MINUTES OF 280th MEETING OF CENTRAL LICENSING BOARD HELD ON APRIL 26-27, 2021

==*=*=*

280thmeeting of the Central Licensing Board (CLB) was held on April 26-27, 2021 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad. Mr.Akhtar Abbas Khan, Representative Division of Quality Assurance and Laboratory Testing Division/Member Central Licensing Board, Drug Regulatory Authority of Pakistan, Islamabad presided the meeting in the absence of Chairman as provided under Rule 8(8) of the Drugs (Licensing, Registering & Advertising) Rules, 1976. Following members attended the meeting:-

S.No	Name & Designation	Status
1.	Mr. Abid Ali, Law Expert, Ministry of Law & Justice Division, Islamabad	Member
2.	Mr. Azhar Jamal Saleemi, Chief Drug Controller, Primary and Secondary Health Department, Government of Punjab, Lahore	Member
3.	Mr. Muhammad Shoaib Ansari, Chief Inspector of Drugs, Government of Sindh, Karachi	Member
4.	Mr. Zahid Khan, Chief Drug Inspector Peshawar, Govt of KPK, Peshawar.	Member
5.	Mr. Manzoor Ali Bozdar, Addl Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
6.	Mr. Tipu Sultan Akram, Representative of PPMA.	Observer
7.	Ms. Sajid Ahmed , Representative, PCDA	Observer
8.	Mr.Nadeem Alamgir Representative of Pharma Bureau.	Observer

The meeting started with the recitation of Holy verses. The Chairperson stated that all the legal and codal formalities would be taken into account for disposal of cases and respective Divisions shall be responsible for the contents, errors and omissions of agenda and minutes thereof. The Central Licensing Board discussed and decided that initial draft minutes of the meeting would be prepared by concerned sections of Divisions and counter verified by the Secretary, Central Licensing Board before submitting to the members of the Board for perusal and concurrence. Secretary Licensing Board presented the agenda before the Board. Mr. Muhammad Arif, Deputy Director (QA), Mst Mahvash Ansari, Deputy Director (QC) Mr. Muhammad Asad Malik, Deputy Director (Licensing), Mr. Muhammad Usman, AD (Lic), Mr. Abdullah Bangash, AD (Lic), Ms. Zunaira Faryad, AD (Lic), Ms. Haleema Shareef AD (Lic), Mr. Sanaullah Babar, AD (QC) assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 278thMEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 279th meeting of the Central Licensing Board (CLB) which was held on 18th February, 2021.

A. DRUG LICENSING DIVISION

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

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s NeoTech Pharmaceuticals (Pvt) Ltd., 28-KM, Gujranwala-Lahore G.T. Road, Chak Hinda, Kamonke.	19-03-2021	**Good**	1. Dr. Zaka-ur-Rehman, COO, PRDTC, Lahore. 2. Dr. Syed Zia Husnain, FID, Lahore. 3. Mehwish Jamil Butt, Assistant Director, DRAP, Lahore.
	"Panel has evaluated documentation in detail shown by the management of the firm and physically inspected the unit. Panel has discussed various technical aspects with the management of the firm at some length. Firm has established only two sections at present including Oral Powder-I (Veterinary) Section and Oral Liquid (Veterinary) Section. After thorough evaluation panel recommended the facility for grant of Drug Manufacturing License to M/s NeoTech Pharmaceuticals (Pvt) Ltd, 28-KM, Gujranwala-Lahore G.T Road, Chak Hinda, Kamonke District Gujranwala, only for following two Veterinary Sections:- 1. Oral Powder-I (Veterinary) Section. 2. Oral Liquid (Veterinary) Section. **Decision of the Central Licensing Board in 280th meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s NeoTech Pharmaceuticals (Pvt) Ltd, 28-KM, Gujranwala-Lahore G.T Road, Chak Hinda, Kamonke District Gujranwala (By way of Formulation) on the recommendations of the panel of experts for the following sections: **Section (02):** 1. Oral Powder-I (Veterinary) Section. 2. Oral Liquid (Veterinary) Section.			
2.	M/s Bioskills Pharmaceuticals, 4-Km Tamboly, GT road, Sadhoke, District Gujranwala **Section (02)** 1) Oral Liquid Section (General Antibiotic) (Veterinary)	**18-02-2021**	**Good**	1) Mr. Zakaur Rehman, COO, PRDTC, Lahore. 2) Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore. 3) Ms. Mehwish Jamil Butt, Assistant Director, DRAP, Lahore.

	2) Oral Dry Powder Section (General Antibiotics) (Veterinary)			
	Recommendations of the panel: "Panel has physically inspected the unit and evaluated various documents in detail, Panel has discussed various technical aspects with the management of the firm at some length. After thorough evaluation panel decided to **recommend** the facility for grant of Drug Manufacturing License to M/s Bioskills Pharmaceuticals, 4-Km Tamboly, GT road, Sadhoke, District Gujranwala for following two veterinary sections: 1) Oral Liquid Section (General Antibiotic) (Veterinary) 2) Oral Dry Powder Section (General Antibiotics) (Veterinary). **Decision of the Central Licensing Board in 280th meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Bioskills Pharmaceuticals, 4-Km Tamboly, GT road, Sadhoke, District Gujranwala (By way of Formulation) on the recommendations of the panel of experts for the following sections: **Section (02):** 1) Oral Liquid Section (General Antibiotic) (Veterinary) 2) Oral Dry Powder Section (General Antibiotics) (Veterinary).			
3.	M/s Kayans Pharmaceuticals Industries,Plot No. 31 &32, Main road, RCCI Industrial Estate, Rawat. **Section/Facility (09)** 1) Oral Powder Section-I (Veterinary) (General). 2) Oral Powder Section-II (Veterinary) (General). 3) Tropical Spray Section (Veterinary) (General). 4) Oral Liquid Section-I (Veterinary) (General). 5) Oral Liquid Section-II (Veterinary) (General). 6) Liquid Injection Section-I (Veterinary) (General). 7) Steroid Injection section (Veterinary). 8) QC Lab and Microbiology. 9) Stores /Warehouse.	**07-04-2021** **&** **12-04-2021**	**Good**	1) Mr. Abdullah, Additional Director (PE &R), DRAP, Islamabad. 2) Mr. Khalid Mahmood, Federal Inspector of Drugs, DRAP, Islamabad. 3) Mr. Sarfraz Nawaz, Assistant Director, DRAP, Islamabad.

	Recommendations of the panel: "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the approval for the Grant of New Drug Manufacturing License By way of Formulation for following sections of M/s Kayans Pharmaceutical Industries Plot No.31,32 Main Road RCCI Industrial Estate, Rawat Rawalpindi HVAC, has been installed in the unit with separate RO Plant and distillation assembly. 1) Oral Powder Section-I (Veterinary) (General). 2) Oral Powder Section-II (Veterinary) (General). 3) Topical Spray Section (Veterinary) (General). 4) Oral Liquid Section-I (Veterinary) (General). 5) Oral Liquid Section-II (Veterinary) (General). 6) Liquid Injection Section-I (Veterinary) (General). 7) Liquid Injection section (Veterinary) (Steroid) **Decision of the Central Licensing Board in 280th meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Kayans Pharmaceutical Industries Plot No.31,32 Main Road RCCI Industrial Estate, Rawat (By way of Formulation) on the recommendations of the panel of experts for the following sections: **Section (07):** 1) Oral Powder Section-I (Veterinary) (General). 2) Oral Powder Section-II (Veterinary) (General). 3) Topical Spray Section (Veterinary) (General). 4) Oral Liquid Section-I (Veterinary) (General). 5) Oral Liquid Section-II (Veterinary) (General). 6) Liquid Injection Section-I (Veterinary) (General). 7) Liquid Injection section (Veterinary) (Steroid)			
4.	M/s Acumen Healthcare (Pvt) Ltd, Plot No. 39 & 40, Street No. S-2, RCCI Industrial Estate, Rawat. **Section (06)** 1) Dry Suspension Section (General) 2) Tablet Section (General) 3) Capsule Section (General) 4) Dry Vial Injection Section (Cephalosporin)	**12-04-2021** **&** **15-04-2021**	**Good**	1) Mr. Akhtar Abbas, Additional Director (QA &LT), DRAP, Islamabad. 2) Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad. 3) Mr. Hasan Afzal, Assistant Director (QA/LT), DRAP, Islamabad.

	5) Dry Suspension Section (Cephalosporin). 6) Capsule Section (Cephalosporin)			
	Recommendations of the panel: **"**Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the approval of DML by the way of formulation to M/s Acumen Healthcare (Pvt) Ltd, Plot#39&40, Street #S-2, RCCI Industrial Estate, Rawat, with following sections of:" 1) Dry Suspension Section (General) 2) Tablet Section (General) 3) Capsule Section (General) 4) Dry Vial Injection Section (Cephalosporin) 5) Dry Suspension Section (Cephalosporin) 6) Capsule Section (Cephalosporin) **Decision of the Central Licensing Board in 280th meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Acumen Healthcare (Pvt) Ltd, Plot#39&40, Street #S-2, RCCI Industrial Estate, Rawat (By way of Formulation) on the recommendations of the panel of experts for the following sections: **Section (06):** 1) Dry Suspension Section (General) 2) Tablet Section (General) 3) Capsule Section (General) 4) Dry Vial Injection Section (Cephalosporin) 5) Dry Suspension Section (Cephalosporin) 6) Capsule Section (Cephalosporin)			
5.	M/s Getz Pharma (Pvt) Ltd, Plot No. 1, Sector 25, Korangi Industrial Area, Karachi. **Section (03):** 1) Tablet (General) 2) Capsule (General) 3) Dry Powder Suspension (General) 4) Quality Control Laboratory 5) Ware House (General)	**09-03-2021**	**V.Good**	1) Director DTL, Govt of Sindh, Karachi. 2) FID DRAP, Karachi. 3) Mr. Awais Ahmed, Assistant Director, CDL, Karachi.

Recommendations of the panel:

M/s Getz Pharma (Pvt) Limited Unit-1, situated at Plot No. 01, Sector 25, Korangi Industrial Area, Karachi was inspected in compliance with instructions contained in DRAP Islamabad letter no. F.2-9/2014-Lic(Vol-I), dated 15th February, 2021 in connection with the grant of new Drug Manufacturing License (By way of Formulation) for the following sections:

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General) Section	2.	Capsules (General) Section
3.	Dry Powder Suspension (General) Section	4.	Warehouse (General)
5.	Quality Control Laboratory	6.	**********

Based on the people met and the documents reviewed and considering the findings of the inspection M/s Getz Pharma (Pvt) Limited, situated at Plot No. 01, Sector 25, Korangi Industrial Area Karachi is considered to be designed and established at an acceptable level of compliance of GMP requirement. Therefore, the panel recommends the approval for the grant of the new Drug Manufacturing License (By way of Formulation).

Decision of the Central Licensing Board in 280th meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Getz Pharma (Pvt) Limited Unit-1, situated at Plot No. 01, Sector 25, Korangi Industrial Area, Karachi (By way of Formulation) on the recommendations of the panel of experts for the following sections:

Section (03):

1) Tablet (General)
2) Capsule (General)
3) Dry Powder Suspension (General)

6.	M/s Biorise Pharmaceuticals, 19-Km, Lahore Road, Multan. **Section (03)** 1) Oral Powder Section (General) Veterinary. 2) Oral Liquid Section (General) Veterinary. 3) Liquid Injection Vial Section (General) Veterinary.	**11-03-2021**	**Good**	1) Mr. Zakaur Rehman, COO, PDTRC, Lahore. 2) Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3) Mr. Akbar Ali, Assistant Director, DRAP, Lahore.

Recommendations of the panel:

"Keeping in view the inspection conducted and provision of manufacturing facility like, building, HVAC system, production Machinery, Equipment in Quality Control and Microbiology Laboratory, Water Treatment System, Testing Facilities, Technical personnel met, documentation, the panel of inspectors **recommends** the grant of new Drug Manufacturing License by way of Formulation to M/s Biorise Pharmaceuticals, 19-km Lahore Road, Multan for following three sections.

1) Oral Powder Section (General) Veterinary.
2) Oral Liquid Section (General) Veterinary.
3) Liquid Injection Vial Section (General) Veterinary."

Decision of the Central Licensing Board in 280th meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Biorise Pharmaceuticals, 19-km Lahore Road, Multan (By way of Formulation) on the recommendations of the panel of experts for the following sections:

Section (03):

1) Oral Powder Section (General) Veterinary.
2) Oral Liquid Section (General) Veterinary.
3) Liquid Injection Vial Section (General) Veterinary.

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s ISIS Pharmaceuticals& Chemical Works, Plot No. 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi. DML No.000126 (Formulation) **Section (01):** Liquid External Preparation (General) - **New**	**12-03-2021** **&** **15-03-2021.**	**Good**	1) Additional Director (E& M) DRAP, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, AD, DRAP, Karachi.

Recommendations of the panel:

"Based on the people met, documents reviewed, and observations made during the inspection, the panel unanimously **recommends** the grant of renewal of Drug Manufacturing License No. 000126 by way of formulation, regularization and grant of additional sections as follows:

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Sterile Ophthalmic Drops (General)
3.	Liquid Syrup (General)	4.	Ophthalmic Ointment (General)
5.	Dry Powder Suspension (General)	6.	Cream/Ointment (Steroids)
7.	Capsule (General)	8.	Tablet (Hormone)
9.	Cream/Ointment/Gel (Hormone)	10.	Sterile Liquid Injection (Hormone)
11.	Liquid Injection SVP (Glass Vial/ampoule)	12.	Liquid Infusion (General) (PP)
13.	Cream/Ointment/Gel (General)	14.	Capsule (Cephalosporin)
15.	Tablet (Cephalosporin)	16.	Dry Powder Injection (Cephalosporin)
17.	Dry Powder Suspension (Cephalosporin)	18.	Dry Powder Suspension (Penicillin)
19.	Tablet (Penicillin)	20.	Capsule (Penicillin)
21.	Liquid Injection (psychotropic)	22.	Tablet (Psychotropic)
23.	Liquid ORS (General)	24.	Powder ORS (General)
25.	Tablet Bolus (Veterinary)	26.	Liquid Syrup (Veterinary)
27.	Dry Powder Suspension (Veterinary)	28.	Liquid Injection (Veterinary)
29.	Injectable Hormone (Veterinary section)	30.	Enema

Additional/New Section			
1.	Liquid External Preparation (General)-New		**********

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of following new section in the name of M/s ISIS Pharmaceuticals& Chemical Works, Plot No. 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi under DML No.000126 (Formulation)on the recommendations of the panel of experts.

Section (01)

1. Liquid External Preparation (General) - **New**

2.	M/s. Abbott Laboratories Pakistan Limited,Opposite Radio Pakistan Transmission Centre Hyderabad Road Karachi. DML No. 000001 (Formulation) Tenure**:** Commencing on 31-03-2020& ending on 30-03-2025. **Facilities (02) :** 1) Microbiology Laboratory- Revised 2) IBC Washing Area at vacant space.	**04-02-2021**	**Good**	1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi. 2) Area FID, DRAP, Karachi. 3) CDI, Sindh, Karachi.

Recommendations of the panel:

Based on the people met, areas visited and commitment of the Firm's management for continuous improvement of personnel, processes and facilities, the panel is of the view to **recommend**:

- Renewal of Drug Manufacturing License (By way of Formulation) No. 000001 to the firm M/s Abbott Laboratories Pakistan Ltd, situated Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi, with following sections:

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Cream/Gel (General)

3.	Granules (General)	4.	Liquid (General)
5.	Injectable (General0	6.	**********

- Grant Amendments in lay out plan for Microbiology Laboratory, IBC washing area and Research and Development Laboratory.
- Re-inspection for renewal of Capsule Section subject to completion of installation/qualification of packing lines in this section.

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved following revised sections/ facility in the name of M/s. Abbott Laboratories Pakistan Limited,Opposite Radio Pakistan Transmission Centre Hyderabad Road Karachiunder DML No.000001 (Formulation)on the recommendations of the panel of experts.

Facilities (02) :

1) Microbiology Laboratory- Revised
2) IBC Washing Area at vacant space.

3.	M/s Vetz Pharmaceutical (Pvt) Ltd, Q-1, SITE, Kotri Sindh. DML No. 000813 (Formulation) **Section (01):** 1. Injectable Section (Hormone) - **New**	**09-03-2021.**	**Good**	1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, AD, DRAP, Karachi.

Recommendation of panel :

Based on the observations, documents reviewed, personnel met and commitment of the firm for continuous up-gradation and intention for export of products to various countries, the panel **recommends** as follows:

a) Grant of renewal of DML No. 000813 (by way of Formulation) to the firm M/s Vetz Pharmaceuticals Pvt Ltd, with following sections:

Sr #	Name of Section	Sr. #	Name of Section
1.	Oral Powder (Veterinary)	2.	Oral Liquid (Veterinary)
3.	Aerosol	4.	Sterile Liquid Vial Injection (Veterinary)
5.	Sterile Powder Vial Injection (Veterinary)	6.	Sterile Liquid Vial Injection Penicillin (Veterinary)
7.	Oral Powder (Penicillin) (Veterinary)		**********

b) Grant of Additional Section namely Injectable (Hormone) (New)

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of following new section in the name of M/s Vetz

<table>
<tr><td></td><td colspan="4">Pharmaceutical (Pvt) Ltd, Q-1, SITE, Kotri Sindh under DML No.000813 (Formulation)on the recommendations of the panel of experts.

<u>Section (01)</u>
1. Injectable Section (Hormone) - New</td></tr>
<tr><td>4</td><td>M/s Avensis Pharmaceuticals,Plot No. F-24/1, Eastern Industrial Zone Port Muhammad Bin Qasim, Karachi.

<u>Sections (02)</u>
1. Tablet (General) New in place of Tablet (Psychotropic) Section.
2. Injectable (Steroid) Section in place of Injectable (Psychotropic) Section.</td><td>15-04-2021</td><td>V.Good</td><td>1) Additional Director,DRAP, Karachi.
2) Federal Inspector of Drugs, DRAP, Karachi.
3) Mr. Krishan Das, AD, DRAP, Karachi.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendation of panel:</u>

Based on the above observations, documents reviewed, personnel met and commitment of the management for continuous up-gradation and intention for export of products to various countries, the panel recommends the grant of following additional section: -

<table><tr><th>Sr #</th><th>Name of Section</th><th>Sr. #</th><th>Name of Section</th></tr><tr><td>1.</td><td>Tablet (General) Section</td><td>2.</td><td>Injectable (Steroids) Section</td></tr></table>
<u>Decision of the Central Licensing Board in 280th meeting</u>

The Board considered and approved the grant of following new sections in the name of M/s Avensis Pharmaceuticals, Plot No. F-24/1, Eastern Industrial Zone Port Muhammad Bin Qasim, Karachiunder DML No.000813 (Formulation)on the recommendations of the panel of experts.

<u>Sections (02)</u>

1. Tablet (General) New in place of Tablet (Psychotropic) Section.
2. Injectable (Steroid) Section Newin place of Injectable (Psychotropic) Section.</td></tr>
<tr><td>5</td><td>M/s Universal Pharmaceuticals (Pvt) Ltd., 131-A, Hayatabad Industrial Estate, Peshawar.

DML No. 000545 (Formulation)

<u>Sections (03).</u>
1) Capsule (Cephalosporin) Section
2) Dry Powder (Cephalosporin) Section</td><td>22-02-2021</td><td>Good</td><td>1) Prof. Dr. Jamshed Ali Khan, Member CLB.
2) Area Federal Inspector of Drugs, DRAP, Peshawar.
3) Mr.Saleem Khan, DG Drugs, Khyber Pakhtunkhwa</td></tr>
</table>

	3) Raw Material (Cephalosporin) Store			
	Recommendations of the panel: - Referenc DRAP's letter No.3-2/2001-Lic (Vol-II) dated 04th February, 2021 the constituted panel inspected the firm M/s Universal Pharmaceuticals (Pvt) Ltd., 131-A, Hayatabad Industrial Estate, Peshawar on the prescribed evaluation form for the purpose of verification ofrevised layout plan for already existing sections i.e Capsule (Cephalosporin) Sections and Dry Powder (Cephalorposirn) Sections alongwith Raw Material Store for Cephalosporin. The panel observed that the firm has revised their above mentioned sections and stores as per layout plan approved by DRAP. They have installed HVAC systems in the sections. Proper Machinery/equipment, QC instruments already exist with the firm. They are advised to replace the manual dry powder filling machine with automatic filling machine. The firm has approved technical staff for the supervision of manufacturing and test/ analysis of starting materials, inprocess materials and finished products. The panel therefore unanimously **recommends** the approval of following revised sections to the firm; i. Capsule (Cephalosporin) Section ii. Dry Powder (Cephalosporin) Section iii. Raw Material (Cephalosporin) Store **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of following revised sections in the name of M/s Universal Pharmaceuticals (Pvt) Ltd., 131-A, Hayatabad Industrial Estate, Peshawar under DML No.000545 (Formulation)on the recommendations of the panel of experts. **Section (03)** **1.** Capsule (Cephalosporin) Section**Revised** **2.** Dry Powder (Cephalosporin) Section**Revised** **3.** Raw Material (Cephalosporin) Store**Revised**			
4.	M/s Aamster Laboratories, Plot No. 18, Street No. SS-2, RCCI, Industrial Estate, Rawat. DML No. 000908 (Formulation) **Section (02)** 1) Oral Powder (Penicillin) (Veterinary) New Section). **2)** Liquid Injection (General) (Veterinary) New Section).	**11-03-2021**	**Good**	1) Mr. Abdullah, Additional Director (PE &R) DRAP, Islamabad. 2) Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad. 3) Mr. Hasan Afzal, Assistant Director (QA), DRAP, Islamabad.
	Recommendations of the panel: "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the approval of following additional(new) section of M/s Aamster			

Laboratories, Plot#18, Street #SS-2, RCCI Industrial estate, Rawat, Rawalpindi:"

1. Oral Powder (Penicillin) (Veterinary-New Section).
2. Liquid Injection (General) (Veterinary-New Section).

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of following new section in the name of M/s Aamster Laboratories, Plot No. 18, Street No. SS-2, RCCI, Industrial Estate, Rawatunder DML No.000908 (Formulation)on the recommendations of the panel of experts.

Section (02)

1. Oral Powder (Penicillin) (Veterinary-New Section).
2. Liquid Injection (General) (Veterinary-New Section).

5.	M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No. 3, Street No. S-5, National Industrial Zone, Rawat. DML No. 000810 (Formulation) **Section (01)** 1) Tablet (Psychotropic) Section (New).	**16-02-2021** **&** **25-02-2021**	**Good**	1) Mr. Akhtar Abbas, Additional Director (QA &LT), DRAP, Islamabad. 2) Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad. 3) Ms. Zunaira Faryad, Assistant Director (Lic), DRAP, Islamabad.

Recommendations of the panel:

"Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the following 1 new/additional & renewal (of the existing 5 sections) of DML No.000810 (By way of formulation) of M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No.3 Street No. S-5, National Industrial Zone Rawat, Islamabad:

New Additional Sections

1) Tablet Psychotropic (New Sectionl)

Existing Sections

1) Tablet (General) Section
2) Cream/Ointment/Gel (General) Section
3) Capsule Section (Cephalosporin)
4) Dry Suspension Section (Cephalosporin)
5) Capsule (General) Section

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of following new section in the name of M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No. 3, Street No. S-5, National Industrial Zone, Rawatunder DML No.000810 (Formulation)on the recommendations of the panel of experts.

Section (01)

1 Tablet (Psychotropic) Section (New).

6.	M/s Ras Pharmaceuticals 25-KM Lahore Road, Multan. DML No. 000821 (Formulation) **Sections (05):** 1) Oral Dry Powder (Penicillin) (Vet). 2) Dry Powder Injection (Penicillin) (Vet). 3) Liquid Injection (Penicillin) (Vet). 4) Liquid Injection (General) (Vet). 5) Warehouse (Revised).	**10-03-2021**	**Good**	1) Dr. Farzana Chowdhary, Member. 2) Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3) Ms. Maham Misbah, Assistant Director, DRAP.

"The facility was developed and constructed as per revised layout plan approved vide DRAP letter No.F.1-46/2010-Lic (Vol-I) dated 12-05-2020 and new layout for penicillins approved vide DRAP letter No.F.1-46/2010/Lic (Vol-I) dated 14-04-2017.

Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control and Microbiology Laboratory, testing facilities, technical personel met and documentation reviewed, the panel of inspectors **recommend** the renewal of Drug Manufacturing License by way of Formulation to M/s Ras Pharmaceuticals 25-KM Lahore Road, Multan for the following three sections: -

1. Oral Liquids (Antibiotic) (Vet).
2. Oral Powders (General) (Vet).
3. Oral Powders (General antibiotic) Vet.

The panel of inspectors also **recommend** the grant of following additional sections:

1. Oral Dry Powder (Penicillin) (Vet).
2. Dry Powder Injection (Penicillin) (Vet).
3. Liquid Injection (Penicillin) (Vet).
4. Liquid Injection (General) (Vet).
5. Warehouse (Revised).

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of following new section in the name of M/s Ras Pharmaceuticals 25-KM Lahore Road, Multanunder DML No.000821 (Formulation)on the recommendations of the panel of experts.

Section (05)

1. Oral Dry Powder (Penicillin) (Vet).
2. Dry Powder Injection (Penicillin) (Vet).
3. Liquid Injection (Penicillin) (Vet).
4. Liquid Injection (General) (Vet).
5. Warehouse (Revised).

7.	M/s. Abbott Laboratories Pakistan Limited, Plot No. 13, Sector 20, Korangi Industrial Area, Karachi. DML No. 000004 (Formulation) **Sections (04):** 1) Packing Dispensing/sampling room & change rooms – Revised. 2) Raw Material Store – Revised 3) Oral Liquid (General) – Amendment 4) Washing area converted into warehouse in RM Store.	**13-04-2021**	**Good**	1) CDI, Govt of Sindh Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Ms. Sidra, AD, DRAP, Karachi.
	Recommendations of the panel: "Based on the stated facts and observations the panel unanimously **recommended** as follows: Grant of renewal of DML No. 000004 (Formulation) for the next five years and the amendments made in layout plan for attaining better level of compliance may be regularized." **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of following revised section in the name of M/s. Abbott Laboratories Pakistan Limited, Plot No. 13, Sector 20, Korangi Industrial Area, Karachiunder DML No.000004 (Formulation)on the recommendations of the panel of experts. **Section (04)** 1) Packing Dispensing/ sampling room & change rooms – Revised. 2) Raw Material Store – Revised 3) Oral Liquid (General) – Amendment 4) Washing area converted into warehouse in RM Store.			
8.	M/s. Kaizen Pharmaceuticals (Pvt) Ltd, Karachi. Plot No. E-127-129, NWIZ, Port Qasim Authority, Karachi. DML No. 000755 (Formulation) **Section (01):** 1) Soft Gelatin Capsule (General) - **New**	**21-04--2021**	**Good**	1) Director DTL, Karachi. 2) Area FID, DRAP, Karachi. 3) Awais Ahmed, AD, (CDL), Karachi.

	Recommendations of the panel: Based on the people met, areas visited and commitment of the management for continuous improvement and upgradation the panel is of the view to **recommend** grant of additional section namely Soft Gelatin Capsule (General) –**New**to the firmM/s. Kaizen Pharmaceuticals (Pvt) Ltd, Karachi. Plot No. E-127-129, NWIZ, Port Qasim Authority, Karachi. **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of following new section in the name of M/s. Kaizen Pharmaceuticals (Pvt) Ltd, Karachi. Plot No. E-127-129, NWIZ, Port Qasim Authority, Karachiunder DML No.000755 (Formulation)on the recommendations of the panel of experts. **Section (01)** 1) Soft Gelatin Capsule (General) - **New**			
9.	M/s Unichem Pakistan Pharmaceuticals (Pvt) Ltd., Plot No.310, Industrial Triangle Kahuta Road, Islamabad. DML No. 000922 (Semi Basic Manufacture). **Name of APIs (10).** 1. Methyl cobalamin- (JP). 2. Domperidone- (Eu.P). 3. Caffeine Anhydrous (Eu.P/USP). 4. Tramadol- (USP). 5. Domperidone Maleate- (Eu.P). 6. Clarithromycin (Eu.P) 7. MoxifloxacinHCl (Eu.P) 8. Levetiracetam (USP) 9. Drotaverine HCl (In-house) 10. Cefradine (USP)	**21-04-2021**	**Good**	1. Additional Director (Licensing), DRAP, Islamabad. 2. Federal Inspector of Drugs, DRAP, Islamabad. 3. Mr. Abdullah Bangash, Assistant Director, DRAP, Islamabad.
	Recommendations of the panel: - "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended the approval** of manufacturing of following APIs products by way of (semi-basic manufacturing) at **M/s** Unichem Pharmaceuticals Pakistan (Pvt) Limited, Plot No. 310 Industrial triangle,			

Kahuta Road, Islamabad

1. **New Products**

1. Methylcobalamin (JP) 2. Domperidone (Eu.P) 3. Caffeine Anhydrous (Eu.P/USP) 4. Tramadol HCl (USP) 5. Domperidone Maleate (Eu.P)

2. **Batch formula and process flows of following products have revised and submitted for approval.**

Replacement of Methylene chloride with other solvents

1. Clarithromycin (Eu.P)
2. MoxifloxacinHCl (Eu.P)
3. Levetiracetam (USP)
4. Drotaverine HCl (In-house)
5. Cefradine (USP)

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of following new API's in the name of M/s. Unichem Pakistan Pharmaceuticals (Pvt) Ltd., Plot No.310, Industrial Triangle Kahuta Road, Islamabad under DML No.000922 (Basic Manufacture)on the recommendations of the panel of experts.

1. **New Products**

1. Methylcobalamin (JP) 2. Domperidone (Eu.P) 3. Caffeine Anhydrous (Eu.P/USP) 4. Tramadol HCl (USP) 5. Domperidone Maleate (Eu.P)

The Baord considered and approved following API to be manufactured using any other solvent as per new flow chart in placement of Methylen Chloride.

1. Clarithromycin (Eu.P)
2. MoxifloxacinHCl (Eu.P)
3. Levetiracetam (USP)
4. Drotaverine HCl (In-house)
5. Cefradine (USP)

Item-III: **GRANT OF RENEWAL OF DML.**

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Cortex Pharmaceuticals, Plot No. 16-A, SS-4, National Industrial Zone, Rawat. DML No.000826 (Formulation) Period: Commencing on30-07-2020& ending on29-07-2025.	**12-02-2021**	**Good**	1) Dr. Hafsa Karam Elahi, Additional Director (QA &LT), DRAP, Islamabad. 2) Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad.
	Recommendations of the panel: Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the approval of renewal of license of M/s Cortex Pharmaceuticals SS4, Plot No.16-A, National Industrial Zone, Rawat, Islamabad." **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of renewal of (DML No. 000826) by way of formulation in the name of M/s Cortex Pharmaceuticals, Plot No. 16-A, SS-4, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period commencing on30-07-2020& ending on29-07-2025 for the following sections:- i. Liquid External Preparation (General) Section ii. Liquid Repacking Section			
2.	M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No. 3, Street No. S-5, National Industrial Zone, Rawat. DML No. 000810 (Formulation) Period: Commencing on02-04-2020& ending on01-04-2025.	**16-02-2021** **&** **25-02-2021**	**Good**	1) Mr. Akhtar Abbas, Additional Director (QA &LT), DRAP, Islamabad. 2) Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad. 3) Ms. ZunairaFaryad, Assistant Director (Lic), DRAP, Islamabad.

	Recommendations of the panel: "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the following 1 new/additional & renewal (of the existing 5 sections) of DML No.000810 (By way of formulation) of M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No.3 Street No. S-5, National Industrial Zone Rawat, Islamabad: **New Additional Sections** 1) Tablet Psychotropic (New Section for Approval) **Existing Sections** 1) Tablet (General) Section 2) Cream/Ointment/Gel (General) Section 3) Capsule Section (Cephalosporin) 4) Dry Suspension Section (Cephalosporin) 5) Capsule (General) Section **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of renewal of (DML No. 000810) by way of formulation in the name of M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No. 3, Street No. S-5, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period commencing on 02-04-2020& ending on01-04-2025 for the following sections:- **Sections (5)** 1) Tablet (General) Section 2) Cream/Ointment/Gel (General) Section 3) Capsule Section (Cephalosporin) 4) Dry Suspension Section (Cephalosporin) 5) Capsule (General) Section			
3.	M/s MedisearchPharmacal (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore. DML No. 000549 (Formulation) Period: Commencing on17-08-2019& ending on16-08-2024.	**22-02-2021**	**Good**	1) Dr. Farzana Chowdhary, Expert Member. 2) Mr. Azhar Jamal Saleemi, Chief Drug Inspector, Punjab. 3) Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: "Keeping in view the facilities like building, HVAC system, Equipment, Instrument, Machinery, Personnel. Documentation, Quality Control and testing facilities, the panel of inspectors is of the opinion to **recommend** the renewal of Drug Manufacturing License to M/s MedisearchPharmacal (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore bearing Lic.No.000549, and regularization of the following approved sections:			

	1) Oral Liquid (General) Section (Renewal & Regularization) 2) External Preparation Section. (Renewal & Regularization) 3) Cream/Ointment (General) Section (Renewal & Regularization) 4) Tablet (General) Section. (Renewal) 5) Capsule (General) Section. (Renewal) 6) Dry Powder Suspension (General) Section. (Renewal) 7) Dry Powder Suspension (Cephalosporin) Section. (Renewal) 8) Capsule (Cephalosporin) Section. (Renewal)" **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of renewal of (DML No. 000549) by way of formulation in the name of M/s Medisearch Pharmacal (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahoreon the recommendations of the panel of experts for the period commencing on17-08-2019& ending on16-08-2024 for the following sections:- **Sections (8)** 1) Oral Liquid (General) Section (Renewal & Regularization) 2) External Preparation Section. (Renewal & Regularization) 3) Cream/Ointment (General) Section (Renewal & Regularization) 4) Tablet (General) Section. (Renewal) 5) Capsule (General) Section. (Renewal) 6) Dry Powder Suspension (General) Section. (Renewal) 7) Dry Powder Suspension (Cephalosporin) Section. (Renewal) 8) Capsule (Cephalosporin) Section. (Renewal)"			
4.	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street No. SS-2, National Industrial Zone, Rawat. DML No. 000698 (Formulation) Period: Commencing on08-12-2020 & ending on 07-12-2025.	**31-03-2021** **&** **08-04-2021**	**Good**	1) Mr. Akhtar Abbas, Additional Director (QA &LT), DRAP, Islamabad. 2) Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad. 3) Mr. Muhammad Usman, Assistant Director (Lic), DRAP, Islamabad.
	Recommendations of the panel: "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the approval of renewal of DML (DML#000698 by way of Formulation) of M/s Inshal Pharmaceutical Industries, Plot No.2, Street SS-2, National Industrial Zone, Rawat with following approved sections for manufacturing of veterinary drugs." 1. Oral Powder (Penicillin). 2. Liquid Injection (Penicillin). 3. Oral Powder (General)			

4. Liquid Injection (General).
5.Liquid Section (General)."

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000698) by way of formulation in the name of M/s Inshal Pharmaceutical Industries, Plot No. 2, Street No. SS-2, National Industrial Zone, Rawaton the recommendations of the panel of experts for the period commencing 08-12-2020 & ending on 07-12-2025 for the following sections:-

Sections (5)

1. Oral Powder (Penicillin).
2. Liquid Injection (Penicillin).
3. Oral Powder (General)
4. Liquid Injection (General).
5. Liquid Section (General)."

5.	M/s Max Pharmaceuticals, Plot No. 12, Street No. N-7, National Industrial Zone, Rawat. DML No. 000671 (Formulation) Period: Commencing on15-10-2019& ending on14-10-2024.	**15-02-2021** **&** **09-04-2021**	**Good**	1) Dr. Hafsa Karam Elahi, Additional Director (QA &LT), DRAP, Islamabad. 2) Mr. Arif Chaudhary, DD (QA), DRAP, Islamabad. 3) Mr. Khalid Mahmood, Federal Inspector of Drugs, DRAP, Islamabad.

Recommendations of the panel:

"Keeping in view the above facts, detailed visits of facility and supporting documents provided by the company, the panel unanimously **recommended** M/s Max Pharmaceuticals, Plot No.12, Street No.N-7, National Industrial Zone, Rawat, Rawalpindi for renewal of Drug Manufacturing License No.000671 (by way of formulation) (w.e.f. 15th October, 2019 to 14th October, 2024) for above mentioned seven sections only as per layout plan and letters of approval of sections."

1) Tablet (General) Section.
2) Capsule (General) Section.
3) Semi Solid (Cream/Ointment) (General) Section.
4) Liquid Syrup Section.
5) Capsule (Cephalosporin) Section.
6) Dry Powder for Suspension (Cephalosporin) Section.
7) Dry Powder for Injection (Cephalosporin) Section.

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000671) by way of

	formulation in the name of M/s Max Pharmaceuticals, Plot No. 12, Street No. N-7, National Industrial Zone, Rawaton the recommendations of the panel of experts for the period commencing on15-10-2019& ending on14-10-2024 for the following sections:- **Sections (7)** 1) Tablet (General) Section. 2) Capsule (General) Section. 3) Semi Solid (Cream/Ointment) (General) Section. 4) Liquid Syrup Section. 5) Capsule (Cephalosporin) Section. 6) Dry Powder for Suspension (Cephalosporin) Section. 7) Dry Powder for Injection (Cephalosporin) Section.			
6.	M/s Gallop Water Sciences, Plot No. 404, Sunder Industrial Estate, Lahore. DML No. 000817 (Formulation) Period: Commencing on 23-06-2020 & ending on 22-06-2025.	**24-02-2021**	**Good**	1) Mr. Shamoon Choudhary, Expert Member, DRAP. 2) Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3) Ms. Mehwish Jamil Butt, Assistant Director, DRAP.
	Recommendations of the panel: "Keeping in view the facilities like Building, HVAC System, Equipment. Instrument, Machinery, Personnel, Documentation, Quality Control and testing facilities, the panel of inspectors is of the opinion to **recommend** the renewal of Drug Manufacturing License to M/s Gallop Water Sciences, Sunder Industrial Estate Lahore bearing Lic No.000817 and regularization of following approved sections: i. Large Volume Parenteral (LVP) ii. Small Volume Parenteral (SVP) iii. Ampoules Section (Liquid injection in LDPE packing)." **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of renewal of (DML No. 000817) by way of formulation in the name of M/s Gallop Water Sciences, Plot No. 404, Sunder Industrial Estate, Lahore.on the recommendations of the panel of experts for the period commencing on 23-06-2020 & ending on 22-06-2025 for the following sections:- **Sections (3)** i. Large Volume Parenteral (LVP) ii. Small Volume Parenteral (SVP)			

	iii. Ampoules Section (Liquid injection in LDPE packing)."			
7.	M/s Jenner Pharmaceuticals (Pvt) Ltd, Plot No.3, M-2, Pharmazone, 26-Km, Lahore Sharaqpur Road, District Sheikhupura. DML No. 000823 (Formulation) Period: Commencing on 30-07-2020 & ending on29-07-2025.	**23-12-2020**	**Good**	1) Dr. Farzana Chowdhary, Expert Member. 2) Mr. Azhar Jamal Saleemi, Chief Drug Inspector, Punjab. 3) Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: "Keeping in view the findings of the inspection, and commitment of the management for future improvement, the members of the panel are of the opinion to **recommend**the grant of renewal of DML (000823) by way of Formulation to M/s Jenner Pharma, 26-Km, Lahore Shariqpur Road, District Sheikhupura." **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of renewal of (DML No. 000823) by way of formulation in the name of M/s Jenner Pharmaceuticals (Pvt) Ltd, Plot No.3, M-2, Pharmazone, 26-Km, Lahore Sharaqpur Road, District Sheikhupura on the recommendations of the panel of experts for the period commencing on 30-07-2020 & ending on 29-07-2025 for the following sections: i. Tablet (General) Section. ii. Capsule (General) Section. iii. Dry Powder Suspension (General) Section. iv. Sachet (General) Section.			
8.	M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore. DML No. 000621 (Basic Manufacture) Period: Commencing on 30-07-2017& ending on 29-07-2022.	**13-07-2020**	**Good**	1) Dr. Farzana Chowdhary, Expert Member. 2) Chief Drug Controller, Member Central Licensing Board. 3) Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: "Keeping in view, the above-mentioned facility, equipments/Machines and the Process Flow the panel of experts is the opinion to **recommend**the renewal of DML (000621) to M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore by way of Basic Manufacture." **Decision of the Central Licensing Board in 280th meeting**			

	The Board considered and approved the grant of renewal of (DML No. 000621) by way of Basic Manufacture in the name of M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahoreon the recommendations of the panel of experts for the period commencing on 30-07-2017& ending on 29-07-2022.			
9.	M/s ISIS Pharmaceuticals& Chemical Works, Plot No. 25/1-3, Sector 12-C, North Karachi Industrial Area Karachi. DML No.000126 (Formulation) **Tenure**: Commencing on 02-10-2020 &ending on 01-10-2025.	**12-03-2021 & 15-03-2021.**	**Good**	1) Additional Director (E& M) DRAP, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, AD, DRAP, Karachi.

Recommendations of the panel: -

Based on the people met, documents reviewed, and observations made during the inspection, the panel unanimously **recommends** the grant of renewal of Drug Manufacturing License No. 000126 by way of formulation, regularization and grant of additional sections as follows:

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Sterile Ophthalmic Drops (General)
3.	Liquid Syrup (General)	4.	Ophthalmic Ointment (General)
5.	Dry Powder Suspension (General)	6.	Cream/Ointment (Steroids)
7.	Capsule (General)	8.	Tablet (Hormone)
9.	Cream/Ointment/Gel (Hormone)	10.	Sterile Liquid Injection (Hormone)
11.	Liquid Injection SVP (Glass Vial/ampoule)	12.	Liquid Infusion (General) (PP)
13.	Cream/Ointment/Gel (General)	14.	Capsule (Cephalosporin)
15.	Tablet (Cephalosporin)	16.	Dry Powder Injection (Cephalosporin)
17.	Dry Powder Suspension (Cephalosporin)	18.	Dry Powder Suspension (Penicillin)
19.	Tablet (Penicillin)	20.	Capsule (Penicillin)
21.	Liquid Injection (psychotropic)	22.	Tablet (Psychotropic)
23.	Liquid ORS (General)	24.	Powder ORS (General)
25.	Tablet Bolus (Veterinary)	26.	Liquid Syrup (Veterinary)
27.	Dry Powder Suspension (Veterinary)	28.	Liquid Injection (Veterinary)
29.	Injectable Hormone (Veterinary section)	30.	Enema
Additional/New Section			
1.	Liquid External Preparation (General)-New		**********

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000126) by way of Formulation in the name of M/s ISIS Pharmaceuticals& Chemical Works, Plot No. 25/1-3, Sector 12-C, North Karachi Industrial Area Karachion the recommendations of the panel of experts for the period commencing on 02-10-2020 &ending on 01-10-2025 for following sections :

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Sterile Ophthalmic Drops (General)
3.	Liquid Syrup (General)	4.	Ophthalmic Ointment (General)
5.	Dry Powder Suspension (General)	6.	Cream/Ointment (Steroids)
7.	Capsule (General)	8.	Tablet (Hormone)
9.	Cream/Ointment/Gel (Hormone)	10.	Sterile Liquid Injection (Hormone)
11.	Liquid Injection SVP (Glass Vial/ampoule)	12.	Liquid Infusion (General) (PP)
13.	Cream/Ointment/Gel (General)	14.	Capsule (Cephalosporin)
15.	Tablet (Cephalosporin)	16.	Dry Powder Injection (Cephalosporin)
17.	Dry Powder Suspension (Cephalosporin)	18.	Dry Powder Suspension (Penicillin)
19.	Tablet (Penicillin)	20.	Capsule (Penicillin)
21.	Liquid Injection (psychotropic)	22.	Tablet (Psychotropic)
23.	Liquid ORS (General)	24.	Powder ORS (General)
25.	Tablet Bolus (Veterinary)	26.	Liquid Syrup (Veterinary)
27.	Dry Powder Suspension (Veterinary)	28.	Liquid Injection (Veterinary)
29.	Injectable Hormone (Veterinary section)	30.	Enema

10	M/s Opal Laboratories (Pvt) Ltd LC-41, L.I.T.E. Landhi Karachi. DML No. 000046 (Formulation) **Tenure**: Commencing on 01-06-2020&ending on31-05-2025.	**24-02-2021**	**Good**	1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi 2) Area FID, DRAP, Karachi. 3) Mr. Affan Ali, AD, CDL, Karachi.

Recommendations of the panel: -

Following are the observations and recommendations of the panel members:

- The firm is constructed as per the approved layout plan/amendments

vide DRAP, Islamabad letter no. F.2-1/2003-Lic (Pt) (Vol-I) dated 18th May, 2020.

- Based on the observations, documents reviewed, personnel met and commitment of the firm for continuous up-gradation and intention for export of products to various countries, the panel recommends the grant of renewal of DML No. 000046 (by way of Formulation) and regularization of manufacturing facility to the firm M/s Opal Laboratories Pvt Ltd, with following sections:

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Urodonal Granules	4.	Ophthalmic/Eye Drops (General)
5.	Ointment/Cream/Gel (General)	6.	Dry Powder Suspension (General)
7.	Oral Liquid/Syrup (General)	8.	Sachet (General)
9.	Tablet (Cephalosporin)	10.	Capsule (Cephalosporin)
11.	Dry Powder Suspension (Cephalosporin)	12.	**********

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000046) by way of Formulation in the name of M/s Opal Laboratories (Pvt) Ltd LC-41, L.I.T.E. Landhi Karachi..on the recommendations of the panel of experts for the period commencing on 01-06-2020&ending on31-05-2025.for following sections :

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Urodonal Granules	4.	Ophthalmic/Eye Drops (General)
5.	Ointment/Cream/Gel (General)	6.	Dry Powder Suspension (General)
7.	Oral Liquid/Syrup (General)	8.	Sachet (General)
9.	Tablet (Cephalosporin)	10.	Capsule (Cephalosporin)
11.	Dry Powder Suspension (Cephalosporin)	12.	**********

11	M/s. Abbott Laboratories Pakistan Limited, Opposite Radio Pakistan Transmission Centre Hyderabad Road Karachi. DML No. 000001 (Formulation) **Tenure:** Commencing on 31-03-2020& ending on 30-03-2025.	**04-02-2021**	**Good**	1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi. 2) Area FID, DRAP, Karachi. 3) CDI, Sindh, Karachi.

Recommendation of the panel:

Based on the people met, areas visited and commitment of the Firm's management for

continuous improvement of personnel, processes and facilities, the panel is of the view to **recommend**:

- Renewal of Drug Manufacturing License (By way of Formulation) No. 000001 to the firm M/s Abbott Laboratories Pakistan Ltd, situated Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi, with following sections:

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Cream/Gel (General)
3.	Granules (General)	4.	Liquid (General)
5.	Injectable (General0	6.	**********

- Grant Amendments in lay out plan for Microbiology Laboratory, IBC washing area and Research and Development Laboratory.
- **Re-inspection for renewal of Capsule Section subject to completion of installation/qualification of packing lines in this section.**

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000001) by way of Formulation in the name of M/s Abbott Laboratories Pakistan Limited, Opposite Radio Pakistan Transmission Centre Hyderabad Road Karachi..on the recommendations of the panel of experts for the period commencing on 31-03-2020& ending on 30-03-2025.for following sections :

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Cream/Gel (General)
3.	Granules (General)	4.	Liquid (General)
5.	Injectable (General0	6.	**********

The Board deffered the renewal of Capsule (General) section on the recommendation of panel of experts and also decided that theLicensee shall rectify the observations made during the inspection within a period which shall not be less than one month and more than three months from the receipt of orders in this regards and during this period the manufacturing in the premises shall remain suspended as required under Rule 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

12	M/s Vetz Pharmaceutical (Pvt) Ltd, Q-1, SITE, Kotri Sindh. DML No. 000813 (Formulation) **Tenure**. Commencing on 22-06-2020 & ending on 21-06-2025.	**09-03-2021.**	**Good**	1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, AD, DRAP, Karachi.
	Recommendation of the panel:			

Based on the observations, documents reviewed, personnel met and commitment of the firm for continuous up-gradation and intention for export of products to various countries, the panel **recommends** as follows:

c) Grant of renewal of DML No. 000813 (by way of Formulation) to the firm M/s Vetz Pharmaceuticals Pvt Ltd, with following sections:

Sr #	Name of Section	Sr. #	Name of Section
1.	Oral Powder (Veterinary)	2.	Oral Liquid (Veterinary)
3.	Aerosol	4.	Sterile Liquid Vial Injection (Veterinary)
5.	Sterile Powder Vial Injection (Veterinary)	6.	Sterile Liquid Vial Injection Penicillin (Veterinary)
7.	Oral Powder (Penicillin) (Veterinary)		**********

d) Grant of Additional Section namely Injectable (Hormone) (New)

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000813) by way of Formulation in the name of M/s Vetz Pharmaceutical (Pvt) Ltd, Q-1, SITE, Kotri Sindh.on the recommendations of the panel of experts for the period commencing on 22-06-2020& ending on21-06-2025.for following sections :

Sr #	Name of Section	Sr. #	Name of Section
1.	Oral Powder (Veterinary)	2.	Oral Liquid (Veterinary)
3.	Aerosol	4.	Sterile Liquid Vial Injection (Veterinary)
5.	Sterile Powder Vial Injection (Veterinary)	6.	Sterile Liquid Vial Injection Penicillin (Veterinary)
7.	Oral Powder (Penicillin) (Veterinary)		**********

13	M/s Scilife Pharma (Pvt) Ltd, FD-57/58-A2, Korangi Industrial Area, Karachi. DML No. 000837 (Formulation) **Tenure**. Commencing on 01-06-2021 & ending on 31-05-2021.	**01-03-2021**	**Good**	1) Additional Director CDL, DRAP, Karachi. 2) Area FID, DRAP, Karachi. 3) Ms. Sanam Kausar, AD, DRAP, Karachi.

Recommendations of the panel:

Based on the people met, documents reviewed, and observations made during the inspection, the panel **recommends** the grant of renewal of Drug Manufacturing License No. 000837 by way of formulation for following sections:

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Ointment/Cream (General)	4.	Sachet (General)
5.	Dry Powder Inhaler (General)	6.	Dry Powder Suspension (General)

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000837) by way of Formulation in the name of M/s Scilife Pharma (Pvt) Ltd, FD-57/58-A2, Korangi Industrial Area, Karachi.on the recommendations of the panel of experts for the period commencing on 01-06-2021 & ending on 31-05-2026.for following sections :

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Ointment/Cream (General)	4.	Sachet (General)
5.	Dry Powder Inhaler (General)	6.	Dry Powder Suspension (General)

14	M/s. Otsuka Pakistan Limited, F/4-9, H.I.T.E. District Lasbella, Baluchistan. DML No. 000281 (Formulation) **Tenure**. Commencing on 21-05-2019 & ending on 20-05-2024. **Sections:** 1) Plabottle (plastic bottles) infusion section 500ml (LVP). 2) SVP glass vials. 3) SVP- Plabottle 4) Aseptically filled injection Plabottle (Plastic bottles)	**17-03-2021.**	**Good**	1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi. 2) Director DTL, Govt of Baluchistan. 3) FID, DRAP, Quetta.

Recommendations of the panel:

The panel inspected the firm in detail including the manufacturing areas, stores and QC Lab and found facility as per their approved layout plan. The facility has been provided with sufficient necessary machineries, utilities and equipment as per required guidelines, necessary

	documents regarding QC and QA, HVAC and qualification of machines were seen in place. The firm is also involved in exporting their formulation in Kenya, Afghanistan and in process to obtaining the registration in Central Asia Countries. Based on the documents reviewed and observation made during the inspection the panel unanimously **recommends** the grant of renewal of Drug Manufacturing License No. 000281 by way of formulation. **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of renewal of (DML No. 000281) by way of Formulation in the name of M/s Otsuka Pakistan Limited, F/4-9, H.I.T.E. District Lasbella, Baluchistan.on the recommendations of the panel of experts for the period commencing on 21-05-2019 & ending on 20-05-2024..for following sections : 1. Plabottle (plastic bottles) infusion section 500ml (LVP). 2. SVP glass vials. 3. SVP- Plabottle 4. Aseptically filled injection Plabottle (Plastic bottles)			
15	M/s. Jfrin Pharmaceutical Laboratories, Plot No. 16,17 & 20, H.I.T.E. Balochistan. DML No. 000580 (Formulation) Tenure. Commencing on 24-06-2020 and ending on 23-06-2025. **Sections :** 1) Bolus (Veterinary) 2) Powder Injection (Veterinary) 3) Powder Premixes (Veterinary) 4) Liquid Injectable (Veterinary)	**17-02-2021**	**Good**	1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi 2) FID, DRAP, Quetta. 3) Assistant Director, DRAP, Quetta.
	Recommendations of the panel: After detailed examination and inspection of operating procedures SOPs and personal met equipments checked panel in view recommend the renewal of Jafrin Pharma as it is functional and operational at satisfactory factory GMP however it's the view of **panel the management should regularized its layout from CLB as soon as possible.** **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of renewal of (DML No. 000580) by way of Formulation in the name of M/s Jfrin Pharmaceutical Laboratories, Plot No. 16,17 & 20, H.I.T.E. Balochistan.on the recommendations of the panel of experts for the period			

	commencing on 24-06-2020 and ending on 23-06-2025.for following sections : 1) Bolus (Veterinary) 2) Powder Injection (Veterinary) 3) Powder Premixes (Veterinary) 4) Liquid Injectable (Veterinary)			
16	M/s. Gelcaps Pakistan Limited, Plot No. B-43, H.I.T.E. District Lasbella, Baluchistan. DML No. 000282 (Semi-Basic) Tenure. Commencing on 20-06-2019 and ending on 19-06-2024. **Sections :** 1) Empty Hard Gelatin Capsule Shells.	**17-02-2021**	**Good**	1) Director DTL, Government of Baluchistan. 2) FID, DRAP, Quetta. 3) Assistant Director, DRAP, Quetta.
	Recommendations of the panel: During Inspection Panel found optional level of compliance in following of SOPs and GMP some documents were revived and checked critically. Based on observation made by panel it is concluded to **recommend** the renewal of License by way of semi basic No. 000282 form 2019 to 2024. **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of renewal of (DML No. 000282) by way of Semi-Basic Manufacture in the name of M/s Gelcaps Pakistan Limited, Plot No. B-43, H.I.T.E. District Lasbella, Baluchistan.on the recommendations of the panel of experts for the period commencing on 20-06-2019 and ending on 19-06-2024.for manufacture of empty hard gelatin capsule shells.			
17	M/s. Bosch Pharmaceuticals (Pvt) Ltd, Plot No. 209, Sector 23, Korangi Industrial Area, Karachi. DML No. 000707 (Formulation) Tenure. Commencing on14-06-2021 and ending on 13-06-2026. **Sections :** 1) Lyophilization (General)	**13-04-2021**	**Good**	1) Director DTL, Karachi 2) FID, DRAP, Karachi. 3) Mr. Awais Ahmed, Assistant Director, CDL, Karachi.

	2) Injectable (Penicillin) 3) Cream/Ointment/Gel (General) 4) Sterile Ophthalmic/Ear Drops and Nebulizer 5) Sterile Injectable (Ampoule) 6) Sterile Infusion (General) -I 7) Sterile Injectable Biotech for liquid lypphillized powder 8) Sterile Infusion (General) -II 9) Quality Control Laboratory.			

Recommendations of the panel:

Panel inspected the firm in detail and observed that the manufacturing section, Raw material store (Penicillin), Q.C Laboratory, Water Treatment Plant, Quality Assurance System etc and critical documents Processes, SOPs and BMRs followed the written procedures, in general. HVAC System seen installed and observed operational in all the production sections. Firm has adequate technical persons with relevant qualifications available on site, that were observed well conversant with the GMP/cGMP concepts. The firm is exporting Products to around 05 countries at present.

Based on the people met, documents reviewed and observation made during the inspection, panel **recommends** the renewal of DML for the sections as mentioned in the aforementioned DRAP letter. It is to further submit that section Lyophilization (General) mentioned on the serial No. 1 and 7 are same. **On physical verification it is to confirm that section mentioned at serial 7 may be read as Lyophilization (General) as stated in serial No. 1.**

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000707) by way of Formulation in the name of M/s Bosch Pharmaceuticals (Pvt) Ltd, Plot No. 209, Sector 23, Korangi Industrial Area, Karachi.on the recommendations of the panel of experts for the period commencing on 14-06-2021 and ending on 13-06-2026.for following sections :

1) Lyophilization (General)
2) Injectable (Penicillin)
3) Cream/Ointment/Gel (General)
4) Sterile Ophthalmic/Ear Drops and Nebulizer
5) Sterile Injectable (Ampoule)
6) Sterile Infusion (General) -I
7) Sterile Infusion (General) -II

The Board deferred the following section for further clarification in the light of recommendation of

	panel of experts. 1) Sterile Injectable Biotech for liquid lypphillized powder			
18	M/s Schazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalalwala Stop, 20-KM, Lahore-Jaranwala Road, District, Sheikhupura. DML No. 000019 (Formulation) Tenure. Commencing on11-06-2019 and ending on 10-06-2024.	**26-02-2021**	**Good**	1) Dr. Ikram Ul Haq, Member CLB. 2) Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 3) Mrs. Majida Mujahid, Area Federal Inspector of Drugs.

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 personnel and documentation etc., the panel recommends the Renewal of Drug Manufacturing License No. 000019 by way of (Formulation) to M/s Schazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalalwala Stop, 20-KM, Lahore-Jaranwala Road, District, Sheikhupura for following sections:-

1. General Solid Oral Dosage form for Tablet, Capsule & Sachet.
2. Oral Liquid Section for suspension and Syrup.
3. (Ampoule) General & Psychotropic Injectable Section.
4. Ophthalmic & Nasal Drops Section.
5. Tablet, Capsule and Oral Dry Powder Suspension (Cephalosporin).

Note: It is submitted that following sections in the inspection report are approved with following nomenclature as per record of Licensing Division at page 89/Corr.

In Inspection Report.	*As per Licensing Division.*
1. Oral Liquid Section for Suspension & Syrup. ***2. Ampoule (General & Psychotropic) Injectable Section.***	***1. Oral Liquid Syrup.*** ***2. Liquid Ampoule.***

It is further submitted that Sachet Section in inspection report is not approved as per record of Licensing Division as it been checked from last renewal letter, from layout plan submitted by firm with renewal application and from panel inspection letter for renewal of DML.

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000019) by way of Formulation in the name of M/ Schazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalalwala Stop, 20-KM, Lahore-Jaranwala Road, District, Sheikhupura.on the recommendations of the panel of experts for the period commencing on 11-06-2019 and ending on 10-06-2024..for following sections :

	1. Tablet (General) 2. Capsule (General) 3. Sachet (General) 4. Oral Liquid Section for suspension and Syrup. 5. (Ampoule) General & Psychotropic Injectable Section. 6. Ophthalmic & Nasal Drops Section. 7. Tablet, Capsule and Oral Dry Powder Suspension (Cephalosporin). The Board defferd following sections for clarification 1. Oral Liquid Section for Suspension & Syrup. 2. Ampoule (General & Psychotropic) Injectable Section. 3. Sachet Section			
19	M/s Searle IV Solutions (Pvt) Ltd, 1.5 – KM, Manga Raiwind Road, Manga Mandi, Distt, Lahore. DML No. 000586 (Formulation) Tenure: Commencing on 06-10-2020 and ending on 05-10-2025.	**02-03-2021**	**Good**	1) Dr. Zaka Ur Rehman, COO, PDTRC, Lahore. 2) Mrs. Majida Mujahid, Area Federal Inspector of Drugs. 3) Ms. Maham Misbah, Assistant Director, DRAP.
	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 personnel and documentation etc., the panel **recommends** the Renewal of Drug Manufacturing License No. 000586 by way of (Formulation) to M/s Searle IV Solutions (Pvt) Ltd, 1.5 – KM, Manga Raiwind Road, Manga Mandi, Distt, Lahore for following sections:- 1. Large Volume Parenteral Section. 2. Oral Liquid Section. 3. Tablet (General) Section. 4. Capsule (General) Section. 5. Sachet (General) Section. 6. Dry Suspension (General) Section. 7. Liquid injectable Vial (General) Section. 8. Liquid Injectable Ampoule (General) Section. 9. Cream Ointment (General) Section. 10. Eye Drops (General) Section. 11. Tablet Section (Psychotropic). 12. Aerosol (General). **Decision of the Central Licensing Board in 280th meeting** The Board considered and approved the grant of renewal of (DML No. 000586) by way of			

	Formulation in the name of M/s Searle IV Solutions (Pvt) Ltd, 1.5 – KM, Manga Raiwind Road, Manga Mandi, Distt, Lahoreon the recommendations of the panel of experts for the period commencing on 06-10-2020 and ending on 05-10-2025.for following sections : 1. Large Volume Parenteral Section. 2. Oral Liquid Section. 3. Tablet (General) Section. 4. Capsule (General) Section. 5. Sachet (General) Section. 6. Dry Suspension (General) Section. 7. Liquid injectable Vial (General) Section. 8. Liquid Injectable Ampoule (General) Section. 9. Cream Ointment (General) Section. 10. Eye Drops (General) Section. 11. Tablet Section (Psychotropic). 12. Aerosol (General).			
20	M/s Ras Pharmaceuticals 25-KM Lahore Road, Multan. DML No. 000821 (Formulation) Tenure: Commencing on 23-06-2020 and ending on 22-06-2025.	**10-03-2021**	**Good**	1) Dr. Farzana Chowdhary, Member. 2) Mr. Abdul Rashid Sheikh, Federal Inspector of Drugs, DRAP, Lahore. 3) Ms. Maham Misbah, Assistant Director, DRAP.
	<u>Recommendations of the panel:</u> "The facility was developed and constructed as per revised layout plan approved vide DRAP letter No.F.1-46/2010-Lic (Vol-I) dated 12-05-2020 and new layout for penicillins approved vide DRAP letter No.F.1-46/2010/Lic (Vol-I) dated 14-04-2017. Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control and Microbiology Laboratory, testing facilities, technical personel met and documentation reviewed, the panel of inspectors recommend the renewal of Drug Manufacturing License by way of Formulation to M/s Ras Pharmaceuticals 25-KM Lahore Road, Multan for the following three sections: - 1. Oral Liquids (Antibiotic) (Vet). 2. Oral Powders (General) (Vet). 3. Oral Powders (General antibiotic) Vet. The panel of inspectors also recommend the grant of following additional sections: 1. Oral Dry Powder (Penicillin) (Vet). 2. Dry Powder Injection (Penicillin) (Vet). 3. Liquid Injection (Penicillin) (Vet). 4. Liquid Injection (General) (Vet). 5. Warehouse (Revised).			

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000821) by way of Formulation in the name of M/s Ras Pharmaceuticals 25-KM Lahore Road, Multan.on the recommendations of the panel of experts for the period commencing on 23-06-2020 and ending on 22-06-2025.for following sections :

1. Oral Liquids (Antibiotic) (Vet).
2. Oral Powders (General) (Vet).
3. Oral Powders (General antibiotic) Vet.

21	M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard West Wharf, Karachi. DML No.000017 (Formulation) **Tenure**: Commencing on 31-03-2020&ending on 30-03-2025.	**29-03-2021**	**Good**	1) CDI, Govt of Sindh Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Ms. SanamKausar, AD, DRAP, Karachi.

Recommendations of the panel: -

"Keeping in view the people met, areas visited and commitment of the firm for continuous improvement the panel **recommends** the regularization of manufacturing facility as per approved layout and renewal of Drug Manufacturer license No. 000017 (By way of Formulation) for following the approved sections:

S. No.	Sections	S. No.	Sections
1.	Topicals General 01 (Ointment/Cream/Gel)	2.	Topicals General 02 (Ointment/Cream&Gel)
3.	Topicals General 03(Lotion)	4.	Eye Ointment Ophthalmic area
5.	Ear Drops	6.	Spansules area (Including NPS)
7.	Oral Powder Area (Sachet)	8.	Ware House
9.	Quality Control Lab	10.	**********

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000017) by way of Formulation in the name of M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard West Wharf, Karachi..on the recommendations of the panel of experts for the period commencing on 31-03-2020&ending on 30-03-2025.for following sections :

S. No.	Sections	S. No.	Sections
1.	Topicals General 01 (Ointment/Cream/Gel)	2.	Topicals General 02 (Ointment/Cream&Gel)
3.	Topicals General 03(Lotion)	4.	Eye Ointment Ophthalmic area

	5.	Ear Drops	6.	Spansules area (Including NPS)	
	7.	Oral Powder Area (Sachet)	8.	Ware House	
	9.	Quality Control Lab	10.	**********	

22	M/s. Abbott Laboratories Pakistan Limited, Plot No. 13, Sector 20, Korangi Industrial Area, Karachi. DML No. 000004 (Formulation) **Tenure**: Commencing on 31-03-2020 &ending on 30-03-2025. **Section (01)** 1. Liquid Syrup (General)	**13-04-2021**	**Good**	1) CDI, Govt of Sindh Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Ms. Sidra, AD, DRAP, Karachi.

Recommendations of the panel: -

"Based on the stated facts and observations the panel unanimously **recommended** as follows:

Grant of renewal of DML No. 000004 (Formulation) for the next five years and the amendments made in layout plan for attaining better level of compliance may be regularized.

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000004) by way of Formulation in the name of M/s Abbott Laboratories Pakistan Limited, Plot No. 13, Sector 20, Korangi Industrial Area, Karachi.on the recommendations of the panel of experts for the period commencing on 31-03-2020 &ending on 30-03-2025.

23	M/s. Martin Dow Marker Limited, 07 Jail Road Quetta. DML No. 000028 (Formulation) **Tenure:** Commencing on 28-04-2020& ending on 27-04-2025.	**26th & 27th February 2021.**	**Good**	1) Director DTL, Govt. of Baluchistan. 2) Area FID, DRAP, Karachi. 3) Assistant Director, DRAP, Quetta.

Recommendation of panel :

"Based on above observations, documents received and people met the panel unanimously **recommend** the renewal of Drug Manufacturing License No. 000028 by way of formulation for next 05 years and regularization of all the section/ facilities mentioned in letter No. F4-2/86-Lic(Vol-VII), dated 10th February, 2021:

Sr. #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)

3.	Liquid Syrup (General)	4.	Dry Powder Suspension (General)
5.	Dry Powder Sachet (General)	6.	Ointment/Cream/Gel (General)
7.	Tablet (Psychotropic)	8.	Injectable Ampoule (General)
9.	Quality Control Laboratory	10.	Ware House (General)

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000028) by way of Formulation in the name of M/s Martin Dow Marker Limited, 07 Jail Road Quetta.on the recommendations of the panel of experts for the period commencing on 28-04-2020& ending on 27-04-2025 for following section :

Sr. #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Liquid Syrup (General)	4.	Dry Powder Suspension (General)
5.	Dry Powder Sachet (General)	6.	Ointment/Cream/Gel (General)
7.	Tablet (Psychotropic)	8.	Injectable Ampoule (General)
9.	Quality Control Laboratory	10.	Ware House (General)

24	M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E. Karachi. DML No. 000233 (Formulation) **Tenure**. Commencing on 10-07-2020 and ending on 09-07-2025.	**08-04-2021**	**Good**	1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, AD, DRAP, Karachi.

Recommendation of panel :

Keeping in view overall GMP compliance and positive intention towards improvement panel **recommends** the regularization of layout plan and renewal of DML No. 000233 (formulation) of the firm M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E. Karachi.

1. Tablet (General)	4. Liquid Syrup (General)	7. Tablet (Penicillin)
2. Capsule (Penicillin)	5. Dry Powder Suspension (Penicillin)	8. Oral Drops (Penicillin)
3. Warehouse (General)	6. Ware House (Penicillin)	9. Quality Control Laborato

The case is hereby submitted for consideration and orders of the Board, please.
Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000233) by way of Formulation in the name of M/ GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E. Karachi..on the recommendations of the panel of experts for the period commencing on 10-07-2020 & ending on 09-07-2025 for following section :

1. Tablet (General)	4. Liquid Syrup (General)	7. Tablet (Penicillin)
2. Capsule (Penicillin)	5. Dry Powder Suspension	8. Oral Drops (Penicillin)

		(Penicillin)		
	3. Warehouse (General)	6. Ware House (Penicillin)		9. Quality Control Laboratory.
25	M/s. Martin Dow Marker Limited, F-126, S.I.T.E. Karachi. DML No. 000043 (Formulation) **Tenure:** Commencing on 31-05-2020 & ending on 30-05-2025.	**25-03-2021.**	**Good**	1) CDI, Govt of Sindh Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Affan Ali, AD, CDL, Karachi.

Recommendation of panel :

"Keeping in view the good facilities of storage, production, quality control, sanitation and hygiene, HVAC operations, calibration, validation of all equipments and process water treatment and other utilities, the panel **recommends** the grant of Drug Manufacturing License, (000043) by way of formulation and regularization of manufacturing facility for following sections:

Sr. #	Name of Section	Sr. #	Name of Section
1.	Soft Gelatin Capsule	2.	Ware House
3.	Quality Control Lab	4.	**********

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000043) by way of Formulation in the name of M/s Martin Dow Marker Limited, F-126, S.I.T.E. Karachi.on the recommendations of the panel of experts for the period commencing on 31-05-2020 & ending on 30-05-2025.for following section :

Sr. #	Name of Section	Sr. #	Name of Section
1.	Soft Gelatin Capsule	2.	Ware House
3.	Quality Control Lab	4.	**********

26	M/s. Reckitt Benckiser Pakistan Limited.F-18, S.I.T.E. Karachi. DML No. 000022 (Formulation) **Tenure:** Commencing on 31-03-2020 and ending on 30-03-2025.	**17-03-2021.**	**Good**	1) Director DTL, Sindh. 2) Area FID, DRAP, Karachi. 3) Ms. Mahrukh Mughal, Assistant Director, CDL, Karachi.

Recommendation of panel :

Based on the people met, areas visited and commitment of the firm management towards continuous improvement of personnel, processes and facilities the panel is of the view to recommend regularization of facility as per approved layout plan and renewal of DML No. 000022(Formulation) to the firm with following sections :

1. Tablet General	4. Tablet (General) Disprol, Dispirin CV.
2. Oral Liquid Syrup Gaviscon (General)	5. External Preparation (General)
3. Warehouse (General)	6. Quality Control Lab

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000022) by way of Formulation in the name of M/s Reckitt Benckiser Pakistan Limited.F-18, S.I.T.E. Karachi..on the recommendations of the panel of experts for the period commencing on 31-05-2020 & ending on 30-05-2025.for following sections :

1. Tablet General	4. Tablet (General) Disprol, Dispirin CV.
2. Oral Liquid Syrup Gaviscon (General)	5. External Preparation (General)
3. Warehouse (General)	6. Quality Control Lab

27	M/s GlaxoSmithKline Pakistan Limited, Plot No. 5, Sector 21, Korangi Industrial Area, Karachi. DML No. 000248 (Formulation) **Tenure:** Commencing on 12-08-2020and ending on 11-08-2025.	**30-03-2021**	**V. Good**	1) CDI, Gov. of Sindh, Karachi. 2) Federal Inspector of Drugs, DRAP, Karachi. 1) Muhammad Usman, AD(Lic), DRAP, Islamabad.

Recommendations of the panel: -

Considering the overall site inspection - covering the facility visit, review of operations/processes/system, interaction with the site team and the review of related

documents and **M/s GlaxoSmithKline Pakistan Korangi** site was considered to be operating at a **'very good'** level of compliance with GMP guidelines as per Drugs Act, 1976 rules & regulations. The panel unanimously **recommends** the grant of renewal of their DML No. 000248 and regularization of current Layout for following sections.

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Liquid Ampoule SVP (General)
3.	Eye Drop (General)	4.	Tablet (Cephalosporin)
5.	Capsule (Cephalosporin)	6.	Dry Powder Suspension (Cephalosporin)
7.	Dry Powder Injection (Cephalosporin)	8.	Warehouse (General)
9.	QC Laboratory	10.	Warehouse (Cephalosporin)

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000248) by way of Formulation in the name of M/sGlaxoSmithKline Pakistan Limited, Plot No. 5, Sector 21, Korangi Industrial Area, Karachi...on the recommendations of the panel of experts for the period commencing on 12-08-2020and ending on 11-08-2025..for following sections :

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Liquid Ampoule SVP (General)
3.	Eye Drop (General)	4.	Tablet (Cephalosporin)
5.	Capsule (Cephalosporin)	6.	Dry Powder Suspension (Cephalosporin)
7.	Dry Powder Injection (Cephalosporin)	8.	Warehouse (General)
9.	QC Laboratory	10.	Warehouse (Cephalosporin)

28	M/s Genome Pharmaceuticals (Pvt) Ltd., 16/1, Phase-IV, Industrial Estate, Hattar,	**02-04-2021**	**Good**	1) Dr. Khalid Javed, Director DTL, Peshawar. 2) Federal Inspector of Drugs, DRAP, Peshawar. 3) Mr. Ziaullah, Assistant

	DML No.000454 (Formulation) Period: Commencing on 27-10-2020& ending on 26-10-2025. **Sections** 1. Tablet (General) 2. Capsule (General) 3. Sachet (General) 4. Tablet (Antibiotic/Quinolone) 5. Dry Powder Suspension (General) 6. Capsule (Cephalosporin) 7. Dry Powder Suspension (Cephalosporin)			Director, DRAP, Peshawar.

Recommendations of the panel:

Base on the observation made during inspection, the manufacturing, quality control and quality assurance facilities provided, the documentation, SOPs reviewed, the qualified staff employed in various department and keeping in view the compliance of the management to further improve the GMP compliance status of the firm with strengthened quality management system, the panel unanimously recommended the renewal of Drug Manufacturing License (DML) No. 0000454 by way formulation granted to M/s Genome Pharmaceuticals (Pvt) Ltd., 16/1, Phase-IV, Industrial Estate, Hattar"

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000454) by way of Formulation in the name of M/sGenome Pharmaceuticals (Pvt) Ltd., 16/1, Phase-IV, Industrial Estate, Hattar,.on the recommendations of the panel of experts for the period commencing on 27-10-2020& ending on 26-10-2025.for following sections :

1. Tablet (General)
2. Capsule (General)
3. Sachet (General)
4. Tablet (Antibiotic/Quinolone)
5. Dry Powder Suspension (General)
6. Capsule (Cephalosporin)
7. Dry Powder Suspension (Cephalosporin)

Item-IV: **MISCELLANEOUS CASES.**

Case No.2 WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTION BY M/S WERRICK PHARMACEUTICALS, PLOT NO. 216-217, I/10-3, INDUSTRIAL AREA, ISLAMABAD UNDER DML NO. 000340 BY WAY OF FORMULATION.

M/s Werrick Pharmaceuticals, Plot No. 216-217, I/10-3, Industrial Area, Islamabad under DML No. 000340 by way of Formulation has submitted request for withdrawal of following licensed section namely:

i. *Aerosol section*

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considered and acceded the request of the firm for withdrawal of following licensed sections of the firm :

i. Aerosol section

The Board also decided to inform the Drug Registration Board for necessary action at their end.

Case No.3 **APPLICATION FOR CHANGE OF NAME/TITLE OF SECTIONS FROM BULK POWDER TO ORAL POWDER.**

The Central Licensing Board in its 277th meeting held on 15-16, October, 2020 has approved and granted Drug Manufacturing License # 000921 (by way of Formulation) to M/s Haarolds Pharmaceuticals (Pvt) Ltd., Plot No.60-64/C, Small Industrial Estate, Bhimber, AJK with fowling sections

i. Bulk Powder Section–I (Veterinary) (General),
ii. Oral Liquid Section -I (Veterinary) (General),
iii. Bulk Powder Section–II (Veterinary) (General),
iv. Oral Liquid Section -I (Veterinary) (General),
v. Liquid Injection Section (Veterinary) General,
vi. Liquid Injectable Section (Veterinary) Penicillin,
vii. Bulk Dry Powder Section (Veterinary) Penicillin,
viii. Spray section (Veterinary) General."

Now the firm M/s Haarolds Pharmaceuticals Pvt Ltd has informed that world "Bulk" creates doubts and uncertainty. The firm also submitted extract of decision the Registration Board, DRAP in its 297th meeting held on 12-14 Jan 2021 an the registration Board has decided that registration letter will be issued after the change of title of Section from Licensing Division, DRAP. Therefore, the firm has requested to change the title and replace the word "Bulk" with "Oral" of following sections ;

i. Bulk k powder (Veterinary General)
ii. Bulk Powder Section-II (Veterinary General)
iii. Bulk Dry powder Section (Veterinary Penicillin).

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considered and approved the change name/ title of sections as under:

i. Oral powder (Veterinary General)
ii. Oral Powder Section-II (Veterinary General)
iii. Oral Dry powder Section (Veterinary Penicillin).

Case No. 4 CHANGE OF MANAGEMENT OF M/S MARTIN DOW MARKER LIMITED. F-126, SITE KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000043 (FORMULATION).

M/s Martin Dow Marker Limited, F-126, S.I.T.E, Karachi under DML No. 000043 by way of formulation has submitted request for change in management of the firm as per Form-29 & Form-A with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Current Management (Year 2020)	New Management as per Form-29 of SECP (Year 2021)
1. Mr. Ali Aamir S/o Abid Ali CNIC No.42301-0740467-9. 2. Syed Anis Ahmed Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870	1. Mr. Javed Ghulam Muhammad S/o Ghulam Muhammad CNIC No. 42201-0556944-9. 2. Mr. Ali Akhai S/o M. Jawed Akhai CNIC No. 42000-3326827-5. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870

Case is submitted for consideration and orders of the Board please

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/s Martin Dow Marker Limited, F-126, S.I.T.E, Karachi under DML No. 000043 way of Formulation as under;

Current Management (Year 2020)	New Management as per Form-29 of SECP (Year 2021)
1. Mr. Ali Aamir S/o Abid Ali CNIC No.42301-0740467-9. 2. Syed Anis Ahmed Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870	1. Mr. Javed Ghulam Muhammad S/o Ghulam Muhammad CNIC No. 42201-0556944-9. 2. Mr. Ali Akhai S/o M. Jawed Akhai CNIC No. 42000-3326827-5. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870

Case No. 5. CHANGE OF MANAGEMENT OF M/S MARTIN DOW MARKER LIMITED. 07 JAILROAD QUETTA UNDER DRUG MANUFACTURING LICENSE NO. 000028 (FORMULATION).

M/s Martin Dow Marker Limited, 07 Jail Road Quetta under DML No. 000028by way of formulation has submitted request for change in management of the firm as per Form-29 & Form-A with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Current Management (Year 2020)	New Management as per Form-29 of SECP (Year 2021)
1. Mr. Ali Aamir S/o Abid Ali CNIC No.42301-0740467-9. 2. Syed Anis Ahmed Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870.	1. Mr. Javed Ghulam Muhammad S/o Ghulam Muhammad CNIC No. 42201-0556944-9. 2. Mr. Ali Akhai S/o M. Jawed Akhai CNIC No. 42000-3326827-5. 3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870.

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/s Martin Dow Marker Limited, 07 Jail Road Quetta under DML No. 000028 (By way of Formulation) as under;

Current Management (Year 2020)	New Management as per Form-29 of SECP (Year 2021)
1. Mr. Ali Aamir S/o Abid Ali CNIC No.42301-0740467-9. 2. Syed Anis Ahmed Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1. 3. Syed Dawood S/o Syed Fasih-uddin	1. Mr. Javed Ghulam Muhammad S/o Ghulam Muhammad CNIC No. 42201-0556944-9. 2. Mr. Ali Akhai S/o M. Jawed Akhai CNIC No. 42000-3326827-5.

Ahmed passport No. LB9262870	3. Syed Dawood S/o Syed Fasih-uddin Ahmed passport No. LB9262870

Case No.6. **RENEWAL OF DML NO. 000473 (FORMULATION) OF M/S SHIFA LAB. (PVT) LTD, LAHORE.**

Drug Manufacturing License No. 000473 (Formulation) was issued to M/s Shifa Lab. (Pvt) Ltd, Lahore, due date of renewal of DML No. 000473 is 07-03-2020.

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

But, in this case the application for renewal of DML for the period 08-03-2020 to 07-03-2025 has not been received till date. Therefore, DML No. 000473 (Formulation) M/s Shifa Lab. (Pvt) Ltd, Lahore is no more valid. However, firm may apply a fresh under Rule 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Proceedings and Decision by the Central Licensing Board in 280th meeting

The Board considering the facts on the record and after thread bare deliberation decided that as the application for renewal of DML No. 000473 (Formulation) of M/s Shifa Lab. (Pvt) Ltd, Lahore is not made after the expiry of the period of validity of License, therefore, Drug Manufacturing License DML No. **000473** (Formulation) is no more valid and stands cancelled.

Case No.7. **RENEWAL OF DML NO. 000690 (FORMULATION) OF M/S MED ASIA PHARMACEUTICALS (PVT) LTD, RISALPUR.**

Drug Manaufacvrturing Licence No. 000690 (Formulation) was issued to M/s Med Asia Pharmaceuticals (Pvt) Ltd., Rislapur and due date for filling of renewal of Licence was 7th Novemner, 2020 for the period 7th December, 2020 to 6th November, 2025 which is received on 26th March, 2021 after the expiry of the validity of Licence.

It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *"if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the*

License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application".

Further more, Rule 5 (3) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 provisdes that if application for renewal of Licnce is made after the expiry of the period of the validity of Licence, it shall be treated as fresh application for the grant of licence.

Therefore, DML No. 000690 (Formulation) M/s Med Asia Pharmaceuticals (Pvt) Ltd., Rislapur is no more valid. However, firm may apply a fresh under Rule 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Proceedings and Decision by the Central Licensing Board in 280th meeting

The Board considering the facts on the record and after thread bare deliberation decided that as the application for renewal of DML No. 000690 (Formulation) of M/s Med Asia Pharmaceuticals (Pvt) Ltd., Risalpuris made after the expiry of the period of validity of License, therefore, Drug Manufacturing License DML No. **000690** (Formulation) is no more valid and stands cancelled.

Case No. 8. GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S. SPENCER & COMPANY (PVT) LTD, KARACHI

	M/s Spencer & Company (Pvt) Ltd, D-105, S.I.T.E, Karachi. DML No. 000272 (Formulation) **Period**: 19-07-2015 to 18-07-2020	**13-09-2018 & 18-10-2018**	**Un-satisfactory**	1. Mr. Syed Muied Ahmed, Member Central Licensing Borad. 2. Director DTL, Sindh Karachi. (**Not available**) 3. Director CDL, DRAP, Karachi 4. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - **Conclusion:-** 1. Firm has some penicillin, veterinary and Topical products which needs to be de-registered forthwith as no dedicated sections exist for them. 2. The available arrangements with the firm for production and quality control of their registered products needs massive up gradation / improvements especially in areas mentioned under pint no. 4 of Observations, for compliance with cGMP regulations. **Recommendations:-** 1. Penicillin, Topical products and veterinary products registered in the name of the firm			

	should be de-Registered forthwith as no dedicated sections exist for them. 2. Renewal of drugs manufacturing license (No. 000272 By way of Formulation) may be deferred till rectification of observations/ Improvements as identified by the panel. **Renewal not recommended**. **Decision by the Central Licensing Board in 267th meeting** The Board considered the case and decided to issue show cause notice under section 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. **Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.** The show cause notice dated 29th January, 2019 was issued to the firm. The reply of the show cause notice is not received. The firm is called for personal hearing vide letter dated 19th February, 2019. **Decision by the Central Licensing Board in 269th meeting** No person appeared on behalf of the company. Moreover, a letter was received on the date meeting from the Company wherein it was requested that they may be called in next meeting to respond the Showcause. The Board after perusal of letter decided to give final opportunity to the firm in the next meeting of the Central Licensing Board.

Firm is also called for personal hearing vide letter Dated : 27-08-2020.

Proceedings and Decision by the Central Licensing Board in 276th meeting:

Mr. Amjad But, Regulatory Manager of the firm appeared before the Board. He contended that time may be given for next meeting as management wanted to appear before the Board. After thorough discussion and deliberations, considering the background of the case and facts on record, the Board decided to direct that the Licensee shall rectify the observations made during the inspection within a period which shall not be less than one month and more than three months from the receipt of orders in this regards and during this period the manufacturing in the premises shall remain suspended as required under Rule 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Accordingly, letter dated 25th September 2020 was issued to the firm in compliance to the decision of the CLB.

No reply/intimation was received from the firm.

In the mean while the validity period of the DML No. 000272 (Formulation) commencing on 19-07-2015 & ending on 18-07-2020 has expired and no request for renewal of DML is received for the tenure and the said license is no more valid as under Rule 5 and 6 of the Drugs (L,R&A) Rules, 1976.

In the meanwhile ,M/s Atco Life Sciences (Pvt) Ltd, Plot No. D-105, S.I.T.E. Karachi,has submitted request for Change of Name / Title with fee of Rs.1,00,000/- on the said DML. The pre-requisite documents of the change of name / title and management are as under: -

i. Change of Name/Title.

Current Title as per Form-29 & Form-A Year 2020	New Title as per Form-29 Year 2020
M/s Spencer & Company (Pvt) Ltd, Plot No. D-105, S.I.T.E. Karachi	M/s Atco Life Sciences (Pvt) Ltd, Plot No. D-105, S.I.T.E. Karachi

ii. Change of Management.

Current Management as per Form-29 (Year 2020)	New Management as per Form A Year 2020
1. Mr. Keky R. Dastur S/o (Late) Mr. Rustomiji B. Dastur CNIC No. 42301-1088742-3. 2. Mr. Shahroakh B. Rabadi S/o (Late) Mr. BurjorRabadi CNIC No. 42201-0392395-1. 3. Mr. Zafar Iqbal Qureshi S/o Mr. Shafiq Ahmed Qureshi CNIC No. 42101-1154540-9.	1. Mr. Saeed Allawala S/o Usman Allawala CNIC No. 42201-0791586-1. 2. Ms. Marium Talha Rahman W/o Talha Rahman CNIC No. 42201-7970767-6. 3. Ms. Gule Rana Saeed W/o Saeed Allawala CNIC No. 42201-0662998-6.. 4. Mr. Tariq Allawala S/o Saeed Allawala CNIC No. 42201-0783698-3. 5. Mr. Adil Allawal S/o Saeed Allawala CNIC No.42201-0783698-9. 6. Mr. Ismail Allawala S/o Saeed Allawala CNIC No. 42201-0783701-5.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the facts on the record and after thread bare deliberation decided that as the application for renewal of DML No. 000272 (Formulation) of M/s Spencer & Company (Pvt) Ltd, D-105, S.I.T.E, Karachiis not made after the expiry of the period of validity of License, therefore, Drug Manufacturing License

DML No. **000272** (Formulation) is no more valid and stands cancelled. However, new management may file and application for grant of licence a fresh.

Case No.9 REGULARIZATION OF LAYOUT PLAN OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, NO. 35- DOCKYARD ROAD, WEST WHARF, KARACHI.KARACHI.

M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard West Wharf,Karachi. Under DML No.000017 (Formulation) had applied for regularization of layout plan of running facility for their existing sections. Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1) CDI,Govt of Sindh Karachi.
2) Federal Inspector of Drugs, DRAP, Karachi.
3) Ms. SanamKausar, AD, DRAP, Karachi

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

Recommendations of the panel:

"Keeping in view the people met, areas visited and commitment of the firm for continuous improvement the panel recommends the regularization of manufacturing facility as per approved layout and renewal of Drug Manufacturer license No. 000017 (By way of Formulation) for following the approved sections:

S. No.	***Sections***	***S. No.***	***Sections***
1.	*Topicals General 01 (Ointment/Cream/Gel)*	*2.*	*Topicals General 02 (Ointment/Cream&Gel)*
3.	*Topicals General 03(Lotion)*	*4.*	*Eye Ointment Ophthalmic area*
5.	*Ear Drops*	*6.*	*Spansules area (Including NPS)*
7.	*Oral Powder Area (Sachet)*	*8.*	*Ware House*
9.	*Quality Control Lab*	*10.*	**********

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the case and approved the regularization of lay out plan in the name of M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard West Wharf,Karachi. Under DML No.000017 (Formulation) on the recommendation of panel of experts for the following sections:-

S. No.	***Sections***	***S. No.***	***Sections***
1.	*Topicals General 01 (Ointment/Cream/Gel)*	*2.*	*Topicals General 02 (Ointment/Cream&Gel)*

3.	*Topicals General 03(Lotion)*	*4.*	*Eye Ointment Ophthalmic area*
5.	*Ear Drops*	*6.*	*Spansules area (Including NPS)*
7.	*Oral Powder Area (Sachet)*	*8.*	*Ware House*
9.	*Quality Control Lab*	*10.*	**********

Case No.10 REGULARIZATION OF LAYOUT PLAN OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, F-268, S.I.T.E. KARACHI.

M/s GlaxoSmithKline Pakistan Limited**,** F-268, SITE, **Karachi**.under DML No. 000233(Formulation), had applied for regularization of layout plan of running facility for their existing sections;

1. Tablet (General)	4. Liquid Syrup (General)	7. Tablet (Penicillin)
2. Capsule (Penicillin)	5. Dry Powder Suspension (Penicillin)	8. Oral Drops (Penicillin)
3. Warehouse (General)	6. Ware House (Penicillin)	9. Quality Control Laboratory.

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

1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi.
2) Federal Inspector of Drugs, DRAP, Karachi.
3) Mr. Krishan Das, AD, DRAP, Karachi.

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

Recommendations of the panel:

Keeping in view overall GMP compliance and positive intention towards improvement panel recommends the regularization of layout plan and renewal of DML No. 000233 (formulation) of the firm M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E. Karachi.

1. Tablet (General)	4. Liquid Syrup (General)	7. Tablet (Penicillin)
2. Capsule (Penicillin)	5. Dry Powder Suspension (Penicillin)	8. Oral Drops (Penicillin)
3. Warehouse (General)	6. Ware House (Penicillin)	9. Quality Control Laboratory.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the case and approved the regularization of lay out plan in the name of M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E. ,Karachi. Under DML No.000233 (Formulation) on the recommendation of panel of experts for the following sections:-

1. Tablet (General)	4. Liquid Syrup (General)	7. Tablet (Penicillin)
2. Capsule (Penicillin)	5. Dry Powder Suspension (Penicillin)	8. Oral Drops (Penicillin)
3. Warehouse (General)	6. Ware House (Penicillin)	9. Quality Control Laboratory.

Case No.11. REGULARIZATION OF LAYOUT PLAN OF M/S MARTIN DOW MARKER LIMITED. F-126, SITE KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000043 (FORMULATION).

M/s Martin Dow Marker Limited, F-126, S.I.T.E, Karachi under DML No. 000043 (Formulation) had applied for regularization of layout plan of running facility for their existing sections;

1. Soft Gelatin Capsule (General)
2. Ware House (General).
3. QC Laboratory.

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

1) CDI,Govt of Sindh Karachi.
2) Federal Inspector of Drugs, DRAP, Karachi.
3) Mr. Affan Ali, AD, CDL, Karachi

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

Recommendations of the panel:

"Keeping in view the good facilities of storage, production, quality control, sanitation and hygiene, HVAC operations, calibration, validation of all equipments and process water treatment and other utilities, the panel recommends the grant of Drug Manufacturing License, (000043) by way of formulation and regularization of manufacturing facility for following sections:

Sr. #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Soft Gelatin Capsule*	*2.*	*Ware House*
3.	*Quality Control Lab*	*4.*	**********

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the case and approved the regularization of lay out plan in the name of M/s Martin Dow Marker Limited, F-126, S.I.T.E, Karachi under DML No. 000043 (Formulation) on the recommendation of panel of experts for the following sections:-

Sr. #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Soft Gelatin Capsule*	*2.*	*Ware House*
3.	*Quality Control Lab*	*4.*	**********

Case No.12. REGULARIZATION OF LAYOUT PLAN OF M/S MARTIN DOW MARKER LIMITED. 07 JAILROAD QUETTA UNDER DRUG MANUFACTURING LICENSE NO. 000028 (FORMULATION).).

M/s Martin Dow Marker Limited, 07 Jail Road Quetta under DML No. 000028(Formulation) had applied for regularization of layout plan of running facility for their existing sections; Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1) Director DTL, Gov. of Balochistan.
2) Federal Inspector of Drugs, DRAP, Quetta.
3) AD, DRAP, Quetta.

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

Recommendations of the panel:

"Based on above observations, documents received and people met the panel unanimously recommend the renewal of Drug Manufacturing License No. 000028 by way of formulation for next 05 years and regularization of all the section/ facilities mentioned in letter No. F4-2/86-Lic(Vol-VII), dated 10th February, 2021:

Sr. #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Liquid Syrup (General)	4.	Dry Powder Suspension (General)
5.	Dry Powder Sachet (General)	6.	Ointment/Cream/Gel (General)
7.	Tablet (Psychotropic)	8.	Injectable Ampoule (General)
9.	Quality Control Laboratory	10.	Ware House (General)

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the case and approved the regularization of lay out plan in the name of M/s Martin Dow Marker Limited, 07-Jail Road, Quetta under DML No. 000028 (Formulation) on the recommendation of panel of experts for the following sections:-

Sr. #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Liquid Syrup (General)	4.	Dry Powder Suspension (General)
5.	Dry Powder Sachet (General)	6.	Ointment/Cream/Gel (General)
7.	Tablet (Psychotropic)	8.	Injectable Ampoule (General)
9.	Quality Control Laboratory	10.	Ware House (General)

Case No.13 REGULARIZATION OF LAYOUT PLAN OF M/S RECKITT BENCKISER PAKISTAN LIMITED, F-18, S.I.T.E. .KARACHI.

M/s. Reckitt Benckiser Pakistan Limited.F-18, S.I.T.E. Karachi. Under DML No. 000022 (Formulation) had applied for regularization of layout plan of running facility for their existing sections;

1. Tablet General	4. Tablet (General) Disprol, Dispirin CV.
2. Oral Liquid Syrup Gaviscon (General)	5. External Preparation (General)
3. Warehouse (General)	6. Quality Control Lab

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

1) Director DTL, Sindh.
2) Area FID, DRAP, Karachi.
3) Ms. Mahrukh Mughal, Assistant Director, CDL, Karachi.

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

Recommendation of panel :

Based on the people met , areas visited and commitment of the firm management towards continuous improvement of personnel, processes and facilities the panel is of the view to recommend regularization of facility as per approved layout plan and renewal of DML No. 000022(Formulation) to the firm with following sections :

1. Tablet General	4. Tablet (General) Disprol, Dispirin CV.
2. Oral Liquid Syrup Gaviscon (General)	5. External Preparation (General)
3. Warehouse (General)	6. Quality Control Lab

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the case and approved the regularization of lay out plan in the name of M/s Reckitt Benckiser Pakistan Limited.F-18, S.I.T.E. Karachi. under DML No. 000022 (Formulation) on the recommendation of panel of experts for the following sections:-

1. Tablet General	4. Tablet (General) Disprol, Dispirin CV.
2. Oral Liquid Syrup Gaviscon (General)	5. External Preparation (General)
3. Warehouse (General)	6. Quality Control Lab

Case No.14 REGULARIZATION OF LAYOUT PLAN OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, NO. PLOT No. 05, SECTOR 21, KORANGI INDUSTRIAL AREA, KARACHI.

M/s GlaxoSmithKline Pakistan Limited, Plot No. 05, Sector 21, Korangi Industrial Area, Karachi. Under DML No.000248 (Formulation) had applied for regularization of layout plan of running facility for their existing sections. Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1) CDI,Govt of Sindh Karachi.
2) Federal Inspector of Drugs, DRAP, Karachi.
3) Mr. Muhammad Usman, AD, DRAP, Islamabad.

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

Recommendations of the panel:

Considering the overall site inspection - covering the facility visit, review of operations/processes/system, interaction with the site team and the review of related documents and **M/s GlaxoSmithKline Pakistan Korangi** site was considered to be operating at a **'very good'** level of compliance with GMP guidelines as per Drugs Act, 1976 rules & regulations. The panel unanimously recommends the grant of renewal of their DML No. 000248 and regularization of current Layout for following sections.

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Tablet (General)*	*2.*	*Liquid Ampoule SVP (General)*
3.	*Eye Drop (General)*	*4.*	*Tablet (Cephalosporin)*
5.	*Capsule (Cephalosporin)*	*6.*	*Dry Powder Suspension (Cephalosporin)*
7.	*Dry Powder Injection (Cephalosporin)*	*8.*	*Warehouse (General)*
9.	*QC Laboratory*	*10.*	*Warehouse (Cephalosporin)*

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the case and approved the regularization of lay out plan in the name of M/s GlaxoSmithKline Pakistan Limited, Plot No. 05, Sector 21, Korangi Industrial Area,,Karachi under DML No.000248 (Formulation) on the recommendation of panel of experts for the following sections:-

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Tablet (General)*	*2.*	*Liquid Ampoule SVP (General)*
3.	*Eye Drop (General)*	*4.*	*Tablet (Cephalosporin)*
5.	*Capsule (Cephalosporin)*	*6.*	*Dry Powder Suspension (Cephalosporin)*

7.	*Dry Powder Injection (Cephalosporin)*	*8.*	*Warehouse (General)*
9.	*QC Laboratory*	*10.*	*Warehouse (Cephalosporin)*

Case No.15 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S PEARL PHARMACEUTICALS, PLOT NO.204, SECTOR 1, I-10/3, INDUSTRIAL AREA, ISLAMABAD**

The firm, M/s Pearl Pharmaceuticals, Plot No.204, Sector 1, I-10/3, Industrial Area, Islamabad submitted the application for renewal of Drug Manufacturing No. **000479 (Formulation).** The application was received on **27-08-2020** which is well on time as validity of License is **01-09-2020** (Page-54/Corr)**.** The firm has submitted a fee of **Rs. 50,000**. The application was evaluated as per Drugs (Licesning, Registering and advertising) Rules 1976 and found following shortcoming for which shortcoming letter No. F. 1-18/90-Lic Vol-III dated 30/09/2020 was issued to the firm;

i. Classes of drugs.
ii. Dosage form of drugs.
iii. Proof of licensed sections from Central Licensing Board.
iv. Updated NOC regarding CRF from STO, DRAP, Islamabad.
v. All documents should be signed and stamped by owner of the firm.

In response to above quoted letter the firm has submitted their response however, the firm has not rectified following shortcoming; subsequently final reminder vide letter No. F. 1-18/90-Lic Vol-III dated 13/01/2021 was issued to the firm;

i. Proof of section(s) approval by Central Licensing Board.

Despite issuance of shortcoming letter and final reminder, the firm has not rectified following shortcomings;

i. Proof of section(s) approval by Central Licensing Board.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000479 (by way of formulation) , M/s Pearl Pharmaceuticals, Plot No.204, Sector 1, I-10/3, Industrial Area, Islamabad may not be suspended or cancelled by Central Licensing Board or application for renewal of DML under Rule 5(2A) may not be rejected.

In light of Decision of The Central Licensing Board held on Show Cause Notice was issued to the firm on 12-03-2021.

The firm M/s Pearl Pharmaceuticals, Plot No.204, Sector 1, I-10/3, Industrial Area, Islamabad has rectified above mentioned shortcomings.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000479 (By way of Formulation) of M/s Pearl Pharmaceuticals, Plot No.204, Sector 1, I-10/3, Industrial Area, Islamabad, for further period.

CASE NO. 16. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AHAD INTERNATIONAL PHARMACEUTICAL, 13-KM MULTAN ROAD, DERA ISMAIL KHAN.

The firm M/s Ahad International Pharmaceutical, Dera Ismail Khan has submitted application for renewal of Drug Manufacturing No. 000433 (Formulation). The application was received on **18-06-2019** which is well on time as validity of License is **23-07-2019** (Page-217/Corr)**.** The firm has submitted a fee of **Rs. 50,000**. The application for renewal of DML was evaluated as per Drugs (LR&A) Rules 1976 and found following shortcomings which were conveyed to the firm vide letter No. F.3-8/92-Lic (Vol-I) dated 18-10-2019;

i. Detail of management at the time of previous renewal and present renewal.
ii. Certified true copy of Form-29 and Form-21 issued by S.E.C.P. alongwith CNIC's copies of all director(s).
iii. Proof of Licensed section (s) from Central Licensing Board.

In response to this Division Shortcoming letter the firm has submitted their reply, however the firm has not rectified following shortcomings and subsequently a reminder was issued vide letter No.F.3-8/92-Lic (Vol-) dated 16-01-2020.

i. Latest original certified true copy of Form-29 issued by S.E.C.P. showing complete detail of directors.

In response to final reminder the firm has submitted notarized copy of Form-29 issued by SECP (Not certified as true Copy by SECP). However, from the notarized copy of Form-29 it was observed that the firm management has been changed from previous management and firm was informed accordingly vide letter no.F.3-8/92-Lic (Vol-I) dated 18-08-2020. Till date, the firm has not rectified following shortcomings;

i. Certified true copy of Form-29 and Form-21 issued by S.E.C.P. alongwith CNIC's copies of all director(s).
ii. Application for change of management as per Drug (Licensing, registering & advertising) Rules 1976 is not submitted by firm.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 and

Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000433(by way of formulation) of M/s Ahad International Pharmaceutical, Dera Ismail Khan may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976..

In light of Decision of The Central Licensing Board held on Show Cause Notice was issued to the firm on 08/01/2021.

The firm M/s Ahad International Pharmaceutical, Dera Ismail has rectified above mentioned shortcomings.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000433 (By way of Formulation)ofM/s Ahad International Pharmaceutical, Dera Ismail for further period.

CASE NO. 17 **GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000575 OF M/S SYNCHRO PHARMACEUTICALS, 77-INDUSTRIAL ESTATE KOT LAKHPAT, LAHORE.**

Case Background:

M/s Synchro Pharmaceuticals, 77-Industrial Estate KotLakhpat, Lahore had applied for renewal of DML No. 000575 by way of formulation for the period of 14-05-2020 to 13-05-2025. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 21st October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form 1A alongwith enclosure / annexure / flags.
2. Classes of Drugs attested.
3. Dosage form of drugs attested.
4. Name(s) of drugs registered / approved.
5. Detail of management at the time of previous renewal and present renewal.
6. Partnership deed alongwith CNICs of all directors.
7. Detail of premises including layout plan
8. Proof of licensed sections from CLB.
9. Attested copies of approval letters of QC and Production Incharge.
10. Up to date nothing due certificate regarding CRF from STO.

All documents should be duly attested.

The firm submitted their reply on 11th November, 2020. After evaluation of the submitted documents, final reminder was issued on 30th November, 2020 to the firm with following shortcomings: -

i. Up to date Nothing Due Certificate regarding CRF from STO.
ii. Proof of licensed sections from CLB, if not available then submit application for regularization.
iii. Submit complete application for change of management along with requisite fee.

All documents should be duly attested.

The firm submits their reply on22nd February, 2021 in response to this Division's Final Reminder. On scrutiny of submitted documents following shortcomings has been still observed:-

i. Application for change of management along with requisite fee is not provided.

Submitted for consideration and orders of the Board.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000575 (by way of formulation) of M/s Synchro Pharmaceuticals, 77-Industrial Estate KotLakhpat, Lahore may not be suspended or cancelled by the Central Licensing Board.

CASE No.18. APPROVAL OF TECHNICAL STAFF PRODUCTION AND QUALITY CONTROL INCHARGE UNDER DRUG MANUFACTURING LICENSE NO. 000529 OF M/S TRISON RESEARCH LABORATORIES (PVT) LTD, PLOT NO. 27-A, PUNJAB SMALL INDUSTRIAL ESTATE, SARGODHA.

Case Background:

M/s Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, Punjab Small Industrial Estate, Sargodha had applied for change of technical staff's application under DML No. 000529 by way of formulation. The application for the change of technical staff was evaluated and a letter for shortcomings / deficiencies was issued to the firm on 18th November, 2019 and final reminder was issued on 8th December, 2020 for following shortcomings:-

For QC Incharge Ms. Fatima Akbar.

1. Resignation / retirement documents of previous QC Incharge.

For Production Incharge Khalil Ahmed.

1. Resignation / retirement documents of previous Production Incharge.
2. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

The firm submitted their reply on 26th March, 2021 and submitted fresh documents for change of technical staff instead of above mentioned technical staff. After evaluation of the submitted documents following shortcomings has been still observed: -

For Pro. Incharge (Mr. Khalid Saleem).	For QC Incharge (Qurat Ul Ain Shahid).
1. Appointment letter (Not provided). 2. Job acceptance letter by the appointee (Not Provided). 3. Copy of CNIC of appointee (Not provided). 4. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not Attested). 5. Registration certificate from Pharmacy Council (in case of Production Incharge) (Not Attested). 6. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not Attested). 7. Resignation / retirement of earlier Production Incharge (Not provided). 8. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Not Provided). 9. Undertaking as whole time employee (Not provided).	1. Appointment letter (Not provided). 2. Job acceptance letter by the appointee Appointment letter (Not provided). 3. Copy of CNIC of appointee (Not provided). 4. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not Attested). 5. Registration certificate from Pharmacy Council (in case of Production Incharge) (Not Attested). 6. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not Attested). 7. Resignation / retirement of earlier Production Incharge (Not provided). 8. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Not Provided). 9. Undertaking as whole time employee (Not provided).

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000529 (by way of formulation) of M/s Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, Punjab Small Industrial Estate, Sargodha may not be suspended or cancelled by the Central Licensing Board.

CASE NO. 19 . GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000464 BY WAY OF (FORMULATION) OF M/S PERFECT PHARMA (PVT) LTD, 5-KM, MANGA ROAD, RAIWIND, LAHORE.

Case Background:

M/S Perfect Pharma (Pvt) Ltd, 5-Km, Manga Road, Raiwind, Lahore had applied for renewal of DML No. 000469 by way of formulation for the period of 01-03-2020 to 31-02-2025. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 16th September, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Latest Certified true copy of Form-29 (Attestation by SECP).
ii. Detail of premises including layout plan.
iii. Proof of licensed sections from CLB.
iv. Name and Qualification of Production Incharge.
v. Up-to-date nothing due certificate regarding CRF from STO.

All documents should be duly attested.

For Quality Control Incharge (Mr. Tanveer Ali Mirza).

i. Copy of degree of M.Sc. (Chemistry).
ii. Undertaking as whole time employee must be on stamp paper signed by both appointee & management.
iii. Copy of job acceptance letter by appointee.
iv. Resignation letter of earlier Quality Control Incharge.

All documents should be duly attested.

The firm submitted their reply. After evaluation of the submitted documents, final reminder was issued on 19th January, 2021 to the firm with following shortcomings: -

For Renewal of DML.

i. Latest Certified true copy of Form-29 (Attestation by SECP).
ii. Up-to-date nothing due certificate regarding CRF from STO.

For Production Incharge (Mr. Khuram Naveed).

i. Experience Certificate as required under Drugs (Licensing, Registering and Advertising) Rules, 1976.

All documents should be duly attested.

The firm submits their reply on 23nd February, 2021 in response to this Division's Final Reminder. On scrutiny of submitted documents following shortcomings has been still observed:-

i. Latest Certified true copy of Form-29 (Attestation by SECP) without statement that "SECP accept no responsibility as to the correctness of the detail given in the document".

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000469 (by way of formulation) of M/s Perfect Pharma (Pvt) Ltd, 5-Km, Manga Road, Raiwind, Lahore may not be suspended or cancelled by the Central Licensing Board.

Case No.20 . <u>M/S PRIX PHARMACEUTICALS (PVT) LTD, PLOT NO. 05, PHARMA CITY, 30-KM, MULTAN ROAD, LAHORE.</u>

M/s Prix Pharmaceuticals (Pvt) Ltd, Plot No. 05, Pharma City, 30-KM, Multan Road, Lahore, DML No. 000587 by way of (Formulation) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Existing Management as per Form-29.	Retiring Management as per Form-29.	New Management as per Form-29.
1. Dr. Syed Abid Abbas S/o Syed Abbas Ali CNIC No. 35201-1295910-1. 2. Syed Baqar Abbas Naqvi S/o Syed Abbas Ali Shah CNIC No. 35201-1556328-7. 3. Mr. Sajjad Mehdi S/o Syed Kazim Hussain CNIC No. 35202-2456437-3.	Mr. Sajjad Mehdi S/o Syed Kazim Hussain CNIC No. 35202-2456437-3.	1.Dr. Syed Abid Abbas S/o Syed Abbas Ali CNIC No. 35201-1295910-1. 2.Syed Baqar Abbas Naqvi S/o Syed Abbas Ali Shah CNIC No. 35201-1556328-7. 3.Syed Hassan Mehdi S/o Syed Saadat Hussain CNIC No. 35202-2476986-3.

<u>Decision of the Central Licensing Board in 280th meeting:</u>

The Board considered and accepted for record the change of management of M/s Prix Pharmaceuticals (Pvt) Ltd, Plot No. 05, Pharma City, 30-KM, Multan Road, Lahore, DML No. 000587 (By way of Formulation) as under;

Existing Management as per Form-29.	Retiring Management as per Form-29.	New Management as per Form-29.
1. Dr. Syed Abid Abbas S/o Syed Abbas Ali CNIC No. 35201-1295910-1. 2. Syed Baqar Abbas Naqvi S/o Syed Abbas Ali Shah CNIC No. 35201-1556328-7. 3. Mr. Sajjad Mehdi S/o Syed Kazim Hussain CNIC No. 35202-2456437-3.	Mr. Sajjad Mehdi S/o Syed Kazim Hussain CNIC No. 35202-2456437-3.	1. Dr. Syed Abid Abbas S/o Syed Abbas Ali CNIC No. 35201-1295910-1. 2.Syed Baqar Abbas Naqvi S/o Syed Abbas Ali Shah CNIC No. 35201-1556328-7. 3.Syed Hassan Mehdi S/o Syed Saadat Hussain CNIC No. 35202-2476986-3.

Case No.21 REGULARIZATION OF LAYOUT PLAN OF M/S MEDISEARCH PHARMACAL(PVT) LTD, 5-KM, RAIWIND MANGA ROAD, LAHORE.

M/s Medisearch Pharmacal (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahoreunder DML No. 000549(Formulation) had applied for regularization of layout plan of running facility for their existing following sections/facility:

Regularized Sections			
1	Oral Liquid (General) Section.	3	Cream/Ointment (General) Section.
2	External Preparation Section.	**********	

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

1) Dr. Farzana Chowdhary, Expert Member.
2) Mr. Azhar Jamal Saleemi, Chief Drug Inspector, Punjab.
3) Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.

Accordingly, Panel has inspected the premises and recommendations of panel are as under:

Recommendations of the panel:

"Keeping in view the facilities like building, HVAC system, Equipment, Instrument, Machinery, Personnel. Documentation, Quality Control and testing facilities, the panel of inspectors is of the opinion to **recommend** the renewal of Drug Manufacturing License to M/s MedisearchPharmacal (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore bearing Lic.No.000549, and regularization of the following approved sections:

1) Oral Liquid (General) Section (Renewal & Regularization)
2) External Preparation Section. (Renewal & Regularization)
3) Cream/Ointment (General) Section(Renewal & Regularization)
4) Tablet (General) Section. (Renewal)
5) Capsule (General) Section. (Renewal)
6) Dry Powder Suspension (General) Section. (Renewal)
7) Dry Powder Suspension (Cephalosporin) Section. (Renewal)
8) Capsule (Cephalosporin) Section. (Renewal)"

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the case and approved the regularization of lay out plan in the name of M/s Medisearch Pharmacal (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore bearing DML No.000549 (Formulation) on the recommendation of panel of experts for the following sections:-

Regularized Sections			
1	Oral Liquid (General) Section.	3	Cream/Ointment (General) Section.
2	External Preparation Section.	**********	

Cse No.22 **REGULARIZATION OF LAYOUT PLAN OF M/S ISIS PHARMACEUTICALS & CHEMICAL WORKS ., PLOT NO. 25/1-3, SECTOR 12-C, NORH KARACHI INDUSTRIAL AREA KARACHI.**

M/s ISIS Pharmaceuticals& Chemical Works, Plot No. 25/1-3, Sector 12-C, North Karachi Industrial Area Karachi.under DML No. 000126 (Formulation), had applied for regularization of layout plan of running facility for their existing sections. Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1) Additional Director (E& M) DRAP, Karachi..
2) Federal Inspector of Drugs, DRAP, Karachi.
3) Mr. Krishan Das, AD, DRAP, Karachi.

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

Recommendations of the panel:

*"*Based on the people met, documents reviewed, and observations made during the inspection, the panel unanimously recommends the grant of renewal of Drug Manufacturing License No. 000126 by way of formulation, regularization and grant of additional sections as follows:

Sr #	**Name of Section**	**Sr. #**	**Name of Section**
1.	Tablet (General)	2.	Sterile Ophthalmic Drops (General)
3.	Liquid Syrup (General)	4.	Ophthalmic Ointment (General)
5.	Dry Powder Suspension (General)	6.	Cream/Ointment (Steroids)
7.	Capsule (General)	8.	Tablet (Hormone)
9.	Cream/Ointment/Gel (Hormone)	10.	Sterile Liquid Injection (Hormone)
11.	Liquid Injection SVP (Glass Vial/ampoule)	12.	Liquid Infusion (General) (PP)
13.	Cream/Ointment/Gel (General)	14.	Capsule (Cephalosporin)
15.	Tablet (Cephalosporin)	16.	Dry Powder Injection

			(Cephalosporin)
17.	Dry Powder Suspension (Cephalosporin)	18.	Dry Powder Suspension (Penicillin)
19.	Tablet (Penicillin)	20.	Capsule (Penicillin)
21.	Liquid Injection (psychotropic)	22.	Tablet (Psychotropic)
23.	Liquid ORS (General)	24.	Powder ORS (General)
25.	Tablet Bolus (Veterinary)	26.	Liquid Syrup (Veterinary)
27.	Dry Powder Suspension (Veterinary)	28.	Liquid Injection (Veterinary)
29.	Injectable Hormone (Veterinary section)	30.	Enema
Additional/New Section			
1.	Liquid External Preparation (General)-New		**********

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the case and approved the regularization of lay out plan in the name of M/s ISIS Pharmaceuticals& Chemical Works, Plot No. 25/1-3, Sector 12-C, North Karachi Industrial Area Karachi.under DML No. 000126 (Formulation) on the recommendation of panel of experts for the following sections:-

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Sterile Ophthalmic Drops (General)
3.	Liquid Syrup (General)	4.	Ophthalmic Ointment (General)
5.	Dry Powder Suspension (General)	6.	Cream/Ointment (Steroids)
7.	Capsule (General)	8.	Tablet (Hormone)
9.	Cream/Ointment/Gel (Hormone)	10.	Sterile Liquid Injection (Hormone)
11.	Liquid Injection SVP (Glass Vial/ampoule)	12.	Liquid Infusion (General) (PP)
13.	Cream/Ointment/Gel (General)	14.	Capsule (Cephalosporin)
15.	Tablet (Cephalosporin)	16.	Dry Powder Injection (Cephalosporin)
17.	Dry Powder Suspension (Cephalosporin)	18.	Dry Powder Suspension (Penicillin)
19.	Tablet (Penicillin)	20.	Capsule (Penicillin)
21.	Liquid Injection (psychotropic)	22.	Tablet (Psychotropic)
23.	Liquid ORS (General)	24.	Powder ORS (General)
25.	Tablet Bolus (Veterinary)	26.	Liquid Syrup (Veterinary)
27.	Dry Powder Suspension (Veterinary)	28.	Liquid Injection (Veterinary)
29.	Injectable Hormone (Veterinary section)	30.	Enema

Case No.23 **REGULARIZATION OF MANUFACTURING FACILITY OF M/S OPAL LABORATORIES (PVT) LTD, LC-41, L.I.T.E. LANDHI, KARACHI - INSPECTION THEREOF..**

M/s Opal Laboratories (Pvt) Ltd, LC-41, L.I.T.E. Landhi **Karachi**.under DML No. 000046 (Formulation), had applied for regularization of layout plan of running facility for their existing sections;

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Urodonal Granules	4.	Ophthalmic/Eye Drops (General)
5.	Ointment/Cream/Gel (General)	6.	Dry Powder Suspension (General)
7.	Oral Liquid/Syrup (General)	8.	Sachet (General)
9.	Tablet (Cephalosporin)	10.	Capsule (Cephalosporin)
11.	Dry Powder Suspension (Cephalosporin)	12.	**********

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

1) Prof. Dr. Abdullah Dayo, Member CLB, Karachi.
2) Area Federal Inspector of Drugs, DRAP, Karachi.
3) Mr. Affan Ali, Assistant Director, CDL, Karachi.

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

Recommendations of the panel:

Following are the observations and recommendations of the panel members:

- The firm is constructed as per the approved layout plan/amendments vide DRAP, Islamabad letter no. F.2-1/2003-Lic(Pt) (Vol-I) dated 18th May, 2020.
- Based on the observations, documents reviewed, personnel met and commitment of the firm for continuous up-gradation and intention for export of products to various countries, the panel recommends the grant of renewal of DML No. 000046 (by way of Formulation) and regularization of manufacturing facility to the firm M/s Opal Laboratories Pvt Ltd, with following sections:

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Urodonal Granules	4.	Ophthalmic/Eye Drops (General)
5.	Ointment/Cream/Gel (General)	6.	Dry Powder Suspension (General)
7.	Oral Liquid/Syrup (General)	8.	Sachet (General)

9.	Tablet (Cephalosporin)	10.	Capsule (Cephalosporin)
11.	Dry Powder Suspension (Cephalosporin)	12.	**********

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board considering the case and approved the regularization of lay out plan in the name of M/s Opal Laboratories Pvt Ltd, Karachi.under DML No. 000046 (Formulation) on the recommendation of panel of experts for the following sections:-

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Urodonal Granules	4.	Ophthalmic/Eye Drops (General)
5.	Ointment/Cream/Gel (General)	6.	Dry Powder Suspension (General)
7.	Oral Liquid/Syrup (General)	8.	Sachet (General)
9.	Tablet (Cephalosporin)	10.	Capsule (Cephalosporin)
11.	Dry Powder Suspension (Cephalosporin)	12.	**********

CASE NO.24 CHANGE OF MANAGEMENT OF M/S. ICE BERG PHARAMCEUTCIALS (PVT) LTD., RISALPUR.

M/s Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No/ 144, Nowshera Industrial Estate, Risalpur, under DML No. 000816 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management as per Form-29	New management as per Form-29
1. Mr. Muhammad Fayaz, CNIC. No. 17101-7193842-7 2. Mr. Najeeb Ullah, CNIC. No. 17301-8989720-9 3. Mr. Muhammad Tahir, CNIC. No. 16101-9356882-3	1. Mr. Muhammad Fayaz, CNIC. No. 17101-7193842-7 2. Mr. Najeeb Ullah, CNIC. No. 17301-8989720-9

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/ Ice Berg Pharmaceuticals (Pvt) Ltd., Plot No/ 144, Nowshera Industrial Estate, Risalpur,underDML No. 000816 (By way of Formulation) as under;

Previous management as per Form-29	New management as per Form-29
1. Mr. Muhammad Fayaz, CNIC. No. 17101-7193842-7 2. Mr. Najeeb Ullah, CNIC. No. 17301-8989720-9 3. Mr. Muhammad Tahir, CNIC. No. 16101-9356882-3	1. Mr. Muhammad Fayaz, CNIC. No. 17101-7193842-7 2. Mr. Najeeb Ullah, CNIC. No. 17301-8989720-9

CASE NO.25 <u>CHANGE OF MANAGEMENT OF M/S TREAT PHARMACEUTICAL INDUSTRY (PVT) LTD., A-37, SMALL INDUSTRIAL ESTATE, TOWNSHIP, KOHAT ROAD, BANNU.</u>

M/s Treat Pharmaceutical Industry (Pvt) Ltd., A-37, Industrial Estate, Township, Kohat Road, Bannu, under DML No. 000352 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management as per Form-29	New management as per Form-A
1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9 2. Mr. Maqbool Khan S/o Lal Mir, CNIC No. 17301-2252149-9.	1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9 2. Mr. Naeem Hayat S/o Hayat Mir, CNIC No. 11101-2863761-7

<u>Decision of the Central Licensing Board in 280th meeting:</u>

The Board considered and accepted for record the change of management of M/sTreat Pharmaceutical Industry (Pvt) Ltd., A-37, Industrial Estate, Township, Kohat Road, Bannu,,under DML No. 000352 (By way of Formulation) as under;

Previous management as per Form-29	New management as per Form-A
1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9 2. Mr. Maqbool Khan S/o Lal Mir, CNIC No. 17301-2252149-9.	1. Mr. Sikandar Hayat S/o Hayat Mir, CNIC No. 11101-8375069-9 2. Mr. Naeem Hayat S/o Hayat Mir, CNIC No. 11101-2863761-7

CASE NO.26 CHANGE OF MANAGEMENT OF M/S BLOOM PHARMACEUTICALS 9PVT) LTD., PLOT NO.30, PHASE-I & II, INDUSTRIAL ESTATE, HATTAR.

M/s Bloom Pharmaceuticals (Pvt) Ltd, Plot No.30, Phase-I & II, Industrial Esate, Hattar, under DML No. 000374 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management as per Form-A & Form-29	New management as per Form-A & Form-29
1. Mrs. Parveen Amjad Qureshi, CNIC No.32102-4340790-0 2. Mrs. Zaib-Un-Nisa, CNIC No. 37405-9974325-8 3. Mr. Ahmed Raza, CNIC No. 35202-8599970-7 4. Sajid Zahoor, CNIC No. 35202-8075941-7	1. Mr. Ahmed Raza S/o Khawaja Abdul Rehman, CNIC No.35202-8599970-7 2. Mr. Junaid Amjad Siddiqui S/o Amjad Saeed Siddiqui, CNIC No.32102-8400418-1 3. Mr. Sajid Zahoor S/o Chaudhary Zahoor Din, CNIC No. 35202-8075941-7

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/sBloom Pharmaceuticals (Pvt) Ltd, Plot No.30, Phase-I & II, Industrial Esate, Hattar, under DML No. 000374 (By way of Formulation) as under;

Previous management as per Form-A & Form-29	New management as per Form-A & Form-29
1. Mrs. Parveen Amjad Qureshi, CNIC No.32102-4340790-0 2. Mrs. Zaib-Un-Nisa, CNIC No. 37405-9974325-8 3. Mr. Ahmed Raza, CNIC No. 35202-8599970-7 4. Sajid Zahoor, CNIC No. 35202-8075941-7	1. Mr. Ahmed Raza S/o Khawaja Abdul Rehman, CNIC No.35202-8599970-7 2. Mr. Junaid Amjad Siddiqui S/o Amjad Saeed Siddiqui, CNIC No.32102-8400418-1 3. Mr. Sajid Zahoor S/o Chaudhary Zahoor Din, CNIC No. 35202-8075941-7

CASE NO.27 CHANGE OF MANAGEMENT OF M/S HASSAN PHARMACEUTICAL, 99-A, INDUSTRIAL ESTATE, HAYATABAD, PESHSAWAR..

M/s Hassan Pharmaceutical, 99-A, Industrial Estate, Hayatabad Peshawar, under DML No. 000357 by way of formulation has submitted request for change in management of the firm as per Partnership Deedwith prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Current managementas per partnership deed	Proposed management as per revised partnershipdeed
1. Mr. Muhammad Nawaz S/o Mr. Muhammad Hayat CNIC No.17301-2891116-7 2. Mrs. Azra Bibi W/o Muhammad Nawaz CNIC No.17301-1086887-0 3. Mr. Hassan Nawaz S/o Muhammad Nawaz CNIC No.17301-5182703-5 4. Mr. Qamar Abbas S/o Muhammad Nawaz CNIC No.17301-1434318-7 5. Mr. Ali Hamza S/o Muhammad Nawaz CNIC No.17301-6125229-9	1. Mr. Hassan Nawaz S/o Muhammad Nawaz CNIC No.17301-5182703-5 2. Mr. Qamar Abbas S/o Muhammad Nawaz CNIC No.17301-1434318-7 3. Mr. Ali Hamza S/o Muhammad Nawaz CNIC No.17301-6125229-9 4. Mrs. Azra Bibi W/o Muhammad Nawaz CNIC No.17301-1086887-0 5. Mst Farina Nawaz D/o Muhammad Nawaz CNIC No. 17301-7519158-8 6. Mst. Hajira Zainab W/o. Mr Ali Raza CNIC No. 17301-6344347-8 7. Mst Maryam Nawaz D/o Muhammad Nawaz CNIC No. 35201-4580283-4

Case is submitted for consideration and orders of the Board please.

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/sHassan Pharmaceutical, 99-A, Industrial Estate, Hayatabad Peshawar, under DML No. 000357 (By way of Formulation) as under;

Current managementas per partnership deed	Proposed management as per revised partnershipdeed
1. Mr. Muhammad Nawaz S/o Mr. Muhammad Hayat CNIC No.17301-2891116-7 2. Mrs. Azra Bibi W/o Muhammad Nawaz CNIC No.17301-1086887-0 3. Mr. Hassan Nawaz S/o Muhammad Nawaz CNIC No.17301-5182703-5 4. Mr. Qamar Abbas S/o Muhammad Nawaz CNIC No.17301-1434318-7	1. Mr. Hassan Nawaz S/o Muhammad Nawaz CNIC No.17301-5182703-5 2. Mr. Qamar Abbas S/o Muhammad Nawaz CNIC No.17301-1434318-7 3. Mr. Ali Hamza S/o Muhammad Nawaz CNIC No.17301-6125229-9 4. Mrs. Azra Bibi W/o Muhammad Nawaz CNIC No.17301-1086887-0 5. Mst Farina Nawaz D/o Muhammad Nawaz CNIC No. 17301-7519158-8 6. Mst. Hajira Zainab W/o. Mr Ali Raza CNIC

5. Mr. Ali Hamza S/o Muhammad Nawaz CNIC No.17301-6125229-9	No. 17301-6344347-8 7. Mst Maryam Nawaz D/o Muhammad Nawaz CNIC No. 35201-4580283-4

CASE NO.28 <u>CHANGE OF MANAGEMENT OF M/S S.N.B. PHARMA (PVT) LTD., PLOT NO.142, INDUSTRIAL ESTATE, HAYATABAD, PESHSAWAR..</u>

M/s S.N.B. Pharma (Pvt) Ltd., Plot No.142, Industrial Estate, Hayatabad, Peshawar, under DML No. 000759 by way of formulation has submitted request for change in management of the firm as per Partnership Deedwith prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management as per Form-29	New management as per Form-A
1. Mr. Sibtain Haider S/o Shahnawaz CNIC No. 17301-0104139-5. 2. Mr. Shahnawaz S/o Muhammad Zaman, CNIC No.17301-4321874-1.	1. Mr. Sibtain Haider S/o Shahnawaz CNIC No. 17301-0104139-5. 2. Mr. Zain-ul-Abidin S/o Muhammad Nawaz, CNIC No.17301-6167153-9.

<u>Decision of the Central Licensing Board in 280th meeting:</u>

The Board considered and accepted for record the change of management of M/sS.N.B. Pharma (Pvt) Ltd., Plot No.142, Industrial Estate, Hayatabad, Peshawar, under DML No. 000759 (By way of Formulation) as under;

Previous management as per Form-29	New management as per Form-A
1. Mr. Sibtain Haider S/o Shahnawaz CNIC No. 17301-0104139-5. 2. Mr. Shahnawaz S/o Muhammad Zaman, CNIC No.17301-4321874-1.	1. Mr. Sibtain Haider S/o Shahnawaz CNIC No. 17301-0104139-5. 2. Mr. Zain-ul-Abidin S/o Muhammad Nawaz, CNIC No.17301-6167153-9.

CASE NO.29 <u>CHANGE OF MANAGEMENT OF M/S PERK PHARMA (PVT) LTD., PLOT NO.197/1-B, MAIN ROAD, INDUSTRIAL ESTATE, GADOON.</u>

M/s Perk Pharma (Pvt) Ltd., Plot No.197/1-B, Main Road, Industrial Estate, GadoonunderDML No. 000857 by way of formulation has submitted request for change in management of the firm as per Partnership Deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management as per Form-29	New management as per Form-29
1. Mr. Naveed Khan S/o Sattar Gul, CNIC No. 17301-5329550-5 2. Mr. Qadeer Hussain S/o Bashir Hussain, CNIC No. 17301-1386012-1 3. Muhammad Ibrahim S/o Abdul Hanan, CNIC No.16202-3672665-3	1. Mr. Naveed Khan S/o Sattar Gul, CNIC No. 17301-5329550-5 2. Mr. Muhammad Fahad Naveed S/o Naveed Khan, CNIC No. 17301-0126938-5 3. Muhammad Ibrahim S/o Abdul Hanan, CNIC No.16202-3672665-3

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/sPerk Pharma (Pvt) Ltd., Plot No.197/1-B, Main Road, Industrial Estate, Gadoon underDML No. 000857 (By way of Formulation) as under;

Previous management as per Form-29	New management as per Form-29
1. Mr. Naveed Khan S/o Sattar Gul, CNIC No. 17301-5329550-5 2. Mr. Qadeer Hussain S/o Bashir Hussain, CNIC No. 17301-1386012-1 3. Muhammad Ibrahim S/o Abdul Hanan, CNIC No.16202-3672665-3	1. Mr. Naveed Khan S/o Sattar Gul, CNIC No. 17301-5329550-5 2. Mr. Muhammad Fahad Naveed S/o Naveed Khan, CNIC No. 17301-0126938-5 3. Muhammad Ibrahim S/o Abdul Hanan, CNIC No.16202-3672665-3

Case No.30 CHANGE OF MANAGEMENT OF M/S. THE SAAKH PHARMA (PVT) LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000588 (SEMI-BASIC MANUFACTURE)

M/s The Saakh Pharma (Pvt) Limited Karachi , Plot No. C-7/1, North Western Industrial Zone, Port Qasim, Karachi underDML No. 000588 (By way of Semi-Basic Manufacture) has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 15,000/-. The detail of management is as under:-

Current Management Year 2020	New Management as per Form-29 of SECP Year 2020
i. Syed Abrar Hussain Kazmi S/o Syed Sajid Hussain Kazmi, CNIC # 42201-0749439-3 (Director)	i. Syed Mujtaba Hussain Kazmi S/o Syed Abrar Hussain Kazmi, CNIC # 42201-6172990-3(Director)

ii. Syed Abrar Hussain Kazmi S/o Syed Sajid Hussain Kazmi,CNIC# 42201-0749439-3 (CEO)	ii. Syeda Sardar Bano W/o Syed Abrar Hussain Kazmi (CNIC # 42201-0635689-4)(CEO)

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/sThe Saakh Pharma (Pvt) Limited Karachi , Plot No. C-7/1, North Western Industrial Zone, Port Qasim, Karachi underDML No. 000588 (By way of Semi-Basic Manufacture) as under;

Current Management Year 2020	**New Management as per Form-29 of SECP Year 2020**
i. Syed Abrar Hussain Kazmi S/o Syed Sajid Hussain Kazmi, CNIC # 42201-0749439-3 (Director) ii. Syed Abrar Hussain Kazmi S/o Syed Sajid Hussain Kazmi,CNIC# 42201-0749439-3 (CEO)	i. Syed Mujtaba Hussain Kazmi S/o Syed Abrar Hussain Kazmi, CNIC # 42201-6172990-3(Director) ii. Syeda Sardar Bano W/o Syed Abrar Hussain Kazmi (CNIC # 42201-0635689-4)(CEO)

Case No.31 CHANGE OF MANAGEMENT OF M/S. THE CKD PHARMACEUTICALS PAKISTAN (PVT) LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000 144 (FORMULATION)

M/s The CKD Pharmaceuticals Pakistan (Pvt) Limited Karachi ,Plot No. 50, Sector 28, Korangi Industrial Area, Karachi underDML No. 000144 (By way of formulation) has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

Current Management	**New Management as per Form-29 of SECP Year 2021**
i. Ms. Naureen Liaqat W/o Liaqat Ali, 42000-0451927-2, Director ii. Mr. Syed Mustafa Hussain Kazmi S/o Syed Abrar Hussain Kazmi,42201-0716021-7 (CEO)	i. Mr. Liaqat Ali S/o Muhammad Shafi, 42000-0575918-9, Director ii. Mr. Syed Mustafa Hussain Kazmi S/o Syed Abrar Hussain Kazmi,42201-0716021-7 (CEO)

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/sThe CKD Pharmaceuticals Pakistan (Pvt) Limited ,Plot No. 50, Sector 28, Korangi Industrial Area, Karachi underDML No. 000144 (By way of Formulation) as under;

Current Management	**New Management as per Form-29 of SECP Year 2021**
i. Ms. Naureen Liaqat W/o Liaqat Ali, 42000-0451927-2, Director ii. Mr. Syed Mustafa Hussain Kazmi S/o Syed Abrar Hussain Kazmi,42201-0716021-7 (CEO)	i. Mr. Liaqat Ali S/o Muhammad Shafi, 42000-0575918-9, Director ii. Mr. Syed Mustafa Hussain Kazmi S/o Syed Abrar Hussain Kazmi,42201-0716021-7 (CEO)

CaseNo.32 CHANGE OF MANAGEMENT OF M/S MACTER INTERNATIONAL LTD, PLOT NO. F-216, S.I.T.E. KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000141 (FORMULATION).

M/s Macter International Ltd, Plot No. F-216, S.I.T.E. Karachi,has submitted request for Change of managment with fee of Rs.50,000/-. The pre-requisite documents of the change of name / title and management are as under: -

Existing Management	**New Management as per Form- 29 Year 2020**
1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3 2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5 3. Mr. Sheikh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5 5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9 6. Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5 7. Mr. Mohammad Aslam S/o Mohammad	1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3 2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5 3. Mr. Sheikh Muhammad Waseem S/o Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5. 5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9 6. Mr. Muhammad Yahya Chawla S/o Abdul Salam CNIC No.42201-6477549-5. 7. Mr. Syed Anis Ahmad Shah S/o Syed Fazal

Ilyas CNIC No.42201-0398175-7 8. Miss Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0 9. Mr. Islahuddin Siddiqui S/o Allaudin Siddiqui CNIC No. 42301-6572835-1	Hussain Shah CNIC No.42301-4602118-1. 8. Miss.Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0 9. Mr. Tariq Wajid S/o Syed Wajid Ali Shah CNIC No. 42301-0366936-1.

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for the change of management of M/sMacter International Ltd, Plot No. F-216, S.I.T.E. Karachi underDML No. 000141 (By way of Formulation) as under;

Existing Management	**New Management as per Form- 29 Year 2020**
1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3 2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5 3. Mr. Sheikh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5 5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9 6. Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5 7. Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 8. Miss Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0 9. Mr. Islahuddin Siddiqui S/o Allaudin Siddiqui CNIC No. 42301-6572835-1	1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3 2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5 3. Mr. Sheikh Muhammad Waseem S/o Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5. 5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9 6. Mr. Muhammad Yahya Chawla S/o Abdul Salam CNIC No.42201-6477549-5. 7. Mr. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1. 8. Miss.Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0 9. Mr. Tariq Wajid S/o Syed Wajid Ali Shah CNIC No. 42301-0366936-1.

CaseNo.33 CHANGE OF MANAGEMENT OF M/S MACTER INTERNATIONAL LTD, PLOT NO. E-40/A, S.I.T.E. KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000641 (FORMULATION).

M/s Macter International Ltd, Plot No. E-40/A, S.I.T.E. Karachi,has submitted request for Change of management with fee of Rs.50,000/-. The pre-requisite documents of the change of name / title and management are as under: -

Existing Management	New Management as per Form- 29 Year 2020
1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3 2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5 3. Mr. Sheikh Muhammad Waseem S/O Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5 5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9 6. Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5 7. Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7 8. Miss Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0 9. Mr. Islahuddin Siddiqui S/o Allaudin Siddiqui CNIC No. 42301-6572835-1	1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3 2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5 3. Mr. Sheikh Muhammad Waseem S/o Sheikh Muhammad Shafi CNIC No. 42301-0823818-1 4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5. 5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9 6. Mr. Muhammad Yahya Chawla S/o Abdul Salam CNIC No.42201-6477549-5. 7. Mr. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1. 8. Miss.Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0 9. Mr. Tariq Wajid S/o Syed Wajid Ali Shah CNIC No. 42301-0366936-1.

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/sMacter International Ltd, Plot No. Plot No. E-40/A, S.I.T.E. Karachi underDML No. 000641 (By way of Formulation) as under;

Existing Management	New Management as per Form- 29 Year 2020
1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3 2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5 3. Mr. Sheikh Muhammad Waseem S/O	1. Mr. Asif Misbah S/o Misbahuddin Khan CNIC No. 42301-6009009-3 2. Mr. Swaleh Misbah S/O Misbahuddin Khan CNIC No. 42301-7508214-5 3. Mr. Sheikh Muhammad Waseem S/o Sheikh

Sheikh Muhammad Shafi CNIC No. 42301-0823818-1	Muhammad Shafi CNIC No. 42301-0823818-1
4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5	4. Mr. Amanullah S/O Kasim CNIC No. 42201-2037618-5.
5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9	5. Mr. Sohaib Umar S/O Muhammad Umar CNIC No. 42201-6581898-9
6. Mr. Shaikh Aamir Naveed S/o Ameeruddin Ahmed CNIC No.42201-1737266-5	6. Mr. Muhammad Yahya Chawla S/o Abdul Salam CNIC No.42201-6477549-5.
7. Mr. Mohammad Aslam S/o Mohammad Ilyas CNIC No.42201-0398175-7	7. Mr. Syed Anis Ahmad Shah S/o Syed Fazal Hussain Shah CNIC No.42301-4602118-1.
8. Miss Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0	8. Miss.Masarrat Misbah D/o Misbahuddin Khan CNIC No. 42301-0983750-0
9. Mr. Islahuddin Siddiqui S/o Allaudin Siddiqui CNIC No. 42301-6572835-1	9. Mr. Tariq Wajid S/o Syed Wajid Ali Shah CNIC No. 42301-0366936-1.

Case No.34 CHANGE OF MANAGEMENT OF M/S. THE SEARLE COMPANY LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000016(FORMULATION)

M/s The Searle Company Limited, Plot No. F-319, S.I.T.E Karachi underDML No. 000016 (By way of formulation) has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

Current Management (Year 2020)	New Management as per Form-29 of SECP (Year 2021)
1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3.	1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3.
2. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.	2. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.
3. Mrs. Shaista Khaliq Rehman W/o Syed Khaliq Abdur Rehman CNIC No. 43201-8797867-2	3. Mrs. Shaista Khaliq Rehman W/o Syed Khaliq Abdur Rehman CNIC No. 43201-8797867-2
4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803.	4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803.
5. Dr. Atta ur Rehman S/o Jamil ur Rehman CNIC No. 42000-3123678-7	5. Dr. Atta ur Rehman S/o Jamil ur Rehman CNIC No. 42000-3123678-7.
	6. Mr. Munis Abdullah S/o Rashid Abdulla CNIC No. 42201-9982517-1.

Decision of the Central Licensing Board in 280th meeting:

The Board considered and accepted for record the change of management of M/sThe Searle Company Limited, Plot No. F-319, S.I.T.E Karachi underDML No. 000016 (By way of Formulation) as under;

Current Management (Year 2020)	New Management as per Form-29 of SECP (Year 2021)
1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3. 2. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9. 3. Mrs. Shaista Khaliq Rehman W/o Syed Khaliq Abdur Rehman CNIC No. 43201-8797867-2 4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803. 5. Dr. Atta ur Rehman S/o Jamil ur Rehman CNIC No. 42000-3123678-7	1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3. 2. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9. 3. Mrs. Shaista Khaliq Rehman W/o Syed Khaliq Abdur Rehman CNIC No. 43201-8797867-2 4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803. 5. Dr. Atta ur Rehman S/o Jamil ur Rehman CNIC No. 42000-3123678-7. 6. Mr. Munis Abdullah S/o Rashid Abdulla CNIC No. 42201-9982517-1.

Case No.35 **APPROVAL OF PRODUCTION INCHARGE UNDER DRUG MANUFACTURING LICENCE NO. 000901 (SEMI-BASIC MANUFACTURE) OF M/s CARRYFOR PHARMACEUTICAL (PVT) LTD, KARACHI.**

M/s Carryfor Pharmaceutical (Pvt) Ltd, Plot No. E-81, North Western Industrial Zone, Port Qasim , Karachi had applied for approval of production in charge Mr. Wasi Ahmed S/o Muhammad Shafi (M.SC Chemistry) CNIC No. 42101-3206838-3.

The application was evaluated and a letter was issued to the firm on 22-05-2019 under Rule 15 of Drugs (Licensing, Registering, Advertising) Rules, 1976 to submit complete set of attested documents (as per checklist) for approval of Production in charge.

The reply was received from the firm on 29th August 2019 which was evaluated and a reminder letter dated 15th October 2019 was issued to the firm for submission of following documents for completion of application for approval of Production incharge.

i. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of appointee.

ii. Resignation of previously approved Production in charge.

In response firm submitted documents for approval of new Production in charge Mr. Faheem Khan S/o Sardar Khan which were again evaluated and a letter of Final Opportunity dated 24-03-2021 was issued to the firm to submit complete set of attested documents (as per checklist) for approval of new Production in charge as the proposed Production in charge Mr. Faheem Khan does not possess the relevant experience as required under Rule 15 (c) of the Drugs (L,R&A) Rules, 1976.

In response firm has submitted documents ofproduction in charge Mr. Wasi Ahmed S/o Muhammad Shafi (M.SC Chemistry) which are evaluated and following documents are still deficient in application for approval of Production in charge.

i. Prescribed fee of Rs. 5000 for approval of new Production in charge.

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

Submitted for consideration of the Board, please.

Decision of the Central Licensing Board in 280th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 15 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000901 (by way of Semi-Basic Manufacture) of M/s Carryfor Pharmaceutical (Pvt) Ltd, Plot No. E-81, North Western Industrial Zone, Port Qasim ,Karachimay not be suspended or cancelled by the Central Licensing Board.

Case No.36 RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000034 (FORMULATION) OF M/s MEDICURE LABORATORIES, KARACHI.

M/s Medicure Laboratories, Plot No. F/109, Hub River Road, S.I.T.E, Karachi had applied for renewal of DML No. 000034 by way of Formulation for the period of 30-04-2020 to 29-04-2025on 24-04-2020. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 11thAugust , 2020under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Application for renewal of DML on Prescribed Form-1A dully signed and stamped by management of the firm along with dully attested all annexures and also submit dully retained fee challan by STO DRAP, Islamabad.

No reply was received from the firm and a reminder letter dated 28th January 2021 was issued to the firm for submission of above mentioned documents for completion of application for renewal of DML.

No reply is received from the firm as of today and the application for renewal of DML No. 000034 (Formulation) is still deficient of above mentioned documents.

Decision of the Central Licensing Board in 280th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000034 (by way of formulation) of M/s Medicure Laboratories, Plot No. F/109, Hub River Road, S.I.T.E, Karachimay not be suspended or cancelled by the Central Licensing Board.

Case No.37 RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000809 (FORMULATION) OF M/s MISSION PHARMACEUTICALS, KARACHI.

M/s Mission Pharmaceuticals, Plot No. A-94, S.I.T.E. Super HighwayKarachi had applied for renewal of DML No. 000809 by way of Formulation for the period of 25-02-2020 to 24-02-2025on 07-01-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 27thFebruary , 2020under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Application for renewal of DML on Prescribed Form-1A dully signed and stamped by current management of the firm.
ii. Name & Attested CNIC Copy of Sole proprietor along with undertaking on stamp paper regarding sole proprietorship.
iii. Detail/names of all licensed sections on firm's letter head along with approval letters of all sections issued from CLB.
iv. Documents should be duly attested.

No reply was received from the firm and a reminder letter dated 02nd April 2021 was issued to the firm for submission of above mentioned documents for completion of application for renewal of DML.

No reply is received from the firm as of today and the application for renewal of DML No. 000809 (Formulation) is still deficient of above mentioned documents.

Decision of the Central Licensing Board in 280th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000809 (by way of formulation) of M/s s Mission Pharmaceuticals, Plot No. A-94, S.I.T.E. Super HighwayKarachimay not be suspended or cancelled by the Central Licensing Board.

Case No.38 SITE VERIFICAATION AND SITE APPROVAL OF M/S SHARQ PHARMA,

M/s Sharq Pharma, **Plot No. Na Class No. 119, Deh Tore, TapoKonkar, Gadap Town, District Malir (Off Main Super highway at M9 Toll Plaza adjacent Agility Ware House) Karachi** submitted application for site verification of proposed plot. After application was completed by the firm, area FID was requested to conduct site inspection of proposed plot and submit report regarding suitability of plot for establishment of pharmaceutical unit.

The FID submitted inspection report which is reproduced below :

1. The purposed site is situated at Plot No. Na Class No. 119, Deh Tore, TapoKonkar, Gadap Town, District Malir (Off Main super Highway M9 Tall Plaza), Karachi and measuring about 04.00 Acres, which will be utilized for industrial purpose as per Mukhttiarkar, Malir letter No. 184/2021 dated 28-01-2021(Annexure-A).
2. This is open land with a boundary wall and no construction work was seen inside the plot.
3. The plot surrounded by a warehouse form South; A Madarsa from North: an open plot from East and A wide road form West.
4. The said plot is termed as non-classified and is open to be used for any purpose. However, the firm has got it converted for industrial purpose after obtaining necessary conversion certificate from respective revenue office (copy attached).
5. The plot will be provided with necessary utilities from respective departments upon request.
6. Based on the above observation, the plot may be considered for the establishment of a pharmaceutical unit as it qualified the provision as laid down under paragraph-1 of Section 1 of Schedule B SRO.470(1)98 darted 15-05-1998) under Rule 15(a) and 16(a) of Drugs (Licensing, Registration & Advertising) Rules 1976 of Drug Act, 1976.

After the evaluation of the submitted report, the FID was requested to submit site inspection report with clear and candid recommendations regarding suitability of site for establishment of pharmaceutical unit.

In reply the FID Mr. Abdul Rasool Sheikh forwarded the site inspection report the contents of which are reproduced below :

> *"In continuation to this office letter of even number dated 18th February, 2021 regarding the above cited subject wherein, the true picture and location of the proposed plot was mentioned. The site seems unfit for the establishment of a pharmaceutical unit as it is surrounded by un-classified plots from three sides, which may be critical in future if the same are used other than industrial purposed.*
>
> *The subject plot* ***does not comply the provision as laid down under paragraph****-1 of Section1 of Schedule-B SRO.470(I)/98 dated 15-05-1998) under Rule 15(a) and 16(a) of Drugs (Licensing, Registering & Advertising) Rules 1976 of Drug Act, 1976, hence considered not suitable for establishment of pharmaceutical unit.*
>
> *Submitted for your kind information and further necessary action as per rules, please."*

Submitted for consideration of the Board, please.

Decision of the Central Licensing Board in 280th meeting

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to the firm Sharq Pharma in the upcoming meeting of the CLB, please.

Case No.39 RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000407 (BASIC-MANUFACTURE) OF M/s DRUG PHARMA CHEMICALS (PVT) LTDKARACHI.

M/s Drug Pharma Chemicals (Pvt) Ltd, Karachi had filled application for renewal of DML No. 000407 (Basic Manufacture) for the period commencing on 16-07-2020 and ending on 15-07-2025. The application was received on 16-07-2020. The application for the renewal of DML of the firm was evaluated. Following documents were found deficient.

i. Additional surcharge fee of Rs. 5,000 for late submission (01 day) of application for renewal of DML.

ii. Dully retained fee challan by AD (Revenue) DRAP, Islamabad.

iii. All attested annexure/enclosures of Form-1A.

iv. Approval letters of API's issued by CLB or if not available then submit layout plan for regularization of manufacturing facility.

v. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.

vi. Complete set of attested documents (as per checklist) for approval of production In charge & Quality Control In charge as required under Rule 15 of the Drugs (L,R&A) Rules, 1976.

vii. Updated NOC of CRF issued from statistical officer DRAP, Islamabad

A letter dated 06th October 2020 was issued to the firm to submit the above mentioned shortcoming/deficient documents.

No reply was received from the firm and a Reminder dated 25th January 2021 was issued to the firm to submit the said documents but no reply/response is received from the firm and the application for renewal of DML is still deficient of above mentioned documents.

Submitted for consideration of the Board, please.

Decision of the Central Licensing Board in 280th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule, 12, Rule, 15 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000407 (by way of Basic Manufacture) of M/s Drug Pharma Chemicals (Pvt) Ltd, Karachi, may not be suspended or cancelled by the Central Licensing Board.

Case No.40 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000438 (FORMULATION) OF M/S SWISS PHARMACEUTICALS (PVT) LTD, PLOT No. A-159, S.I.T.E. II, SUPER HIGHWAY, KARACHI

M/s Swiss Pharmaceuticals (Pvt) Ltd, Karachihas filled application for renewal of DML No. 000438 (Formulation) for the period commencing on 08-09-201907-08-2020 and ending on 07-09-2024.. The application for the renewal of DML of the firm was evaluated and a letter dated 03-01-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Submit layout plan for regularization of manufacturing facility along with prescribed fee.
ii. Detail of current management/directors on firm's letter head along with attested CNIC copies of all directors.
iii. Updated original certified true copy of Form-29 & Form-A issued by SECP.

The reply of the firm was received on 13-10-2020 and the documents submitted by the firm were evaluated and a Reminder dated 04-12-2020 was issued to the firm to submit following documents :

i. Updated original certified true copy of Form-29 & Form-A issued by SECP.
ii. Prescribed fee for change of management.
iii. Detail of all licensed sections on firm's letter head along with prescribed fee and two copies of layout plan for the purpose of regularization.

In response to this Division's Reminder , the firm has not submitted the required documents and instead has submitted letter dated 05-01-2021 and has stated that firm has applied to SECP for issuance of updated Form-29 & Form-A and has requested to give one month time to submit the document of Form-29 along with prescribed fee for change of management and the application is still found deficient of following documents:

i. Updated original certified true copy of Form-29 & Form-A issued by SECP.
ii. Prescribed fee for change of management.
iii. Detail of all licensed sections on firm's letter head along with prescribed fee and two copies of layout plan for the purpose of regularization.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000438(by way of formulation) of M/s Swiss Pharmaceuticals (Pvt) Ltd, Plot no. A-159, S.I.T.E. II, Super Highway,Karachimay not be suspended or cancelled by the Central Licensing Board.

The show cause notice was issued to the firm in compliance to decision of the CLB. The documents submitted by the firm M/s Swiss Pharmaceuticals (Pvt) Ltd, Karachi after issuance of show cause

notice dated 12th March 2021 were evaluated and the application for renewal of DML No. 000438 (Formulation) is still found deficient of following documents :

i. Updated (Original) Form- 29 & Form-A issued by the SECP ..

ii. Submit revised layout plan for regularization in light of the observations/shortcomings in layout plan communicated vide letter dated 19th March 2021.

The firm is called for personal hearing vide letter dated 13th April 2021.

Proceedings and Decision of Central Licensing Board in 256th meeting.

Mr. Huzaifa Umair Director of M/s Swiss Pharmaceuticals (Pvt) Ltd, Karachi, & Mr. Rashid Muneer Advocate appeared before the Board. He contended that there the required documents are submitted to the Division of Licensing. The documents were received on the day of meeting 26-04-2021. The Board after perusal of record and facts mentioned above and deliberations made by representative of the firm decided to defer the case till next meeting of the CLB to check compliance of the firm in the light of submitted documents.

Case No.41 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000470 (FORMULATION) OF M/S ZAFA PHARMACEUTICAL LABORAOTIRES (PVT) LTD, PLOT No. C-208, C-217, H.I.T.E. DISTRICT LASBELLA, BALOCHISTAN

M/s Zafa PharmaceuticalLaboratories (Pvt) Ltd, Baluchistanhas filled application for renewal of DML No. 000470 (Formulation) for the period commencing on 02-03-2020 and ending on 01-03-2025. The application was received on 27-08-2019. The application for the renewal of DML of the firm was evaluated and a letter dated 28-01-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

(i) Original certified true copy of Form-29 & From-A for year 2019 issued from SECP along with attested CNIC copies of all directors.

(ii) Detail/names of all licensed sections on firm's letter head along with approval letters of all sections issued from CLB. Or if not available then submit layout plan for regularization of manufacturing facility.

(iii) Attested copy of Classes of Drugs

(iv) Attested copy of Dosage forms of drug

(v) Attested copy of Name(s) of drugs registered / approved

(vi) Attested copy of Section wise detail of machinery for manufacture

(vii) Attested copy of Section wise detail of machinery for Quality Control Lab

(viii) Attested copy of Name and Qualification of Production In charge.

(ix) Attested copy of Name and Qualification of QC In charge.

The reply of the firm was received on 12-02-2020 and the documents submitted by the firm were evaluated and a Reminder dated 21-05-2020 was issued to the firm to submit following documents:

i) Original certified true copy of Form-29 & From-A for year 2020 issued from SECP along with attested CNIC copies of all directors.

ii) Detail/names of all licensed sections on firm's letter head along with approval letters of all sections issued from CLB. Or if not available then submit layout plan for regularization of manufacturing facility.

In response to this Division's Reminder dated 21-05-2020the firm has not submitted the required documents and instead has stated that firm has already submitted the required documents andthe application is still found deficient of following documents:

i. Original certified true copy of Form-29 & From-A for year 2020 issued from SECP along with attested CNIC copies of all directors.

ii. Detail/names of all licensed sections on firm's letter head along with approval letters of all sections issued from CLB. Or if not available then submit layout plan for regularization of manufacturing facility

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000470(by way of formulation) of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, Plot No. C-208, C-217, H.I.T.E, District Lasbella, Baluchistan, may not be suspended or cancelled by the Central Licensing Board.

The show cause notice was issued to the firm in compliance to decision of the CLB. No reply is received from the firm .

The firm is called for personal hearing vide letter dated 13th April 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person on behalf of the firm appeared before the Board.. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000470(by way of formulation) of M/s

Zafa Pharmaceutical Laboratories (Pvt) Ltd, Plot No. C-208, C-217, H.I.T.E, District Lasbella, Baluchistan, till fulfilment of the codal formalities with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 42 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S UNI-TIECH PHARMACEUTICALS (PVT) LTD, KARACHI UNDER DRUG MNAUFACTURING LICENSE NO. 000356 (FORMULATION)

M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd Karachi Plot No. 4/116-119, Sector 21, Korangi Industrial Area, Karachi, had applied for renewal of DML No. 000356 by way of formulation for the period of 04-10-2019 till 03-10-2024.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 20-12-2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Application on Prescribed Form 1A dully signed by current management of the firm along with dully attested enclosure/annexures.
(ii) Original Certified True Copy of Form-29 & Form-A for the year 2019 issued by SECP.
(iii) Detail/names of all directors on firm's letter head along with attested CNIC copies of all directors.
(iv) Detail of all licensed sections on firm's letter head along with approval letters of sections issued from the Central Licensing Board & if not available then submit layout plan for Regularization of facility.

The firm submitted their reply on 16th April 2020. After evaluation of the submitted documents, Final reminder was issued on 19h May 2020. to the firm to submit following shortcomings: -

1. Application on Prescribed Form 1A dully signed by current management of the firm along.
2. Original Certified True Copy of Form-29 & Form-A (Updated) issued by SECP.
3. Prescribed fee for change of management as the management is changed from last renewal.
4. Detail of all licensed sections on firm's letter head along with approval letters of sections issued from the Central Licensing Board & if not available then submit layout plan for Regularization of facility.
5. **All documents should be duly attested.**

Reply of the firm was received on 10-0-2020 which was evaluated and application for renewal of DML was still found deficient of following documents.

1. Application on Prescribed Form 1A dully signed by current management of the firm.
2. Original Certified True Copy of Form-29 & Form-A (Updated) issued by SECP.
3. Detail of all licensed sections on firm's letter head along with approval letters of sections issued from the Central Licensing Board & if not available then submit layout plan for Regularization of facility.

proceedings and Decision by the Central Licensing Board in 276th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000356 by way of formulation of M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd Karachi Plot No. 4/116-119, Sector 21, Korangi Industrial Area, Karachi , may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Accordingly, the show cause notice Dated : 30-09-2020 was issued to the firm.

Firm has submitted layout plan for regularization of manufacturing facility which was discussed in the LOP committee and observations were observed in the layout plan which are communicated to the firm vide letter Dated : 13-10-2020.

In the meanwhile approved Quality control Incharge of the firm Ms. Amir Zadi as forwarded her resignation stating that she has resigned from the post of Quality control Incharge of M/s Uni-Tiech Pharmaceutical (Pvt) Ltd, Karachi with effect from 15-08-2020.

The firm is called for personal hearing vide letter Dated : 08-10-2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

No person appeared on behalf of the firm. The Board deliberated the case and decided to afford final opportunity for personal hearing to the firm in the next meeting of the Central Licensing Board before taking decision.

The firm also submitted documents for completion of application for renewal of DML which are evaluated and the application for renewal of DML No. 000356 (Formulation) is still found deficient of following documents :

i. Firm does not possess approval letters of licensed sections issued from the CLB and had submitted layout plan for regularization of manufacturing facility which was discussed in LOP committee and a letter regarding shortcomings in layout plan was issued to the firm for which firm has not submitted the revised layout plan.

ii. Updated (Original) Form- 29 & Form-A issued by the SECP containing the names of current directors of the firm.

iii. Prescribed fee for change of management.

iv. Submit complete set of attested documents of new proposed QC In charge (as per checklist) in response to this office letter dated 14th October 2020 as the approved QC In charge

Ms. Amir Zadi has resigned from the firm and has forwarded her resignation to Licensing Division, DRAP.

The firm is called for Personal Hearing vide letter dated 13th April 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person on behalf of the firm appeared before the Board.. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000356 (by way of formulation) of M/s Uni-Tiech Pharmaceuticals (Pvt) Ltd Karachi Plot No. 4/116-119, Sector 21, Korangi Industrial Area , Karachi till fulfilment of the codal formalities with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16& Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

.

Case No. 44. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s ALKEMY PHARMACEUTICAL LABORAOTIRES (PVT) LTD HYDERABAD UNDER DRUG MANUFACTURING LICENSE NO. 000132 (FORMULATION)..

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Alkemy Pharmaceuticals Laboratories (Pvt) Ltd , Karachi on 23rd September, 2020 but firm has not submitted CRF from year 2014. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Submitted for consideration and orders of the Board.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Faraz A. Shaikh Managing Director of the firm appeared before the Board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Bufget and Accounts Division.

Case No.45 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000154 (FORMULATION) OF M/S ARDIN PHARMACEUTICALS, PLOT No. 56, SECTOR 27, KORANGI INDUSTRIAL AREA,KARACHI**

M/s Ardin Pharmaceuticals, Karachihas filled application for renewal of DML No. 000154 (Formulation) for the period commencing on 08-04-2020 and ending on 07-04-2025. The application was received on 25-03-2020. The application for the renewal of DML of the firm was evaluated and a letter dated 16-06-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Application on Prescribed Form-1A signed by current management of the firm along with dully attested annexure/enclosure.

The reply of the firm was received on 07-08-2020 and the documents submitted by the firm were evaluated and a Reminder dated 11-11-2020 was issued to the firm to submit following documents :

I. Application on Prescribed Form-1A signed by current management of the firm along with dully attested annexure/enclosure.

In response to this Division's Reminder dated 11th November 2020 the firm has submitted the documents for completion of application for renewal of DML No. 000154 (Formulation) which are evaluated and the application is still found deficient of following documents:

i. All enclosures/annexure of Form-1A are unattested.

ii. The production in charge **Mr. Tariq Yameen Waseem** & quality control in charge **Mr. Ain-ul-Haq**are not approved and firm has also not submitted the documents for approval of both technical staff**.**

i. Updated NOC of CRF.

ii. Attested Partnership deed (existing & amended) along with attested CNIC copies of all partners/directors.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 16 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000154(by way of formulation) of M/s ArdinPharmaceuticals, Plot No. 56, Sector 27, Korangi Industrial Area, Karachimay not be suspended or cancelled by the Central Licensing Board.

The show cause notice dated 12th March 2021 was issued to the firm. No reply is received from the firm.

Firm is also called for personal hearing vide letter dated 13th April 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Syed Zia Uddin MD of the firm and Mr. Rashid Muneer advocate appeared before the board and contended that the documents are already submitted to the division of Drug Licensing . The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000154 (by way of formulation) of M/s ArdinPharmaceuticals, Plot No. 56, Sector 27, Korangi Industrial Area, Karach till fulfillment of codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decisionand case may be placed before the board for ratification.

Case No.46 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S IMCO PHARMACEUTICAL LABORATORIES (PVT) LTD., 73, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR

The firm, M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar wherein the firm has submitted the application for renewal of Drug Manufacturing No. 000317 (by way of Formulation). The application was received on **13/02/2020.** The firm has submitted a fee of Rs. 50,000**.** The application was evaluated as per Drugs (Licensing, Registering & Advertising) Rules 1976 and found following shortcomings;

i. Form-1A as per prescribed format (attached) duly signed and stamped by CEO/Owner of the firm.
ii. Name(s) of registered drugs.
iii. Detail of management at the time of previous renewal and current renewal.
iv. Updated Form-29 issued and certified true copy by S.E.C.P.
v. Attested copy of CNIC's of all Directors.
vi. Proof of section approval from Central Licensing Board.
vii. Approved master Layout Plan
viii. Attested copy of list of registered Drugs.
ix. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.

x. For approval of proposed production Incharge, submit application as per SOP along with documents and prescribed fee.

Accordingly, shortcoming letter No. 3-4/91-Lic (Vol-II) dated 24/08/2020 was issued to the firm to rectify above mentioned shortcomings.

In response to shortcoming letter the firm has submitted their reply. The same was evaluated and found following shortcoming for which final reminder vide letter No. 3-4/91-Lic (Vol-II) dated 04/11/2020 was issued to rectify these shortcomings;

i. Form-1A as per prescribed format (attached) duly signed and stamped by CEO/Owner of the firm.
ii. Name(s) of registered drugs.
iii. Detail of management at the time of previous renewal and current renewal.
iv. Updated Form-29 issued and certified true copy by S.E.C.P.
v. Attested copy of CNIC's of all Directors.
vi. Proof of section approval from Central Licensing Board.
vii. Approved master Layout Plan
viii. Attested copy of list of registered Drugs.
ix. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.
x. For approval of proposed production Incharge, submit application as per SOP along with documents and prescribed fee.

In response to final reminder the firm submitted their reply, however, as of today, the firm did not rectify following shortcomings;

i. Updated Form-29 issued and certified true copy by S.E.C.P.
ii. Proof of section approval from Central Licensing Board.
iii. Approved master Layout Plan.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5, Rule 19 and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000317(by way of formulation) of M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar may not be suspended or cancelled by Central Licensing Boardor application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to the firm M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar dated 08-01-2021.

In response to Show Cause Notice, the firm submitted their reply which is reproduced as under;

"We have deposited the letter alongwith the relevant documents and approved map in the office of DRAP, Islamabad on 13-02-2020 and

19-11-2020. Moreover, request you to call me for personal hearing to explain my position properly."

Meanwhile another reply is received on 22-04-2021 from the firm which is re-produced as under;

Your office pointed out the following short of the following documents/information

1. ***Updated form 29***
   We have applied for form "H" and after the long procedure we received form H (copy attached)
2. ***Proof of section wise approval***
   We have approved layout plan in 2005 in which the detail of all sections mentioned moreover we provide you the inspection report of our firm in which the inspection team mention the sections of our firm
   a. *Renewal inspection report of 13/11/2008 in which the sections are approved by panel (Copy attached)*
   b. *Inspection report of F.I.D Peshawar 7/4/2014 in which he approved the sections in inspection book (Copy attached)*
   c. *Inspection report of F.I.D Peshawar in 14/5/2018 in which he mention the section of our firm in inspection book (Copy attached)*
3. ***Approval of layout plane***
   We provide you the copy of the letter of approval of layout plane in 2/4/2005 Our firm is established in 1992 and that time only approval of layout plane is issued by the minister of health and the panel team or F.I.D have no objection on the approval of sections at that time if there is any short coming we are ready to overcome the shortcoming.

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision of Central Licensing Board in 256th meeting.

Mr. Imtiaz Ahmed CEO of the firm appeared before the board and contended that the documents are already submitted to the division of Drug Licensing . The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000317 (by way of formulation) of M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd., 73, Industrial Estate, Hayatabad, Peshawar till fulfillment of codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decisionand case may be placed before the Board for ratification.

Case No. 47. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s BLISS INDUSTRIES (PVT) LTD, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000086 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Bliss Industries (Pvt) Ltd, Karachi on 30th September, 2020 but firm has not submitted CRF since 2013. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Submitted for consideration and orders of the Board.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person on behalf of the firm appeared before the board. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

Case No.48 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000148 (FORMULATION) OF M/S MARVI PHARMACEUTICALS, PLOT No. 70, SECTOR 24, KORANGI INDUSTRIAL AREA, KARACHI

M/s Marvi Pharmaceuticals, Karachi has filled/submitted application for renewal of DML No. 000148 (Formulation) for the period commencing on 10-07-2020 and ending on 09-07-2025.The application

for the renewal of DML of the firm was evaluated and a letter dated 08-10-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Application on Prescribed From-1A.
ii. Status of sections whether ready for inspection or otherwise in the light of approved layout plan for regularization vide letter Dated : 16-03-2018.
iii. Detail/names of directors of firm on firm's letter headattested CNIC copies of all directors.
iv. Notarized Updated Partnership deed.
v. Prescribed fee for change of management (if the management is changed from the last renewal of DML).
vi. Updated NOC of CRF issued from statistical officer DRAP.

No reply was received from the firm and a Reminder dated 05th January 2021 was issued to the firm to submit the said documents but no reply/response is received from the firm and the application for renewal of DML is still deficient of above mentioned documents.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 Rule 12 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000148(by way of formulation) of M/s Marvi Pharmaceuticals Plot no. 70, Sector 24, Korangi Industrial Area,Karachi may not be suspended or cancelled by the Central Licensing Board.

The show cause notice was issued to the firm in compliance to decision of the CLB. No reply is received from the firm .

The firm is called for personal hearing vide letter dated 13th April 2021.

Proceedings and Decision of Central Licensing Board in 256th meeting.

Mr. Adnan Saeed Production manager of the firm appeared before the board and contended that the firm is arraging documents for completion of application The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000148 (by way of formulation) of M/s Marvi Pharmaceuticals Plot no. 70, Sector 24, Korangi Industrial Area,Karachi till fulfillment of codal formalities/submission of shortcoming documents under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

Case No. 49. <u>NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s MARVI PHARMACEUTICALS KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000148 (FORMULATION)..</u>

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

<u>Decision by the Central Licensing Board in 269th meeting:</u>

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Marvi Pharmaceuticals, Karachi on24th September, 2020 but firm has not submitted CRF from year 2016. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

<u>Submitted for consideration and orders of the Board.</u>

<u>Proceedings and Decision of Central Licensing Board in 280th meeting.</u>

Mr. Adnan Saeed Production manager of the firm appeared before the board and contended that the documents are submitted to Budget & Account Divison, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Bufget and Accounts Division.

Case No. 50 . <u>NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s</u>

SPECIFIC RESEARCH LABORAOTIRES KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000081(FORMULATION)..

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Specific Research Laboraotires, Karachi on 30th September, 2020 but firm has not submitted CRF till 2010. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Submitted for consideration and orders of the Board.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No Person on behalf of the firm appeared before the board .The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Bufget and Accounts Division.

Case No.51 RENEWAL OF DML NO. 000119 (FORMULATION) OF M/S PAKISTAN PHARMACEUTICAL & CHEMICAL LABORAOTRIES (PVT) LTD, HYDERABAD

The Firm has filled application for renewal of DML No. 000119 (Formulation) for the period commencing on 12-07-2019 and ending on 11-07-2024. The application was received on 23-07-2019

2019. The application for the renewal of DML of the firm was evaluated. Following documents were found deficient.

i. Application on Prescribed Form-1A signed by current management of the firm along with dully attested annexure/enclosure.
ii. Updated NOC regarding CRF from STO, DRAP.
iii. Updatedoriginalcertified true copy of Form-29 & Form-A issued by SECP (original).
iv. Duly attested CNIC copies of all Directors.
v. Section approval letters of all sections approved by CLB, if not available, apply for regularization of layout plan.
vi. Prescribed fee challan for renewal of DML retained by STO DRAP, Islamabad along with additional surcharge fee of Rs. 60,000 as the application is received 12 days late from due date of renewal of DML
vii. Names and Approval letters of Production In charge and Quality Control In charge.

A letter dated 03rd January 2020 was issued to the firm to submit the above mentioned shortcoming/deficient documents.

No reply was received from the firm and a Reminder dated 30th November 2020 was issued to the firm to submit the said documents but no reply/response is received from the firm and the application for renewal of DML is still deficient of above mentioned documents.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 16 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000119(by way of formulation) of **M/s Pakistan Pharmaceutical and Chemical Laboratories (Pvt) Ltd, Hyderabad** may not be suspended or cancelled by the Central Licensing Board.

The show cause notice dated 12th March 2021 was issued to the firm. The firm has submitted documents for completion of application for renewal of DML No. 000119 (formulation) on 1st April 2021 which are evaluated and the application is still deficient of following documents :

i. Application on Prescribed Form-1A signed by current management of the firm along with dully attested annexure/enclosure.
ii. Updated NOC regarding CRF from STO, DRAP.

iii. Updated original certified true copy of Form-29 & Form-A issued by SECP (original).

iv. Duly attested CNIC copies of all Directors.

v. Prescribed fee for change of management.

vi. Section approval letters of all sections approved/issued by CLB, if not available, apply for regularization of layout plan.

vii. Prescribed fee challan for renewal of DML retained by STO DRAP, Islamabad along with additional surcharge fee of Rs. 60,000 as the application is received 12 days late from due date of renewal of DML

In the meanwhile, a letter is received from Mr. Muhammad Humayon Khan, Advocate, Humayon Law Associates, wherein he stated as under:

"Under instructions and on behalf of our clients **Mr. Sadruddin J.Bhimani Khuaia son of Jiva Bhai, Mr. Nooruddin and Ms. Shumaila,Son and Daughter of Sadruddin J . Bhimani Khuaja,** we have to invite your kind attention to the following facts and address you as under:-

Our clients are 50% shareholders in M/s Pakistan Pharmaceutical and Chernical Laboratories (Pvt.) Limited, situated at Plot No. A-34, SITE, Hyderabad.

In the year 2003, our clients entered into a dispute with Mr. Sultan-ul-Haq Qureshi son of Ikram-ul-Haq, who is Shareholder of the remaining 50% shares of the said company. Accordingly, our clients filed Suit No. 34 of 2003 (re-numbered as Suit No.39 of 2007) against the said Mr. Sultan-ul-Haq Qureshi, before the learned Senior Civil Judge, Hyderabad,which was dismissed by Judgment dated24-12-2007.

Against the afore-said Judgment and Decree, our clients preferred Civil Appeal No. 09 of 2008 before the learned District Judge, Hyderabad. The learned Additional District Judge by his impugned Judgment dated 27-03-2010 and Decree dated 08-04-2010 dismissed the said appeal of our clients.

Against the afore-said Judgment and Decree, ourclients preferred CivilRevision No. 186 of 2010 in the Hon'ble High Court of Sindh, Hyderabad Circuit, which is still pending.

During pendency of the said Civil Revision No. 186 of 2010 before the Honourable High Court of Sindh, Hyderabad Circuit, the said Sultan-ul-Haq Qureshi son of Ikram-ul-Hq expired and his legal heirs namely Asad-ul-Haq Qureshi Son of late Sultan-ul-Haq Qureshi, Mst. Sarwat Qureshi and Mst. Saba Qureshi, both daughters of late Sultan-ul-Haq Qureshi and Mst. Rehana Qureshi widow of Sultan-ul-Haq Qureshi were brought on record.

It is pertinent to note that the entire dispute is still sub-judice before the Honourable High Court in Civil Revision No.186 of 2010, **which is now fixed for final hearing on 22-O3-2O21.**

You are, therefore, requested to refrain yourself either to enter any transaction by the said legal heirs of deceased Sultan-ul-Haq Qureshi, in any manner whatsoever, in favour of any party, person, company and authority or to **change the name of the Company in any manner whatsoever** and in any case, if any transaction is entered-into or any change is made, our clients shall bear no responsibility whatsoever and any such action shall be deemed to be illegal and unlawful."

The firm is also called for personal hearing vide letter dated 13th April 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Arif, Admin Manager of the firm appeared before the board and contended that the firm is arraging documents for completion of application and there is management dispute among the owners of the firm. The Board after perusal of record , GMP non-complaince issues of the firm , and based on facts decided to cancel the Drug Manufacturing License No 000119 (by way of formulation) of **M/s Pakistan Pharmaceutical and Chemical Laboratories (Pvt) Ltd, Hyderabad** in larger public interest under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule, 16, Rule, 19, of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 52. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 RENEWAL OF DML NO. 000119 (FORMULATION) OF M/S PAKISTAN PHARMACEUTICAL & CHEMICAL LABORAOTRIES (PVT) LTD, HYDERABAD

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect

these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Pakistan Pharmaceutical &Chemical Laboratories (Pvt) Ltd , Hyderabad on 23rd September, 2020 but firm has not submitted CRF from year 2014. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Submitted for consideration and orders of the Board.

Proceedings and Decision of Central Licensing Board in 256th meeting.

Mr. Arif, Admin Manager of the firm appeared before the board and contended that the firm is arraging documents for completion of application and there is management dispute among the owners of the firm. The Board after perusal of record , GMP non-complaince issues of the firm , and based on facts decided to cancel the Drug Manufacturing License No 000119 (by way of formulation) of **M/s Pakistan Pharmaceutical and Chemical Laboratories (Pvt) Ltd, Hyderabad** in larger public interest under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule, 16, Rule, 19, of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No.53 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000116 (FORMULATION) OF M/S ZUMARS PHARMA FTY (PVT) LTD, 02-MALIR INDUSTRIAL AREA, KARACHI

M/s. Zumars Pharma FTY. (Pvt) Ltd,, Karachi submitted application for renewal of DML No. 000116 (Formulation) for the tenure commencing on 24-08-2020 and ending on 23-08-2025. The application was evaluated and a letter dated 05-10-2020 was issued to the firm to submit following documents for completion of application for renewal of DML.

i. Detail of licensed sections on firm's letter head along with approval lettersissued from the CLB or if not available then submit layout plan for regularization of manufacturing facility.
ii. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
iii. Prescribed fee for change of management (if the management is changed from the last renewal of DML).

iv. Name & approval letters of production Incharge Mr. Altaf Ali Sahito& Quality Control InchargeMr. Mukhtiar Ali or if not available then submit complete set of attested documents (as per checklist).

v. Updated NOC of CRF issued from statistical officer DRAP.

The firm submitted reply/documents on 09-12-2020 which were evaluated and after evaluation Reminder **dated 04-01-2021** was issued to the firm to submit following documents:

i. Detail / names of licensed sections as per dosage forms on firm's letter head.
ii. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
iii. Prescribed fee for change of management (if the management is changed from the last renewal of DML).
iv. Submit complete set of attested documents (as per checklist) for approval of production in charge and QC In charge.
v. Updated NOC of CRF issued from statistical officer DRAP.

In reply to reminder firm has only submitted documents of QC Incharge which are evaluated and following documents are found still found deficient and application for renewal of DML is still deficient of following documents:

i. Detail / names of licensed sections as per dosage forms on firm's letter head.
ii. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
iii. Prescribed fee for change of management (if the management is changed from the last renewal of DML).
iv. Submit complete set of attested documents (as per checklist) for approval of production in charge.
v. Updated NOC of CRF issued from statistical officer DRAP.
vi. Relevant experience certificates of proposed QC Incharge.
vii. Resignation / retirement/Deathof earlier QC Incharge.
viii. Job acceptance letter by the proposed QC Incharge.
ix. Resignation or termination letter of QC Incahrge from the previous firm / promotion letter / transfer letter from the same firm.
x. Undertaking as whole time employee of proposed QC Incharge.

Submitted for consideration of the Board, please.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) & Rule 16 and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000116 (by way of formulation) of M/s. Zumars Pharma FTY. (Pvt) Ltd, Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML under Rule 5(2A) may not be rejected.

The show cause notice dated 12th March 2021 was issued to the firm . The reply of the show cause notice was received from the firm and the documents submitted by the firm in reply to show cause notice dated 12th March 2021 **are evaluated and the application for renewal of DML is still found deficient of following documents :**

i. Updated (Original) Certified True Copy of Form-29 & Form-A issued from SECP.
ii. Updated NDC of CRF issued from statistical officer, DRAP
iii. Details of all licensed sections as per dosage form on firm's letter head.
iv. Relevant experience certificates of Proposed QC Incharge Mr. Liaqat Mugheri.
v. Resignation of previous QC Incharge.
vi. Prescribed fee for change of Production Incharge Mr. Altaf Hussain.
vii. Attested documents of proposed Production Incharge including notarized
viii. Undertaking signed by the appointee and the management of the firm.

The firm is also called for personal hearing vide letter dated 13th April 2021.

Submitted for consideration of the Board, please.

Proceedings and Decision of Central Licensing Board in 256th meeting.

Mr. Muhammad Yaseen Director of the firm appeared before the Board. He contended that there the required documents are submitted to the Division of Licensing. The documents were received on the day of meeting 26-04-2021. The Board after perusal of record and facts mentioned above and deliberations made by representative of the firm decided to defer the case till next meeting of the CLB to check compliance of the firm in the light of submitted documents.

Case No.54 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/s ADVANCED PHARMACEUTICALS, RAWAT.

M/s Advanced Pharmaceuticals, Plot No. 38, Street S-4, National Industrial Zone, RCCI, Rawat had applied for renewal of DML No. 000686 by way of Formulation for the period of 24-06-2020 to 23-06-2025on 03-06-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13thAugust, 2020under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed and stamped Form-1A (as per format)
ii. Duly attested CNIC copies of owner / partners.
iii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management.

iv. Proof of sections/section approved by CLB, if not available, apply for regularization of layout plan.
v. Update NDC regarding CRF from STO (R&D) DRAP, Islamabad.
vi. Documents should be duly attested.

The firm replied to this letter on 29th September, 2020 and reminder letter was issued on 2nd November, 2020 to the firm for completion of application:

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Properly filled, signed and stamped Form-1A (as per prescribed format).

The firm replied to reminder on 12th November, 2020but the application for renewal of DML is still incomplete with following documents being deficient.

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.

Proceedings and Decision by the Central Licensing Board in 279thmeeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000686(by way of formulation) of M/s Advanced Pharmaceuticals, Plot No. 38, Street S-4, National Industrial Zone, RCCI, Rawatmay not be suspended or cancelled by the Central Licensing Board.

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

The Show Cause Notice dated 30th March,2021 was issued to M/s Advanced Pharmaceuticals, Plot No. 38, Street S-4, National Industrial Zone, RCCI, Rawat.

The firm replied to Show Cause Notice and submitted deficient documents. Now, the application for renewal of DML is complete.

A letter of Personal hearing has been issued on 14th April, 2021.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

Dr. Zahid Pasha, CEO of the firm appeared before the board and contended that firm had completed the application for renewal of DML and had submitted the requried documents.The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause

notice in respect of Drug Manufacturing License No.000686 (By way of Formulation) of M/s Advanced Pharmaceuticals, Plot No. 38, Street S-4, National Industrial Zone, RCCI, Rawat., for further period.

Case No.55 M/S MEDICON PHARMACEUTICAL INDUSTRIES (PVT) LTD., B-1/11, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR

The firm, M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar submitted the application for renewal of DML No. 000215 by way of formulation on 26-05-2016 for the period of 14-06-2016 to 13-06-2021, which was well on time. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. To submit renewal of Drug Manufacturing License application on prescribed Form-1A (copy enclosed).
ii. To submit detail of management / owners with attested copies of CNIC's and Form-29 (previous and current).

a. With reference to above letter, it is mentioned that as per available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. Licensing Division issued final reminder on for completion of application of renewal of DML to the firm for information / documents as under;
    i. To submit renewal of Drug Manufacturing License application on prescribed Form-1A (copy enclosed).
    ii. To submit detail of management / owners with attested copies of CNIC's and Form-29 (previous and current).

b. No response of the firm was received with reference to above mentioned letter and final reminder and case was considered in 253rd meeting of the Central Licensing Board.

c. Decision of CLB in its 253rd meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar DML No. 000440 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

(The Drug Manufacturing Number of the firm was erroneously written as "**000440**" instead of the correct Drug Manufacturing License Number i.e. "**000215**" which was corrected **in 255th meeting)**

d. Reply of Firm to Show Cause Notice

We may refer show cause notice dated 21-09-2017, which is received on 25-09-2017, we are sending following documents for consideration

i. Application for renewal of DML on prescribed Form-1A
ii. Detail of management /owners with attested CNICs and Form-29, previous and current alongwith Challan for Rs. 50,000/- being fee of Change of management.

e. The firm has fulfilled rest of the codal formalities for renewal of Drug Manufacturing Licensee excluding proof of approved sections.

f. Proceedings and Decision of Central Licensing Board in 256th meeting.

Dr. Maqbool Ahmed, Chief Executive of the firm appeared before the Board and contended that all codal formalities has been completed and showcause notice may be withdrawn. The Board after hearing representative of the firm advised him to comply the legal requirements in time in future and also decided to cease the operation of the show cause notice issued to the firm.

g. In light of the decision of Central Licensing Board letter was issued to the firm.

h. The firm has submitted LOP for regularization of the following sections;

i. Tablet Section (General)
ii. Capsule Section (General)
iii. Syrup Section (General)
iv. Sachet Section (General)
v. Tablet Section (Psychotropic)
vi. Capsule Section (Penicillin)
vii. Dry Powder Suspension Section (Penicillin)
viii. Capsule Section (Cephalosporin)
ix. Dry Powder Suspension Section (Cephalosporin)
x. Quality Control Lab
xi. Warehouse

i. . The above submitted LOP for regularization was discussed in LOP committee and following shortcomings have been observed;

i. The firm has deposited fee of Rs. 50000/- only whereas there are eleven sections in LOP under discussion and remaining fee of Rs. 5000/- needs to be deposited.
ii. Door for entry from male change room to general production corridor has not been given.
iii. The area for storage of non active material in raw material store (general) needs to be segregated.
iv. Sachet Section (General) needs to be divided into mixing and filling areas.
v. Man and material flow in Syrup Section (General) is not in order i.e. the entry is through packing hall and manufacturing area is away from filling area.
vi. Granulation and drying area has not been provided in Tablet Section (Psychotropic).
vii. Solution preparation area has not been provided with coating area in Tablet Section (Psychotropic).
viii. Door for entering to change room of penicillin area has not been given.

ix. Step over bench has not been shown in change room of penicillin area.
x. Transfer window needs to be installed between bottle blowing and Dry Powder Suspension filling area of Dry Powder Suspension Section (Penicillin).
xi. Sampling and dispensing areas has not been provided with raw material store of penicillin area.
xii. Entry of raw and packing material to the cephalosporin area is not in order.
xiii. Transfer window needs to be installed between bottle blowing and Dry Powder Suspension filling area of Dry Powder Suspension Section (Cephalosporin).

j. The firm was advised to submit revised LOP vide letter NO. 3-7/91-Lic (Vol-III) dated 19/02/2018 and 18/05/2019. However, LOP for regularization was not approved so for because the firm has not submitted Revised LOP for approval.

Now QA/LT Division, DRAP's has informed vide file No. 4-43/89-QA that Area FID, DRAP, Peshawar has conducted routine cGMP of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar on 14-12-2020. In the inspection report the Area FID has given following recommendation;

i. To follow up their application for renewal of DML and remove deficiencies if any pending on the part of firm.
ii. To shift their penicillin sections to separate block.
iii. To regularize their layout plan with consultation of Licensing Divi ion of DRAP Islamabad.
iv. To improve their Microbiology Lab.
v. To purchase primary reference standards initially for three top selling products and then gradually for remaining products.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar DML No. 000215 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

In the light of Central Licensing Board's decision a Show Cause Notice was issued to the firm M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar DML No. 000215(Formulation)dated 10-03-2021.

The firm, M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawarsubmitted revise LOP relocation of Penicillin Section from Ground Floor to First Floor vide letter No. nil dated 20/04/2021 along with fee of Rs 5000/=.

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person on behalf of the firm appeared before the Board.. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000215 (by way of formulation) of M/s

Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar, till fulfilment of the codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO.56. APPROVAL OF TECHNICAL STAFF PRODUCTION INCHARGE UNDER DRUG MANUFACTURING LICENSE NO. 000692 OF M/S ROGEN PHARMACEUTICAL, PLOT NO. 30, S-4, NATIONAL INDUSTRIAL ZONE, RAWAT.

Case background.

The Central Licensing Board in its 279th meeting held on 18th February, 2021 has considered the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to M/s Rogen Pharmaceutical, Plot No. 30, S-4, National Industrial Zone, Rawat and decided as under:-

Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000692 (by way of formulation) of M/s Rogen Pharmaceutical, Rawat may not be suspended or cancelled by Central Licensing Board.

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Rogen Pharmaceutical, Plot No. 30, S-4, National Industrial Zone, Rawat on 16th March, 2021 with following observations:-

For Production Incharge.

i. Copy of CNIC of appointee **(Not Attested).**
ii. Copy of Academic Degrees **(Not Attested).**
iii. Registration certificate from Pharmacy Council **(Not Attested and also not renewed from 1996).**
iv. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 not less than 6 years **(Not Attested).**
v. Resignation / retirement of earlier approved Production Incharge**(Not provided).**
vi. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm **(Not provided).**

In response to Show Cause Notice firm has submitted their reply on 26th March, 2021. On scrutiny of submitted documents following documents has been still deficient:-

For Production Incharge.

i. Copy of Academic Degrees.
ii. Registration certificate from Pharmacy Council.
iii. Resignation / retirement of earlier approved Production Incharge.

Accordingly, a personal hearing letter was issued to the firm on 15th April, 2021.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

Mr. Muhammad Aslam. MD of the firm appeared before the board and contended that firm had submitted the requried documents.The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000692 (By way of Formulation) of M/s Rogen Pharmaceutical, Plot No. 30, S-4, National Industrial Zone, Rawat, for further period.

Case No.57 18.GMP INSPECTION OF M/S NOA HEMIS PHARMACEUTICALS, KARACHI

GMP inspection of M/s Noa Hemis Pharmaceuticals, Karachi was conducted by area FID Mr. Najam-us-saqib on 12-08-2020 by him . During inspection it was observed that all production doors were locked and no production was underway. The reasons for stoppage of production/manufacturing operations without any information to DRAP was enquired from the firm . The management of the firm submitted reply which is reproduced as below :

‘ The production facility ‘ Noa Hemis Pharmaceuticals’ is a partnership firm owned by Mr. Aziz Pervez and Mr. Saeed Jawaid. This is to inform you that Mr. Saeed Jawaid has filed a **suit bearing No. 163 of 2020 before the High court of Sindh at Karachi** . Furthermore, Mr. Saeed Jawaid was managing Human Division and he has stopped all production processed in its enterety on 3rd March 2020 due to the nonpayment of utility bills. Veterinary Divison operated by Mr. Aziz Pervez had sold all the veterinary finished goods by June 2020. And upon stoppage of production veterinary Division immediately ceased its production activities (including packaging) and has been at halt since then. Any claims otherwise are baseless and not provable.

Any letter submitted on behalf of Mr. Saeed Jawaid is not condoned by Mr. Aziz Pervez as a partner in the partnership firm M/s Noa Hemis Pharmaceuticals.

Mr. Jawaid commenced aforementioned as a response to Mr. Aziz’s request for joint-signature implementation of all the firm’s bank accounts. The reasons for the joint-signature by Mr. Aziz include :

1). Non-compliance to access the books of accounts and refusal for an external audit of the Human Division by Mr. Saeed Jawaid.

2) Surreptitious behavior fraudulent activity and disregard of GMP SOPs by Mr. Saeed Jawaid.

The reasons for suspension application by Mr. Aziz :

1) Mr. Aziz came on high alert when it came to his knowledge that the human division was relentiessly abstaining GMP standards and protocoals. And he wanted to investigate them prior to the law suit by Mr. Jawaid.
2) After the halting of the production on 3rd March 2020 Mr. Jawaid laid off all the technical staff including the QC Manager and Production manager. After which Mr. Jawaid commenced a few months spree of packaging of tablets, blisters and liquids by unqualified staff using solar panels(for electricity) at the premises non-qualified and non-equipped by any drug law standards for pharmaceutical packaging. Upon finding occurrence of such activities Mr. Aziz had to emphatically stop such operations and removed all the non- hired personnel immediately.

Appropriately, Mr. Aziz would like to make a 3-part request :

1. Considering the above and to stop jeopardizing pharmaceutical (drug) law of Pakistan, Mr. Aziz requests to suspend the license No. 000525(Formulation) granted to M/s Noa HemisPharmaceuticals.and all its products . Mr. Aziz is not liable for nay activities conducted by or on behalf of Mr. Jawaid and its consequences as the production and packaging of human drugs are non-compliant of GMP standards and can potentially be hazardous to the masses.
2. The brand name of the drugs(both local and export) already registered in the name of the Partnership firm may not be transferred in the name of any other person without the consent of both partners.
3. Proceedings and approvals of contracts related to drug manufacturing by third parties in the name of Partnership firm including but not limited to contract between M/s Seraph Pharma Islamabad and that the Noa Hemis Pharmaceutical (as mentioned in 295th meeting DRAP) may not be approved.

Your attention and nimble execution are highly appreciated in this matter.

As per available record of Licensing Division, DRAP M/s Noa Hemis Pharmaceuticals is a licensed manufacturing facility at Plot No. 154, Sector 23, Korangi Industrial Area, Karachi having a valid DML NO. 000525(formulation).

The management of the firm as per available record of Licensing Division, DRAP is comprising of two partners Mr. Saeed Jawaid and Mr. Aziz Pervez.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No. 000525 by way of formulation of M/s Noa Hemis Pharmaceuticals, Karachimay not be suspended or cancelled by Central Licensing Board.
The Board also decided to seek information from the Drug Regulatory Authority of Pakistan, Kararchi office regarding import of raw material by M/s Noa Hemis Pharmaceuticals, Karachi since renewal of Drug Manufacturing License, if any.

The show cause dated 04th November 2021 was issued to the firm and a letter dated 04th November 2021 was also issued to the Additional Director (E &M) DRAP, Karachi to update regarding import of raw materials by the firm since renewal of DML.
Fazleghani Advocates regarding M/s Noa Hemis Pharmaceuticals, Karachi. The contents are as under:-

Mean while FR was received from Fazleghani advocates wherein the suit no. 163 of 2020 (saeedjawaid versus azizpervez and others) before the high court of sindh at Karachi and the contents are reproduced below:

Dear Sir,

1. We write to you for and on behalf of our client, Mr. Aziz Pervez ("Client").
2. Our Client and Mr. Saeed Jawaid are equal partners in a partnership firm, M/s Noa Hemis Pharmaceuticals ("Partnership [Firm"). The principal place of business of the Partnership Firm

is Plot No.154, Sector 23, Korangi Industrial Area, Karachi ("Subject Premises"). A copy of the partnership deed dated 02 March 2007 is attached as **Annexure A.**

3. The Partnership Firm has a license (number 000525) ("License") to manufacture, at the subject premises, by way of formulation, drugs registered under the I) Drugs Act, 1976 ('1976 Act"). The License was renewed on 21 Septcinber'2016 for a period of five (5) years. A copy of the license is attached as **Annexure B.**

4. Besides this License to manufacture there are a number of local and export drugs that are registered in the name of the Partnership Firm. Copies of the lists enumerating the drugs registered in the name of the Partnership Firm are attached as **Annexures C-1 and C-2.** These lists are illustrative but not exhaustive.
5. We would like to inform you that Mr. Saeed Jawaid has filed a suit bearing Suit No 163 of 2020 before the High Court of Sindh at Karachi ("Suit"). The subject-matter of the Suit is arbitration under Section 20 of the Arbitration Act, 1940. A copy of plaint is attached as **Annexure D.**
6. In view of the foregoing, it is kindly requested that until the disposal of the Suit: -

I. the Licence granted in favour of the Partnership Firm in respect of the Subject Premises may not be renewed/transferred in name of any person unless both partners have signed such request

II. a new licence to manufacture drugs already registered in the name of the Partnership Firm at any other premise(s) may not be granted unless both partners sign such request

III. the brand name of the drugs (both local and export) already registered in the name of the Partnership Firm may not be transferred in the name of any other person without the consent of both partners;

IV. proceedings and approvals related to pending drug registration(s) and contracts related to drug manufacturing by third parties in the name of the Partnership Firm including but not limited to contract between M/s Seraph Pharma Islamabad and the Partnership Firm (See Minutes of 295th and 296th Meeting of Registration Board of DRAP) shall be suspended/held in abeyance.

V. If any drugs that were registered in the name of the Partnership Firm prior to commencement of Suit 163 i.e. 01.02.2020 and have been transferred at the request of any Partner individually, such transfer be cancelled and registration be reversed to its original status i.e. in the name of the Partnership Firm.

A letter is received from Ms. SanamKausar Assistant Director DRAP, Karachi wherein data/record regarding import of raw materials by the firm M/s Noa Hemis Pharmaceuticals, Karachi for the period from 01-01-2015 to 08-01-2020 is enclosed.

The Drug Manufacturing License No. 000525 (Formulation) of the firm was renewed/approved by the CLB in its 270th meeting held on 23rd May 2019 for the tenure/period commencing on 21-09-2018 and ending on 20-09-2023 and the DML was issued to the firm on 17th July 2019.

The firm is also called for personal hearing vide letter dated 13th April 2021.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

Mr. Saad Mumtaz Hashmi Advocate on behalf of the firm appeared before the board and contended that the matter was pending before the Honorable High Court of Sindh at Karachi.He further contended that the firm had no objection if the Drug manufacturing license of the firm is suspended till settlement of dispute. The Board considering the facts on the record and after thread bare deliberation decided to suspend the Drug Manufacturing License No. 000525 by way of formulation of M/s Noa Hemis Pharmaceuticals, Karachi till settlement in the court.

Case No. 58 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ALBRO PHARMACEUTICALS (PVT) LTD, 340-S, QUAID-E-AZAM INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE.

Background of the case

Mr. Abdul Rashid Shaikh, FID and Mrs. Saira Naeem, area ADC, Lahore conducted inspection of the firm M/s Albro Pharmaceutical, Lahore on 12.06.2015, to verify the GMP compliance and production activities. Following critical observations were noticed by the panel during their visit:-

General Information

- Land of the firm does not fulfill the requirements of SRO. 470 (1)/98 dated 15.05.1998 Schedule-B to the Drugs (Licensing, Registration & Advertisement) Rules, 1976. It is advised to shift the manufacturing facility to appropriate area to fulfill the requirement of above said SRO till then; the management is directed to strictly maintain the cGMP requirements for the manufacturing of registered drugs.

Workers Entrance:

- It is advised to improve the workers entrance.

Oral Liquid Section:

- The firm was advised to replace the drains with GMP drains in the section.
- The firm was advised to replace the cooking vessel for the syrup manufacturing.

- The firm was advised to conceal the lights of areas.

Raw Material Store:

- The firm was advised to ensure the availability of closed trolleys for the transportation of dispensed materials from store to production floor.
- The firm was advised to affix the proper labeling with relevant colors on the quarantine materials released or rejected
- The firm was advised to improve the storage condition of liquid materials by keeping in view the safety measures.
- The firm was advised to review and upgrade the dispensing SOPs.

Tablet Section:

- The firm was directed to ensure availability of the Double Cone Mixer.
- The firm was directed to ensure the availability of separate bags for each product for Fluid-bed dryer.
- The firm was directed to review the manufacturing SOPs as far as batch size is concerned.
- The firm was directed to ensure the batch size as per available manufacturing capacity.

Quality Control Laboratory:

- The firm was advised to ensure the FTIR, KARL Fischer and Automatic Polarimeter.
- The firm was advised to upgrade the SOPs for testing methods as per current pharmacopoeia requirements.
- The firm was advised to develop separate and independent Quality Assurance Department under the supervision of senior technical person without fail.
- The firm was advised to get internal and external audit and then its CAPA, and the report be submitted to the office of FID.
- The firm was advised to ensure to make the stability chamber functional, conduct stability of the products and maintain their record as per guidance of stability study.

The FID further directed the management to:-

- Remove the shortcomings at the earliest. The re-inspection will be conducted accordingly.

Action Taken by DRAP:- After receiving inspection report, a show cause notice was issued to the firm on 10.11.2015.

Reply of the firm:- In response of the show cause notice, the firm vide letter No. Nil dated 23.11.2015 informed that many of the observations has been resolved and improved.

Proceedings of the 246th Meeting of CLB

Mr. Waseem Ahmad Bari, Director and Mr. Sibtul Hassan Abbas, Production Manager of the firm M/s Albro Pharma, Lahore appeared before the Board for personnel hearing. Mr. Waseem Ahmad Bari informed to the Board that the existing plot is about 2.5 Kanal and assured that he will purchase the new plot of 4 kanal (size) in next six months. He has submitted an undertaking stating that the facility

will be developed in four years. He further informed that all the observations identified by FID have been rectified and are ready for inspection for verification of the rectification.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and request of Director of the firm M/s Albro Pharma, Lahore, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members.

i. Dr. Zakaur Rehman, Member, CLB
ii. Mr. Abdul Rashid Sheikh, FID, Lahore
iii. Mr. Zia Husnain, FID, Lahore

The Board further decided to ask the panel to also submit the report in tabulated form identifying the previous observations and the current status of the observations noted by the panel in its inspection conducted on 12.06.2015.

To purchase the plot of 4 kanal in 06 months and complete the facility within a period of 2 years

Proceedings and Decision of Central Licensing Board in 257th meeting

The Board considered the case and decided to defer the renewal of DML till next meeting of the Board for want of personal hearing regarding update from the licensee on the decision of the Central Licensing Board for purchase of plot and completion of facility.

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

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

Proceedings and Decision of Central Licensing Board in 259thmeeting

Mr. Waseem Bari, Owner of the firm appeared before the Board. He contested that firm possess three sections, land at new site has been purchased and application for site verification has already been filed. He further contended that considerable time may be allowed to shift to new premises. The Board after hearing the representative of the firm and considering the facts on the record and after thread bare deliberation decided to defer the case for the sake of shifting of the premises to new site within a period of one years. The firm shall get site approval within one month and lay out approval within one month and will apply for grant of license within a period of one year. The firm shall also submit progress report quarterly. If firm fails to comply at any stage the Central Licensing Board shall start proceedings as per law.

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

Decision of the Board was conveyed to the firm vide letter dated 6th June, 2018. The firm filed application for site verification at new premises and site approval letter was issued to the firm on 6th March, 2019. Then the firm submitted layout plan which was approved on 14th November, 2019.

The firm applied for renewal of DML No. 000175 by way of Formulation for the period of 14-06-2020 to 13-06-2025 on 20-05-2020.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 18th August, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed and stamped Form-1A (as per format)
ii. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
iii. Detail of management, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 duly attested by SECP (original).
v. Duly attested CNIC copies of all Directors.
vi. Approval letters of Production Incharge and Quality Control Incharge, if not already approved, submit their complete application alongwith prescribed fee & pre-requisites.
vii. Comply the minimum area requirement of 2000 square yards as under Schedule-B of Drugs (Licensing, Registering and Advertising) Rule, 1976.

The firm repliedto this letter on 18th September, 2020 and reminder letter was issued on 12thOctober, 2020 to the firm for completion of application:

i. Comply the minimum area requirement of 2000 square yards as under Schedule-B of Drugs (Licensing, Registering and Advertising) Rule, 1976.
ii. Prescribed fee of 50,000/- for change in management, as there is change in management of the firm.
iii. Documents should be duly attested.

The firm replied to reminder on 29thOctober, 2020 but failed to Comply the minimum area requirement of 2000 square yards as under Schedule-B of Drugs (Licensing, Registering and Advertising) Rule, 1976. The firm has submitted Undertaking for shifting to new site after construction which is under process.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 19 , Schedule B under Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000175 (by way of formulation) of M/s Albro Pharmaceuticals (Pvt) Ltd, 340-S, Quaid-E-Azam Industrial Estate, KotLakhpat, Lahoremay not be suspended or cancelled by Central Licensing Board.

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

The Show Cause Notice dated 22ndJanuary, 2021 was issued to M/s Albro Pharmaceuticals (Pvt) Ltd, 340-S, Quaid-E-Azam Industrial Estate, KotLakhpat, Lahore.

A letter of Personal hearing has been issued on 19th April, 2021.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

Mr. Waseem Ahmed Bari, Owner of the firm appeared before the Board and contended that two years time may be granted as considerable progress has been made.The Board considering the facts on the record and after thread bare deliberation decided to defer the case till next meeting of the Central Lcensing Board. The Board also constituted following panel to conduct GMP inspection of exisiting unit for submit to the Board within 30 days.

1. Mr. Azher jamal Saleemi, Chief Drug Controller, Punjab
2. Area Federal Inspector of Drugs, DRAP, Lahore
3. Mr. Hasan Afzaal, AD, DRAP, Lahore

Case No. 59 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S WAHABSONS PHARMA (PVT) LTD., 4-KM, BUNNER ROAD, BARIKOT, SWAT.

M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat had applied for renewal of DML No. 000533 by way of formulation for the period of 27-01-2019 to 26-01-2024 on 30-10-2018.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 17th December, 2018 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form-1A alongwith enclosure/Flags/Annexure.
2. Class (es) of Drugs.
3. Dosage(s) forms of drugs.
4. Name(s) of registered drug(s).
5. Detail of management at the time of previous renewal and present renewal.
6. Updated Form-29 from S.E.C.P. attested alongwith CNIC's of all Directors.
7. Approved layout plan.
8. Proof of licensed sections from Central Licensing Board.
9. Detail of section wise equipment and machinery for manufacture and QC Lab.
10. Approval letter of QC Incharge in case of change then submit required documents as per checklist (attached) alongwith prescribed fee.

The firm submitted their reply on 09th January, 2019. After evaluation of the submitted documents, a final reminder was issued on 29th May, 2019 to the firm with following shortcomings: -

2. Form-1A dully signed and attested by the management of firm alongwith all enclosures.

3. Names/detail of Directors of firm on firm's letter head alongwith attested CNIC copies of all directors (at this renewal and at previous renewal).
4. Form-29 and Form-A for year 2019 (certified true copy) issued by S.E.C.P. alongwith prescribed fee for change of management (if management is changed).
5. Proposed QC Incharge Ms. Seema Mughal does not fulfill the requirements of Rule-16 of Drugs (Licensing, Registering & Advertising) Rules, 1976 in terms of required experience, therefore, submit documents of new proposed QC Incharge.
6. Detail of all licensed sections on firms letter head alongwith approval letter(s) of all sections issued from CLB.

The firm submitted their reply to Final Reminder on 15th July, 2019 and following documents are still deficient /short and application for renewal of DML is still incomplete.

1. Form-1A dully signed and attested by the management of firm alongwith all enclosures.
2. Form-29 and Form-A for year 2019 (certified true copy) issued by S.E.C.P. alongwith prescribed fee for change of management (if management is changed).
3. Approval letter(s) of all sections issued from CLB.

Proceedings and Decision by the Central Licensing Board in 276th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat Drug Manufacturing Licence No 000533 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Accordingly a show cause notice was served to the firm dated 25-09-2020. But no reply has been received from the firm till to date. Now a personnel hearing letter issued to the firm on 08-10-2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

No person appeared on behalf of the firm. The Board deliberated the case and decided to afford final opportunity for personal hearing to the firm in the next meeting of the Central Licensing Board before taking decision.

Accordingly, a personal hearing letter was issued to the firm on 19th April, 2021.

The case is hereby submitted for consideration and orders of the Board, please.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Zeeshan Ahmed Admin Officer of the firm appeared before the board and contended that the documents are already submitted to the division of Drug Licensing . The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000533 (by way of formulation) of M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat till fulfillment of codal formalities/submission of required documents under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the

provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decisionand case may be placed before the board for ratification.

Case No.60. <u>NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S APSIS PHARMACEUTICALS, EMINABAD ROAD, KHAN PAYARA, 1.3-KM, G.T ROAD, GUJRANWALA UNDER DML NO. 000855 (FORMULATION).</u>

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **<u>Decision by the Central Licensing Board in 269th meeting:</u>**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Apsis Pharmaceuticals, Eminabad Road, Khan Payara, 1.3-Km, G.T Road, Gujranwala on 23rd September, 2020 as the firm has never submitted CRF till 2019. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

<u>Proceedings and Decision of Central Licensing Board in 280th meeting.</u>

Mr. Umar Altaf Production manager on behalf of the firm appeared before the Board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

Case No.61 NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S MOON PHARMACEUTICALS, PLOT NO. 5, SS-4 ROAD, NATIONAL INDUSTRIAL ZONE, RAWAT UNDER DML NO. 000833 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Moon Pharmaceuticals, Plot No. 5, SS-4 Road, National Industrial Zone, Rawat on23rd September, 2020 as the firm has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Sayed Hussain on behalf of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Bufget and Accounts Division.

Case No.62 **NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S EFFORT PHARMACEUTICALS (PVT) LTD, 28-KM FEROZEPUR ROAD, LAHORE UNDER DML NO. 000879 (FORMULATION).**

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Effort Pharmaceuticals (Pvt) Ltd, 28-Km Ferozepur Road, Lahoreon 23rd September, 2020as the firm has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Now, the firm has replied to Show Cause Notice and submitted Nothing due Certificate regarding CRF valid upto31-12-2020.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Sadaqat Ali Regulatory manager appeared on behalf of the firm before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to cease the operation of Showcause Notice for further period.

Case No.63 NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S LIVEN PHARMACEUTICALS (PVT) LTD, SRAY ROAD, 49-KM, MULTAN ROAD, PHOOL NAGAR, DISTRICT KASUR UNDER DML NO. 000881 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing License may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Liven Pharmaceuticals (Pvt) Ltd, Sray Road, 49-Km, Multan Road, Phool Nagar, District Kasur on 23rd September, 2020 but firm has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Kashif Hussain Director of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Bufget and Accounts Division.

Case No. 64 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BYM/S FASSGEN PHARMACEUTICALS, HATTAR

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Fassgen Pharmaceuticals, Hattar DML No. 000646 (Formulation) dated 15-05-2019.

In response to Show Cause Notice, the firm has responded vide letter No. Nil dated 19/05/2019 which is reproduced as under;

> *"With reference to Show cause Notice # F-3-1 1/2006-Lic of dated 15.05.2019: Please find the fact as:-*
> *That we had deposited the updated CRF on 22.03.2019 & (whose receiving copies are attached herewith), & still waiting for the Certificate from the Revenue department of your own esteemed organization.*
> *Now if you call us for personal hearing, we can present the original application.*
> *Thanks & Regards"*

However, as per available record in Licensing Division, the firm has not submitted CRF till date.

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Zeeshan Director of the firm appffasseared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record

and facts decided to defer the case till next meeting of the board for getting update from Bufget and Accounts Division.

Case No. 65. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S YOUSUF ALI SHAH CHEMICAL INDUSTRIES (PVT) LTD., SWABI

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Yousuf Ali Shah chemical Industries (Pvt) Ltd., Swabi DML No.000371(Formulation) dated 25-09-2020, but firm has not submitted CRF till 2019. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Case is submitted for consideration and orders of the Board please.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Riaz Quality Control Inhcarge of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Bufget and Accounts Division.

Case No. 66 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 M/S IPP (PVT) LTD., SWAT

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s IPP (Pvt) Ltd., Swat DML No.000244 (Formulation) on dated 13-05-2019 as the firm has never submitted CRF.

In response to Show Cause Notice the firm has responded vide letter No. IPP2/07/19 dated 02/07/2019 which is reproduced as under;

> *"In Continuation to your Letter No. F3-10/2011-Lic 27/06/2019 dated 13 May 2019. Dispatched on 26 june 2019 Received on 27/6/2019.*
> *Regarding this connection We have already provided Audit report to office of the statistical officer DRAP.*
> *Also a photo copy of the Audit reports/ financial statement for the year June 30/2016 June 30/17 and June 30/2018 is also enclosed here with for your . office proceeding and record purpose*
> *Thanking you and assuring you the best of our cooperation at all time."*

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Waseem Jawad Partner of the firm appeared before the Board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

Case No.67 NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S FERROZA INTERNATIONAL PHARMACEUTICALS (PVT) LTD, 33-KM, FEROZEPUR ROAD, LAHORE UNDER DML NO. 000389 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur Road, Lahore on 30th September, 2020 as the firm has not submitted CRF from 2016. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Usman Khalid Partner Director of the firm appeared before the board and contended that the firm has obtained NDC of CRF (Updated) from the Budget & Account Division, DRAP, Islamabad and the same was received from the Budget & Account Division, DRAP, Islamabad. The Board after perusal of record and facts decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000389 (By way of Formulation) of M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur Road, Lahore for further period.

Case No.68 NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S ALBERT PHARMACEUTICALS (PVT) LTD, PLOT NO. 127, SUNDER INDUSTRIAL ESTATE, LAHORE UNDER DML NO. 000865 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Albert Pharmaceuticals (Pvt) Ltd, Plot No. 127, Sunder Industrial Estate, Lahore on 30th September, 2020as firm has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Case is Submitted for consideration and orders of the Board.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Umar Habib Managing Director of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

Case No. 69. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s MULTI CAPS, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000876 (SEMI-BASIC MANUFACTURE)..

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Multicaps, Karachi on25th September, 2020 but firm has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person appeared before the board on behlf of the firm. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

Case No. 70 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S IPP,ISLAMABAD

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s IPP, Islamabad DML No. 000370 (Formulation) on dated 14-05-2019 as the firm but firm has not submitted CRF till 2019

In response to Show Cause Notice, the firm has responded vide letter No. IPP/05/19 dated 02/05/2019 which is reproduced as under;

"With references to your letter # 1-16/94-Lic (vol-l) dated 14th May 2019 received on 21st May, 2019. this is you that have NOC regarding above mention that our account is up to 30-6-216. Photo copy of NOC issued by you is attached for ready reference.
It is therefore requested to please amend your record . we are also attaching the receipt CRF regarding 2017 2018.

Thanking you and assuring you best of our co-operation at all the time."

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Ms. Rukhsana Partner /Director of the firm appeared before the board and contended that problem of license ownership is resolved and would submit report within one month. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

Case No. 71 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S DELTA PHARMA (PVT) LTD., RISALPUR

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Delta Pharma (Pvt) Ltd., Risalpur DML No. 000446 (formulation) dated 25-09-2020 but as per available record in licensing Division, the firm has not submitted CRF till date. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Ashfaq Paracha CEO of the firm and Mr. Musa Ashfaq appeared before the board and contended that firm will submit NDC of CRF. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

Case No. 72 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s KOHS PHARMACEUTICALS (PVT) LTD HYDERABAD UNDER DRUG MANUFACTURING LICENSE NO. 000132 (FORMULATION)..

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-

recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Kohs Pharmaceuticals (Pvt) Ltd, Hyderabad on30th September, 2020 but firm has not submitted CRF from year 2012. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person appeared before the board and a letter was received from the firm that the owner of the firm was COVID Positive and copy of report was also forwarded along with the letter. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

Case No.73. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976BY M/S TRILLIUM, FAISALABAD.

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Trillium, Faisalabad on 30th September, 2020 but firm has not submitted CRF till 2019. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Mulazim Hussain CEO of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

Case No.74. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY VANTAGE LABORATORIES (PVT) LTD, FAISALABAD.

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Vantage Laboratories (Pvt) Ltd, Faisalabad on 30th September, 2020 but firm has not submitted CRF till 2019. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person appeared before the board on behalf of the firm. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

Case No.75 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S SIMAX CHEMICAL, PESHAWAR

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Simax Chemical, Peshawar DML No.000843 (Re-Packing) dated 13-05-2019 but firm has not submitted CRF till 2019.

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Muhammad Shahzad CEO and Mr. Arshad Parvez appeared before the board on behalf of the firm and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

Case No.76 CHANGE OF TECHNICAL STAFF UNDER DRUG MANUFACTURING LICENCE NO.000657 (FORMULATION) OF M/S WELBORNE PHARMACHEM & BIOLOGICALS, PLOT NO.51/1,52/2, PHASE I&II, INDSUTRIAL ESTATE, HATTAR.

The firm M/s Welborne Pharmachem & Biologicals, Plot No.51/1, 52/2, Phase I&II, Industrial Estate, Hattar has submitted the application for approval of proposed Production Incharge Mr. Shoukat Zaman S/o Sardar Gul Zaman (B-Pharm) CNIC No.13101-0993556-7. The firm has submitted a fee of **Rs.**

5,000 . The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Attested copy of resignation letter of appointee from previous firm, has not been attached.

Accordingly, shortcoming letter No.F.3-4/2007-Lic (Vol-I) dated 27-07-2018was issued to rectify above mentioned shortcomings.

In response to above quoted letter the firm has submitted documents of new proposed Production Incharge Mr. Shahbaz Khan S/o Haji Muhammad Anwar Khan (B-Pharm) CNIC No.13503-6846957-5 and proposed QC Incahrge Mr. Shah AlijaBaig Mughal S/o Shah TaimurBaig Mughal along with Fee Challans of Rs.10,000/- . The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Resignation letter of previous Production Incharge.
ii. Attested copy of CNIC of proposed QC Incharge.
iii. Resignation letter of previous QC Incharge.
iv. Resignation letter of proposed QC Incharge from previous firm.
v. The proposed QC Incharge does not fulfill the requirements of Rule 16 (e) of (Licensing, Registering & Advertising) Rules, 1976 in terms of relevant experience in testing of drugs.

In response to above quoted letter the firm has submitted documents of new proposed QC Incahrge Mr. Nadeem Ilyas S/o Noor Khan ud Din alongwith Fee Challans of Rs.5,000/-. The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Copy of CNIC.
ii. Copy of academic degree(s).
iii. Experience certificate(s) not less than ten (10) years.
iv. Resignation letter of earlier QC Incharge.
v. Resignation letter of appointee from previous firm.
vi. Undertaking as whole time employee on stamp paper as per format of check list (attached).

Accordingly, shortcoming letter No.F.3-4/2007-Lic (Vol-I) dated 28-02-2019was issued to rectify above mentioned shortcomings.

In response to above quoted letter the firm has not submitted any response and a final reminder issued to the firm on 22-05-2019 with following shortcomings;

Proposed Production Incharge (Mr. Shahbaz Khan)

i. Resignation letter of previous Production Incharge.

Proposed QC Incharge (Mr. Nadeem Ilyas)

i. Copy of CNIC.
ii. Copy of academic degree(s).
iii. Experience certificate(s) not less than ten (10) years.
iv. Resignation letter of earlier QC Incharge.
v. Resignation letter of appointee from previous firm.
vi. Undertaking as whole time employee on stamp paper as per format of check list (attached).

Meanwhile, the firm has submitted another application for approval of proposed Production Incharge Mr. Muhammad Zubair S/o Musa Khan (Pharm-D) CNIC No. 12103-4437883-7 and proposed QC Incahrge Mr. Rehmat Zaman S/o Haider Zaman (M.Sc Chemistry) CNIC No.37406-1607037-7 alongwith fee challans of Rs.10,000/-. The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

Proposed Production Incharge (Mr. Muhammad Zubair)

i. Job acceptance letter
ii. Registration Certificate from Pharmacy Council.
iii. Resignation letter of previous Production Incharge.

Proposed QC Incharge (Mr. Rehmat Zaman)

i. Resignation letter of appointee from previous firm.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000657 (by way of formulation) of M/s Welborne Pharmachem & Biologicals, Plot No.51/1, 52/2, Phase I&II, Industrial Estate, Hattar, may not be suspended or cancelled by Central Licensing Board.

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to the firm M/s Welborne Pharmachem & Biologicals, Plot No.51/1, 52/2, Phase I&II, Industrial Estate, Hattar dated 12-01-2021.

Accordingly, a personal hearing letter was issued to the firm on 15th April, 2021.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

Mr. Iftikhar Ahmed Plant manager of the firm appeared before the board and contended that firm will submit the documents for approval of technical staff. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000657 (by way of formulation) of M/s Welborne Pharmachem & Biologicals, Plot No.51/1, 52/2, Phase I&II, Industrial Estate, Hattar for a period of six (06) months under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 77 M/S BREEZE PHARMA (PVT) LTD, PLOT NO. 125-126-127A, KAHUTA ROAD,ISLAMABAD.

The firm, M/s Breeze Pharma (Pvt) Ltd, Plot No. 125-126-127A, Kahuta Road, Islamabad has submitted application renewal of Drug Manufacturing License No. 000659 (by way Formulation). The application was received on 15-03-2019 and due date of renewal of DML 21/03/2019. The firm has submitted a fee of Rs. 50,000. Upon evaluation of application as per Drugs (Licensing, Registering and advertising) Rules 1976, following shortcomings were observed which were convey to the firm vide letter No No. F. 1-36/2003-Lic(Vol-III) dated 17/03/2020.

i. Change(s) in name of proprietor / directors / partners (if any).
ii. Detail of management at the time of previous renewal and Present renewal.

iii. Updated Nothing due certificate regarding CRF from STO.
iv. Latest updated Form-29 & Form-21 issued by S.E.C.P. along with CNIC copies of all directors.

For Production Incharge (Malik Majid Irfan).

i. Copy of CNIC of appointee.
ii. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
iii. Registration certificate from Pharmacy Council (in case of Pharmacist).
iv. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
v. Resignation / retirement of earlier Production Incharge.
vi. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

For Quality Control Incharge (Mr. Qaiser Iqbal).

i. Copy of CNIC of appointee.
ii. Resignation / retirement of earlier approved Quality Control Incharge.

The firm has not submitted their reply to the shortcoming letter and subsequently final reminder was issued to the firm vide letter No 1-36/2003-Lic(Vol-III) dated 18/09/2020. However, till date the firm has rectified above mentioned shortcoming.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 , Rule 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000659 (by way of formulation) of M/s Breeze Pharma (Pvt) Ltd, Plot No. 125-126-127A, Kahuta Road, Islamabad may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to the firm M/s. Breeze Pharma (Pvt) Ltd, Plot No. 125-126-127A, Kahuta Road, Islamabad dated 11-01-2021.

Accordingly, a personal hearing letter was issued to the firm on 15th April, 2021.

Meanwhile a GMP inspection report from the Federal Inspector of Drugs is recived which is reproduced as under:

"*The undersigned (FID. DRAP Islamabad was directed to visit M/s Breeze Pharma (Pvt) Ltd. Plot No. 125-126-127, Industrial Triangle Kahuta Road Islamabad DML.No.000659in response to complaint no. IS270321-88162443 launched on Pakistan Citizen's Portal.*

2. The crux of the complaint was violation of Schedule B-II of LRA rules 1976, by the above-mentioned firm, in terms of manufacturing activities being carried out without sufficient technical staff, active HVAC, RO treatment plant, Microbiology lab or QA section. Additionally, manufacturing of unregistered and harmful medicine which can cause loss to public health at large was being done in the facility.

3. Desk review of the documents related to M/s. Breeze Pharma revealed that the firm had intimated the FID-I office on 20-04-2020 regarding temporary closing of the firm due to Covid-19. However, no documentary intimation was provided by the subject firm regarding resumption of production in the FID-I office. The firm had applied for renewal of their DML no.000659 by way of formulation on 15th March 2019 which had been due on 22nd march 2019. However, Licensing Division found shortcomings in the firm's application for approval of renewal of their DML and had subsequently issued letters to the firm vide letter no F.1-36/2003-Lic(Vol-III) dated 17-03-2020 and 18-09-2020 to advise them to rectify their shortcomings. The firm failed to comply to the directions of Licensing Division and consequently the case was placed before Central Licensing Board (CLB) in its 278th meeting held on 10th and 11th December 2020 with all the details. As a result, a Show Cause Notice of even no. dated 11th January 2021 was issued to the firm by the Secretary CLB. It is pertinent to note that that till date no further communication from the firm regarding resumption of production activities had been received in the office of the undersigned.

4. In order to investigate veracity of the complaint, the undersigned visited the premises of M/s Breeze Pharma (Pvt) Ltd. Plot No. 125-126-127, Industrial Triangle Kahuta Road Islamabad along with Mr. Hafiz M. Umair, Assistant Director Import & Export (I&E) section, QA&LT Division, DRAP on 19.04.2021. Upon arrival the inspection team noticed a sign displayed on the main gate "Factory Closed due to COVID-19". Gatekeeper also informed the inspection team that the factory is closed however, perusal of personnel and material in & out register revealed that employees had checked into the premises on the day of inspection i.e. 19.04.2021. Three vehicles were also found to be parked inside the factory premises confirming that some employees were present inside the facility.

5. An initial cursory inspection of the production area revealed active manufacturing operations to be taking place including a well-stocked Finished Good Store, Raw Material Store, an abandoned Quality control lab and a packing hall where, it appeared that packing activities were in full swing as there were vials, labels and cartons on the packing lines. However, no personnel were found anywhere in the production area and it appeared that they had been informed about the arrival of inspection team and had fled the facility in the mid of operation. This assessment was confirmed when the inspection team came upstairs and a complete tour around the perimeter revealed multiple entry and exit points into the facility.

6. Considering the enormity of task ahead, the inspection requested Additional Director DRAP Islamabad for backup support under intimation to CEO DRAP. Since the all personnel whose name was mentioned in the entry register, except office boy, gatekeeper and Mr. Qaiserwho purported to be Admin officer and later turned out to be the RMS Incharge, had fled the scene, therefore a call was made to Mr. Anwar, who purported to be CEO of M/s. Breeze Pharma.

7. Upon arrival of the backup team comprising of Mr. Hasan Afzal Assistant Director Quality Assurance section, QA&LT Division, DRAP alongwith 2 assistants Mr. Saleem and Mr. Malik Mushtaq, the team in presence of Mr. Anwar conducted a thorough inspection of the entire facility and made the following observations which are critical in nature:

i. *The whole of the production area including RMS, FGS, and QC Lab were situated in the basement of the facility. There was no electricity (blackout) in the entire production area and whole basement was plunged into pitch darkness even in broad daylight. Despite repeated requests to the personnel present, the electricity was not turned on and all the inspection and documentation had to be carried out by the team in mobile flashlight. The electricity was turned back on at 6:00 pm which indicated that electricity had been deliberately switched off*

upon arrival of the inspection team to make hindrance in the inspection hence causing obstruction in the work of inspector.

ii. *No technical staff were found on the premises, on the other hand, there were entries of personnel in gate entry register who were physically not present in the facility.*

iii. *Production activities were discovered to be in full swing as evidenced by a fully stocked Raw material Store, Finished Goods Store, presence of manufactured batches in the manufacturing vessels in the liquid section, presence of filled vials to be packed alongwith packaging material on packing lines as well as on the floor of the packing hall.*

iv. *The whole facility was littered with rat droppings, layers of accumulated dust and fungus on the floor as well as walls of the production area. There was a noxious odor in the whole facility.*

v. *HVAC was not working in the entire facility, even when the electricity was switched on, and no other means of ventilation were present either which resulted in suffocation and combined with the noxious smell made it difficult to breathe or even stand in the area for any length of time.*

vi. *The door to the water treatment plant was locked and when the keys were requested the team was informed that the person who is custodian of the keys has fled the facility.*

vii. *The Raw Material Store (RMS) had been stocked with a huge quantity of material for which no import evidence was provided by the firm which considering that the management had informed the FID-I office in writing that firm was closed due to COVID-19 was highly suspicious. RMS was however in total disarray, labels were missing on several of the items and the packages and contents of several items seemed to have been torn off and eaten by the rodents. This may result in dispensing of wrong materials which is critical and may be injurious to the consumer.*

viii. *No labels were found on the manufacturing vessels to identify the product, Batch no or the manufacturing/processing date, despite the fact that active manufacturing activities were going on. Rat droppings and remains were found in an unidentified manufactured batch present in a vessel.*

ix. *Manufacturing of sterile products, as evidenced by the amount of stock present in FGS, was being carried out in the absence of HVAC in an extremely dirty, unmaintained, un-classified area. The door to the actual Sterile section was found to be locked. Contents of a liquid Injectable were found to be in open vessel in the corridor of production area.*

x. *No other instruments were found in the Quality Control lab except UV/Visible Spectrophotometer.*

xi. *Finished Good Store was stocked with Liquid Injectables and Powder for Injection including Cephalosporins despite there being no dedicated facility for manufacturing of Cephalosporins which is a critical deficiency as it can lead to cross contamination of non Cephalosporin products and may be health hazard for the consumer. Close examination revealed majority of the stocks had been manufactured in February and March of 2021.*

xii. *Cartons of finished goods and raw material were also found on the ramp leading outdoor with manufacturing date of April 2021. The entire area was covered with accumulated dust and rat excreta.*

xiii. *There were 48 full drums of liquid raw material including IPA and DMSO were found out in the open in an unapproved area, the labels of several of which had been torn off, therefore, name of manufacturer, manufacturing & expiry date as well as batch nos were not present.*

xiv. *Packaging material Store was located outside the main production area in a room at the side of the building where team found a huge quantity of plastic bottles, labels, cartons as well as*

finished goods with manufacturing date of 08-2020 & 09-2020. The PMS was found to be extremely dusty, dirty and without HVAC and several stacks of labels were found opened and on the floor with accumulated dust.

xv. *The whole of the production facility was unkempt, dismal/desolate, visibly dirty, in complete disarray with clear signs of rodent infestation, obnoxious smell and resembled a garbage dump or a haunted house instead of a pharmaceutical manufacturing unit.*

8. Investigation is still under process, including but not limited to verification of legal status/approval for import of raw material, test/analysis reports of the products sampled etc. Final report will be submitted after completion of the investigation.

Action taken:

In consultation with the panel, the FID took following actions under schedule-V of DRAP Act, 2012 and section 18 of Drugs Act, 1976:

a) *Order not to dispose of some material on form-I (Annexure-A)*
b) *Seized some of the materials on Form-2 (Annexure-B)*
c) *Some products were sampled for test/analysis purpose on Form-3 (Annexure-C)*
d) *The premises of subject firm was sealed in exercise of 18(1)(h) of Drugs Act, 1976 in presence of witnesses to ensure that none of the evidence slips out as the quantity of material found was too large to be seized.*

Conclusion and recommendations:

Based on the areas inspected, people met, the documents reviewed and considering findings of the inspection team, i.e. grave/gross GMP violations of critical nature and severe violations of sanitation and hygienic conditions. Since the facility is liable to produce products which can cause morbidity or even mortality of consumer, the inspection panel unanimously recommended ***Cancellation of the License*** *of M/s Breeze Pharma 125,126,127A Industrial Triangle Kahuta Road Islamabad under section 41 of Drugs Act, 1976."*

Proceedings and Decision by the Central Licensing Board in 280th meeting:

No person on behalf of the firm appeared before the Board . The Board after perusal of facts on record and recommendation of the Federal Inspector of Drugs decided to cancel the Drug Manufacturing License No 000659 (by way of formulation) of firm M/s. Breeze Pharma (Pvt) Ltd, Plot No. 125-126-127A, Kahuta Road, Islamabad under Section 41 of the Drugs Act, 1976
read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16, Rule 16, Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No.78 APPROVAL OF QUALITY CONTROL (QC) INCHARGE OF M/S WARAFANA PHARMACEUTICALS, ISLAMABAD

The firm, M/s Warafana Pharmaceuticals, Islamabad has submitted application for approval of proposed Quality Control (QC) Incharge Mr. Shakeel Badshah S/o Amir Bad Shah (M. Sc Chemistry) CNIC.16101-1231406-7. The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Resignation/retirement of earlier Quality Control Incharge is not provided.

Accordingly, a shortcoming letter No.F.1-40/2003-Lic Dated 27-03-2018was issued to the firm to rectify above mentioned shortcoming.

Meanwhile the firm has submitted application for approval of proposed QC Incharge Mr. Majid Riaz S/o Muhammad Riaz (M. Sc Chemistry) CNIC.13101-0757707-3. The firm has deposited the fee of Rs.5,000/. Upon evaluation of application for approval of proposed QC incharge per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Appointment letter not attached.
ii. Job acceptance letter not attached.
iii. Copy of CNIC is not attested.
iv. Copies of academic degrees are not attested.
v. Copy of M. Sc Degree is not readable.
vi. Copies of experience certificates are not attested.
vii. Resignation of already approved QC Incharge not attached.
viii. Resignation letter of appointee from previous firm not attached.
ix. Undertaking as whole time employee on stamp paper not attached.

The firm was advised vide letter No.F.1-40/2003-Lic dated 23-04-2020 to rectify above mentioned shortcoming (Complete set of documents as per checklist)

In response to aforementioned letter, the firm has submitted their reply, however the firm has not rectified following shortcoming;

i. Undertaking as whole-time employee on stamp paper signed and stamped by both appointee and the manager (duly notarized).

Accordingly, a final reminder vide letter No.F.1-40/2003-Lic dated 18-08-2020 was issued to the firm. Till date the firm has not rectified fowling shortcoming;

i. Undertaking as whole-time employee on stamp paper signed and stamped by both appointee and the manager (duly notarized).

Proceedings and Decision by the Central Licensing Board in 278th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000720(by way of formulation) of M/s Warafana Pharmaceuticals, Islamabad may not be suspended or cancelled by Central Licensing Board.

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to the firm M/s Warafana Pharmaceuticals, Islamabad dated 08-01-2021.

Accordingly, a personal hearing letter was issued to the firm on 15th April, 2021.

Proceedings and Decision by the Central Licensing Board in 278th meeting:

Mr. Iftikhar Ahmed, Owner of the firm appeared before the Board and submitted documents of new technical staff and also stated that the production is suspended in the firm/company from last October, 2020.The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000720 (by way of formulation) of firm M/s. M/s Warafana Pharmaceuticals, Islamabad under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till fulfillment of cadal formalities and production shall be resumed after GMP verification by the panel to be constituted by the Board on the request received from the firm . The Board also decided to seek status/data of import of raw material imported by the firm since October 2020 from QA/LT Diviosn, DRAP, Islamabad.

Case No.79 **CHANGE OF MANAGEMENT OF M/S SWAT PHARMACEUTICALS, VALLEY ROAD, SHERARI GULKADA NO. 3, SAIDU SHARIF SWAT KHYBER PAKHTOONKHWA.**

The Drug Manufacturing License No. 0000035 of M/s Swat Pharmaceuticals, was granted/transfer from old premises situated at Saidu Sharif Road, Amankot Mingora, Swat to new premise situated at Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat by CLB in its 277th meeting held on 15-16th October, 2020, accordingly with following detail.

Name, DML #, address and Sections	**Sections**	**Type of Firm**	**Management**	**Rent agreement (Page/17**
M/s Swat Pharmaceuticals, Valley Road, SherariGulkada No. 3, Saidu Sharif Swat Khyber Pakhtoonkhwa.	1. Tablet (General), 2. Tablet (Psychotropic), 3. Capsule (General), 4. Syrup (General), 5. Cream/ointment (General), 6. Sachet (General).	Sole proprietorship	Mr. Mubarak Ali S/o Alamgir CNIC No. 15602-0482661-1 **(Sole Proprietor)**	Rent agreement between Mr. Shahid Fazal S/O Fazal Rabi (owner of the land) and Mr. Mubarak Ali S/o Alamgir for 25 year

Mr. Javed Waseem vide letter No. SP/Lic/008/20 dated 23-11-2020has submitted that management of the firm M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat has been changed and requested for change of management. The applicant also submitted following document with application;

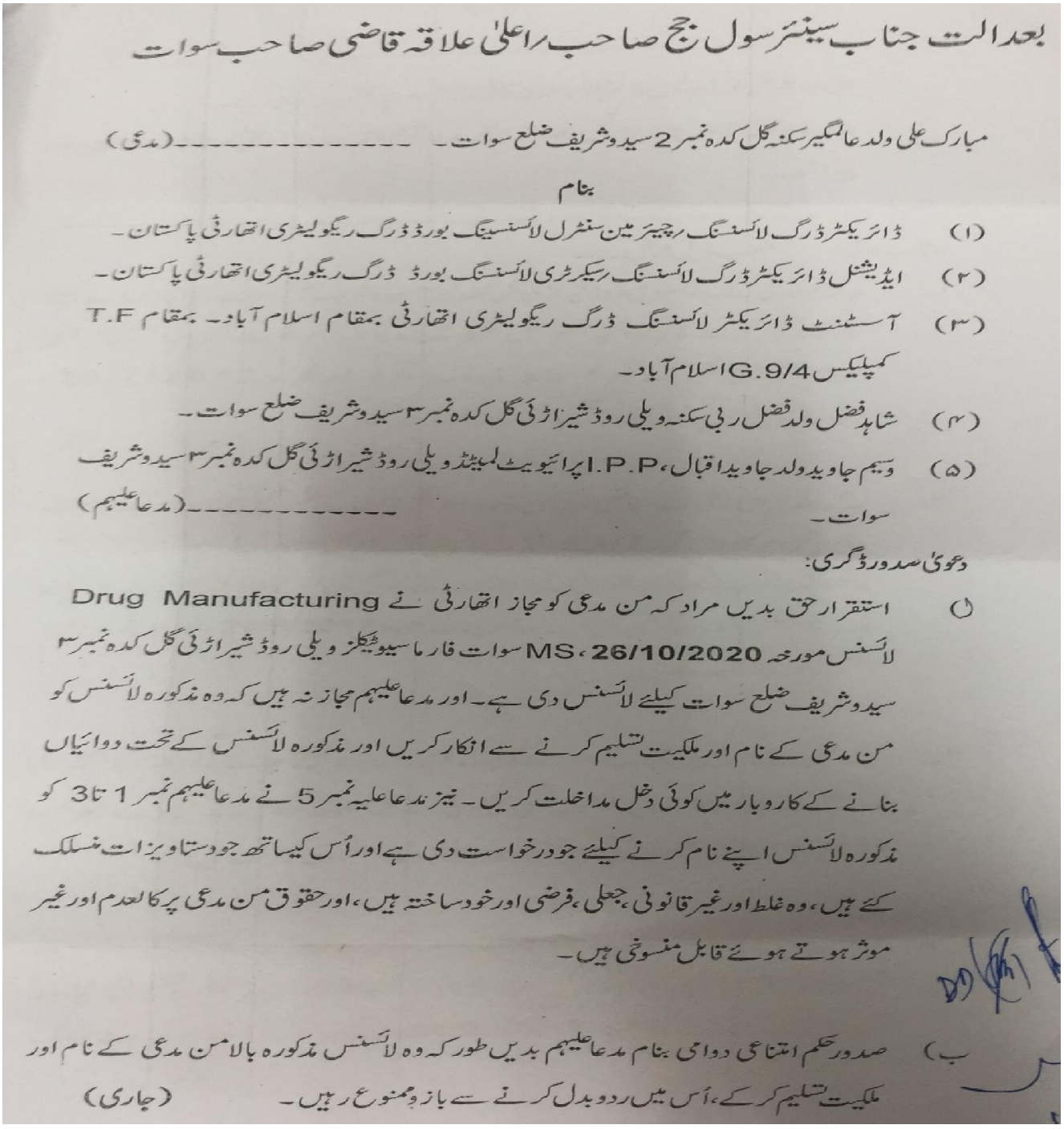
i. Notarized copy of sale agreement (100/100) between Mr. Shahid Fazal Rabi , Mr Javeed Waseem and Mangnaish Kumar,

ii. Notarized copy of sale of share agreement (18/100) between Mr. Mubarak Ali S/o Alamgir and Mr. Shaid Fazal Rabi and Mr Javeed Waseem,
iii. Photocopy of NTN of the firm M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat,
iv. fee of Rs.50,000/- for change of management.

Detail of management is as under;

Previous Management Sole Proprietor Page 59/Corr	**Current Management**
1. Mr. Mubarak Ali S/o Alamgir CNIC No. 15602-0482661-1	1. Mr. Mangnaish Kumar S/o Mr. Ram Saroop CNIC No. 15602-3006910-9

Mr. Mubarak Ali CEO/Sole Proprietor of M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat vide letter No. Nil dated Nil has informed the Licensing Division, DRAP that the information submitted by Mr. Jawed Wasim are **totally wrong**. Mr. Mubarak



بعدالت جناب سینئر سول جج صاحب/اعلیٰ علاقہ قاضی صاحب سوات

مبارک علی ولد عالمگیر سکنہ گل کدہ نمبر 2 سیدو شریف ضلع سوات۔ ----------(مدعی)

بنام

(۱) ڈائریکٹر ڈرگ لائسنسنگ رجسٹرمین سنٹرل لائسنسنگ بورڈ ڈرگ ریگولیٹری اتھارٹی پاکستان۔

(۲) ایڈیشنل ڈائریکٹر ڈرگ لائسنسنگ سیکرٹری لائسنسنگ بورڈ ڈرگ ریگولیٹری اتھارٹی پاکستان۔

(۳) آسسٹنٹ ڈائریکٹر لائسنسنگ ڈرگ ریگولیٹری اتھارٹی بمقام اسلام آباد۔ بمقام T.F کمپلیکس G.9/4 اسلام آباد۔

(۴) شاہد فضل ولد فضل ربی سکنہ ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف ضلع سوات۔

(۵) وسیم جاوید ولد جاوید اقبال، I.P.P پرائیویٹ لمیٹڈ ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف سوات۔ ----------(مدعا علیہم)

دعویٰ صدور ڈگری:

(ا) استقرار حق بدیں مراد کہ من مدعی کو مجاز اتھارٹی نے Drug Manufacturing لائسنس مورخہ MS، 26/10/2020 سوات فارماسیوٹیکلز ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف ضلع سوات کیلئے لائسنس دی ہے۔ اور مدعا علیہم مجاز نہ ہیں کہ وہ مذکورہ لائسنس کو من مدعی کے نام اور ملکیت تسلیم کرنے سے انکار کریں اور مذکورہ لائسنس کے تحت دوائیاں بنانے کے کاروبار میں کوئی دخل مداخلت کریں۔ نیز مدعا علیہ نمبر 5 نے مدعا علیہم نمبر 1 تا 3 کو مذکورہ لائسنس اپنے نام کرنے کیلئے جو درخواست دی ہے اور اُس کیساتھ جو دستاویزات منسلک کیے ہیں، وہ غلط اور غیر قانونی، جعلی، فرضی اور خود ساختہ ہیں، اور حقوق من مدعی پر کالعدم اور غیر موثر ہوتے ہوئے قابل منسوخی ہیں۔

(ب) صدور حکم امتناعی دوامی بنام مدعا علیہم بدیں طور کہ وہ لائسنس مذکورہ بالا من مدعی کے نام اور ملکیت تسلیم کر کے، اُس میں ردوبدل کرنے سے باز و ممنوع رہیں۔ (جاری)

Ali has further submitted that the application submitted by Mr. Waseem Javid for change of management **may not be processed.** Mr. Mubarak Ali CEO/Sole Proprietor of M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat filed an application in the Court of Senior Civil Judge, Swat. The application is in Urdu language and reproduced as under;

مالیت بغرض کورٹ فیس واختیار سماعت مبلغ 200 روپے مقرر کی جاتی ہے۔

بنائے دعویٰ عرصہ چند یوم قبل بعد از انکار مدعاعلیہم اندر حدود و اختیار سماعت عدالت ہذا پیدا شد۔

جناب عالی! حسب ذیل عرض ہے۔

۱۔ یہ کہ من مدعی نے بمقام ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف ضلع سوات، دوائیاں بنانے کیلئے کارخانہ تعمیر کرنے کا ارادہ کیا، اور اس سلسلے میں مدعاعلیہ نمبر 4 سے اُس کی ملکیتی اراضی بمقام شیراڑئی گل کدہ نمبر ۳ سوات، بروئے اقرار نامہ محررہ **22/7/2017**، 25 سال کیلئے لیز پر لے لیا۔ (نقل اقرار نامہ لف ہے)۔

۲۔ یہ کہ بعد ازاں مدعی نے اراضی مذکورہ پر فارماسیوٹیکلز یونٹ کے تعمیر کیلئے مجاز حکام کو درخواست دی، جس پر کاروائی کرتے ہوئے، فیڈرل انسپکٹر آف ڈرگ پشاور نے آسسٹنٹ ڈائریکٹر لائسنسنگ ڈرگ ریگولیٹری اتھارٹی کے احکامات کے روشنی میں موقع ملاحظہ کیا اور جائے مذکورہ فارماسیوٹیکلز یونٹ کے تعمیر کیلئے بروئے رپورٹ محررہ **26/8/2017**، موزوں قرار دی۔ (نقل رپورٹ لف ہے)۔

۳۔ یہ کہ جس کے بعد من مدعی نے دوسرے کوائف کو پورا کرنے کیلئے جائے مذکورہ بالا کا نقشہ بنایا اور مبلغ **-/30,000** روپے مطلوبہ فیس جمع کی، جو کہ متعلقہ حکام نے بروئے لیٹر محررہ **29/11/2017** منظور کیا ہے۔ (نقولات درخواست و منظوری لیٹر لف ہیں)۔

۴۔ یہ کہ بعد ازاں یونٹ میں ایزادگی کرنے کیلئے دوسرا نقشہ بنایا اور اس کے منظوری کیلئے مورخہ **01/01/2019**، مجاز حکام کو درخواست دی اور مبلغ **5000** روپے مطلوبہ فیس جمع کیا، اور جس کی منظوری بروئے لیٹر محررہ **04/02/2019** دی گئی۔ (نقولات درخواست، بینک رسید اور لیٹر، نقشہ لف ہیں)۔

(جاری)

۵۔ یہ کہ اس دوران من مدعی نے مجاز حکام کے ہدایت کی روشنی میں پہلے بمورخہ 31/01/2018 اور پھر بمورخہ 23/07/2018 ، پراگریس رپورٹس دے دی۔ (نقولات رپورٹس لف ہیں)۔

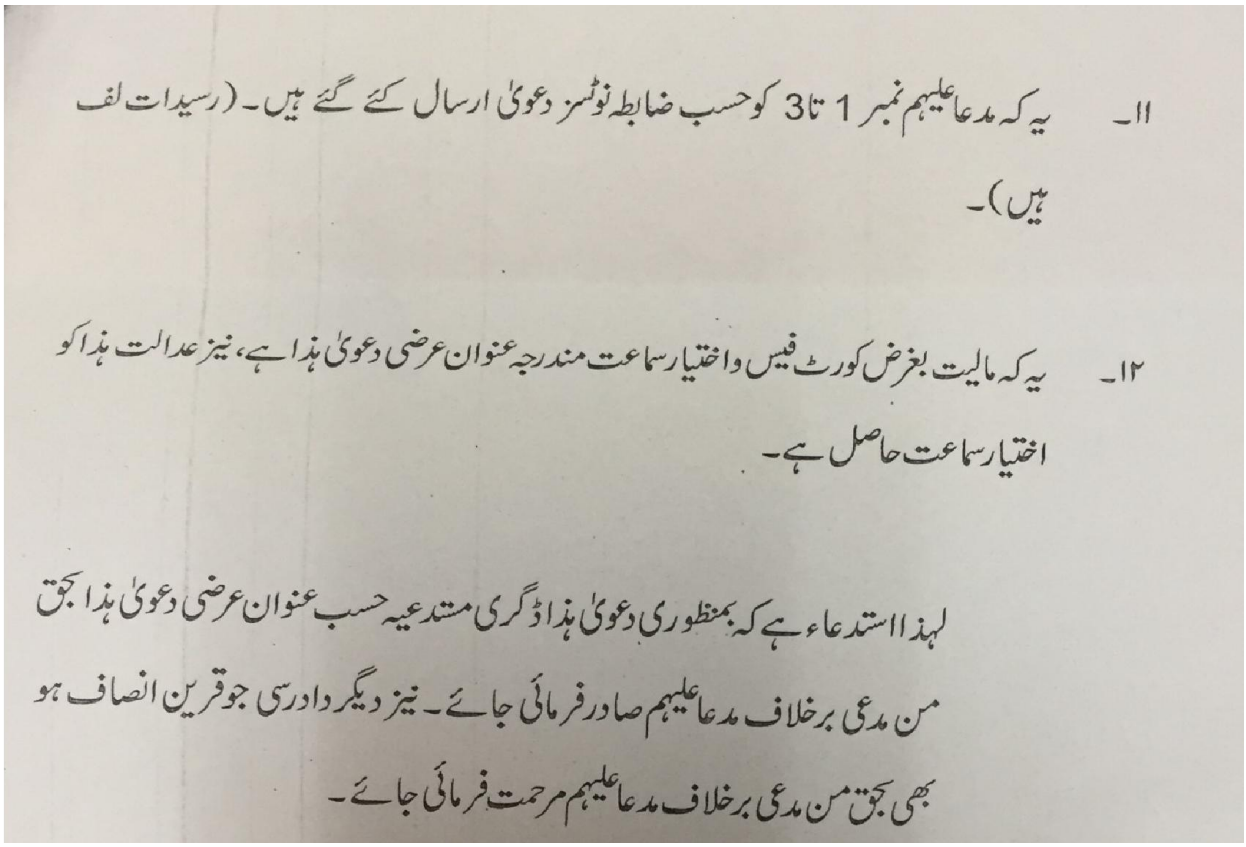
۶۔ یہ کہ بعدازاں مدعاعلیہ نمبر 3 کو لائسنس کے حصول کیلئے مروجہ فارم (الف) بھر کر درخواست دے دی، اور جس کیلئے بھی مطلوبہ فیس مبلغ ایک لاکھ روپے جمع کئے۔ (نقولات لف ہیں)۔

۷۔ یہ کہ جس کے بعد ڈرگ ریگولیٹری اتھارٹی آف پاکستان کے مقرر کردہ Panel نے ستمبر 2020 میں سائٹ کا آخری انسپکشن کیا اور جن کے رپورٹ کے بنیاد پر من مدعی کو لائسنس مذکورہ بالا دی گئی۔ (نقل لائسنس لف ہے)۔

۸۔ یہ کہ بعدازاں مدعاعلیہ نمبر 4 کے نیت میں فتور آکر من مدعی کو فارماسیوٹیکلز یونٹ مذکورہ بالا سے محروم کرنے کے درپے ہوا، اور اس دوران مدعاعلیہ نمبر 5 نے جعلی اور فرضی دستاویزات تیار کر کے جن کے بنیاد پر مدعاعلیہم نمبر 1 تا 3 کو لائسنس مذکورہ میں تبدیلی کیلئے درخواست دی ہے، جس کی وہ ہرگز مجاز نہ ہے۔

۹۔ یہ کہ مدعاعلیہ نمبر 5 کے درخواست پر ہر قسم کے کاروائی غلط، غیر قانونی، جعلی، فرضی اور مبنی بر بد نیتی اور بلا جواز ہے۔

۱۰۔ یہ کہ مدعاعلیہم کو کہا گیا کہ وہ مدعاعلیہ نمبر 5 کے درخواست پر من مدعی کے لائسنس مذکورہ بالا کی نسبت ہر قسم کی کاروائی سے باز و ممنوع رہیں، پہلے تو مدعاعلیہم ٹال مٹول کرتے رہیں اور اب چند یوم قبل صاف انکاری ہوئے، لہذا دعویٰ ہذا کی ضرورت لاحق ہوئی۔



۱۱۔ یہ کہ مدعا علیہم نمبر 1 تا 3 کو حسب ضابطہ نوٹسز دعویٰ ارسال کئے گئے ہیں۔ (رسیدات لف ہیں)۔

۱۲۔ یہ کہ مالیت بغرض کورٹ فیس واختیار سماعت مندرجہ عنوان عرضی دعویٰ ہذا ہے، نیز عدالت ہذا کو اختیار سماعت حاصل ہے۔

لہذا استدعاء ہے کہ بمنظوری دعویٰ ہذا ڈگری مستدعیہ حسب عنوان عرضی دعویٰ ہذا بحق من مدعی برخلاف مدعا علیہم صادر فرمائی جائے۔ نیز دیگر دادرسی جو قرین انصاف ہو بھی بحق من مدعی برخلاف مدعا علیہم مرحمت فرمائی جائے۔

Three summons dated 09/12/2020 were received in Licensing Division, DRAP from Honorable Civil Judge-IV, Mrs. Sidra Aslam, Swat. In these summons, Director Drug Licensing Division/Chairman CLB, Additional Director, Drugs Licensing Division/Secretary CLB, DRAP and Assistant Director Drugs Licensing Division, DRAP were directed to appear before the Honorable Civil Judge, Swat on 04th January, 2021.

Now the firm M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat vide letter NO. SPS/Lic/0001/21, dated 21/02/2021 submitted application for change of management. The firm **has not** deposited fee of Rs.50,000/- for change of management. The detail of management is as under;

Previous Management Sole Proprietor Page 59/Corr	Current (Proposed) Management
2. Mr. Mubarak Ali S/o Alamgir CNIC No. 15602-0482661-1	2. Mr. Mangnaish Kumar S/o Mr. Ram Saroop CNIC No. 15602-3006910-9

The firm has also submitted following documents namely;

i. NOC from Sole proprietor Mr. Mubarak Ali S/o Alamgir wherein he has stated that he has no objection on the transfer of ownership of DML No. 000035 to the name of Mr. Nlangnesh Kumar, NIC No 15602-3006910-9
ii. Swat Civil Court Order 05 dated 06/01/2021 where request for withdrawal of plaintiff is dismissed as withdrawn
iii. Agreement between following
    a. Mr. Mubarak Ali S/o Alamgir,
    b. Mr. Shaid Fazal Rabi S/o Fazal Rabi,
    c. Mr. Waseem Javed S/o Javed Iqbal.

In light of above, documents submitted by Mr. Mubarak Ali S/o Alamgir for site verification and application of FORM-I as per Drugs(Licensing Registering &advertining) Rules 1976, for grant of DML and now application of change of management, it is revealed that the Sole Proprietor of the firm, Mr. Mubarak Ali S/o Alamgir has welling/intentionally concealed ownership/management of the firm.

Proceedings and Decision by the Central Licensing Board in 279th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000035 by way of formulation in the name of M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swat may not be suspended or cancelled by Central Licensing Board.

In the light of Central Licensing Board's decision a Show Cause Notice was issued to the firm M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swatdated 19-03-2021 .
In response to Show cause Notice the firm submitted their response vide letter No.02/21/Lic./DRAP dated 05-04-2021 which is reproduced as under;

"Kindly refer to Show Cause Notice bearing No. F. 3-1/2016-Lic, dated 19th March,2021.

Although responding to the subject Show Cause Notice is responsibility of the existing owner, but being the new buyer of the Pharmaceutical Unit (M/S Swat Pharmaceuticals) the applicant wants to explain his point of view for your kind consideration, hence the applicant humbly submits as under:

1. *That the applicant purchased the pharmaceutical unit (M/S Swat Pharmaceuticals DML No. 000035) vide Sale Deed 19.11.2020. (Attested copy of the Sale Deed attached as Annexure "A").*
2. *That the applicant got the building of the said pharmaceutical unit on lease from the original owners of the building/land. (Copy of Lease agreement attached as Annexure*
3. *That subsequently the applicant submitted an application for the change of the management of the said Pharmaceuticals firm but in the meanwhile a financial dispute arose among the current owners/sellers. The current owner/CEO (MR. Mubarak Ali) filed a Civil Declaratory Suit Against Mr. waseemJwaid and Mr. Shahid Fazal in the court of Civil Judge-VII Swat which was mutually settled through arbitration in the honorable Court vide Court Order dated 06.01_2021. (Attested copies of the court order and otherrelevant documents attached as Annexure*
4. *That the applicant again submitted application for the of management after getting a fresh NOC 18.01-2021 from the current Owner/CEO (Mr. Mubarak Ali)(Copy of NOC attached as Annexure)*
5. *That in the meanwhile the Subject Show Cause Notice was issued to the said pharmaceutical unit. to which is the responsibility of the as applicant has nothing to do wah internal financial disputes current owners/sellers.*
6. *That the applicant is buyer of the said pharmaceutical firm and incase of suspension or cancellation of license, the current owners/sellers will have nothing to lose but he applicant will be the only to but the sufferer and loser with no fault his part.*

7. *That Swat is underdeveloped area having been hit by terrorism for many years and unemployment is also rising due to lack of industries, as Swat Pharmaceuticals is currently providing jobs to many technical/skilled and unskilled workers including male and female so any unfavorable any decision will deprive innocent employees and works of their source of bread.*

In view of above it is humbly requested to kindly consider the submissions of the Applicant on the n humanitarian ground grounds, and grant approval for the management as requested earlier"

Accordingly, a personal hearing letter was issued to the firm on 15th April, 2021.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

Mr. Rashid Ahmed Marketing Manager and Mr. Mangnaish Kumar new Owner of the firm on behalf of the firm appeared before the Board.The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000035 (by way of formulation) of firm M/s of M/s Swat Pharmaceuticals, Valley Road, SherarаiGulkada No.3, Saidu Sharif Swat till ractifications of documents.

Case No.80 RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S OBSONS PHARMACEUTICALS, LAHORE AND SITE APPROVAL AT NEW PREMISES.

Case background. The Central Licensing Board in its 269thmeeting considered the case of M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore under Drug Manufacturing License No. 000416 (Formulation) and decided as under:-

> "Mr Noor Hussain Gondal, Partner of the firm appeared before the Board and contended that he has recently taken over management of the firm and submitted an undertaking on Affidavit that he would shift to new premises for which he has already submitted an application for site verification. The Secretariat of the Licensing Division also confirmed that application for site verification is received and being processed. The Board after hearing the representative of the firm and perusal of orders of the Honourable High Court observed that SRO. 470 (I)/98 which specify the minimum area requirement for a pharmaceutical firm is applicable as renewal of a Drug Manufacturing Licencee is always subject to updated law and rules. The Board considering the commitment of new management decided to give period till August, 2020 to the firm to shift to new premises and for that purpose the applicant shall get its site verified and Lay out plan approved by 30th April, 2019 and shall file application for grant of Licencee before 31st August, 2020".

The decision of Central Licensing Board conveyed to M/s Obsons Pharmaceuticals, Lahore on 7th March, 2019 with direction to get site verified and layout plan approved by 30th April, 2019 and apply for grant of license before 31st August, 2020.

In the light of decision of Central Licensing Board M/s Obsons Pharmaceuticals (Pvt) Ltd submitted an application for site approval located at Khewat No. 14, Khatooni No. 69-71, Sangrai Tehsil

Ferozewala, District Sheikhupura. Upon evaluation of submitted documents following shortcoming has been observed in the site approval application and shortcoming letters issued to the firm on 20th February, 2019, 4th May, 2020 and 17th August, 2020 :-

i. Plot allotment and possession letter in the name of firm.

The firm M/s Obsons Pharmaceuticals has submitted an application in response to this Division's letter dated 7th March, 2019 wherein the firm has requested for extension of validity time. Firm also requested to allow continuing their production activities and purchase of active materials through L.Cs. Firm has also informed that they have purchased 8 kanal land in Quaid-e-Azam Business Park Sheikhupura for shifting of their manufacturing plant.

The Firm M/s Obsons Pharmaceuticals has also requested for renewal of Drug Manufacturing License under DML No. 000416 for next tenure of five years M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, wherein the firm has submitted the documents for renewal of Drug Manufacturing Licencee No. 000416 (by way of Formulation) for the period 07-08-2020 to 06-08-2025. The application was received on 20-07-2020 and due date of renewal of DML 07-08-2020. The firm has submitted a fee of Rs. 50,000/- (Pages 275/Corr) for renewal of DML.
On scrutiny of grant of renewal of Drug Manufacturing License and site approval applications the following observations have been observed:-

For Site approval.

i. Plot allotment and possession letter in the name of firm.

For Renewal of DML.

i. Form 1A as per prescribed formate.
ii. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
iii. Attested CNIC's copies of all Directors.
iv. Detail of premises including layout plan.
v. Proof of licensed sections from CLB.
vi. Approval letter of Production / QC Incharge in case of change than submit required documents as per check list.
vii. Up-to-date nothing due certificate regarding CRF from STO.
viii. All documents duly should be attested.

Firm M/s Obsons Pharmaceuticals, Lahore, has submitted a response to this Division's letter dated 17th August, 2020 wherein the firm has informed that allotment letter is in the process which will be completed soon and will submit the allotment letter when it will be issued by Punjab Industrial Estate Development & Management Company.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000416 by way of formulation of M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahoremay not be

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

Accordingly, a personal hearing letter was issued to the firm on 16th April, 2021.

Proceedings and Decision by the Central Licensing Board in 280th meeting:

Mr. Noor Hussain Gondal partner of the firm appeared before the Board. He contended that plot has been allotted to them in an Industrial area but possession will be given after development of industrial area that may take atleast two years.The Board after perusal of record and facts decided to cancel the Drug Manufacturing License No 000416 by way of formulation of M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat.

Case No.81 NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S DIVINE PHARMACEUTICALS, PLOT NO. 226-A, SUNDER INDUSTRIAL ESTATE, LAHORE UNDER DML NO. 000850 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore 23rd September, 2020 as the firm

has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 19th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Aamir Farooq son of Director of the firm appeared before the Board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Bufget and Accounts Division.

Case No.82 NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that following active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The detail of the firms is as under:-

Sr.	DML No.	Name	Last Contribution Paid upto (FY)
1.	000317	M/s Imco Pharmaceutical Labs (Pvt) Ltd.	2016
2.	000433	M/s AhadInternational Pharmaceutical Limited	2016
3.	000795	M/s Herbion Pakistan (Pvt) Ltd.	2016

4.	000816	M/s Ice Berg Pharmaceuticals (Pvt) Ltd.	Never
5.	000848	M/s Biorific Pharma	Never
6.	000511	M/s CSH Pharmaceutical-North (Pvt) Ltd.	2016
7.	000404	M/s LeamaChemiPharma (Pvt) Ltd.	2016
8.	000797	M/s Oakdale Pharmaceuticals	Never
9.	000440	M/s OnyxPharmaceuticals Industries	2016
10.	000759	M/s S.N.B Pharma (Pvt) Ltd.	Never
11.	000711	M/s Siam Pharmaceuticals	2016
12.	000740	M/s Unisa Pharmaceutical Industries Ltd.	2016
13.	000780	M/s Wisdom Pharmaceutical Industry	Never
14.	000857	M/s Perk Pharma (Pvt) Ltd.	Never
15.	000197	M/s Kohinoor Industries	2016
16.	000257	M/s Medipak Ltd.	2016
17.	000373	M/s Alpha Chemicals (Pvt) Ltd.	2015
18.	000423	M/s Alza Pharmaceuticals	Never
19.	000429	M/s Citi Pharma (Pvt) Ltd.	2016
20.	000471	M/s Farmigea Pakistan (Pvt). Ltd.	2016
21.	000512	M/s Citi Pharma (Pvt) Ltd.	2016
22.	000549	M/s MedisearchPharmacal (Pvt) Ltd.	2016
23.	000593	M/s Miracle Pharmaceuticals (Pvt) Ltd.	2016
24.	000604	M/s Ameer Pharma (Pvt) Ltd.	2016
25.	000660	M/s Aventek Pharmaceuticals	2015
26.	000810	M/s Linta Pharmaceuticals (Pvt) Ltd.	2016
27.	000812	M/s Bio-Oxime Pharmaceuticals	Never
28.	000829	M/s GT Pharma (Pvt) Ltd.	2016
29.	000841	M/s Medipak Ltd.	Never
30.	000845	M/s Genetics Pharmaceuticals (Pvt) Ltd	Never

31.	000854	M/s Karsons Pharmaceuticals	Never
32.	000862	M/s Briell Pharmaceuticals (Pvt) Ltd.	Never
33.	000863	M/s Bio-mark Pharmaceuticals	Never
34.	000867	M/s Evolution Pharmaceuticals (Pvt) Ltd.	Never
35.	000871	M/s AAA Health Pharmaceutical Laboratories	Never
36.	000873	M/s Majestic Pharma	Never
37.	000878	M/s Med Pharm Research Lab	Never
38.	000884	M/s Hi-Med Pharmaceuticals (Pvt) Ltd.	Never
39.	000053	M/s Risma Laboratories	2016
40.	000118	M/s Standard Drug Company	2016
41.	000138	M/s Ahson Drug Co.	2016
42.	000282	M/s Gelcaps (Pakistan) Ltd.	2013
43.	000421	M/s Nexus Pharma (Pvt) Ltd.	2016
44.	000620	M/s Maple Pharmaceuticals (Pvt) Ltd.	2016
45.	000746	M/s Apex Pharmaceuticals (Pvt) Ltd.	2016
46.	000757	M/s Reign Pharmaceuticals	2016
47.	000809	M/s Mission Pharmaceuticals	2016
48.	000822	M/s Mediflow Pharmaceuticals (Pvt) Ltd.	2016
49.	000851	M/s Maxitech Pharma (Pvt) Ltd.	Never
50.	000858	M/s Palpex Pharmaceuticals (Pvt) Ltd.	Never
51.	000866	M/s Inventor Pharma	Never
52.	000870	M/s Newton Health Care (Pvt) Ltd.	Never
53.	000883	M/s Parkar Pharma	Never

Decision by the Central Licensing Board in 269th meeting:

The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and

Advertising) Rules, 1976 as to why their Drug manufacturing License may not be suspended till settlement of Central Research Fund.

Now the following firms has submitted CRF and the Budget and Account Division, DRAP has issued Nothing Due Certificate. The detail of the firms is as under: -

Sr.	DML No.	Name	Last Contribution Paid upto (FY)
1.	000317	M/s Imco Pharmaceutical Labs (Pvt) Ltd.	31-12-2020
2.	000433	M/s AhadInternational Pharmaceutical Limited	31-12-2019
3.	000795	M/s Herbion Pakistan (Pvt) Ltd.	31-12-2020
4.	000816	M/s Ice Berg Pharmaceuticals (Pvt) Ltd.	31-12-2019
5.	000848	M/s Biorific Pharma	31-12-2020
6.	000511	M/s CSH Pharmaceutical-North (Pvt) Ltd.	31-12-2019
7.	000404	M/s LeamaChemiPharma (Pvt) Ltd.	31-12-2021
8.	000797	M/s Oakdale Pharmaceuticals	31-12-2020
9.	000440	M/s OnyxPharmaceuticals Industries	31-12-2019
10.	000759	M/s S.N.B Pharma (Pvt) Ltd.	31-12-2020
11.	000711	M/s Siam Pharmaceuticals	31-12-2021
12.	000740	M/s Unisa Pharmaceutical Industries Ltd.	31-12-2021
13.	000780	M/s Wisdom Pharmaceutical Industry	31-12-2020
14.	000857	M/s Perk Pharma (Pvt) Ltd.	31-12-2020
15.	000197	M/s Kohinoor Industries	31-12-2019
16.	000257	M/s Medipak Ltd.	31-12-2021
17.	000373	M/s Alpha Chemicals (Pvt) Ltd.	31-12-2021
18.	000423	M/s Alza Pharmaceuticals	31-12-2020
19.	000429	M/s Citi Pharma (Pvt) Ltd.	31-12-2020
20.	000471	M/s Farmigea Pakistan (Pvt). Ltd.	31-12-2019

21.	000512	M/s Citi Pharma (Pvt) Ltd.	31-12-2020
22.	000549	M/s MedisearchPharmacal (Pvt) Ltd.	31-12-2019
23.	000593	M/s Miracle Pharmaceuticals (Pvt) Ltd.	31-12-2020
24.	000604	M/s Ameer Pharma (Pvt) Ltd.	31-12-2020
25.	000660	M/s Aventek Pharmaceuticals	31-12-2020
26.	000810	M/s Linta Pharmaceuticals (Pvt) Ltd.	31-12-2021
27.	000812	M/s Bio-Oxime Pharmaceuticals	31-12-2020
28.	000829	M/s GT Pharma (Pvt) Ltd.	31-12-2020
29.	000841	M/s Medipak Ltd.	31-12-2021
30.	000845	M/s Genetics Pharmaceuticals (Pvt) Ltd	31-12-2020
31.	000854	M/s Karsons Pharmaceuticals	31-12-2021
32.	000862	M/s Briell Pharmaceuticals (Pvt) Ltd.	31-12-2020
33.	000863	M/s Bio-mark Pharmaceuticals	31-12-2020
34.	000867	M/s Evolution Pharmaceuticals (Pvt) Ltd.	31-12-2020
35.	000871	M/s AAA Health Pharmaceutical Laboratories	31-12-2020
36.	000873	M/s Majestic Pharma	31-12-2021
37.	000878	M/s Med Pharm Research Lab	31-12-2020
38.	000884	M/s Hi-Med Pharmaceuticals (Pvt) Ltd.	31-12-2021
39.	000053	M/s Risma Laboratories	31-12-2020
40.	000118	M/s Standard Drug Company	31-12-2021
41.	000138	M/s Ahson Drug Co.	31-12-2019
42.	000282	M/s Gelcaps (Pakistan) Ltd.	31-12-2020
43.	000421	M/s Nexus Pharma (Pvt) Ltd.	31-12-2020
44.	000620	M/s Maple Pharmaceuticals (Pvt) Ltd.	31-12-2020
45.	000746	M/s Apex Pharmaceuticals (Pvt) Ltd.	31-12-2021
46.	000757	M/s Reign Pharmaceuticals	31-12-2021
47.	000809	M/s Mission Pharmaceuticals	31-12-2021
48.	000822	M/s Mediflow Pharmaceuticals (Pvt) Ltd.	31-12-2020

49.	000851	M/s Maxitech Pharma (Pvt) Ltd.	31-12-2021
50.	000858	M/s Palpex Pharmaceuticals (Pvt) Ltd.	31-12-2020
51.	000866	M/s Inventor Pharma	31-12-2021
52.	000870	M/s Newton Health Care (Pvt) Ltd.	31-12-2020
53.	000883	M/s Parkar Pharma	31-12-2021
54	**000203**	M/s Sarco Chemical Industries, 17-KM, Peerwala Morr, Qader Pur Ban, Khanwal Road, District Multan.	**31-12-2020**
55	**000259**	M/s Siza International (Pvt) Ltd,18-KM Ferozepur Road, Lahore.	**31-12-2020**
56	**000295**	M/s Pacific Pharmaceuticals Ltd, Plot No. 384, Sunder Industrial Estate, Lahore.	**31-12-2020**
57	**000502**	M/s Ottoman Pharma, 10-KM, Raiwind Road, Lahore.	**31-12-2020**
58	**000875**	M/s Relizon Pharmaceuticals, Plot No. 118-Sundar Industrial Estate, Raiwind Road, Lahore.	**31-12-2020**

Proceedings and Decision by the Central Licensing Board in 280th meeting:

The Board noted that above mentioned firms have submitted the Central Research Fund The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of all above mentioned firmsfor further period.

QUALITY ASSURANCE (QA) CASES

Item No. I DELEGATION OF POWERS

Case No. i: **POWER DELEGATION.**

As per decision of 273rd meeting of CLB, the powers delegated to Director QA&LT and other officers of QA&LT are given below;

"The Central Licensing Board approved and delegated its powers retrospectively with certain modifications to Director Quality Assurance and Laboratory Testing under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) rules, 1976 in order to facilitate timely disposal of routine and day to day business of Central Licensing Board.

S No.	Functions / Powers	Function / Powder Delegated to
Delegation of Functions / Powers related to the Division of Quality Assurance & Laboratory Testing		
1.	Issuance of Show Cause Notice regarding contravention of any of the provision of DRAP Act, 2012 and rules framed there under (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
2.	Advisory letters, explanation letters or any other action as deems fit for the purpose of improvement (in case of GMP matters)	Director Quality Assurance and Laboratory Testing
3.	Suspension of Production (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
4.	Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members. Where the panel is constituted by the Director (QA&LT). However the cases shall be placed before the CLB for information.	Director Quality Assurance and Laboratory Testing
5.	Permission to Lodge FIR	Director Quality Assurance and Laboratory Testing
6.	Panel Constitution (GMP Inspections and related issues etc)	Director Quality Assurance and Laboratory Testing
7.	Constitution/ amendments in constitution of panel for inspection for GMP compliance and quality control matters.	Director Quality Assurance and Laboratory Testing
8.	To continue the period of "not to dispose-of stocks orders passed by FID" for three months or till the finalization of the case (other than registered Drugs).	Director Quality Assurance and Laboratory Testing

9.	To continue custody of the seized stocks by the FID till decision of the case (other than registered Drugs).	Director Quality Assurance and Laboratory Testing
10.	To grant approval for sending Board's portion of drug samples to the Appellate Laboratory (other than registered Drugs).	Director Quality Assurance and Laboratory Testing
11.	Grant of extension in the time of testing to Federal Government Analyst (other than registered Drugs).	Director Quality Assurance and Laboratory Testing
12.	Issuance of Show Cause Notices/Personal hearing letters/Circulars/Communication of Minutes/Decisions/Directions of the Board to the Concerned quarters regarding GMP and Quality Control matters on behalf of Secretary Board. The letter shall be issued with Name & Designation of the officer.	Assistant Director (QA&LT) / Deputy Director (QA&LT)

At present post of Director (QA&LT) is vacant. The matter was discussed in 278th meeting of CLB and the board decided as under;

"The board discussed and deliberated that power delegated to Director (QA&LT) in its 273rd meeting of Central Licensing Board shall be exercised by Additional Director (QA&LT), in case of occurrence of vacancy on the post of Director (QA&LT) or leave for the period more than two weeks."

Proceeding and Decision of 280th meeting of CLB:-

The board deliberated the matter of power delegation and decided as under;

i. For power/function at serial No. 5 i.e. *"Permission to Lodge FIR"*, the board constituted following sub-committee and delegated power to grant "*permission to lodge FIR*" to it until placement of the Director QA<
   a. Mr. Abid Ali (Law Expert) Deputy Draftsman, Ministry of Law & Justice Islamabad.
   b. The Secretary Central Licensing Board DRAP Islamabad.
   c. The Additional Director QA&LT DRAP Islamabad.

ii. To omit power/function at Serial No. 10 i.e. *"To grant approval for sending Board's portion of drug samples to the Appellate Laboratory (other than registered Drugs)."*

Item No. II Personal hearing in compliance to decision of 277th meeting of CLB.

Case-i: M/s Helix Pharma Karachi

Background:-

Mr. Awais Ahmed, area FID DRAP Karachi conducted inspection of the firm M/s Helix Pharma (Pvt.) Ltd., A-56, S.I.T.E., Karachi (DML. No. 000030) on 16-01-2020 & 17-01-2020 to check GMP compliance. The observations reported by FID are reproduced below;

i. Quality Assurance

i. QMS is not well established.
ii. Advised to prepare and improve SOPs and arrange trainings for the staff.

ii. Ware House

i. RMS is congested
ii. Floor of warehouse was broken from many points, needs immediate renovation.
iii. Advised to provide gowning for 2-8 C store.
iv. Some doors of dispensing area were out of order.
v. Magnehelic gauge was also not working at time of inspection.
vi. Interlocking is advised in dispensing area to maintain pressure differential.
vii. Firm is also advised to ensure cleanliness and improve hygiene.
viii. Firm has not provided proper emergency exists, fire alarms and smoke detectors in warehouse.
ix. Training to the staff also advised to ensure personal safety.

iii. Dry Powder Suspension (General &Ceph)

i. Door fixtures of blistering area were out of order.
ii. Material entry is not provided by buffer and interlock. Same entry is also used for over printing room.
iii. Compression room 1 has opening into compression room 2, which has no use, and door was temporarily fixed with tape.
iv. The firm found in violation of DRB decision on segregated section for Psychotropic substances, as firm has no segregated section for Psychotropic Products. Psychotropic product "Estazolim" was being manufactured in general OSD section.
v. HVAC is not provided in blistering area. Air conditioner was installed in blistering room, as product is exposed in blistering room, there are chances of contamination.
vi. Emergency exits not properly assigned and over occupied at some exits.
vii. In granulation section, firm found in violation of approved layout plan, as 2 Compression machines were installed in 2 different cubicles, one assigned for "utensils washing" and other is "assigned for C.M Store" as per approved layout plan.
viii. HVAC inlet of the compression room was closed and looks like it is closed since long.
ix. No dust collector is provided in compression room.
x. No HVAC/ Air Condition is installed in "In-process staging area" and temp & humidity record was also not available.

iv. Oral Liquid/ Syrup

i. No magnehelic gauges provided in Liquid manufacturing area.
ii. Door fixtures of blowing area were out of order at time of inspection.

iii. No temperature and humidity record was available in liquid packaging area at the time of inspection.

v. Liquid Sterile Ampoules/ Infusion/ Ophthalmic/Otic.

i. Primary change room is congested; in secondary change room no interlock is provided.
ii. Corridor is clean, NO HVAC is provided.
iii. No air shower is provided to enter into classified sterile area.
iv. Entrance door from buffer to class B has no interlocking and door fixture was also out of order. Hence it can be established as area is not maintained.
v. In injectable filling area, secondary gowning was not available for visitors even for In-charge, glass view in filling/ manufacturing section was also not provided and therefore manufacturing / filling could not be inspected in detail.
vi. In Injectable Quarantine area no HVAC is installed, Split air conditioner is installed.
vii. In quarantine area ball milling machine was placed.
viii. Firm has 2 autoclaves, one was out of order.

2. The FID concluded the report as under;

*"Based on the area visited, the documents reviewed and findings of the inspection, firm is considered to be operating at **Poor level of Compliance.** Under section 19(7) of the Drugs Act 1976, inspection report is placed before the competent authority for further necessary action into the matter."*

Action Taken by DRAP:

3. Keeping in view the observations and conclusion of report of FID dated 16 & 17-01-2020, the firm was issued an Explanation letter and Suspension of Production orders vide letter No. 4-7/2006-QA dated 12-02-2020.

4. Resumption in OSD and oral liquid section was granted on 18.05.2020 and resumption in Liquid sterile Ampoule/Infusion/ophthalmic otic section was granted on 23.06.2020 based on panel inspections dated 06.05.2020 and 16.06.2020.

Non-compliance of the firm:

4. Mr. Awais Ahmed, area FID DRAP Karachi vide letter dated 06-03-2020 stated that he visit premises of M/s Helix Pharma (Pvt) Ltd S.I.T.E. Karachi on 06-03-2020 to check compliance of this office suspension of production orders dated 12-02-2020.

5. The FID reported that the firm had suspended production activities in sterile area and ***production was underway in other sections.***

6. The FID was directed vide letter dated 08-04-2020 & 29-04-2020 to submit detailed investigation report along with details of violations and clear & candid recommendations on observed violations.

Reply of FID:

7. Mr. Awais Ahmed, area FID DRAP Karachi in compliance to this office letter dated 29-04-2020 submitted detailed report which is reproduced below;

"With reference to the subject cited above and in compliance to letter No. F.4-7/2006-QA received on 11th May, 2020, undersigned visited M/s Helix Pharma (Pvt) Ltd, SITE, Karachi on 14th May, 2020 to investigate the matter. During inspection, it was revealed that suspension of production order issued on 12.02.2020, received by firm on 17.02.2020, however firm continued production till 16th May, 2020. Manufactured stock of all the batches manufactured after suspension of production order s were made "Not to dispose of" on prescribed Form-I for the period of initially 28 days. After detailed investigation, it was concluded that the firm was involved in unauthorized manufacturing in all sections and firm has violated the decision of the competent authority i.e. The Director QA&LT, for suspension of production orders communicated to the firm vide DRAP letter No. even dated 12.02.2020, which is violation of Section 23 (i)(a)(x) and section 23(i)(b) of the Drugs Act 1976, read with Schedule II(A)(1)(x) and Schedule (A)(1)(b) of the DRAP Act 2012.

8. The FID further requested that;

i. The necessary permission for extension in the time period of the stock made ordered not to dispose of on prescribed Form-1 may kindly be granted.
ii. Case may be placed in upcoming CLB meeting for discussion and necessary directions.
iii. Any other action as per the law.

9. The case was placed before the 275th meeting of CLB, Wherein the Board decided as under:-

Decision of the 275thMeeting of CLB:-

After thorough discussion/deliberations, the Central Licensing Board decided to direct the area FID to investigate the matter of production activities till 06.03.2020, in non-compliance to the orders of QA&LT Division dated 12.02.2020 and fix the responsibility. The FID shall submit detailed investigation report with clear and candid recommendation for consideration of the CLB under the law.

10. Decision of 275th meeting of CLB was conveyed to FID vide letter dated 02.07.2020.

Reply of FID:-

The FID in compliance to decision of 275th meeting of CLB vide letter dated 18.08.2020 submitted reply as under:-

"Keeping in view the above stated facts and brief summary of the case, the firm has violated the section 23(i) (a) (x) and section 23(i) (b) of the Drugs Act, 1976 read with Schedule II (A) (I) (x) and Schedule II (A)(I) (b) of the DRAP Act, 2012, and rules made there under. However keeping in view repeated inspections of the firm, rectifications of the observations, overall improvements and resumption of productions in all sections after recommendation by the panel members, it is to be proposed that:

i. Show Cause Notice / Personal hearing may be issued to the following responsible persons for violations of the directions as passed by the QA & LT Division along with violation of above mentioned sections of the Drug Act, 1976 and DRAP Act, 2012.
- *Mr. Tahir Nabi Mirza, Director Quality Assurance & Regulatory Affairs.*
- *Mr. Abu Sagheer, General Manager Production.*

ii. Any other directions as may be passed by the Central Licensing Board."

11. Reply of the FID was placed before the 275th meeting of CLB, Wherein the Board decided as under: -

Decision of 276th Meeting of CLB.

The board decided to refer the case back to QA & LT Division to provide names of Management and Responsible persons of the firm M/s Helix Pharma (Pvt.) Ltd. Karachi (DML No. 000030).

12. The Area FID and Secretary CLB were requested vide letter dated 28.09.2020 to provide requisite information.

13. The Licensing Division vide letter dated 13.10.2020 provided names of management and qualified persons as below:-

i.	Mr. Naveed Nawazish Hakim	Director
ii.	Mrs. Nayyar Jahan Hakim	Director
iii.	Mr. Nawazish Ali Hakim	Director
iv.	Mr. Muhammad Tariq	Production Incharge
v.	Mr. Shakeel Ahmed	Quality Control Incharge

14. The matter was placed before the board in its 277th meeting and the board decided as under;

Decision of 277th meeting of CLB:

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to issue show cause notice to following accused person on *violation of section 23(1) (a) (x) and section 23(1) (b) of the Drugs Act, 1976 read with Schedule II (A) (I) (x) and Schedule II (A)(I) (b) of the DRAP Act 2012* : -

i. Mr. Naveed Nawazish Hakim S/o Nawazish Ali Hakim Director
CNIC. No. 42201-9743780-3

ii. Mrs. Nayyar Jahan Hakim W/o Nawazish Ali Hakim Director
CNIC No. 42201-6458636-4

iii. Mr. Nawazish Ali Hakim S/o Fasihuddin Hakim Director
CNIC No. 42201-8483279-3

iv. Mr. Muhammad Tariq Production Incharge

v. Mr. Shakeel Ahmed S/o Abdul Mateen Quality Control Incharge
CNIC No. 42401-1829863-5

15. In compliance to decision of 277th meeting of board, show cause notice was served to above mentioned person on 28.10.2020.

16. In response to show cause notice, the firm has submitted the following reply;

"We the respondents of Drug Regulatory Authority of Pakistan (DRAP) letter reference No.F.8-4/2020/QA (M-277-CLB), dated 28th October, 2020, would humbly like to submit the following in front of the august forum of CLB:

That we have been given a show cause notice on violation of section 23(1) (a) (x) and section

1. 23(1)(b) of the Drugs Act 1976 read with Schedule II (A) (I) and Schedule II (A)(I) (b) of the Drug Regulatory Authority of Pakistan (DRAP) Act 2012 & rules formulated thereunder. These contraventions carried out by us unintentionally have already caused us great remorse from February 2020 and this show cause has added to that feeling.

2. That Helix Pharma, which we represent is a 6-decade old manufacturing concern and has played role in bringing various multinational companies to the country. We are currently representing Takeda Pharma of Japan which is globally amongst top 10 companies. Our regulatory history has been clean and cooperative with established positive attitude in covering the gaps identified by various regulators during the course of so many inspections conducted by the regulators. Here it is pertinent to mention that we have been participating in various government institutional tenders and have been supplying our medicines to various tertiary care hospitals, which endorses our quality. Helix Pharma has already been started working on a renovated/overhauled plant in January 2020. Our renovation plan has already been approved by division of drug licensing in October 2019 and when the visit of the FID took place work had already been initiated.

3. That based on FIDs observations during his visit of our plant on 17th January, 2020 he had various observations which were clearly laid out in his report sent to the CLB. We inspite of having reservations about some of the observations of FID, acknowledged those observations and immediately started improving on the observations. During FID visit no instructions were issued for the suspension of production, however, we received directions from Asst. Director (QA-II) for the suspension of production. We responded to the directions vide letter dated; 20/02/2020 & 09/03/2020 (copies are enclosed herewith). We also want to submit before the august forum that we were ensuring controls for the quality of our products and it is obvious from the test reports of the samples taken by FID during his first visit & all of them were declared standard quality by CDL. During this correspondence, we continued production & unintentionally contravened the sections of Drugs Act 1976 & Drug Regulatory Authority of Pakistan (DRAP) Act 2012 which we regret for and asking for relief from the board on compassionate grounds.

4. That we are fully cognizant of the seriousness of this violation and can only submit to this august body to take a compassionate view of our case. We have never been reprimanded by the board for any violations and our will and desire to improve has been observed by the panel constituted for the re-inspection of our manufacturing facility after suspension of manufacturing. The comments of the panel inspection are a proof of that desire to improve, ***"positive intention towards improvement".***

5. That we look forward to the board for a considerate view based on the above submissions, however, we also want to present our case before the board in person (if needed).

Submitted for sympathetic consideration of August Forum of Central Licensing Board."

Proceeding of 280th meeting of Board:

17. Mr. Muzaffar Jafri COO M/s Helix Pharma Karachi, Mr. Nadeem Ahmed Director Technical M/s Helix Pharma Karachi and Mr. Tanveer Ahmed GM HR M/s Helix Pharma Karachi appeared before the board and narrated similar statement which they had previously submitted in writing.

18. The board deliberated and decided as under;

Decision of 280th meeting of CLB:

19. After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view available record, investigation report of the FID and offence admitted by the management of the firm before the Board, the board granted permission for prosecution against the following accused in the Drug Court, Karachi for the offences under Section 23 (1) (a)(x), (b) & (c) read with Section 27 of the Drugs Act, 1976 under DRAP Act, 2012: -

i. Mr. Naveed Nawazish Hakim S/o Nawazish Ali Hakim Director

CNIC. No. 42201-9743780-3

ii. Mrs. Nayyar Jahan Hakim W/o Nawazish Ali Hakim Director
CNIC No. 42201-6458636-4

iii. Mr. Nawazish Ali Hakim S/o Fasihuddin Hakim Director
CNIC No. 42201-8483279-3

iv. Mr. Muhammad Tariq Production Incharge

v. Mr. Shakeel Ahmed S/o Abdul Mateen Quality Control Incharge
CNIC No. 42401-1829863-5

Item No. III **CASES OF GMP NON-COMPLIANCE.**

Case No.I:- **M/s Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi. (DML No. 000025).**

Background

Mr. Awais Ahmed FID-IX DRAP Karachi inspected the premises of M/s Pfizer Pakistan Limited, B-2. S.I.T.E. Karachi (DML No. 000025) on 29.12.2020. As per report submitted to this office FID had given following recommendation to the firm for further improvements;

i. To update the SOP for destruction of Narcotic/Psychotropic substances according to SOP issued by DRAP controlled drug division and also review incineration/destruction site change.

ii. To discuss with the management regarding provision of segregated/dedicated section for their steroidal/Hormonal products, as already firm has submitted the application and is in progress, but firm is advised to expedite the process at earliest.

iii. To provide segregated area for printed and packaging material.

2. The conclusion of report is reproduced below;

"Keeping in view above mentioned observation, documents review, persons met, firm is operating at satisfactory level of cGMP compliance, as of today. Furthermore, firm is advised to submit CAPA for above mention observation at the earliest."

3. The firm was asked to submit compliance report on implementation of advises of the FID vide letter dated 12.01.2021. In response to which the firm submitted a reply stating that they will all observations (3 in total) by 21.07.2021.

4. The case was referred to Licensing Division to confirm if any application by M/s Pfizer regarding their Steroidal/Hormonal Sections is under process or not.

5. The Licensing Division informed that the firm M/s Pfizer Pakistan Limited Karachi has submitted layout plan for approval of new Tablet Hormone (Steroidal) section which was discussed in L.O.P committee and it was observed that proposed section needs dedication and a letter dated 06.02.2020 was issued to the firm to submit revised layout plan. Later on, firm submitted revised layout plan which was discussed in L.O.P. committee along with technical persons of the firm and once again it was observed/discussed that proposed hormone (steroidal) section was not dedicated. Accordingly, letter dated 06.10.2020 was issued to the firm to submit revised layout plan. No reply/revised layout plan is received as of today.

Proceeding and Decision of 280th meeting of CLB:-

6. The Board decided that the Licensing Division shall issue show cause notice to the firm.

Case No. II:- M/s Elvin Pharmaceuticals (Pvt.) Ltd. 35-Km Raiwind Road, Lahore (DML No. 000508).

An inspection report of M/s. Elvin Pharmaceuticals (Pvt) Ltd, 35-KM, Raiwind Road, Lahore was forwarded by Ms. Aisha Irfan, FID, DRAP, Lahore dated16-02-202. The report is reproduced as under;

"The inspection of M/s. Elvin Pharmaceuticals (Pvt.) Ltd., 35-Km, Raiwind Road, Lahore was conducted on 16.02.2021, with reference to DRAP's Islamabad letter No. F. 1-8/2010-Lic (Vol-I) dated 02.11.2018 in order to check the current status of the firm as the firm had informed vide its letter No. Nil dated Nil received in this office on 25th June, 2019 that the Licensing Authority had regularized the layout plan of the premises and for those constructional changes 10-12 weeks time period was required for completion. After this no intimation from the firm regarding completion of renovation work was received is this office. Moreover, it is also pertinent to mention here that the firm was last inspected on 03.02.2017 and at that time also Federal Inspector of Drugs report that the renovation work was under process (copy attached). After that time no inspection of the firm was conducted.

Observations:-

During the current visit of the firm, it was observed that the owner Mr. Zafar Gondel was not present. A person named Mumtaz introduced himself as supervisor was present and informed that renovation work including construction, false ceiling, ducting, ducting, pain work etc was under process. Some labours were seen. Mr. Zafar Gondel was asked telephonically to provide detail of renovation work and time of completion of work as the renewal of DML of the firm was due with effect from 26.12.2018 which is already 03 years late. Mr. Zafar Gondal informed that the factory was closed for the last ten years and after he purchased the factory in 2017 it never resumed production activity due to renovation work.

Conclusion:-

In view of above inspection proceedings, it was observed that the renewal of the DML of the firm is pending for the last three years. In the DRAP's letter No. F. 1-8/2010-Lic (Vol-I) dated 02.11.2018, it was written that the firm was ready for inspection so a panel was constituted for the inspection of firm. ***However, it came to the notice that even after lapse of 03 years firm is still not ready for inspection. The case is submitted to Central Licensing Board for further directions."***

Proceeding and Decision of 280th meeting of CLB:-

The Board decided that the Licensing Division shall issue show cause notice to the firm.

Case No. III:- M/s. Effort Pharmaceutical (Pvt) Ltd., 28 Km Ferozepur Road, Lahore.

A Letter vide No.4136/2021-DRAP (L-V) dated 18.03.2021, was received from Ms. Aisha Irfan FID DRAP lahore, attached along with was inspection report of M/s. Effort Pharmaceutical (Pvt) Ltd., 28 Km Ferozepur Road, Lahore, conducted on 13.03.2021 for assessment of the GMP compliance. As per report following the observations/ advises were noted by the FID: -

a. **Building and Facility**
   i. To install smoke detectors and fire alarm in whole building.

b. **Changing Areas**
   i. To install sensor sin air curtains.
   ii. To provide closed shoes and refill the hand sanitizer in the dispensers.
   iii. changing areas needed improvement, with respect to implementation of SOPs
   iv. Open gutterwas seen outside the main executive entry.

c. **Material Management**
   i. Storage conditions werenotmaintainedasACwas off and the humidity was 73% in stores.
   ii. Store In charge with appropriate degree was nothired. Mr. Allah Ditta, qualification FA, Quality Control assistant was performing store dutiesin addition to his own duty in QC.
   iii. It was observed that in the quarantine area 20 drums of diclofenac sodium were placed and the QC assistant informed that only 04 drums were sampled and labeled for "sampled" was not pasted on any drum. Upon query he was unable to identify which drums were sampled. The record of testing of samples was also not available in QC.
   iv. In the receiving bay banned and hazardous material Methylene Chloride 01drum were stored.
   v. Inthesamplinghoodpressuregaugeonhood,andweighingbalancewasnotprovided.
   vi. Sampling log book was also notavailable.
   vii. In the release area, light was not sufficient.
   viii. In the dispensingarea,dispensinghoodwasinstalled,howeverpressure gauge wasrequired.
   ix. Standard weights and dispensing log book were not available.
   x. Closed trollies for dispensed raw.
   xi. material was also not provided. No software for data handling was installed.
   xii. No bin cards or raw material register was provided, for raw materials, at the timeofinspection.
   xiii. No SOP for sampling was being followed such as AP/ starting material was not 100%
   xiv. Forinactivetheformulas square root n+1 was not used.
   xv. In the finished goods store humidity was not maintainedasACwasoff and RH was 76%.
   xvi. In the packaging material store, used and unused Alu foils were placed openly on racks withoutouter

d. **General Tablet Section**
   i. Diclofenac sodium tablet Batch No.DROl wasintheblisteringmachine.However,whenaskedaboutBMRoftheproductthepro duction in charge could not produce the BMRs of diclofenac sodium tablet and the optic 40mg f i l l e d seen in raw material store.
   ii. Thermal mappingofdryer was not conducted
   iii. Flooring in thegranulationarearequiredimprovement

iv. The drains in the section were not proper.
v. In the coating area methylene chloride was being used in coating which is banned item.
vi. Moreover, the blower of coating was very rusted and chances of shedding of rusted particles in to the pan existed.
vii. Manometers were not functional
viii. Number of air changes, differential pressures were not being monitored.

e. **General Capsule Section**

i. Temperature /humidity monitoring was not being done as thermometer / hygrometer was not functional.
ii. Manometer of HVAC system were out of order.
iii. Differential pressures could not be checked.

f. Laboratory Controls

i. Itwas noticed that the QC equipment was not properly being used for test/analysis: As per history of FTIR it was last used on 02-06-2019, after that it was notused.Dissolution apparatus required propersample and QC In-charge wasnot aware about the full function of dissolution apparatus. He did not even know the procedureof takingsamplefromtheapparatus.Similarly,hedidnotknowhowtooperateHPLCandstatedthat he did not know how to operate QC equipment, the owner was also presentand confirmedhisstatement. The QC in charge informed that an analyst performed test and he was not present at the time of inspection.
ii. Certificates of analysis of products were not provided.
iii. Log books for instruments were not available.
iv. Reference Standards were not available.
v. Microbiology Lab was developed but no microbiological water/environment testing was being performed as no microbiologist was hired.

e.Documentation and Records

i. Documentation with respect to material management, BMR, test analysis report etc. were not provided, during inspection proceedings.
ii. Log books of sampling / dispensing hoods / QC equipment were not available. Log books of some machinery ere not filled properly and wrongly filled.
iii. Records were not properly maintained.

g.Quality Management & Self Inspection.

i. No system for quality management was established.
ii. QA department was not functional as there was no person in Quality Assurance.
iii. New Quality Assurance

h. Personnel.

i. Only production and QC In-Charge were present.
ii. No Store In-Charge, QA In-Charge and Production Pharmacist were hired.
iii. The medical record of staff was not available.

i. Water treatment.

i. Cleaning and Validation of R.O plant was required.

j. HAVC System.

i. No concept of internal validation prevailed.

Conclusion /Recommendation.

"In view of above inspection proceedings and facilities verified such as building, production, in process controls, QC testing, material management, machinery/equipment, personnel & documentation etc. it was noticed that the firm had basic facilities such as building, machinery/equipment to manufacture general tablet/capsule, however the GMP practices were not being followed properly in line with GMP guidelines. ***Hence the firm was not operating at a satisfactory level of GMP compliance."***

Proceeding and Decision of 280th meeting of CLB:-

The Board deliberated and review inspection report dated 13.03.2021 and decided to serve show cause notice to the firm M/s. Effort Pharmaceutical (Pvt) Ltd., 28 Km Ferozepur Road, Lahore, on violations of Schedule B-II and not complying with additional conductions of License as mentioned in Rule 20 of the Drugs (LR&A) Rules 1976.

Item No. IV Ratification of decision

Case i: M/s Alkemy Pharma Hyderabad

A letter vide No. SSA-07-15/2018-FID-VIII (K) dated 27-09-2019 was sent by Mr. Sajjad Ahmed Abbasi FID-VIII DRAP Karachi. The subject of letter was *"Manufacture and Sale of Substandard Drug Inj. Martixon 250mg Batch No. X-206, Manufactured by M/s Alkemy Pharmaceuticals Lab (Pvt) Ltd Hyderabad"*

2. In the letter FID had informed that Batch No. X-206 of product Martixon 250mg was declared sub-standard by CDL vide report No. R.K.Q.331/2019. In light of CDL report, the firm had voluntarily stopped production in their sterile area and has initiated root cause analysis of the problem. Furthermore, FID had recommended that production in sterile area must be restored after panel inspection and thorough evaluation/ verification by panel inspection members.

3. The firm vide this office letter No. F.4-16/91-QA(pt) dated 23.12.2019 was directed to not to resume production activities in sterile area without verification of improvements by a panel of experts and subsequent approval from the competent authority.

4. In response to this office letter dated 23.12.2019, M/s. Alkemy Pharmaceutical Laboratories (Private) Limited, Plot No. P/9, S.I.T.E, Hyderabad stated that the product Martixon 250mg batch # X-206 has been extensively tested and has passed all in-house tests.

5. The matter was placed before the Director QA&LT and following panel of experts was constituted for inspection of Sterile Area of M/s. Alkemy Pharmaceutical Laboratories (Private) Limited, Plot No. P/9, S.I.T.E, Hyderabad and for detailed investigation of root cause of the product failure;

i. FID-VIII DRAP Karachi.
ii. Ms. Hira Bhutto AD DRAP Karachi.
iii. Ms. Mehwish Tanveer FID DRAP Karachi.

6. The panel inspected the premises of M/s Alkemy Pharma Hyderabad on 09-06-2020and reported following observations in their report;

i. Sterile Area Production:

a. It was observed that HVAC system in the sterile area was not operational appropriately which is the basic requirement to maintain the classified area.
b. In addition the classified areas were not qualified and maintained with respect to particle sizes and microbiological area monitoring.
c. The flow of material was also found unjustified to ensure the sterility of the filled vials.
d. The firm has not presented the process validation of Injection Martixon 250mg or any other product of sterile area and latest media fill report for their sterile area.

ii. Quality Control Lab:

a. The QC equipments log books and equipments utilization history was not properly maintained,.
b. In addition the sterility testing protocol was not being followed as per established guidelines.
c. The analytical testing methods were not validated / verified, before the actual testing procedures

7. The conclusion of panel inspection report dated 09.06.2020 is reproduced below;

"In the light of meeting with staff, documents reviewed including manufacturing, testing and ware-house record and findings/observations of the inspection stated above, the positive attitude of the firm towards improvement

with submission of the action plan by the firm, placed at Annex-B, the firm M/s Alkemy Pharmaceutical Lab (Pvt.) Ltd. may kindly be given some time for upgradation in their sterile area before restoration of production activities, which should include(but not limited to) re-qualification of their HVAC system, justified material flow for the sterile manufacturing and submission of latest media fill report on standard format, covering all the working scenarios."

8. The firm was directed vide letter dated 29.07.2020 to rectify deficiencies noted by the panel during inspection dated 09.06.2020.

9. The firm submitted compliance letter dated 18.09.2020 stating that they were ready for inspection. In view of firm's request same panel was requested to again verify firm's compliance. Meanwhile Ms. Mehwish Tanveer FID Karachi was transferred to Islamabad and firm requested for reconstitution of panel. The request of firm was placed before the competent authority and it was decided that the rest of the panel (comprising of following 2 members only;) shall verify firm's compliance and give their recommendations.

i. FID-VIII DRAP Karachi.
ii. Ms. Hira Bhutto AD DRAP Karachi.

10. The panel re-inspected the premises of M/s Alkemy Pharmaceutical Laboratories (Pvt.) Ltd. Plot No. P/9, SITE Hyderabad. The panel reported that firm has rectified all the observation and have successfully conducted media fill trials. The conclusion of report is reproduced below;

"In light of compliance of observations by the firm as noted above and commitment of the management to continuously improve and implement the cGMP guidelines as per regulation enforce from time to time, the panel is of the view to recommend resumption of production activities in the Sterile Section of M/s Alkemy Pharmaceutical Laboratories (Pvt.) Ltd. S.I.T.E., Hyderabad. However, post resumption of production activity monitoring inspection shall be ensured by for continuity of compliance in true letter and spirit."

11. The Central Licensing Board in its 273rd meeting delegated power of *"Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members"* to the Director QA&LT and the matter of vacancy of the Director QA&LT was discussed in 278th meeting of CLB and the board decided "*that power delegated to Director (QA&LT) in its 273rd meeting of Central Licensing Board shall be exercised by Additional Director (QA&LT), in case of occurrence of vacancy on the post of Director (QA&LT) or leave for the period more than two weeks."* In view of this, recommendations of panel for resumption of production activities in Sterile Section of M/s Alkemy Pharmaceutical Laboratories (Pvt.) Ltd. S.I.T.E. Hyderabad were placed before the Additional Director QA&LT.

12. The Additional Director QA&LT granted permission for resumption of production activities in Sterile Section of M/s Alkemy Pharmaceutical Laboratories (Pvt.) Ltd. S.I.T.E. Hyderabad on 29.03.2021 along with directions to place the case before the board for ratification as resumption was granted on inspection conducted by a panel comprising 2 members.

Decision of 280th meeting of CLB:-

The Board ratified decision of the Additional Director QA&LT dated 29.03.2021 to grant permission for resumption of production activities in Sterile Section of M/s Alkemy Pharmaceutical Laboratories (Pvt.) Ltd. S.I.T.E. Hyderabad.

Agenda Item No. V: ADDITIONAL AGENDA

Case No. i: M/S. ELITE PHARMA, LAHORE.

Background:

Inspection of the firm M/s. Elite Pharma (Pvt) Ltd, 9.5-KM, Sheikhupura Road, Lahore, was conducted by following panel on 08.08.2019.

i. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore
ii. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore

2. The panel during inspection noticed following observations:-

Entries:-

i. To upgrade the change area as per GMP requirements.
ii. Provide pictorial display and change over instructions.
iii. Provide proper facility for changing of shoes within the change room.
iv. Provide fresh air and ventilation in workers change rooms.
v. Provide lockers / cabinets for keeping uniforms & personal belongings.
vi. Provide hand sanitizer.

Raw Material Store:-

Raw material store of main building was provided with a receiving and de-dusting area, Firm has provided a quarantine area and released areas for excipients. There rooms were given for storage of cephalosporin API's, Penicillin API's, raw material for Ointments, general API's stock was present. Firm was advised to:

i. To provide shade and air curtain outside receiving.
ii. To install AC in quarantine and temperature / humidity motoring devices and maintain record.
iii. Provide separate weighing balance in sampling and dispensing booth for small quantities also advised to install printers with dispensing and analytical balance.
iv. Develop material receiving check list and review and revise raw material receiving SOP.
v. Perform thermal mapping of stores.
vi. Improve lighting in raw material store.
vii. To develop and implement material management SOPs.
viii. Material flow for store to production area should be improved.
ix. Cephalosporin and penicillin API's were stored in general raw material store. Firm was advised to provide completely dedicated &self contained sections as the management inform that they have already submitted their revised layout plan in DRAP, Islamabad.

General Injectable Section:-

i. Vial filling machine was not available / not installed at the time of inspection.

ii. To perform environmental monitoring of the ampoule washing area also and submit report.

Optical Checking:-

i. To perform six monthly eye check up of worker and also check LUX in the area.

Packing Hall:-

i. To segregate that area and remove hoods from wooden fixture & furniture from packing area.

Penicillin Sections:-

i. To provide seamless, non porous ceiling in the area.
ii. To provide false ceiling in packing hall where ducts and pipes could be seen. It should be concealed.

Quinolone Infusion Section:-

i. To upgrade change area.
ii. To improve dispensing area.
iii. To check air balancing in all sterile areas and maintain differential pressure as per recommended guidelines.

Cephalosporin Section:-

i. The Cephalosporin Section was not dedicated. Its entrance was through Quinolone Infusion Section. Firm had provided machinery for Cephalosporin Capsule Dry Powder Injection and Dry Powder Suspension manufacturing.

Finished Goods Store:-

i. To improve the lighting in the area and provide proper solid stairs with railing at the entrance of store.
ii. To provide light in the cold store and fix the handle lock.

Packing Material Store:-

i. The packing material store was found unorganized and in a hap-hazard condition. Sanitation was also poor.
ii. The Al-foil was stored in uncontrolled condition in the packing material store.

Change Areas:-

i. All change areas in the unit including those of penicillin section, cephalosporin section and semi-solid section. Need to improve with reference to maintenance, lighting, ventilation, and house. Keeping and change over facilities. It was observed that there was also a lacking in implementation of change over SOPs.

Action taken by DRAP:

3. The firm M/s. Elite Pharma, Lahore was served Show Cause Notice /Suspension of Production activities order No.F.4-34/98-QA (Vol-I) on 11.11.2019.

Reply of the firm:

4. The firm M/s. Elite Pharma, Lahore vide letter dated 05.12.2019 submitted reply of Show Cause Notice. The firm submitted that they rectified all the observations and ready for re-inspection.

Updated Status:

5. Request of the firm was forwarded to Director (QA&LT). The Director (QA&LT) constituted following panel of experts on 03.12.2019.

i. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore
ii. Mr. Abdul Rashid Shaikh, FID-VI, Lahore
iii. Ms. Maham Misbah, AD, DRAP, Lahore

6. The panel conducted inspection of the firm on 16th December, 2019 and concluded the report as under;

"*In the light of observations, the panel noted that firm has started to rectify the observation made during previous inspection. Penicillin and cephalosporin sections were not dedicated. Vial injectable section was not having proper raw material store. The management informed that they have submitted new layout in Licensing Section for amendments in these sections. At present, only liquid injectable ampoule section and semisolid (cream/ointment) section of firm were having adequate manufacturing facility. Therefore, panel was of the opinion that firm may be allowed to resume production in liquid injectable Ampoule and Semi Solid (Cream/Ointment) Sections only*"

7. As per recommendations of the panel and after approval of the Director QA&LT resumption of production activities was granted in liquid injectable Ampoule and Semi Solid (Cream/Ointment) Sections only vide letter dated 27-12-2019.

Decision of 273rd Meeting of CLB

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

i. Ratify decision of Director QA&LT regarding resumption of production of liquid injectable Ampoule and Semi Solid (Cream/Ointment) Sections.

ii. Production in the Penicillin Section and Cephalosporin Section shall remain suspended till completion of work, request of the firm for inspection, panel inspection and subsequent approval by the Central Licensing Board.

8. In light of the decision of 273rd Meeting of CLB, the firm requested for inspection, subsequently matter was placed before the competent authority and constitution of panel was communicated vide QA letter No. No. F. 4-34/98-QA (Vol-I) dated 29.12.2020, the Panel comprising of Mr. Sheikh Abdul Rashid, Mr. Ajmal Sohail

Asif, Federal Inspector of Drugs, Lahore and Ms. Maham Misbah, Assistant Director, DRAP, Lahore visited the firm, M/s. Elite Pharma (Pvt.)Ltd., 9.5-km,SheikhupuraRoad,DistrictSheikhupura,on03-03-2021,tocheckimprovementsmadebythe firm and concluded as under: -

"Inthelightoftheabove,thepanelnotedthatthefirmhadrectifiedmostoftheobservationswith reference to previous inspections. Penicillin and Cephalosporin sections had been dedicated. Firm had amended the layout in Liquid (General) section, Oral Dry Powder Suspension (Penicillin), warehouse forcream/ointment,warehouseforCephalosporin,warehouseforLiquidInjectableInfusion(General), Capsule (Penicillin), Cream/Ointment/Gel (General) and QC Laboratory and inspection had been conducted by the designated panel, separately. Firm had also rectified most of the shortcomings pointed out during last inspection for regularization of layout plan. However, firm was advised to improve its validation activities and documentationpractices.

Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production Machinery, Equipment in Quality Control and Microbiology Laboratory, Testing Facilities, Technical Personnel met and documentation reviewed ***the panel of inspectors is of the opinion to recommend the resumption of production activities in their following sections as the most of the shortcomings wereaddressedandrectified.PenicillinSection(Capsule&DryPowderSuspension), Cephalosporin Section (Dry Powder Injectable, Dry Powder for Suspension, Capsuleand General Infusions Section(SVP)."***

9. Upon evaluation of the report, following is the current position:-

i. W.r.t the observations dated 08.08.2019 compared to 16.12.2019 compared to 03.03.2021; Out of the Ten (10) observations, Two (02) observations have not been complied, Two (02) have been partly complied and six have been completely complied with.
ii. W.r.t the additional observations noted on 16.12.2019 compared to 03.03.2021; Out of the Forty Seven (47) observations, One (01) observation have not been complied, Twenty (20) have been partly complied and Twenty Six (26) have been completely complied with.

Proceeding and Decision of 280th meeting of CLB:-

10. The Board reviewed the panel inspection report dated 03.03.2021, their recommendations and decided as under;

Considering the conclusion of panel inspection report dated 03.03.2021, the Board decided to allow the resumption of production activities in following sections of M/s Elite Pharma (Pvt) Ltd, 9.5-KM, Sheikhupura Road, Lahore,

i. PenicillinSection(Capsule&DryPowderSuspension),
ii. Cephalosporin Section (Dry Powder Injectable, Dry Powder for Suspension, Capsule)
iii. General Infusions Section(SVP).

QUALITY CONTROL CASES

[F. No. 04-02/2019-QC]

Case No. 01 **MANUFACTURE AND SALE OF UN-REGISTERED DRUGS – M/S PRINCE MEDICOS, K.E 27, DOUBLE ROAD, BILAL COLONY, NEAR GUL AHMED CHOWRANGI. LANDHI KARACHI.**

That Miss. Mehwish Tanvir, FID-VII, Karachi vide letter no. DMK-01-14/2019-FID-VII-(K) dated 08.07.2019 received on 17.07.2019 forward the subject captioned case.

02. That the Miss. Mehwish Tanvir, FID-VII, Karachi informed that Dr. Muhammad Kashif, the-then Federal Inspector of Drugs-VII, Karachi alongwith the team of officers & Officials of DRAP Karachi & Mr. Sajid Ali, Provincial Drug Inspector visited/inspected the premises of M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi on 16th January 2019. During visit following unregistered drugs were recovered and seized on prescribed Form-2 under the Drugs Act 1976 and rules framed thereunder.

Detail of Drugs Seized			
Serial No.	**Name Of Drugs**	**Batch No.**	**Purported to Be Manufactured By:**
01	Tablet Diclocin Forte+	412	M/s. Combitic Global Caplet. LTD. M-15. D-2. D-3. Industrial Area. Sonepat-13 1001 (Ur.) India.
02	Tablet Pinadol CF	PCF-195	..... Do .....
03	Tablet Dynalid-pt	7361	M/s Unmax Laboratories India.
04	Tab. Dynalid-pt	7360	..... Do .....
05	Neurobin Ampoules	240272	M/s. Merck kga A Darmstalt (Germany).
06	Dona Capsules	850	M/s. Faazli Homoeo Pharma Karachi
07	Dona Capsules	852	**.....** Do .....
08	Arfifen 50mg Tablets	ARF31	M/s. Combitic Global Caplet. LTD. M-15. D-2. D-3. Industrial Area. Sonepat-13 1001 (Hr.) India
09	Pyricam-20 Capsules,	PC-141	……..Do……..
10	Citriz Tablets.	CZ 109	……..Do…….
11	Cezin Tablets	MT-17-710 MT-17-	M/s. Maiden Pharmaceutical Sonepat- India
12	Cofcal + Tablets	000822	M/s. Combitic Global Caplet. LTD. M-15. D-2. D-3. Industrial Area. Sonepat-13 1001 (Hr.) India
13	Diclo Tablets 50mg	170842	M/s. Shanxi federal Pharmast Co China
14	Voven Capsules	MC 17-	M/s. Maiden Pharmaceutical Sonepat- India
15	Sulpiride Capsules 50mg	MC-I7-I57	..... Do .....
16	Ring Guard Cream	DG 267	M/s. Rackill Benckieser Health Care India
7	Aobama Tablets		..... Do .....
18	MMG		..... Do .....
19	Cobra-150 Tablet	Nil	M/s. Combitic Global Caplet. LTD. M-15. D-2. D-3. Industrial Area. Sonepat-13 1001 (Hr.) India

20	Sildenafil Citrate Tablets New Panegra	Nil	..... Do .....
21	American Superman Tablets	Nil	M/s. Americal Ernoron medicine nation group.
22	Knight Rider Tablets	Nil	Made in UK
23	Duraza 100 tables	Nil	M/s. Torque Pharmaceutical
24	MM-3 Cream	Nil	U.S.A.
25	Viga 84000 Spray	Nil	Made in Germans.
26	Neherpa Tablets	Nil	M/s. Maiden Pharmaceutical Sonepat- India
27	Rega Tablets	Nil	M/s Indkus Biotech India
28	Dilkhush Tablets	Nil	Torque
29	Zinetac l50mg Tablets	Nil	G.S.K India
30	Grucid Capsules	Nil	M/s. Combitic Global Caplet. LTD. M-15. D-2. D-3. Industrial Area. Sonepat-13 1001 (Hr.) India
31	Spasrid Injection	Nil	M/s Barrett Hodgson Pak Karachi

03. The FID-VII, Karachi informed that following samples of suspected un-registered drugs were taken for the purpose of test analysis on prescribed Form-3 under the Drugs Act 1976:

S. No.	**Name of Drug**	**Batch No.**	**Mfg. By**
DMK-01/19	Tab. Pinodol CF	PCF-195	M/s. Combitic Global Caplet. LTD. M-15. D-2.D-3. Industrial Area. Sonepat-13 1001 (Hr.) India
DMK-02/19	Tab. Diclocin Forte+	DTF-811	..... Do .....
DMK-03/19	Tab. Arfifen 50mg	ARF-31	..... Do .....
DMK-04/19	Cap, Pyricam-20	**PC-141**	..... Do .....
DMK-05/19	Tab. Citriz	CZ-109	..... Do .....
DMK-06/19	Cap. Voven 50mg	MC-17-195	..... Do .....
DMK-07/19	Tab. Cobra-1 50	-NIL-	..... Do .....
DMK-08/19	Tab Zinetac 1 50mg	N5211	..... Do .....
DMK-09/19	Cap. Grucid	GC1221	..... Do .....
DMK-10/19	Tab. Augmentin 375mg	HATB1	M/s. Glaxo SmithKline F-268. S.I.T.E. Karachi.
DMK-11/19	Iodex Ointment	EIADA	..... Do .....
DMK-12/19	Iodex Ointment	EIADA	..... Do .....
DMK-13/19	Iodex Ointment	D1AAS	..... Do .....
DMK-14/19	Iodex Ointment	EIADA	..... Do .....

04. FID-VII, Karachi also informed that the sealed sample of above drugs were sent to Federal Government Analyst. Central Drugs Laboratory, Karachi for the purpose of test/analysis vide memorandum No. DMK-0l to 15/2019-FID VII(K) dated 18th January 2019.

05. FID-VII, Karachi added that the-then FID vide their letter No.F.DMK.24-30/2019-FID-VII DRAP(K) dated 21stJanuary 2019 requested to DRAP Islamabad to grant permission for the safe custody of drugs seized on prescribed Form-2 under the Drugs Act l976.

06. FID-VII, Karachi also added that M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi was asked to provide bill warranty under section 23(1)(i) of the Drugs Act 1976 vide her office letter of No.F.DMK.24-30/2019-FID-VIl-DRAP(K) dated 21stJanuary 2O19.

07. FID-VII, Karachi reported that DRAP Islamabad vide their letter No.F.13-45 2019-(QC) dated 28thFebruary 2019 grant permission to continue the custody of the seized stocks till decision of the case.

08. FID-VII, Karachi informed that the Federal Government Analyst, Central Drugs Laboratory, Karachi declared the following sample of drugs as "**Unregistered Drug Products**". Detail are as under:-

S.NO.	Name of Drug	Batch No.	Mnfd: by	Test Report No & Dale	Test Repor
01	Pipadol CF	PCF-195	M/s Combiotic Global Caplet Ltd: India.	RKQ.51/2019 Dated 18-03-19	Un-Registered Drug Product
02	Diclocin Forte + Tablet	DTF-81 1	M/s Combiotic Global Caplet Ltd: India.	RKQ.52 2019 dated 18-03-19	Un-Registered Drug Product
03	Arfifen 50ntg Tablets	ARF-31	M/s Combiotic Global Caplet Ltd: India.	RKQ.53/2019 dated 18-03-19	Un-Registered Drug Product
04	Pyricam-20 Capsules	PC-141	M/s Combiotic Global Caplet Ltd: India.	RKQ.54 2019 dated 18-03-19	Un-Registered Drug Product
05	Citriz Tablets	CZ-109	M/s Combiotic Global Caplet Ltd: India.	RKQ.55 2019 Dated 18-03-19	Un-Registered Drug Product
06	Voven Capsules	MC-I7-195	M/s Maiden Pharmaceuticals Ltd: India.	RKQ.56 2019 dated 15-03-19	Un-Registered Drug Product
07	Cobra-150 Tablets	Nil	M/s Combiotic Global Caplet Ltd: India.	RKQ.57/2019 dated 28-02-19	Un-Registered Drug Product

08	Grucid Capsules	GC-1221	M/s Combiotic Global Caplet Ltd: India.	RKQ.59/2019 dated 15-03-19	Un-Registered Drug Product

09. FID-VII, Karachi in the light of above test report of Federal Government Analyst, Central Drug Laboratory, Karachi issued explanation letter to M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi, Landhi Karachi. Subsequent reminders were also issued vide her office letters of even number dated 24thApril & 13thMay 2019. No any reply was received from M/s Prince Medicos, Landhi Karachi till the case reporting day i.e. 08.07.2019.

10. FID-VII, Karachi reported that M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi and Mr. Ali Muhammad S/O Nazir Muhammad (owner) were found involved in storing \ selling of unregistered drug products and contravened the section 23(1)(a)(vii) of the Drugs Act 19'6. which is punishable under section 27 of the Drugs Act 1976 and rules framed thereunder.

FID-VII, Karachi stated that the names of responsible person of M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi are as under:

1. M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi.
2. Ali Muhammad S/O Nazir Muhammad (Proprietor).

RECOMMENDATIONS OF FID: -

M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi and Mr. Ali Muhammad S/O Nazir Muhammad (Owner) found involved in the storing & selling of unregistered drug products and violated the section 23(1)(a)(vii) of the Drugs Act,1976 and punishable under section 27 of the Drugs Act 1976. Therefore:-

1. Grant permission to registered FIR against above said accused responsible person.

OR

2. Permission for prosecution in the Drug Court of Sindh. Karachi may be issue against the accused/responsible person.

That the area FID-VII, Karachi submitted the complete case for information and directives action in the matter, as per section 19(7) of Drugs Act, 1976.

11. That the area FID, Karachi vide letter no. DMK-01-14/2019-FID-VII(K) dated 24th July, 2019 submitted her reply as under, in response to a clarificationletter No. 04-02/2019-QC dated 19th July, 2019:

1). As per available record provided by the-then FID, M/s Prine Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi, Landhi, Karachi have no drug sale license. They only provided the copy of paid challan for Rs. 5000 dated 15.10.2018.

2). No qualified person as they have no Drug Sale License.

3). As per CNIC complete address of Ali Muhammad is House No. 201. New Muslimabad Colony, Landhi, Malir, Karachi.

12. Keeping in view the request and recommendation of area FID-VII, Karachi, the Director, QA&LT, DRAP, Islamabad has acceded the requestof FID *"to grant the permission to lodge FIR"* being authorized by the Central Licensing Board in its 237th Meeting held on 01.10.2014 as required under DRAP Act, 2012/the Drugs Act, 1976 and rules framed thereunder. The approval was communicated to FID-IV, Islamabad vide letter **F. No.04-02/2019-(QC)** dated 28th August, 2019 against following persons:

1. M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi.
2. Ali Muhammad S/O Nazir Muhammad (Proprietor).

As per report of area FID, Karachi, the above mentioned accused persons have committed offence in contraventions of Schedule II of DRAP Act 2012 /Section 23 of Drug Act 1976, which is cognizable offence under Schedule-IV(2)(a) of DRAP Act 2012 / section 30(2)(a) and punishable under Schedule III/ Section 27 of Drug Act 1976.

13. That the case was placed before the CLB in its 271st meeting wherein the Board decided as under:

"The Board deliberated the matter in depth, considered the facts of the case and after perusal of record decided to allow recommendations of FIDs as under:

a. Board allowed the ratification of permission granted by the Director (QA&LT) for registration of FIR against following accused persons for contraventions of Schedule II of DRAP Act 2012 /Section 23 of Drug Act 1976, which is cognizable offence under Schedule-IV(2)(a) of DRAP Act 2012 / section 30(2)(a) and punishable under Schedule III/ Section 27 of Drug Act 1976 communicated vide letter no. 04-02/2019-QC dated 28th August, 2019; and

i. M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi.
ii. Ali Muhammad S/O Nazir Muhammad (Proprietor), House No. 201. New Muslimabad Colony, Landhi, Malir, Karachi.

b. Board allowed the ratification of permission granted by the Director (QA&LT) for safe custody of seized stock till decision of the case communicated vide letter no. 13-45/2019-QC dated 28th February, 2019 ; and

c. Board allowed to recommend for non-issuance of license/cacellation of license (if issued) of M/s Prince Medicos, K.E 27, Double Road, Bilal Colony, Near Gul Ahmed Chowrangi. Landhi Karachi."

14. The above-mentioned decision of the Board was communicated to the area FID Karachi, The Decretary Health, Government of Sind, Karachi and Chief Drug Inspector, Government of Sind, Karachi vide letter No. F. 03-44/2019-QC (271-CLB) (Pt-II) dated 11-09-2019.

15. FID VII Karachi vide letter No. DMT.10/6-2020-AD/FID-VII (DRAP) (K) dated 10-06-2020 provided the copy of Interim investigation report in the case FIR NO. 02/2020 of FIA ACC Karachi which was sent to her by Additional Director FIA Sindh, Karachi. Conculsion/recommendation of the interim investigation report are given as under;

CONCLUSION/RECOMMENDATION

The complainant Dr. Muhammad Kashif the then Fedral Drug Inspector of Drugs -VII, DRAP, Karachi, along with the team of officers of DRAAP, Karachi namely Abdul Rasool Shaikh, Federal Drug Inspector, Shoaib Ahmed, Federal Drug Inspector, Farman Ali Bozdar, Federal Drug Inspector & Mr. Sajid Ali, Provincial Drug Inspector, Karachi inspected M/s Prince Medicos situate at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi on 16.01.2019. During course of inspection, they found of un-registered drugs/medicines claimed to be manufactured by India. Available stocks were seized on prescribed Form-2 under Section 18 (1) (f) of the Drugs Act, 1976.

After receiving the request for registration of case against accused Ali Muhammad (Proprietor) of M/s. Prince Medicos, situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi. The undersigned registered the Case FIR No. 02/2020 of FIA, ACC, Karachi u/s. 23&27 (1) (a) (vii) of Drug Act 1976.

After registration of said case at this circle, the undersigned arrested of accused namely Ali Muhammad s/o Nazir Muhammad dated on 13.06.2020, Time 15:30 hrs and produced before the Session Judged Karachi South/Link Judge, Chairman Drugs Court Karachi and obtained the Physical Remand of the accused Ah Muhammad s/o Nazeer Muhammad for 07 days viz 14.02.2020 to 20.02.2020.

During the course of investigation into the remand period, the above named accused confirmed the Federal Drug Inspectors inspected his MedicalStore on 16.01.2019 and recovered & seized the huge quantity of un-registered medicine from his medical store namely M/s. Prince Medicos situated at Landhi, Karachi, he also confirmed he was involve for selling the un-registered medicine and further the above, he also disclosed that he purchase the un-registered medicine from one Muhammad Yaseen s/o Ali Anwar CNIC No. 17301-9134227- 1, from Karkhan Markeet Peshawar & Saifulla Afreedi s/o Fareed Khan Afreedi CNIC No. 14301-7623366-7 from Peshawar. Further he sells this unregistered medicine to the various retail medical stores in Karachi.

After completing the previous remand period the undersigned produce of the above accused before the Session Judged Karachi South/Link Judge, Chairman Drugs Court Karachi of accused Ali Muhammad s/o Nazir Muhammad dated on 21.02.2020 for further remand. Accordingly the above named accused was remanded to judicial custody.

An explanation letters was issued to the owners of M/s Noor Medical Store, Old Muzaffarabad Colony, Landhi, Karachi. M/s. Bilal Medical Store, Sher Paw Colony, Landhi Karachi, M/s. Akhtar Medical Store, Hospital Chowrangi, Landhi Karachi, M/s Asif Medical Store, Sher Paw Colony, Landhi Karachi, M/s Umer Medical Store, Muzafarabad Colony, Landhi Karachi, M/s. Aman Medical Store, Kalapani Muzafarabad Colony, Landhi Karachi & M/s. Bilal Medical Store, Rerhi Goth, Landhi Karachi, but all in vain nobody attended this office.

During the course of investigation accused Ali Muhammad s/o Nazir Muhammad Proprietor of M/s Prince Medicos did not able to provide required documents, i.e. Sale & Purchase Invoices, License for sell of Drugs and the ownership of the said Medical Store.

From the investigation conducted and evidences collected so far on record, it has been established that accused Ali Muhammad s/o Nazeer Muhammad CNIC No. 42501-7448033-7, Proprietor of M/s Prince Medicos situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi, committed the offences u/s 23&27 Drugs Act 1976 punishable ibid and rules framed there under, for which they are liable to be prosecuted before the Hon'ble Drug Court Sindh at Karachi by way of filing a complaint by the Federal Inspector of Drugs, by mentioning the names of accuse.

Since the investigation of the case has been completed, therefore, this Report is being submitted for favour of kind perusal and onward transmission to the Drug Regulatory Authority of Pakistan, Ministry of National Health Services, Regulations &Coordination, Karachi for submission of complaint under the relevant provision of Drugs Act-1976, before the Honourable Drug Court Sindh at Karachi through Federal Inspector of Drug."

16. The Final investigation report of the matter was also forwarded by the area FID vide letter No. DMT.5/10-2020-AD/FID-VIII (DRAP) (K) dated 05-10-2020. Conclusion and recommendations of Inspector FIA Karachi given in the report are stated as under;

"CONCLUSION

From the incestigation conducted and evidences collected so far on recore, it has been established that accused Ali Muhammad s/o Nazeer Muhammad CNIC No. 42501-7448033-7, Proprietor of M/s Prince Medicos situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi committed the offences u/s 23&27 Drugs Act 1976 punishable ibid and rules framed there under, for which they are liable to be prosecuted before Hon'ble Drug court Sindh at Karachi by way of filing a complaint by the Federal Inspector of Drugs, by mentioning the names of accuse.

RECOMMENDATION

Since the investigation of the case has been completed, therefore, this report is being submitted ffor gfavour of kind perusal and oward transmission to the Drug Regulatory Aithoroty of Pakistan, ministry of national Health Services, Regulations & Coordination, Karachi for submission of complaint under the relevant procision of Drugs Act-1976, before the honourable Drug Court Sindh at Karachi through Federal Inspector of Drugs Dr Mehwish Tanveer, Assistant Director/Federal Inspector of Drugs-VII, Karachi."

17. In the light of above-mentioned interim report, it is evident that the accused Ali Muhammad S/o Nazeer Muhammad, CNIC No. 42501-7448033-7, Proprietor of M/s Prince Medicos situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi, committed the offences which are punishable under section 27(1)(a) of the Drugs Act 1976 and rules framed there under, for which they are liable to be prosecuted before the Hon'ble Drug Court Sindh at Karachi by way of filing a complaint by the Federal Inspector of Drugs, by mentioning the names of accused given as under;

i. M/s Prince Medicos situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi through its Owner/Proprietor Ali Muhammad S/o Nazeer Muhammad, CNIC No. 42501-7448033-7 R/O. House No. 201, New Muslimabad Colony, Landhi, Malir, Karachi

ii. Ali Muhammad S/o Nazeer Muhammad, CNIC No. 42501-7448033-7, R/O. House No. 201, New Muslimabad Colony, Landhi, Malir, Karachi, Proprietor of M/s Prince Medicos, Karachi.

Proceedings and Decision of the 277th meeting of the Board:

18. The Board after thorough delbrations and considering the facets of the case decided as under:

a. To issue Show Cause and Personal Hearing notice to the following accused persons for violations which are punishable under section 27(1)(a) of the Drugs Act, 1976:

i. M/s Prince Medicos situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi through its Owner/Proprietor Ali Muhammad S/o Nazeer Muhammad, CNIC No. 42501-7448033-7 R/O. House No. 201, New Muslimabad Colony, Landhi, Malir, Karachi

ii. Ali Muhammad S/o Nazeer Muhammad, CNIC No. 42501-7448033-7, R/O. House No. 201, New Muslimabad Colony, Landhi, Malir, Karachi, Proprietor of M/s Prince Medicos, Karachi.

19. Show-cause notice was issued to the firm vide letter F. No. 03-45/2020-QC dated 29-10-2020 and till date no reply has been received from the accused.

20. The accused were called before the Board for personal hearing.

Procedings and decision of 280th meeting of CLB:

21. The accused, Ali Muhammad (Owner of M/s. Prince Medicose, Karachi) appeared before the Board and submitted a written reply in response to the show-cause notice served to him. Contents of reply are given as under:

"Under the specific instructions and on behalf of our client namely Mr. Ali Muhammad S/o Nazeer Muhammad of M/s Prince Medicos, we have to reply your show cause notice as under: -

1. That it is settled principle of law that when a thing is provided to be done in a particular manner that has to be done in that manner and any other way is not permitted.

2. That, I.O, Federal Drug Inspector as well as Federal Government Analyst are failed to obtain confirmation from the competent authority i.e. Central Drug Licensing Authority and Registering Board regarding unregistered status of the product in question and till Iodate no such letter has been written by the Federal Drug Inspector as well as Federal Government Analyst to the Registering Board, therefore the question of confirmation regarding registered or un-registered drug does not arise at all.

3. That in absence of confirmation of Registering Board, the Central Drug Testing Laboratory/Govemment Analyst have no criteria to decide whether the samples sent by the Drug Inspector are registered one or un-registered. Without any confirmation of Registering Board, the certificate issued by the Central Drug Testing Laboratory/Govemment Analyst of test become illegal, false and managed one.

4. That from bare perusal of test reports it reveals that protocol of test not applied in accordance with the Drug Specification Rules 1978.

5. That it is further revealed that the test reports were issued by the Central Drug Laboratory and not by the Federal Laboratory, which is a grave violation of existing Drugs Laws.

6. That complete details of test protocols are also not available as required under Drug Specification Rules 1978

7. That under section 22(3)(a) of Drugs Act, 1976 it is mandatory to provide test reports to the owner/proprietor of any shop/godown from whom allegedly the products were seized and taken on Form-II, but in the instant matter till todate no test report of the alleged recovered medicines were provided to our client.

In view of above facts & circumstances, your august authority are hereby requested to recall/waive the above said show cause notice and drop the proceding against our client so

that precious time of this august authority and Hon'ble Drug Court may not be wasted in an unwarranted proceeding."

22. The Board considered the facts of the case and reply of accused and granted permission to the area Federal Inspector of Drugs, Karachi for prosecution of case in the court of competent jurisdiction against the following:

i. M/s Prince Medicos situated at K.E 27, Double Road, Bilal Colony, near Gul Ahmed Chowrangi, Landhi Karachi through its Owner/Proprietor Ali Muhammad S/o Nazeer Muhammad, R/O. House No. 201, New Muslimabad Colony, Landhi, Malir, Karachi

ii. Mr. Ali Muhammad S/o Nazeer Muhammad, R/O. House No. 201, New Muslimabad Colony, Landhi, Malir, Karachi, Proprietor of M/s Prince Medicos, Karachi

Case No. 02: **MANUFACTURING, IMPORTING & SELLING OF UNREGISTERED, ADULTERATED & SUB-STANDARD DRUGS RECOEVERD FROM M/S. AL-AZIM MEDICAL STORE PLOT NO. A 12-37, COMMERCIAL AREA RAOD, NO.06, CATTLE COLONY, LANDHI KARACHI IMPORTED BY SAYROZ PHARMA MARKETING KARACHI, PAKSITAN.**

FID VII Karachi visited the premises of M/s Al-Azim Medical Store Karachi alongwith Dr. Abdul Rasool Shaikh FID and Dr. Shoaib Ahmed FID on 25th October 2017 and took samples for test analysis and sent to the CDL, Karachi.

02. The details of the contraventions and test reports as under:-

Drug Name	**Batch No.**	**Reg. No.**	**Test result**	**Manufacturer/Importer name**
Vitamin AD3E Injection	201704 15	Nil	Un registered test report no. RKQ 592/2017 dated 22-12- 2017	Imported by SAYROZ pharma mfg by Hebei New Century Pharmaceutical ltd China
Oligovit injection	201704 14	Nil	Un registered test report R. KQ 594/2017 dated 22-12-2017	-do-
Mouthnil Injection	Mn25	198300 Fake registration number. PE&R Division do not verify this registration number.	Adulterated and substandard test report no. RKQ 595/2017 dated 13th November 2017	Honestan Pharma, Karachi. Not licensed by DRAP
Diconil-50 plus Injection	Nil	Nil Without valid Registration number	Adulterated and substandard test report RKQ 593/2107 dated 12th December 2017.	-do-

03. Mr. Zaheer Ahmed s/o Muhammad Yaseen proprietor AL-Azim medical store plot No. A12-37 commercial area road No.6 cattle colony landhi Karachi, failed to produce invoice warranties of the above-mentioned products despite notices by the area FID. The FID therefore decalred that mr. Zaheer Ahmed s/o Muhammad yaseen proprietor Al- Azim medical store and Mehboob Ali Ismaili S/o Ameer Ali Qualified person are responsible for the offences.

04. The case was presented in 259th meeting of CLB where FID asked for the permission to lodge FIR against the accsued for manufacturing, importing and selling of unregistered, Adulterated and substandard drugs products without valid manufacturing and import licenses as well as purchasing without valid warranty.

05. Decision of the CLB:

A. The Central Licensing Board after examination of the facts of the case and investigation report granted the permission for registration of FIR against the following accused persons: -

1. Zaheer Ahmed s/o Muhammad Yaseen proprietor AL-Azim medical store plot No. A12-37 commercial area road No.6 cattle colony landhi Karachi, failed to produce invoice warranties of the above-mentioned products despite notices by the area FID.
2. Mehboob Ali Ismaili s/o Ameer Ali Qualified person Al Azim medical store plot No. A12-37 commercial area road No.6 cattle colony landhi Karachi are responsible for the offences.

06. Decision of the Board was communicated to FID VII Karachi vide letter F. No. 03-21/2018-QC/pt/(259-CLB) dated 20-04-2018.

07. FID VII Karachi, vide letter No. F. DMT-32-35/17-FID-VII-DRAP(K) dated 08-01-2020 wherein she provided the copy of final investigation report of the matter submitted by Sub-inspector FIA, Anti Corruption circle, Karachi and asked for permission to prosecute the accused in the court of competent jurisdiction.

08. Show-cause for prosecution was issued to the accused vide letter No. F. 04-02/2018-QC dated 04-02-2020. In response to the said show-cause notice, the accused namely Umer Farooq, owner of M/s. Sayroz Pharma marketing, Karachi submitted as under;

> "*That this with reference of your letter No.F.No.04-02/2018-QC dated 04-02- 2020 received to our M/s Sayroz Pharma Marketing Karachi. In order to defense we informed:-*
>
> *The FID VII Karachi visited to M/s Sayroz Pharma Plot No.A 12-37 Commercial Area Road No.06 Cattle Colony Landhi Karachi on 25th October 2017 and took the sample for the purpose of Test /Analysis as required under section 18 (b) of the Drugs Act, 1976 on prescribed forms. In this regard it is stated that we run our business for the last 15 year and during this period we not supplied any illegal product of any other company to any retailer or distributor and we claimed that no complaint has been reported in our business history. Regarding these products the FID Karachi during his investigation not provided any written evidence against M/s Syroz pharma Marketing. After competition of investigation by the authorities it is not proved that we distributed such medicine to the distributers, Medical Stores Pharmacies and any sales points in the country. We had not supplied product to the market because we have started and obtained the relevant information and guide lines to the authorities for such legal process. No any bill warranty and or any other documents related to M/s Sayroz Pharma Marketing Karachi from any sale point in the country because we had not distribute the stock without warranty bill.*
>
> *Regarding Vitamin Injection (AD3E) Batch No 20170415 and Oligovit Injection (For Vet Use) Batch No 20170414 it is stated that It is correct to mention that these drugs were imported by the Undersigned under the name and style of Sayroz Pharma Marketing. However; it is worth mentioning here that these drugs were imported only for the purpose of the "Trial and Not For Sale" and in this support apart from the Custom documentary (Copies Attached) I also have in possession a letter from Chinese Manufacturing Company (Copy Attached), which ostensibly confirms that these drugs were imported under the impression of "Trial and Not For Sale". Besides at the time of raid no document or material has been found or seized which could prove otherwise that these products were stocked for the purpose of the Sale neither any customary Receipt was available nor such items were displayed For Sale. Nevertheless importing product for trial after fulfilling all the formalities is I presume no offence in the eyes of Drug Act or any other Act of Pakistan. As far as allegation of registration is concerned it is respectfully submitted that these items are*

Non-Antibiotic as informed to us by the Chinese Manufacturer (Copy Attached) which company is also registered under Pakistani law by virtue of Form VI. After confirmation of Form VI already obtain by the Chinese company from DRAP (Copy attached) and their go ahead for rights to Sayroz to import of said product we have asked for sample before the commercial import for supply the said products to be satisfied on quality as per standard prescribed by the DRAP.

I believe satisfactory narrative has been advanced by the undersigned for your kind perusal. The undersigned has never been involved in any offence in his lifetime and this is the first time that such allegations have been leveled against the undersigned.

We requested to the sectary central Licensing Board that give us opportunity for personal hearing in the upcoming meeting of the board for present the case"

09. The documents provided by the accused were sent to DRAP Karachi for verification vide letter F. No. 04-02/2018-QC dated 07-05-2020. In response, area FID, DRAP Karachi vide letter NO.F.DMT.32-35/17-FID-VII(DRAP)(K) dated 08-03-2021 submittd as under;

"I have the honour to refer to DRAP Islamabad letter No.F.04-02/2018-QC dated 26th February 2021 on the subject captioned above and to submit that documents enclosed with your letter comprising (19) pages have no relevance with DRAP Karachi office, Therefore, this office not in a position to process/verify the same as desired.

Submitted for your information and further necessary action into the matter please at the earliest."

10. Keeping in view of Final investigation report of FIA, reply of show-cause by the firm and letter of FID Karachi, the accused were issued a notice of personal hearing to appear before the Board.

Procedings and decision of 280th meeting of CLB:

11. The accused, Umar Farooq (owner) of M/s. Sayroz Pharma Karachi along with his Assistant Tariq appeared before the Board. No accused in person or through an authorized counsel appeared before the Board on behalf of M/s. Azim Medical Store Karachi, Zaheer Ahmed s/o Muhammad Yaseen proprietor AL-Azim medical store Karachi and Mehboob Ali Ismaili s/o Ameer Ali Qualified person Al Azim medical store Karachi.

12. The Board after thorough delibrations, considered the facts of the case and statement of the accused granted permission to the area Federal Inspector of Drugs, Karachi for prosecution of case in the court of competent jurisdiction against the following:

i. M/s. Al-Azim medical store, store plot No. A12-37 commercial area road No.6 cattle colony landhi Karachi through its owner/proprietor Zaheer Ahmed s/o Muhammad Yaseen

ii. Zaheer Ahmed s/o Muhammad Yaseen, (Proprietor) M/s. AL-Azim medical store R/o Bin Qasim town, Flat No. 152, mohalla Bhains colony road 2, Malir, Karachi

iii. Mehboob Ali Ismaili s/o Ameer Ali, (Qualified person) M/s. Al Azim medical store plot No. A12-37 commercial area road No.6 cattle colony landhi Karachi

iv. M/s. Sayroz Pharma, plot No. A12-37 commercial area road No.6 cattle colony landhi Karachi through its owner Umar Farooq

v. Umar Farooq, (Owner) M/s. Sayroz Pharma, plot No. A12-37 commercial area road No.6 cattle colony landhi Karachi

Case No. 03: **SALE OF UNREGISTERED DRUGS BY M/S. HAKIM SON HOMEOPATHIC PHARMACY, KARACHI.**

Mr. Abdul Rasool Shaikh, FID-VI, DRAP, Karachi along with the DRAP team inspected M/s Hakim Son Homeopathic Pharmacy, Shop No. 4&5, 5C, STI, Opposite Board of Secondary Education, Nazimabad, Karachi on 21-11-2019. During the inspection, several Health & OTC products were found placed on working shelves without having firm enlistment certificate (Form-6) and product enlistment certificate (Form-7). The stocks of products were ordered "Not to dispose of" on Form-1 and seized on Form-2 under section 18(1) of the Drugs Act, 1976 and Pharmacy was sealed.

02. Below mentioned suspected sample was also taken on prescribed Form-3 and sent to CDL, Karachi for test/analysis and samples of following drugs/creams were taken for purpose of test/analysis on Prescribed Form-3;

S. No.	Name of Drug	Batch No.	Mfg. Date	Exp. Date	Purported to be manufactured by
1.	Magic Energy cream.	Nil	Nil	Nil	M/s Homeo Magic, Karachi.

03. The Federal Government Analyst, CDL, Karachi vide test report No. NTF.KQ.570/2019 dated 20th January, 2020 declared the above-mentioned sample as "Unregistered Drug Product" containing Lidocaine, an allopathic ingredient that was identified in the product.

04. In the light of mentioned test reports, the accused namely, M/s. Hakim Sons Homeopathic Pharmacy, Shop No. 4 & 5, 5C, STI, Opposite Board of Secondary Education Nazimabad, Karachi through its owner Muhammad Talha Ansari, and Muhammad Talha Ansari, Proprietor of M/s. Hakim Sons Homeopathic Pharmacy were issued a show-cause notice vide letter F. No. 04-01/2020-QC dated 17-02-2021 for violation of Section 23(1)(a)(vii), 23(1)(a)(i) & 23(1)(h) of the Drugs Act, 1976 which is punishable under Section 27 of the Drugs Act, 1976.

05. In response to the above-mentioned show-cause notice, the accused Muhammad Talha Ansari has stated that the old management of M/s. Hakim sons Homeopathic Pahrmacy (Formely: M/s. Baseer Laboratories) used to manufacture this product and the product was still present in his shop.

06. The accused were issued a notice of personal hearing to appear before the Board.

Procedings and decision of 280th meeting of CLB:

07. On behalf of the accused Muhammad Talha Ansari (Proprietor), M/s. Hakim Sons Homeopathic Pharmacy, Shop No. 4 & 5, 5C, STI, Opposite Board of Secondary Education Nazimabad, Karachi, his brother, Faisal Ansari appeared before the Board.

08. The Board after thorough delibrations, considered the facts of the case and statement of the accused granted permission to the area Federal Inspector of Drugs, Karachi for prosecution of case in the court of competent jurisdiction against the following:

i. M/s. Hakim Sons Homeopathic Pharmacy, Shop No. 4 & 5, 5C, STI, Opposite Board of Secondary Education Nazimabad, Karachi through its owner Muhammad Talha Ansari

ii. Muhammad Talha Ansari, Proprietor of M/s. Hakim Sons Homeopathic Pharmacy, Shop No. 4 & 5, 5C, STI, Opposite Board of Secondary Education Nazimabad, Karachi

Case No. 04: **SALE OF "UN-REGISTERED DRUG PRODUCTS" BY M/S. ASHRAF MEDICOS, DAWOOD CHORANGI, LANDHI, KARACHI.**

The Assistant Director/Federal Inspector of Drugs, Karachi vide letter no. DMT/46/18 FIDVII(K) dated 11.10.2018 has submitted the complete case in reference to letter of even number dated 28.09.2018 wherein it is informed that FID alongwith Mr. Asfand Yaar Ajab Khan A.D, DRAP Karachi visited /inspected the premises of M/s Ashraf Medicos Main Market, DawoodChowrangiLandhi Karachi on 02.07.2018. During inspection of pharmacy the AD/FID-VII, Karachi recovered the following unregistered drug/medicine and seized on the prescribed Form-2 as per Drugs Act 1976. AD/FID-VII, Karachi also took samples for the purposes of test/analysis on prescribed Form-3.

Details of products seized:

Sr.	Name of drug	Batch No.	Reg. No.	Mfg. date	Exp. Date	Qt.	Mfg. by
1	Tab Penegra	G705344	Nil.	09-2017	08-2020	1x10x4	M/s. Candila Health care Ltd, India.
2	-do-	G705345	Nil.	-do-	-do-	1x11x4	-do-
3	-do-	G705348	Nil.	-do-	-do-	1x10x4	-do-

Details of samples taken for the purpose of test/analysis:

Sr.	Name of drug	Batch No.	Reg. No.	Mfg. date	Exp. Date	Mfg. by
1	Tab Penegra	G705346	Nil	09-2017	08-2020	M/s. Candila Health care Ltd, India.

02. As per report of FID the portion of sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi vide this office memorandum vide letter no. DMT/-R-46/2018-FIDVII(K) dated 03.07.2018. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Un-Registered Drug Product" under the Drugs Act, 1976 and rules framed thereunder vide their test report NO. KQ.501/2018 dated 31.08.2018

03. Area FID informed that Toufique Ahmed (proprietor) of M/s Ashraf Medicos Main Market, Dawood Chowrangi, Landhi Karachi was asked to explained his position and provide bill warranty or any other document regarding purchase/import vide FID's office letter no. DMT-46/2018-FIDVII(K) dated 06.09.2018 with subsequent reminder dated 28.09.2018. FID submitted that Toufique Ahmed (proprietor) of M/s Ashraf Medicos Main Market, Dawood Chowrangi Landhi Karachi vides their letter no. nil dated nil submitted unsatisfactory reply.

04. Area FID concluded that Toufique Ahmed (proprietor) CINC # 42201-8368254-7 of M/s Ashraf Medicos Main Market, Dawood Chowrangi Landhi, Karachi is involved in selling unregistered drug and contravened the Section 23(1)(a)(vii) & 23(1)(c) of the Drugs Act, 1976 which is punishable under section 27(1)(a) of Drugs Act, 1976 and rules framed thereunder and recommended that M/s Ashraf Medicos Main Market, Dawood Chowrangi Landhi, Karachi alongwith its proprietor Mr. Toufique Ahmed S/O Abdul Latif may be prosecuted in the Drug Court Karachi. Moreover, area FID Karachi requested that permission for

registration of FIR may be granted against the following accused "Toufique Ahmed (proprietor) CINC # 42201-8368254-7 of M/s Ashraf Medicos Main Market, Dawood Chowrangi Landhi, Karachi.

05. The case was presented before the Central Licensing Board in its 266th meeting wherein the Board decided as under:

> *"1. to grant the Permission for Lodging FIR against the accused person namely "Mr. Toufique Ahmed S/O Abdul Latif (proprietor) M/s Ashraf Medicos Main Market, Dawood Chowrangi Landhi Karachi holding CINC # 42201-8368254-7" for illegal import without import authorization and selling/storingof Un-Registered Drugswithout product registration and drug import license as required under the law. The accused has committed violations of Schedule-II and III of the DRAP Act, 2012 read with Section 23/27 of the Drugs Act, 1976. The offences of the accused persons are cognizable under schedule IV of the DRAP Act 2012 read with Section 30 of the Drug Act 1976. The FID is directed to file complaint for registration of FIR against the accused person and forward complete case for consideration of the CLB."*

06. Area FID Karachi vide letter No. DMT-46/18-FID-VII (DRAP) (K) dated 13-04-2021 submitted the complete investigation report of the case (FIR No. 14/2020) forwarded by Acting Deputy Director FIA wherein I.O/Inspector FIA, Karachi concluded the report as under;

> *"CONCLUSION/RECOMMENDATION:*
>
> *From the investigation conducted and evidence(s) available on reored, it has been established that accused Taufique Ahmed S/O Abdul Latif holder of CNIC # 42201-8368254-7 Proprietor of M/s Ashraf Medicos, situated at Main Market Daqqood Chowrangi, Landhi, Karachi committed the offences under section 23 (1)(a)(vii) & 23 (1)(c) punishable U/S 27 (1)(a) of Drugs Act-1976, ibid and rules framed there under, for which he is liable to be prosecuted before the Honorable Drug Court of Sindh at Karachi by way of filing a complaint for taking cognizance as per law against accused Taufiq Ahmed S/O Abdul Latif.*
>
> *As such the investigation of the case has been completed, hence under the orders of Competent Authority this Final Investigation Report is submitted accordingly for favour of kind perusal and onward transmission to the Drug Regulatory Authority of Pakistan, Ministry of National Health Services, Regulation & Coordnation, Karachi for submission of proper complaint under the relevant provision of Drugs Acts, before the Honorable Drug Court of Sindh at Karachi through Federal Inspector of Drug Dr. Mehwish Tanveer, Assistant Director/Federal Inspector of Drugs-VII, Karachi (Complainant of above case).*
>
> *The Final Investigation Report is submitted accordingly, for favour of kind perusal and further necessary action please."*

Procedings and decision of 280th meeting of CLB:

07. The Board after thorough deliberations, considering the facts of the case and the Final Investigation report submitted by the I.O FIA Karachi decided to issue show-cause notice for prosecution to the following accusedfor contraventions of section 23(1)(a)(vii) and 23(1)(c) of the Drugs Act, 1976 and the rules framed thereunder:

i. M/s. Ashraf Medicos, Main Market, Dawood Chowrangi, Landhi, Karachi through its Proprietor Taufique Ahmed S/o Abdul Latif

ii. Taufique Ahmed S/O Abdul Latif (Proprietor) M/s. Ashraf Medicos, R/o House No. R-357, Green park city near Abbott Laboratories, Karachi.

Case No. 05: **MANUFACTURE/SALE OF UNREGISTERED DRUGS BY M/SMEDICARE HOMEO STORE & CLINIC, KARACHI.**

Mr. Abdul Rasool Shaikh, FID-VI, DRAP, Karachi along with the DRAP team inspected M/s Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi on 21-11-2019 and samples of following drugs/creams were taken for purpose of test/analysis on Prescribed Form-3;

S. No.	Name of Drug	Batch No.	Mfg. Date	Exp. Date	Purported to be manufactured by
1.	Midnight Cream	Nil	Nil	Nil	M/s UM Homeopathic Pharma, Karachi.
2.	100 Minutes Cream	Nil	Nil	Nil	M/s Medicare Homeopathic Pharma, Karachi.

02. The sealed samples of above drugs/creams were sent by FID to Federal Government Analyst, CDL, Karachi for purpose of test/analysis vide memorandum No. ARS-253/2019-FID-VI(K) dated 22-11-2019.

03. M/s Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi was directed by FID to provide bill warranties/invoices of above drugs/creams vide letters dated 22-11-2019 & 24-12-2019 but no reply was received.

04. The Government Analyst, CDL, Karachi vide test report No. NTF.KQ.572/2019 & No. NTF.KQ.573/2019 dated 20th January, 2020, declared the above-mentioned samples as Unregistered Drug Products as Lidocaine, an allopathic ingredient, was identified in both the creams.

05. In the light of above test reports of Federal Government Analyst, explanation letters date 31-01-2020 & 14-02-2020 were issued by FID to M/s Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi for explaining their position. FID further submitted that the letter No. F. 254-257/2019-FID (K)-VI (NTF) dated 14-02-2020 issued to Medicare Homeo Store & Clinic, Karachi, returned back with the remarks that shop is closed.

06. Keeping in view the above facts, Area FID, stated that M/s Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi, has violated Section 23(1)(a)(vii), 23(1)(a)(i) & 23(1)(h) of the Drugs Act, 1976 which is punishable under Section 27 of the Drugs Act, 1976 and therefore recommended as under;

i. That the permission for prosecution of below mentioned person, in Drug Court, may kindly be granted for manufacturing and selling of unregistered drug products and non-submission of bill warranty/invoice.

a. M/s Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi.

b. Muhammad Younas S/o Muhammad Ahmed (CNIC No. 42301-0878778-7)- Proprietor.

ii. That the Sindh Health Care Commission may be approached for cancellation/suspension of registration certificate No. SHCC/P-KHI/0593 dated 04-06-2018.

07. The case was presented before the Board in its 279th meeting wherein the Board decided as under;

> *"The Central Licensing Board considered the case and decided to allow the permission for prosecution of the accused mentioned in Para 6 as recommended by the federal inspector of drugs. The Board also allowed the request of Federal inspector of Drugs to approach Sindh Health care commission for suspension cancellation of registration certificate No. SHCC/P-KHI/0593 dated 04-06-2018"*

08. It is submitted that in the instant case, the accused were not given a chance of personal hearing before the Board therefore, the case is resubmitted before the Board for granting permission to issue show-cause notice and personal hearing to the accused so the ends of justice can be met. Moreover, one part of the above-stated decision i.e. "*The Board also allowed the request of Federal inspector of Drugs to approach Sindh Health care commission for suspension cancellation of registration certificate No. SHCC/P-KHI/0593 dated 04-06-2018"* was complied with and decision was communicated to the area FID, Karachi.

Procedings and decision of 280th meeting of CLB:

09. To meet the ends of justice, the Board after thorough discussion, reviewed the decision taken in 279th meeting to the extent of part i.e. *"The Central Licensing Board considered the case and decided to allow the permission for prosecution of the accused mentioned in Para 6 as recommended by the federal inspector of drugs"* and decided to issue show-cause notice for prosecution and a chance of personal hearing before the Board in its forthcoming meeting to the following accused:

i. M/s Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi.

ii. Muhammad Younas S/o Muhammad Ahmed (Proprietor), M/s Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi

The meeting ended with the vote of thanks to and by the Chair.