MINUTES OF 272nd MEETING OF CENTRAL LICENSING BOARD HELD ON 17th OCTOBER, 2019

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272nd meeting of the Central Licensing Board (CLB) was held on 17th October, 2019 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.	Dr. Ikram ul Haq, Expert inQC/QA of drugs.	Member
2.	Prof. Dr Abdullah Dayo, Faculty of Pharmacy, University of Sindh, Jamshoro	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.	Mr. Abdul Sattar Sohrani Representative Director (QA/LT), DRAP, Islamabad	Member
8.	Zakir Shah, Drug inspector, Department of Health, Govt of Khyber Pakhtunkhwa.	Member
9.	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
10.	Mr. Khalid Munir & Mr. Adnan Hirani, Representative of PPMA.	Observer
11.	Mr.Nadeem Alamgir Representative of Pharma Bureau.	Observer
12.	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. Zeeshan Nazir, Deputy Director (Quality Assurance), Mr. Arslan Taariq, Assistant Director (QC), Dr. Muhammad Yaqoob AD (Lic.), Dr. Muhammad Usman, AD (Lic) and Dr. Zunaira Farayad, Assistant Director (Lic), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 271st MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 271st meeting of the Central Licensing Board (CLB) which was held on **12th September, 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 Bio-Next Pharmaceuticals, Plot No. 50, Street No. S-10, RCCI, Rawat **Section (01).** 1. Dry Vial Injection Section (Carbapenem)	**15-10-2019**	**Good**	1. Prof. Dr. Gul Majeed, Quaid-e-Azam University, Islamabad could not accompany the panel due to official engagement. 2. Secretary, Central Licensing Board /Additional Director (Lic), DRAP, Islamabad. 3. Assistant Director (Lic-III), DRAP, Islamabad. 4. Federal Inspector of Drugs, Islamabad-III.
	"Keeping in view the manufacturing and testing facility in place, documents reviewed and people met, the panel unanimously **recommends** the grant of Drug Manufacturing License for the section of **Dry Vial Injection Section (Carbapenem)** to M/s Bio-Next Pharmaceuticals, Plot No. 50, Street No. S-10, RCCI, Rawat, (Formulation). **Decision of the Central Licensing Board in 272nd meeting** The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Bio-Next Pharmaceuticals, Plot No. 50, Street No. S-10, RCCI, Rawat with following section: **Section (01)** 1. Dry Vial Injection Section (Carbapenem)			

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 Don Valley Pharmaceuticals (Pvt) Ltd, 31-Km Main Ferozepur road, Lahore. DML No. 000395 (Formulation) **Section (01)** 1. Tablet II (General) Section.	06-08-2019	**Good**	1. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 2. Dr. Zaka ur Rehman, Secretary, Pharmacy Council, Punjab. 3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - Keeping in view the manufacturing and testing facilities, the panel of inspectors recommends to grant permission for production to M/s Don Valley Pharmaceuticals (Pvt) Ltd, 31-Km Main Ferozepur Road, Lahore, License No. 000395 for the additional Tablet II (General) Section. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and approved the grant of one additional section in the name of M/s Don Valley Pharmaceuticals (Pvt) Ltd, 31-Km Main Ferozepur Road, Lahore, License No. 000395 as under: **Section (01)** 1. Tablet II (General) Section.			
2.	M/s Medi-Excel Pharmaceuticals, Plot No.282, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000519 (by way Formulation). **Sections/Facility (14):** 1. Liquid Section (Vet) **Regularization.** 2. Oral Powder Section (Vet) **Regularization.** 3. Vaccine & Biological Section (Vet) **Regularization.** 4. Liquid Antibiotic Injectable Section-1 (Vet) **New.** 5. Liquid Antibiotic Injectable Section-2 (Vet) **New.**	08-10-2019	**Good**	1.Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad. 2.Abdul Sattar Sohrani, Deputy Director (QC) (QALT), DRAP, Islamabad. 3.Babar Khan, Area Federal Inspector of Drugs, Islamabad.

	6. General Injectable Section (Vet) **New**. 7. Steroid Injectable Section (Vet) **New.** 8. Finished Goods Store (Vet)-Revised . 9. Raw Material Store (Vet)-Revised . 10. Penicillin Powder Injectable Section (Vet) **New.** 11. Penicillin Liquid Injectable Section (Vet) **New.** 12. Penicillin Oral Powders Section (Vet) **New.** 13. Bolus Section (Vet) **New.** 14. Quality Control Sections-Revised			
	Recommendations of the panel: - "Keeping in view the above facts on record, the panel unanimously **recommended** the renewal of Drug Manufacturing License by way of formulation and grant / approval of 8+3 new sections and regularization of 3 already existing sections M/s Medi-Excel Pharmaceuticals, Plot No.282, Industrial Triangle, Kahuta Road, Islamabad. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and approved the grant of additional sections and regularization of exisiting sections / facilities in the name of M/s Medi-Excel Pharmaceuticals, Plot No.282, Industrial Triangle, Kahuta Road, Islamabad as under: **Sections/Facility (14):** **1.** Liquid Section (Vet) **Regularization.** 2. Oral Powder Section (Vet) **Regularization.** 3. Vaccine & Biological Section (Vet) **Regularization.** 4. Liquid Antibiotic Injectable Section-1 (Vet) **New.** 5. Liquid Antibiotic Injectable Section-2 (Vet) **New.** 6. General Injectable Section (Vet) **New**. 7. Steroid Injectable Section (Vet) **New.** 8. Finished Goods Store (Vet)-Revised . 9. Raw Material Store (Vet)-Revised . 10. Penicillin Powder Injectable Section (Vet) **New.** 11. Penicillin Liquid Injectable Section (Vet) **New.** 12. Penicillin Oral Powders Section (Vet) **New.** 13. Bolus Section (Vet) **New.** 14. Quality Control Sections-Revised			
3.	M/s Kohinoor Industries, 159-160/ B Small Industrial Estate, Sahiwal.	25-06-2018 & 21-08-2019	**Good**	1. Dr. Syed Shahid Nasir, Expert of Drugs.

	DML No. 000197 (by way Formulation). **Section (01)** 1. Medicated Gauze Dressing Section.			2. Ms. Aisha Irfan, Federal Inspector of Drugs, Lahore 3. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore. 4. Ms. Riffat Naz, Drug Inspector Industries Health Department, Punjab
	Recommendations of the panel: - "Keeping in view the manufacturing facility like Building, HVAC System, sanitation, Production Machinery, Equipments, in Quality Control and Microbiology Laboratory, Testing facilities, Technical Personnel met and documentation, the panel of inspectors **recommends** the renewal of manufacturing License by way of formulation to M/s Kohinoor Industries, 159-160/ B, Small Industrial Estate, Sahiwal. 1. Medical Devices. (Cotton Wool Bandages/ Crepe Bandages, Gauze, Tulle) 2. External Preparation (Topical Solution and Lotions). 3. Cream / Ointment. 4. Sachet Section. 5. Veterinary Oral Powder Section (General). 6. Veterinary Oral Liquid Section (General). 7. Repacking of powder and liquid. The panel of inspectors also recommends the grant of following additional section. 1. Medicated Gauze Dressing Section. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and decided to refer the case pertaining to Medicated Gauze Dressing Section to Division of Medical Devices and Medicated Cosmetics as the subject matter falls under their domain.			
4.	M/s Platinum Pharmaceuticals (Pvt) Ltd., located at plot No.A-20, North Western Industrial Zone, Bin Qasim, Karachi DML NO. 000415 (by way of Formulation) **Sections (07)** 1. Tablet Section (General) - Expansion 2. Capsule Section (General) – Expansion. 3. Sachet Section (General) – Expansion	29-08-2019	**Good**	1. Abdullah Dayo, Member CLB, Karachi. 2. Additional Director (E&M), DRAP, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi.

4. Dry Powder Suspension (General)- Expansion 5. Raw and packaging material store- New 6. Research Development Laboratory 7. Finished Goods Store- New			

Recommendations of the panel: -

M/s Platinum Pharmaceuticals (Pvt) Ltd., located at plot No.A-20, North Western Industrial Zone, Bin Qasim, Karachi was inspected on 29-08-2019 by the Panel constituted as per DRAP letter F.2-3/1994-Lic (Vol-II) dated 23-07-2019 for the Inspection of Amendments / Expansion in following areas as per approved layout plan.

S.No	Ground Floor
1.	Tablet Section (General) - Expansion
2.	Capsule Section (General) - Expansion
3.	Sachet Section (General) - Expansion s
4.	Dry Powder Suspension (General)- Expansion
5.	Raw and packaging material store- New
6.	Research and Development Laboratory
7.	Finished Goods Store- New

Based on the area inspected, the people met and the documents reviewed, and considering the findings of the inspection and vision of the management for export, panel **recommends** the grant of approval for the amendments / expansion of aforesaid areas

Decision by the Central Licensing Board in 272nd meeting

The Board considered and approved the revised sections and new sections/ facilities in the name of M/s Platinum Pharmaceuticals (Pvt) Ltd., located at plot No.A-20, North Western Industrial Zone, Bin Qasim, Karachi as under:

Sections (07)

1. Tablet Section (General) - Expansion
2. Capsule Section (General) – Expansion.
3. Sachet Section (General) – Expansion
4. Dry Powder Suspension (General)- Expansion
5. Raw and packaging material store- New
6. Research Development Laboratory
7. Finished Goods Store- New

5.	M/s Bosch Pharmaceuticals (Pvt) Ltd, Plot No. 209, Sector, 23, Korangi Industrial Area, Karachi. DML NO. 000707 (by way of Formulation) **Section (01)** **i.** Lyophilzation (General) Section	22.05.2019	**Good**	1. Mr. Syed Muied Ahmed, Member Central Licensing Board. 2. Dr. Najam-us-Saqib, Additional Director /Area FID, DRAP, Karachi,
	Recommendations of the panel: - Based on the areas inspected, the people met and the documents reviewed, construction and maintenances of the section as per layout plan approved by DRAP authorities, availability of relevant production and quality control machinery and equipment, panel **recommend** the grant of New Section i-e LYOPHILZATION (GENERAL) SECTION. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and approved the additional sections in the name of M/s Bosch Pharmaceuticals (Pvt) Ltd, Plot No. 209, Sector, 23, Korangi Industrial Area, Karachi as under: **Section (01)** 1. Lyophilzation (General) Section			
6.	M/s Linz Pharmaceuticals (Pvt) Ltd, Plot No. 31-G & 31-H, Sector, 15, Korangi Industrial Area, Karachi DML No. 000540 (by way of Formulation) **Tenure:** 24.07.2019 to 23.07.2024 **Sections** 1. Capsule (General)- Amendments 2. QC Lab- Renewal & Amendments 3. Oral dry powder suspension (Ceph)- Amendments 4. Tablet (General antibiotic) Amendments	18.09.2019	**Good**	1. Abdullah Dayo, Member CLB, Karachi. 2. Additional Director (E&M), DRAP, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi.

	5. Warehouse (Ceph/General)- Amendments			

Recommendations of the panel: -

M/s. Linz Pharmaceuticals (Pvt) Ltd, Karachi was inspected in details by the panel and amendments have been made as per layout plan approved by DRAP authorities. Firm was observed well equipped with necessary machinery and equipments required for the manufacturing and quality control of the product registered in their name. HVAC system is seen installed and observed operational in all the production sections. Necessary measures were being exercised to prevent any chances of contamination and cross contamination. Firm is also conducting stability studies wherein, documents and logs were checked in details and found acceptable in general. QC Lab found equipped adequately with relevant equipments including 3HPLCs, FTIR, TOC Analyzer, LPC etc. Calibration records and log books were available on site. Training records were observed maintained. Methods duly validated/verified as per SOP and Validation Master Plan was in place. Certain documentation regarding analysis of raw materials and finished products were also reviewed.

Based on the areas inspected, people met, documents reviewed, observations listed in the inspection report and export volume of the firm, panel **recommends** the grant of renewal for the above mentioned sections and amendments made as per layout plan approved by DRAP authorities.

Decision by the Central Licensing Board in 272nd meeting

The Board considered and approved the revised sections in the name of M/s Linz Pharmaceuticals (Pvt) Ltd, Plot No. 31-G & 31-H, Sector, 15, Korangi Industrial Area, Karachi as under:

Sections

1. Capsule (General)- Amendments
2. QC Lab- Renewal & Amendments
3. Oral dry powder suspension (Ceph)- Amendments
4. Tablet (General antibiotic) Amendments
5. Warehouse (Ceph/General)- Amendments

7.	M/s Geofman Pharmaceuticals, Plot No. 20, Sector, 23, Korangi Industrial Area, Karachi. DML NO. 000090 (by way of Formulation) **Sections** **1.** Ampoule Compact Line Section (New)	11.10.2019	**Good**	1. Dr. Abdullah Dayo, Member CLB 2. Muhammad Shoaib Ansari, Chief Drug Inspector, Sindh 3. Dr. Najam-us-Saqib, Area FID, DRAP, Karachi,

Recommendations of the panel: -

M/s. Geofman Pharmaceuticals was inspected in details by the panel. The section is built with prefabricated clean room panel and constructed as per layout plan by the DRAP authorities. The section was observed well equipped with necessary machinery and equipment required for the

	manufacturing and quality control of the product registered in their name. HVAC system is seen installed and observed operational. Necessary measures were being exercised to prevent any chances of contamination and cross contamination. Based on the areas inspected, people met, documents reviewed, observations listed in the inspection report an export volume of the firm, panel recommends approval for the Ampoule Compact Line Section. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and approved the additional sections in the name of M/s Geofman Pharmaceuticals, Plot No. 20, Sector, 23, Korangi Industrial Area, Karachi as under: **Sections** 1. Ampoule Compact Line Section (New)			
8.	M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000432 (by way Formulation). **Sections (02):** 1. Capsule Section (Ceph). 2. Dry Suspension Section (Ceph).	01-10-2019	**Good**	1. Prof. Dr. Gul Majeed, Expert / Dean Pharmacy, Quaid-e-Azam University, Islamabad. 2. Dr. Fakhruddin Aamir, Director (HOTC), DRAP, Islamabad. 3. Babar Khan, Area Federal Inspector of Drugs, Islamabad-1.
	"Keeping in view the above facts on record, the panel unanimously **recommended** the renewal and grant of additional sections of Drug Manufacturing License by way of formulation to M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and approved the additional sections in the name of M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad as under: **Sections** 1. Capsule Section (Ceph). 2. Dry Suspension Section (Ceph).			

9.	M/s Shaigan Pharmacetical (Pvt) Ltd. 14-KM Adyala Road Rawalpindi. DML No. 000333 (By way of Formulation) **Sections (01):** i. Lyophilized Injection Vials (Steroidal) Hormone):	25-09-2019	**Good**	1.Dr. Muhammad Usman, Member, Central Licensing Board. 2.Deputy Director (QC), DRAP, Islamabad. 3.Area, FID, DRAP, Islamabad. 4.Area Assistant Director-III (Licensing), DRAP, Islamabad.
	"Keeping in view the above facts, detailed visit of facility and supporting documents (attached with report) provided by the company, the panel unanimously **recommends** M/s Shaigan Pharmaceutical (Pvt) Ltd. 14-KM Adyala Road Rawalpindi for the renewal of Drug Manufacturing License No. 000333 (Formulation) **(16 sections)** and one additional sections namely **Lyophillized Injection Vials (Steroidal) Hormone Non Anabolic)**: **<u>Decision by the Central Licensing Board in 272nd meeting</u>** The Board considered and approved the additional sections in the name of M/s Shaigan Pharmacetical (Pvt) Ltd. 14-KM Adyala Road Rawalpindi as under: **Sections** 1. Lyophilized Injection Vials (Steroidal) Hormone):			
10.	M/s Vetz Pharmaceuticals (pvt) Ltd, Q-01, SITE, Kotri, Sindh. DML NO. 000813 (by way of Formulation) **Sections** **i.** *Aerosol Spray (veterinary)*	25.07.2019	**Good**	i. Dr. Abdullah Dayo, Member CLB ii. Dr. Najam-us-Saqib, Area FID, DRAP, Karachi. iii. Mr. Sajjad Ahmed Abbasi, Area Federal Inspector of Drugs, DRAP, Karachi.
	***Recommendations of the panel**: -* *The panel observed as follows :* *1. The additional section of Aerosol Spray (Veterinary) was seen constructed as per DRAP's authority approved Layout plan.* *2. An appropriate level of sanitation, cleanliness & Worker hygiene was noted.* *3. The firm has adequate number of processing & testing equipment in respective departments, based on requirements of products.* *4. The HVAC system was seen installed and observed in operational condition.*			

	5. *Quality control lab also observed equipped with necessary equipments required for the testing of their registered drugs.* 6. Separate storage areas were noted and noticed well maintained. 7. Personnel met during inspection, observed well conversant with necessary qualification and experience. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and approved the additional sections in the name of M/s Vetz Pharmaceuticals (pvt) Ltd, Q-01, SITE, Kotri, Sindh as under: **Sections** 1. *Aerosol Spray (veterinary)*			
11.	M/s Regent Laboratories, Plot No. C-20, SITE Super Highway, Karachi DML No. 000506 (by way of Formulation) **Sections:-** **1.** *Powder veterinary vitamin (G),* **2.** *Tablet (psychotropic),* **3.** *Capsule (Psychotropic),* **4.** *Tablet (Antibiotic),* **5.** *Capsule (Antibiotic),* **6.** *Sachet (General),* **7.** *Cream/Ointment (Steroidal),* **8.** *Cream/Ointment (Non-Steroidal),* **9.** *Liquid External Preparation,* **10.** *Capsule (G),* **11.** *Capsule (Cephalosporin)* **12.** *Dry Powder Suspension (Cephalosporin)*	09.10.2019	**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: - *Keeping in view the above submission the panel unanimously recommends as follows:* 1. *The grant of renewal of their DML No. 000506 (Formulation) for the next five years with effect from 16/10/2017.* 2. *The grant of additional sections of powder veterinary vitamin (G), Tablet (psychotropic), Capsule (Psychotropic), Tablet (Antibiotic), Capsule (Antibiotic), Sachet (General), Cream/Ointment (Steroidal), Cream/Ointment (Non-Steroidal), Liquid External Preparation, Capsule (G), Capsule (Cephalosporin) and Dry Powder Suspension (Cephalosporin).*			

	3. *And based on the improvements made by the firm in the light of the inspection conducted by area FID on 16/01/2018, the panel also recommends the commencement of manufacturing activities after the forma; approval of board concerned.* **<u>Decision by the Central Licensing Board in 272nd meeting</u>** The Board considered and approved the additional sections in the name of M/s Regent Laboratories, Plot No. C-20, SITE Super Highway, Karachi as under: **Sections:-** **1.** *Powder veterinary vitamin (G),* **2.** *Tablet (psychotropic),* **3.** *Capsule (Psychotropic),* **4.** *Tablet (Antibiotic),* **5.** *Capsule (Antibiotic),* **6.** *Sachet (General),* **7.** *Cream/Ointment (Steroidal),* **8.** *Cream/Ointment (Non-Steroidal),* **9.** *Liquid External Preparation,* **10.** *Capsule (G),* **11.** *Capsule (Cephalosporin)* ***12.*** *Dry Powder Suspension (Cephalosporin)*			
12	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Estate, 20-KM, Ferozepur Road, Lahore. DML No. 000736 (by way of Formulation). **Section (01):** 15. Liquid Injection (General) (Vet).	07-10-2019	**Good**	4.Dr. Farzana Chaudhary, Member, Appellate Board. 5.Syed Shahid Nasir, Member, Appellate Board. 6.Shoaib Ahmed, Federal Inspector of Drugs, Lahore.
	<u>Recommendations of the Panel.</u> "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. **<u>Decision by the Central Licensing Board in 272nd meeting</u>** The Board considered and decided th defer the case for verification of CAPA by the area Federal Inspector of Drugs			

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

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000432 (by way Formulation). **Period**: 15-06-2019 to 14-06-2024.	01-10-2019	**Good**	1. Prof. Dr. Gul Majeed, Expert / Dean Pharmacy, Quaid-e-Azam University, Islamabad. 2. Dr. Fakhruddin Aamir, Director (HOTC), DRAP, Islamabad. 3. Babar Khan, Area Federal Inspector of Drugs, Islamabad-1.
	Recommendations of the panel: - "Keeping in view the above facts on record, the panel unanimously **recommended** the renewal of Drug Manufacturing License by way of formulation to M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000432 (Formulation) in the name of M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road, Islamabad,on the recommendations of the panel of experts for the further period of five years commencing on 15-06-2019 and ending on 14-06-2024.			
2.	M/s Medi-Excel Pharmaceuticals, Plot No.282, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000519 (by way Formulation). **Period**: 20-06-2018 to 19-06-2023.	08-10-2019	**Good**	1. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad. 2. Abdul Sattar Sohrani, Deputy Director (QC) (QALT), DRAP, Islamabad. 3. Babar Khan, Area Federal Inspector of Drugs, Islamabad.

Recommendations of the panel:

"Keeping in view the above facts on record, the panel unanimously **recommended** the renewal of Drug Manufacturing License by way of formulation and grant / approval of 8+3 new sections and regularization of 3 already existing sections M/s Medi-Excel Pharmaceuticals, Plot No.282, Industrial Triangle, Kahuta Road, Islamabad.

Decision by the Central Licensing Board in 272nd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000519 (Formulation) in the name of M/s Medi-Excel Pharmaceuticals, Plot No.282, Industrial Triangle, Kahuta Road, Islamabad, on the recommendations of the panel of experts for the further period of five years commencing on 20-06-2018 and ending on 19-06-2023.

3.	M/s BF Bio Sciences Ltd, 5-Km, Sunder Raiwind Road, Raiwind, Lahore. DML No. 000655 (by way Formulation). Period; Commencing on 30-01-2019 ending on 29-01-2024.	22-08-2019	**Good**	1. Dr. Farzana Chaudhry, Expert Member. 2. Dr Mehmood Ahmad, Ex-Dean, IUB. 3. Ms. Anam Saeed, Area Federal Inspector of Drugs, Islamabad.

Recommendations of the panel: -

"Keeping in view the facilities like Building, HVAC System, Equipments, Instruments, Machinery, Personnel Documents, Quality Control and Testing Facilities, the panel of Inspectors is the opinion to recommend the renewal of Drug Manufacturing License of M/s BF Bio Sciences Ltd, 5-Km, Sunder Raiwind Road, Raiwind , Lahore.

Formulation (s)	Pharmacological Categories(ies)	Activity(ies)
Parenteral	Bio Pharmaceutical Products	Formulation Filling, Sterilization, Lyophilization, Packing.
Parenteral (Campaign Manufacturing vide decision of Drug Appellate Board (letter No. F.1-2018-ADB(M-151), on 04.2.2019)	Non Biopharmaceutical Products.	Formulation Filling, Sterilization, Lyophilization, Packing.

Decision by the Central Licensing Board in 272nd meeting

	The Board considered and approved the renewal of Drug Manufacturing Licence No. 000655 (Formulation) in the name of M/s BF Bio Sciences Ltd, 5-Km, Sunder Raiwind Road, Raiwind, Lahore, on the recommendations of the panel of experts for the further period of five years commencing on 30-01-2019 and ending on 29-01-2024.			
4.	M/s Kohinoor Industries, 159-160/ B Small Industrial Estate, Sahiwal. DML No. 000197 (by way Formulation). Period; Commencing on 25-10-2015 ending on 24-10-2020.	25-06-2018 & 21-08-2019	**Good**	1. Dr. Syed Shahid Nasir, Expert of Drugs. 2. Ms. Aisha Irfa, Federal Inspector of Drugs, Lahore 3. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore. 4. Ms. Riffat Naz, Drug Inspector Industries Health Department, Punjab

Recommendations of the panel: -

"Keeping in view the manufacturing facility like Building, HVAC System, sanitation, Production Machinery, Equipments, in Quality Control and Microbiology Laboratory, Testing facilities, Technical Personnel met and documentation, the panel of inspectors **recommends** the renewal of manufacturing License by way of formulation to M/s Kohinoor Industries, 159-160/ B, Small Industrial Estate, Sahiwal.

1. Medical Devices. (Cotton Wool Bandages/ Crepe Bandages, Gauze, Tulle)
2. External Preparation (Topical Solution and Lotions).
3. Cream / Ointment.
4. Sachet Section.
5. Veterinary Oral Powder Section (General).
6. Veterinary Oral Liquid Section (General).
7. Repacking of powder and liquid.

The panel of inspectors also **recommends** the grant of following additional section.

1. Medicated Gauze Dressing Section.

Decision by the Central Licensing Board in 272nd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000197 (Formulation) in the name of M/s BF Bio Sciences Ltd, 5-Km, Sunder Raiwind Road, Raiwind, Lahore, on the recommendations of the panel of experts for the further period of five years commencing on 30-01-2019 and ending on 29-01-2024 for the following sections except Medical Devices Sections for which case would be referred to the Division of Medical Devices and Medicated Cosmetics as the said sections fall under their domain.

Sections:

	1. External Preparation (Topical Solution and Lotions). 2. Cream / Ointment. 3. Sachet Section. 4. Veterinary Oral Powder Section (General). 5. Veterinary Oral Liquid Section (General). 6. Repacking of powder and liquid.			
5.	M/s Linz Pharmaceuticals (Pvt) Ltd, Plot No. 31-G & 31-H, Sector, 15, Korangi Industrial Area, Karachi DML No. 000540 (by way of Formulation) **Period:** 24.07.2019 to 23.07.2024	18.09.2019	**Good**	i. Abdullah Dayo, Member CLB, Karachi. ii. Additional Director (E&M), DRAP, Karachi. iii. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - M/s. Linz Pharmaceuticals (Pvt) Ltd, Karachi was inspected in details by the panel and amendments have been made as per layout plan approved by DRAP authorities. Firm was observed well equipped with necessary machinery and equipments required for the manufacturing and quality control of the product registered in their name. HVAC system is seen installed and observed operational in all the production sections. Necessary measures were being exercised to prevent any chances of contamination and cross contamination. Firm is also conducting stability studies wherein, documents and logs were checked in details and found acceptable in general. QC Lab found equipped adequately with relevant equipments including 3HPLCs, FTIR, TOC Analyzer, LPC etc. Calibration records and log books were available on site. Training records were observed maintained. Methods duly validated/verified as per SOP and Validation Master Plan was in place. Certain documentation regarding analysis of raw materials and finished products were also reviewed. Based on the areas inspected, people met, documents reviewed, observations listed in the inspection report and export volume of the firm, panel recommends the grant of renewal for the above mentioned sections and amendments made as per layout plan approved by DRAP authorities. **<u>Decision by the Central Licensing Board in 272nd meeting</u>** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000540 (Formulation) in the name of M/s Linz Pharmaceuticals (Pvt) Ltd, Plot No. 31-G & 31-H, Sector, 15, Korangi Industrial Area, Karachi , on the recommendations of the panel of experts for the further period of five years commencing on 24.07.2019 and ending on 23.07.2024.			
6.	M/s Karachi Pharmaceutical Laboratories. Plot No. S/54, Hawkes Bay Road, SITE, Karachi DML No. 000074 (by way of Formulation)	16.10.2018 & 07.07.2017	**Good**	i. Mr. Syed Muied Ahmed, ii. Dr. Najam-us-Saqib, Additional Director, DRAP, Karachi iii. Mr. Sajjad Ahmed Abbasi, FID, DRAP, Karachi.

	Tenure: 30.09.2015 to 29.09.2020			iv. Dr. Afaan, Asst. Director, CDL, Karachi.

Recommendations of the panel: -

M/s. Karachi Pharmaceuticals Laboratories was inspected by the panel members in compliance to DRAP Islamabad letter No. F.1-4/2018-FUD 5-(KPL) dated 04th December, 2018. The panel reviewed their overall documentation, inspected manufacturing Facilities, Quality Control Lab and Stores and met with their technical persons and higher Management. The panel observed as follows:

i. The premises constructed as per DRAP's authority approved Layout plan.
ii. An appropriate level of sanitation, cleanliness & worker hygiene was noted.
iii. The firm has adequate number of processing & testing equipment in respective department.
iv. Separate storage areas were noted and noticed well maintained.
v. Personnel met during inspection, observed well conversant with necessary qualification and experience.

Based on stated observations the panel recommends the grant of renewal of DML No. 000074 (By way of Formulation) for following sections for the next five years

1. Tablet (General)
2. Capsule (General)
3. Oral Liquid
4. Liquid Injection (General)
5. External Preparation (Liquid)
6. Ointment/Cream
7. Oral Rehydration
8. Dry Powder Sterile (Cephalosporin)
9. Dry Powder Suspension & Capsules(Cephalosporin)

Decision by the Central Licensing Board in 272nd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000074 (Formulation) in the name of M/s Karachi Pharmaceutical Laboratories. Plot No. S/54, Hawkes Bay Road, SITE, Karachi, on the recommendations of the panel of experts for the further period of five years commencing on 30.09.2015 and ending on 29.09.2020 for the following sections:

1. Tablet (General)
2. Capsule (General)
3. Oral Liquid
4. Liquid Injection (General)
5. External Preparation (Liquid)
6. Ointment/Cream
7. Oral Rehydration
8. Dry Powder Sterile (Cephalosporin)
9. Dry Powder Suspension (Cephalosporin)
10. Capsules (Cephalosporin)

<table>
<tr>
<td>7.</td>
<td>M/s. Macter International Ltd, Plot No.. F-216, S.I.T.E, Karachi
DML No. 000141 (by way of Formulation)

Tenure:
24.11.2019 to 23.11.2024</td>
<td>10.10.2019</td>
<td>Good</td>
<td>1. Dr. Abdullah Dayo, Member CLB, Karachi.
2. Additional Director (E&M) DRAP, Karachi.
3. Director DTL Sindh, Karachi.
4. Area Federal Inspector of Drugs, DRAP, Karachi.</td>
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<td colspan="4">
Recommendations of the panel: -
1. Renewal of Drug Manufacturing License No. 000141 (by way of formulation to the firm M/s. Macter International Ltd, Situated at Plot No.. F-216, S.I.T.E, Karachi for following sections:
<table>
<tr><td>1. Tablet General</td><td>2. Oral Liquid (Syrup/ Suspension/ Solution)</td><td>3. Tablet Psychotropic</td><td>4. Liquid Injection (LVP)</td></tr>
<tr><td>5. Encapsulation (General) Including DPI Capsule</td><td>6. Encapsulation (Steroid) Including DPI Capsule</td><td>7. Aerosol</td><td>8. Ointment/Cream/Gel-I General</td></tr>
<tr><td>9. Oral Dry Powder Suspension (Ceph)</td><td>10. Oral Dry Powder Injection (Ceph)</td><td>11. Liquid Injections (SVP)</td><td>12. Biotech (Lyophilized /Liquid)</td></tr>
<tr><td>13. Ointment/Cream/Gel–II General</td><td>14. Capsule (Ceph)</td><td colspan="2">15. Dry Powder Suspension(General)</td></tr>
</table>
2. Regularization of following section:
Ground floor: Tablet (General), Tablet (Psychotropic), Oral Liquid, (syrup/suspension/ solutions), Warehouse (RMS/PMS/FGS).
First Floor: Ointment/Cream/Gel-I (General), Ointment/Cream/Gel-II (General, Aerosol Section, Liquid Parental (LVP), Dry Powder Suspension (general), Encapsulation (Ceph) Including DPI Capsule, Biotech (Lyophilized /Liquid Section), Biotech Laboratory, R and D Laboratory.
Second floor (A and B): Dry Powder Suspension (Ceph), Capsule (Ceph), Injectable Section (Ceph), Raw Material Store (Ceph), Encapsulation (Steroid) Including DPI Capsule, Raw Material Store (Steroid), Quality Control Laboratory, Microbiology Laboratory as per DRAP, Islamabad letter no. F.2-13/95-Lic (vol-vi), dated 21.09.2019 as per approved layout plans vide letter no. F. 2-13/95-Lic (Vol-Vi dated, 03.09.2019

<u>Decision by the Central Licensing Board in 272nd meeting</u>
The Board considered and approved the renewal of Drug Manufacturing Licence No. 000141 (Formulation) in the name of M/s. Macter International Ltd, Plot No.. F-216, S.I.T.E, Karachi , on the recommendations of the panel of experts for the further period of five years commencing on 24.11.2019 and ending on 23.11.2024.
</td>
</tr>
</table>

8.	M/s. Macter International Ltd, Plot No.. E-40/A, S.I.T.E, Karachi DML No. 000641 (by way of Formulation) **Tenure:** 12.09.2018 to 11.09.2023	11.10.2019	**Good**	1. Dr. Abdullah Dayo, Member CLB, Karachi. 2. Director DTL Sindh, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - 1. Renewal of Drug Manufacturing License No. 000641 (by way of formulation to the firm M/s. Macter International Ltd, Situated at Plot No.. E-40/A, S.I.T.E, Karachi with following approved sections: a) Tablets. b) Dry Powder for suspension. c) Capsules. d) Sterile area for dry powder injection. **2.** Regularization of following section as per DRAP, Islamabad vide letter no. F.2-3/2005-Lic (Vol-II), dated 26-08-2019. **1.** Tablet Section (Penicillin) 2. Capsule Section (Penicillin 3. Oral Dry Powder Suspension (Penicillin) 4. Dry Powder Injectable (Penicillin) 5. Warehouse (Penicillin) 6. Quality Control Laboratory. **<u>Decision by the Central Licensing Board in 272nd meeting</u>** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000641 (Formulation) in the name of M/s. Macter International Ltd, Situated at Plot No.. E-40/A, S.I.T.E, Karachi, on the recommendations of the panel of experts for the further period of five years commencing on 12.09.2018 and ending on 11.09.2023.			
9.	M/s M.S Enterprises Ltd, 3.5 Km, Raiwind Kot Radha Kishan Road, District Kasur DML No. 000396 (by way of Formulation) **Tenure:** Commencing on 22-06-2016 ending on 21-06-2021.	10-05-2019	**Good**	1. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 2. Dr. Abdul Haleem Khan, Chairman Pharmacy Department, F.C University, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - Keeping in view the facilities like building, HVAC system, machinery and equipment, instruments, personnel, documentation, quality control and testing facilities, the panel concluded that the firm was operating at a good level of GMP compliance and the panel of inspectors was the opinion to			

	recommend renewal of Drug Manufacturing License to M/s M.S Enterprises Ltd, 3.5 Km, Raiwind Kot Radha Kishan Road, District Kasur for the IV Infusion only. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000396 (Formulation) in the name of M/s M.S Enterprises Ltd, 3.5 Km, Raiwind Kot Radha Kishan Road, District Kasur, on the recommendations of the panel of experts for the further period of five years commencing on 22-06-2016 and ending on 21-06-2021 for the IV Infusion only.			
10.	M/s Pliva Pakistan (Pvt) Ltd, Plot No. B-77, Hub Industrial Trading Estate Hub, Baluchistan DML No. 000280 (by way of Formulation) **Tenure:** 21-05-2019 to 20-05-2024.	30.09.2019	**Good**	1. Dr. Ghulam Sarwar, Member DRB. 2. Mr. Syed Salim Shah, Chief Drug Inspector Baluchistan. 3. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - The panel comprising below visited manufacturing unit today and observed overall view as good section wise inspection recorded for each department. Production Section supervises by qualified staff and found as per GMP. HVAC, Storage of Raw Material, Finished Goods store also found as per slandered. Area Drug Inspector Highlighted the Area of improvement and panel recommended task to Area Inspector to monitor and take follow-up. Overall rating is good The panel recommended for Renewal of Drug Manufacturing License. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000280 (Formulation) in the name of M/s Pliva Pakistan (Pvt) Ltd, Plot No. B-77, Hub Industrial Trading Estate Hub, Baluchistan , on the recommendations of the panel of experts for the further period of five years commencing on 21-05-2019 and ending on 20-05-2024			
12.	M/s Stallion Pharmaceuticals (Pvt) Ltd, Plot No. 581, Sunder Industrial estate, Lahore. DML No. 000783 (by way Formulation). Tenure: Commencing on 03-02-2019 ending on 02-02-2024.	16-09-2019	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Dr. Zak ur Rehman, Secretory Pharmacy Council, Punjab. 3. Ms. Anam Saeed, Area Federal Inspector of Drugs, Islamabad.

Recommendations of the panel: -

"Keeping in view the facilities like Building, HVAC System, Equipments, Instruments, Machinery, Personnel Documents, Quality Control and Testing Facilities, the panel of Inspectors is the opinion to **recommend** the renewal of Drug Manufacturing License to M/s Stallion Pharmaceuticals (Pvt) Ltd, Plot No. 581, Sunder Industrial estate, Lahore for the following sections.

Section	Pharmacological Category	Activity(ies)
Oral Dry powder Suspension	Penicillin	Mixing, Filling, Sealing &Packing.
Capsule	Penicillin	Mixing, Encapsulation, Blistering &Packing.
Dry Powder Injectable	Penicillin, Carbapenam	Vial washing, sterilization, Depyrogenation, filling and packing.

Decision by the Central Licensing Board in 272nd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000783 (Formulation) in the name of M/s Stallion Pharmaceuticals (Pvt) Ltd, Plot No. 581, Sunder Industrial estate, Lahore, on the recommendations of the panel of experts for the further period of five years commencing on 03-02-2019 and ending on 02-02-2024 for the following sections:

Sections:

1. Oral Dry powder Suspension (Penicillin)
2. Capsule (Penicillin)
3. Dry Powder Injectable (Penicillin)

13.	M/s Shaigan Pharmaceutical (Pvt) Ltd. 14-KM Adyala Road Rawalpindi. DML No. 000333 (By way of Formulation) **Period**: 07-01-2016 to 06-01-2021.	25-09-2019	**Good**	1. Dr. Muhammad Usman, Member, Central Licensing Board. 2. Deputy Director (QC), DRAP, Islamabad. 3. Area, FID, DRAP, Islamabad. 4. Area Assistant Director-III (Licensing), DRAP, Islamabad.

"Keeping in view the above facts, detailed visit of facility and supporting documents (attached with report) provided by the company, the panel unanimously **recommends** M/s Shaigan Pharmaceutical (Pvt) Ltd. 14-KM Adyala Road Rawalpindi for the renewal of Drug Manufacturing License No. 000333 (Formulation) **(16 sections)** and one additional sections namely **Lyophillized Injection Vials (Steroidal) Hormone Non Anablic)**:

i. Tablet Section (General).
ii. Capsule Section (General).
iii. Oral Liquid Section (General).

	iv. Topical Section (Cream / Ointment / Gel / Lotion) General. v. Sterile Eye Drops Section (General). vi. Pelletization Section (For In House Use Only). vii. Liquid Injectable (Ampoule and Vials) Section. viii. Dry Powder for Injection Section (Cephalosporin). ix. Dry Powder for Suspension Section (Cephalosporin). x. Capsule Section (Cephalosporin). xi. Lyophillized Powder for Injections Section. xii. Sterile Eye Drops (Steroid) Section. xiii. Cream / Ointment Gel (Steroids). xiv. Tablet (Hormone). xv. Cream / Ointment / Gel (Hormone). xvi. Liquid Injection Ampoule (Hormone). **Decision by the Central Licensing Board in 272nd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000333 (Formulation) in the name of M/s Shaigan Pharmaceutical (Pvt) Ltd. 14-KM Adyala Road Rawalpindi, on the recommendations of the panel of experts for the further period of five years commencing on 07-01-2016 and ending on 06-01-2021 for the following sections: **Sections:** 1. Tablet Section (General). 2. Capsule Section (General). 3. Oral Liquid Section (General). 4. Topical Section (Cream / Ointment / Gel / Lotion) General. 5. Sterile Eye Drops Section (General). 6. Pelletization Section (For In House Use Only). 7. Liquid Injectable (Ampoule and Vials) Section. 8. Dry Powder for Injection Section (Cephalosporin). 9. Dry Powder for Suspension Section (Cephalosporin). 10. Capsule Section (Cephalosporin). 11. Lyophillized Powder for Injections Section. 12. Sterile Eye Drops (Steroid) Section. 13. Cream / Ointment Gel (Steroids). 14. Tablet (Hormone). 15. Cream / Ointment / Gel (Hormone). 16. Liquid Injection Ampoule (Hormone).			
14.	M/s Alina Combine Pharmaceuticals (Pvt) Ltd, Plot No. A-127, SITE Super Highway Industrial Area, Karachi DML No. 000441 (by way of Formulation) **Tenure:** 30.10.2014 to 29.10.2019	03.10.2019	**Good**	i. Dr. Abdullah Dayo, Member CLB, Karachi. ii. Chief Inspector of Drugs Sindh, Member CLB, Karachi. iii. Area Federal Inspector of Drugs, DRAP, Karachi.

	Sections **i.** *Tablet (G),* **ii.** *Capsule (G),* **iii.** *Liquid Syrup (G),* **iv.** *Cream/Ointment,* **v.** *Dry Powder Suspension (G),* **vi.** *Sterile Liquid Injection (Ampoule/Vials),* **vii.** *Liquid Syrup (Vet),* **viii.** *Dry Powder (Vet),* **ix.** *Sterile Dry Powder Injection (Ceph),* **x.** *Dry Powder Injection (Ceph),* **xi.** *Dry Powder Syrup (Ceph),* **xii.** *Capsule (Ceph)* **xiii.** *Seven Seas (Repacking areas)*			

Recommendations of the panel: -

During the inspection panel observed that the firm has facilities to manufacture Tablet (G), Capsule (G), Liquied Syrup (G), Cream/Ointment, Dry Powder Suspension (G), Strile Liqid Injection (Ampoule/Vials), Liquid Syrup (Vet), Dry Powder (Vet), Sterile Dry Powder Injection (Ceph), Dry Powder Injection (Ceph), Dry Powder Syrup (Ceph), Capsule (Ceph) and Seven Seas (Repacking areas). The facility has appropriately been designed as per approved drawing and separate air-handing units were provided in each section, which are periodically monitored with regard to efficiency of filters and other aspects of environmental monitoring. The facility tenders appropriate flow of men and material and can suitable mitigate the chance of contamination and cross-contamination. Dedicated sections are designed with separate change rooms, machines and AHUs. Each section has been provided with separate required machines, which were seen well-installed, qualified and in good working conditions, required SOPs, and log books were in place. The firm has required equipment in QC Lab, methods are validated and each in-coming material is appropriately tested as per approved methods. Waters and other utilities are tested as well. QA department has been established to carry out, proper trainings, self-inspection, stability testing, vendor selection, OOS/Failures investigation, controlling Deviations and to treat Market Complaint. Required working SOPs in QA department were seen in place. In-process testing and line clearance is carried out as per SOP. The firm has sufficient technical and experience person in each department. Spacious and well-defined warehouses are provided, seen satisfactory maintained under the supervision of qualified pharmacist. Based on the above stated observation and keeping in view the attitude of the management of the firm towards constant improvements, the panel unanimously recommends the grant of renewal of their DML No. 000441 (Formulation) with effect from 30/10/2014.

Decision by the Central Licensing Board in 272nd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000441 (Formulation) in the name of M/s Alina Combine Pharmaceuticals (Pvt) Ltd, Plot No. A-127,

	SITE Super Highway Industrial Area, Karachi , on the recommendations of the panel of experts for the further period of five years commencing on 30.10.2014 and ending on 29.10.2019 for the following sections: **Sections:** **i.** *Tablet (G),* **ii.** *Capsule (G),* **iii.** *Liquid Syrup (G),* **iv.** *Cream/Ointment,* **v.** *Dry Powder Suspension (G),* **vi.** *Sterile Liquid Injection (Ampoule/Vials),* **vii.** *Liquid Syrup (Vet),* **viii.** *Dry Powder (Vet),* **ix.** *Sterile Dry Powder Injection (Ceph),* **x.** *Dry Powder Injection (Ceph),* **xi.** *Dry Powder Syrup (Ceph),* **xii.** *Capsule (Ceph)* *Seven Seas (Repacking areas)*			
15.	M/s Regent Laboratories, Plot No. C-20, SITE Super Highway Industrial Area, Karachi DML No. 000506 (by way of Formulation) **Tenure:** 26.10.2017 to 25.10.2022	09.10.2019	**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: - *Keeping in view the above submission the panel unanimously recommends as follows:* 1. *The grant of renewal of their DML No. 000506 (Formulation) for the next five years with effect from 16/10/2017.* 2. *The grant of additional sections of powder veterinary vitamin (G), Tablet (psychotropic), Capsule (Psychotropic), Tablet (Antibiotic), Capsule (Antibiotic), Sachet (General), Cream/Ointment (Steroidal), Cream/Ointment (Non-Steroidal), Liquid External Preparation, Capsule (G), Capsule (Cephalosporin) and Dry Powder Suspension (Cephalosporin).* 3. *And based on the improvements made by the firm in the light of the inspection conducted by area FID on 16/01/2018, the panel also recommends the commencement of manufacturing activities after the forma; approval of board concerned.* **Decision by the Central Licensing Board in 272nd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000506 (Formulation) in the name of M/s Regent Laboratories, Plot No. C-20, SITE Super Highway Industrial Area, Karachi, on the recommendations of the panel of experts for the further period of five years commencing on 26.10.2017 and ending on 25.10.2022.			

ITEM – V MISC CASES

CASE NO.1 CHANGE OF MANAGEMENT OF M/S JASKAN PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Jaskan Pharmaceuticals (Pvt) Ltd, Lahore under DML No. 000796 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management as per Form-1A	Added Management	Current Management as per Form-29
1. Mr. Khan Ahmad Chaudhry S/o Ch. Ghulam Muhammad CNIC No. 34603-2180715-7. 2. Mst. Nasira Ahmad W/o Khan Ahmad Chaudhry CNIC No. 34603-2114114-8.	1. Ms. Sara Ahmad W/o Ahmad Younus CNIC No. 61101-6441627-2. 2. Ms. Adeena Khan D/o Khan Ahmad Chaudhry CNIC No. 34603-0984070-4.	1. Mr. Khan Ahmad Chaudhry S/o Ch. Ghulam Muhammad CNIC No. 34603-2180715-7. 2. Mst. Nasira Ahmad W/o Khan Ahmad Chaudhry CNIC No. 34603-2114114-8. 3. Ms. Sara Ahmad W/o Ahmad Younus CNIC No. 61101-6441627-2. 4. Ms. Adeena Khan D/o Khan Ahmad Chaudhry CNIC No. 34603-0984070-4.

Decision by the Central Licensing Board in 272nd meeting:

The Board considered and endorsed the change of management of M/s Jaskan Pharmaceuticals (Pvt) Ltd, Lahore under DML No. 000796 by way of formulation as under ;

Previous Management as per Form-1A	Added Management	Current Management as per Form-29
1. Mr. Khan Ahmad Chaudhry S/o Ch. Ghulam Muhammad CNIC No. 34603-2180715-7. 2. Mst. Nasira Ahmad W/o Khan Ahmad Chaudhry CNIC No. 34603-2114114-8.	1. Ms. Sara Ahmad W/o Ahmad Younus CNIC No. 61101-6441627-2. 2. Ms. Adeena Khan D/o Khan Ahmad Chaudhry CNIC No. 34603-0984070-4.	1. Mr. Khan Ahmad Chaudhry S/o Ch. Ghulam Muhammad CNIC No. 34603-2180715-7. 2. Mst. Nasira Ahmad W/o Khan Ahmad Chaudhry CNIC No. 34603-2114114-8. 3. Ms. Sara Ahmad W/o Ahmad Younus CNIC No. 61101-6441627-2. 4. Ms. Adeena Khan D/o Khan Ahmad Chaudhry CNIC No. 34603-0984070-4.

Case No. 2 **CHANGE OF MANAGEMENT OF M/S WISE PHARMACEUTICALS, PLOT NO. 3-A, STREET NO. S-1, RCCI, INDUSTRIAL ESTATE, RAWAT, RAWALPINDI.**

M/s Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi, under DML No. 000625 (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 Partnership Deed	Retiring Management As Per Partnership Deed	New Management As Per Partnership Ship Deed
1. Dr. Pervaiz Ahmaed Chattha S/o Gul Muhammad Chattha CNIC No. 37301-2181685-3. 2. Dr. Abdul Qayyum Choudhary S/o Ch. Abdul Malik CNIC No. 37301-5239110-5. 3. Dr. Muhammad Yousuf Niazi S/o Sheikh Hussain CNIC No. 37203-1597267-5. 4. Dr. Muhammad Abdullah S/o Abdul Aziz CNIC No. 34502-8482732-5. 5. Dr. Javed Malik S/o Malik Ollia Khan CNIC No. 61101-1969659-9. 6. Mr. Rajab Sultan Raja S/o Raja Sultan Khan CNIC No. 61101-5635249-1.	1.Dr. Pervaiz Ahmaed Chattha S/o Gul Muhammad Chattha CNIC No. 37301-2181685-3. 2.Mr. Rajab Sultan Raja S/o Raja Sultan Khan CNIC No. 61101-5635249-1.	1. Dr. Abdul Qayyum Choudhary S/o Ch. Abdul Malik CNIC No. 37301-5239110-5. 2. Dr. Muhammad Yousuf Niazi S/o Sheikh Hussain CNIC No. 37203-1597267-5. 3. Dr. Muhammad Abdullah S/o Abdul Aziz CNIC No. 34502-8482732-5. 4. Dr. Javed Malik S/o Malik Ollia Khan CNIC No. 61101-1969659-9.

Decision by the Central Licensing Board in 272nd meeting:

The Board considered and endorsed the change of management of M/s Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi, under DML No. 000625 (By way of formulation) as under ;

Existing Management As Per Partnership Deed	Retiring Management As Per Partnership Deed	New Management As Per Partnership Ship Deed
1. Dr. Pervaiz Ahmaed Chattha S/o Gul Muhammad Chattha CNIC No. 37301-2181685-3. 2. Dr. Abdul Qayyum Choudhary S/o Ch. Abdul Malik CNIC No. 37301-5239110-5.	1. Dr. Pervaiz Ahmaed Chattha S/o Gul Muhammad Chattha CNIC No. 37301-2181685-3. 2. Mr. Rajab Sultan Raja S/o Raja Sultan Khan	1. Dr. Abdul Qayyum Choudhary S/o Ch. Abdul Malik CNIC No. 37301-5239110-5. 2. Dr. Muhammad Yousuf Niazi S/o Sheikh Hussain CNIC No. 37203-1597267-5.

3. Dr. Muhammad Yousuf Niazi S/o Sheikh Hussain CNIC No. 37203-1597267-5. 4. Dr. Muhammad Abdullah S/o Abdul Aziz CNIC No. 34502-8482732-5. 5. Dr. Javed Malik S/o Malik Ollia Khan CNIC No. 61101-1969659-9. 6. Mr. Rajab Sultan Raja S/o Raja Sultan Khan CNIC No. 61101-5635249-1.	CNIC No. 61101-5635249-1.	3. Dr. Muhammad Abdullah S/o Abdul Aziz CNIC No. 34502-8482732-5. 4. Dr. Javed Malik S/o Malik Ollia Khan CNIC No. 61101-1969659-9.

Case No. 3. <u>CHANGE OF MANAGEMENT OF M/S BIOREX PHARMACEUTICALS, KAHUTA ROAD, ISLAMABAD.</u>

M/s Biorex Pharmaceuticals, Kahuta Road, Islamabad, under DML No. 000528 (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 partnership	Retiring Management	New Management as per partnership deed
1. Mr. Mueen Ud Din S/o Ghulam Haider CNIC No. 61101-8505659-3. 2. Mr. Mohammad Abdullah S/o Asmat Ullah CNIC No. 61101-2008129-5.	1. Mr. Mohammad Abdullah S/o Asmat Ullah CNIC No. 61101-2008129-5.	1. Mr. Mueen Ud Din S/o Ghulam Haider CNIC No. 61101-8505659-3. 2. Mr. Mohammad Asad Mueen S/o Mueen Ud Din CNIC No. 61101-4139360-1.

<u>Decision by the Central Licensing Board in 272nd meeting:</u>

The Board considered and endorsed the change of management of M/s Biorex Pharmaceuticals, Kahuta Road, Islamabad, under DML No. 000528 (By way of formulation) as under ;

Previous Management as per partnership	Retiring Management	New Management as per partnership deed
1. Mr. Mueen Ud Din S/o Ghulam Haider CNIC No. 61101-8505659-3. 2. Mr. Mohammad Abdullah S/o Asmat Ullah CNIC No. 61101-2008129-5.	1. Mr. Mohammad Abdullah S/o Asmat Ullah CNIC No. 61101-2008129-5.	1. Mr. Mueen Ud Din S/o Ghulam Haider CNIC No. 61101-8505659-3. 2. Mr. Mohammad Asad Mueen S/o Mueen Ud Din CNIC No. 61101-4139360-1.

CASE NO.4 CHANGE OF MANAGEMENT OF M/S AXIS PHARMACEUTICALS, LAHORE.

M/s Axis Pharmaceuticals, Lahore under DML No. 000667 by way of Formulation has submitted request for change in management of the firm as per partnership deed with prescribed Fee Challan of Rs.50,000/- . The detail of management of the firm is as under;

Previous Management as per Partnership deed	Retiring Management	Current Management as per Partnership Deed
1. Mr. Sheikh Muhammad Asghar S/o Sheikh Muhammad Hussain CNIC No. 33100-6660996-5. 2. Mr. Imran Asghar S/o Sheikh Muhammad Asghar CNIC No. 33100-6234926-9. 3. Mr. Sheikh Muhammad Akhtar S/o Sheikh Muhammad Hussain CNIC No.33100-2411997-5. 4. Mr. Zahid Mehmood S/o Sheikh Muhammad Hussain CNIC No.33100-8410438-1. 5. Mr. Sheikh Muhammad Akbar S/o Sheikh Muhammad Hussain CNIC No.33100-5927081-5.	1. Mr. Sheikh Muhammad Akbar S/o Sheikh Muhammad Hussain CNIC No.33100-5927081-5.	1. Mr. Sheikh Muhammad Asghar S/o Sheikh Muhammad Hussain CNIC No. 33100-6660996-5. 2. Mr. Imran Asghar S/o Sheikh Muhammad Asghar CNIC No. 33100-6234926-9. 3. Mr. Sheikh Muhammad Akhtar S/o Sheikh Muhammad Hussain CNIC No.33100-2411997-5. 4. Mr. Zahid Mehmood S/o Sheikh Muhammad Hussain CNIC No.33100-8410438-1.

Decision by the Central Licensing Board in 272nd meeting:

The Board considered and endorsed the change of management of M/s Axis Pharmaceuticals, Lahore under DML No. 000667 by way of Formulation as under ;

Previous Management as per Partnership deed	Retiring Management	New Management as per Partnership Deed
1. Mr. Sheikh Muhammad Asghar S/o Sheikh Muhammad Hussain CNIC No. 33100-6660996-5. 2. Mr. Imran Asghar S/o Sheikh Muhammad Asghar CNIC No. 33100-6234926-9.	1. Mr. Sheikh Muhammad Akbar S/o Sheikh Muhammad Hussain CNIC No.33100-5927081-5.	1. Mr. Sheikh Muhammad Asghar S/o Sheikh Muhammad Hussain CNIC No. 33100-6660996-5. 2. Mr. Imran Asghar S/o Sheikh Muhammad Asghar CNIC No. 33100-6234926-9.

3. Mr. Sheikh Muhammad Akhtar S/o Sheikh Muhammad Hussain CNIC No.33100-2411997-5. 4. Mr. Zahid Mehmood S/o Sheikh Muhammad Hussain CNIC No.33100-8410438-1. 5. Mr. Sheikh Muhammad Akbar S/o Sheikh Muhammad Hussain CNIC No.33100-5927081-5.		3. Mr. Sheikh Muhammad Akhtar S/o Sheikh Muhammad Hussain CNIC No.33100-2411997-5. 4. Mr. Zahid Mehmood S/o Sheikh Muhammad Hussain CNIC No.33100-8410438-1.

Case No. 5 **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.

Case No.6 GRANT OF DRUGS FOR RE-PACKING:

M/s Health Care Pharmaceuticals, 40-Km, Lahore Road, Multan, under Drug Manufacturing Licence No. 000905 by way of formulation has submitted Application for Grant of Re-packing drugs as per Schedule-D. Firm has submitted challan Fee of 5,000/ per product.

Sr. No.	Drug	Schedule-D
01	Ferrous Sulphate	Yes
02	Gentian Violet	Yes
03	Iodine	Yes
04	Methyl Salicylate	Yes
05	Chloral Hydrate	Yes
06	Benzoic Acid	Yes
07	Aluminium Hydroxide Gel Dried	Yes
08	Ammonium Chloride	Yes
09	Kaolin	Yes
10	Zinc Sulphate	Yes
11	Soft Yellow Paraffin	Yes
12	Sodium Citrate	Yes
13	Sodium Chloride	Yes
14	Sodium Bicarbonate	Yes

Proceedings and Decision of Central Licensing Board in 272nd meeting.

The Board considered and approved repacking drugs in the name of M/s Health Care Pharmaceuticals, 40-Km, Lahore Road, Multan, under Drug Manufacturing Licence No. 000905 by way of formulation as under.

Sr. No.	Drug
01	Ferrous Sulphate
02	Gentian Violet
03	Iodine
04	Methyl Salicylate
05	Benzoic Acid
06	Aluminium Hydroxide Gel Dried
07	Kaolin
08	Zinc Sulphate
09	Soft Yellow Paraffin
10	Sodium Citrate
11	Sodium Chloride
12	Sodium Bicarbonate

Case No. 7 GRANT OF DRUGS FOR RE-PACKING:

M/s Zakfas Pharmaceuticals, (Pvt) Ltd, 12-Km, Lutaf Abad, Bosan Road, Multan, under Drug Manufacturing Licence No. 000603 by way of formulation has submitted Application for Grant of Re-packing drugs as per Schedule-D. Firm has submitted challan Fee of 5,000/ per product.

Sr. No.	Drug	Schedule-D
01	Sodium Salicylate	Yes
02	Kaoline	Yes

Proceedings and Decision of Central Licensing Board in 272nd meeting.

The Board considered and approved repacking drugs in the name of M/s Zakfas Pharmaceuticals, (Pvt) Ltd, 12-Km, Lutaf Abad, Bosan Road, Multan, under Drug Manufacturing Licence No. 000603 by way of formulation as under.

Sr. No.	Drug
01	Sodium Salicylate
02	Kaoline

Case No. 8 GRANT OF DRUGS FOR RE-PACKING:

M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha, under Drug Manufacturing Licence No. 000465 by way of formulation has submitted application for Grant of Re-packing drug as per Schedule-D. Firm has submitted challan Fee of 5,000/ per product.

Sr. No.	Drug	Schedule-D
01	Boric Acid	Yes

Proceedings and Decision of Central Licensing Board in 272nd meeting.

The Board considered and approved repacking drugs in the name of M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha, under Drug Manufacturing Licence No. 000465 by way of formulation as under.

Sr. No.	Drug
01	Boric Acid

Case No. 9 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S TRISON RESEARCH LABORATORIES (PVT) LTD, SARGODHA.

M/s Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, P.S.I.E Sargodha had applied for renewal of DML No. 000529 by way of Formulation for the period of 27-01-2019 to 26-01-2024 on 15-01-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 21st February, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed and stamped Form-1A (as per Format).
ii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management.
iii. Duly attested CNIC copies of all Directors.
iv. Latest certified true copy of Form-29 (attestation by SECP).
v. Section approval letter of Tablet (General) section issued by CLB.
vi. Nothing due certificate regarding CRF from STO.
vii. Name and qualification of technical staff working in Production and Quality Control departments.

The firm replied on 03-April, 2019 but application was incomplete and Final Reminder letter was issued on 3rd July, 2019 to the firm for submission of following documents.

i. Properly filled, signed and stamped Form-1A (as per Format).
ii. Nothing due certificate regarding CRF from STO (Updated).
iii. Section approval letter of Tablet (General) section issued by CLB.
iv. Prescribed fee of 50,000/- along with proper application for change of management as there seems to be change in management of firm.
v. Name and qualification of all technical staff working in Production and Quality Control departments.
vi. All Documents should be duly attested.

The firm replied to final reminder on 7th August, 2019 and application for renewal of DML is still incomplete with following documents.

i. Prescribed fee of 50,000/- along with proper application for change of management as there is change in management of firm.
ii. Nothing due certificate regarding CRF from STO (Updated).
iii. Section approval letter of Tablet (General) section issued by CLB.

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, 5(2A), and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, P.S.I.E Sargodha, Drug Manufacturing Licence No 000529 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 10 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 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

Case No. 11. REGULARIZATION OF LAYOUT PLAN OF M/S. MACTER INTERNATIONAL LTD, SITUATED AT PLOT NO.. F-216, S.I.T.E, KARACHI.

M/s. Macter International Ltd, Situated at Plot No.. F-216, S.I.T.E, Karachi, DML No. 000141 (Formulation), has applied for regularization of layout plan of running facility for their existing sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory:
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.

i. Dr. Abdullah Dayo, Member CLB, Karachi.
ii. Additional Director (E&M) DRAP, Karachi.
iii. Director DTL Sindh, Karachi.
iv. Area Federal Inspector of Drugs, DRAP, Karachi.

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

Recommendations of the panel: -

1. Renewal of Drug Manufacturing License No. 000141 (by way of formulation to the firm M/s. Macter International Ltd, Situated at Plot No.. F-216, S.I.T.E, Karachi for following sections:

4. Tablet General	5. Oral Liquid (Syrup/ Suspension/ Solution)	6. Tablet Psychotropic	7. Liquid Injection (LVP)
8. Encapsulation (General) Including DPI Capsule	9. Encapsulation (Steroid) Including DPI Capsule	10. Aerosol	11. Ointment/Cream/Gel-I General
12. Oral Dry Powder Suspension (Ceph)	13. Oral Dry Powder Injection (Ceph)	14. Liquid Injections (SVP)	15. Biotech (Lypholization /Liquid)

16. Ointment/Cream/Gel–II General	17. Capsule (Ceph)	18. Dry Powder Suspension

2. Regularization of following section:

Ground floor: Tablet (General), Tablet (Psychotropic), Oral Liquid, (syrup/suspension/ solutions), Warehouse (RMS/PMS/FGS).

First Floor: Ointment/Cream/Gel-I (General)**,** Ointment/Cream/Gel-II (General, Aerosol Section, Liquid Parental (LVP), Dry Powder Suspension (general), Encapsulation (Ceph) Including DPI Capsule, Biotech (Lypholization/Liquid Section), Biotech Laboratory, R and D Laboratory.

Second floor (A and B): Dry Powder Suspension (Ceph), Capsule (Ceph), Injectable Section (Ceph), Raw Material Store (Ceph), Encapsulation (Steroid) Including DPI Capsule, Raw Material Store (Steroid), Quality Control Laboratory, Microbiology Laboratory as per DRAP, Islamabad letter no. F.2-13/95-Lic (vol-vi), dated 21.09.2019 as per approved layout plans vide letter no. F. 2-13/95-Lic (Vol-Vi dated, 03.09.2019.

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

The Board considered and approved regularization of of Lay out plan in the name of M/s. Macter International Ltd, Situated at Plot No.. F-216, S.I.T.E, Karachi on the recommendation of the panel of experts for the following sections:-

Ground floor:

1. Tablet (General),
2. Tablet (Psychotropic),
3. Oral Liquid, (syrup/suspension/ solutions),
4. Warehouse (RMS/PMS/FGS).

First Floor:

1. Ointment/Cream/Gel-I (General)**,**
2. Ointment/Cream/Gel-II (General,
3. Aerosol Section,
4. Liquid Parental (SVP),
5. Liquid Parental (LVP),
6. Dry Powder Suspension (general),
7. Encapsulation (General) Including DPI Capsule,
8. Biotech (Lypholization/Liquid Section),

Second floor (A and B):

1. Dry Powder Suspension (Ceph),

2. Capsule (Ceph),
3. Injectable Section (Ceph),
4. Raw Material Store (Ceph),
5. Encapsulation (Steroid) Including DPI Capsule,
6. Raw Material Store (Steroid),
7. Quality Control Laboratory

The Board also decided to confirm availability of required equipments and machinery for General Dry Powder Inhaler manufacturing by the area Federal Inspector of Drugs in the light of the decision of the Drug Registraation Board as the same is confirmed by the panel in respect of DPI steroidal section and mentioned in the report.

CASE NO.12. <u>REGULARIZATION OF LAYOUT PLAN OF M/S. MACTER INTERNATIONAL LTD, SITUATED AT PLOT NO.. E-40/A, S.I.T.E, KARACHI.</u>

M/s. Macter International Ltd, Situated at Plot No.. E-40/A, S.I.T.E, Karachi., DML No. 00641 (Formulation), has applied for regularization of layout plan of running facility for their existing sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory:
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.

i. Dr. Abdullah Dayo, Member CLB, Karachi.
ii. Director DTL Sindh, Karachi.
iii. Area Federal Inspector of Drugs, DRAP, Karachi.

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

Recommendations of the panel: -

1. Renewal of Drug Manufacturing License No. 000641 (by way of formulation to the firm M/s. Macter International Ltd, Situated at Plot No.. E-40/A, S.I.T.E, Karachi with following approved sections:
    e) Tablets.
    f) Dry Powder for suspension.
    g) Capsules.
    h) Sterile area for dry powder injection.
2. Regularization of following section as per DRAP, Islamabad vide letter no. F.2-3/2005-Lic (Vol-II), dated 26-08-2019.

Tablet Section (Penicillin) 2. Capsule Section (Penicillin 3. Oral Dry Powder Suspension (Penicillin) 4. Dry Powder Injectable (Penicillin) 5. Warehouse (Penicillin) 6. Quality Control Laboratory.

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

The Board considered and approved regularization of of Lay out plan in the name of M/s. Macter International Ltd, Situated at Plot No.. E-40/A, S.I.T.E, Karachi on the recommendation of the panel of experts for the following sections:-

1. Tablet Section (Penicillin)
2. Capsule Section (Penicillin)
3. Oral Dry Powder Suspension (Penicillin)
4. Dry Powder Injectable (Penicillin)
5. Warehouse (Penicillin)
6. Quality Control Laboratory.

Case No. 13 APPROVAL OF PRODUCTION INCHARGE OF M/S WELL CARE PHARMACEUTICALS, SARGODHA.

Ms. Nasreen Akhtar, approved Production Incharge of M/s Well Care Pharmaceuticals, /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 on 30th 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, /7, P.S.I.E Sargodha may not be suspended or cancelled by Central Licensing Board

Case No.14. CORRECTION IN CHANGE OF MANAGEMENT OF M/S HISUN PHARMACEUTICAL INDUSTRIES, DISTRICT SWABI.

M/s Hisun Pharmaceutical Industries, 37-A, R-02, Industrial Estate Gadoon Amazai, District Swabi under DML No. 000617 by 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-H & Partnership Deed	Retiring management as per Partnership Deed	CURRENT Management as per Form-H & Partnership Deed
1. Mr. Muhammad Nawaz S/o Rana Muhammad Aslam CNIC No. 34601-9588618-1 2. Mr. Shafiq Ur Rehman S/o Abdul Wadood CNIC No.16101-8654128-5. 3. Mr. Muhammad Burhan-ud-Din S/o Haji Yousaf Shah CNIC No.15602-8203622-9	1. Mr. Shafiq Ur Rehman S/o Abdul Wadood CNIC No.16101-8654128-5 2. Mr. Muhammad Burhan-ud-Din S/o Haji Yousaf Shah CNIC No.15602-8203622-9	1. Mr. Rana Munawar Hussain S/o Rana Muhammad Ramzan CNIC No.34601-4783864-1 2. Mr. Rana Muhammad Sarwar S/o Rana Muhammad Ramzan CNIC No.34601-8623941-3 3. Mr. Muhammad Nawaz S/o Rana Muhammad Aslam CNIC No. 34601-9588618-1

Decision by the Central Licensing Board in 272nd meeting:

The Board considered and endorsed the change of management of M/s Hisun Pharmaceutical Industries, 37-A, R-02, Industrial Estate Gadoon Amazai, District Swabi under DML No. 000617 by way of formulation as under ;

PREVIOUS Management as per Form-H & Partnership Deed	Retiring management as per Partnership Deed	New Management as per Form-H & Partnership Deed
4. Mr. Muhammad Nawaz S/o Rana Muhammad Aslam CNIC No. 34601-9588618-1 5. Mr. Shafiq Ur Rehman S/o Abdul Wadood CNIC No.16101-8654128-5. 6. Mr. Muhammad Burhan-ud-Din S/o Haji Yousaf Shah CNIC No.15602-8203622-9	3. Mr. Shafiq Ur Rehman S/o Abdul Wadood CNIC No.16101-8654128-5 4. Mr. Muhammad Burhan-ud-Din S/o Haji Yousaf Shah CNIC No.15602-8203622-9	4. Mr. Rana Munawar Hussain S/o Rana Muhammad Ramzan CNIC No.34601-4783864-1 5. Mr. Rana Muhammad Sarwar S/o Rana Muhammad Ramzan CNIC No.34601-8623941-3 6. Mr. Muhammad Nawaz S/o Rana Muhammad Aslam CNIC No. 34601-9588618-1

Case No.15. <u>CORRECTION IN CHANGE OF MANAGEMENT OF M/S MACTER INTERNATIONAL LIMITED, KARACHI DML NO.000141.</u>

M/s Macter International Limited, Plot No. F/216, SITE, Karachi under DML No. 000141 has submitted request for change in management of the firm as per Form 29 and Form 1A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3	Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9	Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3
2.	Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5	Syed Salman Ahmed CNIC No.42000-1954567-7	Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5
3.	Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1	Mr. Zubeid Qureshi CNIC No. 42301-1491744-1	Mr. Sheikh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1
4.	Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7	Mr. Muhammad Asif CNIC No.42301-5182030-1	Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5
5.	Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9	Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1	Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9

6.	Syed Salman Ahmed CNIC No.42000-1954567-7	********	Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5
7.	Mr. Zubeid Qureshi CNIC No. 42301-1491744-1	********	Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7
8.	Mr. Muhammad Asif CNIC No.42301-5182030-1	********	Miss Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0
9.	Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1	********	**Mr. Islahuddin Siddiqui S/o Allaudin Siddiqui CNIC No. 42301-6572835-1**

Decision by the Central Licensing Board in 272nd meeting:

The Board considered and endorsed the change of management of M/s Macter International Limited, Plot No. F/216, SITE, Karachi under DML No. 000141 by way of formulation as under ;

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3	Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9	Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3
2.	Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5	Syed Salman Ahmed CNIC No.42000-1954567-7	Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5
3.	Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1	Mr. Zubeid Qureshi CNIC No. 42301-1491744-1	Mr. Sheikh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1
4.	Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7	Mr. Muhammad Asif CNIC No.42301-5182030-1	Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5
5.	Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9	Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1	Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9
6.	Syed Salman Ahmed CNIC No.42000-1954567-7	********	Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5

7.	Mr. Zubeid Qureshi CNIC No. 42301-1491744-1	********	Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7
8.	Mr. Muhammad Asif CNIC No.42301-5182030-1	********	Miss Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0
9.	Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1	********	**Mr. Islahuddin Siddiqui S/o Allaudin Siddiqui CNIC No. 42301-6572835-1**

Case No.16. <u>CORRECTION IN CHANGE OF MANAGEMENT OF M/S MACTER INTERNATIONAL LIMITED, KARACHI DML NO.000641.</u>

M/s Macter International Limited, Plot No E-40A, SITE, Karachi under DML No. 000641 by way of formulation has submitted request for change in management of the firm as per Form 29 and Form 1A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3	Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9	Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3
2.	Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5	Syed Salman Ahmed CNIC No.42000-1954567-7	Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5
3.	Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1	Mr. Zubeid Qureshi CNIC No. 42301-1491744-1	Mr. Sheikh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1
4.	Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7	Mr. Muhammad Asif CNIC No.42301-5182030-1	Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5
5.	Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9	Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1	Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9
6.	Syed Salman Ahmed CNIC No.42000-1954567-7	********	Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5
7.	Mr. Zubeid Qureshi CNIC No. 42301-1491744-1	********	Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7

8.	Mr. Muhammad Asif CNIC No.42301-5182030-1	********	Miss Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0
9.	Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1	********	**Mr. Islahuddin Siddiqui S/o Allaudin Siddiqui CNIC No. 42301-6572835-1**

Decision by the Central Licensing Board in 272nd meeting:

The Board considered and endorsed the change of management of M/s Macter International Limited, Plot No E-40A, SITE, Karachi under DML No. 000641 by way of formulation as under ;

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3	Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9	Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3
2.	Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5	Syed Salman Ahmed CNIC No.42000-1954567-7	Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5
3.	Mr. Shekh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1	Mr. Zubeid Qureshi CNIC No. 42301-1491744-1	Mr. Sheikh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1
4.	Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7	Mr. Muhammad Asif CNIC No.42301-5182030-1	Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5
5.	Mr. Muhammad Sajid S/O Muhammad Umer CNIC No. 42201-0514888-9	Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1	Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9
6.	Syed Salman Ahmed CNIC No.42000-1954567-7	********	Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5
7.	Mr. Zubeid Qureshi CNIC No. 42301-1491744-1	********	Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7
8.	Mr. Muhammad Asif CNIC No.42301-5182030-1	********	Miss Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0

9.	Mr. Mirza Muhammad Aamir CNIC No.34501-2014746-1	********	**Mr. Islahuddin Siddiqui S/o Allaudin Siddiqui CNIC No. 42301-6572835-1**

Case No.17. <u>CHANGE OF MANAGEMENT OF M/S. ZEPHYR PHARMATEC (PVT) LTD, PLOT NO. A-39, SITE-II, SUPER HIGHWAY, KARACHI.</u>

M/s. Zephyr Pharmatec (Pvt) Ltd, Plot No. A-39, SITE-II, Super Highway, Karachi under DML No. 000403 by way of formulation has submitted request for change in management of the firm as per Form 29 and Form 1A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Rubeel Ali S/o Riaz Ali CNIC NO. 42301-5472377-7	Mr. Rubeel Ali S/o Riaz Ali CNIC NO. 42301-5472377-7	Mr. Imran Khalil S/o Khalil-ur-Rehman CNIC NO. 42201-6242450-7
2.	Mr. Zahid Anees CNIC 42301-5472377-7	Mr. Zahid Anees CNIC 42301-5472377-7	Mr. Rehan Khalil S/o Khalil-ur-Rehman CNIC NO. 42201-0750789-5
3.	********	********	Mr. Khalil-ur-Rehman S/o Abdul Jabbar CNIC NO. 42201-0613202-7
4.	********	********	Mr. Adnan Khalil S/o Khalil-ur-Rehman CNIC NO. 42301-9532648-1

<u>Decision by the Central Licensing Board in 272nd meeting:</u>

The Board considered and endorsed the change of management of M/s. Zephyr Pharmatec (Pvt) Ltd, Plot No. A-39, SITE-II, Super Highway, Karachi under DML No. 000403 by way of formulation as under ;

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Rubeel Ali S/o Riaz Ali CNIC NO. 42301-5472377-7	Mr. Rubeel Ali S/o Riaz Ali CNIC NO. 42301-5472377-7	Mr. Imran Khalil S/o Khalil-ur-Rehman CNIC NO. 42201-6242450-7
2.	Mr. Zahid Anees CNIC 42301-5472377-7	Mr. Zahid Anees CNIC 42301-5472377-7	Mr. Rehan Khalil S/o Khalil-ur-Rehman CNIC NO. 42201-0750789-5
3.	********	********	Mr. Khalil-ur-Rehman S/o Abdul Jabbar CNIC NO. 42201-0613202-7

4.	********	********	Mr. Adnan Khalil S/o Khalil-ur-Rehman CNIC NO. 42301-9532648-1

CASE NO.18. **REGULARIZATION OF LAYOUT PLAN OF M/S. PLIVA PAKISTAN (PVT) LIMITED, SITUATED AT PLOT NO B-77, H.I.T.E, BALOCHISTAN.**

M/s. Pliva Pakistan (Pvt) Ltd, Situated at Plot No.. B-77, H.I.T.E, Balochistan., DML No. 000280 (Formulation), has applied for regularization of layout plan of running facility for their existing sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory:
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.

i. Mr. Ghulam Sarwar, Member DRB, Karachi.
ii. Chief Drug Inspector, Balochistan.
iii. Area Federal Inspector of Drugs, DRAP, Karachi.

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

***Recommendations of the panel**: -*
The panel comprising below visited manufacturing unit today and observed overall view as good section wise inspection recorded for each department. Production Section supervises by qualified staff and found as per GMP. HVAC, Storage of Raw Material, Finished Goods store also found as per slandered. Area Drug Inspector Highlighted the Area of improvement and panel recommended task to Area Inspector to monitor and take follow-up. Overall rating is good The panel recommended for Renewal of Drug Manufacturing License. Regularization of map in reference to CLB directions visited and found satisfactory as per Lay Out Plan so recommended for consideration.

Sr. No	Name of Sections	Sr. No	Name of Sections
GROUND FLOOR			
i.	Tablet (General)	ii.	Capsule Section (General)
iii.	Liquid Syrup (General)	iv.	Dry Suspension General
v.	Cream/Ointment General	vi.	Liquid Injection (vial/ampoule) SVP
vii.	Ophthalmic Section (General	viii.	Raw material Store General
ix.	Finished Goods Store General	x.	Packing Material Store
xi.	Raw Material Store (Penicillin)	xii.	Capsule Section (Penicillin)
xiii.	Dry Suspension (Penicillin)	xiv.	Sachet Section (General)
FIRST FLOOR			

xv.	Raw material Store (Cephalosporin)	xvi.	Capsule Section (Cephalosporin)
xvii.	Dry Powder Injectable (Cephalosporin)	xviii.	Tablet Section (Psychotropic)
xix.	Dry Powder Injectable vial (Chloramphenicol)	xx.	Dry Powder Injectable (Penicillin)
xxi.	Quality Control Laboratory	xxii.	Dry Powder Suspension (Cephalosporin)

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

The Board considered and approved regularization of of Lay out plan in the name of M/s. Pliva Pakistan (Pvt) Ltd, Situated at Plot No.. B-77, H.I.T.E, Balochistan., DML No. 000280 (Formulation), on the recommendation of the panel of experts for the following sections:-

Sr. No	Name of Sections	Sr. No	Name of Sections
GROUND FLOOR			
i.	Tablet (General)	ii.	Capsule Section (General)
iii.	Liquid Syrup (General)	iv.	Dry Suspension General
v.	Cream/Ointment General	vi.	Liquid Injection (vial/ampoule) SVP
vii.	Ophthalmic Section (General	viii.	Raw material Store General
ix.	Finished Goods Store General	x.	Packing Material Store
xi.	Raw Material Store (Penicillin)	xii.	Capsule Section (Penicillin)
xiii.	Dry Suspension (Penicillin)	xiv.	Sachet Section (General)
FIRST FLOOR			
xv.	Raw material Store (Cephalosporin)	xvi.	Capsule Section (Cephalosporin)
xvii.	Dry Powder Injectable (Cephalosporin)	xviii.	Tablet Section (Psychotropic)
xix.	Dry Powder Injectable vial (Chloramphenicol)	xx.	Dry Powder Injectable (Penicillin)
xxi.	Quality Control Laboratory	xxii.	Dry Powder Suspension (Cephalosporin)

QUALITY CONTROL CASES

ITEM NO. 1

ONGOING / NEW CASES OF QUALITY CONTROL SECTION

Case No. 01: -

Subject: 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)

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 respose 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 himself nor through any authorized counsel appear before the board. He also did not submit 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.**

Case No. 02: -

Subject: Seizure Of Stock Under Section 18 (1) (f) of the Drugs Act, 1976 From M/s. Cheap Medical Store (Pvt.) Ltd., New Anarkali, Lahore.

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 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. 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	04/21 4	04/201 7	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 Bilty No. 46105 Sender Ayup Bhatti, receiver Cheap medical store at 4:15pm.	-	-	-	-	10kg.
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;

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. 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. 17. 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.**

ITEM NO. 2

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

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

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

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

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

That Mr. 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

Case No. III **MANUFACTURING STOCKING FOR SALE AND SELLING OF UN-REGISTERED DRUG NAMELY SYP ZING B.NO.RP799 MFG BY REIGN NUTRO PHARMA PVT LTD KARACHI.**

That Mr. Syed Abdul Saleem, FID Quetta forwarded vide letter No.SAS-21-2010-FID(Q)/344 dated 12th May 2010. The FID Quetta stated that during visit AMN Traders Quetta on 18.03.2010 and a sample of drug namely Syp Zing B.No. RP799 claimed to be manufactured by M/s Reign Nutro Pharma Pvt Ltd Karachi marketed by M/s Nexsus Pharma Pvt Ltd karachi was drawn along with other samples of drug on Form -3.

02. The FID Quetta submitted that the sealed sample of Syp Zing B.No.RP799 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-21-22/2010-FID (Q) -209 dated 19-03-2010 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-21-22/2010-FID(Q)/222 dated 19-03-2010 and manufacturer portion sent to the said manufacturer vide his office letter No. SAS-21-22/2010-FID(Q)/229 dated 19-03-2010.

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi declared said sample of drug as un-registered vide his test report No. R.281/2010 dated 07.04.2010.

04. M/s Reign Nutro Pharma Pvt Ltd karachi was served with a show cause notice vide his letter No. SAS-21/2010-FID(Q)/273 dated 12.04.2010 to explain its position for manufacturing and sale of un-registered drug namely Syp Zing B.No.RP799.

05. M/s Reign Nutro Pharma Pvt Ltd Karachi submitted its reply vide its letter dated 19.04.2010 wherein stating that they stopped further manufacturing of said unregistered drug and applied to the Ministry of Health for Drug Manufacturing License The firm also submitted the site verification report beraring No. F.3-3/2010-FID(K)-III dated 30.03.2010 of proposed site of the said manufacturing unit issued by Mr. Abdul Rasool Sahikh FID Karachi. The firm further added that the site plan of the manufacturing unit has also been sent to the Ministry of Health

In light of the test report No. R.281/2010 dated 07.04.2010 of FGA, M/s Reign Nutro Pharma Pvt Ltd Karachi had violated the section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c) of Drug Act 1976

06. The FID submitted the case for placement before the CLB for its consideration and further guidance on the matter as firm had stopped further manufacturing of said un registered drug and applied for Drug manufacturing License under Drug Act 1976.

07. The M/s Reign Nutro Pharma Pvt ltd 213, Block-A SMCHS karachi served a show cause notice vide letter No.3-58/2010-DDC(QC-I) dated 20th September 2010 and the firm was called for personal

hearing before the Drug Registration Board on 13.10.2010 at 10:00am in Ministry of Health. The firm had replied and stated that they already attended a personal hearing in the 227 registration board meeting regarding this type of matter dated August 27th August 2010 at Ministry of Health the firm informed that they have stopped manufacturing since February 25th, 2010.

08. ***The matter was wrongly placed before the DRB and the said Board in its 228th meeting decided to issue warning to the accused persons.***

Permission for Show cause

09. It is therefore submitted that M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui through its Chief Executive, Farhan Khan may be show caused for manufacturing and selling of **unregistered** and drugs without manufacturing license.

Proceedings and Decision of 271st meeting of Central Licensing Board

10. 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 Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui through its Chief Executive, Farhan Khan
2. Farhan Khan, Chief Executive, M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui

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.

11. 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.

12. 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 Federal Inspector of Drugs (FID), Quetta forwarded case vide letter No.SAS-21-2010-FID(Q)/344 dated 12th May 2010. The FID Quetta stated that during visit of M/s AMN Traders Quetta on 18.03.2010 and a sample of drug namely Syp Zing B.No. RP799 claimed to be manufactured by M/s Reign Nutro Pharma Pvt. Ltd., Karachi marketed by M/s Nexsus Pharma Pvt Ltd karachi was drawn along with other samples of drug on Form -3.

03. The-then FID Quetta submitted that the sealed sample of Syp Zing B.No.RP799 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-21-22/2010-FID (Q)-209 dated 19-03-2010 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-21-22/2010-FID(Q)/222 dated 19-03-2010 and manufacturer portion sent to the manufacturer vide his office letter No. SAS-21-22/2010-FID(Q)/229 dated 19-03-2010.

04. The-then FID Quetta further informed that the Government Analyst, CDL, Karachi declared said sample of drug as ***un-registered vide his test report No. R.281/2010 dated 07.04.2010 (copy enclosed)****.*

05. The-then FID, Quetta informed that M/s Reign Nutro Pharma Pvt Ltd karachi was served with a show cause notice vide his letter No. SAS-21/2010-FID(Q)/273 dated 12.04.2010 to explain its position for manufacturing and sale of un-registered drug namely Syp Zing B.No.RP799.

06. The-then FID, Quetta also informed that M/s Reign Nutro Pharma Pvt. Ltd., Karachi submitted its reply vide its letter dated 19.04.2010 wherein stating that they stopped further manufacturing of said unregistered drug and applied to the Ministry of Health for Drug Manufacturing License The firm also submitted the site verification report beraring No. F.3-3/2010-FID(K)-III dated 30.03.2010 of proposed site of the said manufacturing unit issued by Mr. Abdul Rasool Sahikh FID Karachi. The firm further added that the site plan of the manufacturing unit has also been sent to the Ministry of Health.

07. The-then FID, Quetta in light of the test report No. R.281/2010 dated 07.04.2010 of FGA, M/s Reign Nutro Pharma Pvt Ltd Karachi had violated the section ***23(1)(a)(vii), 23(1)(a)(x), 23(1)(b) and 23(1)(c)*** *of Drug 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 Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui, Off University Road, Karachi through its Chief Executive, Farhan Khan*
2. *Farhan Khan, Chief Executive M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui, Off University Road, Karachi.*

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."

13. That the firm M/s REIGN Nutro Pharma, Karachi replied to the Show Cause & Personal hearing notice vide their letter No. **Nil** dated 11.10.2019, which is reproduced as under:

Dear Sir,
This is to reference to your letter No.F.03-44/2019-QC(Pt-I)(271-CLB) dated October 04, 2019 regarding above mentioned subject.
Sir, here I want to inform you that already I attended the personal hearing in the 227th Meeting of the Drug Registration held on August 27, 2010, in the Committee Room, 1st Floor, Block "C" Pak Secretariat, Ministry of Health, Islamabad.
The concensus of the 227th Meeting of the Drug Registration Board were:

To issue "warning" letter to REIGN Nutro Pharma (Pvt.) Ltd. vide letter no.F. 3-5/2010-DDC(QC-I) dated September 29, 2010 according to this letter compahad recalled stocks from the market & verification of the stoppage of production/sales and recall by the concerned FID (Send to the Federal Inspector of Drug-III, Karachi) vide letter No.F.3-5/2010-DDC(QC-I) dated September 29, 2010. (Both letter Copy attached).
It is further submitted that after comply all the above mentioned letters, concern AFID-III, Karachi had issued the final settlement of the matter vide letter No.F.3-6/2010-FID(K)-III dated October 19, 2010. (Copy attached)

Keeping in view of above mentioned gorund realities the matter had already been resolved.
It is requested that I may please be exempted fro personal hearing dated October 17, 2019 at 10:30AM in committee room, 4th Floor, TF Complex, G9/4, Islmabad.
Early response is highly appreciated."

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

14. That Farhan Khan (CNIC No.: 42101-1704677-7) appeared as Chief Executive Offier (CEO) of M/s REIGN Nutro Pharma, Karachi before the Board and pleaded the case in the light of written reply as mentioned vide para 13 above.

15. The Central Licensing Board also acknowledged that the case was wrongly placed before the Drug Registraion Board as the instant case is regarding manufacturing stocking for sale and selling of un-registered drug, which has to be placed before Central Licensing Board under sub-rule (2) of rule (4) of the Drugs (Federal Inspectors, Federal Drug Laboratory and federal government Analysts) Rules, 1976. The Baord 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 ***Section 23 (1) (a) (vii), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c) read with Section 27 of the Drugs Act, 1976:***

   1. *M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui, Off University Road, Karachi through its Chief Executive, Farhan Khan*
   2. *Farhan Khan, Chief Executive M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui, Off University Road, Karachi.*

B. The Centtral Licensing Board granted permission to the Federal Inspector of Drugs for prosecution of above accused. The Federal Inspector of Drugs, DRAP, Quetta should submit complaint before the court of competent jurisdiction along with relevant record and submit compliance report for information.

Case No IV:- **MANUFACTURING Stocking for sale and selling of UN-REGISTERED DRUG NAMELY Prozinc B.No.RP796 Mfg by Reign Nutro Pharma Pvt Ltd Karachi**

That Mr. Syed Abdul Saleem, FID Quetta forwarded vide letter No.SAS-158/2009-FID(Q)/206 dated 16th March 2010. The FID Quetta stated that during visit M/s Fine Enterprises Quetta on 12.11.2009 and a sample of drug namely Syp Prozinc B.No. RP796 claimed to be manufactured by M/s Reign Nutro Pharma Pvt Ltd Karachi was drawn along with other samples of drug on Form -3.

02. The FID Quetta submitted that the samples was sent to the Government Analyst, Central Drug Laboratory, Karachi on Form-4 vide his office memorandum No. SAS-157-158/2009-FID (Q) /16 dated 12-11-2009 a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-157-158/2009-FID(Q) dated 12-11-2009 and manufacturer portion sent to the manufacturer vide office letter No. SAS-157-158/2009-FID(Q) dated 12-11-2009

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi declared said sample of drug as **un-registered and substandard**vide his test report No. RSCD.497/2009 dated 31.12.2009.

04. M/s Reign Nutro Pharma Pvt Ltd Karachi was served with a show cause notice vide his letter No. SAS-158/2009-FID(Q)/127 dated 06.01.2010 to explain its position for manufacturing and sale of **un-registered and substandard**drug namely Syp Prozinc B.No.RP796.

05. M/s Reign Nutro Pharma Pvt Ltd Karachi submitted its reply vide its letter dated 14.01.2010 wherein stating that the said product is food supplement and being manufactured in collaboration with PCSIR Laboratories Karachi The firm also submitted references from FDA USP etc along with its reply but it revealed that the certification and interpretation of the firm has contradiction and mis-represented by calming false statement/ references on label as FDA approved and USP specification and alo offer for treatment as drug for cure of disease without establishment of official references for growth retardation in children prevention of Diarrhea attention disorder delayed wound healing anoxia and hair loss. This is clear violation of Drug Act 1976.

06. M/s Reign Nutro Pharma Pvt Ltd Karachi again asked vide office letter No. SAS-158/2009-FID(Q) /173 dated 11.02.2010 for clarification of some points and required information/documents but no response is received as yet.

07. Keeping in view of above stated facts it revealed that M/s Reign Nutro Pharma Karachi involved in manufacturing and selling of Unregistered and substandard drug namely Prozinc syrup and violated the section 23(1)(a)(vii) 23(1)(a)(v) 23(1)(a)(x) 23(1)(b) 23(1)(c) 23(1)(h) and 27 (3) of Drug Act 1976.

The matter was wrongly placed before the DRB and the said Board decided to issue warning to the accused persons in its 227th Meeting held on 27th August, 2010.

Permission for Show cause Notice.

08. It is therefore submitted that M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui through its Chief Executive, Farhan Khan may be show cause notice for manufacturing and selling of unregistered and substandard 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)(v), 23 (1) (a) (x), 23 (1) (b), 23 (1) (c), 23 (1) (h) and 27 (3) read with Section 27 of the Drugs Act, 1976 against the following accused

1. M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui through its Chief Executive, Farhan Khan
2. Farhan Khan, Chief Executive, M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui

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. Syed Abdul Saleem, the-then FID Quetta forwarded vide letter No.SAS-158/2009-FID(Q)/206 dated 16thMarch 2010. The FID Quetta stated that during visit M/s Fine Enterprises Quetta on 12.11.2009 a sample of drug namely Syp Prozinc B.No. RP796 claimed to be manufactured by M/s Reign Nutro*

Pharma Pvt Ltd Karachi was drawn along with other samples of drug on Form - 3.

03. The-then FID Quetta submitted that the samples was sent to the Government Analyst, Central Drug Laboratory, Karachi on Form-4 vide his office memorandum No. SAS-157-158/2009-FID(Q)/16 dated 12-11-2009 a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-157-158/2009-FID(Q) dated 12-11-2009 and manufacturer protion sent to the manufacturer vide office letter No. SAS-157-158/2009-FID(Q) dated 12-11-2009.

04. The FID Quetta further informed that the Government Analyst, CDL, Karachi declared said sample of drug as ***un-registered and substandard*** *vide his test report No. RSCD.497/2009 dated 31.12.2009.*

05. The-then FID, Quetta informed that M/s Reign Nutro Pharma Pvt Ltd Karachi was served with a show cause notice vide his letter No. SAS-158/2009-FID(Q)/127 dated 06.01.2010 to explain its position for manufacturing and sale of ***un-registered and substandard*** *drug namely Syp Prozinc B.No.RP796.*

06. The-then FID, Quetta also informed that M/s Reign Nutro Pharma Pvt Ltd Karachi submitted its reply vide its letter dated 14.01.2010 wherein stating that the said product is food supplement and being manufactured in collaboration with PCSIR Laboratories Karachi The firm also submitted references from FDA USP etc along with its reply but it revealed that the certification and interpretation of the firm has contradiction and mis-represented by calming false statement/ references on label as FDA approved and USP specification and alo offer for treatment as drug for cure of disease without establishment of official references for growth retardation in children prevention of Diarrhea attention disorder delayed wound healing anoxia and hair loss. This is clear violation of Drug Act 1976.

07. The-then FID, Quetta stated that M/s Reign Nutro Pharma Pvt Ltd Karachi again asked vide office letter No. SAS-158/2009-FID(Q) /173 dated 11.02.2010 for clarification of some points and required information/documents but no response is received as yet.

08. The-then FID, Quetta also stated that keeping in view of above stated facts it revealed that M/s Reign Nutro Pharma Karachi involved in manufacturing and selling of Unregistered and substandard drug namely Prozinc syrup and violated the section 23(1)(a)(vii), 23(1)(a)(v), 23(1)(a)(x), 23(1)(b), 23(1)(c), 23(1)(h) and 27(3) of Drug Act 1976.

09. 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)(v), 23(1)(a)(x), 23(1)(b), 23(1)(c), 23(1)(h) and 27(3)read with Section 27 of the Drugs Act, 1976 against the following accused:

1. *M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui, Off University Road, Karachi through its Chief Executive, Farhan Khan*
2. *Farhan Khan, Chief Executive M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui, Off University Road, Karachi.*

10. 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)(v), 23(1)(a)(x), 23(1)(b), 23(1)(c), 23(1)(h) 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.*

11. 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.
12. 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."

12. That the firm M/s REIGN Nutro Pharma, Karachi replied to Show Cause & Personal hearing notice vide their letter No. **Nil** dated 11.10.2019, which is reproduced as under:

Dear Sir,
This is to reference to your letter No.F.03-44/2019-QC(Pt-I)(271-CLB) dated October 04, 2019 regarding above mentioned subject.
Sir, here I want to inform you that already I attended the personal hearing in the 227th Meeting of the Drug Registration held on August 27, 2010, in the Committee Room, 1st Floor, Block "C" Pak Secretariat, Ministry of Health, Islamabad.
The concensus of the 227th Meeting of the Drug Registration Board were:

To issue "warning" letter to REIGN Nutro Pharma (Pvt.) Ltd. vide letter no.F. 3-5/2010-DDC(QC-I) dated September 29, 2010 according to this letter compahad recalled stocks from the market & verification of the stoppage of production/sales and recall by the concerned FID (Send to the Federal Inspector of Drug-III, Karachi) vide letter No.F.3-5/2010-DDC(QC-I) dated September 29, 2010. (Both letter Copy attached).
It is further submitted that after comply all the above mentioned letters, concern AFID-III, Karachi had issued the final settlement of the matter vide letter No.F.3-6/2010-FID(K)-III dated October 19, 2010. (Copy attached)

Keeping in view of above mentioned gorund realities the matter had already been resolved.
It is requested that I may please be exempted fro personal hearing dated October 17, 2019 at 10:30AM in committee room, 4th Floor, TF Complex, G9/4, Islmabad.
Early response is highly appreciated."

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

13. That Farhan Khan (CNIC No.: 42101-1704677-7) appeared as Chief Executive Offier (CEO) of M/s REIGN Nutro Pharma before the Board and pleaded the case in the light of written reply as mentioned vide para 12 above.

14. The Central Licensing Board also acknowledged that the case was wrongly placed before the Drug Registraion Board as the instant case is regarding manufacturing stocking for sale and selling of un-registered & sub-standard drug, which has to be placed before Central Licensing Board under sub-rule (2) of rule (4) of the Drugs (Federal Inspectors, Federal Drug Laboratory and federal government Analysts) Rules, 1976. The Baord 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 ***Section 23(1)(a)(vii), 23(1)(a)(v), 23(1)(a)(x), 23(1)(b), 23(1)(c), 23(1)(h) and 27(3) read with Section 27 of the Drugs Act, 1976:***
   1. *M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui, Off University Road, Karachi through its Chief Executive, Farhan Khan*
   2. *Farhan Khan, Chief Executive M/s Reign Nutro Pharma Pvt Ltd TBIC, PCSIR Laboratories Complex Shahra e Dr. Salim uz Zama Sidiqui, Off University Road, Karachi.*

B. The Centtral Licensing Board granted permission to the Federal Inspector of Drugs for prosecution of above accused. The Federal Inspector of Drugs, DRAP, Quetta should submit complaint before the court of competent jurisdiction along with relevant record and submit compliance report for information.

Case No.V: Import and sale of un-registered Drug Namely Caps Flexeze. B,No. 901121 Mfg by M/s Gold Shield Crooxt, UK Marketed by M/s Biogenics Pakistan Pvt Ltd Karachi.

That Mr. Syed Abdul Saleem, FID Quetta forwarded vide letter No.F.SAS-86/2009-FID(Q)/201 dated 11thMarch 2010. The FID Quetta stated that during visit Haji Nizamuddin & Sons Quetta on 01.10.2009 during the visit sample of drug namely Caps Flexeze Batch No. 021121 claimed to be manufactured by M/s Gold Shield Crooxt UK marketed by M/s Biogenics Pakistan Pvt Ltd Karachi was taken along with other samples of drugs on Form-3.

02. The FID Quetta submitted that the sealed sample of Caps Flexeze B.No.021121 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-84-93/2009-FID (Q)-3019 dated 05-10-2009 a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-86/2009-FID(Q)/3036 dated 09-10-2009 with advise to provide the copy of registration along with acknowledgment of its receipt but not response is received as yet.

03. The FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report bearing No.729/2009 dated 30-12-2009 **declared the Un-registered.**

04. M/s Biogenics Pvt Ltd Karachi was served with a show cause notice bearing No. SAS-86/2009-FID (Q)/116 dated 04.01.2010 to explain its position for selling said unregistered drug M/s Biogenics Pakistan Pvt Ltd Karachi submitted its reply without required documents/information vide its letter dated 18.01.2010 stating that said drug is nutritional supplements and quoted references but no any documentary evidence was found attached with its reply it is further added that the same formulation i.e. Ascorbic Acid and Glucosamine is being manufactured and registered with different manufactures in different brand names but said firm imported it as nutritional supplement without having registration.

05. FID stated that the firm also submitted copy of letter No.PQCB/Rp.179-11/2009 dated 25-11-2006 of Secretary PQCB Punjab through which the District QCB was directed not to launch prosecution against the firm in Drug Court M/s Biogenics Pakistan Pvt Ltd Karachi was again asked to provide information/ documents and also current status of the case with Provincial Quality Control Board Punjab vide this office letter No. SAS-86/2009-|FID(Q)/116 dated 06.02.2009 but not reply response is received as yet.

06. The FID Quetta submit the above mentioned facts and revealed that the firm has violated the section 23(1)(a)(vii), 23(1)(e),23(1)(f) 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 M/s Biogenics Pakistan Pvt Ltd Karachi**.

Permission for Show cause

08. It is therefore submitted that **NasirMehmood, GM Technical Operations of M/s Biogenics Pakistan Pvt Ltd Karachi**and M/s **Haji Nizamuddin & Sons Patel Bagh of Jinnah Road, Quetta Opposite Nagi Hospital through it owner/proprietor i.e. Fawad Mehmood**may be served show caused for manufacturing and selling of **unregistered** and 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)(e), 23(1)(f) and 27(3) read with Section 27 of the Drugs Act, 1976 against the following accused

1. M/s Biogenics Pakistan Pvt Ltd Karachi through Nasir Mehmood, GM Technical Operations
2. Nasir Mehmood, GM Technical Operations of M/s Biogenics Pakistan Pvt Ltd Karachi
3. M/s Haji Nizamuddin & Sons Patel Bagh of Jinnah Road, Quetta Opposite Nagi Hospital through it owner/proprietor Fawad Mehmood
4. Fawad Mehmood, owner/ proprietor M/s Haji Nizamuddin & Sons Patel Bagh of Jinnah Road, Quetta Opposite Nagi Hospital

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

iii. Prosecution in the Court of competent jurisdiction

iv. 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. Syed Abdul Saleem, FID Quetta forwarded case vide letter No.F.SAS-86/2009-FID(Q)/201 dated 11thMarch 2010. The FID Quetta stated that during visit Haji Nizamuddin & Sons Quetta on 01.10.2009 a sample of drug namely Caps Flexeze Batch No. 021121 claimed to be manufactured by M/s Gold Shield Crooxt UK marketed by M/s Biogenics Pakistan Pvt Ltd Karachi was taken along with other samples of drugs on Form-3.*

03. The-then FID Quetta submitted that the sealed sample of Caps Flexeze B.No.021121 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-84-93/2009-FID (Q)-3019 dated 05-10-2009 a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-86/2009-FID(Q)/3036 dated 09-10-2009 with advise to provide the copy of registration along with acknowledgment of its receipt but not response is received as yet.

04. The-then FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report bearing No.729/2009 dated 30-12-2009 ***declared the sample as Un-registered.***

05. The-then FID, Quetta informed that M/s Biogenics Pvt Ltd Karachi was served with a show cause notice bearing No. SAS-86/2009-FID (Q)/116 dated 04.01.2010 to explain its position for selling said unregistered drug M/s Biogenics Pakistan Pvt Ltd Karachi submitted its reply without required documents/information vide its letter dated 18.01.2010 stating that said drug is nutritional supplements and quoted references but not any documentary evidence was found attached with its reply it is further added that the same formulation i.e. Ascorbic Acid and Glucosamine is being manufactured and registered with different manufacturers in different brand names but said firm imported it as nutritional supplement without having registration.

06. The-then FID stated that the firm (M/s Biogenics) also submitted copy of letter No. PQCB/Rp.179-11/2009 dated 25-11-2006 of Secretary PQCB Punjab through which the District QCB was directed not to launch prosecution against the firm in Drug Court. The-then FID also stated that the M/s Biogenics Pakistan Pvt Ltd Karachi was again asked to provide information/documents and also current status of the case with Provincial Quality Control Board Punjab vide this office letter No. SAS-86/2009-\|FID(Q)/116 dated 06.02.2009 but not reply response is received as yet.

07. The-then FID Quetta submit keeping in view of above facts, it revealed that the firm (M/s Biogenics) has violated the section 23(1)(a)(vii), 23(1)(e), 23(1)(f) 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)(e), 23(1)(f) and 27(3) read with Section 27 of the Drugs Act, 1976 against the following accused:***

1. *M/s Biogenics Pakistan Pvt Ltd., 201, Fortune Centre, Block-6, P.E.C.H.S., Share Faisal, Karachi through its GM Technical Operations, Nasir Mehmood Mughal.*
2. *Nasir Mehmood Mughal, GM Technical Operations of M/s Biogenics Pakistan Pvt Ltd Karachi.*
3. *M/s Haji Nizamuddin & Sons Patel Bagh of Jinnah Road, Quetta Opposite Nagi Hospital through its owner/proprietor Fawad Mehmood.*
4. *Fawad Mehmood owner/proprietor M/s Haji Nizamuddin & Sons Patel Bagh of Jinnah Road, Quetta Opposite Nagi Hospital.*

*09. You are hereby served this show cause notice that why not the following actions shall be taken against y**ou <u>for violating the Section 23(1)(a)(vii), 23(1)(e), 23(1)(f) 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.</u>***

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."

12. No other accused person submitted written reply to the show cause notice issued vide letter no. 03-44/2019-QC(Pt-I)(271-CLB) dated 04.10.2019.

<u>Proceedings & Decision of 272nd CLB held on 17th October, 2019:</u>

13. The Firm M/s Biogenics Pakistan (Pvt.) Ltd. 201, Fortune Centre, Block-6, PECHS, Sharae Faisal, Karachi submitted their reply to show cause & personal hearing notice vide their letter No. **Nil** dated 14.10.2019 that was received one day before the meeting of the Board. The reply was discussed in the meeting, which is reproduced as under:

"Dear Honorable Secretary,

*We have received your show cause notice on the subject **import and sale of unregistered drugs namely Caps Flexeze. B.No. 901121 Mfg By M/s Gold Shield, UK Marketed by M/s Biogenics Pakistan Pvt Ltd Karachi** and would like to submit our reply as hereunder:*

In the letter you have accused Biogenics of not submitting any documentary evidence in reply to you Show Cause Notice bearing No.SAS-86/2009-FID(Q)/116 daed 04.01.2010 to explain our position regarding selling "unregister drug" namely flxzee Caspsuels. We would like to submit that we did reply to the said letter, as we did to all the letters on the same subject before and after it, and we did submit the documentary evidence which was required of us. We are enclosing our all such replies from our end along with the documentary evidence has shared and receiving here.

It is further submitted that a case of similar nature involving the durg flxzee was filed against us in the Drugs Court, Khyber Pakhtunkhwa Peshawar (Spl. Case No. 198.2010) which was subsequently ruled in our favor. A copy of he order of this case is attached to this letter as well.

Last but none the least, it is informed that on October 2012 we issued a circular (BIO 126-A/2012) regarding discontinuation of Flxzee and withdrawal of the same form the market. However, we had a started recalling the product form our distributors before that. We can submit proofs of withdrawals in terms of Sales Return Note from different distributors if required. A copy of the said circular is also attached to this reply.

In light of the mounting evidence presented in this reply, we humbly requested that your office withdraw the said charges gainst us regarding Flxzee and close this chapter once and for all.

Yours Sincerely

Hussain Haider Karrar

Managing Director

Biogenics Pakistan (Pvt.) Ltd."

14. That none of the accused (neither in person nor by authorized pleader/attorney) appreaed before the Board. even after receiving of show cause & personal hearing notice.

15. The Baord 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 ***Section 23(1)(a)(vii), 23(1)(e), 23(1)(f) and 27(3) read with Section 27 of the Drugs Act, 1976:***

   1. *M/s Biogenics Pakistan Pvt Ltd., 201, Fortune Centre, Block-6, P.E.C.H.S., Share Faisal, Karachi through its GM Technical Operations, Nasir Mehmood Mughal.*
   2. *Nasir Mehmood Mughal, GM Technical Operations of M/s Biogenics Pakistan Pvt Ltd Karachi.*
   3. *M/s Haji Nizamuddin & Sons Patel Bagh of Jinnah Road, Quetta Opposite Nagi Hospital through its owner/proprietor Fawad Mehmood.*
   4. *Fawad Mehmood owner/proprietor M/s Haji Nizamuddin & Sons Patel Bagh of Jinnah Road, Quetta Opposite Nagi Hospital.*

B. The Centtral Licensing Board granted permission to the Federal Inspector of Drugs for prosecution of above accused. The Federal Inspector of Drugs, DRAP, Quetta should submit complaint before the court of competent jurisdiction along with relevant record and submit compliance report for information.

Case No. VI:- **Stocking for sale and selling of un-registered drugs by M/s. Al-Hamd, medical store, Kuchlak, Quetta.**

01 Proceeding and Decision of 227th Meeting of CLB:

That F.I.D, Quetta alongwith F.I.A raided Al-Hamd Medical Store, situated by pass road Kuchlak, Quetta from and recovered/ seized un-registered medicines (Hi Tulsi containing Sildenafil Citrate, Vega 100 tablets containing Sildenafil Citrate, Deuroran-50 tablets containing Diclofenac Sodium, Voren Tablet containing Diclofenac Sodium etc). Occupant of the premises Ham-Ullah s/o Muhammad Shah failed to provide any drug sale license, warranty etc for the seized stock. Sample sent to Central Drugs Laboratory, Karachi has been declared Un-Registered by the Federal Government Analyst. F.I.R was launched by the F.I.A against Hamd-Ullah and Shafi-Ullah. F.I.A has recently submitted the Challan to F.I.D, Quetta. Which was faxed by the F.I.D just a day before meeting. The Board was informed that on receipt of complete case from F.I.D, as per procedure, show cause notices will be issued to the accused and they will be offered opportunity of personnel hearing before a decision by the Board.

Decision of 227th Meeting of CLB:-

The Board instructed the F.I.D to submit complete case immediately so that show cause notices be issued to the accused. The Board further authorized its Chairman to grant personnel hearing to the accused and take appropriate decision on behalf of the Central Licensing Board.

02. That Mr. Syed Abdul Saleem, FID Quetta forwarded the case vide letter No.12-7/DCA-QTA/Al-Hamd Medical Store-580 dated 08th June 2011 details of which are reproduced as under:

"Respected sir,

I have the honor to refer case for placement before Central Licensing and Registration Board for the grant of prosecution in the drug court against persons nominated in the pray, Summary of the along with enclosures, evidence etc is as follows.

1. That report from reliable source is received on 19th March, 2011 to FIA Quetta a person named Hamd Ullah S/o Mohammad Shah resident of Killi new Khoratabad Kuchlak involved in Un-registered Drug trafficking and keeping huge volume at Al-Hamd Medical store Kuchlak.

2. Assistant Director Crime wing constituted a raiding team undersigned associated as expert and proceeded to by road Kuchlak and raid to Al-Hamd Medical Store a person named Hamd Ullah S/0 Mohammad Shah was present at the premises, he failed to show any drug sale license or warrant bill or legal

reason for stoking these medicines, therefore all available stock was seized after entry on Form-2 (Annex A).

3. A portion from each also taken on Form-3 for Central Drug Laboratory Karachi for test /Analysis purpose (Annex B).

4. The accused was taken into custody by F.I.A for further investigation, as the huge quantity of medicine is not possible to keep in office therefore adter taking receipt stock is handed over to F.I.A. for safe custody, F.I.R also launched by F.I.A. crime cell under various section of Pakistan penal code against culprit copy of same is placed here as (Annex-C)

5. That the Federal Government Analyst Central Drugs Laboratory Karachi vide his Test Report No. 240 to 256 dated 14th April, 2011 declared the sample of drugs as Un-Registared copy of test reports Annex as D.

6. A portion of sample also sent to the Chairman, Cnetral Licensing & Registration Board Islamabad vide his Office letter No. SAS-162-171/2011-FID(Q)/623 dated 22-03-2011, (Annex-E).

7. The culprit Mr. Hamd Ullah was produce to adrug court by F.I.A. on 19th April,2011 with enterioum Challan, undersigned also attended court & requested honorable Chairman Drug Court not o grant bail as his production is not possible after bail, so the bail application was rejected.

8. S.H.O FIA Quetta completed his investigation and provided challan No. 311 dated 9th April, 2011 to FIA Quetta for further necessary action under the Drugs Act, 1976, copy of the challan is placed here as (Annex-F).

9. In the light of above narrated facts the owner of the medical store Mr. Hamd Ullah S/o Mohammad Shah resident of Killi New Khoratabad found in the keeping of Un-Registered smugguled Indian Medicine and violated section 23(1)(a)(i) 23(1)(a)(ii) 23(1)(a)(iii) 23(1)(b) 23(1)(c) and 27(1)(c) of the drugs Act, 1976, therefore the case is being submitted to your good office for placement before the Central Registration Board for its consideration and permission of prosecution against Mr. Hamd Ullah S/o Mohammad Shah resident of Killi Khoratabad, Kuchlak, Ditrict Quetta in the Drug Court."

03. Challan is submitted by Investigation officer FIA on 19-03-2011 registered the case was registered against accused Hamdullah S/o Muhammad Shah was arrested and transfer to judicial lock up

however another accused Shafiullah S/o Muhammad Shah still not arrested and FIA has strong efforts for arrest him.

On 19-03-2011 as per information Hamdullah and Shafiullah S/o Muhammad Shah cast Sulemankhail resident of Kuckhlak owner of Alhamd Medicine Agency Kuchlak trade illegally un registered spurious, substandard medicines business so under the supervision of Mr. Habibullah Naran Assistant Director ACW, FIA Quetta along with inspector Muhammad Hashim, Inspector Hukum Dad, ASI Bahadur Khan Bazai, Muhammad Zaman HC, Muhammad Sidique FC and Muhammad Hanif, Kuckhlak Bye Pass, and FID Quetta Mr. Syed Abdul Saleem. The person present at Alhamd medicine Agency informed that his name is Hamdullah S/o Muhammad Shah and stated that he along with his brother Shafiullah are linked with business of medicines and for this they hold license by way of whole sale in the name of Shafiullah but he could not furnish any permit or license regarding presence of foreign medicines in his shop. That the Federal Drug Inspector Syed Abdul Saleem cheked all available medicines in the shop who declared all the medicines as unregistered and foreign origin and stated that these medicines does not belong to any registered company in Pakistan hence he took samples for the purpose of test/analysis from all medicines individually and as prescribed handed over other medicines to the custody of FIA. As prescribed the accused Hamdullah was arrested and after completion of investigation has been transferred to Judicial Lockup. Accused Shafiullah who ran off to avoid arrest, whose arrest warrant was obtained from the court of competent jurisdiction. The mentioned accused got arrested on 04-06-2011 after cancellation of interim bail as prescribed and after completion of investigation has been transferred to Judicial Lockup on 18-06-2011. Many evidences are available on record against the accused shafiullah. The Challan against the accused Hamdullah along with all relevant record has been handed over to Federal Inspector of Drugs on 09-04-2011. Hence, it is prayed vide this letter along with sent record that this initial report against accused Hamdullah and this report against accused Shafiullah, the Challan is prepared to be sent to the Court of Competent Jurisdiction for the purpose of prosecution/hearing.

04. Show cause notice was issued to the accused vide letter no. 13-20/2019-QC dated 22.03.2019. The copy of the same was forwarded to Officer In-Charge Quetta @ Karachi with request to ensure the delivery of this letter to the accused and acknowledge the receipt. The acknowledgement receipt was forwarded by AD, DRAP, Quetta vide letter NO. 12-7/DCA-QTA/Al-Hamd Medical Store-72 dated 17.06.2019.

Submitted for show cause notice to prosecute:

05. It is therefore submitted that **Hamdullah S/o Muhammad Shah R/o Killi New Khoratabad, District Quetta, Shafiullah S/o Muhammad Shah R/o Killi New Khoratabad, District Quetta and**

Al-hamd medical Store, Quetta through its owner/proprietor may be served show caused for violations conveyed to the accused persons vide show cause notice dated 22.03.2019.

Proceedings and Decision of 271st meeting of Central Licensing Board

06. Request of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Quetta @Karachi vide letter No.3-1/2019-FID (Q) K dated 5th August, 2019, the case was placed before the Central Licensing Board. Furthermore, the matter was also referred by the Honourable Chairman, Drug Court Balochistan, Quetta. The Board deliberated the matter in depth, considered the facts of the case and perused the available record. It was revealed that a showcause notice for prosecution has been issued vide letter No. 13-20/2019-QC dated 22.3.2019 for which acknowledgement receipt has been forwarded by Assistant Director, DRAP, Quetta vide letter No. 12-7/DCA-QTA/Al_Hamd Medical Store-72 dated 17.06.2019. Keeping in view the facts the Board decided that all the accused persons may be given final opportunity of personal hearing either in person or through authorized counsel may be afforded in the forthcoming meeting of the Board.

07. 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. In continuation to show cause notice for prosecution communicated vide letter no. 13-20/2019-QC dated 22.03.2019, no reply is received till todate.* ***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.*** *Board delibrated the matter in depth, considered the facts of the case and available record including FIA Challan, service of Show Cause Notice for prosecution etc.*
>
> *03. The Board decided to give you final opportunity of personal hearing on 17-10-2019 at 10:00AM before CLB. Therefore, you are directed to appear in person or through authorized legal counsel on forthcoming meeting of Central Licensing Board.*
>
> *04. In case of failure to appear in person before the Board, it will be presumed that you have nothing in your defense and an ex-parte decision under the law shall be taken on the merits of the case as per available record."*

08. None of the accused person submitted written reply to the show cause notice issued vide letter no. 13-20/2019-QC dated 22.03.2019.

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

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

10. The Board delibrated 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 **Section 23(1)(a)(i), 23(1)(a)(ii), 23(1)(a)(iii), 21(1)(a)(x), 23(1)(b), 23(1)(c) and 27(1)(c) of the Drugs Act, 1976:**

i. Al-hamd medical store, Quettta through its owner/proprietor, Killi New Khoratabad, District quetta.
ii. Hamdullah S/o Muhammad Shah R/o Killi New Khoratabad, District Quetta
iii. Shafiullah S/o Muhammad Shah R/o Killi New Khoratabad, District Quetta

B. The Centtral Licensing Board granted permission to the Federal Inspector of Drugs for prosecution of above accused. The Federal Inspector of Drugs, DRAP, Quetta should submit complaint before the court of competent jurisdiction along with relevant record and submit compliance report for information.

Case No. VII:- **STOCKING FOR SALE AND SELLING UN REGISTERED DRUGS SEIZURE ON FORM-2 – M/S ZARGHOON VETERINARY QUARRY ROAD QUETTA.**

Mr. Syed Abdul Saleem, FID Quetta forwarded the case vide letter No. 12-1/DCA-QTA/M. Survey 180 dated 16th February 2010. The FID Quetta visited along with FIA to **M/s Zarghoon Veterinary Quarry Road Quetta** 04.11.2009 during the visit some unregistered drugs were found placed in its godown located at Room No.2 Arbab Plaza, Quarry Road, Quetta The FID seized the all available stocks of unregistered drugs on Form-2 it is further added that stocking for sale and sale of unregistered drugs is violation of provisions of Drug Act 1976 and Rules made there under. The details of the seized stock as under:-

S.No.	Name of Drug	B.No.	Quantity	Mfg date	Exp date	Purported by Mfg by
01.	Albendazole 150mg	090310	50 botles 1x500	03-2009	03-2012	Made in China
02.	Sulphadimiciline 600	090310	50 bottles x1x400	03-2009	3-2012	Made in China
03.	Niclosemide 125mg	090309	50 bottles x1x370	03-2009	3-2012	Made in China
04.	Niclosam 125mg	090320	100 bottles x1x100	03-2009	3-2012	Made in China
05.	Deyletsrcyeline 50mg/ml inj	090770	50mlx1x190	07-2009	7-2012	Made in China
06.	Noromcetine Injection	090773	50mlx1x80	07-2009	7-2012	Made in China
07.	Alamycine-LA inj	090771	50mlx1x320	07-2009	7-2012	Made in China

02. The same was reported for further instructions/guidance on the matter and permission of safe custody of seized stocks of unregistered drugs vide office letter No.F.12-1/DCA-QTA/M.Survey dated 05.11.2009 and subsequent request vide letter No.12-1/DCA-QTA/M Survey/80 dated 12.12.2009

03. M/s Zarghoon veterinary Quetta was called to explain its position for stocking for sale and selling unregistered drugs vide letter No.F.12-1/DCA-QTA/M.Survey-44 dated 15.11.2009 but no response is received as yet.

04. The FID Quetta is submitted the case for placement before CLB for its consideration and permission of **prosecution against Khushhal Khan Proprietor Mr.Rahat Ahmed Qualified person and Mr. Khuda-e-Noor persons present of M/s Zarghoon Veterinary Quarray Road Quetta for stocking for sale and selling unregistered drugs.**

Submitted for show cause notice to prosecute:

05. It is therefore submitted that **Khushhal Khan Proprietor, Rahat Ahmed Qualified person and Khuda-e-Noor persons present of M/s Zarghoon Veterinary, Quarray Road, Quetta** may be served show caused **for stocking for sale and selling unregistered drugs**.

Proceedings and Decision of 271st meeting of Central Licensing Board

06. 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 Zarghoon Veterinary, Quarray Road, Quetta through Khushhal Khan Proprietor
2. Khushhal Khan Proprietor, M/s Zarghoon Veterinary, Quarray Road, Quetta
3. Rahat Ahmed Qualified person M/s Zarghoon Veterinary, Quarray Road, Quetta
4. Khuda-e-Noor persons present of M/s Zarghoon Veterinary, Quarray 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.

07. 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.

08. 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. Mr. Syed Abdul Saleem, FID Quetta forwarded the case vide letter No. 12-1/DCA-QTA/M. Survey 180 dated 16th February 2010. The FID Quetta visited along with FIA to ***M/s Zarghoon Veterinary Quarry Road Quetta*** *04.11.2009 during the visit some unregistered drugs were found placed in its godown located at Room No.2 Arbab Plaza, Quarry Road, Quetta The FID seized the all available stocks of unregistered drugs on Form-2 it is further added that stocking for sale and sale of unregistered drugs is violation of provisions of Drug Act 1976 and Rules made there under. The details of the seized stock as under: -*

S.No.	*Name of Drug*	*B.No.*	*Quantity*	*Mfg date*	*Exp date*	*Purported by Mfg by*
01.	*Albendazole 150mg*	*090310*	*50 botles 1x500*	*03-2009*	*03-2012*	*Made in China*
02.	*Sulphadimiciline 600*	*090310*	*50 bottles x1x400*	*03-2009*	*3-2012*	*Made in China*
03.	*Niclosemide 125mg*	*090309*	*50 bottles x1x370*	*03-2009*	*3-2012*	*Made in China*
04.	*Niclosam 125mg*	*090320*	*100 bottles x1x100*	*03-2009*	*3-2012*	*Made in China*
05.	*Deyletsrcyeline 50mg/ml inj*	*090770*	*50mlx1x190*	*07-2009*	*7-2012*	*Made in China*
06.	*Noromcetine Injection*	*090773*	*50mlx1x80*	*07-2009*	*7-2012*	*Made in China*
07.	*Alamycine-LA inj*	*090771*	*50mlx1x320*	*07-2009*	*7-2012*	*Made in China*

03. The same was reported for further instructions/guidance on the matter and permission of safe custody of seized stocks of unregistered drugs vide office

letter No.F.12-1/DCA-QTA/M Survey dated 05.11.2009 and subsequent request vide letter No.12-1/DCA-QTA/M Survey/80 dated 12.12.2009
04. M/s Zarghoon veterinary Quetta was called to explain its position for stocking for sale and selling unregistered drugs vide letter No.F.12-1/DCA-QTA/M.Survey-44 dated 15.11.2009 but no response is received as yet.
05. in the light of request of FID Quetta @ Karachi vide letter No. 3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Central Licensing Board in its 271st meeting. The Board after delibration decided ***to issue showcause notice under rule 8 (13) of the Drugs (Licensing, Registration 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 Zarghoon Veterinary& Poultry Clinic, Quarray Road, Quetta through its proprietor Khushhal Khan.*
2. *Khushhal Khan Proprietor, M/s Zarghoon Veterinary& Poultry Clinic, Quarray Road, Quetta.*
3. *Rahat Ahmed Qualified person M/s Zarghoon Veterinary& Poultry Clinic, Quarray Road, Quetta.*
4. *Khuda-e-Noor persons present M/s Zarghoon Veterinary& Poultry Clinic, Quarray Road, Quetta.*

06. 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.

07. 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.
08. 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."

08. None of the accused person submitted written reply to the show cause notice issued vide letter no. 03-44/2019-QC(Pt-I)(271-CLB) dated 04.10.2019.

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

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

10. The Baord 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 ***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:***

1. *M/s Zarghoon Veterinary & Poultry Clinic, Quarray Road, Quetta through its proprietor Khushhal Khan.*
2. *Khushhal Khan Proprietor, M/s Zarghoon Veterinary& Poultry Clinic, Quarray Road, Quetta.*
3. *Rahat Ahmed Qualified person M/s Zarghoon Veterinary& Poultry Clinic, Quarray Road, Quetta.*
4. *Khuda-e-Noor persons present M/s Zarghoon Veterinary& Poultry Clinic, Quarray Road, Quetta.*

B. The Centtral Licensing Board granted permission to the Federal Inspector of Drugs for prosecution of above accused. The Federal Inspector of Drugs, DRAP, Quetta should submit complaint before the court of competent jurisdiction along with relevant record and submit compliance report for information.

Case No. VIII: **MANUFACTURING DRUGS WITHOUT HAVING DRUG MANUFACTURING LICENSE STOCKING FOR SALE SELLING UN-REGISTERED DRUGS IN SHAPE OF NUTRITIONAL SUPLIMENT AND KEEPING PHYSICIAN SAMPLE OF REGISTERED DRUGS _ - RANA TRADERS, QUETTA.**

That Mr. Syed Abdul Saleem Shah forwarded the case vide letter No. 12-1/DCA-QTA/M. Survey 179 dated 16th February 2010. The FID Quetta informed that during visited along with FIA team to M/s Rana Traders Flat No.1, 1st Floor Saleem Medical Complex Jinnah Road Quetta 11.11.2009 during the visit some unregistered drugs were found available with claimed to have nutritional/food supplements but suspected to have allopathic ingredients along with labels of registered drugs and physician samples of registered drugs were found placed in ready shelves for sale with other registered drugs. The FID Quetta ordered seized all available stocks of said un-registered drugs and labels on Form-2. The FID Quetta further informed that stocking for sale and sale of unregistered drugs and keeping labels of registered drugs is violation provision of Drugs Act 1976 and rules frame there under. The details of the seized products as under

i. Ronil Tabs	M/s Bio Naturo Lahore	Unregistered
ii. Calcid D3 Cap	M/s SPC Ltd Lahore	Unregistered
iii. Lakostat Cap	M/s Sehafi Natural Lab Lahore	Unregistered
iv. Semen Tab	M/s BiocareNeturo Kraft Lahore	Unregistered
v. Rebion Tab	M/s Muwadat Pharma Lahore	Unregistered
vi. Iromums Tab	-do-	Unregistered
vii. IsonimsSyp	-do-	Unregistered
viii. Irocal-M Tab	M/s Mason Lahore	Unregistered
ix. Irocal-M tab	-do-	Unregistered
x. Irocal-M tab	M/s Naturo Kraft Lahore	Unregistered
xi. Iro C sachet	-do-	Unregistered
xii. Oro-C Sachet	M/s Cosmo Pharma Karachi	Unregistered
xiii. RonilSyp	M/s Muwadat Pharma Lahore	Unregistered
xiv. RemaltSyp	-do-	Unregistered
Details of Printed empty carton/Label of registered/ unregistered drugs along with quantity seized is as under		
xv. Canpril tab 10mg		M/s convell labs Swat
xvi. ConrineTabl		M/s convell labs Swat
xvii. Veldox Tab		M/s convell labs Swat
xviii. Olamsaf tab		M/s Saaf Pharmaceutical Risalpur
xix. Mina Inj 2ml		M/s Vision Pharmaceutical Islamabad
xx. Bactil 250mg cap		M/s convell labs Swat
xxi. Conflox tab 200mg		M/s convell labs Swat
xxii. Meprawin cap 20mg		M/s WNS field Pharmaceutical Hattar
xxiii. Sajd Inj.2ml		M/s vision Pharmaceuticals Islamabad

02. The FID Quetta stated that the same was reported for further instructions/guidance on the matter and permission of safe custody of said seized unregistered drugs and labels of registered drugs vide letter No.F.12-1/DCA-QTA/M. survey dated 13.11.2009 and subsequent request letter No. F.12-1/DCA-QTA/M. survey 81 dated 12.12.2009. The FID informed that the M/s Rana Traders Quetta was called to explain its position for stocking for sale and selling unregistered drugs and keeping labels of registered drugs vide ltter No. F.12-1/DCA-QTA/M. survey-34 dated 21.11.2009 and on not response a reminder vide letter No. F.12-1/DCA-QTA/M. survey 92 dated 16.02.2009. M/s Rana Traders Quetta submitted its reply vide letter No.RTQ/Drugs/12/2009 dated 18.12.2009. it is mention that the invoice submitted by M/s Rana Traders Quetta for said unregistered drugs were also not verified from the supplier/manufacturers are received back un delivered.

03. The FID Quetta is submitted the case for placement before Central Registration Board for its consideration and permission of prosecution against Mr. Rana Sarwer Shad. Proprietor & Mr. Saleem Mansoor, Qualified persons of M/s Rana Traders Quetta and Mr. Imran Saeed and Rana Anwer Saeed persons present for stocking of sale and selling unregistered drugs and keeping labels of registered drugs at your earliest possible

Submitted for show cause notice to prosecute:

04. It is therefore submitted **that Rana M Sarwer Shad S/o Muhammad Ramzan, Proprietor & Saleem Mansoor S/o Nazeer Ahmed, Qualified persons of M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta and Imran Saeed and Rana Anwer Saeed persons present** may be served show causedfor stocking of sale and selling unregistered drugs and keeping labels of registered drugs.

Proceedings and Decision of 271st meeting of Central Licensing Board

05. 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 stocking for sale and selling of unregistered drugs and keeping labels of registered drugs against the following accused

1. M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta through Rana M Sarwer Shad S/o Muhammad Ramzan, Proprietor
2. Rana M Sarwer Shad S/o Muhammad Ramzan, Proprietor M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta
3. Saleem Mansoor S/o Nazeer Ahmed, Qualified persons of M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta
4. Imran Saeed persons present M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta
5. Rana Anwer Saeed persons present M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, 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.

06. 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.

07. 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 Shah forwarded the case vide letter No. 12-1/DCA-QTA/M. Survey 179 dated 16th February 2010. The FID Quetta informed that during visited along with FIA team to M/s Rana Traders Flat No.1, 1st Floor Saleem Medical Complex Jinnah Road Quetta 11.11.2009 during the visit some unregistered drugs were found available with claimed to have nutritional/food supplements but suspected to have allopathic ingredients along with labels of registered drugs and physician samples of registered drugs were found placed in ready shelves for sale with other registered drugs. The FID Quetta ordered seized all available stocks of said un-registered drugs and labels on Form-2. The FID Quetta further informed that stocking for sale and sale of unregistered drugs and keeping labels of registered drugs is violation provision of Drugs Act 1976 and rules frame there under. The details of the seized products as under

i. Ronil Tabs	*M/s Bio Naturo Lahore*	*Unregistered*
ii. Calcid D3 Cap	*M/s SPC Ltd Lahore*	*Unregistered*
iii. Lakostat Cap	*M/s Sehafi Natural Lab Lahore*	*Unregistered*
iv. Semen Tab	*M/s BiocareNeturo Kraft Lahore*	*Unregistered*
v. Rebion Tab	*M/s Muwadat Pharma Lahore*	*Unregistered*
vi. Iromums Tab	*-do-*	*Unregistered*
vii. IsonimsSyp	*-do-*	*Unregistered*
viii. Irocal-M Tab	*M/s Mason Lahore*	*Unregistered*
ix. Irocal-M tab	*-do-*	*Unregistered*
x. Irocal-M tab	*M/s Naturo Kraft Lahore*	*Unregistered*
xi. Iro C sachet	*-do-*	*Unregistered*
xii. Oro-C Sachet	*M/s Cosmo Pharma Karachi*	*Unregistered*
xiii. RonilSyp	*M/s Muwadat Pharma Lahore*	*Unregistered*
xiv. RemaltSyp	*-do-*	*Unregistered*
Details of Printed empty carton/Label of registered/ unregistered drugs along with quantity seized is as under		
xv. Canpril tab 10mg		*M/s convell labs Swat*
xvi. ConrineTabl		*M/s convell labs Swat*
xvii. Veldox Tab		*M/s convell labs Swat*
xviii. Olamsaf tab		*M/s Saaf Pharmaceutical Risalpur*
xix. Mina Inj 2ml		*M/s Vision Pharmaceutical Islamabad*
xx. Bactil 250mg cap		*M/s convell labs Swat*
xxi. Conflox tab 200mg		*M/s convell labs Swat*
xxii. Meprawin cap 20mg		*M/s WNS field Pharmaceutical Hattar*

xxiii. Sajd Inj.2ml		*M/s vision Pharmaceuticals Islamabad*

03. That the FID Quetta stated that the same was reported for further instructions/guidance on the matter and permission of safe custody of said seized unregistered drugs and labels of registered drugs vide letter No.F.12-1/DCA-QTA/M. survey dated 13.11.2009 and subsequent request letter No. F.12-1/DCA-QTA/M. survey 81 dated 12.12.2009. The FID informed that the M/s Rana Traders Quetta was called to explain its position for stocking for sale and selling unregistered drugs and keeping labels of registered drugs vide ltter No. F.12-1/DCA-QTA/M. survey-34 dated 21.11.2009 and on not response a reminder vide letter No. F.12-1/DCA-QTA/M. survey 92 dated 16.02.2009 M/s Rana Traders Quetta submitted its reply vide letter No.RTQ/Drugs/12/2009 dated 18.12.2009. it is mention that the invoice submitted by M/s Rana Traders Quetta for said unregistered drugs were also not verified from the supplier/manufacturers are received back un delivered.

04. 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 stocking for sale and selling of unregistered drugs and keeping labels of registered drugs against the following accused

1. *M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta through Rana M Sarwer Shad S/o Muhammad Ramzan, Proprietor*
2. *Rana M Sarwer Shad S/o Muhammad Ramzan, Proprietor M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta*
3. *Saleem Mansoor S/o Nazeer Ahmed, Qualified persons of M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta*
4. *Imran Saeed persons present M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta*
5. *Rana Anwer Saeed persons present M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta*

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

06. 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.

07. 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."

08. None of the accused person submitted written reply to the show cause notice issued vide letter no. 03-44/2019-QC(Pt-I)(271-CLB) dated 04.10.2019. It is pertinent to mention that none of the show cause & personal hearing notice is received back un-delivered.

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

09. That Advocate Dawood Kamal appeared before the Board for one of the accused i.e. Rana Muhammad Sarwar (CNIC No. 34601-8623941-3), Proprietor of M/s Rana Traders Quetta and pleaded the case. He said that his client has already submitted all the relevant documents/invoices to the-then FID, Quetta as required. During personal hearing Rana Muhammad Sarwar (CNIC No. 34601-8623941-3), proprietor of M/s Rana Traders Quetta admitted before the Board that seized labels were placed in his shop and requested pardon. During personal hearing the Board directed the pleader of accused to submit a written reply alongwith all evidences and details of reply are as under;

"R/ Sir,
The applicant submit as under,
That the applicant received a show cause notice from your office, Wherein the allegations of manufacturing drugs without having DML stocking for sale and selling unregistered drugs in shape of nutritional supplements and keeping of physicians samples of registered drugs are leveled against us.
That on 11-11-2009 the FID concerned visited the premises of the applicant situated at flat No.5 1st floor saleem medical plaza, patail bagh Jinnah road quetta and seized the stock on Form-2 being un-registered drugs.
3. That the honorable FID did not send the samples of seized drugs for test and analysis to the Govt, analyst, and without any plausible evidence/ reason, declared the drugs un registered on assumption only. No drug can be declared spurious as such are otherwise without laboratory test PLJ1996 (Pesh)l 14(DB) That the applicant Furnished all relevant invoices and warranties to the honorable inspector as mentioned in his letter No. 12-1/DCA-QTM-Survey-92 dated 16-12-2009.(letter attached)
That during transportation packing of same products were found damaged, for the replacement of which request was made to manufacturer.
6. That the applicant made full co-operation with the honorable inspector and is ever ready to be Co-operative in future too.
7. That the applicant has already sold out the his business in the year 2012(Sale deed attached) for your kind perusal.
8. That not a single word was mentioned in the letter by the FID about selling the Physician sample. It is the duty of the prosecution to have produce evidence to show that the appellant was selling the drugs recovered from his possession while keeping in his shop appeal is accepted sentence is set aside the accused is acquitted (KLR 1994 Cr. C445).
It is therefore most humbly prayed that the humble submission of the applicant for closing the case may kindly be accepted"

10. That rest of the accused (neither in person nor by authorized pleader/attorney) appreaed before the Board.

11. The Baord 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 Drugs Act, 1976 and rules framed thereunder by ***stocking for sale and selling of unregistered drugs and keeping labels of registered drugs:***

1. *M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta through Rana M Sarwer Shad S/o Muhammad Ramzan, Proprietor*
2. *Rana M Sarwer Shad S/o Muhammad Ramzan, Proprietor M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta*
3. *Saleem Mansoor S/o Nazeer Ahmed, Qualified persons of M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta*
4. *Imran Saeed persons present M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta*
5. *Rana Anwer Saeed persons present M/s Rana Traders, Jinnah Road, Saleem M.C 1st Floor, Shop No.5, Quetta*

B. The Centtral Licensing Board granted permission to the Federal Inspector of Drugs for prosecution of above accused. The Federal Inspector of Drugs, DRAP, Quetta should submit complaint before the court of competent jurisdiction along with relevant record and submit compliance report for information.

Case No. IX. **STOCKING FOR SALE AND SELLING UNREGISTERED DRUGS ALONG WITH REGISTERED DRUG WITHOUT HAVING DRUG SALE LICENSE – M/S BILAL VETERINARY, QUETTA**

Mr. Syed Abdul Saleem Shah forwarded the case vide letter No. 12-1/DCA-QTA/M. Survey 181 dated 16th February 2010. The FID Quetta informed that during visited along with FIA team to M/s Bilal Veterinary Mecongy Road Quetta 04.11.2009 during the visit some unregistered drugs were found placed in ready shelves for sale with other registered drugs as well as in its godown adjacent to it during visit Mr. Ali Khan claimed proprietor failed to produce in his Drug Sale License The unregistered seized the all stocks of unregistered drugs on Form-2 The FID Quetta further added that socking for sale and ale of unregistered drugs is violation of provisions of Drug Act 1976 and rules framed there under. The details of the seized drugs as under:-

1.	**M/s Bilal Veterinary Mecongy Road, Quetta.**		
i.	Ivectin 1% inj	Unregistered	M/s Razak Lab Tehran Iran
ii.	Ivectin 3% Inj.	Unregistered	-do-
iii.	Ivectin 5% Inj	Unregistered	-do-
iv.	Ivectin 5%	Unregistered	-do-
v.	OxyteracycleneInje. 50mg/5ml	Unregistered	M/s Shanghai Medicine china
vi.	Dehorning Paste	Unregistered	M/s is not readable
vii.	Oxytetracycline Injection 50mg	Unregistered	M/s Shanghai Medicine china
viii.	Albandazole Oral susp2.5%wv	Unregistered	M/s Cipla Ltd Mumbai India
ix.	Albandazole Oral susp2.5%wv	Unregistered	
x.	Loramisole Granules	Unregistered	Made in Iran
xi.	Calciject-40 solution for injection	Unregistered	M/s NooCLBook Lab Ltd Northern Irelan
xii.	Ciprofloxacin Powder 20mg	Unregistered	M/s Made in Iran
xiii.	Multivitamin Sacet	Unregistered	M/s Made in Iran
xiv.	Pen & Strep suspension for Injection	Unregistered	NooCLBook Labs Ltd Carlisle
xv.	Triclaz 250 Bouls	Unregistered	M/s Razak Lab Tehran Iran
xvi.	Sulphadimine 2.5gm	Unregistered	Made in Iran
xvii.	Albandazole 152 mg	Unregistered	M/s Domlgran Pharma
xviii.	Mac tac 125%	Unregistered	M/s Made in Iran

02. The FID Quetta stated that the same was reported for further instructions/guidance on the matter and permission of safe custody of said seized unregistered drugs and labels of registered drugs vide letter No.F.12-1/DCA-QTA/M. survey dated 06.11.2009 and subsequent request letter No. F.12-1/DCA-QTA/M. survey 78 dated 12.12.2009. The FID informed that the M/s Bilal Veterinary and poultry Services Quetta was called to explain its position for stocking for sale and selling unregistered drugs and registered drugs without Drugs Sale License vide ltter No. F.12-1/DCA-QTA/M. survey-36 dated 23.11.2009. M/s Bilal Veterinary Quetta submitted its reply through Mr. Muhammad Akram Sales man informed that proprietor went to Karachi for treatment of his child and requested for grant of time of one month period for proper reply on the matter vide letter No. Nil dated 03.12.2009 and no further reply is received as yet

03. The FID Quetta is submitted the case for placement before Central Registration Board for its consideration and **permission of prosecution against Mr. Ali Khan Proprietor of M/s Bilal**

Veterinary Mecongy road Quetta for stocking of sale and selling unregistered drug without having Drug Sale License at your earliest possible

Submitted for show cause notice to prosecute:

04. It is therefore submitted that **Ali Khan Proprietor of M/s Bilal Veterinary Mecongy Road Quetta** may be served show caused **for stocking of sale and selling unregistered drug without having Drug Sale License**.

Proceedings and Decision of 271st meeting of Central Licensing Board

05. 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 stocking for sale and selling of unregistered drugs without having Drug Sale Licence against the following accused

1. M/s Bilal Veterinary Mecongy Road Quetta through Ali Khan S/o Sarfroz Khan , Proprietor
2. Ali Khan S/o Sarfroz Khan (CNIC No. 54400-034418-5) R/o H. No. 10, Ghora (Veterinary) Hospital Colony, Quetta Proprietor of M/s Bilal Veterinary Mecongy 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.

06. 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.

07. 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 Shah forwarded the case vide letter No. 12-1/DCA-QTA/M. Survey 181 dated 16th February 2010. The FID Quetta informed that during visited along with FIA team to M/s Bilal Veterinary Mecongy Road Quetta 04.11.2009 during the visit some unregistered drugs were found placed in ready shelves for sale with other registered drugs as well as in its godown adjacent to it during visit Mr. Ali Khan claimed proprietor failed to produce in*

his Drug Sale License The unregistered seized the all stocks of unregistered drugs on Form-2 The FID Quetta further added that socking for sale and sale of unregistered drugs is violation of provisions of Drug Act 1976 and rules framed there under. The details of the seized drugs as under: -

1.	***M/s Bilal Veterinary Mecongy Road, Quetta.***		
i.	*Ivectin 1% inj*	*Unregistered*	*M/s Razak Lab Tehran Iran*
ii.	*Ivectin 3% Inj.*	*Unregistered*	*-do-*
iii.	*Ivectin 5% Inj*	*Unregistered*	*-do-*
iv.	*Ivectin 5%*	*Unregistered*	*-do-*
v.	*OxyteracycleneInje. 50mg/5ml*	*Unregistered*	*M/s Shanghai Medicine china*
vi.	*Dehorning Paste*	*Unregistered*	*M/s is not readable*
vii.	*Oxytetracycline Injection 50mg*	*Unregistered*	*M/s Shanghai Medicine china*
viii.	*Albandazole Oral susp2.5%wv*	*Unregistered*	*M/s Cipla Ltd Mumbai India*
ix.	*Albandazole Oral susp2.5%wv*	*Unregistered*	
x.	*Loramisole Granules*	*Unregistered*	*Made in Iran*
xi.	*Calciject-40 solution for injection*	*Unregistered*	*M/s NooCLBook Lab Ltd Northern Irelan*
xii.	*Ciprofloxacin Powder 20mg*	*Unregistered*	*M/s Made in Iran*
xiii.	*Multivitamin Sacet*	*Unregistered*	*M/s Made in Iran*
xiv.	*Pen & Strep suspension for Injection*	*Unregistered*	*NooCLBook Labs Ltd Carlisle*
xv.	*Triclaz 250 Bouls*	*Unregistered*	*M/s Razak Lab Tehran Iran*
xvi.	*Sulphadimine 2.5gm*	*Unregistered*	*Made in Iran*
xvii.	*Albandazole 152 mg*	*Unregistered*	*M/s Domlgran Pharma*
xviii.	*Mac tac 125%*	*Unregistered*	*M/s Made in Iran*

03. That the FID Quetta stated that the same was reported for further instructions/guidance on the matter and permission of safe custody of said seized unregistered drugs and labels of registered drugs vide letter No.F.12-1/DCA-QTA/M. survey dated 06.11.2009 and subsequent request letter No. F.12-1/DCA-QTA/M. survey 78 dated 12.12.2009. The FID informed that the M/s Bilal Veterinary and poultry Services Quetta was called to explain its position for stocking for sale and selling unregistered drugs and registered drugs without drugs sale license vide letter No. F.12-1/DCA-QTA/M. survey-36 dated 23.11.2009. M/s Bilal Veterinary Quetta submitted its reply through Mr. Muhammad Akram Sales man informed that proprietor went to Karachi for treatment of his child and requested for grant of time of one month period for proper reply on the matter vide letter No. Nil dated 03.12.2009 and no further reply is received as yet.

04. ***In the light of 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 stocking for sale and selling of unregistered drugs without having Drug Sale Licence against the following accused:***

1. *M/s Bilal Veterinary Mecongy Road Quetta through Ali Khan S/o Sarfroz Khan, Proprietor*

2. *Ali Khan S/o Sarfroz Khan (CNIC No. 54400-034418-5) R/o H. No. 10, Ghora (Veterinary) Hospital Colony, Quetta Proprietor of M/s Bilal Veterinary Mecongy Road Quetta*

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

06. 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.
07. 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."

08. None of the accused person submitted written reply to the show cause notice issued vide letter no. 03-44/2019-QC(Pt-I)(271-CLB) dated 04.10.2019.

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

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

10. The Baord 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 Drugs Act, 1976 and rules framed thereunder by ***stocking for sale and selling of unregistered drugs without having Drug Sale Licence:***

1. *M/s Bilal Veterinary Mecongy Road Quetta through Ali Khan S/o Sarfroz Khan, Proprietor*
2. *Ali Khan S/o Sarfroz Khan (CNIC No. 54400-034418-5) R/o H. No. 10, Ghora (Veterinary) Hospital Colony, Quetta Proprietor of M/s Bilal Veterinary Mecongy Road Quetta*

B. The Centtral Licensing Board granted permission to the Federal Inspector of Drugs for prosecution of above accused. The Federal Inspector of Drugs, DRAP, Quetta should submit complaint before the court of competent jurisdiction along with relevant record and submit compliance report for information.

Case No.X:- **MANUFACTURE AND SALE OF SUBSTANDARD UNREGISTERED AND MISBRAND DRUG NAMELY CM 1000 TABS B.NO.001**

Mr. Usman Hameed FID Quetta, submitted that then FID Mr Muhammad Adnan Faisal Saim visited the premises of M/s Seema Marketing 201-2nd Floor Universal Complex Quetta on 03-08-2005 and took samples of CM 1000 Tablets labeled to be manufactured by M/s Painex Pharma Germany along with the others samples for the purpose of test analysis on prescribed Form-3 along with copy of CNIC No.38403-3018079-4.

02. As per information of FID Quetta the sample of said drug along with other samples of drugs was sent to the Government Analyst/Director CDL Karachi vide office memorandum No.F/5/DCA-QTA/Sample-3332A dated 05-08-2005 on form-4 under Section 19(3)(i) of Drug Act 1976 and a portion of the said drugs also sent to the Chairman CLB and CLB Islamabad vide letter No.F.5/DCA-QTA/Sample-3334 dated 05-08-2005 under section 19(3)(ii) of Drug Act 1976. The firm M/s Seema marketing Quetta was sent various reminders to provide the invoices bill warranties for the said drugs vide letter No.F.5/DCA-QTA/Sample-3362 dated 12-08-2005, .F.5/DCA-QTA/Sample-3577 dated 07-10-2005 and .F.5/DCA-QTA/Sample-4031 dated 24-12-2005 under Section 23(1)(i) of Drug Act 1976 but the firm failed to provide the requisite information.

03. That the Government Analyst CDL Karachi declared the sample C.M1000 Tablet B.No.001 mfg by M/s Painex Pharma Germany as Substandard un registered and Misbranded drug vide test report No.R1899/2005 dated 25-09-2006 copy of test analysis certificate is enclosed as required under section 22(3)(c) of Drug Act 1976.

04. In light of Government Analyst, CDL, Karachi a show cause notice was issued vide letter No.F.12-216/06 DCA Sample-1106 dated 13-03-2007 was accordingly issued to M/s Seema Marketing Quetta for explaining the position in the matter of manufacturing and selling of the above mentioned Misbranded and substandard Drug and not providing the invoices bill warranty in respect of said drug.

05. The FID informed that the above referred letter is returned back by Pakistan Post on 03-04-2007 with remarks that the office of Seema Marketing has been shifted from the 201 Phase No.2ndFloor Universal Complex Quetta The firm have violated section 23(1)(a)(iii)(v) and (vii) and section 23(1)(h)(i) of Drug Act 1976 as per above referred test report of Government Analyst CDL Karachi

Submitted for show cause notice to prosecute:

06. It is therefore submitted that **Mudassir Rafique& Chaudhary Rabina Warraich (NSM/Proprietor), M/s** Seema Marketing, Phase No.2, 2ndFloor Universal Complex Quetta may be served show caused **for stocking of sale and selling unregistered, Misbranded and Substandard drug**.

Proceedings and Decision of 271st meeting of Central Licensing Board

07. 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 stocking for sale and selling of unregistered, misbranded and substandard against the following accused

1. M/s Seema Marketing, Phase No.2, 2nd Floor Universal Complex Quetta through Mudassir Rafique, Proprietor

2. Mudassir Rafique, Proprietor M/s Seema Marketing, Phase No.2, 2nd Floor Universal Complex Quetta

3. Chaudhary Rabina Warraich NSM, M/s Seema Marketing, Phase No.2, 2nd Floor Universal Complex Quetta

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

ii. Prosecution in the Court of competent jurisdiction

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

08. 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.

09. 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. Usman Hameed FID Quetta, submitted that then FID Mr Muhammad Adnan Faisal Saim visited the premises of M/s Seema Marketing 201-2nd Floor Universal Complex Quetta on 03-08-2005 and took samples of CM 1000 Tablets labeled to be manufactured by M/s Painex Pharma Germany along with the others samples for the purpose of test analysis on prescribed Form-3 along with copy of CNIC No.38403-3018079-4.

03. That as per information of FID Quetta the sample of said drug along with other samples of drugs was sent to the Government Analyst/Director CDL Karachi vide office memorandum No.F/5/DCA-QTA/Sample-3332A dated 05-08-2005 on form-4 under Section 19(3)(i) of Drug Act 1976 and a portion of the said drugs also sent to the Chairman CLB and CLB Islamabad vide letter No.F.5/DCA-QTA/Sample-3334 dated 05-08-2005 under section 19(3)(ii) of Drug Act 1976. The firm M/s Seema marketing Quetta was sent various reminders to provide the invoices bill warranties for the said drugs vide letter No.F.5/DCA-QTA/Sample-3362 dated 12-08-2005, .F.5/DCA-QTA/Sample-3577 dated 07-10-2005 and .F.5/DCA-QTA/Sample-4031 dated 24-12-2005 under Section 23(1)(i) of Drug Act 1976 but the firm failed to provide the requisite information.

04. That the Government Analyst CDL Karachi declared the sample C.M1000 Tablet B.No.001 mfg by M/s Painex Pharma Germany as Substandard un registered and Misbranded drug vide test report No. R1899/2005 dated 25-09-2006 copy of test analysis certificate is enclosed as required under section 22(3)(c) of Drug Act 1976.

05. In light of Government Analyst, CDL, Karachi a show cause notice was issued vide letter No.F.12-216/2006 DCA Sample-1106 dated 13-03-2007 was accordingly issued to M/s Seema Marketing Quetta for explaining the position in

the matter of manufacturing and selling of the above mentioned Misbranded and substandard Drug and not providing the invoices bill warranty in respect of said drug.

06. That the FID informed that the above referred letter is returned back by Pakistan Post on 03-04-2007 with remarks that the office of Seema Marketing has been shifted from the 201 Phase No.2nd Floor Universal Complex Quetta. The firm have violated section 23(1)(a)(iii)(v) and (vii) and section 23(1)(h)(i) of Drug Act 1976 as per above referred test report of Government Analyst CDL Karachi

07. ***In 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 stocking for violation of section 23(1)(a)(iii)(v) and (vii) and section 23(1)(h)(i) of Drug Act 1976 for sale and selling of unregistered, misbranded and substandard against the following accused:***

1. M/s Seema Marketing, Phase No.2, 2nd Floor Universal Complex Quetta through Mudassir Rafique, Proprietor

2. Mudassir Rafique, Proprietor M/s Seema Marketing, Phase No.2, 2nd Floor Universal Complex Quetta

3. Chaudhary Rabina Warraich NSM, M/s Seema Marketing, Phase No.2, 2nd Floor Universal Complex Quetta

08. You are hereby served this show cause notice that why not the following actions shall be taken against you for selling of unregistered drugs. 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."

10. None of the accused person submitted written reply to the show cause notice issued vide letter no. 03-44/2019-QC(Pt-I)(271-CLB) dated 04.10.2019.

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

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

12. The Baord 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 ***Section 23(1)(a)(iii)(v) and (vii) and section 23(1)(h)(i) of Drug Act 1976 for sale and selling of unregistered, misbranded and substandard durg:***

1. *M/s Seema Marketing, Phase No.2, 2nd Floor Universal Complex Quetta through Mudassir Rafique, Proprietor*

2. *Mudassir Rafique, Proprietor M/s Seema Marketing, Phase No.2, 2nd Floor Universal Complex Quetta*

3. *Chaudhary Rabina Warraich NSM, M/s Seema Marketing, Phase No.2, 2nd Floor Universal Complex Quetta*

B. The Centtral Licensing Board granted permission to the Federal Inspector of Drugs for prosecution of above accused. The Federal Inspector of Drugs, DRAP, Quetta should submit complaint before the court of competent jurisdiction along with relevant record and submit compliance report for information.

Case No. XI:- **IMPORT AND SALE OF UNREGISTERED DRUGS IN SHAPE OF NUTRITIONAL SUPLIMENT ORDERED NOT TO DISPOSE OFF – SHAHEEN MEDICINE AGENCY.**

Mr. Syed Abdul Saleem FID Quetta informed that during visit M/s Shaheen Medicine Agency Flat No. 1,2nd Floor Rana Plaza Archer Road Quetta 07.11.2009 during the visit some unregistered drugs namely Q-Role Soft Gel B.No.364658 claimed to be manufactured by M/s NHK Labs Sante FE Springs USA Imported by M/s MPC and Tabs. Vivit B.No.82081020 claimed to be imported and re-packed by M/s RSA Faisalabad were found placed in ready shelves for sale with other registered drugs The FID Quetta ordered Not to dispose of all available stocks of said unregistered drugs on Form-1 for a period of 14 days it is further added that stocking for sale and sale of unregistered drugs is violation of provisions of Drugs Act 1976 and Rules made there under. The details of the seized products as under:-

1. M/s Shaheen Medicine Agency Archer Road, Quetta		
i. Vivit tablet Batch No.820081020	Imported & Repacked by M/s RSA Faisalabad	Unregistered
ii. Q-Role Softgel	M/s NHK Lab Santa USA	Unregistered

The same was reported for further instructions/guidance on the matter and extension of said orders of unregistered drugs vide letter No.F.12-1/DCA-QTA/M. Survey dated 09-11.2009 and subsequent request vide letter No. No.F.12-1/DCA-QTA/M. Survey/73 dated 12-12.2009. M/s Shaheen Medicine Agency Quetta was called to explain its position for stocking for sale and selling unregistered drugs vide letter No. No.F.12-1/DCA-QTA/M. Survey 31 dated 21-11.2009 and on not response a reminder vide letter No. No.F.12-1/DCA-QTA/M. Survey/94 dated 17-12.2009 was also issued but not reply is received as yet

The FID Quetta submitted the case for placement before Central Registration Board for its consideration and permission of **Prosecution against Mr. Qaiser Riaz Proprietor and Mr. Qaser Khan Qualified persons of M/s Shaheen Medicine Agency Archer Road Quetta for stocking of sale and selling unregistered drugs at your earliest possible**

Submitted for show cause notice to prosecute:

02. It is therefore submitted that**Qaiser Riaz Proprietor and Qaser Khan Qualified persons of M/s Shaheen Medicine Agency Dr. Bano Roada Quetta** may be served show caused**for stocking of sale and selling unregistered drugs**.

Proceedings and Decision of 271st meeting of Central Licensing Board

03. 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 stocking for sale and selling of unregistered, drugs against the following accused

1. M/s Shaheen Medicine Agency Archer Road Quetta Mr. Qaiser Riaz Proprietor
2. Mr. Qaiser Riaz Proprietor M/s Shaheen Medicine Agency Archer Road Quetta

3. Mr. Qaser Khan Qualified persons of M/s Shaheen Medicine Agency Archer 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.

04. 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.

05. 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 informed that during visit M/s Shaheen Medicine Agency Flat No. 1,2nd Floor Rana Plaza Archer Road Quetta 07.11.2009 during the visit some unregistered drugs namely Q-Role Soft Gel b.No.364658 claimed to be manufactured by M/s NHK Labs Sante FE Springs USA Imported by M/s MPC and Tabs. Vivit B.No.82081020 claimed to be imported and re-packed by M/s RSA Faisalabad were found placed in ready shelves for sale with other registered drugs The FID Quetta ordered Not to dispose of all available stocks of said unregistered drugs on Form-1 for a period of 14 days it is further added that stocking for sale and sale of unregistered drugs is violation of provisions of Drugs Act 1976 and Rules made there under. The details of the seized products as under: -

1.	***M/s Shaheen Medicine Agency Archer Road, Quetta***					
iii.	*Vivit tablet Batch No.820081020*	*Imported & Repacked by M/s RSA Faisalabad*	*Unregistered*			*As per available record in the Quality Control Section i.e Diary dispatch/register record, files record and Computerized record have not shown this case record after checking available record of the section*
iv.	*Q-Role Softgel*	*M/s NHK Lab Santa USA*	*Unregistered*			*-do-*

The same was reported for further instructions/guidance on the matter and extension of said orders of unregistered drugs vide letter No.F.12-1/DCA-QTA/M. Survey dated 09-11.2009 and subsequent request vide letter No. No.F.12-1/DCA-QTA/M. Survey/73 dated 12-12.2009. M/s Shaheen Medicine Agency Quetta was

called to explain its position for stocking for sale and selling unregistered drugs vide letter No. No.F.12-1/DCA-QTA/M. Survey 31 dated 21-11.2009 and on not response a reminder vide letter No. No.F.12-1/DCA-QTA/M. Survey/94 dated 17-12.2009 was also issued but not reply is received as yet

03. ***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 stocking for sale and selling of unregistered, drugs against the following accused:***

1. *M/s. Shaheen Medicine Agency Archer Road Quetta Mr. Qaiser Riaz Proprietor*
2. *Qaiser Riaz, Proprietor M/s. Shaheen Medicine Agency Archer Road Quetta*
3. *Qaser Khan, Qualified persons of M/s. Shaheen Medicine Agency Archer Road Quetta*

04. You are hereby served this show cause notice that why not the following actions shall be taken against you for import and selling of unregistered drugs. 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.*

05. 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.

06. 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."

06. None of the accused person submitted written reply to the show cause notice issued vide letter no. 03-44/2019-QC(Pt-I)(271-CLB) dated 04.10.2019.

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

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

07. The Baord 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 Drugs Act, 1976 and rules framed thereunder ***for stocking for sale and selling of unregistered drugs:***

1. *M/s. Shaheen Medicine Agency Archer Road Quetta thorugh Qaiser Riaz Proprietor*
2. *Qaiser Riaz, Proprietor M/s. Shaheen Medicine Agency Archer Road Quetta*

3. Qaser Khan, Qualified persons of M/s. Shaheen Medicine Agency Archer Road Quetta

B. The Centtral Licensing Board granted permission to the Federal Inspector of Drugs for prosecution of above accused. The Federal Inspector of Drugs, DRAP, Quetta should submit complaint before the court of competent jurisdiction along with relevant record and submit compliance report for information.

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

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 **Unregistered** 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

Case No.XIII: <u>MANUFACTURING AND SELLING OF COUNTERFEIT DRUGS NAMELY BECOFEN 400MG BATCH NO. BKF-002</u>

FID, Quetta inspected the Business premises of M/s Unique Traders, Dr. Bano Road, Quetta on 10-11-2009, and took the sample of said product on Form-3 in the presence of Proprietor Muhammad S/o Umair (CNIC No. 54401-1733748-9) r/o 227 Block-2, Satellite Town, Quetta.
The said sample was sent to Federal Government Analyst for the purpose of test/analysis.
The Government Analyst declared the sample as "**<u>Counterfeit</u>**" vide test report No. R.SCD.476/2009 dated 09-12-2009.
That M/s Unique Traders, Dr. Bano Raod Quetta, Submitted invoice/ cash memo No. FM0286 dated 10-10-2009 signed and issued by FM Traders Lajpat Road, Hyderabad.
That M/s FM Traders Lajpal Road, Hyderabad failed to produce invoice warranty of said drug.
That M/s Unique Traders failed to produce warranted invoice and is also responsible for the offence.
The case was processed for Registration Board. The due process of law was completed and the accused were served with Show Cause Notice and given chance of personal hearing. The Registration Board in its 228th Meeting decided to prosecute the accused in the Drug Court of competent jurisdiction. Prosecution permission was communicated vide letter no. 03-38/2009-DDC(QC-I) dated 26.01.2011.
<u>It is therefore requested that permission may be granted to issue show cause notice to the following accused persons for manufacturing and selling of counterfeit product (imitation product of Brufen 400mg of M/s Abbott Laboratories, Karachi):</u>

i. Proprietor –Muhammad S/o Umair (CNIC No. 54401-1733748-9) r/o 227 Block-2, Satellite Town, Quetta – M/s Unique Traders, Dr. Bano Road, Quetta.
ii. M/s FM Traders, Lajpat Road, Hyderabad through its owner/proprietor

<u>Proceedings and Decision of 271st meeting of Central Licensing Board</u>

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 selling of counterfeit drugs against the following accused

1. M/s Unique Traders, Dr. Bano Road, Quetta Proprietor –Muhammad S/o Umair

2. Muhammad S/o Umair (CNIC No. 54401-1733748-9) r/o 227 Block-2, Satellite Town, Quetta – Proprietor – M/s Unique Traders, Dr. Bano Road, Quetta.
3. M/s FM Traders, Lajpat Road, Hyderabad through its owner/proprietor

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 Area FID, Quetta inspected the Business premises of M/s Unique Traders, Dr. Bano Road, Quetta on 10-11-2009, and took the sample of said product on Form-3 in the presence of Proprietor Muhammad S/o Umair (CNIC No. 54401-1733748-9) r/o 227 Block-2, Satellite Town, Quetta.And the said sample was sent to Federal Government Analyst for the purpose of test/analysis.*
> *03. That the Government Analyst declared the sample as "**Counterfeit**" vide test report No. R.SCD.476/2009 dated 09-12-2009.*
> *04. That M/s Unique Traders, Dr. Bano Raod Quetta, submitted invoice/ cash memo No. FM0286 dated 10-10-2009 signed and issued by FM Traders Lajpat Road, Hyderabad.*
> *05. That M/s FM Traders Lajpal Road, Hyderabad failed to produce invoice warranty of said drug.*
> *06. That M/s Unique Traders failed to produce warranted invoice and is also responsible for the offence*
> *07. **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 selling of counterfeit drugs against the following accused:***
>
> 1. *M/s Unique Traders, Dr. Bano Road, Quetta Proprietor – Muhammad S/o Umair*
> 2. *Muhammad S/o Umair (CNIC No. 54401-1733748-9) r/o 227 Block-2, Satellite Town, Quetta – Proprietor – M/s Unique Traders, Dr. Bano Road, Quetta.*
> 3. *M/s FM Traders, Lajpat Road, Hyderabad through its owner/proprietor*

08. 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. 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."

05. None of the accused person submitted written reply to the show cause notice issued vide letter no. 03-44/2019-QC(Pt-I)(271-CLB) dated 04.10.2019.

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

06. That None appeared on behalf of the accused before the Board (neither in person nor by any attorney/pleader).

07. The Central Licensing Board also acknowledged that the case was wrongly placed before the Drug Registraion Board as the instant case is regarding manufacturing stocking for sale and selling of counterfeit product of a registered drug, which has to be placed before Central Licensing Board under sub-rule (2) of rule (4) of the Drugs (Federal Inspectors, Federal Drug Laboratory and federal government Analysts) Rules, 1976. The Baord 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 Drugs Act, 1976 and rules framed thereunder for manufacturing and selling of counterfeit drugs:

1. M/s Unique Traders, Dr. Bano Road, Quetta Proprietor –Muhammad S/o Umair
2. Muhammad S/o Umair (CNIC No. 54401-1733748-9) r/o 227 Block-2, Satellite Town, Quetta – Proprietor – M/s Unique Traders, Dr. Bano Road, Quetta.
3. M/s FM Traders, Lajpat Road, Hyderabad through its owner/proprietor

B. The Centtral Licensing Board granted permission to the Federal Inspector of Drugs for prosecution of above accused. The Federal Inspector of Drugs, DRAP, Quetta should submit complaint before the court of competent jurisdiction along with relevant record and submit compliance report for information.

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

01 ThatMr. 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. *Prosceution 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

Meeting ended with the vote of thanks to and by the chair