/s. Mehmood Pharmacy, Property No. S-36-R-2(D),/2,Chowk Mayo Hospital, Lahore on 30-01-2017 alongwith Mr. Abdul Rashid Sheikh, Federal Inspector Of Drugs, Lahore-I and Rana Ihsan ul Haq Athar, Assistant Drugs Controller, DRAP, Lahore and send the case vide letter No.1548/2017-DRAP (L-V) dated 31-01-2017.

02. FID informed that she seized the products at Sr. No. 01 being unregistered/ smuggled and the products at Sr. No. 02-05 are being sold without enlistment on Form-7 in violation to SRO 412(1)/2014, of Schedule-II of DRAP Act, 2012 and sections 23 and 27 of Drugs Act, 1976. Qualified person was also not present at the time of inspection. The Drugs were seized in the presence of Mr. Saqib Maqsood, (preson present)/ Incharge Mehmood Pharmacy, chowk Mayo Hospital, Lahore.

Sr. No.	Name Of Products/ Batch No.	Date Of Mfg.	Date Of Exp.	Manufactured By	Quantity
01.	MyDacla 60 (Daclatasavir Dihydrochloride) Tablets 60 mg/ MYDA 16020	09-2016	08-2018	M/s Natco Pharma Limited Kokjhar, Mirza Garru Bazar, District Kamrup Guwahati India.	28 Tablets
02.	Alopia 004	02-2016	03-2020	Nil	11 Packs
03.	Alopia Hair Food 004	02-2016	Use Within 03 Years	Nil	07 Packs
04.	Alopia Hair Food Plus 004	02-2016	Use Within 03 Years	Nil	02 Packs
05.	Alopia Hair Loss Solution 002	03-2016	Use Within 03 Years	M/s Primose 293 A-1, Gulberg-III, Lahore.	05 Packs

03. The FID requested to grant the permission to keep the seized stock in safe custody of drugs mentioned on Form-2 till decision of the case under Section 19(5) of the Drug Act, 1976. The permission for safe custody has been granted on 17th February, 2017.

04. FID Lahore-V, Mrs. Aisha Irfan forwarded the complete case vide reference letter No.5533/2017-DRAP (L-V) dated 26th April, 2017.

05. Findings:

FID recommended that the sale of Un-registered drugs prohibited under Section 23 of the Drugs Act, 1976 read with section A(1) (a) (vii) of Schedule-II of the DRAP Act, 2012 which is punishable under Section 27 of the Drugs Act, 1976 read with section (1) (a) of Schedule-III of the DRAP Act, 2012, therefore the case may be placed before the central Licensing Board. 06. 06. ***Permission For FIR against the following accused persons may be granted to the FID Lahore For selling un registered drugs in violation to the Drug Act 1976 and DRAP Act 2012***:-

i. M/s Mehmood Pharmacy through Mr. Arjumand maqsood.
ii. Mr. Saqib Maqsood, person present/ incharge Mehmood Pharmacy, R/O House No.07, street No.98, Kocha Mehar Faizan Main Bazar Mozang, Lahore.
ii. Muhammad Arjumand Maqsood R/o House No.92, Army Housing Society, Defense, Lahore.
iii. Ms. Anem Saeed Qualified person, R/o House No.92 Street No.117, Nisbat Road, Lahore.

06. "Decision of the Case in 259th Meeting of CLB:-

The Central Licensing Board examined/evaluated the facts of the case in the light of investigations conducted by the FIDs and Quality Assurance Division and decided to grant permission for registration of FIR against the following accused persons:-

i. M/s Mehmood Pharmacy through Mr. Arjumand maqsood.
ii. Mr. Saqib Maqsood, person present/ incharge Mehmood Pharmacy, R/O House No.07, street No.98, Kocha Mehar Faizan Main Bazar Mozang, Lahore.
ii. Muhammad Arjumand Maqsood R/o House No.92, Army Housing Society, Defense, Lahore.
iii. Ms. Anem Saeed Qualified person, R/o House No.92 Street No.117, Nisbat Road, Lahore

The accused persons are involved in contraventions of the provision of schedule-II and schedule-III of the DRAP Act 2012 as under:-

i. Sale of un registered drugs/therapeutic goods
ii. Sale of drugs without warranty.
iii. Manufacturing/import without authorization from the DRAP.

The offence is punishable under section 1 (a) and para (4) (contraventions of rules) of schedule-III of DRAP Act 2012.

Proceeding of 264th Meeting of CLB

07. **The accused Mr. Muhammad Arjumand Maqsood etc, filed a writ petition no. 211763 of 2018 in the Lahore High Court, Lahore.**

08. The FID Lahore (L-VI) has submitted the Honorable Lahore High Court, Lahore orders dated 11.06.2018 passed in writ petitions 211268-18 + 211763-18 reproduced as under:

" This constitutional petition calls into question the letter dated 24-04-2018 whereby Secretary, Central Licensing Board Respondent No. 2 has requested the Federal Inspector of Drugs to file complaint for registration of FIR against the present petitioner.

2. The grouse of petitioner is that the said letter has been issued without affording opportunity of hearing to them. It is, therefore, requested that buy setting aside the letter dated 24-04-2018 Respondent No. 2 be directed to afford opportunity of hearing to the petitioner and thereafter pass a fresh order in accordance with law.

3. The above noted request is not opposed by the Assistant Director (Legal Affairs), DRAP

4. in view of above, letter dated 24-04-2018 is hereby set aside and consequently the matter shall be deemed to be pending before respondent no. 2, who shall decide the same afresh strictly in accordance with law, after affording opportunity of hearing to the petitioners; and through a well-reasoned speaking order.

5. Disposed of."

09. In compliance to the orders of the Honorable Court, the accused have called for personal hearing in the meeting.

10. **Decision of the case in 264th meeting of CLB:-**

Mr. Waqar Ahmad Warraich, Authorized Attorney appeared before the CLB on behalf of the accused persons Mr. Arjumand Maqsood & Mr. Muhammad Zeeshan. He submitted request for adjournment of the cases because of the reason that his clients (Mr. Arjumand Maqsood & Mr. Muhammad Zeeshan) are abroad since 9th& 12th June, 2018, respectively. He also submitted photocopies of passports and tickets of the accused persons. He further stated that he has been telephonically informed that the accused will return on 21st& 28th July, 2018. The CLB after considering he request his request and evaluation of tickets & passports unanimously decided to adjourn the case till upcoming meeting of CLB after 28th July, 2018..

Proceeding and Decision of 265th Meeting of CLB

Waqar Ahmed Warraich Counsel for Mr. Arjumand Maqsood (Proprietor) M/s Mehmood Pharmacy Chowk Mayo Hospital, Lahore and Saqib Masood (Ex-employee) appeared before the Central Licensing Board (CLB) in its 265th Meeting held on 09th and 10th August, 2018. The Counsel stated that mother of Mr. Arjumand Maqsood is admitted in hospital hence he is unable to attend the meeting and also submitted a Medical Certificate of his mother. Counsel also admitted that his client (Mr. Arjumand Maqsood) is the owner of M/s Mehmood Pharmacy Chowk Mayo Hospital, Lahore. Mr. Saqib Masood (Ex-employee) of Mehmood Pharmacy Chowk Mayo Hospital, Lahore appeared before the Board and stated that he had left the job at pharmacy 5 months back and he came to visit his friend working at Mehmood Pharmacy and on the demand of the client he purchased Mydecla Tablet from the Lohari Market but he failed to identify the person and place from whom he purchased. The accused persons were given two opportunities of hearing in 264th and 265th Meetings of CLB but they failed to provide invoice warranty for the purchase of un-registered medicines and prove their innocence. The Board after hearing the counsel of the accused persons and statement of accused person (Mr. Saqib Masood) decided to uphold the decision of the CLB taken in its 259th Meeting and directed to proceed for the registration of FIR against the accused persons involved in the sale of un-registered drugs.

Case No 06.

Subject: SEIZURE OF STOCK UNDER SECTION 18 (1) (H) OF THE DRUGS ACT, 1976 FROM M/S. SYED MEDICAL COMPLEX, SIALKOT.

Proceeding of 261st Meeting of CLB.

The FID MajidaMuhajid Lahore informed that she alongwith Dr. Akbar Ali, Assistant Director, DRAP, Lahore and Mr. Shahrukh Ali, Assistant Director, DRAP, Lahore visited the premises of M/s. Syed Medical Complex, Islamia College Road, Sialkot on 11-04-2018.

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

Sr. No.	Name of drug/ Reg. No.	Batch No.	Mfg. Date	Exp. Date	Manufacturer	Quantity
01.	**Wilgesic Forte Tabs., Reg. No. 056980**	9036	02-2018	02-2020	M/s. Wilson′s Pharmaceuticals, 387-388, 1-9 Industrial Area, Islamabad.	3 X 100 Tabs.
02.	**Jaslokan-SR Caps. Reg. No. 078644**	JU 11	12-17	12-19	M/s. Jaskan Pharmaceuticals (Pvt.) Ltd., Plot No. 50 Sundar Industrial Estate, Lahore.	5 X 20 Caps.
03.	**Amarit Plus Tab. Reg. No. 057257**	1572	01-18	01-20	M/s. RekoPharmacal (Pvt.) Ltd., 13-Km, Multan Road, Lahore.	10 X 30 Tabs.
04.	**Nulcer Tabs. Reg. No. 015120**	18329	11-17	10-19	M/s. Bosch Pharmaceuticals (Pvt.) Ltd., 221, Sector 23, Korangi Industrial Area, Karachi.	10 X 10 Tabs.

03. The FID informed that above mentioned drugs were recovered and seized in the presence of Mr. ShabbirHussain S/o. GhulamHussain was present at the time of raid and qualified person was not present. The witnesses were also recorded on the seizure form.

04. **The FID requested the Competent Authority for permission of the Competent Authority for safe custody of the seized drugs as mentioned above till the decision of the case under prevision of the Drug Act, 1976 and DRAP Act, 2012.**

05. The FID also informed that after recovering above mentioned materials, among huge quantity of drugs was sealed in a room of factory under section 18 (1) (h) of the Drugs Act, 1976 and Schedule V of the DRAP Act, 2012, as evidence of case.

06. **FID also requested the Competent Authority to grant possession to keep the premises to extension sealed till decision of the case.**

07. Mr. ShabbirHussain S/o. GhulamHussain CNIC No.34602-0743658-9 proprietor of the premises has contravened the provisions of schedule II and schedule III of DRAP Act 2012 and permission for lodging the FIR may be allowed against the accused person.

Decision of the case in 261st Meeting of CLB:

1. **Allowed safe custody to the Federal Inspector of drugs till the finalization of the case.**
2. **The Board also extended the extension the sealing period of the premises for further 90 days**

Proceeding of 265thMeeting of CLB:

9. The decision of said case was communicated to FID Lahore vide f. no. 3-33/2018-QC (pt-261-CLB) dated 24thMay, 2018.

10. In response, the FID Lahore submitted the reply wherein FID stated that M/s Syed pharmacy, Sialkot has submitted the license to sell drug in a pharmacy bearing no. 09-343-0152-032292P.

10. M/s Syed Pharmacy, Sialkot stated that they have submitted all the requisite documents to the office of Ms. Majida Mujahid, FID Lahore andSyed Pharmacy, Sialkot also **requested to Chairman, Central Licensing Board, DRAP that consideration may please be made to de-seal the medical store/ pharmacy.**

Decision of the case:

The Central Licensing Board (CLB) after through deliberations and examination of the record decided as under:

1. **The area FID, Lahore shall de-seal the premises of the M/s. Syed Medical Complex, Sialkot.**
2. **Take legal action under the law if there exist any violation. It was also decided that the area FID, Lahore shall verify the warranties and submit the details to the board concerned.**

Case No. 07

Subject: **i. Manufacture & Sale of Sub-Standard Drugs by M/S Standard Drug Company, Hyderabad. –Recommendation of Cancellation of Drug Manufacturing License (DML) of 12 Samples of M/S Standard Drug Company, Hyderabad, "Under Section 41 of Drugs Act, 1976".**

ii Non compliance to the conditions of license identified by the Appellate panel–Recommendation of Cancellation of Drug Manufacturing License (DML) under Section 41 of Drug Act 1976.

The case of M/s Standard Drug Company, Hyderabad was considered in 262nd meeting of CLB and decided as under:-

The CLB examined and considered the Appellate panel inspections report, reply of the firm to the show cause notice and personal hearing of the MD of the M/s Standard Drug Company Hyderabad.

The Board considered the case at length. Mr. Syed Muid Ahmed who was also member of the Appellate panel briefed the members about the shortcomings and deficiencies. After detailed debate following was decided**:-**

1. **The firm shall submit fresh layout plan for approval by the licensing Division as per current requirements of law.**
2. **The firm will submit compliance report in the light of layout approval and shortcomings/deficiencies identified by the Appellate panel as conveyed in the show cause notice.**
3. **Following panel will inspect the premises and verify compliance report in the light of approved layout plan and observations of Appellate panel.**
    a. **Syed Muid Ahmed (member CLB)**
    b. **Professor Dr. Abdullah Dayo Dean Faculty of Pharmacy University of Sindh Jamshoro (member CLB)**
    c. **Additional Director Karachi**
    d. **Area FID.**
4. **Meanwhile the production shall remain suspended as per decision of the Appellate Board. Any violation to this condition will be considered as non compliance and matter will be decided in the light of show cause notice.**
5. **The show cause notice will remain intact till matter is finalized by CLB which will decide the fate of the manufacturing license in the light of inspection report or any violation report whichever is received in this context.**

Accordingly the decision of CLB was conveyed vide letter no. No. 03-50/2018-QC (CLB-262M) to the Firm. The Managing Director, M/s Standard Drug Company, Hyderabad dated 11th July, 2018 in response to this division letter No. 03-50/2018-QC (CLB-262M), has addressed to chairman Central Licensing Board:

"wherein they have shown their concerns that the learned member Syed Muid Ahmad had inspected their premises as a member of panel constituted by the Appellate Board, which is a forum higher than the Central Licensing Board. Therefore they don't find it justified and

proper that the said member is included in the panel constituted by the Central Licensing Board, a forum lower than the Appellate Board. The firm further added that the said member would be inspecting their premises with a specific mind set, having already been the member of the Appellate inspection panel."

6. **The firm has requested that the said member may be substituted with some other member of the Central Licensing Board from Karachi for re-inspection of their manufacturing facility.**

Decision of the case:

The Central Licensing Board (CLB) after through deliberations, examination of the record and request made by the firm regarding change of panel has decided as under:

1. **That the Board revised the panel on the request of the firm as under:**
   - i. **Dr. Sarwar, Member DRB**
   - ii. **Professor Dr. Abdullah Dayo Dean Faculty of Pharmacy University of Sindh Jamshoro (member CLB)**
   - iii. **Additional Director Karachi**
   - iv. **Area FID, Karachi.**

Case No. 08

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

1. The Federal Inspector of Drugs-IV, Islamabad vide letter No. F. 4-1/2018-FID-IV dated 23.07.2018 has informed that With reference to the re-notification of National Task Force for eradication of spurious and unregistered drugs, she has been appointed as Federal Inspector of Drugs-IV, Islamabad. As per approved plan of activities, I alongwith Mr. Rashid, Dtaff Car Driver, DRAP visited Attock on 10.07.2018 and inspected a number of medical stores/pharmacies under the statutory powers of Inspector of Drugs under section 18 of Drugs Act, 1976 read with schedule 5 of DRAP Act, 2012.

2. The FID-IV, ISB informed that after inspection of few medical stores/pharmacies, she visited Khalid Saeed Hospital (35 beds) and introduced herself as area Federal Inspector of Drugs. She enquired about the drug sale license and qualified person of the pharmacy but it was stated that we don't need drug sale license and qualified person to dispense medicines in the hospital. In the incidence report the FID-IV, ISB pertinently mentioned that the sated premises was designated as Pharmacy and the invoices were also issued under the name of Khalid Saeed Pharmacy/Khalid Saeed Medical Centre. During the inspection, Mr. Tariq Mehmood was called at the premises who introduced him as President, Attock Chamber of Commerce and Industry. At the same time he (Mr. Tariq Mehmood) telephonically contacted with Syed Tariq Masud Shah, Drug Controller, District Attock and handed over

his mobile phone to her (FID-IV, ISB) to talk with him (Syed Tariq Masud Shah, Drug Controller, District Attock). The said Drug Controller after introduction threatened the FID-IV, Islamabad and stated as under:

i) How dare you visited this area? You don't know who am I?
ii) How you visited this hospital without my permission or without informing me?
iii) Be careful in future being a lady officer?
iv) It is possible that an untoward incident could be happened with you.

3. The FID-IV, Islamabad reported that meanwhile, she collected the following documents for said purpose:-

i) Certificate of Medical Registration of Dr. Khalid Saeed Khan
ii) Sale Invoices in the name of Dr. Khalid Saeed Pharmacy
iii) Visiting card of President, Chamber of Commerce & Industry, Attock

4. As report of FID-IV, ISB it is important to mentioned here 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-IV, Islamabad the act of the accused person 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 Dr. Khalid Saeed, proprietor of the pharmacy obstructed the FID 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. The FID-IV, Islamabad further submitted that Drug Control, Attock instead of extending cooperation with the FID supported the owners of the pharmacy of M/s Dr. Khalid Saeed Hospital in violation to the above mentioned provisions of Drugs Act, 1976 and DRAP Act, 2012.
7. In view of above explanation, FID-IV, Islamabad requested that permission for prosecution may be granted against the following accused persons for the sale of the drugs without drug sale license and obstruction in official duties in violation to para 3 of schedule-III of DRAP Act, 2012:-

i) Dr. Khalid Saeed, Proprieter/owner of the Khalid Saeed Hospital as well as Pharmacy, 26, Iqbal Road, Attock Cantt.

ii) Mr. Tariq Mehmood, President Attock Chamber of Commerce, 43, Aslam Plaza, Fawara Chowk, Attock City.

8. The FID-IV, Islamabad further submitted that as per clarification by Chief Drug Controller, Punjab vide their letter No. CDC/4-1/2018 dated 05.05.2018 registered medical practitioners as defined in the PMDC Ordinance, 1962 can dispense medicine to his own patients or serves his own prescriptions provided record of schedule B&D is maintained as prescribed under the rules. It was further directed that the registered medical practitioners will not mention the premises as Pharmacy or Medical Store, rather only write the word "Dispensary". It was further provided that the dispensary of registered medical practitioners will not deal to any prescription from the outside that clinic/hospital.
9. **The FID-IV, Islamabad also submitted that the Central Licensing Board may recommend legal/departmental action against Syed Tariq Masud Shah, Drug Controller, District Attock for non-cooperation and un-lawful support to the accused persons as well as un-licensed pharmacy.**
10. **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:**
    - **i) Dr. Khalid Saeed, Proprieter/owner of the Khalid Saeed Hospital as well as Pharmacy, 26, Iqbal Road, Attock Cantt.**
    - **ii) Mr. Tariq Mehmood, President Attock Chamber of Commerce, 43, Aslam Plaza, Fawara Chowk, Attock City.**

Decision of the case:

The Central Licensing Board (CLB) after through deliberations and examination of the record decided as under:

1. **The matter of Syed Tariq Masud Shah, Drug Controller Disrict Attock shall be referred to the Chief Drug Controller, Punjab for appropriate disciplinary proceedings by deliberate intervention in the official duties of the area Federal Inspector of Drugs-I, Islamabad and his failure to initiate legal action against the Khalid Saeed Pharmacy, 26, Iqbal Road, Attock Cantt which was running without Drug Sale License under his notified area jurisdiction.**
2. **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."***

i) Dr. Khalid Saeed, Proprieter/owner of the Khalid Saeed Hospital as well as Pharmacy, 26, Iqbal Road, Attock Cantt.

ii) Mr. Tariq Mehmood, President Attock Chamber of Commerce, 43, Aslam Plaza, Fawara Chowk, Attock City.

Case No. 09

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

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 Fakhruddin Aamir, 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. Munib Shahid 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 the case:

The Central Licensing Board (CLB) after through deliberations and examination of the record decided as under:

1. **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

2. **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**

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