MINUTES OF 273rd MEETING OF CENTRAL LICENSING BOARD HELD ON 15th JANUARY, 2020

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273rd meeting of the Central Licensing Board (CLB) was held on 15thJanuary, 2020 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.	Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar	Member
3.	Mr. Muhammad Israr, Law Expert, Ministry of Law & Justice Division.	Member
4.	Dr. Muhammad Usman, Expert member Manufacturing of Drugs	Member
5.	Dr. Munawar Hayat, Chief Drug Controller, Primary and Secondary Health Care Department, Govt. of Punjab, Lahore	Member
6.	Syed Abdul Saleem, Chief Inspector of Drugs, Department of Health, Government of Balochistan, Quetta	Member
7.	Dr. Hafsa Karam Ellahi, Representative Director (QA/LT), DRAP, Islamabad	Member
8.	Zakir Shah, Drug inspector, Department of Health, Govt of Khyber Pakhtunkhwa.	Member
9.	Shoaib Ahmed Ansari, Chief Drugs inspector, Sindh.	Member
10.	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
11.	Mr Saleem iqbal and Ms. Mahwish Representatives of PPMA.	Observer
12.	Mr.Nadeem Alamgir Representative of Pharma Bureau.	Observer
13.	Mr. Kamran Anwar, Representative PC&DA	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. The Central Licensing Board discussed and decided that initial draft minutes of the meeting would be prepared by concerned sections of Divisions and counter verified by the Secretary, Central Licensing Board before submitting to the members of the Board. Mr. Ayyaz Ahmed, Deputy Director (Licensing), Mr. Abdul Sattar Sohrani, Deputy Director (Quality Control) , Mr. Zeeshan Nazir, Deputy Director (Quality Assurance), Mr. Arslan Tariq, Assistant Director (QC),Mr. Sanaullah Babar Assistant Director (QC) Mr. Muhammad Yaqoob AD

(Lic.), Mr. Muhammad Usman, AD (Lic), Mr. Farman Ali Bozdar Assistant Director (Lic), and Ms. Zunaira Farayad, Assistant Director (Lic), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 272nd MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 272nd meeting of the Central Licensing Board (CLB) which was held on 17th October, 2019.

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 D. Haans Pharma (Pvt) Ltd., Plot No. 9/A, Industrial Estate, Bhimber, AJK. **Sections (04)** 1) Oral Liquid Section-I (Vet). 2) Oral Liquid Section-II (Vet). 3) Oral Powder Section-I (Vet). 4) Oral Powder Section-II (Vet).	**12-12-2019**	**Good**	1. Prof. Dr. Muhammad Usman, Member, CLB. 2. Additional Director (Lic), DRAP, Islamabad. 3. Area FID, DRAP, Islamabad. 4. Assistant Director (Lic), DRAP, Islamabad.
	Recommendations of the panel: - "Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s D.Haans Pharma (Pvt)			

	Ltd., Plot No. 9/A, Industrial Estate, Bhimber, AJK for the grant of Drug Manufacturing License (Formulation) for the following sections namely; 1) Oral Liquid Section-I (Vet). 2) Oral Liquid Section-II (Vet). 3) Oral Powder Section-I (Vet). 4) Oral Powder Section-II (Vet). **Decision of the Central Licensing Board in 273rd meeting** The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s D.Haans Pharma (Pvt) Ltd., Plot No. 9/A, Industrial Estate, Bhimber, AJK with following sections: **Sections (04)** 1) Oral Liquid Section-I (Vet). 2) Oral Liquid Section-II (Vet). 3) Oral Powder Section-I (Vet). 4) Oral Powder Section-II (Vet).			
2	M/s Enzon Pharma Labs (Pvt) Ltd,5-Km, Off Raiwind Manga Road, Lahore. **Sections (03)** 1) Large Volume Parenteral (LVP) (General) Section. 2) Small Volume Parenteral (SVP) (General) Section. 3) Ampoule (LDPE) (General) Section.	**05-12-2019 & 12-12-2019**	**Good**	1) Dr. Ikram-ul- Haq, Member Central Licensing Board. 2) Dr. Munawar Hayat, Chief Drugs Controller, Punjab. 3) Ms. Ufaq Tanveer Federal Inspector of Drugs, Lahore. 4) Ms. Anam Saeed, Assistant Director, Lahore.
	Recommendations of the panel: - "Keeping in view the approval of site and building, layout plan approved by DRAP, Islamabad and the facilities like building, HVAC system, machinery & equipments, instruments and personnel, documentation, Quality Control, Microbiological Lab, water			

	treatment and testing facilities, the panel of inspectors**recommended** grant of Drug Manufacturing License M/s Enzon Pharma Labs (Pvt) Ltd, 5-Km, Off Raiwind Manga Road, Lahore for the following sections. 1) Large Volume Parenteral (LVP) (General) Section. 2) Small Volume Parenteral (SVP) (General) Section. 3) Ampoule (LDPE) (General) Section." **Decision of the Central Licensing Board in 273rd meeting** The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Enzon Pharma Labs (Pvt) Ltd, 5-Km, Off Raiwind Manga Road, Lahore with following sections: **Sections (03)** 1) Large Volume Parenteral (LVP) (General) Section. 2) Small Volume Parenteral (SVP) (General) Section. 3) Ampoule (LDPE) (General) Section			
3	M/s Variant Pharmaceuticals (Pvt) Ltd, Plot No. 5, M2-Pharma Zone, 26-km Lahore Sharikpur Road, Sheikhupura. **Sections (04)** 1) Tablet Section (General). 2) Capsule Section (General). 3) Sachet Section (General). 4) General Dry Powder Injection Section (Pre-Lyophilized) Vial.	**09-12-2019 & 20-12-2019**	**Good**	1) Dr. Ikram-ul- Haq, Member Central Licensing Board. 2) Dr. Munawar Hayat, Chief Drugs Controller, Punjab. 3) Mrs. Majida Mujahid, Federal Inspector of Drugs, Lahore. 4) Ms. UzmaBarkat, Assistant Director, Lahore.
	Recommendations of the panel: - "In the light of inspection conducted by the panel and based on the findings, the panel of inspectors **recommends** grant Of Drug Manufacturing License by way of formulation of			

	M/s Variant Pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharm Zone, 26-KM, Lahore Sharaqpur Road, Sheikhupura for following sections:-" 1) Tablet Section (General). 2) Capsule Section (General). 3) Sachet Section (General). 4) General Dry Powder Injection Section (Pre-Lyophilized) Vial. **Decision of the Central Licensing Board in 273rd meeting** The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Variant Pharmaceuticals (Pvt) Ltd, Plot No. 5, M2-Pharma Zone, 26-km Lahore Sharikpur Road, Lahore with following sections: **Sections (04)** 1) Tablet Section (General). 2) Capsule Section (General). 3) Sachet Section (General). 4) General Dry Powder Injection Section (Pre-Lyophilized) Vial.			
4	M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Khan Road, Rawat, Rawalpindi. **Name of Sections/Facility (19).** **Ground Floor. Dedicated Facility.** 1) Dry Suspension (Cephalosporin) 2) Capsule Section (Cephalosporin) 3) Dry Vial Section (Cephalosporin) 4) Penem Injection Section	**12-12-2019**	**Good**	1. Dr. Muhammad Usman, Member, CLB. 2. Additional Director (QA/LT), DRAP, Islamabad. 3. Area FID-II, DRAP, Islamabad.

	5) Ware House. **First Floor.** 1) Tablet Section (General). 2) Capsule Section (General). 3) Sachet Section (General). 4) Cream Section (General). 5) Ointment Section (General). 6) Lotion Section (General). 7) Dry Vial Section (General). **Second Floor.** 1) Ampoule Section SVP (General). 2) Infusion Section (General). 3) Hydrocortisone Injection (Steroid). 4) Soft Gel Capsule General. 5) Quality Control Lab. 6) Microbiology Lab.			

Recommendations of the panel: -

"Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Road, Rawat, Rawalpindi for the grant of Drug Manufacturing License for the following sections as of today;

Ground Floor

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

	Dedicated Facility.		**Dedicated Facility.**
3.	Dry Vial Section (Cephalosporin) **Dedicated Facility.**	4.	Penem Injection Section **Dedicated Facility.**
5.	Ware House.	6.	Ware House.
First Floor			
1.	Tablet Section (General).	2.	Capsule Section (General).
3.	Sachet Section (General).	4.	Cream Section (General).
5.	Ointment Section (General).	6.	Lotion Section (General).
7.	Dry Vial Section (General)		
Second Floor			
1.	Ampoule Section SVP (General).	2.	Infusion Section (General).
3.	Hydrocortisone Injection (Steroide).	4.	Soft Gel Capsule General.
5.	Quality Control Lab.	6.	Microbiology Lab.

Decision of the Central Licensing Board in 273rd meeting

The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Road, Rawat, Rawalpindi with following sections:

Ground Floor			
1.	Dry Suspension (Cephalosporin) **Dedicated Facility.**	2.	Capsule Section (Cephalosporin) **Dedicated Facility.**
3.	Dry Vial Section (Cephalosporin) **Dedicated Facility.**	4.	Penem Injection Section **Dedicated Facility.**
5.	Ware House.	6.	Ware House.
First Floor			
1.	Tablet Section (General).	2.	Capsule Section (General).
3.	Sachet Section (General).	4.	Cream Section (General).
5.	Ointment Section (General).	6.	Lotion Section (General).
7.	Dry Vial Section (General)		
Second Floor			
1.	Ampoule Section SVP (General).	2.	Infusion Section (General).

	3.	Hydrocortisone Injection (Steroide).	4.	Soft Gel Capsule General.
	5.	Quality Control Lab.	6.	Microbiology Lab.

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

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Estate, 20-KM, Ferozepur Road, Lahore. DML No. 000736 (Formulation). **Section (01):** 1) Liquid Injection (General) (Vet).	**07-10-2019**	**Good**	1.Dr. Farzana Chaudhary, Member, Appellate Board. 2.Syed Shahid Nasir, Member, Appellate Board. 3.Shoaib Ahmed, Federal Inspector of Drugs, Lahore.
	Recommendations of the Panel. The panel of inspectors **recommends** the grant of additional new Liquid Injection (General) (Veterinary) Section subject to the firm (M/s Evergreen Pharmaceuticals, License to manufacture by way of formulation No. 000736), fulfilling all the deficiencies (Annex-I) highlighted by the panel during the two visits as mentioned in the CAPA submitted by the firm (Annex-II). The firm should inform the area FID about all the corrective measures for further action by the authorities. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and decided to defer the case for verification of CAPA by the area Federal Inspector of Drugs. **Proceedings of Licensing Division**			

	Licensing Division intimated the decision of Central Licensing Board to Area Federal Inspector of Drugs vide letter dated 7thNovember 2019. **Recommendation of the FID** Area Federal Inspector of Drugs inspected the firm on 14th November, 2019 to verify the CAPA submitted by the firm and the **conclusion** of the report is as under: "In view of rectification / compliance of the observation / short coming which were pointed out during the previous inspection dated 07-10-2019, the observation are rectified / complied, of letter No. F. 1-31/2010-Lic (Vol-I) dated 07-11-2019, the observation are rectified / complied, therefore the previous recommendation of report dated 07-10-2019, may be considered for the grant of additional new Liquid Injection (General) (Veterinary) Section M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Estate, 20-KM, Ferozepur Road, Lahore under DML No. 000736". **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of one additional section in the name of M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Estate, 20-KM, Ferozepur Road, Lahore. License No. 000736 as under: **Section (01)** 1. Liquid Injection (General) (Veterinary)			
2	M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore. DML No. 000461 (Formulation). **Section (01):** 1) Capsule (General).	26-06-2019& 16-09-2019	**Good**	1.Dr. Farzana Chaudhary, Member, Appellate Board. 2.Mr. Munawar Hayat, Chief Drugs Controller, Punjab. 3.Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore.
	Recommendations of the Panel. "Keeping in view the manufacturing facility like building, HVAC system, sanitation, production			

	Machinery, Equipment in Quality Control Laboratory, testing facilities, the technical personnel met and the review of documentation, the panel of inspectors **recommended** the renewal of Drug Manufacturing License by way of formulation to M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore for Tablet Section (General) and the panel of inspectors also **recommended** the grant of following additional section / expansion. Capsule Section (General)." **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of one additional section in the name of M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore. DML No. 000461 (Formulation). as under: **Section (01)** 1. Capsule (General).			
3	M/s Zafa Chemie, RaiwindManga Bypass, Near Sundar Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore. DML No. 000589 (Basic Manufacture). **API (06):** 1) Cefixime Trihydrate (BP) 2) Cefradine (BP) 3) Ofloxacin(BP) 4) Levofloxacin (USP) 5) Moxifloxacin (BP) 6) Montelukast Sodium/ (BP). **Manufacturing Facility (10):** 1) Building No. 1 (Multipurpose (General)) 2) Building No. 2 (Multipurpose (General))) 3) Building No. 3 (Multipurpose (General)))	**23-10-2019**	**Good**	1. Dr. Ikram Ul Haq, Member, Central Licensing Board. 2. Dr. Farzana Chaudhary, Expert Member. 3. Ms. Ufaq Tanveer Federal Inspector of Drugs, Lahore.

	4) Building No. 4-A (Penicillin) 5) Building No. 4-B (Cephalosporin) 6) Building No. 5 (Paracetamol) 7) Building No. 6 (Multipurpose (General))) 8) Building No. 7 (Multipurpose (General))) 9) Building No. 8 (Multipurpose (General))) 10) Quality Control Laboratory & Microbiology Laboratory.			

Recommendations of the Panel.

"Keeping in view the above observation, the evaluation of premises, equipments documentation materials, personnel of production, quality Control and EHS, validations, sanitation & hygiene, environment and utilities, layout of manufacturing facility and infrastructure available for manufacturing, the panel **recommend** the grant of revised layout and following additional APIs, to M/s Zafa Chemie, Raiwind Manga Bypass Near Sunder Industrial Estate, Mouza Bahikot, Tehsil & Distt Lahore".

1) Cefixime Trihydrate (BP)
2) Cefradine (BP)
3) Ofloxacin(BP)
4) Levofloxacin (USP)
5) Moxifloxacin (BP)
6) Montelukast Sodium/ (BP)".

Decision by the Central Licensing Board in 273nd meeting

The Board considered and approved the grant of following additional APIs and manufacturing facility in the name of M/s Zafa Chemie, Raiwind Manga Bypass, Near Sundar Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore. DML No. 000589 (Basic Manufacture).

APIs (06)

1) Cefixime Trihydrate (BP)
2) Cefradine (BP)
3) Ofloxacin(BP)

	4) Levofloxacin (USP) 5) Moxifloxacin (BP) 6) Montelukast Sodium/ (BP) **Manufacturing Facility (10):** 1) Building No. 1 (Multipurpose(General) 2) Building No. 2 (Multipurpose (General) 3) Building No. 3 (Multipurpose (General) 4) Building No. 4-A (Penicillin) 5) Building No. 4-B (Cephalosporin) 6) Building No. 5 (Paracetamol) 7) Building No. 6 (Multipurpose (General) 8) Building No. 7 (Multipurpose (General) 9) Building No. 8 (Multipurpose(General) 10) Quality Control Laboratory & Microbiology Laboratory".			
4	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, NIZ, Rawat, Rawalpindi. DML No. 000892 (Formulation) **<u>Sections (03)</u>** 1) Dry Powder Injection Section (Cephalosporin). 2) Dry Powder for Suspension Section (Cephalosporin). 3) Capsule Section (Cephalosporin).	**12-12-2019**	**Good**	1. Dr. Muhammad Usman, Member, CLB. 2. Deputy Director (Lic), DRAP, Islamabad. 3. Area FID-II, DRAP, Islamabad.
	Recommendations of the panel: - "Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, NIZ, Rawat, Rawalpindi for the grant of Additional Sections namely; 1. Dry Powder Injection Section (Cephalosporin). 2. Dry Powder for Suspension Section (Cephalosporin).			

	3. Capsule Section (Cephalosporin). **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of Three (03)additional sections in the name of M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, NIZ, Rawat, Rawalpindi. DML No. 000892 (Formulation) as under: **Sections (03)** 1) Dry Powder Injection Section (Cephalosporin). 2) Dry Powder for Suspension Section (Cephalosporin). 3) Capsule Section (Cephalosporin).			
5	M/s Chemiworld (Pvt) Ltd, 97-J, Hayatabad Industrial Estate, Peshawar. DML No. 000579 (Basic Manufacture). **Name of APIs (02).** 1) Iron Sucrose Complex. 2) Iron Protein Succinylate..	**11-10-2019 & 05-11-2019**	**Good**	1. Prof. Dr. Jamshed Ali Khan, Member CLB. 2. Director DTL, Peshawar. 3. Area Federal Inspector of Drugs, DRAP, Peshawar.
	Recommendations of the panel: - "The panel after detailed inspection of the firm concluded that the firm has adequate facility for the production and testing of Iron Sucrose complex and **recommends** the grant of Iron Sucrose Complex API only to the firm. However the firm shall market the API after conduction of successful stability studies which is already under process". **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of One (01) additional APIs in the name of M/s Chemiworld (Pvt) Ltd, 97-J, Hayatabad Industrial Estate, Peshawar. DML No. 000579 (Basic Manufacture) as under: 1) Iron Sucrose Complex. The Board considered and did not approve the grant of API namelyIron Protein Succinylate as the firm has not yet developed any manufacturing and testing method for Iron Protein Succinylate and no tial batches were obseved.			

6	M/s ICI Pakistan Limited, S-33, Hawkes Bay Road, Karachi. DML No. 000006 (Formulation) **Section (01):** 1) Liquid Syrup(General)(Revised)	**19-12-019**	**Good**	1. Mr. Abdullah Dayo Member Central Licensing Board. 2. Chief Drug Inspector - Sindh 3. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - The panel visited and verified the Liquid Syrup (General) section- Expansion reviewed the relevant documents and LOP, met with their technical persons. The panel observed the area found neat/cleaned, machines were installed appropriately the workers were found working with proper dress, the HVAC system found installed and installed. Based on stated observations the panel **recommends** grant of expansion of third line of 'Liquid General Section'. **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of following Section in the name of M/s ICI Pakistan Limited, S-33, Hawkes Bay Road, Karachi.DML No. 000006 (Formulation) as under: **Sections (01)** 1) Liquid Syrup (General) (Revised)			
7	M/s Abbott Laboratories Pakistan Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi DML No. 000001 (Formulation) **Facility**	8-11-2019	Good	1. Mr. Abdullah Dayo Member Central Licensing Board. 2. Additional Director (E&M) Karachi . 3. Area Federal Inspector of Drugs, DRAP, Karachi.

	1) Raw Material Store (amendments)			
	Recommendations of the panel: - The premises of above mentioned area was visited and related documents were reviewed. The panel observed that fume hood was installed in center of the room while it was in corner in approved layout plan via letter No. F. 2-5/2003-Lic (vol-III) dated 31st October 2018. In response to panel observation, firm submit a letter to revise the location of fume hood in layout plan to the division of Licensing via letter No. Nil dated 21st November,2019. In view of above, the panel **recommends** the grant of amendments in Raw Material Store i.e installation of fume hood for de-cartooning subject to necessary revision of approved layout plan." **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of following Section/facility in the name of M/s Abbott Laboratories Pakistan Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi DML No. 000001 (Formulation) as under: **Facility** **1)** Raw Material Store (Revised)			
8	M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, Phool Nagar, District Kasur. DML No. 000429 (Semi Basic Manufacture) **API(02):** 1) Additional enzymatic process line for penicillin: i. Amoxicillin Trihydrate (By enzymatic process). ii. Ampicillin Trihydrate (By enzymatic process).	**02-09-019**	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Dr. Munawar Hayat, CDC, Punjab, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, Lahore.

	Recommendations of the panel: - "Keeping in view the findings of the inspection, technical people met and the documents reviewed, the panel **recommends** the grant of addition of enzymatic process line for synthesis of Penicillin (Amoxicillin Trihydrate and Ampicillin Trihydrate.". **<u>Decision by the Central Licensing Board in 273nd meeting</u>** The Board considered and approved the grant of following in the name of M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, Phool Nagar, District Kasur.DML No. 000429 (Semi Basic Manufacture) as under: **API(02):** 1) Additional enzymaticprocess line for penicillin: i. Amoxicillin Trihydrate (By enzymatic process). ii. Ampicillin Trihydrate (By enzymatic process).			
9	M/s Pharmasol (Pvt) Ltd, Plot No. 549, Sunder Industrial Estate, Lahore. DML No. 000872 (Formulation **Section (01):** 1) Soft Gelatin Capsule.	04-12-2019	Good	1. Dr. Haleem Khan, Chairman Pharmacy Department, F.C University. 2. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - "Keeping in view the facilities like building, HVAC, machinery, equipments, instruments, personnel, documentation and quality Control, testing facilities, the panel of inspectors is of the opinion to**recommend** the grant of additional section to M/s Pharmasol (Pvt) Ltd, Plot No. 549, Sunder Industrial Estate, Lahore for the following section only: 1) Soft Gelatin Capsule section." **<u>Decision by the Central Licensing Board in 273nd meeting</u>** The Board considered and approved the grant of one (01) additional section in the name of M/s Pharmasol (Pvt) Ltd, Plot No. 549, Sunder Industrial Estate, Lahore. DML No. 000872 (Formulation as under:			

	Section (01): 1) Soft Gelatin Capsule.			
10	M/s British Pharmaceuticals, 23-Km Sheikhupura Road, Lahore. Drug Manufacturing License No. 000729 (Formulation) **Section (03):** 1) Capsule Section (General) (New) 2) Dry Powder Section (General) (New). 3) Tablet Section (General) (New).	**19-08-019 & 27-12-019**	**Good**	1. Dr. Farzana Ch, Member, Technical Expert. 2. Mr. Shahid Nasir, Quality Control Expert. 3. Dr. Jamil Anwar, Secretary PQCB, Punjab, Lahore. 4. Mrs. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - The firm has made a number of improvements, which were pointed out during previous inspections regarding installation of new machines/equipments. Improvements in process flow, improvements in documentation system. Keeping in view the improvements made by the firm, and commitments for future improvement, the members of the panel are of opinion to **recommend** the grant of new production sections as well as renewal of Drug Manufacturing License (000729) by way of Formulation for the following sections: 1) Liquid Syrup/Suspension (Existing section). 2) Capsule Section (General) (New) 3) Dry Powder Section (General) (New). 2) Tablet Section (General) (New). **<u>Decision by the Central Licensing Board in 273nd meeting</u>**			

	The Board considered and approved the grant of three (03) additional sections in the name of M/s British Pharmaceuticals, 23-Km Sheikhupura Road, Lahore. Drug Manufacturing License No. 000729 (Formulation) as under: **Sections (03):** 1) Capsule Section (General) (New) 2) Dry Powder Section (General) (New). 3) Tablet Section (General) (New).			
11	M/s Medizan Pharmaceuticals, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad. **Section (01).** 1.Psychotropic (Tablet) Section (in place of Quinolones Tablet Section).	**09-01-2020**	**Good**	1. Dr. Muhammad Usman, Member, CLB. 2. Additional Director (QA/LT), DRAP, Islamabad. 3. Area FID-II, DRAP, Islamabad.
	"Keeping in view the above facts on record and the people met during the visit, the panel unanimously **Recommended** the approval of following additional (new) section of M/s Medizan Pharmaceuticals, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad 1. Tablet Section (Psychotropic). **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of One (01) additional section in the name of M/s Medizan Pharmaceuticals, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad Drug Manufacturing License No. 000572 (Formulation) as under: **Section (01).** 1) Tablet Section (Psychotropic) (in place of Tablet Section (Quinolones)).			
12.	M/s Sclife Pharma (Pvt Ltd, Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi. DML No. 000837 (by	10-01-2020	Good	1. Mr. Abdullah Dayo Member Central Licensing Board. 2. Chief Drug Inspector, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi.

	way of Formulation) **Sections (05).** i. Dry Powder Inhaler (General)-New ii. Sachet Section (General)-Relocated iii. Capsule section (General)-Relocated iv. Raw Material Store-Amendment v. WIP room-Relocated			

Recommendations of the panel: -

The section are built, relocated and made amendments as per layout plan approved by DRAP authorities Islamabad vide DRAP letter No. F.2-4/11-lic. Dated 9th December 2019. Necessary utilities, machineries and equipments as required under the guidelines are seen available onsite. Necessary documents relating to QC, QA, installation qualification of machines, HVAC and other utilities were also verified under the scope and found satisfactory.

Based on the above stated facts the panel recommends the following:

i. Dry Powder Inhaler (General)-New
ii. Sachet Section (General)-Relocated
iii. Capsule section (General)-Relocated
iv. Raw Material Store-Amendments
v. WIP room-Relocated

Decision by the Central Licensing Board in 273nd meeting

The Board considered and approved the grant of following sections in the name of M/s Sclife Pharma (Pvt Ltd, Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi. DML No. 000837 (by way of Formulation) as under:

Sections/Facility(05)

i. Dry Powder Inhaler (General)-**New**
ii. Sachet Section (General)-**Revised**
iii. Capsule section (General)- **Revised**

	iv.	Raw Material Store- **Revised**
	v.	WIP room- **Revised**

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.

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1	M/s McOLSON Research Laboratories (Pvt) Ltd, 26-Km, Lahore- Sharikpur Road, District Sheikhupura. DML No. 000664 (Formulation). **Period**: Commencing on 15-06-2019 ending on 14-06-2024.	**24-10-2019**	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Dr. Munawar Hayat, CDC, Punjab, Lahore. 3. Mrs. Majida Mujahid, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - Keeping in view the improvements made by the firm, implementation, of the GMP commitment for future improvement, the member of the panel are opinion to **recommend** the grant of Renewal of Drug Manufacturing License 000664 by way of formulation for the following section". 1) Capsule Section (Cephalosporin) 2) Dry Powder Suspension (Cephalosporin) 3) Dry Powder Injection Section (Cephalosporin). 4) Tablet Section (General) 5) Capsule Section (General) **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000664			

	(Formulation) in the name of M/s McOLSON Research Laboratories (Pvt) Ltd, 26-Km, Lahore-Sharikpur Road, District Sheikhupuraon the recommendations of the panel of experts for the further period of five years Commencing on 15-06-2019 ending on 14-06-2024 for following sections:- 1) Capsule Section (Cephalosporin) 2) Dry Powder Suspension (Cephalosporin) 3) Dry Powder Injection Section (Cephalosporin). 4) Tablet Section (General) 5) Capsule Section (General)			
2	M/s Hamaz Pharmaceuticals (Pvt) Ltd, 13-Km, Lutafabad Bosan Road, Multan. DML No. 000427 (Formulation). **Period**: Commencing on 01-04-2016 ending on 31-03-2021.	**29-08-2019**	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Director Drug Testing Laboratory, Multan. 3. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore. 4. Assistant Director, DRAP, Lahore.
	Recommendations of the panel: Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and review of the production facilities, building, equipments, quality control and quality Assurance, the panel of the opinion to **recommend** the Renewal of Drug Manufacturing License 000427 by way of Formulation to M/s Hamaz Pharmaceuticals (Pvt) Ltd. 13-Km, Boan Road, Lutufabad, Multan for the following section". 1) Tablet Section (General& Antibiotic) 2) Capsule Section (General & Antibiotic) 3) Dry Powder Suspension (General) 4) Oral liquid Section (General) 5) Liquid Injection (Ampoule & Vial) (General) section. 6) Sachet Section (General) 7) Cream Section (General)			

	8) Capsule Section (Cephalosporin) 9) Dry Powder suspension (Cephalosporin) 10) Dry Powder for Injection (Cephalosporin) 11) Dry Powder suspension (Penicillin) 12) Capsule section (Penicillin) 13) Tablet Section (Penicillin) **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000427 (Formulation) in the name of M/s Hamaz Pharmaceuticals (Pvt) Ltd, 13-Km, Lutafabad Bosan Road, Multan on the recommendations of the panel of experts for the further period of five years Commencing on 01-04-2016 ending on 31-03-2021 for following sections:- 1) Tablet Section (General & Antibiotic) 2) Capsule Section (General & Antibiotic) 3) Dry Powder Suspension (General) 4) Oral liquid Section (General) 5) Liquid Injection (Ampoule & Vial) (General) section. 6) Sachet Section (General) 7) Cream Section (General) 8) Capsule Section (Cephalosporin) 9) Dry Powder suspension (Cephalosporin) 10) Dry Powder for Injection (Cephalosporin) 11) Dry Powder suspension (Penicillin) 12) Capsule section (Penicillin) 13) Tablet Section (Penicillin)			
3	M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore. DML No. 000461 (Formulation). **Period**: Commencing on 05-08-2017 ending on 04-08-2022.	**26-06-2019 & 16-09-2019**	**Good**	1.Dr. Farzana Chaudhary, Member, Appellate Board. 2.Mr. Munawar Hayat, Chief Drugs Controller, Punjab. 3.Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore.

	Recommendations of the Panel. "Keeping in view the manufacturing facility like building, HVAC system, sanitation, production Machinery, Equipment in Quality Control Laboratory, testing facilities, the technical personnel met and the review of documentation, the panel of inspectors **recommends** the renewal of Drug Manufacturing License by way of formulation to M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore for Tablet Section (General) and the panel of inspectors also **recommend** the grant of following additional section / expansion. Capsule Section (General)." **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No000461 (Formulation) in the name of M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore on the recommendations of the panel of experts for the further period of five years Commencing on 05-08-2017 ending on 04-08-2022 for following section:- 1. Tablet Section (General)			
4	M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore- Sheikhupura Road, Lahore. DML No. 000532 (Formulation). **Period:** Commencing on 26-01-2019 ending on 25-01-2024.	**31-10-2019**	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Mr. Munawar Hayat, Chief Drugs Controller, Punjab. 3. Mrs. Majida Mujahid, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - "The firm has made a number of improvement which were pointed out during previous inspections regarding installation of new machine/equipment. Improvements in process flow, improvement in documentation system and addition in installation of safety equipment. Keeping in view, the improvements made by the firm, implementation of the GMP and commitment for future improvement, the member of the panel are of opinion to **recommend** the grant of renewal of Drug Manufacturing License (00532) by way of formulation for the following sections:- 1) Tablet (General)			

	2) Tablet (Non Penicillin Antibiotics) 3) Capsule 4) Liquid Injectable 5) Eye Drops. 6) Eye / Ear Drops (Steroidal). 7) Topical Preparation. 8) Ophthalmic Ointment" **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence 000532 (Formulation) in the name of M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore-Sheikhupura Road, Lahore on the recommendations of the panel of experts for the further period of five years Commencing on 26-01-2019 ending on 25-01-2024 for following sections:- 1) Tablet (General) 2) Tablet (Non Penicillin Antibiotics) 3) Capsule 4) Liquid Injectable 5) Eye Drops. 6) Eye / Ear Drops (Steroidal). 7) Topical Preparation. 8) Ophthalmic Ointment"			
5	M/s Popular Chemical Works (Pvt) Ltd, 9-Km, Lahore Sheikhupura Road, Lahore. DML No. 000076 (Formulation). **Period**: Commencing on 30-08-2015 ending on 29-08-2020.	**29-05-2019**	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 3. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore. 4. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore.

	Recommendations of the Panel. "During inspection some points were discussed with the management and advised for improvement and the management agreed. Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control and Microbiology Laboratory. Testing facilities, technical personnel met and documentation, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of Formulation to M/s Popular Chemical Works (Pvt) Ltd, 9.f Km, Sheikhupura Road, Lahore for the followings sections: 1) Tablet section (General& Psychotropic). 2) Capsule section (General). 3) Oral Liquid section (General). 4) Liquid Injectable Ampoule section (General). 5) Dry Powder Suspension section (Penicillin). 6) Capsule section (Penicillin)" **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence 000076 (Formulation) in the name of M/s Popular Chemical Works (Pvt) Ltd, 9-Km, Lahore Sheikhupura Road, Lahore on the recommendations of the panel of experts for the further period of five years Commencing on 30-08-2015 ending on 29-08-2020 for following sections:- 1) Tablet section (General& Psychotropic). 2) Capsule section (General). 3) Oral Liquid section (General). 4) Liquid Injectable Ampoule section (General). 5) Dry Powder Suspension section (Penicillin). 6) Capsule section (Penicillin)"			
6	M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Khan Road, Rawat, Rawalpindi. DML No. 000639 (Formulation) **Period**: Commencing on 19-06-2018 ending 18-06-2023.	**25-11-2019**	**Good**	1. Dr. Muhammad Usman, Member, CLB. 2. Abdul Sattar Sohrani, Deputy Director (QC-I), DRAP, Islamabad. 3. Khalid Mahmood, FID-II, DRAP, Islamabad.

Recommendations of the panel: -

Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Road, Rawat, Rawalpindi for the grant of Drug Manufacturing License No. 000639 (Formulations) w.e.f. 19th June, 2018.

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence 000639 (Formulation) in the name of M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Khan Road, Rawat, Rawalpindi on the recommendations of the panel of experts for the further period of five years Commencing on 19-06-2018 ending 18-06-2023 for following sections: -

i. Oral Liquid (General) Vetarinary
ii. Oral Powder (General) Vetarinary
iii. Liquid Injection (Vial) (General) Section Vetarinary
iv. Tablet (General) Section (Human)
v. Cream/Ointment/Gel (General) Human

7	M/s. Nabi Qasim Industries Private Limited, 17/24, Korangi Industrial Area, Karachi DML No. 000105 (formulation) **Period**: Commencing on 12-07-2019 ending 11-07-2024	**04-12-2019**	**Good**	1. Dr. Abdullah Dayo, Member CLB. 2. Additional Director (E&M)/ Area Federal Inspector of Drugs, DRAP, Karachi.

Recommendations of the panel: -

Based on the people met, documents reviewed and considering the observation made during the inspection including huge exports to about fourty one counties of the world, panel recommends the renewal of Drug Manufacturing License for the following sections

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Capsule (ceph)	ii.	Oral dry powder suspension (Ceph)
iii.	Lyophilized vial (General)	iv.	Tablet (General)

v.	Capsule (General)	vi.	Sachet (General)
vii.	Liquid syrup(General)	viii.	Cream/Ointment (General)
ix.	Ear Drops/Topical solution	x.	Eye Drops
xi.	Dry Powder (General/Antibiotic)	xii.	Enema
xiii.	Tablet Harmone	xiv.	Harmone (Vaginal Tablet/Gel)

The panel has not submitted any recommendations regarding renewal of Licensed section with the title Tablet (Cephalosporin).

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence 000105 (formulation) in the name of M/s. Nabi Qasim Industries Private Limited, 17/24, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the further period of five years Commencing on 12-07-2019 ending 11-07-2024 for following sections:-

Sr. No	**Name of Sections**	**Sr. No**	**Name of Sections**
i.	Capsule (ceph)	ii.	Oral dry powder suspension (Ceph)
iii.	Lyophilized vial (General)	iv.	Tablet (General)
v.	Capsule (General)	vi.	Sachet (General)
vii.	Liquid syrup(General)	viii.	Cream/Ointment (General)
ix.	Ear Drops/Topical solution	x.	Eye Drops
xi.	Dry Powder (General/Antibiotic)	xii.	Enema
xiii.	Tablet Harmone	xiv.	Harmone (Vaginal Tablet/Gel)

The Borad decieded to seek clarification from the panel regarding not recommending the renewal of Licensed section namely Tablet (Cephalosporin).

8	M/s Sami Pharmaceuticals (Pvt) Ltd , Plot No F-129, S.I.T.E Karachi	**05-11-2019**	**Good**	1. Dr. Ghulam Sarwar, Member DRB. 2. Chief Drug Inspector, Sindh

	Drug Manufacturing License No. 000731 (By way of Repacking) **Period**: 20-06-2016 to 19-06-2021			3. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - Keeping in view the management's commitment for continues improvement, existing technical staff and facilities provided; the panel recommends Grant of Renewal of Drug Manufacturing License No. 000731 (By Way of Repacking) to the firm M/s. Sami Pharmaceuticals (Pvt) Ltd situated at Plot no. F-129, S.I.T.E, Karachi. As per DRAP, Islamabad letter No. F.2-2/10-Lic dated 17th September 2019." **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000731 (By way of Repacking) in the name of M/s Sami Pharmaceuticals (Pvt) Ltd , Plot No F-129, S.I.T.E Karachi on the recommendations of the panel of experts for the further period of five years Commencing on 20-06-2016 ending 19-06-2021.			
9	M/s Ray Pharma (Pvt) Ltd, Plot No S-58, S.I.T.E Karachi Drug Manufacturing License No. 000642 (By way formulation) **Period**: 05-09-2018 to 04-09-2023	**21-11-2019**	**Good**	1. Dr. Abdulah Dayo, Member CLB. 2. Additional Director (E&M), DRAP, Karachi 3. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - Based on the stated observations, the panel recommends the renewal of following sections:			

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Capsule (General)
iii.	Liquid Ampoule (General)	iv.	Oral dry powder suspension (General)

	v.	Cream/Ointment/Gel (General)	vi.	Ophthalmic Drops (General)	

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000642 (By way formulation) in the name of M/s Ray Pharma (Pvt) Ltd, Plot No S-58, S.I.T.E Karachi on the recommendations of the panel of experts for the further period of five years Commencing on 05-09-2018 ending 04-09-2023 for following sections:-

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Capsule (General)
iii.	Liquid Ampoule (General)	iv.	Oral dry powder suspension (General)
v.	Cream/Ointment/Gel (General)	vi.	Ophthalmic Drops (General)

10	M/s AGP Limited, D-109, S.I.T.E Karachi Drug Manufacturing License No. 000044 (Formulation) **Period**: 15-07-2019 to 14-07-2024	**07-11-19**	**Good**	1. Dr. Abdulah Dayo, Member CLB. 2. Director DTL, Sindh Karachi 3. Area Federal Inspector of Drugs, DRAP, Karachi.

Recommendations of the panel: -

Keeping in view overall GMP compliance and intend towards improvement, panel unanimously recommend the renewal of DML No. 000044 and regularization of Manufacturing facility of M/s. AGP Limited, Plot No. D-109, S.I.T.E Karachi.

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000044 (Formulation) in the name of M/s AGP Limited, D-109, S.I.T.E Karachi on the recommendations of the panel of experts for the further period of five years Commencing on 15-07-2019 ending 14-07-2024.

11	M/s Sapient Pharma, 123/S	**19-09-2019**	**Good**	1. Dr. Farzana Chowdhary,

	Industrial Area, Kot Lakhpat, Lahore. Drug Manufacturing License No. 000207 (Formulation) **Period**: Commencing on 09-02-2016 ending on 08-02-2021.	**&** **18-11-2019**		Member. 2. Ms. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - In view of above inspection proceedings and facilities checked such as company, profile building machinery material, management, personnel, documentation and quality control testing, etc, the panel **recommends** the renewal of Drug Manufacturing License to M/s Sapient Pharma, 123/S, Industrial Estate, Kot Lakhpat, Lahore by way of formulation for the following sections only:- 1) Oral Liquid Section. 2) General Tablet Section. 3) Cream/Ointment Section. 4) External Preparation Section. 5) Ear Drop Section. 6) Suppository Section". In addition to this it was observed that the area of the firm was 2 Kanal 4 Marlas, however the management of the firm informed that the adjacent land of 2 Kanal 1 Marla was purchased by the firm and now the total area is 04 Kanal 05 Marla as per requirement of Drugs Act 1976/DRAP Act 2012,. The panel advised the firm to submit documents of acquired land for regularization to Licensing Division, DRAP, Islamabad. **<u>Decision by the Central Licensing Board in 273rd meeting</u>** The Board considered and defferred the renewal of Drug Manufacturing Licence No. 000207 (Formulation) in the name of M/s Sapient Pharma, 123/S Industrial Area, Kot Lakhpat, Lahore.for seeking clarification from the firm regarding minimum area of establishment in the light of observation of the panel.			
12	M/s British Pharmaceuticals, 23-Km Sheikhupura Road,	**19-08-2019** **&**	**Good**	1. Dr. Farzana Ch, Member. 2. Mr. Shahid Nasir, Quality

	Lahore. Drug Manufacturing License No. 000729 (Formulation) **Period**: Commencing on 22-06-2016 ending on 21-06-2021.	**27-12-2019**		Control Expert. 3. Dr. Jamil Anwar, Secretary PQCB, Punjab, Lahore. 4. Mrs. MajidaMujahid, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - The firm has made a number of improvements, which were pointed out during previous inspections regarding installation of new machines/equipments. Improvements in process flow, improvements in documentation system.Keeping in view the improvements made by the firm, and commitments for future improvement, the members of the panel are of opinion to **recommend** the grant of new production sections as well as renewal of Drug Manufacturing License (000729) by way of Formulation for the following sections: 1) Liquid Syrup/Suspension (Existing section). 2) Capsule Section (General) (New) 3) Dry Powder Section (General) (New). 4) Tablet Section (General) (New). **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000729 (Formulation) in the name of M/s British Pharmaceuticals, 23-Km Sheikhupura Road, Lahore. on the recommendations of the panel of experts for the further period of five years Commencing on 22-06-2016 ending on 21-06-2021. 1) Liquid Syrup/Suspension			
13	M/s Horizon Healthcare (Pvt) Ltd, Plot No. 33, Sunder Industrial Estate, Lahore. Drug Manufacturing License No. 000782 (Formulation) **Period**: Commencing on 03-	**20-09-2019 & 21-11-2019**	**Good**	1. Dr. Farzana Ch, Expert. 2. Mr. Jamil Anwar, Secretary PQCB, Punjab, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore. 4. Ms. Anam Saeed, Assistant

	02-2019 ending on 02-02-2024.			Director, DRAP, Lahore.
	Recommendations of the panel: - The panel inspections of the firm M/s Horizon Healthcare (Pvt) Ltd, Plot No. 27, Sunder Industrial Estate, Lahore were conducted on 20-09-2019 & 21-11-2019 for grant of renewal of Drug Manufacturing License. All the areas were inspected in detail including stores, production areas, Quality Control, HVAC, water treatment etc and documents were reviewed which were found satisfactory.*But it was noticed during visit that the firm had obtained approval of their revised layout plan in August, 2018 and the building was partially constructed according to the revised layout plan while rest of the areas (including warehouse & some areas of tablet and capsule section) were not in line with the approved layout.*The firm applied for this revision in DRAP Islamabad on 13-12-2019 and submit copy in this office. So, the panel members are of the opinion that the renewal of DML is subject to the condition of approval/ regularization of their existing layout from DRAP Islamabad. **<u>Decision by the Central Licensing Board in 273rd meeting</u>** The Board considered and defferred the renewal of Drug Manufacturing Licence No. 000782 (Formulation) in the name of M/s Horizon Healthcare (Pvt) Ltd, Plot No. 33, Sunder Industrial Estate, Lahore till regularizaiton /approval Layout plan and verification by Area FID .			
14	M/s RemingtonPharmaceutical Industries (Pvt) Ltd, 18-Km Multan Road, Lahore. Drug Manufacturing License No. 000061 (Formulation) **Period**: Commencing on 19-06-2018 ending on 18-06-2023.	**12-06-2019 & 17-07-2019 & 30-09-2019**	**Good**	1. Dr. Farzana Ch, Expert Member. 2. Syed Shahid Nasir, Expert Member. 3. Dr. Zaka ur Rehman, Secretary Punjab Pharmacy council, Lahore. 4. Ms. UzmaBarkat, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: -			

	"The firm was directed to get the existing layout plan approved /regularization from DRAP, Islamabad without fail. 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 Remington Pharmaceutical Industries (Pvt) Ltd, Lahore for the following section," i. Tablet Section (General & Antibiotics) ii. Dry Powder Suspension Section (General& Antibiotics) iii. Capsule Section (General & Antibiotics) iv. Sachet Section General. v. Oral Liquid Section (General) Syrup/Suspension. vi. Eye, Ear & Nose Drops Section (General & Steroid) Solution/ Suspension vii. Eye Ointment Section (General & Steroid) viii. Ear, Nose & Throat Section (General & Steroid) Solution/ Suspension (Ear Drops/ Nasal Spray) ix. Skin Ointment/Cream/Lotion Section (General & Steroid) **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000061 (Formulation) in the name of M/s Remington Pharmaceutical Industries (Pvt) Ltd, 18-Km Multan Road, Lahore on the recommendations of the panel of experts for the further period of five years Commencing on 19-06-2018 ending on 18-06-2023 for following secions:- i. Tablet Section (General & Antibiotics) ii. Dry Powder Suspension Section (General& Antibiotics) iii. Capsule Section (General & Antibiotics) iv. Sachet Section General. v. Oral Liquid Section (General) Syrup/Suspension. vi. Eye, Ear & Nose Drops Section (General & Steroid) Solution/ Suspension

	vii. Eye Ointment Section (General & Steroid) viii. Ear, Nose & Throat Section (General & Steroid) Solution/ Suspension (Ear Drops/ Nasal Spray) ix. Skin Ointment/Cream/Lotion Section (General & Steroid) The borad also decided to advise the firm for regularization of layout plan of existing facility as recommended by the panel.			
15.	M/s Espoir Pharmaceuticals PCSIR KLC, PCSIR Laboratories Complex, Shahrah-e-Drsalim-uz-zamanSiddique, ,Off University Road KLC, Karachi Drug Manufacturing License No. 000754 (By way formulation) **Period**: Commencing on 05-10-2017 ending on 04-10-2022	**19-12-2019**	**Good**	1. Dr. Abdulah Dayo, Member CLB. 2. Additional Director E&M, DRAP Karachi 3. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - Keeping in view the status of observation, current compliance status the panel recommends the resumption of production activates and renewal of DML by way of formulation for following sections: a) Liquid Syrup b) Tablet (General) c) Sachet d) Capsule (General) e) Dry Powder Suspension **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No.			

	000754 (By way formulation) in the name of M/s Espoir Pharmaceuticals PCSIR KLC, PCSIR Laboratories Complex, Shahrah-e-Drsalim-uz-zamanSiddique, ,Off University Road KLC, Karachi on the recommendations of the panel of experts for the further period of five years Commencing on 05-10-2017 ending on 04-10-2022 for following secions:- 1. Liquid Syrup 2. Tablet (General) 3. Sachet 4. Capsule (General) 5. Dry Powder Suspension The borad alos decided to resume the production of the firm as per recommendation of the panel of experts.			
16.	M/s Ahson Drug Company, T/1 SITE, Tando Adam ,Sindh. Drug Manufacturing License No. 000138 (By way formulation) Tenure 17-12-2014 to 16-12-2019	**14-10-2019**	**Good**	1. Dr. Abdullah Dayo, Member CLB. 2. Chief Drug Inspector, Sindh. 3. Additional Director E&M, DRAP Karachi 4. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - Based on the people met, documents reviewed and observations made during the inspection and intention of the management towards export, the panel recommends :- A- The renewal of their DML No. 000138 (By way of Formulation) for following sections : 1. Syrup (General) 2. Tablet (General) 3. Dry Powder Suspension 4. Capsule (General) 5. Ointment (General) 6. Sterile Area (vial/ampoule) 7. Eye Drops 8. Ointment (sterile) B- The panel also advises to the management to submit the layout plan to the			

	DRAP authorities for regularization purposes. **Decision by the Central Licensing Board in 273rd meeting** The borad also decided to advise the firm for regularization of layout plan of existing facility as recommended by the panel.			
17	M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore. DML No. 000493(Formulation) **Period**: Commencing on27-02-2017ending on26-02-2022	**12-06-2019**	**Satisfactory / Average** (w.r.t. Liquid repacking and external preparation sections) **Un-satisfactory (**w.r.t all other sections**)**	1. Dr. Ikram-ul-Haq, Member CLB. 2. Mr. Jamil Anwar, Secretary PQCB, Punjab, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 4. Dr. Akbar Ali, Assistant Director, DRAP, Lahore.
	Case Background:- Panel Inspection report dated 26-11-2018 was received from DRAP, Lahore for renewal of Drug Manufacturing License with following recommendations of the panel. **Recommendations of the panel: -** The Panel of inspectors **does Not Recommend** the renewal of DML bearing No. 000493 issued in favour of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore. **Decision by the Central Licensing Board in 267th meeting** The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. **Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.** The Show Cause notice dated 29th January, 2019 was issued to M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore.			

	The firm has replied to show cause notice and the firm has requested to provide sufficient time to explain their position in writing. **A letter of Personal hearing has been issued on 19-02-2019** **Decision by the Central Licensing Board in 269th meeting** Mr . Arjumand Bhutta, Director of the company appeared before the Board and contended that almost most of the shortcomings have been rectified as advised during the panel inspection and report recived with Showcause Notice. He further contended that period of one month is required to rectify rest of the shortcomings as reported in the report. The Board after hearing the representative of the firm decided to give one month period to the firm. The company shall submit request for re-inspection of the unit once rectification are made and accordingly a panel would be constituted to conduct inspection for consideration of the Board. Meanwhile Licence of the company shall remain suspended. **Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.** The Licensing Division issued Drug Manufacturing License suspension letter dated 13-03-2019. The firm submitted compliance report and request for re-inspection. Following panel of experts were constituted dated 06-05-2019. 1. Dr. Ikram-ul-Haq, Member CLB. 2. Mr. Jamil Anwar, Secretary PQCB, Punjab, Lahore. 3. Area Federal Inspector of Drugs, DRAP, Lahore. 4. Area Assistant Director, DRAP, Lahore. Inspection report has been received from DRAP, Lahore with following recommendations of the panel. **Recommendations of the panel: -** The Panel of Inspectors **Recommends** the renewal of DML bearing No. 000493 issued in favour of M/s Nawabsons Laboratories (Pvt) Ltd in respect of Liquid repacking and external preparation sections only. The Panel of Inspectors **does not recommend** the renewal in respect of all other sections. The Panel further recommends suspension of production in all the section which are not recommended for renewal till the rectification of shortcoming and GMP compliance. **Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**

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

Decision by the Central Licensing Board in 271st meeting

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

Sections

1. Liquid Repacking
2. External Preparation Sections

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

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

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

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

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

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

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

for renewal till the rectification of shortcomings and GMP compliance".

Decision by the Central Licensing Board in 273rd meeting

1. The Board considered and approved the renewal of Drug Manufacturing Licence No. 000493 (Formulation) in the name of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore on the recommendations of the panel of experts for the further following sections
    i. Oral liquid Section General
    ii. Tabelt section General
2. The Borad did not approved the renewal of Secions namely Tablet (Antibiotic), Capsule, cream/ointment and oral dry powder suspension sections, on the recommendation of panel of Experts / Inspector till the rectification of shortcomings and GMP compliance the production shall remain suspended till rectification made and verified by the panel constituted by the Board.
3. The board also decieded to advise the firm for regularization of layout plan for better GMP compliance.

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ITEM – V MISC CASES

CaseNo.1 CHANGE OF MANAGEMENT OF M/S AMSON VACCINES & PHARMA (PVT) LTD, 154, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD

M/s Amson Vaccines & Pharma (Pvt) Ltd., 154, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000393 (By way of formulation) has submitted request for change in management of the firm as per Form-1A along with prescribed Fee Challan of 50,000/- as under: -

Previous Management as per Form 29	**Outgoing Management**	**New Management as per Form 29**
1. Mr. Dilawar Khan S/o Roshan Khan, CNIC No. 161019-288045-5. 2. Syed Saleem Asghar S/o Asghar Ali Sagheer, CNIC No. 37405-0386356-5. 3. Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan CNIC No. 37405-9227345-7.	Mr. Dilawar Khan S/o Roshan Khan, CNIC No. 161019-288045-5.	1.Syed Saleem Asghar S/o Asghar Ali Sagheer, CNIC No. 37405-0386356-5. 2.Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan CNIC No. 37405-9227345-7. 3.Mr. Abbas Khan S/o Dilawar Khan CNIC No. 16101-9382481-7.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s Amson Vaccines & Pharma (Pvt) Ltd., 154, Industrial Triangle, Kahuta Road, Islamabadunder DML No. 000393 by way of Formulationas under ;

Previous Management as per Form 29	**Outgoing Management**	**New Management as per Form 29**
1. Mr. Dilawar Khan S/o Roshan Khan, CNIC No. 161019-288045-5. 2.Syed Saleem Asghar S/o Asghar Ali Sagheer, CNIC No. 37405-0386356-5. 3.Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan CNIC No. 37405-9227345-7.	1.Mr. Dilawar Khan S/o Roshan Khan, CNIC No. 161019-288045-5.	1. Syed Saleem Asghar S/o Asghar Ali Sagheer, CNIC No. 37405-0386356-5. 2.Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan CNIC No. 37405-9227345-7. 3.Mr. Abbas Khan S/o Dilawar Khan CNIC No. 16101-9382481-7.

CaseNo.2 **CHANGE OF MANAGEMENT OF M/S MEDWELL PHARMACEUTICALS, 1-KM, TERBELLA ROAD, LAWRENCEPUR, FAQIRABAD.**

M/s Medwell Pharmaceuticals, 1-Km, Terbella Road, Lawrencepur, Faqirabad, under DML No. 000699 (By way of formulation) has submitted request for change in management of the firm as per Form-1A along with prescribed Fee Challan of 50,000/- as under:-

Previous Management	Outgoing Management	New Management
1. Mr. Jvaied Iqbal Chishti S/o Abdul Hameed CNIC No. 37406-6558480-7. 2. Mr. Shabeer Ahmad S/o Shamsuddin CNIC No. 38403-7945363-1. 3. Mr. Mohammad Munir S/o Shamsuddin CNIC No. 38403-4474939-7.	1.Mr. Jvaied Iqbal Chishti S/o Abdul Hameed CNIC No. 37406-6558480-7. 2.Mr. Shabeer Ahmad S/o Shamsuddin CNIC No. 38403-7945363-1. 3.Mr. Mohammad Munir S/o Shamsuddin CNIC No. 38403-4474939-7.	1. Syed Mansoor Ali Shah S/o Syed Mehmood Ali Shah CNIC No. 37485-7498787-9. 2. Mr. Umer Hayat Khan S/o Qamar Hayat Khan CNIC No. 35201-0568913-5.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management M/s Medwell Pharmaceuticals, 1-Km, Terbella Road, Lawrencepur, Faqirabad, under DML No. 000699 by way of Formulation as under;

Previous Management	Outgoing Management	New Management
1. Mr. Jvaied Iqbal Chishti S/o Abdul Hameed CNIC No. 37406-6558480-7. 2. Mr. Shabeer Ahmad S/o Shamsuddin CNIC No. 38403-7945363-1. 3. Mr. Mohammad Munir S/o Shamsuddin CNIC No. 38403-4474939-7.	1. Mr. Jvaied Iqbal Chishti S/o Abdul Hameed CNIC No. 37406-6558480-7. 2.Mr. Shabeer Ahmad S/o Shamsuddin CNIC No. 38403-7945363-1. 3.Mr. Mohammad Munir S/o Shamsuddin CNIC No. 38403-4474939-7.	1. Syed Mansoor Ali Shah S/o Syed Mehmood Ali Shah CNIC No. 37485-7498787-9. 2. Mr. Umer Hayat Khan S/o Qamar Hayat Khan CNIC No. 35201-0568913-5.

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

M/s Trigon Pharmaceuticals (Pvt) Ltd, 8-Km, Thokar Raiwind road, Lahore,under DML No. 000342 by way of Formulationhas submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-29	Added Management as per Form-29	New Management as per Form-29
1. Mr. Shahid Munir S/o Muhammad Munir Khan CNIC No. 35202-2938966-1. 2. Mr. Khalid Munir S/o Muhammad Munir Khan CNIC No. 35202-6378136-7. 3. Mr. Muhammad Irshad S/o Muhammad Shafi CNIC No. 35202-1660976-3.	1.Mr. Rizwan Ahmed Khan S/o Muhammad Khan, CNIC No. 36302-5064463-5. 2.Mr. Muhammad Safder S/o Ch. Muhammad Shafi CNIC No. 36501-3646813-9.	1. Mr. Muhammad Safder S/o Ch. Muhammad Shafi CNIC No. 36501-3646813-9. 2. Mr. Rizwan Ahmed Khan S/o Muhammad Khan, CNIC No. 36302-5064463-5.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management ofM/s Trigon Pharmaceuticals (Pvt) Ltd, 8-Km, Thokar Raiwind road, Lahore, under DML No. 000342 by way of Formulation as under;

Previous Management as per Form-29	Added Management as per Form-29	New Management as per Form-29
1. Mr. Shahid Munir S/o Muhammad Munir Khan CNIC No. 35202-2938966-1. 2. Mr. Khalid Munir S/o Muhammad Munir Khan CNIC No. 35202-6378136-7. 3. Mr. Muhammad Irshad S/o Muhammad Shafi CNIC No. 35202-1660976-3.	1. Mr. Rizwan Ahmed Khan S/o Muhammad Khan, CNIC No. 36302-5064463-5. 2.Mr. Muhammad Safder S/o Ch. Muhammad Shafi CNIC No. 36501-3646813-9.	1. Mr. Muhammad Safder S/o Ch. Muhammad Shafi CNIC No. 36501-3646813-9. 2. Mr. Rizwan Ahmed Khan S/o Muhammad Khan, CNIC No. 36302-5064463-5.

Case No.4 **CHANGE OF MANAGEMENT OF M/S PERFECT PHARMA (PVT) LTD, LAHORE.**

M/s Perfect Pharma (Pvt) Ltd, 5-Km, Manga Road, Raiwind, Lahore, under DML No. 000469 by way of Formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under: -

Previous Management as per Form-29	Retire Management as per Form-29	Management as per Form-29
1. Mr. Aijaz Ahmad S/o Malik Muhammad Hussain CNIC No. 35202-6647750-3. 2. Mr. Asad Aijaz Malik S/o Aijaz Ahmad CNIC No. 35202-8924661-3-9. 3. Mr. Azhar Aijaz S/o Aijaz Ahmad CNIC No. 35202-2884870-9.	1. Mr. Aijaz Ahmad S/o Malik Muhammad Hussain CNIC No. 35202-6647750-3. 2. Mr. Asad Aijaz Malik S/o Aijaz Ahmad CNIC No. 35202-8924661-3-9. 3. Mr. Azhar Aijaz S/o Aijaz Ahmad CNIC No. 35202-2884870-9.	1. Mr. Salman Shafi S/o Muhammad Jameel Akhtar CNIC No. 42101-4318679-9. 2. Mr. Farhan Jawed S/o Jawed Iqbal CNIC No.42201-0699080-5.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s Perfect Pharma (Pvt) Ltd, 5-Km, Manga Road, Raiwind, Lahore, under DML No. 000469 by way of Formulation as under;

Previous Management as per Form-29	Retiring Management as per Form-29	New Management as per Form-29
1. Mr. Aijaz Ahmad S/o Malik Muhammad Hussain CNIC No. 35202-6647750-3. 2. Mr. Asad Aijaz Malik S/o Aijaz Ahmad CNIC No. 35202-8924661-3-9. 3. Mr. Azhar Aijaz S/o Aijaz Ahmad CNIC No. 35202-2884870-9.	1. Mr. Aijaz Ahmad S/o Malik Muhammad Hussain CNIC No. 35202-6647750-3. 2. Mr. Asad Aijaz Malik S/o Aijaz Ahmad CNIC No. 35202-8924661-3-9. 3. Mr. Azhar Aijaz S/o Aijaz Ahmad CNIC No. 35202-2884870-9.	1. Mr. Salman Shafi S/o Muhammad Jameel Akhtar CNIC No. 42101-4318679-9. 2. Mr. Farhan Jawed S/o Jawed Iqbal CNIC No.42201-0699080-5.

Case No.5 **CHANGE OF MANAGEMENT OF M/S STANDPHARM PAKISTAN (PVT) LTD, 20-KM FEROZEPUR ROAD, LAHOR**

M/s StandPharm Pakistan (Pvt) Ltd, 20-Km Ferozepur Road, Lahore under DML No. 000051 (Formulation) has submitted request for change in management of the firm as per Form-1A along with prescribed Fee Challan of 50,000/- as under:-

Previous management As per Form-1A	Added New Management	New Management As per Form-1A & Form-29
1. Mr. Farooq Ahmed Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2645836-7. 2. Mr. Abdul Quddos Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2647942-3. 3. Mr. Munir Ahmed S/o Mushtaq Ahmad, CNIC No. 35200-1550943-7	1. Mr. Tahir Mustafa Ahmed S/o Mushtaq Ahmad CNIC No. 35202-8036372-7	1. Mr. Farooq Ahmed Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2645836-7. 2. Mr. Abdul Quddos Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2647942-3. 3. Mr. Munir Ahmed S/o Mushtaq Ahmad, CNIC No. 35200-1550943-7 4. Mr. Tahir Mustafa Ahmed S/o Mushtaq Ahmad CNIC No. 35202-8036372-7

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management ofM/s StandPharm Pakistan (Pvt) Ltd, 20-Km Ferozepur Road, Lahore under DML No. 000051 (Formulation) as under;

Previous management As per Form-1A	Added New Management	New Management As per Form-1A & Form-29
1. Mr. Farooq Ahmed Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2645836-7. 2. Mr. Abdul Quddos Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2647942-3. 3. Mr. Munir Ahmed S/o Mushtaq Ahmad, CNIC No. 35200-1550943-7	1. Mr. Tahir Mustafa Ahmed S/o Mushtaq Ahmad CNIC No. 35202-8036372-7	1. Mr. Farooq Ahmed Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2645836-7. 2. Mr. Abdul Quddos Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2647942-3. 3. Mr. Munir Ahmed S/o Mushtaq Ahmad, CNIC No. 35200-1550943-7

		4. Mr. Tahir Mustafa Ahmed S/o Mushtaq Ahmad CNIC No. 35202-8036372-7

CaseNo.6 **CHANGE OF NAME / TITLE AND MANAGEMENT OF UNLICENSED PHARMACEUTICALS UNIT M/S M&J PHARMACEUTICALS, PLOT NO.L 28, STREET NO. SS-2, RCCI, INDUSTRIAL ESTATE, RAWAT, RAWALPINDI.**

M/s M&J Pharmaceuticals, Plot No. 28, Street No. SS-2, RCCI, Industrial Estate, Rawat, Rawalpindi has submitted request for Change of Name / Title and management of unlicensed Pharmaceutical Unit with fee of Rs.10,000/-. The pre-requisite documents of the change of name / title and management are as under: -

i. Change of Name/Title.

Previous Name	**New Name**
M&J Pharmaceuticals.	Pharmonix Pharmaceuticals.

ii. Change of Management.

S.#.	**Old Management.**	**New Management.**
1.	i. Naraish Perkash. ii. Roop Chand.	i. Muhammad Waqas Ali S/o Muhammad Azmat Ali, CNIC No. 17301-1520035-9. ii. Amjad Ali Zeb S/o Muhammad Aurangzeb, CNIC No. 42201-3056252-3. iii. Muhammad Ishaq Badshah S/o Muhammad Azmat Ali, CNIC No.16102-4145509-5.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of title of M/s M&J Pharmaceuticalsas under;

Previous Name	**New Name**
M&J Pharmaceuticals.	Pharmonix Pharmaceuticals.

The Board considered and endorsed the change of management of Pharmonix Pharmaceuticals as under;

S.#.	**Old Management.**	**New Management.**
1.	i. Naraish Perkash. ii. Roop Chand.	i. Muhammad Waqas Ali S/o Muhammad Azmat Ali, CNIC No. 17301-1520035-9. ii. Amjad Ali Zeb S/o Muhammad Aurangzeb, CNIC No. 42201-

		3056252-3. iii. Muhammad Ishaq Badshah S/o Muhammad Azmat Ali, CNIC No.16102-4145509-5.

Case No.7. CHANGE OF MANAGEMENT OF M/S ICI PAKISTAN LTD, 32/2A, PHASE-III, INDUSTRIAL ESTATE, HATTAR.

M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar under DML No. 000363by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

Previous management as per Form-29 of S.E.C.P.	Retiring Management as per Form-29 of S.E.C.P	Current management as per Form-A & Form-29 of S.E.C.P.
1. Mr. Asif Jooma CNIC No.42301-3175078-7 . 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Saboor Ahmad CNIC No.35202-2339737-9.	1.Mr. Saboor Ahmad CNIC No.35202-2339737-9.	1. Mr. Asif Jooma CNIC No.42301-3175078-7. 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Kamal A Chinoy CNIC No. 42301-1401852-5. 6. Mr. Jawed Yunus Tabba CNIC No. 42201-21111104-7. 7. Amina Abdul Aziz Bawany CNIC No. 42000-3004991-0. 8. Khawaja Iqbal Hassan CNIC No. 42301-8986425-7.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar under DML No. 000363by way of formulation as under;

Previous management as per Form-29 of S.E.C.P.	Retiring Management as per Form-29 of S.E.C.P	New management as per Form-A & Form-29 of S.E.C.P.
1. Mr. Asif Jooma CNIC No.42301-3175078-7 . 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Saboor Ahmad CNIC No.35202-2339737-9.	1.Mr. Saboor Ahmad CNIC No.35202-2339737-9.	1. Mr. Asif Jooma CNIC No.42301-3175078-7. 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Kamal A Chinoy CNIC No. 42301-1401852-5. 6. Mr. Jawed Yunus Tabba CNIC No. 42201-

		21111104-7. 7. Amina Abdul Aziz Bawany CNIC No. 42000-3004991-0. 8. Khawaja Iqbal Hassan CNIC No. 42301-8986425-7.

Case No.8. CHANGE OF TITLE OF M/S ICI PAKISTAN LTD, 32/2A, PHASE-III, INDUSTRIAL ESTATE, HATTAR.

M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar under DML No. 000363by way of Formulation has submitted request for change of title of the firm as per Form-29 along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

Current Title of firm.	Proposed title of Firm.
M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase-III, Industrial Estate, Hattar.	M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of title of M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar under DML No. 000363by way of Formulation as under;

Current Title of firm.	New title of Firm.
M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase-III, Industrial Estate, Hattar.	M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar.

CaseNo.9 CHANGE OF MANAGEMENT OF M/S MEDITECH, PESHAWAR.

M/s Meditech, Peshawar, under DML No. 000544 By way of Formulationhas submitted request for change in management of the firm as per Form-1A along with prescribed Fee Challan of 50,000/- as under:-

Current Management as per Sole proprietor	Incoming management as per Partnership Deed	New Management as per Form-H & Partnership Deed
1. Mr. Nadeem Shahzad Nawaz S/o Haji Abdul Rasheed CNIC No.17301-9554612-3.	1. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-276733-5	1. Mr. Nadeem Shahzad Nawaz S/o Haji Abdul Rasheed CNIC No.17301-9554612-3 2. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-276733-5

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s Meditech, Peshawar, under DML No. 000544 By way of Formulation as under;

Current Management as per Sole proprietor	Incoming management as per Partnership Deed	New Management as per Form-H & Partnership Deed
1. Mr. Nadeem Shahzad Nawaz S/o Haji Abdul Rasheed CNIC No.17301-9554612-3.	1. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-276733-5.	1. Mr. Nadeem Shahzad Nawaz S/o Haji Abdul Rasheed CNIC No.17301-9554612-3 2. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-276733-5

Case No. 10. <u>CHANGE OF MANAGEMENT OF M/S PHARMATEC PAKISTAN (PRIVATE) LIMITED, D-86/A, SITE, KARACHI.</u>

M/S Pharmatec Pakistan (Private) Limited, D-86/A, SITE, Karachi under DML No. 000024 (By way of formulation) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Existing Management as per Form 29 (year 2016)	Retiring Management	New Management as per Form 29 (year 2019)
1.Dr. Shahida Qaisar W/o Qazi Qamar Uddin CNIC No. 42201-0704198-1 2.Mr. Pervez Hayat Noon	1.Mr. Pervez Hayat Noon	1 Dr. Shahida Qaisar W/o Qazi Qamar Uddin CNIC No. 42201-0704198-1 2. Mr. Qazi Zia Uddin S/O Mr. Qazi Qamar Uddin CNIC No. 42201-0704198-1

<u>Decision by the Central Licensing Board in 273rd meeting:</u>

The Board considered and endorsed the change of mangement of M/S Pharmatec Pakistan (Private) Limited, D-86/A, SITE, Karachi under DML No. 000024 By way of Formulation as under;

Existing Management as per Form 29 (year 2016)	Retiring Management	New Management as per Form 29 (year 2019)

1.Dr. Shahida Qaisar W/o Qazi Qamar Uddin CNIC No. 42201-0704198-1 2.Mr. Pervez Hayat Noon	1.Mr. Pervez Hayat Noon	1 Dr. Shahida Qaisar W/o Qazi Qamar Uddin CNIC No. 42201-0704198-1 2. Mr. Qazi Zia Uddin S/O Mr. Qazi Qamar Uddin CNIC No. 42201-0704198-1

Case No. 11. <u>CHANGE OF MANAGEMENT OFM/S RAY PHARMA (PVT) LTD, PLOT NO S-58, S.I.T.E KARACHI</u>

M/s Ray Pharma (Pvt) Ltd, Plot No S-58, S.I.T.E Karachi under Drug Manufacturing License No. 000642 (By way formulation)) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Sr. No	Existing Management	Retiring Management	Existing Management
1.	Mr. Farouq Habib Rahimtoola S/o Habib Ibrahim Rahimtoola CNIC NO. 42000-0447756-1	Ms. Nadia Abbas Rahimtoola	Mr. Farouq Habib Rahimtoola S/o Habib Ibrahim Rahimtoola CNIC NO. 42000-0447756-1
2.	Mr. Abbas Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-0447648-7	Mr. Mustafa Jaffar	Mr. Abbas Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-0447648-7
3.	Mr. Aly Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-9497690-3	Mr. Stephen Christopher Smith	Mr. Aly Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-9497690-3
4.	Mr. Hassan Maqbool	********	Mr. Hassan Maqbool

	Rahimtoola S/o Maqbool HH Rahimtoola CNIC NO. 42201-0432772-1		Rahimtoola S/o Maqbool HH Rahimtoola CNIC NO. 42201-0432772-1
5.	Ms. Nadia Abbas Rahimtoola	********	Mr. Shahab Bilal S/o Sajjad Haider CNIC NO. 42201-0592770-7
6.	Mr. Mustafa Jaffar	********	Mr. Muhammad Habib Abbas Rahimtoola S/o Abbas Farouq Rahimtoola CNIC NO. 42000-1868817-3
7.	Mr. Stephen Christopher Smith	********	********

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s Ray Pharma (Pvt) Ltd, Plot No S-58, S.I.T.E Karachi under Drug Manufacturing License No. 000642 By way of Formulation as under;

Sr. No	Existing Management	Sr. No	Retiring Management	Sr. No	Existing Management
1.	Mr. Farouq Habib Rahimtoola S/o Habib Ibrahim Rahimtoola CNIC NO. 42000-0447756-1	1.	Ms. Nadia Abbas Rahimtoola	1	Mr. Farouq Habib Rahimtoola S/o Habib Ibrahim Rahimtoola CNIC NO. 42000-0447756-1
2.	Mr. Abbas Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-0447648-7	2.	Mr. Mustafa Jaffar	2	Mr. Abbas Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-0447648-7
3.	Mr. Aly Farouq Rahimtoola S/o Farouq	3.	Mr. Stephen Christopher Smith	3.	Mr. Aly Farouq Rahimtoola S/o Farouq

	Habib Rahimtoola CNIC NO. 42000-9497690-3				Habib Rahimtoola CNIC NO. 42000-9497690-3
4.	Mr. Hassan Maqbool Rahimtoola S/o Maqbool HH Rahimtoola CNIC NO. 42201-0432772-1		********	4.	Mr. Hassan Maqbool Rahimtoola S/o Maqbool HH Rahimtoola CNIC NO. 42201-0432772-1
5.	Ms. Nadia Abbas Rahimtoola		********	5.	Mr. Shahab Bilal S/o Sajjad Haider CNIC NO. 42201-0592770-7
6.	Mr. Mustafa Jaffar		********	6.	Mr. Muhammad Habib Abbas Rahimtoola S/o Abbas Farouq Rahimtoola CNIC NO. 42000-1868817-3
7.	Mr. Stephen Christopher Smith		********		********

Case No. 12. <u>CHANGE OF MANAGEMENT OFM/S BOSCH PHARMACEUTICALS (PVT) LTD, PLOT NO 221, SECTOR 23, KORANGI INDUSTRIAL AREA KARACHI</u>

M/s Bosch Pharmaceuticals (Pvt) Limited, Plot No. 221, Sector 23, Korangi Industrial Area, Karachi under Drug Manufacturing License No. 000350 (By way formulation)) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Sr. No	Existing Management	Incoming Management	New Management
1.	Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7	Mr. Ambia Nasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3	Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7

2.	Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1	Ms. Farzana Faisal	Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1
3.	Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3	********	Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3
4.	Mr. Zakraria Nasib S/O Mr. Ahmed Nasib CNIC NO. 42201-2340655-3	********	Mr. Zakraria Nasib S/O Mr. Ahmed Nasib CNIC NO. 42201-2340655-3
	********	********	Mr. Ambia Nasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s Bosch Pharmaceuticals (Pvt) Limited, Plot No. 221, Sector 23, Korangi Industrial Area, Karachi under Drug Manufacturing License No. 000350 (By way formulation as under;

Sr. No	Existing Management	Incoming Management	New Management
1.	Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7	Mr. Ambia Nasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3	Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7
2.	Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1	Ms. Farzana Faisal	Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1
3.	Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3	********	Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3
4.	Mr. Zakraria Nasib S/O Mr. Ahmed	********	Mr. Zakraria Nasib S/O Mr. Ahmed Nasib CNIC NO.

	Nasib CNIC NO. 42201-2340655-3		42201-2340655-3
	********	********	Mr. Ambia Nasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3

Case No. 13. <u>CHANGE OF MANAGEMENT OFM/S OBS PAKISTAN (PRIVATE) LIMITED, C-14, MANGOPIR ROAD, S.I.T.E KARACHI</u>

M/s OBS Pakistan (Private) Limited, C-14, Mangopir Road, S.I.T.E Karachi under Drug Manufacturing License No. 000012 (By way formulation)) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Sr. No	Existing Management	Interim Management	New Management
1.	Mr. Tarek Khan	Mr. Tariq Moinuddin Khan S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1	Mr. Munis Abdullah S/o Mr. Rashid Abdullah CNIC No. 42201-9982517-1
2.	Dr. Jehanzeb Akram	Ms Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2	Miss. Faiza Naeem W/o Mr. Naeem Idress Allahwala CNIC No. 42201-0540338-0
3.	**********	Ms. Nusrat Munshi D/o Alauddin Munshi CNIC NO. 42301-7644816-8	Mr. Mudassir Habbib Khan S/o Mr. Musharaf Zaman Khan CNIC No. 42000-0528026-1
4.	**********	Mr. Mirza Anjum Fahim S/o Mr. Mirza Fahim Uddin CNIC No. 42101-7618398-1	Mr. Hammad Bin Kafeel S/o Mr. Kafeel Ahmed CNIC No. 42101-1938271-9
5.	**********	Mr Muhammad Arif Mian S/o Mian	Mr. Mirza Anjum Fahim S/o Mr. Mirza

		Muhammad Ali CNIC No. 37405-2992199-9	Fahim-ud-Din CNIC No. 42101-7618398-1
6.	**********	Mr. Muhammad Arsalan Batla S/o Muhammad Younus Batla CNIC No. 42201-7571901-7	Mr. Tariq Moin-ud-din S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s OBS Pakistan (Private) Limited, C-14, Mangopir Road, S.I.T.E Karachi under Drug Manufacturing License No. 000012 By way of Formulationas under;

Sr. No	Existing Management	Interim Management	New Management
1.	Mr. Tarek Khan	Mr. Tariq Moinuddin Khan S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1	Mr. Munis Abdullah S/o Mr. Rashid Abdullah CNIC No. 42201-9982517-1
2.	Dr. Jehanzeb Akram	Ms Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2	Miss. Faiza Naeem W/o Mr. Naeem Idress Allahwala CNIC No. 42201-0540338-0
3.	**********	Ms. Nusrat Munshi D/o Alauddin Munshi CNIC NO. 42301-7644816-8	Mr. Mudassir Habbib Khan S/o Mr. Musharaf Zaman Khan CNIC No. 42000-0528026-1
4.	**********	Mr. Mirza Anjum Fahim S/o Mr. Mirza Fahim Uddin CNIC No. 42101-7618398-1	Mr. Hammad Bin Kafeel S/o Mr. Kafeel Ahmed CNIC No. 42101-1938271-9
5.	**********	Mr Muhammad Arif Mian S/o Mian Muhammad Ali CNIC No. 37405-2992199-9	Mr. Mirza Anjum Fahim S/o Mr. Mirza Fahim-ud-Din CNIC No. 42101-7618398-1
6.	**********	Mr. Muhammad	Mr. Tariq Moin-ud-

		Arsalan Batla S/o Muhammad Younus Batla CNIC No. 42201-7571901-7	din S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1

CASE NO. 14. <u>CORRECTION IN CHANGE OF MANAGEMENT OF M/S JAENS PHARMACEUTICAL INDUSTRIES (PVT) LTD, LAHORE</u>

M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore under DML No. 000352 by way of formulation has submitted request for change in management of the firm as per Form-A with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;-

Previous Management as per Form-1A	**Restring Management**	**New Management as per Form-A**
1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9. 5. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9.

<u>Decision by the Central Licensing Board in 271st meeting:</u>

The Board considered and endorsed the change of management of M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore under DML No. 000352 by way of formulation as under ;

Previous Management as per Form-1A	Restring Management	New Management as per Form-A
1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9. 5. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. 3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9.

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

It is pertinent to mention here that in the minutes of 271st meeting of CLB, the name of one Director was mistakenly written as Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal instead of Mr. Nasim Iqbal S/o Muhammad Iqbal.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the correction in change of management of M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore under DML No. 000352 by way of formulation as under;

Previous Management as per Form-1A	Restring Management	New Management as per Form-A

1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9. 5. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. Mr. Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9.

Case No. 15. <u>CORRECTION IN CHANGE OF MANAGEMENT OF M/S SAMI PHARMACEUTICALS (PVT) LTD, F-129, SITE, KARACHI</u>

M/s Sami Pharmaceuticals (Pvt) ltd, F-129, SITE, Karachi under DML No. 000731 (By way of Re-packing) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7
2.	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3	********	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3
3.	Mrs. Nafees Yaseen Malik	********	Mr. Abdul Salam S/O

	W/O Yaseen Malik CNIC NO. 42301-4246934-6		Zikr-ur-Rehman CNIC No. 42201-6555398-5
4.	********	********	Mr. Shohaib Shamim S/O Shamim Ahmed CNIC No. 42201-0709871-7
5.	********	********	Mr. Owais Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-5
6.	********	********	Mr. Muhammad yaseen Malik S/o Hameed eid Muhammad CNIC No.42301-0668555-7
7.	********	********	Mr. Zubair Shamim S/o Shamim Ahmed CNIC No.42201-07079872-3

Decision by the Central Licensing Board in 271st meeting:

The Board considered and endorsed the change of management of M/s Sami Pharmaceuticals (Pvt) ltd, F-129, SITE, Karachi under DML No. 000731 (By way of Re-packing) as under ;

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7
2.	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3	********	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3
3.	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	********	Mr. Abdul Salam S/O Zikr-ur-Rehman CNIC No. 42201-6555398-5
4.	********	********	Mr. Shohaib Shamim S/O Shamim Ahmed CNIC

			No. 42201-0709871-7
5.	********	********	Mr. Owais Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-5
6.	********	********	Mr. Muhammad yaseen Malik S/o Hameed eid Muhammad CNIC No.42301-0668555-7
7.	********	********	Mr. Zubair Shamim S/o Shamim Ahmed CNIC No.42201-07079872-3

Decision by the Central Licensing Board in 271st meeting:

The Board considered and endorsed the change of management of M/s Sami Pharmaceuticals (Pvt) ltd, F-129, SITE, Karachi under DML No. 000731 (By way of Re-packing) as under ;

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7
2.	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3	********	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3
3.	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	********	Mr. Abdul Salam S/O Zikr-ur-Rehman CNIC No. 42201-6555398-5
4.	********	********	Mr. **Shoaib** Shamim S/O Shamim Ahmed CNIC No. 42201-0709871-7
5.	********	********	Mr. Owais Shamim S/O

			Shamim Ahmed CNIC No. 42201-0709876-5
6.	********	********	Mr. Muhammad yaseen Malik S/o Hameed eid Muhammad CNIC No.42301-0668555-7
7.	********	********	Mr. Zubair Shamim S/o Shamim Ahmed CNIC No.42201-**0709872**-3

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

It is pertinent to mention here that in the minutes of 271st meeting of CLB, the name of one Director was mistakenly written as Mr. Shohaib Shamim instead of Shoaib Shamim and CNIC of one of the director Mr. Zubair Shamim was mentiond as 42201-07079872-3 instead of 42201-0709872-3

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the correction in change of management of M/s Sami Pharmaceuticals (Pvt) ltd, F-129, SITE, Karachi under DML No. 000731 by way of Re-packing as under;

Sr. No	**Existing Management**	**Retiring Management**	**New Management**
1.	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7
2.	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3	********	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3
3.	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	********	Mr. Abdul Salam S/O Zikr-ur-Rehman CNIC No. 42201-6555398-5
4.	********	********	Mr. ShoaibShamim S/O

			Shamim Ahmed CNIC No. 42201-0709871-7
5.	********	********	Mr. Owais Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-5
6.	********	********	Mr. Muhammad yaseen Malik S/o Hameed eid Muhammad CNIC No.42301-0668555-7
7.	********	********	Mr. Zubair Shamim S/o Shamim Ahmed CNIC No.42201-0709872-3

Case No. 16 <u>RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MYRTLE PHARMA, KARACHI</u>

M/s Myrtle Pharma Karachi Plot No. E-100, North Western industrial Zone,Bin Qasim Karachi, had applied for renewal of DML No. 000722 by way of formulation for the period of 22-06-2016 t21-06-2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 01-02-2018 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i) Form-1A duly attested and signed by owner/ Director of firm alongwith all attested enclosures.
ii) Detail of management on firm's letter head alongwith attested CNIC copies of Partners or Sole proprietor at present renewal and at the time of previous renewal of DML.
iii) Approval Complete set of duly attested documents for proposed Production Incharge and Quality Control Incharge as (per check list)..

The firm submitted their reply on 07th March 2017. After evaluation of the submitted documents, Final reminder was issued on 17th May 2018. to the firm to submit following shortcomings: -

1. Undertaking on stamp paper of Proposed Quality Incharge & Production Incharge
2. Attested copy of CNIC and academic degree along with Registration Certificate issued from Pharmacy Council of proposed Production Incharge Mr. Rana Akram (dully attested).
3. Experience certificates of proposed Production Incharge.
4. Relevant experience certificates in testing of drugs of 10 years of Proposed Quality Incharge.
5. **All documents should be duly attested.**

No reply is received from the firm till date and application for renewal of DML is still incomplete as of today.

Proceedings and Decision by the Central Licensing Board in 271st meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Myrtle Pharma Karachi Plot No. E-100, North Western industrial Zone, Bin Qasim Karachi, Drug Manufacturing Licence No 000722 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.

A show cause notice Dated : 16th October 2019 was issued to the firm. The reply of show cause notice is received from the firm M/s Myrtle Pharma, Karachi wherein firm has stated that due to sudden death of the father of Deputy Chief Executive Ms. Arhama Nasim and subsequent stoppage of activities due to the absence of any male family member who could took over the responsibility immediately, she has recently involved in the company matters and has requested to give some time (at least two months) to fulfill required information.

The firm is also called for Personal Hearing vide letter Dated : 16th October 2020.

Decision by the Central Licensing Board in 273rd meeting

No person appeared on behalf of the firm. The Board after considering the facts decided to defer the case for giving final opportunity to the firm to plead his case.

Case No. 17.RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S. KALIGON AGRO INDUSTRIES (PVT) LTD, BALUCHISTAN

1	M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Hub Chowki Road (RCD), Lasbella, Baluchistan DML No. 000277 (Formulation) **Period**: 11.02.2016 to 10.02.2021	**20.12.2018**	**Good**	i.Dr. Ghulam Sarwar Member DRB. ii. Additional Director (E&M), DRAP, Karachi. iii. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - *M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Tehsil Hub, Lasbella, Baluchistan was inspected by the panel members in compliance to DRAP's letter No. F.4-3/86-Lic (Vol-II) dated 31st October, 2018. The panel reviewed their overall documentation, inspected Manufacturing Facility, Quality Control Lab & Store and met with their technical persons. Following are the observations:* 1. *The panel observed the premises constructed as per DRAP's **approved** LoP.* 2. ***As per record, at the time of grant of license. M/s Kaligon Agro Industries was situated at industrial area under Hub industrial Trading Estate (HITE), however at present, M/s. Kailgon Agro Industries is not covered under the said industrial estate i.e. HITE. However, the management of firm is planning to shift the facility from current site to another suitable site and submitted the affidavit** (enclosed as Annex-E).* 3. *An appropriate level of sanitation, cleanliness & workers hygiene was noted.* 4. *Personnel met during inspection were observed having prescribed*			

qualification and experience and were well conversant regarding GMP compliance.

5. *Basic equipment required for tests/analysis of the registered products seen in place and in operational condition.*

Based on the stated observations, the panel recommends the grant of renewal of their DML no. 000277 By way of Formulation (subject to approval of location of the facility by the Central Licensing Board) for following sections, for the next five years.

1. ***Dry Powder (VET)***
2. ***Liquid / Suspension (VET)***
3. ***Tablet (VET)***

However, the panel does not recommend the renewal of Injection Section (as it does not comply with the GMP requirement) until the UP-gradation with necessary arrangements as required for parenteral drugs production.

Decision by the Central Licensing Board in 270th meeting

The Board considered the case and afer thread bare deliberation decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for Liquid vial Section (Human General) may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain suspended in liquid vial injection (Human General) till decision by CLB .

The Board also d**effered the case for** the renewal of Drug Manufacturing Licence No. 000277 (Formulation) in the name of M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Hub Chowki Road (RCD), Lasbella, Baluchistan for seeking clarification from Area FID regarding exact location of the firm.

The Show cause notice dated 18th July, 2019 was issued to the firm but no reply is received. The firm is called for the personal hearing vide letter dated, 04th September, 2019.

Decision by the Central Licensing Board in 270th meeting

	The Board considered the case and afer thread bare deliberation decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for Liquid vial Section (Human General) may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain suspended in liquid vial injection (Human General) till decision by CLB . The Board also d**effered the case for** the renewal of Drug Manufacturing Licence No. 000277 (Formulation) in the name of M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Hub Chowki Road (RCD), Lasbella, Baluchistan for seeking clarification from Area FID regarding exact location of the firm. **The Show cause notice dated 18thJuly, 2019 was issued to the firm but no reply is received. The firm is called for the personal hearing vide letter dated, 04th September, 2019.** **<u>Proceedings and Decision by the Central Licensing Board in 271st meeting:</u>** No person appeared on behalf of the firm the Board decided to seek clarification from the Federal Inspector of Drugs, Drug Regulatory Authority, Quetta @ Karachi and to serve final opportunity to firm before taking final decision. The reply of the firm is received in which firm has stated that no show cause notice has been received to this office as mentioned in proceeding and Decision paras of the minutes issued. Representative of the firm visited DRAP office Islamabad on 1st July 2019 and during the visits it was communicated that certain clarification regarding manufacturing plant location has been asked from the area FID. With regard to the location of M/s Kalgon Agro Industries is located in general area HITE, Baluchistan, where certain other manufacturing facilities are also constructed and operational (Google image is attached vide Annexure A) All basic industrial amenity connections have been provided by the Government Department i.e, Electricity, Water, Gas, Road infrastructure and Sanitation/Sewerage. The situation adjacent with the factory premises is clear from the populated area as construction of the manufacturing facility is in the center of the available space of 16940 Square yards Area (approximately 3.5 Acres). (Google image is attached vide Annexure B)

	It is highlighted that No Objection Certificate for establishment of Manufacturing Plant was issued from Government of Baluchistan, Industries Department vide BOI (IND) 3-10-75 Dated 25 Feb 1981 (Copy enclosed). Subsequently, Drug Manufacturing license was issued from Ministry of Health, Pakistan on fulfilling all departmental requirements vide DML 000277 (copy enclosed) and renewals were accorded. Efforts to keep the area as per the sensitive requirements of drug manufacturing is always the priority of the management and same was already acknowledge by the inspection team and endorsed in the visit report. It is also highlighted that the delay in obtaining license renewal is causing severe financial constraint on the management, which is further effecting the desired expansion requirement. In view of above, following is submitted for consideration:- Renewal of license may be issued at the earliest. In future letter may be send on office address of M/s. Kailgon Agro Industries at " C-8 Ruqia Square Block 14 F.B Area Karachi" as management is always available to clarify all the requirement of your Esteemed Office as and when intimated. Also a clarification letter is received from Mr. Sajjad Ahmed Abbasi, Area FID, Quetta wherein he has stated that the site location of M/s. Kailgon Agro industries is not covered under the hub, However the firm obtained NO Objection Certificate with certain conditions, for establishment of the facility on 25 February, 1981 (Copy of NOC is enclosed). Another NOC was issued by Health Division, Ministry of Health, Government of Pakistan on 27 October, 1985 (copy enclosed). In addition, the management of firm has also submitted the affidavit for shifting of said facility to designated industrial area (the affidavit has already been submitted along with the panel inspection report: te copy is enclosed). The firm is called for personal hearing vide letter Dated : 08th January,2020.

Decision by the Central Licensing Board in 273rd meeting

No person appeared on behalf of the firm. The Board after considering the facts decided to defer the case to give final opportunity to the firm to plead his case as the letter of personal hearing was not delivered on right address.

Case No.18. M/s REHMAT PHARMA, LAHORE.

A copy of letter is received from Secretary, Provincial Quality Control Board, Punjab wherein he has informed that Provincial Quality Control Board has considered the case of M/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahore in its 206th meeting held on 23rd May, 2019 and Provincial Quality Control Board decided to recommend the **cancellation** of the Drug Manufacturing License of M/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahore to Central Licensing Board, DRAP, Islamabad due to violation of non-compliance / violation of Schedule B-II (GMPs) of Drug (L, R & A) Rule 1976 and manufacturing for sale of Drugs under unhygienic conditions. Orders of the Provincial Quality Control Board, Punjab marked as **Annex-I**.

Proceedings and Decision by the Central Licensing Board in 271st meeting:

The Board considering the facts and report of PQCB Punjab 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 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing Licence No 000476 ofM/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahore, may not be cancelled by Central Licensing Board on the recommendation of Punjab Quuality Control Board.

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

The Show Cause notice dated 5th December, 2019 was issued to M/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahore,

The firm replied to Show Cause Notice which is reproduced is as under:

S.No.	Objections	Observation	Stances
2.	Water Treatment / Reverse Osmosis Plant was out of order, dirty and dusty.	Water Testing is not performed as per requirement. (TDS and Microbial count is not performed).	We are doing water testing as per requirements. Relevant proof / documents are attached at page number 1, as for Microbial Count (we are not operating injectable section).

			Page # 1 –1 – C
3.	Heating, ventilation air conditioning (HVAC) system was found out of order in all areas where installed	Neither operational, nor validation conducted.	HVAC is operational Page # 2
4.	Standards manufacturing procedures (SMPs) of products were not available.	Partially complied requiring further improvements.	Now fully complied with as we have made improvements regarding manufacturing procedures (SMPs) as per instructions given by the inspection team. Relevant documentary proof is attached at Page # 3 – 85
5.	Log books record of production machinery and quality control instruments were not being maintained.	Partially complied	Log books are being maintained properly, relevant documents are attached at page number 86 – 133
6.	HEPA (High Efficiency Particulate Air) filter were not installed in sampling as well as dispensing hoods furthermore their differential pressures were not being maintained.	DOP test not performed	DOP test is performed for Dispensing Hood HEPA Filter. Page # 134 – 134 – C
7.	Identification test of active pharmaceutical ingredients for each container were not being performed	FTIR available but not working.	FTIR is working properly, documentary proof is attached at Page # 135 – 173.
8.	Officers and workers were found walking in the production area in their street clothes without	The company claimed that training of the staff has been conducted in this regard however	We trained our staff about proper gowning necessity in the production area of pharmaceuticals. Record for

	following prescribed gowning techniques.	training record is not available.	the training with documentary proof is attached Page # 174 – 181
9.	Environmental monitoring, temperature humidity etc. was not being carried out.	Partially complied	Now fully complied with documentary proof is attached at Page # 182 – 201.
10	Vender validation / qualifications were not performed.	Not complied	SOP is prepared and qualification has been done with venders. Documentary proof is attached at Page # 202 – 230.
15.	Production process and quality control testing methods were not validated.	Not complied	Validation of production processes and quality control methods have been done and are been done continuously. Documentary proof is attached at Page # 232 – 416.
18.	Product recall system was not available	SOP developed but mock exercise was not carried out to verify the system.	We did mock exercise just after few days of last inspection. Documentary proof is attached at Page # 417 – 423.
20.	Complaint Register, Procedure for complaints handling, CAPA (Corrective and preventive action) and change control system were not prepared and initiated.	Not complied.	Complaint register is prepared, procedure for complaints handling, CAPA and change control system is prepared. Documentary proof is attached at Page # 424 – 444.
22.	Qualification / Calibration of the jacketed vessel with mixer 200 kg RPM-01, silverson mixer 100 Liter,	Not complied	Now complied with. The required calibration had been done. Documentary proof is

	an SS RO container RPM-05 manufactured by Haji Aslam Engineering was not done.		attached at Page # 445.
23.	Paint work on the walls, floors and roof was eroded.	Not complied	Overall new paint in all areas has been applied. Page # 446.
24.	Electric thermometers were not calibrated.	Not complied	All of the electric thermometers of all areas has been calibrated. Certificates are attached Page # 447 – 456.
27.	Temperature and humidity of raw material store was 29.2 C and 52 % respectively.	Partially complied	Temperature and humidity of raw material store is now in range, documentary proof is attached at Page # 182 – 201.
28.	Standard Operating Procedures (SOP) for de-dusting area, quarantine area were not available, Log record in quarantine and rejected area were not maintained. 30.4C temperature with 50% humidity was recorded in quarantine are.	SOPs not available.	SOPs are prepared for De-Dusting are and Quarantine are, Documentary proof is attached at Page # 457 – 468.
30.	Famotidine 40mg Film Coated Tablet 1* 10s batch number FT – 091 manufactured on ……. Was found in quarantine area without ensuring storage conditions at	Partially complied	Now fully complied with as Temperature of quarantine area is maintained and is checked on daily basis. Documentary proof is attached at Page # 182 – 201.

	temperature 31.3C and 59% humidity.		
31.	Compendia testing as per pharmacopeial monographs was not employed to test / analyze raw materials. Intermediates and finished products.	Partially complied	Now fully complied with as we are performing compendia testing as per pharmacopeial monographs, documentary proof is attached at Page # 469 – 515.
32.	Procedure for self-inspection and or quality control audit were not established.	Not complied.	Now complied with as Both procedure for self-inspection and quality control audit have been established. Documentary proof is attached at Page # 516 – 534.

A letter of personal hearing has been issued to the firm on 8th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr . Bashir Ahmad (CEO), Mr. Shoukat Joya (Advocate) andMr. Sajjad Bashir appeared before the Board and pleaded that they have rectified the observations pointed out during the inspection by the officials of Govt. of Punjab. Howover, upon enquiring they admitted that they were purchasing the core tablet of Ferrous sulphate from unknown source and only the process of tablet coating was being done in the industry .Since, it is heinous crime therefore, the Board after hearing the representative of the firm decided to cancel the Drug Manufacturing License No. 000476 (Formulation) of M/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahoreon the recommendation of Punjab Quality Control Board under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 19 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S CITI PHARMA (PVT) LTD, LAHORE.

01	M/s Citi Pharma (Pvt) Ltd, 3-	**19-03-2019**	**Good** (w.r.t Oral	5. Dr. Farzana

	km, Head Balloki Road, Bhai Pheru, Distt Kasur. DML No. 000512 (Formulation) **Period**: Commencing on 26-06-2018 ending on 25-06-2023. **Sections** 1. Oral Liquid (General) 2. Tablet (General) 3. Capsule (General) sections 4. Oral Dry Powder Suspension Section 5. Capsule Sections		Liquid, Tablet & Capsule Sections) **Unsatisfactory** (w.r.t. Oral Powder Suspension & Capsule Ceph. Sections)	Chowdhary, Expert. 6. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 7. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 8. Mr. Shahrukh Ali, Assistant Director, DRAP, Lahore.

Recommendations of the panel: -

The panel of inspectors **recommends** the renewal of DML bearing No. 000512 issued in favour of M/s Citi Pharma, (Pvt) Ltd, Lahore in respect of Oral Liquid (General) Tablet (General) & Capsule (General) sections only, The panel of inspectors **Does Not Recommend** the renewal in respect of Cephalosporin (Oral Dry Powder Suspension and Capsule Sections).

Decision by the Central Licensing Board in 270th meeting

1. The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000512 (Formulation) in the name of M/s Citi Pharma (Pvt) Ltd, 3-km, Head Balloki Road, Bhai Pheru, Distt Kasur on the recommendations of the panel of experts for the further period of five years commencing on 26-06-2018 and ending on 25-06-2023 in respect of Oral Liquid (General) Tablet (General) & Capsule (General) sections.

	2. The Board considered and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for Cephalosporin (Oral Dry Powder Suspension and Capsule) Section may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain stopped/suspended in Cephalosporin (Oral Dry Powder Suspension and Capsule) Section till decision by CLB.

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

The Show Cause notice dated 26th September, 2019 was issued to M/s Citi Pharma (Pvt) Ltd, 3-km, Head Balloki Road, Bhai Pheru, Distt Kasur.

The firm replied to Show cause notice and stated that after renewal inspection and recommendation of the panel, Citi Pharma decided to shift the Cephalosporin facility to new block to fulfill aa dedication and segregation requirements. For this purpose, they submitted layout plan and got approval from DRAP and now they are in the phase of Civil work and hopefully will be ready for inspection within 6 months. The firm has requested to renew their License as per recommendation of panel and they will try to get approval of Cephalosporin facility as soon as possible and during this period will hold the production.

A letter of personal hearing has been issued to the firm on 8th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr . Zamir Ul Hassan, Director Operations of the firm appeared before the Board and contended that the firm is in the process of Civil work and will be ready for inspection within 6 months and they will with hold the production in Cephalosporin facility during this period. The Board after hearing the representative of the firm decided to suspend production in Cephalosporin facility till completion of new facility.

CASE NO. 20. M/S SAFINA PHARMACEUTICALS (PVT) LTD, LAHORE.

Drug Manufacturing License No. 000654 (Formulation) was issued to M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore. It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *"if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application"*. But, in this case the application for renewal of DML for the period 30-01-2019 to 29-01-2024 has not been received till date. Therefore, DML No. 000654 (Formulation) M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore is no more valid.

Proceedings and Decision of Central Licensing Board in 271st meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000654 by way of formulation M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore may not be declared cancelled.

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

The Show Cause notice dated 15th October, 2019 was issued to M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore.

A letter of personal hearing has been issued to the firm on 8th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Muhammad Nadeem, CEO of the firm appeared before the Board. He contended that due to illness of his brother, the firm could not file application for renewal of DML.The Board after hearing the representative of the firm and after considering the facts on the record and thread bare deliberation observed that the Drug Manufacturing Licence 000654 by way of Formulation of M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahoreas already expired after completion of the the tenure 30-01-2014 to 29-01-2019. Hence , stand cancelled under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering

and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Manufacturing of drugs is prohibited and punishable offence under Section 23 and Section 27 and rules framed thereunder.

Case No. 21 APPROVAL OF PRODUCTION INCHARGE OF M/S GMP PHARMACEUTICALS, LAHORE.

M/s GMP Pharmaceuticals, 28-Km, Sheikhupura Road, Lahore had applied for approval of Mr. Muhammad Iqbal as Production Incharge on 03rd January, 2019. The application for the was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 27th February, 2019.

1. Appointment letter
2. Job acceptance letter by the appointee.
3. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of Production Incharge (Not less than 10 years in relevant experience).
4. Resignation / retirement of earlier Production Incharge.
5. Undertaking as whole time employee on stamp paper duly signed by management and appointee.
6. **Documents should be duly attested.**

The firm submitted their reply on 15th March, 2019. After evaluation of the submitted documents, final reminder was issued on 17th May, 2019 to the firm with following shortcomings: -

1. CNIC copy of Production Incharge.
2. Undertaking as whole time employee on stamp paper duly signed by management and appointee.
3. **Documents should be duly attested / notarized.**

The firm has replied to Final reminder on 12th June, 2019with following shortcomings: -

1. Undertaking as whole time employee on stamp paper duly signed by management and appointee.
2. **Documents should be duly attested / notarized.**

In the meanwhile the firm appointed Mr. Dilawar Hussain as Production Incharge and applied on 18th July, 2019. The application is short of following documents:

i. Resignation / retirement of earlier Production Incharge (Mr. Muhammad Iqbal).
ii. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
iii. Undertaking as whole time employee on stamp paper.
iv. Documents should be duly attested.

Proceedings and Decision of Central Licensing Board in 271st 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 Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the DML No. 000815 by way of formulation of M/s GMP Pharmaceuticals, 28-Km, Sheikhupura Road, Lahore may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 15th October, 2019 was issued to M/s GMP Pharmaceuticals, 28-Km, Sheikhupura Road, Lahore.

The firm has replied to show cause notice and submitted the deficient documents in the application.

A letter of personal hearing has been issued to the firm on 8th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Zia ur Rehman, Director and Mr. Dilawar Hussain, Production Incharge of the firm appeared before the Board. He submitted that since legal and codal formalities has been complied therefore showcause may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of the showcause Notice. The Board also decided to issue warning to the firm to be careful in future for compliance of the law.

Case No. 22 **APPROVAL OF PRODUCTION INCHARGE OF M/S WELL CARE PHARMACEUTICALS, SARGODHA.**

Ms. Nasreen Akhtar, approved Production Incharge of M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha, under Drug Manufacturing Licence No. 000465 by way of formulation had resigned w.e.f, 30-08-2018 and the firm was asked to apply for approval of new Production Incharge. The firm filed application for approval of new Production Incharge on 11th October, 2018.The application was evaluated and reminder for following shortcomings / deficiencies was issued to the firm on30th November, 2018.

i. CNIC copy of appointee.
ii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not less than 10 years).
iii. Resignation / retirement of earlier Production Incharge.
iv. Undertaking as whole time employee on stamp paper.
v. All documents should be attested.

The firm submitted their reply on 5th December, 2018. The application is still short of following documents:

i. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not less than 10 years).
ii. Registration certificate from Pharmacy council.

Proceedings and Decision by the Central Licensing Board in 272nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing Licence No 000465 by way of formulation of M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha 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 8th November, 2019 was issued to M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha.

The firm replied to show cause notice and completed the application of application for approval of Production Incharge.

A letter of personal hearing has been issued to the firm on 8th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Malik Saeed, Managing Director of the firm appeared before the Board. He submitted that since legal and codal formalities has been complied therefore showcause may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of the showcause Notice. The Board also decided to issue warning to the firm to be careful in future for compliance of the law.

Case No.23 SURRENDERING OF APPROVED SECTION M/S LEGACY PHARMACEUTICALS (PVT) LTD., PLOT NO. 111, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR.

M/s Legacy Pharmaceuticals (Pvt) Ltd., Plot No.111, Industrial Estate, Hayatabad, Peshawar, has submitted request for surrendering following two sections;

Section Name	Pharmacological Category (ies)	Remarks
Veterinary Liquid Syrup	General	According to the firm no registration has been granted in the section yet. No production activity is observed at the time of inspection. The firm intends to surrender the section
Veterinary Dry Powder	General	According to the firm no registration has been granted in the section yet. No production activity is observed at the time of inspection. The firm

		intends to surrender the section

Decision by the Central Licensing Board in 270th meeting

The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000632 (Formulation) in the name of M/s Legacy Pharmaceuticals (Pvt) Ltd., Plot No.111, Industrial Estate, Hayatabad, Peshawar on the recommendations of the panel of experts for the further period of five years Commencing on 19-06-2018 and ending on 18-06-2023for following sections:-

1 Tablet (General).
2 Capsule (General).
3 Tablet (Psychotropic).
4 Capsule (Cephalosporin).
5 Sachet General
6 Cream/Ointment (General).
7 Oral Liquid Syrup (General).
8 Dry Powder suspension (penicillin).
9 Dry Powder Suspension (General).
10 Tablets hormone
11 Dry Powder suspension (Cephalosporin).

The Board after perusal of recommendation of the panel of experts decided to issue show cause notices as to why following sections may not be cancelled under section 41 of the Drug Act 1976.

1. Veterinary Liquid Syrup.
2. Veterinary Dry Powder.

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

Accordingly, Show Cause Notice was issued to the firm on 3rd September, 2019. In compliance of the Decision of the Central Licensing Board the firm submitted their reply and place on the file. Accordingly, a letter for personal hearing is issued on 7th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Amin Ullah, Managing Director and Mr Umar Farooq Prodcution pharmacist of the firm appeared before the Board and pleaded that they are voluntarly surrendering the sections and would submit future plan for utility of the sections . The Board after hearing the representative of the firm acceded the request of the firm regarding cancellation of Veterinary Liquid Syrup section and Veterinary Dry Powder section.

Case No. 24 SITE VERIFICATION OF M/S STEFANIE PHARMACEUICALS PLOT/BLOCK NO.69-B, LARGE INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR .

M/s Stefanie Pharmaceuticals, Peshawar vide their application dated Nil has forwarded a request for approval of site to establish a pharmaceutical unit located at Plot/Block No.69-B, Large Industrial Estate, Hayatabad, Peshawar. Accordingly Area FID, DRAP, Peshawar was directed vide letter dated 19th April, 2018 for verification of site. Area FID, DRAP, Peshawar, after visiting the site has forwarded site verification report of the said firm. The recommendation of the Area FID, DRAP, Peshawar is as under;

Size of the plot:

The management has already submitted "Transfer Lease" for the proposed site which shows it is 1.0 (one) Acres plot and dimensions are (370' 0 ½" X 115' 3") which measures about 44464.0 sq. Ft. However, the management has spared 150627.73 Sq. Ft for M/s Stefanie Health Care" and rest for "M/s Stefanie Pharmaceutical" i.e 28457.27 Sq. Ft. the rest for the offices i.e 944.00.

Location:

The proposed site is located at Hayatabad Industrial Estate, Peshawar, the boundaries are as under;

Surroundings:

On North side is Plot No.69B (M/s Oriental Enterprises).

On South side is Plot No.69C. (M/s Shanghai UPVC)

On East side is Plot No.70 and 70A (M/s United Rubber (Pvt) Ltd.)

On West side is Road S/3

Environment:

Smoke pollution is seen from in its surrounding (east side) as the Rubber factory is emitting dense black fumes at the time of visit.

Conclusion:

As per requirement laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(I)/98 dated 15.05.1998) under rule 16(a) of the Drugs (Licensing, Registering & Advertising) Rules, 1976, the proposed premises is **not suitable** to construct a pharmaceutical unit as of today.

Sketch of plot and its adjoining area is attached as desired.

2. Meanwhile, another application is received from M/s Stefanie Pharmaceutical, Peshawar for re-inspection of the site alongwith prescribed fee of Rs.5,000/- and he has also submitted an affidavit wherein he has stated that he will install HVAC system in the building.

Decision by the Central Licensing Board in 272nd meeting:

The Board considered and decided to call the representative of the firm for personal hearing before taking final decision.

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

Accordingly, a letter for personal hearing was issued on 7th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Ehsan Ullah, CEO of the firm appeared before the Board and contended thatRubber factory which was emitting smoke has taken precautionary measures to avoid smoke contamination & he also presented provisional NOC from EPA.The Board after hearing the representative of the firm decided to re-inspect the firm for site verification after submission of NOC from EPA.

Case No. 25 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AVANT PHARMACEUTICALS (PVT) LTD, BALOCHISTAN

M/s Avant Pharmaceuticals (Pvt) Ltd., Plot M-28, H.I.T.E., Balochistan	**N/A**	**N/A**	i. Dr. Abdullah Dayo Member Central Licensing Board. ii. Additional Director (E&M), Karachi. iii. Area Federal Inspector of

DML No. 000786 (Formulation) **Period**: Commencing on 03-02-2019 ending on 01-02-2024.			Drugs, DRAP, Karachi.

Letter of FID: -

The firm, M/s Avant Pharmaceuticals (Pvt) Ltd., Baluchistan, vide their letter (copy enclosed) has informed that they are doing some renovation work at their facility and not ready for panel inspection.

It is therefore kindly requested to your good office that the necessary directions may kindly be passed to the undersigned in the light of Drugs (Licensing, Registering and Advertising) Rules, 1976, for further necessary action in this regard.

Decision by the Central Licensing Board in 271st meeting

The Board considered the letter of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Kararchi and attached letter of the firm M/s Avant Pharmaceuticals (Pvt) Ltd., Plot M-28, H.I.T.E., Balochistan wherein firm was doing renovation work with intimation of the Board and avoiding inspection for renewal of Drug Manufacturing Licence. The Board decided to suspend the production of drugs in manucaturing facility till renovation is made by the firm. The firm shall inform the Board for its readiness for inspection. The Board shall pass orders for inspection accordingly. The production shall remain suspend till final orders by the Board on the recommendations of the panel of experts.

The decision of the CLB was conveyed to the firm vide letter Dated : 16th October 2019.

Now firm has informed for readiness for renewal of the Drug Manufacturing License and has requested for constitution of the panel of experts.

Decision by the Central Licensing Board in 273rd meeting

The Board considered the facts and after threadbare deliberation constituted the following panel of experts to reinspect the firm for the purpose of renewal of DML No. 000786 (Formulation) of M/s Avant Pharmaceuticals (Pvt) Ltd., Plot M-28, H.I.T.E., Balochistan:

1. Dr. Abdullah Dayo Member Central Licensing Board.

2. Chief Drugs Inspector, Balochistan.

3. Area Federal Inspector of Drugs, DRAP, Quetta.

Case No. 26 **RENEWAL OF DML OF M/S HERBION PAKISTAN (PVT) LTD, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad. DML No. 000795 (Formulation) **Period**: Commencing on 25-03-2019 ending on 24-03-2024. **Sections** 1. Syrup (General) 2. Plasters. 3. Capsules (General) 4. Tablets (General) 5. Creams/Ointment (General) 6. Sachet (General)	**21-05-2019**	**Good**	1. Professor Dr. Muhammad Usman, Member Central Licensing Board. 2. Deputy Director (QC), DRAP, Islamabad. 3. Area FID, DRAP, Islamabad. 4. Dr. Muhammad Usman, Assistant Director (Licensing), DRAP, Islamabad.

Recommendations of the panel: -

Keeping in view the facts on record, the panel unanimously ***recommends the approval of renewal of Drug Manufacturing License by way of Formulation DML N:000795 to*** M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Humak, Islambad for following two (2) sections only:

1. Syrup (General)
2. Plasters.

While the approval/renewal of sections namely capsules, Tablets, Creams/Ointment and sachet will be subject to completion of work and subsequent panel inspection and approval by Licensing Board. Hence, the panel did not recommend the renewal of aforementioned sections.

Decision by the Central Licensing Board in 270th meeting

1. The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000795 (Formulation) in the name of M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the further period of five years

commencing on 25-03-2019 and ending on 24-03-2024 in respect of Syrup(General) section.

2. The Board considered and alsodecided to issue **showcause notice** under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for capsules, Tablet, Creams/Ointment Sections may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain **stopped/suspended** in capsules, Tablets, Creams/Ointment till decision by CLB.

The Board also decided to **refer** the mater of Plasters Section to MD&MC Division for further processing the case as the subject matter falls under the domain of MD&MC Division.

Accordingly, a Show Cause Notice dated 26th February, 2018 was issued to M/s Herbion Pakistan (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad as per decision of Central Licensing Board in its 270th meeting held on 23rd May, 2019. .

Accordingly, Show Cause Notice was issued to the firm on 4th September, 2019. In compliance of the Decision of the Central Licensing Board. The firm has submitted their reply and informed that they are ready for inspection. Chairman Central Licensing Board has been pleased to constitutes a panel of inspectors / experts for above sections.

Decision by the Central Licensing Board in 273rd meeting

The Board considered the facts and after threadbare deliberation decided to cease the operation of the showcause Notice issued to M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad.DML No. 000795 (Formulation).The Board also decided to issue warning to the firm to be careful in futurefuture for compliance of the law.

Case No. 27 **SUSPENSION OF LICENSES OF ABSCONDER ACCUSED PERSONS IN CASE NO. 42/2016, THE STATE VS M/S FRIENDS PHARMA (PVT) LTD & OTHERS.**

Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta, directed the Licensing Division to provide information regarding accused persons namely Meheryab, Quality Control Manager and Ms. Shabana Malik, Production Manger of M/s Friends Pharma Pvt Ltd, 31-Km, Ferozepur Road, Lahore that whether they are registered/license-holder in any other company / firm by our office in case No. 42/2016 The State Vs M/s Friends Pharma Pvt Ltd, Lahore. Licensing Division informed the Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta via letter dated 22nd May, 2019 that as per available record of Licensing Division, M/s Friends Pharma (Pvt) Ltd, 31-Km, Ferozepur Road, Lahore promoted Ms. Shabana Malik D/o Fazal Karim CNIC No. 35202-2380250-0 as Production Incharge w.e.f 18-04-2018 as per promotion letter and working on the same post till date. Mr. Meheryab S/o Muhammad Akram CNIC No. 35201-1676468-3 joined the firm as Quality Control Incharge w.e.f 07-07-2014 as per appointment letter and he resigned from his post w.e.f. 06-2015. Furthermore, Mr. Meheryab joined M/s Theramed Pharmaceutical (Pvt) Ltd, Lahore DML No. 00696 (formulation) as Quality Control Incharge w.e.f 06-02-2018 and working on the same post till date. Now, Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta ordered that the licenses of both the qualified persons i.e. Meheryab and Shabana Malik be suspended forthwith being the willful absconders of the Court as both are reluctant to appear the Court and concealing themselves in this connection, due to which Court has already declared them as proclaimed offenders.

Decision by the Central Licensing Board in 273rd meeting

The Board considering the orders of the Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta and after thread bare deliberation decided to serve Show Cause Notice to the accused persons namely Meheryab, Quality Control Manager and Ms. Shabana Malik, Production Manger, who were workimg inM/s Friends Pharma Pvt Ltd, 31-Km, Ferozepur Road, Lahore and now working inM/s TheramedPharmaceuticals (Pvt) Ltd, 45-Km Multan Road, Lahore andM/s Friends Pharma Pvt Ltd, 31-Km, Ferozepur Road, Lahorerespectivelyunder Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and

Advertising) Rules, 1976as to why their approval as technical staffmay not be cancelled on the orders of the Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta.

Case No.28 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEGA PHARMACEUTICALS LTD LAHORE.**

M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore had applied for renewal of DML No. 000537 by way of formulation for the period of 17-04-2019 to 16-04-2024 on 19-02-2019

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 06th March, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of Rs. 50,000/- for change of management.
ii. Latest certified true copy of Form-29 (Attestation by SECP).
iii. Duly attested CNIC copies of all Directors.

The firm replied to this letter on 29th March, 2019. A Reminder letter was issued on 03thJuly, 2019 of following shortcomings.

i. Latest certified true copy of Form-29 having complete detail of CEO/Directors of the firm (duly attested by SECP).
ii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of Rs. 50,000/- for change of management.

The firm has replied to Final Reminder on 23rd July, 2019 but the application for renewal of DML is still incomplete with following shortcoming:

i. Prescribed fee of Rs. 50,000/- for change of management.
ii. Latest certified true copy of Form-29 or Form-A mentioning detail of Directors (Attestation by SECP).

Proceedings and Decision by the Central Licensing Board in 271st meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore, Drug Manufacturing Licence No 000537 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 15th October, 2019 was issued to M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore.

The firm has replied to show cause notice and completed the application for renewal of DML.

Decision by the Central Licensing Board in 273rd meeting

The Board considering the facts on the record and after thread bare deliberation decided to revoke the show cause notice issused to M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore, Drug Manufacturing Licence No 000537 by way of Formulation. The Board also decided to issue warning to the firm to be careful in futurefuture for compliance of the law.

Case No.29 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AVENTEK PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore had applied for renewal of DML No. 000660 by way of formulation for the period of 27-03-2019 to 26-03-2024 on 27-02-2019

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 7th March, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of Rs. 50,000/- for change of management.
ii. Nothing due certificate regarding CRF from STO (Updated).
iii. Section approval letters of all sections issued by Central Licensing Board, if not available, apply for regularization of layout plan along with prescribe fee of Rs. 5,000/- per each section.
iv. Latest certified true copy of Form-29 (Attestation by SECP).
v. CNIC copies of all Directors.
vi. Jab acceptance letter of proposed Quality Control Incharge.
vii. Undertaking as whole time employee on stamp paper signed by appointee and management. (Quality Control Incharge).
viii. Experience certificate from M/s Pulse Pharmaceuticals (Pvt) Ltd, Lahore of proposed Quality Control Incharge.
ix. Resignation / retirement of earlier Quality Control Incharge.
x. The proposed Production Incharge completed the degree of Pharm-D on 17th March, 2009 and 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. You are, therefore, directed to submit complete set of duly attested documents of new proposed Production Incharge who fulfills the requirements of Rule 16 of Drugs (Licensing, Registering and Advertising) rules 1976 in terms of Qualification and relevant experience (as per Checklist).
xi. Documents should be duly attested.

The firm replied to this letter on 18th March, 2019. A Reminder letter was issued on 14th May, 2019 of following shortcomings.

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

ii. Prescribed fee of Rs. 50,000/- for change of management as there seems to be change in management of the firm.
iii. Latest certified true copy of Form-29 (Attestation by SECP).
iv. Undertaking as whole time employee on stamp paper duly signed by appointee and management. (Quality Control Incharge and Production Incharge).
v. Appointment letter, academic degree of B. Pharm (Production Incharge).
vi. Registration certificate from Pharmacy council (Production Incharge).
vii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of Production Incharge (Not less than 10 years).
viii. Resignation / retirement of earlier (Production Incharge)..
ix. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Production Incharge).
x. Documents should be duly attested.

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

Proceedings and Decision by the Central Licensing Board in 271st meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore, Drug Manufacturing Licence No 000660 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 15th October, 2019 was issued to M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore.

The firm has replied to show cause notice and submitted the deficient documents in the application.

Decision by the Central Licensing Board in 273rd meeting

The Board considering the facts on the record and after thread bare deliberation decided to revoke the show cause notice issused to M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore, Drug Manufacturing Licence No 000660 by way of Formulation. The Board also decided to issue warning to the firm to be careful in futurefuture for compliance of the law.

Case No. 30. APPROVAL OF LAYOUT PLAN FOR REGULARIZATION UNDER DRUG MANUFACTURING LICENSE NO.000044 (FORMULATION) OF M/S AGP LIMITED, D-109, S.I.T.E KARACHI.

M/s AGP Limited, D-109, S.I.T.E Karachi , DML No. 000044 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections: -

1. Tablet Section-I (Ceph).
2. Dry syrup Section (Ceph).
3. Capsule Section (Ceph).
4. Warehouse (Ceph).
5. Quality Control laboratory.

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

1. Dr. Abdulah Dayo, Member CLB.
2. Director DTL, Sindh Karachi
3. Area Federal Inspector of Drugs, DRAP, Karachi.

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

Recommendations:-

Keeping in view overall GMP compliance and intend towards improvement, panel unanimously recommend the renewal of DML No. 000044 and regularization of Manufacturing facility of M/s. AGP Limited, Plot No. D-109, S.I.T.E Karachi.

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved regularization of of Lay out plan in the name of M/s AGP Limited, D-109, S.I.T.E Karachi , DML No. 000044 (Formulation) on the recommendation of the panel of experts for the following sections:-

1. Tablet Section-I (Ceph).
2. Dry syrup Section (Ceph).
3. Capsule Section (Ceph).
4. Warehouse (Ceph).
5. Quality Control laboratory.

Case No. 31 . <u>APPROVAL OF LAYOUT PLAN FOR REGULARIZATION UNDER DRUG MANUFACTURING LICENSE NO.000275 (FORMULATION) OF M/S BROOKES PHARMA LIMITED, KARACHI</u>

M/sBrookes Pharma (Pvt) Ltd, Karachi, DML No. 000275(Formulation), has applied for regularization of layout plan of running facility for their following existing sections: -

GROUND FLOOR			
Sr. No	**Name**	**Sr. No**	**Name**
1.	Tablet (General) Section.	8.	Capsule (General Antibiotic) Section.
2.	Capsule (General) Section.	9.	Dry Syrup (Cephalosporin) Section.
3.	Liquid Syrup (General) Section	10.	Capsule (Cephalosporin) Section.
4.	Liquid Injectbale (General) Section.	11.	Sachet (Cephalosporin) Section.
5.	Large Volume Parentrals (General) Section.	12.	Dry Powder Injectable (Cephalosporin) Section.
6.	Nasal Drop Section.	13.	Packing Material Store.
7.	Tablet Section (General Antibiotic) Section.	14.	Raw Material Store & Finished Goods Store.
FIRST FLOOR			
1.	Small Volume Parentrals (General)Section	2.	Dry Suspension (Pencillin) Section
3.	Capsule Pallet Filling (General)Section	4.	Cream/Ointment section

5.	Injectable (Hormone) Section	6.	Ampoule Compact Line Section **(additional)**
7.	Tablet (Pencillin) Section	8.	Quality Control Laboratory
9.	Capsule (Pencillin) Section	10.	**********

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

1. Dr. Abdulah Dayo, Member CLB.
2. Additional Director (E&M), DRAP, Karachi
3. Area Federal Inspector of Drugs, DRAP, Karachi.

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

Recommendations:-

The panel inspected all the manufacturing sections, stores and QC Lab and found the facility as per approved layout plan. The facility has been provided with necessary utilities, machineries and equipment as required under the guidelines. Necessary documents relating to QC, QA, installation qualification of machines, HVAC and other utilities were also verified under the scope and noted an optimal level of compliance.

Based on the above stated facts the panel recommends the grant of regularization of sections as per Evaluation form."

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved regularization of of Lay out plan in the name of M/sBrookes Pharma (Pvt) Ltd, Karachi, DML No. 000275(Formulation) on the recommendation of the panel of experts for the following sections:-

GROUND FLOOR			
Sr. No	**Name**	**Sr. No**	**Name**
1.	Tablet (General) Section.	8.	Capsule (General Antibiotic) Section.
2.	Capsule (General) Section.	9.	Dry Syrup (Cephalosporin) Section.
3.	Liquid Syrup (General) Section	10.	Capsule (Cephalosporin) Section.
4.	Liquid Injectbale (General) Section.	11.	Sachet (Cephalosporin) Section.
5.	Large Volume Parentrals (General)	12.	Dry Powder Injectable

	Section.		(Cephalosporin) Section.
6.	Nasal Drop Section.	13.	Packing Material Store.
7.	Tablet Section (General Antibiotic) Section.	14.	Raw Material Store & Finished Goods Store.
FIRST FLOOR			
1.	Small Volume Parentrals (General)Section	2.	Dry Suspension (Pencillin) Section
3.	Capsule Pallet Filling (General)Section	4.	Cream/Ointment section
5.	Injectable (Hormone) Section	6.	Ampoule Compact Line Section **(additional)**
7.	Tablet (Pencillin) Section	8.	Quality Control Laboratory
9.	Capsule (Pencillin) Section	10.	**********

Case No. 32 **CHANGE OF LICENSED SECTION NAME OF M/S HUDSON PHARMA PVT) LIMITED, No. D-93, NORTH WESTERN INDUSTRIAL ZONE, PORT QASIM, KARACHI.**

M/s Hudson Pharma (Pvt) Ltd, Plot No. D-93, North western Industrial zone, Port Qasim, Karachi under DML.No 000842(Formulation) has submitted requested for change of licensed section name from Capsule (General) section to Capsule DPI Steroidal Section.

Proceedings and Decision by the Central Licensing Board in 272nd meeting:

The Board considered the case and decided to seek verification of facility of separate dispensing booth for DPI steroidal products by the following panel:

1. Dr Abdullah Dayo, Member Central Licensing Board
2. Additional Director, DRAP, Karachi
3. Federal Inspector of Drugs of area, DRAP, Karachi

Panel Inspection report is received and recommendation are as follows:-

Based on the people met, documents reviewed and finding of inspection, panel hereby verify the existence of separate dispensing both available and installed for dispensing of steroidal products.

Decision by the Central Licensing Board in 273rd meeting

The Board considered the facts on record and after threadbare deliberation decided to approve the change of Licensed section name of M/s Hudson Pharma (Pvt) Ltd, Plot No. D-93, North western Industrial zone, Port Qasim, Karachi under DML.No 000842(Formulation) from Capsule (General) section to Capsule (DPI Steroidal) Section.

Case No. 33 DELEGATION OF POWERS UNDER RULE 8 (10) OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976.

The Rule 8 (10) empowers the Central Licensing Board to authorize Chairperson or any of its member for performing any specific functions of the Board including the disposal of day to day business of the Board through Secretary of the Central Licensing Board or any authorized officer. According, following proposal and are made for the consideration of the Central Licensing Board.

S#.	Powers	Powder to be Delegated to
	Delegation of Power related to Division of Drug Licensing	
1.	Show Cause Notice regarding contravention of any of the provision of the Drugs Act, 1976 and rules framed there under.	Chairman CLB
2.	Issuance of Inspection Book	Secretary CLB
3.	Approval of layout plan and constitution of committee for evaluation of layout plan. (The committee shall be constituted for the purpose of evaluation / assessment and analysis of the layout plan and shall furnish its recommendations accordingly to the Chairman CLB for approval).	Chairman CLB
4.	Approval of change of name of a firm for licensed units/unlicensed units (after the site approval).	Chairman CLB
5.	Enlistment of drugs / APIs (Molecules) for basic, and semi basic manufacturing. (The inspections shall be made mandatory before grant of any item(s) / drugs/ APIs under respective Schedule etc.)	Chairman CLB
6.	Implementation of decisions of Appellate Board related to Division of Drug Licensing	Chairman CLB
7.	Approval of Repacking items under Schedule D of Drugs Act 1976 and Rules framed there under. (The inspections shall be made mandatory before grant of any item(s) / drugs/ APIs under respective Schedule etc.)	Chairman CLB
8.	Constitution / amendments in constitution of panel for inspection for grant/renewal of Drug Manufacturing License, Grant of Additional Sections and Verification / Checking of conditions of License etc of firms.	Chairman CLB
9.	Extension in Sealing period of Licensed manufacturers where Contraventions(s) is / are of Conditions of DMLs only.	Chairman CLB

10.	Correction of typographical error in recording of agenda and minutes of the CLB.	Chairman CLB
11.	Approval of change of management / Director / Owner etc of licensed firm after verification of relevant legal documents.	Chairman CLB
12.	Approval of Technical Staff and communication / Issuance of decisions of Central Licensing Board.	Secretary CLB
13.	Site approval for establishment of pharmaceutical units.	Secretary CLB
14.	Approval of change of name of an unlicensed firm / unit (before the approval of site).	Secretary CLB

Decision by the Central Licensing Board in 273rd meeting

The Central Licensing Board approved and delegated its functions/powers related to Division of Drug Licensing to its Chairman and Secretary under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 in order to facilitate timely disposal of routine and day to day business of Central Licensing Board as under:

S#.	Powers	Powder to be Delegated to
1.	Issuance of Inspection Book	Secretary CLB
2.	Approval of layout plan and constitution of committee for evaluation of layout plan. (The committee shall be constituted for the purpose of evaluation / assessment and analysis of the layout plan and shall furnish its recommendations accordingly to the Chairman CLB for approval).	Chairman CLB
3.	Approval of change of name/management of a firm for unlicensed units (after the site approval).	Chairman CLB
4.	Constitution / amendments in constitution of panel for inspection for grant/renewal of Drug Manufacturing License, Grant of Additional Sections and Verification / Checking of conditions of License etc of firms.	Chairman CLB
5.	Correction of typographical error in recording of agenda and minutes of the CLB.	Chairman CLB
6.	Approval of Technical Staff	Secretary CLB
7.	Site approval for establishment of pharmaceutical units.	Chairman CLB

The delegation of power accorded in any of the previous meetings shall stand superceeded with immediate effect.

QUALITY CONTROL SECTION

AGENDA ITEM. A - OLD/QUETTA CASES

OLD CASES RELATED TO DRAP OFFICE, QUETTA REFERRED BY HONORABLE DRUG COURT QUETTA.

It is submitted that the FID, Q@K vide letter vide letter 3-1/2009-FID(Q)K dated 28.01.2019 stated that the Honorable Drug Court, Quetta has passed the orders during proceedings on 3rd December, 2018 in the case titled "Surat Khan Medical Store and others" to provide the list of pending cases of DRAP, Quetta. Moreover, the FID Quetta requested vide letter No.3-1/2019-FID(Q) K dated 05th August 2019 "the old pending cases may kindly be discussed in the Boards concerned on priority basis and necessary decisions may kindly be passed in order to submit the status/copies of decisions in the Honorable Drug Court, Quetta".

In the light of directions of the Honorable Drug Court Quetta, a list of cases was handed over to the DRAP representative for necessary proceedings under the law. The Court has highlighted its serious concerns on the state of affairs about the cases pended in the DRAP without any reason. The record of the QA&LT Division was thrashed out and it was found that the list of cases forwarded by the court contained following categories of cases:

i. Some of the cases were decided by the CLB but prosecutions not launched.
ii. Some of the cases were decided but name of the accused persons were not given in the prosecution permission letters.
iii. Some of the cases of un-registered were disposed of by the Registration Board.
iv. Some of the cases of un-registered/spurious drugs were disposed of by giving warning.
v. Some of the cases are pended being incomplete on the part of FID and/or stuck during the shifting of the records after devolution of de-funct Ministry of health under the 18th CONSTITUTIONAL AMENDMENT.

The record of the QA&LT Division was sorted out and it was matched with the copies of record from FID, Quetta. In light of both records and keeping in view the request from FID Quetta, the agenda of cases have been prepared according to records available in the section and the records

shared by DRAP Office Quetta, for the consideration of Board please. The details of the cases are as under:-

Case No. I-A **MANUFACTURING AND SALE OF UN-REGISTERED DRUG NAMELY TRISH ZEE BATCH NO.TZ001**

That Syed Abdul Saleem, FID Quetta forwarded vide letter No.F.SAS-122-124/2009-FID(Q)/195 dated 08th March 2010. The FID Quetta stated that during visit some un-registered drugs were found available without having Drug Sale license. The FID ordered Not to dispose of all available stocks of said drugs.The same was reported the Chairman CLB for extension of time of said orders vide this office letter No. F.12-1/DCA-QTA/M. The FID survey dated 07-11-2009 and subsequent request vide No.F.12-1/DCA-QTA/M survey dated 12.12.2009 a sample of drug namely Trish Zee Tabs B.No. ZT001 claimed to be manufactured by M/s Starix Nutraceuticals Karachi was also taken along with other samples of drugs for the purpose of test/analysis.

02. The-then FID Quetta submitted that the sealed sample of Trish Zee B.No.TZ001 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-122-124/2009-FID (Q) -16 dated 06-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-122-124/2009-FID(Q) dated 11-11-2009. A portion of said sample of drug was also sent to M/s Starix Nutraceutical Karachi vide letter No.SAS-122-124/2009-FID (Q) dated 11-11-2009 and same was received back un-delivered.

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report No.SCD.202/2009 dated 09-12-2009 **declared the sample of Trish Zee Tablets B.No.ZT001 and Un-registered.**

04. The FID, Quetta also informed that M/s Starix Nutraceuticals Karachi was called to show cause and explain for its position for manufacturing and selling un-registered drug vide this office show-cause notice No.SAS-122-124/2009-FID (Q)/87dated 15-12-2009 but same was also received back undelivered.

05. The FID Quetta stated that M/s Kozak Traders Quetta was also called to explain its position vide his office letter No.F.12-1/DCA-QTA/M survey -30 dated 21-11-2009. M/s Kozak submitted copies of invoices of invoices for drugs that were ordered not to dispose off on receipt of test report from CDL Karachi M/s Kozak Traders Quetta again called to show cause notice and explain its position vide this office letter No. SAS-122-124/2009-FID(Q)/86 dated 15-12-2009 but no response is received as yet.

06. The FID Quetta submitted the above mentioned facts and revealed that M/s Kozak Traders Quetta involved in manufacturing and selling of un-registered drug namely tablets Trish Zee with a fake name M/s Starix Nutraceuticals Karachi and violated the section 23(1)(a)(x), 23(1)(b),23(1)(c) and 27(3) of the Drugs Act 1976.

07. The FID Quetta is submitted for placement before CLB for its **consideration and permission of prosecution against Mr. Muhammad Ashraf proprietor of M/s Kozak Traders Quetta along with M/s Starix Nutraceuticals Karachi.**

08. The case was put up for approval of show cause notice to the accused persons on 13-05-2010 in Quality Control Section vide F.No.3-37/2009-DDC(QC). A **show cause notice was issued** to the M/s Kozak Traders Archer Road Quetta and M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi dated 04th August 2010 **on behalf of Drug Registration Board with approval of Chairman, DRB**. Personal hearing letter was also issued to the M/s Kozak Traders Archer Road Quetta and M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi on 21st June 2011 **to appear before the Drug Registration Board** for personal hearing on 25th June 2011 at 11:00 am in committee Room of Ministry of Health Islamabad.

09. That the-then DDC(QC-I) vide letter no. F.03-37/2009-DDC(QC-I) dated 2nd April, 2014 requested for appraisal of the latest position of the case on priority basis to the-then FID-Quetta for which no reply is available in the record. ***The matter was wrongly processed for DRB.***

Permission for Show cause Notice to prosecute.

10. It is therefore submitted that ***Muhammad Ashraf proprietorM/s Kozak Traders Archer Road Quetta through and M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi*** may be served with show cause notice for selling of unregistered and manufacturing of drugs without manufacturing license.

Proceedings and Decision of 271st meeting of Central Licensing Board

11. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused

1. M/s Kozak Traders Archer Road Quetta through its proprietor Muhammad Ashraf
2. Muhammad Ashraf proprietor M/s Kozak Traders Archer Road Quetta

3. M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi through its owner/ proprietor / CEO/ MD

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

i. Prosecution in the Court of competent jurisdiction

ii. Any other action the Board may deem fit under the law.

12. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

13. In the light of the decision of the Board, Show cause and personal hearing notice was issued to accused vide letter No. 03-44/2019-QC(Pt-I) dated 04-10-2019 contents of which are as under:

"Refer to the subject cited above, I am directed to communicate the decision of 271st Meeting of Central Licensing Board held on 12th September, 2019.

02. That Mr. Syed Abdul Saleem, the-then FID Quetta forwarded case vide letter No.F.SAS-122-124/2009-FID(Q)/195 dated 08thMarch 2010. The FID Quetta stated that he visited the M/s Kozak Traders Archer Road Quetta on 05-11-2009, during the visit some un registered drugs were found available without having Drug Sale License. The FID survey dated 07-11-2009 and subsequent request vide No.F.12-1/DCA-QTA/M.survey-75 dated 12.12.2009 a sample of drug namely sample of Trish Zee B.No.TZ001 claimed to be manufactured by M/s Starix Nutraceuticals Karachi was also taken along with other samples of drugs for the purpose of test/analysis.

03. The-then FID Quetta submitted that the sealed sample of Trish Zee B.No.TZ001 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-122-124/2009-FID(Q)-16 dated 06-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-122-124/2009-FID(Q) dated 11-11-2009. A portion of said sample of drug was also sent to M/s Starix Nutraceutical Karachi vide letter No.SAS-122-124/2009-FID (Q) dated 11-11-2009 and same was received back un-delivered.

04. The FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report No.SCD.202/2009 dated 09-12-2009 ***declared the sample of Trish Zee Tablets B.No.ZT001 and Un-registered (copy enclosed).***

05. The FID, Quetta also informed that M/s Starix Nutraceuticals Karachi was called to show cause and explain for its position for manufacturing and selling un-registered drug vide this office show-cause notice No.SAS-122-124/2009-FID (Q)/87 dated 15-12-2009 but same was also received back undelivered.

06. The FID Quetta stated that M/s Kozak Traders Quetta was also called to explain its position vide his office letter No.F.12-1/DCA-QTA/M survey -30 dated 21-11-2009. M/s Kozak submitted copies of invoices for drugs that were ordered not to dispose off. On receipt of test report from CDL Karachi, M/s Kozak Traders Quetta again called to show cause notice and explain its position vide this office letter No. SAS-122-124/2009-FID(Q)/86 dated 15-12-2009 but no response is received as yet.

07. The FID Quetta submitted in the light of above mentioned facts that M/s Kozak Traders Quetta found involved in manufacturing and selling of un-registered drug namely tablets Trish Zee with a fake name M/s Starix Nutraceuticals Karachi and violated the section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c) and 27(3) of the Drugs Act 1976.

08. ***In the light of request of FID, Quetta @ Karachi vide letter dated 05.08.2019, the matter was placed before the Central Licensing Board in its 271st Meeting held on 12th September, 2019. Furthermore, the matter has also been referred by Honorable Drug Court, Quetta.*** *The Board after delibration decided* ***to issue showcause notice under Rule 8 (13) of the Drug (Licensing, Registrating and Advertisement) Rules, 1976 for violating the section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c), and 23(1)(a)(vii) read with Section 27 of the Drugs Act 1976, against the following accused:***

1. *M/s. Kozak Traders, Archer Road Quetta through its proprietor Muhammad Ashraf*
2. *Muhammad Ashraf proprietor M/s. Kozak Traders Archer Road Quetta*
3. *M/s. Starix Nutraceuticals, D-36 Farzana Arcade, Shaheed-e-Millat Road, Karachi through its owner/proprietor/CEO/MD*

09. You are hereby served this show cause notice that why not the following actions shall be taken against you ***for violating the section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c), and 23(1)(a)(vii) read with Section 27 of the Drugs Act 1976. Your reply should reach within seven (07) days of receipt of this letter.***

i. Prosceution in Court of competent jurisdiction.

ii. Any other action the Board may deem fit under the law.

10. The Board further decided to give you final opportunity of personal hearing in order to meet the ends of justice. Therefore, you are directed to appear in person or through authorized legal counsel on 17-10-2019 at 10:30AM in Committee room, 4th Floor, TF Complex, G9/4, Islamabad.

11. In case of failure to reply in writing and/or appear in person before the Board, an ex-parte decision under the law shall be taken on the merits of the case as per available record."

Proceedings & Decision of 272nd CLB held on 17th October, 2019:

14. Central Licensing Board (CLB) was apprised that the Show Cause & Personal Hearing notice were forwarded through Urgent Mail Service which were receive back un-delivered.

15. Keeping in view the above facts, the Board unanimously decided that following means at a time should be adopted for the service of show cause & personal hearing notice to the accused in order to meet the ends of justice and to avoid delays:

i. Through registered posts/courier service direct on their address(s)
ii. Through area Federal Inspector of Drugs
iii. Through area Chief Drug Controller/Inspector
iv. By publishing show cause & personal hearing notice in the prominent Print Media in the reputable English & Urdu Newspapers

16. In compliance to the decision of the Board following means were adopted to ensure the delivery of show cause and personal hearing notice to the accused persons:

i. Through registered posts/courier service direct on their address(s) vide letter no. 13-185/2019-QC (272-CLB) dated 12.11.2019 which were received back un-delivered.
ii. Through area Federal Inspector of Drugs vide letter no. 13-185/2019-QC (272-CLB) dated

    12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.
iii. Through area Chief Drug Controller/Inspector, Balochistan @ Quetta vide letter no. 13-185/2019-QC (272-CLB) dated 12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.
iv. By publishing show cause & personal hearing notice in the three (03) Newspapers with Nationwide circulation on Wednesday, 25.12.2019.

Proceedings & Decision of 273rd CLB held on 15th January, 2020:

17. That none of the accused (neither in person nor by authorized pleader/attorney) appeared before the Board despite the publication of Show Cause Notice and personal hearing letter in three (03) leading newspaper i.e. Daily "The News" (combined), Daily Express (Combined), Daily Ausaf (Combined) on 25.12.2019 (Wednesday).

18. The Board deliberated the matter in depth, considered the facts of the case and perused the available record and decided as under:

A. That the following accused persons have committed offence by violating the provisions of ***section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c), and 23(1)(a)(vii) which are punishable under the provisions of Section 27 of the Drugs Act 1976:***

1. *M/s. Kozak Traders, Archer Road Quetta through its proprietor Muhammad Ashraf*
2. *Muhammad Ashraf proprietor M/s. Kozak Traders Archer Road Quetta*
3. *M/s. Starix Nutraceuticals, D-36 Farzana Arcade, Shaheed-e-Millat Road, Karachi through its owner/proprietor/CEO/MD*

B. The Federal Inspector of Drugs, DRAP, Quetta is directed to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.

Case No.I-B: MANUFACTURING AND SELLING OF UN-REGISTERED DRUG NAMELY BELT LIQUID B.NO.BS03.

That Mr. Syed Abdul Saleem, FID Quetta forwarded case vide letter No.F.SAS-122-124/2009-FID(Q)/194 dated 08thMarch 2010. The FID Quetta stated that he visited the M/s Kozak Traders Archer Road Quetta on 05-11-2009, during the visit some un registered drugs were found available without having Drug Sale License. The FID ordered Not to dispose of all available stocks of said drugs. The same was reported the Chairman CLB for extension of time of said orders vide this office letter No. F.12-1/DCA-QTA/M. The FID survey dated 07-11-2009 (copy Annex B) and subsequent request vide No.F.12-1/DCA-QTA/M survey75 dated 12.12.2009 (copy annex C) a sample of drug namely Belt Liquid B.No. BS.03 claimed to be manufactured by M/s Starix Nutraceuticals Karachi was also taken along with other samples of drugs for the purpose of test/analysis.

02. The FID Quetta submitted that the sealed sample of Belt Liquid B.No. BS.03 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-122-124/2009-FID (Q) -16 dated 06-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-122-124/2009-FID(Q) dated 11-11-2009. A portion of said sample of drug was also sent to M/s Starix Nutraceutical Karachi vide letter No.SAS-122-124/2009-FID (Q) dated 11-11-2009 and same was received back un-delivered.

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report No.SCD.204/2009 dated 31-12-2009 **declared the sample of Beld Liquid B.No.BS03 Un-registered.**

04. FID, Quetta informed that M/s Starix Nutraceuticals Karachi was called to show cause and explain for its position for manufacturing and selling un-registered drug vide this office show-cause notice No.SAS-122-124/2009-FID (Q)/121 dated 06-1-2010 but same was also received back undelivered.

05. The FID Quetta stated that M/s Kozak Traders Quetta was also called to explain its position vide his office letter No.F.12-1/DCA-QTA/M survey-30 dated 21-11-2009. M/s Kozak submitted copies of invoices for drugs that were ordered not to dispose off on receipt of test report from CDL Karachi. M/s Kozak Traders Quetta again called to show cause notice and explain its position vide this office letter No. SAS-122-124/2009-FID(Q)/124 dated 06-01-2010 but no response is received as yet.

06. The FID Quetta submitted the above mentioned facts and revealed that M/s Kozak Traders Quetta involved in manufacturing and selling of un-registered drug namely **Belt Liquid B.No.BS03** with a fake name M/s Starix Nutraceuticals Karachi and violated the section 23(1)(a)(x), 23(1)(b),23(1)(c) and 27(3) of the Drugs Act 1976

07. The FID Quetta is submitted for placement before CLB for its consideration and **permission of prosecution against Mr. Muhammad Ashraf proprietor of M/s Kozak Traders Quetta along with M/s Starix Nutraceuticals Karachi**.

Permission for Show cause Notice to prosecute.

08. It is therefore submitted that ***Muhammad Ashraf proprietorM/s Kozak Traders Archer Road Quetta through and M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi*** may be served with show cause notice for selling of unregistered and manufacturing of drugs without manufacturing license.

Proceedings and Decision of 271st meeting of Central Licensing Board

09. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused

1. M/s Kozak Traders Archer Road Quetta through its proprietor Muhammad Ashraf
2. Muhammad Ashraf proprietor M/s Kozak Traders Archer Road Quetta
3. M/s Starix Nutraceuticals D-36 Farzana Arcade Shaheed-e-Millat Road Karachi through its owner/ proprietor / CEO/ MD

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

i. Prosecution in the Court of competent jurisdiction

ii. Any other action the Board may deem fit under the law.

10. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

11. In the light of the decision of the Board, Show cause and personal hearing notice was issued to accused vide letter No. 03-44/2019-QC(Pt-I) dated 04-10-2019 contents of which are as under:

"Refer to the subject cited above, I am directed to communicate the decision of 271st Meeting of Central Licensing Board held on 12th September, 2019.

02. That Mr. Syed Abdul Saleem, the-then FID Quetta forwarded case vide letter No.F.SAS-122-124/2009-FID(Q)/194 dated 08thMarch 2010. The FID Quetta stated that he visited the M/s Kozak Traders Archer Road Quetta on 05-11-2009, during the visit some un registered drugs were found available without having Drug Sale License. The FID ordered not to dispose of allavailable stocks of said drugs. The same was reported the Chairman CLB for extension of time of said orders vide letter No. F.12-1/DCA-QTA/M. The FID survey dated 07-11-2009 and subsequent request vide No.F.12-1/DCA-QTA/M.survey-75 dated 12.12.2009. A sample of drug namely Belt Liquid B.No. BS.03 claimed to be manufactured by M/s Starix Nutraceuticals Karachi was also taken along with other samples of drugs for the purpose of test/analysis.

03. The-then FID Quetta submitted that the sealed sample of Belt Liquid B.No. BS.03 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-122-124/2009-FID (Q) -16 dated 06-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-122-124/2009-FID(Q) dated 11-11-2009. A portion of said sample of drug was also sent to M/s Starix Nutraceutical Karachi vide letter No.SAS-122-124/2009-FID (Q) dated 11-11-2009 and same was received back un-delivered.

04. The-then FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report No.SCD.204/2009 dated 31-12-2009 ***declared the sample of Belts Liquid B.No.BS03 Un-registered (copy enclose).***

05. The-then FID, Quetta informed that M/s Starix Nutraceuticals Karachi was called to show cause and explain for its position for manufacturing and selling un-registered drug vide this office show-cause notice No.SAS-122-124/2009-FID(Q)/121 dated 06-01-2010 but same was also received back undelivered.

06. The FID Quetta stated that M/s Kozak Traders Quetta was also called to explain its position vide his office letter No.F.12-1/DCA-QTA/M survey-30 dated 21-11-2009.

M/s Kozak submitted copies of invoices for drugs that were ordered not to dispose of. On receipt of test report from CDL Karachi, M/s Kozak Traders Quetta was again show causeed notice to explain its position vide this office letter No. SAS-122-124/2009-FID(Q)/124 dated 06-01-2010 but no response is received as yet.

07. The-then FID Quetta submitted the above mentioned facts and revealed that M/s Kozak Traders Quetta involved in manufacturing and selling of un-registered drug namely ***Belt Liquid B.No.BS03*** *with a fake name of M/s Starix Nutraceuticals Karachi.*

08. ***In the light of request of FID, Quetta @ Karachi vide letter dated 05.08.2019, the matter was placed before the Central Licensing Board in its 271st Meeting held on 12th September, 2019. Furthermore, the matter has also been referred by Honorable Drug Court, Quetta.*** *The Board after delibration decided* ***to issue showcause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused:***

1. M/s. Kozak Traders, Archer Road Quetta through its proprietor Muhammad Ashraf

2. Muhammad Ashraf proprietor M/s. Kozak Traders Archer Road Quetta

3. M/s. Starix Nutraceuticals, D-36 Farzana Arcade, Shaheed-e-Millat Road, Karachi through its owner/proprietor/CEO/MD

09. You are hereby served this show cause notice that why not the following actions shall be taken against you ***for violating the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976. Your reply should reach within seven (07) days of receipt of this letter.***

i. Prosceution in Court of competent jurisdiction.

ii. Any other action the Board may deem fit under the law.

10. The Board further decided to give you final opportunity of personal hearing in order to meet the ends of justice. Therefore, you are directed to appear in person or through authorized legal counsel on 17-10-2019 at 10:30AM in Committee room, 4th Floor, TF Complex, G9/4, Islamabad.

11. In case of failure to reply in writing and/or appear in person before the Board, an ex-parte decision under the law shall be taken on the merits of the case as per available record."

Proceedings & Decision of 272nd CLB held on 17th October, 2019:

12. Central Licensing Board (CLB) was apprised that the Show Cause & Personal Hearing notice were forwarded through Urgent Mail Service which were receive back un-delivered.

13. Keeping in view the above facts, the Board unanimously decided that following means at a time should be adopted for the service of show cause & personal hearing notice to the accused in order to meet the ends of justice and to avoid delays:

i. Through registered posts/courier service direct on their address(s)
ii. Through area Federal Inspector of Drugs
iii. Through area Chief Drug Controller/Inspector
iv. By publishing show cause & personal hearing notice in the prominent Print Media in the reputable English & Urdu Newspapers

14. In compliance to the decision of the Board following means were adopted to ensure the delivery of show cause and personal hearing notice to the accused persons:

i. Through registered posts/courier service direct on their address(s) vide letter no. 13-185/2019-QC (272-CLB) dated 12.11.2019 which were received back un-delivered.
ii. Through area Federal Inspector of Drugs vide letter no. 13-185/2019-QC (272-CLB) dated

    12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.
iii. Through area Chief Drug Controller/Inspector, Balochistan @ Quetta vide letter no. 13-185/2019-QC (272-CLB) dated 12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.
iv. By publishing show cause & personal hearing notice in the three (03) Newspapers with Nationwide circulation on Wednesday, 25.12.2019.

Proceedings & Decision of 273rd CLB held on 15th January, 2020:

15. That none of the accused (neither in person nor by authorized pleader/attorney) appeared before the Board despite the publication of Show Cause Notice and personal hearing letter in

three (03) leading newspaper i.e. Daily "The News" (combined), Daily Express (Combined), Daily Ausaf (Combined) on 25.12.2019 (Wednesday).

16. The Board deliberated the matter in depth, considered the facts of the case and perused the available record and decided as under:

A. That the following accused persons have committed offence by violating the provisions of ***section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c), and 23(1)(a)(vii) which are punishable under the provisions of Section 27 of the Drugs Act 1976:***

1. *M/s. Kozak Traders, Archer Road Quetta through its proprietor Muhammad Ashraf*
2. *Muhammad Ashraf proprietor M/s. Kozak Traders Archer Road Quetta*
3. *M/s. Starix Nutraceuticals, D-36 Farzana Arcade, Shaheed-e-Millat Road, Karachi through its owner/proprietor/CEO/MD*

B. The Federal Inspector of Drugs, DRAP, Quetta is directed to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.

Case No. I-C: MANUFACTURING AND SALE OF UN REGISTERED DRUG NAMELY SYP IRO-C B.NO. 123

Syed Abdul Saleem, FID Quetta forwarded vide letter No.F.SAS-122-124/2009-FID(Q)/196 dated 08th March 2010. The FID Quetta stated that during visit some un-registered drugs were found available without having Drug Sale license. The FID ordered Not to dispose of all available stocks of said drugs (Copy of Form-I Annex A) the same was reported the Chairman CLB for extension of time of said orders vide this office letter No. F.12-1/DCA-QTA/M. The FID survey dated 07-11-2009 (copy Annex B) and subsequent request vide No.F.12-1/DCA-QTA/M survey 75 dated 12.12.2009 (copy annex C) a sample of drug namely IRO-C, B.No.123 claimed to be manufactured by M/s Welldone Pharma Nutraceuticals Division Multan was also taken along with other samples of drugs for the purpose of test/analysis

02. The FID Quetta submitted that the sealed sample of IRO-C, B.No. 123 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-122-124/2009-FID (Q) -16 dated 06-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-122-124/2009-FID(Q) dated 11-11-2009. A portion of said sample of drug was also sent to M/s Welldone Pharma Multan vide letter No.SAS-122-124/2009-FID (Q) dated 11-11-2009 and same was received back un-delivered.

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report No.SCD.203/2009 dated 31-12-2009 **declared the sample of IRO-C B.No.123 Un-registered.**

04. M/s Welldone Pharma Multan was called to show cause and explain for its position for manufacturing and selling un-registered drug vide his office show-cause notice No.SAS-122-124/2009-FID (Q)/122 dated 06-01-2010 but same was also received back undelivered.

05. The FID Quetta stated that M/s Kozak Traders Quetta was also called to explain its position vide his office letter No.F.12-1/DCA-QTA/M survey -30 dated 21-11-2009. M/s Kozak submitted copies of invoices of invoices for drugs that were ordered not to dispose off on receipt of test report from CDL Karachi M/s Kozak Traders Quetta again called to show cause notice and explain its position vide this office letter No. SAS-122-124/2009-FID(Q)/123 dated 06-01-2010 but no response is received as yet.

06. The FID Quetta submit the above mentioned facts and revealed that M/s Kozak Traders Quetta submitted invoices bearing No.282 dated 02-11-2009 of M/s Allah Waley Food Products

Trading Town Hall Multan in respect of said drug. M/s Allah Waley Food Products Trading Multan was asked to verify its invoice with warrantee and provide further invoice with warranty and provide further invoice with warrantee vide his office letter No. SAS.122-124/2009-FID(Q)/100 dated 21.12.2009 but same was received back un delivered.

The FID Quetta stated that on the basis of facts it is reveled that M/s Kozak Traders Quetta involved in manufacturing and selling of un registered drug namely Syp IRO-C with a fake name M/s Welldone Pharma Multan and violated the section 23(1)(a)(x), 23(1)(b),23(1)(c) and 27(3) of the Drugs Act 1976

07. The FID Quetta is submitted for placement before CLB for its consideration and permission of **prosecution against Mr. Muhammad Ashraf proprietor of M/s Kozak Traders Quetta along with M/s Allah Waley Food Products Trading Town Hall Multan and M/s Welldone Pharma Multan.**

Permission for Show cause Notice to prosecute.

08. It is therefore submitted that ***Muhammad Ashraf (CNIC No.: 54400-4016531-7) proprietorM/s Kozak Traders Archer Road Quetta through along with M/s Allah Waley Food Products Trading Town Hall Multan and M/s Welldone Pharma Multan*** may be served with show cause notice for selling of unregistered and manufacturing of drugs without manufacturing license.

Proceedings and Decision of 271st meeting of Central Licensing Board

09. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused

1. M/s Kozak Traders Archer Road Quetta through its proprietor Muhammad Ashraf
2. Muhammad Ashraf proprietor M/s Kozak Traders Archer Road Quetta
3. M/s Allah Waley Food Products, Trading Town Hall, Multan
4. M/s Welldone Pharma (Nutraceutical Division), Multan

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

i. Prosecution in the Court of competent jurisdiction

ii. Any other action the Board may deem fit under the law.

10. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

11. In the light of the decision of the Board, Show cause and personal hearing notice was issued to accused vide letter No. 03-44/2019-QC(Pt-I)(271-CLB) dated 04-10-2019 contents of which are as under:

"Refer to the subject cited above, I am directed to communicate the decision of 271st Meeting of Central Licensing Board held on 12th September, 2019.

02. That Syed Abdul Saleem, the-then FID Quetta forwarded case vide letter No.F.SAS-122-124/2009-FID(Q)/196 dated 08th March 2010. The FID Quetta stated that he visited the M/s Kozak Traders Archer Road Quetta on 05-11-2009, during the visit some un registered drugs were found available without having Drug Sale License. The FID ordered Not to dispose of all available stocks of said drugs. the same was reported the Chairman CLB for extension of time of said orders vide letter No. F.12-1/DCA-QTA/M. The FID survey dated 07-11-2009 and subsequent request vide No.F.12-1/DCA-QTA/M.survey-75 dated 12.12.2009. A sample of drug namely IRO-C, B.No.123 claimed to be manufactured by M/s Welldone Pharma Nutraceuticals Division Multan was also taken along with other samples of drugs for the purpose of test/analysis

03. The-then FID Quetta submitted that the sealed sample of IRO-C, B.No. 123 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-122-124/2009-FID(Q)-16 dated 06-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-122-124/2009-FID(Q) dated 11-11-2009. A portion of said sample of drug was also sent to M/s Welldone Pharma Multan vide letter No.SAS-122-124/2009-FID (Q) dated 11-11-2009 and same was received back un-delivered.

04. The-then FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report No.SCD.203/2009 dated 31-12-2009 ***declared the sample of IRO-C B.No.123 Un-registered (copy enclosed).***

05. The-then FID, Quetta informed that M/s Welldone Pharma Multan was called to show cause and explain for its position for manufacturing and selling

un-registered drug vide his office show-cause notice No.SAS-122-124/2009-FID (Q)/122 dated 06-01-2010 but same was also received back undelivered.

06. The FID Quetta stated that M/s Kozak Traders Quetta was also called to explain its position vide his office letter No.F.12-1/DCA-QTA/M survey -30 dated 21-11-2009. M/s Kozak submitted copies of invoices for drugs that were ordered not to dispose of. On receipt of test report from CDL Karachi M/s Kozak Traders Quetta again called to show cause notice and explain its position vide letter No. SAS-122-124/2009-FID(Q)/123 dated 06-01-2010 but no response is received as yet.

07. The-then FID Quetta submitted the above-mentioned facts and revealed that M/s Kozak Traders Quetta submitted invoices bearing No.282 dated 02-11-2009 of M/s Allah Waley Food Products Trading Town Hall Multan in respect of said drug. M/s Allah Waley Food Products Trading Multan was asked to verify its invoice with warrantee vide his office letter No. SAS.122-124/2009-FID(Q)/100 dated 21.12.2009 but same was received back un delivered.

08. The FID Quetta stated that on the basis of facts it is reveled that M/s Kozak Traders Quetta is involved in manufacturing and selling of un registered drug namely Syp IRO-C with a fake name M/s Welldone Pharma Multan and violated the section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c) and 27(3) of the Drugs Act 1976.

08. ***In the light of request of FID, Quetta @ Karachi vide letter dated 05.08.2019, the matter was placed before the Central Licensing Board in its 271st Meeting held on 12th September, 2019. Furthermore, the matter has also been referred by Honorable Drug Court, Quetta. The Board after delibration decided to issue showcause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976 against the following accused:***

1. M/s. Kozak Traders, Archer Road Quetta through its proprietor Muhammad Ashraf

2. Muhammad Ashraf proprietor M/s. Kozak Traders Archer Road Quetta

3. M/s Allah Waley Food Products Trading Town Hall Multan and

4. M/s Welldone Pharma (Nutraceutical Division) Multan

09. You are hereby served this show cause notice that why not the following actions shall be taken against you ***for violating the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (a) (vii) read with Section 27 of the Drugs Act, 1976. Your reply should reach within seven (07) days of receipt of this letter.***

i. Prosceution in Court of competent jurisdiction.

ii. Any other action the Board may deem fit under the law.

10. The Board further decided to give you final opportunity of personal hearing in order to meet the ends of justice. Therefore, you are directed to appear in person or through authorized legal counsel on 17-10-2019 at 10:30AM in Committee room, 4th Floor, TF Complex, G9/4, Islamabad.

11. In case of failure to reply in writing and/or appear in person before the Board, an ex-parte decision under the law shall be taken on the merits of the case as per available record."

Proceedings & Decision of 272nd CLB held on 17th October, 2019:

12. Central Licensing Board (CLB) was apprised that the Show Cause & Personal Hearing notice were forwarded through Urgent Mail Service which were receive back un-delivered.

13. Keeping in view the above facts, the Board unanimously decided that following means at a time should be adopted for the service of show cause & personal hearing notice to the accused in order to meet the ends of justice and to avoid delays:

i. Through registered posts/courier service direct on their address(s)
ii. Through area Federal Inspector of Drugs
iii. Through area Chief Drug Controller/Inspector
iv. By publishing show cause & personal hearing notice in the prominent Print Media in the reputable English & Urdu Newspapers

14. In compliance to the decision of the Board following means were adopted to ensure the delivery of show cause and personal hearing notice to the accused persons:

i. Through registered posts/courier service direct on their address(s) vide letter no. 13-185/2019-QC (272-CLB) dated 12.11.2019 which were received back un-delivered.
ii. Through area Federal Inspector of Drugs vide letter no. 13-185/2019-QC (272-CLB) dated

12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and

acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.

iii. Through area Chief Drug Controller/Inspector, Balochistan @ Quetta vide letter no. 13-185/2019-QC (272-CLB) dated 12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.

iv. By publishing show cause & personal hearing notice in the three (03) Newspapers with Nationwide circulation on Wednesday, 25.12.2019.

Proceedings & Decision of 273rd CLB held on 15th January, 2020:

15. That none of the accused (neither in person nor by authorized pleader/attorney) appeared before the Board despite the publication of Show Cause Notice and personal hearing letter in three (03) leading newspaper i.e. Daily "The News" (combined), Daily Express (Combined), Daily Ausaf (Combined) on 25.12.2019 (Wednesday).

16. The Board deliberated the matter in depth, considered the facts of the case and perused the available record and decided as under:

A. That the following accused persons have committed offence by violating the provisions of ***section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c), and 23(1)(a)(vii) which are punishable under the provisions of Section 27 of the Drugs Act 1976:***

1. *M/s. Kozak Traders, Archer Road Quetta through its proprietor Muhammad Ashraf*
2. *Muhammad Ashraf proprietor M/s. Kozak Traders Archer Road Quetta*
3. *M/s Allah Waley Food Products Trading Town Hall Multan Through its owner/proprietor and*
4. *M/s Welldone Pharma (Nutraceutical Division) Multan through its owner/proprietor/CEO/MD*

B. The Federal Inspector of Drugs, DRAP, Quetta is directed to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.

Case No. 02: MANUFACTURING AND SELLING OF SPURIOUS AND UN-REGISTERED DRUG NAMELY INJ. EXIR 1 GM B.NO. A0001.

ThatMr. Syed Abdul Saleem, FID Quetta forwarded vide letter No.F.SAS-140-141/2009-FID(Q)/198 dated 10thMarch 2010. The FID Quetta stated that during visit M/s Malik & Sons Dr. Bano Road Quetta on 10-11-2009 during the visit sample of drug namely Inj. Exir 1gm B.No. A0001 claimed to be manufactured by M/s Winner Pharmaceuticals Pvt Ltd Korangi Industrial area Karachi was taken along with other samples of the drugs for the purpose of test analysis.

02. The FID Quetta submitted that the sealed sample of Inj. Exir 1gm B.No. A0001 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-140-141/2009-FID (Q) -12 dated 11-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-140-141/2009-FID(Q) dated 11-11-2009 with advise to rpvide the copy of registration along with acknowledgment of its receipt but no response from your side is received as yet.

03. The Federal Government Analyst CDL karachi vide issued test report bearing No. SCD.479/2009 dated 21-12-2009 without final opinion but with remarks as Since registration number of Drug Product is not available therefore laboratory is unable to decide the quality and regulatory compliance .

04 M/s Malik and Sons Quetta submitted copy of invoice bearing No. 1170 dated 18.10.2009 M/s Winner Pharmaceuticals Pvt Ltd Karachi was served with a show cause notice bearing No. SAS-140-141/2009-FID(Q)/23 dated 20-11-2009 to explain its position for selling said un registered drug but same is received back undelivered. The copy of said notice was also endorsed to the Deputy Director General (E&M) Karachi with request address of said manufacturer may kindly be verified and inspection of premises may be inspected through are FID Karachi but no response is received as yet. On receipt of test report of CDL Karachi show cause notice again issued to M/s Winner Pharmaceuticals Pvt Ltd Karachi vide No. F.SAS-140-141/2009-FID(Q)/131 dated 08-01-2010 but same again received back un delivered M/s Malik & Sons Quetta was also served with a show cause notice vide letter No.F.SAS-140-141/2009-FID (Q)/132 dated 08.01.2010 but no response in this regard is received as yet.

05. The FID Quetta stated of above mentioned facts of the case it reveled that M/s Malik &Sons Quetta is involved in manufacturing and selling spurious and un-registered drug namely Inj.Exir 1gm in name of M/s Winner Pharmaceuticals Pvt Ltd Karachi which is fake firm and

violated section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c) and 27(3) of Drug Act 1976 it is added that before considering the case against M/s Malik & Sons Quetta the existence of manufacturer i.e. M/s Winner Pharmaceuticals Karachi may kindly be verified through are FID Karachi as same is still awaited which is also mentioned above.

06. The FID Quetta submitted the above mentioned facts and requested to the CLB and CLB for its consideration and **permission of prosecution against M/s Malik & Sons Quetta for above mentioned violation.**

Permission for Show cause Notice to prosecute.

07. It is therefore submitted that ***Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor*** **M/s Malik & Sons,Dr. Bano Road, Quetta**may be served with show cause notice for selling of unregistered and manufacturing of drugs without manufacturing license.

Proceedings and Decision of 271st meeting of Central Licensing Board

08. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for violation of the **section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c) and 27(3) of Drug Act 1976, against the following accused:**

1. M/s. Malik & Sons, Dr. Bano Road, Quetta through its proprietor Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5).
2. Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor M/s Malik & Sons, Dr. Bano Road, Quetta.

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

i. Prosecution in the Court of competent jurisdiction

ii. Any other action the Board may deem fit under the law.

09. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

10. In the light of the decision of the Board, Show cause and personal hearing notice was issued to accused vide letter No. 03-44/2019-QC(Pt-I)(271-CLB) dated 04-10-2019 contents of which are as under:

"Refer to the subject cited above, I am directed to communicate the decision of 271st Meeting of Central Licensing Board held on 12th September, 2019.

02. That Mr. Syed Abdul Saleem, the-then FID Quetta forwarded case vide letter No.F.SAS-140-141/2009-FID(Q)/198 dated 10th March 2010. The FID Quetta stated that during visit M/s Malik & Sons Dr. Bano Road Quetta on 10-11-2009 sample of drug namely Inj. Exir 1gm B.No. A0001 claimed to be manufactured by M/s Winner Pharmaceuticals Pvt. Ltd., Korangi Industrial Area, Karachi was taken along with other samples of the drugs for the purpose of test analysis.

03. The-then FID Quetta submitted that the sealed sample of Inj. Exir 1gm B.No. A0001 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-140-141/2009-FID(Q)-12 dated 11-11-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-140-141/2009-FID(Q) dated 11-11-2009 with advise to provide the copy of registration along with acknowledgment of its receipt but no response from your side is received as yet.

04. The Federal Government Analyst CDL Karachi vide issued test report bearing No. SCD.479/2009 dated 21-12-2009 without final opinion but with remarks as since registration number of Drug Product is not available therefore laboratory is unable to decide the quality and regulatory compliance.

05. The-then FID, Quetta informed that M/s Malik and Sons Quetta submitted copy of invoice bearing No. 1170 dated 18.10.2009 M/s Winner Pharmacetuicals Pvt Ltd Karachi was served with a show cause notice bearing No. SAS-140-141/2009-FID(Q)/23 dated 20-11-2009 to explain its position for selling said un registered drug but same is received back undelivered. The copy of said notice was also endorsed to the Deputy Director General (E&M) Karachi with request address of said manufacturer may kindly be verified and inspection of premises may be inspected through are FID Karachi but no response is received as yet. On receipt of test report of CDL Karachi show cause notice again issued to M/s Winner Pharmacetuicals Pvt. Ltd., Karachi vide No. F.SAS-140-141/2009-FID(Q)/131 dated 08-01-2010 but same again received back un delivered. M/s

Malik & Sons, Quetta was also served with a show cause notice vide letter No.F.SAS-140-141/2009-FID (Q)/132 dated 08.01.2010 but no response in this regard is received as yet.

06. The FID Quetta stated on the basis of above-mentioned facts it reveled that M/s Malik &Sons Quetta is involved in manufacturing and selling ***spurious*** *and* ***un-registered*** *drug namely Inj.Exir 1gm in name of M/s Winner Pharmaceuticals Pvt Ltd Karachi which is fake firm and violated section* ***23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c) and 27(3)*** *of Drug Act 1976. It is added that before considering the case against M/s Malik & Sons Quetta the existence of manufacturer i.e. M/s Winner Pharmaceuticals Karachi may kindly be verified through are FID Karachi as same is still awaited which is also mentioned above.*

07. In the light of request of FID, Quetta @ Karachi vide letter dated 05.08.2019, the matter was placed before the Central Licensing Board in its 271st Meeting held on 12th September, 2019. Furthermore, the matter has also been referred by Honorable Drug Court, Quetta. The Board after delibration decided to issue showcause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for violation of the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c) and 27 (3) read with Section 27 of the Drugs Act, 1976 against the following accused:

1. M/s. Malik & Sons, Dr. Bano Road, Quetta through its proprietor Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5).

2. Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor M/s Malik & Sons, Dr. Bano Road, Quetta.

08. You are hereby served this show cause notice that why not the following actions shall be taken against you ***for violating the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c) and 27 (3) read with Section 27 of the Drugs Act, 1976. Your reply should reach within seven (07) days of receipt of this letter.***

i. Prosceution in Court of competent jurisdiction.

ii. Any other action the Board may deem fit under the law.

09. The Board further decided to give you final opportunity of personal hearing in order to meet the ends of justice. Therefore, you are directed to appear

in person or through authorized legal counsel on 17-10-2019 at 10:30AM in Committee room, 4th Floor, TF Complex, G9/4, Islamabad.

10. In case of failure to reply in writing and/or appear in person before the Board, an ex-parte decision under the law shall be taken on the merits of the case as per available record."

Proceedings & Decision of 272nd CLB held on 17th October, 2019:

11. Central Licensing Board (CLB) was apprised that the Show Cause & Personal Hearing notice were forwarded through Urgent Mail Service which were receive back un-delivered.

12. Keeping in view the above facts, the Board unanimously decided that following means at a time should be adopted for the service of show cause & personal hearing notice to the accused in order to meet the ends of justice and to avoid delays:

i. Through registered posts/courier service direct on their address(s)
ii. Through area Federal Inspector of Drugs
iii. Through area Chief Drug Controller/Inspector
iv. By publishing show cause & personal hearing notice in the prominent Print Media in the reputable English & Urdu Newspapers

13. In compliance to the decision of the Board following means were adopted to ensure the delivery of show cause and personal hearing notice to the accused persons:

i. Through registered posts/courier service direct on their address(s) vide letter no. 13-185/2019-QC (272-CLB) dated 12.11.2019 which were received back un-delivered.
ii. Through area Federal Inspector of Drugs vide letter no. 13-185/2019-QC (272-CLB) dated

    12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.
iii. Through area Chief Drug Controller/Inspector, Balochistan @ Quetta vide letter no. 13-185/2019-QC (272-CLB) dated 12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.
iv. By publishing show cause & personal hearing notice in the three (03) Newspapers with Nationwide circulation on Wednesday, 25.12.2019.

Proceedings & Decision of 273rd CLB held on 15th January, 2020:

15. That none of the accused (neither in person nor by authorized pleader/attorney) appeared before the Board despite the publication of Show Cause Notice and personal hearing letter in three (03) leading newspaper i.e. Daily "The News" (combined), Daily Express (Combined), Daily Ausaf (Combined) on 25.12.2019 (Wednesday).

16. The Board deliberated the matter in depth, considered the facts of the case and perused the available record and decided as under:

A. That the following accused persons have committed offence by violating the provisions of ***the Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c) and 27 (3) which are punishable under the provisions of Section 27 of the Drugs Act 1976:***

1. *M/s. Malik & Sons, Dr. Bano Road, Quetta through its proprietor Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5).*
2. *Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor M/s Malik & Sons, Dr. Bano Road, Quetta*

B. The Federal Inspector of Drugs, DRAP, Quetta is directed to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.

Case No. 03: <u>MANUFACTURING AND SELLING OF UNREGISTERED DRUG NAMELY TABS. KALPHOMEX POWDER (FOR VET. USE ONLY) B.NO. ARX-3459</u>

Mr. Abdul Saleem the then FID Quetta forwarded the case vide letter No.SAS-94-102/2009-FID(Q)/229 dated 25th March 2010 wherein informed that the FID Quetta visited to M/s Chiltan Veterinary Quarry Road Quetta on 06-10-2009 and a sample of drug namely Kalphomex Powder (For Vet Use only) B.No.ARX-3459 claimed to be manufactured by M/s Afrasco laboratories Lahore was taken for the purpose of test/analysis.

02. The sealed sample of above drug with other samples of drugs was sent to the Federal Government Analyst Central Drug Laboratory karachi for the purpose of test analysis vide office letter No.SAS-94-102/2009-FID(Q)-3024 dated 07-10-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing & Registration Board Islamabad vide letter No.SAS-94-95/2009-FID(Q)-3028 dated 07-10-2009 a portion of said sample was also sent to the manufacturer vide letter No.SAS-94-95/2009-FID(Q)-3047 dated 09-10-2009 with advise to provide the copy of registration along with acknowledgment of its receipt.

03. It is to inform that M/s Chiltan Veterinary Quetta submitted invoice No.402 dated 07-08-2009 of M/s Afrasco Laboratories Lahore.

04. That the Federal Government Analyst Central Drugs Laboratory Karachi vide test report No.737/2009 dated 19-11-2009 declared the sample of Kalphomex powder (For Vet use only) as **<u>Unregistered</u>** A copy of test analysis certificate was also sent by FID under section 22(3) (c) of drugs Act 1976

05. The firm M/s Afrasco Laboratories Lahore was served with a show cause notice was issued vide letter No.SAS-94-102/2009-FID(Q)-59 dated 05-12-2009 to explain its position for manufacturing and selling the said unregistered drug M/s Afrasco Lab Lahore submitted its reply through its legal advisor Mr. Ahson Mehmood claiming that the said drug contains 100% indigenous sources but no documentary evidence submitted in support of its reply. He further challenged the powers of FID and quoted references The firm was again asked to provide required information/documents as asked vide letter dated 05-12-2009 vide letter No. SAS-94-102/2009-FID(Q)-172 dated 10-02-2010 but again no response is received as yet.

06. In the light of test report of Federal Government Analyst Central Drug Laboratories Karachi the firm M/s Afrasco Lab Lahore violated the section 23(1)(a)(vii) 23(1)(a)(x) 23(1)(b) 23(1)(c) and 27(3) of Drug Act 1976.

07. Keeping in view of above stated facts the case is being submitted for placement before Central Licensing & Registration Board for its consideration and **permission of prosecution against M/s Afrasco Lab Lahore.**

Submitted for show cause notice to prosecute:

08. It is therefore submitted that**M/s Afrasco Laboratories, Umar Khan Road,Manawan,Lahoreand Tariq Mehmood S/o Nasarullah Kahn (CNICNo. 54400-9743364-1) address r/o 8-18/4, Kansi Road, Teen Town, Quetta, proprietor chiltan Veterinary, Quarry Raod, Quetta** may be served show caused**for manufacturing and selling of unregistered drugs**.

Proceedings and Decision of 271st meeting of Central Licensing Board

09. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for manufacturing and selling of unregistered, drugs against the following accused

1. M/s Afrasco Laboratories, Umar Khan Road,Manawan, Lahore through owner / proprietor
2. M/s chiltan Veterinary, Quarry Raod, Quetta through Tariq Mehmood S/o Nasarullah Kahn proprietor
3. Tariq Mehmood S/o Nasarullah Kahn (CNICNo. 54400-9743364-1) address r/o 8-18/4, Kansi Road, Teen Town, Quetta, proprietor chiltan Veterinary, Quarry Raod, Quetta

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

i. Prosecution in the Court of competent jurisdiction

ii. Any other action the Board may deem fit under the law.

10. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

11. In the light of the decision of the Board, Show cause and personal hearing notice was issued to accused vide letter No. 03-44/2019-QC(Pt-I)(271-CLB) dated 04-10-2019 contents of which are as under:

"Refer to the subject cited above, I am directed to communicate the decision of 271st Meeting of Central Licensing Board held on 12th September, 2019.

02. That Mr. Abdul Saleem the then FID Quetta forwarded the case vide letter No.SAS-94-102/2009-FID(Q)/229 dated 25th March 2010 wherein informed that the FID Quetta visited to M/s Chiltan Veterinary Quarry Road Quetta on 06-10-2009 and a sample of drug namely Kalphomex Powder (For Vet Use only) B.No.ARX-3459 claimed to be manufactured by M/s Afrasco laboratories Lahore was taken for the purpose of test/analysis.

03. That the sealed sample of above drug with other samples of drugs was sent to the Federal Government Analyst Central Drug Laboratory karachi for the purpose of test analysis vide office letter No.SAS-94-102/2009-FID(Q)-3024 dated 07-10-2009 on Form-4 and a portion of the said drugs also sent to the Chairman Central Licensing & Registration Board Islamabad vide letter No.SAS-94-95/2009-FID(Q)-3028 dated 07-10-2009 a portion of said sample was also sent to the manufacturer vide letter No.SAS-94-95/2009-FID(Q)-3047 dated 09-10-2009 with advise to provide the copy of registration along with acknowledgment of its receipt.

04. That M/s Chiltan Veterinary Quetta submitted invoice No.402 dated 07-08-2009 of M/s Afrasco Laboratories Lahore.

05. That the Federal Government Analyst Central Drugs Laboratory Karachi vide test report No.737/2009 dated 19-11-2009 declared the sample of Kalphomex powder (For Vet use only) as ***Unregistered*** *A copy of test analysis certificate was also sent by FID under section 22(3) (c) of drugs Act 1976*

06. That M/s Afrasco Laboratories Lahore was served with a show cause notice was issued vide letter No.SAS-94-102/2009-FID(Q)-59 dated 05-12-2009 to explain its position for manufacturing and selling the said unregistered drug M/s Afrasco Lab Lahore submitted its reply through its legal advisor Mr. Ahson Mehmood claiming that the said drug contains 100% indigenous sources but no documentary evidence submitted in support of its reply. He further challenged the powers of FID and quoted references. The firm was again asked to provide required information/documents as asked vide letter dated 05-12-2009 vide letter No. SAS-94-102/2009-FID(Q)-172 dated 10-02-2010 but again no response is received as yet.

07. In the light of test report of Federal Government Analyst Central Drug Laboratories Karachi the firm M/s Afrasco Lab Lahore

08. ***The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for violation of the section 23(1)(a)(vii), 23(1)(a)(x) 23(1)(b) 23(1)(c) and 27(3) of Drug Act 1976 for manufacturing and selling of unregistered, drugs against the following accused:***

1. M/s Afrasco Laboratories, Umar Khan Road,Manawan, Lahore through owner / proprietor

2. M/s chiltan Veterinary, Quarry Raod, Quetta through Tariq Mehmood S/o Nasarullah Kahn proprietor

3. Tariq Mehmood S/o Nasarullah Kahn (CNICNo. 54400-9743364-1) address r/o 8-18/4, Kansi Road, Teen Town, Quetta, proprietor chiltan Veterinary, Quarry Raod, Quetta

09. You are hereby served this show cause notice that why not the following actions shall be taken against you for stocking and selling of unregistered drugs and violation of the section 23(1)(a)(vii), 23(1)(a)(x) 23(1)(b) 23(1)(c) and 27(3) of Drug Act 1976. Your reply should reach within seven (07) days of receipt of this letter.

i.Prosceution in Court of competent jurisdiction.

ii.Any other action the Board may deem fit under the law.

10. The Board further decided to give you final opportunity of personal hearing in order to meet the ends of justice. Therefore, you are directed to appear in person or through authorized legal counsel on 17-10-2019 at 10:30AM in Committee room, 4th Floor, TF Complex, G9/4, Islamabad.

11. In case of failure to reply in writing and/or appear in person before the Board, an ex-parte decision under the law shall be taken on the merits of the case as per available record."

Proceedings & Decision of 272nd CLB held on 17th October, 2019:

12. Central Licensing Board (CLB) was apprised that the Show Cause & Personal Hearing notice were forwarded through Urgent Mail Service which were receive back un-delivered.

13. Keeping in view the above facts, the Board unanimously decided that following means at a time should be adopted for the service of show cause & personal hearing notice to the accused in order to meet the ends of justice and to avoid delays:

i. Through registered posts/courier service direct on address(s)
ii. Through area Federal Inspector of Drugs
iii. Through area Chief Drug Controller/Inspector
iv. By publishing show cause & personal hearing notice in the prominent Print Media in the reputable English & Urdu Newspapers

14. In compliance to the decision of the Board following means were adopted to ensure the delivery of show cause and personal hearing notice to the accused persons:

i. Through registered posts/courier service direct on their address(s) vide letter no. 13-185/2019-QC (272-CLB) dated 12.11.2019 which were received back un-delivered.
ii. Through area Federal Inspector of Drugs vide letter no. 13-185/2019-QC (272-CLB) dated

    12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.
iii. Through area Chief Drug Controller/Inspector, Balochistan @ Quetta vide letter no. 13-185/2019-QC (272-CLB) dated 12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.
iv. By publishing show cause & personal hearing notice in the three (03) Newspapers with Nationwide circulation on Wednesday, 25.12.2019.

Proceedings & Decision of 273rd CLB held on 15th January, 2020:

15. That none of the accused (neither in person nor by authorized pleader/attorney) appeared before the Board despite the publication of Show Cause Notice and personal hearing letter in three (03) leading newspaper i.e. Daily "The News" (combined), Daily Express (Combined), Daily Ausaf (Combined) on 25.12.2019 (Wednesday).

16. The Board deliberated the matter in depth, considered the facts of the case and perused the available record and decided as under:

A. That the following accused persons have committed offence by violating the provisions of ***section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c), and 27 (3) which are punishable under the provisions of Section 27 of the Drugs Act 1976:***

1. *M/s Afrasco Laboratories, Umar Khan Road,Manawan, Lahore through owner / proprietor*
2. *M/s Chiltan Veterinary, Quarry Raod, Quetta through Tariq Mehmood S/o Nasarullah Kahn proprietor*
3. *Tariq Mehmood S/o Nasarullah Khan (CNIC No. 54400-9743364-1) address r/o 8-18/4, Kansi Road, Teen Town, Quetta, proprietor chiltan Veterinary, Quarry Raod, Quetta*

B. The Federal Inspector of Drugs, DRAP, Quetta is directed to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.

Case No. 04: **MANUFACTURING AND SELLING OF UN-REGISTERED AND SPURIUOS DRUGS NAMELY SUN-C TABLETS BATCH NO. SP-101 MANUFACTUERD BY SIMILE NUTRITION, PVT LTD, LAHORE**

That Mr. Syed Abdul Saleem, FID, Quetta inspected the Business premises of M/s Malik & Sons, Dr. Bano Road,46 Ahmed Complex,Quetta on 10-11-2009, and took the sample of said product on Form-3 in the presence of Proprietor Zahoor Ahmed S/o Malik Abdul Ghani (CNIC No. 54400-8436784-5).

The said sample was sent to Federal Government Analyst for the purpose of test/analysis vide No.F.SAS-140-141/2009-FID(Q)-12 dated 11-11-2009.

The Government Analyst declared the sample as "**Spurious and Un-registerd**" vide test report No. R.SCD.480/2009 dated 11-12-2009.

That FID issued show cause notice to the M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahroe to explain their position, wherein the firm (M/s Simile Nutition)in their reply,claimed that Vitamin-C is drived from Rose hip and Embilica officinalis, Zinc is derived from wheat germ and calcium carbonate was purchased from bakery stuff vandors which is of food grade.

The case was properly processed forCenteral Licensing Board. The due process of law was completed and the accused were served with Show Cause Notice and given chance of personal hearing. The CLB in its 227th Meeting decided to prosecute the accused in the Drug Court of competent jurisdiction. Prosecution permission was communicated vide letter no. 03-40/2009-DDC(QC-I) dated 28.06.2011.

As the prosecution permission doesn't contain the names of the accused persons therefore the case is re-submitted for issuance of show cause notices to prosecute the following accused persons:

1. ***Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor*** **M/s Malik & Sons, Dr. Bano Road, Quetta**
2. Wasim Ahmed, M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahore
3. M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahore through its Chief executive/MD.

Proceedings and Decision of 271st meeting of Central Licensing Board

02. The request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause

notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for manufacturing and sale of spurious and unregistered drugs against the following accused

1. M/s Malik & Sons,Dr. Bano Road, Quetta through Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor
2. Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor M/s Malik & Sons,Dr. Bano Road, Quetta
3. Wasim Ahmed, M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahore
4. M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahore through its Chief executive/MD.

That why not following action shall not be taken against the above mentioned accused persons for the said violations:

i. Prosecution in the Court of competent jurisdiction
ii. Any other action the Board may deem fit under the law.

03. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of the Board.

04. In the light of the decision of the Board, Show cause and personal hearing notice was issued to accused vide letter No. 03-44/2019-QC(Pt-I)(271-CLB) dated 04-10-2019 contents of which are as under:

"Refer to the subject cited above, I am directed to communicate the decision of 271st Meeting of Central Licensing Board held on 12th September, 2019.

02. That Mr. Syed Abdul Saleem, FID, Quetta inspected the Business premises of M/s Malik & Sons, Dr. Bano Road,46 Ahmed Complex, Quetta on 10-11-2009, and took the sample of said product on Form-3 in the presence of Proprietor Zahoor Ahmed S/o Malik Abdul Ghani (CNIC No. 54400-8436784-5).

*03. That the said sample was sent to Federal Government Analyst for the purpose of test/analysis vide No.F.SAS-140-141/2009-FID(Q)-12 dated 11-11-2009 and the Government Analyst declared the sample as "**Spurious and Un-registerd**" vide test report No. R.SCD.480/2009 dated 11-12-2009.*

04. That FID issued show cause notice to the M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahroe to explain their position, wherein the firm (M/s Simile Nutition) in their reply,claimed that Vitamin-C is drived from Rose hip and Embilica officinalis, Zinc is derived from wheat germ and calcium carbonate was purchased from bakery stuff vandors which is of food grade.

05. That the case was properly processed forCenteral Licensing Board. The due process of law was completed and the accused were served with Show Cause Notice and given chance of personal hearing. The CLB in its 227th Meeting decided to prosecute the accused in the Drug Court of competent jurisdiction. Prosecution permission was communicated vide letter no. 03-40/2009-DDC(QC-I) dated 28.06.2011.

06. ***In the light of the request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @ Karachi vide letter No. 3-1/2-19-FID (Q) K dated 5th August, 2019 the case was placed before the Central licensing Board. The Board after deliberation decided to issue show cause notice under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for manufacturing and sale of spurious and unregistered drugs against the following accused:***

1. M/s Malik & Sons, Dr. Bano Road, Quetta through Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor

2. Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor M/s Malik & Sons, Dr. Bano Road, Quetta

3. Wasim Ahmed, M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahore

4. M/s Simile Nutition, 140 Jinnah Colony, Ichra-Lahore through its Chief executive/MD.

07. You are hereby served this show cause notice that why not the following actions shall be taken against you for stocking and selling of unregistered drugs. Your reply should reach within seven (07) days of receipt of this letter.

i.Prosecution in Court of competent jurisdiction.

ii.Any other action the Board may deem fit under the law.

08. The Board further decided to give you final opportunity of personal hearing in order to meet the ends of justice. Therefore, you are directed to appear in person or through authorized legal counsel on 17-10-2019 at 10:30AM in Committee room, 4th Floor, TF Complex, G9/4, Islamabad.

09. In case of failure to reply in writing and/or appear in person before the Board, an ex-parte decision under the law shall be taken on the merits of the case as per available record."

Proceedings & Decision of 272nd CLB held on 17th October, 2019:

05. Central Licensing Board (CLB) was apprised that the Show Cause & Personal Hearing notice were forwarded through Urgent Mail Service which were receive back un-delivered.

06. Keeping in view the above facts, the Board unanimously decided that following means at a time should be adopted for the service of show cause & personal hearing notice to the accused in order to meet the ends of justice and to avoid delays:

i. Through registered posts/courier service direct on address(s)
ii. Through area Federal Inspector of Drugs
iii. Through area Chief Drug Controller/Inspector
iv. By publishing show cause & personal hearing notice in the prominent Print Media in the reputable English & Urdu Newspapers

07. In compliance to the decision of the Board following means were adopted to ensure the delivery of show cause and personal hearing notice to the accused persons:

i. Through registered posts/courier service direct on their address(s) vide letter no. 13-185/2019-QC (272-CLB) dated 12.11.2019 which were received back un-delivered.
ii. Through area Federal Inspector of Drugs vide letter no. 13-185/2019-QC (272-CLB) dated

    12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.
iii. Through area Chief Drug Controller/Inspector, Balochistan @ Quetta vide letter no. 13-185/2019-QC (272-CLB) dated 12th November, 2019 and 2nd January, 2020 with request to ensure the delivery and acknowledge the receipt under intimation to this Division, till date no acknowledgement receipt is received in the Division.
iv. By publishing show cause & personal hearing notice in the three (03) Newspapers with Nationwide circulation on Wednesday, 25.12.2019.

Proceedings & Decision of 273rd CLB held on 15th January, 2020:

15. That none of the accused (neither in person nor by authorized pleader/attorney) appeared before the Board despite the publication of Show Cause Notice and personal hearing letter in

three (03) leading newspaper i.e. Daily "The News" (combined), Daily Express (Combined), Daily Ausaf (Combined) on 25.12.2019 (Wednesday).

16. The Board deliberated the matter in depth, considered the facts of the case and perused the available record and decided as under:

A. That the following accused persons have committed offence by violating the provisions of ***section 23 of the Drugs Act, 1976 which are punishable under the provisions of Section 27 of the Drugs Act 1976 as they are involved in manufacturing and selling of spurious and unregistered drugs:***

1. *M/s Malik & Sons, Dr. Bano Road, Quetta through Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor*
2. *Zahoor Ahmed S/o Malik Iqbal (CNIC NO: 54400-8436784-5) proprietor M/s Malik & Sons, Dr. Bano Road, Quetta*
3. *Wasim Ahmed, M/s Simile Nutrition, 140 Jinnah Colony, Ichra-Lahore*
4. *M/s Simile Nutrition, 140 Jinnah Colony, Ichra-Lahore through its Chief executive/MD.*

B. The Federal Inspector of Drugs, DRAP, Quetta is requested to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.

Case No. 05: MANUFACTURING AND SALE OF "COUNTERFEIT" MINTODINE TABLET BATCH NO. MD/202 MANUFACTURED BY M/S S.H PHARMACY HYDERABAD. (NO. F. 3-39/2009-DDC QC)

Proceeding and decision of 225th meeting of CLB dated 22-10-2010

Mr Syed Abdul Saleem, FID Quetta, during inspection of M/s Unique Traders Quetta on 10-11-2009 took the sample of Mintodine Tablets batch no. MD/202 manufactured by M.s S.H. Pharmacy Hyderabad, FID Quetta sent the sample to Federal Government Analyst the FGA vide his test report no. R. SCD. 475/2009 dated 10-12-2009 declared the sample as "Counterfeit Quality according to the Drug Act 1976 on the grounds that it resembles with the registered drug product Metodine Tablets of M/s Searle Pakistan Ltd Karachi

02. The firm M/s S.H Pharmacy Hyderabad in reply to the show cause notice of the FID/Licensing board challenged the report of the Central Drug Laboratory Karachi. But since the product was claimed to be the homeopathic origin therefore the firm was issued show cause notice for contravention of the provision of Section 23(1)(a)(ii) of the Drugs Act 1976. M//s S.H Pharmacy was called for personal hearing. No one appeared before the Board.

Decision of the Board

03. **"The Board after scrutiny of available record the Board decided to allow the FID Quetta to launch prosecution against the proprietor/ responsible persons of M/s S.H Pharmacy Hyderabad in Drug Court Quetta".**

04. The decision was communicated to the FID Quetta Vide letter No. 3-39/2009-DDC dated 01st January 2011 where in the FID was allowed to launch the Prosecution against the proprietor/responsible person of M/s S.H. Pharmacy Hyderabad.

05. Now the FID Quetta Mr. Sajjad Ahmed Abbassi requested to Division of QA&LT vide letter No. SAS-134-137/2009-FID (Q) dated 14th May 2019 wherein he stated that he prepared the challan of the case for submission in the Honorable Drugs Court of Balochistan Quetta but the prosecutor pointed out that there is no name of accused person is mentioned in the permission of Prosecution granted vide letter No. F.3-39/2009-DDC QC dated 01st January 2011. Furthermore the FID Quetta stated that the Syed Abdul Saleem the than FID Quetta also requested the Chairman, CLB for inclusion of name of accused person i.e M. Yousaf Khanani the proprietor of M/s S.H. Pharmacy Hyderabad vide his letter No. SAS-134-137/2009-FID (Q)-550 dated 12th January 2011 but no necessary corrigendum for inclusion of name of accused person in the permission of prosecution is not available in the case file, it may not be received as yet. Mr. Syed Abdul Saleem vide letter No. SAS-134-137/2009-FID(Q)-550 dated 12th January 2011 has requested to Chairman CLB that the names and complete addresses of accused persons

may kindly be provided through area FID Hyderabad at Karachi and same included the prosecution letter so that they can be prosecuted in the Drug Court Quetta.

06. Furthermore FID Quetta at Karachi requested in the light of point raised by the Government prosecutor and letter No. SAS-134-137/2009-FUID (Q)-550 dated 12th January 2011 that necessary corrigendum for inclusion of name of accused person M. Yousaf Khanani, proprietor S.H. Pharmacy Hyderabad. Which may kindly be issued at an earliest possible to enable the FID to file the case challan in the Honorable Drug Court Balochistan Quetta.

07. In the light of above explanation, as the case is belated for more than 08 years, it is therefore submitted that permission to amend the prosecution against the accused person as under may be allowed:-

1. **S.H. Pharmacy Hyderabad through M. Yousaf Khanani, proprietor**.

Because already the permission was conveyed as under:-

"proprietor/responsible persons of M/s S.H Pharmacy Hyderabad".

Which does not mentioned the name of the Proprietor.

08. Proceedings and Decision of 270th meeting of CLB:

The case was deliberated at length and CLB after evaluation of record decided as under:

1. **To issue show cause notice for prosecution in the court of competent jurisdiction and personal hearing to the following accused persons for the offences committed by them as stated herein below in para 2:**
   a. **M/s. S.H. Pharmacy Hyderabad through M. Yousaf Khanani, proprietor.**
   b. **M. Yousaf Khanani, proprietor M/s. S.H. Pharmacy Hyderabad.**
2. **The mentioned accused persons contravened the provision of Section 23(1)(a)(ii) of the Drugs Act 1976.**

09. In compliance to the decision of the Board show cause notice for prosecution was issued vide letter no. 03-33/2019-(QC)(270-CLB) dated 20.09.2019, no reply is received till to date.

Proceedings & Decision of 273rd CLB held on 15th January, 2020:

10. That none of the accused (neither in person nor by authorized pleader/attorney) appeared before the Board.

11. The Board deliberated the matter in depth, considered the facts of the case and perused the available record and decided as under:

A. That the following accused persons has violated ***the provision of Section 23(1)(a)(ii) of the Drugs Act 1976 which is punishable under the provisions of Section 27 of the Drugs Act 1976***:

1. **M/s. S.H. Pharmacy Hyderabad through M. Yousaf Khanani, proprietor.**
2. **M. Yousaf Khanani, proprietor M/s. S.H. Pharmacy Hyderabad..**

B. The Federal Inspector of Drugs, DRAP, Quetta is directed to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.

Case No. 01: Manufacturing and sale of substandard injection Hepaferon (Interferon) B. no. 85 by M/s Pharmedic lab, Lahore.

That following samples of Hepaferon Injection 3MIU (Interferon Alpha 2a), Batch No.80-87 manufactured by M/s Pharmedic Lab, Lahore were declared Sub-Standard from NCLB

S.No.	Name of Drug	B.No. and Temperature	Test Report No. & date	Results/ Remarks
01.	Hepaferon Injection 3 MIU (Interferon Alpha 2a)	80(+38 C)	FS-2013/17 14-10-2013	Substandard
02.	do	81(4.7 C)	FS-2013/13 14-10-2013	Substandard
03.	do	82(+38 C)	FS-2013/13 14-10-2013	Substandard
04.	do	82(4.7 C)	FS-2013/13 14-10-2013	Substandard
05.	do	83(+38 C)	FS-2013/13 14-10-2013	Substandard
06.	do	83(4.7 C)	FS-2013/13 14-10-2013	Substandard
07.	do	84(4.7 C)	FS-2013/13 14-10-2013	Substandard
08.	do	85(35C)	FS-2013/13 14-10-2013	Substandard
09.	do	87(+38 C)	FS-2013/13 14-10-2013	Substandard

On the request of Director Hepatitis Program KPK and the DRAP Islamabad issued direction to Fid Lahore to take samples from the stock of KPK Government lying with M/s Pharmedic Lahore custody quantity is 837894 vide letter No.4186/PHCP dated 13-01-2014

In continuation to DRAP letter direction Mr. Ajmal sohail area FID Lahore and Dr. Akbar Ali area ADC Lahore visited the premises of M/s Pharmedic Lahore an checked the stock of Hepaferon of the stock of KPK government and it was observed that all the stock of interferon of B.No. 81, 82, 88, 89, 90, 91, 92, 93, 94 and 95 was found kept at room temperature.

Proceeding and Decision of 291st meeting of Registration Board.

The case was presented before the Registration Board in its 291st meeting held on 04th September, 2019 and Board consider the following records:

- Case forwarded by the FID, DRAP, Peshawar.
- Inspection report of M/s Pharmedic laboratories by FID, DRAP, Lahore and ADC, DRAP, Lahore dated 20-03-2014.

- Test reports by the Federal Government Analyst, NCLB, Islamabad.
- Show cause notice issued to the M/s Pharmadic and accused persons.
- Reply to the show cause notice as well as correspondence by the firm.
- Personal hearing in different meetings of Registration Boards (286th , 289th)

Decision of Registration Board in its 291st Meeting:

The Board after thorough evaluation of above mentioned records, personal hearings, inspection reports and reply to the show cause notices unanimously decided as under:

i. **The firm failed to comply with the condition of registration prescribed under the law. At the time of inspection dated 20-03-2014 it was revealed that requisite storage facilities (2-8 ºC) were not sufficient to store the manufacture stocks at the recommended temperatures and humidity. The stocks were kept in the corridors at room temperature. This reveals manufacturing and storage conditions do not corresponds in terms of capacity.**

ii. **That the FID recorded the temperature at the time of sampling, which revealed the samples picked up at the controlled temperature (2-8 ºC) were also, declared of substandard quality.**

iii. **On the basis of above findings, the Board decided to cancel the registration of the product i.e. (Hepaferon Injection 3 MIU) Interferon Alpha 2a Registration No.029537 due to failure of the registration holder to meet the conditions for registration of drugs prescribed under the rules.**

iv. **The Board also decided to recommend the cancellation of the section to the central licensing board approved for manufacturing of biological products.**

Proceedings & Decision of 273rd CLB held on 15th January, 2020:

Central Licensing Board after detailed discussion and deliberations considering the facts of the case including recommendations of Registration Board decided to issue show cause notice and give personal hearing to M/s Pharmedic Laboratories (PVT) LTD, 16-Km, Multan Road, Lahore through its CEO/MD for cancellation of the section approved for manufacturing of biological products.

Case No. 02: <u>PERMISSION FOR PROSECUTION IN DRUG COURT- M/S EHSAN MEDICOS & GENERAL STORE, SURVEY NO.287, BUKHARI COLONY, MANGOPIR ROAD, ORANGI TOWN, KARACHI.</u>

The complete case forwarded by FID-IX, Karachi vide his letter No.SA-31-40/2018-FID-(K)-IX dated 03.04.2019 received on 10.04.2019. The Federal Inspector of Drugs, Karachi-IX along with Dr. Kirshan Das, AD, DRAP Karachi conducted the market survey at Orangi Town Medicine Market, Karachi. During visit at the premises of Ehsan Medicos & General Store, Survey No.287, Bukhari Colony, Mangopir Road, Orangi Town, Karachi undersigned recovered suspected/un-registered stocks of drugs and seized on prescribed Form-2 on 2lst May 2018 and samples also taken for the purpose of test/analysis on prescribed form -3 on dated 23rd May 2018 under the Drugs Act1976 and DRAP Act 20l2.

The detail of seized drugs are as under.

Sr. No.	Name of Drugs	Reg. No.	Batch No.	Mfg Date	Expiry Date	Purported to be manufactured by:
1.	Dona Capsules	Nil	850	02-2018	01-2021	M/s Faazzli Homeo Pharma, Karachi
2.	Bella Capsules	Nil	148	02-2018	01-2021	M/s Pure Homeo Pharma, Mir Pur Azad Kashmir.
3.	Relief-Extra Tablets	Nil	RR-625	Oct.2017	Sep. 2021	M/s Combitic Global Caplet (Pvt) Ltd. India
4.	Cofcal Plus Tablets	Nil	COC-714	09-2017	08-2021	M/s Combitic Global Caplet (Pvt) Ltd. India
5.	Grucid Capsules	Nil	GC-1128	Mar.2017	Feb.2021	M/s Combitic Global Caplet (Pvt) Ltd. India
6.	Pipadol-CF Tablets	Nil	PCF159	02-2017	01-2021	M/s Combitic Global Caplet (Pvt) Ltd. India
7.	Zinatac 150mg Tablets	Nil	N5203	01-2017	12-2018	M/s GlaxoSmithKline Pharmaceuticals, India
8.	Ceten Tablets	Nil	AT1709 6	06-2017	05-2020	M/s Arbro Pharmaceutical Ltd. India
9.	Vega-100 Tablets	Nil	SC-135	01-2017	06-2021	M/s Combitic Global India
10.	Diclocin Forte + Tablets	Nil	DTF-653	Jan 2017	Dec. 2020	-Do-

11.	Knight Rider Tester	Nil	Nil	Nil	Nil	Nil
12.	Moov Rapid Relief	Nil	Nil	Nil	Nil	Nil

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

Sr. No.	Name of Drugs	Reg. No.	Batch No.	Mfg Date	Expiry Date	Purported to be manufactured by:
1.	Dona Capsules	Nil	850	02-2018	01-2021	M/s Faazzli Homeo Pharma, Karachi
2.	Bella Capsules	Nil	148	02-2018	01-2021	M/s Pure Homeo Pharma, Mir Pur Azad Kashmir.
3.	Relief-Extra Tablets	Nil	RR-625	Oct.2017	Sep. 2021	M/s Combitic Global Caplet (Pvt) Ltd. India
4.	Cofcal + Tablets	Nil	COC-714	09-2017	08-2021	M/s Combitic Global Caplet (Pvt) Ltd. India
5.	Grucid Capsules	Nil	GC-1128	Mar.2017	Feb.2021	M/s Combitic Global Caplet (Pvt) Ltd. India
6.	Pipadol CF Tablets	Nil	PCF159	02-2017	01-2021	M/s Combitic Global Caplet (Pvt) Ltd. India
7.	Zinatac 150mg Tablets	Nil	N5203	01-2017	12-2018	M/s GlaxoSmithKline Pharmaceuticals, India
8.	Ceten Tablets	Nil	AT17096	06-2017	05-2020	M/s Arbro Pharmaceutical Ltd. India
9.	Vega-100 Tablets	Nil	SC-135	01-2017	06-2021	M/s Combitic Global India
10.	Diclocin Forte + Tablets	Nil	DTF-653	Jan 2017	Dec. 2020	-Do-

03. The FID informed that the M/s, Ehsan Medicos & General Store, Survey No.287, Bukhari Colony, Mangopir Road,Orangi Town,Karachi was asked to provide bill warranty under section 23(1)(i) of the drugs Act,l976 vide this office letter of even number dated 24th May,

2018. The FID vide his office letter of even number dated 23rd May 2018 requested Director (QA & LT), DRAP Islamabad for safe custody of unregistered drugs seized on prescribed Form-2.

04. The FID reported that the sealed samples of drugs was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for the purpose of test/analysis vide this office memorandum No.SA-31-40/2018-FID-(K)-IX dated 31st May-2018.

05. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the following sample/drugs as "Un-Registered Drug Product" under the Drugs Act 19:76 vide their test reports No.R.KQ.425/2018 to R.KQ.425/2018 dated-03rd August 201 8.

S.NO.	Name of Drug	Batch No.	Purported to be manufactured by	Test Report No. & Date	CDL Remarks
01	Dona Capsules	850	M/s Faazzli Homeo Pharma, Karachi	R.KQ. 425/2018 Date: 30.07.2018	Testing cannot be done as per current scope and available facilities in the Laboratory, Karachi
02	Bella Capsules	148	M/s Pure Homeo Pharma, Mir Pur Azad Kashmir.	R.KQ. 426/2018 Date: 30.07.2018	Testing cannot be done as per current scope and available facilities in the Laboratory, Karachi
03	Relief-Extra Tablets	RR-625	M/s Combitic Global Caplet (Pvt) Ltd. India	R.KQ. 427/2018 Date: 03.08.2018	Un-Registered
04	Cofcal Plus Tablets	COC-714	-Do-	R.KQ. 428/2018 Date: 03.08.2018	Un-Registered
05	Grucid Capsules	GC-1128	-Do-	R.KQ. 429/2018 Date: 03.08.2018	Un-Registered
06	Pipadol CF Tablets	PCF159	-Do-	R.KQ. 430/2018 Date: 03.08.2018	Un-Registered
07	Zinatac 150mg Tablets	N5203	M/s GlaxoSmithKline Pharmaceuticals, India	R.KQ. 431/2018 Date: 03.08.2018	Un-Registered
08	Ceten Tablets	AT17096	M/s Arbro Pharmaceutical Ltd. India	R.KQ. 432/2018 Date: 03.08.2018	Un-Registered
09	Vega-100	SC-135	M/s Combitic Global India	R.KQ. 433/2018 Date: 03.08.2018	Un-Registered

	Tablets				
10	Diclocin Forte + Tablets	DTF-653	-Do-	R.KQ. 434/2018 Date: 03.08.2018	Un-Registered

06. The FID reported that in the light of above test report of Federal Government Analyst, Central Drug Laboratory, Karachi M/s, Ehsan Medicos & General Store, Survey No.287, Bukhari Colony, Mangopir Road, Orangi Town, Karachi was asked to explain their position vide this office letter of even number dated 13th August 2018.

07. The Deputy Director (QC), DRAP, Islamabad vide their letter No.F.3-58/2018-QC(265-CLB) dated 04th September 2018 communicated the decision of 265th meeting of CLB regarding safe custody of seized unregistered drugs to Federal Inspector of Drugs till the finalization of the case.

05. Deputy Director (QC), DRAP, Islamabad vide their letter No.F.3-58/2018-QC(265-CLB) dated 04th September 2018 issued show cause notice to M/s Ehsan Medicos & General Store, Survey No.287, Bukhari Colony, Mangopir Road, Orangi Town, Karachi and Muhammad Hussain S/O Muhammad Rehman (Proprietor) H.NO. A-74, Pir Abad Colony 06, Manghopir Road, Orangi Town, Karachi to explain their position that why following action may not be taken against them.

1. Prosecute in the Drug Court.
2. Any Other action the Board may deem fit.

08. The FID informed that the M/s Ehsan Medicos & General Store, Survey No.287, Bukhari Colony, Mangopir Road, Orangi Town, Karachi submitted self-explanatory reply vide their letter No. Nil dated Nil directly to The Deputy Director, Quality Control, DRAP, Islamabad under intimation to this office, which is received in DRAP office Karachi on dated 14th September,2018

09. The FID stated that in the light of Federal Government, CDL, test reports M/s Ehsan Medicos & General Store, Survey No.287, Bukhari Colony, Mangopir Road,Orangi Town, Karachi and Muhammad Hussain S/O Muhammad Rehman (Proprietor) H.NO. A-74, Pir Abad Colony 06, Manghopir Road, OrangiTown, Karachi involved in manufacturing & selling of unregistered drugs and contravene Schedule-ll and III of DRAP Act 2012/ section 23(l)(a)(vii) of the Drugs Act 1976 and punishable under section 27 of the Drugs Act 1976 and rules framed thereunder.

10. The FID informed that in view of the above violations M/s Ehsan Medicos & General Store, Survey No.287, Bukhari Colony, Mangopir Road, Orangi Town, Karachi and Muhammad Hussain S/O Muhammad Rehman (Proprietor) H.NO. A-74, Pir Abad Colony 06, Manghopir Road, Orangi Town, Karachi may kindly be prosecuted in Drug Court Karachi.

11. Proceedings and Decision of 270th meeting of CLB:

The case was deliberated at length and CLB after evaluation of record decided as under:

1. **To issue show cause notice for prosecution in the court of competent jurisdiction and personal hearing to the following accused persons for the offences committed by them as stated herein below in para 2:**

   a. **M/s Ehsan Medicos & General Store, Survey No.287, Bukhari Colony, Mangopir Road,Orangi Town, Karachi through its proprietor, Muhammad Hussain S/O Muhammad Rehman (Proprietor) R/O H.NO. A-74, Pir Abad Colony 06, Manghopir Road, OrangiTown, Karachi**

   b. **Muhammad Hussain S/O Muhammad Rehman (Proprietor)R/O H.NO. A-74, Pir Abad Colony 06, Manghopir Road, OrangiTown, Karachi**

2. **The mentioned accused persons are involved in manufacturing & selling of unregistered drugs and contravene Schedule-II and III of DRAP Act 2012 / section 23(l)(a)(vii) of the Drugs Act 1976 and punishable under section 27 of the Drugs Act 1976 and rules framed there under.**

12. That in the light of decision of the Board, Show Cause Notice for prosecution was issued to the accused persons vide letter No. 03-33/2019-QC (270-CLB) dated 30.09.2019.

13. That the accused vide letter no **Nil** dated **Nil** submitted following reply to the Show Cause Notice:

"Reference NOS: - F. NO. 3 - 58/2018 - QC (265 - CLB) dated 04th September, 2018 and F.03-33/2019 (QC) (270 CLB) dated 30th September, 2019.

R/sir,

It is respectfully submitted that earlier to above reference show cause undersigned had replied to show cause notice, copy was also endorsed to your

kind office which were received back undelivered with the remarks "REFUSED" as an evidence undersigned hereby sending photo state copy remarks put on courier delivery envelop.

Sir, response to query is as under;

a. That Federal Inspector of Drugs IX did NOT complied mandatory provisions of section 103 Cr.P.C. as no local witness called to witness proceedings;

b. That copies of Test or Analysis certificate sent vide letter # SA.31 - 40/2018-FID- IX (K) dated 13th& 16th August, 2018 respectively are neither complete as details are elaborated nor issued on prescribe FORM, further certificate is NOT issued by the Federal Laboratory instead issued by Central Drug Testing Laboratory, Karachi as mandatory under the provision of section 14 of the Drugs Act, 1976, moreover above reference letter/notice dated 04th September, 2018 requires to submit reply within 07 days of receipt of the letter is the infringement of mandatory provision of sub section (4) of section 22 of the Drugs Act, 1976, in this connection the Honourable Special Court Drugs Sindh Karachi had observed and acquitted accused persons in case NO: 08 of 2010 State through Federal Inspector of Drugs Karachi v/s Muhammad Ali & others reported case (SBLR 2014 189);

c. That the Government Analyst, CDL Karachi had NOT applied the protocols of test or analysis in accordance with the "Drug (Specification) Rules 1987 e.g. instead USP 41, USP 40 applied; Reference reported case Inspector of Drugs v/s Opal Laboratories (Pvt) Ltd SBLR 2002 Trib 83(d);

d. That test or analysis certificate is NOT issued by the properly appointed Government Analyst as required under section 16 of the Drugs Act, 1976, appointment of the Government Analyst is devoid of authorization of class of drugs to be tested; reference reported case in this regard is NLR 1993 Cr.L.J v/s Muhammad Ashiq Mirza;

e. That it is relevant to mention here that in recent past the Honourable Drugs Court Lahore vide judgment # 187/16 case titled as Gulzar Ahmed v/s State in this instant drug case accused persons were acquitted, Honorable Court elaborated that Law enforcing agencies are under obligation to implement laws in letter and spirit and the above stated decision of the Honourable Court also

uphold by the Division Bench of Lahore in Criminal Revision NO: 24532/17 dated 11th May, 2017.

Sir, in future care will be observed, therefore it is requested that keeping in view facts available on record kindly withdraw SHOW CAUSE NOTICE issued in this behalf as there is no possibility of punishment/conviction during trial except loss of precious time of concerned authorities.

Hoping for favorable action please

FOR EHSAN MEDICOS & BROTHERS"

Proceedings & Decision of 273rd CLB held on 15th January, 2020:

14. ThatMuhammad Hussain (CNIC No. 42401-1893928-1) S/O Muhammad Rehman R/o H. No. A-174, Pir Abad Colony 01, Manghopir Road, Orangi Town, Karachi appeared before the Board and admitted all the allegations leveled against him as well as M/s Ehsan Medicos & General Store, Survey No.287, Bukhari Colony, Mangopir Road, Orangi Town, Karachi. He also submitted the admission of allegations as written statement before the Board. Furthermore, he informed the Board that at the time of raid they had applied for Drug Sales License (DSL) but it was not issued.

15. That the Board after detailed discussion and deliberations considering the facts of the case decided as under:

A. Granted permission for prosecution in the court of competent jurisdiction against the following accused persons for the offences committed by them as stated herein below in para B:

a. M/s Ehsan Medicos & General Store, Survey No.287, Bukhari Colony, Mangopir Road,Orangi Town, Karachi through its proprietor, Muhammad Hussain S/O Muhammad Rehman (Proprietor) R/O H.NO. A-74, Pir Abad Colony 06, Manghopir Road, OrangiTown, Karachi

b. Muhammad Hussain S/O Muhammad Rehman (Proprietor)R/O H.NO. A-74, Pir Abad Colony 06, Manghopir Road, OrangiTown, Karachi

B. The above mentioned accused persons are involved in manufacturing & selling of unregistered drugs and contravene Schedule-II and III of DRAP Act 2012 / section 23(l)(a)(vii) of the Drugs Act 1976 and punishable under section 27 of the

Drugs Act 1976 and rules framed there under.

C. The Federal Inspector of Drugs, DRAP, Karachi is directed to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof..

Case No. 03: **MANUFACTURE AND SALE OF SPURIOUS AND SUB-STANDARD DRUG RECOVERED FROM M/S NEHAL MEDICOS LANDHI NO. 06 GHOUSIA REHMANIA MASJID LANDHI KARACHI AND PERMISSION OF SHOW CAUSE FOR PROSECUTION THEREOF.**

01. That Dr. Mehwish Tanveer forwarded the case vide letter No. F.DMK/R-24-27/2019-FID-VII(K) 26/19 dated 11th October 2019.

02. That Dr. Muhammad Kashif the-then FID-VII DRAP Karachi inspected/visited the premises of M/s Nehal Medicos Landhi No. 06 Ghousia Rehmania Masjid Landhi Karachi on 16-01-2019 wherein following sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3 Details is as under:-

S.No.	Name of Drugs	Reg.No.	Batch No.	Mfg Date	Expiry Date	Purported to be Mfg by
1.	Galtran Tablet	061316	815	Jan - 2018	Jan-2020	M/s Gaba Pharmaceuticals
2.	Chlorpheniramine Syrup	009071	113	May - 2017	April-2019	M/s Gaba Pharmaceuticals

03. That FID, reported that the Sealed sample of above drug was sent to Federal Government Analyst Central Drug Laboratory Karachi for the purpose of test/analysis vide memorandum No.DMK/R-24 to 27/2019-FID-VII(K) dated 18th January 2019.

04. That FID, reported that Portion of sealed sample was sent to Chairman Central Licensing Board DRAP Islamabad vide this office letter of even number dated 18th January 2019.

05. That FID, reported that a portion of sealed sample sent to M/s Gaba Pharmaceutical Lab S/76, S.I.T.E Mauripur Road Karachi vide this office letter of even number dated 18th January 2019.

06. That FID, reported that M/s Nehal Medicos Landhi No.06 Ghousia Rehmania Masjid Landhi Karachi was asked to provide bill warranty vide this office letter No.DMT-24/18 to 27/2018-FID-VII(K) dated 17th January 2019

07. That FID, reported that the Federal Government Analyst Central Drugs Laboratory Karachi declared the above said sample as follows:

S. No.	Name of Drugs	Reg. No.	Batch No.	Mfg Date	Exp Date	Purported to be Mfg by	Declared by CDL	Report No.
1.	Galtran Tablet	061316	815	Jan - 2018	Jan-2020	M/s Gaba Pharmaceuticals	Spurious and Sub-standard	KQ.76/2019 Dated 06th March, 2019
2.	Chlorpheniramine Syrup	009071	113	May - 2017	April-2019	M/s Gaba Pharmaceuticals	Spurious	KQ.75/2019 Dated 18th March, 2019

A. COMPLETE CASE OF GALTRAN TABLET - BATCH NO. 815 CLAIMED TO BE MANUFACTURED BY M/S GABA PHARMACEUTICALS KARACHI.

"I have the honour to refer to the subject captioned above and to submit that Dr. Muhammad Kasliif the then Federal Inspector of Drugs-VI! DRAP Karachi inspected/visited the premises of M/s Nehal Medicos. Landhi No.06. Ghousia Rehmania Masjid, Landhi Karachi on 16-01-2019, wherein following sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3. (Annexure-A). Detail is as under:-

Serial No.	***Name Of Drugs***	***Reg-No.***	***Batch No.***	***Manfg: Date***	***Expiry Date***	***Purported to Be Manufactured***
01	*Galtran Tablet*	*061316*	*815*	*Jan.2018*	*J an,2020*	*M/s Gaba*

The sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory. Karachi for the purpose of test/analysis vide memorandum No.DMK/R-24 to 27/2019-F1D-V11(K) dated I8'h January 2017 (Annexure-B).

Portion of Sealed sample was sent to Chairman. Central Licensing Board. DRAP Islamabad vide this office letter of even number dated 18lh January 2019. (Annexure-C).

A portion of sealed sample sent to M/s Gaba Pharmaceuticals Lab: S/76. S.l.T.E. Mauripur Road. Karachi vide this office letter of even number dated 18th January 20l9.(Annexure-D)

M/s Nehal Medicos. Landhi No.06. Ghousia Rehmania Masjid. Landhi Karachi was asked to provide bill warranty vide this office letter No.DMT-24/18 to 27/20l8-F!D-VII(K) dated I7,h January 2OI9.(Annexure-E)

The Federal Government Analyst. Central Drugs Laboratory. Karachi declared the above said sample as "Spurious under section 3(z-b) (i) & "Sub-Standard"under section under section 3(z-z) of the Drugs Act 1976 vide their test report No.R.KQ.76/2019 dated 06th March 2019. (Annexure-F)

In the light of above test report of Federal Government Analyst, Central Drug Laboratory, Karachi an explanation letters of even number dated 11th March 2019 alongwith test report No.R.KQ.76/2019 dated 06th March 2019 was accordingly issued to M/s Gaba Pharmaceuticals Lab: S/76, S.l.T.E, Mauripur Road. Karachi & M/s Nehal Medicos. Landhi No.06. Ghousia Rehmania Masjid. Landhi Karachi for explaining their position in the matter of manufacturing/selling of above mentioned Spurious and Sub-Standard drug.(Annexure-G & H).

Letter dispatched to M/s Gaba Pharmaceuticals Lab: S/76. S.l.T.E. Mauripur Road. Karachi received back to this office undelivered with the remarks written on envelope "Refused to receive and firm is closed" (Annexure-1)

M/s Gaba Pharmaceuticals Lab: S/76. S.l.T.E, Mauripur Road, Karachi was asked again to explain their position vide this office letter of even number dated 04th April 2O19.(Annexure-J)

M/s Gaba Pharmaceuticals Lab: S/76. S.l.T.E. Mauripur Road. Karachi vide their letter No. nil dated 19"' April 2019 informed that they are not involved in manufacturing & selling of Galtran Tablet batch No.815 nor sale any drug to Nehal Medicos.(Annex-K)

M/s Nehal Medicos, Landhi No.06, Ghousia Rehmania Masjid. Landhi Karachi vide their letter dated 15,h March 2019 has / submitted that they have purchased the drug in question from supplier and have no bill warranty, supplier is not traceable.(Annexure-L)

M/s Nehal Medicos. Landhi No.06. Ghousia Rehmania Masjid. Landhi Karachi vide their letter dated 10th May 2019 has provided the bill warranty No.A.401 date 06-02-2019 of M/s Syed Medical Store Plot No.D-10, New 592 shop No.2, Kashmir Town Orangi Town, Karachi in connection with purchase of Galtran GABA Pharma Batch No.815 quantity 10 Tin 10 Tin.(Annexure-M & N)

Undersigned vide this office letter of even number dated I4th May 2019 informed M/s Nehal Medicos. Landhi No.06. Ghousia Rehmania Masjid, Landhi Karachi that bill warranty for Galtran provided by you is not acceptable as the date of bill warranty is 06,h February 2019 while the then FID took the sample from his premises on 16th January 2019.(Annexure-O)

M/s Nehal Medicos. Landhi No.06. Ghousia Rehmania Masjid. Landhi Karachi vide their letter dated 03rd June 2019 has provided the bill warranty No.A.0419 date 10th January 2019 of M/s Syed Medical Store Plot No.D-10. New 592 shop No.2,Kashmir Town Orangi Town. Karachi in connection with purchase of Galtran GABA Pharma Batch No.815 quantity 10 Tin.(Annexure-P & Q)

M/s Syed Medical Store Plot No.D-10, New 592 shop No.2,Kashmir Town Orangi Town. Karachi was asked to provide bill warranty from whom they purchased the drug in question vide this office letter No.DMK-24-27/19 FID-VII(K) dated 18lh June 2OI9.(Annexure-R)

Letter dispatched to M/s Syed Medical Store Plot No.D-10. New 592 shop No.2.Kashmir Town Orangi Town. Karachi received back to this office undelivered. (Annexure-S)

Undersigned vide this office letter of even number dated 26th July 2019 informed M/s Nehal Medicos, Landhi No.06. Ghousia Rehmania Masjid. Landhi Karachi that letter sent to M/s Syed Medical Store Plot No.D-10. New 592 shop No.2.Kashmir Town Orangi Town. Karachi received undelivered therefore he should provide correct bill warranty. (Annexure-T) No reply has been received so far from M/s Nehal Medical Store Landhi Karachi.

As per Federal Government Analyst. Central Drug Laboratory. Karachi test report No.R.KQ.76/2019 dated 06''' March 2019 following persons is involved in selling of Spurious & Substandard drug Galtran T ablet batch No.815 claimed to be manufactured by M/s Gaba Pharmaceuticals S/76. S.l.T.E Mauripur Road Karachi and violated the Section 23(1)(a)(i), 23(1)(a)(v), 23(1)(l) & 23(1)(f) of the Drugs Act 1976 and rules framed thereunder.

Names of responsible persons who involved in manufacturing & selling of Spurious & Substandard drug:-

1. M/s NIHAL MEDICAL STORE, Shop No.4. Ghousia Rehmania Masjid. Landhi No.6. Karachi.DSL(Annexure as U)

2. Mr.Nihaluddin Khan(Proprietor), M/s Nihal Medical Store, Shop No.4, Ghousia Rehmania Masjid. Landhi No.6. Karachi H.No. 1,Gali No.3 Area A-2. Landhi No.3. Karachi.copy of CNIC is (Annexure as V)

3. Mr.Abdul Majid Shaikh (Qualified Person). M/s Nihal Medical Store. Shop No.4. Ghousia Rehmania Masjid. Landhi No.6. Karachi."

B. <u>COMPLETE CASE OF CHLORPHENIRAMINE SYRUP - BATCH NO. 113 CLAIMED TO BE MANUFACTURED BY M/S GABA PHARMACEUTICALS KARACHI.</u>

"*I have the honor to refer to the subject captioned above and to submit the Dr. Muhammad Kashif the then FID-VII DRAP Karachi inspected/visited the premises of M/s Nehal Medicos Landhi No. 06 Ghousia Rehmania Masjid Landhi Karachi on 16-01-2019 wherein following sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3 Details is as under:-*

S.No.	***Name of Drugs***	***Reg.No.***	***Batch No.***	***Mfg Date***	***Expiry Date***	***Purported to be Mfg by***
1.	*Chlorpheniramine Syrup*	*009071*	*113*	*May - 2017*	*April-2019*	*M/s Gaba Pharmaceuticals*

The Sealed sample of above drug was sent to Federal Government Analyst Central Drug Laboratory Karachi for the purpose of test/analysis vide memorandum No.DMK/R-24 to 27/2019-FID-VII(K) dated 18th January 2017

Portion of sealed sample was sent to Chairman Central Licensing Board DRAP Islamabad vide this office letter of even number dated 18th January 2019.

A portion of sealed sample sent to M/s Gaba Pharmaceutical Lab S/76, S.I.T.E Mauripur Road Karachi vide this office letter of even number dated 18th January 2019.

M/s Nehal Medicos Landhi No.06 Ghousia Rehmania Masjid Landhi Karachi was asked to provide bill warranty vide this office letter No.DMT-24/18 to 27/2018-FID-VII(K) dated 17th January 2019

The Federal Government Analyst Central Drugs Laboratory Karachi declared the above said sample as spurious under section 3(z-b) (i) of the Drug Act 1976 vide their test report No.KQ75/2019 dated 18th March 2019

In the light of above test report of FGA CDL, Karachi an explanation letter No.F.DMK/R-25/2019-FID-VII (K) dated 27th March 2019 alongwith test report No.KQ.75/2019 dated 18th March 2019 was accordingly issued to M/s Gaba Pharmaceutical Lab S/76, S.I.T.E Mauripur Road Karachi & M/s Nehal Medicos Landhi No. 06 Ghousia Rehmania Masjid Landhi Karachi for explaining their position in the matter of manufacturing selling of above mentioned spurious drug

M/s Gaba Pharmaceutical Lab S/76, S.I.T.E Mauripur Road Karachi vide their letter No.Nil dated 08th April 2019 informed that they are not involved in manufacturing and selling of Chlorpheniramine Syrup B.No.113 nor sale any drug to Nehal Medicos.

M/s Nehal Medicos Landhi No.06 Ghousia Rehmania Masjid Landhi Karachi vide their letter dated 10th May 2019 has provided the bill warranty No.A.403 date 07-02-2019 of M/s Syed Medical Store plot No.D-10, New 592 shop No.2 Kashmir Town Orangi Karachi in connection with purchase of Chlorpheniramine Syrup Ba.No.113 quantity 1X60.

Undersigned vide this office letter of even number dated 28th May 2019 informed M/s Nehal Medicos Landhi No.06 Ghousia Rehmania Masjid Landhi Karachi that bill warranty for Chlorpheniramine Syrup B.No.113 provided by you is not acceptable as the date of bill warranty is 06th February 2019 while the then FID took the sample from his premises on 16th January 2019.

M/s Nehal Medicos Landhi No.06 Ghousia Rehmania Masjid Landhi Karachi vide their letter dated 03rd June 2019 has provided the bill warranty No.A.419 date 10th January 2019 of M/s Syed Medical Store Plot No.D-10, New 592 Shop No. 2 Kashmir Town Orangi Town Karachi in connection with purchase of Chlorpheniramine Syrup 450ml GABA Pharam B.No.113 quantity 1x60.

M/s Syed Medical Store Plot No. D-10 New 592 Shop No. 2 Kashmir Town Organi Karachi was asked to provide bill warranty from whom they purchased the drug in question vide this office letter No. DMK-24-27/19-FID VII (K) dated 18th June 2019

Letter dispatched to M/s Syed Medical Store plot No. D-10 New 592 shop No. 2 Kashmir Town Orangi Town Karachi received back to this office undelivered.

Undersigned vide this office letter of even number dated 26th July 2019 informed M/s Nehal Medicos Landhi No.06 Ghousia Rehmania Masjid Landhi Karachi that letter sent to M/s Syed Medical Store Plot No.2 Kashmir Town Orangi Town Karachi received undelivered therefore he should provide correct bill warranty No reply has been received so far from M/s Nehal Medical Store Landhi Karachi.

As per FGA, CDL, Karachi test report No.KQ75/2019 dated 18th March 2019 following person is involved in selling of spurious drug Chlorpheniramien syrup B.No.113 claimed to be manufactured by M/s Gaba Pharmaceutical S/76 S.I.T.E Mauripur Road Karachi and violated the Section 23(1)(a)(i) 23(1)(I) & 23(1)(f) of the Drug Act 1976 and rules framed thereunder.

Names of responsible persons who involved in manufacturing and selling of Spurious and substandard drug

1. *M/s Nihal Medical Store No. 4 Ghousia Rehmania Masjid Landhi No. 06 Karachi.*
2. *Mr. Nihaluddin Khan (Proprietor) M/s Nehal Medial Store Shop No. 4 Ghousia Rehmanida Masjid Landhi Karachi H.No.1 Gali No.3 Area A-2 Landhi No.3 Karachi copy of CNIC is annex.*
3. *Mr. Abdul Majid Shaikh (Qualified person) M/s Nihal Medical Store shop No. 4 Ghousia Rehmania Masjid Landhi No. 6 Karachi Copy of CNIC is annexed as.*"

Recommendations by FID, Karachi

In the light of above stated facts it is submitted that M/s Nihal Medical Store Shop No. 4 Ghousia Rehmania Masjid Landhi No.06 Karachi and above said owner and qualified person were found involved in selling of spurious Chlorpheniramine Syrup Batch No. 113 and Spurious and Sub-standard Galtran Tablet Batch no. 185 and contravened the provision of section

23(1)(a)(i), 23(1)(a)(v), 23(1)(a)(x), & 23(1)(f) punishable under section 27(1)(a) of the Drug Act 1976 read with schedule-II (A)(1)(a)(i), schedule-II (A)(1)(a)(v), & schedule II (A)(1)(f) punishable under schedule-III (1)(a) and schedule III(6) of the DRAP Act 2012 Therefore grant permission for prosecution in Drug Court.

Submitted to grant permission to issue Show Cause Notice and personal hearing for prosecution against following accused persons:

1. *M/s Nihal Medical Store No. 4 Ghousia Rehmania Masjid Landhi No. 06 Karachi.*
2. *Mr. Nihaluddin Khan (Proprietor) M/s Nehal Medial Store Shop No. 4 Ghousia Rehmanida Masjid Landhi Karachi H.No.1 Gali No.3 Area A-2 Landhi No.3 Karachi copy of CNIC is annex.*
3. *Mr. Abdul Majid Shaikh (Qualified person) M/s Nihal Medical Store shop No. 4 Ghousia Rehmania Masjid Landhi No. 6 Karachi Copy of CNIC is annexed as.*"

Proceedings & Decision of 273rd CLB held on 15th January, 2020:

Board after detailed discussion and deliberations considering the facts of the case decided to issue show cause notice for prosecution and give personal hearing in forthcoming meeting to the following accused persons for selling of spurious Chlorpheniramine Syrup Batch No. 113 and Spurious & Sub-standard Galtran Tablet Batch no. 185 and contravening the section 23(1)(a)(i), 23(1)(a)(v), 23(1)(a)(x), & 23(1)(f) punishable under section 27(1)(a) of the Drug Act 1976 read with schedule-II (A)(1)(a)(i), schedule-II (A)(1)(a)(v), schedule-II (A)(1)(a)(x), & schedule II (A)(1)(f) punishable under schedule-III (1)(a) and schedule III(6) of the DRAP Act 2012:

1. M/s Nihal Medical Store No. 4 Ghousia Rehmania Masjid Landhi No. 06 Karachi.
2. Mr. Nihaluddin Khan (Proprietor) M/s Nehal Medial Store Shop No. 4 Ghousia Rehmanida Masjid Landhi Karachi H.No.1 Gali No.3 Area A-2 Landhi No.3 Karachi.
3. Mr. Abdul Majid Shaikh (Qualified person) M/s Nihal Medical Store shop No. 4 Ghousia Rehmania Masjid Landhi No. 6 Karachi.

Case No. 05 **SEIZURE OF DRUGS UNDER DRAP ACT, 2012. PERMISSION FOR SAFE CUSTODY OF SEIZED DRUGS – M/S WALTON PHARMACY, SHOP NO. 12, SHAQUIT PLAZA, I-10 MARKAZ, ISLAMABAD.**

That FID-IV, Islamabad vide reference No.F.4-1/2018-FID-IV (ISD) dated 22nd Nov, 2019 received on 10-12-2019 addressed to The Chairman, Central Licensing Board, DRAP, Islamabad informed that she inspected the premises of M/s Walton Pharmacy, Shop No. 12, Shaquit Plaza, I-10 Markaz, Islamabad on 06-11-2019, wherein following batch of unregistered drug Viagra 100mg Sildenafil citrate film coated tablets having different manufactured & expiry date exhibited/ offered for sale, recovered from M/s Walton Pharmacy, Shop No. 12, Shaquit Plaza, I-10 Markaz, Islamabad, which of some stocks was stored in nearby basement of un-licensed premises shop no. 14, owned by owner/proprietor of M/s Walton Pharmacy, Shop No. 12, Shaquit Plaza, I-10 Markaz, Islamabad as per his claim but owner ship document for same could not be provided by owner/proprietor at the time of inspection. The stocks recover were seized under section 18(1)(f) of the Drugs Act, 1976 and same was sampled for test analysis under section 18(1)(c) of Drugs Act, 1976 and unlicensed premises from where stocks was being delivered i.e. basement of un-licensed premises shop no. 14 was sealed under section 18(1)(h) of Drugs Act, 1976 and seized key was handed over to the owner/proprietor/qualified person of M/s Walton Pharmacy, Shop No. 12, Shaquit Plaza, I-10 Markaz, Islamabad in the presence of witnesses. The detail of unregistered drug seized is mentioned below:-

S.#	Name of Drug	Batch No. & Quanitity	Manufacturer	Reason for Seizure
1	Viagra 100mg Sildenafil Citrate film coated tablets Reg. No. Nil Mfg. Date: Oct-17 Exp. Date: Oct-23	MALL 19990544AG (6 X 9 Packs)	M/s Pfizer Brooklyn, Packed by M/s Pfizer, Australia, Under Authority Pfizer, USA	Un-registered
2	Viagra 100mg Sildenafil Citrate film coated tablets Reg. No. Nil Mfg. Date: Feb-18 Exp. Date: Feb-22	MALL 19990544AG (6 X 3 Packs)	M/s Pfizer Brooklyn, Packed by M/s Pfizer, Australia, Under Authority Pfizer, USA	Un-registered

02. The FID requested for the grant of permission for keeping the above mentioned seized material in safe custody till the decision of the case and extension of sealing of un-licensed

premises till decision of the case, under clause (b) of heading (5) of procedure for inspector in of Schedule-V of DRAP Act, 2012 read with Section 19(5)(b) of the Drugs Act, 1976.

03. In the light of request of FID, Islamabad the permission to continue the safe custody of seized material was granted till decision of the case vide letter no. 13-200/2019-QC dated 30.12.2019 after due approval from Director QA&LT being authorized by CLB in its 237th meeting held on 01-10-2014.

04. Meanwhile, request for "De-sealing of Store of Walton Pharmacy" is received in this Division from accused Fakhir Raza (B.Pham, BZU) [CNIC No.: 32304-1650108-1, Cell No.: 0300-6862448] vide letter no. Nil dated December 18, 2019. The contents of request for De-sealing are reproduced as under:

> *"Distinguished Sir,*
>
> *I hope this humble request letter find you in good health. With utmost regard it is stated that* ***Store of Walton Pharmacy*** *located at* ***Basement number 14, Shoukat Plaza, I-10/3 Islamabad",*** *has been sealed by Area Drug Inspector(FID) on November 6th, 2019. Sir as my store has been sealed, it is going to cost me unbearable financial losses as there are different products which are going to expire very soon.*
>
> *I humbly pray to your office that kindly de-seals the store of Walton Pharmacy so that we may continue our operations in a smooth manner and serve our local community in optimal capacity. I further request your esteemed office to serve us from financial losses, as delay in de-sealing will smoother us economically. We will really appreciate your cooperation in this regard."*

Proceedings & Decision of 273rd CLB held on 15th January, 2020:

Board after detailed discussion and deliberations considering the facts of the case including the request of area FID-IV, Islamabad for extension in the sealing period of unlicensed Store of Walton Pharmacy located at Basement number 14, Shoukat Plaza, I-10/3 Islamabad decided to extend the sealing period of aforesaid sealed unlicensed premises till decision of the case and regretted the request of De-sealing of Store of Walton Pharmacy received from the accused Fakhir Raza (proprietor and qualified person) of M/s Walton Pharmacy, Shop No. 12, Shaquit Plaza, I-10 Markaz, Islamabad.

Board further directed the area FID-IV, Islamabad, to complete the investigation of the case as the earliest after fulfilling all legal/codal formalities and submit complete case for consideration of the Board.

Case No. 06:

STOCKING FOR SALE & SELLING OF UN-REGISTERED DRUGS – M/S AL-TAWAKAL MEDICOS, SHOP NO.B-2, TAJ COMPLEX, M. A. JINNAH ROAD, KARACHI.

That FID-V, Karachi vide reference No.SAA-07-15/2018-FID-V(K) dated 26th April, 2019 received on 08-05-2019.

02. The FID informed that he along with Mr. Abdul Rasool Shaikh, FID(DRAP), Karachi, inspected the premises of M/s Al-Tawakal Medicos, Shop No.B-2, Taj Complex, M. A. Jinnah Road, Karachi on 28.01.2019 at around 02:00 pm in a routine market survey. During visit 31 different un-registered drugs were found available in a carton placed under cash counter of said premises. The FID `took the following three samples from said un-registered drugs on form-3 for the purpose of test analysis and remaining stocks of all un-registered drugs were seized on Form-2under Section 19(f) of the Drugs Act, 1976

Form-3							
S.#	**Name of Drug**	**Reg. No.**	**Batch No.**	**Quantity**	**Mfg. Date**	**Expiry Date**	**Manufacturer by**
1	Tab Viagra 50mg	Nil	Nil	6 x2	Nil	Nil	Pfizer Brooklyn, USA
2	Tab Erectal Gold	Nil	1325502	1x10x3	10/17	09/20	WBB Tech Co. Ltd, USA
3	Tab Penegra 100mg	Nil	G70534	1x4x2	Nil	Nil	Cadila Healthcare, India

Sr. No.	**NAME OF DRUG**	**BATCH No**	**QUANITY**	**MFG DATE**	**EXP DATE**	**MANUFACTURED BY**
1.	Novomix 30 Plexpen 100U/ml	GT 6B642	3ml X 3	09/2017	08/2019	M/s Novo Nardisk France
2.	Novomix 30 Plexpen 100U/ml	GT 6C770	3ml X1X 5	11/2017	10/2019	M/s Novo Nardisk France
3.	Tabs. Centrum Silver	T 93992	125 Tabs X1X 4	NIL	12/2019	Made in Canada
4.	Tabs. Centrum Silver	W 11011	125 Tabs X 1X1	NIL	12/2019	Made in Canada
5.	Tabs. Viagra 50mg	MAL19990545AG	6 Tabs X1X9	07/2016	07/2020	M/s Pfizer USA
6.	Questran 4g	1994	12 Bustine X 1	NIL	06/2020	M/s Bristol Myers Squib Roma
7.	Questran 4g	1985	12 Bustine X 1	NIL	06/2020	M/s Bristol Myers Squib Roma

8.	Questran 4g	1979	12 Bustine X 2	NIL	06/2020	M/s Bristol Myers Squib Roma
9.	Tabs. YTiG	T0606	2 Tabs X 2	12/2018	12/2020	M/s Trends Pharmaceuticals (Pvt) Ltd; Lahore
10.	Tabs. Caltrate	PF18-008	60 Tabs X1X 5	NIL	12/2019	Marketed by M/s Pfizer USA
11.	Tabs. Centrum Silver	T93988	80 Tabs X 1	NIL	10/2019	Made in Canada
12.	Tabs. Centrum Adult	W94625	130 Tabs X 1	NIL	12/2019	Marketed by M/s Pfizer USA
13.	Caps. Epanutin 100mg	171797103	70 Caps	NIL	01/2020	M/s Pfizer Instanbul
14.	Tabs. Sinemet Plus	W170190	20 Caps	NIL	02/2022	M/s Merck Shop dohm, Haosten
15.	Tabs. Imuran 50mg	810943	100 Tabs X1X 3	NIL	06/2023	M/s Aspen Pharma, Ireland
16.	Tabs. Imuran 50mg	611160	75 Tabs.	NIL	09/2021	M/s Aspen Pharma, Ireland
17.	Inj. Ipraton 500mcg/2ml	G72200831	20 Inj X 2	NIL	08/2020	Made in Turkey
18.	Tabs. Penegra	Different batches	4 Tabs X 28	02/2017	08/2020	M/s Cadila Healthcare India
19.	Tabs. Metrex	18001	100 Tabs	20.03.2018	19.03.2021	M/s Daehan New Pharma Korea
20.	Tabs. Sorafenib 200mg	6J80745	30 Tabs X 1	6/2018	05/2020	M/s Cipla Ltd; India
21.	Tabs. Sorafenib 200mg	6J80967	30 Tabs X 1	9/2018	08/2020	M/s Cipla Ltd; India
22.	Tabs. Sorafenib 200mg	6J80746	30 Tabs X 1	6/2018	05/2020	M/s Cipla Ltd; India
23.	Caps. Temosido 100	6J70925	5 Caps X1x 3	10/2017	09/2019	M/s Cipla Ltd; India
24.	Caps. Kreon 10,000IU	55625	100 Caps X1x2	NIL	09/2019	M/s Abbott Labs, Almanya
25.	Tabs. Marevan 5mg	A526846	100 Tabs X 2	03/2018	09/2020	M/s GSK
26.	Tabs. Lioresal 10mg	KD 527	100 Tabs	NIL	11/2020	M/s Novartis Istanbul
27.	Tabs. PTU 100	1171003	1000 Tabs	19/02/2018	19/02/2021	M/s T. O. Chemical Bankok

28.	Tabs, Furotin 100mg	1805422	30 Tabs X 2	Nil	Nil	M/s IASIS Pharma, Greece
29.	Tabs. Florinef 100mcg	7F5332	100 Tabs	05/2017	05/2020	M/s Aspen Pharma Austria
30.	Inj. Konakion 10mg/ml	F3261F03	5 Amps X 1	05/2017	05/2020	M/s F. Hoffman Roche France
31.	Tabs. Endoxan	G803069	100 Tabs	05/2018	04/2020	M/s Baxler, Germany

03. The FID informed that the Division of QA&LT was intimated regarding the seizure of drugs with request of permission for safe custody of the seized stock vide this office letter dated 29-01-2019. The same was received on 13-02-2019 in concerned section.

04. The FID further informed that the sample of the drugs (suspected to have sildenafril citrate) were sent to the Central Drugs Laboratory, Karachi on prescribed form-4 dated 29.01-2019. The Show case notice was served by FID to M/s Al-Tawakal Medicos vide letter dated 29-01-2019 for stocking/sale of un-registered drugs. The M/s Al Tawakal medicos Taj Complex Karachi submitted its reply dated 04-02-2019 which was incomplete and un-satisfactory. The FID informed that *M*/s Al Tawakal Medicos Karachi was asked to appear in person in the office of FID on 15th February 2019 under Section 18(1)(g) of the Drugs Act 1976 to explain its position with clear/satisfactory submission of their reply.

05. The CDL Karachi vide test report No. RKQ 119/2019 dated 04-03-2019 issued the report for tablet Erectal Gold batch no. 1325502 in which the suspected ingredient "sildenafil citrate" was not identified.

06. The FID informed that the Division of QA&LT vide letter No. F13-44/2019-QC dated 28-02-2019, received to FID on 05th March 2019 granted the permission for safe custody of the seized. The reminder letter of dated 11-03-2019 was sent to M/s Al-Tawakal Medicos Karachi to appear in person in the FID office to explain its position and submission of satisfactory reply.

07. The CDL Karachi vide report no. **RKQ 120/2019 dated 04-03-2019 declared the sample of Tab penegra batch no. G705345 as unregistered drug product**. The M/s Al-Tawakal Medicos Karachi was asked to explain its position and submit the bill warranty purchase record or any document in the defense for stocking sake of unregistered drug vide office letter No. SAA-07-12/2019 FID V K dated 12-03-2019.

08. **The CDL vide report no. RKQ118/2019 dated 01-04-2019 declared the sample of Tab .Viegra 50mg batch no MAL 199905 as unregistered drug product**. M/s Al Tawakal

Medicos Karachi was asked again to explain its position and submit the bill/warranty purchase record or any document in their defense for stocking/sale of unregistered drugs vide letter no. SAA-07-12/2019-FID-V K dated 09-04-2019.

09. The FID further informed that Mr. Naveed Ahmed S/o Abdul Hameed Proprietor of M/s Al-Tawakal Medicos Karachi appeared in person in the office of FID on dated 22-04-2019 along with his submission vide letter dated 15th April 2019 along with explanation about the proprietorship of the shop with supporting copy of agreement.

10. The FID submitted regarding the submissions/stated facts M/s Al-Tawakal Medicos Karachi is involved in stocking/sale of un-registered drugs which is violation of Section 23(1)(a) (vii) punishable under section 27 (1) (a) of the Drug Act 1976 and Schedule-II A. (1) (a)(vii) punishable under Schedule-III (1) (a) of the DRAP Act 2012

11. The FID submitted the names of accused persons of the firm:-

a. M/s Al-Tawakal Medicos Shop No.B-2 Taj Complex M.A Jinnah Road Karachi.
b. Mr. Naveed Ahmed S/o Abdul Hameed (Propretor of M/s Al-Tawakal Medicos).

10. The FID requested on the facts personal appearance and submission of replies by M/s Al-Tawakal Medicos Taj Complex Karachi the permission for prosecution of the accused persons may kindly be granted to initiate the trial before the Drug Court Karachi.

11. Proceedings and Decision of 270th meeting of CLB:

The case was deliberated at length and CLB after evaluation of record decided as under:

1. **To issue show cause notice for prosecution in the court of competent jurisdiction and personal hearing to the following accused persons for the offences committed by them as stated herein below in para 2:**
   a. **M/s Al-Tawakal Medicos Shop No.B-2 Taj Complex M.A Jinnah Road Karachi.**
   b. **Mr. Naveed Ahmed S/o Abdul Hameed (Proprietor of M/s Al-Tawakal Medicos).**
2. **The mentioned accused persons are involved in stocking / sale of un-registered drugs which is violation of Section 23(1)(a) (vii) punishable under section 27 (1) (a) of the Drug Act 1976 and Schedule-II A. (1) (a)(vii) punishable under Schedule-III (1) (a) of the DRAP Act 2012.**

12. In the light of decision of Board, show cause notice was issued to the accused persons vide

No. F. 03-33/2019-(QC) (270-CLB) dated 02-01-2020.

Proceedings and decision of 273rd Meeting held on 15th January, 2020

No person appeared before the Board. The Board after considering the facts decided to defer the case for giving final opportunity to the accused to plead their case.

Case No 07: MANUFACTURE AND SALE OF UN-REGISTERED VITAMIN-K CAPSULES (FOR ANIMALS USE ONLY) B.NO.1021 MFG BY J.R. NUTRITION DIVISION KARACHI

That Mr. Abdul Rasool Shiekh, FID Karachi forwarded the complete case vide letter No. F.ARS-21/2018-FID-VI(K) dated 29th March 2019. The FID Karachi inspected M/s Samara International Shop No. A-3 Cosmo Plaza Block 16 FB area Karachi on 19-03-2018 and collected the below mentioned sample of drug for test/analysis purpose on prescribed Form-3

Name of Drug	Reg. No.	Batch No.	Mfg Date	Exp Date	Claimed to be Mfg by
Cap. Vitamin K (F.No.Nil)	Nil	1021	09-17	09-19	M/s J.R Nutration Division Karachi

02. The FID Karachi informed that the sealed sample of the above drug was sent to the CDL Karachi for test analysis purpose vide this office memorandum No. ARS-21-24/2018-FID-VI (K) dated 19-03-2018. The M/s Samara International Shop No. A-3, Cosmo Plaza, Block-16, FB Area Karachi was directed to provide bill warranty/invoice as required under Section 23(1)(i) of the Drug Act 1976 vide this office letter No. F.DK-21-24/2018-FID-VI(K) dated 26-03-2018 and 27-04-2018. M/s Samara International Karachi vide letter dated 11th May 2018 has produced the bill No. 76 dated 22-02-2017 of M/s Munfarid Marketing Services B-61, Block –I North Nazimabad Karachi as a proof of their purchase, the Munfarid Marketing Services Karachi vide their letter dated 21st May 2018 had informed that they have not supplied the capsule Vitamin-K B.No.1021 to Samara Vet Complex FB area Karachi and did not verified the said warranty.

03. The FID further mentioned that M/s Samara International Karachi was again directed to provide genuine bill warranty of aforesaid drug and explain the position for submission of fake warranty vide this office letter No. F.DK-21-24/2018-FID-VI(K) dated 22-05-2018.

04. The FGA, CDL, Karachi vide test report No.R.K.Q171/2018 dated 16th May 2018 declared the sample as un-registered Drug product as Vitamin-K was identified which is violation of section 23(1)(a)(vii) of the Drug Act 1976.

05. In light of above test report of FGA, CDL Karachi an explanation letter of even numbers dated 29th May 2018 and reminder dated 13th June 2018 were accordingly issued to M/s Samara International Karachi for explaining their position in the matter for importing stocking and selling of un-registered drug product. M/s Samara International Karachi submitted their reply vide letter dated 29th June 2018, in which they informed that they have purchased capsule

vitamin-K from M/ Munfarid marketing Services Karachi who had issued the sale invoice on ordinary sale receipt.

PERMISSION FOR LODGING THE PROSECUTION

06. The FID Karachi stated that the M/s samara International A-3, Cosmos Plaza, block-16, FB area Karachi has violated Section 23(1)(a)(vii), 23(1)(i) and 23(1)(h) of Drug Act 1976, which is punishable under Section 27 of Drug act 1976 therefore it is recommended that permission for prosecution Drug Court of below mentioned persons may kindly be granted for importing, stocking and selling of un-registered drug product and submission of fake/false bill warranty:-

1. ***M/s Samara International, Shop No. A-3, Cosmos Plaza, Block-16, FB Area, Karachi (Drug Sale License No. 0207)***
2. ***Muhammad Aslam son of Noor Elahi, proprietor (CNIC.No.42101-8985214-3), H No. R-898 Block-16 F.B. Area Karachi.***
3. ***Muhammad Shahjahan (CNIC.No.42101.4955643-3) Shop No. A-3, Cosmos Plaza, Block-16, FB Area, Karachi.***

07. In order to complete due process of law and the Director, QA&LT, DRAP, Islamabad being authorized by the Central Licensing Board in its 237th Meeting held on 01.10.2014 granted permission to issue show cause notice to the accused persons regarding contravention mentioned in para 6 above. In the light of permission granted a **show cause notice** was issued to the accused vide letter **F. No.04-60/2018-(QC)** dated 10th May, 2019.

08. That M/s Samara International, Shop No. A-3, Cosmos Plaza, Block-16, FB Area, Karachi (Drug Sale License No. 0207) submitted reply to the show cause notice vide their letter no. **Nil** dated **18.05.2019,** reproduced as under:

> "Please refer to your letter No. F.No.04-60.2018-QC dated 10th May, 2019 on the above noted subject and in this regard we like to submit the following facts as follows:
> We have doing our business of Sale of Vet. Drugs since last more than 20 years and ever complied with all rules and regulations and have a clean record in all matters.
> Since inception we have purchased the stock of Drugs along with other from Dr. Muneer *of M/s Munfarid Marketing. During March, 2018 your Drug Inspector collect the sample of Cap. Vitamin-K from our Stock which was purchased by us from Dr. Muneer of M.s Munfarid Marketing who have issue the Sale Invoice on an ordinary Sale Receipt.*
> *At your demand we have submitted the said Sale Receipt alongwith other requisite documents. Your office reject the said Sale Receipt and had requested for a proper printed Sale Receipt. At the situation when we contacted to Dr. Muneer of M/s Munfarid Marketing he not only denied to issue the proper Sale Receipt but also extend threats if we submit or show his name from whom the Medicine is question was purchased.*
> *However, we hereby once again reiterated that the Medicine in question was Purchased from Dr. Muneer of M/s Munfarid Marketing and now we extend our full cooperation to your Department for any inquiry/investigation against Dr. Muneer of M/s Munfarid Marketing.*

Keeping in view of all above and in order to enable me/us clarify the matter I have requested to kindly allow a personal hearing before Central Licensing Board for which may kindly intimate a suitable date and time in order to enable me clarify the matter in person.

Further requested to please withdraw your Show Cause Notice referred above and oblige."

09. **It is submitted that the letter of Personal hearing was served to the accused vide letter F.No. 03-44/2019-QC dated 06th September 2019 to call in the accused for personal hearing before the CLB**.

Proceeding & Decision of the 271th Meeting:

10. Neither accused persons nor any person on their behalf appeared before the Board. The Board deliberated the matter and decided to give final opportunity of personal hearing to all the accused persons.

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

11. That the Muhammad Shahjahan (CNIC.No.42101.4955643-3) Shop No. A-3, Cosmos Plaza, Block-16, FB Area, Karachiappeared before the Board and admitted all the allegations leveled against him and co-accused.

12. That the Board after detailed discussion and deliberations considering the facts of the case decided as under:

A. Grant permission for prosecution in the court of competent jurisdiction to the following accused persons for the offences committed by them as stated herein below in para B:

a. M/s Samara International, Shop No. A-3, Cosmos Plaza, Block-16, FB Area, Karachi (Drug Sale License No. 0207)

b. Muhammad Aslam son of Noor Elahi, proprietor (CNIC.No.42101-8985214-3), H No. R-898 Block-16 F.B. Area Karachi.

c. Muhammad Shahjahan (CNIC.No.42101.4955643-3) Shop No. A-3, Cosmos Plaza, Block-16, FB Area, Karachi.

B. The above mentioned accused persons have violated Section 23(1)(a)(vii), 23(1)(i) and 23(1)(h) of Drug Act 1976, which is punishable under Section 27 of Drug act 1976 read with relevant provisions of the DRAP Act, 2012.

C. The Federal Inspector of Drugs, DRAP, Karachi is directed to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.

Case No. 08-A: **MANUFACTURE AND SALE OF UN-REGSTERED DRUGS (M/s. SIMAXX CHEMICAL, HAYATABAD, PESHAWAR).**

Brief facts of the case are as under;

02. FID II, Peshawar Lahore vide letter No.F.12-05/2019-Simaxx-DRAP(P)-FID-II-1672 dated 29-04-2019 on subject cited above informed about inspection of M/s. Simaxx Chemical, Plot No. 188-A, Industrial Estate Hayatabad Jamrud road, Peshawar conducted on 25-04-2019 in response to a complaint by QA&LT Division, Islamabad's complaint regarding manufacture and sale of un-registered drugs. The mentioned letter is reproduced as under;

"The undersigned alongwith Mr. Muhammad Arif Choudry, Federal Inspector of Drugs-II Peshawar conducted inspection of M/s Simaxx Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Jamrud Road, Peshawar on 25-04-2019 regarding a complaint forwarded by Quality Assurance and Laboratory Testing Division of DRAP's Islamabad regarding manufacture and sale of un-registered drugs.

2. Upon investigation they were found to be involved in the manufacturing and sale of following un-registered products for which they were not authorized as they have Drug Manufacturing License by way of repacking only.

S.No	*Name of Product*	*Batch No.*	*Manufacturing Date*	*Expiry Date*	*Claimed to be manufactured by*
01	*Siwax (Soda Glycerin) Ear Drops*	*001*	*01-02-2017*	*30-01-2020*	*M/s Simaxx Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Jamrud Road, Peshawar*
02	*Hydrogen Peroxide Solution 60m1*	*001*	*11-18 .*	*10-21*	*-do-*
03	*Iodine Povidone Solution 10% W/v*	*Unknown*	*Unknown*	*Unknown*	*-do-*
04	*Calamine Lotion 120m1*	*001*	*07-18*	*06-21*	*-do-*
05	*Siwax (Soda Glycerin) Ear Drops*	*002*	*01-02-2018*	*30-01-2021*	*-do-*

3. At the time of inspection Glycerin Pure 125 gm having Batch. No. 002, Manufacturing Date 09.-19, Expiry Date 08-23 printed on label was under process of re-packing, however both of their approved qualified persons i.e Production Incharge and Quality Control Incharge were absent. No proper record e.g Batch Manufacturing Record,
Stock Registers etc were present at premises at the time of inspection.

4. Two unit cartons oof SiWax eardrops 15ml batch No. 002 Mfg. Date 01-02-2018, Exp. Date 30-01-2021 and an empty drum of Povidone Iodine were recovered and seized on Form-2 under section 18(1)(f) of the Drugs Act, 1976. The Re-Packing block of factory was sealed under section 18(1)(h) of the Drug Act, 1976.

5. The report is forwarded for information and further necessary actions, please."

03. Alongwith the report, area FID, Peshawar submitted the reply of firm and copy of Form-2.

04. Permission to continue the custody of seized stock/material was granted to FID-II Peshawar vide letter F.No. 04-11/2019-(QC) dated 30-05-2019 by the competent authority i.e. Director, QA&LT, DRAP, Islamabad authorized by Central Licensing Board in its 237th meeting held on 1st October, 2014.

05. Area FID, Peshawar vide letter No.F.12-5/2019-Simaxx-DRAP2532 dated Nil. submitted his findings which are reproduced as under;

"Please refer to DRAP, Islamabad letter No. F. 4-11/2019 (QC), dated 30/05/2019 on the subject cited above. Following information is submitted for further necessary action please:

S. No.	***Documents***	***Remarks***
1.	*Copy of Form-2*	*Attached as Annexure-I*
2.	*Copy of Inspection Report*	*Attached as Annexure-II*
3.	*Copy of Affidavit of the Firm*	*Attached as Annexure-III*
4.	*Copy of letter to the firm for provision of information*	*Attached as Annexure-IV*
5.	*Copy of letter received from the firm (View of the firm) providing information along with copies of CNIC of the owner, production Incharge and QC, Incharge.*	*Attached as Annexure-V*
6.	*Contravention detaiails, if any.*	*Section 23 (1) (a) (vii) of the Drug Act, 1976.*
7.	*Recommendations*	*The firm has violated Section 23 (1) (a) (vii) of the Drug Act, 20176, punishable under Section 27 (1) (a). The firm has confessed the violation and considered it a mistake as a result of some misunderstandings. The firm has also requested for de-sealing of their premises for repacking of authorized products.*

06. Show-Cause Notice vide F.No. 04-11/2019-QC dated 24-07-2019 was served to the accused contents of which are as under;

"I am directed to refer to letter No.F. 12-05/2019-Simaxx-DRAP (P)-FID-II dated 29-04-2019 from FID II, Peshawar on the subject cited above wherein FID has informed,

02. That an inspection of M/s Simaxx Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Jamrud Road, Peshawar on 25-04-2019 was conducted by FID II Peshawar along with Mr. Muhammad Arif Choudry regarding a complaint forwarded by Quality Assurance and Laboratory Testing Division of DRAP, Islamabad regarding manufacture and sale of un-registered drugs.

03. That upon investigation it was found that M/s. Simaxx Chemical, Peshawar was involved in the manufacturing and sale of following un-registered products for which they were not authorized as they have Drug Manufacturing License by way of repacking only.

S.No	***Name of Product***	***Batch No.***	***Manufacturing Date***	***Expiry Date***	***Claimed to be manufactured by***

01	*Siwax (Soda Glycerin) Ear Drops*	*001*	*01-02-2017*	*30-01-2020*	*M/s. Simaxx Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Jamrud Road, Peshawar*
02	*Hydrogen Peroxide Solution 60m1*	*001*	*11-18*	*10-21*	*-do-*
03	*Iodine Povidone Solution 10% W/V*	*Unknown*	*Unknown*	*Unknown*	*-do-*
04	*Calamine Lotion 120ml*	*001*	*07-18*	*06-21*	*-do-*
05	*Siwax (Soda Glycerin) Ear Drops*	*002*	*01-02-2018*	*30-01-2021*	*-do-*

04. That at the time of inspection Glycerin Pure 125 gm having Batch. No. 002, Manufacturing Date 09.-19, Expiry Date 08-23 printed on label was under process of re-packing, however both of their approved qualified persons i.e. Production In-charge and Quality Control In-charge were absent. No proper record e.g. Batch Manufacturing Record, Stock Registers etc. were present at premises at the time of inspection.

05. That two unit cartons of Siwax eardrops 15ml batch No. 002 Mfg. Date 01-02-2018, Exp. Date 30-01-2021 and an empty drum of Povidone Iodine were recovered and seized on Form-2 under section 18(1)(f) of the Drugs Act, 1976. The Re-Packing block of factory was sealed under section 18(1)(h) of the Drug Act, 1976.

06. That FID-II Peshawar was granted permission to continue the custody of seized stock vide letter F.No.04-11/2019-(QC) dated 30-05-2019 with instructions to thoroughly investigate the matter and submit a comprehensive report, after fulfilling all legal formalities, covering full details of the case highlighting the nature of violation, fixing the responsibility (Names, Designations, complete addresses and copies of CNIC of accused person(s), comments/views on the response of accused, if any, and clear & candid recommendations on priority basis for consideration of the Board concerned.

07. That FID-II Peshawar vide letter No.F.12-5/2019-Simaxx-DRAP 2532 dated 03-07-2019 submitted a report along with copy of Form-2, copy of inspection report, copy of affidavit of the firm, copy of letter to the firm for provision of information, copy of letter received from the firm (views of the firm) providing information along with copies of CNIC of the owner, Production In-charge and QC In-charge, details of contravention and recommendation of FID II Peshawar.

08. That FID-II, Peshawar vide letter No.F.12-5/2019-Simaxx-DRAP 2532 dated 03-07-2019 enclosed reply of the firm wherein firm provided following details of the accused persons reproduced as under;

i. *Muhammad Shahzad (CEO of M/s. Simaxx Chemixal, Peshawar) S/o Muhammad Ishaq R/o Dabragi, House No. 4457, Mohalla Afridi Khan, Dak'khana Namak Mandi, Peshawar.*
ii. *Mrs. Farah Aftab (Production In-charge, M/s. Simaxx Chemical, Peshawar) W/o Saeed Akhtar Siddqui R/o Dak'khana Zargarabad, House No. 19, Street No. 3, Mohalla Shadbagh Colony, Peshawar.*

iii. *Waqar Ahmad (QC Manager, M/s. Simaxx Chemical, Peshawar) S/o Muhammad Rasheed R/o Dorah Road Kohat Road, House No. 2998-t, Street No. 5, Mohalla Sharifabad Chowk, Peshawar.*

09. That FID-II Peshawar vide letter No.F.12-5/2019-Simaxx-DRAP 2532 dated 03-07-2019 has stated that the mentioned accused persons violated Section 23 (1) (a) (vii) of the Drugs Act, 1976 that is punishable under Section 27 (1) (a) of the Drug Act, 1976.

10. That the case was placed before the competent authority and after approval, you are hereby served this show cause notice for violating Section 23 (1) (a) (vii) of the Drugs Act, 1976 which is punishable under Section 27 (1) (a) of the Drug Act, 1976 and to explain your position that why any or all of the following actions shall not be initiated against you;

i. Registration of FIR.
ii. Prosecution in the Court of competent jurisdiction for above-mentioned offences.
iii. Any other action that the board may deem fit.

11. If you desire to be heard in person or through authorized legal counsel, you are required to intimate this office within 07 days. In case of failure to reply to this show cause notice, it would be assumed that you have nothing to say in your defense and action will be taken against you in accordance with law."

07. In repose to the show cause notice served, M/s. Simaxx Chemicals, Hayatabad, Peshawar replied that is reproduced as under;

"Respected Sir,
Reference to your office show cause letter No F. No 04.11/2019-QC dated 24.07.2019 wherein the undersigned are directed to explain their position in the matter as mentioned in the show cause notice.
In this respect we had already submitted our statement and reply in response to the FID show cause notice on which reply we further want to be head in person in board.
Thanking you in anticipation"

08. Furthermore, CEO, M/s. Simaxx Chemicals Hayatabad, Peshawar vide letter No. Nil dated 16-08-2019 on the subject **REQUEST FOR THE DE SEALING OF M/S SIMAXX CHEMICALS** submitted as under;

" Referring to the inspection report of Mr. Atiq ul Bari (Area Federal Drug Inspector) Peshawar along with Mr. Arif Chaudry FID-I Peshawar inspected the premises of M/S SIMAXX CHEMICALS Plot No: 188-A, Industrial Estate Hayatabad Peshawar on the directions of QA & LT division of Drap Islamabad on 24-04-2019.

During inspection they observed that the labour was involved in the re-packing f pure glycerine 125g having batch No.002, Mfg. Date 09-018, Exp. Date 08-2023 printed on the label under the supervision of pharmacist Mr. Mudassar Ahmad.

The inspection team inquired and complaint abnout the production of products like soda-glycerine drops, Hyrdogen per oxide solution 60ml, Iodine-povidone solution 10% and Calamine lotion, about which we not only confessed but also given them a written acknowledgement that the above mentioned poducts

were being manufactured in the beginning only once due to misguidance and misunderstanding and in future we will never manufacture them again.

Actually the basic reason of misguidance or misunderstanding was the similarity in the names of the product for which we have been issued a License to repack the following items.

- *Glycering*
- *Calamine*
- *Iodine etc.*

Apart from that all above we contacted our few customers and took remaining unsold stocks (which was in negligible quantities) was destroyed as per verbal instructions of Mr. Atiq ul Bari Sahib.

Regardless of the above facts it s quite pertinent to note that at the time of inspection the company was neither involved in the manufacture of unregistered products mentioned in the report nor any raw material or packing material relating to the above mentioned products was found in spite of extensive search by the inspection team.

It is also important to note that on the day of raid our both approved qualified persons Mr. Waqar Ahmad Q.C in-charge and Mrs. Farrah Aftab production in-charge were absent due to their age related health problems, but Mr. Mudassar Ahmad a newly appointed pharmacist was present under whom supervision the glycerine was being re-packed. Mr. Mudassar ahmad was unaware of the BMR (batch manufacturing record) and stock registers etc which were in the custody of our approved qualified staff and was present in the cupboards.

Here it is also important to note that we fully cooperate with the authorities and not resisted at all at any stage of inspection even at the time of sealing of our unit because we were not guilty conscience and were of the view that we would be served with the show cause notice in a week or two atleast. But unluckily it took more than two months that our unit is sealed and suffering from irrepareable financial loss.

In the light of above facts we humbly request you to sympathetically consider our case and de seal our unit as soon as possible so that we can re-pack the products for which we have been issued License by way of re-packing.

Please also find enclosed the photocopies of FID report and acknowledgment."

09. It is submitted that the letter of Personal hearing was served to the accused vide letter F.No. 03-44/2019-QC dated 06-09-2019 to call in the accused for personal hearing before the CLB.

Proceedings and Decision of 271st Meeting of CLB: -

10. The accuse Mrs. Farah Aftab (Production In-charge, M/s. Simaxx Chemical, Peshawar) W/o Saeed Akhtar Siddqui and Waqar Ahmad (QC Manager, M/s. Simaxx Chemical, Peshawar) S/o Muhammad Rasheed appeared before the Board. Mrs. Samina Naz appeared before the board on behalf of her husband Muhammad Shahzad (CEO of M/s. Simaxx Chemixal, Peshawar)

S/o Muhammad Ishaq and informed the Board that the accused Muhammad Shahzad is critically ill and is admitted in the hospital. The accused Waraq Ahmad while admitting the offence before the Board submitted that they manufactured the mentioned poducts only once due to misguidance and misunderstanding and are not manufacturing them anymore and in future they will never manufacture the products in question again. He further added that at the time of inspection he was not present at the premises and Mr. Mudassar Ahmad, a newly appointed

pharmacist was present under whom supervision the glycerine was being re-packed. He also claimed that during the inspection, FID did not recoeverd any of the products in question.

11. The facts of the case and available record were placed before the board. After perusal of the record it reveled that FID during inspection recovered two unit cartons oof SiWax eardrops 15ml batch No. 002 Mfg. Date 01-02-2018, Exp. Date 30-01-2021 and an empty drum of Povidone Iodine and seized the same on Form-2 under section 18(1)(f) of the Drugs Act, 1976. It is pertinent to mention that contrary to the facts, the accused in their personal hearing and written reply against the showcause notice denied the recovery of any alleged product/raw material/packing material which is submitted as under;

> *"…Regardless of the above facts it s quite pertinent to note that at the time of inspection the company was neither involved in the manufacture of unregistered products mentioned in the report nor any raw material or packing material relating to the above mentioned products was found in spite of extensive search by the inspection team…"*

12. The Board after giving personal hearing to the accused and deliberated the case at length decided as under;

i. The QC section will verify the names and designations of the accused from the division of Drugs Licensing.
ii. Clear and candid recommendations and proposal will be submitted by the concerned FID regarding the case that will include nature of violation, Names and designations of the accused and fixation of responsibility on the accused.
iii. It will be clarified from the FID that whether he took samples for the purpose of test/analysis from the premises during the inspection.
iv. A final opportunity of personal hearing will be given to Muhammad Shahzad (CEO of M/s. Simaxx Chemixal, Peshawar) S/o Muhammad Ishaq R/o Dabragi, House No. 4457, Mohalla Afridi Khan, Dak'khana Namak Mandi, Peshawar either in person or through his authorized council.

13. In compliance of the decision of 271st meeting of CLB, details of names and designations of the accused were verified by the QC section from the Division of Drugs Licensing details of which are as under;

Management / Directors / CEO of M/s. Simaxx Pharmaceuticals, Hayatabad Peshawar;

i. Mr. Muhammad Shahzad S/o Muhammad Ishaq
ii. Mrs. Saima Naz W/o Muhammad Shahzad

Production In-charge of M/s. Simaxx Pharmaceuticals, Hayatabad Peshawar;

i. Ms. Farah Aftab

Quality Control In-charge of M/s. Simaxx Pharmaceuticals, Hayatabad Peshawar;

i. Mr. Waqar Ahmad

14. Decision of CLB was communicated to are FID Peshawar vide No. F. 03-44/2019-QC (271-CLB) (pt-II) dated 11-09-2019 and in response to the said letter, area FID Peshawar vide letter No. F. 12-05/2019-Simaxx-DRAP (P)-FID-II 8019 dated 09-12-2019 submitted as under;

> *"Please refer to DRAP Islamabad Letter No. F.03-44/2019-QC (271-CLB) (pt-II) dated 11th November, 2019 on the subject cited above and in continuation to this*

office letter No. F.12-05/2019-Simaxx-DRAP (P)-FID-II-2532 dated 03-07.2019. Following details are submitted as required:-

S.No	*Documents/actions*	*Remarks*
01	*Nature of Violation*	*The firm has violated section 23(1)(a)(vii) of the Drug Act, 1976.*
02	*Names and designations of the accused and fixation of responsibility on the accused.*	*i. Muhammad Shahzad (CNIC No. 17301-1370689-7); CEO of the firm.* *ii. Mr. Waqar Ahmad (CNIC No. 17301-7269571-1); Quality Control Incharge of the firm* *iii. Mrs. Farah Saeed Siddiqui (CNIC No. 17301-1589863-0) Production Incharge of the firm*
03	*Clarification of sampling*	*The undersigned did not take any samples for the purpose of test/analysis from the premises during the inspection.*

15. Furthermore, in compliance to the decision of the Board,Muhammad Shahzad (CNIC No. 17301-1370689-7), CEO of the firm vide letter F. No. 3-01/2020-QC dated 03-01-2020 is called for final opportunity of personal hearing.

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

16. That Muhammad Shahzad (CNIC.No.17301-1370689-7), CEO M/s. Simaxx Chemicals, Peshawar appeared before the Board and admitted all the allegations leveled against him.

17. That the Board after detailed discussion and deliberations considering the facts of the case decided as under:

A. Grant permission for prosecution in the court of competent jurisdiction against the following accused persons for the offences committed by them as stated herein below in para B:

a. M/s. Simaxx Chemical, Plot No. 188-A, Industrial Estate Hayatabad, Peshawar through its owner/CEO Muhammad Shahzad (CNIC No. 17301-1370689-7)S/o Muhammad Ishaq R/o Dabgari, House No. 4457, Mohalla Afridi Khan, Peshawar.

b. Muhammad Shahzad, CEO of M/s. Simaxx Chemicals, (CNIC No. 17301-1370689-7)S/o Muhammad Ishaq R/o Dabgari, House No. 4457, Mohalla Afridi Khan, Peshawar.

c. Waqar Ahmad, Quality Control In-charge (CNIC No. 17301-7269571-1) S/o Muhammad Rasheed, R/o Dorah Road Kohat Road, House No. 2998-t, Street No. 5, Mohalla Sharifabad Chowk, Peshawar.

d. **Mrs. Farah Aftab, Production In-charge, R/o Dak'khana Zargarabad, House No. 19, Street No. 3, Mohalla Shadbagh Colony, Peshawar**

B. The above mentioned accused persons have violated Section 23(1)(a)(vii) of Drug Act 1976.

C. The Federal Inspector of Drugs, DRAP, Peshawar is directed to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.

Case No. 08-B: **REQUEST FOR THE DE-SEALING OF M/S. SIMAXX CHEMICAL, PESHAWAR.**
MANUFACTURE AND SALE OF UN-REGSTERED DRUGS (M/s. SIMAXX CHEMICAL, HAYATABAD, PESHAWAR).

CEO, M/s. Simaxx Chemicals Hayatabad, Peshawar vide letter No. Nil dated 16-08-2019 on the subject **REQUEST FOR THE DE SEALING OF M/S SIMAXX CHEMICALS** submitted as under;

" Referring to the inspection report of Mr. Atiq ul Bari (Area Federal Drug Inspector) Peshawar along with Mr. Arif Chaudry FID-I Peshawar inspected the premises of M/S SIMAXX CHEMICALS Plot No: 188-A, Industrial Estate Hayatabad Peshawar on the directions of QA & LT division of Drap Islamabad on 24-04-2019.

During inspection they observed that the labour was involved in the re-packing f pure glycerine 125g having batch No.002, Mfg. Date 09-018, Exp. Date 08-2023 printed on the label under the supervision of pharmacist Mr. Mudassar Ahmad.

The inspection team inquired and complaint abnout the production of products like soda-glycerine drops, Hyrdogen per oxide solution 60ml, Iodine-povidone solution 10% and Calamine lotion, about which we not only confessed but also given them a written acknowledgement that the above mentioned poducts were being manufactured in the beginning only once due to misguidance and misunderstanding and in future we will never manufacture them again.

Actually the basic reason of misguidance or misunderstanding was the similarity in the names of the product for which we have been issued a License to repack the following items.

- *Glycering*
- *Calamine*
- *Iodine etc.*

Apart from that all above we contacted our few customers and took remaining unsold stocks (which was in negligible quantities) was destroyed as per verbal instructions of Mr. Atiq ul Bari Sahib.

Regardless of the above facts it s quite pertinent to note that at the time of inspection the company was neither involved in the manufacture of unregistered products mentioned in the report nor any raw material or packing material relating to the above mentioned products was found in spite of extensive search by the inspection team.

It is also important to note that on the day of raid our both approved qualified persons Mr. Waqar Ahmad Q.C in-charge and Mrs. Farrah Aftab production in-charge were absent due to their age related health problems, but Mr. Mudassar Ahmad a newly appointed pharmacist was present under whom supervision the glycerine was being re-packed. Mr. Mudassar ahmad was unaware of the BMR (batch manufacturing record) and stock registers etc which were in the custody of our approved qualified staff and was present in the cupboards.

Here it is also important to note that we fully cooperate with the authorities and not resisted at all at any stage of inspection even at the time of sealing of our unit because we were not guilty conscience and were of the view that we would be served with the show cause notice in a week or two atleast. But unluckily it took more than two months that our unit is sealed and suffering from irrepareable financial loss.

In the light of above facts we humbly request you to sympathetically consider our case and de seal our unit as soon as possible so that we can re-pack the products for which we have been issued License by way of re-packing.
Please also find enclosed the photocopies of FID report and acknowledgment."

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

02. The Board after thorough deliberation decided to de-seal the premises of M/s. Simaxx Chemical, Peshawar with directions to the area FID Peshawar to seize the any available stock of unregistered drugs present on the premises.

Case No. 09: <u>Seizure Of Drugs, Government Hospital Property/ Un-Registered And Expired Drugs Under Section 18 (1) (f) Of Drugs Act, 1976 (Raid on M/s. Amin Pharmacy, Shop No. 01, underpass, outside of Services Hospital, Jail road, Lahore)</u>

01. Brief facts of the case are as under;

02. The Federal Inspector of Drugs IV, Lahore informed that upon direction of Additional Director, Lahore visited the premises of M/s. Amin Pharmacy, Shop No. 1, Under pass, outside of services Hospital, Jail Road, Lahore alongwith Mr. Ajmal Sohail Asif, FID, Lahore on 16-11-2017 at 1:45 pm.

03. The FID further informed that when the team reached at the pharmacy, more than four (4) persons were present at pharmacy. Upon seeing the raiding team, three of them ran away from the premises, except one, who introduced himself as Mr. Adeel. Upon query, he told that he has - fled away from the pharmacy were Mr. Babar Bhatti (Owner), Mr. Mushtaq (Salesman) and Mr. Hafeez (Salesman). He was asked to call the owner but he replied that he did not has a phone number of the owner.

04. He further informed that the team noted that as per Drug Sale License of the pharmacy, name of the Proprietor was Mr. Ashraf and Qualified person was Ms. Khadeeja with the help of neighboring medical stores, Mr. Ashraf (Proprietor), was contacted telephonically and asked to come at the pharmacy, but he says that I am in Sheikhupura at this time and cannot come he further told that though he was proprietor but he had rented out the pharmacy to another person, namely Mr. Babar Bhatti.

05. The FID further informed that he seized the therapeutic goods on Form-2 under Para (1) (f) of the Schedule-V of the DRAP Act, 2012. The team recovered huge quantity of different Government Hospital Property, Un-registered drugs and expired drugs from the Pharmacy as detailed below:

Sr. No.	Name Of Product	Quantity
01.	Clexane Injection 6000 IU/0.6ml in blisters without outer/ unit pack, seems to be the property of services Hospital, as label was stamped "Services Hospital, Not For Sale" Recovered from main counter in a plastic bag.	60 Injections
02.	Solu-Medrol Injection 1000mg Vials without unit carton seems to be the property of Services Hospital. The stamp on the label to this effect was tried to be removed/ erased. Recovered from main counter.	03 Injections

03.	Iopamiro 50ml Injection Un-registered without outer carton.	01 Injection
04.	Heparin Injection 5000 IU/ml purported to be Govt. property as evident from label (stamp to this effect was removed/raised)	02 Injections
05.	Tygacil 50mg Injection Un-registered recovered from main counter.	05 Injections
06.	Neo-pyrolate Injection 01ml, expired, expiry dated: 10-17 Batch no. 107K5, 106K5	02 Injections

06. The FID informed that all the mentioned therapeutic goods were recovered and seized in the presence of Ms. Khadeejah Khan (Qualified person), absent at the time of raid but jointed later at about 03:00pm. She told that she was asked by Muhammad Ashraf, Proprietor, to reach the pharmacy. The seizure was made in the presence of witnesses.

07. The FID requested the competent authority to grant permission for safe custody of seized therapeutic goods till decision of the case under Schedule-V of the DRAP Act, 2012 and the permission to continue safe custody was granted to FID vide letter F.No.04-42/2017-QC dated 13-12-2017 and FID IV Lahore was requested to thoroughly investigate the matter and after completing all the legal formalities, submit a comprehensive report to the QA&LT Division, DRAP, Islamabad, highlighting the nature of violation and comments/views on the response of accused, if any, for the consideration of the Board.

08. The FID informed that sale/ stock of un-registered, expired and hospital supplies drugs (Services Hospital Property-Not for Sale) without any warranty are offence under Schedule II of the DRAP Act, 2012 which is punishable under Schedule III of the DRAP Act, 2012 and refferdthe case to the competent authority as required under Schedule-V of the DRAP Act, 2012 to seek orders as to the action to be taken in respect of said contraventions of the DRAP Act, 2012, as mentioned above against the following persons:

i. **Muhammad Ashraf S/o Muhammad Amin, Proprietor** of M/s. Amin Pharmacy, Shop No. 1, Under Pass Jail Road, Lahore (CNIC No. 35202-6400446-7), person absent.

ii. **Ms. Khadeeja D/o Muhammad Yahya (Qualified person)** of M/s. Amin Pharmacy, Shop No. 1, Under Pass Jail road, Lahore (CNIC No. 35404-9671214-2), absent at the time of raid and joined later at about 03:00pm).

09. The FID VI Lahore vide letter no. 9301/2018-DRAP (L-VI) dated 10-7-18 informed that showcause notice was issued to Mr. Muhammad Ashraf, proprietor of M/s Amin Pharmacy, Lahore and Ms. Khadeejah, Qualified person vide Lahore DRAP office letter no. 17468/2017-DRAP (L-VI) dated 23-11-2017 and reminders were also issued. In response, Ms Khadeejah and Mr. Muhammad Ashraf have submitted their written statement. Similarly, Medical Superintendent, Service Hospital Lahore also submitted his reply regarding the verification and investigation the matter on 09-02-2018 in response to DRAP Lahore office letter 17366/2017-DRAP (L-VI) dated 20-11-2017, 19-12-2017, 29-12-2017, 12-01-2018 and 24-01-2018.

10. Muhammad Ashraf, Owner of M/s. Amin Pharmacy, Lahroe, filed an application in the drug court, Lahore for de-sealing of M/s Amin Pharmacy, Lahore and was fixed on 28 Nov, 2017. The Honorable Drug Court, Lahore, passed the order, to the FID is directed that with the assistance and coordination of Provincial Drug Inspector (Area D.I to de-seal the premises in the presence of petitioner and after completion the investigation/ proceedings, reseal the premises and submit report on next date of hearing which was fixed for 05-12-2017.

11. The FID Lahore along with area D.I visited the premises and de-seal the premises in the presence of Mr. Muhammad Ashraf and Ms. Khadeejah Khan, qualified person. The premises was inspected and premises was again sealed, report was sent to the Honorable Drug Court, Lahore.

12. The FID Lahore appeared before Honorable Drug Court, Lahore on 05-12-2017. The Honorable Drug Court, Lahore passed the order to de-seal the premises. The FID, Lahore de-sealed the premises on 7-12-2017 in the presence of applicant and qualified person and report was also sent to the honorable drug court.

13. FID VI Lahore vide letter F.No.04-42/2017-QC dated 13-08-2018 was again requested to thoroughly investigate the matter and after completing all the legal formalities, submit a comprehensive report to the QA&LT Division, DRAP, Islamabad, highlighting the nature of violation and comments/views on the response of accused, if any, for the consideration of the Board.

14. In response to the mentioned letter, FID VI, vide letter Ref. No.721/2019-DRAP (L-VI) dated 14-01-2019 requested that the matter may please be placed before the Central Licensing Board under section 19(7) of the Drugs Act, 1976 for further orders to him as the action to be taken in this regard keeping in view all the above facts and court orders in this regard as the sale of unregistered/ Government property/ expired drug is prohibited under Schedule II of the DRAP

Act, 2012, read with section 23 and punishable under Schedule III of DRAP Act, 2012 read with Section 27 of the Drugs Act, 1976.

15.It is therefore submitted that the mentioned accused persons may be show caused for the offences committed by them him as informed by FID VI Lahore.

Proceedings and Decision 270th meeting of CLB:

The case was deliberated at length and CLB after evaluation of record decided as under:

1. To issue show cause notice and personal hearing to the following accused persons for the offences committed by them as stated herein below in para 2::

   a. Muhammad Ashraf S/o Muhammad Amin, Proprietor of M/s. Amin Pharmacy, Shop No. 1, Under Pass Jail Road, Lahore (CNIC No. 35202-6400446-7).

   b. Ms. Khadeeja Khan D/o Muhammad Yahya (Qualified person) of M/s. Amin Pharmacy, Shop No. 1, Under Pass Jail road, Lahore (CNIC No. 35404-9671214-2).

2. The mentioned accused persons are involved the sale/ stock of un-registered, expired and hospital supplies drugs (Services Hospital Property-Not for Sale) without any warranty that are offence under Schedule II of the DRAP Act, 2012 which is punishable under Schedule III of the DRAP Act, 2012.

Call FID in the upcoming meeting of CLB along with case property.

16. In the light of the decision of the Board, Show cause and personal hearing notice was issued to accused vide letter No. 03-33/2019-QC(270 CLB) dated 30-09-2019 contents of which are as under:

> *"In the light of decision of 270th meeting of CLB held on 23.05.2019 it is to inform you,*
> *01. That the Federal Inspector of Drugs IV, Lahore informed that upon direction of Additional Director, Lahore visited the premises of M/s. Amin Pharmacy, Shop No. 1, Under pass, outside of services Hospital, Jail Road, Lahore along with Mr. Ajmal Sohail Asif, FID, Lahore on 16-11-2017 at 1:45 pm.*
> *02. That when the team reached at the pharmacy, more than four (4) persons were present at pharmacy. Upon seeing the raiding team, three of them ran away from the premises, except one, who introduced himself as Mr. Adeel. Upon query, he told that he has -fled away from the pharmacy were Mr. Babar Bhatti (Owner), Mr. Mushtaq (Salesman) and Mr. Hafeez (Salesman). He was asked to call the owner but he replied that he did not has a phone number of the owner.*

03. That the team noted that as per Drug Sale License of the pharmacy, name of the Proprietor was Mr. Ashraf and Qualified person was Ms. Khadeeja with the help of neighboring medical stores, Mr. Ashraf (Proprietor), was contacted telephonically and asked to come at the pharmacy, but he says that I am in Sheikhupura at this time and cannot come he further told that though he was proprietor but he had rented out the pharmacy to another person, namely Mr. Babar Bhatti.

04. That the FID seized the therapeutic goods on Form-2 under Para (1) (f) of the Schedule-V of the DRAP Act, 2012 and the team recovered huge quantity of different Government Hospital Property, Un-registered drugs and expired drugs from the Pharmacy as detailed below:

Sr. No.	***Name of Product***	***Quantity***
01.	*Clexane Injection 6000 IU/0.6ml in blisters without outer/ unit pack, seems to be the property of services Hospital, as label was stamped "Services Hospital, Not For Sale" Recovered from main counter in a plastic bag.*	*60 Injections*
02.	*Solu-Medrol Injection 1000mg Vials without unit carton seems to be the property of Services Hospital. The stamp on the label to this effect was tried to be removed/ erased. Recovered from main counter.*	*03 Injections*
03.	*Iopamiro 50ml Injection Un-registered without outer carton.*	*01 Injection*
04.	*Heparin Injection 5000 IU/ml purported to be Govt. property as evident from label (stamp to this effect was removed/raised)*	*02 Injections*
05.	*Tygacil 50mg Injection Un-registered recovered from main counter.*	*05 Injections*
06.	*Neo-pyrolate Injection 01ml, expired, expiry dated: 10-17 Batch no. 107K5, 106K5*	*02 Injections*

05. That the FID informed that all the mentioned therapeutic goods were recovered and seized in the presence of Ms. Khadeejah Khan (Qualified person), absent at the time of raid but jointed later at about 03:00pm. She told that she was asked by Muhammad Ashraf, Proprietor, to reach the pharmacy. The seizure was made in the presence of witnesses.

06. That the FID requested the competent authority to grant permission for safe custody of seized therapeutic goods till decision of the case under Schedule-V of the DRAP Act, 2012 and the permission to continue safe custody was granted to FID vide letter F.No.04-42/2017-QC dated 13-12-2017 and FID IV Lahore was requested to thoroughly investigate the matter and after completing all the legal formalities, submit a comprehensive report to the QA&LT Division, DRAP,

Islamabad, highlighting the nature of violation and comments/views on the response of accused, if any, for the consideration of the Board.

07. That the FID informed that sale/ stock of un-registered, expired and hospital supplies drugs (Services Hospital Property-Not for Sale) without any warranty are offence under Schedule II of the DRAP Act, 2012 which is punishable under Schedule III of the DRAP Act, 2012 and referred the case to the competent authority as required under Schedule-V of the DRAP Act, 2012 to seek orders as to the action to be taken in respect of said contraventions of the DRAP Act, 2012, as mentioned above against the following persons:

i. ***Muhammad Ashraf S/o Muhammad Amin, Proprietor*** *of M/s. Amin Pharmacy, Shop No. 1, Under Pass Jail Road, Lahore (CNIC No. 35202-6400446-7), person absent.*

ii. ***Ms. Khadeeja D/o Muhammad Yahya (Qualified person)*** *of M/s. Amin Pharmacy, Shop No. 1, Under Pass Jail road, Lahore (CNIC No. 35404-9671214-2), absent at the time of raid and joined later at about 03:00pm).*

08. That the FID VI Lahore vide letter no. 9301/2018-DRAP (L-VI) dated 10-7-18 informed that show-cause notice was issued to Mr. Muhammad Ashraf, proprietor of M/s Amin Pharmacy, Lahore and Ms. Khadeejah, Qualified person vide Lahore DRAP office letter no. 17468/2017-DRAP (L-VI) dated 23-11-2017 and reminders were also issued. In response, Ms Khadeejah and Mr. Muhammad Ashraf have submitted their written statement. Similarly, Medical Superintendent, Service Hospital Lahore also submitted his reply regarding the verification and investigation the matter on 09-02-2018 in response to DRAP Lahore office letter 17366/2017-DRAP (L-VI) dated 20-11-2017, 19-12-2017, 29-12-2017, 12-01-2018 and 24-01-2018.

09. That Muhammad Ashraf, Owner of M/s. Amin Pharmacy, Lahore, filed an application in the drug court, Lahore for de-sealing of M/s Amin Pharmacy, Lahore and was fixed on 28 Nov, 2017. The Honorable Drug Court, Lahore, passed the order, to the FID is directed that with the assistance and coordination of Provincial Drug Inspector (Area D.I) to de-seal the premises in the presence of petitioner and after completion the investigation/ proceedings, reseal the premises and submit report on next date of hearing which was fixed for 05-12-2017.

10. That the FID Lahore along with area D.I visited the premises and de-seal the premises in the presence of Mr. Muhammad Ashraf and Ms. Khadeejah Khan, qualified person. The premises was inspected and premises was again sealed, report was sent to the Honorable Drug Court, Lahore.

11. That the FID Lahore appeared before Honorable Drug Court, Lahore on 05-12-2017. The Honorable Drug Court, Lahore passed the order to de-seal the premises. The FID, Lahore de-sealed the premises on 7-12-2017 in the presence of applicant and qualified person and report was also sent to the honorable drug court.

12. That the FID VI Lahore vide letter F.No.04-42/2017-QC dated 13-08-2018 was again requested to thoroughly investigate the matter and after completing all the legal formalities, submit a comprehensive report to the QA&LT Division, DRAP, Islamabad, highlighting the nature of violation and comments/views on the response of accused, if any, for the consideration of the Board.

13. That in response to the mentioned letter, FID VI, vide letter Ref. No.721/2019-DRAP (L-VI) dated 14-01-2019 requested that the matter may please be placed before the Central Licensing Board under section 19(7) of the Drugs Act, 1976 for further orders to him as the action to be taken in this regard keeping in view all the above facts and court orders in this regard as the sale of unregistered/ Government property/ expired drug is prohibited under Schedule II of the DRAP Act, 2012, read with section 23 and punishable under Schedule III of DRAP Act, 2012 read with Section 27 of the Drugs Act, 1976.

14. That the case was presented before the Central Licensing Board in its 270th meeting and the Board decided as under: -

*"**The case was deliberated at length and CLB after evaluation of record decided as under:***

1. To issue show cause notice and personal hearing to the following accused persons for the offences committed by them as stated herein below in para 2::

a. Muhammad Ashraf S/o Muhammad Amin, Proprietor of M/s. Amin Pharmacy, Shop No. 1, Under Pass Jail Road, Lahore (CNIC No. 35202-6400446-7).

b. Ms. Khadeeja Khan D/o Muhammad Yahya (Qualified person) of M/s. Amin Pharmacy, Shop No. 1, Under Pass Jail road, Lahore (CNIC No. 35404-9671214-2).

2. The mentioned accused persons are involved the sale/ stock of un-registered, expired and hospital supplies drugs (Services Hospital Property-Not for Sale) without any warranty that are offence under Schedule II of the DRAP Act, 2012 which is punishable under Schedule III of the DRAP Act, 2012.

3. Call FID in the upcoming meeting of CLB along with case property."

15. In view of above it is evidently proven that you are involved in the sale/ stock of un-registered, expired and hospital supplies drugs (Services Hospital Property-Not for Sale) without any warranty which is an offence under Schedule II of the DRAP Act, 2012 and punishable under Schedule III of the DRAP Act, 2012. You are hereby served show cause notice under section 41 of the Drugs Act, 1976 and rules framed thereunder to explain your position that why you should not be prosecuted for the above-mentioned offences in the Court of competent jurisdiction to award you punishment under the law.

16. If you desire to be heard in person or through your authorized legal counsel, you are directed to intimate this division within seven (7) days of receipt of this letter"

17. The show cause notice were returned back to the section undelivered with comment that no one lives at the mentioned address since a long time.

18. A personal hearing notice was also issued to the accused vide F. No. 03-33/2019-QC(270 CLB) dated 11.10.2019

19. As per directions of the Board, the area FID was also issued a letter to appear before the Board along with the case property in compliance of the decision of the Board. Details of the letter are given as under:

"I am directed refer to the subject cited above and to communicate the decision of 270th meeting of Central Licensing Board held on 23.05.2019 which is reproduced as under;

"The case was deliberated at length and CLB after evaluation of record decided as under:

1. To issue show cause notice and personal hearing to the following accused persons for the offences committed by them as stated herein below in para 2:

a. Muhammad Ashraf S/o Muhammad Amin, Proprietor of M/s. Amin Pharmacy, Shop No. 1, Under Pass Jail Road, Lahore (CNIC No. 35202-6400446-7).

b. Ms. Khadeeja Khan D/o Muhammad Yahya (Qualified person) of M/s. Amin Pharmacy, Shop No. 1, Under Pass Jail road, Lahore (CNIC No. 35404-9671214-2).

2. The mentioned accused persons are involved the sale/ stock of un-registered, expired and hospital supplies drugs (Services Hospital Property-Not for Sale) without any warranty that are offence under Schedule II of the DRAP Act, 2012 which is punishable under Schedule III of the DRAP Act, 2012.

3. Call FID in the upcoming meeting of CLB along with case property."

02. It is therefore requested to comply with the decision of the Board in true letter and spirit."

20. As per the decision of the Board, the accused are called for personal hearing and the FID is called before the Board along with the case property.

Proceedings & Decision of 272nd meeting of CLB held on 17th October, 2019:

21. Central Licensing Board (CLB) was apprised that the Show Cause & Personal Hearing notice were forwarded through Urgent Mail Service. Show cause notice served to Muhammad Ashraf (Proprietor) S/o Muhammad Amin was receive back un-delivered.

22. Accused Khadeeja Khan (Qualified Person) D/o Yahya Khan appeared before the Board and submitted her written reply as under;

> *"Sir,*
> *With due respect, l, Khadeejah khan (Qualified person), here to explain my position. lwas working in Symans Pharmaceuticals in Sheikhupura since June 2014 (attached copy).*
> *ln September 2017, I was introduced to Amin Pharmacy. They said, we want to do business in pharmacy setup so we need a pharmacy licence. lf you give pharmacy licence, after getting registration, we will assign you as a qualified person on the pharmacy. As I was thinking to change my job from industrial to retail setup, I gave my licence. They got their pharmacy registration licence and started their business but they said to me, we are still in-process they will update me later on.*
> *ln November 2017, the pharmacy store was raided. I was on job in industry in Sheikhupura, they called me to come urgently to Amin pharmacy as per address they gave to me. I reached pharmacy store at 3:00 pm. Drug inspectors were waiting for me as all the shop-workers ran away except one worker because they were selling unregistered, expired drugs and government samples (not for sale) in my absence. So as a qualified person, I had to signed the recovered samples, unregistered, expired drugs (not for sale) on the order of Drug lnspector. I called the proprietor so many times but he didn't receive my call. So I had to face all the situation alone.*
> *After the raid, I decided not to change my job, on a very next day I applied for cancellation of my licence after that Amin pharmacy closed on the cancellation of my licence.*
> *No doubt, it's my fault to trust an unknown person blindly. I am really sorry and apologise for this blunder mistake in my life. Hoping to be favoured with great kindness.*
> *Thanks"*

23. Accused Muhammad Ashraf (Proprietor) S/o Muhammad Amin neither did by himself nor through any authorized counsel appear before the board. He also did not submitted reply to the show-cause notice issued to him.

24. To reach the appropriate decision in the light of law, the Board decided as under:

i. **Provide final opportunity of personal hearing to accused Muhammad Ashraf S/o Muhammad Amin Proprietor of M/s Amin Pharmacy, Shop No.1, Underpass, Jail road, Lahore R/o 8-A Waris Road, Lahore and ensure the delivery of the letter through the office of Chief Drugs Controller, Punjab and area FID, DRAP.**

ii. **Federal Inspector of Drugs shall appear before the Board along with case file except case property.**

25. In compliance to the decision of 272nd meeting of the CLB, Area Federal Inspector of drugs is called before the Board.

26. The accused is called before the Board for final opportunity of personal hearing.

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

27. In compliance to the decision of 272nd meeting of CLB, Mr. Abdul Rasheed Sheikh, Area Federal Inspector of Drugs Lahore, appeared and presented the case before the Board. He further informed the Board regarding the service/delivery of Show-cause notice to the accused by special messenger that was received by person namely Mushtaq Hussain (Present at M/s. Amin Pharmacy, Lahore) on 28-11-2019.

28. The accused Muhammad Ashraf, Proprietor of M/s. Amin Pharmacy, Shop No. 1, Underpass, Jail Road, Lahore despite the service of show-cause notice, did not appeared before the Board in person neither by himself nor through any authorized legel counsel and also did not submitted a written reply in response to the served show-cause notice.

29. After thorough deliberation and keeping in view the statement of area FID Lahore and facts of the case, the Board decided as under;

A. **Board granted permission for prosecution against the accusedMuhammad Ashraf(Owner/proprietor of M/s. Amin Pharmacy, Shop No. 1, Underpass, Jail Road, Lahore R/o 8-A, Waris Road, Lahore. (CNIC No. 35202-6400446-7)and M/s. Amin Pharmacy, Shop No. 1, Underpass, Jail Road, Lahore through its owner/proprietor from where the products were seized in the presence of Ms. Khadija khan (qualified person) who joined the seizure process at the time of preparation of recovery memo as witness as she was not present at the initial time of raid. She was called by the owner to join the proceedings and to sign recovery memo by qualified person as seconded by the Federal Inspector of Drugs.**

B. **The above mentioned accused person has violated Schedule-II of DRAP Act, 2012 read with Section 23 of the Drugs Act 1976 and punishable under Schedule-III of the DRAP Act 2012 read with Section 27 of the Drugs Act 1976.**

C. **The Federal Inspector of Drugs, DRAP, Lahore is requested to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.**

Case No. 10: <u>Seizure Of Stock Under Section 18 (1) (f) of the Drugs Act, 1976 From M/s. Cheap Medical Store (Pvt.) Ltd., New Anarkali, Lahore.</u>

The Abdul Rashid Shaikh Federal Inspector of Drugs Lahore vide letter. No, 10211/2018-DRAP(L-VI) which is being reproduced as under: The Director, Federal Investigation Agency, Temple Road Lahore Sub: Request for Lodging FIR Against the Management of M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore Inter-alia for the Manufacturing, Re-Packing and Sale of Un-Registered Drugs/Therapeutic Goods Without Any Drug Manufacturing Licence /Drug Sale License/Drug Import License. I am directed to state that the undersigned along with Mr. Asim Rauf, Additional Director, DRAP, Lahore, Mr. Ajmal Sohail Asif, Federal inspector of Drugs, Lahore, Dr. Akbar Ali, Assistant Director, DRAP, Lahore, Mr. Ahsan-ul-HaqAthar, Assistant Director, DRAP, Lahore and Mr. Shahrukh Ali, Assistant Director, DRAP,Lahore conducted inspection of the premises of M/s. Cheap Medical Store (Pvt.) Ltd,27-New Anarkali, Lahore on 02-04-2018.

02. The following drugs /therapeutic goods were seized on Form-2 under Section 18 (1) (f) of the Drugs Act 1976 being unregistered/smuggled drugs, that were stored in query very'unhygienic, dirty and unfavorable storage conditions;

S. No.	Name of Drug(s) / Reg. No.	Manufacturer	Quantity
01	CPM Raw Material (White Powder Purported to be Chlorphenaramine Maleate in Poly Bag)		500gram x1x2
02	Chloral hydrate (Raw Material China)	China	500gram x1x2
03	Dic/Pot Raw Material (White Powder Purported to be diclofenac potassium in poly bag)	-	500gram x1x2
04	l.b.u (White Powder purport to be Ibuprofen in Poly bag)	-	500gram x1x2
05	P Raw Material (White Powder Purported to be Paracetamol in Poly Bag)	-	lOOOgram x1x2
06	Caffine Citrate (Raw Material)	Pakistan	500gram x1x2
07	A.C (White Powder Purported to be Aspirin)		500gram x1x2
08	Barium Sulphate (Raw Material)	China.	200gram x1x2
09	Aspartame (Raw Material Holland)	Holland	500gram x1x2
10	Isoniazid (Raw Material China)	China	500x1x1
11	Mercury Raw	Made in Japan.	1.5 kg x1x3
12	Atenolol Raw Material	Made in China	200gram x1
13	Cetrizine 2HCI Raw Material	Made in India	150gram x1
14	Piroxicam Raw Material	Made in India	200gram x1
15	Testosterone Raw Material	Made in Germany.	2gram x1
16	Prednisolone Raw Material	Made in France	02gram (Approx) x1
17	Atropine Sulphate Raw Material	Made in China	02gram (Approx) x1
18	Strychnine Sulphate Raw Material	Made in England	05 gram (Approx) x1
19	Gentamycin Sulphate Raw Material	Made in China	SOOgram

			(Approx) x1
20	Propranolol Raw Material	Made in China	500gram (Approx) x1
21	OMPR Raw Material (pallets purported to be omeprazole)		1 kg x1x4
22	Paracetamol Raw Material	Citi Pharma, Pakistan.	25kg x 2 box
23	Hydroquinine	-	20kg x1 drum
24	Mannitol Raw Material	Made in China	25kg x 2 drum
25	Tablet Dapsone 100mg	Made by GSK India	600 (Appxox)
26	Inventory/stock register		02 Nos.
27	Tablet Duraga 100mg	M/s. Tarque Pharmaceuticals, Indua.	150x03
28	Tablet Zeytadatic 20mg	M/s. Combitic Global, India	136x02
29	Tablet nCHrPA 100mg (Foreign Language)	- Do -	40x04
30	Tablet Dapsone 100mg	M/s. GSK, India	04x1000
31	Tablet Cialis 20mg	M/s. Made in USA	01x03
32	Tablet Buskopan 300mg	M/s. Combitic Global, India	500x10
33	Tablet Rovigon Expired	-Do -	05x10
34	Grucid (Omeprazole Capsule) 20mg (Expiry date: Oct. 2015)	-Do -	1 strip x 10's x400 strips
35	Omepro-D Capsule	Maiden Pharmaceuticals, India	1x10'sx60 Strips
36	ML-GACID Capsules	Milan Labs, Indis	1x10's x 5 Strips
37	Famotidine ablets 40mg	M/s. Combitic Global, India	1x10's x 100 Blister
38	Ceten (Ceteizine Hydrochloride) Tablets	Arbro Pharmaceuticals, India.	1x10's x8 blister

03. Explanation letters were issued to Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed and Sheikh Mehmood Ahmed, CEO, M/s. Cheap Medical Store (Pvt.) Ltd., Lahore, on respective their residential address vide letter No. 5007/2018-DRAP (L-VI), dated 12-04-2018. A reminder letter was also issued vide letter No. 5270/2018-DRAP (L-VI). dated 18-04-2018 through special messenger, whereas letter No. 5270/2018-DRAP (L-VI) dated, 18-04-2018 was personly received by Sheikh Muhammad Mushtaq in the office of the undersigned, but no reply has yet been received in this office.

04. The following drugs were taken also on Form-3, from the premises of M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore, for test /analysis purpose on 02-04-2018;

S. No	**Name of Product(s) /Reg. No.**	**Batch No.**	**Mfg. Date.**	**Exp. Date.**	**Manufactured by**	**Quantity**
1.	CPM (White Powder Purported to be	-	-	-	-	500 gram

	Chlorpheniramine Maleate (Raw Material in Poly Bag)					
2.	Chloral hydrate (Raw Material China).	-	-	-	China	500 gram
3	Dic/Pot Raw Material (White Powder Purported to be diclofenac potassium in Poly bag)	-	-	-	-	500 gram
4	Ibu (White Powder Purported to be Ibuprofen in Poly Bag)	-	-	-	-	500 gram
5	P (White Powder Purported to be Paracetamol Raw Material in Poly Bag)	-	-	-	-	500 gram
6	Caffeine Citrate Raw Material (White Powder Purport to Caffeine) Made in Pakistan.	-	-	-	Pakistan.	500 gram
7	A C (White Powder Purported to be Aspirin) in Poly Bag.	-	-	-	-	500 gram
8	Barium Sulphate (Raw Material Made in China).	-	-	-	China	200 gram
9	Aspartame Raw Material (Holland)	-	-	-	Holland	500 gram
10	OMP (Pallets Purported to be Omeprazole in Poly bag.	-	-	-	-	1000 gram
11	Deltacortril 5mg Tablets Reg. No. 000443Suspected to be Spurious	1796102	12/2017	11/2020	M/s. Pfizer Pakistan Ltd., B-2, S.l. T.E, Karachi.	1000 Tablets
12	Buskopan Tablets 300mg Reg. No. Nil Suspected to be Spurious/unregistered.				M/s. Combitic Global Caplet (Pvt.) Ltd., India.	10x10 Tablets
13	Zevtadatic-20 Tablets Suspected to be Spurious/unregistered.	ZTT2-01	Sep.2017-	Aug. 20121	M/s. Combitic Global Caplet (Pvt.) Ltd., India.	20x2Tablets

05. The sample were sent to Central Drugs Laboratory, Karachi for test /analysis. The Federal Government Analyst declared them as pharmaceuticals raw materials and unregistered drugs / products vide following Test Report's;

S. No.	Test Report No. & Date
01	Test Report No. RM.SC.25/2018, Dated 16-04-2018
02	Test Report No. RM.SC.26/2018, Dated 16-04-2018
03	Test Report No. RM.SC.27/2018, Dated 16-04-2018
04	Test Report No. RM.SC.28/2018, Dated 16-04-2018

05	Test Report No. RM.SC.29/2018, Dated 16-04-2018
06	Test Report No. RM.SC.30/2018, Dated 16-04-2018
07	Test Report No. RM.SC.31/2018, Dated 16-04-2018
08	Test Report No. RM.SC.32/2018, Dated 16-04-2018
09	Test Report No. RM.SC.33/2018, Dated 16-04-2018
10	Test Report No. RM.SC.34/2018,Dated 17-04-2018
11	Test Report No. LHR. Sc.45/2018, Dated 13-04-2018
12	Test Report No. LHR. SC.46/2018, Dated 10-05-2018
13	Test Report No. LHR. SC.47/2018, Dated 25-04-2018

06. In compliance with Order, dated 16-04-2018 passed by the honourble Drug Court, Lahore, the following therapeutic goods/materials/articles were seized on Form-2 on 23-04-2018, under Schedule-V to the DRAP Act, 2012 read with Section 18 (1) (f) of the Drugs Act, 1976, being unregistered, being sold without any valid license and being stored in very un-hygienic and dirty conditions, as perdirection of the Drug Court, Lahore;

S. No.	Name of Therapeutic goods/Materials/Article	Batch No.	Mfg Date.	Exp. Date	Manufacturer	Quantity
01	Paracetamol (Raw Material)	PGP17-371	10-2017	10-2022	Citi Pharma (Pvt.) Ltd.	01x25kg
02	Paracetamol (Raw Material)	PGP18-117	03-2018	03-2023	-Do -	01x25kg
03	Paracetamol (Raw Material)	PGP18-032	01-2018	01-2023	-Do -	02x25kg
04	Lactose IMP USP-NF/ph Eur/JP	102U14C	11-2017	10-2020	DMV-Fonterra Exceipients GMbH/G., KG Neitherland.	25x25kg 19x25kg
05	Megnesium Sulphate (Raw Material)	20141128	Nov.28 2014	Nov.27 2017	-	6x50kg
06	Ammonium Chloride (Raw Material)	-	-	-	Dalian China	10x25kg
07	Sulphadiamidine Sodium (RM)	-	-	-	China	I 7x500gm Jars
08	Salicylic Acid (RM)	-	-	-	China	15x500gm Jars
09	Ferric Ammonium citrate (RM)	-	-	-	Pakistan	6x5kg
10	Iron Oxide Red (RM)	-	-	-	Everlonght China	2x25kg
11	Magnesium Stearate USP (RM)	20160705	2016-07-5	2019-7-4	Huzhou City Linghu Zinwang China.	10x20kg
12	Magnesium Hydroxide B.P	MH 116/230	May 2016	5 years	Oceanic Pharma Chen, India	1x20kg
13	Sodium Bromide Powder (RM)	-	-	-	Texchem Industry, India	2x25kg /
14	Amoniom Bromide (RM)	060912	-	-	China	2x25kg /

15	Dicaicium Phosphate (RM)	1710070	-	-	China	05x25kg
16	Zinc Sulphate USP (RM)	0000263480	-	-	Made in E.U	1x25kg
17	Aluminum, Hydroxide Dried gel.	-	-	-	China	35x300gm Packs
18	Zinc Sulphate monohydrate	-	-	-	China	54x500gm
19	Propyl Paraben	-	-	-	Japan	200x500gm
20	Ferrrous Sulphate (RM)	-	-		Germany	80x 500gm
21	Zinc Gluconate (RM)	15081325	-	-	Shandong Xinhna Pharmaceuticals Co., Ltd., China.	2x25kg
22	Ferrous Sulphate (RM)	63282F965	04/214	04/2017	India	1x25kg
23	Salicylic Acid BP (RM)	170228	28-2-2017	27-2-2020	Qinadar Sun Chemicals, China.	3x25kg
24	Vitamin C	1160550120	05/16	05/21	China.	1x25kg
25	Calcium Sulphate	16240502	05/16	05/20	-	1x50kg
26	Potassium Hydroxide Pellets (85%)	-	-	-	Unid Co. Ltd., Seoul, Korea	1x50kg
27	Biotin (Vit-H) (RM)	-	-	-	Roche	6x500gm
28	Vitamin-A dry Acetate 5 Lac I.U/g	-	-	-	China	15x250gm
29	Quinine Sulphate	-	-	-	-	100 gm Approx.
30	Myristic Acid	-	-	-	-	400 gm Approx.
31	Silymarin	-	-	-	-	50 gm Approx
32	Naphthalene Ball	-	-	-	-	50 gm Approx
33	Vit-K3	-	-	-	-	50 gm Approx
34	Nux Vomica Powder	-	-	-	-	100 gm Approx
35	Caffeine Citrate	-	-	-	-	400 gm Approx
36	Pepsin 1:300	-	-	-	-	200 gm Approx
37	Pectin Citrus	-	-	-	-	500 gm Approx
38	Cetrimide	-	-	-	-	300 gm Approx
39	Potassium Dichromate	-	-	-	-	300 gm Approx
40	Copper Carbonate	-	-	-	-	100mg Approx.
41	Chlorxylenol	-	-	-	-	200mg

						approx.
42	Copper Citrate	-	-	-	-	100mg approx.
43	Calcium D Penthonate	-	-	-	-	50mg approx.
44	Metochlopramide	-	-	-	-	300mg approx.
45	Metronidazole	-	-	-	-	200mg approx.
46	Ferri-Et-quinine Citrate	-	-	-	-	100mg approx.
47	Permathrin Powder 100%	-	-	-	-	100mg approx.
48	Acetainilide	-	-	-	-	200mg approx.
49	Aspirin	-	-	-	-	300mg approx.
50	Sodium Dihydrogen Phosphate Dihydrate	-	-	-	-	500mg approx.
51	Sodium Sacehrrin	-	-	-	-	500mg approx.
52	Pottassium Citrate	-	-	-	-	300mg approx.
53	Pattassium Carbonate.	-	-	-	-	200mg approx.
54	Sodium Carbonate	-	-	-	-	100mg approx.
55	Potassium Iodate	-	-	-	-	200mg approx.
56	Sodium Hydroxide	-	-	-	-	100mg approx.
57	Synthetic Camphor	-	-	-	-	50mg approx.
58	Electrical Balance large Acs-digital scale	-	-	-	Golden Tigen Japan Standard	1 unit
59	Electrical Balance SE-400	-	-	-	-	1 unit
60	PVC Sealer	-	-	-	-	2 units
61	Plastic Jars for repacking	-	-	-	-	12 Sacs
62	Barium sulphate				China	200gm x 60 packs
63	Glycerine	5150161003 A	-	-	Pacific derchemicals Malaysia	250kg x 2 drums
64	Chloroform	708-111	08-2017	-	- NovocheboksarskRussra	290kgx1drum
65	White Minerial Oil	-	-	-	Sontt Korea	170 kg 1 drum
66	Mercury Oxide Yellow received through bilty during the time of inspection	-	-	-	-	10kg.

	Bilty No. 46105 Sender Ayup Bhatti, receiver Cheap medical store at 4:15pm.					
67	Register / ledgers	-	-	-	07	-

07. After seizure of above-mentioned drugs/therapeutic goods/material/articles as evidence of commission of offence, the premises were re-sealed again. The report thereof was submitted in the honourable Drug Court, Lahore vide office letter No. 5434/2018-DRAP (L-VI) dated 24-04-2018. The case was also sent to Central Licensing Board vide this office letter No. 5730/2018-DRAP (L-VI) dated 27-04-2018.

08. Explanation letters were again issued to Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed and Sheikh Mehmood Ahmed, CEO, M/s. Cheap Medical Store (Pvt.) Ltd., Lahore on their residential address vide letter No. 5766/2018-DRAP (L-VI), dated 27-04-2018. The explanation letter No. 5766/2018-DRAP (L-VI), dated 27-04-2018 was received by Sh. Muhammad Mushtaq personally in the office of the undersigned. Reminder letters were also issued vide letter No.6855/2018-DRAP (L-VI), dated 18-05-2018 and letter No. 6856/2018-DRAP (L-VI) dated, 18-05-2018. No reply has yet been received in this office.

09. That in compliance with honourable Drug Court Order's dated 27-04-2018 and 16-05-2018, the premises of M/s. Cheap Medical Store (Pvt.) Ltd, Lahore, were de-sealed on 07-06-2018, in presence of the Sheikh Muhammad Mushtaq (person present at the time of sealing) and Mr. Sanaullah Saif, area Provincial Drug Inspector and other witnesses.

10. In compliance with Order, dated 27-04-2018 and 16-05-2018 passed by the honourable Drug Court, Lahore, premises of M/s. Cheap Medical Store (Pvt.) Ltd., New Anarkali, Lahore was re-sealed by the undersigned along with Mr. Ajmal Sohail Asif, FID, DRAP, Lahore on 27-06-2018.

11. A Criminal Revision was filed by the State in the honourable Lahore High Court, Lahore against the Order's dated 27-04-2018 and 16-05-2018 passed by the honourable Drug Court, Lahore. The honourble Lahore High Court, Lahore, vide its Orders, dated 27-06-2018, suspended the impugned Orders of the honourable Drug Court, Lahore, dated 27-04-2018 and 16-05-2018.

12. Copies of test reports were supplied to Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed, of M/s. Cheap Medical Store (Pvt.) Ltd., Lahore on his residential address vide letters Nos. 5542/2018-DRAP (L-VI), dated 24-04-2018, 6167/2018-DRAP (L-VI) dated 04-05-2018 & No. 7091/2018-DRAP (L-VI) dated 23-05-2018 to explain their position and submit the requisite information. Letter No. 5542/2018-DRAP (L-VI), dated 24-04-2018 & No. 6167/2018-DRAP (L-VI) dated 04-05-

2018 were received by Sh. Muhammad Mushtaq, personally in the office of the undersigned. A reminder letter was also issued to Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed, and Sheikh Mehmood Ahmed, CEO, M/s. Cheap Medical Store (Pvt.) Ltd., Lahore on their respective residential address vide letter No.6854/2018-DRAP (L-VI), dated 18-05-2018. No reply has yet been received in this office.

13. The matter was placed before Central Licensing Board. The Board inter-alia, granted extension of sealing period, allowed safe custody of sized drugs till the finalization of case also and granted permission to lodge FIR against the following accused persons vide letter No. F. No. 03-33/2018-QC (pt-261-CLB), dated 24-05-2018;

1. **M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore through Proprietor Sheikh, Mehmood Ahmed CEO;**
2. **Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed, (CNIC No. 35202-2973889-9 M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.**
3. **Yousaf Ejaz S/o. Sh. Ejaz Ahmed (Partner) M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.**
4. **Sheikh Mehmood Ahmed CEO and qualified person M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore**

14. The above accused persons have committed offence by violating provisions of heading A of Schedule-II to the DRAP Act 2012 read with Section 23 of the Drugs Act, 1976. The offences are cognizable under schedule-IV to the DRAP Act, 2012 read with section 30 (2) (a) of the Drugs Act 1976, and are punishable under Schedule-III to the DRAP Act, 2012 read with section 27 of the Drugs Act 1976.

15. Furthermore, the Urdu part of the incomplete challan states that the IO FIA declared the mentioned accused person namely, Sheikh Muhammad Mushtaq and Sheikh Mehmood Ahmad were found guilty in the light of statements witnesses and documentary evidences. Whereas, due to lack of insufficient evidence, Yousaf Ijaz S/o Shaikh Ijaz Ahmad cannot be declared guilty at the moment. It is therefore, the IO FIA submitted the incomplete challan and has requested to start the legal proceedings in the Court of competent jurisdiction.

16. In the light of investigation and findings of the IO, FIA, Lahore, the accused persons namely, Sheikh Muhammad Mushtaq and Sheikh Mehmood Ahmad have been declared guilty for violating provisions of heading A of Schedule-II to the DRAP Act 2012 read with Section 23 of the Drugs Act, 1976. The offences are cognizable under schedule-IV to the DRAP Act, 2012 read with section 30 (2) (a) of the Drugs Act 1976, and are punishable under Schedule-III to the DRAP Act, 2012 read with section 27 of

the Drugs Act 1976. It is therefore submitted that the mentioned accused persons may be show caused for the offences committed by them as stated herein above in this para.

Proceedings and Decision 270th meeting of CLB:

The case was deliberated at length and CLB after evaluation of record decided as under:

1. **To issue show cause notice and personal hearing to the following accused persons for the offences committed by them as stated herein below in para 2:**
   a. **M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore through Proprietor Sheikh, Mehmood Ahmed CEO;**
   b. **Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed, (CNIC No. 35202-2973889-9 M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.**
   c. **Yousaf Ejaz S/o. Sh. Ejaz Ahmed (Partner) M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.**
   d. **Sheikh Mehmood Ahmed CEO and qualified person M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore**
2. **The mentioned accused persons have committed offence by violating provisions of heading A of Schedule-II to the DRAP Act 2012 read with Section 23 of the Drugs Act, 1976. The offences are cognizable under schedule-IV to the DRAP Act, 2012 read with section 30 (2) (a) of the Drugs Act 1976, and are punishable under Schedule-III to the DRAP Act, 2012 read with section 27 of the Drugs Act 1976.**
3. **Call FID in the upcoming meeting of CLB along with case property.**

17. In the light of the decision of the Board, Show cause and personal hearing notice was issued to accused vide letter No. 03-33/2019-QC(270 CLB) dated 30-09-2019 contents of which are as under:

"In the light of decision of 270th meeting of CLB held on 23.05.2019 it is to inform you,

01. That the Federal Inspector of Drugs Lahore vide letter. No, 10211/2018-DRAP(L-VI) informed about the inspection of M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore on 02-04-2018.

02. That following drugs /therapeutic goods were seized on Form-2 under Section 18 (1) (f) of the Drugs Act 1976 being unregistered/smuggled drugs, that were stored in very unhygienic, dirty and unfavorable storage conditions;

S. No.	*Name of Drug(s) / Reg. No.*	*Manufacturer*	*Quantity*
01	*CPM Raw Material (White Powder Purported to be Chlorphenaramine Maleate in Poly Bag)*		*500gram x1x2*

02	Chloral hydrate (Raw Material China)	China	500gram x1x2
03	Dic/Pot Raw Material (White Powder Purported to be diclofenac potassium in poly bag)	-	500gram x1x2
04	l.b.u (White Powder purport to be Ibuprofen in Poly bag)	-	500gram x1x2
05	P Raw Material (White Powder Purported to be Paracetamol in Poly Bag)	-	1000 gram x1x2
06	Caffine Citrate (Raw Material)	Pakistan	500gram x1x2
07	A.C (White Powder Purported to be Aspirin)		500gram x1x2
08	Barium Sulphate (Raw Material)	China.	200gram x1x2
09	Aspartame (Raw Material Holland)	Holland	500gram x1x2
10	Isoniazid (Raw Material China)	China	500x1x1
11	Mercury Raw	Made in Japan.	1.5 kg x1x3
12	Atenolol Raw Material	Made in China	200gram x1
13	Cetrizine 2HCI Raw Material	Made in India	150gram x1
14	Piroxicam Raw Material	Made in India	200gram x1
15	Testosterone Raw Material	Made in Germany.	2gram x1
16	Prednisolone Raw Material	Made in France	02gram (Approx) x1
17	Atropine Sulphate Raw Material	Made in China	02gram (Approx) x1
18	Strychnine Sulphate Raw Material	Made in England	05 gram (Approx) x1
19	Gentamycin Sulphate Raw Material	Made in China	500 gram (Approx) x1
20	Propranolol Raw Material	Made in China	500gram (Approx) x1
21	OMPR Raw Material (pallets purported to be omeprazole)		1 kg x1x4
22	Paracetamol Raw Material	Citi Pharma, Pakistan.	25kg x 2 box
23	Hydroquinine	-	20kg x1 drum
24	Mannitol Raw Material	Made in China	25kg x 2 drum
25	Tablet Dapsone 100mg	Made by GSK India	600 (Appxox)
26	Inventory/stock register		02 Nos.
27	Tablet Duraga 100mg	M/s. Tarque Pharmaceuticals, Indua.	150x03
28	Tablet Zeytadatic 20mg	M/s. Combitic Global, India	136x02
29	Tablet nCHrPA 100mg (Foreign Language)	- Do -	40x04
30	Tablet Dapsone 100mg	M/s. GSK, India	04x1000
31	Tablet Cialis 20mg	M/s. Made in USA	01x03
32	Tablet Buskopan 300mg	M/s. Combitic Global, India	500x10
33	Tablet Rovigon Expired	-Do -	05x10
34	Grucid (Omeprazole Capsule) 20mg (Expiry date: Oct. 2015)	-Do -	1 strip x 10's x400 strips
35	Omepro-D Capsule	Maiden Pharmaceuticals, India	1x10'sx60 Strips
36	ML-GACID Capsules	Milan Labs, Indis	1x10's x 5 Strips
37	Famotidine ablets 40mg	M/s. Combitic Global, India	1x10's x 100 Blister
38	Ceten (Ceteizine Hydrochloride) Tablets	Arbro Pharmaceuticals, India.	1x10's x8 blister

03. That explanation letters were issued to Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed and Sheikh Mehmood Ahmed, CEO, M/s. Cheap Medical Store (Pvt.) Ltd., Lahore, on their residential address vide letter No. 5007/2018-DRAP (L-VI), dated 12-04-2018. A reminder letter was also issued vide letter No. 5270/2018-DRAP (L-VI) dated 18-04-2018 through special messenger, whereas letter No. 5270/2018-DRAP (L-VI) dated, 18-04-2018 was personally received by Sheikh Muhammad Mushtaq in the office of the area FID Lahore, but no reply to the letter was received.

04. That following drugs were taken also on Form-3, from the premises of M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore, for test /analysis purpose on 02-04-2018;

S. No	*Name of Product(s) /Reg. No.*	*Batch No.*	*Mfg. Date.*	*Exp. Date.*	*Manufactured by*	*Quantity*
1.	*CPM (White Powder Purported to be Chlorpheniramine Maleate (Raw Material in Poly Bag)*	*-*	*-*	*-*	*-*	*500 gram*
2.	*Chloral hydrate (Raw Material China).*	*-*	*-*	*-*	*China*	*500 gram*
3	*Dic/Pot Raw Material (White Powder Purported to be diclofenac potassium in Poly bag)*	*-*	*-*	*-*	*-*	*500 gram*
4	*Ibu (White Powder Purported to be Ibuprofen in Poly Bag)*	*-*	*-*	*-*	*-*	*500 gram*
5	*P (White Powder Purported to be Paracetamol Raw Material in Poly Bag)*	*-*	*-*	*-*	*-*	*500 gram*
6	*Caffeine Citrate Raw Material (White Powder Purport to Caffeine) Made in Pakistan.*	*-*	*-*	*-*	*Pakistan.*	*500 gram*
7	*A C (White Powder Purported to be Aspirin) in Poly Bag.*	*-*	*-*	*-*	*-*	*500 gram*
8	*Barium Sulphate (Raw Material Made in China).*	*-*	*-*	*-*	*China*	*200 gram*
9	*Aspartame Raw Material (Holland)*	*-*	*-*	*-*	*Holland*	*500 gram*
10	*OMP (Pallets Purported to be Omeprazole in Poly bag.*	*-*	*-*	*-*	*-*	*1000 gram*
11	*Deltacortril 5mg Tablets Reg. No. 000443Suspected to be Spurious*	*1796102*	*12/2017*	*11/2020*	*M/s. Pfizer Pakistan Ltd., B-2, S.l. T.E, Karachi.*	*1000 Tablets*
12	*Buskopan Tablets 300mg Reg. No. Nil Suspected to be Spurious/unregistered.*				*M/s. Combitic Global Caplet (Pvt.) Ltd., India.*	*10x10 Tablets*
13	*Zevtadatic-20 Tablets Suspected to be Spurious/unregistered.*	*ZTT2-01*	*Sep.2017-*	*Aug. 20121*	*M/s. Combitic Global Caplet (Pvt.) Ltd., India.*	*20x2Tablets*

05. *That the samples were sent to Central Drugs Laboratory, Karachi for test /analysis. The Federal Government Analyst declared them as pharmaceuticals raw materials and unregistered drugs / products vide following Test Reports;*

S. No.	*Test Report No. & Date*
01	*Test Report No. RM.SC.25/2018, Dated 16-04-2018*
02	*Test Report No. RM.SC.26/2018, Dated 16-04-2018*
03	*Test Report No. RM.SC.27/2018, Dated 16-04-2018*
04	*Test Report No. RM.SC.28/2018, Dated 16-04-2018*
05	*Test Report No. RM.SC.29/2018, Dated 16-04-2018*
06	*Test Report No. RM.SC.30/2018, Dated 16-04-2018*
07	*Test Report No. RM.SC.31/2018, Dated 16-04-2018*
08	*Test Report No. RM.SC.32/2018, Dated 16-04-2018*
09	*Test Report No. RM.SC.33/2018, Dated 16-04-2018*
10	*Test Report No. RM.SC.34/2018, Dated 17-04-2018*
11	*Test Report No. LHR. Sc.45/2018, Dated 13-04-2018*
12	*Test Report No. LHR. SC.46/2018, Dated 10-05-2018*
13	*Test Report No. LHR. SC.47/2018, Dated 25-04-2018*

06. That in compliance with order, dated 16-04-2018 passed by the honourable Drug Court, Lahore, the following therapeutic goods/materials/articles were seized on Form-2

on 23-04-2018, under Schedule-V to the DRAP Act, 2012 read with Section 18 (1) (f) of the Drugs Act, 1976, being unregistered, being sold without any valid license and being stored in very un-hygienic and dirty conditions;

S. No.	Name of Therapeutic goods/Materials/Article	Batch No.	Mfg Date.	Exp. Date	Manufacturer	Quantity
01	Paracetamol (Raw Material)	PGP17-371	10-2017	10-2022	Citi Pharma (Pvt.) Ltd.	01x25kg
02	Paracetamol (Raw Material)	PGP18-117	03-2018	03-2023	-Do -	01x25kg
03	Paracetamol (Raw Material)	PGP18-032	01-2018	01-2023	-Do -	02x25kg
04	Lactose IMP USP-NF/ph Eur/JP	102U14C	11-2017	10-2020	DMV-Fonterra Exceipients GMbH/G., KG Neitherland.	25x25kg 19x25kg
05	Megnesium Sulphate (Raw Material)	20141128	Nov.28 2014	Nov.27 2017	-	6x50kg
06	Ammonium Chloride (Raw Material)	-	-	-	Dalian China	10x25kg
07	Sulphadiamidine Sodium (RM)	-	-	-	China	7x500gm Jars
08	Salicylic Acid (RM)	-	-	-	China	15x500gm Jars
09	Ferric Ammonium citrate (RM)	-	-	-	Pakistan	6x5kg
10	Iron Oxide Red (RM)	-	-	-	Everlonght China	2x25kg
11	Magnesium Stearate USP (RM)	20160705	2016-07-5	2019-7-4	Huzhou City Linghu Zinwang China.	10x20kg
12	Magnesium Hydroxide B.P	MH 116/230	May 2016	5 years	Oceanic Pharma Chen, India	1x20kg
13	Sodium Bromide Powder (RM)	-	-	-	Texchem Industry, India	2x25kg
14	Amoniom Bromide (RM)	060912	-	-	China	2x25kg
15	Dicaicium Phosphate (RM)	1710070	-	-	China	05x25kg
16	Zinc Sulphate USP (RM)	0000263480	-	-	Made in E.U	1x25kg
17	Aluminum, Hydroxide Dried gel.	-	-	-	China	35x300gm Packs
18	Zinc Sulphate monohydrate	-	-	-	China	54x500gm
19	Propyl Paraben	-	-	-	Japan	200x500gm
20	Ferrrous Sulphate (RM)	-	-		Germany	80x 500gm
21	Zinc Gluconate (RM)	15081325	-	-	Shandong Xinhna Pharmaceuticals Co., Ltd., China.	2x25kg
22	Ferrous Sulphate (RM)	63282F965	04/214	04/2017	India	1x25kg
23	Salicylic Acid BP (RM)	170228	28-2-2017	27-2-2020	Qinadar Sun Chemicals, China.	3x25kg
24	Vitamin C	1160550120	05/16	05/21	China.	1x25kg
25	Calcium Sulphate	16240502	05/16	05/20	-	1x50kg
26	Potassium Hydroxide Pellets (85%)	-	-	-	Unid Co. Ltd., Seoul, Korea	1x50kg
27	Biotin (Vit-H) (RM)	-	-	-	Roche	6x500gm
28	Vitamin-A dry Acetate 5 Lac I.U/g	-	-	-	China	15x250gm
29	Quinine Sulphate	-	-	-	-	100 gm Approx.
30	Myristic Acid	-	-	-	-	400 gm Approx.
31	Silymarin	-	-	-	-	50 gm Approx
32	Naphthalene Ball	-	-	-	-	50 gm Approx
33	Vit-K3	-	-	-	-	50 gm Approx
34	Nux Vomica Powder	-	-	-	-	100 gm Approx
35	Caffeine Citrate	-	-	-	-	400 gm Approx
36	Pepsin 1:300	-	-	-	-	200 gm Approx
37	Pectin Citrus	-	-	-	-	500 gm Approx
38	Cetrimide	-	-	-	-	300 gm Approx

39	Potassium Dichromate	-	-	-	-	300 gm Approx
40	Copper Carbonate	-	-	-	-	100mg Approx.
41	Chlorxylenol	-	-	-	-	200mg approx.
42	Copper Citrate	-	-	-	-	100mg approx.
43	Calcium D Penthonate	-	-	-	-	50mg approx.
44	Metochlopramide	-	-	-	-	300mg approx.
45	Metronidazole	-	-	-	-	200mg approx.
46	Ferri-Et-quinine Citrate	-	-	-	-	100mg approx.
47	Permathrin Powder 100%	-	-	-	-	100mg approx.
48	Acetainilide	-	-	-	-	200mg approx.
49	Aspirin	-	-	-	-	300mg approx.
50	Sodium Dihydrogen Phosphate Dihydrate	-	-	-	-	500mg approx.
51	Sodium Sacehrrin	-	-	-	-	500mg approx.
52	Pottassium Citrate	-	-	-	-	300mg approx.
53	Pattassium Carbonate.	-	-	-	-	200mg approx.
54	Sodium Carbonate	-	-	-	-	100mg approx.
55	Potassium Iodate	-	-	-	-	200mg approx.
56	Sodium Hydroxide	-	-	-	-	100mg approx.
57	Synthetic Camphor	-	-	-	-	50mg approx.
58	Electrical Balance large Acs-digital scale	-	-	-	Golden Tigen Japan Standard	1 unit
59	Electrical Balance SE-400	-	-	-	-	1 unit
60	PVC Sealer	-	-	-	-	2 units
61	Plastic Jars for repacking	-	-	-	-	12 Sacs
62	Barium sulphate				China	200gm x 60 packs
63	Glycerine	5150161003A	-	-	Pacific derchemicals Malaysia	250kg x 2 drums
64	Chloroform	708-111	08-2017	-	- NovocheboksarskRussra	290kgx1drum
65	White Minerial Oil	-	-	-	Sontt Korea	170 kg 1 drum
66	Mercury Oxide Yellow received through bilty during the time of inspection Bilty No. 46105 Sender Ayup Bhatti, receiver Cheap medical store at 4:15pm.	-	-	-	-	10kg.
67	Register / ledgers	-	-	-	07	-

07. That after seizure of above-mentioned drugs/therapeutic goods/material/articles as evidence of commission of offence, the premises were re-sealed again. The report thereof was submitted in the honorable Drug Court, Lahore vide office letter No. 5434/2018-DRAP (L-VI) dated 24-04-2018. The case was also sent to Central Licensing Board by the area FID vide letter No. 5730/2018-DRAP (L-VI) dated 27-04-2018.

08. That the explanation letters were again issued to Sheikh Muhammad Mushtaq S/o. Sheikh Maqsood Ahmed and Sheikh Mehmood Ahmed, CEO, M/s. Cheap Medical Store (Pvt.) Ltd., Lahore on their residential address vide letter No. 5766/2018-DRAP (L-VI), dated 27-04-2018. The explanation letter No. 5766/2018-DRAP (L-VI), dated 27-04-2018 was received by Sh. Muhammad Mushtaq personally in the office of the

area FID, Lahore. Reminder letters were also issued vide letter No.6855/2018-DRAP (L-VI), dated 18-05-2018 and letter No. 6856/2018-DRAP (L-VI) dated, 18-05-2018. No reply has yet been received by the area FID Lahore till date.

09. That in compliance with honorable Drug Court Order's dated 27-04-2018 and 16-05-2018, the premises of M/s. Cheap Medical Store (Pvt.) Ltd, Lahore, were de-sealed on 07-06-2018, in presence of the Sheikh Muhammad Mushtaq (person present at the time of sealing) and Mr. Sanaullah Saif, area Provincial Drug Inspector and other witnesses.

10. That in compliance with Order, dated 27-04-2018 and 16-05-2018 passed by the honorable Drug Court, Lahore, premises of M/s. Cheap Medical Store (Pvt.) Ltd., New Anarkali, Lahore was re-sealed by the area FID, Lahore along with Mr. Ajmal Sohail Asif, FID, DRAP, Lahore on 27-06-2018.

11. That a Criminal Revision was filed by the State in the honorable Lahore High Court, Lahore against the Order's dated 27-04-2018 and 16-05-2018 passed by the honorable Drug Court, Lahore. The honorable Lahore High Court, Lahore, vide its Orders, dated 27-06-2018, suspended the Orders of the honorable Drug Court, Lahore, dated 27-04-2018 and 16-05-2018.

12. That the copies of test reports were supplied to Sheikh Muhammad Mushtaq S/o. Sheikh Maqsood Ahmed, of M/s. Cheap Medical Store (Pvt.) Ltd., Lahore on his residential address vide letters Nos. 5542/2018-DRAP (L-VI), dated 24-04-2018, 6167/2018-DRAP (L-VI) dated 04-05-2018 & No. 7091/2018-DRAP (L-VI) dated 23-05-2018 to explain their position and submit the requisite information. Letter No. 5542/2018-DRAP (L-VI), dated 24-04-2018 & No. 6167/2018-DRAP (L-VI) dated 04-05-2018 were received by Sh. Muhammad Mushtaq, personally in the office of the area FID, Lahore. A reminder letter was also issued to Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed, and Sheikh Mehmood Ahmed, CEO, M/s. Cheap Medical Store (Pvt.) Ltd., Lahore on their respective residential address vide letter No.6854/2018-DRAP (L-VI), dated 18-05-2018. No reply has yet been received by the area FID, Lahore.

13. That the matter was placed before Central Licensing Board. The Board

inter-alia, granted extension of sealing period, allowed safe custody of sized drugs till the finalization of case also and granted permission to lodge FIR against the following accused persons vide letter No. F. No. 03-33/2018-QC (pt-261-CLB), dated 24-05-2018;

i. ***M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore through Proprietor Sheikh, Mehmood Ahmed CEO;***
ii. ***Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed, (CNIC No. 35202-2973889-9 M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.***
iii. ***Yousaf Ejaz S/o. Sh. Ejaz Ahmed (Partner) M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.***
iv. ***Sheikh Mehmood Ahmed CEO and qualified person M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore***

14. That the above accused persons have committed offence by violating provisions of heading A of Schedule-II to the DRAP Act 2012 read with Section 23 of the Drugs Act, 1976. The offences are cognizable under schedule-IV to the DRAP Act, 2012 read with section 30 (2) (a) of the Drugs Act 1976, and are punishable under Schedule-III to the DRAP Act, 2012 read with section 27 of the Drugs Act 1976.

15. That IO FIA declared that mentioned accused person namely, Sheikh Muhammad Mushtaq and Sheikh Mehmood Ahmad were found guilty in the light of statements witnesses and documentary evidences. Whereas, due to lack of insufficient evidence, Yousaf Ijaz S/o Shaikh Ijaz Ahmad cannot be declared guilty at the moment. It is therefore, the IO FIA submitted the incomplete challan and has requested to start the legal proceedings in the Court of competent jurisdiction.

16. That in the light of investigation and findings of the IO, FIA, Lahore, the accused persons namely, Sheikh Muhammad Mushtaq and Sheikh Mehmood Ahmad have been declared guilty for violating provisions of heading A of Schedule-II to the DRAP Act 2012 read with Section 23 of the Drugs Act, 1976. The offences are cognizable under schedule-IV to the DRAP Act, 2012 read with section 30 (2) (a) of the Drugs Act 1976, and are punishable under Schedule-III to the DRAP Act, 2012 read with section 27 of the Drugs Act 1976.

17. That the case was deliberated at length and CLB, in its 270th meeting, after evaluation of record decided as under:

"1. To issue show cause notice and personal hearing to the following accused persons for the offences committed by them as stated herein below in para 2:

a. M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore through Proprietor

Sheikh, Mehmood Ahmed CEO;

b. ***Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed, (CNIC No. 35202-2973889-9 M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.***
c. ***Yousaf Ejaz S/o. Sh. Ejaz Ahmed (Partner) M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.***
d. ***Sheikh Mehmood Ahmed CEO and qualified person M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore***

2. ***The mentioned accused persons have committed offence by violating provisions of heading A of Schedule-II to the DRAP Act 2012 read with Section 23 of the Drugs Act, 1976. The offences are cognizable under schedule-IV to the DRAP Act, 2012 read with section 30 (2) (a) of the Drugs Act 1976, and are punishable under Schedule-III to the DRAP Act, 2012 read with section 27 of the Drugs Act 1976.***

3. ***Call FID in the upcoming meeting of CLB along with case property."***

15. In view of above it is evidently proven that you are involved in violating the provisions of heading A of Schedule-II to the DRAP Act 2012 read with Section 23 of the Drugs Act, 1976. The offences are cognizable under schedule-IV to the DRAP Act, 2012 read with section 30 (2) (a) of the Drugs Act 1976, and are punishable under Schedule-III to the DRAP Act, 2012 read with section 27 of the Drugs Act 1976. You are hereby served show cause notice under section 41 of the Drugs Act, 1976 and rules framed thereunder to explain your position that why you should not be prosecuted for the above-mentioned offences in the Court of competent jurisdiction to award you punishment under the law.

16. If you desire to be heard in person or through your authorized legal counsel, you are directed to intimate this division within seven (7) days of receipt of this letter."

18. The show cause notice were returned back to the section undelivered with comment that despite various visits, the shop was closed.

19. A personal hearing notice was also issued to the accused vide F. No. 03-33/2019-QC(270 CLB) dated 11.10.2019

20. As per directions of the Board, the area FID was also issued a letter to appear before the Board along with the case property in compliance of the decision of the Board. Details of the letter are given as under:

"I am directed refer to the subject cited above and to communicate the decision of 270th meeting of Central Licensing Board held on 10.01.2019 which is reproduced as under;

"1. To issue show cause notice and personal hearing to the following accused persons for the offences committed by them as stated herein below in para 2:

a. M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore through Proprietor Sheikh, Mehmood Ahmed CEO;
b. Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed, (CNIC No. 35202-2973889-9 M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.
c. Yousaf Ejaz S/o. Sh. Ejaz Ahmed (Partner) M/s. Cheap Medical Store (Pvt.)

Ltd., 27-New Anarkali, Lahore.
d. Sheikh Mehmood Ahmed CEO and qualified person M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore
2. The mentioned accused persons have committed offence by violating provisions of heading A of Schedule-II to the DRAP Act 2012 read with Section 23 of the Drugs Act, 1976. The offences are cognizable under schedule-IV to the DRAP Act, 2012 read with section 30 (2) (a) of the Drugs Act 1976, and are punishable under Schedule-III to the DRAP Act, 2012 read with section 27 of the Drugs Act 1976.

3. Call FID in the upcoming meeting of CLB along with case property."

02. It is therefore requested to comply with the decision of the Board in true letter and spirit."

21. As per the decision of the Board, the accused are called for personal hearing and the FID is called before the Board along with the case property.

Proceedings & Decision of 272nd meeting of CLB held on 17th October, 2019:

22. Central Licensing Board (CLB) was apprised that the Show Cause & Personal Hearing notice were forwarded through Urgent Mail Service which were received back undelivered.

23. To reach the appropriate decision in the light of law, the Board decided as under:

i. Provide final opportunity of personal hearing to following accused and ensure the delivery of the letter through the office of Chief Drugs Controller, Punjab and area FID, DRAP.

- **a. M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore through Proprietor Sheikh, Mehmood Ahmed CEO;**
- **b. Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed, (CNIC No. 35202-2973889-9 M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.**
- **c. Yousaf Ejaz S/o. Sh. Ejaz Ahmed (Partner) M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.**
- **d. Sheikh Mehmood Ahmed CEO and qualified person M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.**

ii. Federal Inspector of Drugs shall appear before the Board along with case file except case property.

24. In compliance to the decision of 272nd meeting of the CLB, Area Federal Inspector of drugs is called before the Board.

25. Furthermore, Personal hearing notice vide F. No. 3-01/2020-QC dated 03-01-2020 was sent to following to appear before the Board for final chance of personal hearing,

a. M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore through Proprietor Sheikh, Mehmood Ahmed CEO;

b. Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed, (CNIC No. 35202-2973889-9 M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.

c. Yousaf Ejaz S/o. Sh. Ejaz Ahmed (Partner) M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.

d. Sheikh Mehmood Ahmed CEO and qualified person M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

26. In compliance to the decision of 272nd meeting of CLB, Mr. Abdul Rasheed Sheikh, Area Federal Inspector of Drugs Lahore, appeared and presented the case before the Board. Area FID agreed to the incomplete challan submitted by IO FIA. He further informed the Board that the show cause notice through special messenger was not delivered but the copies of show cause notice were sent to the residential addresses of the accused persons through TCS.

28. None of the accused appeared before the Board neither by themselves nor through any counsel. They also did not submit a written reply to the served show cause notices.

29. After thorough deliberation and keeping in view the statement of area FID Lahore and facts of the case, the Board decided as under;

A. Board granted permission for prosecution against the following accused for the contraventions of the DRAP Act 2012 and The Drugs Act 1976 as given in Para B.

a. M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore through Proprietor Sheikh, Mehmood Ahmed CEO

b. Sheikh Muhammad Mushtaq s/o. Sheikh Maqsood Ahmed, (CNIC No. 35202-2973889-9 M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore

c. Sheikh Mehmood Ahmed CEO and qualified person M/s. Cheap Medical Store (Pvt.) Ltd., 27-New Anarkali, Lahore.

B. The mentioned accused persons have committed offence by violating provisions of heading A of Schedule-II to the DRAP Act 2012 read with Section 23 of the Drugs Act, 1976. The offences are cognizable under schedule-IV to the DRAP Act, 2012 read with section 30 (2) (a) of the Drugs Act 1976, and are punishable under Schedule-III to the DRAP Act, 2012 read with section 27 of the Drugs Act 1976.

C. The Area Federal Inspector of Drugs, DRAP, Lahore is requested to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.

D. The accused Yousaf Ejaz S/o Sh. Ejaz Ahmed was exonerated on the basis of report submitted by FIA U/s 173 Cr.P.C. where in accused is placed in Column 2 and FID (Investigation officer) agreed with said report. Hence the operation of show cause notice to the extent of accused Yousaf Ejaz S/o. Sh. Ejaz Ahmed is ceased with immediate effect.

Case No. 11: -PERMISSION FOR PROSECUTION W.R.T. SALE OF UNREGISTERED DRUGS BY M/S. NEW SHIFA PHARMACY, 71-JAIL ROAD, OPP. SERVICES HOSPITAL, LAHORE

Proceedings And Decision Of 260th Meeting Of CLB:

Abdul Rashid Shaikh, FID-VI, Lahore vide letter No. 4138/2018-DRAP (L-VI) dated 27-03-2018 reference to special compaign regarding eradication of Spurious/ Sub-standard/ Un-registered drugs on the direction of Honorable Supreme Court of Pakistan.

02. The FID informed that he alongwith Mr. Ajmal Sohail Asif, FID, Lahore and Dr. Akbar Ali, Assistant Director, DRAP, Lahore and hafiz Jawad Muhammad Jawad Ali, Assistant Director, DRAP, Lahore visited the premises of M/s. New Shifa Pharmacy, 71-Jail Road, Opp. Services Hospital, Lahore on 22-03-2018.

03. The FID further informed that he seized the following drugs on Form-2 under Section 18 (1) (f) of the Drugs Act, 1976 & DRAP Act, 2012 and also sealed the premises under Section 18 (1) (h) of the Drug act, 1976.

S. No.	Name of Drug(s) /Articles	Company/Country	Quantity
1.	(Voriconazole) Vorier 200mg Tablets	M/s. Ravian Life science, India	02 Packs x 04's (08 Tablets
2.	Trajenta 5mg Tablets	M/s. Boehringer Ingelheim Roxane, USA	01 Packs x 30's (30 Tablets)
3.	Questran Tablets	M/s. BMS Roma	07 Packs x 12's
4.	Injection colomycin	M/s. Cipla, India.	28 vials
5.	Tablet Pirfenex	M/s. Cipla, India.	23 Packs x 30's
6.	Ferrous Fumrate 210mg Tablets	M/s. Aver Healtcare, UK.	02 Packs x 84's (168 Tablets)
7.	Zovirax 200mg Tablets	M/s. Glaxo Wellcome SA, Spain.	02 Packs x 25's (50 Tablets)
8.	Dioralyte Relief (Powder for Oral Solution)	M/s. Sanoft, UK.	01 Packs x 6's (06 Sachets)
9.	Tablets Anabol	M/s. British, Thailand	One pack of 1000's
10.	Tablets PTU	M/s. T.O. Chemical, Thailand.	300's Tablets
11.	Injection Bonviva	M/s. Roche, Germany.	03 Packs
12.	Injection BCG (Once BCG)	M/s. Serum Institute, India.	07 Packs
13.	Injection Setrol	M/s. Samarth, India.	08 Ampoules.
14.	Injection Acton	M/s. Ferring Germany.	04 Injections
15.	Injecction redox-C	M/s. Bayer, Istanbul.	05 Ampoules
16.	Drop Xalatan	M/s. Pfizer, Istanbul	04 Packs
17.	Tablet Famvir (250mg)	M/s. Novartis, Istanbul.	03 Packs Packs of 21's
18.	Tablets Femara (2.5mg0	M/s. Novartis, Istanbul.	04 Packs Packs of 30's

19.	Tablets Yasmin	M/s. Bayer, Germany.	02 Packs Packs of 21's
20.	Tablets Valcyte (450mg)	M/s. Roch, Istanbul.	01 Packs Packs of 60's
21.	Tablet Marevan (5mg)	M/s. GSK, KSA.	07 Packs Packs of 100's
22.	Tablet Eltroxin 50mg	M/s. Aspen, Ireland	05 Packs Packs of 100's
23.	Tablet Dapson (100mg)	M/s. GSK, Mumbai.	Total tablets 1500's Packs of 1000's
24.	Tablet Bendroflumethiazide 2.5mg	M/s. Actaavis, UK.	04 Packs Packs of 28's
25.	Tablets Hydrocortisone 10mg	M/s. Sanofi, France.	06 Packs Packs of 25's
26.	Tablets Arimidex 1mg	M/s. Astrazenca, Istanbul.	03 Packs Packs of 28's
27.	Tablets Modiodal	M/s. TEVA, Istanbul.	03 Packs Packs of 30's
28.	Tablets Futhyrox (50mcg)	M/s. Merck, Istanbul.	03 Packs Packs of 50's
29.	Tablets Endoxan	M/s. Cadila, Goa, India	02 Packs Packs of 100's
30.	Tablets Genkort 10mg	M/s. Biopharma, Istanbul.	03Packs Packs of 60's
31.	Tablets Methycobal	M/s. Tokyo, Japan.	i) . 03 Packs Pack of 30's ii).. Pack of 100's One Pack
32.	Tablets brilinta 90mg	M/s. Astrazencea, Sweden.	03 Packs Pack of 56's
33.	Tablets Lipior 40 mg	M/s. Pfizer, Istanbul.	03 Packs Packs of 30's
34.	Tablets Hydrocortisone (20mg)	M/s. Institute of Pharmaceutical, S.A.	02 Packs Packs of 30's
35.	Tablets Evista (60mg)	M/s. Daiichi-Synkyo.	08 Packs Packs of 28's
36.	Tablets Singular 10mg	M/s. MSD, Istanbul.	07 Packs Packs of280's
37.	Tablets Imuran 50mg	M/s. Aspen, Germany.	04 Packs Packs of 100's
38.	Tablets Proscar	M/s. MSD, Istanbul.	05 Packs Packs of 28's
39.	Cozaar 50mg Tablets	M/s. MSD, Istanbul.	12 Packs x 28's (336 Tablets)
40.	Crestor 10mg Tablet	M/s. Astrazenca, UK	04 Packs x 28's (112 Tablets)
41.	Crestor 5mg Tablets	M/s. IPR Pharmaceuticals Puerto Rico.	02 Packs x 28's (56 Tablets)
42.	Crestor 20mg Tablets	AstraZeneca UK Ltd, Porto	02 Packs x 28's

		Riko.	(56 Tablets)
43.	Cipralex 20mg Tablets	M/s. Lundbeck ILac Tic Ltd, Istanbul.	05 Packs x 28's (140 Tablets)
44.	Lipitor 10mg Tablets	M/s. Pfizer, Istanbul.	10 Packs x 30's (300 Tablets)
45.	Ceucept 500mg Tablets	M/s.F. Hoffmann, La Roche ltd., Basel.	05 Packs x 50's (250 Tablets)
46.	Tablets Quinine Sulfate (300mg)	M/s. Almus, UK	02 Packs Pack of 28's
47.	Tablets Cipralex (10mg)	M/s. Lundbeck, Istanbul.	07 Packs Pack of 28's
48.	Capsule Flomax (0.4mg)	M/s. Astellas Pharma, Hollanda.	06 Packs Pack of 30's
49.	Tablets Neurobion	M/s. merck, Austria.	08 Packs Pack of 20's
50.	TabletsFlutamide	M/s. Samarth, India.	05 Packs Pack of 30's
51.	Tablets Lipitor 20mg	M/s. Pfizer, Istanbul.	04 Packs Pack of 30's
52.	Tablets Largactil (10mg)	M/s. Aventis, Istanbul.	05 Packs Total Tab: 160's Pack of 30's
53.	Prograf 0.5 mg Capsule	M/s. Astellas, Ireland.	03 Packs x 50's (150 Capsules)
54.	Avodart 0.5mg Capsules	M/s. GSK, Polonya (Poland)	03 Packs x 30's (90 Capsules)
55.	Roaccutane 20mg Capsules	M/s. F. Hoffmann, La Roche, Basel.	02 Packs x 30's (60 Capsules)
56.	Lioresal 10mg Tablets	M/s. Novartis Pharma AG, Basel.	05 Packs x 50's (250 Capsules)
57.	Nicorette 2mg gum	M/s. Johnson & Johnson Hellas consumer AE.	03 Packs x 105's (315gums units)
58.	Premarin Vaginal Cream 14g	M/s. Pfizer Canda.	05 Packs x 01's (05 Tubes)
59.	Desmopressin Nasal Spray 2.5ml Vial	M/s. Ferring GMbH, Germany.	08 Packs x 01's (08 Spray Vials)
60.	Ucholine 5mg Tablets	M/s. M & H Manufacturing Co. Ltd., Thailand.	01 Packs x 100's (100 Tablets)
61.	Tablets Eltroxin 100mg	M/s. Aspin, Germany.	10 Bottles Pack of 100's.
62.	Tablets Furolin	M/s. Iasis Greece	05 Packs Pack of 30's.
63.	Tablets Salazopyrin 500mg	M/s. Pharmacia, Sweden	02 Packs Pack of 100's.

64.	Tablets Zyprexa	M/s. Lilly, Istanbul.	05 Packs Pack of 28's.
65.	Capsule Kreon- 1000IU	M/s. Abbott, Germany.	05 Packs Pack of 1000's.
66.	Tablets Mysoline	M/s. Siti Lab. S.r.l.	04 Packs Pack of 30's.
67.	Tablets Xoponex Solution	M/s. Oak, Pharma.	02 Packs Pack of 24's.
68.	Capsule Neuron 300mg	M/s. Pfizer, Cypres Branch.	03 Packs Pack of 50's.
69.	Ventolin Solution	M/s. GSK, Australia	02 Packs Pack of20's.
70.	Injection Methycobal	M/s. Eisa, Japan.	Total 22 Inj. Pack of 10's.
71.	Capsule Enfluvir 75mg	M/s. Ataby, Istanbul.	04 Packs Pack of 10's.
72.	Tablets Dostirex	M/s. Pfizer, Istanbul.	05 Packs Pack of 08's.
73.	Tablets Trental 400mg	M/s. Sanofi, Germany.	03Packs Pack of 20's.
74.	Capsule Tamiflu	M/s. Roche, USA	03 Packs Pack of 10's.
75.	Prograf 1mg Capsule	M/s. Astellas Ireland Co., Ltd.,. Killorglin, Irlanda	03 Packs x 50's (150 Capsules)
76.	Simvastatin 20mg Tablets	M/s. Aurobindo Pharma Ltd, UK	04 Packs x 28's (112 Tablets)
77.	Natrilix SR 1.5mg Tablets	M/s. Les Laboratories Servier, France.	03 Packs x 30's (90 Tablets)
78.	Soranib 200mg Tablets	M/s. Cipla Ltd., Goa, India.	04 Packs x 30's (120 Tablets)
79.	Epanutin 100mg Capsules	M/s. Pfizer, Istanbul.	180 Tablets
80.	Amphotret 50mg Lyophilized for Injection	M/s. Gufic Biosciences Ltd., Gujrat, India.	04 Packs x 01's (04 Vials)
81.	Ucholine 10mg Tablets	M/s. M & H Manufacturing Co., Ltd., Thailand.	01 Packs x 100's (100 Tablets)
82.	Myotonine 25mg Tablets	M/s. Glenevood GMBH, Germany.	01 Packs x 100's (100 Tablets)
83.	Bayer 81mg Tablets	Bayer, Spain.	04 Packs x 120's (480 Tablets)
84.	Diprofos Injection (2mg+5mg/ml) (2ml Ampoule).	M/s. Schering Plugh, Belgium.	06 Packs x 01's (06 Ampoules)
85.	Sabril 500mg Tablets	M/s. Patheon, France.	01 Packs x 100's (100 Tablets)
86.	Spiriva 18ug Inhaler	M/s. Boehringer Ingelheim Pharma GmbH, Germany.	01 Packs of 30 Capsules + Inhaler device)
87.	HYZAAR Tablets	M/s. MSD, Istanbul.	01 Packs x 28's (28 Tablets)

88.	Phenoxymethy I Pencillin Tablets 250mg	M/s. Cresent Pharma Ltd., UK.	10 Packs x 28's (280 Tablets)
89.	Zyprexa 5mg Tablets	M/s. Lilly SA, Spain.	01 Packs x 28's (28 Tablets)
90.	Zyprexa 10mg Tablets	M/s. Lilly SA, Spain	01 Packs x 28's (28 Tablets)
91.	Exelon Patch Transdermal	M/s. Novartis Pharma AG, Basel.	01 Packs x 30's (30 Patches)
92.	Exelon Patch 10	M/s. Novartis, Switerland.	03 Packs Packs of 30's
93.	Tablets Dulcolax	M/s. Boehringer, Germany.	02 Packs Packs of 30's
94.	Tablets Mestinon	M/s. MEDA Switzerland.	01 Packs Packs of 150's
95.	Injection Konkion	M/s. Roche, Istanbul.	Total 08 Ampoules Packs of 05 Ampoules
96.	Tablets Leukeram 2mg	M/s. Aspen, Ireland.	03 Packs Packs of 25's
97.	Capsules Lenalidomide	M/s. Natco, India	01 Packs Packs of 30's
98.	Tablets Alkceran 2mg	M/s. Aspen, Ireland.	02 Packs Packs of 25's
99.	Tablets Tylenol 500mg	M/s. Mcneil, Canada.	100 + 24 Tablets Packs of 100's
100.	Tablets Zaroxolyn 5mg	M/s. Teofarma s.r.l.	02 Packs Packs of 50's
101.	Tablets Mydekla 60	M/s. Mylan, India	On Pack Pack of 28's.
102.	Injection Zoledronic Acid (Zoldrea) 4mg	M/s. Cipla, India	01 Pack
103.	Napa 250 Suppositories	M/s. Beximco Pharmaceuticals, Bangladesh.	01 Pack
104.	Tablets Zytanix 5	M/s. Zydus Healthca, India.	70 Tablets
105.	Tablets Cytotec 200	M/s. Pfizer Ltd., UK	02 Pack 60 120 Tablets
106.	Conugated Estrogen Vaginal Cream (Dremasin)	M/s. Pfizer Inc, Canada.	03 Packs
107.	Emla 5% Cream	M/s. Astra Zeneca, Sweden	02 Packs
108.	Injection Plymyxin B (500000 Units)	M/s. Samarth Life Sciences Sconss (Pvt.) Ltd., India.	04 packs + 15= 19 Packs
109.	Tablets Moxal Plus	M/s. Julphar Gluf Pharma, U.A.E.	01 Pack 30 Tablets.
110.	Tablets Votrient 400mg	M/s. Glaxo Wellcome S.A, Spain.	01 Pack
110-A	Injection amphotret 50mg	M/s. Gufic Biosciences India	02 Pack.
111.	Tablets Viagra 100mg	M/s. Pfizer UK	03 Pack x 4
112.	Tablets Cialis 20mg	M/s. Eliy Lilly, UK	(10x6) Packs

			60 Tablets
113.	Tablets Viagra 50mg	M/s. Pfizer, USA.	(6x6) Packs 36 Tablets
114.	Tablets Viagra 100mg	M/s. Pfizer, USA	(60x6) Packs 24 Tablets
115.	Tablets Valis Gold 20mg	M/s. Eliy Lilly, USA	(03x10) 30 Tablets
116.	Tablets Pengra 100mg	M/s. Scadia Health Care, India	05 Pack x 4 (20 Tablets)
117.	Tablets Cialis 20mg	M/s. Eliy Lilly, Spain	06 Tablets
118.	Procomil Spray (Long time spray for men)	M/s. Water Putter Pharmaceutical Germany.	02 Packs
119.	Tablets Red Viagra	M/s. Force Cwmite, USA.	02 Packs x 10 20 Tablets
120.	Tablets Viagra Gold, USA	M/s. USA	01 Pack 10 Tablets
120-A	Tablets Pengra 100mg	M/s. Maiden Pharmaceutical Kudu, India.	200 Tablets
121.	Glutax 5GS Micro	M/s. Dermedical Skin Sumces, UK	One Pack.
122.	Injection Zoladex 3.6 mg Depot	M/s. Astra Zenica, Sweden	02 Packs
123.	Tablets Plaquenil 200mg	M/s. Sanofi, Istanbul.	04 Packs x 30 120 Tablets
124.	Injection coverject 20mcg Microgram	M/s. Pfizer, UK.	03 Pack x 02 06 Injection
125.	Oramin-F Soft Capsule	M/s. Daewo Pharm, Korea	03 Pack x 30 90 Capsules
125-A	Injection fungigove 50mg	M/s. Bristol Mayer Squibb, Istanbul.	06 Packs
126.	Tablets Everlong 60 mg	M/s. Everest Pharma, Islamabad	05 Packs x10 50 Tablets
127.	Injection TAD 600mg / 4ml	M/s. Bio Medica Foscama, S.P.A.	05 Injection
128.	Solcoserye Jelly 10%	M/s. Legacy Pharmaceuticals, Switzerland.	05 Packs
129.	Tablets Sroquel 100mg	M/s. Astra Jeneca, Istanbul.	05 Packs x 30 150 Tablets
130.	Tablets Bonviva 150mg	M/s. Roche Istanbul	03 Packs x 03 09 Tablets
130-A	Injection Fluanxol Depot 20mg	M/s. Lundbeck, Copenhagen	01 Packs x10 10 Injection
131.	Tablets Cialis Black 200mg	M/s. UK (Claimed)	04 Packs x06 24 Tablets
132.	Tablets Cialis 05mg	M/s. Eliy Lilly, Spain.	1x28 Tablets
133.	Tablets Soft Viagra 100mg	M/s. Pfizer	02 Pack x 8 16 Tablets
134.	Tablets Cialis 20mg	M/s. Eliy Lilly, Spain.	03 Pack x 02

			06 Tablets
135.	Tablets Levitra 20mg	M/s. Bayer, Istanbul.	02 Pack x04 08 Tablets
136.	Lipitor Tablets 10mg	M/s. Pfizer, Istanbul.	04 Box Box of 30's
137.	Capsule Anagrelide 0.5mg	M/s. Teva Pharma, USA.	04 Bottles Box of 100's
138.	Injection Neurobion 3ml (Ampoule)	M/s. Merck Germany.	Box of 3's x 10
139.	Tablets Ebixa 10mg	M/s. Lundbock Istanbul.	Box of 100's x 2
140.	Tablets Ebixa 20mg	M/s. Lundbock Istanbul.	Box of 28's Total Tablets 98.

04. The FID further informed that the above mentioned were recovered and seized in the presence of

1. Mr. Mehmood Manzoor, Proprietor (Person Present)
2. Ms. Iqra Afzal, a newly appointed qualified person (Person Present), as proprietor has applied for change of the qualified person (Person Present),
3. Mr. Tariq Mehmood, Partner also arrived there.

05. The witnesses were also recorded on the seizure form. The premises were also sealed under section 18 (1) (h) of the Drugs Act, 1976 and sealed keys were handed over to Mr. Mehmood Manzoor, Proprietor at the spot in the presence of the above witnesses.

i. **The FID requested the competent authority to grant permission for safe custody of seized drugs as mentioned above till decision of the case under Section 19 (5) (b) of the Druga Act, 1976 read with Schedule-V to the DRAP Act, 2012.**

ii. **The FID also requested the Competent Authority for continuing the sealing period of the premises may also be granted under the relevant provision of the Drugs Act, 1976/ DRAP Act, 2012.**

06. The accused persons have violated schedule II and schedule III of DRAP Act 2012 as under:-

i. sale/storage of unregistered drugs.

ii. sale/storage of drugs without invoice warranties.

iii. **Sale/storage smuggled drugs without import authorization**

07. The said violations are cognizable offence under schedule IV of DRAP Act 2012, it is therefore submitted that permission for Registration of FIR against the accused persons may be allowed to the FID. However decision about qualified person may be done as deemed appropriate as he is not officially appointed and approved under the rules.

08. The central Licensing Board in its 260th meeting held on 16-04-2018 Decided as under:

1. **Allowed safe custody to the Federal Inspector of drugs till the finalization of the case.**
2. **permission for Registration of FIR against the accused persons was allowed to the FID**

    1. **Mr. Mehmood Manzoor, Proprietor (Person Present)**
    2. **Ms. Iqra Afzal, a newly appointed qualified person (Person Present), as proprietor has applied for change of the qualified person (Person Present),**
    3. **Mr. Tariq Mehmood, Partner also arrived there.**

3. **Sealing period was extended for further 90 days as prescribed under the law**

Proceedings of 261st meeting of CLB:

09. The accused person filed de-sealing application No. 36/2018 in the Drug Court Lahore and the Drug Court Lahore de sealed the premises on the following grounds:-

i. We understand that this is a licensed premises of the petitioner and has been sealed for one month. We note that however the only point of any merit before the this court was fact that if the premises is not de-seal than the legal medicines would deteriorate as air conditioning is not turned on accordingly we allow the premises de-selaed subject to the condition of affidavit that petitioner will not contravened the provision of Drug Act 1976 and to provide two sureties in some of rupees five hundred thousand each to the satisfaction of this court:-, further we direct the CDC to carry out or review of Drug Sale license of the New Shifa medical store as it is quite apparent that the premises operating in breach of licensing rules and qualified person was not present at the time of inspection.

10. It is pertinent to mentioned that 140 unregistered drugs products were recovered from the accused and the FIDs issued letter No. 4139/2018 dated 27-03-2018 and 4975/2018 dated 12-04-2018 but they failed to produced invoice warranties of seized drugs accordingly but Drug Court de sealed the premises vide their order dated 24-04-2018. Accordingly the premises was de-sealed by the FID on 25-04-2018.

11. As there are huge contraventions by the petitioners and Drug Court has also directed CDC to review the Drug Sale license of the New Shifa Pharmacy Lahore it is therefore submitted to the Board for the grant of

a. **To file appeal before the High Court against the decision of Drug Court Lahore to restore the sealing of M/s New Shifa Pharmacy Lahore till the finalization of**

the case, as the CLB has already approved extension of sealing period for further 90 days but the same could not be conveyed to the FID timely, as the minutes were under approval.

b. **To allow Additional Director DRAP (E&M) to file appeal against the decisions of the Drug Courts.**
c. **To recommend CDC Punjab for cancellation of Drug Sale License of M/s New Shifa Pharmacy Lahore as per order of the Drug Court Lahore. FID shall be directed to provide the copy of the decision of the Drug Court along with decision of CLB to CDC Punjab for cancellation of Drug Sale License**

12. The central Licensing Board in its 261st meeting held on 02-05-2018 Decided as under:

a. **To file appeal before the High Court against the decision of Drug Court Lahore to restore the sealing of M/s New Shifa Pharmacy Lahore till the finalization of the case, as the CLB has already approved extension of sealing period for further 90 days but the same could not be conveyed to the FID timely, as the minutes were under approval.**
b. **Allowed Additional Director DRAP (E&M), Karachi, Lahore, Peshawar and Islamabad to file appeal against the decisions of the Drug Courts as and when required. CLB also allowed to file appeal in the instant case.**
c. **Recommended to the CDC Punjab for cancellation of Drug Sale License of M/s New Shifa Pharmacy Lahore as per order of the Drug Court Lahore. FID shall be directed to provide the copy of the decision of the Drug Court along with decision of CLB to CDC Punjab for cancellation of Drug Sale License**

13. The decision of 261st meeting of CLB held on 2nd May, 2018 was communicated vide letter no 3-33/2018-QC(pt-261-CLB) dated 24th May 2018 to area FID Lahore, as under;

"*Recommended to the CDC Punjab for cancellation of Drug Sale License of M/s. New Shifa Pharmacy Lahore. FID shall be directed to provide the copy of the decision of the Drug Court along with decision of CLB to CDC Punjab for cancellation of Drug Sale License"*

14. The area FID Lahore vide letter No. 7948/2018-DRAP (L-VI) dated 07-06-2018 communicated the recommendations of the CLB to The Chief Drugs Controller Punjab.

15. In compliance to the decision of 260th meeting of CLB held on 16-04-2018 the area FID Lahore vide letter No.8226/2018-DRAP-(L-VI) dated 12-06-2018 requested FIA CCC, Lahore to lodge FIR against the accused persons. Subsequently the FIA CCC, Lahore registered FIR No. C-150/2018 with date and hour of reporting 17-07-2018 at 1:00pm against the accused persons.

16. The area FID Lahore vide letter No. 12615/2018-DRAP (L-VI) dated 28-09-2018 submitted incomplete challan of accused persons of M/s. New Shifa Pharmacy, 71-Jail Road, Opp. Services Hospital, Lahore which is reproduced as under;

"Brief facts of the case generated sir, please refer to the contents of FIR registered by the undersigned it is submitted that Istighasa received from Abdul Rashid Shaikh Federal Inspector of Drugs Lahore vide letter No. 8226/2018-DRAP-(L-IV) which is being reproduced as under: The Direcrot, Federal Investigation Agency, Temple Road Lahore Sub: Request for lodging FIR Against the Management of M/s. New Shifa Pharmacy, 71-Jail Road, Opp. Services Hospital,

Lahore. I am directed to refere to the subject cited above and to say that the undersigned along with Mr. ajmal Sohail Asif, Federal Inspector of Drugs, DRAP Lahore and Hafiz Muhammad Jawad Ali, Assistant Director, DRAP, Lahore inspected the premises of M/s. New Shifa Pharmacy, 71-Jail Road, Opp. Services Hospital, Lahore, on 22-03-2018 out about 1:00pm. The following drugs / therapeutic goods were seized on From-2, under section 18 (1) (f) of the Drugs Act 1976 read with schedule-V to the DRAP Act, 2012 and also sealed the premises due to sale and stocking of huge quantity of un-registered / smuggled drugs. Copy of sealing memo(23 pages), Form-2 and sealed keys were handed over to Mr. Mehmood Manzoor, Proprietor, at the spot in the presence of the Qualified Person, namely Ms. Iqra Afzal and above witnesses (Annex A/I to A/23):

S. No.	***Name of Drug(s) /Articles***	*Company/Country*	*Quantity*
1.	*(Voriconazole) Vorier 200mg Tablets*	*M/s. Ravian Life science, India*	*02 Packs x 04's (08 Tablets*
2.	*Trajenta 5mg Tablets*	*M/s. Boehringer Ingelheim Roxane, USA*	*01 Packs x 30's (30 Tablets)*
3.	*Questran Tablets*	*M/s. BMS Roma*	*07 Packs x 12's*
4.	*Injection colomycin*	*M/s. Cipla, India.*	*28 vials*
5.	*Tablet Pirfenex*	*M/s. Cipla, India.*	*23 Packs x 30's*
6.	*Ferrous Fumrate 210mg Tablets*	*M/s. Aver Healtcare, UK.*	*02 Packs x 84's (168 Tablets)*
7.	*Zovirax 200mg Tablets*	*M/s. Glaxo Wellcome SA, Spain.*	*02 Packs x 25's (50 Tablets)*
8.	*Dioralyte Relief (Powder for Oral Solution)*	*M/s. Sanoft, UK.*	*01 Packs x 6's (06 Sachets)*
9.	*Tablets Anabol*	*M/s. British, Thailand*	*One pack of 1000's*
10.	*Tablets PTU*	*M/s. T.O. Chemical, Thailand.*	*300's Tablets*
11.	*Injection Bonviva*	*M/s. Roche, Germany.*	*03 Packs*
12.	*Injection BCG (Once BCG)*	*M/s. Serum Institute, India.*	*07 Packs*
13.	*Injection Setrol*	*M/s. Samarth, India.*	*08 Ampoules.*
14.	*Injection Acton*	*M/s. Ferring Germany.*	*04 Injections*
15.	*Injecction redox-C*	*M/s. Bayer, Istanbul.*	*05 Ampoules*
16.	*Drop Xalatan*	*M/s. Pfizer, Istanbul*	*04 Packs*
17.	*Tablet Famvir (250mg)*	*M/s. Novartis, Istanbul.*	*03 Packs Packs of 21's*
18.	*Tablets Femara (2.5mg0*	*M/s. Novartis, Istanbul.*	*04 Packs Packs of 30's*
19.	*Tablets Yasmin*	*M/s. Bayer, Germany.*	*02 Packs Packs of 21's*
20.	*Tablets Valcyte (450mg)*	*M/s. Roch, Istanbul.*	*01 Packs Packs of 60's*
21.	*Tablet Marevan (5mg)*	*M/s. GSK, KSA.*	*07 Packs Packs of 100's*
22.	*Tablet Eltroxin 50mg*	*M/s. Aspen, Ireland*	*05 Packs Packs of 100's*
23.	*Tablet Dapson (100mg)*	*M/s. GSK, Mumbai.*	*Total tablets 1500's Packs of 1000's*
24.	*Tablet Bendroflumethiazide*	*M/s. Actaavis, UK.*	*04 Packs*

	2.5mg		*Packs of 28's*
25.	*Tablets Hydrocortisone 10mg*	*M/s. Sanofi, France.*	*06 Packs* *Packs of 25's*
26.	*Tablets Arimidex 1mg*	*M/s. Astrazenca, Istanbul.*	*03 Packs* *Packs of 28's*
27.	*Tablets Modiodal*	*M/s. TEVA, Istanbul.*	*03 Packs* *Packs of 30's*
28.	*Tablets Futhyrox (50mcg)*	*M/s. Merck, Istanbul.*	*03 Packs* *Packs of 50's*
29.	*Tablets Endoxan*	*M/s. Cadila, Goa, India*	*02 Packs* *Packs of 100's*
30.	*Tablets Genkort 10mg*	*M/s. Biopharma, Istanbul.*	*03Packs* *Packs of 60's*
31.	*Tablets Methycobal*	*M/s. Tokyo, Japan.*	*i) . 03 Packs* *Pack of 30's* *ii).. Pack of 100's* *One Pack*
32.	*Tablets brilinta 90mg*	*M/s. Astrazencea, Sweden.*	*03 Packs* *Pack of 56's*
33.	*Tablets Lipior 40 mg*	*M/s. Pfizer, Istanbul.*	*03 Packs* *Packs of 30's*
34.	*Tablets Hydrocortisone (20mg)*	*M/s. Institute of Pharmaceutical, S.A.*	*02 Packs* *Packs of 30's*
35.	*Tablets Evista (60mg)*	*M/s. Daiichi-Synkyo.*	*08 Packs* *Packs of 28's*
36.	*Tablets Singular 10mg*	*M/s. MSD, Istanbul.*	*07 Packs* *Packs of280's*
37.	*Tablets Imuran 50mg*	*M/s. Aspen, Germany.*	*04 Packs* *Packs of 100's*
38.	*Tablets Proscar*	*M/s. MSD, Istanbul.*	*05 Packs* *Packs of 28's*
39.	*Cozaar 50mg Tablets*	*M/s. MSD, Istanbul.*	*12 Packs x 28's* *(336 Tablets)*
40.	*Crestor 10mg Tablet*	*M/s. Astrazenca, UK*	*04 Packs x 28's* *(112 Tablets)*
41.	*Crestor 5mg Tablets*	*M/s. IPR Pharmaceuticals Puerto Rico.*	*02 Packs x 28's* *(56 Tablets)*
42.	*Crestor 20mg Tablets*	*AstraZeneca UK Ltd, Porto Riko.*	*02 Packs x 28's* *(56 Tablets)*
43.	*Cipralex 20mg Tablets*	*M/s. Lundbeck ILac Tic Ltd, Istanbul.*	*05 Packs x 28's* *(140 Tablets)*
44.	*Lipitor 10mg Tablets*	*M/s. Pfizer, Istanbul.*	*10 Packs x 30's* *(300 Tablets)*
45.	*Ceucept 500mg Tablets*	*M/s.F. Hoffmann, La Roche ltd., Basel.*	*05 Packs x 50's* *(250 Tablets)*
46.	*Tablets Quinine Sulfate (300mg)*	*M/s. Almus, UK*	*02 Packs* *Pack of 28's*
47.	*Tablets Cipralex (10mg)*	*M/s. Lundbeck, Istanbul.*	*07 Packs* *Pack of 28's*

48.	*Capsule Flomax (0.4mg)*	*M/s. Astellas Pharma, Hollanda.*	*06 Packs* *Pack of 30's*
49.	*Tablets Neurobion*	*M/s. merck, Austria.*	*08 Packs* *Pack of 20's*
50.	*TabletsFlutamide*	*M/s. Samarth, India.*	*05 Packs* *Pack of 30's*
51.	*Tablets Lipitor 20mg*	*M/s. Pfizer, Istanbul.*	*04 Packs* *Pack of 30's*
52.	*Tablets Largactil (10mg)*	*M/s. Aventis, Istanbul.*	*05 Packs* *Total Tab: 160's* *Pack of 30's*
53.	*Prograf 0.5 mg Capsule*	*M/s. Astellas, Ireland.*	*03 Packs x 50's* *(150 Capsules)*
54.	*Avodart 0.5mg Capsules*	*M/s. GSK, Polonya (Poland)*	*03 Packs x 30's* *(90 Capsules)*
55.	*Roaccutane 20mg Capsules*	*M/s. F. Hoffmann, La Roche, Basel.*	*02 Packs x 30's* *(60 Capsules)*
56.	*Lioresal 10mg Tablets*	*M/s. Novartis Pharma AG, Basel.*	*05 Packs x 50's* *(250 Capsules)*
57.	*Nicorette 2mg gum*	*M/s. Johnson & Johnson Hellas consumer AE.*	*03 Packs x 105's* *(315gums units)*
58.	*Premarin Vaginal Cream 14g*	*M/s. Pfizer Canda.*	*05 Packs x 01's* *(05 Tubes)*
59.	*Desmopressin Nasal Spray 2.5ml Vial*	*M/s. Ferring GMbH, Germany.*	*08 Packs x 01's* *(08 Spray Vials)*
60.	*Ucholine 5mg Tablets*	*M/s. M & H Manufacturing Co. Ltd., Thailand.*	*01 Packs x 100's* *(100 Tablets)*
61.	*Tablets Eltroxin 100mg*	*M/s. Aspin, Germany.*	*10 Bottles* *Pack of 100's.*
62.	*Tablets Furolin*	*M/s. Iasis Greece*	*05 Packs* *Pack of 30's.*
63.	*Tablets Salazopyrin 500mg*	*M/s. Pharmacia, Sweden*	*02 Packs* *Pack of 100's.*
64.	*Tablets Zyprexa*	*M/s. Lilly, Istanbul.*	*05 Packs* *Pack of 28's.*
65.	*Capsule Kreon- 1000IU*	*M/s. Abbott, Germany.*	*05 Packs* *Pack of 1000's.*
66.	*Tablets Mysoline*	*M/s. Siti Lab. S.r.l.*	*04 Packs* *Pack of 30's.*
67.	*Tablets Xoponex Solution*	*M/s. Oak, Pharma.*	*02 Packs* *Pack of 24's.*
68.	*Capsule Neuron 300mg*	*M/s. Pfizer, Cypres Branch.*	*03 Packs* *Pack of 50's.*
69.	*Ventolin Solution*	*M/s. GSK, Australia*	*02 Packs*

			Pack of20's.
70.	*Injection Methycobal*	*M/s. Eisa, Japan.*	*Total 22 Inj.* *Pack of 10's.*
71.	*Capsule Enfluvir 75mg*	*M/s. Ataby, Istanbul.*	*04 Packs* *Pack of 10's.*
72.	*Tablets Dostirex*	*M/s. Pfizer, Istanbul.*	*05 Packs* *Pack of 08's.*
73.	*Tablets Trental 400mg*	*M/s. Sanofi, Germany.*	*03Packs* *Pack of 20's.*
74.	*Capsule Tamiflu*	*M/s. Roche, USA*	*03 Packs* *Pack of 10's.*
75.	*Prograf 1mg Capsule*	*M/s. Astellas Ireland Co., Ltd.,. Killorglin, Irlanda*	*03 Packs x 50's (150 Capsules)*
76.	*Simvastatin 20mg Tablets*	*M/s. Aurobindo Pharma Ltd, UK*	*04 Packs x 28's (112 Tablets)*
77.	*Natrilix SR 1.5mg Tablets*	*M/s. Les Laboratories Servier, France.*	*03 Packs x 30's (90 Tablets)*
78.	*Soranib 200mg Tablets*	*M/s. Cipla Ltd., Goa, India.*	*04 Packs x 30's (120 Tablets)*
79.	*Epanutin 100mg Capsules*	*M/s. Pfizer, Istanbul.*	*180 Tablets*
80.	*Amphotret 50mg Lyophilized for Injection*	*M/s. Gufic Biosciences Ltd., Gujrat, India.*	*04 Packs x 01's (04 Vials)*
81.	*Ucholine 10mg Tablets*	*M/s. M & H Manufacturing Co., Ltd., Thailand.*	*01 Packs x 100's (100 Tablets)*
82.	*Myotonine 25mg Tablets*	*M/s. Glenevood GMBH, Germany.*	*01 Packs x 100's (100 Tablets)*
83.	*Bayer 81mg Tablets*	*Bayer, Spain.*	*04 Packs x 120's (480 Tablets)*
84.	*Diprofos Injection (2mg+5mg/ml) (2ml Ampoule).*	*M/s. Schering Plugh, Belgium.*	*06 Packs x 01's (06 Ampoules)*
85.	*Sabril 500mg Tablets*	*M/s. Patheon, France.*	*01 Packs x 100's (100 Tablets)*
86.	*Spiriva 18ug Inhaler*	*M/s. Boehringer Ingelheim Pharma GmbH, Germany.*	*01 Packs of 30 Capsules + Inhaler device)*
87.	*HYZAAR Tablets*	*M/s. MSD, Istanbul.*	*01 Packs x 28's (28 Tablets)*
88.	*Phenoxymethy I Pencillin Tablets 250mg*	*M/s. Cresent Pharma Ltd., UK.*	*10 Packs x 28's (280 Tablets)*
89.	*Zyprexa 5mg Tablets*	*M/s. Lilly SA, Spain.*	*01 Packs x 28's (28 Tablets)*
90.	*Zyprexa 10mg Tablets*	*M/s. Lilly SA, Spain*	*01 Packs x 28's (28 Tablets)*
91.	*Exelon Patch Transdermal*	*M/s. Novartis Pharma AG, Basel.*	*01 Packs x 30's (30 Patches)*
92.	*Exelon Patch 10*	*M/s. Novartis, Switerland.*	*03 Packs* *Packs of 30's*
93.	*Tablets Dulcolax*	*M/s. Boehringer, Germany.*	*02 Packs*

			Packs of 30's
94.	*Tablets Mestinon*	*M/s. MEDA Switzerland.*	*01 Packs* *Packs of 150's*
95.	*Injection Konkion*	*M/s. Roche, Istanbul.*	*Total 08 Ampoules* *Packs of 05 Ampoules*
96.	*Tablets Leukeram 2mg*	*M/s. Aspen, Ireland.*	*03 Packs* *Packs of 25's*
97.	*Capsules Lenalidomide*	*M/s. Natco, India*	*01 Packs* *Packs of 30's*
98.	*Tablets Alkceran 2mg*	*M/s. Aspen, Ireland.*	*02 Packs* *Packs of 25's*
99.	*Tablets Tylenol 500mg*	*M/s. Mcneil, Canada.*	*100 + 24 Tablets* *Packs of 100's*
100.	*Tablets Zaroxolyn 5mg*	*M/s. Teofarma s.r.l.*	*02 Packs* *Packs of 50's*
101.	*Tablets Mydekla 60*	*M/s. Mylan, India*	*On Pack* *Pack of 28's.*
102.	*Injection Zoledronic Acid (Zoldrea) 4mg*	*M/s. Cipla, India*	*01 Pack*
103.	*Napa 250 Suppositories*	*M/s. Beximco Pharmaceuticals, Bangladesh.*	*01 Pack*
104.	*Tablets Zytanix 5*	*M/s. Zydus Healthca, India.*	*70 Tablets*
105.	*Tablets Cytotec 200*	*M/s. Pfizer Ltd., UK*	*02 Pack 60* *120 Tablets*
106.	*Conugated Estrogen Vaginal Cream (Dremasin)*	*M/s. Pfizer Inc, Canada.*	*03 Packs*
107.	*Emla 5% Cream*	*M/s. Astra Zeneca, Sweden*	*02 Packs*
108.	*Injection Plymyxin B (500000 Units)*	*M/s. Samarth Life Sciences Sconss (Pvt.) Ltd., India.*	*04 packs + 15= 19 Packs*
109.	*Tablets Moxal Plus*	*M/s. Julphar Gluf Pharma, U.A.E.*	*01 Pack 30 Tablets.*
110.	*Tablets Votrient 400mg*	*M/s. Glaxo Wellcome S.A, Spain.*	*01 Pack*
110-A	*Injection amphotret 50mg*	*M/s. Gufic Biosciences India*	*02 Pack.*
111.	*Tablets Viagra 100mg*	*M/s. Pfizer UK*	*03 Pack x 4*
112.	*Tablets Cialis 20mg*	*M/s. Eliy Lilly, UK*	*(10x6) Packs* *60 Tablets*
113.	*Tablets Viagra 50mg*	*M/s. Pfizer, USA.*	*(6x6) Packs* *36 Tablets*
114.	*Tablets Viagra 100mg*	*M/s. Pfizer, USA*	*(60x6) Packs* *24 Tablets*
115.	*Tablets Valis Gold 20mg*	*M/s. Eliy Lilly, USA*	*(03x10)* *30 Tablets*
116.	*Tablets Pengra 100mg*	*M/s. Scadia Health Care, India*	*05 Pack x 4 (20 Tablets)*
117.	*Tablets Cialis 20mg*	*M/s. Eliy Lilly, Spain*	*06 Tablets*

118.	*Procomil Spray (Long time spray for men)*	*M/s. Water Putter Pharmaceutical Germany.*	*02 Packs*
119.	*Tablets Red Viagra*	*M/s. Force Cwmite, USA.*	*02 Packs x 10 20 Tablets*
120.	*Tablets Viagra Gold, USA*	*M/s. USA*	*01 Pack 10 Tablets*
120-A	*Tablets Pengra 100mg*	*M/s. Maiden Pharmaceutical Kudu, India.*	*200 Tablets*
121.	*Glutax 5GS Micro*	*M/s. Dermedical Skin Sumces, UK*	*One Pack.*
122.	*Injection Zoladex 3.6 mg Depot*	*M/s. Astra Zenica, Sweden*	*02 Packs*
123.	*Tablets Plaquenil 200mg*	*M/s. Sanofi, Istanbul.*	*04 Packs x 30 120 Tablets*
124.	*Injection coverject 20mcg Microgram*	*M/s. Pfizer, UK.*	*03 Pack x 02 06 Injection*
125.	*Oramin-F Soft Capsule*	*M/s. Daewo Pharm, Korea*	*03 Pack x 30 90 Capsules*
125-A	*Injection fungigove 50mg*	*M/s. Bristol Mayer Squibb, Istanbul.*	*06 Packs*
126.	*Tablets Everlong 60 mg*	*M/s. Everest Pharma, Islamabad*	*05 Packs x10 50 Tablets*
127.	*Injection TAD 600mg / 4ml*	*M/s. Bio Medica Foscama, S.P.A.*	*05 Injection*
128.	*Solcoserye Jelly 10%*	*M/s. Legacy Pharmaceuticals, Switzerland.*	*05 Packs*
129.	*Tablets Sroquel 100mg*	*M/s. Astra Jeneca, Istanbul.*	*05 Packs x 30 150 Tablets*
130.	*Tablets Bonviva 150mg*	*M/s. Roche Istanbul*	*03 Packs x 03 09 Tablets*
130-A	*Injection Fluanxol Depot 20mg*	*M/s. Lundbeck, Copenhagen*	*01 Packs x10 10 Injection*
131.	*Tablets Cialis Black 200mg*	*M/s. UK (Claimed)*	*04 Packs x06 24 Tablets*
132.	*Tablets Cialis 05mg*	*M/s. Eliy Lilly, Spain.*	*1x28 Tablets*
133.	*Tablets Soft Viagra 100mg*	*M/s. Pfizer*	*02 Pack x 8 16 Tablets*
134.	*Tablets Cialis 20mg*	*M/s. Eliy Lilly, Spain.*	*03 Pack x 02 06 Tablets*
135.	*Tablets Levitra 20mg*	*M/s. Bayer, Istanbul.*	*02 Pack x04 08 Tablets*
136.	*Lipitor Tablets 10mg*	*M/s. Pfizer, Istanbul.*	*04 Box Box of 30's*
137.	*Capsule Anagrelide 0.5mg*	*M/s. Teva Pharma, USA.*	*04 Bottles Box of 100's*
138.	*Injection Neurobion 3ml (Ampoule)*	*M/s. Merck Germany.*	*Box of 3's x 10*
139.	*Tablets Ebixa 10mg*	*M/s. Lundbock Istanbul.*	*Box of 100's x 2*

140.	*Tablets Ebixa 20mg*	*M/s. Lundbock Istanbul.*	*Box of 28's Total Tablets 98.*

3. *An explanation letter and a reminder thereof, were sent to the following persons of M/s. New Shifa Pharmacy, 71-Jail Road, Opp. Services Hospital, Lahore vide letter No. 4139/2018-DRAP (L-VI), dated 27-03-2018, and letter No. 4975/2018-DRAP (L-VI), dated 12-04-2018 respectively. i) Mr. Mehrnood Manzoor, Proprietor of M/s. New Shifa Pharmacy, 71-Jail Road. Opp. Services Hospital, Lahore Residence of House No. 189-A. Block D-2, Mohallah Gulshan-e-Ravi. Lahore. ii) Mr. Tariq Mehmood, Partner of M/s. New· Shifa Pharmacy, 71-Jail Road. Opp. Services Hospital, Lahore Residence of House No. 189-A. Block D-2, Mohallah Gulshan-e-Ravi. Lahore. iii) Ms. lqra Afzal, Qualified Person of M/s. New Shifa Pharmacy. 71-Jail Road. Opp. Services Hospital, Lahore.*
4. *The said Mehmood Manzoor and Tariq Mahmood of M/s. New Shifa Pharmacy, 71-Jail Road, Opp. Services Hospital. Lahore. could not provide any invoice / warranty or import documents of the seized drugs and submitted un-satisfactory replies by disowning the seized drugs/ therapeutic goods vide both letters No. Nil, dated. Nil received in this office on 10-05-2018.*
5. *Ms. Iqra Afzal. Qualified Person of M/s. New Shifa Pharmacy. 71-Jail Road. Opp. Services Hospital, Lahore submitted has reply. whereby she also showed her ignorance as to presence/availability of the seized drugs/ therapeutic goods, and informed that she had recently been employed, and had not yet been approved as Qualified person, vide her reply/letter No. Nil dated. Nil*
6. *In the meantime M/s. Shifa Pharmacy, 71-jail Road. Lahore, as desaled on 25-04-2018 in compliance with the de-sealing Order, dated 23-04-2018, passed by honourable Drug Court, Lahore. Copy of the Orders dated 23-04-20 I 8, is attached as **(Annex-G).***
8. *The matter was placed before Central Licensing Board. The Board after evaluation of the facts of the case, inter-alia, allowed safe custody of the seized drug till finalization of the case, and granted permission to lodge FIR against the following accused persons vide letter No. F. No. 03-26/2018-QC 206-CLB), dated, 10-05-2018. (Copy attached as **Annex-G):-***

1) Mr. Mehrnood Manzoor. Proprietor (Person Present). 2) Ms. Iqra Afzal, a newly appointed qualified person (Person Present), as proprietor has applied for change of qualified person. 3) Mr. Tariq Mehmood, Partner.

8. *The above accused persons have committed offence by violating provision of sub-clause (vii) & (x) of clause (a), and clause (i) of paragraph (1) of heading A of Schedule-II to the DRAP, Act 2012, read with Section 23 (1) (a) (vii) and (x), 13(1) (i) of' the Drugs Act, 1976, and chapter II of het Drugs (Import & Export) Rules, 1976, is the same of un-registered therapeutic goods/drugs cognizable offence under clause (a) or paragraph (2) of' the Schedule-IV to the DRAP Act, 2012, read with section 30 (2) (a) of the Drugs Act, 1976. These offences are punishable under sub clause (a) of clause (1) clause (4); and clause (6) of Schedule-III to the DRAP Act, 2012. It is, therefore, requested that FIR against the aforementioned accused persons may please be lodged accordingly.Sd/-Abdul Rashid Shaikh Federal Inspector of Drugs Lahore."*

17. Furthermore, the Urdu part of the incomplete challan states that there was no evidence / proof of Mr. Tariq Mehmood, being partner of M/s New Shifa Pharmacy, Lahore and thus has been declared innocent by I/O FIA CCC, Lahore. Whereas on the day of raid, Ms. Iqra Afzal was present as the qualified person in the pharmacy. However, as per available Drug sale license (Valid till 31-03-2018), Ms. Arshi D/O Muhammad Aslam R/O Muslim bin Aqeel St., Imamia Colony, Shahdara was the Qualified Person. On investigation it was revealed that the application for renewal of Drug Sale License was submitted in the CDC Lahore office since 15-02-2018 with the name of Ms. Iqra Afzal as the qualified person. Moreover, Ms. Iqra Afzal also signed as the qualified person on the prescribed Form 2 and hence was found guilty. At the time of raid, Mr. Mehmood Manzoor was present at the pharmacy premises and signed the prescribed Form 2 as the proprietor of the M/s New Shifa Pharmacy, Lahore. FIA has submitted incomplete challan and found guilty Mahmood Manzoor (proprietor) and Iqra Afzal (Qualified Person). They have requested to star t the proceedings against the accused persons.

18. During scrutiny of the challan it was observed that one of the accused i.e. Mr. Tariq Mehmood, partner of M/s New Shifa Pharmacy, Lahore has been declared innocent by I/O FIA CCC, Lahore. Subsequently the area FID Lahore vide letter No. 4-16/2018-QC dated 16-10-2018 was requested to furnish input and recommendations regarding the accused persons of M/s. New Shifa Pharmacy, 71-Jail Road, Opp. Services Hospital, Lahore in the light of FIR No. C-150/2018 dated 17-07-2018 and incomplete challan U/S 173 Cr.P.C provided FIA CCC, Lahore for consideration of the Board. But no reply / recommendations / input has been received till to date by area FID Lahore.

19. The area FID Lahore vide letter 16125/2018-DRAP (L-VI) dated 12-12-2018 forwarded the copy of order dated 04-12-2018 passed by Honorable Chairperson, Lahore Drug Court, Lahore while hearing the **BAIL APPLICATION NUMBER 113/2018 TITLED MEHMOOD MANZOOR VS. THE STATE (CASE FIR NO. C-150/2018 OF M/S. NEW SHIFA PHARMACY, 71-JAIL ROAD, OPP. SERVICES HOSPITAL, LAHORE)**. The orders are reproduced as under;

> ***"[…] 7. Having considered all the available evidence and information in the shape of police investigation, report of D.I. and other connected materials, Court comes to the conclusion that is not appropriate case for grant of post-arrest bail. Accordingly, this bail petition stand dismissed.***
>
> ***8. Central Licensing Board (DRAP) is directed to expedite the matter in view of the incarceration of the petitioner and ensure that Challan / complaint is submitted within 2-months. If the prosecution fails to do so, then the Court will consider that to be a change in circumstances and the petitioner will be at liberty to file afresh bail petition before this Court.***
>
> ***9. Consigned to record."***

Proceedings & Decision of 267th meeting of CLB:

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

1. **To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the committed offences as stated herein below:**
    i. **M/s. New Shifa Pharmacy, 71-Jail Road, Opp. Services Hospital, Lahore through Mr. Mehrnood Manzoor (Proprietor).**

ii. **Mr. Mehrnood Manzoor, Proprietor of M/s. New Shifa Pharmacy, 71-Jail Road. Opp. Services Hospital, Lahore Residence of House No. 189-A. Block D-2, Mohallah Gulshan-e-Ravi. Lahore.**

iii. **Mr. Tariq Mehmood, Partner of M/s. New· Shifa Pharmacy, 71-Jail Road. Opp. Services Hospital, Lahore Residence of House No. 189-A. Block D-2, Mohallah Gulshan-e-Ravi. Lahore.**

iv. **Ms. lqra Afzal, Qualified Person of M/s. New Shifa Pharmacy. 71-Jail Road. Opp. Services Hospital, Lahore.**

2. **The above accused persons have committed offence by violating provision of sub-clause (vii) & (x) of clause (a), and clause (i) of paragraph (1) of heading A of Schedule-II to the DRAP, Act 2012, read with Section 23 (1) (a) (vii) and (x), 23(1) (i) of' the Drugs Act, 1976, and chapter II of the Drugs (Import & Export) Rules, 1976. The sale of un-registered therapeutic goods/drugs cognizable offence under clause (a) or paragraph (2) of' the Schedule-IV to the DRAP Act, 2012, read with section 30 (2) (a) of the Drugs Act, 1976. These offences are punishable under sub clause (a) of clause (1) clause (4); and clause (6) of Schedule-III to the DRAP Act, 2012.**
3. **Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB."**

20. In the light of decision of the Central Licensing Board taken in 267th Meeting dated 31.12.2018 the showcause and personal hearing letters have been communicated vide letter No. 03-91/2018-QC(267-CLB) dated 20.02.2019 to following accused persons;

Sr. No.	Name of Accused
1	**M/s. New Shifa Pharmacy, 71-Jail Road, Opp. Services Hospital, Lahore through Mehmood Manzoor (Proprietor).**
2	**Mehmood Manzoor, Proprietor of M/s. New Shifa Pharmacy, 71-Jail Road. Opp. Services Hospital, Lahore Resident of House No. 189-A. Block D-2, Mohallah Gulshan-e-Ravi. Lahore.**
3	**Mr. Tariq Mehmood, Partner of M/s. New· Shifa Pharmacy, 71-Jail Road. Opp. Services Hospital, Lahore Resident of House No. 189-A. Block D-2, Mohallah Gulshan-e-Ravi. Lahore.**
4	**lqra Afzal, Qualified Person of M/s. New Shifa Pharmacy. 71-Jail Road. Opp. Services Hospital, Lahore**

Proceedings and Decision 269th meeting of CLB:

11. Central Licensing Board (CLB) was apprised that Show Cause Notice & Personal Hearing letters were served to the accused as mentioned in agenda through Courier/Urgent Mail Service.

12. Advocate Ch. Munawr Iqbal appeared before the CLB on behalf of Mehmood Manzoor (Proprietor, New Shifa Pharmacy), Tariq Mehmood (Partner, New Shifa Pharmacy) and Iqra Afzal (Qualified Person, New Shifa Pharmacy) gave written statement requesting 2 weeks period from the CLB for the completion of case. Contents of the application are reproduced as under;

"Sir,

I, Munawar Iqbal Advocate High Court representing on behalf of (1) M/s New Shifa Pharmacy, (2) Mehmood Manzoor (3) Tariq Mehmood (4) Iqra Afzal. I request 2 week date for submission of the detailed written reply on behalf of the above saind persons."

13. **CLB granted 2 weeks period for submission of detailed written reply to the council of accused and the case was deffered till next meeting of CLB.**

14. Mr. Amir Jalil Siddiqui Advocate and Ch Munawar Iqbal Advocate submitted the reply on the behalf of accused on 22-07-2019 which is as under;

Reply of M/s. New Shifa Pharamcy, Lahore through its Proprietor Mehmood Manzoor and Mehmood Manzoor S/o Manzoor, R/o House No. 189-A. Block D-2, Mohallah Gulshan-e-Ravi. Lahore,

*"**REPLY ON BEHALF OF MEHMOOD MANZOOR PROPRIETOR OF M/S NEW SHIFA PHARMACY 71 JAIL ROAD OPP SERVICES HOSPITAL LAHORE RESIDENT OF HOUSE NO 189-A BLOCK D-2 MOHALLA GULSHAN RAVI LAHORE***

1. *That the answering accused has been falsely implicated in this case. The premises from where the purported unlicensed drug have been recovered is not related to the M/s New Shifa Pharmacy. The raiding party has conducted the allegedly raid at upper portion of the building wherein New Shifa pharmacy is being operated at Lower portion/ground portion as tenant. This fact is supported from the rent deed in favor of the M/s New Shifa Pharmacy.*

2. *That the purported allegedly unlicensed drug has not been recovered in presence of answering accused and any such presence is concocted one. The answering accused did not sign any seizure memo.*

3. *That the raiding party has not been conducted the raid in accordance with law and in order to show the performance has falsely implicated M/S New Shifa Pharmacy and answering accused.*

4. *That the answering respondent is innocent and has been wrongly implicated in this case.*

5. *That the answering accused is law abiding citizen and doing his business under the four corners of law without having any complaint.*

6. *That M/s New Shifa is well reputed pharmacy and subject case is an attempt to cause damage to the goodwill of the M/ s New Shifa Pharmacy.*

7. *That without conceding anything, the purported alleged drug recovered from the M/S New Shifa Pharmacy is not hazardous to the human health.*

8. *That grant of sanction and proceedings of the trial will serve no purpose and will resulted into wastage of precious time of the Honourable Court*

It is requested that case against the answering accused may kindly be cancelled and sanction for prosecution must not be granted in the best interest of justice, fairness and equity."

Reply of Tariq Mahmood S/o Mahmood Manzoor R/o House No. 189-A. Block D-2, Mohallah Gulshan-e-Ravi. Lahore,

*"**REPLY ON BEHALF OF TARIQ MAHMOOD SON OF MANZOOR RESIDENT 189-A GULSHAN RAVI LAHORE**.*

1. *That the answering accused has been falsely implicated in this case.*
2. *That the answering accused has no concern with the business/business premises of M/s Shifa Pharmacy.*
3. *That the answering accused has been declared innocent by the Investigation agency.*
4. *That the answering accused is even not residing in the Pakistan and doing his own business at Dubai.*
5. *That the answering accused has no concern with M/S New Shifa Pharmacy even in the Form 9 it is reflected that answering accused has no concern with it.*
6. *That grant of sanction and proceedings of the trial will serve no purpose and will resulted into wastage of precious time of the Honourable Court*

It is requested that case against the answering accused may kindly be cancelled and sanction for prosecution must not be granted in the best interest of justice, fairness and equity."

Reply of lqra Afzal, Qualified Person of M/s. New Shifa Pharmacy. 71-Jail Road. Opp. Services Hospital, Lahore R/o House No. 51-E/5 Dector G-1 Part 2, Mirpur, Azad Kashmir.

*"**REPLY ON BEHALF OF IQRA AFZAL WIFE OF HAMZA ANWAR RESIDENT OF HOUSE NO 51-E/5 SECTOR G-l PART 2, MIR PUR AZAD KASHMIR.***

1. *That the answering accused has been falsely implicated in this case.*
2. *That the answering accused has no concern with the business/business premises of M/s Shifa Pharmacy.*
3. *That the answering accused is B pharmacist and worked according to laws and regulation and has not violated any provision of law.*
4. *That the answering accused was newly appointed at the M/s New Shifa Pharmacy and nothing has been recovered M/s New Shifa Pharmacy in the presence of answering accused.*
5. *That the answering accused is innocent and has been wrongly implicated in this case.*
6. *That grant of sanction and proceedings of the trial will serve no purpose and will resulted into wastage of precious time of the Honourable Court*

It is requested that case against the answering accused may kindly be cancelled and sanction for prosecution must not be granted in the best interest of justice, fairness and equity."

09. It is to inform that the letter of Personal hearing was served to the accused vide letter F.No. 03-44/2019-QC dated 06-09-2019 to call in the accused for personal hearing before the CLB.

Proceedings and Decision of 271st Meeting of CLB: -

10. Mr. Amir Jalil Siddiqui Advocate and Ch Munawar Iqbal Advocate, on behalf of accused namely Mehmood Manzoor, Proprietor of M/s. New Shifa Pharmacy, Lahore, Tariq Mehmood, of M/s. New· Shifa Pharmacy, Lahore and lqra Afzal, Qualified Person of M/s. New Shifa Pharmacy, Lahore appeared before the Board. Mr. Amir Jalil Siddiqui Advocate submitted that there is no evidence that can prove that Tariq Mehmood is a partner in M/s. New Shifa

Pharamcy, Lahore and the same has been submitted by the IO FIA/CCC/LHR in incomplete challan dated 26-09-2018 in relation to FIR No. 150/2018 dated 17-07-2018. He further submitted that the unregistered drugs were recoeverd from upper portion of the building wherein New Shifa pharmacy is being operated at Lower portion/ground portion as tenant and this fact is supported from the rent deed in favor of the M/s New Shifa Pharmacy, Lahore.

11. The Board after giving personal hearing to the accused and deliberated the case at length decided as under;

i. Clear and candid recommendations and proposal will be submitted by the concerned FID regarding the case that will include nature of violation, Names and designations of the accused and fixation of responsibility on the accused.
ii. Call in FID in the next meeting of CLB to present the case before the Board.

12. Decision of the 271st meeting of CLB was communicated to Area FID Lahore vide letter No. F.03-44/2019-QC (271-CLB)(pt-II) dated 11.11.2019 with subsequent reminder on 02.01.2020.

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

13. In compliance to the decision of 271st meeting of CLB, Mr. Abdul Rasheed Sheikh, Area Federal Inspector of Drugs Lahore, appeared and presented the case before the Board. Area FID Lahore agreed to the incomplete challan submitted by the IO FIA.

14. After thorough deliberation and keeping in view the statement of area FID Lahore and facts of the case, the Board decided as under;

A. Board granted permission for prosecution against following accused for the contraventions of the DRAP Act 2012 and The Drugs Act 1976 as given in Para B.

a. M/s. New Shifa Pharmacy, 71-Jail Road, Opp. Services Hospital, Lahore through Mehmood Manzoor (Proprietor).
b. Mehmood Manzoor, Proprietor of M/s. New Shifa Pharmacy, 71-Jail Road. Opp. Services Hospital, Lahore Resident of House No. 189-A. Block D-2, Mohallah Gulshan-e-Ravi. Lahore.
c. lqra Afzal, Qualified Person of M/s. New Shifa Pharmacy. 71-Jail Road. Opp. Services Hospital, Lahore

B. The above mentioned persons have committed offence by violating provision of sub-clause (vii) & (x) of clause (a), and clause (i) of paragraph (1) of heading A of Schedule-II to the DRAP, Act 2012, read with Section 23 (1) (a) (vii) and (x), 23(1) (i) of' the Drugs Act, 1976, and chapter II of the Drugs (Import & Export) Rules, 1976. The sale of un-registered therapeutic goods/drugs cognizable offence under clause (a) or paragraph (2) of' the Schedule-IV to the DRAP Act, 2012, read with section 30 (2) (a) of the Drugs Act, 1976. These offences are punishable under sub clause (a) of clause (1) clause (4); and clause (6) of Schedule-III to the DRAP Act, 2012.

C. The Area Federal Inspector of Drugs, DRAP, Lahore is requested to file complaint for prosecution of above mentioned accused persons before the court of competent jurisdiction along with relevant record and submit compliance report thereof.

D. The accused Tariq Mehmood was exonerated on the basis of report submitted by FIA U/s 173 Cr.P.C. where in accused is placed in column 2 and FID (Investigation officer) showed his agreement with said report. Hence the operation of show cause notice to the extent of accused Tariq Mehmood is ceased with immediate effect.

Case No. 12: PERMISSION FOR PROSECUTION AGAINST THE MANAGEMENT OF M/S EVEREST PHARMACEUTICALS FOR THE ILLEGAL IMPORT OF PHARMACEUTICAL RAW MATERIAL THROUGH FORGED IMPORT CLEARANCE CERTIFICATE WITHOUT ANY DRUG IMPORT LICENSE.

12.1 Incomplete Challan for FIR No. C-69/2018 dated 16/05/2018:

The Federal Inspector of Drugs DRAP Lahore vide letter No. 6246/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Colleotorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Deciaration-GD-i, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity

M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore	SPKGC15001	02-04-2015	Xanthan Gum Pharma Grade Mesh	3000 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

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

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore , through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after

investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

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

i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman

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

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

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

10. The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

12.2. <u>Incomplete Challan for FIR No. C-70/2018 dated 16/05/2018:</u>

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6246/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Colleotorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Deciaration-GD-i, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity

M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore	SPKGC15003	02-04-2015	Xanthan Gum Pharma Grade Mesh	3000 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

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

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s.

Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

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

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

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

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

10. The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

12.3. Incomplete Challan for FIR No. C-100/2018 dated 25/05/2018:

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6261/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Collectorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s. Everest Pharmaceuticals, Office No.13, 3rd Floor, Gohar Centre, Wahdat Road, Lahore	N15AS23387	15.06.2015	1) Phloroglucinnol Dihydrate 2) 1) Phloroglucinnol Trimethyl	1) 100 kg 2) 100kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

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

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under

section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

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

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

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

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

10. The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

12.4. <u>Incomplete Challan for FIR No. C-107/2018 dated 30/05/2018:</u>

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6256/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Collectorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s. Everest Pharmaceuticals, 86-G, Model town Lahore	16IXTXI-0842	21.07.2016	Vitamin B6 HCl	100 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

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

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is

cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

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

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

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

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

10. The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

12.5. <u>Incomplete Challan for FIR No. C-81/2018 dated 17/05/2018:</u>

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6249/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Collectorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s. Everest Pharmaceuticals, 86-G, Model town Lahore	DE14W004	31.12.2014	Clotrimazole	100 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

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

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is

cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

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

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

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

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

10. The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

12.6. <u>Incomplete Challan for FIR No. C-85/2018 dated 23/05/2018:</u>

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6244/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Collectorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s. Everest Pharmaceuticals, 86-G, Model town Lahore	MT-1505115	07.02.2015	Microcrystalline cellulose	2000 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

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

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the

Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

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

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

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

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

10. The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

12.7. Incomplete Challan for FIR No. C-86/2018 dated 23/05/2018:

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6241/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Collectorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s. Everest Pharmaceuticals, 86-G, Model town Lahore	4182-01	31.05.2015	Lactose Monohydrate	3000 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

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

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is

cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

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

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

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

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

10. The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

Item No. I DELEGATION OF POWERS

Case No. i: POWER DELEGATION.

As per decision of 271st meeting of CLB the powers delegated to Director QA&LT and other officers of QA&LT in 237th meeting of CLB are given below;

"The Central Licensing Board approved and delegated its powers retrospectively with certain modifications to Director Quality Assurance and Laboratory Testing under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) rules, 1976 in order to facilitate timely disposal of routine and day to day business of Central Licensing Board.

S No.	Functions / Powers	Function / Powder Delegated to
Delegation of Functions / Powers related to the Division of Quality Assurance & Laboratory Testing		
1.	Show Cause Notice regarding contravention of any of the provision of Drugs Act, 1976 and rules framed there under (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
2.	Advisory letters, explanation letters or any other action as deems fit for the purpose of improvement (in case of GMP matters)	Director Quality Assurance and Laboratory Testing
3.	Suspensions of Production (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
4.	Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members	Director Quality Assurance and Laboratory Testing
5.	Permission to Lodge FIR	Director Quality Assurance and Laboratory Testing
6.	Panel Constitution (GMP Inspections and related issues etc)	Director Quality Assurance and Laboratory Testing
7.	Constitution/ amendments in constitution of panel for inspection for GMP compliance and quality control matters.	Director Quality Assurance and Laboratory Testing
8.	To continue the period of "not to dispose-of stocks orders passed by FID" for three months or till the finalization of the case (in case of un-registered/Spurious Drugs).	Director Quality Assurance and Laboratory Testing
9.	To continue custody of the seized stocks by the FID till decision of the case (in case of un-registered/Spurious Drugs).	Director Quality Assurance and Laboratory Testing
10	To grant approval for sending Board's portion of drug samples to the Appellate Laboratory (in case of un-registered/Spurious Drugs).	Director Quality Assurance and Laboratory Testing
11	Grant of extension in the time of testing to Federal Government Analyst (in case of un-registered/Spurious Drugs).	Director Quality Assurance and Laboratory Testing
12	Issue of Show Cause Notices/Personal hearing	Assistant Director (QA&LT) /

	letters/Circulars/Communication of Minutes/Decisions/Directions of the Board to the Concerned quarters regarding GMP and Quality Control matters on behalf of Secretary Board.	Deputy Director (QA&LT)

Proceedings of 273rd meeting:-

Quality Assurance Division place the case of delegation of power before the Board. The Board discussed the power delegation in length.

Decision of the 273rdMeeting of CLB

After thorough discussion/deliberations, the Central Licensing Board delegated the powers as under:-

S No.	Functions / Powers	Function / Powder Delegated to
Delegation of Functions / Powers related to the Division of Quality Assurance & Laboratory Testing		
1.	Issuance of Show Cause Notice regarding contravention of any of the provision of DRAP Act, 2012 and rules framed there under (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
2.	Advisory letters, explanation letters or any other action as deems fit for the purpose of improvement (in case of GMP matters)	Director Quality Assurance and Laboratory Testing
3.	Suspension of Production (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
4.	Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members. Where the panel is constituted by the Director (QA&LT). However the cases shall be placed before the CLB for information.	Director Quality Assurance and Laboratory Testing
5.	Permission to Lodge FIR	Director Quality Assurance and Laboratory Testing
6.	Panel Constitution (GMP Inspections and related issues etc)	Director Quality Assurance and Laboratory Testing
7.	Constitution/ amendments in constitution of panel for inspection for GMP compliance and quality control matters.	Director Quality Assurance and Laboratory Testing
8.	To continue the period of “not to dispose-of stocks orders passed by FID” for three months or till the finalization of the case (other than registered Drugs).	Director Quality Assurance and Laboratory Testing
9.	To continue custody of the seized stocks by the FID till decision of the case (other than registered Drugs).	Director Quality Assurance and Laboratory Testing

10.	To grant approval for sending Board's portion of drug samples to the Appellate Laboratory (other than registered Drugs).	Director Quality Assurance and Laboratory Testing
11.	Grant of extension in the time of testing to Federal Government Analyst (other than registered Drugs).	Director Quality Assurance and Laboratory Testing
12.	Issuance of Show Cause Notices/Personal hearing letters/Circulars/Communication of Minutes/Decisions/Directions of the Board to the Concerned quarters regarding GMP and Quality Control matters on behalf of Secretary Board. The letter shall be issued with Name & Designation of the officer.	Assistant Director (QA&LT) / Deputy Director (QA&LT)

Item No. II CORRECTION IN APPROVED MINUTES

Following cases were placed before the 272nd meeting of CLB held on 17-10-2019 for resumption of production activities;

i. M/s. Uni-Tiech Pharmaceuticals, Karachi.
ii. M/s Harmann Pharmaceutical Laboratories (Pvt) Limited, Lahore

2. During preparation of minutes of the meeting, inadvertently some typographic mistakes were made, which were rectified by approval of the Chairman CLB and corrigendum were issued vide letters No.F.8-4/2019-QA (M-272-CLB) dated 06-12-2019.

S. No	Case
1	**Case No. i: M/S. UNI-TIECH PHARMACEUTICALS, KARACHI.**
	Decision in approved Minutes of 272nd Meeting of CLB. After thorough discussion/deliberations, considering all the pros and cons of the case and panel inspection report dated 09.10.2019 constituted in 271st meeting of CLB, the Central Licensing Board decided to:- i. Allow resumption of production activities in all sections except Sterile Liquid Section of the firm M/s Uni-Tiech Pharmaceuticals, Karachi, as per recommendation of panel inspection report dated 09.10.2019. ii. Production of the Sterile Liquid Section of the firm M/s Uni-Tiech Pharmaceuticals (pvt) Limited, Karachi shall remain suspended till recommendation by panel and subsequent approval by the CLB.
	Corrigendum issued. After thorough discussion/deliberations, considering all the pros and cons of the case and panel inspection report dated 09.10.2019 constituted in 271st meeting of CLB, the Central Licensing Board decided to:- i. Allow resumption of production activities in all sections except Sterile Liquid ***infusion*** Section of the firm M/s Uni-Tiech Pharmaceuticals, Karachi, as per recommendation of panel inspection report dated 09.10.2019. ii. Production of the Sterile Liquid***infusion***Section of the firm M/s Uni-Tiech Pharmaceuticals (pvt) Limited, Karachi shall remain suspended till recommendation by panel and subsequent approval by the CLB.
2	**Case No. ii. M/S HARMANN PHARMACEUTICAL LABORATORIES (PVT) LIMITED, LAHORE**
	Decision in approved Minutes of 272nd Meeting of CLB. After thorough discussion/deliberations, considering all the pros and cons of the case and panel inspection report dated 13.06.2019 &08.10.2019 constituted in 266thmeeting of CLB, the Central Licensing Board decided to:-

	i. Allow resumption of production activities in all sections except Sterile Liquid Section of the firm M/s Harmann Pharmaceutical Laboratories, Lahore in, as per recommendation of panel inspection report dated 09.10.2019, in following sections. a) Sterile Section I (General Injection) b) Sterile Section III (Hormonal Injection) ii. Regularize the layout plan of Hormonal Section, as per recommendations of the panel in its report dated 13.06.2019 & 08.10.2019.
	Corrigendum issued. After thorough discussion/deliberations, considering all the pros and cons of the case and panel inspection report dated 13.06.2019 &08.10.2019 constituted in 266th meeting of CLB, the Central Licensing Board decided to:- i. Allow resumption of production activities of the firm M/s Harmann Pharmaceutical Laboratories, Lahore, as per recommendation of panel inspection report dated ***08.10.2019***, in following sections. a) Sterile Section I (General Injection) b) Sterile Section III (Hormonal Injection) **ii.** Regularize the layout plan of Hormonal Section, as per recommendations of the panel in its report dated 13.06.2019 & 08.10.2019.

Proceedings of 273rd meeting:-

Quality Assurance Division place the case before the Board for ratification of the corrections made in minutes of 272nd meeting of CLB in the case of the firms M/s Uni-tiech Pharmaceuticals, Karachi and M/s Harmann Pharmaceutical Laboratories (pvt) Limited, Lahore after approval from Chairman, CLB.

Decision of the 273rdMeeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board ratified decision of the Chairman, CLB.

Item No. III GMP NON-COMPLIANCE CASES (NEW)

Case No. i: M/S. TG PHARMA, KARACHI.

Background:

Inspection of the firm M/s. T.G. Pharma (Pvt) Ltd, Plot No. E-30, Sector 15, Korangi Industrial Area, Karachi was conducted on 17.05.2019 by the following panel of experts. The inspection was carried out on complaint through email.

i. Mrs. Muneeza Khan, FID-II, Karachi
ii. Mr. Abdul Rasool Shaikh, FID-IV, Karachi
iii. Dr. Shoaib Ahmed, FID-IX, Karachi
iv. Dr. Kirshan, Assistant Director, Karachi

2. The panel during inspection noted the following critical observations:-

i. Very poor hygienic conditions.
ii. Non availability of HVAC system.
iii. Manufacturing was carried without qualified/technical staff.
iv. Lack of GMP compliant equipment/machinery for test/analysis in QC.
v. Lack of GMP compliant equipment/machinery for manufacturing in production area.
vi. Non availability of SOPs, Validation, Qualification, Calibration and Documents/records.
vii. Severe non GMP compliance was observed in all sections from change room till final production.

Action taken by DRAP:

3. The firm M/s. T.G. Pharma (Pvt) Ltd, Karachi was served Show Cause Notice and suspension of production activities order No. F.4-16/2009-QA on 21.05.2019.

Reply of the firm:

The firm M/s. TG Pharma, Karachi vide letter dated 18.07.2019 submitted reply of Show Cause Notice and informed that they have proposal for the state of the art building with GMP compliance.

4. The case was placed in 271st meeting of CLB. Wherein the board decided as under:-

Decision of the 271stMeeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to provide final opportunity of personal hearing to the firm, under Section 41 of the Drugs Act, 1976 and rules made there under.

5. Decision of the 271st meeting was conveyed to the firm vide letter No. F. 8-3/2019-QA (CLB-M-271) on 01.10.2019.

Proceedings of 273rd Meeting of CLB

Dr. Wasim Siddiqui, Managing Director of the firm M/s. TG Pharma (pvt) Limited, Karachi appeared before the Board. Dr. Wasim Siddiqui submitted that they have stopped all the manufacturing process and are going for toll manufacturing. He added that they are unable to copy the GMP in present condition. Dr. Wasim Siddiqui submitted written statement stating that "*our contract manufacturing case already discussed in 293rd Registration Board meeting. The plant activates are suspended and we are waiting for toll permission and likely to start rebuilding facility"*.

Decision of 273rd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case and statement of Dr. Wasim Siddiqui, Managing Director of the firm, the Board decided to cancel the Drug Manufacturing License of the firm *M/s TG Pharma (pvt) Limited,E-30, Korangi Industrial Area, Karachi*under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (L, R&A) Rules, 1976, for non-compliance of Rule 16 and 19 of the Drugs (L, R&A) Rules, 1976, from the date of issuance of decision of the 273rd meeting of CLB.

Case No. ii: M/S. DOSACO LABORATORIES, LAHORE.

Background:

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

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

2. The panel noticed following observations:-

Executive Entrance:-

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

Workers Entrance:-

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

Raw Material Store:-

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

Finished Goods Store:-

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

Quality Control Laboratory:-

i. To properly install Liquid Particle Counter and all others as per requirements and also develop log books for all major equipment and machines.
ii. To ensure availability of FTIR for testing of raw materials.
iii. Stability testing was not being done advised to provide stability chambers, develop SOPs & protocols and perform stability studies as per recommended guidelines.
iv. Advised to strengthen the quality control department.
v. To ensure one additional HPLC and appoint more technical staff in QC Department and in other sections as per requirement of Drugs Act and make all the equipment functional.

Microbiological Laboratory:-

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

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

Quality Assurance Department:-

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

Liquid Injectable Area 1 (General):-

Ampoule Washing:-

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

Solution Preparation Room:-

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

Filling Room:-

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

Autoclave Room:-

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

Optical Checking Areas:-

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

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

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

Oral Liquid Section:-

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

Tablet Section:-

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

Documentation:-

v. To review and upgrade documentation and record keeping as per current requirement.

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

Conclusions:-

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

Action taken by DRAP:

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

Reply of the firm:

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

Proceedings of 273rd Meeting of CLB

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

Decision of 273rdMeeting of CLB

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

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

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

Case No. iii: M/S. ELITE PHARMA, LAHORE.

Background:

Inspection of the firm M/s. Elite Pharma (Pvt) Ltd, 9.5-KM, Sheikhupura Road, Lahore, was conducted by following panel on 08.08.2019.

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

2. The panel during inspection noticed following observations:-

Entries:-

i. To upgrade the change area as per GMP requirements.
ii. Provide pictorial display and change over instructions.
iii. Provide proper facility for changing of shoes within the change room.
iv. Provide fresh air and ventilation in workers change rooms.
v. Provide lockers / cabinets for keeping uniforms & personal belongings.
vi. Provide hand sanitizer.

Raw Material Store:-

Raw material store of main building was provided with a receiving and de-dusting area, Firm has provided a quarantine area and released areas for excipients. There rooms were given for storage of cephalosporin API's, Penicillin API's, raw material for Ointments, general API's stock was present. Firm was advised to:

i. To provide shade and air curtain outside receiving.
ii. To install AC in quarantine and temperature / humidity motoring devices and maintain record.
iii. Provide separate weighing balance in sampling and dispensing booth for small quantities also advised to install printers with dispensing and analytical balance.
iv. Develop material receiving check list and review and revise raw material receiving SOP.
v. Perform thermal mapping of stores.
vi. Improve lighting in raw material store.
vii. To develop and implement material management SOPs.
viii. Material flow for store to production area should be improved.
ix. Cephalosporin and penicillin API's were stored in general raw material store. Firm was advised to provide completely dedicated & self-contained sections as the management inform that they have already submitted their revised layout plan in DRAP, Islamabad.

General Injectable Section:-

i. Vial filling machine was not available / not installed at the time of inspection.
ii. To perform environmental monitoring of the ampoule washing area also and submit report.

Optical Checking:-

i. To perform six monthly eye checkup of worker and also check LUX in the area.

Packing Hall:-

i. To segregate that area and remove hoods from wooden fixture & furniture from packing area.

Penicillin Sections:-

i. To provide seamless, non porous ceiling in the area.
ii. To provide false ceiling in packing hall where ducts and pipes could be seen. It should be concealed.

Quinolone Infusion Section:-

i. To upgrade change area.
ii. To improve dispensing area.
iii. To check air balancing in all sterile areas and maintain differential pressure as per recommended guidelines.

Cephalosporin Section:-

i. The Cephalosporin Section was not dedicated. Its entrance was through Quinolone Infusion Section. Firm had provided machinery for Cephalosporin Capsule Dry Powder Injection and Dry Powder Suspension manufacturing.

Finished Goods Store:-

i. To improve the lighting in the area and provide proper solid stairs with railing at the entrance of store.
ii. To provide light in the cold store and fix the handle lock.

Packing Material Store:-

i. The packing material store was found unorganized and in a hap-hazard condition. Sanitation was also poor.
ii. The Al-foil was stored in uncontrolled condition in the packing material store.

Change Areas:-

i. All change areas in the unit including those of penicillin section, cephalosporin section and semi-solid section. Need to improve with reference to maintenance, lighting, ventilation, and house. Keeping and change over facilities. It was observed that there was also a lacking in implementation of change over SOPs.

Action taken by DRAP:

3. The firm M/s. Elite Pharma, Lahore was served Show Cause Notice /Suspension of Production activities order No.F.4-34/98-QA (Vol-I) on 11.11.2019.

Reply of the firm:

4. The firm M/s. Elite Pharma, Lahore vide letter dated 05.12.2019 submitted reply of Show Cause Notice. The firm submitted that they rectified all the observations and ready for re-inspection.

Updated Status:

5. Request of the firm was forwarded to Director (QA&LT). The Director (QA&LT) constituted following panel of experts on 03.12.2019.

i. Mr. Ajmal Sohail,
ii. FID-VI, Lahore
iii. Ms. Maham Misbah, AD, DRAP, Lahore

6. The panel conducted inspection of the firm on 16th December, 2019 and concluded the report as under;

"*In the light of observations, the panel noted that firm has started to rectify the observation made during previous inspection. Penicillin and cephalosporin sections were not dedicated. Vial injectable section was not having proper raw material store. The management informed that they have submitted new layout in Licensing Section for amendments in these sections. At present, only liquid injectable ampoule section and semisolid (cream/ointment) section of firm were having adequate manufacturing facility. Therefore, panel was of the opinion that firm may be allowed to resume production in liquid injectable Ampoule and Semi Solid (Cream/Ointment) Sections only"*

7. As per recommendations of the panel and after approval of the Director QA&LT resumption of production activities was granted in liquid injectable Ampoule and Semi Solid (Cream/Ointment) Sections only vide letter dated 27-12-2019.

Proceedings of 273rd Meeting of CLB

Division of QA&LT presented the case before the CLB. Mr. Haroon Ayub (Director Technical) and Bilal Mahmood (Director) of the firm M/s. Elite Pharma (Pvt) Ltd, 9.5-KM, Sheikhupura Road, Lahore appeared before the Board. Mr. Haroon Ayub submitted that they have started to rectify the observations noted by the panel. He stated that they have submitted revised layout of the Penicillin Section, cephalosporin section and Semi Solid (Cream/Ointment) Section. They will start civil work after approval of layout plan. It will take about 6-8 weeks for completion of work, after approval of layout plan.

Decision of 273rdMeeting of CLB

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

i. Ratify decision of Director QA&LT regarding resumption of production of liquid injectable Ampoule and Semi Solid (Cream/Ointment) Sections

ii. Production in the Penicillin Section and Cephalosporin Section shall remain suspended till completion of work, request of the firm for inspection, panel inspection and subsequent approval by the Central Licensing Board.

Case No. v: M/S. RAAZEE THERAPUTICS (PVT.) LTD, KASUR.

Background:

Inspection of the firm M/s. Raazee Therapeutics (Pvt.) Ltd., 48-KM, Lahore-Kasur Road, Kasur was conducted in compliance to letter No. F. 03-41/2019-QC (291-RB) dated 19.09.2019. The following panel conducted inspection on 03.10.2019.

i. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore
ii. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore
iii. Ms. Maham Misbah, AD, DRAP, Lahore

2. The panel during inspection noticed as under:-

Background of the case:-

- A product of the firm namely Narobe Infusion Batch No. 104092 was declared substandard by CDL and the Board in its 234th meeting decided to suspend the registration of the product for 2 months along with direction for panel inspection and resumption after satisfactory report of such inspection. The decision was communicated to firm, and in its reply on 28.08.2012 the firm provided a stay order against the decision of the Board from Honorable Islamabad High Court.
- FID communicated the reply of the firm to Board vide letter No. 10377/2012-DRAP (L-I) dated 13.09.2012 and requested for further guidance. However, no directions were received from the Board for further action. Thus, in the presence of stay order no action was taken in the light of the Board's decision.
- Later on, FID inspected the firm on 16.03.2017 and reported the Liquid Injectable Section of the firm was not operating at satisfactory level of GMP compliance. Hence firm was directed by Central Licensing Board to suspend the production activity in this section.
- A panel was constituted to re-inspect the firm, the panel comprising Dr. Ikram-Ul-Haq, Member CLB, Additional Director (E&M), DRAP, Lahore and Mr. Abdul Rashid Shaikh, FID inspected the firm on 14.12.2017 & 15.03.2018 and recommended the resumption of the production in Liquid Injectable Section. Accordingly, the firm was allowed to resume the production in this section on 07.08.2018.

Decision of 291st Meeting of the Registration Board:-

- In compliance to Board's direction the decision was communicated to firm for implementation, however, the status of the above-mentioned stay order of Honorable Islamabad High Court is not yet clarified / communicated by the Board for enforcement of the decision regarding suspension of the product.
- A panel also inspected the firm on 03.10.2019 as per directions of the Board for qualitative investigation of the case. The findings are as follow:-
  i. Since the case was about 7 years old, there were no remaining samples available for the specific batch of the product in question i.e. Narobe Infusion.
  ii. The firm was manufacturing Narobe Infusion and it was available in the finished store.
  iii. FID took the samples of two different batches of Narobe Infusion along with two other Liquid Injectables for test analysis.
  iv. Firm was not having any investigating report for the product declared sub-standard.
  v. Firm was not having official reference standards for any of its registered products including Metronidazole (API of Narobe Infusion).

vi. Regarding QC testing of the products the firm was not properly maintain log books and failed to prove the actual testing of this product on HPLC.
vii. Microbiology laboratory was not appropriate, sterility suit was not having proper buffers. Only two buffers were provided which even were housing equipment like refrigerator. HVAC was not functioning appropriately and pressure gradients were not accordingly adjusted.
viii. Liquid Injectable manufacturing area / section was not well maintained. Epoxy on floors was damaged, paint on walls was peeled off at many places. Pressure gradients were not maintained. Doors of the sterile manufacturing area were made of aluminum / glass and were not maintained, they were not closing properly, gaskets were broken, glass were broken. Windows were not smooth. Turn table of the filling machine carrying empty vials before filling was not covered under LFC and the sterile vials seemed to be exposed outside the Class A area.
ix. In general, the firm did not appear to follow good practices in manufacturing and QC of products with reference to Liquid Injectable Section.

Conclusion:-

"Samples of the available batches of the product under investigation were drawn and sent to CDL for test analysis. The panel of inspectors was of the view that the firm was not operating at a satisfactory level of compliance with GMP with respect to Liquid Injectable Section. The firm was advised to upgrade the section immediately to meet GMP requirements."

Action taken by DRAP:

3. The firm M/s. Raazee Therapeutics (Pvt.) Ltd, Kasur was served Show Cause Notice /Suspension of Production activities in Liquid Injectable Section order No.F.4-17/2002-QA (Vol-I) on 05.12.2019.

Reply of the firm:

4. Reply of the firm M/s. Raazee Therapeutics (Pvt.) Ltd, Kasur dated 27-12-2019 was received in this office on 01-01-2020 wherein they have stated that they have initiated and completed all necessary steps to rectify the shortcomings pointed out by the respected members of panel. Furthermore they have requested for constitution of panel for inspection of Injectable section in order to resume production in the said section.

Proceedings of 273rd Meeting of CLB

Division of QA&LT presented the case before CLB. Mr. Ghalib Raazee (Director), Ijaz Ahmad (Production Incharge) and Mr. Rehmat Ali (QCM) of the firm M/s. raazee Therapeutics (Pvt) Ltd, 48-KM, Lahore-Kasur Road, Kasur appeared before the Board. Mr. Ghalib Raazee submitted that they have started to rectify the observations noted by the panel in its report dated 03.10.2019.

Decision of 273rdMeeting of CLB

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

i. Constitute following panel of experts for detailed GMP inspection of the firm,:-

- Dr. Munawar Hayat, CDI, Punjab.
- Mr. Ajmal Sohail Asif, FID, Lahore
- Area FID, Lahore

ii. Direct the panel to submit detailed report with clear and candid recommendations.

iii. Production in the Liquid Injectable Section shall remain suspended till verification by panel of experts and subsequent approval by the Central Licensing Board.

iv. Refer the case to Drug Registration Board for necessary action at their end regarding manufacturing and sale of substandard Narobe Infusion, Batch No. 104092.

Item No. IV PERSONAL HEARING IN COMPLIANCE TO 270TH & 271STEETING OF CLB

Case No. i M/S PHARMEDIC LABORATORIES, LAHORE

Background:-

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

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

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

Decision of the 256th Meeting of CLB

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

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

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

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

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

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

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

Inspection of FID on 20.08.2018: -

Ms. Uzma Barkat, area FID along with Mr. Shoaib Ahmed, FID and Ms. Maham Misbah, AD (DRAP), Lahore visited the firm on 20.08.2018 and informed that "she *visited the raw material store and General Injectable Section of the firm and reported that firm was manufacturing Onset (Ondensetron) 4mg and 8mg injections in their General Injectable Section, in violation of show cause / suspension of production orders in Liquid Injectable (General)*

Section vide letter No. F. 4-49/2004-QA (Vol-III) dated 18.09.2017 and area FID further ordered the firm for not to dispose of the stock of Ondensetron for 28 days on Form-I and requested to grant further extension for three months for not to dispose of the said stock."

Updated Status: -

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

4. The firm M/s. Pharmedic Laboratories (Pvt) Ltd, Lahore has violated the direction of Show Cause Notice / Suspension of production order in General Injectable Section, decision of 256th meeting of CLB and start manufacturing in the General Injectable Section without panel inspection and subsequent approval from the Central Licensing Board. The case was placed in 266th meeting of CLB. Wherein the Board decided as under:-

Decision of the 266th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, the Board decided as to issue show cause notice to the firm M/s Pharmedic Laboratories, Lahore on manufacturing in the Injectable Section (General), which is violation of the directions of show cause notice / suspension of production order in Liquid Injectable (General) Section dated 18.09.2017.

Action Taken by DRAP: - Accordingly, Show Cause Notice in compliance to decision of 266th meeting was issued to the firm on 05.12.2018.

Decision of the 267th Meeting of CLB:-

After thorough discussion/deliberations and keeping in view the panel GMP inspection report of the firm in compliance to 256th meeting of the CLB, the Central Licensing Board decided to continue the suspension of the production activities in the Liquid Injectable (General) Section, till the decision of unauthorized manufacturing in the Liquid Injectable (General) Section. The Board further decided to direct the area FID to investigate the matter of production in the Liquid Injectable Section (General) in non-compliance to the orders of QA&LT Division dated 18.09.2017 and fix the responsibility. The FID shall submit detailed investigation report with clear and candid recommendation for consideration of the CLB.

Reply of the FID in compliance to decision of 267th meeting of CLB:-

The firm in their reply vide letter ref. No. PH/LHR/REG/144 dated 14th September, 2018 stated that *"at the time of said surprise inspection, the idle workers were just made busy by asking them to sort already manufactured Ondensetron HCl 4mg Injection Batch no. 299 and 8mg injection batch no. 320".* Moreover, in their reply, the company failed to provide the party wise sales record and copies of invoices of both the batches which was required from them to submit to this office.

i. In the raw material consumption record of Ondensetron HCl (Injectable Grade) submitted by the firm, following details were given:

Product name	Batch No.	Batch size (ampoules)	Consumed quantity (KG)
Onset Injection 4mg	299	55813	0.312
Onset Injection 8mg	320	95200	1.040

ii. However, following information was found in the BMRs provided at the time of inspection and same batch size was given on the batch COA.

Product name	Batch No.	Quantity of Raw material dispensed (kg)	Theoretical Batch size (ampoules)	Actual yield (ampoules)	In-process stock actually present in the premises at the time of inspection (ampoules by weight)
Onset Injection 4mg	299	0.130	23,250	19,748 (10,958 physician sample ampoules + 8,790 Commercial ampoules)	**48,734 approx.**
Onset Injection 8mg	320	0.520	47,600	39,600 (passed after optical checking)	**76,767 approx.**

iii. The firm in their consumption record has stated that 21.824kg of Ondensetrone HCl (Injectable grade) raw material is in balance as of 25-05-2018. However, at the time of inspection, when it was physically verified, the raw material was found to be less than 20 kg.

iv. During investigation, it was found that M/s Babar Medicine Company, Peco Road, Lahore, is one of the distributors of the said products. Supply details of Onset 8mg Injection Batch No. 320 to M/s Clinix Plus Main warehouse, Multan Road, Lahore in throughout year 2018 are enclosed. Therefore, letter no. 3556/2019-DRAP (L-VIII) dated 14-03-2019 was sent to M/s Babar Medicine Company, Peco Road, Lahore, to provide the sale/purchase details of the said products from August 2017 onwards but they failed to provide the data despite written (letter no. 4054/2019-DRAP (L-VIII) dated 22-03-2019) and telephonic reminders.

v. From the finding of the investigation, it is concluded that the firm was involved in unauthorized manufacturing of the said products while production in the relevant section had been suspended by the competent authority. Moreover, there was mis-declaration of information and hiding of facts by the firm.

vi. The case is being referred to the competent authority and the responsibility is fixed on the following for violating the provision of Section 23 of the Drugs Act, 1976 read with Schedule II of DRAP Act, 2012, punishable under Section 27 of the Drugs Act, 1976 read with Schedule III of DRAP Act, 2012, and may be prosecuted in Drug Court.

I. M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore through its CEO
II. Management of M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore as per Form-29 of SECP
    i. Mr. Waqar A. Sheikh CNIC No. 35202-9152354-3
    ii. Mr. Adeel A. Sheikh CNIC No. 35202-9143709-3
III. Mr Jamshaid Ghani, Production Incharge S/o Abdul Ghani, CNIC No. 54400-0548981-5

IV. Mr Muhammad Nouman Ahmed, Quality Control Incharge, S/o Muhammad Anwar Ul Haq, CNIC No.35202-2745122-9

vii. The cGMP inspections of the firm were conducted on 07-08-2018, 04-09-2018 & 22-11-2018, with reference to DRAP Islamabad letter No. F. 8-5/2017-QA (M-256-CLB) (Pt) dated 03-01-2018 wherein panel was required by the Central Licensing Board in light of its 256th meeting to conduct GMP inspection of the firm on approved Schedule B-II format and also submit a brief report in tabulated form identifying previous observations and current status. Inspection report was forwarded to the concerned division with the following recommendation:

a) Based on the findings of the inspection and the improvements made by the firm, the panel of inspectors recommends resumption of production in the Liquid Injectable Section (General).

b) The matter of unauthorized production in Liquid Injectable Section (General) had already been forwarded to the directorate of Quality Assurance & Lab Testing vide letter No. 11210/2018-DRAP (L-VIII) dated 24-08-2018 for necessary action.

c) Firm was advised to rectify the observations made during the cGMP inspection and submit compliance report.

5. The case was placed in 270th Meeting of CLB. Wherein the Board after detailed discussion decided as under:-

Decision of the 270thMeeting of CLB

The board after detailed discussion on the investigation report of FID dated 13.05.2019, in compliance to 267th meeting of CLB, decided to issue Sow Cause notice to the following accused persons and give them opportunity of personal hearing in the next meeting of CLB on the matter of unauthorized manufacturing in the Liquid Injection Section (General).

I. M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore through its CEO
II. Management of M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore as per Form-29 of SECP
    i. Mr. Waqar A. Sheikh CNIC No. 35202-9152354-3
    ii. Mr. Adeel A. Sheikh CNIC No. 35202-9143709-3
III. Mr Muhammad Nouman Ahmed, Quality Control Incharge, S/o Muhammad Anwar Ul Haq, CNIC No.35202-2745122-9
IV. Mr Jamshaid Ghani, Production Incharge S/o Abdul Ghani, CNIC No. 54400-0548981-5

Action Taken by DRAP: - Keeping in view decision of 270th Meeting of CLB. Show Cause Notice in compliance to decision of 270th meeting was issued to the following accused persons on 24.06.2019.

I. M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore through its CEO
II. Management of M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore as per Form-29 of SECP

i. Mr. Waqar A. Sheikh CNIC No. 35202-9152354-3
ii. Mr. Adeel A. Sheikh CNIC No. 35202-9143709-3

III. Mr Muhammad Nouman Ahmed, Quality Control Incharge, S/o Muhammad Anwar Ul Haq, CNIC No.35202-2745122-9

IV. Mr Jamshaid Ghani, Production Incharge S/o Abdul Ghani, CNIC No. 54400-0548981-5

6. The case was placed in 271st meeting of CLB.

Proceedings of 271st meeting:-

Quality Assurance Division presented the case before the Board. The Board was informed that the Show Cause Notices were sent through official dak and FID was also directed to convey the directions of personal hearing before the Board. Mr. Hasan Javed, Regulatory Affairs Executive appeared before the Board. He requested for the adjournment of the case due to some emergency.

Decision of the 271stMeeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to provide final opportunity of personal hearing to the following accused, under Rule 8 (13) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

I. M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore through its CEO

II. Management of M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore as per Form-29 of SECP
   a. Mr. Waqar A. Sheikh CNIC No. 35202-9152354-3
   b. Mr. Adeel A. Sheikh CNIC No. 35202-9143709-3

III. Mr Muhammad Nouman Ahmed, Quality Control Incharge, S/o Muhammad Anwar Ul Haq, CNIC No.35202-2745122-9

IV. Mr Jamshaid Ghani, Production In-charge S/o Abdul Ghani, CNIC No. 54400-0548981-5

7. Decision of the 271st meeting was conveyed to the firm and accused persons vide letter No. F. 8-3/2019-QA (CLB-M-271) on 01.10.2019.

Proceedings of 273rd Meeting of CLB

Division of QA&LT presented the case before the CLB in compliance to decision of 271st meeting of CLB. It was informed to the Board that the FID has submitted detailed investigation report. Mr. Waqar A. Sheikh (Managing Director & CEO), Mr. Jamshed Ghani (Production In-charge) and Mr. Muhammad Nouman Ahmed (QCM) of the firm M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore appeared before the Board. The Board raised query regarding the unauthorized manufacturing of Onset Injection by them, as per investigation of FID. Mr. Waqar A. Sheikh replied that alleged stock was an old stock and was not newly manufactured. On further query Mr. Jamshed Ghani stated that the stock was placed in in-

process quarantine and was brought in the production area for optical check. The Board ask Mr. Jamshed Ghani, whether optical checking is part of manufacturing or otherwise. Mr. Jamshed Ghani stated that it was for the purpose of training of staff. The board raised further queries on the huge quantity of product Onset Injection with different Batch Nos. Mr. Waqar A. Sheikh admitted that it was a mistake and violation was committed by them unintentionally.

Decision of 273rd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view available record, investigation report of the FID, mis-declaration of information and hiding of facts by the firm from Investigation team, offence admitted by the management of the firm before the Board and recommendation of the FID to prosecute the firm following in the Drug Court, Lahore for the offences under Section 23 (1) (a)(x), (b) & (c) read with Section 27 of the Drugs Act, 1976 under DRAP Act, 2012:-

I. M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore through its CEO
II. Management of M/s Pharmedic Laboratories (Pvt) Ltd., 16km Multan Road, Lahore as per Form-29 of SECP
    a. Mr. Waqar A. Sheikh CNIC No. 35202-9152354-3
    b. Mr. Adeel A. Sheikh CNIC No. 35202-9143709-3
III. Mr Muhammad Nouman Ahmed, Quality Control Incharge, S/o Muhammad Anwar Ul Haq, CNIC No.35202-2745122-9
IV. Mr Jamshaid Ghani, Production In-charge S/o Abdul Ghani, CNIC No. 54400-0548981-5

Case No. ii M/s Rex Pharmaceutical Pakistan, Karachi

Background of the case

Mr. Abdul Rasool Sheikh, FID, Karachi conducted inspection of the firm M/s Rex Pharmaceutical Pakistan, Karachi on 06.03.2013. During inspection the FID pointed out number of serious/critical shortcomings in all sections. Accordingly showcause notice/stop production order was issued on 23.04.2013. The case was presented before CLB in its 232nd meeting held on 29&30th July 2013. The Board had decided as under:-

i) The case was deferred by Central Licensing Board till its next meeting as per your request that the Director of the firm had gone to Saudi Arabia for performing Umrah and requested to defer the case till next meeting of CLB.

ii) The production will remain stopped / suspended till the final approval for resumption of production by the Central Licensing Board.

2. The case was presented before the 233rd Meeting of CLB, wherein the CLB had decided as under:-

Decision of 233rd Meeting of CLB:

After thorough discussion and deliberations, considering the background of the case and facts on record, Board unanimously decided to suspend the DML of the firm for period of three months under Rule 13 of Drugs (Licensing, Registering and Advertising) Rules, 1976. The Board further decided to issue show cause notice and personal hearing to the firm and advised for market survey of production manufactured by firm.

3. Decision of the CLB was conveyed to the firm on 24.02.2014.The firm vide letter No. Nil dated 02.04.2014 replied that they have removed all the shortcomings and ready for inspection. The Area FID visited the firm on 18.11.2014 and recommended for cancellation of DML. The case was placed before the CLB in its 245th Meeting held on 30.12.2015.

4. The case was again presented before the 245th Meeting of CLB, wherein the CLB had decided as under:-

Decision of 245th Meeting of CLB:

The Board after thorough discussion, keeping in view the available record, observations of the FID in its inspection conducted on 06.03.2013, track record and non-serious attitude of the firm, and report of the FID dated 18.11.2014 which categorically stated that “The DML of the firm may be cancelled in larger public interest”, has decided to suspend the DML of the firm M/s Rex Pharmaceuticals Pakistan, Karachi for a period of 06 months, under Rule 12 of the Drugs (LR&A) Rules, 1976.

5. The decision of the CLB was conveyed to the firm on 09.02.2016.

Recommendations of FID

Mr. Abdul Rasool Shaikh, FID, Karachi vide letter dated 24.01.2017 informed that the firm was inspected on 06.01.2017 and found non-operational, no one was there except watchman who told that factory is closed since 2011 and owners are reported to be living in USA now days. Based on the current conditions of the firm it is recommended that their DML by way of formulation may be cancelled in larger public interest.

6. The recommendations of FID were presented before the 252nd Meeting of CLB, wherein the CLB had decided as under:-

Decision of the 252nd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the Federal Inspector of Drugs in its letter dated 24.01.2017, in which the FID recommended to cancel the DML of the firm in the larger public interest, casual attitude of the firm towards GMP compliance, track record of the firm and nonappearance of representatives of the firm before the Board to defend the case, the Board decided to *cancel the Drug Manufacturing License of the firm M/s Rex Pharmaceutical Pakistan, Karachi*, under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (L,R&A) Rules, 1976, from the date of issuance of decision of the 252nd meeting of CLB.

6. The firm file appeal in Appellate Board under section 9th of the Drugs Act, 1976 147th. The Board decided as under:-

Decision of Appellate Board in its 147th Meeting

M/s Rex Pharmaceutical Pakistan, Karachi filed an appeal against the decision of the CLB regarding cancellation of DML. The case was considered in 147th meeting of the Appellate Board held on 28.08.2017, wherein the appellate board decided to suspend the operation of impugned order of CLB dated 15.03.2017 communicated on 24.04.2017 and remand the appeal back to the CLB. The appellate board constituted a panel of following panel to inspect the premises of the appellant who shall submit its report within 30 days from the date of communication:-

a. Dr. Kifayat Ullah, CDC, Gilgit, Baltistan
b. Prof. Dr. Maqsood Ahmed, Ripah International University, Lahore
c. Syed Muied Ahmed, Expert in Manufacturing, Karachi

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

7. The panel inspected the firm on 12.12.2017 and noticed observation which still needs rectification:-

The panel further concluded and recommended that:-

The panel observed a number of shortcomings in building, production machinery, HVAC system, documentation etc. Therefore, based on the areas inspected, the people met and documents reviewed and considering the findings of inspection the panel recommends that the Drug Manufacturing License may be granted to M/s Rex Pharmaceuticals Pakistan, Karachi, for two sections only namely Oral Liquids and Tablet (after addressing the observations in this report).

7. The panel inspection report was placed before 257th meeting of CLB. Wherein the Board decided as under:-

Decision of 257th Meeting of CLB:-

The case was placed before the Central Licensing Board in its 257th Meeting held on 24-25 Jan, 2018 and decided as under:-

"After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the panel of experts in its report dated 12.12.2017 decided to

i. Re-inspect the firm M/s Rex Pharmaceutical Pakistan, Karachi by following panel of experts, constituted by the Appellate Board in its 147th Meeting:-

a. Dr. Kifayat Ullah, CDC, Gilgit, Baltistan
b. Prof. Dr. Maqsood Ahmed, Ripah International University, Lahore
c. Syed Muied Ahmed, Expert in Manufacturing, Karachi

ii. The panel shall submit the detailed report alongwith rectification status of the observations in the Tablet Section and Liquid Syrup Section noted by the panel in the report dated 12.12.2017. Further more the panel will also submit detailed report regarding the quality control laboratory and storage facilities of the firm. The report shall be placed in the forthcoming meeting of Central Licensing Board for consideration.

8. The Decision of the 257th meeting of CLB was conveyed to the firm and quarters concerned on 06.03.2018.

9. The firm vide letter No. Nil dated 20.03.2018 received on 27.03.2018 informed that they have rectified the observations recommended by the panel. In the meanwhile one of the respected panel member Dr. Kifayat Ullah, CDC, Gilgit passed away.

10. The case was placed before 259th meeting of CLB. The Board decided as under:-

Decision of the 259th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case and intimation of the firm regarding death of the worthy panel member Dr. Kifayatullah, Chief Drug Controller, Gilgit Baltistan, the Central Licensing Board decided to replace name of deceased member Dr. Kifayatullah, Chief Drug Controller, Gilgit Baltistan with Additional Director, Karachi, other members of the panel shall remain same.

11. Mr. Syed Muied Ahmad, Member, CLB vide letter dated 25.04.2019 addressed to Chairman CLB informed that he could not conduct regulatory inspections due to illness of his mother.

12. Request of Mr. Syed Muied Ahmad, Member, CLB was placed before 270th meeting of CLB. The Board decided as under:-

Decision of the 270thMeeting of CLB

After thorough discussion/deliberations and keeping in view the request of Mr. Syed Muied Ahmad. The board decided to nominate Dr. Abdullah Dayo, Memebr, CLB in lieu of Mr. Syed Muied Ahmad. However, in case of Regent Pharma, Karachi the panel constituted for

renewal of DML shall be given mandate to verify the status of observations noted by the FID in its report dated 16.01.2018 in compliance to decision of 260th meeting of CLB.

13. Decision of 270th meeting was conveyed to the quarters concerned. The panel conducted inspection of the firm on 12.07.2019 submitted comparison of observations noted on 12.12.2017 and 12.07.2019. The panel concluded as under:-

"Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, it was noticed that no technical person (in Quality Control laboratory, Production sections and ware house) was available in the firm to represent and answer, technically, the observations of the panel. The firm was being represented by Mr. Muhammad Amin along with his son and daughter. Moreover, Quality Control Laboratory required to be upgraded in terms of equipment and testing procedures. Management also couldn't display the equipment in working condition as no power supply was seen in the QC Laboratory and re-calibration was also due for available equipments. HVAC system, in general, requires to be commissioned and qualified and air balancing to be performed to avoid any chance of contamination and cross-contamination. Power supply was also seen inadequate and insufficient to run the production operations smoothly including HVAC system. The management of M/s. Rex Pharmaceutical Pakistan couldn't improve / upgrade the production and testing facility as identified by the panel during inspection on dated 12.12.2017.

Keeping in view the above stated facts, Panel does not recommend the commencement of the production in these sections in larger public interest."

14. The case was placed in 271st meeting of CLB.

Proceedings of 271st meeting:-

Quality Assurance Division presented the case before the Board keeping in view the recommendations of panel in its report dated 12.07.2019. The board discussed the case in detail including decision of 252nd meeting of CLB, wherein the Board decided to cancel the DML of the firm. The Board also go through the decision of 147th meeting of Appellate Board and subsequent recommendations of the panel in its report dated 12.07.2019, in compliance to 270th meeting of CLB.

Decision of the 271stMeeting of CLB

After thorough discussion/deliberations, the Board considered the report of the panel of experts dated 12.07.2019 and recommendations of the panel of experts. The Board also considered the background history of the case and failure on the part of the firm for complying the conditions of License as enumerated under Rule, 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 and Schedule B framed under the Drugs Act, 1976. The Board, therefore decided to serve Show Cause Notice under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 to the firm M/s Rex Pharmaceuticals Pakistan, DP-3, Sector 12-D, North Karachi Industrial Area, Karachi as to why their Drug Manufacturing License No. 000536 by way of formulation may not be suspended or cancelled for failure to maintain conditions of License as enumerated under Rule, 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 and Schedule B framed under the Drugs Act, 1976 and reported by the panel of experts in their inspection report dated 12.07.2019.

15. The firm was issued show cause No. F. 8-3/2019-QA (CLB-M-271) on 01.10.2019 in compliance to decision of 271st meeting of CLB.

Proceedings of 273rd Meeting of CLB

Division of QA&LT presented the case before the CLB. Mr. Amin Akhai (Owner of the firm) and his Son Mr. Zaid Akhai of the firm M/s. Rex Pharmaceuticals Pakistan, Karachi appeared before the Board. Mr. Amin Akhai stated that they did not receive show cause notice or personal hearing letter. On query raised by Board regarding information of meeting. He stated that one of his friend told him about the personal hearing so he reached Islamabad. Accordingly copy of show cause notice and personal hearing letter was handed over to Mr. Amin Akhai in the Board. Secretary, CLB and Deputy Director (QA) inform to the Board that the firm also file a writ petition No D-6473/2019 in the High Court of Sindh at Karachi. Mr. Amin Akhai requested that the correspondence may also be made on the address *"A-35, Muhammad Ali Jinnah Society, Karachi"* in addition to the factory Address.

Decision of 273rdMeeting of CLB

Without prejudice any order of any court including High Court & Supreme Court and after thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view available record and request of the firm, the Board decided to provide:-

i. Final opportunity to the submit reply of Show Cause notice dated 01.10.2019 within 15 days.
ii. Last chance of personal hearing in the forthcoming meeting of CLB.

Item No. V. RATIFICATION OF DECISION OF 272ND MEETING OF CLB

Case No. i: M/S. GULF PHARMACEUTICALS, RAWAT

Background:

Mr. Hasan Afzaal, FID, Islamabad conducted inspection of the firm M/s. Gulf Pharmaceuticals, Plot No 49, St. No. S-5, National Industrial Zone, Rawat (DML No. 000750) on 12.07.2019.

2. The FID during inspection noted critical observations.

Action taken by DRAP:

The firm M/s Gulf Pharmaceuticals, Rawat was served Show Cause Notice and suspension of production activities order No.F.4-57/2012-QA on 26.07.2019.

Reply of the firm:

The firm M/s Gulf Pharmaceuticals, Rawat vide letter dated 08.08.2019 submitted reply of Show Cause Notice and requested that they want to avail opportunity of statutory of personal hearing before the competent authorities. The firm vide letter dated 09.08.2019 requested for constitution of independent panel of experts for inspection.

3. The case was placed in 271st meeting of CLB, wherein the Board decided as under:-

Decision of the 271stMeeting of CLB

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

i. Constitute following panel of experts for verification of the observations noted by the FID in its report dated 12.07.2019 before resumption of production:-

   a) Dr. Munawar Hayat, Chief Drugs Controller, Punjab.
   b) Dr. Hafsa Karam Elahi, Addl. Director (QA&LT), DRAP, Islamabad
   c) Area Federal Inspector of Drugs, Islamabad.

ii. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 12.07.2019, with clear and candid recommendations.

iii. Production of the firm M/s Gulf Pharmaceuticals, Rawat shall remain suspended till recommendation by panel and subsequent approval by the CLB.

Request of the firm:-

The firm vide letter dated 07.10.2019 submitted request for the reconstitution of panel. The firm stated that Dr. Hafsa karam Elahi, Additional Director is on leave and not available.

4. The Director (QA&LT) considered the request of the firm and replace Dr. Hafsa Karam Elahi, Additional Director with Mr. Zeeshan Nazir, Deputy Director (QA&LT)

5. The case was placed before the 272nd meeting of CLB. Wherein Board decided as under:-

Decision of the 271stMeeting of CLB

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

i. Ratify the decision of replacement of panel member Dr. Hafsa Karam Elahi, Addl. Director (QA) with Mr. Zeeshan Nazir, Deputy Director (QA).

ii. Recommendation of panel shall be placed before the Director (QA&LT) for orders.

iii. Decision of the Director (QA&LT) shall be placed before the CLB for ratification of orders of Director (QA&LT)

Updated Status:

The panel conducted inspection of the firm M/s Gulf Pharma, Rawat on 07.11.2019 & 21.11.2019 and concluded as under:-

"Keeping in view the above stated observations during inspection, areas visited, documents reviewed and people met it is concluded that the firm M/s Gulf Pharmaceuticals, Plot 49, S-5, National Industrial Zone Rawat has rectified majority of the observation from the previous inspection and the fact that the cases mentioned against the observations noted on serial No. 02 and 08 shall be pursued concurrently, the panel is of the opinion that the report may be forwarded to the Competent Authority for resumption of production activities".

6. Recommendations of the panel were placed before the Director (QA&LT). Resumption of production was allowed on 05.12.2019.

Proceedings of 273rd Meeting of CLB

Division of QA&LT presented the case before the CLB in compliance to decision of 271st meeting of CLB. Dr. Munawar Hayat, CDC, Punjab stated that action need to be done at para 2 and 8 of the report, as mentioned in conclusion of the report.

Decision of 273rdMeeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case and panel inspection report dated 07.11.2019 & 21.11.2019, the Central Licensing Board decided to:-

i. Ratify decision of Director QA&LT regarding resumption of production of the firm M/s Gulf Pharmaceuticals, Plot 49, S-5, National Industrial Zone Rawat.

ii. QA Section will refer the case to FID for further necessary action at para 02 & 08 of Inspection report.

Item No. I GMP NON-COMPLIANCE CASES (NEW)

Case No. i: M/S. NBS PHARMA, LAHORE.

Background:

Mr. Ajmal Sohail Asif, FID, Lahore conducted inspection of the firm M/s. NBS Pharma, 8-KM, Thokar - Raiwind Road, Lahore on 04.12.2018 to check the GMP compliance and production activities of the firm.

2. The FID during inspection noticed critical observations.

Action taken by DRAP:

The firm M/s. NBS Pharma, Lahore was served Show Cause Notice and suspension of production activities on 07.02.2019.

3. The case was placed in 270th meeting of CLB. Wherein the Board decided as under:-

Decision of the 270thMeeting of CLB

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

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

   a) Dr. Ikram ul Haq, Member, CLB
   b) Chief Drug Controller, Punjab
   c) Area Federal Inspector of Drugs, Lahore

ii. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 04.12.2018, with clear and candid recommendations.

iii. Production of the firm M/s NBS Pharma, Lahore shall remain suspended till recommendation by panel and subsequent approval by the Director (QA&LT).

4. In compliance to the decision of 270th meeting of CLB, the panel conducted inspection of the firm on 20.09.2019 and submitted detail report. The panel concluded as under:-

"Based on the area inspected, the people met and the documents reviewed, and considering the findings of the inspection. The panel was of the opinion that the firm has rectified most of the shortcomings pointed out during last inspection. The panel recommends that M/s NBS Pharma, Lahore may be allowed to resume the production in all sections".

Proceedings of 273rd meeting:-

Quality Assurance Division presented the panel inspection report of the firm M/s NBS Pharma, 8-KM, Thokar - Raiwind Road, Lahore dated 20.09.2019 in compliance to decision of 270th meeting of CLB.

Decision of the 273rd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case and panel inspection report dated 20.09.2019 constituted in 270th meeting of CLB, the Central Licensing Board decided to allow resumption of production activities of the firm M/s NBS Pharma, 8-KM, Thokar - Raiwind Road, Lahore, as per recommendation of panel inspection report dated 20.09.2019 from the date of issuance of decision of 273rd meeting of CLB.

Case No. ii M/s Wisdom Pharma, Peshawar

Background:-

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

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

Action taken by DRAP:

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

3. The case was placed in 266th meeting of CLB.

Decision of the 266thMeeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case and compliance by the C.E.O. of the firm Wisdom Pharmaceuticals, Peshawar, the Central Licensing Board decided to:-

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

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

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

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

4. In compliance to the decision of 266th meeting of CLB, the panel conducted inspection of the firm on 09.10.2019 & 03.12.2019 and submitted detail report. The panel concluded as under:-

"The firm has rectified majority of the observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered for resumption of production. However the firm should be inspected more frequently on risk based approach after resumption of production".

Proceedings of 273rd meeting:-

Quality Assurance Division presented the panel inspection report of the firm M/s. Wisdom Pharmaceutical, Peshawar dated 09.10.2019 & 03.12.2019 in compliance to decision of 266th meeting of CLB.

Decision of the 273rdMeeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case and panel inspection report dated 09.10.2019 & 03.12.2019 constituted in 266th meeting of CLB, the Central Licensing Board decided to allow resumption of production activities of the firm M/s. Wisdom Pharmaceutical, Peshawar, as per recommendation of panel inspection report dated 09.10.2019 & 03.12.2019 from the date of issuance of decision of 273rd meeting of CLB.