MINUTES OF 293rd MEETING OF CENTRAL LICENSING BOARD HELD ON 20TH NOVEMBER, 2023

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293rd meeting of the Central Licensing Board (CLB) was held on 20th November, 2023 in the Committee Room, Drug Regulatory Authority of Pakistan, Ground Floor, NCLB, 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	Member
3.	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Baluchistan, Quetta	Member
4.	Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Government of Khyber Pakhtunkhwa	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. Mrs. Ume Liala Deputy Director (Lic), Mr. Mubashir Iqbal Deputy Director (Lic), Mr. Yaqoob Kakar, Assistant Director (Lic), Abdullah Assistant Director (Lic), Mr. Hasan Afzaal DD QA, Mr. Sannaullah DD (QC), Muhammad Umar DD (QA) and Mr. Bilal Bin Akbar DD (Legal Affairs) assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 292nd MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 292nd meeting of Central Licensing Board which was held on 4th October, 2023.

A. DRUG LICENSING DIVISION

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 Otsuka Pakistan Limited, F/4-9, Hub Industrial Trading Estate, District Lasbela, Baluchistan. DML No.000281 (Formulation) **Section (01):** i. Liquid Infusion General (LVP) Plabottle – Revised. ii. Liquid Infusion General (LVP) Glass Vial – Withdrawn (Evaluator: Mr MubashirIqbal)	16-10-2023	Good	1. Mr. Muhammad Salik Zahid, Chief Drug Inspector, Quetta. 2. Mr. Kirshan Area FID, DRAP, Quetta. 3. Mr. Abdul Waheed, Assistant Director (I&E), DRAP, Quetta.

M/s Otsuka Pakistan Limited, F/4-9, Hub Industrial Trading Estate, District Lasbela, Baluchistan having DML No. 000281 (Formulation) was visited and inspected in detail on 16th October, 2023 in compliance to the directions contained in DRAP, Islamabad Letter No.F.2-1/89-Lic (Vol-III) dated 28th September, 2023, in connection with Grant of Revised/Amended Sections.

The panel inspected the firm in detail including manufacturing sections (revised), stores and QC Lab and found the facility as per approved lay out plan. The facility has been provided with necessary utilities, machines and equipment as required under the guidelines. Necessary documents related to QC, QA and production and installation qualification of machines, 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 grant of revised/amended sections as following:

S.No.	Name of Section
01	Liquid Infusion General (LVP) Plabottle – Revised.
02	Liquid Infusion General (LVP) Glass Vial – Withdrawn.

Decision of the Central Licensing Board in 293rd meeting:

On the recommendations of the panel of experts, the Board considered and approved the grant of following revised section in the name of M/s Otsuka Pakistan Limited, F/4-9, Hub Industrial Trading Estate, District Lasbela, Baluchistan under DML No. 000281 (Formulation) subject to verification of testing equipments (M-290th CLB):-

i. Liquid Infusion General (LVP) Plabottle – Revised.

The Board also decided to cancel the following section under intimation to Drugs Registration Board regarding registered products for further necessary action at their end.

i. Liquid Infusion General (LVP) Glass Vial – Withdrawn/Cancelled

2	M/s. Bosch Pharmaceuticals (Pvt) Ltd., Plot No.209, Sector 23, Korangi Industrial Area, Karachi. DML No.000707 (Formulation) **Section (04):** i. Capsules/Pellets Filling Section (General) – **New**. ii. Dry Powder Suspension Section (General) – **New** iii. Sachet Section (General) – **New** iv. Research and Development Laboratory – **New** (Evaluator: Mr Mubashir Iqbal)	10-10-2023	Good	1. Mr Ghulam Ali Lakho, Chief Drug Inspector, Sindh. 2. Mr. Abdul Rasool Sh. Area FID, DRAP, Karachi / Additional Director, DRAP, Karachi.

M/s. Bosch Pharmaceuticals (Pvt) Ltd., Plot No.209, Sector 23, Korangi Industrial Area, Karachi was inspected in connection with the Grant of new sections under Drug Manufacturing License No.000707 (Formulation) as per DRAP, Islamabad letter No.F.2-19/2006-Lic (Vol-II) dated 28th September, 2023 for the following sections: -

S.No.	Name of Sections	Purpose
i.	Capsules/Pellets Filling Section (General)	New
ii.	Dry Powder Suspension Section (General)	New
iii.	Sachet Section (General)	New
iv.	Research and Development Laboratory	New

Following are the observations:

	As per instruction contained in DRAP Islamabad letter No.F.2-19/2006-Lic (Vol-II) dated 28th September 2023, the panel inspected in detail the targeted OSD Sections, R&D Lab, Stores newly built as per approved design at second floor of the main building, the panel under the scope also inspected in detail their QC Lab facilities, reviewed in detail documents relating to installation of machines, equipment, HVAC System & other utilities, Organogram, QMS, Quality manuals, HVAC design, approved design and other GMP vital documents were also reviewed and discussed at length and observed an optimal level of compliance. Based on the stated observations the panel unanimously recommends the grant of following additional sections under DML No.000707 possessed by Ms. Bosch Pharmaceuticals (Pvt) Ltd., Plot No.209 Sector-23 Korangi Industrial Area Karachi:- i. Capsules/Pellets Filling Section **(G) (New)** ii. Dry Powder Suspension Section (**G) (New)** iii. Sachet Section **(G) (New)** iv. Research and Development Laboratory (**New)** **Decision of the Central Licensing Board in 293rd meeting:** On the recommendations of the panel of experts, the Board considered and approved the grant of following additional sections in the name of M/s. Bosch Pharmaceuticals (Pvt) Ltd., Plot No.209, Sector 23, Korangi Industrial Area, Karachi, DML No.000707 (Formulation) subject to verification of testing equipments (M-290th CLB). i. Capsule **(General) - New** ii. Oral Dry Powder for Suspension **(General) - New** iii. Sachet **(General) - New** iv. Research and Development Laboratory - **New**			
3.	M/s Medicraft Pharmaceuticals (Pvt.) Ltd, 126-B, Industrial Estate, Hayatabad, Peshawar. DML#000390 (Formulation) (Evaluator: Mr. Muhammad Yaqoob)	08-08-2023	Good	i. Dr. Abbas Khan, DG Drugs, KPK. ii. Mr. Faisal Shahzad, Additional Director, DRAP, Peshawar. iii. Mr. Atiq-ul-Bari, Area FID, DRAP, Peshawar.
	Recommendation; Remarks were recorded on the inspection report. Based on the areas inspected, the people met, documents reviewed, the intension towards further improvements the panel unanimously recommends the grant of following additional sections to M/s Medicraft Pharmaceuticals (Pvt.) Ltd, 126-B, Industrial Estate, Hayatabad, Peshawar. i. Oral Liquid (Psychotropic)- Regularization **Decision of the Central Licensing Board in 293rd meeting:** It was appraised by the secretariat of the Board that the firm has already submitted NOC dated 14.03.2022 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 therefore, the Board considered and approved the grant of following additional sections in the name of M/s Medicraft Pharmaceuticals (Pvt.) Ltd, 126-B, Industrial Estate, Hayatabad, Peshawar DML#000390			

	(Formulation) on the recommendations of the panel of experts subject to verification of testing equipment (M-290th CLB):- i. Oral Liquid (Psychotropic) – Regularized ii.			
4.	M/s Amson Vaccine & Pharma (Pvt) Ltd, Plot No. 154 Kahuta Triangle, Islamabad. DML No. 000393 (Formulation). **Section:** 1. Water for Injection Section (Relocation). (Evaluator: Mr Muhammad Yaqoob)	**26-10-2023**	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Saadia Mahwish, Area Federal Inspector of Drugs, DRAP, Islamabad. 3. Saima Hussain, Assistant Director (PE&R Division), DRAP. Islamabad.
	Recommendations of Inspector (s): Keeping in view the above facts on record and the people met, documents reviewed during the visit, the panel unanimously recommended the grant / relocation of following additional section to M/s Amson Vaccines & Pharma (Pvt) Ltd, Plot No. 154 Industrial Triangle, Kahuta Road, Islamabad. 1. Water for Injection Section **Decision of the Central Licensing Board in 293rd meeting:** On the recommendations of the panel of experts, the Board considered and approved the grant of following section in the name of M/s Amson Vaccine & Pharma (Pvt) Ltd, Plot No. 154 Kahuta Triangle, Islamabad, DML No. 000393 (Formulation) subject to verification of testing equipment (M-290th CLB): i. Water for Injection Section (Revised)			
5	M/s. Himont Pharmaceuticals (Pvt.) Ltd., 17-km Ferozepur Road, Lahore DML No. 000231 (Formulation). **Sections:** 1. Liquid Injectable (Biological Section) (Evaluator: Mr Abdullah)	25-07-2023 and 24-10-2023	**Good**	1. Ms, Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP Lahore. 3. Mr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore.
	Recommendations of Inspector (s): In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment,			

	material, management, air handling, water treatment system, personnel and documentation etc. the panel recommends for additional section i.e, Liquid Injectable (Biological Section) to M/s. Himont Pharmaceuticals (Pvt.) Ltd, 17-km, Ferozepur Road, Lahore by way of formulation. Note. It is submitted for information that the firm has requested for approval of revision of the LOP for above mentioned section and the LOP is not yet approved. It was also observed in the proposed LOP that the firm has not provided proper dedication. Moreover, it is also mentioned in the inspection report that firm was advised to install the interlocking in the change rooms and firm has added the additional change room for entrance to the solution preparation rooms. **Decision of the Central Licensing Board in 293rd meeting:** After threadbare deliberation, the Board decided to defer the case. The firm shall get approval of the LOP first as per Drugs (LRA), Rules 1976 for the proposed changes and then the Board will consider the case for final decision.

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 Parker Pharma (Pvt) Ltd., Plot No.07/A, S.I.T.E., Kotri, Sindh. **DML No. 000883 (Formulation)** **Period:** Commencing on 11-04-23 ending on 10-04-2028 (Evaluator: Mr Mubashir Iqbal)	**17-10-2023**	**Good**	1. Mr. Abdul Rasool Sh. Additional Director, DRAP, Karachi. 2. Area FID, DRAP, Karachi. 3. Assistant Director, DRAP, Karachi.
	Production In-charge:	Mr. Ghulam Mustafa s/o Sain Bakhsh (B-Pharm) CNIC No.44204-2450937-7.		
	Quality Control In-charge:	Mr. Haji Muhammad Alias Fahad S/o Haji Noor Ahmed (M.Sc Analytical Chemistry) CNIC No.41303-2893037-5.		
	Recommendations of the panel: *"Based on people met, areas visited and commitment of the management for continuous improvement, expansion and export potential, the panel unanimously was of the view to* ***recommend Renewal of Drug Manufacturing License No.000883 as per DRAP, Islamabad letter of even no. dated 16th May, 2023*** *to the firm M/s Parker Pharma (Pvt.) Ltd., Plot No.07/A, S.I.T.E., Kotri, Sindh for following approved sections:*			

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

Decision of the Central Licensing Board in 293rd meeting:

The Board considered and approved the grant of renewal of DML No. 000883 by way of Formulation in the name of M/s Parker Pharma (Pvt) Ltd., Plot No.07/A, S.I.T.E., Kotri, Sindh on the recommendations of the panel of experts for the period Commencing on 11-04-23 ending on 10-04-2028 for the following sections subject to verification of testing equipments (M-290th CLB).

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

2.	M/s Nextar Pharma (Pvt) Ltd., Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi. **DML No. 000777 (Formulation)** **Period:** Commencing on 15-03-23 ending on 14-03-2028. (Evaluator: Mr Mubashir Iqbal)	**12-10-2023**	**Good**	1. Mr. Abdul Rasool Sh. Additional Director, DRAP, Karachi. 2. Mr. Saif-ur-Rehman, Director CDL, Karachi. 3. Area FID, DRAP, Karachi.
	Production In-charge:	Mr. Atif Muhammad Khan S/o Saad Muhammad Khan (B-Pharm) CNIC No.42201-1038326-7.		
	Quality Control In-charge:	Mr. Wajahat Ali S/o Liaquat Ali (M.Sc Chemistry) CNIC No.42401-8742434-1.		

Recommendations of the panel:

"M/s Nextar Pharma (Pvt) Ltd., was inspected by the panel as per directions contained in DRAP, Islamabad letter no.F.2-4/2004-Lic dated 08th Sep 2023. The following observations were made:

1) *M/s Nextar Pharma (Pvt) Ltd., is pharmaceutical company that has been constructed in accordance with the layout plan approved by the Drug Regulatory Authority of Pakistan (DRAP).*
2) *The company has all of the necessary equipment and machinery for the production, quality control, and storage of registered biopharmaceutical products, as well as a team of relevant technical experts.*
3) *The company has installed the requisite HVAC system in its production, QC, and QA areas, which is managed by a Building Management System and was operational at he time of inspection. The fact that the HVAC system is managed by a BMS also indicated that the company is taking steps to ensure the quality and safety of its products.*
4) *The company's compliance with DRAP requirements and its state-of-the-art facilities and equipment demonstrate its commitment to producing high-quality biopharmaceutical products.*

	5) *Overall, M/s Nextar Pharma (Pvt) Ltd., appears to be a well-equipped and well-managed Premises that is capable of producing high-quality biopharmaceutical products.* *Based on the people met, documents reviewed, inspection findings, management's commitment to continuous improvement and compliance with the DRAP Act 2012, and efforts towards exports to various countries, the inspection* ***panel recommends renewal of Drug Manufacturing License No.000777 to M/s Nextar Pharma (Pvt) Ltd., for Pre Filled Syringes and Injectable Ampoule Sections."*** **Decision of the Central Licensing Board in 293rd meeting:** The Board considered and approved the grant of renewal of DML No. 000777 by way of Formulation in the name of M/s Nextar Pharma (Pvt) Ltd., Plot No. E-58, North Western Industrial Zone, Port Qasim, Karachi on the recommendations of the panel of experts for the period Commencing on 15-03-23 ending on 14-03-2028 for the following sections subject to verification of testing equipments (M-290th CLB). 1. Pre Filled (General) Syringes 2. Injectable Ampoule (General) Sections			
3	M/s Nimral Pharma, Plot No.24, Street No. S-3, National Industrial Zone RCCI Zone, Rawat, Rawalpindi. **DML No. 000611 (Formulation)** **Period:** Commencing on 21-03-2022 ending on 20-03-2027. (Evaluator: Ms Ume Laila)	**29-10-2023**	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Dr. Mahvash Ansari, Additional Director (QA/LT), DRAP, Islamabad. 3. Mrs. Umm-e-Laila, Deputy Director (Licensing), DRAP, Islamabad.
	Production In-charge:	Mr. Sohail Akram S/o Muhammad Akram, (B-Pharm) CNIC No.32304-8464003-3.		
	Quality Control In-charge:	Mr. Shahid Nadeem S/o Manzoor Ahmad (M.Sc Chemistry) CNIC No.34602-0674909-7.		
	Recommendations of the panel: *"The establishment has made marked improvement in their sterile sections and made significant changes. Further, the establishment has submitted compliance to the observations made in the follow-up inspection (attached). The establishment has the necessary equipment/machinery for production and equipment / apparatuses for QC except FTIR, therefore, in the light of the above, the panel recommends the following sections for renewal w.e.f. 21-03-2022:* i. Eye Drops (General) Section ii. Liquid Injection (SVP) (General) Section iii. Liquid Injection (Infusion) (General Antibiotic) Section **Decision of the Central Licensing Board in 293rd meeting:** The Board observed that the renewal of license has already been approved in 289th meeting. On the recommendations of the panel of experts the board considered and approved the grant of renewal of following sections of M/s Nimral Pharma, Plot No.24, Street No. S-3, National Industrial Zone			

	RCCI Zone, Rawat, Rawalpindi for the period Commencing on 21-03-2022 ending on 20-03-2027 for the following sections subject to verification of testing equipment (like FTIR etc). i. Eye Drops (General) Section ii. Liquid Injection (SVP) (General) Section iii. Liquid Injection (Infusion) (General Antibiotic) Section			
4	M/s Siza International (Pvt) Ltd, 18-Km, Ferozepur Road, Lahore. **DML No. 000259 (Formulation)** Period: Commencing on 26-10-2019 ending on 25-10-2024 (Evaluator: Ms Ume Laila)	**19-10-2023**	**Good**	1. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 2. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore. 3. Mr. Ishtiaq Shafiq, AD, DRAP, Lahore.
	Production Incharge:	Mr. Muhammad Imran Khalil S/o Ch. Khalil Ahmad (B-Pharm) CNIC No.35202-9390776-9.		
	Quality Control Incharge:	Mr. Riasat Ali S/o Nawazish Hussain (M.Sc Chemistry) CNIC No.35401-0493702-3.		
	Recommendations of the panel: *"In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, water treatment system, personnel and documentation etc. the panel* ***recommends the renewal of Drug Manufacturing License by way of formulation and regularization of layout plan of following sections to M/s Siza International (Pvt) Ltd, situated at* 18-Km, Ferozepur Road, Lahore:** 1. Injectable (Ampoule) 2. Injectable (Vial) 3. Tablet Section (General) 4. Capsule Section (General) 5. Dry Powder Suspension Section (General) 6. Tablet Section (Cephalosporin) 7. Capsule Section (Cephalosporin) 8. Dry Powder Suspension Section (Cephalosporin) 9. Oral Liquid (General) **Decision of the Central Licensing Board in 293rd meeting:** The Board considered and approved the grant of renewal of DML No. 000259 by way of Formulation in the name of M/s Siza International (Pvt) Ltd, 18-Km, Ferozepur Road, Lahore on the recommendations of the panel of experts for the period Commencing on on 26-10-2019 ending on 25-10-2024 for the following sections subject to verification of equipment like FTIR. 1. Injectable (Ampoule) 2. Injectable (Vial) 3. Tablet Section (General)			

	4. Capsule Section (General) 5. Dry Powder Suspension Section (General) 6. Tablet Section (Cephalosporin) 7. Capsule Section (Cephalosporin) 8. Dry Powder Suspension Section (Cephalosporin) 9. Oral Liquid (General)

Item-V: **MISCELLANEOUS**

Case No.1 **ESTABLISHMENT OF PHARMACEUTICAL UNIT – M/S. VETERINARY RESEARCH INSTITUTE LAHORE (VRI).**

M/s. Veterinary Research Institute Lahore submitted application for site verification vide letter No. 893 dated 30/1/2010. Additional Director (E&M), DRAP, Lahore was requested to inspect the site situated at Veterinary Research Institute, Zarrar Shaheed Road, Lahore vide letter No. 1-14/2010-Lic dated 11/02/2010. In light of above letter, FID, DRAP, Lahore submitted its inspection report as under;

> *"In the light of above, the location and surrounding of the proposed site may be considered as per requirement laid down"*

There were no clear recommendations hence the final decision was not taken.

The University of Veterinary and Animal Sciences (UVAS) organized a conference on biological production on Monday, Oct 09, 2023 to encourage the indigenous vaccine development for livestock. CEO DRAP Mr. Asim Rauf along with Dr. Syed Zia Husnain Additional Director, DRAP attended the conference and during a meeting the matter of site verification of the above site was discussed. The FID Lahore was again asked to give its report. Now inspection report of the same site is also received from FID, DRAP, Lahore vide letter Dy. No. 3132/2023(AD-I&E/LHR) dated 27/10/2023 as under;

"I am directed to refer to the Drug Regulatory Authority of Pakistan, Islamabad letter No.F.1-2/2021-Lic dated 10-03-2022, on the subject cited above.

Site inspection of M/s. Veterinary Research Institute Lahore was conducted by the undersigned along with Dr. Ishtaiq Shafiq, Assistant Director, DRAP, Lahore on 20-10-2023. Dr. Sajjad Hussain, Director General (Research), Livestock & Dairy Development Department, Punjab along with his team accompanied at the time of visit.

The management informed that Pakistan did not inherit any research organization or biological production unit at the time of independence and had to start work in a small two room Centre established at the Veterinary College, Lahore in 1948. The Bureau of Disease Investigation and Biological Production were established in 1959 at the present site of Ghazi Road, which was eventually raised to the status of Directorate of Veterinary Research Institute, Lahore (VRI) in 1962 by the order of Governor West Pakistan. At that time the site was out of populated area in the Lahore cantonment. The Institute is arranged in seven divisions with an overall establishment of huge numbers of Professional and Para-professional/non-professional/ministerial staff.

The institute is involved in manufacturing of different type of vaccines, Sera and Diagnosis Agents for livestock and poultry. The proposed site plan is attached herewith report.

1	***Location***	*The proposed site is located at the Main Zarrar Shaheed Road, Lahore Cantt since 1962 (Veterinary Research Institute).*
2	***Surrounding***	*On the Front side of the site there was 112 feet Double Road named Main Zarrar Shaheed, Road.* *On the Left side of the site there was Residential / Commercial Area of Al-Faisal Town after 27 feet Road.* *On the Back side of the site there was Ghaziabad Residential Area after 117 feet Road named Ghaziabad Road.* *On the Right side of the site there was PAF Residential Colony after 42 feet Road.*
3	***Size***	*Total area of the land is 956300 sq. ft.*
4	***Recommendations***	*In light of the abovementioned findings regarding surroundings of the proposed site and history of the institute, the case is being forwarded for consideration by the Competent Authorities as per requirements laid down."*

The inspectors did not give its clear recommendations due to presence of residential and commercial buildings. The FID Lahore was again asked to give its clear and candid recommendations. In response, the FID Lahore has responded as under.

> "keeping in view the national interest and history of the institute the case may be considered by the competent authority in national interest."

The matter was submitted before the DRAP Authority for its consideration and decision in its 175th meeting held on 3rd November, 2023 and the DRAP Authority decided as under;

> *"The Authority noted that:-*
>
> *i. Veterinary Research Institute (VRI) is located at the Main Zarrar Shaheed Road, Lahore Cantt since 1962.*
> *ii. Total area of VRI is 956300 sq. ft area.*
> *iii. Since its establishment this institute is involved in the research on veterinary vaccines.*
> *iv. Total area of the institute is large enough to establish an industrial zone.*
> *v. Country's large dependence on Veterinary vaccines is on imports and there is a dire need to enhance local production of these vaccines to reduce such dependency.*
> *vi. Encouragement of local Veterinary Research Institutes is necessary to enhance local production of veterinary vaccines.*
>
> *Therefore, the Authority advised Licensing Division to process the case of grant of license to M/s Veterinary Research Institute, Lahore."*

Decision of the Central Licensing Board in 293rd meeting:

The Board after threadbare deliberation and fact and in the larger public interest decided to approve the proposed site of M/s. Veterinary Research Institute Lahore.

Case No. 2 **SITE VERIFICATION OF M/S BIO PANACEA LABORATORIES, SHEIKHUPURA.**

M/s Bio Panacea Laboratories, 13-Km, Sheikhupura-Lahore Road, Lahore applied for site verification of proposed plot. After application was completed by the firm, FID 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. Abdul Rashid Shaikh, FID, DRAP, Lahore and the recommendations are as under: -

2.	Location	:	The proposed site was located in agricultural area at 13-Km, Sheikhupura-Lahore Road, Lahore Sheikhupura.
3.	Surrounding	:	The dimensions of the plot are as follows: On the front side of the plot, there was 20 feet wide un-paved rasta. On the back side of the proposed site, there were agricultural land. On the right side of proposed side there was there was agricultural land. On the left side the site there was Bashir Polymers with in the same boundary wall, however the management allocate about 04 Kanals land for the proposed unit.
4.	Size	:	The plot size (234*86=20124) sq. feet. Documents of the proposed site are attached as provided by the management. The site plan /dimension of the plot is also annexed with report.
5.	Recommendations	:	At the distance of 300-400 meters there was a very active border / paper mill which was producing huge quantity of smoke and the approach was also not appropriate. The above observation led to the conclusion that the site is not as per requirement, laid down under paragraph 1 of section 1 of schedule "B" (SRO 470 (1)/98, dated 15-05-1998) under Rule 16(a) of the of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Hence the proposed site is not suitable for establishment a pharmaceutical unit as of today as the same was also discussed in detail with the owners.

Decision of the Central Licensing Board in 292nd meeting

The Board considering the facts on the record and after thread bare deliberations decided to give personal hearing to the firm M/s Bio Panacea Laboratories, 13-Km, Sheikhupura-Lahore Road, Lahore in the upcoming meeting of the Board

The Board further decided to authorize Chairman CLB to constitute 2-member panel (other than the officer already inspected the site) for re-inspection of the same site if desired by the applicant. Moreover, Chairman CLB is authorized to issue notice to the applicant for personal hearing before the CLB.

A letter of personal hearing was served on 10th November, 2023 to the said firm for 293rd meeting of Central Licensing Board schedule to be held on 20-11- 2023.

Decision of the Central Licensing Board in 293rd meeting:

No one presented before the board for personal hearing therefore the Board after discussion decided to reject the proposed site of M/s Bio Panacea Laboratories situated at 13-Km, Sheikhupura-Lahore Road, Lahore.

Case No .3 **WITHDRAWAL OF DRUG MANUFACTURING LICENSE NO. 000937 BY WAY OF BASIC MANUFACTURE OF M/S HERBION PAKISTAN (PVT) LTD, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

M/s Herbion Pakistan (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad, wherein firm has submitted an application for withdrawal of their Drug Manufacturing License No. 000937 by way of Basic Manufacture. Firm has also returned original DML (Form-2) and inspection book.

Decision of the Central Licensing Board in 292nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to the firm M/s Herbion Pakistan (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad DML No. No. 000937 by way of Basic Manufacture in the upcoming meeting of the Board.

A letter of personal hearing was served on 10th November, 2023 to the said firm for 293rd meeting of Central Licensing Board schedule to be held on 20-11- 2023.

Decision of the Central Licensing Board in 293rd meeting:

Mr. Shiraz Khan, GM Plant appeared before the Board and contended that manufacturing of Alprazolam (a psychotic substance) API is not affordable/economical as compared to API imported from China etc. the Board after personal hearing and threadbare deliberation decided to accede the firm request for withdrawal Drug Manufacturing License No. 000937 by way of Basic Manufacture of M/s Herbion Pakistan (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad. Moreover, as the DML was grated for manufacturing of Alprazolam (a psychotic substance) therefor all the equipment and technology will be dismantling and liquidated under intimation and subsequent approval from the Board.

Case No .4 **SITE VERIFICATION REPORT OF M/S PREMIER LIFE PHARMACEUTICAL ((PVT) LTD, PLOT NO. 181/1, ROAD L.9, INDUSTRIAL ESTATE GADOON AMAZAI, SWABI.**

Site verification report of M/s Premier Life Pharmaceutical ((Pvt) Ltd, Plot No. 181/1, Road L.9, Industrial Estate Gadoon Amazai, Swabi. The inspection was conducted by Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad and Atiq Ul Bari, Federal Inspector of Drugs, Peshawar in response to this office letter No. 3-6/2022-Lic dated 29th May, 2023. The recommendations of the inspection report are as under: -

The undersigned inspected the Plot No. 181/1, Road L-9, Industrial Estate, Gadoon Amazai, Swabi, Khyber Pakhtunkhwa on 22-06-2023. The said plot is proposed site for M/s Premier Life Pharmaceutical (Pvt) Ltd. The plot is situated in the Industrial Estate of Gadoon Amazai, Swabi, KPK having the necessary amenities such as road infrastructure, water and electrical supply. No environmental pollution was found at the time of inspection and a unit of chip board is situated 100 meters away from the back corner of the plot.

The premises have already built halls with partitions / rooms and a double story built block for security guards / admin. The pictures are attached with the report.

Further the Establishment has already submitted an undertaking that they would build a technical floor as per DRAP's requirement. Therefore, the proposed premises is suitable for the construction of the pharmaceutical unit.

Decision of the Central Licensing Board in 292nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to the firm M/s Premier Life Pharmaceutical ((Pvt) Ltd, Plot No. 181/1, Road L.9, Industrial Estate Gadoon Amazai, Swabi before the forth-coming meeting of CLB.

A letter of personal hearing was served on 20th November, 2023 to the said firm for 293rd meeting of Central Licensing Board schedule to be held on 20-11- 2023.

Decision of the Central Licensing Board in 293rd meeting:

Syed Sultan Director of the firm along with Aziz Ahmad, appeared before the Board and contended that the chip board is situated 100 meters away from the proposed site and also played video of the proposed site and chip factory. They requested for re-verification. The Board after discussion in detail decided that the proposed site will be inspected by three-member panel constituted by Chairman of the Board.

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.

CASE NO.5 . SITE VERIFICATION OF M/S OSUM PHARMACEUTICALS, RAWALPINDI

(Evaluator: - Umme Laila (DD-Lic)

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, FID 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 (QA/LT), 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 is 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. **Recommendations** : 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.

Case No. 6 **REQUEST FOR APPROVAL OF EXTERNAL LIQUID SOLUTION PREPARATION SECTION FOR POVIDONE IODINE ONLY OF M/S MISAQ PHARMACEUTICALS (PVT) LTD, 7-B, WOVEN GARMENTS ZONE, VALUE ADDITION CITY, 1.5-KM, KHURRIANWALA-SAHIANWALA ROAD, FAISALABAD (DRUG MANUFACTURING LICENSE NO. 000985-FORMULATION).**

(Evaluator: Ms Ume Laila)

M/S Misaq Pharmaceuticals (Pvt) Ltd, 7-B, Woven Garments Zone, Value Addition City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad has requested for change in name of the following approved section: -

S.No	Name of Licensed Section	S.No.	Proposed Section Name
1.	External Liquid Solution Preparation Section	1.	Povidone Iodine Only

It is submitted for information that the Board its 292nd meeting held on 4th October, 2023 the grant of Drug Manufacturing License by way of Formulation in the name of M/s Misaq Pharmaceutical (Pvt) Ltd, Plot No. 7-B, Value Addition City, Khurrianwala, Sahianwala (FIEDMC), Faisalabad on the recommendations of the panel of experts for the following section along with other section;

1. External Liquids Section (Except povidone iodine)

Decision of the Central Licensing Board in 293rd meeting:

The Board after discussion and fact on record and request of the firm approved change in the title of the section as under;

1. External Liquids Section (povidone iodine only)

Case No. 7 **GRANT OF ADDITIONAL / REVISED SECTION OF M/S WINBRAINS RESEARCH LABORATORIES, HATTAR.**

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members

1.	M/s Winbrains Research Laboratories, Hattar. DML No. 000725 (Formulation). **Section (01):** **i.** Liquid Injectable Section with Lyophilized Facility.	**26-04-2023**	**Good**	i. Mr. Faisal Shahzad, Additional Director / Area Federal Inspector of Drugs, DRAP, Peshawar. ii. Mr. Muneeb Ahmed Cheema, Deputy Director, (Registration), DRAP, Islamabad. iii. Mr. Adnan Ali Shah, Assistant Director, DRAP, Peshawar.

Recommendations:

Based on documentation reviewed, technical / management people met, materials / processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab and allied facilities, the panel unanimously recommends revised **Liquid Injectable Section with Lyophilized Facility** as per DRAP Islamabad letter No.F.3-7/2007-Lic (Vol-I) dated 12-01-2023. The panel also recommends that firm shall install automatic filling and stoppering machine for better process controls and shall submit process validation data for products to be manufactured with registration applications at the time of consideration of registration by the Registration Board.

Decision of the Central Licensing Board in 290th meeting

The Board considered and deferred the grant of additional section for recommendation of the committee regarding use of semi-automatic filling machine (details in M/s Welwink Pharmaceutical case).

Decision of the Central Licensing Board in 293rd meeting:

The Board considered and deferred the grant of additional section for recommendation of the committee regarding use of semi-automatic filling machine (details in M/s Welwink Pharmaceutical case).

Case No. 8 **CHANGE OF MANAGEMENT OF M/S NEOMEDIX, PLOT NO. 5, N/5, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD. UNDER DRUG MANUFACTURING LICENSE NO. 000539 BY WAY OF (FORMULATION).**

M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, DML No.000557 by way of formulation has submitted request for change in management of the firm as per partnership deed with prescribed fee. The detail of management of the firm is as under: -

Previous Management as per record	New Management as per partnership deed
i. Mr. Muhammad Saleem Qureshi S/o S. Muhammad Iqbal CNIC No. 37405-0513987-3. ii. Muhammad Usman Qureshi S/o Mr. Muhammad Saleem Qureshi CNIC No. 37405-0505114-3.	i. Mian Tariq Mahmood S/o Mian Muhammad Karim, CNIC No. 37405-0216880-7 ii. Mr. Muhammad Arslan Butt S/o Muhammad Adeeb Butt, CNIC No. 37405-7756573-5 iii. Mr. Bilal Butt S/o Muhammad Adeeb Butt, CNIC No. 37405-4463095-1

	iv. Mrs. Robina Khalid W/o Mian Khalid Mahmood, CNIC No. 42201-9792203-6

Decision of the Central Licensing Board in 293rd meeting

The Board considered and deferred the case for provision of following documents:
1. Form-H issued by registrar of firm
2. NOC from previous management

Case No. 9 **CHANGE OF MANAGEMENT OF M/S NOVAMED PHARMACEUTICAL (PVT) LTD, 28-KM, FEROZEPUR ROAD, LAHORE.DML NO. 000590 (FORMULATION). UNDER DRUG MANUFACTURING LICENSE NO. 000539 BY WAY OF (FORMULATION).**

(Evaluator: Ms Ume Laila)

M/s Novamed Pharmaceutical (Pvt) Ltd, 28-Km, Ferozepur road, Lahore. DML No. 000590 (formulation has submitted request for change in management of the firm as per SECP Form-29 with prescribed fee. The detail of management of the firm is as under: -

Previous Management	New Management as per Form-29
1. Mr. Muhammad Idrees S/o Muhammad Siddique CNIC No. 35201-9897239-7. 2. Mr. Sohaib Shafiq S/o Shafiq Ahmed Abbasi CNIC No. 35202-7332022-1. 3. Mr. Akmal Zia S/o Iqbal Ahmed, CNIC No. 35202-3051744-9	1. Mr. Muhammad Idrees S/o Muhammad Siddique CNIC No. 35201-9897239-7. 2. Mr. Sohaib Shafiq S/o Shafiq Ahmed Abbasi CNIC No. 35202-7332022-1. 3. Mr. Tahir Iqbal S/o Iqbal Ahmed, CNIC No. 42301-0717658-7

Decision of the Central Licensing Board in 293rd meeting

The Board considered and accepted for record the change of management of M/s Novamed Pharmaceutical (Pvt) Ltd, 28-Km, Ferozepur road, Lahore. DML No. 000590 (formulation) as under;

Previous Management	New Management as per Form-29
4. Mr. Muhammad Idrees S/o Muhammad Siddique CNIC No. 35201-9897239-7. 5. Mr. Sohaib Shafiq S/o Shafiq Ahmed Abbasi CNIC No. 35202-7332022-1. 6. Mr. Akmal Zia S/o Iqbal Ahmed, CNIC No. 35202-3051744-9	4. Mr. Muhammad Idrees S/o Muhammad Siddique CNIC No. 35201-9897239-7. 5. Mr. Sohaib Shafiq S/o Shafiq Ahmed Abbasi CNIC No. 35202-7332022-1. 6. Mr. Tahir Iqbal S/o Iqbal Ahmed, CNIC No. 42301-0717658-7

Case No. 10: **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 Welcome Pakistan Trading Pharma (Pvt) Ltd, Chakri Interchange, Gangawala, Rawalpindi. Ms. Ume Laila DD Lic	**16-11-2023**	**Good**	1. Dr. Ghazanfar Ali Khan, Additional Director (QA&LT), DRAP, Islamabad. 2. Mr. Akbar Ali, Deputy Director (QA/LT), DRAP, Islamabad. 3. Mrs. Ume Laila, Deputy Director (Licensing), DRAP, Islamabad.
	Production Incharge:	Mr. Tahir Iqbal Mughal S/o Mr. Muhammad Iqbal Mughal (B-Pharm) CNIC No. 37201-5535959-7.		
	Quality Control Incharge:	Mr. Muhammad Hanif S/o Mirza Khan (M.Sc Chemistry) CNIC No. 13302-1039291-3.		

SUMMARY AND CONCLUSION:

In view of the inspection conducted, reviewing the documents, interview of technical team and intent of the management, the panel unanimously recommends the Grant of Drug Manufacturing License by of formulation to M/s Welcome Pakistan Trading Pharma (Pvt) Ltd, Chakri Interchange, Gangawala for following two sections: -

1. Dry Powder Suspension (General) Section.
2. Capsule (General) Section.

Decision of the Central Licensing Board in 292nd meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Welcome Pakistan Trading Pharma (Pvt) Ltd, Chakri Interchange, Gangawala on the recommendations of the panel of experts for the following section: -

1. Dry Powder Suspension (General) Section.
2. Capsule (General) Section.

Case No. 11 **GRANT OF ADDITIONAL / REVISED SECTION OF M/S HERBION PAKISTAN (Pvt.) LTD., INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

S #	Name of the firm	Date of Inspection	Ranking / Evaluation	Inspection Panel Members
1.	M/s Herbion Pakistan (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000795 (Formulation).	**12-10-2023**	**Good**	i. Dr. Ghazanfar Ali Khan, Additional Director (Field Office) DRAP, Islamabad. ii. Mr. Muhammad Arif Ch, Additional Director, (CD), DRAP, Islamabad. iii. Ms. Saadia Mahwish, FID-I, DRAP, Peshawar.

Recommendations:

Keeping in view the above facts on record and the people met / interviewed, documents reviewed during the visit, the panel unanimously **recommended the approval** for the change in name / withdrawal of the following sections of **M/s Herbion Pakistan (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad**:

1. Withdrawal of Bulk Warehouse.
2. Syrup Section General into Oral Liquid General Section.
3. Sachet Section (General) into Sachet (Powder / Granules) General Section.
4. Creams & Ointments Section (General) into Cream / Ointment / Gel Section General.

Decision of the Central Licensing Board in 292nd meeting:

The Board considered the facts and approved the change of title of following sections of the M/s Herbion Pakistan (Pvt.) on the recommendations of the panel of experts: -

1. Syrup Section General to Oral Liquid General Section.
2. Sachet Section (General) to Sachet (Powder / Granules) General Section.
3. Creams & Ointments Section (General) to Cream / Ointment / Gel Section General.

The Board deferred the request of the firm for withdrawal of Bulk Warehouse for clarification.

Item-V: **MISCELLANEOUS**

Case No. 10 CHANGE OF MANAGEMENT M/S STAR LABORATORIES (PVT) LTD, 23-KM, MULATAN ROAD, LAHORE.

The firm, M/s Star Laboratories (Pvt) Ltd, 23-KM, Multan Road, Lahore, wherein the firm has submitted application for change of management with relevant fee of Rs.75,000/. The detail of management is as under;

Previous Management as per Form-IA	Current Management as per Form-29
1. Ch. Rehmat Ullah S/o Muhammad Bashir CNIC No. 35202-3035965-92. 2. Mr. Muhammad Asrar H. Malik S/o Iqbal Malik CNIC No.35202-2257887-3. 3. Mr. Muhammad Ashar H. Malik S/o Iqbal H Malik CNIC No. 35202-2766524-7.	1. Mr. Muhammad Asrar Hussain Malik S/o Iqbal Malik CNIC No.35202-2257887-3. 2. Mr. Muhammad Ashar Hussain Malik S/o Iqbal H Malik CNIC No. 35202-2766524-7. 3. Mr. Iqbal Hussain Malik S/o Jaml Din CNIC No. 35202- 8890175-3.

Decision of the Central Licensing Board in 293rd meeting

The Board considered and deferred the change of management of M/s Star Laboratories (Pvt.) Ltd, 23-KM, Multan Road, Lahore as firm has not provided detail of director / ceasing of officer in form 29 as per decision of CLB in meeting 288th.

QUALITY ASSURANCE CASES (GMP NON-COMPLIANCE)		
S. No.	**Case Subject**	
	Item No. I Personal Hearing	
I.	M/s Wahabsons Pharma, Swat.	
II.	M/s Novae Pharmaceutical, Haripur Hazara	
III.	M/s Swat Pharmaceuticals, Swat.	
IV.	M/s Rotex Pharma (Pvt) Ltd.	
V.	M/s Al-Rasheed Medical and Surgical Wooden Cabin No.6-A, Karachi.	
VI.	M/s Yaseen, Anjam Colony, Baldia Town, Karachi	
QUALITY CONTROL CASES (PRODUCT RELATED ISSUES)		
S. No	**Case Subject**	
I.	Manufacture and sale of unregistered Nrufen suspension by M/s. Perfect Pharma (Pvt.) Ltd., Lahore.	

QUALITY ASSURANCE CASES (GMP NON-COMPLIANCE)

Case No. I **M/S WAHABSONS PHARMA (PVT) LTD, SWAT**

Mr. Zia Ullah, FID, Peshawar on 25.10.2018 conducted inspection of the firm M/s. Wahabsons Pharma (Pvt) Ltd, Plot No.402, 4 Km, Bunir Road, Bairkot Swat.

2. The FID noticed number of critical observations reproduced hereunder: -

i. To shift the washbasins from the change rooms and install at some appropriate place outside the change rooms.
ii. To replace the existing old almirahs and racks with new almirahs and racks (Aluminum or S.S) as the currently available are too old, having rough surface and difficult to be kept clean appropriately.
iii. To provide suitable partitions in the male change room so that privacy can be observed during uniform change.
iv. To provide hand sanitizers in both the change rooms and to replace immediately the non-functional insecticutor in the female change room.
v. To clean the change rooms on regular basis and keep record thereof;
vi. To replace the dust collecting exhaust hood with a proper laminar flow dispensing booth with HEPA filters for the dispensing operation.
vii. To provide an S.S sampling rod for drawing samples of the raw and in-process bulk materials for test and analysis purpose.
viii. To develop a separate receiving bay area with rack and de-dusting facilities as no separate receiving bay area is available.
ix. To install false/dropped ceiling in the area for better lighting, temperature and humidity control.
x. To replace air curtain at the receiving bay entrance.
xi. To arrange an S.S cabinet/shelf for placement of various dispensing tools.
xii. The firm is advised to arrange one more stability chamber.
xiii. The firm is advised to purchase latest editions of Official books and upgrade their testing methods / SOPs accordingly.
xiv. The firm is further advised to strengthen their quality control lab by providing TLC and Karl Fischer Apparatus.

xv. To develop an independent quality assurance department and appoint an experienced quality assurance manager.

xvi. To improve the water treatment system, by installing double RO system along with the currently installed de-ionizer system.

3. In the report the FID had also informed regarding the Dry Powder Suspension Section (Cephalosporin) that at the time no operation was underway at the time of inspection. The firm has got registration of 05 Cephalosporin products in 2004 in the Dry Powder Cephalosporin Section; although the firm has provided dedicated HVAC unit to the section, other dedicated facilities like separate change rooms, storage areas, dispensing area, blistering, packing areas etc. are not available.

4. The FID further informed that the Dry Powder Cephalosporin Section had not been recommended by the panel constituted for the renewal of DML in 2015 and observed that *"existing layout plan of Cephalosporin is not up to the mark as per cGMP requirements. The panel is of the opinion that Cephalosporin section (Dry Syrup) may be modified / upgraded".* He further informed that the CLB in its 245th meeting held on 30th December, 2015 has also deferred the renewal of the Dry Powder Cephalosporin Section and directed the firm to address the observations of panel and rectify the same and inform CLB accordingly. It was informed by the management of the firm, that they intend to withdraw / surrender the Dry Powder Cephalosporin Section and products registered therein and will approve it as General Dry Powder Section after making necessary changes in the layout plan and approval from the Licensing Division of the same.

5. Therefore the FID had directed the firm to immediately suspend the production activities in this section and expedite the layout plan revision / submission process. He has also instructed the firm to intimate the Area FID about the withdrawal of the Dry Suspension Cephalosporin Section and the products registered therein. The FID has concluded that ***"All the above points were discussed with firm's management and they agreed to comply them at the earliest under intimation to the area FID".***

ACTION TAKEN BY DRAP

6. The firm M/s Wahabsons Pharma (Pvt) Ltd, Swat was served Show Cause Notice and suspension of production orders in Dry Powder for Suspension Section (Cephalosporin) on 13.12.2018.

7. The Case was placed before the 267th meeting of CLB. Wherein the Board decided as under: -

DECISION OF THE 267TH MEETING OF CLB

8. After thorough discussion/deliberations, the Central Licensing Board decided to suspend the Drug Manufacturing License of the firm M/s. Wahabsons Pharma (Pvt) Ltd, Swat under section 41 of the Drug Act, 1976 read with Rule 12 of the Drugs (LRA) Rules, 1976 till rectification of the observations noted by the FID in its report dated 25.10.2018.

9. The firm M/s. Wahabsons Pharma (Pvt) Ltd, Swat vide letter dated 25.10.2018 submitted compliance report and requested for verification of the observations. Compliance report is reproduced as under: -

RESPONSE FROM THE FIRM

10. The firm vide letter dated 22.10.2020 submitted compliance report and requested for verifications of GMP compliance and rectification status.

11. The vide letter no Nil, dated Nil, received in this office on 24.01.2022 submitted compliance report bearing subject "Rectification by Wahabsons Pharma (Pvt) Ltd, as mentioned in inspection by FID dated 24.05.2021 have been made. However, the said report is not available in this office record.

DECISION OF THE 279TH MEETING OF CLB

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

i. *Inspect the premises for verification of improvements made by the firm M/s Wahabsons Pharma (Pvt) Ltd, Swat by following panel of experts: -*
    a) *Prof. Dr. Jamsahid Ali Khan, Member CLB.*
    b) *Federal Inspector of Drugs, Peshawar.*
    c) *Mr. Adnan Shahid Ullah, AD, DRAP, Peshawar.*

ii. *Production of the firm shall remain suspended in Dry Powder for Suspension Section (Cephalosporin) till recommendations by panel and subsequent approval by the CLB.*

iii. *The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 25.10.2018, with clear and candid recommendations.*

ACTION TAKEN BY DRAP; INSPECTION DATED 04.09.2023

13. The Area FID-I, Peshawar along with FID-II inspected the firm and found it involved in manufacturing of Winocef 100mg/5ml Reg No. 032409 (suspected to be cancelled; reference already sent to the Division of PE&R),

pack size 30 ml batch No.817 mfg date 09/23 expiry date 08/25 quantity found was 10800. The panel has referred the to the CLB for legal action under DRAP Act, 2012.

RECOMMENDATIONS OF QA&LT

14. In view of the scenario detailed above and the fact that the instant inspection was conducted to verify the compliance of the decision of the CLB from tis 279th meeting; the QA&LT Division recommends that, under rule **12 of the Drugs (Licensing Registering and Advertising) Rules 1976; the proceeding for Cancellation or Suspension of Licenses may be initiated under 12 (1)** *If licensee does not comply with any of the conditions of a license or violates any of the provisions of the Ordinance or the rules, …, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a license or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to which it relates*. **Through formal procedure under rule 12 (2)** *The Central Licensing Board shall, before cancelling or suspending a license under sub-rule (1), provide an opportunity of being heard to the licensee. Accordingly, the firm was informed to nominate a representative to appear in person before the Central Licensing Board on 20.11.2023. The case was placed before the Board in light of the recommendation of QA&LT for Cancellation of Drug Manufacturing License after giving personal hearing to the firm.*

PROCEEDINGS OF 293rd MEETING OF CLB: -

Representatives of the Division of QA&LT briefed the case before the CLB, the firm's representative was given a personal hearing; Mr. Arshad Riaz CEO, M/s Wahabsons Pharmaceuticals, Swat and Mr. Zeeshan Ahmed Regulatory Affairs M/s Wahabsons Pharmaceuticals, Swat appeared before the Central Licensing Board and admitted that the above stated offences have been committed by the firm due to "*business pressure"*. The instant matter was deliberated in detail by all the members of the board.

DECISION OF 293rd MEETING OF CLB: -

Following a comprehensive examination of the pertinent facts, the Board issued its considered decision. It has been determined that M/s Wahabsons Pharmaceuticals, Swat, has been involved in the illegal manufacturing of drugs, in addition to non-compliance of GMP which is violation of:

i. Section A(1)(a)(vii), A(1)(a)(x), and Section A(1)(b) of Schedule II of the DRAP Act 2012, with associated charges subject to prosecution under Section 1(a) and 1(b) of Schedule III of the DRAP Act 2012.

ii. Rule 20 of the Drugs (Licensing, Registering & Advertising) Rules 1976, proscribed under Section 23 of the Drugs Act, 1976, in conjunction with Schedule II of the DRAP Act, 2012. This violation carries penalties under Section 27 of the Drugs Act, 1976, read in conjunction with Schedule III of the DRAP Act 2012.

In accordance with the provisions set forth in Rule 12(1) and 12(2) of the Drugs (Licensing Registering and Advertising) Rules 1976, the Board decided to cancel the Drug Manufacturing License No. 000533 (Formulation), issued to M/s Wahabsons Pharmaceuticals (Pvt) Ltd., Swat, with immediate effect and also allowed the process for prosecution of case in Court of Law.

Moreover, the Board directed the Area FID to conduct a meticulous investigation into the matter of illegal manufacturing of unregistered drugs in unapproved manufacturing section with the objective to ascertain responsibility among the implicated parties and submit a report for consideration of the Board.

Case No. II **M/S NOVAE PHARMACEUTICALS, HARIPUR HAZARA**

Mr. Faisal Shahzad Area FID, DRAP Peshawar has informed that M/s Novae Pharmaceuticals was visited on 27.06.2023 for verification of availability of Technical Staff as per SRO 1460(I)/2019.

2. The FID has further reported that Plant Manager Mr. Naseeb Khan, PM. Mr. Waqar Shaah and QCM. Mr. Aijaz Shah were available. The QA In-Charge has not been hired and information regarding the Microbiologist was not available in the report.

3. The FID has informed the firm has not even submitted CAPA report against inspection dated 08.10.2021 and the renewal inspection is also due since 13.02.2018. The FID has directed that firm should submit CAPA and intimate the panel for inspection within 15 days.

4. However, even after the lapse of almost two months the firm has not submitted the desired information to this office.

ACTION TAKEN BY DRAP

5. The firm M/s Novae Pharmaceuticals, Haripur Hazara was served Show Cause Notice on 01.09.2023 and subsequent reminder dated 13.11.2023. The FID also issued letter intimating the firm about the Show Cause Notice dated 08.11.2023

RESPONSE FROM THE FIRM

6. The firm has not submitted any response to this office letters dated vide letter dated 01.09.2023 and 13.11.2023. The FID also issued letter intimating the firm about the Show Cause Notice dated 08.11.2023, which has also not been responded.

RECOMMENDATIONS OF QA&LT

7. In view of the scenario detailed above and suggesting the lack of seriousness of the firm towards compliance of directions; the QA&LT Division recommends that, under rule **12 of the Drugs (Licensing Registering and Advertising) Rules 1976; the proceeding for Cancellation or Suspension of Licenses may be initiated under 12 (1)** *If licensee does not comply with any of the conditions of a license or violates any of the provisions of the Ordinance or the rules, …, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a license or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to which it relates*. **Through formal procedure under rule 12 (2)** *The Central Licensing Board shall, before cancelling or*

suspending a license under sub-rule (1), provide an opportunity of being heard to the licensee. Accordingly, the firm was informed to nominate a representative to appear in person before the Central Licensing Board on 20.11.2023. The case is placed before the Board in light of the recommendation of QA&LT for Cancellation of Drug Manufacturing License after giving personal hearing to the firm.

PROCEEDINGS OF 293rd MEETING OF CLB: -

Representative of the Division of QA&LT briefed the case before the CLB, the firm's representative was given a personal hearing; Mr. Amer Tahir Raja, Manager Regulatory Affairs M/s Novae Pharmaceuticals, Haripur Hattar appeared before the Central Licensing Board and claimed that the said CAPA had already been submitted, he also gave a copy of the said document. The representative of QA&LT evaluated the document, pointed out that this CAPA was for Clarinave Dry Suspension, submitted to Chairman Registration Board on 15.11.2021 on a separate unrelated matter and not the GMP related Explanation Letter issued vide QA letter No. F.4-114/2014-QA dated 29.11.2021. The instant matter was deliberated in detail by all the members of the board.

DECISION OF 293rd MEETING OF CLB: -

After considering the inspection report, hearing the version of firm's representative and extensive deliberation on the matter, the Board determined that the firm was not operating at an acceptable level of GMP at time of inspection, which is violation of Rule 20 of the Drugs (Licensing, Registering & Advertising) Rules 1976.

Furthermore, subsequent to a comprehensive evaluation of the renewal application for the Drug Manufacturing License (DML), the Board had determined that the firm has not submitted a complete application for renewal of its DML and failed to submit an appropriate response addressing the communicated shortcomings by the Licensing Division till date.

Consequently, the Board decided to Cancel the Drug Manufacturing License No. 000771 (Formulation) issued to M/s Novae Pharmaceuticals, with immediate effect, under Rule 12(1) and 12(2) of the Drugs (Licensing Registering and Advertising) Rules 1976.

Case No. III **M/S SWAT PHARMACEUTICALS, SAIDU SHARIF, SWAT**

Mr. Faisal Shahzad Area FID, DRAP Peshawar has informed that M/s Swat Pharmaceuticals was visited on 14.07.2023 Wherein the FID has informed that the firm has not done satisfactory Corrective actions/ rectifications in compliance to the inspection date 30.06.2021; subsequent correspondence from this office in the form of **Explanation letter** issued on 29.09.2021 and subsequent letter dated 29.10.2021 stating that the **CAPA submitted by the firm was not satisfactory**.

2. The FID had informed further that nothing substantial has improved in the facility. The firm doesn't even have some QA personnel set aside a functional section/department of QA. The FID has added that this indicates lack of will for improvement at the firm's end; and stated that the firm is not operating at an acceptable level of GMP compliance. The FID has directed the firm to immediately stop production till verification of GMP compliance by competent authority and issuance of resumption of production order by DRAP.

3. The FID has informed further that during the inspection a small locked store was noticed, upon inquiry it was informed that this was a rejected material store; however, on inspection of the store it was revealed that a number of Pharmaceutical APIs were stored in the said premises without record and improper storage conditions, hence the materials were ordered not to dispose of on the prescribed form-1 and product Panacetol was seized for further investigation. The FID has ordered not to dispose of the following

S.No	Name of Drugs	Quantity
1.	Cefixime (Compaced) API	04 Kgs
2.	Cefixime (Micro) API	157 Kgs
3.	Cephradine (Compacted) API	8.5 Kgs
4.	Cephradine (Micro) API	3.5 Kgs
5.	Ciprofloxacin API	135 Kgs
6.	Ceftriaxone API	70 Kgs
7.	Arthemether API	43 Kgs
8.	Azithromycin API	28 Kgs
9.	Albendazole API	219 Kgs
10.	Diphenhydramin API	471 kgs

11.	Diclofenac Na API	20 Kgs
12.	Vit D3 API	01 Kgs
13.	Vit A API	20 Kgs
14.	Escitalopram API	36 Kgs
15.	Ibuprofen API	1000 Kgs
16.	L-Mycine API	99.6 Kgs
17.	Levocetirizine API	06 Kgs
18.	Lansoprazole API	110 Kgs
19.	Tramadol API	04 Kgs
20.	Montelukast API	8 Kgs
21.	Tizanidine API	2.7 Kgs
22.	Meloxicam API	122 Kgs
23.	Sitagliptin API	22 Kgs
24.	Pregabalin API	133 Kgs
25.	Piroxicam API	54.9 Kgs
26.	Trical Phosphate API	200 Kgs
27.	Mango Flavour, Easy coat, Ethanol (Excipients)	2.5 Ltr,+ 13 Kgs + 20 Ltr

4. The FID has informed further that "*on ground of having same registration number despite different packing without justification*". Below mentioned stock was seized under Schedule-V (1) (f) of DRAP Act, 2012 read with section 18 (1) (f) of the Drugs Act, 1976. Details are as under

Sr. No.	**Name Drugs/Reg. No.**	**Batch No.**	**Mfg. date**	**Exp. date**	**Manufactured by**	**Quantity**

01.	Panasetol Tablet (Blisters) Registration No.073328	(091) License No.000035	12-2022	11-2024	M/s Swat Pharmaceuticals, Valley Road, Sherarai Gulkada No.3 Saidu Sharif Swat.	01 x 200 Tablets
02.	Panasetol Tablet (Blisters) Registration No.073328	113	05-2023	04-2025	M/s Swat Pharmaceuticals, Valley Road, Sherarai Gulkada No.3 Saidu Sharif Swat.	01 x 200 Tablets
03.	Panasetol Tablet (Blisters) Registration No.073328	074	09-2022	08-2024	M/s Swat Pharmaceuticals, Valley Road, Sherarai Gulkada No.3 Saidu Sharif Swat.	01 x 200 Tablets

ACTION TAKEN BY DRAP

5. The firm M/s Swat Pharmaceuticals, Saidu Sharif was served Show Cause Notice on 17.08.2023.

RESPONSE FROM THE FIRM

6. The firm has submitted any response to this office letters dated17.08.2023 vide letter dated 24.08.2023.

EVALUATION OF QA&LT

7. The firm has submitted response, which upon evaluation is found to be rudimentary since no root cause analysis has been performed. Furthermore, the corrective action and preventive actions are clubbed together without any risk management; the references are also missing for change management; though evidences are provided however, these are not referenced hence difficult to navigate. In conclusion, the CAPA is not satisfactory.

RECOMMENDATIONS OF QA&LT

8. In view of the scenario detailed above and suggesting the lack of seriousness of the firm towards compliance of directions; the QA&LT Division recommends that, under rule **12 of the Drugs (Licensing Registering and Advertising) Rules 1976; the proceeding for Cancellation or Suspension of Licenses may be initiated under 12 (1)** *If licensee does not comply with any of the conditions of a license or violates any of the provisions of the Ordinance or the rules, …, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a license or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to which it relates*. **Through formal procedure under rule 12 (2)** *The Central Licensing Board shall, before cancelling or suspending a license under sub-rule (1), provide an opportunity of being heard to the licensee. Accordingly, the firm was informed to nominate a representative to appear in person before the Central Licensing Board on 20.11.2023*

PROCEEDINGS OF 293rd MEETING OF CLB: -

Representative of the Division of QA&LT briefed the case before the CLB, the firm's representative was given a personal hearing; Mr. Murad Khan, Manager Regulatory Affairs M/s Swat Pharmaceuticals, Sherarai Gulkada, Saidu Sharif Swat appeared before the Central Licensing Board and stated that the raw materials were expired and had been placed in a make shift rejection store. The instant matter was deliberated in detail by all the members of the board.

DECISION OF 293rd MEETING OF CLB: -

After considering the inspection report, hearing the version of firm's representative and extensive deliberation on the matter, the Board determined that the firm was not operating at an acceptable level of GMP and GSP with reference to manufacturing, QC and purchase and storage of starting materials which is violation of Rule 20 of the Drugs (Licensing, Registering & Advertising) Rules 1976.

Consequently, the Board decided to cancel the Drug Manufacturing License (DML) bearing No, 000035 (Formulation) issued to M/s Swat Pharmaceuticals, Sherarai Gulkada, Saidu Sharif, with immediate effect, under Rule 12(1) and 12(2) of the Drugs (Licensing Registering and Advertising) Rules 1976 and allowed the process for prosecution of case in Court of Law.

Case No. IV: SHOW CAUSE NOTICE / PERSONAL HEARING OF M/S ROTEX PHARMA, PLOT # 206, 207, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD.

BACKGROUND OF THE MATTER

1. The background of the matter is that M/s Rotex Pharma Pvt. Ltd. ('**Rotex Pharma**') has been issued Drug Manufacturing License under Section 5 of the Drugs Act, 1976, read with the Rule 3 of the Drugs (Licensing, Registration and Advertising) Rules, 1976 ('**Rules, 1976**'). Rotex Pharma is a high risk manufacturing facility which has a chequered history of manufacturing without complying with the 'Good Manufacturing Practices' ('**GMP**') *[as defined under Rule 2 (t) of the Rules, 1976]*. A panel of inspectors including the area Federal Inspector of Drug inspected the Rotex Pharma on 01-02-2023 to investigate a complaint received from a consumer related to safety and quality of Rotex Pharma's anticancer product Tab Capex 500mg (Capecitabine). The Panel's Report noted very serious violations of GMP in the manufacturing process of Rotex Pharma. The Panel also recommended creation of a Panel of Experts to undertake a more thorough inspection of the manufacturing facility to ensure compliance with GMP and to avoid any risk to human health. Relevant excerpts are reproduced as under:

"…Based on the areas inspected, people met, the documents reviewed and considering the lack of Dedication of Oncology Section, containment studies, risk assessment based on OEL, appropriate cleaning validation, failure of regulatory compliance in terms of validations, absence of PQS, Quality by design concept and data integrity, absence of an effectively designed & maintained air filtration system as well as non-adherence to guidelines for HVAC mentioned earlier in point no. vii, it is evident that the firm is not only liable to manufacture products with observed quality defects, but also the practices of the firm or lack thereof may cause a serious health hazard to the personnel, product quality as well as the environment. Due to lack of dedication in layout as well as failure of instituting appropriate checks in critical processes/practices, there is also a serious risk of cross-contamination not only within the oncology section but also of Oncology medicine with General Medicines/products & Cephalosporins etc.

[…] It would also be pertinent to note that this inspection was limited to the investigation of subject complaint, it is therefore crucial that a full scale & exhaustive GMP audit of the firm should be carried out by a larger panel to ascertain whether the identified deficiencies exist in the rest of the manufacturing facility as well since the firm is involved in manufacturing of several critical products". *(emphasis has been added)*

2. Previously the inspection of Rotex Pharma was conducted on 11th and 12th of August, 2020 by a Panel of Inspectors, which also noted stark violations of GMP in its manufacturing facility. It was in this context that the Director Quality Assurance and Laboratory Testing constituted the Panel of Experts for inspection of Rotex Pharma in order to ensure its compliance with statutorily imposed GMP, based on the Report of which the instant Show Cause was issued. The 'Central Licensing Board' ('**CLB**') *[created under Section 3 (e) read with Section 5 of the Drugs Act, 1976]* has powers under Rule 8 (17)

of the Rules, 1976 to "appoint a panel of experts" to inspect manufacturing units and submit a report to it. CLB has in its 273rd Meeting held on 15-01-2020 by exercising its powers under Rule 8 (10) of the Rules, 1976, delegated, inter alia, its powers to constitute panel for inspection of GMP, issuance of Show Cause to the 'Director Quality Assurance and Laboratory Testing'. The said Director is also a member of the CLB under Rule 8 (1) (b) of the Rules, 1976.

3. Through letter dated 06-02-2023 Rotex Pharma was informed of Panel of Experts who were to undertake GMP Inspection of its manufacturing facility. The inspection was duly planned and informed to the company vide office letter dated 09-02-2023. The same was communicated to Ms. Muavra Bukht, the Director Operations of Rotex Pharma via electronic communication by a member of the Panel. Subsequently, frequent exchange of information between the Director Operations of Rotex Pharma and the Panel took place. The Inspection continued from 20-02-2023 to 22-02-2023.

4. The Inspection Report was finalized by the Panel and forwarded to the Director Quality Assurance and Laboratory Testing through letter dated 03-03-2023. Several shortcomings and GMP non-compliances were noted during the course of inspection from which it was clearly evident that the various quality systems were either non-existent or not in a state of control; the Report very thoroughly highlighted parts of Schedule B which were violated by Rotex Pharma. The Inspection Report, *inter alia*, concluded the following:

> "Based on the findings of the inspection, review of documents and records, systems, utilities, physical inspection of areas in the manufacturing facility mentioned above, and interview of personnel, it is concluded that the firm is not operating at an acceptable level of cGMP compliance. 21 Critical, 14 major and 03 other deficiencies were observed related to the product quality, risk of contamination and cross contamination, data integrity, qualification of processes personnel, equipment, and overall facility."

5. The Inspection Report after being prepared in time was then discussed with a team of experts called "Inspection Evaluation Committee", the meeting of which was held on 29th and 30th of March, 2023: the report was thoroughly and critically discussed, analyzed and scrutinized. The Minutes of the Meeting were forwarded to the Director Quality Assurance and Laboratory Testing through letter dated 20-04-2023. This second layer of analysis precluded any arbitrariness from the Inspection Report.

6. This Inspection Report was first challenged by Rotex Pharma before the learned Civil Court, Islamabad in a Suit titled "Rotex Pharma *Vs.* DRAP". The case is still pending, but no interim injunction restraining proceedings of the CLB has been granted. Subsequently, Show Cause Notice dated 28-04-

2023 was issued to Rotex Pharma, which was challenged by it along with the Inspection Report before the Honorable Islamabad High Court, Islamabad in Writ Petition No. 1766 of 2023. The Honorable Court through Order dated 28-05-2023 while granting interim relief was pleased to direct Rotex Pharma to file reply to the Show Cause Notice in the following words:

"**C. M. No. 01/2023 Notice.**

Meanwhile, to the extent that an order has been passed to suspend production, such order will stay suspended till the next date of hearing. The respondents may continue with show cause proceedings and the petitioner will appear and file appropriate response."

7. Rotex Pharma was issued reminder of the Show Cause Notice dated 25-05-2023 but it did not file any reply. It was called for hearing in the 291st Meeting of the CLB held on 30th of May, 2023. Rotex Pharma represented by its learned Counsel Mr. Haroon Dugal, instead of filing reply and arguing the matter sought time to appeal against the Inspection Report which was granted in the interests of justice. Relevant excerpts from the Minutes of the Meeting are reproduced as hereunder:

> "In compliance to letter dated 28th April 2023, firm's representative i.e. Mr. Haroon Dugal (Legal Advisor), Mr. Umar (CEO), Mrs. Mauvra Khawaja appeared before the Board and presented their stance, in which they submitted that they intend to challenge the inspection report. The firm requested to grant them an adjournment for enabling them to avail the statutory remedy against the inspection under the GMP Inspection Committee (Appeal) Regulations, 2017(S.R.O.1012(I)/2017
>
> **DECISION OF 291ST MEETING OF CLB: -**
>
> The Board after considering the statement of firm's representative and deliberation on the matter decided to accede the firm's request and adjourned the matter till the decision of GMP inspection committee as per S.R.O.1012(I)/2017."

8. Rotex Pharma appealed against the Inspection Report under Regulation 4 of the GMP Inspection Committee (Appeal) Regulations, 2017 hearing in which was held on 31-07-2023. The learned Counsel for Rotex Pharma Mr. Haroon Dugal again instead of arguing the matter or even arguing for interim relief, simply sought adjournment due to pendency of the instant matter before the Honorable Islamabad High Court, Islamabad. Rotex Pharma in the meantime continued production in violation of GMP.

9. The Honorable Islamabad High Court, Islamabad, through Order dated 08-11-2023 passed in W.P. No. 1766 of 2023 while setting aside directions contained in the Show Cause Notice to stop production was pleased to direct the following:

"The challenge of the petitioner claiming that the impugned show cause notice is corum non judice has not convinced the Court. The DRAP is therefore free to continue its show cause proceeding and pass an order in accordance with provisions of the Drugs Act and the Rules of 1976 after affording the petitioner an opportunity to be heard."

10. Consequent to the above reproduced directions of the Honorable Court, Second Reminder of the Show Cause Notice was issued to Rotex Pharma on 14-11-2023 with approval of the competent authority i.e. Director Quality Assurance and Laboratory Testing. Rotex Pharma was asked to file reply and was warned to definitely argue the matter before meeting of CLB to be held on 20-11-2023 with caution of a decision upon its failure, in the following words:

"7. Therefore, no adjournment on any count will be granted. In case, the matter is not argued by our form i.e. M/s Rotex Pharma, appropriate Order will be passed by the Central Licensing Board after perusal of the record."

11. The Counsel for Rotex Pharma Mr. Haroon Dugal again filed adjournment dated 17-11-2023 on the ground of pendency of other cases before the Honorable Lahore High Court, Lahore. However, on the very date on which the instant Meeting of CLB was to be held i.e. 20-11-2023, the learned Counsel for Rotex Pharma Mr. Haroon Dugal filed W.P. No. 75919 of 2023 before the Honorable Lahore High Court, Lahore on behalf of Rotex Pharma seeking interim relief with the effect of restraining the holding of the instant Meeting of CLB.

12. The Honorable Lahore High Court through Order dated 20-11-2023 dismissed the Petition while noting the malafide attempt of Rotex Pharma to abuse the process of Court to frustrate the instant Show Cause Notice, in the following words:

"[…] Learned counsel for the petitioner questioned that what coercive measures are being taken in pursuance to the Inspection Report. She submits that Show-Cause Notice dated 14.11.2023 has been issued but same is not appended with this petition.

2. Learned counsel for the respondent-DRAP entered appearance and submitted that on same subject-matter the petitioner filed Writ Petition No. 1766 of 2023 before the Islamabad High Court, which was decided on 08.11.2023 and the DRAP was allowed to continue its Show-Cause Notice proceedings, hence, reminder dated 14.11.2023 has been issued. Submits that without disclosing above facts, this petition has been filed at Lahore frustrate the Show-Cause Notice proceedings, which are already upheld by the Islamabad High Court. Submits that the petitioner has intentionally not approached the Islamabad High Court but this Court by not disclosing the correct facts including pendency of Civil Suit, where Inspection Report has been challenged.

3. Learned counsel for the petitioner, when confronted, seeks to withdraw this petition, which is **dismissed** being not pressed."

13. Reply to Show Cause was filed by Rotex Pharma dated 17-11-2023.

PROCEEDINGS OF THE CENTRAL LICENSING BOARD

14. Mr. Waheed Alam, Advocate appeared as proxy counsel for Mr. Haroon Dugal, the counsel for Rotex Pharma, and requested for adjournment. He was given chance to present and argue the case on behalf of Rotex Pharma but he chose not to. On query, he agreed that no Court or appellate authority or committee had granted interim relief restraining the proceedings by CLB. However, he contended that denial of adjournment would deprive Rotex Pharma from the right of hearing and thus would render the instant proceedings in violation of Article 10A of the Constitution of the Islamic Republic of Pakistan, 1973 (the '**Constitution**').

DISCUSSIONS

15. The first issue before CLB is as to whether the matter has to be adjourned on request by Mr. Haroon Dugal, learned Counsel for Rotex Pharma. It was noted that the learned Counsel has repeatedly sought adjournments on one count or another to delay adjudication of the matter; he had earlier been granted adjournment in the 291st Meeting of the CLB held on 30th of May, 2023 on the pretext of being given a change to appeal against the Inspection Report. In the Appellate Committee, the learned Counsel again sought adjournment.

16. Second Reminder of the Show Cause Notice issued to Rotex Pharma on 14-11-2023 gave a specific warning to definitely argue the matter before meeting of CLB to be held on 20-11-2023 with caution of a decision upon its failure, in the following words:

> "7. Therefore, no adjournment on any count will be granted. In case, the matter is not argued by our form i.e. M/s Rotex Pharma, appropriate Order will be passed by the Central Licensing Board after perusal of the record."

17. Despite being granted a clear warning, the learned Counsel filed the adjournment for instant hearing which were conducted on 20-11-2023. On the very date he filed W.P. No. 75919 of 2023 before the Honorable Lahore High Court, Lahore, in a bid to frustrate and thwart the instant proceedings by misleading the Honorable Court. The purpose of adjournment seems to be merely an attempt tp buy

time to stall the instant proceedings, therefore, this request has been filed with unclean hands and merits no indulgence.

18. The conduct of Rotex Pharma in using adjournment in order to frustrate the instant proceedings by forum shopping before the Honorable Lahore High Court, is spat with malafide and depreciable. Therefore, on this score alone, the request for adjournment is found to be tainted with malice and is turned down.

19. Even otherwise, hearing by CLB has already been adjourned once on request by Rotex Pharma and therefore, the proceedings cannot be perpetually adjourned on its whim and caprice. As the learned Counsel has willingly absented himself from the right of hearing in a bid to frustrate the instant proceedings, therefore, he has willingly chosen not to avail the opportunity of personal hearing on behalf of Rotex Pharma. In **PLD 2020 Isl. 343** the Honorable Islamabad High Court was confronted with a matter wherein a show caused person sought continuous adjournments from hearing before a departmental authority. The Honorable Court upheld the ex-parte decision by the departmental authority upon the record in the following words:

"27. As regards the contention of the learned counsel for the appellants that Messrs Labbaik had not been provided an adequate opportunity of hearing, the same is contrary to the record. Vide the show cause notice dated 03.12.2019, the licencee/Messrs Labbaik was directed through its Chief Executive Officer ("C.E.O.") to appear for a personal hearing on 10.12.2019. On the said date, the C.E.O. of Messrs Labbaik did not appear before the respondent. However, on the request of Messrs Labbaik's authorized representative, Ms. Naila Noureen, Advocate, the hearing was rescheduled for 16.12.2019, on which date, neither the C.E.O. of Messrs Labbaik, nor his principal counsel appeared before the respondent. Yet another request for an adjournment was made which was not acceded to by the respondent. The respondent or its personal hearing committee is under no obligation to adjourn or reschedule personal hearings simply because the broadcast media or distribution service operator or its principal counsel happens to be preoccupied elsewhere. Enough indulgence had been shown by the respondent to Messrs Labbaik by rescheduling/adjourning the personal hearing on 10.12.2019 to 16.12.2019. In the case of Messrs Evernew Agencies v. Customs, Central Excise and Sales Tax Appellate Tribunal, Lahore (2006 PTD 207), it had been held that a party absenting himself to appear before an Authority could not claim that he was not provided an opportunity of a hearing. Additionally, in the case of Water and Power Development Authority, Lahore v. Messrs Bhatti Ice and Rice Mills, Buchiki (2004 YLR 1263), it had been held that where the petitioner was granted several opportunities to appear and file a reply but failed to do so, he cannot be subsequently allowed to take the plea that the order was passed in violation of the principles of natural justice."

20. A Division Bench of the Honorable Lahore High Court in **2006 PTD 207** also held the same in the following words:

"The appellant who has absented himself to appear cannot claim that he was not provided 'opportunity of hearing."

21. In **2008 MLD 132** similar maxim of law has been held:

"The right of hearing is qualified with attendance, and cannot be made an excuse to perpetuate an illegality […]"

22. The Honorable Supreme Court in **2010 SCMR 1119** also affirmed the trite law in the following words:

"11. The Court cannot force the party to address the arguments. It can at best afford him an opportunity to address it. If the party does not avail of that opportunity it can decide the matter on the basis of material available before the Court."

23. As Rotex Pharma had been issued warning with caution that matter would be decided based upon the available material, therefore, as per the latest judgment of the Honorable Supreme Court in **2023 SCMR 636**, CLB has to honor the warning and decide the matter. Relevant excerpts are reproduced as under:

"Where the Court has passed an order granting the last opportunity, it has not only passed a judicial order but also made a promise to the parties to the lis that no further adjournments will be granted for any reason. The Court must enforce its order and honour its promise. There is absolutely no room or choice to do anything else."

24. Lastly, as Rotex Pharma has been manufacturing life-saving drugs and medicines in non-compliance of the statutorily required GMP, therefore, granting adjournment would expose the people to drugs with compromised safety and quality. It is trite law that pubic interest would trump limited private interests; hence, for this and the above discussed reasons, the request for adjournment by the learned Counsel for Rotex Pharma is turned down and dismissed.

25. The Board minutely reviewed the Inspection Report and Reply by Rotex Pharma dated 17-11-2023 and framed the following issues for decision:

i. As to whether the Inspection has been undertaken in accordance with the law?
ii. As to whether CLB can undertake proceedings during pendency of Rotex Pharma's appeal against the Inspection Report under Regulation 4 of the GMP Inspection Committee (Appeal) Regulations, 2017?
iii. As to whether Rotex Pharma has violated the law by manufacturing in non-compliance of GMP? If yes, then has it impacted the safety, quality and efficacy of the manufacturing process and thus endangered public health?

Seriatim findings on the above framed issues is as under:

Issue No. I: <u>As to whether the Inspection has been undertaken in accordance with the law?</u>

27. Rotex Pharma in Para. No. 3 of its Reply has contended that inspection of its manufacturing facility was undertaken on "Risk Based Benchmarking" based on alleged draft rules; that in Para. No. 4 of the Reply it has been argued that it was told that the inspection was only for academic purposes and for training of DRAP officials by the visiting WHO team and hence, the Inspection Report could not be used for any other purpose; that Para. No. 5 (iii) of the Reply emphasizes that GMP compliance inspection cannot be taken in the absence of any Federal Inspector of Drugs. Apart from these, Rotex Pharma has raised no objection regarding constitution or functioning of the Panel for Inspection.

28. It is stated as a way background that Drug Manufacturing License ('**DML**') is issued under Section 5 of the Drugs Act, 1976, read with the Rule 3 of the Rules, 1976. The DML holder has to meet the conditions as provided under Rule 16, 19 and 20 of the Rules, 1976. As a part of the aforementioned conditions, the License Holder has to **mandatorily** abide by GMP as provided under Schedule B of the Rules, 1976.

29. In order to ensure continuous compliance of GMP conditions to ensure safety, quality and efficacy of the drugs and medicines, under Rule 8 (17) of the Rules, 1976, CLB has powers to "appoint a panel of experts" to inspect manufacturing units and submit a report to it. Since the very purpose of inspection is to ensure compliance of manufacturing with the applicable laws/ conditions of license, therefore, the panel has to necessarily undertake GMP Inspection since GMP are a part of the Rules, 1976. Furthermore, as discussed in Para. No. 3 above, the Panel has been constituted strictly in accordance with the law.

30. Since compliance with GMP is a continuous process, therefore, regulator has to also adopt a dynamic process which continuously ensures compliance of pharmaceutical manufacturers with the GMP. International Council for Harmonization[1] in its Guideline titled "Quality Risk Management" mandates the process of Risk based Quality Management to ensure a science-based decision making system for adherence to GMP by pharmaceutical manufacturers for ensuring quality of the drug (medicinal) product. <u>This system provides a proactive means and system for DRAP as National Regulator to</u>

[1] The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is an international forum that brings together regulatory authorities and pharmaceutical industry to harmonize scientific and technical aspects of pharmaceutical product development. The Harmonized Guidelines issued by ICH, *inter alia*, provide cutting edge safeguards for ensuring quality, safety, efficacy, and regulatory obligations to protect public health.

perform its statutory duty of identifying and controlling potential quality issues and compliance with GMP by the pharmaceutical manufacturers. **Section 7** (c) (ix) of the DRAP Act, 2012 casts statutory duty on DRAP to 'implement' the ICH Guidelines. Therefore, the term 'Risk Based Benchmarking" has been used for which is otherwise in substance a GMP compliance inspection of Rotex Pharma's manufacturing facility in accordance with the Rules, 1976. Rotex Pharma's contention that it arises out of some draft Rules is not based on facts and is fallacious.

31. Rule 8 (17) of the Rules, 1976, uses the term "panel of experts **or** inspectors". The word 'or' is disjunctive in nature and hence, both a panel of experts or inspectors are treated differently and both can freely exercise the powers to undertake GMP Inspection. The powers of Federal Inspector of Drugs under Section 18 do not preclude any Panel of Experts from undertaking GMP compliance inspection. Even powers of Federal Inspector of Drugs under Section 18 (1) of the Drugs Act, 1976, are made subject to rules; as Rules, 1976, expressly grant power to the Panel of Experts to inspect GMP compliance of manufacturers, therefore, this contention of Rotex Pharma also has no basis in law.

32. Lastly, Rotex Pharma has claimed that it was "emphatically told that the risk-based benchmarking is only for academic purposes and for the training of DRAP officials/ inspectors by the visiting WHO team. The Company was assured several times that the aforesaid inspection would not entail any penal consequences and report, if any, would be released for academic purposes only." This is a false and frivolous accusation. The alleged person who gave such undertaking has not been named and no means or time of such purported communication has also been identified. Therefore, this ground being baseless is also dismissed.

33. The instant Issue is decided against Rotex Pharma. The Panel of Inspection was formed in accordance with the law; subsequently, the inspection and its consequent report was also reached strictly in accordance with the law.

Issue No. II: As to whether CLB can undertake proceedings during pendency of Rotex Pharma's appeal against the Inspection Report under Regulation 4 of the GMP Inspection Committee (Appeal) Regulations, 2017?

34. Rotex Pharma in Para. No. 2 of the Reply has argued in brief that its appeal against the Inspection Report under Regulation 4 of the GMP Inspection Committee (Appeal) Regulations, 2017 is currently pending. Therefore, as per the principles of fair trial and the scheme of drug laws when an Inspection Report is under challenge, then no action can be taken by CLB on the basis of the said Report.

35. The said contention is wrong in law as there is no such compulsion for CLB to restrain its proceedings during the pendency of appeal against the Inspection Report. Even otherwise, it is trite law that mere pendency of appeal does not operate as stay of proceedings as held by the Honorable Islamabad High Court, Islamabad in **2016 CLD 2293**. Relevant excerpt is reproduced as under:

"The respondents ought not to have stayed their hands simply because the appellant had filed an appeal before this Court. Mere filing or pendency of an appeal does not operate as a stay of proceedings or as a suspension of the order against which an appeal is filed, unless a specific stay or injunctive order is passed. Reference in this regard may be made to the law laid down in the cases of Shah Wali v. Ghulam Din (PLD 1966 SC 983), Mst. Irshad Begum v. Mst. Gul Farasha (2003 YLR 724), Agro Dairies (Pvt.) Limited v. Agricultural Development Bank of Pakistan (2004 CLD 232) and Naeem Ullah Khalid v. Dr. Hafiz Mushtaq Ahmed (2007 YLR 1418)."

27. As discussed in Para. No. 9 above, Rotex Pharma did not argue the appeal on 31-07-2023 and sought adjournment on account of pendency of the matter before the Honorable Islamabad High Court. Rotex Pharma did not argue even to obtain interim relief knowing well that the authority with the power to grant final relief also has the power to grant interim relief. Since Rotex Pharma itself used adjournment as a strategy to protract the decision of the appeal, therefore, it cannot reap benefit from it to avoid the process of law in the instant matter.

28. In light of the foregoing, this Issue is also decided against Rotex Pharma.

Issue No. III. As to whether Rotex Pharma has violated the law by manufacturing in non-compliance of GMP? If yes, then has it impacted the safety, quality and efficacy of the manufacturing process and thus endangered public health?

29. The jurisprudence is by now settled that drug have to be manufactured mandatorily under conditions and practices required by the GMP regulations to assure that quality is built into the design and manufacturing process at every step. Any small and minor deviation can adversely affect the life of the patients and wreak a public health emergency.

30. The Board has minutely reviewed and discussed the Inspection Report and found it to be exhaustive and its findings to be well reasoned. The Report's findings have disclosed severe violations of GMP which severely impair safety and quality of the manufacturing process. The Report has catalogued the deficiencies and also referenced to the applicable laws which have been violated; for the sake of brevity

the complete chart if not reproduced here but is to be read as a part of this Order. The Inspection Report before presentation before CLB was discussed with a team of experts called "Inspection Evaluation Committee", the meeting of which was held on 29th and 30th of March, 2023: the report was thoroughly and critically discussed, analyzed and scrutinized. This second layer of analysis precluded any arbitrariness from the Inspection Report.

31. The Board has reviewed the Reply of Rotex Pharma which apart from raising broad based and bland accusations against the Inspection Report and its findings has not raised any specific objection contradiction the Inspection Report's findings. It has been claimed by Rotex Pharma in Para. No. 5 (iv) of the Reply that "no complaint vis-à-vis the products manufactured by the company has been received so far"; as discussed in Para. No. 2 and 3 above, Rotex Pharma is a high risk manufacturing facility which has a chequered history of manufacturing without complying with GMP.

32. Rotex Pharma has relied upon some old reports to contend that it is GMP Compliant. The said Reports were of inspections carried with the limited purpose of verifying the suitability of granting additional Sections for manufacturing; none of them undertook a comprehensive GMP Compliance Inspection. Even otherwise the last thorough GMP inspection of the company was conducted on 11th and 12th of August, 2020 by a Panel of Inspectors to check compliance to GMP requirements which as discussed in Para. No. 2 above highlighted serious discrepancies in GMP Compliance by Rotex Pharma. The GMP certificate was valid till 11-08-2022, whereafter Rotex Pharma has not been issued a GMP Compliance Certificate. Even otherwise, compliance with GMP is a continuous process; compliance determined at one point in time, does not automatically mean that compliance will be deemed for all time to come. Therefore, Rotex Pharma's contention is false in law and wrong in facts.

33. Any violation of GMP adversely affect the quality, safety and efficacy of drugs, which might not even be reflected in the test reports. Hon'ble Lahore High Court through Order dated 09-09-2016 in W.P. No. 27314 of 2016 emphasized the importance of ensuring compliance with the 'Good Manufacturing Practices' to ensure safety, quality and efficacy of the drugs in accordance with the WHO Guidelines, in the following words:

> "11. The WHO Guidelines provide the determinants for ensuring pharmaceutical quality. These guidelines determine the safety, potency and efficacy of the pharmaceutical drugs. The procedures for enforcement of these guidelines have been adopted and have comprehensively and exhaustively been provided for in Schedule B-1 and B-1A of the *Drugs (Licensing, Registering and Advertising) Rules, 1976* (the **Rules**) framed by the Federal Government pursuance to section 43 of the Drugs Act. Schedule B-II of the Rules provides for *"Good Manufacturing Practices (GMPs) for License to manufacture by way of formulation"*. GMP is part of a quality system covering the manufacture and testing of pharmaceutical dosage forms or

drugs and active pharmaceutical ingredients, diagnostics, pharmaceutical products and medical devices. Quality Assurance is a wide-ranging concept covering all matters, which individually or collectively influence the quality of a product. GMP is the aspect of quality assurance that ensures that medicinal products are produced, manufactured and controlled to the quality standards appropriate to their intended use and as required by the product specification. GMP defines quality measured for both production and quality control and defines general measures to ensure that processes necessary for production and testing are clearly defined, validated, reviewed, and documented , and that the personnel, premises and materials are suitable for the production of pharmaceuticals and biologicals including vaccines. GMP also has legal components, covering responsibilities for distribution, contract manufacturing and testing, and responses to product defects and complaints. "

"13. […] In short, the Rules comprehensively cover and provide for all aspect of quality control appropriate to the manufacture of pharmaceutical products."

"15. […] The system of drug regulation, is fashioned in a manner in which standards are prescribed, in the shape of Good Manufacturing Practices, WHO Guidelines and also through grant of licenses for manufacture and import of drugs. The task to inspect the, manufacturing facilities also falls on the shoulders of the Federal and Provincial Governments through their inspectors. The various Boards/authorities created under the two enactments are, inter alia, charged with the functions of […] granting licenses for manufacturing and sale of drugs; inspecting the premises of the manufacturer to ensure compliance with regulations and GMPs […] taking action for suspension/ cancellation of licenses …" *(emphasis has been added)*

34. The Honorable Islamabad High Court, Islamabad, through Order dated 22-02-2022 in W.P. No. 3086/ 2021 by relying on the abovementioned **Macter International** Judgment, upheld decision by the CLB to cancel Manufacturing License of an entity which was manufacturing without compliance with GMP.

35. Due to defects in Good Manufacturing Practices, a number of patients died in the Punjab Institute of Cardiology, Lahore. The learned Judicial Commission headed by Hon'ble Mr. J. Ijaz-ul-Ahsan in the Report on Defective Drug in the Punjab Institute of Cardiology, also concluded that the lack of adherence to 'Good Manufacturing Practices' resulted in the loss of lives and directed its strong enforcement:

"13.1 (b). During the course of proceedings before the Tribunal it has transpired that a large number of manufacturers engaged in manufacture of pharmaceuticals in Punjab and other provinces may not be in compliance of provisions of Drugs Act, 1976. Further, we have reason to believe that an equal number of manufacturers all over the country are not cGMP compliant. This is an alarming situation for the reason that the only safety net against errors, omissions, defects, contamination etc. of drugs and preventing such drugs from reaching the hospitals, markets and patients is at the stage of manufacturing. Compliance with cGMP requirements minimizes the possibility of defective or injurious drugs reaching the hospital, markets or patients. Once a defective, contaminated or injurious drug comes out of the factory, it is extremely difficult to detect the same and where an exercise of such detection is undertaken, it takes time, effort and resources, which in most instances are not available in Pakistan. This is an all the more reason to stress on strict compliance of cGMP requirements." *(emphasis has been added)*

36. The Honorable Supreme Court through Order dated 28-07-2020 passed in C.P. No. 70-K of 2019 has held that regulatory action safety and quality of the manufacturing process of drugs and medicines "has

direct nexus with the rights of public at large guaranteed under the constitution". On the one hand Rotex Pharma is vigorously contesting the matter, on the other hand it has submitted a Corrective and Preventive Action as annexure with its Reply in which it while admitting all deficiencies highlighted by the Inspection Report has contended that the same have since been corrected and risks prevented.

37. Corrective and Preventive Action cannot be determined merely from documents; it requires a thorough inspection of the manufacturing facility. Review of the Inspection Report along with tacit admission by Rotex Pharma of the deficiencies by submitting Corrective and Preventive Action as annexure with its Reply, reveals that Rotex Pharma was manufacturing without following the applicable GMP as mandated under the law. The deficiencies are of such a serious nature which severely and adversely affect safety, quality and efficacy of the manufacturing process and thus endangered public health. Therefore, Rotex Pharma has not only violated the terms and conditions of its Drug Manufacturing License but the Rules, 1976 as well by manufacturing drugs and medicines in non-compliance of GMP. This issue is also decided against Rotex Pharma.

DECISION OF 293rd MEETING OF CLB:

For the foregoing reasons and discussions, the Central Licensing Board has decided that it is sufficiently proven that M/s Rotex Pharma Pvt. Ltd. was manufacturing drugs and medicines without following the applicable Good Manufacturing Practices as mandated under the law. The deficiencies are of such a serious nature, which severely and adversely affect safety, quality and efficacy of the manufacturing process and endangers public health. Therefore, M/s Rotex Pharma Pvt. Ltd. has not only violated the terms and conditions of its Drug Manufacturing License but Drugs (Licensing, Registration and Advertising) Rules, 1976 as well by manufacturing drugs and medicines in non-compliance of Good Manufacturing Practices which endangers public health;

Hence, the Drug Manufacturing License of M/s Rotex Pharma Pvt. Ltd. is suspended with immediate effect under Section 41 of the Drugs Act, 1976, read with Rule 8 (16) of the Drugs (Licensing, Registration and Advertising) Rules, 1976. It shall remain suspended till verification by a Panel of Experts that all deficiencies have been removed and M/s Rotex Pharma Pvt. Ltd. which were noted in the Inspection Report and the manufacturing process is in accordance with Good Manufacturing Practices and the applicable law;

The Panel of Experts is constituted as below by exercising powers under Rule 8 (17) of the Drugs (Licensing, Registration and Advertising) Rules, 1976. A comprehensive report in this regard will be placed by it before the Central Licensing Board:

i. Chief Drug Inspector, Punjab.
ii. Additional Director PE&R, DRAP Islamabad.
iii. Additional Director Licensing, DRAP Islamabad.
iv. Area FID, DRAP Islamabad.

Legal Affairs Division of DRAP is requested to place the instant Order before the Honorable High Islamabad High Court, Islamabad in compliance of its Order dated 08-11-2023 passed in W.P. No. 1766 of 2023,

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

1. 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.

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.

5. Mr. Wajid Ali S/O Mehruddin Malik is a qualified person at M/s Al Rasheed Medical and Surgical Wooden Cabin No.6A on A-1 land, Opposite NICH, Jinnah Hospital Karachi. The conclusion/recommendation from Final Investigation report from FIA is

"*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.*"

6. Show cause notice to the following accused has been served.

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

7. 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.

8. A personal hearing letter dated 14th November 2023 was issued to the accused from QA&LT division for 293rd meeting of CLB.

PROCEEDING OF 293RD MEETING OF CLB:

9. No person or on behalf of the accused appeard before the Board.

DECISION OF 293rd CLB:

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 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

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

1. 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.

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)(vii), 23(1)(i) of Drugs Act 1976 punishable under section 27 of Drugs Act 1976 was registered.

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

"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 Honourable Courts of Drugs, Sindh at Karachi"

5. Show cause notice to the following accused was issued on 31st October 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.

6. A personal hearing letter dated 14th November 2023 was issued to the accused from QA&LT division for 293rd meeting of CLB

PROCEEDING OF 293RD MEETING OF CLB:

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

DECISION OF 293rd CLB:

08. 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.

QUALITY CONTROL CASES (PRODUCT RELATED ISSUES)

Case No. I: MANUFACTURE AND SALE OF UNREGISTERED NRUFEN SUSPENSION BY M/S. PERFECT PHARMA (Pvt.) Ltd., LAHORE.

A complaint was received from M/s. Abbott Laboratories Pakistan regarding manufacture and sale of product namely "Nrufen suspension" by M/s. Perfect Pharma (Pvt.) Ltd., Lahore, name and packaging desing of which is similar to registered product of M/s. Abbott Laboratories Karachi namely "Brufen Suspension".

02. A letter vide F. No. 13-196/2019-QC (Vol-I) dated 27-04-2021 was issued to area FID Lahore for investigation of the matter. Area FID Lahore submitted a report of inspection conducted on 08-06-2021 for verification of the said complaint. The report is reproduced as under:

"**Purpose of inspection:**

With reference to DRAP Islamabad's Letter No. F. No. 13- 196/2019-QC (Vol- I) dated 27-04-2021 on the subject, "Manufacturing/ Sale of Unregistered Drugs by M's Perfect Pharma (Pvt) Ltd,5km Manga Road, Raiwind, Lahore", a panel comprising of Mrs. Majida Mujahid (Area Federal Inspector of Drugs) and Ms. Maham Misbah (Assistant Director, DRAP, Lahore) conducted a surprise visit of M/s Perfect Pharma (DML No. 00469) located at 5km Manga Raiwind Road, Lahore an 08-06-2021.

Firm's representatives present during the inspection:

The representatives of the firm who were present at the time of inspection included Mr. Salman Shafi (CEO), Mr, M. Yamin (Production Incharge), Mr. M. Nasir (Quality Control Manger) and Mr. Ashfaq Ahmad (Manager), among others. Proceedings of the inspection dated 08-06-2021:

The firm was asked about the production of its purported product Nrufen Suspension. The firm's management responded that they had recently taken over the firm from the previous management. The Central Licensing Board in its 273rd meeting held on 15-012020 had endorsed the change of management and the decision had been communicated vide DRAP, Islamabad letter No. F. 1-15/98-Lic (Vol-III) dated 10-06-2020. (Letter of change of management attached, Annex 1). The CEO of the firm informed the panel that his firm had not manufactured Nrufen Suspension (Ibuprofen Suspension) since the change of management neither had they received any record of production (BMR) of Nrufen Suspension from the previous management, at the time of change of management. He further stated that his team did not receive any registration letter of Nrufen Suspension from the previous management, therefore, the same could not be produced before the panel.

Nrufen Suspension was not included in the Section-wise registered product list of the firm, as shown to the panel. No Ibuprofen API, unit carton or label of Nrufen suspension was found in the premises at the time of inspection. Further, no production record of Nrufen Suspension, testing record of

Ibuprofen API, testing record of finished Nrufen suspension or any retained samples of Nrufen Suspension were found in the premises at the time of inspection.

However, the panel conducted an Inspection to check the firm's conformance to cGMP on 08-06-2021 and concluded as follows:

"Overall, the sanitary and hygenic conditions of the firm were poor at the time of inspection. The civic work, working of HVAC and condition of equipment was found unsatisfactory at the time of inspection included Mr. Salman Shafi (CEO), Mr. Shehzad Ali Shah (Patter), Mr. M Yamin (Production In-charge), Mr. M. Nasir (Quality Control Manger), Mr. Waqas bin Aftab (Quality Assurance Manager) and Mr. Ashfaq Ahmad (Manager), among others.

The matter of complaint was once again investigated by the panel on 22-09-2021 and the same observations were noted as on 08-06-2021, in the instant matter. Meanwhile, this office's record of import of Ibuprofen API by M/s Perfect Pharma was also scrutinized. As per available office record of DRAP, Lahore office, the firm had applied for import clearance of 1000kg Ibuprofen raw material vide letter Ref No. 220/PPL/202I dated 18-03-2021 (Diary No. 4544 dated 22-03-2021) for purported use in the manufacturing of Nrufen Suspension (Drug Registration No. 093957), as stated in application by the firm. The firm had got clearance certificate for import vide Dispatch No. 4739/2021- DRAP dated 30-03-2021. Further, the firm had submitted undertaking with their application that they will submit the original documents later on but till date they have not provided original documents.

Accordingly, the firm was directed to clarify its position vide this office's letter No. 14339/2021-DRAP-AD dated 23-09-2021 regarding the manufacturing of unregistered drug and importing material based on mis-declaration made in its application submitted in this office for clearance certificate of Ibuprofen API for purported use in the manufacturing of Nrufen Suspension, having Drug Registration No. 093957 (as mentioned in the firm's application). (Copy of letter attached, Annex 3.)

The firm submitted its response vide letter No. REF: 322/PPU2021 dated 24-09-2021 (Diary No. 14115 dated 27-09-2021) wherein they have stated the following:

"Please refer to your letter: 14339/2021-DRAP-AD dated 23-092021 regarding the afore mentioned subject. Ever since we have taken over the factory from the previous management, as per DRAP Islamabad Letter No. F.l-15/98-Lic (Vol-Ill) dated 10-062020, we have never manufactured the product Nrufen Suspension.

Our stance regarding the manufacturing of the said product has been extremely straightforward. Our commitment has been assured since the day of the surprise visit of FID Lahore on 0806-2021 and on personal hearing in front of the Central Licensing Board, in its 282nd meeting held on 31-08-

2021. Furthermore, it was also evidentfrom the report of FID sent to DRAP Islamabad, mentioned in the Letter No: F.8-8/2021-QA (M-282-CLB) of DRAP, Islamabad dated 14th September 2021. The product was also not included in the registered product list of the firm, as shown to the FID.

After acquisition, the previous management informed us that the product has been registered in 284th meeting of Registration Board held on 31 July to 1 August 2018 and that they will provide us with the necessary registration letters. Due to certain notable factors, C0VID-I9, primarily, and base of operations of new management in Karachi, no communication could be established with the previous management for over a year.

In the interim, we applied for the import of raw material of Ibuprofen based on the previous management's claim of possession of the required registration letter. After the raw material was acquired, we demanded for the registration letters, however, the previous management failed to deliver on this promise. After repeated notifications there was no response from them. In the interim, the previous owner passed away.

The absence of the registration letter for the said product came as an immediate shock for us and signaled lack of professionalism on their part. Currently, we possess the entirety of the raw material and the relevant documentation. This affirms our Integrity and work ethic to not allow unethical business activity. We hope that this letter clarifies the issue at hand." (Reply attached at Annex 4)."

Submitted again for further necessary action, please."

03. In the light of information provided by area FID Lahore in the above mentioned report, names of both new and old management of M/s. Perfect Parma Lahore were obtained from the division of Drugs Licensing DRAP which are given as under:

Old management	Aijaz Ahmad S/o Malik Muhammad Hussain Asad Aijaz Malik S/o Aijaz Ahmad Azhar Aijaz S/o Aijaz Ahmad.
New management	Salman Shafi S/o Muhammad Jameel, CEO M/s. Perfect Pharma (Pvt.) Ltd., Lahore Farhan Jawed S/o Jawed Iqbal

04. Show-cause notice vide letter F. No. 04-04/2021-QC dated 14-03-2022 was also issued to both old and new management of M/s. Perfect Pharma Lahore. Replies of both are given as under:

Reply of old management:

"Dear Sir,

Please refer to you Lettet No: F.04-04/2021-QC dated 14th March, 2022 regarding above mentioned subject. It is stated that we have absolutely no knowledge of the above mentioned case as we have already sold our factory on 17-04-2019.

It is also for your information that the Chief Executive at that time Mr. Aijaz Ahmad has passed away on 16-02-2021. It is therefore requested that above refer notice be recalled."

Reply of new management:

"In light of the show cause notice issued on grounds of manufacturing and sale of Nrufen suspension please acknowledge our response below. As per inspection conducted on 8th June 2021, by Mrs. Majida Mujahid - Area FID and Ms. Maham Misbah - AD DRAP, the following was quoted by the inspectors in relation to our response submitted under F.88/2021-QA (M-282-CLB) of DRAP, Islamabad, dated 14th Sep 2021:

"Nrufen Suspension was not included in the Section-wise registered product list of the firm, as shown to the panel. No Ibuprofen API, unit carton or label of Nrufen suspension was found in the premises at the time of inspection. Further, no production record of Nrufen suspension, testing record of Ibuprofen API, testing record of finished, Nrufen suspension or any retained samples of Nrufen suspension were found in the premises at the time of inspection."

In view of all above submissions we have clarified our position that we have not manufactured Ibuprofen Suspension (Nrufen)

However, we are also willing to appear personally before the relevant authority or board for further clarification, if required.

It is therefore requested that SHOW CAUSE Notice under reply dated March 14th 2022 be recalled."

05. The representatives of the firm are called before personal hearing.

Proceedings and Decision of 287th meeting of the Central Licensing Board:

06. In response to the personal hearing notice issued, Mr. Salman Shafi, CEO M/s. Perfect Pharma, 5-Km Manga Raiwind road Lahore alongwith Mr. Sarfaraz Sajid Advocate appeared before the Board. In response to the allegations leveled against him, Mr. Salman Shafi submitted before the Board that the clearance of 1000kg Ibuprofen API was made strictly in accordance to law and till date the firm has not utilized the material. Moreover, he denied that firm was involved in the manufacturing and sale of product namely "Nrufen Suspension" since it is not registered till date. No one on behalf of old management of M/s. Perfect Pharma Lahore appeared before the Board.

07. The Board after considering the facts of case, reply of management and thorough deliberations decided as under:

The considering the arguments of the firm decide to call certified photocopy of the set of documents submitted with DRAP, Lahore for clearance of raw material. Moreover, DRAP Karachi would be requested in the light of documents received from DRAP, Lahore office to verify lying of the said material at given address in Karachi. The Board also decided to seek surveillance of the market in Karachi and Lahore for existence of product under investigation. The Drug Registration Board may be requested to provide detail of filling of registration application and proposed name of the drug.

i. Board decided to call certified photocopy of the set of documents submitted by M/s. Perfect Pharma Lahore with DRAP, Lahore for clearance of raw material.
ii. DRAP Karachi would be requested in the light of documents received from DRAP, Lahore office to verify lying of the said material at given address in Karachi House No. 215, Haji Fareer Dad Village (Goth) Liaqatabad, Karachi.
iii. The Board also decided to seek surveillance of the market in Karachi and Lahore for existence of product under investigation
iv. The Drug Registration Board may be requested to provide detail of filling of registration application and proposed name of the drug

08. FID-II DRAP, Karachi in compliance to decision of the board communicated vide letter No. F.03-31/2022-QC (287-CLB) dated 26th July, 2022 visited the said premises House No. 215 Haji Faqer Dad Goth Liaqatabad Karachi on 19-08-2022, to verify the goods laydown there as per the claim of the manufacturer. During the visit it was found that 40 drums each of 25Kg of Ibuprofen raw material having Batch No. 20123232 with manufacturing date 27-12-2020 and expiry date 12-2024 were stored there.

The Drug Registration Board was requested to provide detail of filling of registration application and proposed name of the drug requisite information is as under:

i. As per available record of PE&R Division, Nrufen Suspension is not found registered in the name of M/s. Perfect Pharma.

ii. Firm has submitted application for registration of Nrufen Suspension 100mg/5ml which was approved in 284th meeting of Registration Board. Furthermore, registration letter of said product has not yet been issued due to brand name resemblance.

iii. Additional Director DRAP, Lahore in compliance to decision of the board communicated vide letter No. F.10941/2022-DRAP (Add.Dir) dated 13th October, 2022 following certified photocopy of the set of documents submitted by M/s. Perfect Pharma Lahore with DRAP, Lahore for clearance of raw material:

i) Form-8
ii) Undertaking of source approval

iii) Undertaking for consumpaton of said material in registered product

iv) Undertaking for submission of original documents

v) Commercial invoice

vi) Packing and weight list

vii) Form 3

viii) Form 7

ix) Certificate of analysis

x) Certificate of GMP

xi) License DML copy

xii) Renewal of DML

xiii) Fee deposit slip DIL

xiv) Form 2 Application for license to import drugs

Proceedings and Decision of 289th meeting of the Central Licensing Board:

i) To direct area FID for 100% Sampling (all containers) of illegally imported API Ibuprofen having Batch No. 20123232 held at Karachi for identification testing by CDL for confirmation of Ibuprofen.

ii) After sampling, seizure of small quantity (1-2 Containers) as case property (evidence of illegal import) and remaining quantity to be ordered not to dispose at the storage premises.

iii) Assistant Director DRAP Lahore to investigate the matter of illegal import of API Ibuprofen by the firm based on mis-declaration/fake/forged documents and to submit a comprehensive report with clear recommendations and fixing the responsibility of unlawful import with reference to relevant provisions of Act/Rules.

09. In compliance to the decision of 289th meeting of the Board, division of QA&LT issued directions to DRAP Lahore and Karachi office vide letter F. No. 03-03/2023-QC (289-CLB) dated 13-04-2023. In response to the said letter, FID-II/Addl. Director DRAP Karachi vide letter No. F. 03-02/2022-FID-II (K) Misc. dated 02-05-2023 reported the compliance of the decision of the Board i.e., sampling for the purpose to test/analysis of Ibuprofen API and seizure of samall quanityt and issuing order not to dispose of for remaining quantity of the ibuprofen API present at godown of M/s. Perfect Pharma situated at House No. 215, Haji Faqeer Dad Goth Liaqatabad Karachi. Division of QA&LT granted "permission to keep safe custody of seized stocks" and "extension in order not to dispose of" to FID II/Addl. Director Karachi vide letter F. No. 04-08/2021-QC dated 25-05-2023 whereas the details of Test/Analysis report received from CDL Karachi are given as under:

S.	***Test***	***Acceptance Criteria***	***Result***	***Reference***

No.				
1.	*Identification*	*The identification test must identify ibuprofen.*	*Complies*	*USPNF 2022*

10. Additional Director DRAP Lahore vide Document No. 4399768 dated 15-11-2023 submitted the investigation report wherein the panel comprising of Mr. Ishtaiq Shafiq Asst. Director DRAP Lahore and Mr. Farooq Aslam Asst. Director Lahore after investigating the matter and hearing the representatives of the firm in person has provided following facts:

a) Firm had imported the raw material without having product registration. New Management had to ensure the registration letter prior to import.
b) Firm had submitted the mis-declaration that they would consume raw material in registered product.
c) The firm had submitted mis-declaration that they would provide original documents
d) Firm had stored the imported 1000 kg raw material outside the licensed premises i.e. House No. 215 Haji Faqer Dad Goth Liaqatabad Karachi (which is not a licensed premises).
e) Assistant Director, DRAP, Lahore, had written a letter vide reference no. 14339/2021-DRAP-AD, dated 23-09-2021, to the firm wherein it is stated:

In light of DRAP Islamabad's Letter No.F.No.13-196/2019-QC (Vol-I) dated 27-04-2021 and complaint received from an organization, you have manufactured and sold Nrufen Suspension (un-registered) in the market.

As per available record of this office, you applied for import clearance of 1000kg Ibuprofen raw material vide letter Ref No. 220/PPL/2021 dated 18-03-2021 received on 22-03-2021 Diary No. 4544 for use in the manufacturing of Nrufen Suspension, as stated in your application. You got import clearance vide Dispatch No. 4739/2021-DRAP dated 30-03-2021. Further you had submitted undertaking with your application that you will submit the original documents later on but till date you have not provided original documents.

Accordingly, you are hereby directed to clarify your position regarding the manufacturing of unregistered drug and importing material based on mis-declaration made in your application for import NOC submitted in this office for this raw material.

But the firm had not submitted original documents including registration letter till date.

11. Keeping in view the facts of the case and evaluation of the documents submitted by the management of the firm, Panel has concluded their report as under:

"In light of the afore-mentioned it is crystal clear that firm had imported the raw material without having product registration letter. Moreover, the firm had submitted mis-declarations. It is

therefore, proposed that the firm may be prosecuted under Schedule II, Schedule III of DRAP Act 2012 and Drugs Act 1976 or any other action deem fit by the Board."

12. Furthermore, the panel has nominated following persons responsible for the offences mentioned in the para above:

a) Mr. Salman Shafi S/o Muhammad Jameel Akhtar, Chief Executive Officer (CNIC No.42101-4318679-9)
b) Mr. Farhan Jawed S/o Jawed Iqbal (CNIC No.42201-0699080-5)
c) Muhammad Yamin S/o Muhammad Shafi (B Pharmacy) (Production Incharge) (CNIC-32102-0907085-9)
d) Muhammad Nasir S/o Muhammad Ibrahim (MSc Chemistry) (Quality Control Manager) (CNIC-36401-0257435-7)

Proceedings and decision of 293rd meeting of CLB:

13. In compliance to the decision of 289th meeting of the Central Licensing Board, report of CDL Karachi, status of seizure of stock as case property and order not to dispose of remaining stocks present at House No. 215, Haji Faqeer Dad Goth Liaqatabad Karachi by area FID Karachi and the investigation report submitted by DRAP Lahore was presented before the Board. The Board after thorough deliberations and keeping in view the recommendations of investigation report decided as under:

i. Lodge prosecution in the court of competent jurisdiction against the accused namely Salman Shafi S/o Muhammad Jameel Akhtar, Chief Executive Officer (CNIC No.42101-4318679-9) and Farhan Jawed S/o Jawed Iqbal, Director (CNIC No.42201-0699080-5) of M/s. Perfect Pharma (Pvt.) Ltd., 5-Km Manga-Raiwind road Lahore, for import of the 1000kg Ibuprofen API without having product registration letter, mis-declaration of registration status of Nrufen suspension at the time of clearance of Ibuprofen API and storage of said material outside the licensed premises at House No. 215 Haji Faqer Dad Goth Liaqatabad Karachi (which is not a licensed premises) that are violations of section A(1)(a)(vii), section A(1)(e) and section A(1)(f) of Schedule II of the DRAP Act 2012 and punishable under section 1(c) of Schedule III of the DRAP Act 2012.