MINUTES OF 298th MEETING OF CENTRAL LICENSING BOARD HELD ON 26th July, 2024

298th meeting of the Central Licensing Board (CLB) was held on 26th July, 2024 in the Committee Room, Ground Floor, NCLB, Drug Regulatory Authority of Pakistan (DRAP) National Institute of Health (NIH), Chak Shahzad, Islamabad. Dr. Muhammad Akhtar Abbas Khan, Director (Licensing), Drug Regulatory Authority of Pakistan, Islamabad Chaired the meeting. Following members attended the meeting: -

S.No	Name & Designation	Status
1.	Mr. Babar Khan Additional. Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
2.	Mr. Azher Jamal Saleemi, Chief Drugs Controller, Government of Punjab, Lahore (participated through zoom link)	Member
3.	Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Government of Khyber Pakhtunkhwa	Member
4.	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Baluchistan, Quetta	Member
5.	Mr. Abdul Hafeez Tunio, Chief Inspector of Drugs, Government of Sindh, Karachi	Member
6.	Mr. Abid Ali, Deputy Draftsman, Ministry of Law & Justice Division, Islamabad	Member
7.	Ms. Mahvish Ansari, Additional Director, representative from QALT, DRAP	Member

Mr. Babar Khan Additional Director/Secretary Licensing Board presented the agenda before the Board. Mr. Mubashir Iqbal, Deputy Director (Lic), Mr. Yaqoob Kakar, Assistant Director (Lic), Ms. Zunaira Faryad, Assistant Director (Lic), Mr. Abdullah, Assistant Director (Lic), Hafiz Sanaullah Babar, Deputy Director (QC) and Mr. Hassan Afzal Deputy Director (QA) assisted the Secretary, Central Licensing Board in presenting the agenda.

Item-I CONFIRMATION OF THE MINUTES OF 297th MEETING

All members of the Central Licensing Board (CLB) formally confirmed the minutes of 297th meeting of the Central Licensing Board (CLB) held on 2nd May, 2024. The board also took following decisions.

- **Manufacturing requirements for Cephalosporin products**

The Board discussed that the operations related to the manufacture, processing, and packing of cephalosporin should be performed in facilities segregated / separate from those used for other drug

products for human use. This is due to their potential for causing allergic reactions. Earlier, the Board in its 296th meeting held on 2nd April, 2024 decided that penicillin, carbapenems, and monobactams shall only be manufactured, processed, and packed in segregated / separate and dedicated facilities.

Therefore, regarding new facilities, the Board also decides that cephalosporin shall only be manufactured, processed, and packed in separate and dedicated facilities. A separate manufacturing facility is a design that has, Separate manufacturing area from the main plant for manufacturing of other products, separate HVAC System, Separate Equipment, Separate Workforce, Separate Laundry, Separate Canteen and Separate Washrooms.

The Board Authorized Chairman CLB to issue the renewal of the Cephalosporin / Penicillin/ Penem Sections after receiving the undertaking for establishing a separate dedicated facility for Penicillin/ cephalosporin/Carbapenem injectable within 2 years.

Manufacture of veterinary medicinal products containing penicillin

Based on the explanations provided online by the USFDA and European Union, the Board approved the use of veterinary penicillin in designated areas.

"Animal penicillin and cephalosporin drugs can be manufactured in the same facility as non-penicillin and non-cephalosporin animal drugs. Operations should be performed in dedicated production areas, which can include separate facilities, separate air handling equipment and/or separate process equipment, unless cleaning procedures are established, implemented, and maintained to prevent cross-contamination. Dedicated manufacturing lines within the facility reduce the risk of cross contamination. Risks for cross-contamination are assessed during preapproval inspections (when applicable) and during routine surveillance current good manufacturing practice (CGMP) inspections of the facility (https://www.fda.gov/animal-veterinary/resources-you/manufacturing-considerations-penicillin-or-cephalosporin-animal-drugs).

"The use of penicillin in veterinary medicine does not present the same risks of hypersensitivity in animals as in humans. Although incidents of hypersensitivity have been recorded in horses and dogs, there are other materials which are toxic to certain species, e.g. the ionophore antibiotics in horses. Although desirable, the requirements that such products be manufactured in dedicated, self-contained facilities (point 3.6) may be dispensed with in the case of facilities dedicated to the manufacture of veterinary medicinal products only. However, all necessary measures should be taken to avoid cross contamination and any risk to operator safety in accordance with the guide. In such circumstances, penicillin-containing products should be manufactured on a campaign basis and should be followed by appropriate, validated decontamination and cleaning procedures".

(https://health.ec.europa.eu/document/download/940ed86d-0537-46aa-b43e-1b8f32bc7418_en?filename=anx04en200408_en.pdf)

- **Establishment of A Registry of Technical Persons**

The Central Licensing Board (CLB) of Drug Regulatory Authority of Pakistan (DRAP) has proposed the establishment of a registry of technical persons in the pharmaceutical industry, specifically focusing on production managers and Quality Control Managers. The purpose of this registry is to facilitate the early approval of changes in technical personnel by providing a reliable database of qualified individuals in the field of pharmaceutical manufacturing in Pakistan.

The registry will be established through an online application system, where individuals with the required experience will be able to register themselves. Upon submission of the necessary documents, applicants will be evaluated and granted a certificate. This certificate will contain all the necessary details about the individuals, including their name, photograph, experience, registration with any professional bodies like pharmacy councils, and any other relevant information. The inclusion of a photograph and registration details in the certificate will enhance its authenticity and serve as a proof of qualification. This certificate will not only serve as a recognition of the individuals' expertise but also provide them with an advantage when applying for an early approval of changes in technical personnel.

By maintaining a registry of technical persons, the CLB of DRAP aims to provide a centralized resource for the pharmaceutical industry. This registry will enable companies to access a pool of qualified individuals, making it easier for them to recruit or find a suitable replacement for technical positions. It will also help in regulating and monitoring the qualifications of technical personnel, ensuring the consistent quality of pharmaceuticals manufactured in Pakistan.

- **Late renewal Inspection by the retired panel members**

The Central Licensing Board (CLB) has observed a significant delay in the conduct of inspections for the renewal of the Drug Manufacturing License (DML). This has resulted in a significant lapse of time without any inspection reports being received. To address these concerns and ensure timely inspections, the CLB has implemented a new policy that requires all inspections to be conducted within six months after the constitution of the inspection panel. This timeframe will ensure that the necessary inspections are undertaken promptly, minimizing any delays in the renewal of the DML. The CLB also emphasizes that it is the responsibility of firms to cooperate fully and facilitate the inspection process. The CLB expects firms to cooperate fully and facilitate the inspection process, and any reluctance or uncooperative behaviour will be promptly communicated to the CLB. Furthermore, any reluctance or

uncooperative behaviour by firms regarding the inspection process will be promptly communicated to the CLB by the additional director field office, allowing appropriate measures to be taken.

- **Biometric verification of technical persons**

The Central Licensing Board (CLB) has observed a concern in the process of approving technical persons (Production manager and Quality Control manager), where the firm acts as the applicant, but the technical person themselves are not fully involved in the application. The approval of technical persons may be obtained without their consent. To address this issue and ensure only certified and technically qualified personnel are involved in drug manufacturing, the CLB has decided to collaborate with the National Database and Registration Authority (NADRA) for biometric verification of qualified staff.

By implementing this biometric verification process, the CLB aims to enhance security and reduce the risk of identity fraud in the drug manufacturing sector. The biometric verification system will provide an additional layer of security to the approval process. The Board referred the case to DRAP authority for consideration.

Item-I **GRANT OF NEW DRUG MANUFACTURING LICENSE.**

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1	M/s Tovida Pharmaceuticals (Pvt.) Ltd., Plot No.07, S-7, National Industrial Zone, Rawat, Islamabad. (New License) *(Evaluator: - Abdullah (AD-Lic)*	05-07-2024, 08-07-2024 & 23-07-2024	Good	1. Dr. Ghazanfar Ali Khan, Additional Director Field Office (QA&LT), DRAP, Islamabad. 2. Mrs. Tehreem Sara, FID-IV, DRAP, Islamabad. 3. Hafiz Sanaullah Babar, Deputy Director (QC) DRAP, Islamabad.
	QC In-charge	Rakhshanda Jabeen D/o Abdut Sattar CNIC No.12104-0910691-2 (B-Pharm)		
	Production In-charge	Maria Ejaz D/o M. Ejaz Ahmed CNIC No.37405-9530621-0 (Pharm-D)		
	Recommendations of the panel: -			

	Based on the inspection of the premises and the available machinery and equipment in production and Quality Control, the panel recommends the grant of the Drug Manufacturing License, subject to the regularization of the layout plan. **Decision of the Central Licensing Board in 298th meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of Tovida Pharmaceuticals (Pvt) Ltd., Plot No.07, S-7, National Industrial Zone, Rawat, Islamabad on the recommendations of the panel of experts for the following sections subject to the regularization of the layout plan; i. Tablet (General) ii. Capsule (General) iii. Cream/Ointment/Gel/Lotion (General) iv. Sachet (General) v. Quality Control Laboratory vi. Microbiology Laboratory vii. R&D Facility viii. Store (RMS, FGS &PMS) The CLB further authorized its Charmian for approval of any amendments in Layout plan.

Item-II **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 Axis Pharmaceuticals, 3-B, Value Addition City, 1.5 Km, Khurrianwala-Sahianwala Road, Faisalabad. **DML No. 000667 (Formulation)** **Section (03):** i. Capsule Section (Cephalosporin) ii. Dry Powder Suspension Section (Cephalosporin) iii. Dry Powder Injection Section (Cephalosporin) Evaluator:- *Zunaira Faryad (AD-Lic)*	**27-05-2024**	**Good**	1. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 2. Mrs. Tehreem Sara, Federal Inspector of Drugs, DRAP, Lahore. 3. Muhammad Akhtar Abbas Khan, Director (Licensing), DRAP, Islamabad.

	Recommendations of the panel: In view of above inspection proceedings and the facility verified, such as company profile, building, material management, production, in process controls, Quality Control Testing, machinery/equipment, air handling, water treatment system, personnel and documentation etc the panel is of the opinion to **recommend** the grant of additional sections to M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5 Km, Khurrianwala-Sahianwala Road, Faisalabad for the following sections: i. Capsule Section (Cephalosporin) ii. Dry Powder Suspension Section (Cephalosporin) iii. Dry Powder Injection Section (Cephalosporin) **Decision of the Central Licensing Board in 298th meeting:** The Board considered and approved the following sections (separate cephalosporin block) in the name of M/s Axis Pharmaceuticals, 3-B, Value Addition City, 1.5 Km, Khurrianwala-Sahianwala Road, Faisalabad under DML No. 000667 (Formulation) on the recommendations of the panel of experts. i. Capsule Section (Cephalosporin) ii. Dry Powder Suspension Section (Cephalosporin) iii. Dry Powder Injection Section (Cephalosporin).			
2	M/s Martin Dow Marker Ltd, F-126 S.I.T.E., Karachi DML No.000043 (Formulation). *Evaluator: - Mubashir Iqbal (DD-Lic)*	19-04-2024	Good	1. Dr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 2. Dr. Shoaib Ahmad, Area FID DRAP, Karachi. 3. Mr. Abdul Waheed, Assistant Director, DRAP, Karachi.
	Recommendations of the panel: - The overall visit of Martin Dow Marker, Karachi Site was good. The newly constructed warehouse (Raw material and Packing material) is well maintained. Utility areas containing HVAC units, Water system etc., are well maintained. Keeping in view of above, the Panel hereby **recommends** approval of the newly built warehouse. **Decision of the Central Licensing Board in 298th meeting:** The Board considered and approved the revision of following area in the licensed facility of M/s Martin Dow Marker Ltd, F-126 S.I.T.E., Karachi under DML No. 000043 (Formulation) on the recommendations of the panel of experts: i. Warehouse (RMS & PMS)- Revision			

3	M/s GlaxoSmithKline Pakistan Ltd, 35-Dockyard Road, West Wharf, Karachi. DML No.000017 (Formulation). (Grant of Additional Sections) *Evaluator: - Mubashir Iqbal (DD-Lic)*	21-02-2024	V. Good	1. Mr. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 2. Dr. Shoaib Ahmad, Area FID DRAP, Karachi. 3. Mr. Abdul Waheed, Assistant Director, DRAP, Karachi.
	Recommendations of the panel: - The firm has installed locally manufactured sampling booths with separate MAL and PAL in their approval area as per their layout plan equipments were found commissioned and duly qualified. Based on the Area visited, people met and documents received. Panel **recommends** the grant of their revised section of raw material warehouse. **Decision of the Central Licensing Board in 298th meeting:** The Board considered and approved the revision of following area in the licensed facility of M/s GlaxoSmithKline Pakistan Ltd, 35-Dockyard Road, West Wharf, Karachi under DML No. 000017 (Formulation) on the recommendations of the panel of experts. i. Warehouse (RMS)-Revised			
4	M/s Sante (Pvt.) Ltd., A/97, S.I.T.E Super Highway, Karachi. DML No.000702 (Formulation) (Grant of Additional Sections) Warehouse-2 (General) *Evaluator: - Mubashir Iqbal (DD-Lic)*	29-04-2024	Good	1. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 2. Abdul Rasool Shaikh, Area FID DRAP, Karachi. 3. Mst. Sanam Kausar Jahan, Assistant Director, DRAP, Karachi.
	Recommendations of the panel: - In conclusion, the inspection findings indicate that the new Finished Goods warehouse & Packing Materials Store demonstrate compliance with the regulatory requirements set forth by the Drug Regulatory Authority of Pakistan (DRAP) for the approval of new Finished Goods (FG) and Packing Materials Store. The facility's adherence to Good Storage Practices (GSP) and the implementation of appropriate quality control measures contribute to the assurance of product quality and safety. Based on the area inspected facilities, available facilities and amenities, people met, documents reviewed and considering the finding of inspection the panel recommends the approval for grant of Finished Good & Packing Material Warehouse of the firm. **1.** Warehouse-2 (General)			

	Decision of the Central Licensing Board in 298th meeting: The Board considered and approved the following area in the licensed facility of M/s Sante (Pvt.) Ltd., A/97, S.I.T.E Super Highway, Karachi under DML No. 000702 (Formulation) on the recommendations of the panel of experts. **1.** Warehouse-2 (FGS & PMS)			
5	M/s Crystolite Pharmaceuticals, Plot No.1&2, S-2, National Industrial Zone, Rawat, Islamabad. DML No.000778 (Formulation) **Section (02):** i. Dry Powder Suspension (General) ii. Dry Powder Injection Section (Vial) (General) Evaluator:- *Zunaira Faryad (AD-Lic)*	08-07-2024	Good	1. Dr. Ghazanfar Ali Khan, Additional Director Field Office (QA&LT), DRAP, Islamabad. 2. Mrs. Tehreem Sara, FID-IV, DRAP, Islamabad. 3. Mr. Muhammad Yaqoob, Assistant Director (Licensing), DRAP, Islamabad.
	Recommendations of the panel: - In view of the inspection conducted, reviewing the documents, interview of technical team, intent of the management and verification of manufacturing and testing facility such as FTIR, Atomic Absorption spectrophotometer, three (03) HPLC, Spectrophotometer, Dissolution Apparatus, LFC, TOC, Liquid Particle Counter, Particle counter, Air Sampler polarimetry, ultrasonic bath, and other QC equipment along with 03 stability chambers (list already attached) the panel unanimously **recommends** the grant of following additional sections.. 1. Dry Powder Suspension (General) 2. Dry Powder Injection Section (Vial) (General) **Decision of the Central Licensing Board in 298th meeting:** The Board considered and approved the following sections in the name of M/s Crystolite Pharmaceuticals, Plot No.1&2, S-2, National Industrial Zone, Rawat, Islamabad under DML No. 000778 (Formulation) on the recommendations of the panel of expert. 1. Dry Powder Suspension (General) 2. Dry Powder Injection Section (Vial) (General)			
6	M/s BioLabs (Pvt) Ltd., 145, Industrial Triangle, Kahuta Road, Islamabad. DML No.000296 (Formulation)	24-06-2024	Good	1. Dr. Ghazanfar Ali Khan, Additional Director Field Office (QA&LT), DRAP, Islamabad. 2. Ms. Saadia Mahwish, Area FID, DRAP, Islamabad.

	Section (02): i. Research & Development (R&D) Section ii. Cream Section Evaluator: -*Muhammad Yaqoob (AD-Lic)*			3. Mr. Hafiz Sanaullah Babar, Deputy Director (QA&LT), DRAP, Islamabad.
	Recommendations of the panel: - Keeping in view the above facts, documents reviewed & the people met during the visit, the panel unanimously **recommended regularization of following sections** of M/s BioLabs (Pvt) Ltd., 145, Industrial Triangle, Kahuta Road, Islamabad DML # 000296 1. Research & Development (R&D) Section 2. Cream Section **Decision of the Central Licensing Board in 298th meeting:** The Board considered and approved the regularization of following section / area in the name of M/s Bio Labs (Pvt) Ltd., 145, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000296 (Formulation) on the recommendations of the panel of experts. 1. Research & Development (R&D) Lab-Regularization 2. Cream / Ointment/ Gel (General) -Regularization			
7	M/s Hirra Pharmaceutical Laboratory, 1.3-Km, Asil Raiwind Road, Lodhaky Bhular, Lahore. DML No.000449 (Formulation) **Section (01):** i. Oral Powder (Penicillin) (Veterinary) Section - New Evaluator: - *Zunaira Faryad (AD-Lic)*	19-07-2024	Good	1. Mr. Muhammad Shamoon Ch. Expert Member. 2. Dr. Zaka Ur Rehman, Expert Member. 3. Mr. Abdul Rshid Shaikh, FID, DRAP, Lahore.
	Recommendations of the panel: - Keeping in view the manufacturing facilities like building and available facilities of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation on the day of inspection, the panel of inspectors is of the opinion to recommend the grant of additional section to M/s Hirra Pharmaceutical			

	Laboratory, 1.3-Km, Asil Raiwind Road, Lodhaky Bhular, Lahore for **Oral Powder (Penicillin) (Veterinary) Section new only**. **<u>Decision of the Central Licensing Board in 298th meeting:</u>** The Board considered and approved the additional section in the name of M/s Hirra Pharmaceutical Laboratory, 1.3-Km, Asil Raiwind Road, Lodhaky Bhular, Lahore under DML No. 000449 (Formulation) on the recommendations of the panel of experts for following sections: 1. Oral Powder (Penicillin) (Veterinary) additional Section			
8.	M/s Pharmagen Limited, **Kot Nabi Baksh Wala** 34-Km, Ferozpur Road, Lahore. DML No. 000325 (Semi-Basic) API's (10): i. Ibuprofen Sodium (in-House Specifications) ii. Dexibuprofen (Base) (In-House specification) iii. Ciprofloxacin (Base) (USP/ Ph.Eur.) iv. Metopine (In-House specifications) v. DL-Carnitine Hydrochloride (In-House specifications) vi. Cephradine (USP /PS. Eur.) vii. Emaglifozin (In-House specification) viii. Ibuprofen (USP / Ph. Eur.) ix. Cefuroxime Sodium Sterile (USP / Ph. Eur.) Evaluator:- Abdullah(AD-Lic)	11-07-2024	Good	1. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 2. Abdul Rasheed Shaikh, FID, DRAP, Lahore. 3. MR. Farooq Aslam, Assistant Director, DRAP, Lahore.
	<u>Recommendations of the panel:</u> Based on the areas inspected, people met and documents reviewed and considering the finding od inspection on the day of inspection. The panel of inspectors recommends: **I. Manufacturing of new Active Pharmaceutical Ingredient (API) by way of semi-basic manufacturing:** 1. Ibuprofen Sodium (in-House Specifications) 2. Dexibuprofen (Base) (In-House specification)			

	3. Ciprofloxacin (Base) (USP/ Ph.Eur.) 4. Metopine (In-House specifications) 5. DL-Carnitine Hydrochloride (In-House specifications) II. **Revision of manufacturing pathway of already approved Active Pharmaceutical Ingredients:** 1. Cephradine (USP /PS. Eur.) 2. **Empagliflozin** (In-House specification) 3. Ibuprofen (USP / Ph. Eur.) 4. Cefuroxime Sodium Sterile (USP / Ph. Eur.) Note; Flow chart/ manufacturing pathways of above 1-9 products are annexed at the end of the minutes. **Decision of the Central Licensing Board in 298th meeting:** On the recommendations of the panel of experts, the Board considered and approved the grant of following new API's and revised manufacturing pathway in the name of M/s Pharmagen Limited, 34-Km, Ferozpur Road, Lahore under DML No.000325 (Basic Manufacture). **I. Manufacturing of new Active Pharmaceutical Ingredient (API) by way of semi-basic manufacturing:** 1. Ibuprofen Sodium (in-House Specifications) 2. Dexibuprofen (Base) (In-House specification) 3. Ciprofloxacin (Base) (USP/ Ph.Eur.) 4. Metopine (In-House specifications) 5. DL-Carnitine Hydrochloride (In-House specifications) II. **Revision of manufacturing pathway of already approved Active Pharmaceutical Ingredients:** 1. Cephradine (USP /PS. Eur.) 2. Empagliflozin (In-House specification) 3. Ibuprofen (USP / Ph. Eur.) 4. Cefuroxime Sodium Sterile (USP / Ph. Eur.) Note; Flow chart/ manufacturing pathways of above 1-9 products are annexed at the end of the minutes.

Item-III **GRANT OF RENEWAL / REGULARIZATION OF LOP OF DRUG MANUFACTURING LICENSES.**

Following cases have been forwarded by the respective panel of experts for grant of Renewal of Drug Manufacturing Licenses and regularization. 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 Don Valley Pharmaceuticals (Pvt) Ltd., 31-Km, Main Ferozepur Road, Lahore. DML No. 000395 (Formulation) Period: Commencing on 30-01-2024 ending on 29-01-2029. Evaluator:- Zunaira Faryad (AD-Lic)	22-03-2024	Good	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore.
	QC In-charge	Mr. Muhammad Ishfaque (MSc Chemistry)		
	Production In-charge	Ms. Shabana Malik (B.Pharm)		

Recommendations of the panel:

*"*In view of above inspection proceedings and facilities verified, such as company profile, building, material management, production, in-process controls, Quality Control Testing, machinery/equipment, air handling, water treatment system, personnel and documentation etc. the panel is of the opinion to **recommend** the renewal of Drug Manufacturing License section to M/s Don Valley Pharmaceuticals (Pvt) Ltd, 331-Km, Main Ferozepur Road, Lahore for the following sections:

S. No.	Name of Sections	S. No.	Name of Sections
1	Tablet-I (General)	2	Tablet-II (General)
3	Tablet (Psychotropic)	4	Dry Powder Suspension (General)
5	Capsule (General)	6	Sachet (General)
7	Oral Liquid (General)	8	Tablet (Penicillin)
9	Dry Powder Suspension (Penicillin)	10	Capsule (Penicillin)
11	Ointment Cream (General)	12	Dry Powder Oral Suspension (Cephalosporin)
13	Capsule (Cephalosporin)	14	Dry Powder Vial Injection (Cephalosporin)

Moreover, the panel has intimated that following approved sections were non-operational at the time of inspection:

i. Tablet (Anti-Cancer) Section.
ii. Tablet Hormone (Bulk import &local repacking) Section.

Decision of the Central Licensing Board in 298th meeting

The Board considered and approved the renewal of DML No. 000395 by way of Formulation in the name of M/s Don Valley Pharmaceuticals (Pvt) Ltd., 31-Km, Main Ferozepur Road, Lahore on the recommendations of the panel of experts for the period commencing on 30-01-2024 ending on 29-01-2029 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for Psychotropic Section:

S. No.	Name of Sections	S. No.	Name of Sections
1	Tablet-I (General)	2	Tablet-II (General)
3	Tablet (Psychotropic)	4	Dry Powder Suspension (General)
5	Capsule (General)	6	Sachet (General)

The Board Authorized Chairman CLB to issue the renewal of the following penicillin and Cephalosporin Sections after receiving the undertaking for establishing a segregated dedicated facility for within 2 years.

1.	Tablet (Penicillin)	2.	Capsule (Penicillin)
3.	Dry Powder Suspension (Penicillin)	4.	Dry Powder Vial Injection (Cephalosporin)
5.	Ointment Cream (General)	6.	Dry Powder Oral Suspension (Cephalosporin)
7.	Capsule (Cephalosporin)	8.	

2.	M/s Aventek Pharmaceuticals (Pvt) Ltd., Plot No.44-C, Sunder Industrial Estate, Lahore. DML No. 000660 (Formulation) Period: Commencing on 27-03-2019 &ending on 26-03-2024. Evaluator:- Zunaira Faryad(AD-Lic)	29-01-2024	Good	1. Dr. Zaka-ur-Rehman, Expert Member. 2. Mr. Abdul Rashid Shaikh, Additional Director, DRAP, Lahore. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore.
	QC In-charge	Ms. Sumara Qamar (Pharm-D)		
	Production In-charge	Hafiz Muhammad Naeem Sarwar (B. Pharm)		

Recommendations of the panel:

Keeping in view the manufacturing facility like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors **recommend** the renewal of Drug Manufacturing License to M/s Aventek Pharmaceuticals (Pvt) Ltd., Plot No.44-C, Sunder Industrial Estate, Lahore, for the following Sections:

1. Tablet Section (General)
2. Capsule Section (General)
3. Sachet Section (General)
4. Dry Suspension Section (Cephalosporin)
5. Dry Injection Section (Cephalosporin)
6. Capsule Section (Cephalosporin)

	Decision of the Central Licensing Board in 298th meeting The Board considered the inspection report and accepted the report for record since the renewal period Commencing on 27-03-2019 & ending on 26-03-2024 of DML No. 000395 by way of Formulation in the name of M/s Aventek Pharmaceuticals (Pvt) Ltd., Plot No.44-C, Sunder Industrial Estate, Lahore has already expired. The Board advised the licensing division to direct the firm to complete the renewal application and submit undertaking for establishing a segregated dedicated facility for following Cephalosporin Sections within 2 years. 1. Dry Suspension Section (Cephalosporin) 2. Dry Injection Section (Cephalosporin) 3. Capsule Section (Cephalosporin)			
3.	M/s CCL Pharmaceuticals (Pvt) Ltd, (Formerly Dynatis Pakistan (Pvt) Ltd.,) Plot No.710, Sundar Industrial Estate, Lahore. DML No. 000891(Formulation) Period: Commencing on 08-01-2024 ending on 07-01-2029. Evaluator:- Zunaira Faryad (AD-Lic)	28-03-2024	Good	1. Dr. Farzana Chaudhary, Expert Member. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore.
	QC In-charge	Mr. Muhammad Waseem (M. Sc Chemistry)		
	Production In-charge	Mr. Faizan Masood (Pharm-D)		
	Recommendations of the panel: In view of above inspection proceedings and the facility verified, such as company profile, building, material management, production, in process controls, quality control testing, machinery/equipment, air handling, water treatment system, personnel and documentation etc. the panel is of the opinion to **recommend** the renewal of Drug Manufacturing License and also recommends grant of revised section of Dry Powder Suspension to M/s Dynatis Pakistan (Pvt) Ltd., Plot No.710-Sunder Industrial Estate, Lahore for the following sections: 1. Tablet Section (General) 2. Capsule Section (General) 3. Sachet Section (General) 4. Lotion Section (General) 5. Cream/Ointment, Gel Section (General) 6. Cream/Ointment, Gel Section (Steroid) 7. Dry Powder Suspension Section (General) (Revised) **Decision of the Central Licensing Board in 298th meeting** The Board considered and approved the renewal of DML No. 000891 by way of Formulation and an additional section in the name of M/s CCL Pharmaceuticals (Pvt) Ltd, (Formerly			

Dynatis Pakistan (Pvt) Ltd.,) Plot No.710, Sundar Industrial Estate, Lahore on the recommendations of the panel of experts for the period commencing on 08-01-2024 ending on 07-01-2029 for the following sections.

Renewal of sections:

1. Tablet Section (General)
2. Capsule Section (General)
3. Sachet Section (General)
4. Lotion Section (General)
5. Cream/Ointment, Gel Section (General)
6. Cream/Ointment, Gel Section (Steroid)

Additional Section:

1. Dry Powder Suspension Section (General) Additional Section.

4.	M/s Nicholas Pharmaceuticals, Plot No.34, Street No. SS-2, National Industrial Zone RCCI, Rawat, Islamabad. DML No. 000886 (Formulation) Period: Commencing on 29-08-2023 ending on 28-08-2028. Evaluator:- Zunaira Faryad (AD-Lic)	07-05-2024	Good	1. Dr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad. 2. Mr. Umer Latif, Deputy Director (QA/LT), DRAP, Islamabad. 3. Ms. Mehwish Tanveer, Assistant Director (QA/LT), DRAP, Islamabad.
	QC In-charge	Mr. Said Umer (M.ScChemistry)		
	Production In-charge	Mr. Shahid Saleem (B-Pharm)		

Recommendations of the panel:

The panel is of the opinion that the establishment meets the requirements of renewal of license as laid down in Drug Act, 1976, DRAP Act, 2012 and the rules framed their under. Further, seeing the positive attitude and intent of the management, reviewing their documents and inspecting the premises, and the QC equipments/apparatus such as functional FTIR, UV-Visible Spectrometer, Atomic Absorption Spectrometer, HPLCs, Karl-Fischer analyzer, Hot/Cold Incubators, Stability Chambers etc., the panel **recommends** the establishment for renewal of Drug Manufacturing License w.e.f 29-08-2023 to 28-08-2023 for the following sections:

S.No.	Name of Sections
1.	Capsule Section (Cephalosporin)
2.	Dry Powder Suspension Section (Cephalosporin)
3.	Dry Powder Injection Section (Cephalosporin)
4.	Dry Powder Injection Section (Carbapenem)

Decision of the Central Licensing Board in 298th meeting

The Board considered and approved the renewal of DML No. 000886 by way of Formulation in the name of M/s Nicholas Pharmaceuticals, Plot No.34, Street No. SS-2, National Industrial

Zone RCCI, Rawat, Islamabad on the recommendations of the panel of experts for the period commencing on 29-08-2023 ending on 28-08-2028. Furthermore, the Board authorized Chairman CLB to issue the renewal of the following penicillin and Cephalosporin and Carbapenem Sections after receiving the undertaking for establishing a segregated dedicated facility for within 2 years.

S.No.	Name of Sections
1.	Capsule Section (Cephalosporin)
2.	Dry Powder Suspension Section (Cephalosporin)
3.	Dry Powder Injection Section (Cephalosporin)
4.	Dry Powder Injection Section (Carbapenem)

5.	M/s Akhai Pharmaceuticals (pvt) Ltd, Plot No.A-248, A-256 to A259, H.I.T.E., Hub, Balochistan DML No. 000640 (Formulation). **Period:** Commencing on 19.06.2023&ending on 18.06.2028 Evaluator: - Mubashir Iqbal (DD-Lic)	17.05.2024 & 21.05.2024	**Good**	1. Mr. Muhammad Salik Zahid, Chief Drug Inspector Balochistan/Member CLB. 2. Dr. Kirshan, Area FID, DRAP, Quetta. 3. Mr. Abdul Waheed, Assistant Director, DRAP, Quetta.
	QC In-charge	Mr. Muhammad Arif S/o Muhammad Shamim (M.S.c Chemistry) CNIC No.42401-2083659-3.		
	Production In-charge	Ms. Uzma Irshad W/o Ahtasham Ul Haq (B.Pharm) CNIC No.42201-0406757-2.		

Recommendations of the panel:

M/s Akhai Pharmaceuticals (Pvt) Limited, Plot A-248, A-256 to A259, H.I.T,E, Hub, Baluchistan, was visited and inspected in detail on 17th & 21s May, 2024 in compliance to the directions contained in DRAP, Islamabad letter No.F.4-2/2005 (Vol-IV) dated 26th April, 2024, in connection with renewal of Drug Manufacturing License (Formulation) (DML No. 000640)

The panel inspected the firm in detail including manufacturing sections, stores and QC Lab and found the facility constructed as per approved lay out plan and compliant. The facility has been provided with necessary utilities, machineries/equipment & sufficient technical staff as required under the guidelines. Necessary documents related to QC, QA and production and qualification of machines/equipments, HVAC and other utilities were also seen in place.

Based on the people met, documents reviewed, and observations made during the inspection, the panel **recommends** the renewal of Drug Manufacturing License (Formulation) (DML No. 000640) for following Sections: -

Sr. No.	Name of Section
01	Tablet (General) Section
02	Capsule (General) Section

03	Tablet (Psychotropic) Section
04	Topical (Cream/Ointment) General Section

Decision of the Central Licensing Board in 298th meeting

The Board considered and approved the renewal of DML No. 000640 by way of Formulation in the name of M/s Akhai Pharmaceuticals (pvt) Ltd, Plot No.A-248, A-256 to A259, H.I.T.E., Hub, Baluchistan on the recommendations of the panel of experts for the period commencing on 19.06.2023& ending on 18.06.2028 for the following sections subject to verification of necessary testing equipment and submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for Psychotropic Section.:

Sr. No.	Name of Section
01	Tablet (General) Section
02	Capsule (General) Section
03	Tablet (Psychotropic) Section
04	Topical (Cream/Ointment) General Section

6.	M/s Alina Combine Pharmaceutical (Pvt) Ltd, Plot No. A-127, S.I.T.E., Superhighway Industrial Area, Karachi. DML No. 000441 (Formulation). **Period:** Commencing on 30.10.2019 ending on 29.10.2024. *Evaluator: - Mubashir Iqbal (DD-Lic)*	14-06-2024	Good	1. Prof. Dr. Abdullah Dayo 2. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 3. Dr. Shoaib Ahmad, FID-III, DRAP, Karachi.
	QC In-charge	Mr. Khan Muhammad S/o Muhammad Suleman (M.Sc. Chemistry) CNIC No.452014-9370257-9.		
	Production In-charge	Syed Naveed Hasnain Zaidi S/o Syed Feroz Hasnain Zaidi (Pharmacy) CNIC No.42201-0602822-7.		

Recommendations of the panel:

1. M/s Alina Combine Pharmaceuticals Pvt. Ltd., Plot No. A-127 SITE-II, Super Highway, Karachi was inspected and visited in detail on 14-06-2024 in compliance to the directions contained in DRAP Islamabad Letter No. F.2-6/94-Lic (Vol-IV) Dated: 18th February 2020in connection with grant of renewal of DML 00441 (Formulation).

The panel inspected all the manufacturing sections, stores and QC Lab and found the facility as per approved layout plan. The facility has been provided with necessary utilities, machineries and equipment as required under the Schedule B-I of Drugs Act 1976 and other prevailing guidelines. Necessary documents relating to QC/QA, installation qualification of machines, HVAC and other utilities were also verified under the scope and noted an optimal level JO compliance.

2. Keeping in view of the above, people met, documents reviewed and attitude of management towards continuous improvement, panel is of the opinion to **recommend** the grant of renewal of their DML No. 000441 (By way of Formulation) for the following sections due from October 2019 for the next five years: -

1. Tablet (General)	2. Liquid Syrup (General)	3. Capsule (General)
4. Cream/Ointment	5. Seven Seas Filling & Packaging Area	6. Dry Powder Suspension (General)
7. Sterile Dry Powder Injection (Cephalosporin)	8. Capsule (Cephalosporin)	9. Dry Powder Suspension (Cephalosporin)
10. Liquid Syrup (Veterinary)	11. Sterile Liquid Injection (Veterinary)	12. Dry Powder (Veterinary)
13. Sterile Liquid Injection Ampoule /Vial (G)		

Decision of the Central Licensing Board in 298th meeting

The Board considered and approved renewal of DML No. 000640 by way of Formulation in the name of M/s Alina Combine Pharmaceuticals Pvt. Ltd., Plot No. A-127 SITE-II, Super Highway, Karachi on the recommendations of the panel of experts for the period commencing on 30.10.2019 ending on 29.10.2024 for the following sections subject to verification of necessary testing equipment:

1. Tablet (General)	2. Liquid Syrup (General)	3. Capsule (General)
4. Cream/Ointment	5. Dry Powder Suspension (General)	6. Liquid Syrup (Veterinary)
7. Sterile Liquid Injection (Veterinary)	8. Dry Powder (Veterinary)	9. Sterile Liquid Injection Ampoule /Vial (G)

The Board Authorized Chairman CLB to issue the renewal of the following Cephalosporin Sections after receiving the undertaking for establishing a segregated dedicated facility for within 2 years.

1. Sterile Dry Powder Injection (Cephalosporin)	2. Capsule (Cephalosporin)	3. Dry Powder Suspension (Cephalosporin)

	The Board observed that a section named "seven seas filling and packing area' does not clarify the objective of the licensed activities. The Board authorized its Chairman to get clarification from firm regarding the following approved section and to issue / defer renewal of the said section based on available current facts/references. 1. Seven Seas Filling & Packaging Area			
7.	M/s Neomedix, Plot No.05, N-5, National Industrial Zone, Rawat. DML No. 000539 (Formulation) Period: Commencing on 02-04-2024 ending on 01-04-2029. Evaluator:- Zunaira Faryad (AD-Lic)	29-03-2024 & 29-05-2024	Good	1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Mr. Akbar Ali, Deputy Director (QA&LT), DRAP, Islamabad. 3. Mr. Muhammad Yaqoob, Assistant Director (Licensing), DRAP, Islamabad.
	QC In-charge	Mr. Ghulam Ghaus (M. Sc Chemistry).		
	Production In-charge	Mr. Muhammad Shoaib (B. Pharm)		

Recommendations of the panel:

In view of the inspection conducted, reviewing the documents, interview of technical team, intent of the management and verification of manufacturing and testing facility such as FTIR, HPLC, Spectrophotometer, Dissolution Apparatus, Polarimetry, Ultrasonic Bath, and other QC equipment along with 3 stability chambers, the panel unanimously **recommends** grant of additional section, i-e Cream/ointment (General) as per approved LOP and also **recommends** grant of renewal of Drug manufacturing License by way of formulation to M/s Neomedix, plot No.05, N-5, National Industrial Estate, Rawat, DML 000539, for following six sections (unbold) as under:

i. Dry Powder Suspension (Cephalosporin) Section
ii. Capsule (Cephalosporin) section
iii. Tablet (General) Section
iv. Dry Powder Suspension (General) section
v. Capsule Section (General)
vi. Oral Syrup (General) section
vii. Cream/ointment (General) - additional section

Decision of the Central Licensing Board in 298th meeting

The Board considered and approved the grant of regularization and renewal of DML No. 000539 by way of Formulation in the name of M/s Neomedix, plot No.05, N-5, National Industrial Estate, Rawat on the recommendations of the panel of experts for the period commencing on 02-04-2024 ending on 01-04-2029 for the following sections subject to verification of necessary testing equipment:

i. Tablet (General) Section
ii. Dry Powder Suspension (General) section

	iii. Capsule Section (General) iv. Oral Syrup (General) section v. **Cream/ointment (General) - additional section** The Board Authorized Chairman CLB to issue the renewal of the following Cephalosporin Sections after receiving the undertaking for establishing a segregated dedicated facility within 2 years. i. Dry Powder Suspension (Cephalosporin) Section ii. Capsule (Cephalosporin) section			
8.	M/s Fahmir Pharma (Pvt) Ltd., Main Mandiwala Stop, 26-Km, Lahore Jaranwala Road, Tehsil Sharaqpur Sharif, District Sheikhupura. DML No. 000880 (Formulation) Period: Commencing on 11-04-2023 ending on 10-04-2028. Evaluator:- Zunaira Faryad (AD-Lic)	21-05-2024	Good	1. Dr. Muhammad Shamoon Ch., Expert Member. 2. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.
	QC In-charge	Mr. Muhammad Shahid (M.Sc. Chemistry)		
	Production In-charge	Mr. Laeeq Shahzad Chishti (B-Pharm)		
	<u>Recommendations of the panel:</u> Keeping in view the manufacturing facility like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors **recommends** the renewal of DML to M/s Fahmir Pharma (Pvt) Ltd., 26-Km, Lahore Road, Sharaqpur, District Sheikhupura for the following sections: i. Tablet Section (General) section ii. Capsule Section (General) section iii. Sachet Section (General) section. It is pertinent to mention here that Mr. Laeeq Shahzad Chishti, Production In-charge of the firm has resigned from the firm w.e.f 31-05-2024 on one-month notice. **<u>Decision of the Central Licensing Board in 298th meeting</u>** The Board considered the facts on ground and deferred the renewal of M/s Fahmir Pharma (Pvt) Ltd., Main Mandiwala Stop, 26-Km, Lahore Jaranwala Road, Tehsil Sharaqpur Sharif, District Sheikhupura. DML No. 000880 (Formulation). A verbal complaint was also received that firm do not hire the technical persons on permanent basis. They call them as and when			

	required. The board further advised the Additional Director Lahore to verify the availability of technical persons in the firm.			
9.	M/s Global Pharmaceuticals (Pvt) Ltd., Plot No.204-205, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000417 (Formulation) Period: Commencing on 26-02-2023 ending on 25-02-2028. Evaluator:- Muhammad Yaqoob (AD-Lic)	02-05-2024, 09-05-2024, 15-05-2024 & 21-05-2024	Good	1. Dr. Ghazanfar Ali Khan, Additional Director (QA/LT), DRAP, Islamabad. 2. Ms. Saadia Mehwich, Federal Inspector of Drugs, DRAP, Islamabad 3. Mr. Muhammad Yaqoob, Assistant Director, DRAP,Islamabad.
	QC In-charge	Mr. Shahbaz Daood S/o Daood Ur Rehman		
	Production In-charge	Mr. Shahid Ullah S/o Fazal Sher		

Recommendations of the panel:

Keeping in view the above facts on record, documents reviewed people met during the visit & compliance of the firm to the directions of inspection team, the panel unanimously **recommended renewal/regularization/revision/relocation of** following sections of Global Pharmaceuticals (Pvt) Ltd., Plot No.204-205, Industrial Triangle, Kahuta Road, Islamabad. DML# 000417:

i. Tablet Section-I (General) (Regularization)
ii. Tablet Section-II (General)
iii. Tablet Section (Psychotropic) (Regularization)
iv. Capsule Section (General) (Relocated)
v. Capsule Section (Cephalosporin)
vi. Dry Powder Suspension Section (Cephalosporin)
vii. Dry Powder Injection Vial Section (Cephalosporin)
viii. Soft Gel Capsule Section (Steroid)
ix. Liquid Injectable Ampoule Section (General) (Regularization)
x. Psychotropic and Narcotic Injectable Section
xi. Dry Powder Injection Section (Penicillin) (Regularization)
xii. Dry Powder Injection Section (Carbapenem)
xiii. Cream/Ointment/Gel (General) (Revised)
xiv. Liquid Syrup Section (General)
xv. Warehouse (RMS, FGS, PMS)
xvi. R&D Lab
xvii. QC Lab & Micro Lab

Decision of the Central Licensing Board in 298th meeting

The Board considered and approved the regularization and renewal of DML No. 000417 by way of Formulation in the name of M/s Global Pharmaceuticals (Pvt) Ltd., Plot No.204-205, Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the period commencing on 26-02-2023 ending on 25-02-2028 for the following sections subject to verification of necessary testing equipment and submission of NOC from Ministry

	of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 for Psychotropic Section: i. Tablet Section-I (General) (Regularization) ii. Tablet Section-II (General) iii. Tablet Section (Psychotropic) (Regularization) iv. Capsule Section (General) (Relocated) v. Soft Gel Capsule Section (Steroid) vi. Liquid Injectable Ampoule Section (General) (Regularization) vii. Psychotropic and Narcotic Injectable Section viii. Cream/Ointment/Gel (General) (Revised) ix. Liquid Syrup Section (General) x. Store (RMS, FGS, PMS) xi. R&D Lab xii. QC Lab & Micro Lab The Board Authorized Chairman CLB to issue the renewal of the following Penicillin and Cephalosporin Sections after receiving the undertaking for establishing a segregated dedicated facility within 2 years. i. Dry Powder Injection Section (Penicillin) (Regularization) ii. Dry Powder Injection Section (Carbapenem) iii. Capsule Section (Cephalosporin) iv. Dry Powder Suspension Section (Cephalosporin) v. Dry Powder Injection Vial Section (Cephalosporin)			
10.	M/s Prix Pharmaceutica (Pvt) Ltd., 05-Pharma City, 30-Km, Multan Road, Lahore. DML No. 000587 (Formulation) Period: Commencing on 16-10-2020 ending on 15-10-2025. Evaluator:- Abdullah (AD-Lic)	08-05-2024	Good	1. Dr. Farzana Chaudhary, Expert Member. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	QC In-charge	Mr. Majid Ali (M.Sc Chemistry)		
	Production In-charge	Mr Mohsin Amin (B-Pharm)		
	Recommendations of the panel: In view of above inspection proceedings and the facility verified, such as company profile, building, material management, production, in process controls, Quality Control Testing, machinery/equipment, air handling, water treatment system, personnel and documentation etc **the panel is of the opinion to recommend the renewal of Drug Manufacturing License** to M/s Prix Pharmaceutica (Pvt) Ltd., 05-Pharmacity, 30-Km, Multan Road, Lahore for the following sections: i. Bolus Section (Veterinary) ii. Oral Powder Section (General) Veterinary iii. Oral Powder Section (General Antibiotic) iv. Oral Liquid Section (Veterinary)			

	v. Liquid Injectable Section (General) (Veterinary) vi. Oral Powder Section Penicillin – Veterinary vii. Liquid Injectable (Vial) (Penicillin) Section Veterinary **Decision of the Central Licensing Board in 298th meeting** The Board considered and approved the renewal of DML No. 000587 by way of Formulation in the name of M/s Prix Pharmaceutica (Pvt) Ltd., 05-Pharmacity, 30-Km, Multan Road, Lahore on the recommendations of the panel of experts for the period commencing on 16-10-2020 ending on 15-10-2025 for the following sections subject to verification of necessary testing equipment: i. Bolus Section (Veterinary) ii. Oral Powder Section (General) Veterinary iii. Oral Powder Section (General Antibiotic) iv. Oral Liquid Section (Veterinary) v. Liquid Injectable Section (General) (Veterinary) The Board Authorized Chairman CLB to issue the renewal of the following Cephalosporin Sections after confirming the dedication of facility. i. Oral Powder Section Penicillin – Veterinary ii. Liquid Injectable (Vial) (Penicillin) Section Veterinary			
11.	M/s Albert Pharmaceuticals (Pvt) Ltd., Plot No.127, Sundar Industrial Estate, Lahore. DML No. 000865 (Formulation) Period: Commencing on 21-06-2022 ending on 20-06-2027. Evaluator:- Zunaira Faryad (AD-Lic)	05-06-2024	Good	1. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Farooq Aslam, Assistant Director, DRAP, Lahore.
	QC In-charge	Ms. Ahdania Batool (Pharm-D)		
	Production In-charge	Mr. Gul Muhammad (B-Pharm)		
	Recommendations of the panel: Keeping in view the manufacturing facility like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors **recommends** the renewal of DML to M/s Albert Pharmaceuticals (Pvt) Ltd., Plot No.127, Sundar Industrial Estate, Lahore for the following sections: i. Tablet Section (General) ii. Capsule Section (General) iii. Oral Dry Powder Suspension Section (General) **Decision of the Central Licensing Board in 298th meeting** The Board considered and approved the grant of regularization and renewal of DML No. 000865 by way of Formulation in the name of M/s Albert Pharmaceuticals (Pvt) Ltd., Plot			

	No.127, Sundar Industrial Estate, Lahore on the recommendations of the panel of experts for the period commencing on 21-06-2022 ending on 20-06-2027 for the following sections subject to verification of necessary testing equipment: i. Tablet Section (General) ii. Capsule Section (General) iii. Oral Dry Powder Suspension Section (General)			
12.	M/s Pharmacare Laboratories (Pvt) Ltd., 129/1, Industrial Estate, Kot Lakhpat, Lahore. DML No. 000255 (Formulation) Period: Commencing on 13-06-2019 ending on 13-06-2024. Evaluator:- Abdullah (AD-Lic)	15-05-2024	Good	1. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	QC In-charge	Mr. Ghulam Mustafa S/o. Mr. Hafiz Nazir Ahmad) CNIC 35200-1425647-3 M.Sc. Chemistry		
	Production In-charge	Babar Mahmud S/o Ch. Sultan Mamud CNIC No.35201-8048967-5 (B-Pharm)		
	Recommendations of the panel: In view of above inspection proceedings and the facility verified, such as company profile, building, material management, production, in process controls, Quality Control Testing, machinery/equipment, air handling, water treatment system, personnel and documentation etc the panel is of the opinion to recommend the renewal of Drug Manufacturing License, Regularization of Layout plan and grant of revised Section to M/s Pharmacare Laboratories (Pvt) Ltd., 129/1, Industrial Estate, Kot Lakhpat, Lahore, for the following sections: i. Tablet Section (General) ii. Tablet Section (Psychotropic) (Revised) **Note** Panel of inspection was constituted for following sections i. Table (General) ii. Capsule (Cephalosporin) iii. Oral Dry Powder (Cephalosporin) iv. Tablet (Psychotropic) v. Quality Control Laboratory vi. Warehouse **Decision of the Central Licensing Board in 298th meeting** The Board considered the inspection report and accepted the report for record since the renewal period commencing on 13-06-2019 ending on 13-06-2024 in the name of M/s Pharmacare Laboratories (Pvt) Ltd., 129/1, Industrial Estate, Kot Lakhpat, Lahore and under DML No. 000255 by way of Formulation has already expired.			

	The Board also considered and approved the regularization of following sections in the name of M/s Pharmacare Laboratories (Pvt) Ltd., subject to verification of necessary testing equipment and submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD dated 10/11/2020 for Psychotropic Section: i. Tablet Section (General) ii. Tablet Section (Psychotropic) (Revised) The Board discussed that as the panel submitted in its report that firm was not ready for inspection for following section. Therefore, the Board decided to stop production of the firm in the following sections with immediate effect; i. Capsule (Cephalosporin) ii. Oral Dry Powder (Cephalosporin)			
13.	M/s Avicenna Laboratories (Pvt) Ltd., 14 Km, Faisalabad Sheikhupura Road, Bhikhi, Sheikhupura. DML No. 000328 (Formulation) Period: Commencing on 05-10-2022 ending on 04-10-2027. Evaluator:- Zunaira Faryad (AD-Lic)	31-05-2024	Good	1. Prof. Dr. Mehmood Ahmad, Ex-Dean IUB/Member PQCB, Lahore. 2. Mr. Faisal Shahzad, Additional Director, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, Assistant Director, DRAP, Lahore.
	QC In-charge	Mr. Manzoor Hussain (M.Sc Chemistry)		
	Production In-charge	Mr. Munawar Shahid Bhatti (B-Pharm)		
	Recommendations of the panel: In view of above inspection proceedings and facilities verified, such as company profile, building, material management, production, in-process controls, Quality Control Testing, machinery/equipment, air handling, water treatment system, personnel and documentation e.t.c the panel is of the opinion to **recommends** the Renewal of Drug Manufacturing License and grant of revised section to M/s Avicenna Laboratories (Pvt) Ltd., 14 Km, Faisalabad Sheikhupura Road, Bhikhi, Sheikhupura, for the following sections: 1. Oral Powder (Veterinary) Section (Renewal) 2. Oral Liquid (Veterinary) Section (Renewal) 3. Injectable Vial (LVP) Section (General) (Revised) 4. Microbiology Laboratory (Revised) **Decision of the Central Licensing Board in 298th meeting** The Board considered and approved the renewal of DML No. 000328 by way of Formulation and an additional section in the name of M/s Avicenna Laboratories (Pvt) Ltd., 14 Km, Faisalabad Sheikhupura Road, Bhikhi, Sheikhupura on the recommendations of the panel of experts for the period commencing on 05-10-2022 ending on 04-10-2027 for the following sections subject to verification of necessary testing equipment:			

<table>
<tr><td></td><td colspan="4">1. Oral Powder (Veterinary) Section (Renewal)
2. Oral Liquid (Veterinary) Section (Renewal)
3. Injectable Vial (LVP) Section (General) (Additional Section)
4. Microbiology Laboratory (Revised)</td></tr>
<tr><td>14.</td><td>M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Hummak, Islamabad.
DML No. 000795 (Formulation)

Period: Commencing on 25-03-2024 ending on 24-03-2029.
Evaluator:- Muhammad Yaqoob(AD-Lic)</td><td>30-05-2024, 04-06-2024 & 02-07-2024</td><td>Good</td><td>1. Ms. Saadia Mahwish, Area FID, DRAP, Islamabad. Dr.
2. Dr. Ghazanfar Ali Khan, Additional Director QA&LT (Field Office), DRAP, Islamabad.
3. Muhammad Akhtar Abbas Khan, Director (Licensing), DRAP, Islamabad.</td></tr>
<tr><td></td><td>QC In-charge</td><td colspan="3">Mr. Muhammad Zahid S/o Mian Nisar Muhammad</td></tr>
<tr><td></td><td>Production In-charge</td><td colspan="3">Mr. Khalid Rehman Khattak S/o Abdul Rehman Khattak</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>
Keeping in view of the above facts on record, documents reviewed people met during the visit & compliance of the firm to the directions of inspection team, the panel unanimously <u>recommends renewal</u> following sections of M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Humak, Islamabad, DML #000795:
<u>Renewal of Drug Manufacturing License by way of Formulation</u>
1. Tablet Section (General)
2. Capsule Section (General)
3. Sachet Section (Powder/Granules) (General)
4. Cream/Ointment/Gel Section (General) subject to installation of GMP compliant filling machine
5. Oral Liquid Section (General)

<u>Decision of the Central Licensing Board in 298th meeting</u>
The Board considered and approved the grant of regularization and renewal of DML No. 000795 by way of Formulation in the name of M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Humak, Islamabad on the recommendations of the panel of experts for the period commencing on 25-03-2024 ending on 24-03-2029 for the following sections subject to verification of necessary testing equipment:
1. Tablet Section (General)
2. Capsule Section (General)
3. Sachet Section (Powder/Granules) (General)
4. Cream/Ointment/Gel Section (General) subject to installation of GMP compliant filling machine
5. Oral Liquid Section (General)

The Board authorized its chairman to issue the renewal of Cream/Ointment/Gel Section (General) after confirmation of installation of GMP compliant filling machine in the section by firm.</td></tr>
</table>

15	M/s Eros Pharmaceuticals (Pvt) Ltd, 94-95/23 Korangi Industrial Area, Karachi. DML No. 000147 (Formulation). Period: Commencing on 21.08.2020 ending on 20.08.2025 Evaluator: - Mubashir Iqbal (DD-Lic)	26-04-2024	Good	1. Mr. Qaisar Muhammad, Expert Member. 2. Abdul Rasool Shaikh, Additional Director/FID-II, DRAP Karachi. 3. Mr. Sajjad Ahmed Abbasi, Deputy Director, Central Drug Laboratory, Karachi.
	QC In-charge	Ms. Zakia BiBi W/o Mr. Sheikh Saeed Ahmed (M.S.c Chemistry) CNIC No.42201-0381513-2.		
	Production In-charge	Mr. Mehmood Ali S/o Munshi Khan		

Recommendations of the panel:

1. M/s. Eros Pharmaceuticals Pvt. Ltd., Plot ON 94-95, Sector 23 Korangi Industrial area Karachi was inspected and visited in detail on 26-04-2024 in compliance to the directions contained in DRAP Islamabad Letter ON F.2-10-2005-Lie (Vol-I) dated 17th May, 2022 connection with renewal of DML. The panel inspected all the manufacturing sections, stores and QC Lab and found the facility as per approved layout plan. The facility has been provided with necessary utilities, machineries and equipment's as required under the guidelines. Necessary documents relating to QC/QA, installation qualification of machines, HVAC and other utilities were also verified under the scope and noted an optimal level of compliance.

2. Keeping in view of the above, people met, documents reviewed and attitude of the management towards continuous improvement, the panel is of the opinion to recommend the grant of renewal of their DML ON 000147 (By way of Formulation) for the following sections commencing from 21-08-2010 and regularization of layout plan: -

1. Tablet (General-I)	2. Tablet (General-II)	3. Oral Liquid Syrup (General)
4. Capsule (General)	5. Ointment/Cream (General)	6. Dry Powder Suspension (General)
7. Eye/ENT Drops (General)	8. Capsule (Cephalosporin)	9. Dry Powder Suspension (Cephalosporin)
10. Dry Powder Injection (Cephalosporin)	11. Liquid External Preparation	12. QC Laboratory
13. Warehouse	**********	**********

Decision of the Central Licensing Board in 298th meeting

	The Board considered and approved the renewal of DML No. 000147 by way of formulation in the name of M/s. Eros Pharmaceuticals Pvt. Ltd., Plot ON 94-95, Sector 23, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 21.08.2020 ending on 20.08.2025 for the following sections subject to verification of necessary testing equipment: 1. Tablet (General-I) 2. Tablet (General-II) 3. Oral Liquid Syrup (General) 4. Capsule (General) 5. Ointment/Cream (General) 6. Dry Powder Suspension (General) 7. Eye/ENT Drops (General) 8. Liquid External Preparation 9. QC Laboratory 10. Store (RMS, FGS & PMS) The Board Authorized Chairman CLB to issue the renewal of the following Cephalosporin Sections after receiving the undertaking for establishing a segregated dedicated facility within 2 years. 1. Capsule (Cephalosporin) 2. Dry Powder Suspension (Cephalosporin) 3. Dry Powder Injection (Cephalosporin) The Board further authorized its Chairman to verify the manufacturing of Povidone preparations in External Preparations Section and in case of presence of Povidone the Section should be dedicated for it.			
16	M/s Cibex (Pvt) Ltd, Plot No.F-405, S.I.T.E., Karachi DML No. 000784 (Formulation). Period: Commencing on 03.02.2024 ending on 02.02.2029 Evaluator: - Mubashir Iqbal (DD-Lic)	03.07.2024	Good	1. Mr. Abdul Hafeez Tunio, Chief Drug Inspector Sindh. 2. Abdul Rasool Shaikh, Additional Director, DRAP, Karachi. 3. Dr. Shoaib Ahmad, FID-III, DRAP, Karachi. 4. Mr. Abdul Waheed, Assistant Director, DRAP, Karachi.
	QC In-charge	Mr. Umer Farooq S/o Muhammad (M.Sc. Chemistry) CNIC No.42101-9872647-5.		
	Production In-charge	Mr. Muhammad Rizwan S/o Abdul Aziz (Pharm-B) CNIC No.44102-9391637-1.		
	Recommendations of the panel: 1. M/s. Cibex Pvt Ltd., F-405, SITE, Karachi was inspected and visited in detail on 03-07-2024 in compliance the directions contained in DRAP Islamabad Letter No. F.2-5/2008-Lic (Vol-1) dated 26th June 2024 in connection with renewal of DML. The panel inspected all manufacturing sections, stores and QC Lab and found the facility as per approved layout plan. The facility has been provided with necessary utilities,			

machineries and equipment's as required under the guidelines. Necessary documents relating to QC/QA, HVAC and other utilities were also verified under the scope and noted an optimal level of compliance.

2. Keeping in view of above, documents reviewed and positive approach of the management towards continuous improvement, the panel is of the opinion to recommend the grant of renewal of their DML No. 000784 (By way of Formulation) for the following sections commencing from 03-02-2 2024.
    1. Tablet (General)
    2. Capsule (General)
    3. Dry Syrup (General Antibiotic)
    4. Tablet (General Antibiotic)
    5. Capsule (General Antibiotic)
    6. Sachet (General)
    7. Cream/Ointment (Steroid)
    8. Cream/Ointment (Non-Steroid)

Decision of the Central Licensing Board in 298th meeting

The CLB considered the case and observed that a matter related to licensing of a section of firm is lying pending before the Appellate Board. The CLB deferred the application for renewal till decision by the Appellate Board.

17.	M/s Ipram International, Plot No.26, Street No.SS-3, National Industrial Zone, Rawat, Rawalpindi. **DML No. 000551 (Formulation)** **Period:** Commencing on 27-08-2019 ending on 26-08-2024. Evaluator:- Zunaira Faryad (AD-Lic)	**08-07-2024**	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director, QA&LT, DRAP, Islamabad. 2. Mr. Fahad Nadeem, Deputy Director (PER), DRAP, Islamabad. 3. Mr. Umer Latif, Deputy Director, DRAP, Islamabad.
	QC In-charge	Mrs. Sadia Yasmeen, (M.Sc Chemistry)		
	Production In-charge	Mr. Anees Ur Rehman, (Pharm-D)		

Recommendations of the panel:

A Risk-based inspection of the establishment was carried out in 2003 and 111 obervations/shortcomings were pointed out. The CAPA for these observations was verified thrice and the establishment complied with all the observations in June 2024. The panel of inspectors for DML renewal believes that the establishment has the purpose-built facility, machinery/equipment for manufacturing and Quality Control such as HPLCs, FTIR, Stability Chambers, UV Spectrophotometer, etc., and qualified technical staff, therefore, the establishment is recommended for Renewal of DML for following sections:

1. Sterile Dry Powder for Injection (Ceph)
2. Oral Dry Powder Suspension (Ceph)
3. Liquid Injectable Ampoule (General)
4. Capsule (General)
5. Dry Powder Injection (Carbapenem)
6. Capsule (Ceph)

	Decision of the Central Licensing Board in 298th meeting The Board considered and approved the renewal of DML No. 000551 by way of Formulation in the name of M/s Ipram International, Plot No.26, Street No.SS-3, National Industrial Zone, Rawat, Rawalpindi on the recommendations of the panel of experts for the period commencing on 27-08-2019 ending on 26-08-2024 for the following sections: 1. Liquid Injectable Ampoule (General) 2. Capsule (General) The Board Authorized Chairman CLB to issue the renewal of the following Cephalosporin and carbapenem Sections after receiving the undertaking for establishing a segregated dedicated facility within 2 years. 1. Sterile Dry Powder for Injection (Ceph) 2. Oral Dry Powder Suspension (Ceph) 3. Dry Powder Injection (Carbapenem) 4. Capsule (Ceph)

Item-IV Miscellaneous Cases

Case No.1 CHANGE OF MANAGEMENT OF M/S FYNK PHARMACEUTICALS, LAHOREUNDER DRUG MANUFACTURING LICENSE NO. 000494 BY WAY OF FORMULATION.

M/s Fynk Pharmaceuticals, 19-Km, G.T. Road, Kalashah Kaku, Lahore has submitted request for change in management of the firm with the prescribed fee. The detail of the management of the firm as per amended partnership deed is as under:

Previous Management	New management as per Partnership Deed dated 16-01-2024
1. Mr. Kashif Liaqat S/o Liaqat Ali CNIC No. 35201-6647318-3. **2. Mr. Liaqat Ali S/o Mehar Abdul Aziz CNIC No. 35202-0481987-3.** **3. Mrs. Shahida Liaqat W/o Liaqat Ali CNIC No. 35202-0840329-4.**	**1.** Mr. Kashif Liaqat S/o Liaqat Ali CNIC No. 35201-6647318-3. **2. Mr. Qaiser Liaqat Ali S/o Liaqat Ali CNIC No.35201-5957648-3.** **3. Mr. Yasir Liaqat Ali S/o Liaqat Ali CNIC No. 35201-7274645-7.**

Decision of the Central Licensing Board in 298th meeting

Based on change of management in Partnership deed, the Board considered and accepted for record the change of management of M/s Fynk Pharmaceuticals, 19-Km, G.T. Road, Kalashah Kaku, Lahore under DML No. 000494 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	New management as per Partnership Deed dated 16-01-2024
1. Mr. Kashif Liaqat S/o Liaqat Ali CNIC No. 35201-6647318-3. **2. Mr. Liaqat Ali S/o Mehar Abdul Aziz CNIC No. 35202-0481987-3.** **3. Mrs. Shahida Liaqat W/o Liaqat Ali CNIC No. 35202-0840329-4.**	**1.** Mr. Kashif Liaqat S/o Liaqat Ali CNIC No. 35201-6647318-3. **2. Mr. Qaiser Liaqat Ali S/o Liaqat Ali CNIC No.35201-5957648-3.** **3. Mr. Yasir Liaqat Ali S/o Liaqat Ali CNIC No. 35201-7274645-7.**

Case No.2 **CHANGE OF MANAGEMENT OF M/S HIMARK LABORATORIES (PVT) LTD., LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000909 BY WAY OF FORMULATION.**

M/s. Himark Laboratories (Pvt) Ltd., 37-A, Sunder Industrial Estate, Lahore has submitted request for change in management of the firm with the prescribed fee. The detail of the management of the firm is as under:

Previous Management	New management as per Form-A dated 20-03-2023& Form-29 dated 20-03-2023
1. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7. (**CEO**) 2. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**Director**) 3. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3.**(Director)** 4. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5.**(Director)** 5. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**	1. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7 (**Director**) 2. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**CEO**) 3. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3.**(Director)** 4. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5.**(Director)** 5. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**

Decision of the Central Licensing Board in 298th meeting

Based on Form-A dated 20-03-2023 & Form-29 dated 20-03-2023 issued by SECP, the Board considered and accepted for record the change of management (only CEO) of M/s. Himark Laboratories (Pvt) Ltd., 37-A, Sunder Industrial Estate, Lahore under DML No. 000909 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	New management
6. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7. (**CEO**) 7. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**Director**)	6. Mr. Arslan Anjum S/o Mushtaq Ahmad CNIC 35202-4173832-7 (**Director**) 7. Mr. Mushtq Ahmad S/o Muhammad Boota CNIC No. 35202-8073548-7. (**CEO**)

8. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3.**(Director)** 9. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5.**(Director)** 10. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**	8. Mr. Sohail Anjum S/o Mushtaq Ahmad CNIC No. 35202-5901604-3.**(Director)** 9. Mr. Zeeshan Anjum S/o Mushtaq Ahmad CNIC No.35202-7127299-5.**(Director)** 10. Mr. Shahzad Anjum S/o Mushtaq Ahmad CNIC No.35202-7090186-3.**(Director)**

Case No.3 **CHANGE OF MANAGEMENT OF M/S FAST PHARMACEUTICALS (PVT) LTD., RAWAT UNDER DRUG MANUFACTURING LICENSE NO. 000954 BY WAY OF FORMULATION.**

M/s Fast Pharmaceuticals (Pvt) Ltd., Plot No.55, Street No. S-4, National Industrial Zone, RCCI, Rawat has submitted request for change in management of the firm with the prescribed fee. The detail of the management of the firm is as under:

Previous Management	**New management as per Form-A dated 02-01-2024 & Form-29 dated 02-01-2024**
1. Mr. Muhammad Akram S/o Muhammad Din CNIC No. 35302-2002466-9. 2. Mrs. Rabia Tasneem W/o Muhammad Akram CNIC No.37405-7807023-0. 3. Mr. Muhammad Imran S/o Fateh Muhammad CNIC No.35301-4333874-3.	**1. Mr.Shaikh Muhammad Farooq S/o Shaikh Rehman Baksh CNIC No. 42301-3893546-7.** **2. Mr. Muhammad Kashif Shaikh S/o Wahid Noor Shaikh CNIC No. 42201-4884842-7.** 3. **Ms. Rafia Kashif W/o Muhammad Kashif Shaikh CNIC No. 42201-8290317-2.**

Decision of the Central Licensing Board in 298th meeting

Based on the Form-A dated 02-01-2024 & Form-29 dated 02-01-2024 issued by SECP, the Board considered and accepted for record the change of management of M/s Fast Pharmaceuticals (Pvt) Ltd., Plot No.55, Street No.S-4, National Industrial Zone, RCCI, Rawat under DML No. 000954 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	**New management**
1. Mr. Muhammad Akram S/o Muhammad Din CNIC No. 35302-2002466-9. 2. Mrs. Rabia Tasneem W/o Muhammad Akram CNIC No.37405-7807023-0. 3. Mr. Muhammad Imran S/o Fateh Muhammad CNIC No.35301-4333874-3.	**1. Mr.Shaikh Muhammad Farooq S/o Shaikh Rehman Baksh CNIC No. 42301-3893546-7.** **2. Mr. Muhammad Kashif Shaikh S/o Wahid Noor Shaikh CNIC No. 42201-4884842-7.**

	3. **Ms. Rafia Kashif W/o Muhammad Kashif Shaikh CNIC No. 42201-8290317-2.**

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

M/s Friends Pharma (Pvt) Ltd., 31-Km, Ferozepur Road, Lahore has submitted request for change in management of the firm with the prescribed fee. The detail of the management of the firm is as under:

Previous Management	New management as per Form-29 dated 02-03-2024
1. Mr. Naveed Zafar S/o Zafar Ali CNIC No. 35202-2903328-9. 2. Ms. Sajeela Sarwar W/o Nadeem Zafar CNIC No. 35202-2842681-8.	1. Mr. Rana Anwar S/o Bashir Ahmad CNIC No. 35202-2110920-7. 2. Mr. Nadeem Zafar S/o Zafar Ali CNIC No. 35202-2903329-5

Decision of the Central Licensing Board in 298th meeting

Based on Form-29 dated 02-03-2024 issued by SECP, the Board considered and accepted for record the change of management of M/s Friends Pharma (Pvt) Ltd., 31-Km, Ferozepur Road, Lahore under DML No. 000531 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	New management
1. Mr. Naveed Zafar S/o Zafar Ali CNIC No. 35202-2903328-9. 2. Ms. Sajeela Sarwar W/o Nadeem Zafar CNIC No. 35202-2842681-8.	1. Mr. Rana Anwar S/o Bashir Ahmad CNIC No. 35202-2110920-7. 2. Mr. Nadeem Zafar S/o Zafar Ali CNIC No. 35202-2903329-5

Case No.5 **CHANGE OF MANAGEMENT OF M/S GLOBAL PHARMACEUTICALS (PVT) LTD, PLOT NO. 204-205, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD UNDER DRUG MANUFACTURING LICENSE NO. 000417 BY WAY OF (FORMULATION)**

M/s Global Pharmaceuticals (Pvt) Ltd, Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad, Drug Manufacturing License No. 000417 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm are as under: -

Previous Management as per Form-29.	New Management as per Form-9 dated 01-03-2024.

1. **Mr. Aslam Afghani S/o Muhammad Ismail Afghani CNIC 42201-4112170-1.** 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	1. **Mr. Nadeem Panjatan S/o Syed Muhammad Yousaf CNIC 42101-1397557-5.** 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

Decision of the Central Licensing Board in 298th meeting

Based on Form-9 dated 01-03-2024 issued by SECP, the Board considered and accepted for record the change of management of M/s Global Pharmaceuticals (Pvt) Ltd, Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000417 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per Form-29.	**New Management as per Form-9 dated 01-03-2024.**
1. **Mr. Aslam Afghani S/o Muhammad Ismail Afghani CNIC 42201-4112170-1.** 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	1. **Mr. Nadeem Panjatan S/o Syed Muhammad Yousaf CNIC 42101-1397557-5.** 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

Case No.6 **CHANGE OF MANAGEMENT OF M/S LUCKY CORE INDUSTRIES LIMITED, 32/2A, PHASE-III, INDUSTRIAL ESTATE, HATTAR UNDER DRUG MANUFACTURING LICENSE NO. 000363 BY WAY OF (FORMULATION).**

M/s Lucky Core Industries Limited, 32/2A, Phase-III, Industrial Estate, Hattar, Drug Manufacturing License No.000363 by way of formulation has submitted request for change in management of the firm as per Form-9 with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-29.	**New Management as per Form-9 dated 02-05-2024.**

1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. **3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No. 4220153554927.** 4. Mr. Muhammad SohailTabba S/o Muhammad YunusTabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.	1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. **3. Mr. Ariful Islam S/o Amin Ul Islam CNIC No. 42301-1035569-1** 4. Mr. Muhammad SohailTabba S/o Muhammad Yunus Tabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.

Decision of the Central Licensing Board in 298th meeting

Based on Form-9 dated 02-05-2024 issued by SECP, the Board considered and accepted for record the change of management of M/s Lucky Core Industries Limited, 32/2A, Phase-III, Industrial Estate, Hattar under DML No. 000363 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per Form-29.	**New Management as per Form-9 dated 02-05-2024.**
1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. **3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No. 4220153554927.** 4. Mr. Muhammad SohailTabba S/o Muhammad YunusTabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910.	1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. **3. Mr. Ariful Islam S/o Amin Ul Islam CNIC No. 42301-1035569-1** 4. Mr. Muhammad SohailTabba S/o Muhammad YunusTabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910.

8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.	8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.

Case No.7 **CHANGE OF MANAGEMENT OF M/S VISION PHARMACEUTICALS (PVT) LTD, PLOT NO. 22-23, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD UNDER DRUG MANUFACTURING LICENSE NO. 000517 BY WAY OF (FORMULATION).**

M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad (000517) by way of formulation has submitted request for change in management of the firm as per Form-29 with the prescribed fee. The detail of the management of the firm is as under:

Previous Management as per form 29	**Current management as per Form-9 dated 01-03-2024.**
1. Mr. Muhammad Aslam S/o Muhammad Ismail Afghani CNIC 42201-4112170-1. 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	**1. Mr. Nadeem Panjatan S/o Syed Muhammad Yousaf CNIC 42101-1397557-5.** 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

Decision of the Central Licensing Board in 298th meeting

Based on Form-9 dated 01-03-2024 issued by SECP, the Board considered and accepted for record the change of management of M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000517 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per form 29	**Current management as per Form-9 dated 01-03-2024.**
1. Mr. Muhammad Aslam S/o Muhammad Ismail Afghani CNIC 42201-4112170-1. 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5.	**1. Mr. Nadeem Panjatan S/o Syed Muhammad Yousaf CNIC 42101-1397557-5.** 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5.

3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

Case No.8 **CHANGE OF MANAGEMENT OF M/S VISION PHARMACEUTICALS (PVT) LTD, PLOT NO. 22-23, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD UNDER DRUG MANUFACTURING LICENSE NO. 000806 BY WAY OF (SEMI BASIC MANUFACTURING).**

M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad (Semi Basic Manufacture 000806) has submitted request for change in management of the firm as per Form-29 with the prescribed fee. The detail of the management of the firm is as under:

Previous Management as per form 29	**Current management as per Form-9 dated 01-03-2024.**
1. Mr. Muhammad Aslam S/o Muhammad Ismail Afghani CNIC 42201-4112170-1. CEO 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	**1. Mr. Nadeem Panjatan S/o Syed Muhammad Yousaf CNIC 42101-1397557-5. CEO** 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

Decision of the Central Licensing Board in 298th meeting

Based on Form-9 dated 01-03-2024 issued by SECP, the Board considered and accepted for record the change of management of M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000806 (Semi Basic Manufacture). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per form 29	**Current management as per Form-9 dated 01-03-2024.**
1. Mr. Muhammad Aslam S/o Muhammad Ismail Afghani CNIC 42201-4112170-1. CEO 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9.	**1. Mr. Nadeem Panjatan S/o Syed Muhammad Yousaf CNIC 42101-1397557-5. CEO** 2. Mr. Muhammad Asad S/o Khawaja Muhammad Yaqoob CNIC No. 37405-0823280-5. 3. Khawaja Sajid Yaqoob S/o Khawaja Muhammad Yaqoob CNIC No. 37405-6963909-9.

4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.	4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No. 37405-3917505-1.

Case No.9 **CHANGE OF MANAGEMENT OF M/S UNICHEM PHARMACEUTICALS PAKISTAN (PVT) LTD LTD, PLOT NO.310, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

The firm, M/s Unichem Pharmaceuticals Pakistan (Pvt) Ltd, Plot No.310, Industrial Triangle, Kahuta Road, Islamabad under DML No. Semi Basic Manufacture 000922 wherein the firm has submitted application for change of management with relevant fee of Rs.22500/. The detail of management is as under;

Previous Management as per Form-29	**Current Management as per Form-9 dated 04-06-2024.**
1. Syed Asghar Ilyas S/o Syed Ilyas Hussain CNIC No. 14301-8350565-1. 2. Mr. Mohammad Imran Khan S/o Mirza Faiz Ullah Khan CNIC No. 54400-0558607-5. 3. Mr. Munir Ahmed Baloch S/o Sher Ali Khan CNIC No.54104-8410918-5. 4. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No.37405-3917505-1. 5. Mr. Faisal Saud Dar S/o Muhammad Afzal CNIC No.34202-0636103-5.	1. Syed Asghar Ilyas S/o Syed Ilyas Hussain CNIC No. 14301-8350565-1. 6. Mr. Mohammad Imran Khan S/o Mirza Faiz Ullah Khan CNIC No. 54400-0558607-5. 2. Mr. Munir Ahmed Baloch S/o Sher Ali Khan CNIC No.54104-8410918-5. 3. Syed Akbar Ilyas S/o Syed Ilyas Hussain CNIC No. 17301-1647855-7 4. Bibi Rubina Shah D/o Syed Ilyas Hussain CNIC No. 14301-3135949-2

Decision of the Central Licensing Board in 298th meeting

Based on Form-9 dated 04-06-2024 issued by SECP, the Board considered and accepted for record the change of management of The firm, M/s Unichem Pharmaceuticals Pakistan (Pvt) Ltd, Plot No.310, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000922 (Semi Basic Manufacture). This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per Form-29	**Current Management as per Form-9 dated 04-06-2024.**
7. Syed Asghar Ilyas S/o Syed Ilyas Hussain CNIC No. 14301-8350565-1. 8. Mr. Mohammad Imran Khan S/o Mirza Faiz Ullah Khan CNIC No. 54400-0558607-5.	5. Syed Asghar Ilyas S/o Syed Ilyas Hussain CNIC No. 14301-8350565-1. 12. Mr. Mohammad Imran Khan S/o Mirza Faiz Ullah Khan CNIC No. 54400-0558607-5.

9. Mr. Munir Ahmed Baloch S/o Sher Ali Khan CNIC No.54104-8410918-5. 10. Mr. Muhammad Abid S/o Khawaja Muhammad Yaqoob CNIC No.37405-3917505-1. 11. Mr. Faisal Saud Dar S/o Muhammad Afzal CNIC No.34202-0636103-5.	6. Mr. Munir Ahmed Baloch S/o Sher Ali Khan CNIC No.54104-8410918-5. 7. Syed Akbar Ilyas S/o Syed Ilyas Hussain CNIC No. 17301-1647855-7 8. Bibi Rubina Shah D/o Syed Ilyas Hussain CNIC No. 14301-3135949-2

Case No.10 **CHANGE OF MANAGEMENT OF M/S LUCKY CORE INDUSTRIES LIMITED, 45-KM, OFF MULTAN ROAD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000811 (FORMULATION).**

M/s Lucky Core Industries Limited, 45-Km, Off Multan Road, Lahore Under Drug Manufacturing License No. 000811 (Formulation) has submitted request for change in management of the firm as per Form-9 with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-29.	**New Management as per Form-9 dated 02-05-2024.**
1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. **3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No. 4220153554927.** 4. Mr. Muhammad SohailTabba S/o Muhammad YunusTabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.	1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. **3. Mr. Ariful Islam S/o Amin Ul Islam CNIC No. 42301-1035569-1** 4. Mr. Muhammad SohailTabba S/o Muhammad YunusTabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.

Decision of the Central Licensing Board in 298th meeting

Based on Form-9 dated 02-05-2024 issued by SECP, the Board considered and accepted for record the change of management of M/s Lucky Core Industries Limited, 45-Km, Off Multan Road, Lahore under DML No. 000811 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending

liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per Form-29.	New Management as per form 9
1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. **3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No. 4220153554927.** 4. Mr. Muhammad SohailTabba S/o Muhammad YunusTabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.	1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. **3. Mr. Ariful Islam S/o Amin Ul Islam CNIC No. 42301-1035569-1** 4. Mr. Muhammad SohailTabba S/o Muhammad YunusTabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.

Case No.11 **CHANGE OF MANAGEMENT OF M/S CCL PHARMACEUTICALS (PVT) LTD, 62-INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000052 (FORMULATION)**

M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore under Drug Manufacturing License No. 000052 by way of (formulation)has submitted request for change in management of the firm as per SECP Form-29 & Form-A. The firm has deposited the fee of Rs.75000/- The detail of management of the firm is as under: -

Previous Management as per Form-29	New Management as per Form-A dated 13-11-2023
1. Mr. Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 2. Mr. Nadeem B. J. Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3. 3. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7. 4. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9.	1. Mr. Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 2. Mr. Nadeem B. J. Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3. 3. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7. 4. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9. 5. **Mr. Muhammad Ali Masood S/o Muhammad Masood Ullah Siddiqui CNIC No. 44201-7853423-9.**

Decision of the Central Licensing Board in 298th meeting

Based on Form-A dated 13-11-2023 issued by SECP, the Board considered and accepted for record the change of management of M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore under DML No. 000052 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per Form-29	New Management as per Form-A dated 13-11-2023
1. Mr. Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 2. Mr. Nadeem B. J. Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3. 3. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7. 4. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9.	1. Mr. Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 2. Mr. Nadeem B. J. Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3. 3. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7. 4. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9. 5. **Mr. Muhammad Ali Masood S/o Muhammad Masood Ullah Siddiqui CNIC No. 44201-7853423-9.**

Case No.12 CHANGE OF MANAGEMENT OF M/S SANTE (PVT) LTD, PLOT NO. A-97, S.I.T.E. SUPER HIGHWAY, KARACHI UNDER DML NO 000702 (FORMULATION).

Evaluator: - Mubashir Iqbal (DD-Lic)

M/s Sante (Pvt) Ltd, Plot No. A-97, S.I.T.E., Super Highway, Karachi submitted the documents for change in management under DML No.000702 (Formulation). The firm has deposited fee of Rs. 75,000/- for change of management. The detail is as under;

Previous Management	New Management as per Form-29 dated 21-12-2022
1. **Mr. Jawaid Hamid Nagi S/o Abdul Hamid Nagi CNIC No.42301-10919408-5.** 2. Syed Mohammad Anis Ur Rab S/o Syed Moiz Ur Rab CNIC No.422011-935195-9. 3. Mr. Anwer Saeed S/o Qazi Mehboob Ilahi CNIC No.421011-852920-7.	1. **Shabnam Jawaid Nagi W/o Jawaid Hamid Nagi CNIC No.42301-2809833-4.** 2. Syed Mohammad Anis Ur Rab S/o Syed Moiz Ur Rab CNIC No.422011-935195-9. 3. Mr. Anwer Saeed S/o Qazi Mehboob Ilahi CNIC No.421011-852920-7.

4. Mohammad Ali Mirza S/o Mirza Mohammad Hasan CNIC No.420008-319150-5. 5. Mr. Jeffrey Alderson Passport No.538644538. **6. Mr. Umer Daraz S/o Muhammad Bakhsh CNIC No.384039-920835-7.**	4. Mohammad Ali Mirza S/o Mirza Mohammad Hasan CNIC No.420008-319150-5. 5. Mr. Jeffrey Alderson Passport No.538644538.

Decision of the Central Licensing Board in 298th meeting

Based on Form-29 dated 21-12-2022 issued by SECP, the Board considered and accepted for record the change of management of M/s Sante (Pvt) Ltd, Plot No. A-97, S.I.T.E., Super Highway, Karachi under DML No. 000702 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management	New Management as per Form-29 dated 21-12-2022
1. Mr. Jawaid Hamid Nagi S/o Abdul Hamid Nagi CNIC No.42301-10919408-5. 2. Syed Mohammad Anis Ur Rab S/o Syed Moiz Ur Rab CNIC No.422011-935195-9. 3. Mr. Anwer Saeed S/o Qazi Mehboob Ilahi CNIC No.421011-852920-7. 4. Mohammad Ali Mirza S/o Mirza Mohammad Hasan CNIC No.420008-319150-5. 5. Mr. Jeffrey Alderson Passport No.538644538. **6. Mr. Umer Daraz S/o Muhammad Bakhsh CNIC No.384039-920835-7.**	**1. Shabnam Jawaid Nagi W/o Jawaid Hamid Nagi CNIC No.42301-2809833-4.** 2. Syed Mohammad Anis Ur Rab S/o Syed Moiz Ur Rab CNIC No.422011-935195-9. 3. Mr. Anwer Saeed S/o Qazi Mehboob Ilahi CNIC No.421011-852920-7. 4. Mohammad Ali Mirza S/o Mirza Mohammad Hasan CNIC No.420008-319150-5. 5. Mr. Jeffrey Alderson Passport No.538644538.

Case No.13 CHANGE OF MANAGEMENT OF M/S LUCKY CORE INDUSTRIES LIMITED, SS-3, HAWKES BAY ROAD, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000006 BY WAY OF (FORMULATION).

M/s Lucky Core Industries Limited, SS-3, Hawkes Bay Road, Karachi under Drug Manufacturing License No.000006 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-29.	New Management as per Form-9. Dated 29-04-2024
1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217.	1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217.

3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No. 4220153554927. 4. Mr. Muhammad SohailTabba S/o Muhammad YunusTabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.	**3. Mr. Ariful Islam S/o Amin Ul Islam CNIC No. 42301-1035569-1** 4. Mr. Muhammad SohailTabba S/o Muhammad YunusTabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.

Decision of the Central Licensing Board in 298th meeting

Based on Form-9 Dated 29-04-2024 issued by SECP, the Board considered and accepted for record the change of management of M/s Lucky Core Industries Limited, SS-3, Hawkes Bay Road, Karachi under DML No. 000006 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per Form-29.	**New Management as per Form-9. Dated 29-04-2024**
1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. **3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No. 4220153554927.** 4. Mr. Muhammad SohailTabba S/o Muhammad YunusTabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.	1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No. 4230131750787. 2. Syed Muhammad Shabbar Zaidi S/o Muhammad Tahawur Zaidi CNIC No. 4230117405217. **3. Mr. Ariful Islam S/o Amin Ul Islam CNIC No. 42301-1035569-1** 4. Mr. Muhammad SohailTabba S/o Muhammad YunusTabba CNIC No. 4200005683725. 5. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No. 4220164642473. 6. Mr. Jawed YunusTabba S/o Muhammad Yunus CNIC No. 4220121111047. 7. Amina Abdul Aziz Bawany w/o Abdul Aziz CNIC No. 4200030049910. 8. Mr. Adnan Afridi S/o Iqbal Afridi CNIC No. 4230130392303.

Case No.14 **CHANGE OF MANAGEMENT OF M/S AGP Limited, D-109, S.I.T.E., KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000044 BY WAY OF (FORMULATION).**

M/s AGP Limited, D-109, S.I.T.E., Karachi under Drug Manufacturing License No.000044 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-29.	New Management as per Form-29. Dated 04-01-2024
1. Muhammad Yar Hiraj S/o Sardar Allah Yar Hiraj CNIC No.35200-2240100-7 2. Mr. Tariq Moinuddin Khan S/o K.A-Moinuddin Khan CNIC No.42301-0725070-1. 3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed CNIC No.42301-3817237-5. 4. Mr. Muhammad Kamran Nasir S/o Muhammad Nawaz Nasir Adeeb CNIC No.35202-2435463-3. 5. Mr. Naved Abid Khan S/o Mohammad Abid Khan CNIC No.42301-1101720-5. 6. Mr. Zafar Iqbal Sobani S/o Muhammad HashimSobani CNIC No.42301-0714944-5. 7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No.42301-9154917-3. **8. Ms. Nusrat Munshi D/o Alauddin Munshi CNIC No.42301-7644816-8. [Director by virtue of CEO position]**	1. Mr. Mahmud Yar Hiraj S/o Sardar Allah Yar Hiraj (CNIC No. 35200-2240100-7) 2. Mr. Tariq Moinuddin Khan S/o K.A. Moinuddin Khan (CNIC No. 42301-0725070-1) 3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed (CNIC No. 42301-3817237-5) 4. Mr. Naved Abid Khan S/o Mohammad Abid Khan (CNIC No. 42301-1101720-5) 5. Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani (CNIC No. 42301-0714944-5) 6. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza (CNIC No. 42301-9154917- **7. Mr. Muhammad Kamran Nasir S/o Muhammad Nawaz Nasir Adeeb (CEO) (CNIC No. 35202-2435463-3)**

Decision of the Central Licensing Board in 298th meeting

Based on Form-29 Dated 04-01-2024 issued by SECP, the Board considered and accepted for record the change of management of M/s AGP Limited, D-109, S.I.T.E., Karachi under DML No. 000044 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per Form-29.	New Management as per Form-29. Dated 04-01-2024
1. Muhammad Yar Hiraj S/o Sardar Allah Yar Hiraj CNIC No.35200-2240100-7 2. Mr. Tariq Moinuddin Khan S/o K.A-Moinuddin Khan CNIC No.42301-0725070-1.	1. Mr. Mahmud Yar Hiraj S/o Sardar Allah Yar Hiraj (CNIC No. 35200-2240100-7) 2. Mr. Tariq Moinuddin Khan S/o K.A. Moinuddin Khan (CNIC No. 42301-0725070-1)

3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed CNIC No.42301-3817237-5. 4. Mr. Muhammad Kamran Nasir S/o Muhammad Nawaz Nasir Adeeb CNIC No.35202-2435463-3. 5. Mr. Naved Abid Khan S/o Mohammad Abid Khan CNIC No.42301-1101720-5. 6. Mr. Zafar Iqbal Sobani S/o Muhammad HashimSobani CNIC No.42301-0714944-5. 7. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza CNIC No.42301-9154917-3. **8. Ms. Nusrat Munshi D/o Alauddin Munshi CNIC No.42301-7644816-8. [Director by virtue of CEO position]**	3. Mr. Kamran Nishat S/o Shaikh Nishat Ahmed (CNIC No. 42301-3817237-5) 4. Mr. Naved Abid Khan S/o Mohammad Abid Khan (CNIC No. 42301-1101720-5) 5. Mr. Zafar Iqbal Sobani S/o Muhammad Hashim Sobani (CNIC No. 42301-0714944-5) 6. Mr. Muhammad Kamran Mirza S/o Muhammad Jamil Mirza (CNIC No. 42301-9154917- **7. Mr. Muhammad Kamran Nasir S/o Muhammad Nawaz Nasir Adeeb (CEO) (CNIC No. 35202-2435463-3)**

Case No.15 **CHANGE OF MANAGEMENT OF M/S RASCO PHARMA, 5.5-KM, NEAR ALI RAZA ABAD, HOLIDAY PARK, PLOT NO. 27-28, RAIWIND ROAD, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000175 BY WAY OF (FORMULATION).**

The case for change of management of M/s Rasco Pharma, 5.5-Km, near Ali Raza Abad, Holiday Park, Plot No. 27-28, Raiwind Road, Lahore under drug manufacturing license no. 000530 by way of (formulation) was placed before the CLB in its 292nd meeting held on 04-10-2023 and the Board considered and accepted for record the change of management of M/s Rasco Pharma, 5.5-Km, near Ali Raza Abad, Holiday Park, Plot no. 27-28, Raiwind Road, Lahore Under drug manufacturing license no. 000530 by way of (formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 : -

Previous management	New management (Meeting 292nd)
1. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1 2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7	1. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1 2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7 3. Mr. Zaid Jamshed S/o Jamshed Jamil, CNIC No. 35202-9206546-5

Accordingly, the firm was advised to submit NOC from for submission of Ministry of Narcotics vide letter No.F.1-18/2001-Lic (Vol-III) dated 30-11-2023.

Now the firm M/s Rasco Pharma, 5.5-Km, near Ali Raza Abad, Holiday Park, Plot no. 27-28, Raiwind Road, Lahore under drug manufacturing license no. 000530 by way of (formulation) has again applied for change of management as per partnership deed. The detail of management of the firm is as under: -
;

Previous management as per partnership deed	New management as per partnership deed
1. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1 2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7. **3. Mr. Zaid Jamshed S/o Jamshed Jamil, CNIC No. 35202-9206546-5**	1. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1 2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7

Decision of the Central Licensing Board in 298th meeting

Based on the partnership deed dated 04-10-2023 the Board considered and accepted for record the change of management of M/s Rasco Pharma, 5.5-Km, near Ali Raza Abad, Holiday Park, Plot No. 27-28, Raiwind Road, Lahore under DML No. 000530 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous management as per partnership deed	New management as per partnership deed
1. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1 2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7. **3. Mr. Zaid Jamshed S/o Jamshed Jamil, CNIC No. 35202-9206546-5**	1. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1 2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7

Case No.16 CHANGE OF MANAGEMENT OF M/S SEARLE IV SOLUTIONS (PVT) LTD., LAHOREUNDER DRUG MANUFACTURING LICENSE NO. 000586 BY WAY OF (FORMULATION).

M/s Searle IV Solutions (Pvt) Ltd., 1.5-KM, Manga Raiwind Road, Manga Mandi, District Lahore Drug Manufacturing License No.000586 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per Form-29.	New Management as per Form-29.
1. Mr. Muhammad Mansoor Dilawar S/o Muhammad Maqsood, CNIC No. 35202-6194911-3. 2. Mr. Khawaja Mushtaq Ahmed S/o Khawaja Noor Elahi, CNIC No.38403-5384555-5.	1. Mr. Raja Imran Hussain S/o Raja Qurban Hussain CNIC No.42301-4326511-7. 2. Syed Nadeem Ahmed S/o Syed Mumtaz Ahmed CNIC No.42301-0859989-9. 3. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No.42201-5080780-3.

3. Ms. Abida Mansoor W/o Muhammad Mansoor Dilawar, CNIC No.35202-7276319-6	

Decision of the Central Licensing Board in 298th meeting

Based on Form-29 dated 11-09-2023 issued by SECP, the Board considered and accepted for record the change of management of M/s Searle IV Solutions (Pvt) Ltd., 1.5-KM, Manga Raiwind Road, Manga Mandi, District Lahore under DML No. 000586 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per Form-29.	New Management as per Form-29.
1. Mr. Muhammad Mansoor Dilawar S/o Muhammad Maqsood, CNIC No. 35202-6194911-3. 2. Mr. Khawaja Mushtaq Ahmed S/o Khawaja Noor Elahi, CNIC No.38403-5384555-5. 3. Ms. Abida Mansoor W/o Muhammad Mansoor Dilawar, CNIC No.35202-7276319-6	1. Mr. Raja Imran Hussain S/o Raja Qurban Hussain CNIC No.42301-4326511-7. 2. Syed Nadeem Ahmed S/o Syed Mumtaz Ahmed CNIC No.42301-0859989-9. 3. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No.42201-5080780-3.

Case No.17 CHANGE OF TITLE AND MANAGEMENT OF M/S SIAM PHARMACEUTICALS PLOT NO. 217 INDUSTIRAL TRIANGLE KAHUTA ROAD ISLAMABAD.

M/s Cell Health Sciences Plot No. 217 Industrial Triangle Kahuta Road Islamabad, [*Formerly* Siam Pharmaceuticals,.] wherein the firm has submitted an application for change of title and management of the company under Drug Manufacturing License No.000711 by way of (Formulation). The firm details are as follows: -

Change of Title.

Previous Title of the firm.	Proposed Title of the firm dated 29-05-2024
M/S. SIAM Pharmaceutical Plot No.217 Industrial Triangle Kahuta Road Islamabad.	M/S.CELL HEALTH SCIENCES Plot No.217 Industrial Triangle Kahuta Road Islamabad.

Change of Management

Previous Management as per Partnership deed	New management as per Partnership deed dated 10-08-2023.
1. Mr. Abdul Hafeez S/o Khursheed Ahmad CNIC: 36302-5010906-1	1. Mr. Abdul Hafeez S/o Khursheed Ahmad CNIC: 36302-5010906-1

2. Mr. Kamran Rasheed S/o Abdul Rasheed CNIC: 35201-3140240-7 3. Mr. Muhammad Asif Chaudhry S/o Muhammad Faiz Chaudhry CNIC: 35202-6983391-3 4. Mr. Sadiq Hussain S/o Noor Muhammad Khan CNIC: 17301-1298527-9 5. Mr. Shahid Mahmood S/o Irshad Ahmad CNIC: 33100-8311735-9 **6. Mr. Qasim Farooq S/o Ansar Farooq CNIC: 37405-5587025-9**	2. Mr. Kamran Rasheed S/o Abdul Rasheed CNIC: 35201-3140240-7 3. Mr. Muhammad Asif Chaudhry S/o Muhammad Faiz Chaudhry CNIC: 35202-6983391-3 4. Mr. Sadiq Hussain S/o Noor Muhammad Khan CNIC: 17301-1298527-9 5. Mr. Shahid Mahmood S/o Irshad AhmadCNIC: 33100-8311735-9

Decision of the Central Licensing Board in 298th meeting

The Board considered and approved the new title of firm based on form D issued by Registrar of firms Islamabad, M/S.CELL HEALTH SCIENCES Plot No.217 Industrial Triangle Kahuta Road Islamabad.

Based on Partnership deed dated 10-08-2023, the Board considered and accepted for record the change of management of M/s Cell Health Sciences Plot No. 217 Industrial Triangle Kahuta Road Islamabad under DML No. 000711 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per Partnership deed	**Current management as per Partnership deed dated 10-08-2023.**
1. Mr. Abdul Hafeez S/o Khursheed Ahmad CNIC: 36302-5010906-1 2. Mr. Kamran Rasheed S/o Abdul Rasheed CNIC: 35201-3140240-7 3. Mr. Muhammad Asif Chaudhry S/o Muhammad Faiz Chaudhry CNIC: 35202-6983391-3 4. Mr. Sadiq Hussain S/o Noor Muhammad Khan CNIC: 17301-1298527-9 5. Mr. Shahid Mahmood S/o Irshad Ahmad CNIC: 33100-8311735-9 **6. Mr. Qasim Farooq S/o Ansar Farooq CNIC: 37405-5587025-9**	1. Mr. Abdul Hafeez S/o Khursheed Ahmad CNIC: 36302-5010906-1 2. Mr. Kamran Rasheed S/o Abdul Rasheed CNIC: 35201-3140240-7 3. Mr. Muhammad Asif Chaudhry S/o Muhammad Faiz Chaudhry CNIC: 35202-6983391-3 4. Mr. Sadiq Hussain S/o Noor Muhammad Khan CNIC: 17301-1298527-9 5. Mr. Shahid Mahmood S/o Irshad AhmadCNIC: 33100-8311735-9

Case No.18 CHANGE OF TITLE AND MANAGEMENT OF M/S AURIK PHARMACEUTICALS PLOT NO. 6 &7, STREET NO.S-9, NATIONAL INDUSTIRAL ZONE, RAWAT, RAWALPINDI.

M/s Aurik Pharmaceuticals (Pvt) Ltd., Plot No. 6 & 7, Street No. S-9, National Industrial Zone, Rawat, Rawalpindi, [*Formerly M/s Aurik Pharmaceuticals*.] wherein the firm has submitted an application for

change of title and management of the company under Drug Manufacturing License No.000802 by way of (Formulation). The firm details are as follows: -

Change of Title.

Previous Title of the firm	New Title of the firm as Certificate of Incorporation with SECP dated 30-05-2023.
M/s Aurik Pharmaceuticals Plot No. 6 & 7, Street No.S-9, National Industrial Zone, Rawat, Rawalpindi.	**M/s Aurik Pharmaceuticals (Pvt) Ltd.,** Plot No. 6 & 7, Street No.S-9, National Industrial Zone, Rawat, Rawalpindi

Change of Management

Previous Management as per Partnership deed	Current management as per Form-9 dated 23-05-024
1. **Mr. Muhammad Azam S/o Haji Muhammad Yaqoob CNIC No.61101-6487873-1.** 2. Mr. Saidal Khan Tareen S/o Saleh Muhammad CNIC No.51602-5407767-7. 3. Mr. Anwaradil Kakar S/o Malik Syed Muhammad CNIC No.54400-9696035-7. 4. Mr. Naqeeb Ur Rehman S/o Muhammad Akram CNIC No.54400-6844853-1.	**1. Mr. Zia Ud Din S/o Naseeb Ullah CNIC No.54400-9716415-9.** 2. Mr. Saidal Khan Tareen S/oSaleh Muhammad CNIC No.51602-5407767-7. 3. Mr. Anwaradil Kakar S/o Malik Syed Muhammad CNIC No. 54400-9696035-7. 4. Mr. Naqeeb Ur Rehman S/o Muhammad Akram CNIC No.54400-6844853-1.

Decision of the Central Licensing Board in 298th meeting

The Board considered and approved the new title of firm based on Certificate of Incorporation with SECP dated 30-05-2023, M/s Aurik Pharmaceuticals (Pvt) Ltd., Plot No. 6 & 7, Street No. S-9, National Industrial Zone, Rawat, Rawalpindi.

Based on Form-9 dated 23-05-024 issued by SECP, the Board considered and accepted for record the change of management of M/s Aurik Pharmaceuticals (Pvt) Ltd., Plot No. 6 & 7, Street No.S-9, National Industrial Zone, Rawat, Rawalpindi, under DML No. 000802 (Formulation) subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 (if applicable) as under. This approval shall not absolve company from its previous/pending liabilities/obligations of whatsoever nature. The change of management shall be effective from the change of management in SECP / Registrar of firms / sale deed.

Previous Management as per Partnership deed	Current management as per Form-9 dated 23-05-024
1. **Mr. Muhammad Azam S/o Haji Muhammad Yaqoob CNIC No.61101-6487873-1.** 2. Mr. Saidal Khan Tareen S/o Saleh Muhammad CNIC No.51602-5407767-7. 3. Mr. Anwaradil Kakar S/o Malik Syed Muhammad CNIC No.54400-9696035-7. 4. Mr. Naqeeb Ur Rehman S/o Muhammad Akram CNIC No.54400-6844853-1.	**1. Mr. Zia Ud Din S/o Naseeb Ullah CNIC No.54400-9716415-9.** 2. Mr. Saidal Khan Tareen S/oSaleh Muhammad CNIC No.51602-5407767-7. 3. Mr. Anwaradil Kakar S/o Malik Syed Muhammad CNIC No. 54400-9696035-7. 4. Mr. Naqeeb Ur Rehman S/o Muhammad Akram CNIC No.54400-6844853-1.

Case No.19 **TECHNICAL STAFF/QUALIFIED PERSON FOR SUPERVISION OF MANUFACTURING AS REQUIRED UNDER THE DRUGS (LICENSING, REGISTERING & ADVERTISING) RULES, 1976.**

Content of the case

i. Firm cases with discrepancies
ii. SOP for approval for Production and QC in-charge
iii. Proposed SOP for approval of QA in-charge

FIRM CASES WITH OBSERVATIONS

As per Rule 15 & 16 of Drugs (Licensing, Registering & Advertising) rules, 1976, the manufacture of Drugs shall be conducted under active directions and personal supervisions of qualified staff. Moreover, under rule 19 of the aforesaid Rules, any change in the technical staff shall be immediately notified to the Central Licensing Board, under intimation to the area Federal Inspector of Drugs.

The Central Licensing Board has delegated the power to Secretary, Central Licensing Board for approval of qualified staff. Application for appointment should be submitted prior or immediately for approval of qualified/Technical staff if the already approved qualified staff resign or terminated by the firm. As per approved guideline/SOP, the firms submit application for the approval of qualified staff (Production In-charge /Quality Control In-charge) as per following checklist through eapp.dra.gov.pk.

Sop for Approval of Production and Qc In-charge

As per approved guideline/SOP, the firms submit application for the approval of qualified staff (Production In-charge/Quality Control In-charge) as per following checklist through eapp.dra.gov.pk

1. Proper application on covering letter on letter head.
2. Prescribe fee of Rs. 75,00/- for proposed Production or Q.C In-charge .
3. Appointment letter.
4. Job acceptance letter by the appointee.
5. Copy of CNIC of appointee.
6. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
7. Registration certificate from Pharmacy Council (in case of Production In-charge).
8. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
9. Resignation / retirement of earlier Production In-charge/ QC In-charge.
10. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
11. Undertaking as whole time employee on stamp paper.

The proposed technical person is approved if fulfill the requirement of the Rule 16 of Drugs (L,R&A) Rules, 1976 in term of academic qualification and relevant experience, accordingly from the date of joining.

While evaluating the various applications for change of technical person division of licensing has noted certain serious observations as detailed below:

S. No.	Name of Firm	Application for	Observation(s)
1	M/s Wilshire Laboratories (Pvt) Ltd., 124/1 Industrial Estate KotLakhpat Lahore under DML No. 000232 (Formulation)	**Production In-charge** Syeda Anita Marium Mehdi W/o Syed Hassan Mehdi CNIC (B.Pharm).	The firm appointed Mr. Ali Asghar Ali as production In-chargeon a temporary basis with effect from March 4th , 2024 to March 18th, 2024, i.e., from the last day of Ms. Samra Farooq's tenure as the previously approved production In-chargeto the first day of the proposed production In-charge . The firm stated that to ensure continuity in production oversight during the recruitment process for a permanent replacement, they assigned temporary charge to Mr. Ali Asghar (Pharmacist) effective March 4, 2024 to March 18th, 2024. The firm submitted application for approval of Mr. Ali Asghar. However, as per document submitted by firm, Mr. Ali Asghar does not fulfill the requirement in term of relevant experience.
2	M/s Vetec Laboratories, Plot No. 20, Street No. S-5, RCCI, Rawat under DML No. 000894 (Formulation)	**Production In-charge**. Mr. Mubashir Iqbal S/o. Javid Iqbal (Pharm.D).	The previous production In-chargeMr. AmjadIkram resigned on March 24, 2022 and the proposed production In-chargecommenced duties on May 6, 2022. The firm submitted an **apology** for the delay. The firm reply was unsatisfactory, subsequently in light of power delegated by CLB in its 292nd meeting held on 4th October, 2023, Showcause was issued to the firm for rectification of the said clarification. In response to the show cause notice, the firm acknowledged receiving Show Cause Notice No: -F.1-34/2016-Lic, dated 13th March 2024. They expressed regret for the late submission of documents by their Technical Staff (Production Pharmacist) due to unforeseen circumstances. The firm apologized and requested approval for the documents of

			their Production In-charge , assuring that such delays would not recur in the future.
3	M/s Unexo Labs (Pvt) Ltd., 9.5-Km Sheikhupura Road Lahore, 000065 Formulation	**Production In-charge.** Mr. Nadeem Ahmad Akhtar s/o Ahmad din (Pharm-D)	The Firm was asked to clarify that the date of death of the previously approved Production In-charge was October 17, 2023, while the proposed production In-charge has been appointed as the new In-charge effective from April 15, 2024. What was the last working day of the deceased production In-charge. Additionally, what was the status of manufacturing activity during the said period? The firm has submitted their response which is reproduced as under: "The last working Date of the previous approved Production In-charge was 14th of October 2023 (Saturday). The new Production In-charge was selected and joined on the 20th of December 2023. The clearance from the current Production In-charge previous employer took till April 2024, hence the stated joining date of 15th April 2024, along-with the supporting documents. The absence of Production In-charge necessitates the temporary delegation of responsibilities to ensure continuous and efficient production operations. These duties are assumed by the individual who has sufficient experience and is well-versed in the production processes, regulatory requirements, and standard operating procedures (SoPs). From 17th October till 19th of December 2023, the production was being supervised by the Plant Manager (Pharmacist with experience of 25+ years) and the assistant Production In-charge (Experience of 09 years in Production)." Accordingly, firm was asked to submit another application with all relevant documents and application processing fee

			for approval of production In-charge (Plant manager) for the intended period. However, no application is received approval of production In-charge(Plant manager) so for.
4	M/s Citi Pharma (Pvt) Ltd., 3.5-Km Head Balloki Road Phool Nagar Kasur DML No. 000429 (Semi Basic Manufacture)	**Production In-charge** Khurshid Alam Duri Aman (B. Pharm)	The firm was asked to submit clarification for the gap 05/05/2023 to 02/03/2024 i.e., from last day of previous approved production In-charge and first day of proposed production In-charge. The firm replied that the previous Production In-charge resigned on May 5, 2023. They submitted an application for approval of the proposed Production In-charge Mr. Ahmad Raza S/O. Mr, Talib Hussain CNIC No. 35301-6382056-1 (BS Chemical Engineering) (Semi-Basic) on June 12, 2023, which was subsequently rejected by DRAP on February 29, 2024 (as he does not fulfill the requirement of the Rule 16 of Drugs (L, R&A) Rules, 1976 in term of relevant experience. The new proposed Production In-chargecommenced duty on March 2, 2024. We resubmitted an application for approval of the Proposed Production In-chargeon May 3, 2024.
5	M/s Pine Pharmaceuticals, Plot No. 40, Street No. S-4, RCCI, Industrial Estate, Rawat 000955 Formulation	<u>QC In-charge</u> Shafiullah S/o. Muhammad Atiq (Pharm-D)	The proposed production In-chargewas appointment in 1st January, 2023, while the application for approval was made in 1st May, 2024 and firm was ask to submit clarification in this regard. The replied that M/s Pine pharmaceuticals is new license facility, they are working in R&D till date, due to their negligence they have applied late for approval of technical staff (QC In-charge). they further submitted that this type of negligence will never happen again.

			In the light of decision of the Central Licensing Board (CLB) in its 292nd meeting held on 4th October, 2023, showcause was issued to the firm, accordingly. The firm's reply to the show cause notice indicated that the earlier QC In-chargehad resigned with only 15 days' notice. Due to the short time frame, hiring a new QC In-chargewas challenging. Instead, they assigned additional responsibilities to FazalUlRehman, the Deputy Quality Control Manager with 9 years of experience in the Quality Control department. During the 45-day gap between the resignation and the appointment of the new QC In-charge, all QC work was efficiently managed by the Deputy QCM, ensuring uninterrupted technical staff support. The attachment includes evidence of the Deputy Quality Control Manager's appointment and acceptance letter.
6	M/s Focus &RulzPharmceuticals (Pvt), 44-Industrial Triangle, kahuta Ltd, Islamabad. DML No. 000628 (Formulation)	<u>QC In-charge</u> Zia Ur Rehman Zia S/o. Khan Sherin (Msc. Chemistry)	The proposed technical person fulfills the requirement of the Rule 16 of Drugs (L, R&A) Rules, 1976 in term of academic qualification and relevant experience and may be approved. however, it is pertinent to mention that upon initial evaluation of application for approval of QC In-charge, it was observed that proposed QC In-chargewas appointment in 01-02-2024, while the previous QC In-chargehas resigned on 25-01-2024 and firm was asked to submit clarification regarding absence of QC In-chargeduring the period from 26-01-2024 to 31-01-2024 in this regard. *"From 26-01-2024 to 29-01-2024 Mr. Faisal was available in the office. On the 30th and 31st Mr. Faisal was available on call due to some issues which prevented him from joining the office. On the 30th and 31st our GM of Quality operation*

			(Muhammad Irfan Bhatti) handled office matters"
7	M/s N.S Pharma, Plot No.576-577, Sundar Industrial State, Lahore. DML No. 000869 (Formulation)	Production In-charge Mr. Naveed Ahmad S/o Abdul Majeed (Pharm-D)	The proposed qualified person fulfills the requirement of the Rule 16 of Drugs (L, R&A) Rules, 1976 in term of academic qualification and relevant experience. It is pertinent to mention here that the firm had appointed him w.e.f 18-08-2021 and filed application for his approval on 28-01-2022. Application was incomplete and shortcomings were conveyed to the applicant. Now, the firm has replied and completed the application, however, the firm is manufacturing without approved Production In-charge.
8	M/s N.S Pharma, Plot No.576-577, Sundar Industrial State, Lahore. DML No. 000869 (Formulation)	Quality Control In-charge Ms. NaurinaManzar D/o Manzar Qureshi (M. Sc Chemistry)	The proposed qualified person fulfills the requirement of the Rule 16 of Drugs (L, R&A) Rules, 1976 in term of academic qualification and relevant experience. It is pertinent to mention here that the firm had appointed him w.e.f 09-06-2021 and filed application for his approval on 28-01-2022. Application was incomplete and shortcomings were conveyed to the applicant. Now, the firm has replied and completed the application, however, the firm is manufacturing without approved Production In-charge .
9	M/s May & Baker (Pvt) Ltd, 43-Km Main Multan Road, Lahore. DML No. 000953 (Formulation)	Quality Control In-charge Mr. Muhammad Aslam S/o Muhammad Faazil (M. SC Analytical Chemistry)	The proposed qualified person fulfills the requirement of the Rule 16 of Drugs (L, R&A) Rules, 1976 in term of academic qualification and relevant experience. It is pertinent to mention here that previous QC In-chargeMs. Haniya Hussain resigned on 04-05-2024. The firm appointed Ms. Nadia Saeed on 05-05-2025 but she could not join.

			Then, Muhammad Aslam joined as QC In-charge w.e.f 07-05-2024.
10	M/s Ambrosia Pharmaceuticals, Plot No. 18, Street No. 9, National Industrial Zone, Rawat. DML No. 000561 (Formulation)	Quality Control In-charge Mr. Malik Zaheer Ahmed.	Previous QC In-chargeof the firm resigned w.e.f 16-11-2023. The firm promoted Ms. Isma Akhtar as QC In-chargew.e.f 16-11-2023 and submitted her application to Licensing Division for approval. Ms. Isma Akhtar resigned from the firm on 31-12-2023. However, the firm did not notify to this office of her resignation and appointment of Mr. Malik Zaheer Ahmed on 01-01-2024. The firm has clarified their position which is reproduced as under: "*Our previous QCM before Ms. Isma Akhter, Ms. NusratZaheen submitted her resignation on 15.10.2023 with 1-month notice period. Her resignation was accepted with her last day of working as per notice period on 16.11.2023. Ms. Isma Akhter who was already working with us was promoted as QCM effective 15.11.2023* *However, Ms. Isma Akhtar got a better opportunity and resigned on 30.11.2023 with 1-month notice period. Her resignation was accepted with her last day of working as per notice period on 31.12.2023. Mr. Malik Zaheer Ahmed was offered employment during this notice period and he joined us as QCM on 01.01.2024.* *There was some issue with our online portal on EApp because of which we were not able to file the application online. When*

			this issue was resolved we first filled the application of Ms. Isma Akhter and were awaiting approval of the same so that we could then file the application for Mr. Malik Zaheer Ahmed as QCM so that all records are updated with proper timeline of QCM to DRAP."

It is pertinent to mention that when an approved technical person resigns or terminated by the firm and there is no availability of suitable technical/qualified person to be appointed as permanent/regular technical person, and the provision for assigning charge to any technical person on **interim** basis is not provided under the Drug (Licensing, Registering and Advertising) Rules-1976.

Decision of the Central Licensing Board in 298th meeting

The Board considering the facts on the record and after detailed deliberation decided that

a. The proposed technical person is approved as they fulfill the requirement of the Rule 16 (or 15) of Drugs (L, R&A) Rules, 1976 in term of academic qualification and relevant experience, accordingly from the date of joining.
b. Biometric verification shall be submitted along application for approval of Production, QC and QA In-charges
c. Serve Show Cause Notice to the above firms (those firms to which showcase notice have not been issued) 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, 15/16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License of above firms may not be suspended or cancelled by the Central Licensing Board.
d. Refer the case of interim/temporary/alternative appointment of technical person to the DRAP Authority for is recommendations.
e. Refer the case for not complying the provision of Rule, 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 to the Legal affair division for their comments

Case No.20 PROPOSED SOP FOR APPROVAL OF QUALITY ASSURANCE IN-CHARGE

As per Rule 16 of (Licensing, Registering and Advertising) Rules, 1976, (notified vide S.R.O. 1460(I)/2019 dated Islamabad, the 27th November, 2019) that there shall be an independent head of quality assurance for the quality assurance of the drugs being manufactured who shall possess a degree in pharmacy with seven years' experience having minimum five years' experience in quality control and testing of drugs.

It is submitted that firms usually do not apply for approval of QA in-charge. It is proposed that we may issue a notification to all stakeholders to direct their member firms to get approval of QA In-charge as per following documents and prescribed fee.

1. Proper application on covering letter on letter head.
2. Prescribe fee of Rs. 75,00/-

3. Appointment letter.
4. Job acceptance letter by the appointee.
5. Copy of CNIC of appointee.
6. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
7. Registration certificate from Pharmacy Council
8. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
9. Resignation / retirement of earlier QA In-charge
10. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
11. Undertaking as whole time employee on stamp paper.

Decision of the Central Licensing Board in 298th meeting

The Board considering the facts on the record and after detailed deliberation decided that all Licensed unit shall apply for approval of Quality Assurance In-charge along with documents as per following checklist. The QA In-charge shall be an independent head of quality assurance of the drugs being manufactured who shall possess a degree in pharmacy with seven years' experience having minimum five years' experience in quality control and testing of drugs.

1. Proper application on covering letter on letter head.
2. Prescribe fee of Rs.75,00/-
3. Appointment letter.
4. Job acceptance letter by the appointee.
5. Copy of CNIC of appointee.
6. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
7. Registration certificate from Pharmacy Council
8. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
9. Resignation / retirement of earlier QA In-charge
10. Resignation or termination letter of appointee/proposed QA Incharge from the previous firm / promotion letter / transfer letter from the same firm.
11. Undertaking as whole time employee on stamp paper.

Case No.21 SITE VERIFICATION OF M/S VET-GLOBE PHARMACEUTICA, PLOT NO. A-29, EXPORT PROCESSING ZONE, RISALPUR, NOWSHERA

M/s Vet-Globe Pharmaceutical, Plot No. A-29, Export Processing Zone, Risalpur, Nowshera applied for site verification of the proposed Plot. After application was completed by the firm, Additional Director Peshawar DRAP was requested to conduct site inspection of proposed site and submit report regarding suitability of plot for establishment of pharmaceutical unit.

In response of this office letter dated 1st March, 2024. The Area Federal Inspector of Drugs has submitted report on 25-03-2024. The recommendation of the report is as under:

"The undersigned inspected the Plot No.A-29, Export Processing Zone, Risalpur, District Nowshera, Khyber Pakhtun Khwa, The said plot is proposed site for M/s Vet-Globe Pharmaceuticals. The specifications / dimensions of the plot are as under: -

Total Area: 30964 square feet.
East: Main Road of Export Processing Zone, Risalpur.
West: Link Road of Export Processing Zone, Risalpur.
South: Link Road of Export Processing Zone, Risalpur.
Environment: the plot is situated in the Industrial Estate i.e Export Processing Zone, Risalpur, District Nowshera. No pollution was found in its surrounding at the time of inspection.
***Note:** The firm has recently constructed an open hall having covered area of about 10,000 square feet and height of about 17 feet on the western side of the plot however the firm has sufficient open green field are on the eastern side of the plot as well.*
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, Registration & Advertising) Rules, 1976, the proposed premises is suitable to construct a pharmaceutical unit as of today.
Sketch of plot and its adjoining area is attached as desired "
In light of the above recommendation, the Federal Inspector of Drugs DRAP Peshawar was requested to give clear and candid recommendations for the proposed site in the decision taken in the 294th meeting of CLB. The Decision is as follows,
"It was also observed by the Board that some firms apply for site verification where a multipurpose grey structure is already constructed and it does not qualify for establishment of the pharma units. The Board also decided that in future, green field sites (without any construction) for pharmaceutical units will only be considered for approval. In certain cases, where public interest is involved, applications shall be considered on case to case basis."
In response to the above letter dated 13-05-2024, The Federal Inspector of Drugs has submitted their views/comments which are as under;
"It is submitted that firm has recently conducted an open hall having covered area of about 10,000 square feet and height of about 17 feet on the western side of the plot, however, the firm has sufficient open green field area on the eastern side of the plot as well. The said hall was not a multipurpose grey structure already constructed but recently constructed for the purpose of the pharmaceutical unit. It is therefore submitted that this may be considered on case to case basis as already submitted vide this office letter of even number dated 25th March, 2024. "

Decision of the Central Licensing Board in 298th meeting

The Board discussed that in 293rd Meeting held on 20-11-2023, CLB has already decided that green field sites without any construction for pharmaceutical units will only be considered for approval. The Board while considering the facts on the record and after detailed deliberation decided to reject the application for site verification application of M/s Vet-Globe Pharmaceutical, Plot No. A-29, Export Processing Zone, Risalpur, Nowshera.

Case No.22 SITE VERIFICATION REQUEST OF M/S PINNACLE BIOTECH (PVT.) LTD.KARACHI.

The Division of Licensing DRAP has received an application for site verification of M/s Pinnacle Biotech (Pvt.) Ltd. Karachi at Plot no. WH-01-20-A7-A8_Bin Qasim Industrial Park Karachi, Pakistan for the establishment of Pharmaceutical & Nutraceutical Plant. The plot size as per submitted documents is 10 Acres. The firm has provided following documents: i. Fee ii. Article of Association iii. Memorandum of Association iv. Form-A and Form-29 v. CNICs of Directors vi. Certificate of Incorporation vii. Land Documents with copy of Site Map.

The firm was asked which biotech products they intend to manufacture as the name of the firm could be misleading. As per memorandum of association, they intend to do businesses of non-pharma products, nutraceuticals etc. as well. The firm replied as follows:

"Thank you for your query regarding the biotech products that our firm intends to manufacture and clarification required in our Principal Line of Business. As per our Memorandum of Association, the firm is primarily focused on pharma products. However, we understand the need for clarification and would like to provide further information. While biotech products are indeed part of our future expansion plans, our immediate focus is on establishing a specialized plant for Cephalosporin products.
Moreover, for a comprehensive understanding of our firm's business activities, we would like to draw your attention to the SECP Attested Form-A and Form 29. These documents clearly indicate that Pinnacle Biotech (Pvt.) Ltd.'s principal line of business is in the field of Pharmaceuticals. I have attached the SECP Attested Form-A for your reference and clearance."
The matter is placed before the Central Licensing Board for deliberation and directions.

Decision of the Central Licensing Board in 297th meeting:
Board members discussed the request of the firm and decided that "biotech" title cannot be approved for a company that does not manufacture biotech products. The Board advised the firm to change the firm's name before site verification.

Reply of Firm:

With reference to the 297th Central Licensing Board meeting "Board members discussed the request of our firm and decided that "Biotech" title cannot be approved for a company that does not manufacture biotech products. The Board advised the firm to change the firm's name before site verification" We have already communicated you via official response of query dated April, 2024 that "Biotech products are indeed part of our future expansion plans, our immediate focus is on establishing a specialized plant for Cephalosporin products". We want to further clarify that Pinnacle Biotech (Pvt.) Ltd Intends to Manufacture Biotech Products which will be incorporated in next step which is Layout Plan & Section Approvals, currently we are seeking approval for Site verification only. Therefore, the current decision of the 297th Central Licensing Board meeting does not apply to us in this case, as we will manufacture biotech products as well. As you are already aware of extreme shortages of essentials and life-saving drugs, we aim to address and resolve national market shortages of these critical products in our new facility, which includes Insulins, Vaccines, Antibiotics, Anti-viral & Nutrition for Infants and Adults, which will be designed in compliance with WHO & FDA guidelines. We request you to please facilitate us to overcome national market shortages. Our project falls under Federal Government, Special Economic Zone & Board of Investment, we have huge pressure from Prime Minister Office & Ministry of Industries & Production to Initiate Project as soon as possible.

Decision of the Central Licensing Board in 298th meeting

After detailed deliberation, the Board, considering the facts on record, upheld its decision in the 297th meeting held on 2nd May, 2024 that "biotech" titles cannot be approved for companies that do not manufacture biotech products. The Board advised the firm to change the firm's name.

Case No.23 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000613 (FORMULATION) OF M/S GOODMAN LABORATORIES (PVT) LTD, RAWAT.**

Case Background:

M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat is licensed firm having DML No. 000613 by way of Formulation with validity of 20-03-2022. However, it is submitted that as per available record, application for renewal of DML No. 000613 by way of Formulation for the period 21-03-2022 to 20-03-2027 of M/s Goodman Laboratories (Pvt) Ltd, Rawat has not been received in Licensing Division.

It pertinent to mention that as per Rule 5 (6) of Drug (L, R & A) Rule, 1976 "if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application". Furthermore, Rule 5(3) states that "If the application for renewal of the License is made after the expiry of the period of the validity of the License, it shall be treated as a fresh application for the grant of a License."

In light of above, DML No. 000613 by way of formulation, M/s Goodman Laboratories (Pvt) Ltd, Rawat is no more valid.

Proceedings and Decision by the Central Licensing Board in 287th 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 as to why Drug Manufacturing License No 000613(by way of formulation) of M/s Goodman Laboratories (Pvt) Ltd, Rawat may not be declared cancelled by the Central Licensing Board as application for renewal of Drug Manufacturing License is not filed under Rule 5 and Rule 6 of Drug (Licensing, Registering and Advertising) Rule, 1976.

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

The Show Cause Notice was issued to M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat on 4th July, 2022.

The firm has replied that they have paid DML renewal fee of Rs. 75,000/- within due date on 18-03-2022 and submitted In-Process data through PIRIMS and still waiting for approval.

A letter of Personal hearing has been issued on 6th October, 2022.

Proceedings and Decision by the Central Licensing Board in 288th meeting:

No person appeared on behalf of the firm. The Board considering the facts on record and after thread bare deliberation decided to cancel the Drug Manufacturing License No. 000613 (Formulation) of M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat as the Drug Manufacturing License No. 000613 (Formulation) is no more valid as under Rule 5 (6) of Drug (L, R & A) Rule, 1976.

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

DML cancellation letter was issued to the firm on 19th December, 2022. The firm then filed appeal against decision of CLB. The Appellate Board considered the case of M/s Goodman Laboratories (Pvt) Ltd, Islamabad in its 163rd meeting held on 20th December, 2022 and decided as under:

"The Drug Manufacturing License (DML) of the appellant was cancelled by the Central Licensing Board (CLB) in its 288th meeting held on 18.10.2022 due to non-submission of renewal application within prescribed time under the Drugs (Licensing, Registering and Advertising) Rules, 1976.
The appellant argued that the prescribed fee along with application (Form 1A) for renewal of DML was submitted timely on 18.03.2022 while the licensing expired on 22.03.2022. However, the DML has been erroneously cancelled by the CLB. It was further submitted that the appellant would be satisfied if the case is remanded back to the CLB for reconsideration after verification of record and the operation of the impugned decision be suspended till that time."

Admin Division of DRAP verified that M/s Goodman Labs. submitted its application of renewal of DML in R&I of DRAP on 18-March-2022.

Licensing Division evaluated the application of the firm received on 27-06-2022 and following shortcomings has been noted:

i. Properly filled, signed and stamped Form-1A along with its all annexures.
ii. Updated nothing due certificate regarding CRF.
iii. Detail of management, if any change, file application for change of management.
iv. Duly attested copies of CNIC of all Directors.
v. Approval letters of Production In-charge& Quality Control In-charge .
vi. Approval letter of sections approved by CLB, if not available, file application for regularization of layout plan.
vii. Latest certified true copy of Form-29 issued by SECP (Original).

Decision of the Central Licensing Board in 296th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 19 , Schedule B under Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000613 (by way of formulation) of M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause Notice was issued to the firm on 03-06-2024.
The firm has replied but application for renewal of DML is still deficient of following documents:

i. Updated nothing due certificate regarding CRF.
ii. Duly attested copies of CNIC of all Directors.
iii. Approval letter of sections approved by CLB, if not available, file application for regularization of layout plan.
iv. Latest certified true copy of Form-29 issued by SECP (Original).

A letter of personal hearing has been served to the firm on 19-07-2024.

Mr. Muhammad Bashir, Judge Accountability Court-I Islamabad in view of the statement of Investigation Officer and record placed on file and orders of the Director General NAB who is representative of Chairman NAB, property mentioned in para-4 of the petition which is noted below **stands frozen through attachment till final disposal of the case & orders of Chairman NAB stands confirmed:**

Goodman Laboratories, Plot No. 5. Road S-5, RCCI.

Proceedings and Decision by the Central Licensing Board in 298th meeting:

The Board observed that the assets of the firm has been taken over by the National Accountability Bureau Rawalpindi. Mr. Zubair Saeed (Production In-charge) and Syed Shahram (Director Operations) of the firm appeared before the board. Both confirmed that the firm is paying rent to the NAB. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000613 by way of Formulation of M/s Goodman Laboratories (Pvt) Ltd, Plot No. 5, Street No. S-5, National Industrial Zone, Rawat till fulfilment of codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No.24 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000108 (FORMULATION) OF M/S IRZA PHARMA (PVT) LTD, 10.2 KM, SHEIKHUPURA ROAD, LAHORE.**

Case Background:

1	M/s. Irza Pharma (Pvt.) Ltd, 10.2 Km Sheikhupura Road, Lahore. DML No. 000108 (Formulation). Period: Commencing on 12-07-2019 ending on 11-07-2024.	25-11-2022	**Good**	1. Dr. Zaka Ur Rehman, Chief Operating Officer, PDTRC, Lahore. 2. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3. Hafiz Sanaullah Babar, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: Keeping in view the manufacturing facility like, building, production, machinery, Equipment in Quality Control and microbiology laboratory, testing facilities, utilities and documentation reviewed, the panel of inspectors **recommends** the renewal of Drug Manufacturing License and Regularization of Layout Plan to M/s. Irza Pharma (Pvt) Ltd, 10.2 Km Sheikhupura Road, Lahore for the following sections only: i. Tablet (General) Section ii. Capsule (General)Section. iii. Tablet (Steroid) Section iv. Syrup Section (General). v. Capsule (Penicillin) Section			

	vi. Dry Powder Suspension (Penicillin) Section. vii. Liquid External Preparation Section. viii. Capsule (Cephalosporin) Section. ix. Dry Powder Suspension (General) Section. x. Dry Powder Suspension (Cephalosporin) Section. And the firm also given undertaking for the following sections which are under revamping/renovation (copy of undertaking is attached) and they will not start production till the inspection of these sections: i. Liquid Injectable (Ampoule) (General) ii. Liquid Repacking. iii. Drop Section. iv. Ointment (General) Decision of the Central Licensing Board in 289th meeting The Board considered and approved the grant of renewal of DML No. 000108 by way of Formulation in the name of M/s. Irza Pharma (Pvt) Ltd, 10.2 Km Sheikhupura Road, Lahore on the recommendations of the panel of experts for the period Commencing on Commencing on 12-07-2019 ending on 11-07-2024. for the following sections: - i. Tablet (General) Section ii. Capsule (General)Section. iii. Tablet (Steroid) Section iv. Syrup Section (General). v. Capsule (Penicillin) Section vi. Dry Powder Suspension (Penicillin) Section. vii. Liquid External Preparation Section. viii. Capsule (Cephalosporin) Section. ix. Dry Powder Suspension (General) Section. x. Dry Powder Suspension (Cephalosporin) Section. The Board further decided that to serve the Show Cause to the firm and stop the production till rectifications of the observation made during inspection for following sections: i. Liquid Injectable (Ampoule) (General) ii. Liquid Repacking. iii. Drop Section. iv. Ointment (General)

Proceedings of Licensing Division in the light of decision of Central Licensing Board:

The Show Cause Notice was issued to the firm on 13th March, 2023.

The firm has replied that these sections were not inspected as they were under maintenance. Now, they have completed the renovation and requested to constitute panel for inspection of Liquid Injectable (Ampoule) Section (General) and Drops (General) Section.

Proceedings and Decision by the Central Licensing Board in 298th meeting:

The Board considering the facts on the record and after detailed deliberation decided to give an opportunity of personal hearing to the firm in next meeting of the Board.

Case No.25 **GRANT OF NEW DRUG MANUFACTURING LICENSE M/S NUTRION (PVT.) LTD, PLOT NO. 186, 192, 193/S, NEW INDUSTRIAL ESTATE, MIRPUR, AJ&K.**

It is submitted that case of grant of DML by way of formulation of M/s Nutrion (Pvt.) Ltd, Plot No. 186, 192, 193/S, New Industrial Estate, Mirpur, AJ&K was considered by f the Central Licensing Board in 292nd meeting held on 4th October, 2023. The Board decided as under;

"The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Nutrion (Pvt) Ltd, Plot No. 186, 192, 193/S, New Industrial Estate, Mirpur, AJ&K on the recommendations of the panel of experts for the following section subject to confirmation of necessary equipment specially FTIR, TOC analyzer, HPLC Stability Chamber etc;

1. Liquid Syrup (General-Vet) Section."

Now the firm has requested that due to some financial issues they are unable to purchase FTIR at the movement and they will purchase within 8-9 months. Furthermore, they have stated that M/s Nutrion (Pvt) Ltd, Plot No. 186, 192, 193/S, New Industrial Estate, Mirpur, AJ&K has already signed MOU/agreement with M/s. Medifine Pharmaceutical Pvt. Ltd, AJK to entertain the testing facilities for their liquid veterinary section only (Copy attached). They have further requested for issuance of DML.

Decision of the Central Licensing Board in 298th meeting

The Board considering the facts on the record and after detailed deliberation decided to not accede request of the firm.

Case No.26 **RENEWAL OF M/S ENGLISH PHARMACEUTICALS INDUSTRIES, LAHORE**

The case for renewal of DML of M/s English Pharmaceuticals Industries, Link Kattar Band Road, Thokar Niaz Baig, Lahore was presented in 296th meeting of CLB held on 02-04-2024 and decided as under;

11	M/s English Pharmaceuticals Industries, Link Kattar Band Road, Thokar Niaz Baig, Lahore. DML No.000339 (Formulation). **Period:** Commencing on 19-07-2024 ending on 18-07-2029. *Evaluator: - Zunaira Faryad (AD-Lic)*	13.03.2024	Good	1. Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Muhammad Arif Ch. Director (Biologicals) DRAP, Islamabad. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore
	Production In-charge	Syeda Anita Marium Mehdi W/o Syed Hassan Mehdi CNIC No. 54400-0446845-2 (Pharm-D)		
	Quality Control In-charge	Mr. Muhammad Asif Chattha S/o Muhammad Sadiq Chattha CNIC No.36501-1821295-9.(M.Sc. Chemistry)		
	Recommendations of the panel: - Keeping in view the manufacturing facilities like building and availability of HVAC system, sanitation, production machinery, equipment in quality control/testing facilities, technical personnel and documentation, the panel of inspectors **recommended** the renewal of DML to			

	M/s English Pharmaceuticals Industries, Link Kattar Band Road, Thokar Niaz Baig Multan Road, Lahore for the following sections: 1. Tablet Section (General Antibiotic) 2. Oral Liquid Section (General) 3. Oral Dry Suspension Section (General) 4. Oral Dry Powder Suspension Section (Cephalosporin) 5. Capsule Section (Cephalosporin) 6. Dry Powder Injection Section (Cephalosporin) 7. Liquid Injectable (Ampoule) Section (General) 8. Liquid Injection SVP (General). 9. Sterile Dry Powder Injection Section (Penicillin) 10. Dry Powder Injection Vial Section (General) 11. Capsule Section (General). **Decision of the Central Licensing Board in 296th meeting** The Board considered and approved the grant of renewal of DML No. 000339 by way of Formulation in the name of M/s English Pharmaceuticals Industries, Link Kattar Band Road, Thokar Niaz Baig, Lahoreon the recommendations of the panel of experts for the period commencing on 19-07-2024 ending on 18-07-2029 for the following sections. i. Tablet Section (General Antibiotic) ii. Oral Liquid Section (General) iii. Oral Dry Suspension Section (General) iv. Oral Dry Powder Suspension Section (Cephalosporin) v. Capsule Section (Cephalosporin) vi. Dry Powder Injection Section (Cephalosporin) vii. Liquid Injectable (Ampoule) Section (General) viii. Liquid Injection SVP (General). ix. Dry Powder Injection Vial Section (General) x. Capsule Section (General). Accordingly, the Board decided to defer the renewal of the following section and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for penicillin section. 1. Sterile Dry Powder Injection Section (Penicillin)

Now, the firm has replied that they are already establishing segregated dedicated facility. Layout plan of segregated and dedicated Penicillin section is already approved. Furthermore, construction of the section is in progress and they will shift to the new facility within a year.

Decision of the Central Licensing Board in 298th meeting

The Board considering the facts on the record and after detailed deliberation decided to approve the grant of renewal of DML No. 000339 by way of formulation in the name of M/s English Pharmaceuticals Industries, Link Kattar Band Road, Thokar Niaz Baig, Lahore on the recommendations of the panel of experts for the period commencing on 19-07-2024 ending on 18-07-2029 for the following section.

1. Sterile Dry Powder Injection Section (Penicillin)

As well, the Board advised the firm to move into a dedicated segregated Penicillin facility as soon as possible, which should not take more than two years.

Case No.27 **CORRECTION IN MINUTES OF 271st MEETING OF CLB IN THE CASE OF GRANT OF ADDITIONAL SECTIONS OF M/S B.J PHARMACEUTICALS, LAHORE.**

The case for grant of additional sections of M/s B.J Pharmaceuticals., 18-Km, Lahore-Sheikhupura Road, Lahore was presented in 271st meeting of CLB held on 12th September, 2019 and decided as under;

M/s B.J Pharmaceuticals, Mandiali Stop, Bhattianwala Road, 18-Km, Lahore Sheikhupura Road, Lahore. DML No. 000770(Formulation) **Section / Facility (03)** 1. Capsule (Cephalosporin) Section. 2. Oral Dry Powder (Suspension) Section. 3. Ware House (Cephalosporin) Section	**16-05-2019**	**Good**	1. Dr. Ikram-ul-Haq, Member CLB. 2. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.
Recommendations of the panel: - Keeping in view the observations, the members of the panel are of the opinion to recommend the grant of following new additional section of Capsule (Cephalosporin) Section, Oral Dry Powder (Cephalosporin) Section and Ware House (Cephalosporin) Section to M/s B.J Pharmaceuticals, Mandiali Stop, Bhattianwala Road, 18-Km, Lahore Sheikhupura Road, Lahore as per layout plan approved by DRAP. **Decision by the Central Licensing Board in 271st meeting** The Board considered and approved the grant of following three additional sections/ facility in the name of M/s B.J Pharmaceuticals, Mandiali Stop, Bhattianwala Road, 18-Km, Lahore Sheikhupura Road, Lahore. **Section / Facility (03)** 1. Capsule (Cephalosporin) Section. 2. Oral Dry Powder (Suspension) Section. 3. Ware House (Cephalosporin) Section			

Now, the firm has requested for correction in title of Oral Dry Powder Suspension section as the firm got layout plan approval of Oral Dry Powder Suspension (Cephalosporin) section.

Decision of the Central Licensing Board in 298th meeting:

The Board considered the case and approved the correction in title of section from Oral Dry Powder Suspension to Oral Dry Powder Suspension (Cephalosporin) section.

Case No.28 **CORRECTION IN MINUTES OF 296TH MEETING OF CLB IN THE CASE OF RENEWAL OF DML OF M/S SAFFRON PHARMACEUTICALS (PVT) LTD., 19-KM, SHEIKHUPURA ROAD, FAISALABAD)**

The case for renewal of DML of M/s Saffron Pharmaceuticals (Pvt) Ltd., 19-Km, Sheikhupura Road, Faisalabad under DML No.000616 (Formulation) was presented in 296th meeting of CLB held on 02-04-2024 and decided. The Board approved the grant of regularization and renewal of DML No. 000616 by way of Formulation in the name of M/s Saffron Pharmaceuticals (Pvt) Ltd., 19-Km, Sheikhupura Road, Faisalabadon the recommendations of the panel of experts for the period commencing on 12-04-2022 and ending on 11-04-2027 for the following sections (including other sections)

i. Cream/ Ointment/ Gel Section (General)

M/s Saffron Pharmaceuticals (Pvt) Ltd., 19-Km, Sheikhupura Road, Faisalabad submitted application and has requested for correction in the title of the above section as follow

Title of section mention in the minutes	Correct title of the section
Cream/ Ointment/ Gel Section (General)	Cream/ Ointment/ Gel/lotion Section (General)

It is pertinent to mention that title of the section was inadvertently mentioned as Cream/ Ointment/ Gel Section (General) instead Cream/ Ointment/ Gel/Lotion Section (General) in agenda and minutes of the of 296th meeting of CLB held on 02-04-2024. Subsequently letter was issued with section title as Cream/ Ointment/ Gel Section (General).

Decision of the Central Licensing Board in 298th meeting:

The Board considered the case and approved the correction in title of section from Cream/ Ointment/ Gel Section (General) to Cream/ Ointment/ Gel/ with separate filling line for Lotion (General)

Case No.29 **CORRECTION IN RNEWAL OF DRUG MANUFACTURING LICENSE OF M/S W. WOODWARD PAKISTAN (PVT) LTD, KARACHIUNDER DRUG MANUFACTURING LICENSE NO. 000042 BY WAY OF (FORMULATION).**

M/s W. Woodward Pakistan (Pvt) Ltd., F-275, S.I.T.E., Karachi. DML No. 000042 (Formulation). **Period:** Commencing on 13-02-2021 ending on 12-02-2026.	**20-02-2024**	**Good**	1. Dr. Saif-ur-RehmanKhattak, Additional Director, CDL, DRAP, Karachi. 2. Mr. Abdul Rasool Sheikh, Additional Director (E&M), DRAP, Karachi. 3. Dr. Shoaib Ahmed, FID-III, DRAP, Karachi.

Evaluator: - Mubashir Iqbal (DD-Lic)			
QC In-charge	Ms. Anjum Basit D/o M.A Basit Siddiqui (Pharm-D) CNIC No.42201-0319698-6.		
Production In-charge	Syed Kamranuddin Ahmed (B.Pharm)		

Recommendations of the panel:

"M/s W.Woodward Pakistan (Pvt) Ltd., F-275, S.I.T.E., Karachi was inspected as per DRAP letter No.F.2-36/85-Lic (Vol-V) dated 06th September, 2021 and 06th May 2021 in connection with grant of Renewal of DML & Regularization of layout.

***Following are the observations**:*

The firm was found built as per layout plan approved by the DRAP authorities Islamabad vide letter No.F.2-36/85-Lic. (Vol-V), No.F.1-65/84-Lic (Vol-III) (M211) on dated 27th July, 18th December 2017 and 30th October 2008. All production, quality control, research and development laboratory, warehouse and storage facilities were observed well maintained and continuous monitoring system were seen in placed. Equipment were found calibrated and qualified, in general. Adequate technical personnel were available at the site and observed well conversant with the requirements of the cGMP standards. An appropriate & adequate HVAC system operating air process according to grades of rea. The facility is segregated, dedicated and fully contained for Cephalosporin products with access control for staff, who have been assigned responsibilities only for Cephalosporin facility. Key staff has required qualification, experience and skill according to the position and job description for employees.

Based on the people met and the documents reviewed and considering the findings of the inspecting Panel M/s W. Woodward Pakistan (Pvt.) Ltd., F-275, S.I.T.E., Karachi is considered to be designed, established and operating at an acceptable level of compliance of GMP requirements. Therefore, the panel unanimously ***recommends*** *the approval for the grant of Renewal of their DML no. 000042 by way of formulation and regularization of old section with reference to the DRAP letter No. F.2-36/85-Lic (Vol-V) dated 6th September 2021 & 6th May 2021.*

Following are the sections mentioned in the above referred panel letters;

i. Tablet (General-Antibiotic)
ii. Capsule (Cephalosporin)
iii. Dry Powder Suspension (Cephalosporin)
iv. Cream/ Ointment (General-Antibiotic)
v. Sachet (General)
vi. Oral Liquid Syrup (General) – Regularization
vii. Capsule (General) – Regularization
viii. Dry Powder Suspension (General) – Regularization

Decision of the Central Licensing Board in 296th meeting

The Board considered and approved the grant of regularization and renewal of DML No. 000042 by way of Formulation in the name of M/s W. Woodward Pakistan (Pvt) Ltd., F-275, S.I.T.E., Karachi on the recommendations of the panel of experts for the period commencing on 13-02-2021 ending on 12-02-2026 for the following sections subject to verification of necessary testing equipment:

i. Tablet (General)
ii. Capsule (Cephalosporin)
iii. Dry Powder Suspension (Cephalosporin)
iv. Cream/ Ointment (General)

v.	Sachet (General)
vi.	Oral Liquid Syrup (General) – Regularization
vii.	Capsule (General) – Regularization
viii.	Dry Powder Suspension (General) – Regularization

The firm has stated that one of their section "Additional Oral Liquid Syrup (General) First Floor" is missing which might be a typo error. The firm has submitted missing section evaluation form duly signed and recommended by the panel members as per direction of Central Licensing Board along with list of equipment verified by Area FID.
Firm has submitted the request that kindly incorporate missing section.

Decision of the Central Licensing Board in 298th meeting

The Board while considering the facts on the record observed that the panel of inspectors has not listed approved sections in their recommendation in inspection report. The Board decided to refer the application to Additional Director DRAP Karachi to verify the two sections i.e. Oral Liquid Syrup-I (General) and Oral Liquid Syrup-II (General) along with other approved sections. The Board authorized the Chairman CLB to issue the renewal after verification.

Case No.30 DEDICATED AND SELF-CONTAINED FACILITIES FOR THE PRODUCTION OF PARTICULAR CLASSES OF DRUGS

The firm M/S Star Laboratories submitted application for extension of following sections on 30/08/2023

1. Injectable Hormone Section

It is pertinent to mention that Schedule B of the Drugs (Licensing, Registering &Advertising) Rules, 1976 states that dedicated and self-contained facilities for the production of specific drugs must be provided. These facilities are in addition to general facilities and are necessary for highly sensitizing materials (such as penicillin), biological preparations (including live microorganisms), cytotoxic substances, radiopharmaceuticals, veterinary immunological preparations, sterile products, and other highly active pharmaceutical products or antibiotics. The Central Licensing Board identifies these requirements at any stage to minimize the risk of serious medical hazards due to cross-contamination.
Furthermore, the Board decided during its 296th meeting to advise firms already manufacturing biological preparations (eg: live microorganisms), Vaccines and hormonal preparations/products in the same building to promptly shift to a segregated or dedicated facility responsible for producing biological preparations (eg: live microorganisms), Vaccines and hormonal preparations. Furthermore, the Board also decided to defer the renewal of the related section(s) until compliance with the above requirements is ensured.

Therefore, the Committee on Layout plan advised the firm to submit revised proposed LOP in the light of decision of Central Licensing Board in its 296th meeting that segregated and dedicated facility which implies an entire dedicated building, is required for hormonal manufacturing section.

The firm submitted their reply that a dedicated facility may not always be necessary to have separate building. Our subject facility for manufacturing of hormonal products is absolutely dedicated

by all means. It is designed to ensure the control of cross-contamination probability up to the practically possible residual levels. Area designated for hormonal products is separated by complete physical barrier with separate entrance, staff facilities, material storage, testing facilities and air handling system. The firm submitted following references

A. **Annex 3 WHO good manufacturing practices for pharmaceutical products containing hazardous substances (World Health Organization WHO Technical Report Series, No. 957, 2010),** Facilities should be designed and operated in accordance with the main GMP principles, as follows:
    1. to ensure quality of product;
    2. to protect the operators from possible harmful effects of products containing hazardous substances;
    3. to protect the environment from contamination and thereby protect the public from possible harmful effects of products containing hazardous substances.
    4. ***The production of certain products containing hazardous substances should generally be conducted in separate, dedicated, self-contained facilities. These self-contained facilities may be in the same building as another facility but should be separated by a physical barrier and have, e.g. separate entrances, staff facilities and air-handling systems. The extent of the separation from adjacent facilities and sharing of common services should be determined by risk assessment.***
    5. In general, these manufacturing facilities should be regarded as containment facilities.
    6. The effective operation of a facility may require the combination of some or all of the following aspects:
        i. appropriate facility design and layout, with the emphasis on safely containing the materials being handled. Manufacturing processes using closed systems or barrier technology enhance operator and product protection;
        ii. manufacturing process controls including adherence to standard operating procedures (SOPs);
        iii. appropriately designed environmental control systems (ECS) or heating, ventilation and air-conditioning (HVAC);
        iv. extraction systems;
        v. personal protective equipment (PPE);
        vi. appropriate de-gowning and decontamination procedures;
        vii. industrial hygiene (monitoring staff exposure levels);
        viii. medical surveillance (monitoring staff exposure levels);
        ix. administrative controls

B. The WHO Guideline to the inspection of hormone product manufacturing facilities", QAS/08.256, 2008 stated that Hormone facilities should be separate, dedicated facilities and should not form part of any other non-hormone facility. They may be in the same building as another facility but should be separated by a physical barrier and have separate entrances, staff facilities, air handling systems, etc.

On the other hand, in terms of GMP requisites, paragraph 4.1 of the same handbook reads that not all hormone products are equally potent and that a risk assessment should be carried out to determine the potential hazards to operators and to the environment.

It is pertinent to mention that the the Central Licensing Board (CLB) in its 296th meeting held on 2nd April, 2024 decided to defer the renewal of the following section of the respective firms and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for hormonal preparations.

S. No.	Manufacturer	Section
1	M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi. DML No. 000327 (Formulation).	1. Dedicated Sterile Liquid Injectable Veterinary (Hormone/Steroid)
2	M/s. Hansel Pharmaceuticals (Pvt) Ltd, Plot No.2, Pharma City, 30-Km Multan Road, Lahore. DML No.000581 (Formulation).	1. Tablet Section (Hormone) 2. Liquid Injectable Section (Hormone)
3	M/s Wnsfeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar. DML No. 000610 (Formulation)	1. Tablet (Steroidal Hormone) Section
4	M/s Saffron Pharmaceuticals (Pvt) Ltd., 19-Km, Sheikhupura Road, Faisalabad. DML No.000616 (Formulation).	1. Tablet Section (Steroidal-Hormone)

Decision of the Central Licensing Board in 298th meeting:

After careful consideration of the facts on record and a thorough deliberation, the Board has come to the following decision:

1. Products containing androgens, contraceptives shall be manufactured in the segregated dedicated facilities (Separate building).
2. Products containing hormonal substances (other than androgens and contraceptives) may be manufactured in the same building, provided certain conditions are met. Separate entries, HVAC systems, and other precautions should be taken to ensure complete segregation.

In the future, the Board will closely monitor any updates published by any relevant reference regulatory authorities or the World Health Organization (WHO). These updates may warrant further decisions by the Board, depending on the nature and content of the information. By adhering to these guidelines, the Board aims to ensure the safety and integrity of products containing hormonal substances while allowing for their manufacture in the same building. The decision takes into account the specific circumstances

and risks associated with such products. It is important to emphasize that the Board will continue to review and reassess the situation as new information becomes available. Any updates to the regulatory framework or scientific discoveries may require adjustments to the Board's decision.

In the Light of above decision, the also decided to approved the grant of renewal of DML of following firm for following sections

S. No.	Manufacturer	Section
1	M/s Manhattan Pharma, 209/3-B, Sector 5, Korangi Industrial Area, Karachi. DML No. 000327 (Formulation).	1. Dedicated Sterile Liquid Injectable Veterinary (Hormone/Steroid)
2	M/s. Hansel Pharmaceuticals (Pvt) Ltd, Plot No.2, Pharma City, 30-Km Multan Road, Lahore. DML No.000581 (Formulation).	1. Tablet Section (Hormone) 2. Liquid Injectable Section (Hormone)
3	M/s Wnsfeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar. DML No. 000610 (Formulation)	1. Tablet (Steroidal Hormone) Section
4	M/s Saffron Pharmaceuticals (Pvt) Ltd., 19-Km, Sheikhupura Road, Faisalabad. DML No.000616 (Formulation).	1. Tablet Section (Steroidal-Hormone)

Case No.31 SITE VERIFICATION OF M/S ROBUST PHARMACEUTICALS (PVT.) LIMITED, FAISLABAD

M/s. Robust Pharmaceuticals (pvt.) Limited, Plot No 93-94, Allama Iqbal Industrial City, Faisalabad, has applied for site verification of proposed plot.

Upon evaluation it was observed that the plot is allocated to another firm, namely M/s, Ahmad Saeed Textile (Pvt)Ltd.). The firm was asked to submit land documents on the name of firm i,e., Robust Pharmaceuticals (Pvt.) Limited.

The firm replied that the plot (Total 5 acres) is allocated to namely M/s Ahmad Saeed Textile (Pvt.) Limited and M/s Robust Pharmaceuticals (pvt.) Limited is a subsidiary of M/s Ahmad Saeed Textile (Pvt.) Limited, 60 percent shareholding of Robust Pharmaceuticals (pvt.) Limited is with M/s Ahmad Saeed Textile (Pvt.) Limited.

Decision of the Central Licensing Board in 298th meeting

The Board considering the facts on the record and after detailed deliberation decided to reject the application for site verification application of M/s. Robust Pharmaceuticals (pvt.) Limited, Plot No 93-94, Allama Iqbal Industrial City, Faisalabad,

Case No.32 SITE VERIFICATION OF M/S OSUM PHARMACEUTICALS, RAWALPINDI.

M/s Osum Pharmaceuticals, 0.5-Km, SS Road, Mandra, Rawalpindi, has applied for site verification of proposed plot. After application was completed by the firm, Additional Director DRAP Islamabad was requested to conduct site inspection of proposed site and submit report regarding suitability of plot for establishment of pharmaceutical unit.
The inspection was conducted by Mr. Ghazanfar Ali Khan, Additional Director, DRAP, Islamabad and the recommendations are as under: -

2.	Location	The proposed site was located at Khewat No. 652, 636, 657 Khatooni No. 1330-1328, 1319-1321, 1331-1333, Tehsil Gujar Khan, District Rawalpindi.
3.	Surrounding	The premises are away from filthy environment and no adjacent open sewerage, drain, public lavatory or factory emitting obnoxious / disagreeable odor or fumes or large quantities of soot, dust or smoke exists. However, fie brick kilns do exist, two are within 300 meters from premises but are dormant / inactive, one is more than 1000 meter but inactive and two are active but more than 1000 meter away. The premises is on the main road approximately one km from the GT Road with 100 feet front. Boundary wall is given in front and on both sides but back is still without boundary wall.
4.	Size	The size of the plot is 100 x 275=27500 sq. feet which is equivalent to 5 kanal. The establishment has given an undertaking confirming that the three documents pertaining to the land are proposed site / plot. A huge hall is constructed on the site.
5.	**Recommend ations**	Considering that the premises has access to road, electricity, free from filthy environment and of suitable size is recommended for setting up of veterinary manufacturing unit.

Decision of the Central Licensing Board in 293rd meeting:

The Board after discussion in detail decided that the proposed site will be inspected by two-member panel constituted by Chairman of the Board.
Accordingly, in the light of above decision of the Board, the Chairman constituted following two-member panel for inspection

1. Additional Director DRAP Islamabad
2. Ms. Tehreem Sara FID, DRAP Islamabad

The above panel has inspected the site and submit its inspection report of M/s Osum Pharmaceuticals (Pvt) ltd. Rawalpindi vide letter 2-01/2023-FID-II No. dated 04/06/2024 in response of para 20-23/N. The report is reproduced as under:
Inspection Team: The undersigned and Dr. Ghazanfar Ali Khan, Additional Director, Field Office. (DRAP), Islamabad vide letter No.1-1/2022-Lic dated 19-12-2023 form Secretary Central Licensing Board, DRAP Islamabad.
Date of Visit: 29-05-2024
Location: Khewat No. 652, 656, 657 Khatooni No. 1330-1328, 1319-1321, 1331-1333, Tehsil Gujar Khan, District Rawalpindi
1. Location and Surroundings
The proposed site for the pharmaceutical unit is situated away from environmental contaminants. Notably, there are no open sewerage systems, drains, public lavatories, or factories emitting offensive odors, fumes, soot, dust, or smoke in the vicinity. However, the following brick kilns are present near the site:

- Two dormant/inactive kilns within 300 meters.
- One inactive kiln over I 000 meters away.

· Two active kilns more than 1000 meters away.

The site is located on the main road, approximately one kilometer from the GT Road, with a frontage of 100 feet. Boundary walls are constructed at the front and sides of the property, though the back remains without a boundary wall. Left side has a go-down as informed by the management

2. Size and Infrastructure

The plot measures 100 x 275 feet, totaling 27,500 square feet (equivalent to 5 kanals). An undertaking has been provided by the establishment confirming that the three documents pertaining to the land are for the proposed site/plot. A large hall has been constructed on the site.

3. Utilities and Access

The site has access to the main road and is connected to electricity. The environment is clean, and the site is free from any potential sources of contamination that could affect manufacturing processes.

4. Observations

Environmental Compliance: The site 1s sufficiently distanced from potential sources of contamination.

Infrastructure: The large hall and partially constructed boundary walls indicate ongoing development appropriate for a manufacturing unit.

Documentation: Land ownership documents have also been attached and match the proposed site.

Conclusion

Based on the inspection previously, the panel confines the location with the same attributes however, the site at Tehsil Gujar Khan, District Rawalpindi, demonstrates seems to be suitable for the establishment of a pharmaceutical unit. The location is accessible, the environment is clean, and the plot size is appropriate for such an establishment. The firm has also submitted that they inclined to establish a veterinary pharmaceutical unit and will provide it with a technical floor for HVAC and other cabling guidelines. However, further assessment and compliance with specific regulatory requirements should be considered in the final decision.

Decision of the Central Licensing Board in 298th meeting,

On recommendation of the panel and considering the facts on the record and after detailed deliberation the Board decided to approve site located at Khewat No. 652, 636, 657 Khatooni No. 1330-1328, 1319-1321, 1331-1333, Tehsil Gujar Khan, District Rawalpindi.

Case No.33 SURRENDERING OF ALREADY APPROVED HUMAN SECTIONS OF M/S SEATLE (PVT) LTD., 45 KM MULTAN ROAD LAHORE.

The firm M/s Seatle (Pvt) Ltd., 45 KM Multan Road Lahore under the DML No. 000481 (Formulation) has submitted request for surrendering of following licensed sections

1. Tablet (Psychotropic)
2. Capsule (Psychotropic)

It is pertinent to mention that the CLB has granted Tablet and Capsule Psychotropic sections to the firm in its 271st meeting held on 12th Sep 2019.

Decision of the Central Licensing Board in 298th meeting

The Board approved the withdrawal of following Section of M/s Seatle (Pvt) Ltd., 45 KM Multan Road Lahore under DML No. 000481 and decided to notify the Drug Registration Board to take the necessary action in regard to the cancellation of the firm's relevant preparations.

1. Tablet (Psychotropic)
2. Capsule (Psychotropic)

Case No.34 **SURRENDERING OF ALREADY APPROVED HUMAN SECTIONSOF M/S NEUTRO PHARMA (PVT) LTD., 9.5-KM SHEIKHUPURA ROAD LAHORE.**

The firm, M/s Neutro Pharma (Pvt) Ltd., 9.5-Km Sheikhupura Road Lahore under the DML No. 000576 (Formulation) has submitted request for surrendering of following licensed sections

1. Tablet (Psychotropic)
2. Capsule (Psychotropic)
3. Liquid Injection (Psychotropic)

It is pertinent to mention that the CLB has granted above sections to the firm in its 224th meeting held on 15/07/2010 and same were renewed in 287th meeting held on 24/06/2022.

Decision of the Central Licensing Board in 298th meeting

The Board approved the withdrawal of following Section of M/s Neutro Pharma (Pvt) Ltd., 9.5-Km Sheikhupura Road Lahore under DML No. 000576 and decided to notify the Drug Registration Board to take the necessary action in regard to the cancellation of the firm's registrations granted for the following sections.

1. Tablet (Psychotropic)
2. Capsule (Psychotropic)
3. Liquid Injection (Psychotropic)

Case No.35 **GRANT RE-PACKING PRODUCTS TO M/S SKIMS PHARMACEUTICALS, 10-B VALUE ADDITION CITY KHURRANWALA FAISALABAD.**

The CLB in its 296th meeting held on 2nd April, 2024 considered and approved the grant of renewal of DML No. 000830 by way of Formulation in the name of M/s Skims Pharmaceuticals, 10-B, Value Addition City, Khurrianwala, Faisalabad on the recommendations of the panel of experts for the period commencing on 03-12-2020 ending on 02-12-2025 for the following sections subject to verification of necessary testing equipment:

i. Liquid Syrup Section (General)
ii. Tablet Section (General)
iii. Sachet Section (General)
iv. Capsule Section (General)
v. Oral Dry Powder Suspension Section (General)

In the 296th meeting Oral Liquid (Re-Packing) section was deferred with the direction to firm to submit the applications along with fee for enlistment of repacking items.

Now the firm, M/s Skims Pharmaceuticals, 10-B Value Addition City Khurranwala Faisalabad under Drug Manufacturing Licence No. 000830 by way of formulation has submitted application for Grant of Re-packing drug as per Schedule-D. Firm has submitted challan Fee of 7,500/ per product.

1. Glycerin
2. Liquid paraffin (heavy)
3. Castor oil.

The firm was advised to provide details of tests they shall perform on above repacking products for detection of impurities (like diethyl glycol & ethylene glycol impurities etc) especially in Glycerin.

The firm responded that they have tested their product namely Glycerin from the Central Drug Laboratory (CDL) for the presence of impurities (like diethyl glycol & ethylene glycol). They further

stated that the testing results confirm that their product meets the required standards and specifications, and the impurity levels are within the acceptable limits.

Decision of the Central Licensing Board in 298th meeting

The Board considered and approved the grant of renewal of DML No. 000830 by way of Formulation in the name of M/s Skims Pharmaceuticals, 10-B, Value Addition City, Khurrianwala, Faisalabad on the recommendations of the panel of experts for the period commencing on 03-12-2020 ending on 02-12-2025 for The Oral Liquid (Re-Packing) section.

The Board considered and approved the grant of approval of following repacking products

1. Glycerine
2. Liquid paraffin (heavy)
3. Castor oil.

The Board further decided that firm shall perform on every batch/consignment of above repacking products for detection of impurities (like diethyl glycol & ethylene glycol impurities etc) from the Central Drug Laboratory (CDL), Lahore.

Case No.36 M/S UNIPHARMA (PVT) LTD., 4.5 KM, MANGA RAIWIND ROAD LAHORE UNDER THE DRUG MANUFACTURING LICENSE NO. 000412 (FORMULATION)

The firm M/s Unipharma (Pvt) Ltd., 4.5 KM, Manga Raiwind Road Lahore under the Drug Manufacturing License No. 000412 (formulation) submit application for renewal of DML from 19-06-2015 to 18-06-2020 and was processed accordingly. However, as per available data in the Licensing Division, DRAP, application for renewal of DML for the duration from 19-06/2020 to 18-06/2025 has not been received.

It pertinent to mention that as per Rule 5 (6) of Drug (L, R & A) Rule, 1976 "if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application". Furthermore, Rule 5(3) states that "If the application for renewal of the License is made after the expiry of the period of the validity of the License, it shall be treated as a fresh application for the grant of a License.

Therefore, Drug Manufacturing License No. 000412 (formulation) of M/s Unipharma (Pvt) Ltd., 4.5 Km, Manga Raiwind Road Raiwind Lahore) is invalid and stand cancelled.

Decision of the Central Licensing Board in 298th meeting

The Board considering the facts on the record and after detailed deliberation decided the Drug Manufacturing License No. 000412 (formulation) of M/s Unipharma (Pvt) Ltd., 4.5 Km, Manga Raiwind Road Raiwind Lahore) is invalid and stand cancelled from date 19-06-2020.

Case No.37 INTIMATION NOTICE CONCERNING CONTROL OF ELKO ORGANIZATION (PVT.) LIMITED, KARACHI

FR is received from M/s Elko Organization (Pvt.) Ltd, Karachi wherein they are stated that "I am writing to intimate to you about the management situation of the subject company.

That despite the undersigned being the CEO and Director of the above mentioned company, the undersigned has been ousted from active management and control of the company since January 2022 As the other Director and the undersigned's brother Mr. Shakil Ahmed Chandna in collusion with the distributor of the company Mr. Javed Tahir.

Further, the said director Mr. Shakil Ahmed Chandna has replaced the previous professional employees of the company with his own relatives amongst his in laws despite my opposition in this regard, the undersigned has also started proceedings before the S.E.C.P. (Securities and Exchange Commission of Pakistan) for the redressal of his grievance which have yet not materialized. That the said Mr. Shakil has also tried to falsely Show before certain forums that the undersigned has been present in some management meetings of the company.

That this is false and that the said Mr. Shakil exerts sole and exclusive control over management, all production sales and other matters of the company while the undersigned has no role whatsoever since 2022.

You are thus requested to kindly note the same and for all purposes consider the undersigned to be ousted from the control and management of the company. That the said Mr. Shakil Ahmed Chandna (Director) should deemed exclusively and solely responsible for all the good and bad concerning the subject company including any liabilities howsoever arising from 2022 onwards."

Decision of the Central Licensing Board in 298th meeting

The Board considering the facts on the record and after detailed deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License Drug Manufacturing License No 000245 by way of formulation of M/s Elko Organization (Pvt.) Ltd, Karachi, may not be suspended or cancelled by Central Licensing Board.

Case No.38 APPLICATIONS FOR STEM CELL GMP FACILITY FOR EXPERIMENTAL PURPOSE

The Division of Licensing DRAP has received applications from different centers regarding approval of the layout plan and issuance of License for Experimental Purpose for aseptic isolation/preparation/manufacturing of Stem Cells *in vitro* xeno-free proliferation, and characterization and conducting trials on humans.

- Dr Sheikh Riazuddin, Stem Cell Lab, Jinnah Burn & Reconstructive Surgery Centre, Lahore

The matter was placed before the DRAP Authority meeting dated 11th & 13th Oct 2022, the decision of which is cited below:

1. The Authority decided to refer back the case to Licensing division to suggest a way forward for licensing of stem cells manufacturing facilities in light of international practices.
2. The Authority further decided to send a reference to Health-care commission and Heart & Organ Transplant Authority (HOTA) for their input as per their and DRAP'S scope.

Hence in the light of the decision, the Licensing Division solicited comments from BE&R Division regarding the manufacturing facility requirement for stem cells, in the light of international practices which are as follows:

"It is submitted EMA, WHO & USFDA websites were searched for requirements on manufacturing facilities for manufacturing of stem cell.

a) It is submitted that no concrete requirement has been found on the relevant websites the mentioned regulatory authorities however it has mentioned that manufacturing of stem cell /cell-based medicinal products (CBMPs)/Advanced Therapy Medicinal Product requires a strict control in c-GMP facilities as required for other Biological Drugs along with product specific requirement i.e. justified production & testing facility. For more details, & specific requirement for manufacturing of stem cell, the Licensing division may be requested to obtain expert opinion from relevant expert of the field."

b). Furthermore, in its intended use the applicant has mentioned (as described in para-9/N) that "*We intend to prepare stem cells for experimental purposes only*" & "*We will employ stem cells for the repair of damaged tissue including but not limited to liver, kidney, skin, cartilage, spinal cord, cornea, and retina in human subjects. For that purpose, the treatment will be totally free of cost and no expenditures will be paid by the patient at any stage of the study. Further, the patient may choose not to take part in the study for any reason at any stage.*" From which it seems that the applicant wants to conduct clinical trial on human subjects therefore the opinion of Pharmacy services division may also be sought in this regard.

It is further submitted that the subject matter is of highly sensitive nature due to direct involvement of the humans during experimental stage and some ethical issues/requirements as per available data on the internet therefore the matter is placed before the Central Licensing Board for deliberation and guidance please.

Currently, the only stem cell-based treatment that is routinely reviewed and approved by the U.S. Food and Drug Administration (FDA) is hematopoietic (or blood) stem cell transplantation. It is used to treat patients with cancers and disorders that affect the blood and immune system.

The only stem cell-based products that are FDA-approved for use in the United States consist of blood-forming stem cells (hematopoietic progenitor cells) derived from cord blood.

HEJ research institute of chemistry and DrPanjwant center for molecular medicine and drug research has also applied for approval of design for stem cell GMP facility. After various discussions division of licensing could not reach on a conclusion due to ethical issues related to the therapy.

Decision of the Central Licensing Board in 295th meeting:

The board decided to form following working group.

1. Dr Obaidullah, Director Pharmacy Services (Chairman)
2. Mr Babar Khan, Additional Director (Lic.)
3. MsMahvash Ansari, Additional Director (QC.)
4. MrMubashir Iqbal, Deputy Director (Lic.)

TORs of the Working group.

The terms of reference of the working group will include but not limited to the following:

i. The group will consider international references for the requirements of GMP of the Stem Cell manufacturing facilities.
ii. The group will go through the ethical aspects of the clinical trials/experiments.
iii. The group will find out the way forward for regulatory mechanism.
iv. The group will submit its recommendations for the Central Licensing Board for its consideration and final decision in the subject matter.

The Chairman of the Working group may opt any expert / person for assistance and discussion on the subject matter.

The working group has submitted the report which is reproduced as under:

"Stem Cell Therapy Working Group Report:

The Stem Cell Working Group was constituted by the Central Licensing Board (CLB) in its 295th meeting held on 11th January, 2024 while considering the applications for stem cell GMP facility for experimental purpose.

Members of the Working Group:

1. Dr. Obaidullah, Director Pharmacy Services Division (Chairman)
2. Mr. Babar Khan, Add. Director Lic. Division (Member)
3. Ms. Mahvash Ansari, Add. Director Q.C. Division (Member)
4. Mr. MubashirIaqbal, Deputy Director Lic. Division (Secretary)
5. Mr. Affan Ali, Deputy Director Q.M.S. Division (Co-opted Member)

Scope / TORs of Working Group:

The CLB gave the mandate of below mentioned terms of reference to the working group in order to make decision regarding applications for approval of layout and grant of licenses for experimental purpose for aseptic isolation/preparation/manufacturing of the stem cells in-vitro xeno-free proliferation, characterization and conducting trials on humans. The TORs of the working group are as follows;

1. The group will consider international references for the requirements of GMP of the stem cell manufacturing facilities.
2. The group will go through the ethical aspects of the clinical trials/experiments.
3. The group will find out the way forward for regulatory mechanism.

4. The group will submit its recommendations for the Central Licensing Board for its consideration and decision in the subject matter.

The working group held four meetings in detail on the subject matter under the given scope/mandate from the Central Licensing Board (CLB), DRAP.

Findings and Recommendations of the Working Group:

a. As per decision of the Authority (73rd meeting held on 6th November, 2019) and international practices stem cells are considered as biological products. Thus, all the requirements for the regulations of biologicals will be applicable for stems cell as such.

b. The Schedule B-II of Drugs (Licensing, Registering and Advertising) Rules, 1976 does not cover GMP requirements for biological including ATMPs. However, WHO TRS 999 is being used for inspection of biological manufactures by DRAP but this guideline also does not cover GMP requirements for ATMPs.

c. The review of different documents (regulations/guidelines) of Reference Regulatory Authorities reveal that various nomenclature are used for such biological products, like USFDA under 21CFR part 1271 use Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), while EU and PIC/S use the term Advanced Therapy Medicinal Products (ATMPs).

d. Stem cells are covered under the same type of the biological products. The GMP for stem cells is the same for all ATMPs or HCT/Ps, generally the guidelines for sterile biological products are used as a baseline document for GMP evaluation of such facilities with some specific requirements defined under various guidelines by different regulatory/ international bodies, as per following details:

   - USFDA has defined GMP guide as current Good Tissue Practices under 21 CFR part 1271 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/eligibility-determination-donors-human-cells-tissues-and-cellular-and-tissue-based-products-:~:text=The%20regulations%20under%2021%20CFR%20part%201271%2C%20subpart,cells%2C%20tissues%2C%20and%20cellular%20and%20tissue-based%20products%20%28HCT%2FPs%29., Annexure-I).
   - EU has defined GMP as Good Manufacturing Practice specific to Advanced Therapy Medicinal Products (https://health.ec.europa.eu/system/files/2017-11/2017_11_22_guidelines_gmp_for_atmps_0.pdf, Annexure-II).
   - PIC/S has defined GMP as GMP for Manufacture of Advanced Therapy Medicinal Products for Human Use (https://picscheme.org/docview/6608, Annexure-III).

e. The above GMP guidelines or any other guideline of Reference Regulatory Authority can be used for GMP of facilities for experimental and commercial manufacturing of these products as decided by Central Licensing Board.

f. For ethical considerations related to clinical trial/experiments National Bioethics Committee (NBC) is the competent forum. As per Bio Study Rules 2017, ICH GCP guidelines are being followed for regulatory oversight of the clinical trials/study. However, EU Guidelines for Good Clinical Practices for ATMPs or guidelines on GCP from any other Reference Regulatory Authorities may be used as a reference document for overseeing the GCP aspect of clinical trials of such types of products if the specific requirements are not available in the ICH GCP guidelines and such decision may be taken by Clinical Study Committee.

g. As DRAP has already outlined / mapped regulatory processes for various therapeutic goods, thus these regulatory frameworks may be used for regulation of ATMPs / stem cells being biological drug products. However, if Licensing and Pharmacy Services Divisions identify any regulatory challenge in processing of such case then case may be processed for consideration by relevant forum for appropriate decisions.

h. A disclaimer should be added to the license: *"Central Licensing Board considered the application on the basis of requirements laid down under the referred GMP guidelines (as CLB may deem appropriate), however, the issuance of license does not guarantee approval of Clinical Trail/ Experiment and is subject to the approval of relevant forum i.e. National Bioethics Committee and Clinical Study Committee."*

Proceedings and Decision by the Central Licensing Board in 298th meeting:

The Board discussed the case in detail. On request of Center for excellence in molecular biology, university of the Punjab the CLB decided to invite their expert for presentation in next meeting.

Case No.39 APPLICATIONS FOR REVAMPING OF EXISTING MANUFACTURING FACILITY BY M/S GETZ PHARMA (PVT) LTD, KARACHI.

- M/s. Getz pharma Karachi has requested to manufacture Semaglutide injection in the same area where they are manufacturing human insulin. The firm is manufacturing insulin glargine injection and regular human insulin injection using insulin crystals as raw material. They said that they are not performing any biotechnological activity using any microbes. They have applied for a change in the status of Sterile Facility II to a dedicated Biotech section for the production of Semaglutide injection. For the biological or biotechnology products a dedicated facility is required.

- The firm was granted Biotech Facility (for manufacturing of rDNA technology products only) on 5 October 2012.
- In 2018, the firm applied to convert the same biotech facility into "Dry Powder Inhaler Section". The Biotech section was withdrawn in 266th meeting of Central Licensing Board held on 24-10-2018. The Dry powder inhaler section was approved on 25-06-2019.
- In the most recent renewal letter issued on 30-10-2019, approval was granted for the Dry Powder Inhaler section only (in place of the biotech facility).
- Upon examining the records, it was observed that M/s. Getz Pharma does not currently have a Sterile Facility II within its premises. This prompted the Licensing division vide letter F. 2-5/86-Lic (Vol-I-Pt) dated 1st July 2024, to request clarification from the firm regarding the proposed conversion of Sterile Facility II into a Biotech section. If the biotech section has already been converted into a dry powder inhaler section, then which facility they need to convert back was unclear.
- In response to the above query, M/s. Getz Pharma has submitted a letter dated 02nd July 2024, in which they have provided clarification regarding the conversion of Biotech section into a Sterile Facility II. The firm asserts that they have divided the Dry Powder Inhaler section into two sections, namely Dry Powder Inhaler section and Sterile Facility II. However, it is important to note that this Sterile Facility II has not been approved or recorded in the official records. The firm has also provided a Layout Plan signed by a DRAP officer, which purports to show these two sections within the manufacturing facility but no official record supports this claim.
- The firm sought opinion from WHO Representative Mr. Vimal Sachdeva through email the extract from email reply of the representative is as follows:

  "The decision to manufacture different types of biologicals on the same premises is complex and influenced by factors such as product characteristics, production processes, and regulatory requirements (e.g. biosafety). Crucially, the Quality Risk Management (QRM) process plays a pivotal role in determining whether and to what extent premises should be dedicated to a particular product, underscoring the importance of effective risk management in our operations. Usually, a shared fill and finishing facility is acceptable for biologicals, provided adequate measures for preventing cross-contamination are in place. Dedicated facilities are only mandatory in specific cases, as described in WHO TRS 999 (pathogenic microorganisms of Biosafety level 3 or 4, spore-forming organisms, BCG, and usually live viruses). A documented QRM process should be conducted for each additional product within a shared facility. This process should involve a potency and toxicological assessment focused on cross-contamination. Also, the manufacturers are required to follow the current WHO TRS 1033 Annex 2, about determining health-based exposure limits using Permitted Daily Exposure (PDE) guideline.

Though, PDE might not be necessary for biologicals because of the nature of the cleaning processes (biological macromolecules and peptides are susceptible to degradation and denaturation when subjected to extremes of pH and heat), you are still require a holistic risk assessment. In cases where other potential routes of cross-contamination are present (e.g., excipients, preservatives, and others), the risks should also be assessed individually.

We hope the abo re explanation is helpful for you to make an appropriate assessment before introducingDNA technology peptides (like GLP-1 receptor agonist, such as Semaglutide etc) on the same facility where finished formulation of human Insulin (+DNA technology product) crystals filled and packed."

- An email has also been sent to the WHO prequalification team lead from Division of Licensing, DRAP to clarify whether human insulin and Semaglutide injection can be manufactured in the same manufacturing facility/area?

Decision:

The Board discussed the case in detail and decided to issue a warning letter to the firm for bifurcating the facility into two sections without approval of CLB. The firm may apply for the regularization of sterile area. Furthermore, the licensing division shall take independent opinion of the WHO expert and place the case in forthcoming meeting.

Case No.40 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S EFFORT PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Effort Pharmaceuticals (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore had applied for renewal of DML No. 000879 by way of Formulation for the period of 11-04-2023 to 10-04-2028 on 29-03-2023.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13th April, 2023 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Updated nothing due certificate regarding CRF.
2. Duly Notarized latest certified true copy of Form-29 issued by SECP.
3. Duly attested CNIC of all Directors.
4. Detail of management, if there is any change, file application along with prescribed fee of Rs. 75,000/-.

In response to the shortcoming letter, the firm submitted reply on 29th May, 2023 but application was incomplete with following shortcomings and reminder letter was issued on 23rd June, 2023 to the firm for completion of application:

1. Updated nothing due certificate regarding CRF.
2. Latest certified true copy of Form-29 issued by SECP without stamp that SECO does not take responsibility of correctness of contents.

3. Detail of management, if there is any change, file application along with prescribed fee of Rs. 75,000/-.

The firm submitted documents on 07th September, 2023 in reply to final reminder but application for renewal of DML is still incomplete with following documents being deficient.

1. Latest certified true copy of Form-29 issued by SECP without stamp that SECP does not take responsibility of correctness of contents.
2. Detail of management, if there is any change, file application along with prescribed fee of Rs. 75,000/-.

Decision of the Central Licensing Board in 298th meeting

The Board 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 Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000879 by way of formulation of Effort Pharmaceuticals (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore, may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No.41 REQUEST FOR WITHDRAWAL OF PENICILLIN SECTION OF M/S ACME PHARMACEUTICALS, RAWAT.

M/s Acme Pharmaceuticals, Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat got approval of layout plan of Oral Powder (Penicillin) Veterinary. Now, the firm has requested for withdrawal of their unlicensed Penicillin facility as they intend to establish dedicated Nutraceutical facility in replacement of Penicillin Section.

Notification of Division of Health & OTC Division:

No. 8-3/2019 -H&OTC_ In exercise of the powers conferred by the clause (c) of section 7 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan is cased to issue the following guidelines for manufacturing of Alternative Medicines, Health Products and probiotics, by the Drug Manufacturing License (DML) Holders;

a) The drug/medicine and alternative medicines (Excluding usage of crude herbs) & health products and probiotics can be manufactured in the same plot in dedicated sections after getting regulatory approval. The same Quality Control Laboratory can be used.

b) The pharmaceutical drug/medicine and alternative medicines, if crude herbs are being used as raw material, can be manufactured in the same plot in a separate dedicated building after getting regulatory approval. Separate Micro biology, Photochemistry, Physical and Chemical Laboratory is mandatory to be established in case of crude herbs.

Decision of the Central Licensing Board in 298th meeting

The Board considering the facts on the record and after detailed deliberation decided to accept the request of the firm for withdrawal of unlicensed Oral Powder (Penicillin) Veterinary section. Board members unanimously agreed that Nutraceuticals should be manufactured on a separate floor. The Board further decided to refer the matter of requirement of dedication of separate floor for manufacturing of Nutraceutical preparation to the DRAP Authority.

Case No.42 **SITE VERIFICATION OFM/S. USMAN PHARMACEUTICALS, PLOT NO.55, STREET S5, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD**

The firm, M/s. Usman Pharmaceuticals applied for site verification of proposed plot to establish pharmaceutical unit situated at Plot No.55, Street S5, National Industrial Zone, Rawat, Islamabad. As per document submitted by the firm, Mr. Ishtiaq Ahmad Khan S/o. Mr. Abdul Ghafoor Khan is the sole owner/proprietor of the firm and sole owner of the proposed site is Mr. Ishtiaq Ahmad Khan S/o. Mr. Abdul Ghafoor Khan.
It is submitted for information that the CLB in its 294th meeting held on 27th December, 2023 cancelled the license No. 000718 previously granted at Plot No. 55, Street S5, National Industrial Zone, Rawat, Islamabad to M/s Medisynth Pharmaceuticals which was shifted to another premise located at Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, Distt. Rawalpindi.

Decision of the Central Licensing Board in 298th meeting

The Board considering the facts on the record and after detailed deliberation authorized Chainman CBL to constitute panel of expert for inspection of the proposed site and building with reference to suitability of its design / environment for manufacturing of medicines and take decision on the recommendation of the Panel.

Case No.43 **CHANGE OF MANAGEMENT OF M/S GREATER PHARMA, RAWAT.**
Case Background:

The Central Licensing Board in its 279th Meeting held on 18th February, 2021 considered and endorsed the change of management of M/s Greater Pharma, Plot No. 35, Street No. SS-3, National Industrial Zone, RCCI, Rawat under DML No. 000896 by way of Formulation as under:

Previous Management	New Management as per Affidavit
1. Mr. Abdul Wadood Khan S/o Masood Khan CNIC No. 17301-0355625-1.	1. Mr. Muhammad Dawood S/o Haji Momeen CNIC No. 54201-2468331-5.

Accordingly**,** Decision of the Board was conveyed to the firm on 30th March, 2021.
Then, letters/complaints received from **Mr. Abdul Wadood Khan** which are reproduced as under:
"I am a sole owner of the factory "Greater Pharma" situated at Plot No.35, Street SS-3, Industrial Zone, Rawat Islamabad and a license has been issued by your worthy Office (copy Attached). Sir unluckily I was suffering from serious injuries and mental disability and was also in comma for long period due to road accident on 14-08-2020. When I came to normal life, surprisingly it reveals that my factory has been fraudantly transferred to Mr M. Dawood via fake Deed Dated 15-01-2021 by my nearest relative namely Sajid Masood S/o Manzoor and they have illegally occupied my suste factory

and it's all machinery and items. Sir Mr. M. Dawood has been manufacturing the medicines/items without having any authority which is highly illegal and it may damage the public at large, thus it required attention of your worthy office. Furthermore, I did not attend any board meeting which is essential for granting permission or authority for manufacturing. It is therefore, requested, that stern action may kindly be taken against Muhammad Dawood or any other person if involved and manufacturing may discontinue in the interest of public at large."

&

"I have an accident on motorway 14th August 2020 along with wife, after accident I was admitted in RMI and North West hospital Hayatabad Peshawar. I was suffering, in comma disease and mentally abnormal. That time I was treated with Prof Tariq hashim and Khalid mufti. All hospital evidence records with me in hospital.

1. *1 have submitted complaint in DRAP Islamabad two weeks ago. But I am waiting reply from DRAP.*
2. *I have already submitted complaint in Chairman NAB Islamabad for legal action.*
3. *My factory was rented to Mr. Daud through fraud agreement.*
4. *The Meezan Bank Hayatabad Peshawar through evidence Mr. Sajid masood received all payment, ID CARD copy attaches in bank record.*
5. *The DRAP has taken decision without my presence, I have no physical visit to DRAP Islamabad, according to 1976 Rule regulation agreement is against rules, regulation and Director (Licencing) according to DRAP Rule and regulation agreement was not follow through DRAP Rules and regulation."*

Complaint of Mr. Abdul Wadood Khan was forwarded to the firm for their comments. **Reply of the firm** is as under:

"With ref of your letter dated 10/sep/2021, subjected justification and comments on complain of Mr. Abdul wadood. We here by justify the complaint as follows. I Muhammad Dawood CNIC NO 54201-2468331-5 (CEO) Greater pharmaceuticals Pvt Ltd plot 35, Street SS-3 Rawat Industrial zone Islamabd,

COMMENTS OF C.E.O

Abdul Wadood's complain is based on absolutely fake statement, he was in his own senses as per described with evidences as follow, his fake allegations are only based on malicious, he is just miss guiding the DRAP and doing a fraud complain and as well damaging the time and goodwill of DRAP,we have submitted all the required documents in DRAP, after the NOC of Abdul Wadood and many more documents DRAP have issued the change of management letter, on the bases of DRAP's said letter we applied for new sections approval, after the receiving of new approved map from DRAP we started construction, we have invested a huge amount on new sections construction, machinery HVAC system, equipments, market and many more, According to his statement majorly he have dispute with his own family and he is mixing up the dispute with our deal and confusing the DRAP,

FURTHER JUSTIFICATIONS WITH EVIDENCES AND WITNESSES

Mr. Abdul Wadood's accident and discharging date. According to his statement he had accident on 17 Aug 2020 as per his hospital reports, he was hospitalized for 15 days only, from dated 17 Aug 2020 to 2 Sep 2020 and he was discharged on 2 September 2020, he was ok and his own senses.

SALE AND PURCHASE

After 6 months of his accident Mr Abdul Wodood visited the Greater pharma to us, he was absolutely in his senses, then we matured the deal (agreement attached) and Agreement was signed personally by Mr Abdul. Wadood (pictures are attached for evidence) in the presence of following witnesses. Personal appearance of all following witnesses is absolutely possible if DRAP required.

1. *Mr. Naeem shah (Ex owner of Goodman Lab rawat)*
2. *Mr. Masood khan (Father of Abdul Wodood khan)*
3. *Mr. Waheedullah (Brother of Abdul Wadood)*
4. *Mr. Sajid masood s/o Manzoor khan*
5. *Mr. Huzaifawodood (son of Abdul wadood khan)*
6. *Mr. Masood s/o (M. Dawood)*

Payments to Mr. Abdul wadood

We have paid the payment as per attached agreement to Mr. Abdul wadood by cheqs (cheq copies are attached) and Mr. Wodood personally received all the cheq (signed receipts are available) with his named title (Abdul wodood khan) and he collected all the payment from banks. (Bank record is attached).

We are requesting to DRAP kindly do not entertain such kind of nonsense complains which have no legal documents, proofs and any evidences. And this is only based on malicious."

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing both parties in next meeting of the Board.

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

Letter received from Mr. Abdul Wadood Khan which is reproduced as under:

"I HAVE GREATER PHARMA ON MY NAME. THE DRAP ISLAMABAD ISSUED LICENSE ON 05-93-2019. THEREFORE, REQUEST TO DRAP ISLAMABAD TO STOP GREATER PHARMA FACTORY PRODUCTION AND RAW MATERIAL PROCESS THE GREATER PHARMA HAS BEEN MANUFACTURE PRODUCTS SINCE JANUARY 2021. TIE DAWOOD AND HIS SON MASOOD GOT ILLEGALLY PERMISSION FROM DRAP ISLAMABAD. I HAVE DONE ACCIDENT ON MOTORWAY ADMITTED IN NORTH WEST HOSPITAL HAYATABAD. NOW I HAVE GOOD HEALTH AND MENTALLY GOOD CONDITION FROM BRAIN FIT FOR BUSINESS THROUGH DOCTORS CERTIFICATE, THE DAWOOD BELONG TO AFGHANISTAN MADE FAKE PAKISTAN JID FROM PASHEEN QUETTA. (ID CARD OF PAKISTAN :) THEREFORE KINDLY TAKE ACTION AGAINT DAWOOD AND HIS WSON MASOOD THROUGH DRAP RULES THROUGH I'IA ISLAMABAD AND STOP BANK ACCOUNT FROM FBR PAKISTAN ISLAMABAD. AFTER THIS LETTER I AM NOT RESPONSIBLE FOR DAWOOD AND MASOOD PRODUCTS IN BUSINESS MARKET."

Request for change of title also received from Mr. Abdul Wadood Khan which is reproduced as under:

Previous Title	New Title
M/s Greater Pharmaceutical, Plot No.35, Street SS-3, National Industrial Zone, Rawat, Islamabad.	**M/s Al Wadood Pharmaceutical,** Plot No.35, Street SS-3, National Industrial Zone, Rawat, Islamabad.

Letters of Personal hearing has been issued on 7th March, 2022 to the firm and Mr. Abdul Wadood Khan.

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

Mr. Masood Khan, managing Director appeared on behalf of the firm. He contended that all transactions have carried in the presence of witnesses which includes his brother and son. He further stated that his written reply may be considered as his statement. He prayed that his representation may be dropped as same are based on malafide.

The complainant Mr. Abdul Wadood Khan did not appear before the Board. The Board considering the facts observed that matter pertains to private transactions between two parties. Therefore, there is nothing to intervene. However, aggrieved party may approach court of competent jurisdiction for redressal of his grievance.

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

Decision of CLB was conveyed to the firm and Mr. Abdul Wadood Khan through letter dated 07-03-2022.

Now, Mr. Muhammad Jamal Afridi, Advocate Supreme Court, Islamabad has requested for personal hearing of Mr. Abdul Wadood before CLB as he claimed that personal hearing has not been served to his client.

Request was forwarded to Division of Legal Affairs, DRAP, Islamabad for their opinion which is reproduced as under:

*"Reference to para 35/N, it is submitted that it is the rule of the Natural Justice that **Audi Alteram Partem** means that no one should be condemned unheard. Hence, Central Licensing Board may grant a last & final opportunity to the complainant with warning in the personal hearing letter that if he will fail to appear before Board this time then the matter will be proceeded as ex-parte."*

Accordingly, a letter of personal hearing has been issued to Mr. Abdul Wadood Khan on 19-07-2024 but didn't appeared before the CLB.

Proceedings and Decision by the Central Licensing Board in 298th meeting:

The Board considering the facts on the record and after detailed deliberation decided to give final opportunity of personal hearing to the applicants in next meeting of the Board.

Case No.44 RENEWAL OF DRUG MANUFACTURING LICENSE NO.000148 (FORMULATION) OF M/S MARVI PHARMACEUTICALS, KARACHI.

The case for renewal of Drug Manufacturing License No.000148 (Formulation) of M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi was presented in 296th meeting of CLB and decided as under;

M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi. DML No. 000148 (Formulation). **Period:** Commencing on 10-07-2020 ending on 09-07-2025. *Evaluator: - Mubashir Iqbal (DD-Lic)*	19-01-2024	Good	1. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Karachi, Member CLB. 2. Mr. Abdul Rasool Shaikh, Additional Director /Federal Inspector of Drugs, DRAP, Karachi. 3. Mr. Awais Ahmad, Assistant Director, CDL, Karachi
QC In-charge	Mr. Muhammad Aamir S/o Syed Shamimul Haq (M.Sc Chemistry) CNIC No.42201-0542257-3		
Production In-charge	Mr. Adnan Saeed S/o Saeed Ahmed (B-Pharm) CNIC No.42201-0683097-7		

Recommendations of the panel:

M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi was visited and inspected in detail on 19-01-2024 in compliance to the directions contained in DRAP, Islamabad letter No.F.2-29/84-Lic (Vol-III) dated 08th September, 2023 regarding grant of renewal of DML. Following are the observations: -

The panel inspected the firm in detail including all the manufacturing sections, stores and QC Lab and found the facility as per approved lay out plan. The facility has been provided with necessary utilities, machineries and equipment as required under the guidelines. Necessary documents relating to QC, QA and installation qualification of machines, HVAC and other

utilities were also seen in place. It is further to mention that the firm is built on Plot No.70 and 71 whereas only Plot No. 70 is mentioned on their DML. As their last submission to concerned division the firm had submitted their recent drawing clearly mentioning both plots including 71. The firm holds the ownership of both plots hence it was advised to them to go for regularization of the same and approach the concerned division for further guidance.

Based on the people met, documents reviewed and observations made during the inspection, the panel unanimously **recommends** the grant of renewal of Drug Manufacturing License No.000148 by way of formulation due on 10-07-2020 for sections as follows: -

i. Tablet (General)
ii. Capsule (General)
iii. Liquid Syrup/Suspension (General)
iv. Cream/Ointment (General)
v. Capsule (Penicillin)
vi. Dry Powder Suspension (Penicillin)

Note: The Capsule (Penicillin) and Dry Powder Suspension (Penicillin) are on the same floor along with other General Section and facility. Further, as per available record the firm has been granted DML with address/on Plot No.70, Street No.24, Korangi Industrial Area, Karachi. Whereas the firm didn't apply for Plot No.71, Street No.24, Korangi Industrial Area, Karachi in the Division of Licensing, DRAP.

Decision of the Central Licensing Board in 296th meeting

The Board considered and deferred the renewal of DML No. 000148 by way of Formulation in the name of M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi for confirmation of approval of site on plot No. 71, lay out approval and any construction over the plot.

Furthermore, the Board decided to defer the renewal of the following section and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for penicillin sections.

i. Capsule (Penicillin)
ii. Dry Powder Suspension (Penicillin)

Accordingly, a letter was issued to the firm on 04-07-2024. Now the firm has submitted reply which is re-produced as under;

"With reference to your letter No.F.2-29/84-Lic (Vol-III) dated 04th July, 2024 regarding captioned subject. It is submitted that we already came to know through Minutes of 296th meeting of Central Licensing Board held on 02nd April, 2024 available on DRAP website while consideration of our case for renewal of Drug Manufacturing Licensing No.000148 (Formulation) regarding following decision of Board:-

The Board considered and deferred the renewal of DML No. 000148 by way of Formulation in the name of M/s Marvi Pharmaceuticals, Plot No.70, Street No.24, Korangi Industrial Area, Karachi for confirmation of approval of site on plot No. 71, lay out approval and any construction over the plot.

Furthermore, the Board decided to defer the renewal of the following section and instructed licensing division to notify the company of its decision regarding segregated, dedicated facilities requirements for penicillin sections.

i. Capsule (Penicillin)

ii. Dry Powder Suspension (Penicillin)

Sir, as per above decision, we submitted our reply via online submission through DRAP, MIS Division vide their acknowledgement / application submission receipt on DRAP eApplication System on 11-06-2024 and tracking number of applications is 2JI-US8-7HE4 (copy enclosed)

Regarding approval of site, layout approval and any construction on Plot No.71, it is stated that Marvi Pharmaceuticals was established In 1968. The manufacturing unit has been in the same location since the beginning and has not changed. We have made numerous inspections over the last 5 decades which include 5-yearly manufacturing license renewals as well as GMP inspections etc. The layout of the company had been approved by DRAP and even after renovations, the last amended layout had also been sent to DRAP in 2018 mentioning Plot 70 as well as Plot 71. The amended layout was processed and approved by the Licensing Department at DRAP and a regularization panel was created to inspect the premises as per the layout. The team inspected the unit in April 2018 and sent the inspection report to DRAP which then approved and regularized our manufacturing unit.

We are attaching all correspondence received from DRAP regarding regularization of our units as well as the inspection report of the panel which visited as to inspect the panel.

With numerous inspection of our facility this was the first time it was pointed out to us that our DML did not include Plot 71 in our DML address. With the regularization process that took place in 2018 we had assumed that all of our documents were in check and the facility was up-to date according to the documents approved by DRAP which we now realize was an oversight.

We request the panel to consider the facts and change the address on our DML to mention both of our plots as the regularization process has already taken place in 2018 and has been approved by DRAP.

With reference to the minutes of the meeting of Licensing Board 296th meeting of central licensing board held on 2nd April, 2024, the board had directed us to halt Penicillin production in our unit as it did not comply with the new regulations issued by DRAP for Penicillin production.

We learned of the new developments and instructions issued by DRAP recently and have been working on the solution which would comply with the regulations and require time to move our Penicillin section there.

Since Penicillin is our main product, and with the current economic condition of the country survival is becoming difficult by the day, we request the panel to grant us 2 years to shift this section to our new building while we operate it in its current position.

We assure you that the current section, while being in the same building, has separate INS and out and does not, in any way, link to other manufacturing sections. With separate HVACs as well as isolating it from other sections we have eliminated the risk of cross contamination.

We can start the process of moving our section as soon as we are granted the relevant approvals and will abide by the time frame we have requested you to grant us.

In view of above submission, you are requested to renew our Drug Manufacturing License and allow us to continue the production of our penicillin products and grant us a period of 02 years to shift this section to our new building, we start the process of moving our section as soon as we are granted the relevant approvals.

Sir, we again furnished our above submission and requested to placed our case for renewal of Drug Manufacturing License in forthcoming 298th meeting of Central Licensing Board to be held on 10th July, 2024 and we also intend to avail opportunity of personal hearing on the same date and time

Your cooperation will highly be obliged."

Proceedings and Decision by the Central Licensing Board in 298th meeting:

The Board considering the facts on the record and after detailed deliberation decided to served warning to the firm. The Board Further decided that firm shall apply for amalgamation of the proposed site as per SOP.

Case No.45 RENEWAL OF M/S CRYSTOLITE PHARMACEUTICALS, RAWAT

The case for renewal of DML of M/s Crystolite Pharmaceuticals, Plot No. 1 & 2, Street S-2, National Industrial Zone, Rawat was presented in 294th meeting of CLB held on 27th December, 2023 and decided as under;

<table>
<tr><td rowspan="4">3.</td><td>M/s Crystolite Pharmaceuticals.
DML No.000778 (Formulation).
Period: Commencing on 30-8-2023 to 29-08-2028
Evaluator:- Zunaira Faryad (AD-Lic)</td><td>14-12-2023</td><td>Good</td><td>1. Dr. Ghazanfar Ali Khan, Additional Director (QA/LT), DRAP, Islamabad.
2. Mrs. Tehreem Sara, FID-IV, DRAP, Islamabad.
3. Mr. Umer Lateef, Deputy Director (QA&LT), DRAP, Islamabad.</td></tr>
<tr><td>Quality Control In-charge</td><td colspan="3">Abdul Basit B-Pharm</td></tr>
<tr><td>Production In-charge</td><td colspan="3">Aamir Raza M. Sc Chemistry</td></tr>
<tr><td colspan="4">Summary of inspection:
In view of the inspection conducted, reviewing the documents, interview of technical team, intent of the management and verification of manufacturing and testing facility such as FTIR, Atomic Absorption spectrometer, three (03) HPLC, Spectrometer, Dissolution Apparatus, LFC, TOC, Liquid Particle Counter, Air Sampler, polarimetry, ultrasonic bath, and other QC equipment along with 03 stability chambers (list already attached, the panel unanimously recommends the Grant of renewal of Drug manufacturing License by way of formulation (000778) to along with Quality Control, Microbiology as under:
1. Tablet Section (General)
2. Capsule Section (General)
3. Cream/Ointment Section (General)
4. Topical Lotion Section (General)
5. Cream / Ointment Section (Steroidal)
6. Topical Lotion Section (Steroidal)
7. Oral Sachet Section (General)
8. Soft Gelatin Capsule (General)
9. Syrup Section (General)
10. Dry Vial Injection Section (Cephalosporin)
11. Capsule Section (Cephalosporin)
12. Oral Dry Suspension section (Cephalosporin)
13. Dry Vial Injection Section (Carbapenem)
And also recommend the grant of following additional sections
1. Lyophilized liquid vial for injection section (General)
2. Liquid Injectable (Vial) (General) Section</td></tr>
</table>

	3. Liquid Injectable (ampoule)(General) Section 4. Eye Drop (General) Section 5. Eye Cream & Ointment (General) section Decision of the Central Licensing Board in 294th meeting: The Board considered and approved the grant of renewal of DML No. 000778 by way of Formulation in the name of M/s Crystolite Pharmaceuticals Rawat on the recommendations of the panel of experts for the period Commencing on 30-8-2023 to 29-08-2028 for the following sections. **The Board observed that Dry Vial Injection Section (Carbapenem) section is not segregated and dedicated facility and did not renew the Dry Vial Injection Section (Carbapenem).** 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointment Section (General) 4. Topical Lotion Section (General) 5. Cream / Ointment Section (Steroidal) 6. Topical Lotion Section (Steroidal) 7. Oral Sachet Section (General) 8. Soft Gelatin Capsule (General) 9. Syrup Section (General) 10. Dry Vial Injection Section (Cephalosporin) 11. Capsule Section (Cephalosporin) 12. Oral Dry Suspension section (Cephalosporin)

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

Decision of CLB was conveyed to the firm. The firm has replied that they will construct segregated building for Carbapenem Section as per decision of Central Licensing Board and will submit layout plan as soon as possible.

Proceedings and Decision by the Central Licensing Board in 298th meeting:

The Board considering the facts on the record and after detailed deliberation decided to approve the grant of renewal of DML No. 000778 by way of Formulation in the name of M/s Crystolite Pharmaceuticals Rawat on the recommendations of the panel of experts for the period Commencing on 30-8-2023 to 29-08-2028 for **Dry Vial Injection Section (Carbapenem).**

As well, the Board advised the firm to move into a dedicated segregated penicillin facility as soon as possible, which should not take more than two years.

MINUTES OF QA&LT CASES FOR 298th MEETING OF CENTRAL LICENSING BOARD

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06	MANUFACTURE AND SALE OF UN-REGISTERD DRUG PRODUCT- M/S. MEDICAL STORE, KARACHI
07	MANUFACTURE AND SALE OF SPURIOUS AND SUBSTANDARD DRUGS-M/S. HOORAIN IMPEX, KARACHI.
08	SALE OF SPURIOUS AND UN-REGISTERED DRUG PRODUCT BY M/S AL-RASHEED MEDICAL AND SURGICAL WOODEN CABIN NO.6-A, KARACHI
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Case No. 01: NON-COMPLIANCE TO GMP AGENDA FOR M/S FASSGEN PHARMACEUTICAL, HATTAR.

I. BACKGROUND

Inspection of the firm M/s. Fassgen Pharmaceuticals, Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar conducted on 08.02.2021. A surprise inspection of the firm in order to evaluate adherence of the firm toward cGMP. The FID during inspection, noticed following observations: -

Change Rooms: -

i. Overall maintenance of change rooms is required with reference to smooth flooring, walls, cupboards and ceiling.
ii. Washing areas in change rooms needs to be closed permanently or removed to avoid contamination.
iii. Implementation of SOPs for entry / exit by personnel needs to be implemented strictly. It was observed that staff / workers do not follow change room protocols. Training of staff is also required in this context.
iv. Air curtains / doors of change rooms need cleaning / maintenance.
v. Re-organization of change rooms to better fulfill their purpose.

Storage Areas: -

i. Proper receiving bay with necessary equipment to remove dust / dirt from the incoming materials outer packing.
ii. Proper sampling booth as well as dispensing booth for raw material sampling / dispensing with LFH to avoid any contamination.
iii. Segregated Rejection / Recall area needs to be designated with entry from outside the warehouse with proper lock and key and authorized entry system.
iv. Storage conditions of primary packing materials need to be improved i.e., properly packed to avoid dust / dirt / moisture and properly labeled.
v. Materials flow process needs to be improved in stores with reference to quarantine / approved areas. Necessary steps need to be ensured to avoid mix-ups.

Tablet (General Section): -

i. Tools of compression machines needs to be placed in SS boxes with proper cleaning procedure and storage.
ii. Cleaning SOPs needs to be revised with defined timelines for equipment to be cleaned and re-cleaning time if the cleaned equipment is not used for several days.
iii. Fluidized bed dryer is provided, however, only single bag is being used. The firm is advised to provide at least molecule wise FBD bag with proper washing / cleaning SOP for avoiding cross contamination.
iv. Overall area maintenance is required w.r.t. floor, walls, ceiling, electrical panels etc.

Capsule and Dry Suspension (Ceph Section): -

i. In capsule area, general maintenance of the area for smooth surfaces, electric panels and proper storage of filled capsules in SS containers.
ii. Bottle blowing procedure in dry suspension area needs to be improved with reference to quality of blowing air, visual checking of bottle and staging / transfer of cleaned bottles to filling area.
iii. Nitrogen purging procedure needs to be improved and clean Nitrogen supply through filtration is required.
iv. Optical checking counter needs to be provided for bottles after blowing for detection of any contamination / glass particles / broken glass bottles etc.
v. Moisture control measures need to be improved considering the moisture sensitivity of Ceph products.

"Common observations of above four oral dosage form sections which also need to be addressed;"

a) Temperature / humidity monitoring with proper record keeping in all areas.
b) Fulfilling Class-D air requirement via documented / implemented HVAC system.
c) General cleanliness and maintenance of areas / equipment and allied facilities.

Capsule and Dry Suspension (Ceph Sections): -

i. Validation of HVAC system in the area.
ii. Sterilization process validation of vials after washing.
iii. The firm has provided R.O. water for vial washing, however, final rinsing with distil water is recommended.
iv. The firm has provided vial cool down area after sterilization through double door sterilizer. The cool down area is of class B as per firm's information. The product is not terminally sterilized and placing sterile vials in class B without validation data poses risk to the product. Hence, the firm was advised to review their process flow. After sterilization, vials only be exposed in class A area. Option of laminar flow hood or duly designed transfer trolley having laminar flow with continuous power supply up to class A vial filling / stoppering area was discussed by the firm for rectifying the issue.

Quality Control: -

i. The firm has operational HPLC but testing methods of registered products have not been shifted on HPLC method provided in latest pharmacopeia(s). The firm is advised to immediately take action for shifting their testing methods to latest pharmacopeial methods.
ii. The firm has two stability chambers. Stability studies are being performed but protocol for study design in not properly prepared. Stability studies protocol needs to be devised in light of ICH guidelines and according studies should be conducted for the reliability of data.
iii. Separate electricity backup must be provided for all the sensitive equipment in QC along with UPS backup.
iv. Stepwise purchase of Reference Standards from authentic source is also recommended.
v. Authenticity of data must be ensured through data loggers / software based systems.

Quality Assurance: -

"The firm has appointed one QA personnel working in the QC department but not share qualification of QA person. The firm is advised to;"

i. Establish separate QA department independent of QC.
ii. Strengthen QA department with well experienced staff to develop proper Quality Management System and validation / qualification purpose.
iii. QA department must be assigned the task of master validation plan. Cleaning validation and validation of HVAC system especially in dry vial Injectable needs to be started immediately to avoid contamination / cross contamination of pharmaceutical products.
iv. System of self-inspection needs to be strengthened.

Personnel: -

i. Training of staff needs to be done for better understanding of cGMP guidelines. Trainings on firefighting system / emergency situation may also be performed.

Conclusion: -

"*Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection, the firm is considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under. Further, section wise observations need to be addressed for improvement in their manufacturing unit.*"

2. In view the observations noticed by the FID, the firm was issued **explanation letter** for and directed to present their reasons serious violations and to submit compliance report of the rectification of the observations.

3. M/s. Fassgen Pharmaceuticals, Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar, with reference to this office letter of even No. dated 18.03.2021, submitted plan for rectification of the observations which were observed in GMP inspection of their firm conducted on 08.02.2021.

4. It was observed during the evaluation of compliance report submitted by the firm that they are not familiar with the Pharmaceutical Quality System (PQS) as the submitted documents lack the basic components i.e. the CAPA is not as per standard format as both corrective action and preventive actions are placed in one head. Secondly Risk assessment and mitigation has not been done to ascertain the impact of changes done. Root Cause Analysis also not preformed. Furthermore, the compliance report does not have any evidence to support whether or not the rectifications have been made.

5. In view the reply of the firm, the Additional Director, DRAP, Peshawar was requested to direct the area FID to guide the manufacturer on the subject matter and conduct an inspection to verify the status of the rectification

II. Initial Seizure and Request for Safe Custody

On 28.11.2022, Mr. Faisal Shehzad, Additional Director/FID-I, DRAP, Peshawar, issued a letter (No. 10-166/2021-Fassgen-DRAP) regarding the seizure of drugs under Section 18(1)(f) of the Drugs Act 1976. The letter detailed the non-compliance issues discovered during the inspection, which included significant deviations from Good Manufacturing Practices (GMP). These deviations posed potential risks to product quality and patient safety. Additionally, the letter requested the safe custody of the seized drugs and an extension of the "Not to dispose of" period for three months under Section 18(1)(i) of the Drugs Act 1976 to allow for further investigation and resolution of the issues. The request for grant of extension in not to dispose of period was acceded in light of the Decision of 273rd meeting of CLB.

In the above report GMP non-compliance including lapses in documentation, inadequate quality control procedures, improper handling and storage of raw materials, and failure to maintain a clean and hygienic production environment were also reported. These violations necessitated immediate corrective measures to prevent any adverse impact on product quality and patient safety It underscored the importance of maintaining control over potentially unsafe drug stocks until compliance could be assured. The firm was issued the following letters dated 17.01.2023: -

i. Seizure of Drugs under DRAP Act 2012, permission for safe custody of seized drugs.
ii. Extension in period of not to dispose of.
iii. Explanation letter/ Suspension of production in injectable section.

III. Firm's 1st Response

On 31.05.2024, the firm responded to the FID inspection report dated 08.02.2021, but the response was found lacking in critical aspects. The firm's response failed to adequately address essential elements of Corrective and Preventive Actions (CAPA). Specifically, it did not include a thorough Root Cause Analysis, which is fundamental for identifying the underlying reasons for the non-compliance issues. Furthermore, the response lacked a clear Correction plan and Methodology for Corrective Action, both of which are necessary to rectify the identified deficiencies. The firm also did not outline a robust Preventive Action strategy to ensure that such issues do not recur in the future. Additionally, the response was deficient in providing a Validation process through Quality Risk Management, which is crucial for ensuring that the corrective measures are effective and sustainable. Overall, the response lacked specific details on how the firm planned to rectify the deficiencies and prevent their recurrence, thus failing to meet the regulatory requirements for a comprehensive CAPA.

IV. Show Cause Notice by FID

On March 7, 2023, the office of FID, Peshawar issued an **unprecedented Show Cause Notice** to M/s Fassgen Pharmaceuticals. The Notice underscored the severity of the firm's non-compliance with Good Manufacturing Practices (GMP) and demanded a detailed explanation for the observed deficiencies. It explicitly warned of potential consequences, such as suspension of production activities, if prompt corrective actions were not taken. This measure was aimed at compelling the firm to address the identified GMP issues urgently and to ensure strict adherence to regulatory standards.

V. Action by QA&LT Division:

The firm's response being inadequate and the seriousness of the GMP non-compliance issues identified, several critical actions were already taken including ensuring the;

i. safe custody of seized drugs to mitigate potential risks to public health,
ii. temporarily suspending production activities in the affected sections until full GMP compliance is achieved,
iii. issuing a formal Show Cause Notice

to prompt immediate corrective actions, and preparing the case for discussion at the Central Licensing Board (CLB) to address the firm's non-compliance at a strategic regulatory level.
firm's inadequate response and the situation's gravity necessitated including the firm in the inspection plan for a thorough GMP assessment.

VI. Firm's 2nd Response

On 28.06.2024, the firm responded to this office letter, the firm's response was acceptable as it had provided a brief Root Cause Analysis, CA/PA, Timeline and Status of the observations to adequately address essential elements. However, it lacked the validation through QRM.

RECOMMENDATION FROM QA&LT

In view of the scenario detailed above since the firm had claimed to have made rectifications and ample time for the same was given to the firm; the QA&LT Division recommends that prior the initiation of any punitive action against the firm, it may be given an audience before the esteemed Board an if deemed appropriate the CLB may constitute a panel of investigate the matter pertaining to Seizure & Not to Dispose of and submit the report to the Director of QA&LT for further processing the case and subsequently the developments thereon be placed before the CLB in its upcoming meeting.

Accordingly, the firm was informed to nominate a representative to appear in person before the Central Licensing Board on 10.07.2024

PROCEEDINGS OF CLB 298TH MEETING

The representative of the firm Mr. Zeeshan Fasih (Director), Mr. Hameed Ullah Khan (QC In Charge) and Mr. Waqar Shah (Production In-Charge) appeared before the board in response to the Show Cause Letter.

DECISION OF CLB 298th MEETING

Pursuant to the personal hearing of the firm's aforementioned representative before the Board, and subsequent to thorough deliberations and due diligence, the Central Licensing Board has resolved to constitute the following panel:

i. *Mr. Yunus Khattak, Chief Drug Inspector of KPK*
ii. *Mr. Atiq Ul Bari, Federal Inspector of Drugs (FID), DRAP Peshawar*

iii. *Hafiz Sanaullah Babar, Deputy Director QA&LT, DRAP Islamabad*

This panel is entrusted with the mandate to conduct an exhaustive review of the firm's compliance status with Good Manufacturing Practice (GMP) guidelines as delineated in the Drugs Act, 1976, and the corresponding regulations. Specifically, the panel shall:

i. *Scrutinize the areas inspected, personnel interviewed, and documents reviewed during the initial inspection.*
ii. *Rigorously verify the firm's submitted compliance report, with particular emphasis on the adequacy and implementation of Corrective and Preventive Actions (CAPA), including Root Cause Analysis and risk mitigation strategies.*

The panel is required to compile a comprehensive report based on the findings from their review and follow-up inspection. This report shall be submitted to the Director of QA&LT for further processing and shall include clear and candid recommendations for the Board's consideration

Case No 02: <u>RECOVERY AND SEIZURE OF 99, UNREGISTERED DRUGS FROM UNLICENSED PREMISES: STORE/OFFICE/GODOWN OF M/S SHAHEEN PHARMACY (SHAHEEN CHEMIST) AND ITS SEALING.</u>

That FID-IV, Islamabad vide her letter No.F. 4-1/2019-FID-IV (ISD) dated June 25th, 2019 informed that she along with Mr. Hasan Afzaal (FID-III, DRAP, Islamabad), Miss Maria Zafar (Drug Inspector, ICT), Mr. Mushtaq Ahmad (Assistant In-Charge, DRAP, Islamabad) visited the unlicensed premises i.e. Office No. 310, 3rd Floor, Capital Trade Center, F-10 Markaz, Islamabad, being used as store/godown for drugs of M/s Shaheen Pharmacy (Shaheen Chemist) on 24.06.2019 at 1130 Hrs with reference to the complaint number KP270419-2445432 via Pakistan Citizen's Portal. Mudassir Khan S/O Hashim Khan R/O Jibghai Post Office, Heroshah, Tehsil Dargai, District Malakand bearing CNIC # 15401-1834310-7 was present at the time of visit. He did not allow FID and her team to enter into the store unless until the management of the unlicensed premises (i.e. M/s Shaheen Pharmacy (Shaheen Chemist) situated at Capital Trade Center, F-10 Markaz, Islamabad) allows him to do so. FID, Islamabad also informed that upon contacting Qayyum Mumtaz S/o Mumtaz Hussain, CNIC # 37405-9481772-7, the qualified person, and the representatives Amir & Beenish came up and Amir asked the Mudassir Khan to close the door who acted upon the direction so given and closed the door from inside.

2. FID, Islamabad added that she asked Qayyum Mumtaz, Amir and Beenish to get opened the closed door and remain present and cooperate in the inspection of Office No. 310, 3rd Floor, Capital Trade Center, F-10 Markaz, Islamabad (referred hereafter as "the said unlicensed premises") keeping in view the strong reasons to believe about presence of Un-registered drugs in the said unlicensed premises. The Qualified Person, Staff and representatives named-above did not get opened the door, disobeyed the lawful authority of the FID, Islamabad and did not allow the her to inspect the unlicensed premises by stating that the she will not be allowed to enter and inspect the unlicensed premises until the arrival of Mr. Talat Mehmood purported/referred to as proprietor/owner of M/s Shaheen Pharmacy (Shaheen Chemist).

3. FID, Islamabad also added that she was informed by Amir and Mst. Beenish that Talat Mehmood who is the occupant of Office No. 310, 3rd Floor, Capital Trade Center, F-10 Markaz, Islamabad & proprietor of the said unlicensed premises will arrive shortly (around 1300 hrs); however, he did not arrive at the site till the completion of inspection of the said unlicensed premises (2300 hrs).

4. FID, Islamabad informed that upon the lapse of 4 hours in wait due to physical resistance by the persons mentioned in para-2 above, she telephonically requested the ICT Police and the Area Assistant Commissioner to help and facilitate in inspection of the said unlicensed premises. Despite the fact that FID, Islamabad, Drug Inspector ICT, Officers of 15-Police Islamabad, Duty Officers (ASI etc., PS Shalimar, Islamabad) and the Area Assistant Commissioner Islamabad directed multiple times the representatives (Mr. Amir & Miss. Beenish) of M/s Shaheen Pharmacy (Shaheen Chemist), Islamabad to get inspected the said unlicensed premises i.e. Office No. 310, 3rd Floor, Capital Trade Center, F-10 Markaz, Islamabad. The representatives (Mr. Amir & Miss. Beenish) of M/s Shaheen Pharmacy (Shaheen Chemist), Capital Trade Center, F-10 Markaz disobeyed/obstructed the aforementioned lawful authorities of above officers in their prescribed jurisdiction by foCLBidding Mudassir Khan S/O Hashim Khan R/O Jibghai Post Office, Heroshah, Tehsil Dargai, District Malakand bearing CNIC # 15401-1834310-7 to open the door of the said unlicensed premises.

5. FID, Islamabad also informed that the Senior Drug Inspector/ Secretary PQCB ICT arrived at said unlicensed premises at 1830 hrs; subsequent to his contact and discussion with the management of M/s Shaheen Pharmacy (Shaheen Chemist), F-10 Markaz, Islamabad, the representatives i.e. Amir & Miss. Beenish, directed at about **1915 hrs** to the above-referred Mudassir Khan (who had closed the door from inside) to open the door who subsequently opened it.

6. FID, Islamabad stated that she entered the unlicensed premises i.e. Office No. 310, 3rd Floor, Capital Trade Center, F-10 Markaz, Islamabad at about 1915 hrs along with Sardar Shabbir The Senior Drug Inspector/ Secretary PQCB ICT, Mr. Hasan Afzaal (FID-III, DRAP, Islamabad), Miss Maria Zafar (Drug Inspector, ICT), Mr. Mushtaq Ahmad (Assistant In-Charge, DRAP, Islamabad) etc. in the presence of Mr. Naazir Khan S/O Muhammad Younis bearing CNIC# 13302-0379588-3, Purchase officer of M/s Shaheen Pharmacy (Shaheen Chemist), Mr. Amir & Mst. Beenish, wherein all witnessed the presence of Mudassir Khan S/O Hashim Khan R/O Jibghai Post Office, Hero Shah, Tehsil Dargai, District Malakand bearing CNIC # 15401-1834310-7, who had closed the door from inside for the whole time i.e. from 1130 hrs till the time of opening the door i.e. 1915 hrs and recovered 99 different Un-registered products, stored at uncontrolled conditions, Packing Materials of dawaai.pk (online site/application for sale of drugs) and seized the same on the prescribed **Form-2**, at 2100 hrs in the presence of witnesses namely, Mr. Hasan Afzaal (FID-III, DRAP, Islamabad and Mr. Mushtaq Ahmad (Assistant In-Charge, DRAP, Islamabad. The Form-2 was duly signed and acknowledged with signatures and thumb impression by Mr. Naazir Khan S/O Muhammad Younis, bearing CNIC# 13302-0379588-3, Purchase officer of M/s Shaheen Pharmacy (Shaheen Chemist), Capital Trade Center, F-10 Markaz, Islamabad on behalf of management of M/s Shaheen Pharmacy (Shaheen Chemist), F-10 Markaz, Islamabad in the presence of witnesses. Details of 99 un-registered drugs are as under:

Sr No.	**Name of Drug**	**Batch No./ Parti No./ Lot No./ Control No.**	**Quantity**	**Claimed Manufacturer**
1.	Forziga 10mg Film Coated Tab	NX685	1x28x65 Tabs	Astrazeneca, Istanbul
2.	Viagra 100mg tab	MAL 19990545AG	6 x 12 Tabs	Pfizer, USA
3.	Cialis Gold tab	57J9087K	5 x 10 Pack (37 TAB)	Lilly, Uk
4.	Cialis tab	Nil	5 x 6 Tab	Lilly, Uk
5.	Sialdenafil Accord Tab100mg	W00971	5 x 8 Tabs	Accord Healthcare, UK
6.	Diazepam Rectal Solution	18001124	5*3 Tubes	Desiten, Arzneimittel, GmbH
7.	Co-Codamol 30/500ml	1297	100*6 Tabs	M & A Pharma Chem. England
8.	Cypionax	338136	2ml x 10 Amps	TP Drug Lab, Thailand
9.	Sustanon 400mg/ml	SU3/26	3x1 (400mg/ml)	LA Pharma S.r.l
10.	Sinemet Plus Tablet	03P0223(3) 02P0594(2)	50 x 5 Tabs	B & S Healthcare, UK
11.	Testolic 100mg	338124 338004	10*3 ampoules	TP Drug lab Thialand
12.	Neurorubine IM	T16649A	13 x 5 Amp.	Acino, Switzerland
13.	Napa 250mg Supp.	CLBK034(18) CLBK035(6) CLBJ013(3) CLBJ008(1)	20*28 Supp	Beximco Pharmaceuticals Bangladesh

14.	Depsone Tab	N444	1000 Tabs (compound pack)	GSK Pharmaceutical, Pvt Ltd Mumbai
15.	Jardiance 10mg	N/A	30x9 tabs	Boehringer Ingelheim Pharma, Gmbh
16.	Bione Folic Acid 800 mcg	702037	90x10	Alaska Westberry mkt by Heal the World
17.	Delay Spray with Vit E	NIL	2 Packs	HS David GmbH
18.	Agiolax 250gm heCLBal	G1800715	20 Packs	Madaus GmbH
19.	Questran Sachet	696	1 Pack	BMS Ireland
20.	Ventolin Nebules	XW0471	20x4	GSK Australia for Pfizer Istambul
21.	Eliquis Tabs	W94294	60x2 Packs	BMS Porto Riko
22.	Aldare Cream 5%	GTE015B(2) GSK088B(1) GTDO75D(1)	12x4 Packs	Meda AB Sweden
23.	Solcoseryl Ointment 20g	112006(14) 111479(5)	1x19 tubes	Meda pharma Switzerland
24.	Stalevo tab 100/20/200mg	1816821	100x2 Tabs	Novartis Istanbol Mfg Orion, Finland
25.	Cipralex 20mg	2561732	10 Packs	Lundbeck Denmark
26.	Furolin Tab 100mg	1809205 (3) 1805422 (5)	30*8 Tabs	IASIS Pharma Greece
27.	Casodex Tab 50mg	NX317	50*1 Tabs	AstraZeneca PLC GmbH
28.	Cipralex 10mg	1808008 (4) 1808010 (3) 1808011 (3)	28*10 Tabs	Pharma Vision Istanbul
29.	Ebixa Tab 20mg	706430(3) 602575 (1)	28*4 tabs	Lundbeck Istanbul
30.	Hyzaar 50/12.5 mg	003018	28*07 tabs	Merk Sharp Dohme Levent Istanbul
31.	Cozaar 50mg	004058	28*4 Tabs	Merk Sharp Dohme Levent Istanbul
32.	Co-codamol 30mg/500mg	1632352	50*01 Tabs	Wockhardt UK
33.	Endoxan	G803068 G803245	100*02 Tabs	TM of Baxter Onocology Germany
34.	Eltroxin Tab 100mcg	18K004	100*14 Tabs	Aspen, Germany
35.	Emla Cream	SI6703	01 Pack	AstraZeneca A.E
36.	Zyprexa Tab 10mg	C936340(5)	28* 5 Tabs	Catalent UK
37.	Zyprexa Tab 5mg	C921661 (3) C926866(2) C857538(1)	28*6 Tabs	Catalent UK
38.	Pirfenex Tab	SN80743(4) SN80715(1)	30*05 Tabs	Cipla India

39.	Neurorubine Inj 3ml	T14876A	5x06 Inj	Merckle, Germany
40.	Loceryl 5% w/v	7212329 8212316	03	France
41.	Brufen Paedratic 100ml	1075960	01 pack	Abbott Italy
42.	Brufen Paedratic 100ml	1068541	03 pack	Abbott Italy
43.	Hydrocortisone Roussel 10mg	7PU8A(5) 8K06A(6)	25*11 Tabs	Sanofi-aventis France
44.	Hydrocortisone Tab	1556	30*06 Tabs	Institute of Pharmaceutical Research & Technology S.A
45.	Allopurinol Tab 100mg	GW0103	28*04 Tabs	Accord Health Care U.K
46.	Simvastatin Tab 40mg	A17308	28*02 Tabs	Crescent Pharma U.K
47.	Simvastatin Tab 20mg	PW04814	28*04 Tabs	Accord Healthcare U.K
48.	Adol suppositories	0081	10*1 Supp.	Julphar, U.A.E
49.	Night Nurse	7JW0048	10*02 Caps	GSK U,K
50.	Day Nurse	7HW0140	20*05 Caps	GSK U.K
51.	Day & Night Nurse	7JW0008	24*02 Caps	GSK U.K
52.	Panadal Cold-Flu	UH2L	10*01 Caps	SmithKline Beecham Spain
53.	Warfarin 5mg	02140 02396	28*2 Tabs	Crescent Pharma Overtone
54.	Warfarin 1mg	7700594A	28*2 Tabs	Crescent Pharma Overtone
55.	Satolol 80mg	102014	28*13 Tabs	Teva UK
56.	Satolol HCl 80mg	11183	1 pack	Tellomed Lab, Cambridgeshire
57.	Papavarine HCl 50mg	50516003	1 Pack x 10amp	Galen Istanbul
58.	Medela purelan 100	180305-A	3 Packs	Medela AG EU
59.	Flomax MR 0.4mg	17G07/31	30*6 Tabs	Astella Pharma, Europe
60.	Evista 60mg	C828890(4) C7481173(1)	28*5 Tabs	Lilly SA Spain
61.	Atarax 10mg	190921	25*1 Tabs	UCB SA Pharma Sector Belgium
62.	Florinef 0.1mg	8J8290A	100*1 Tabs	Aspen, Baar
63.	Prograph 0.5 mg	0E3098N	50*03 Caps	Astellas Pharma, Ireland
64.	Levothyroxine 25 Micrograms	85117	28*05 Tabs	Mercury Pharmaceutical U.K
65.	Levothyroxine 50 micrograms	85143	28*17 Tabs	Mercury Pharmaceutical U.K

66.	Levothyroxine 100 micrograms	85104	28*09 Tabs	Mercury Pharmaceutical U.K
67.	Crestor Tab 20mg	PK352	28*3 Tabs	Astrazeneca, Porto Riko
68.	Rilutek Tab 50mg	6NA2D	56*2 Tabs	Sanofi Aventis France
69.	Lipitor 10mg	843108	30*14 Tabs	Pfizer, Istanbol
70.	Cytotec Tab 200mg	B19970	60*06 Tabs	Pfizer U.K
71.	Xarelto 15mg	BXHSR2(3) BXHSR1(2)	28*05 Tabs	Bayer Istanbul
72.	Lioresal 10mg	K0263(1) KF534(6)	50*07 Tabs	Novarits Istanbul
73.	Casodex Tab 50mg	NX317(2) NY472(2) NK753(1)	50*5 Tabs	AstraZeneca
74.	Plaquenil 200mg	8LB1572	30*05 Tabs	Sanofi Mfg Zentiva
75.	Crestor 10mg	NY399	28*02 Tabs	AstraZeneca Porto Riko
76.	Lipitor 40mg	843110	02 packs	Pfizer Turkey
77.	Lipitor 20mg	W99993 AG1238	30*02 Tabs	Pfizer Turkey
78.	Glucophage SR 500mg	Y03627	56*1 Tabs	Merck Sereno U.K
79.	Roaccutane 20mg	B9439B03, B9357B01	30*02 Caps	Roche Germany
80.	Ucholine 10mg	23BKX	100*01 Tabs	M & H Thailand
81.	Ucholine 05mg	13BRX	100*01 Tabs	M & H Thailand
82.	Ebixa 10mg	708835(3) 707254(1)	100*4 Tabs	Rottendorf Pharma GmbH, Ennigerloh/ Almanya
83.	Daclatasvir Tab 60mg	8059250	28*03 Tabs	Mylan Pharmaceutical, Maharashtra India
84.	Clenbuterol 40mcg	C2/A41	100*4 Tabs	LA Pharma S.r.l
85.	T3 Cytomel 100mcg	TC24	100*2 Tabs	LA Pharma S.r.l
86.	Tri-Test 500 Multidose Inj	2197	01 Inj	Infiniti Laboratories
87.	Stanozolol 10mg	S2/B14	100*1 Tabs	LA Pharma S.r.l
88.	Veboldex 250mg 10ml	TH1609	1 vial	Thaiger Pharma
89.	Solcoseryl Ointment 20gms	111588(11) 195281(5) 109806(2)	1*18 Tubes	Legacy Pharmaceutical Switzerland
90.	Napa 125 mg	CLBL004(4) CLBH009(3)	20*9 Supp.	Beximco Pharmaceuticals, Bangladesh

		CLBK005(2)		
91.	Zyprexa Velotab 10mg	1607091A	28*2 Tabs	Catalent UK
92.	Night Nurse	7JW0037	10*1 Caps	GSK UK
93.	Forziga 10mg Tab	NX490	28*1 Tab	Astrazeneca, Istanbul
94.	Danabol DS 10mg	TE/14921	500 *1 Tabs	March Pharmaceuticals Thailand
95.	Prograph 1 mg	1E3363A(1) 1E3357A(1)	50*2 Caps	Astella, Ireland
96.	Warfarin 3mg	01332	28*2 Tabs	Actavis, UK
97.	Cardura 4mg	F10319034	20*1 tabs	Pfizer, Germany
98.	Rogain 5% Minoxdil	0748RD1	4*5 cans	J & J, Italy
99.	Sustanon 10ml 250mg/ml	---	I vial	Black dragon pharma Thailand
*	Empty containers/ outer cartons of dawai.pk		12 units	

7. FID, Islamabad also informed that Bill invoices and warranties in the name of M/s Shaheen Pharmacy (Shaheen Chemist), F-10 Markaz, Islamabad were stacked in the room. Additionally, following documents were recovered which were sealed inside the unlicensed premises.Copy of sealing memo was also forwarded.

Affidavits		
Sr #	**Affidavit #**	**Issued to**
1. A117025	8712/21-12-17	M/s Shaheen Pharmacy (Shaheen Chemist)
2. 057156	454/08-06-16	Talat Mehmood
3. A343430	21350/07-05-19	Ahtesham Ali
4. 352084	4497/03-10-17	Khawaja Tayyab S/o Talat Mehmood
5. 930973	3454/10-09-18	Talha Hasan Talat S/o Talat Mehmood
Cheque No.		**Pay order**
1. 03360967		1. 001733501
2. 57034417		
3. 57034418		
4. 57034419		
5. 57034420		
6. 61792462		
7. 11330349		
8. 11330350		
9. 6348623		
Bill invoice(s)/warranties of Shaheen Pharmacy (Shaheen Chemist)		

FID added pertinently mentioned that the representatives of ICT Drug inspectorate had left the unlicensed premises at the time of seizure of unregistered drugs and sealing of unlicensed premises and did not witnessed the same for the reasons best known to them.

8. FID, Islamabad also stated that the unlicensed premises was sealed under **Schedule-V(1)(h)** of **DRAP Act 2012** read with **section 18(1)(h),** in the presence of witnesses on sealing memo, on 24-06-

2019 at 2300 hrs and sealed, marked and duly signed by the purchase officer of M/S Shaheen Pharmacy (Shaheen Chemist) in the presence of above mentioned witnesses. The sealed keys duly signed and marked were handed over to the above-referred.

9. FID, Islamabad stated that Mr. Amir and Miss. Beenish had obstructed the undersigned in the exercise of power conferred upon by and under the Act and disobeyed the lawful authority of inspector thus violated Schedule III(3) of DRAP Act 2012 read with section 27 (3) of Drugs Act 1976 which is punishable offence under the law.

10. FID, Islamabad also stated that the owner/management of the unlicensed premises as well as M/s Shaheen Pharmacy (Shaheen Chemist), F-10 Markaz, Islamabad **etc**. has been involved in violation of Schedule II(A)(1)(a)(vii)(x), (b), (c), (d), (i) and (B)(a), of DRAP Act 2012 /Section 23(1)(vii)(x), (b), (c), (d), (i) and Section 24(i), of Drug Act 1976, which is cognizable offence under Schedule-IV(2)(a) of DRAP Act 2012 / section 30(2)(a) and punishable under Schedule III(1)(a), (b) , (c) and (2), (3), (4), (6)/ Section 30(2)(a) of Drug Act 1976. Mr. Amir and Miss. Beenish have created hindrance in performing of official duties within the notified area of jurisdiction, due to which the said unlicensed unlicensed premises could not be opened/accessed till 1915 hrs.

11. FID, Islamabad stated that the case is under investigation and is submitted for the grant of permission to her for safe custody of the seized drug/materials/articles till the decision of the case, as required under section 19 (5)(b) of the Drugs Act, 1976, as well as the extension in sealing period of the above said unlicensed premises and cancellation of Drug Sale License of M/s Shaheen Pharmacy (Shaheen Chemist) as per law.

12. FID, Islamabad also stated that in the light of credible evidence collected the following accused persons have contravened the provisions of Schedule II of DRAP Act 2012 read with section 23 of Drug Act 1976, which are punishable under schedule III of DRAP Act 2012 read with section 27 of Drug Act 1976 and Rules framed thereunder as enumerated in paras 9 and 10 supra. It is therefore she requested that permission for lodging of F.I.R in the Crime Circle, Federal Investigation Agency, Islamabad, may kindly be granted against following accused persons, to further investigate and to resolve the following queries:

- What is the source of purchase of unregistered Drugs?
- Who is the supplier of these unregistered drugs recovered from unlicensed premises?
- Where these unregistered are being manufactured/imported/sold/obtained?
- Whether identified Documents including bill invoices/warranties, affidavits, check(s)(and associated bank Accounts) sealed within the unlicensed premises, belong to M/s Shaheen Pharmacy (Shaheen Chemist) and proceeds the illegal business of sale of unregistered drugs in violation of Law?

i. M/s Shaheen Pharmacy (Shaheen Chemist), Capital Trade Centre F-10 Markaz Islamabad, through its owner/proprietor
ii. Mr Talat Mehmood S/o Mumtaz Hussain R/o P.O Khas, Bhadana, Tehsil Gujar Khan, Rawalpindi, bearing CNIC# 61101-5146264-3, owner/proprietor of M/s Shaheen Pharmacy (Shaheen Chemist), Capital Trade Centre F-10 Markaz, (copy of DSL attached)
iii. Mudassir Khan S/O Hashim Khan R/O Jibghai Post Office, Heroshah, Tehsil Dargai, District Malakand bearing CNIC # 15401-1834310-7
iv. Mr. Amir, claimed to be Representative of M/s Shaheen Pharmacy (Shaheen Chemist), Capital Trade Center, F-10 Markaz
v. Miss. Beenish, claimed to be Representative of M/s Shaheen Pharmacy (Shaheen Chemist), Capital Trade Center, F-10 Markaz
vi. Naazir Khan S/O Muhammad Younis, bearing CNIC# 13302-0379588-3, Purchaser of M/s Shaheen Pharmacy (Shaheen Chemist), Capital Trade Centre F-10 Markaz, Islamabad

vii. Mr. Qayyum Mumtaz S/o Mumtaz Hussain, bearing CNIC # 37405-9481772-7 Qualified Person of M/s Shaheen Pharmacy (Shaheen Chemist), Capital Trade Centre F-10 Markaz, Islamabad. (copy of DSL attached)

13. Keeping in view the request and recommendation of FID, Islamabad, the Director, QA&LT, DRAP, Islamabad has acceded the requestof FID*"to grant the permission to continue the custody of seized stocks till decision of the case and permission to lodge FIR"*being authorized by the Central Licensing Board in its 237th Meeting held on 01.10.2014 as required under DRAP Act, 2012/the Drugs Act, 1976 and rules framed thereunder. The approval was communicated to FID-IV, Islamabadvide two(02) letters F. No.04-13/2019-(QC) dated 10th July, 2019.

14. That the case is placed before the CLB for:

a. ratification of permission granted by the Director (QA&LT) for registration of FIR against accused persons mentioned in para 12 above for violations mentioned in para 9 & 10 above; and
b. ratification of permission granted by the Director (QA&LT) for safe custody of seized stock; and
c. the Board's consideration regarding extension in the sealing of Office No. 310, 3rd Floor, Capital Trade Center, F-10 Markaz, Islamabad till finalization of the case; and
d. Recommendation for cancellation of drug sales license of M/s Shaheen Pharmacy, Business Trade Centre, Shops No. 14, 15 & 16, 2-G & 2-H, F-10 Markaz, Islamabad to ICT Health Administration.

Proceeding & Decision of the 271st Meeting:

15. The Board deliberated the matter in depth, considered the facts of the case and after perusal of record decided as under:

i. Board ratified the permission granted by the Director (QA&LT) for registration of FIR against accused persons mentioned in para 12 above for violations mentioned in para 9 & 10 above, communicated vide letter no. 04-13/2019-QC dated 10th July, 2019; and
ii. Board ratified the permission granted by the Director (QA&LT) for safe custody of seized stock till decision of the case, communicated vide letter no. 04-13/2019-QC dated 10th July, 2019; and
iii. Board extended the sealing period of Office No. 310, 3rd Floor, Capital Trade Center, F-10 Markaz, Islamabad till finalization of the case till finalization of case; and
iv. Board recommended the cancellation of license (DSL NO. 390ICT/2013) of M/s. Shaheen Pharmacy, Business Trade Centre, Shops No. 14, 15 & 16, 2-G & 2-H, F-10 Markaz, Islamabad.

16. The then area FID Islamabad vide letter No. 4-1/2019-FID-IV (ISD) dated 11-07-2019 had submitted request to lodge FIR against the accused to the Director ACC FIA Islamabad. Moreover, in compliance to the decision of the Board, the division of QA&LT issued letter vide No. F. 03-44/2019-QC (271-CLB) (pt-II) dated 11-11-2019 to the DHO Islamabad, Sr. Drug Inspector (ICT) Islamabad and the then area FID Islamabad.

17. FID IV Islamabad vide letter F. No. 4-1/2019-FID-IV (ISD) dated 28-03-2024 submitted the report/challan dated 13-03-2024 provided by the Sub-Inspector/IO FIA ACC Islamabad U/S 173 Cr. P.C wherein the IO, keeping view the facts of the case and investigations carried out, concluded as under:

"In view of above mentioned circumstances, examination of relevant record and after recording the statements of witnesses u/s 161 Cr. PC, the accused person Nazir han s/o Muhammad Younus CN1C 13302-0379588-3 has been found guilty in the instant case for sale/purchase of unregistered drugs. Efforts were made for his arrest but he has willfully concealed himself to avoid arrest and he has been declared as proclaimed offender by the competent court. Report u/s 512 Cr. PC against accused person Nazir Khan is submitted whereas Talat Mehmood s/o Ghulam Khawaja (proprietor of M/s Shaheen Pharmacy) located at Business Trade Centre, F-10, Markaz Islamabad is being placed in Column No. 02 and is placed at the mercy of the Honorable Court. However, during the course of further investigation, if any incriminating material against M/s Shaheen Pharmacy came on record, supplementary report/challan shall be submitted."

18. Moreover, FID IV Islamabad in the above-mentioned letter has requested CLB to grant the permission for prosecution in The Drug Court against the following accused for violation of Schedule II(A)(1)(a)(vii), (x) and Schedule II(A)(1)(b),(c) and Schedule II(B)(a) of DRAP Act 2012 read with Section 23(1)(a)(vii), (x), and Section 23(1)(b), (c), (d), (i) and Section 24(1) of the Drugs Act 1976 which is punishable under Schedule-III(1)(a),(b),(c) and (2),(3),(4), (6) of DRAP Act 2012 read with Section 30(2)(a) of the Drugs Act 1976:

i. M/s. Shaheen Pharmacy (Shaheen Chemist), Capital Business Trade Centre, F-10 Markaz, Islamabad through its owner/proprietor.
ii. Talat Mehmood S/o Ghulam Khwaja (owner/proprietor)
iii. Naazir Khan S/o Muhammad Younis (Purchaser/front man)

19. Keeping in view the challan submitted by IO FIA ACC Islamabad and letter of FID IV Islamabad, show-cause notice vide letter No. F. 04-13/2019-QC dated 10-06-2024 was issued to above mentioned accused. The show cause notice issued to Talat Mehmood (owner) was returned to the Division of QA&LT with the comments from the courier that he has tried multiple times i.e. on 11th, 12th, and 13th June 2024 but recipient is not available to receive the letter. Moreover, no reply has been received from Naazir Khan (Purchaser/Front man). Letter of personal hearing has also been issued the accused to appear before the Board for personal hearing.

Proceedings and Decision of 298th meeting of CLB:

In response to the show cause and personal hearing notice issued by the division of QA&LT the accused neither by themselves nor through any counsel appeared before the Board.

The Board after thorough deliberations on the facts of the case, challan submitted by the IO FIA ACC Islamabad, request of FID-IV Islamabad and keeping in view the fact that despite of multiple attempts, the accused neither received/respond to the show-cause notice issued by the division of QA&LT nor appeared before the Board, decided to grant FID-IV Islamabad permission to prosecute following accused for violation of Schedule II(A)(1)(a)(vii), (x) and Schedule II(A)(1)(b),(c) and Schedule II(B)(a) of DRAP Act 2012 read with Section 23(1)(a)(vii), (x), and Section 23(1)(b), (c), (d), (i) and Section 24(1) of the Drugs Act 1976 which is punishable under Schedule-III(1)(a),(b),(c) and (2),(3),(4), (6) of DRAP Act 2012 read with Section 30(2)(a) of the Drugs Act 1976 in the court of competent jurisdiction:

i. M/s. Shaheen Pharmacy (Shaheen Chemist), Capital Business Trade Centre, F-10 Markaz, Islamabad through its owner/proprietor.
ii. Talat Mehmood S/o Ghulam Khwaja (owner/proprietor)
iii. Naazir Khan S/o Muhammad Younis (Purchaser/front man)

Case No. 03: <u>JOINT RAID AT HOUSE NO. 669-A, PIB COLONY, KARACHI AND RECOVERY OF SPURIOUS/UNREGISTERED DRUGS.</u>

01. Federal Inspector of Drugs-III Karachi informed the division of QA&LT DRAP Islamabad regarding a joint raid of DRAP Karachi headed by Additional Director Karachi along with team of Provincial Inspectors of Drugs Sindh assisted by local police at on 12-12-2023 at House No. 669-A PIB Colony Karachi. During the raid, the joint team recovered huge quantities of fake medicines, different raw materials, bulk liquid syrups, packing materials, finished and semi-finished fake drugs of different fake/ghost pharma companies. The FID-III Karachi took samples for the purpose of test/analysis for 15 products on Form-3 and other available products/items were ordered not to dispose of on Form-1 whereas the premises were locked and sealed under section 18 (1)(h) of Drugs Act 1976.

02 The registration status of products recovered from the said premises was verified from the division of PE&R DRAP. Details are as under:

S. No.	Name of Drug	Claimed to be Mfg. By	Registration Status under section 7 of the Drugs Act, 1976 and Rules framed thereunder.
1	Amcox Suspension 250mg/5ml (Amoxycillin) (Reg#017613)	M/s. Alcons Laboratories (Pvt) Ltd Pot No. G-240, Phase II, Super Highway Road, SITE, Karachi.	Not registered.
2	Uniclav Suspension 156.25/5ml (Co-amoxiclav) (Reg#001324)	M/s. Uni-Tiech Pharmaceutical (Pvt) Ltd, Plot No. 4/116, Sector 21, K.I.A., Karachi.	Not registered.
3	Amcox DS Suspension 125mg/5ml (Amoxycillin)	M/s. Alcons Laboratories (Pvt) Ltd Pot No. G-240, Phase II, Super Highway Road, SITE, Karachi.	Not registered.
4	Snagxone Inj 1gm (Ceftriaxone Sodium) (Reg#55799)	M/s. Leckman Laboratories (Pvt) Ltd, Plot G-138, Phase II, Super Highway Road, SITE-II, Karachi.	Not registered.
5	Baenel 400mg capsule	M/s. Medicure Lab F-109 SITE Karachi.	Not registered.
6	Snagxone Inj 1gm (Ceftriaxone Sodium) (Reg#55799)	M/s. Leckman Laboratories (Pvt) Ltd, Plot G-138, Phase II, Super Highway Road, SITE-II, Karachi.	Not registered.
7	Water for Injection	Ms. Wuhan Grand Pharmaceuticals Group Co. Ltd. Chia	Not registered.
8	Epocain Inj 10mg/ml (Lignocaine Hcl BP 10mg/ml) (Reg#047129)	M/s. Epoch Pharmaceutical, Plot No. 85, Sector 15, K.I.A., Karachi	Registered (dated 20 09-2007)
9	KUFLU Syrup 450ml (Diphenhydramine B.P) (Reg#007148)	M/s. Medicure lab, F- 109, Hub River Road, Karachi	All registrations issued to M/s Medicure, Karachi (DML No.000034) were cancelled vide letter dated 18-01-2022.
10	ZEE Inject (Reg#073339)	M/s. Shazeb Pharmaceutical Ind Ltd, Hazara, Trunk Road, Sarae Gadace, Haripur K.P.K	Registered (dated 07 09-2012)
11	Ezomine Capsule 20mg (Esomeprazole) (Reg.001310)	M/s. Uni-Tiech Pharmaceutical (Pvt) Ltd, Plot No. 4/116, Sector 21, K.I.A., Karachi.	Not registered.

12	Askprol Tablets (Paracetamol)	M/s. Alcon Labss Pvt Ltd Karachi.	Askprol Tablet is not registered in favor of purported manufacturer.
13	Sinoxime 100mg/5ml Suspension (Cefixime USP) (Reg#004892)	M/s. Alcons Laboratories (Pvt) Ltd Pot No. G-240, Phase II, Super Highway Road, SITE, Karachi.	Not registered.
14	Flox-G 500mg (Levofloxacin) (Reg#054810)	M/s. Alcons Laboratories (Pvt) Ltd Pot No. G-240, Phase II, Super Highway Road, SITE, Karachi.	Not registered.
15	AL COXIME 400mg (Cefixime) (Reg#017146)	M/s. Alpine Laboratories (Pvt) Ltd Plot #A-41 SITE, Inds. Area, Sector #3, North Karachi Super Highway.	Not registered.
16	Wisdom Inj 1gm	Trigon Pharmaceutical Pvt Ltd. Lahore.	Registered (dated 05 04-2006) (R#042732)
17	Injexone 500mg Inj	Not mentioned in Para 1/N	All registrations issued to M/s. Medicure, Karachi (DML No.000034) were cancelled vide letter dated 18-012022
18	Einoximeds	Not provided	Not registered.
19	Bimix Suspension	Not provided	Registered (R. No. 061495) in favor of M/s. Brand Pharma, Karachi. However, all registration issued to M/s. Brand Pharma, Karachi (DML No. 000684) were cancelled in Sep, 2021.
20	Sinoxime Cap	Not provided	Not registered.

03. Results of test/analysis of samples forwarded to the CDL Karachi by FID-III Karachi are given as under:

S. No.	Name of Drug	Batch No.	Claimed to be Mfg. By	Test Report No. & Date.	Result
01	Epocain lnj 10mg/ml (Lignocaine Hcl BP 10mg/ml) (Reg#047129)	062	M/s. Epoch Pharmaceutical, Plot No. 85, Sector 15, K.I.A., Karachi	KQ-12-23-000157 dated 20th December 2023	Standard
02	KUFLU Syrup 450ml (Diphenhydramine B.P) (Reg#007148)	065	M/s. Medicure lab, F-109, Hub River Road, Karachi	KQ-12-23-000158 dated 20th December 2023	**"Sub-Standard"**

03	ZEE Inject (Reg#073339)	W1666	M/s. Shazeb Pharmaceutical Ind Ltd, Hazara, Trunk Road, Sarae Gadace, Haripur K.P.K	KQ-12-23-000159	Standard
04	Uniclav Suspension 156.25/5ml (Co-amoxiclav) (Reg#001324)	0126	M/s. Uni-Tiech Pharmaceutical (Pvt) Ltd, Plot No. 4/116, Sector 21, K.I.A., Karachi.	KQ-12-23-000160 dated 26th December 2023	**"Spurious" (Falsified)**
05	Ezomine Capsule 20mg (Esomeprazole) (Reg.001310)	006	M/s. Uni-Tiech Pharmaceutical {Pvt) Ltd, Plot No. 4/116, Sector 21, K.I.A., Karachi.	-	**"Spurious" (Falsified)**
06	JHK-SOL NS Infusion (Reg#114643)	1231457	M/s. JHK Pharma Noushera, K.P.K	KQ-12-23-000162 dated 20th December 2023	Standard
07	ASKPROL Tab (Paracetamol B.P) (Reg# 030726)	22AT070	M/s. Citi Pharma Ltd, Formerly Askari Pharmaceutical 3-KM, Kasur-Pakistan.	KQ-12-23-000163 dated 20th December 2023	Standard
08	Amcox Suspension 125mg/5ml (Amoxycillln) (Reg#017613)	23217	M/s. Alcons Laboratories (Pvt) Ltd Pot No. G-240, Phase II, Super Highway Road, SITE, Karachi.	KQ-12-23-00016-S dated 21st December 2023 1	**"Spurious" (Falsified)**
09	Flox-G 500mg (Levofloxacln) (Reg#054810)	760	M/s. Alcons Laboratories (Pvt) Ltd Pot No. G-240, Phase II, Super Highway Road. SITE, Karachi-	KQ-12-23-00016S dated 20th December 2023	**"Spurious" (Falsified)**
10	Fox-G 250mg (Levofloxacin) (Reg#0S4809)	761	M/s. Alcons Laboratories (Pvt) Ltd Pot No. G-240, Phase II, Super Highway Road, SITE, Karachi.	KQ-12-23-000166 dated 20th December 2023	**"Spurious" (Falsified)**
11	AL COXIME 400mg (Cefixime) (Reg#0i7l46)	110	M/s. Alpine Laboratories (Pvt) Ltd Plot #A-41 SITE, Inds. Area, Sector #3, North Karachi Super Highway.	KQ-12-23-000167	**"Spurious" (Falsified)**
12	Snagxone Inj lgm (Ceftriaxone Sodium) (Reg#SS799)	L23-4	M/s. Leckman Laboratories (Pvt) Ltd, Plot G-138, Phase II, Super Highway Road, SITE-II, Karachi.	KQ-12-23-000168 dated 21st December 2023	**"Spurious" (Falsified)**
13	Sinoxime 100mg/5ml Suspension (Cefixime USP) (Reg#004892)	101S13	M/s. Alcons Laboratories (Pvt) Ltd Pot No. G-240, Phase II, Super Highway Road, SITE, Karachi.	KQ-12-23-000170 dated 20th December 2023	**"Spurious" (Falsified)**
14	Leckzolid Tab 600mg (Linezolid USP) (Reg#S5821)	002	M/s. Leckman Laboratories (Pvt) Ltd, Plot G-138, Phase II, Super Highway Road, SITE-II, Karachi.	KQ-12-23-000171 dated 21st December 2023	**"Spurious" (Falsified)**
15	Wisdom lg (Ceftiraxone Sodium USP) (Reg#042732)	WSL-044	M/s. Trigon Pharmaceuticals (Pvt.) Ltd, 8-km, Thokar Raiwnd Road, Lahore.	KQ-12-23-000172 dated 20th December 2023	**Standard**

04. In the light of above-mentioned, FID-III Karachi issued a show-cause letter to Allah Rakha Qasim, Landlord of House No. 669-A, Ground Floor, PIB Colony, Karachi and Waqas S/o Muhammad Farooq, Tenant of above mentioned premises to explain their position in the matter. In response to mentioned show cause notice

Allah Rakha Qasim S/o Qasim (Landlord) House No. 669-A, PIB Colony, Karachi submitted his reply wherein he claimed that ground floor of his property was given on rent to Waqas s/o Muhammad Farooq, CNIC No. 42101-3201007-3 for use of residence & godown for storing chocolate and I have no relation with the unauthorized business of Mr. Waqas s/o Muhammad Farooq.

05. Keeping in view the above-mentioned facts, FID III Karachi concluded that accused Waqas S/o Muhammad Farooq Tenant of Ground floor, House No. 669-A, PIB Colony, Karachi and resident of flat No. 1204, Mohalla Azizabad, FB Area, Block-2, Karachi along with Allah Rakha Qasim S/o Qasim, Landlord/Owner of House No. 669-A PIB Colony, Karachi have been found in manufacturing, storage and sale of Spurious and Sub-standard products which is violation of Section 23(1)(a)(i), 23(1)(a)(v), 23(1)(a)(x), 23(1)(b) and 23(1)(i) of the Drugs Act 1976 and punishable under Section 27(1)(a)(i), 27(1)(b) and 27(4) of the Drugs Act 1976 therefore, permission to prosecute the mentioned accused be granted to FID-III Karachi.

06. In response to the submissions made by FID III Karachi, the division of QA&LT issued show cause notice to the mentioned accused vide letter F. No. 04-18/2023-QC dated 09-07-2024. Till date no reply from neither accused has been received. The accused are called before the Board for personal hearing.

Proceedings and Decision of 298th meeting of CLB:

In response to the show cause and personal hearing notice issued by the division of QA&LT the accused neither by themselves nor through any counsel appeared before the Board. Keeping in view the aforementioned, the Board after thorough deliberations on the facts of the case and investigations submitted by the FID-III Karachi decided to direct FID-III Karachi to lodge FIR against following accused in FIA Karachi:

i. Allah Rakha S/o Qasim (CNIC:42201-0728673-3) owner of house No. 669-A PIB Colony, Karachi.
ii. Waqas s/o Muhammad Farooq (CNIC: 42101-3201007-3) R/o Flat No. 1204, Mohallah Azizabad, FB Area, Block-2, Karachi.

Case No 04: <u>MANUFACTURE AND SALE OF UNREGISTERED DRUG "N-GAISK PLUS TABLETS" AND "SUGAR XL CAPSULES" CLAIMED TO BE MANUFACTURED BY M/S. NAZ HOMOEO PHARMACY KARACHI.</u>

FID-IV, Karachi along with officers of DRAP, Karachi, Provincial Inspector of Drugs and police officials on 24-03-2023 raided the unauthorized premises purported to be of Ms. NAZ Homoeo Pharmacy, plot No.29,38 and 39, Gulshan-e-Jami, Model colony, Malir, Karachi holding a Trade License issued by Malir Town Karachi to keep store or sale pharmacy covered under the respective Bye laws. At the time of inspection, Farkhunda Maqsood and her husband; Maqsood Iqbal were present at the premises and they also owned the premises.

2. During raid, they found manufacturing equipment's such as compression machine, coating machine, active drawing area under the stair case, mixing, liquid manufacturing tanks. FID sealed the premises along with the above said equipment's at plot No.29,38 and 39, Gulshan-e-Jami, Model colony, Malir, Karachi on form-1. Fid further took the suspected samples on form-3 and sent to CDL, Karachi for test/analysis. The manufacturing address on products was mentioned as M/s Naz Homeo Pharmacy, Falak Naz view, Shop No.23, Opposite Jinnah Terminal, Shrah e Faisal, Karachi. Following samples were declared as unregistered by CDL, Karachi:

Name of Product	**Claimed to be Manufactured by**	**Reg. no.**	**Batch no.**	**Mfg. Date**	**Exp. Date**	**CDL remarks**
N-Gaisk Plus Tablets	M/s. Naz Homoeo Pharmacy, Karachi	Nil	004	Aug 2022	Aug 2026	Diclofenac Sodium (allopathic drug) identified as 24.81mg per tablet. The sample is not registered with DRAP, hence it is declared as unregistered drug product.
Sugar XL capsules	M/s. Naz Homoeo & Pharmacy, Karachi	Nil	004	Aug 2022	Aug 2028	Glibenclamide (allopathic drug) identified as 3.34mg per capsule. The sample is not registered with DRAP, hence it is declared as unregistered drug product.

3. FID Karachi requested for permission to lodge FIR dated 27-06-2023 under sections 23(1)(vii),23(1)(viii),23(1)(ix),23(1)(a)(x),23(1)(b),23(1)(h),23(1)(i), punishable under sections 27(1)(a), (b) and 27(4) of Drugs Act read with schedule -II A(1)(a)(vii),A(1)(a)(viii),A(1)(a)(ix),A(1)(a)(x) and Schedule-II (A)(1) (b),A(1)(h) and A(1)(i) of DRAP Act 2012 which is punishable under schedule -III of DRAP Act 2012 against the following:

(i) Maqssod Iqbal s/o Khan Muhammad, (CNIC 42501-0756404-6)

(ii) Rakhshanda Maqssod w/o Maqsood Iqbal (CNIC 42501-2574173-3)

4. Permission of FIR has been granted dated 07-07-2024 by Director QA&LT as CLB has delegated its power for permission to lodge FIR in case of manufacturing and sales of un-registered drugs without DML to Director QA/LT in its 273rd meeting.

5. FID forwarded the final investigation report of Additional Director ACC, FIA Karachi dated 08-01-2024. As per report, it has been established that accused persons committed the offences under section 23(1)(a)(vii), 23(1)(a)(viii), 23(1)(a)(ix), 23(1)(a)(x), 23(1)(b), 23(1)(h), and 23(1)(i) of the Drug

Act 1976 punishable under Section 27(1)(a), 27(1)(b) and 27(4) of the Drug Act 1976 read with schedule –II-A(1)(a)(vii), II-A(1)(a)(viii), II-A (1)(a)(ix), II-A (1)(a)(x), II-A (1)(b), II-A(1)(h) and A(1)(i) of the DRAP Act 2012 and punishable under schedule –III(1)(a), III(1)(b) and III(4) of the DRAP Act 2012. FID requested for permission for prosecution in Drug Court.

6. A show cause notice has been sent to the accused dated 11-03-2024.

7. Mr. Shukat Ali Shehroze Advocate High Court, Karachi submitted reply of showcause notice vide Ref no. RL 2004/2024 dated 20-04-2024 on behalf of (1) Ms. Naz Homeo Pharmacy, (2) Mst. Farkhunda Maqsood and (3) Maqbool Iqbal; reply is reproduced as:

i. "That it is correct that the products as mentioned in the letter were recovered from the premises situated at Plot no 29, 38 &39, Gulshan-e-Jami, Model colony, Malir Karachi, however it is submitted that all these products are old stocks lying therein.
ii. That our clients have already windup/closed their business of homeopathy medicine much earlier then the raid, but they failed to dispose off the said stocks lying in the premises, which is fault and mistake on part of their clients, which they admit and tendor apology for such mistake, however it is submitted that our clients are neither carrying any business of medicine, nor has any desire to carry out the same in the future.
iii. That our client being ashamed and apologetic for their above said mistake and fault and as such they ask forgiveness from your authority and request that they may be forgiven/discharged from the above charge while considering the above said mistake as their last and final mistake, as our client No. 2 & 3are old aged persons and also suffering from various old-aged diseases."

8. They are called for personal hearing before the Board.

Proceedings and Decision of 298th meeting of CLB:

In response to the show cause and personal hearing notice issued by the division of QA&LT the accused neither by themselves nor through any counsel appeared before the Board.

The Board after thorough deliberations on the facts of the case, challan submitted by the IO FIA ACC Karachi and investigations of FID-IV Karachi decided to grant FID-IV Karachi to prosecute following accused for violation of section 23(1)(a)(vii), 23(1)(a)(viii), 23(1)(a)(ix), 23(1)(a)(x), 23(1)(b), 23(1)(h), and 23(1)(i) of the Drug Act 1976 punishable under Section 27(1)(a), 27(1)(b) and 27(4) of the Drug Act 1976 read with schedule –II-A(1)(a)(vii), II-A(1)(a)(viii), II-A (1)(a)(ix), II-A (1)(a)(x), II-A (1)(b), II-A(1)(h) and A(1)(i) of the DRAP Act 2012 and punishable under schedule –III(1)(a), III(1)(b) and III(4) of the DRAP Act 2012 in the court of competent jurisdiction:

i. M/s. Naz Homeo Pharmacy, Plot No. 29, 38 & 39, Gulshan-e-Jami, Model Colony, Malir, Karachi through its owner/proprietor.
ii. Maqssod Iqbal s/o Khan Muhammad, (CNIC 42501-0756404-6) Plot No. 29, 38 & 39, Gulshan-e-Jami, Model Colony, Malir, Karachi.
iii. Rakhshanda Maqssod w/o Maqsood Iqbal (CNIC 42501-2574173-3) Plot No. 29, 38 & 39, Gulshan-e-Jami, Model Colony, Malir, Karachi.

Case No 05: - <u>MANUFACTURE AND SALE OF UN-REGISTERED DRUG PRODUCT- M/S. IRFAN MEDICOS, KARACHI.</u>

FID visited the premises of M/s. Irfan Medicos, Plot No. 30, Sector-14A, Metroville-I, Block-2, Gulshan-e-Iqbal Karachi on 18-10-2021 wherein following samples of suspected drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3. Detail is as under:

S. No.	Name of Drug	Reg; No	Batch No.	Mfg. Date	Exp. Date	Mfg; by
ARS-35/21	Relif extra Tablets	Nil	RR-788	JAN/ 2019	DEC/ 2022	M/s. Combitic Global India.
ARS-36/21	Levitra 20mg Tablets	Nil	BXHNZEI	30/12/ 2018	30/12/2023	M/s. Bayer Germany.
ARS-37/21	Penagra Tablets	Nil	NPC-41	FEB/ 2020	JAN/2024	M/s. Combitic Global India.
ARS-38/21	Cobra - 150Tablets	Nil	Nil	Nil	03/ 2023	M/s. Bliss UAE
ARS-39/21	Vega-100 Tablets	Nil	SC-214	FEB/ 2020	JAN/2024	M/s. Combitic Global India.
ARS-40/21	Knight Rider Tablets	Nil	Nil	01/ 2019	01/2024	M/s. Made in UK.

2. FID sent sealed samples to Federal Government Analyst, Central Drugs Laboratory, Karachi for the purpose of test/analysis. FID asked to M/s. Irfan Medicos, Karachi to provide bill warranty in connection with the purchase of above said drugs. No reply had been received.

3. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said samples as "un-registered drug product" quality. In the light of reports, an explanation letter was issued by FID to M/s. Irfan Medicos, Karachi for explaining their position in the matter of manufacturing/selling of above mentioned "un-registered drug product". But no reply has been received. Reminder -01 of explanation letter was issued by FID to M/s. Irfan Medicos, Karachi was returned undelivered.

4. <u>Details of Un-Registerd drugs samples:</u>

Name of Drug	Identification	Reg; No.	Batch No.	Mfg. by
Relif extra Tablets	Paracetamol, Diclolenac Sodium and Chlorpheniramine Maleate identified	Nil	RR-788	M/s. Combitic Global India.
Levitra 20mg Tablets	Verdenafil (as hydrochloride trihydrate)	Nil	BXHNZEI	M/s. Bayer Germany.
Penagra Tablets	Sildenafil Citrate	Nil	NPC-41	M/s. Combitic Global India.
Cobra - 150Tablets	Sildenafil Citrate	Nil	Nil	M/s. Bliss UAE
Vega-100 Tablets	Sildenafil Citrate	Nil	SC-214	M/s. Combitic Global India.
Knight Rider Tablets	Sildenafil Citrate	Nil	Nil	M/s. Made in UK.

5. In the light of Federal Government Analyst, CDL, Karachi test reports, FID submitted that M/s. Irfan Medicos, Plot No. 30, Sector-14A, Metroville-I, Block-2, Gulshan-e-Iqbal Karachi found involved in selling of unregistered drugs and violated the section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c) & 23(1)(i) of the Drugs Act 1976. Punishable under section 27 (1) (a), 27(1) (b) & 27(4) of the Drug Act, 1976.

FID's Recommendations:-

6. It is therefore recommended that following accused may kindly be prosecuted in the Drug Court Karachi: -

1. M/s. Irfan Medicos, Plot No. 30, Sector-14A, Metroville-I, Block-2, Gulshan-e-Iqbal Karachi
2 Mr. Uzair Irfan S/o Muhammad Irfan (Owner M/s. Irfan Medicos, Plot No. 30, Sector-14A, Metroville-I, Block-2, Gulshan-e-Iqbal Karachi
3 Mr. Rafiq Ahmed S/o Muhammad Ibhrahim Quallified person M/s. Irfan Medicos, Plot No. 30, Sector-14A, Metroville-I, Block-2, Gulshan-e-Iqbal Karachi

Proceeding and Decision of 288th meeting of CLB: -

7. The Central Licensing Board considered the fact of the case and decided to show cause the accused person under Section 23 of the Drugs Act 1976 read with Schedule III of DRAP Act 2012 and called them for personal hearing in next meeting.

8. Decision of CLB was communicated vide office letter F.No.4-18/2022-QC (288-CLB) dated 26-01-2023. Letters had been returned undelivered.

9. As directed, undelivered showcause notices of M/s. Irfan Medicos, Karachi were sent to Additional Director Karachi and Secretory PQCB vide office letter No.F.04-18/2022-QC9288-CLB) dated 09-02-2023 with request to direct area inspector to deliver the show cause notice to accused.

10. Provincial Drugs Inspector vide letter no. DCA/PID/KHI/138/- dated 16-02-2023 submitted that premises of M/s. Irfan Medicos was closed and letter remain undelivered. While FID, Karachi wrote letters dated 17-02-2023 to accused and sent copy of letters to QA&LT Division.

11. An office letter No.F.No.4-18/2022-QC (288-CLB) dated 02-05-2023 to FID as per directions was sent to investigate in coordination with provincial Drug regulatory authorities and get Drug Sales License of the premises, accused contact information including CNIC and category and registration details of qualified persons mentioned on DSL etc., covering all aspects of the case and submit comprehensive reply with clear and candid recommendations at earliest for consideration of the Central Licensing Board with subsequent reminders dated 21-09-2023 and 14-11-2023.

12. No reply of show cause received from accused. They are called for personal hearing before the Board.

Proceedings and Decision of 298th meeting of CLB:

In response to the show cause and personal hearing notice issued by the division of QA&LT the accused neither by themselves nor through any counsel appeared before the Board.

The Board after thorough deliberations on the facts of the case and investigations of area FID Karachi decided to grant permission to prosecute following accused for violation of section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c) & 23(1)(i) of the Drugs Act 1976 which is punishable under section 27 (1) (a), 27(1) (b) & 27(4) of the Drug Act, 1976 in the court of competent jurisdiction:

i. M/s. Irfan Medicos, Plot No. 30, Sector-14A, Metroville-I, Block-2, Gulshan-e-Iqbal Karachi.
ii. Uzair Irfan S/o Muhammad Irfan (Owner M/s. Irfan Medicos), Plot No. 30, Sector-14A, Metroville-I, Block-2, Gulshan-e-Iqbal Karachi
iii. Rafiq Ahmed S/o Muhammad Ibhrahim (Quallified person M/s. Irfan Medicos), Plot No. 30, Sector-14A, Metroville-I, Block-2, Gulshan-e-Iqbal Karachi.

Case No. 06: - <u>MANUFACTURE AND SALE OF UN-REGISTERD DRUG PRODUCT- M/S. MEDICAL STORE, KARACHI</u>

FID visited the premises of M/s. Medical Store, Suite No. 508, Al Fizza Glass Tower, Gulshan e Iqbal Block-10-A, Karachi wherein following samples of suspected drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3. Details are:

Name of Drug	Reg; No	Lot No/ Batch No.	Mfg. Date	Exp. Date	Claimed to be Mfg.; by
Furolin 100mg Tablets	Nil	8210223	May-2021	May-2024	M/s. IASIS Pharma, Greece.
Marevan Tablets	Nil	Gk7G	11/2020	05/2023	M/s. GlaxoSmithKline, Cairo, Egypt.
Eltroxin 100mg Tablets	Nil	21A001	21.01.2021	21.01.2023	M/s. Aspen Bad, Germany.
HydrocortisoneRousse 10mg Tablets	Nil	1L71A	Nil	02/2024	M/s. Sanofi Aventis France.
Panadol Cold +Flu Caplets	Nil	DJ959	Mar/2021	Feb/2024	M/s. Aspen Pharma Australia.
Panadol Advance Tablets	Nil	3M4W	Apr/2021	Mar-2024	M/s GSK, Ireland

2. The sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for the purpose of test/analysis. M/s. Medical Store, Karachi was asked by FID to provide bill warranty in connection with the purchase of above said drug but no any reply has been received till date.

3. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said samples as "UN-REGISTERD DRUG PRODUCT" quality. In the light of test report, an explanation letter of even number dated 24th, January 2022, was accordingly issued to M/s. Medical Store, Karachi by FID with subsequent reminder, no any reply has been received.

4. <u>Details of Un-Registerd drugs samples:</u>

Name of Drug	Batch # Lot No.	Mfg. Date	Exp. Date	Claimed to be Mfg; by	Test Report No.	Remarks
Furolin 100mg Tablets (Nitrofurantoin)	8210223	May-2021	May-2024	M/s. IASIS Pharma, Greece.	R.KQ.336/2021 Dated. 17th, January 2022	Un-registered drug product
Marevan Tablets (Warfarin Sodium)	Gk7G	11/2020	05/2023	M/s. GlaxoSmithKline, Cairo, Egypt.	R.KQ.337/2021 Dated. 19th, January 2022	Un-registered drug product
Eltroxin 100mg Tablets (Thyroxine Sodium (INN Levothyroxine Sodium))	21A001	21.01.2021	21.01.2023	M/s. Aspen Bad, Germany	KQ.338/2021 Dated. 27th, January 2022	Un-registered drug product

Hydrocortisone Roussel 10mg Tablets (Hydrocortisone)	1L71A	Nil	02/2024	M/s. Sanofi Avents France.	KQ.339/2021 Dated. 27th, January 2022	Un-registered drug product
Panadol Cold+Flu Caplets (Paracetamol, Pseudoephedrine HCl and Chlorpheniramine Maleate.)	DJ959	Mar/2021	Feb/2024	M/s. Aspen Pharma Pty Ltd, Australia	R.KQ.340/2021 Dated. 21st, January 2022	Un-registered drug product
Panadol Advance Tablets (Paracetamol)	3M4W	Apr/2021	Mar-2024	M/s GSK, Ltd, Ireland.	R.KQ.341/2021 Dated. 21st, January 2022	Un-registered drug product

5. In the light of Federal Government Analyst, CDL, Karachi test; FID submitted that M/s. Medical Store, Suite No. 508, Al Fizza Glass Tower, Gulshan e Iqbal Block-10-A, Karachi found involved in selling of un-registered drugs product and violated the section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c) & 23(1)(i) of the Drugs Act 1976. Punishable under section 27 (1) (a), 27(1) (b) & 27(4) of the Drug Act, 1976.

FID's Recommendations: -

6. It is therefore recommended that following accused may kindly be prosecuted in the Drug Court Karachi: -

1 M/s. Medical Store, Suite No. 508, Al Fizza Glass Tower, Gulshan e Iqbal Block-10-A, Karachi. (Mobil No. 0323-6334225.)

2 Mr. Muhammad Sikandar Lakhani S/o Muhammad Munir Lakhani CNIC No. 42101-9340022-7, (Relative of Owner M/s. Medical Store, Suite No. 508, Al Fizza Glass Tower, Gulshan e Iqbal Block-10-A, Karachi)

Proceeding and Decision of 288th meeting of CLB: -

7. The Central Licensing Board considered the fact of the case and decided to show cause the accused person under Section 23 of the Drugs Act 1976 read with Schedule III of DRAP Act 2012 and called them for personal hearing in next meeting.

8. Decision of CLB was communicated vide office letter F.No.4-18/2022-QC (288-CLB) dated 26-01-2023. Letters had been returned undelivered.

9. As directed, undelivered showcause notices of Ms. Medical Store, Karachi were sent to Additional Director Karachi and Secretory PQCB vide office letter No.F.04-18/2022-QC9288-CLB) dated 09-02-2023 with request to direct area inspector to deliver the show cause notice to accused.

10. Provincial Drugs Inspector vide letter no. DCA/PID/KHI/138/- dated 16-02-2023 submitted that premises of Ms. Medical store was closed and letter remain undelivered. While FID, Karachi wrote letters dated 17-02-2023 to accused and sent copy of letters to QA&LT Division.

11. An office letter No.F.No.4-18/2022-QC (288-CLB) dated 02-05-2023 to FID as per directions was sent to investigate in coordination with provincial Drug regulatory authorities and get Drug Sales License of the premises, accused contact information including CNIC and category and registration details of qualified persons mentioned on DSL etc., covering all aspects of the case and submit comprehensive reply with clear and candid recommendations at earliest for consideration of the Central Licensing Board with subsequent reminders dated 21-09-2023 and 14-11-2023.

12. No reply of show cause received from accused. They are called for personal hearing before the Board.

Proceedings and Decision of 298th meeting of CLB:

In response to the show cause and personal hearing notice issued by the division of QA&LT the accused neither by themselves nor through any counsel appeared before the Board.

The Board after thorough deliberations on the facts of the case and investigations of area FID Karachi decided to grant permission to prosecute following accused for violation of section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c) & 23(1)(i) of the Drugs Act 1976 which is punishable under section 27 (1) (a), 27(1) (b) & 27(4) of the Drug Act, 1976 in the court of competent jurisdiction:

i. M/s. Medical Store, Suite No. 508, Al Fizza Glass Tower, Gulshan e Iqbal Block-10-A, Karachi. (Mobil No. 0323-6334225.)
ii. Mr. Muhammad Sikandar Lakhani S/o Muhammad Munir Lakhani CNIC No. 42101-9340022-7, (Relative of Owner M/s. Medical Store, Suite No. 508, Al Fizza Glass Tower, Gulshan e Iqbal Block-10-A, Karachi)

Case No 07: <u>MANUFACTURE AND SALE OF SPURIOUS AND SUBSTANDARD DRUGS-M/S. HOORAIN IMPEX, KARACHI.</u>

Area FID along with FIA team raided the premises of M/s. Hoorain Impex Lasani Arcade Mezzanine floor, Ranchore line, Karachi on 18-01-2022 as per information received from FIA Office, Corporate Crime Circle, Karachi that Muhammad Zeeshan of M/s. Hoorain Impex Lassani Arcade Mezzanine floor, Neckless Street Ramswami, Ranchore line, Karachi is involved in manufacturing of fake/spurious medicines in the name of different Pharmaceutical Industries.

2. At the time of visit Muhammad Zeeshan was found available and huge stock of following suspected spurious/ fake/ counterfeit medicine were recovered which were taken in custody by FIA officials.

S.No.	Name of medicine
01	Disprin Tablet
02	Aldactone atbelet
03	Cefixime Suspension
4	Cefim Suspension
5	Ventoline expectorant
6	Inocef injection
7	Cefim DS suspension
8	Kinz Injection
9	Water for injection
10	Norvasc Tablet

3. On enquiry Muhammad Zeeshan admitted that he is the owner of above mentioned premises and engaged in the business of supply of medicine. He also admitted that he has purchased the raw material (Cefixime) from local market and repack the same product with the label of Cefim and Cefim DS suspension of M/s Hilton Pharma Karachi. He further disclosed that the repacking activity is being carried out at the premises of Muhammad Moiz situated at Liaquatabad Karachi. He further admitted that Mr Sikander pick the bottles without labelling and return the same in packing of Cefim and Cefim DS suspension of M/s Hilton Pharma. On further inquiry Mr Zeeshan admitted that the printing material of Hilton Pharma and other brands were provided to him By Mr Mirza Nadeem Baig. Mr zeeshan informed that Mr Adnan is his brother and he is also involved in purchasing and selling of medicine in question.

4. FID along with FIA team immediately raided the premises situated at House No.ROW-7, Street 1, C-1 Area Liaquatabad Dakhana Karachi. Moiz Ahmed was available at the time of raid and in his presence the team searched the premises and found powder filled and empty bottles of suspected Cefixime suspension without any label in bulk quantity. Moiz Ahmed admitted that Mr Sikandar provides him filled bottles of suspected cefixime suspension without labelling to him for repacking and he return the same to Mr Sikander after labelling/repacking into Cefim suspension and cefim DS suspension of M/s Hilton Pharma

5. FID alongwith FIA team also raided the premises of Mr Nadeem Baig situated at House No.B-11/75, Bismillah Hotel, Asif Colony Manghopir Road, Karachi. Mirza Nadeem Baig was found available at the premises.

On enquiry he admitted that he had supplied the printing material of M/s Hilton Pharma and other brands to Mr Muhammad Zeeshan. During search various unit cartons and literatures of M/s Hilton & Other brands were recovered from the premises which were taken in custody by FIA officials. Mirza Nadeem Baig also disclosed that Mr.Hameed provided the printed material to him.

6. Several samples of drugs suspected to be fake/spurious were taken for the purpose of test/analysis on prescribed Form-3 and sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for the purpose of test/analysis

7. At the time of inspection Muhammad Zeeshan, & Mirza Nadeem Baig were asked to provide bill warranty or legal documents in connection with the medicines & printing material available in the said premises but they failed to provide the same.

8. In the light of above Mr. Muhammad Zeeshan of M/s. Hoorain Impex Lassani Arcade Mezzanine floor, Neck lass Street Ramswami, Ranchore line, Karachi and others found involved in manufacturing in unlicensed premises, labelling & repacking of suspected fake/spurious drug and violated the Section 23 & 27 of Drugs Act, 1976 and rules framed thereunder.

FID's RECOMMENDATION: -

9. Grant permission to register FIR against following accused: -

	e of Accused	**C No.**	**RESS**
	Hoorain Impex		Lassani Arcade Mezzanine floor, Neckeass Street Ramswami, Ranchore line, Karachi.
	mmad Zeeshan S/O Muhammad Haroon Memon	-7632141-7	No.601, Madina Corner Nakcless Street, Nashtar Road,Ranchoe line, Karachi.
	mmad Adnan S/o Muhammad Haroon Memon	-4370766-9	No. 501, Safa Marwa Tower Ranchorline Arba Arcade Karachi.
	dar Abdul Aziz S/o Abdul Aziz		No. 08, Seema Manzil, Meethadar Karachi.
	Ahmed S/o Iftikhar Ahmed	-5352131-7	e No. ROW-7, Street 1, C-1 Area Liaquatabad Dakhkhana Karachi
	Nadeem Baig S/o Mirza Abdul Salam		House No. B-11/75, Bismillah Hotel Asif Colony, Manghopir Road Karachi.

10. Permission to lodge FIR was granted with approvals and communicated vide office letter of even number dated 28-01-2022.

11. Area FID submitted investigation report of FIA and requested for grant of permission of prosecution against the accused.

12. As per investigation report; following were involved in illegal manufacturing / alteration / sale & purchase of spurious / sub-standard drugs / medicine, thereby committed the offence punishable U/s 23 & 27 r/w Section 30 of Drug Act-1976 R/w 109 PPC.

1. Muhammad Zeeshan S/o Muhammad Haroon Memon
2. Muhammad Adnan S/o Muhammad Haroon Memon
3. Sikandar Abdul Aziz S/o Abdul Aziz
4. Moiz Ahmed S/o Iftikhar Ahmed
5. Mirza Nadeem Baig S/o Mirza Abdu Salam

13. Further accused from serial No 01 to 05 had been arrested while one accused namely Hameed s/o Unknown is still at large who used to give printed material to above mentioned accused.

14. Conclusion of report:

"During investigation, it has been concluded so far that accused Muhammad Zeeshan in connivance of accused Sikander, Muhammad Moiz, Mirza Nadeem and Muhammad Adnan and others are involved in illegal manufacturing /alteration / sale & purchase of spurious / sub-standard drugs / medicine."

Proceedings and Decision of 289th Meeting of Central Licensing Board:

15. The Central Licensing Board considered the facts of the case and decided to show cause the accused persons under Section 23 of the Drugs Act 1976 read with Schedule III of DRAP Act 2012 and called them for personal hearing in next meeting. Board further directed that area FID will coordinate with FIA for necessary arrangements into the matter please.

16. Decision of CLB has been communicated vide office letter F.No.3-03/2022-QC (289-CLB) dated 02-05-2023. Reminder dated 21-09-2023 and 14-11-2023 to Area FID, Karachi have been sent for implementation of decision of 289th meeting of CLB.

17. FID submitted that accused are on bail. A show cause of even number was sent to accused person on the given address through UMS. All letters received undelivered with the remarks "Address incomplete".

18. In view of above, they are called for personal hearing before the Board.

Proceedings and Decision of 298th meeting of CLB:

In response to the show cause and personal hearing notice issued by the division of QA&LT the accused neither by themselves nor through any counsel appeared before the Board.

The Board after thorough deliberations on the facts of the case and investigations of area FID Karachi decided to grant permission to prosecute following accused for illegal manufacturing / alteration / sale & purchase of spurious / sub-standard drugs, thereby committed the offence punishable U/s 23 & 27 read with Section 30 of the Drugs Act 1976 in the court of competent jurisdiction:

i. Muhammad Zeeshan S/o Muhammad Haroon Memon
ii. Muhammad Adnan S/o Muhammad Haroon Memon
iii. Sikandar Abdul Aziz S/o Abdul Aziz
iv. Moiz Ahmed S/o Iftikhar Ahmed

v. Mirza Nadeem Baig S/o Mirza Abdu Salam

Case No. 08: **SALE OF SPURIOUS AND UN-REGISTERED DRUG PRODUCT BY M/S AL-RASHEED MEDICAL AND SURGICAL WOODEN CABIN NO.6-A, KARACHI**

Mr. Abdul Rasool Sheikh, the then FID raided at M/s Al Rasheed Medical and Surgical Wooden Cabin No.6A on A-1 Land, opposite National Institute of Child Health Jinnah, Karachi on 16-11-2021 wherein few samples were taken.

S. No.	Name of Drug	Reg; No.	Batch No.	Mfg. by	Test Report No. & Date	Remarks
ARS-56/21	Viagra 50mg Tablets	Nil	19990545AG	M/s. Pfizer Inc Brooklyn, New York, USA	R.KQ.331/2021 Dated. 14th, January 2022	UN-REGISTERED DRUG PRODUCT
ARS-57/21	Viagra 100mg Tablets	Nil	19990544AG	M/s. Brooklyn, Ne	R.KQ. 332/2021 Dated. 14th, January 2022	SPURIOUS
ARS-58/21	Cialis 20mg Tablets	Nil	Nil	M/s. Eli Lilly and company, (Ireland) Limited, Ireland.	R.KQ.333/2021 Dated. 06th, January 2022	UN-REGISTERED DRUG PRODUCT
ARS-59/21	Relief Extra Tablets	Nil	RR-962	M/s. Combitic Global Caplet Pvt Ltd. M-15. D-2, D-3, Industrial Area Sonepat -131001 (Hr.) India	R.KQ.334/2021 Dated. 27th, December 2021	UN-REGISTERED DRUG PRODUCT

2. The Federal Government analyst declared the samples "Un-registered Drug Product" and "Spurious" vide letter no.F.5-3(K)/2022-CDL/S-47, S-1565, S-02, S-46

3. FIR was granted on permission from Director QA&LT dated 13th October 2022.

FIA INVESTIGATION REPORT:

4. Case FIR no. 08/2023 dated 17-01-2023 was registered on recovery of unregistered stock of different drugs. Final investigation report has been submitted by the IO/SI of Federal Investigation Agency which concludes/recommend as

> "*From the facts and investigation conducted so far and keeping in view the Oral and documentary evidence placed on record, it is prime facie established that 1) M/s Al Rasheed Medical and Surgical Wooden cabin no 6A on A-1 land, Opposite National Institute of Child Health Jinnah Hospital, Karachi 2) Mr. Asim Rasheed S/o malik Abdul Rasheed CNIC No 42301-4291937-7 (Owner of M/s Al Rashhed Medical and Surgical Wooden) and 3) Muhammad Ismail S/o Abdul Ghafoor CNIC 42301-3045477-5 Cell no 03340038557/0321-2461983 were involved in purchasing/selling/supplying of spurious and unregistered drugs and violated the provision section 23(1)(a)(i), 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(c), & 23(1)(i) of the Drugs Act 1976, Punishable under section 27(1)(a), 27(1)(b)and 27(1)(b), 27(4) of the Drug Act 1976*.

During examination and investigation nothing incriminating could come on record which may connect accused/qualified person namely Mr. Wajid Ali S/O Mehruddin Malik with the alleged offence. Under these circumstances, accused/qualified person namely Wajid Ali s/o Mehruddin malik cannot be prosecuted for want of any material against him.

In view of above the competent authority has approved the investigation report , it is submitted to persue the final investigation report and submit the final challan/ complaint before the Honorable Drug Court of Sindh at Karachi. However, the name of accused/qualified person namely Wajid Ali S/o Mehruddin Malik may be placed in column No.2 of the final challan /complaint being not sent up for trail"

5. Show cause notice/personal hearing to the following accused has been served vide letter no F.6-1/2023-QA dated 31st October 2023 and 14th November 2023.

a) M/s Al Rasheed Medical and Surgical	**b) Mr. Asim Rasheed s/o Malik Abdul Rasheed**	**c) Mr. Ismail s/o of Abdul Ghafoor**
Wooden Cabin No.6A on A-1 land, Opposite NICH, Jinnah Hospital Karachi.	**CNIC No. 42301-4291937-7 (**Owner of M/s Al Rasheed Medical and Surgical Wooden Cabin No.6A on A-1 land, Opposite NICH, Jinnah Hospital Karachi.)	CNIC NO. 42301-3045477-5 Cell No. 0334-0038557/ 0321-2461983 Product supplier at M/s Al Rasheed Medical and Surgical

1ST REPLY FROM THE PROPRIETOR/ FIRM

6. Reply from Mr. Malik Asim Rashid proprietor of M/s Al-Rasheed Medical/Surgical Wooden Cabin No.06, A on A-1 Land Opposite Jinnah hospital Karachi was received stating the same trail is pending before the provincial Drug Court Karachi as same case was fixed on 01-11-2023 and next date is fixed on 11-12-2023, a person cannot be prosecuted at two forums in same time so Double Jeopardy prohibit any one from being prosecuted twice for substantially the same offence.

PROCEEDING OF 293RD MEETING OF CLB:

7. No person or on behalf of the accused appeared before the Board.

DECISION OF 293rd CLB:

8. The Board decided to grant a final opportunity for personal hearing to the following accused as nominated in the final investigation report of Federal Investigation Agency:

a) M/s Al Rasheed Medical and Surgical	**b) Mr. Asim Rasheed s/o Malik Abdul Rasheed**	**c) Mr. Ismail s/o of Abdul Ghafoor**
Wooden Cabin No.6A on A-1 land, Opposite NICH, Jinnah Hospital Karachi.	**CNIC No. 42301-4291937-7 (**Owner of M/s Al Rasheed Medical and Surgical	CNIC NO. 42301-3045477-5 Cell No. 0334-0038557/ 0321-2461983 Product supplier at M/s Al Rasheed Medical and Surgical

	Wooden Cabin No.6A on A-1 land, Opposite NICH, Jinnah Hospital Karachi.)	

ACTION TAKEN BY QA&LT

9. The firm was communicated the decision of 293rd CLB for grant of final opportunity for personal hearing letter on 25th January 2024.

2ND REPLY FROM THE PROPRIETOR:

10. In response of the personal hearing letter dated 14th November 2023, the accused i.e. Malik Asim Rasheed proprietor of M/s Al-Rasheed Medical/Surgical Wooden Cabin no 6,A on A-1 land opposite Jinnah Road, Karachi replied through his letter dated 20th November 2023 that I am not involved in sale and purchase of unregistered medicines, neither the same were recovered from my possession, but FIA and other officials to show their efficiency and non-fulfillment of these illegal demands they implicated me so, I have no nexus with the alleged offence.

b. That the FIR under Drug Act 1976 have been registered at PS FIA anticorruption circle Karachi in which investigation officer has conducted investigation where no any piece of evidence is available against me. I have huge respect for the law and I always obey the rules and regulations without any violation and Inshallah same will be continue in mu near future.

c. Due to viral infection I could not attend my personal appearance for that hearing may be exempted, so this reply/statement may be treat as part and partial reply of this show cause notice whatsoever stated is best of my knowledge.

RECOMMENDATION FROM QA&LT

11. In view of the scenario detailed above the QA&LT Division recommends that as per report of the FID and FIA the accused committed the offence u/s 23(1)(a)(i), 23(1)(a)(x), 23(1)(a)(vii), 23(1)(b), 23(1)(c), 23(1)(I)of Drugs Act 1976, which is punishable under section 27 of the Drugs Act 1976 and rules framed there under for which he is liable to be prosecuted before the Honorable Courts of Drugs, Sindh at Karachi.

12. The firm was also issued reminder for personal hearing on 18th July 2024 but no reply was received yet.

PROCEEDINGS OF 298TH MEETING OF CENTRAL LICENSING BOARD:

9. No one appears on behalf of the accused.

Decision of 298th meeting of CLB:

After thorough deliberation, considering the FID and FIA investigation report and all the facts, the board decided as under:

i. Allowed Federal Inspector of Drugs, Karachi for filling prosecution in the Drug Court for contravention of 23(1)(a)(i), 23(1)(a)(x), 23(1)(a)(vii), 23(1)(b), 23(1)(c), 23(1)(I)of Drugs Act 1976, and Schedule II-A(1)(a)(i), Schedule II-A(1)(a)(vii) , Schedule II-A(1)(a)(x), Schedule II-A(1)(a)(c), Schedule II-A(1)(a)(i)of the DRAP Act 2012, which is punishable under section 27 of the Drugs Act 1976, Schedule -III of the Drap Act 2012 and rules framed there under against the following;

a) M/s Al Rasheed Medical and Surgical	**b) Mr. Asim Rasheed s/o Malik Abdul Rasheed**	**c) Mr. Ismail s/o of Abdul Ghafoor**
Wooden Cabin No.6A on A-1 land, Opposite NICH, Jinnah Hospital Karachi.	**CNIC No. 42301-4291937-7 (**Owner of M/s Al Rasheed Medical and Surgical	CNIC NO. 42301-3045477-5 Cell No. 0334-0038557/ 0321-2461983 Product supplier at M/s Al Rasheed Medical and Surgical

	Wooden Cabin No.6A on A-1 land, Opposite NICH, Jinnah Hospital Karachi.)	

Case No. 09: <u>JOINT RAID WITH FIA AT SHAN CHORANGI NEAR PSO PUMP KORANGI INDUSTRIAL AREA, KARACHI.</u>

On the source information of FIA, ACC Karachi a joint raid was conducted on 22-5-2023 at around 7pm, wherein, an online booker/seller had been taken into custody by HA who came to deliver an unregistered Injection Boostin to his client waiting at Shan Chorangi near NO Pump Korangi Industrial Area. Karachi. The following stock of unregistered, unwarranted and expired was recovered from Naveed S/O Hamid Ali and the same was seized on form-2 under section 18 of Drugs Act 1976 and rules made therein,

Sr No.	Name of Drug	Reg No.	Batch No.	Quantity	Mfg date	Exp Date	Manufactured by
1	Inj. Boostin	Nil	BS20063	1x2mlx5x10	30Jul 2020	29 July 2022	Ms LG Chem Korea

2. The above act of offence is violation of Section 23(1) (a)(vii). 23(1)(i) & 23(1)(a)(x) of Drug Act. 1976 and punishable under Section 27 of Drug Act. 1976 p 2012 and rules framed there under.

ACTION TAKEN BY QA&LT

3. The Director QA&LT Islamabad vide letter No. F.14-3/2023-QA dated 23rd May 2023 conveyed the permission for registration of FIR against the accused person i.e. Naveed Ali.

4. Show cause notice/personal hearing to the following accused was issued on 24th May 2024

Mr. Naveed Ali s/o Hamid Ali (CNIC 4220190974135)	Mr. Muhammad Tahir s/o Muhammad Yaqoob (CNIC 36103-1511779-1)	Mr. Muhammad Shahid Ranjha s/o Muhammad Younus (CNIC 42501-545305-5)	Mr. Habib-ur-Rehman (Alias Farooq) s/o Shah Fazal (CNIC 42501-1476560-7)
House no 8, Mohalla Korangi no 3, Sector 34/1, Tehsil and district Korangi, Karachi	House no17, Gali no 2, Block 13, Khanewal	House no R-108, Mohallah Cattle colony, Road no 10, Landhi, Karachi	House no 729-730, Labor colony, Sector F-1 Landhi, Karachi

5. No reply has been received from the accused.

FIA INVESTIGATION REPORT:

6. Case FIR No. 15/2023 was registered on recovery of un-registered / un-warranted Drugs and Expired Injections of Boostin. Final investigation report has been submitted by the IO/SI of Federal Investigation Agency which concludes/recommend as

"*From taking stock of the facts and circumstances as well as the evidence(s) available on case file it has been established that accused Naveed s/o Hamid Ali has been found involved in sale / purchase of 'Unregistered, Unwarranted Drugs" 'Boostin Injection' of international origin already recovered from his possession at the time of raid.*

b. Furthermore, the names of accused persons namely, 1) Muhammad Tahir s/o Muhammad Yaqoob, holder of CNIC No.36103-1511770-1, 2) Muhammad Shahid Ranjha s/o Muhammad Younus, holder of CNIC No.42501-545305-5 and 3) Habib-ur-Rehman (alias Farooq) s/o Shah Fazal, holder of CNIC No.42501-

1476560-7 were disclosed by accused Naveed Ali and the Interim charge sheet had already submitted before the Honourable court against them. Whereas nothing incriminating or any connected evidence has come on record against above 03-accused persons namely, Muhammad Tahir, Muhammad Shahid Ranjha and Habib-ur-Rehman @ Farooq, however, it would be appropriate at this stage that fate of said 03- accused persons may be left on the mercy of Honourable Court to obtain Judicial Verdict.

c. Thereby the accused Naveed Ali s/o Hamid Ali and his associates/ co-accused persons 1) Muhammad Tahir sio Muhammad Yacpob, holder of CNIC No.36103- 1511779-1, 2) Muhammad Shahid Ranjha s/o Muhammad Younus, holder of CNIC No.42501-545305-5 and 3) Habib-ur-Rehman (alias Farooq) s/o Shah Fazal, holder of CNIC No.42501-1476560-7 committed the offences which is violation of Section 23(1)(a)(vii), 23(1)(i) of Drugs Act, 1976, punishable under Section 27 of the Drugs Act, 1976 and rules framed there under, for which they are liable to be prosecuted before the Honourable Drugs Court of Sindh at Karachi.

d. In view of above discussed facts and circumstances a prima fade case has been made out against accused Naveed ski Hamid Ali, (CNIC No.42201-9097413-5) whereas no direct connected evidence(s) has not come on case file as disclosed by accused Naveed regarding his associates/ co-accused persons namely, 1) Muhammad Tahir s/o Muhammad Yaqoob. holder of CNIC No.36103-1511779-1, 2) Muhammad Shahid Ranjha s/o Muhammad Younus, holder of CNIC No.42501-545305-5 and 3) Habib-ur-Rehman (alias Farooq) s/o Shah Fazal. holder of CNIC No.42501-1476560-7 and for such reasons the fate of said co-accused persons may be left on honourable court to be decided during trial, hence under the orders of Competent Authority this Final Investigation Report is issued accordingly, for submission of Final Challan! Final Complaint before the Honourable Drugs Court of Sindh at Karachi through the Federal Inspector of Drugs-II, Drug Regulatory Authority of Pakistan (DRAP), Karachi being competent to file the Challan! Complaint, against (1) accused Naveed his associates/ co-accused persons namely, 2) Muhammad Tahir s/o Muhammad Yaqoob, holder of CNIC No.36103-1511779-1. (3) Muhammad Shahid Ranjha s/o Muhammad Younus, holder of CNIC No.42501-545305-5 and (4) Habib-ur-Rehman (alias Farooq) s/o Shah Fazal, holder of CNIC No.42501-1476560-7 for their committed offences and violation of Section 23(1)(a)(vii), 23(1)(i) of Drugs Act, 1976, punishable under Section 27 of the Drugs Act, 1976 and rules framed there under, for which they are liable to be prosecuted before the Honourable Drugs Court of Sindh at Karachi.

e. The investigation of the case has been completed, hence, under the orders of competent authority, this Final Investigation Report is submitted accordingly, for onward transmission to the Drug Regulatory Authority of Pakistan, Ministry of National Health Services Regulation & Coordination, Karachi for submission of proper complaint under the relevant provision of Drugs Act, 1976 before the Honorable Drug Court of Sindh at Karachi"

RECOMMENDATION FROM QA&LT

7. In view of the scenario detailed above the QA&LT Division recommends that as per report of the FID and FIA the accused committed the offence u/s 23(1)(a)(i), 23(1)(a)(x), 23(1)(a)(vii), 23(1)(b), 23(1)(c), 23(1)(I)of Drugs Act 1976, which is punishable under section 27 of the Drugs Act 1976 and rules framed there under for which he is liable to be prosecuted before the Honorable Courts of Drugs, Sindh at Karachi

8. The firm was also issued reminder for personal hearing on 19th July 2024 but no reply was received yet.

PROCEEDINGS OF 298TH MEETING OF CENTRAL LICENSING BOARD:

9. No one appears on behalf of the accused.

Decision of 298th meeting of CLB:

After thorough deliberation, considering the FID and FIA investigation report and all the facts, the board decided as under:

i. Allowed Federal Inspector of Drugs, Karachi for filling prosecution in the Drug Court for contravention of 23(1)(a)(vi), 23(1)(a)(vii), 23(1)(a)(x) of Drugs Act 1976, and Schedule II-A(1)(a)(vi), Schedule-II-A(1)(2)(vii), Schedule-II-A(1)(2)(x) of the Drap Act 2012, which is punishable under section 27 of the Drugs Act 1976, Schedule -III of the Drap Act 2012 and rules framed there under against the following;

Mr. Naveed Ali s/o Hamid Ali (CNIC 4220190974135) House no 8, Mohalla Korangi no 3, Sector 34/1, Tehsil and district Korangi, Karachi	**Mr. Muhammad Tahir s/o Muhammad Yaqoob (CNIC 36103-1511779-1)** House no17, Gali no 2, Block 13, Khanewal	**Mr. Muhammad Shahid Ranjha s/o Muhammad Younus (CNIC 42501-545305-5)** House no R-108, Mohallah Cattle colony, Road no 10, Landhi, Karachi	**Mr. Habib-ur-Rehman (Alias Farooq) s/o Shah Fazal (CNIC 42501-1476560-7)** House no 729-730, Labor colony, Sector F-1 Landhi, Karachi

Case No. 10: RAID AT (TENANT) OFFICE NO.7, BURHANI GARDEN, MEZZANINE FLOOR, NEAR PAKISTAN CHOWK, KARACHI- M/S YASIN S/O MUHAMMAD IBRAHIM

Federal Inspector of Drugs has conducted Joint raid with FIA at premises of Office no. 07, Burhani Garden, Mezzanine floor, near Pakistan Chowk, Karachi, wherein unregistered and expired stock of different drugs of International origin were recovered along with the copy of rent agreement in the name of Muhammad Yaseen s/o Muhammad Ibrahim CNIC no. 42402-3467402-3 R/O House No. 1733/467, Ghanchi Mohallah, Anjam Colony, Baldia Town Karachi.

The details of the products are:

01. ✓ Menactra
Vaccina Antimeningococica, L UG633AC, → 192 (Packs)
m/s. Sanofi Pasteur Inc. USA

02. Pirfenidone Tab 200mg PTS-20001 / Sep-20 / Aug-22 — 8pcks

~~02 Caltrate Tab. 600+D3~~
~~m/s. Pfizer. USA.~~

02. ✓ Glucantime 1,5g/5ml 950 / 8/19 - 7/22 23 (Packs)
m/s. Haupt Pharma, France.

03. ✓ Omnipaque 350mg I/ml 1471121 / 6/19 - 6/22 — 14 (Packs 500ml)
Solution for Inj/Infusion 17 (packs 100ml)

04. ✓ Myfortic 360mg (strip) WKR19 / 04/19 - 3/22 → 62 (strips)
mycophenolate sodium
m/s. Novartis.

05. ✓ Typhim Vi (Vaccin) T2A032M / 25/2/19 - 01/22 → 117 (Packs).

06. ✓ Sandostatin LAR 20mg STK33 / 01/22 → 6 (Packs)
(Oktreotid Steril)

07. ✓ Sitafen 20mg Inj / 03/22 → 22 packs
(Kofein Sitrat)

08. ✓ Florinef 0.1mg Tab 0F1712 / 04/22 → 11 (Packs.
(Fludrocortisone acetas)
m/s. Aspen Pharma GmbH.

09. ✓ Invanz 1g T041273 / 3/6/22 → 15pcks
m/s. MSD, France

10. ✓ Vacanex 200mg IV 2070004 / 07/2022 → 10 pcks
m/s MS Pharma.

11. ~~Florinef 0.1mg (Fludrocortisone acetas)~~ 0F1712 / 04/22 → 01 pcks

12. Anexate 1mg I.V R1001P05 / 4/2016 - 11/2021 → 01 pcks
(Flumazenil)

(DR. SHOAIB AHMED)
Federal Inspector of Drugs
Government of Pakistan
Drug Regulatory Authority of Pakistan

Acetazolamide 250 (Acetazolamide 250mg) m/s. Mehr Darou, Iran. | 079 / 15/9/22 | — 26packs

14. Mitoxantrone Inj USP (Nitcol) 20mg m/s. Neon Laboratories Ltd, India | 176418 / 12/19 – 3/21 | — 01packs

15. ✓ Opdivo 40mg/4ml m/s. Bristol-Myers-Squibb | 2021 | — 38packs

16. ✓ Opdivo 100mg/10ml m/s. Bristol-Myers Squibb. | 2/2020 | — 64packs

17. ✓ Calcium Polystyrene Sulphonate Powder 15g | C0L4 / 12/20 – 11-22 | — 4packs

18. ✓ Lucivand 300 Tab (Vandetanib) m/s. Lucius Pharma, Colombo | 7B0011/UD / Sep-20 – Aug-22 | — 2 Pens

19. Marevan Tab. 5mg (Warfarin Sodium 5mg) m/s. GSK | AS3124S / 12/19 – 06-22 | — 32 Pen

20. Euthyrox 50mcg Tab. (Levothyroxine Sodium) | 600A9C / 09/2022

21. ✓ Dacarbazine for Inj USP 200mg m/s. Celon Laboratories Pvt Ltd. India | D221937BC / 5/19 – 4/22 | — 30 Pen

22. Heparin Sodium Inj IP 25000IU/5ml (Medlop 25) | BHS00320 / Nov 20 — Oct-22 | — 01 packs

23. Thiotepa for Inj BP (Thiomed) Lyophilized m/s. Brück, Oman | 2342001A / 09/20 – 8/22 | — 01 packs

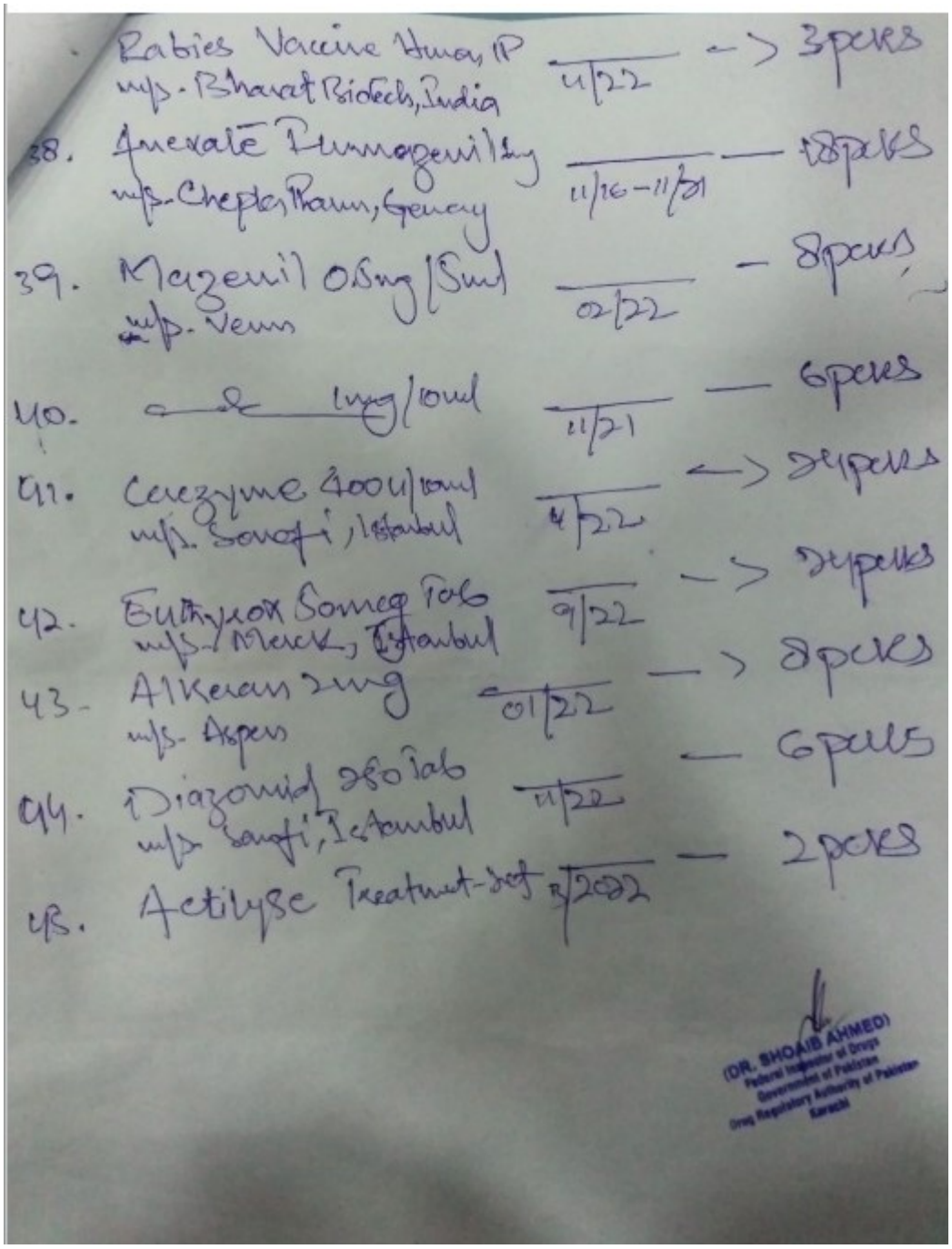
24. ✗ ~~Acetazolamide Tab. IP 250mg m/s. MGA Pharmaceutical India~~ | BTN-200615 / 10/20 — 09/22 | — 01packs

25. Aryosevan | 3/2022 | → 16 packs

DR. SHOAIB AHMED
Federal Inspector of Drugs
Government of Pakistan
Drug Regulatory Authority of Pakistan
Karachi

	Mejopac 100 m/s. MBA Pharma, India	20HPP01M / 8/20 – 7/22	—	13 (Packs).
26.	Jectra 10mg m/s. Nerm	11/22	→	26 (Packs).
27.	Sedocream m/s. Teva UK, Ireland	134294 / 10/10/21	→	5 (Packs).
28.	Ascorvit 500mg/5ml m/s. MS Pharma	1450012 / 11/22	→	74 (Packs).
29.	Sandimmun Neoral 100mg m/s. Novartis, Germany	KF6409 / 08/2021	→	8 packs
30.	Primaquine Phosphate Tab PQ – 7.5 m/s. Ridley, India	PQ-1803 / Sep-18 – Aug-21	—	1 Pack
31.	Docetaxel Inj IP Concentrate 120mg/3ml Docemax 120 m/s. GLS Pharma, India	DX12008C / 7/20 – 6-22	—	19 (Packs)
32.	Favinol 200mg (Favipiravir) m/s. Neutec, Italy	33547 / 10-22	—	01 packs
33.	Salazopyrin 500mg m/s. Pfizer Istanbul	04/22.	—	01 packs
34.	Desmex Nasal Spray m/s. Sina Daru, Iran	105-178 / 05/24	→	39 (Packs)
~~35.~~	~~Pegatron Vi m/s. Sanofi Pasteur~~	~~P2A0328 / 01/22~~		
35.	Visipaque 320mg 100ml	30/11/2021		2 pcks
36.	Anixtra 2.5mg/0.5ml	3/2022	—	5 pcks

(DR. SHOAIB AHMED)
Federal Inspector of Drugs
Government of Pakistan
Drug Regulatory Authority of Pakistan
Karachi



ACTION TAKEN BY QA&LT

2. The Director QA&LT Islamabad vide letter No. F.6-1/2023-QA dated 02-03-2023 conveyed the permission for registration of FIR against the accused person

3. Case FIR No. 13/2023 dated 09-05-2023 under section 23(1)(a)(vi), 23(1)(a)(vii), 23(1)(a)(x) of Drug Act, 1976 and Schedule II-A(1)(a)(vi), Schedule II-A(1)(a)(vii) of the DRAP Act 2012 punishable under section 27 of Drugs Act 1976 was registered.

FIA INVESTIGATION REPORT:

4. Final Investigation report was received from Federal Investigation agency dated 18-09-2023 wherein the matter is concluded/recommended as under:

"*From taking stock of the facts and circumstances as well as the evidence(s) available on case file it has been established that accused Muhammad yaseen obtained the premises viz. Office No. 07, Burhani Garden, Near Pakistan Chowk Karachi to run his business of medicines, executed rental agreement and said rental/tenancy agreement was registered in Sindh Police Tenant & Employee Registration System. Therefore, during joint raid conducted by teams of FIA and DRAP staff a huge quantity have been recovered of unregistered and expired drugs of different international origin. Besides, during preliminary stage the Federal Inspector of Drugs-III/Dr. Shoaib Ahmed of DRAP, Karachi already issued two explanation letters addressed to accused Muhammad Yaseen and sent at his residential as well as office addresses, but at this time too, the accused Muhamad Yaseen did not respond nor submitted his explanation regarding recovery of above expired and unregistered drugs from his possession available at the premises obtained by him on rent.*

It has been established that accused "Muhammad Yaseen s/o Muhammad Ibrahim CNIC No. 42402-3467402-3 committed the offence U/S 23(1)(a)(vii), 23(1)(i) of Drugs Act 1976, which is punishable under section 27 of the Drugs Act 1976 and rules framed there under for which he is liable to be prosecuted before the Honorable Courts of Drugs, Sindh at Karachi"

5. Show cause notice/personal hearing to the following accused was issued on 31st October 2023 and 14th November 2023.

M/s Yasin S/O Muhammad Ibrahim **CNIC NO. 42402-3467402-3** (Tenant) Office No.7, Burhani Garden, Mezzanine Floor, Near Pakistan Chowk, Karachi. House No. 1733/467, Ghanchi Mohallah, Anjam Colony, Baldia Town Karachi.

PROCEEDING OF 293RD MEETING OF CLB:

6. No person or on behalf of the accused appear before the Board.

DECISION OF 293rd CLB:

7. The Board after thorough deliberations and considering the facts of case presented decided to grant a final opportunity of personal hearing to the accused in its forthcoming meeting.

RECOMMENDATION FROM QA&LT

8. In compliance to the decision of 293rd meeting, a final opportunity for personal hearing letter dated No. F.6-1/2023-QA has been issued dated 25th January 2024.

In view of the scenario detailed above the QA&LT Division recommends that the accused "Muhammad Yaseen s/o Muhammad Ibrahim CNIC No. 42402-3467402-3 has been given personal hearing opportunity but no person or on behalf of the accused appear before the Board or replied. The accused committed the offence under section 23(1)(a)(vi), 23(1)(a)(vii), 23(1)(a)(x) of Drug Act, 1976 and Schedule II-A(1)(a)(vi), Schedule II-A(1)(a)(vii) of the DRAP Act 2012 which is punishable under section 27 of the Drugs Act 1976 and rules framed there under for which he is liable to be prosecuted before the Honorable Courts of Drugs, Sindh at Karachi.

PROCEEDINGS OF 298TH MEETING OF CENTRAL LICENSING BOARD:

9. No one appears on behalf of the accused.

Decision of 298th meeting of CLB:

After thorough deliberation, considering the FID and FIA investigation report and all the facts, the board decided as under:

i. Allowed Federal Inspector of Drugs, Karachi for filling prosecution in the Drug Court for contravention of section 23(1)(a)(vi), 23(1)(a)(vii), 23(1)(a)(x) of Drug Act, 1976 and Schedule II-A(1)(a)(vi), Schedule II-A(1)(a)(vii) of the DRAP Act 2012, which is punishable under section 27 of the Drugs Act 1976, Schedule -III of the Drap Act 2012 and rules framed there under, against the following;

M/s Yasin S/O Muhammad Ibrahim
CNIC NO. 42402-3467402-3
(Tenant) Office No.7, Burhani Garden, Mezzanine Floor, Near Pakistan Chowk, Karachi.
House No. 1733/467, Ghanchi Mohallah, Anjam Colony, Baldia Town Karachi.

Case No. 11: <u>SALE OF UN-WARRANTED AND UN-REGISTERED DRUG PRODUCT BY M/S AMANULLAH TRADERS, M.A JINNAH ROAD, KARACHI</u>

Federal Inspector of Drugs-III (FID), Karachi, conducted a joint raid of DRAP Karachi along with FIA, ACC Karachi was conducted at M/s Amanullah Traders MA Jinnah Road Karachi (DSL No.315 dated 18.01.2023) on 01.02.2023 and huge unwarranted stocks of different drugs including vaccines, biologicals and other injection of local and international origin was found stored at uncontrolled temperatures and under unhygienic conditions, hence ordered not to dispose of on Form-I u/s 18(1) of Drugs Act 1976 initially for 28 days as suspected theft stocks or unwarranted drugs. The FID has further informed that the people working there found engaged erasing the printed prices and names of institutions printed on unit cartons. Three unregistered drugs Bactrim Injection, Centrum Tablet and Peyona and packing material for imported Gammaras injection its leaflet and stamps used in manipulation and disguising of original used were seized on Form-2.

The details of the products are:

FORM 2
(See Rule 6)

GOVT OF PAKISTAN
Drug Regulatory Authority of Pakistan
FID-III

406

RECIEPT FOR STOCK OF DRUGS SEIZED UNDER SECTION 8 (f) OF THE DRUGS ACT, 1976

The stock of drugs/materials/articles detailed below has this day been seized by me under the provision of clause (f) of Section 19 of the Drugs Act 1976, from the premises of M/S Amanullah Traders M.A. Jinnah Road situated at Shop No. 01 Ibrahim Ilyas Building Victoria Street M.A. Jinnah Road, Karachi

Date 01/2/23

Inspector (DR. SHOAIB AHMED) Federal Inspector of Drugs Government of Pakistan Drug Regulatory Authority of Pakistan Karachi

Details of Drugs Seized.

Sr. No	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Purported to be Manufactured By
01	Peyona 20mg/2ml	201002	1x10 Ampoule		25/1/25	Istanbol, Turkey
02	Ceftrom Tab	-	12 Packs			
03	Bactrim Syrup	-	20 Ampoule			
	Reason of Seizure: Un-registered.					

Certified that the above items were actually present in my Stores/Factory /Godown/Premises referred above at the time of inspection by the Inspector of Drugs. I have signed this receipt form and I have got a copy of this form-2.

Sabeen Abdul Majeed
42301-0967389-2
Store Incharge

Date

Inspector (DR. SHOAIB AHMED) Federal Inspector of Drugs Government of Pakistan Drug Regulatory Authority of Pakistan

Mr. Salman Majeed (Store Incharge)
(42301-8767589?-7)
M/s Amanullah Traders
M.A. Jinnah Road

Time: 4:30pm to 7:30pm

Form-I
(See Rule 5)

ORDER UNDER SECTION 18(1) OF THE DRUGS ACT, 1976, REQUIRING A PERSON NOT TO DISPOSE OF STOCKS IN HIS POSSESSION

GOVT OF PAKISTAN – Drug Regulatory Authority of Pakistan, Karachi – FID-III – 133

Whereas I have reason to believe that the stocks of the drugs in your possession detailed below contravenes the provisions of the Drugs Act, 1976 or rules made there under, and whereas I have reported the facts to the board concerned or the authority and have been authorized by it to take action under clause (i) of Section 18 of the said Act;

I hereby require you not to dispose of the said stocks for a period of 28 days from this date.

Inspector (DR. SHOAIB AHMED) Federal Inspector of Drugs, Government of Pakistan, Drug Regulatory Authority of Pakistan, Karachi

Date 01/2/23

Details of Stocks of drugs

Sr. No	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Purported to be Manufactured By
	As per List attached Stocks of Different Medicines/including Vaccine, Biological and other injection of local and International origin taken on Form-I as suspected unwarranted & theft stocks from Different Government hospitals/Institutions caught red-handed with manipulation of price & erasing of name of institutions at above place hence order not to dispose of initially for 28 days under Drugs Act, 1976.					

میرے بیان سے 68 اور [illegible] آئٹم امانت اللہ ٹریڈرز کے گودام [illegible] FIA [illegible]
کی ٹیم نے [illegible] ویکسین اور [illegible] منع کیا ہے اور [illegible]

سلمان ولد [illegible]
42301 8767589-7
اسٹور انچارج امانت اللہ ٹریڈرز

Inspector (DR. SHOAIB AHMED) Federal Inspector of Drugs, Government of Pakistan, Drug Regulatory Authority of Pakistan, Karachi

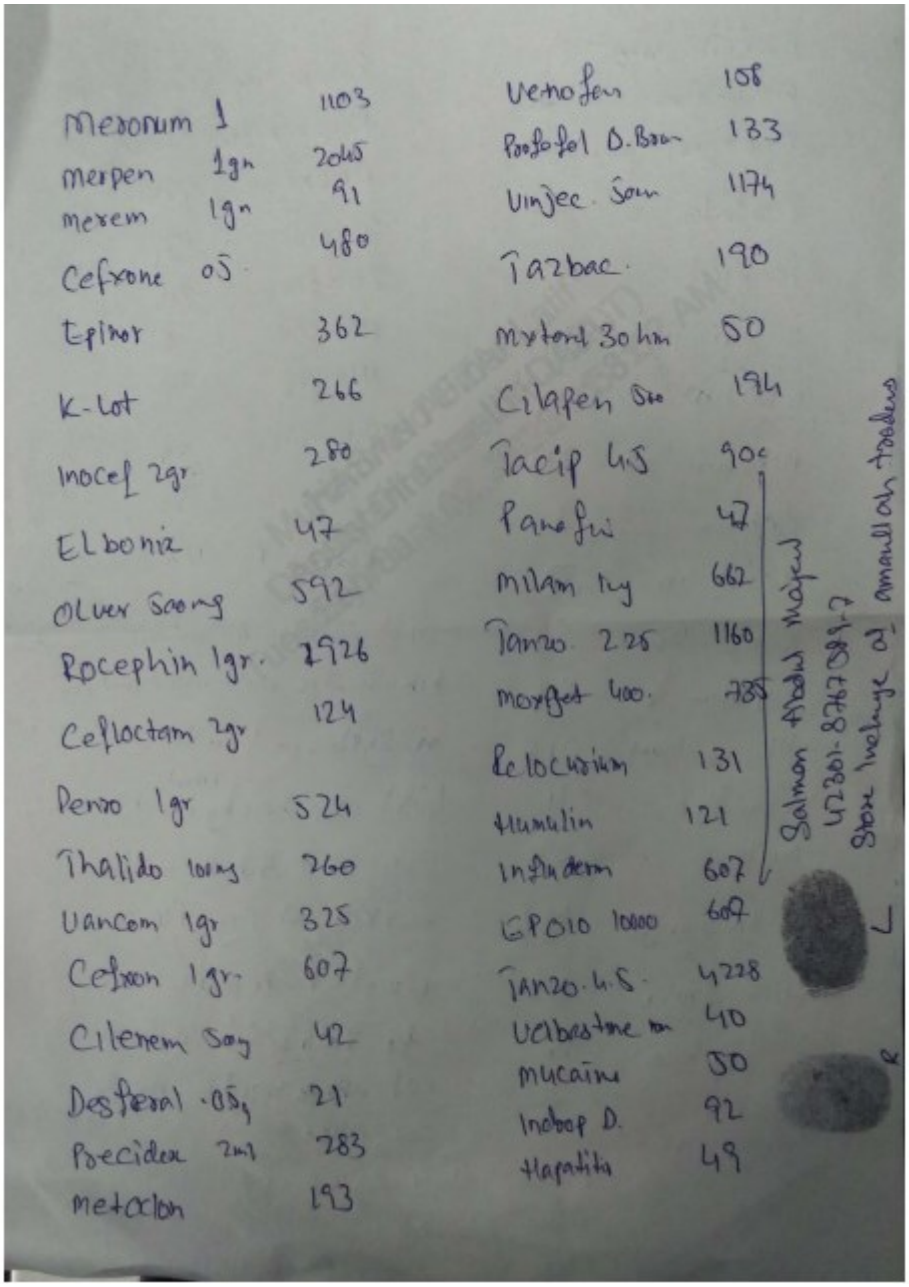
Date 01/2/23

Erlonib. 150mg.	8
Aminoleban	100
Cyclogest 200mg	543
Rhofalac	21
Ferinject	95
onset inj	1081
Epocan 2000	749
Albumin 50ml.	213
Palbem	3
Maxef 500	87
Kinz 10ml	83
Ciprocin 2g	126
Albumin 100ml	906
Lorin Depot	4
hysolon	090
Lignocaine gel	4316
Anti Snake	315
Gerepo 4000	10
Victoza	18
Rabio inj	817
Novo mix 30	9
Amvax.	224
Troopin	139
Zoladex	40
Novo mix	8
Varigrip	70
momentum	35
Humalog -	3
Tetagem P.	123

And others medicine which are not mentioned in system and in this List are hereby ordered not to Sale or distribute in the market and any Place I will Responsible for Saling and moment of above mention medicine and others

L R

Salman. S/o Abdul Majeed
42301-8767589-7
Store Incharge of Amanullah Traders



ACTION TAKEN BY QA&LT

2. The Director QA&LT Islamabad vide letter No. F.6-1/2023-QA dated February 2023 conveyed the permission for registration of FIR against the accused person.

3. Case FIR No. 09/2023 dated 02-02-2023 was registered.

FIA INVESTIGATION REPORT

4. Final Investigation report was received from Federal Investigation agency wherein the matter is concluded/recommended as under:

"*From the investigation conducted and evidences collected so far during the course of investigation, it is concluded that the accused namely 1) M/s Amanullah Traders, MA Jinnah Road, Karachi (DSL No. 915 dated 18-1-2023, 2) Zeeshan Amanullah S/o of Amanullah Arman, Proprietor of Ms Amanuallah Traders 3)Salman Abdul Majeed –Store Incharge who signed form-1, form-2, form-3.*

Similarly, since at the time of joint raid at M/s Marfani Medical MA Jinnah Road Karachi on 9-2-2023, and recovery of unregistered and unwarranted stock of imported medicines under form-2 were signed by accused

Umair Marfani which is violation of section 23 of Drugs Act 1976. From the copy of Drug License No. 750 on Form-6 (Retail Sale) issued vide letter No. DHODSK (DRUG)/-389/- dated 21-7-2022 it transpires that it was issued to Muhammad Zubair Marfani S/O Abdul Jabbar Marfani, Ms Marfani Medical situated at Shop no. 45,46 Qureshi Bazar OPP: Khaliq Dena Halla M.A Jinnah Road, Karachi, therefore both the accused brothers namely 1) Muhammad Zubair Marfani S/O Abdul Jabbar Marfani, proprietor of Ms Marfani Medical store CNIC No. 42201-2026200-9 and 2) Muhammad Umair S/o Abdul Jabbar CNIC No. 42201-8786693-3 are also liable for prosecution.

b. The above act on the part of accused persons namely (1) M/s Amanullah traders MA Jinnah Road Karachi (DSL No. 915 dated: 18.01.2023 , 2) Zeeshan S/O Amanullah Arman, Proprietor of M/s Amanullah Traders, and (3) Salman Abdul Majeed Store lncharge (4) Muhammad Zubair Marfani s/o Abdul Jabbar Proprietor of M/s Marfanis Medical Store, and (5) Muhammad Umair s/o Abdul Jabbar constitue the commission of offences under Sections 23(1)(a)(vii), 23(1)(i) of Drugs Act, 1976, punishable under Section 27 of the Drugs Act, 1976 and DRAP Act, 2012 for which they are liable for prosecution before the Hon'ble Drug Court of Sindh at Karachi where the Interim Charge Sheet No. 11/2023 dated 17.02.2023 has already been submitted against them whereas the name of Mohammad Waqar s/o Abdul Razzaq, Qualified Person of M/s Amanullah Traders is recommended to be placed in Column No. 2 (as not sent up for trial) of the final Charge Sheet. Since as a result of subsequent raid at M/s RG Medicos Kutch' Gali no recovery of any incrimmiating articles was made and complaint was also not against M/s RG Medicos / Traders by Complainant (FID-DRAP), therefore, the names of accused persons namely Abdul Razzaq s/o Abdul Sattar, Sohail Ahmed s/o Riazuddin Malik and Abdul Ghaffar s/o Ibrahim are recommended to be placed in Column No. 2 (as not sent up for trial) of the charge sheet, as nothing incriminating could come on record against them during the course of investigation.

c. Since from the investigation conducted and evidences collected so far, it has been established that accused namely (1) M/s Amanullah Traders MA Jinnah Road Karachi (DSL No. 915 dated: 18.01.2023), (2) Zeeshan s/o Amanullah Arman, Proprietor of M/s Amanullah Traders, (3) Salman Abdul Majeed Store Incharge, (4) Muhammad Zubair Marfani s/o Abdul Jabbar Proprietor of M/s Marfanis Medical Store, and (5) Muhammad Umair s/o Abdul Jabbar have committed the offences under Sections 23(1)(a)(vii), 23(1)(i) of Drugs Act, 1976, punishable under Section 27 of the Drugs Act, 1976 and DRAP Act, 2012, therefore, it is recommended that the DRAP authorities be moved for submission of final Charge Sheet against them by placing the names of accused persons namely (1) Mohammad \Nagar s/o Abdul Razzaq, Qualified Person of M/s Amanullah Traders, (2) Abdul Razzaq s/o Abdul Sattar, (3) Sohail Ahmed s/o Riazuddin Malik, and (4) Abdul Ghaffar s/o Ibrahim, S.No. 02 to 04 of M/s RG Medicos, in Column No. 2 (as not sent up for trial) of the charge sheet.

d. The Final investigation report is submitted for kind perusal and onward transmission to DRAP for submission of final Charge Sheet before the Hon'ble Drug Court of Sindh at Karachi, please"

5. Show cause notice/personal hearing to the following accused was issued on 22nd December 2023

M/s Amanullah Traders (DSL No. 915 dated 18-01-2023) Shop no.01, Ibrahim Ilyas Building Picture	**Zeeshan Amanullah S/o of Amanullah Arman,** Proprietor of M/s Amanullah Traders Shop no.01, Ibrahim Ilyas Building	**Salman Abdul Majeed,** Store In-charge of (M/s Amanullah Traders) Shop no.01, Ibrahim Ilyas Building Picture	**Muhammad Umair S/o Abdul Jabbar** M/s Marfanis Medical store (DSL 750)	**Muhammad Zubair Marfani S/o Abdul Jabbar** Proprietor of M/s Marfanis Medical store (DSL 750)

Street, M.A Jinnah Road Karachi	Picture Street, M.A Jinnah Road Karachi	Street, M.A Jinnah Road Karachi	Shop no 45,46 Qureshi bazar Opp: Khaliq Dena Halla M.A Jinnah Road, Karachi.	Shop no 45,46 Qureshi bazar Opp: Khaliq Dena Halla M.A Jinnah Road, Karachi.

REPLY FROM THE PROPRIETOR/ FIRM

6. Reply received from Shehroze law associates on behalf of clients namely Muhammad Umair and Muhammad Zubair Marfani Both sons of Abdul jabbar. That our clients are carrying their business in the name and style as "Marfani Traders" situated at Shop no 45,46 Qureshi bazar Opp: Khaliq Dena HallaM.A Jinnah Road, Karachi. There is no role or connection of our clients with the alleged crime/incident of FIR No. 09/2023 and they have wrongly dragged in FIR no. 09/2023 on the basis of alleged recovery of FIR no.10/2023, which amount to double jeopardy and not permitted under Constitution of Islamic republic of Pakistan 1973.

In view of above facts and circumstances, your august authority is hereby requested to recall/waive the above said show cause notice.

RECOMMENDATION FROM QA&LT

7. In view of the scenario detailed above the QA&LT Division recommends that as per report of the FID and FIA the accused committed the offence u/s 23(1)(a)(i), 23(1)(a)(x), 23(1)(a)(vii), 23(1)(b), 23(1)(c), 23(1)(I) of Drugs Act 1976, which is punishable under section 27 of the Drugs Act 1976 and rules framed there under for which he is liable to be prosecuted before the Honorable Courts of Drugs, Sindh at Karachi

8. A personal hearing letter dated 18th July 2024 was issued for appearance in 298th meeting. No reply was received yet.

PROCEEDINGS OF 298TH MEETING OF CENTRAL LICENSING BOARD:

9. No one appears on behalf of the accused.

<u>Decision of 298th meeting of CLB:</u>

After thorough deliberation, considering the FID and FIA investigation report and all the facts, the board decided as under:

i. Allowed Federal Inspector of Drugs, Karachi for filling prosecution in the Drug Court for contravention of 23(1)(a)(i), 23(1)(a)(x), 23(1)(a)(vii), 23(1)(b), 23(1)(c), 23(1)(I) of Drugs Act 1976, and Schedule II-A(1)(a)(x), Schedule II-A(1)(a)(c), Schedule II-A(1)(a)(i), Schedule II-A(1)(a)(vii) of the DRAP Act 2012 which is punishable under section 27 of the Drugs Act 1976 and Schedule-III of the Drap Act 2012, and rules framed there under, against the following;

M/s Amanullah Traders (DSL No. 915 dated 18-01-2023) Shop no.01, Ibrahim Ilyas Building Picture	**Zeeshan Amanullah S/o of Amanullah Arman,** Proprietor of M/s Amanullah Traders Shop no.01, Ibrahim Ilyas Building	**Salman Abdul Majeed,** Store In-charge of (M/s Amanullah Traders) Shop no.01, Ibrahim Ilyas Building Picture	**Muhammad Umair S/o Abdul Jabbar** M/s Marfanis Medical store (DSL 750) Shop no 45,46 Qureshi bazar Opp:	**Muhammad Zubair Marfani S/o Abdul Jabbar** Proprietor of M/s Marfanis Medical store (DSL 750)

Street, M.A Jinnah Road Karachi	Picture Street, M.A Jinnah Road Karachi	Street, M.A Jinnah Road Karachi	Khaliq Dena Halla M.A Jinnah Road, Karachi.	Shop no 45,46 Qureshi bazar Opp: Khaliq Dena Halla M.A Jinnah Road, Karachi.