MINUTES OF 276th MEETING OF CENTRAL LICENSING BOARD HELD ON 03RD SEPTEMBER, 2020

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276th meeting of the Central Licensing Board (CLB) was held on 03rd September, 2020 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Dr. Masud ur Rehman, Director Drug Licensing, Drug Regulatory Authority of Pakistan, Islamabad. Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Prof. Dr. Abdullah Dayo, Dean Faculty of Pharmacy, University of Sindh, Jamshoro	Member
2.	Prof.Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar.	Member
3.	Mr. Muhammad Israr, Law Expert, Ministry of Law & Justice Division, Islamabad	Member
4.	Mr. Azhar Jamal Saleemi, Chief Drug Controller, Primary and Secondary Health Department, Government of Punjab, Lahore	Member
5.	Mr Saleem Shah, Chief Inspector of Drugs, Government of Balochistan, Quetta	Member
6.	Mr Shoaib Ahmed Ansari, Chief Inspector of Drugs, Government of Sindh, Karachi	Member
7.	Mr. Zakir Khan, Sr Drug Inspector, Department of Health, Govt of Khyber Pakhtunkhwa.	Member
8.	Dr. Hafsa Karam Ellahi, Additional Director Representative Director (QA/LT), DRAP, Islamabad	
9.	Mr. Manzoor Ali Bozdar, Addl Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
10.	Mr. Saleem Iqbal, Representative of PPMA.	Observer
11.	Ms. Mahwish , Representative of PPMA.	Observer
12.	Mr. Kamran Anwar, Representative, PCDA	Observer
13.	Mr.Nadeem Alamgir Representative of Pharma Bureau.	Observer

The meeting started with the recitation of Holy verses. Fateha was offered for late Mr. Ghulam Rasool Dutani , Ex-Director, Division of Drug Licenisng/ Chairman, Central Licensing Board and late Dr. Muhammad Usman , Member Central Licenisng Board who passed away recently. Their contribution to the Central Lincenising Board was acknowledged in best terms.

The Chairman Central Licensing Board welcomed the honorable members. The members also exchanged good wishes as it was the first meeting of Chairman. He stated that all the legal and codal formalities would be taken into account for disposal of cases and respective Divisions shall be responsible for the contents, errors and omissions of agenda and minutes 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. Secretary Licensing Board presented the agenda before the Board. Mr. Zeeshan Nazir, Deputy Director (QA), Ms. Mahvash Ansari, Deputy Director (QC), Mr. Ayyaz Ahmed, Deputy Director (Licensing), Mr. Muhammad Usman, AD (Lic), Mr. Abdullah Bangash, AD (Lic), Ms. Zunaira Faryad, AD (Lic) and Ms. Haleema Shareef (Lic) Mr. Sanaullah Babar, AD (QC), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

DRUG LICENSING DIVISION

Item-I CONFIRMATION OF THE MINUTES OF 275th MEETING

The Central Licensing Board (CLB) formally confirmed the minutes of its 275th meeting of the Central Licensing Board (CLB) which was held on **25th June, 2020.**

Item-II: GRANT OF NEW DRUG MANUFACTURING LICENSES.

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Alpenglow Pharmaceuticals (Pvt) Ltd., Plot No. A7, Risalpur Export Processing Zone, Risalpur. **Sections (05)** i. Capsule (Cephalosporin) ii. Dry Powder Suspension (Cephalosporin) iii. Dry Powder Injection (Cephalosporin) iv. Tablet (Psychotropic)	02-07-2020 and 17-07-2020	Good	1. Prof. Dr. Jamshed Ali Khan, Member CLB. 2. Director DTL, KPK, Peshawar. 3. Mr. Attique Ul Bari, AD/FID, DRAP, Peshawar.
	Recommendations of the panel: - Keeping in view the above, the panel unanimously recommends the grant of Drug Manufacturing License (Formulation) for following sections to M/s Alpenglow Pharmaceuticals (Pvt) Ltd., Plot No.A7, Risalpur Export Processing Zone, Risalpur. i. Capsule (Cephalosporin) ii. Dry Powder Suspension (Cephalosporin) iii. Dry Powder Injection (Cephalosporin)			

iv. Tablet (Psychotropic)

Decision of the Central Licensing Board in 276th meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Alpenglow Pharmaceuticals (Pvt) Ltd., Plot No.A7, Risalpur Export Processing Zone, Risalpur on the recommendations of the panel of experts for the following sections:

Sections (4)

i. Capsule (Cephalosporin)
ii. Dry Powder Suspension (Cephalosporin)
iii. Dry Powder Injection (Cephalosporin)
iv. Tablet (Psychotropic)

2.	M/s JASM Pharmaceutical (Pvt) Ltd., Plot No.4-A, Export Processing Street, Risalpur Industrial Estate, Nowshera. **Sections (05)** i. Tablet Section (General) ii. Capsule Section (General) iii. Dry Powder Section (General) iv. Liquid Syrup Section (General) v. Cream/Ointment Section (General)	03-07-2020 and 27-07-2020	Good	1. Prof. Dr. Jamshed Ali Khan, Member CLB. 2. Additional Director (E&M), DRAP, Peshawar. 3. Area Federal Inspector of Drugs, DRAP, Peshawar. 4. Area Assistant Director, DRAP, Peshawar.

***Recommendations of the panel**: -*

Keeping in view the above, the panel unanimously recommends the grant of Drug Manufacturing License (Formulation) for following sections to M/s JASM Pharmaceutical (Pvt) Ltd., Plot No.4-A, Export Processing Street, Risalpur Industrial Estate, Nowshera, Khyber Pakhtun Khwa Pakistan;

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

Decision of the Central Licensing Board in 276th meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of

	Formulation in the name of M/s JASM Pharmaceutical (Pvt) Ltd., Plot No.4-A, Export Processing Street, Risalpur Industrial Estate, Nowshera, Khyber Pakhtun Khwa, on the recommendations of the panel of experts for the following sections: **Sections (5)** i. Tablet Section (General) ii. Capsule Section (General) iii. Dry Powder Section (General) iv. Liquid Syrup Section (General) v. Cream/Ointment Section (General)

3	v. M/S Winbrains Research Laboratories 69/1 Phase II Hatttar KPK	02-07-2020, 27-08-2020 & 01-09-2020 Semi Basic manufacture)	Good	i) Prof. Dr. Jamshed Ali Khan, Member CLB. ii) Mr. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad. iii) Mr. Adnan Shahid Ullah, Assistant Director, DRAP, Peshawar.

Recommendations

The panel unanimously recommends the grant of Drug manufacturing license (**semi Basic manufacture**) to M/s Winbrains Research Laboratories Plot No. 69/1 Block B PhaseI-II Industrial Estate Hattar.

The panel also recommends following molecules/APIs to be manufactured by way of semi basic manufacture in above mentioned facility;

S. No	Names of API
1)	Citric Acid Coated Granules
2)	Itraconazole Coated Pellets
3)	Linezolid Taste Mask Granules
4)	Sodium Bicarbonate Coated Granules
5)	Ibuprofen Taste Mask Granules
6)	Orlistat Pellets
7)	Loratadine Pellets
8)	Risperidone Taste Mask Granules
9)	Riboflavin Coated Granules
10)	Duloxetine Enteric Coated Pellets
11)	Duloxetine Hcl Pellets
12)	Levofloxacin Taste Mask Pellets/Granules
13)	Azithromycin Taste Mask Pellets
14)	Mebeverine HCL Taste Mask Pellets
15)	Dexlansoprazole Pellets

16)	Rabeprazole Pellets
17)	Lansoprazole Pellets
18)	Venlafaxine SR Pellets
19)	Aceclofenac SR Pellets
20)	Folic Acid IR Coated Granules
21)	Nitroglycerine XR Pellets
22)	Ketoprofen SR Pellets
23)	Ferrous Fumarate Coated Granules
24)	Zinc Sulphate Coated Granules
25)	Famotidine Taste Mask Granules
26)	Doxycyline Coated Granules
27)	Pyridoxine Coated Granules
28)	Lornoxicam Coated Granules
29)	Levocetrizine Taste Mask Granules
30)	Cyclobenzaprine Hcl Pellets
31)	Aspirin Pellets
32)	Clarithromycin Taste Mask Pellets
33)	Ciprofloxacin Taste Mask Pellets
34)	Diclofenac Sodium Pellets
35)	Domperidone Pellets
36)	Esomeprazole EC Pellets
37)	Tamsolusin Coated Pellets
38)	Pantoprazole Pellets
39)	Omeprazole Pellets
40)	Fexofenadine Hcl IR Coated Granules
41)	Tizanidine HCL SR Pellets
42)	Theophylline SR Pellets
43)	Clopidogrel IR Coated Granules
44)	Diclofenac Potassium XR Pellets
45)	Itopride HCL pellets

Decision of the Central Licensing Board in 276th meeting

The Board considered and approved the grant of Drug Manufacturing License by way of Semi Basic Manufacture in the name of M/s Winbrains Research Laboratories, Plot No. 69/1 Block B PhaseI-II Industrial Estate Hattar with the following API's;

S. No	Names of API
1)	Citric Acid Coated Granules
2)	Itraconazole Coated Pellets
3)	Linezolid Taste Mask Granules
4)	Sodium Bicarbonate Coated Granules
5)	Ibuprofen Taste Mask Granules
6)	Orlistat Pellets
7)	Loratadine Pellets
8)	Risperidone Taste Mask Granules

		9)	Riboflavin Coated Granules	
		10)	Duloxetine Enteric Coated Pellets	
		11)	Duloxetine Hcl Pellets	
		12)	Levofloxacin Taste Mask Pellets/Granules	
		13)	Azithromycin Taste Mask Pellets	
		14)	Mebeverine HCL Taste Mask Pellets	
		15)	Dexlansoprazole Pellets	
		16)	Rabeprazole Pellets	
		17)	Lansoprazole Pellets	
		18)	Venlafaxine SR Pellets	
		19)	Aceclofenac SR Pellets	
		20)	Folic Acid IR Coated Granules	
		21)	Nitroglycerine XR Pellets	
		22)	Ketoprofen SR Pellets	
		23)	Ferrous Fumarate Coated Granules	
		24)	Zinc Sulphate Coated Granules	
		25)	Famotidine Taste Mask Granules	
		26)	Doxycyline Coated Granules	
		27)	Pyridoxine Coated Granules	
		28)	Lornoxicam Coated Granules	
		29)	Levocetrizine Taste Mask Granules	
		30)	Cyclobenzaprine Hcl Pellets	
		31)	Aspirin Pellets	
		32)	Clarithromycin Taste Mask Pellets	
		33)	Ciprofloxacin Taste Mask Pellets	
		34)	Diclofenac Sodium Pellets	
		35)	Domperidone Pellets	
		36)	Esomeprazole EC Pellets	
		37)	Tamsolusin Coated Pellets	
		38)	Pantoprazole Pellets	
		39)	Omeprazole Pellets	
		40)	Fexofenadine Hcl IR Coated Granules	
		41)	Tizanidine HCL SR Pellets	
		42)	Theophylline SR Pellets	
		43)	Clopidogrel IR Coated Granules	
		44)	Diclofenac Potassium XR Pellets	
		45)	Itopride HCL pellets	

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

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1.	**M/s S.J & G Fazul Ellahie (Pvt) Ltd,** F/46, S.I.T.E **Karachi** **DML No. 000083(formulation)** **1. Raw Material Store-New**	**23-07-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Director DTL, Karachi. 3. Area FID, DRAP, Karachi.
	Recommendations of the panel: - Keeping in view the facilities provided and commitment of the management for continuous improvement the panel recommends grant of Additional Section namely the New Raw Material Store (located on the First Floor) and further divided in Human and Veterinary sections to the firm M/s S. J. G. Fazul Ellahi Pvt. Ltd situated Plot No. E-46, S.I.T.E., Karachi **Decision of the Central Licensing Board in 276th meeting** The Board considered and approved the grant of additional facility in the name of M/s S. J. G. Fazul Ellahi Pvt. Ltd situated Plot No. E-46, S.I.T.E., Karachi under DML No. 000083(Formulation); **Facility (1)** **i. Raw Material Store-New**			
2.	M/s Quaper (Pvt) Ltd, 26-A, Small Industrial Estate Lahore Road, Sargodha. DML No. 000609 by way (Formulation) **Section (04)** 1. Tablet (General) Section (Revised). 2. Capsule (General) Section (New) 3. R&D Laboratory (New) 4. Sachet (General). (New)	16-06-2020 & 18-06-2020	**Not mentioned**	1. Dr. Ikram-ul-Haq, Member, CLB. 2. Mr. Azher Jamal Saleemi, Chief Drug Controller, Punjab. 3. Mrs. Majida Mujahid, FID, DRAP, Lahore.
	Recommendations of the panel: - Firm has done considerable improvement in microbiological section which are appreciated by panel. Keeping in view the above observations, the members of the panel are of the opinion to recommend			

	the grant of following new Additional Sections to M/s Quaper (Pvt) Ltd, 26-A, Small Industrial Estate Lahore Road, Sargodha as per lay out plan approved by DRAP: i. Tablet (General) Section (Revised). ii. Capsule (General) Section (New) iii. R&D Laboratory (New) iv. Sachet (General). (New) **Decision of the Central Licensing Board in 276th meeting** The Board considered the case and sought comments regarding the firm from Mr. Azhar Jamal Saleemi, Chief Drug Controller who was member of the panel. He opined that facility may be rated as good. The Board after hearing the comments from the worthy member decide to approve following new Additional and revised Sections in the name of M/s Quaper (Pvt) Ltd, 26-A, Small Industrial Estate Lahore Road, Sargodha on the recommendations of the panel of experts: **Sections (4)** i. Tablet (General) Section (Revised). ii. Capsule (General) Section (New) iii. R&D Laboratory (New) iv. Sachet (General). (New) The Board also decided to advise Federal Inspector of Drugs to submit reports on prescribed proforma in future.			
3.	M/s Medicraft Pharmaceuticals (Pvt) Ltd., 126-B, Hayatabad Industrial Estate, Peshawar. Name of Section **Section (01)** 1. Dry Powder Injection (Carbapenem)	03-06-2020	**Good**	1. Prof. Dr. Jamshed Ali Khan, Member CLB. 2. Chief Drug Inspector, Khyber Pakhtunkhwa. 3. Area Federal Inspector of Drugs, DRAP, Peshawar.
	Recommendations of the panel: - Keeping in view the above, the panel unanimously recommends the grant of following additional section to M/s Medicraft Pharmaceuticals (Pvt) Ltd., Peshawar; **S.N** | **Name of Section** 1. | Dry Powder Injection (Carbapenem) **Decision of the Central Licensing Board in 276th meeting** The Board considered and approved the grant of Additional section in the name to M/s Medicraft Pharmaceuticals (Pvt) Ltd., 126-B, Hayatabad Industrial Estate, Peshawar on the recommendations of the panel of experts; **Section (1)** **i. Dry Powder Injection (Carbapenem)**			

4.	M/s Cure Laboratories (Pvt) Ltd, Plot No. 11&12, Street No. NS-2, National Industrial Zone, Rawat. **Section (02)** i. Tablet Section (General) ii. Capsule Section (General)	29-06-2020 & 12-08-2020	**GOOD**	1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT-I), DRAP, Islamabad. 2. Dr. Muhammad Usman, Member, Central Licensing Board. 3. Mr. Khalid Mahmood, Federal Inspector of Drugs, DRAP, Islamabad.

Recommendations of the panel: -

Keeping in view the above facts, detail visit of facility and supporting documents provided by the company, the panel unanimously **Recommended**M/s Cure Laboratories (Pvt) Ltd, Plot No. 11&12, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi for grant of following two additional sections as of today as per mandate given vide letter No. F. 1-13/2017-Lic dated 22nd June, 2020.

Sections (2)

i. Tablet Section (General)

ii. Capsule Section (General)

DISCLAIMER:- *The assessment for strength of building does not fall under the ambit mandate and scope of the inspection for which the firm has been advised to get certification form relevant Building Control Authorities (BCA) as per prevailing laws and ensure proper emergency exits along with firefighting equipment in the premises. The quality of individual batches of registered products and their safety shall remain the responsibility of the manufacturer as envisaged under the Drug Act, 1976 read with DRAP Act, 2012.*

Decision of the Central Licensing Board in 276th meeting

The Board considered and approved the grant of Additional section in the name to M/s Cure Laboratories (Pvt) Ltd, Plot No. 11&12, Street No. NS-2, National Industrial Zone, Rawat on the recommendations of the panel of experts:-

Sections (2)

i. Tablet Section (General)

ii. Capsule Section (General)

Moreover, the Board decided that Dr. Hafsa Karam Elahi shall come up with opinion after consulting Federal Inspector of Drugs with respect to Disclaimer.

5.	M/s Cunningham Pharmaceuticals (Pvt) Ltd, Plot No. 81, Sunder Industrial Estate, Lahore DML No. 000840 (Formulation) **<u>Section (07)</u>** i. Eye Drop (General)Section. ii. Tablet (Psychotropic) Section. iii. Liquid Injection (Psychotropic) Section (In place of liquid vial section). iv. Steroid Ophthalmic Section (In place of Additional Finished Goods Store). v. Liquid Injectable (SVP) Section (General) (Additional). vi. Liquid Injectable (LVP) Section (General) (Additional). vii. Liquid Injectable (Ampoule) Section (General) (Revised),	14-07-2020 & 18-07-2020	**GOOD**	1. Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 2. Dr.Ikram ul Haq, Member, Central Licensing Board. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - Keeping in view the facility like building, HVAC system, Machinery and equipment, Instruments, personnel, documentation quality control, testing facility. The panel of inspectors is of the opinion to recommend the grant of the following new section to M/s Cunningham Pharmaceuticals (Pvt) Ltd, Plot No. 81, Sunder Industrial Estate, Lahore.			

	i. Eye Drop (General)Section. ii. Tablet (Psychotropic) Section. iii. Liquid Injection (Psychotropic) Section (In place of liquid vial section). iv. Steroid Ophthalmic Section (In place of Additional Finished Goods Store). v. Liquid Injectable (SVP) Section (General) (Additional). vi. Liquid Injectable (LVP) Section (General) (Additional). vii. Liquid Injectable (Ampoule) Section (General) (Revised) **As there is no registration product of Psychotropic Capsules till date, so the section is not recommended for Grant of New License.** **Decision of the Central Licensing Board in 276th meeting** The Board considered and approved the grant of Additional section in the name to M/s Cunningham Pharmaceuticals (Pvt) Ltd, Plot No. 81, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts:- **Sections (7)** **i. Eye Drop (General)Section.** **ii. Tablet (Psychotropic) Section.** **iii. Liquid Injection (Psychotropic) Section (In place of liquid vial section).** **iv. Steroid Ophthalmic Section (In place of Additional Finished Goods Store).** **v. Liquid Injectable (SVP) Section (General) (Additional).** **vi. Liquid Injectable (LVP) Section (General) (Additional).** **vii. Liquid Injectable (Ampoule) Section (General) (Revised).** The Board observed that there are products in Capsule dosage form for other firms which contain psychtropic/ narcotic (controlled substance). The Board, therefore, decided to refer back the case to panel for reconsideration of the recommendations pertaining to Capsule Section (Psychotropic).			
6.	M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-5, National Industrial Zone, Rawat DML No. 000718 (Formulation) **Section (02)**	**08-07-2020**	**Good**	1. Dr. Hafa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad. 2. Prof. Dr. Muhammad Usman, Member CLB. 3. Mr. Hasan Afzaal, Federal Inspector of Drugs, DRAP, Lahore.

	1. Cream / Ointment Section (General). 2. Oral dry powder for Sachet (General).			

Recommendations of the panel: -

Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Medisynth Pharmaceutical, Plot No. 55, Street No. S-5, RCCI, Rawat, Rawalpindi for the following sections namely;

Sections (2)

1. Cream / Ointment Section (General).
2. Oral dry powder for Sachet (General).

Upon the completion of inspection the panel agreed upon the above statement, however prior to the formal endorsement of the report one of the panel member (Prof. Dr. Usman Member CLB) passed away. Hence the report is being submitted for the consideration of the board.

Decision of the Central Licensing Board in 276th meeting

The Board considered and deferred the grant of additional section in the name of M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-5, National Industrial Zone, Rawat as inspecition was carried out by two members instead of Three (full) member of the constituted panel. The Board decided to re-inspect the premisis and panel will be constituted by the Chairman Central Licensing Board

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

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Pharmatec Pakistan (Pvt) Ltd, Plot No. D-86/A, S.I.T.E, , Karachi DML No. 000024 (Formulation) **Period**. 31-03-2020 to 30-03-2025 Sections : 1) Tablet (General) 2) Capsule (General) 3) Sterile Liquid Ampoule (General) 4) Liquid (General)	**15-07-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director (E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi.
	Recommendations of the panel: - Keeping in view overall GMP compliance and positive intentions towards improvement, panel unanimously recommends the renewal of (DML No. 000024) by way of formulation to the M/s. Pharmatec Pakistan (Pvt) Ltd, Karachi. **Decision of the Central Licensing Board in 276th meeting** The Board considered and approved the grant of renewal of (DML No. 000024) by way of formulation in the name of M/s. Pharmatec Pakistan (Pvt) Ltd, Karachi on the recommendations of the panel of experts for the period commencing on 31-03-2020 and ending on 30-03-2025 for the following sections: **Sections (4):** 1) Tablet (General) 2) Capsule (General) 3) Sterile Liquid Ampoule (General)			

	4) Liquid (General)			
2.	M/s Avant Pharmaceuticals (Pvt) Ltd, Plot No. M-28, Hub Industrial Estate, Hub, Baluchistan DML No. 000786 (Formulation) **Period**. 03-02-2019 to 02-02-2024. Sections : 1) Tablet (General) 2) Capsule (General)	**21-07-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Chief Drug Inspector, Balochistan. 3. Officer Incharge /Area FID, DRAP, Quetta.

Recommendations of the panel: -

Panel constituted by CLB vide letter no. F.4-1/2010-Lic Vol-I) dated 13thFebruary 2020 visited the premises of M/s. Avant Pharmaceuticals on 21st July 2020. The plant was found as approved layout plan. The required personals were present at the site. Therefore, as per existing facilities, machinery, personnel are commitment of the firm the panel recommends resumption of manufacturing and renewal of Drug Manufacturing License No. 000786 (Formulation) of the firm.

Area FID has also forwarded covering letter of report and on that letter it is stated:-

"Inspection was conducted while the production was stopped in the premises, therefore, the real-time performance of the personnel and the equipments along with the real analysis of the firm with respect to the working efficiency and efficacy was not analyzed as the same could not be analyzed in real-time which is necessary in the best interests of the people of Baluchistan specifically and whole Pakistan generally as well as othercountries, if the drugs of this firm are exported to other countries in the future. It is, therefore, requested that this report may please be considered only for the resumptions of the production of the firm, if this esteemed Board considers appropriate. But as far as the Renewal of Drug Manufacturing License (000786)is concerned the same may not be granted until real-time inspection of the firm is carried out, by the experienced and well-trained inspectors, during the active production of the firm with respect to both the approved section.

Please also bring in to the knowledge of the worthy Board that the under signed though posted by DRAP Authority Administration as FID Balochistan but has not been duly appointed by the Federal Government in this behalf thus a letter was also written to the Secretary CLB for

	guidance but no such guidance was received and on the other hand verbal direction was received from CEO DRAP to be a part of the panel as officer incharge DRAP Quetta Balochistan in furtherance to approach of some high official best know to the worty CEO DRAP and also from your kind office for reasons best known to your office. Undersigned has not been provided with any training regarding GMP Inspections or ICH guidelines whatsoever because of which the inspection carried out by the under signed might not be of that quality as that of respected trained inspectors. Submitted for consideration and further necessary action.'' **Decision of the Central Licensing Board in 276th meeting** The Board considered and approved the grant of renewal of (DML No. 000024) by way of formulation in the name of M/s Avant Pharmaceuticals (Pvt) Ltd, Plot No. M-28, Hub Industrial Estate, Hub, Baluchistan on the recommendations of the panel of experts for the period commencing on 03-02-2019 and ending on 02-02-2024 for the following sections: **Sections (2):** 1) Tablet (General) 2) Capsule (General) The Board also decied to allow the resumption of the production on the recommendations of the panel of experts. The Board perused the contents of the covering letter written by the Federal Inspector of Drugs and observed that it is against the norms whereas Federal Inspector of Drugs carried the inspection with panel he agreed and recommended the renewal of Drug Manufacturing Licence and resumption of production and also written the inspection report and signed after developing consensus with other panel members. Giving after thoughts and writing of covering letter with language contrary to consensus which is serious and warrants administrative consideration. The Board, therefore, decided to refer the matter to Chief Executive Officer, Drug Regulatory Authority of Pakistan for his perusal.			
3	M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad DML No. 000806 (Semi-Basic Manufacture) **Period**:	23-06-2020	**Good**	1. Dr. Muhammad Usman, Member CLB. 2. Additional Director (QA), DRAP, Islamabad(could not attend). 3. Area Federal Inspector of Drugs, DRAP, Islamabad. **However panel inspection was conducted by following members,**

	02-12-2019 to 01-12-2024			**1. Dr. Muhammad Usman, Member CLB.** **2. Area 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 renewal of DML by The Way of Semi Basic (000806)** of Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahtua Road, Islamabad-Pakistan. **Decision of the Central Licensing Board in 276th meeting** The Board considered and deferred the grant of renewal of Drug manufacturing License by Way of **Semi Basic Mnufacture** in the name of Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahtua Road, Islamabad-Pakistan as inspecition was carriedout by two members instead of three (full) member of the constituted panel. The Board decided to re-inspect the premisis and panel to be constituted by the Chairman Central Licensing Board.			
4.	M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad DML No. 000517 (Formulation) **Period**: 01-04-2019 to 31-03-2024	22-06-2020	**Good**	1. Dr. Muhammad Usman, Member CLB. 2. Additional Director (QA), DRAP, Islamabad (Could not attend). 3. Area Federal Inspector of Drugs, DRAP, Islamabad. **However panel inspection was conducted by following members,** **1. Dr. Muhammad Usman, Member CLB.** **2. Area 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 renewal of DML by The Way of Formulation (000517)** of Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahtua Road, Islamabad-Pakistan. **Decision of the Central Licensing Board in 276th meeting** The Board considered and deferred the grant of renewal of Drug manufacturing License by Way of Fomrumaltion in the name of Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahtua Road, Islamabad-Pakistan as inspecition was carriedout by two members instead of three (full) member of the constituted panel. The Board decided to re-inspect the premisis and panel to be constituted by the Chairman Central Licensing Board.			
5.	M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat. DML No. 000680 (Formulation) **Period**: 04-02-2020 to 03-02-2025	04-08-2020 & 12-08-2020	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT-I), DRAP, Islamabad. 2. Dr. Muhammad Usman, Member, Central Licensing Board. 3. Mr. Khalid Mahmood, Federal Inspector of Drugs, DRAP, Islamabad.
	Recommendations of the panel: - Keeping in view the above facts, detail visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat, Rawalpindi for renewal of Drug Manufacturing License No. 000680 (Formulation) as of today as per mandate given vide letter No.F. 1-36/2006-Lic (Vol-II) dated 1st June, 2020 for following section in addition to already approved section by Central Licensing Board in mid of 2019 as above also. Request for inspection of Add. Sections (Liq. Vial Vet (Gen))& Steroid submitted by the firm as per LOP. 1. Oral Liquid Section (Veterinary). 2. Viral Vaccine Section (Live) 3. Viral Vaccine Section (Killed) 4. Bacterial Killed Vaccine Section.			

	5. Bolus Section (General) (Veterinary). 6. Oral Powder Section (General) (Veterinary). 7. Oral Liquid Section (General) (Veterinary) 8. Oral Powder Section (Penicillin) (Veterinary). 9. Dry Powder Injection Section Vials(Penicillin) (Veterinary) 10. Liquid Injection Section Vials (Penicillin) (Veterinary). DISCLAIMER:- *The assessment for strength of building does not fall under the ambit mandate and scope of the inspection for which the firm has been advised to get certification form relevant Building Control Authorities (BCA) as per prevailing laws and ensure proper emergency exits along with firefighting equipment in the premises. The quality of individual batches of registered products and their safety shall remain the responsibility of the manufacturer as envisaged under the Drug Act, 1976 read with DRAP Act, 2012.* **Decision of the Central Licensing Board in 276th meeting** The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period commencing on 04-02-2020 and ending on 03-02-2025 for the following sections: 1. Oral Liquid Section (Veterinary). 2. Viral Vaccine Section (Live). 3. Viral Vaccine Section (Killed) 4. Bacterial Killed Vaccine Section. 5. Bolus Section (General) (Veterinary). 6. Oral Powder Section (General) (Veterinary). 7. Oral Liquid Section (General) (Veterinary) 8. Oral Powder Section (Penicillin) (Veterinary). 9. Dry Powder Injection Section Vials(Penicillin) (Veterinary) 10. Liquid Injection Section Vials (Penicillin) (Veterinary). Moreover, the Board decided that Dr. Hafsa Karam Elahi shall come up with with opinion after consulting Federal Inspector of Drugs with respect to Disclaimer.			
6.	M/s English Pharmaceutical Industries, Link Kattar Bund Road, Thoker Niaz Beg, Lahore DML No. 000339	31-01-2020 & 12-03-2020	**Good**	1. Dr. Farzana Chaudhary, Expert Member. 2. Dr Munawar Hayat, Chief Drugs Controller, Punjab. 3. Mr Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore

	(Formulation). **Period**: 19-07-2019 to 18-07-2024			

Recommendations of the panel: -

"Based on the areas inspected, the technical people met and the documents reviewed and considering the findings of the inspection the panel verified a satisfactorily maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirement of DML as per Drug (Licensing , Registering and Advertising) Rules, 1976 and capacity & capability of the firm in respect of manufacturing and quality control of all registered products and approved sections except Penicillin (Oral Dry Powder Suspension, Tablet & Capsule) Sections.

The Panel of Inspectors**Recommends** the renewal bearing DML No. 000339 in respect of all approved sections **except Penicillin (Oral Dry Powder Suspension, Tablet & Capsule) Sections**which may be suspended / cancelled till the rectification of all shortcomings in the area".

Decision of the Central Licensing Board in 276th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s English Pharmaceutical Industries, Link Kattar Bund Road, Thoker Niaz Beg, Lahore on the recommendations of the panel of experts for the period commencing on 19-07-2019 and ending on 18-07-2024 for following approved section **except Penicillin (Oral Dry Powder Suspension, Tablet & Capsule) Sections** ".

Sections (10)

i. Tablet Section –II (General Antibiotics)
ii. Liquid Syrup (General)
iii. Oral Dry Suspension (General)
iv. Oral Dry Powder Suspension (Ceph)
v. Capsule Section (Ceph)
vi. Dry Powder Injection Vial (Ceph)
vii. Liquid Injection Ampoule (General)
viii. Liquid Infusion SVP (General)
ix. Sterile Dry Powder Injection (Penicillin)
x. Dry Powder Injection Vial (General)

The Board, therefore, decided to serve Show Cause Notice to M/s English Pharmaceutical

	Industries, Link Kattar Bund Road, Thoker Niaz Beg, Lahore under Section 41 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for **Penicillin (Oral Dry Powder Suspension, Tablet & Capsule) Sections** may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain stopped / suspended in Penicillin (Oral Dry Powder Suspension, Tablet & Capsule) Sections till decision by the Central Licensing Board.

ITEM – IV MISC CASES

Case No. 01. CHANGE OF MANAGEMENT OF M/S. NOVARTIS PHARMA (PAKISTAN) LTD, 15 WEST WHARF ROAD, KARACHI.

M/s. Novartis Pharma (Pakistan) Ltd, 15 west wharf road, Karachi under DML No. 000193(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 as per Form-29 Year 2016	New Management as per Form-29 Year 2020
1. Mr. Christopher Snook S/o David Patrick Snook Passport No. 507622357. 2. Mr. Badaruddin fatehali vellani S/o fatehali Wali Muhammad vellani CNIC No. 42301-0918221-7. 3. Mr. Syed Khalid Noor S/o Syed Muhammad Noor ul huda CNIC No.42201-0506204-1. 4. Mr. Shahab Rizvi S/o Syed Mohsin Hussain Rizvi CNIC No. 42201-7372422-3	1. Mr. Imran Rasheed S/o Abdul Rasheed CNIC No. 37405-9936790-1. 2. Mr. Ziad bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhrey CNIC No. 42000-0519991-5. 3. Mr. Badaruddin fatehali vellani S/o fatehali Wali Muhammad vellani CNIC No. 42301-0918221-7. 4. Mr. Syed Khalid Noor S/o Syed Muhammad Noor ul huda CNIC No.42201-0506204-1. 5. Mr. Christopher Snook S/o David Patrick Snook Passport No. 507622357.

Submitted for consideration of the board, please.

Decision of the Central Licensing Board in 276th meeting:

The Board considered and endorsed the change of management of M/s Novartis Pharma (Pakistan) Ltd, 15 west wharf road, Karachi under DML No. 000193 by way of formulation as under:-

Current Management as per Form-29 Year 2016	New Management as per Form-29 Year 2020
1. Mr. Christopher Snook S/o David Patrick Snook Passport No. 507622357. 2. Mr. Badaruddin fatehali vellani S/o fatehali Wali Muhammad vellani CNIC No. 42301-0918221-7. 3. Mr. Syed Khalid Noor S/o Syed Muhammad Noor ul huda CNIC No.42201-0506204-1. 4. Mr. Shahab Rizvi S/o Syed Mohsin	1. Mr. Imran Rasheed S/o Abdul Rasheed CNIC No. 37405-9936790-1. 2. Mr. Ziad bin Wasim Chowdhrey S/o Muhammad Wasim Chowdhrey CNIC No. 42000-0519991-5. 3. Mr. Badaruddin fatehali vellani S/o fatehali Wali Muhammad vellani CNIC No. 42301-0918221-7.

Hussain Rizvi CNIC No. 42201-7372422-3	4. Mr. Syed Khalid Noor S/o Syed Muhammad Noor ul huda CNIC No.42201-0506204-1. 5. Mr. Christopher Snook S/o David Patrick Snook Passport No. 507622357.

Case No. 02. <u>CHANGE OF MANAGEMENT OF M/S. ABBOTT LABORATORIES (PAKISTAN) LTD, PLOT NO. 13, SECTOR 20, KORANGI INDUSTRIAL AREA, KARACHI.</u>

M/s. Abbott Laboratories (Pakistan) Ltd, Plot No. 13, Sector 20, Korangi Industrial Area, KArachi under DML No. 000004 (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

Sr. No	Existing Management as per Form 1A (year 2015)	Current Management as per Form 29 (year 2020)
1.	Mr. Ehsan Ali Malik CNIC No. 42301-7554100-1	Mr. Ehsan Ali Malik S/o Ali Mohammed Malik CNIC No. 42301-7554100-1
2.	Mr. Syed Anis Ahmed S/O Qazi Ali ibad CNIC No. 42101-9990908-5	Mr. Syed Anis Ahmed S/O Qazi Ali ibad CNIC No. 42101-9990908-5
3.	Mr. Shamim Ahmad Khan S/O CNIC No. 61101-7006861-7	Ms. Ayla Majid D/O Khalid Majid CNIC No. 37405-2247801-4
4.	Mr. Kamran Yousuf Mirza S/O Yousuf Aziz Mirza CNIC No. 42301-1126838-3	Mr. Muhammad Anjum Latif Rana S/O Rana Muhammad Latif CNIC No. 35201-1678289-7
5.	Shaikh Munir Ahmed Passport NO. USA 488072827	Miss Seema Khan W/O Mateen Ahmad Khan CNIC No. 42501-2987789-0
6.	Mr. Atif Aslam Bajwa	Mr. Mohsin Ali Nathani S/O Ghulam Ali Raheem Nathani CNIC No. 42000-3154946-1
7.	Mr. Arshad Saeed Husain	Shaikh Munir Ahmed Passport NO. USA 488072827

Submitted for consideration of the Board, please.

<u>Decision of the Central Licensing Board in 276th meeting:</u>

The Board considered and endorsed the change of management of M/s Abbott Laboratories (Pakistan) Ltd, Plot No. 13, Sector 20, Korangi Industrial Area, KArachi under DML No. 000004 by way of formulation as under:-

Sr. No	Existing Management as per Form 1A (year 2015)	Current Management as per Form 29 (year 2020)
1.	Mr. Ehsan Ali Malik CNIC No. 42301-7554100-1	Mr. Ehsan Ali Malik S/o Ali Mohammed Malik CNIC No. 42301-7554100-1
2.	Mr. Syed Anis Ahmed S/O Qazi Ali ibad CNIC No. 42101-9990908-5	Mr. Syed Anis Ahmed S/O Qazi Ali ibad CNIC No. 42101-9990908-5
3.	Mr. Shamim Ahmad Khan S/O CNIC No. 61101-7006861-7	Ms. Ayla Majid D/O Khalid Majid CNIC No. 37405-2247801-4
4.	Mr. Kamran Yousuf Mirza S/O Yousuf Aziz Mirza CNIC No. 42301-1126838-3	Mr. Muhammad Anjum Latif Rana S/O Rana Muhammad Latif CNIC No. 35201-1678289-7
5.	Shaikh Munir Ahmed Passport NO. USA 488072827	Miss Seema Khan W/O Mateen Ahmad Khan CNIC No. 42501-2987789-0
6.	Mr. Atif Aslam Bajwa	Mr. Mohsin Ali Nathani S/O Ghulam Ali Raheem Nathani CNIC No. 42000-3154946-1
7.	Mr. Arshad Saeed Husain	Shaikh Munir Ahmed Passport NO. USA 488072827

Case No. 03 . <u>CHANGE OF MANAGEMENT OF M/S. ABBOTT LABORATORIES (PAKISTAN) LTD, OPPOSITE RADIO PAKISTAN TRANSMISSION CENTRE, HYDERABAD ROAD LANDHI, KARACHI.</u>

M/s. Abbott Laboratories (Pakistan) Ltd, opposite radio Pakistan transmission centre Hyderabad road Karachi under DML No. 000001 (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:-

Sr. No	Existing Management as per Form 1A (year 2015)	Current Management as per Form-29(Year 2020)
1.	Mr. Ehsan Ali Malik CNIC No. 42301-7554100-1	Mr. Ehsan Ali Malik S/o Ali Mohammed Malik CNIC No. 42301-7554100-1
2.	Mr. Syed Anis Ahmed S/O Qazi Ali ibad CNIC No. 42101-9990908-5	Mr. Syed Anis Ahmed S/O Qazi Ali ibad CNIC No. 42101-9990908-5
3.	Mr. Shamim Ahmad Khan S/O CNIC No. 61101-7006861-7	Ms. Ayla Majid D/O Khalid Majid CNIC No. 37405-2247801-4
4.	Mr. Kamran Yousuf Mirza S/O Yousuf Aziz Mirza CNIC No. 42301-1126838-3	Mr. Muhammad Anjum Latif Rana S/O Rana Muhammad Latif CNIC No. 35201-1678289-7
5.	Shaikh Munir Ahmed Passport NO. USA 488072827	Miss Seema Khan W/O Mateen Ahmad Khan CNIC No. 42501-2987789-0
6.	Mr. Atif Aslam Bajwa	Mr. Mohsin Ali Nathani S/O Ghulam Ali Raheem Nathani CNIC No. 42000-3154946-1
7.	Mr. Arshad Saeed Husain	Shaikh Munir Ahmed Passport NO. USA 488072827

Submitted for consideration of the board, please.

Decision of the Central Licensing Board in 276th meeting:

The Board considered and endorsed the change of management of M/s Abbott Laboratories (Pakistan) Ltd, opposite radio Pakistan transmission centre Hyderabad road Karachi under DML No. 000001 by way of formulation as under:-

Sr. No	Existing Management as per Form 1A (year 2015)	Current Management as per Form 29 (year 2020)
1.	Mr. Ehsan Ali Malik CNIC No. 42301-7554100-1	Mr. Ehsan Ali Malik S/o Ali Mohammed Malik CNIC No. 42301-7554100-1
2.	Mr. Syed Anis Ahmed S/O Qazi Ali ibad CNIC No. 42101-9990908-5	Mr. Syed Anis Ahmed S/O Qazi Ali ibad CNIC No. 42101-9990908-5
3.	Mr. Shamim Ahmad Khan S/O CNIC No. 61101-7006861-7	Ms. Ayla Majid D/O Khalid Majid CNIC No. 37405-2247801-4
4.	Mr. Kamran Yousuf Mirza S/O Yousuf Aziz Mirza CNIC No. 42301-1126838-3	Mr. Muhammad Anjum Latif Rana S/O Rana Muhammad Latif CNIC No. 35201-1678289-7

5.	Shaikh Munir Ahmed Passport NO. USA 488072827	Miss Seema Khan W/O Mateen Ahmad Khan CNIC No. 42501-2987789-0
6.	Mr. Atif Aslam Bajwa	Mr. Mohsin Ali Nathani S/O Ghulam Ali Raheem Nathani CNIC No. 42000-3154946-1
7.	Mr. Arshad Saeed Husain	Shaikh Munir Ahmed Passport NO. USA 488072827

Case No. 04. <u>CHANGE OF MANAGEMENT OF M/S. ASPIN PHARMA (PVT) LTD, PLOT NO. 10 & 25, KORANGI INDUSTRIAL AREA, KARACHI.</u>

M/s. Aspin Pharma (Pvt) Ltd, Plot No. 10 & 25, Korangi Industrial Area, **<u>Karachi</u>** under DML No. 000045 (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:-

Submitted for consideration of the board, please.

Sr. No	**Existing Management as per Form 1A [(year 2015)**	**New Management as per Form 29 [(year 2020)**
1.	Mr. Tariq Moinuddin Khan S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1	Mr. Tariq Moinuddin Khan S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1
2.	Ms Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2	Ms Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2
3.	Mr. Syed Zeeshan Muhsin	Ms. Nusrat Munshi D/o Alauddin Munshi CNIC NO. 42301-7644816-8
4.	********	Mr. Muhammad Kamran Mirza S/o Mr. Muhammad Jamil Mirza CNIC No. 42301-9154917-3
5.	********	Mr. Muhammad Arsalan Batla S/o Muhammad Younus Batla CNIC No. 42201-7571901-7

<u>Decision of the Central Licensing Board in 276th meeting:</u>

The Board considered and endorsed the change of management of M/s Aspin Pharma (Pvt) Ltd, Plot No. 10 & 25, Korangi Industrial Area, **<u>Karachi</u>** under DML No. 000045 by way of formulation as under:-

Sr. No	Existing Management as per Form 1A [(year 2015)	New Management as per Form 29 [(year 2020)
1.	Mr. Tariq Moinuddin Khan S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1	Mr. Tariq Moinuddin Khan S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1
2.	Ms Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2	Ms Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2
3.	Mr. Syed Zeeshan Muhsin	Ms. Nusrat Munshi D/o Alauddin Munshi CNIC NO. 42301-7644816-8
4.	********	Mr. Muhammad Kamran Mirza S/o Mr. Muhammad Jamil Mirza CNIC No. 42301-9154917-3
5.	********	Mr. Muhammad Arsalan Batla S/o Muhammad Younus Batla CNIC No. 42201-7571901-7

CASE NO. 05 **CHANGE OF MANAGEMENT OF M/S ICI PAKISTAN LIMITED LIFE SCIENCES, LAHORE.**

M/s ICI Pakistan Limited Life Sciences, 45-Km, Off Multan Road, Lahore under DML No. 000811 by way of Formulation has submitted request for change in management of the firm as per Form-29with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management as Form-A	Current Management as per Form-29
1. Mr. Muhammad Ali Tabba S/o Abdul Razak Tabba CNIC No.42201-6464247-3. 2. Mr. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No.42000-0568372-5. 3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No.42201-5355492-7. 4. Mr. Yunus TabbaCNIC No. 42301-3534123-	1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No.42301-3175078-7. 2. Mr. Muhammad Ali Tabba S/o Abdul Razak Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba S/o Muhammad Younus TabbaCNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No.42201-5355492-7.

9. 5. Ms. Amina Abdul Aziz Bawany W/o Abdul Aziz Bawany CNIC No. 42000-3004991-0. 6. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No. 42301-8986425-7. 7. Mr. Ali Asrar Hussain Aga CNIC No. 35201-1528414-3.	5. Mr. Jawed Yunus Tabba S/o Muhammad Yunus CNIC No. 42201-2111104-7. 6. Ms. Amina Abdul Aziz Bawany W/o Abdul Aziz BawanyCNIC No. 42000-3004991-0. 7. Mr. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No. 42301-8986425-7. 8. Mr. Syed Muhammad Shabbar Zaidi S/o Syed Muhammad Tehwar Zaidi CNIC No. 42301-1401852-5.

Decision of the Central Licensing Board in 276th meeting:

The Board considered and endorsed the change of management of M/s ICI Pakistan Limited Life Sciences, 45-Km, Off Multan Road, Lahoreunder DML No. 000811 by way of Formulation as under:-

Previous Management as Form-A	New Management as per Form-29
1. Mr. Muhammad Ali Tabba S/o Abdul Razak Tabba CNIC No.42201-6464247-3. 2. Mr. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No.42000-0568372-5. 3. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No.42201-5355492-7. 4. Mr. Yunus TabbaCNIC No. 42301-3534123-9. 5. Ms. Amina Abdul Aziz Bawany W/o Abdul Aziz Bawany CNIC No. 42000-3004991-0. 6. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No. 42301-8986425-7. 7. Mr. Ali Asrar Hussain Aga CNIC No. 35201-1528414-3.	1. Mr. Asif Jooma S/o Omar Valli Jooma CNIC No.42301-3175078-7. 2. Mr. Muhammad Ali Tabba S/o Abdul Razak Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba S/o Muhammad Younus TabbaCNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No.42201-5355492-7. 5. Mr. Jawed Yunus Tabba S/o Muhammad Yunus CNIC No. 42201-2111104-7. 6. Ms. Amina Abdul Aziz Bawany W/o Abdul Aziz BawanyCNIC No. 42000-3004991-0. 7. Mr. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No. 42301-8986425-7. 8. Mr. Syed Muhammad Shabbar Zaidi S/o Syed Muhammad Tehwar Zaidi CNIC No. 42301-1401852-5.

CASE NO.06 CHANGE OF MANAGEMENT OF M/S IZFAAR PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Izfaar Pharmaceuticals (Pvt) Ltd, 542/A&B, Sunder Industrial Estate, Lahore under DML No. 000800 by way of Formulation has submitted request for change in management of the firm as per Form-Awith prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	Current Management as per Form-A
1. Mr. Muhammad Israr Hussain Malik S/o Mr. Iqbal Hussain Khan CNIC No. 35202-2257887-3. 2. Mr. Hafiz Mohammad Yousaf S/o Mr. Mohammad Amin CNIC No. 35202-2957078-9.	1. Mr. Muhammad Israr Hussain Malik S/o Mr. Iqbal Hussain Khan CNIC No. 35202-2257887-3. 2. Mr. Hafiz Mohammad Yousaf S/o Mr. Mohammad Amin CNIC No. 35202-2957078-9. 3. Mr. Muhammad Amir S/o Muhammad Ahsan-ul-Haq CNIC No. 35202-2313048-1. 4. Mr. Muhammad Anwar S/o Ch. Tufail Hussain CNIC No. 33100-2588383-9.

Decision of the Central Licensing Board in 276th meeting:

The Board considered and endorsed the change of management of M/s Izfaar Pharmaceuticals (Pvt) Ltd, 542/A&B, Sunder Industrial Estate, Lahore under DML No. 000800 by way of Formulation as under:-

Previous Management	New Management as per Form-A
1. Mr. Muhammad Israr Hussain Malik S/o Mr. Iqbal Hussain Khan CNIC No. 35202-2257887-3. 2. Mr. Hafiz Mohammad Yousaf S/o Mr. Mohammad Amin CNIC No. 35202-2957078-9.	1. Mr. Muhammad Israr Hussain Malik S/o Mr. Iqbal Hussain Khan CNIC No. 35202-2257887-3. 2. Mr. Hafiz Mohammad Yousaf S/o Mr. Mohammad Amin CNIC No. 35202-2957078-9. 3. Mr. Muhammad Amir S/o Muhammad Ahsan-ul-Haq CNIC No. 35202-2313048-1. 4. Mr. Muhammad Anwar S/o Ch. Tufail Hussain CNIC No. 33100-2588383-9.

CASE NO. 07CHANGE OF MANAGEMENT OF M/S CCL PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s CCL Pharmaceuticals (Pvt) Ltd, 62- Industrial Estate, Kot Lakhpat Lahore under DML No. 000052 by way of formulation has submitted request for change in management of the firm as per Form-A& Form-29with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	Current Management as per Form-A& Form-29
1. Kashif Sajjad Sheikh CNIC: 35201-8114696-9. 2. Hassan Zubair CNIC: 35201-1670274-7. 3. Asim Dilwar Sheikh CNIC: 35201-1739536-5. 4. Nadeem B.J. SheikhCNIC: 35201-1492726-3.	1. Mr. Shahzad Khan S/o Shahbaz Ahmad Khan CNIC No. 35202-3335871-1. 2. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7. 3. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9. 4. Mr.Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 5. Mr. Nadeem B.J Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3.

Decision of the Central Licensing Board in 276th meeting:

The Board considered and endorsed the change of management of M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat Lahore under DML No. 000052 by way of Formulationas under:-

Previous Management	New Management as per Form-A& Form-29
1. Kashif Sajjad SheikhCNIC: 35201-8114696-9. 2. Hassan ZubairCNIC: 35201-1670274-7. 3. Asim Dilwar SheikhCNIC: 35201-1739536-5. 4. Nadeem B.J. SheikhCNIC: 35201-1492726-3.	1. Mr. Shahzad Khan S/o Shahbaz Ahmad Khan CNIC No. 35202-3335871-1. 2. Mr. Hassan Zubair Sheikh S/o S.M Zubair CNIC No. 35201-1670274-7. 3. Mr. Kashif Sajjad Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-8114696-9. 4. Mr.Asim Dilawar Sheikh S/o Sajjad Hussain Sheikh CNIC No. 35201-1739536-5. 5. Mr. Nadeem B.J Sheikh S/o Javaid Sheikh CNIC No.35201-1492726-3.

CASE NO. 08 CHANGE OF MANAGEMENT OF M/S AURIK PHARMACEUTICALS, RAWAT.

M/s Aurik Pharmaceuticals, Plot No. 6&7, Street No. S-9, National Industrial Zone, RCCI, Rawat under DML No. 000802 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-1	Current Management as per Partnership Deed
1. Mr. Muhammad Azam S/o Haji Muhammad Yaqoob CNIC No. 61101-6487873-1.	1. Mr. Muhammad Azam S/o Haji Muhammad Yaqoob CNIC No. 61101-6487873-1. 2. Mr. Naqeeb ur Rehman S/o Muhammad Akram CNIC No. 54400-6844853-1. 3. Mr. Saidal Khan Tareen S/o Saleh Muhammad CNIC No. 51602-5407767-7. 4. Mr.Anwar Adil Kakar S/o Malik Syed Muhammad CNIC No. 54400-9696035-7.

Decision of the Central Licensing Board in 276th meeting:

The Board considered and endorsed the change of management of M/s Aurik Pharmaceuticals, Plot No. 6&7, Street No. S-9, National Industrial Zone, RCCI, Rawat under DML No. 000802 by way of Formulation as under:-

Previous Management as per Form-1	New Management as per Partnership Deed
1. Mr. Muhammad Azam S/o Haji Muhammad Yaqoob CNIC No. 61101-6487873-1.	1. Mr. Muhammad Azam S/o Haji Muhammad Yaqoob CNIC No. 61101-6487873-1. 2. Mr. Naqeeb ur Rehman S/o Muhammad Akram CNIC No. 54400-6844853-1. 3. Mr. Saidal Khan Tareen S/o Saleh Muhammad CNIC No. 51602-5407767-7. 4. Mr.Anwar Adil Kakar S/o Malik Syed Muhammad CNIC No. 54400-9696035-7.

CASE NO. 09 CHANGE OF MANAGEMENT OF M/S GILLMAN PHARMACEUTICALS, 41/2-A, PHASE-I&II, INDUSTRIAL ESTATE, HATTAR.

M/s Gillman Pharmaceuticals, 41/2-A, Phase-I&II, Industrial Estate, under DML No. 000683 by way of formulation has submitted request for change in management of the firm as per Partnership deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management as per Partnership Deed	New management as per Partnership Deed
1. Syed Muhammad Amir Shah S/o /Syed Muhammad Shah Bukhari, CNIC. No. 17301-1366931-7 2. Mr. Muhammad Abdullah S/o Asmat Ullah, CNIC. No. 61101-2008129-5	1. Mr. Hussain Ahmad S/o Rooh Ul Amin, CNIC No.16101-7091314-7 2. Zahid Umar S/o Umar Gul Khan, CNIC No.16101-4919535-1.

Decision of the Central Licensing Board in 276th meeting:

The Board considered and endorsed the change of management of M/s Gillman Pharmaceuticals, 41/2-A, Phase-I&II, Industrial Estate, under DML No. 000683 by way of formulation as under ;

Previous management as per Partnership Deed	New management as per Partnership Deed
3. Syed Muhammad Amir Shah S/o /Syed Muhammad Shah Bukhari, CNIC. No. 17301-1366931-7 4. Mr. Muhammad Abdullah S/o Asmat Ullah, CNIC. No. 61101-2008129-5	3. Mr. Hussain Ahmad S/o Rooh Ul Amin, CNIC No.16101-7091314-7 4. Zahid Umar S/o Umar Gul Khan, CNIC No.16101-4919535-1.

CASE NO.10 CHANGE OF MANAGEMENT OF M/S MEDIZAN LABORATORIES (PVT) LTD., PLOT NO.313, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

M/s Medizan Laboratories (Pvt) Ltd., Plot No.313, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000572 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 SECP dated 31-10-2014	Current Management as per Form-29 SECP dated 01-11-2016
1. Mr. Naveed Akbar Tanvir S/o Mohammad Akbar, CNIC No.33303-7187839-5. 2. Syed Mohammad Ali S/o Syed Akhtar Ali, CNIC No.37405-0340658-1. 3. Mrs. Shabana Zaherr Khan S/o Pervaiz Khan,	1. Mr. Ansar Farooq S/o Muzamal Hussain, CNIC No.37405-1956534-9. 2. Mr. Qasim Farooq S/o Ansar Farooq, CNIC No.37405-5587025-9. 3. Mr. Arif Jan S/o Mohammad Jan Khan,

CNIC No.920080-102618-0.	CNIC No.17301-7652042-3.

Decision of the Central Licensing Board in 276th meeting:

The Board considered and endorsed the change of management ofM/s Medizan Laboratories (Pvt) Ltd., Plot No.313, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000572 by way of formulation as under;

Previous Management as per Form-29 SECP dated 31-10-2014	Current Management as per Form-29 SECP dated 01-11-2016
1. Mr. Naveed Akbar Tanvir S/o Mohammad Akbar, CNIC No.33303-7187839-5. 2. Syed Mohammad Ali S/o Syed Akhtar Ali, CNIC No.37405-0340658-1. 3. Mrs. Shabana Zaherr Khan S/o Pervaiz Khan, CNIC No.920080-102618-0.	1. Mr. Ansar Farooq S/o Muzamal Hussain, CNIC No.37405-1956534-9. 2. Mr. Qasim Farooq S/o Ansar Farooq, CNIC No.37405-5587025-9. 3. Mr. Arif Jan S/o Mohammad Jan Khan, CNIC No.17301-7652042-3.

CASE NO.11 CHANGE OF MANAGEMENT OF M/S. FEROZSONS LABORATORIES LTD., AMANGARH, NOWSHERA.

M/s. Ferozsons Laboratories Ltd., Amangarh, Nowshera, under DML No. 000038 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 SECP	New management as per Form-A & Form-29 SECP
1. Mrs. Akhter Khalid Waheed W/o Late Mr. Khalid Waheed, CNIC. No. 37405-0348706-0 2. Mr. Osman Khalid Waheed S/o Mr. Khalid Waheed, CNIC. No. 37405-0384955-7 3. Mrs. Amna Paracha Khan W/o Mr. Saleem Zulfiqar Khan, CNIC. No. 61101-7905821-6 4. Mrs. Munize Azhar Pirahca W/o Mr. Azhar Mahmood Piracha	1. Mrs. Akhter Khalid Waheed W/o Late Mr. Khalid Waheed, CNIC. No. 37405-0348706-0 2. Mr. Osman Khalid Waheed S/o Mr. Khalid Waheed, CNIC. No. 37405-0384955-7 3. Mrs. Amna Paracha Khan W/o Mr. Saleem Zulfiqar Khan, CNIC. No. 61101-7905821-6 4. Mrs. Munize Azhar Pirahca W/o Mr. Azhar Mahmood Piracha

CNIC No. 35202-2778956-0 5. Mr. Nihal Cassim S/o Firozuddin Cassim, CNIC. No.42301-8289704-9 6. Mr. Shahid Anwar S/o Mr. Abdul Rehman Farooqui CNIC No. 42201-0442011-5 7. Mr. Farooq Mazhar S/o Mr. Mazhar ul Haq, CNIC No.42301-1068186-9	CNIC No. 35202-2778956-0 5. Mr. Nihal Cassim S/o Firozuddin Cassim, CNIC No.42301-8289704-9 6. Mr. Shahid Anwar S/o Mr. Abdul Rehman Farooqui CNIC No. 42201-0442011-5 7. Mr. Arshad Saeed Husain S/o Mian Shahid Husain, CNIC No. 42000-0504011-9

Decision of the Central Licensing Board in 276th meeting:

The Board considered and endorsed the change of management ofM/s. Ferozsons Laboratories Ltd., Amangarh, Nowshera, under DML No. 000038 by way of formulation as under;

Previous management as per Form-29 SECP	**New management as per Form-A & Form-29 SECP**
1. Mrs. Akhter Khalid Waheed W/o Late Mr. Khalid Waheed, CNIC. No. 37405-0348706-0 2. Mr. Osman Khalid Waheed S/o Mr. Khalid Waheed, CNIC. No. 37405-0384955-7 3. Mrs. Amna Paracha Khan W/o Mr. Saleem Zulfiqar Khan, CNIC. No. 61101-7905821-6 4. Mrs. Munize Azhar Pirahca W/o Mr. Azhar Mahmood Piracha CNIC No. 35202-2778956-0 5. Mr. Nihal Cassim S/o Firozuddin Cassim, CNIC. No.42301-8289704-9 6. Mr. Shahid Anwar S/o Mr. Abdul Rehman Farooqui CNIC No. 42201-0442011-5 7. Mr. Farooq Mazhar S/o Mr. Mazhar ul Haq, CNIC No.42301-1068186-9	1. Mrs. Akhter Khalid Waheed W/o Late Mr. Khalid Waheed, CNIC. No. 37405-0348706-0 2. Mr. Osman Khalid Waheed S/o Mr. Khalid Waheed, CNIC. No. 37405-0384955-7 3. Mrs. Amna Paracha Khan W/o Mr. Saleem Zulfiqar Khan, CNIC. No. 61101-7905821-6 4. Mrs. Munize Azhar Pirahca W/o Mr. Azhar Mahmood Piracha CNIC No. 35202-2778956-0 5. Mr. Nihal Cassim S/o Firozuddin Cassim, CNIC No.42301-8289704-9 6. Mr. Shahid Anwar S/o Mr. Abdul Rehman Farooqui CNIC No. 42201-0442011-5 7. Mr. Arshad Saeed Husain S/o Mian Shahid Husain, CNIC No. 42000-0504011-9

CASE NO. 12 CHANGE OF MANAGEMENT OF M/S ICI PAKISTAN LTD., [CIRIN PHARMACEUTICALS (PVT) LTD] 32/2A, PHASE III, INDUSTRIAL ESTATE, HATTAR.

M/s ICI Pakistan Ltd., (Formerly M/s Cirin Pharmaceuticals (Pvt) Ltd.), 32/2A, Phase-III, Industrial Estate, Hattar under DML No. 000363 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 of S.E.C.P.	New management as per Form-A & Form-29 of S.E.C.P.
1. Mr. Asif Jooma CNIC No.42301-3175078-7. 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Kamal A Chinoy CNIC No. 42301-1401852-5. 6. Mr. Jawed Yunus Tabba CNIC No. 42201-21111104-7. 7. Amina Abdul Aziz Bawany CNIC No. 42000-3004991-0. 8. Khawaja Iqbal Hassan CNIC No. 42301-8986425-7.	1. Mr. Asif Jooma CNIC No.42301-3175078-7. 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Jawed Yunus Tabba CNIC No. 42201-21111104-7. 6. Amina Abdul Aziz Bawany CNIC No. 42000-3004991-0. 7. Khawaja Iqbal Hassan CNIC No. 42301-8986425-7. 8. Syed Muhammad Shabr Zaidi CNIC No 42301-1740521-7

Decision of the Central Licensing Board in 276th meeting:

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

Previous management as per Form-29 of S.E.C.P.	New management as per Form-A & Form-29 of S.E.C.P.
1. Mr. Asif Jooma CNIC No.42301-3175078-7. 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Kamal A Chinoy CNIC No. 42301-1401852-5. 6. Mr. Jawed Yunus Tabba CNIC No. 42201-	1. Mr. Asif Jooma CNIC No.42301-3175078-7. 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Jawed Yunus Tabba CNIC No. 42201-21111104-7.

21111104-7. 7. Amina Abdul Aziz Bawany CNIC No. 42000-3004991-0. 8. Khawaja Iqbal Hassan CNIC No. 42301-8986425-7.	6. Amina Abdul Aziz Bawany CNIC No. 42000-3004991-0. 7. Khawaja Iqbal Hassan CNIC No. 42301-8986425-7. 8. Syed Muhammad Shabr Zaidi CNIC No 42301-1740521-7

CASE NO.13 <u>CHANGE OF MANAGEMENT OF M/S GLAXOSMITHKLINE PAKISTAN LIMITIED, KARACHI.</u>

M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road west wharf Karachiunder DML No. 000017 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management as per Form-1A Year 2015	New Management as per Form-29 Year 2020
1. Mr. Salman Burney 2. Mr. Yahya Zakaria 3. Mr. Mehmood Mandviwalla 4. Mr. Hussain Lawai 5. Mr. Renaud Savary 6. Ms. Fariha Salahuddin 7. Mr. Dave Cooper	1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3. 2. Mr. Dmytro Olinyk , Passport No. PU 125808. 3. Mr. Mark Robert Dawson, Passport No. 761323952. 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf Jee Mandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.

<u>Decision of the Central Licensing Board in 276th meeting:</u>

The Board considered and endorsed the change of management ofM/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road west wharf Karachi under DML No. 000017 by way of formulation as under;

Previous Management as per Form-1A Year 2015	New Management as per Form-29 Year 2020 (
1. Mr. Salman Burney 2. Mr. Yahya Zakaria 3. Mr. Mehmood Mandviwalla 4. Mr. Hussain Lawai	1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3. 2. Mr. Dmytro Olinyk , Passport No. PU 125808.

5. Mr. Renaud Savary 6. Ms. Fariha Salahuddin 7. Mr. Dave Cooper	3. Mr. Mark Robert Dawson, Passport No. 761323952. 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf Jee Mandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.

CASE NO.14 <u>CHANGE OF MANAGEMENT OF M/S GLAXOSMITHKLINE PAKISTAN LIMITIED, KARACHI.</u>

M/s GlaxoSmithKline Pakistan Limited, Plot No. 05, Sector-21, Korangi Industrial Area, Karachi under DML No. 000248 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management as per Form-1A Year 2015	New Management as per Form-29 Year 2020 (
1. Mr. Hussain Lawai 2. Mr. M Aziz ul Haq 3. Mr. Mehmood Mandviwalla 4. Mr. Abdul Samad 5. Mr. Dylan Jackson 6. Mr. Nicolas Ragot 7. Mr. Syed Abbas Naqvi.	1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3. 2. Mr. Dmytro Olinyk , Passport No. PU 125808. 3. Mr. Mark Robert Dawson, Passport No. 761323952. 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf Jee Mandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.

<u>Case is submitted for consideration and orders of the Board please.</u>

<u>Decision of the Central Licensing Board in 276th meeting:</u>

The Board considered and endorsed the change of management of M/s GlaxoSmithKline Pakistan Limited, Plot No. 05, Sector-21, Korangi Industrial Area, Karachi under DML No. 000248 by way of formulation as under;

Previous Management as per Form-1A Year 2015	New Management as per Form-29 Year 2020
1. Mr. Hussain Lawai 2. Mr. M Aziz ul Haq 3. Mr. Mehmood Mandviwalla 4. Mr. Abdul Samad 5. Mr. Dylan Jackson 6. Mr. Nicolas Ragot 7. Mr. Syed Abbas Naqvi.	1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3. 2. Mr. Dmytro Olinyk , Passport No. PU 125808. 3. Mr. Mark Robert Dawson, Passport No. 761323952. 4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf Jee Mandviwala CNIC No. 42301-2010228-1. 5. Ms. Erum Shakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0. 6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6. 7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7.

CASE NO. 15 **CORRECTION IN CHANGE OF MANAGEMENT OF M/S HARMANN PHARMACEUTICAL LABORATORIES (PVT) LTD, LAHORE.**

M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, P.O Chung, 16-Km, Multan Road, Lahore under DML No. 000145 by way of formulation has submitted request for change in management of the firm as per Form-A with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	New Management
1. Mr. Muhammad Haseeb Khan. 2. Mst. Roshi Asif. 3. Mst. Abida Begum. 4. Mst. Uzma Mamon.	1. Mr. Muhammad Haseeb Khan S/o Mian Karm Elahi CNIC No. 35202-9014907-5. 2. Mr. Muhammad Hafeez Khan S/o Mian Karm Elahi CNIC No. 35202-8478971-5. 3. Mr. Muhammad Tahir Khan S/o Muhammad Hafeeb Khan CNIC No. 35202-4615722-5. 4. Mrs. Abida Begum W/o Dr. Muhammad Hafeez Khan CNIC No. 35202-4047487-0.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore under DML No. 000537 by way of formulationas under ;

Previous Management	New Management
1. Mr. Muhammad Haseeb Khan. 2. Mst. Roshi Asif. 3. Mst. Abida Begum. 4. Mst. Uzma Mamon.	1. Mr. Muhammad Haseeb Khan S/o Mian Karm Elahi CNIC No. 35202-9014907-5. 2. Mr. Muhammad Hafeez Khan S/o Mian Karm Elahi CNIC No. 35202-8478971-5. 3. Mr. Muhammad Tahir Khan S/o Muhammad Hafeeb Khan CNIC No. 35202-4615722-5. 4. Mrs. Abida Begum W/o Dr. Muhammad Hafeez Khan CNIC No. 35202-4047487-0.

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

It is pertinent to mention here that in the minutes of 275th meeting of CLB, the name of Directors name was mistakenly written as Mr. Muhammad Haseeb Khan S/o Mian Karm Elahiand Mr. Muhammad Tahir Khan S/o Muhammad Hafeeb Khan instead of Mr. Muhammad Haseeb Khan S/o Muhammad Hafeez Khan and Mr. Muhammad Tahir Khan S/o Muhammad Hafeez Khan and in the decision name of the firm was mistakenly written as Mega Pharmaceuticals.

Decision of the Central Licensing Board in 276th meeting:

The Board considered and endorsed the change of management of M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, P.O Chung, 16-Km, Multan Road, Lahore under DML No. 000145 by way of Formulation as under:-

Previous Management	New Management
1. Mr. Muhammad Haseeb Khan. 2. Mst. Roshi Asif. 3. Mst. Abida Begum. 4. Mst. Uzma Mamon.	1. Mr. Mr. Muhammad Haseeb Khan S/o Muhammad Hafeez Khan CNIC No. 35202-9014907-5. 2. Mr. Muhammad Hafeez Khan S/o Mian Karm Elahi CNIC No. 35202-8478971-5. 3. Mr. Mr. Muhammad Tahir Khan S/o Muhammad Hafeez Khan CNIC No. 35202-4615722-5. 4. Mrs. Abida Begum W/o Dr. Muhammad Hafeez Khan CNIC No. 35202-4047487-0.

Case No. 16 **CORRECTION IN CHANGE OF MANAGEMENT OF M/S PHARMATEC (PAKISTAN) LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000024 (FORMULATION)**

The Central Licensing Board in its 273rd meeting held on 15th Januaury 2020 considered and endorsed the change of mangement of M/S Pharmatec Pakistan (Private) Limited, D-86/A, SITE, Karachi under DML No. 000024 By way of Formulation as under;

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

In the agenda and subsequently in the minutes of the 273rd meeting of the CLB the name and CNIC No. of Ms. Shahida Qaiser was in correctly written asW/o Qazi Qamar Uddin CNIC No. 42201-0704198-1 while the correct name and CNIC is Dr. Shahida Qaisar W/o Qaiser Hussain Siraj CNIC No. 42301-7825489-4.. The detail of the correct management is as under :

Existing Management as per Form 29 (year 2016)	**New Management as per Form 29 (year 2019)**
1. **Dr. Shahida Qaisar W/o Qaiser Hussain Siraj CNIC No. 42301-7825489-4.** 2.Mr. Pervez Hayat Noon	1 **Dr. Shahida Qaisar W/o Qaiser Hussain Siraj CNIC No. 42301-7825489-4.** 2. Mr. Qazi Zia Uddin S/O Mr. Qazi Qamar Uddin CNIC No. 42201-0704198-1

Decision of the Central Licensing Board in 276th meeting:

The Board considered and endorsed the coorection in change of management of M/s Pharmatec Pakistan (Private) Limited, D-86/A, SITE, Karachi under DML No. 000024 by way of formulation as under;

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

1. **Dr. Shahida Qaisar W/o Qaiser Hussain Siraj** **CNIC No. 42301-7825489-4.** 2.Mr. Pervez Hayat Noon	1 **Dr. Shahida Qaisar W/o Qaiser Hussain Siraj** **CNIC No. 42301-7825489-4.** 2. Mr. Qazi Zia Uddin S/O Mr. Qazi Qamar Uddin CNIC No. 42201-0704198-1

Case No. 17. **RENEWAL OF DRUG MANUFACTURING LICENCE AND REGULARIZATION OF M/S STANDPHARM PAKISTAN (PVT) LTD, 20-KM, FEROZEPUR ROAD, LAHORE.**

DRAP, Lahore submitted a corrigendum in continuation of their letter No.6943/2020-DRAP (L-V), dated 8th June, 2020 for Renewal of Drug Manufacturing License No. 000051 by way (Formulation) and Regularization of approved layout plan of M/s Standpharm Pakistan (Pvt) Ltd, 20-KM, Ferozepur Road, Lahore. He is informed that the recommendation in the inspection report of M/s Standpharm Pakistan (Pvt) Ltd, 20-KM, Ferozepur Road, Lahore may please be read as under:-

M/s Standpharm Pakistan (Pvt) Ltd, 20-KM, Ferozepur Road, Lahore DML No.000051 (Formulation). **Period**: 08-09-2019 to 07-09-2024	18-02-2020	**Good**	1. Dr. Farzana Chowdhary, Expert Member. 2. Dr. Munawar Hayat, Chief Drug Controller, Punjab, Lahore. 3. Mr. Shoaib Ahmed, FID, DRAP, Lahore.

Recommendations of the panel: -

"The panel of inspectors recommends the renewal and regularization of approved layout plan of M/s Standpharm Pakistan (Pvt) Ltd, 20-KM Ferozepur Road, Lahore located at 20-KM, Ferozepur Road, Lahore located at 20-KM Ferozepur Road, bearing DML No. 000051(Formulation) of following approved sections:-

1. Tablet (General).
2. Tablet General (Antibiotics).
3. Tablet Psychotropic.
4. Liquid Syrup General.
5. Sachet (General).
6. QC Laboratories.
7. Oral Dry Powder Suspension Antibiotics.
8. Injectable Liquid Ampoule (General).
9. Injectable Liquid Infusion (General).
10. Capsule General.
11. Dry Powder Injection Cephalosporin.
12. Oral Dry Powder Suspension Cephalosporin.
13. Capsule Cephalosporin.
14. Tablets (Cephalosporin).

15. Warehouse.

Decision of the Central Licensing Board in 276th meeting

The Board considered and approved the grant of additional sections and regularization of existing sections / facilities in the name of M/s Standpharm Pakistan (Pvt) Ltd as under:

1. Tablet (General).
2. Tablet General (Antibiotics).
3. Tablet Psychotropic.
4. Liquid Syrup General.
5. Sachet (General).
6. QC Laboratories.
7. Oral Dry Powder Suspension Antibiotics.
8. Injectable Liquid Ampoule (General).
9. Injectable Liquid Infusion (General).
10. Capsule General.
11. Dry Powder Injection Cephalosporin.
12. Oral Dry Powder Suspension Cephalosporin.
13. Capsule Cephalosporin.
14. Tablets (Cephalosporin).
15. Warehouse.

Case No. 18. 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.

i. Application on Prescribed Form 1A dully signed by current management of the firm.
ii. Original Certified True Copy of Form-29 & Form-A (Updated) issued by SECP.
iii. 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.

Case No. 19. WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTION BY M/S MAPLE PHARMACEUTICALS (PVT) LTD KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000620(FORMULATION)

M/s. Maple Pharmaceuticals (Pvt) Ltd, Plot No. 147, Sector 23, Korangi Industrial Area, **Karachi** under DML No. 000620 (By way of formulation) has submitted request withdraw of license Dry Powder Suspension (General) Section at the time of submitting layout plan for regularization of manufacturing facility.

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

The Board considered and acceded the request fo the firm for withdraw of license Dry Powder Suspension(General) Section.

Case No. 20. **WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTION BY M/S PHARMATEC (PAKISTAN) LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000024 (FORMULATION)**

M/s Pharmatec Pakistan (Pvt) Ltd, Plot No. D-81, S.I.T.E, Karachi Industrial Area, Karachi under DML No. 000024 (By way of formulation)has submitted request for withdrawal of licensed section namely Ointment/Cream/Gel (General) Section.

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

The Board considered and acceded the request for the firm for withdraw of licensed section namely Ointment/Cream/Gel (General) Section.

Case No. 21 **COMPLAINT UNDER SECTION 30 OF THE DRAP ACT,2012 READ WITH OTHER ENABLING PROVISIONS OF THE LAW FOR THE SALE OF MISBRANDED PRODUCTS UNDER THE TRADEMARK /TRADE NAME BAXTER BY BAXTER PHARMACEUTICALS, KARACHI.**

A letter was received from Ali & Associates, Advocate & Legal consultants Trademark & copyright Attorneys, Karachi wherein they had stated that Honorable High court has restrained the said party from using the mark BAXTER in any matter whatsoever. They have further requested to cancel their drug registrations and/or direct the infringers to change their infringing name with immediate effect. Legal opinion of the Legal Affairs, Division DRAP was sought on the subject matter and opinion of the Legal Affairs, Division DRAP is REPRODUCED AS below:

"As per record "BAXTER'' is a registered trademark of M/s Baxter International. Inc a multinational pharmaceutical company headquartered in Illinois, USA. Another company M/s Baxter Pharmaceuticals Ltd, Karachi is operating under the name and style of Baxter" and has also acquired DML No. 000700 (Formulation) from DRAP. The deceptively similar mark is being used in the same classification of goods as well as in the same industry as that of M/s Baxter International. Inc, USA. A representation of the mark used by both entities is given below:

M/s Baxter International. Inc, also filed suit NO. 2010 of 2017 in the High court of Sindh, Karachi and obtained restraining order dated 150.902017 against M/s Baxter Pharmaceuticals Ltd, Karachi and M/s Arafat Traders, Karachi.

Section 3(s) (iv) of the Drugs Act, 1976 provides that "misbranded drug'' means a drug the label or container of which or anything accompanying which bears any statement design or device which makes any false claim for the drug or which is false or misleading in any particular. Manufacturing for sale or selling any misbranded drugs comes under the prohibitions contained in section 23 of the Drugs Act,1976 read with Schedule –II of the DRAP Act, 2012 which is punishable offence under section 27 of the Drugs Act, 1976 read with Schedule-III of the DRAP Act,2012.

Forgoing in view, the matter may be placed before the CLB for appropriate directions which may include issuance of show cause Notice to M/s Baxter Pharmaceuticals Ltd, Karachi for carrying out business under the name and style of 'BAXTER' .

The orders of the Honor'able High Court of Sindh at Karachi in the suit No. 2010 of 2017 M/s Baxter International Inc veruses M/s Baxter Pharmaceuticals (Respondent No. 1), M/s Arafat Traders (Respondent No. 2) & Mr. DRAP (Respondent No. 3) are reproduced as below : .

"It is inter alia contended that the plaintiff is a company incorporated under the laws of State of Delaware (USA) and this suit has been filed through their attorney. The Plaintiff develops, manufactures and markets products to cater the needs of patients dealing with various illnesses such as immune disorders, kidney failure or disease, trauma, infectious diseases as well as other chronic and acute medical conditions. In paragraph 14 of the plaint the plaintiff has mentioned the worldwide registration of their trademarked at least in 40 countries. The learned counsel argued that the defendant No. 2 has started business under the name and style of "Baxter Pharmaceuticals" and also hosting a website with same company profile. He has also published advertisement through their website for inviting applications for employment. The website details and advertisement is available on record. The learned consulfurther argued that the trademark and or business name which is being used by the defendant Nos. 1 and 2 is identical with the trademark of the plaintiff in relation to the pharmaceuticalproducts and it is also deceptively similar in relation to the plaintiff trademark which is a sheer infringement and there exists likelihood of confusion and deception to the general public. Let notice be issued to the defendants as well as D.A.G for 21.09.2017. Tillnext date of hearing the defendant Nos. 1 and 2 are restrained from using or operating their business under the trademark "Baxter"

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

The Board considered the case and decided to seek afresh status of the case from DRAP, Kararchi for the Central Licensing Board including the stay order of the court where after Board will proceed accordingly.

Case No. 22.RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S. KALIGON AGRO INDUSTRIES (PVT) LTD, BALUCHISTAN

1	M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Hub Chowki Road (RCD), Lasbella, Baluchistan DML No. 000277 (Formulation) **Period**: 11.02.2016 to 10.02.2021	**20.12.2018**	**Good**	i.Dr. Ghulam Sarwar Member DRB. ii. Additional Director (E&M), DRAP, Karachi. iii. Area Federal Inspector of Drugs, DRAP, Karachi.

Recommendations of the panel: -

M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Tehsil Hub, Lasbella, Baluchistan was inspected by the panel members in compliance to DRAP's letter No. F.4-3/86-Lic (Vol-II) dated 31st October, 2018. The panel reviewed their overall documentation, inspected Manufacturing Facility, Quality Control Lab & Store and met with their technical persons. Following are the observations:

1. *The panel observed the premises constructed as per DRAP's* ***approved*** *LoP.*
2. ***As per record, at the time of grant of license. M/s Kaligon Agro Industries was situated at industrial area under Hub industrial Trading Estate (HITE), however at present, M/s. Kailgon Agro Industries is not covered under the said industrial estate i.e. HITE. However, the management of firm is planning to shift the facility from current site to another suitable site and submitted the affidavit*** *(enclosed as Annex-E).*
3. *An appropriate level of sanitation, cleanliness & workers hygiene was noted.*
4. *Personnel met during inspection were observed having prescribed qualification and experience and were well conversant regarding GMP compliance.*
5. *Basic equipment required for tests/analysis of the registered products seen in place and in operational condition.*

Based on the stated observations, the panel recommends the grant of renewal of their

DML no. 000277 By way of Formulation (subject to approval of location of the facility by the Central Licensing Board) for following sections, for the next five years.

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

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

Decision by the Central Licensing Board in 270th meeting

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

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

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

Decision by the Central Licensing Board in 270th meeting

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

decision by CLB .

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

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

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

No person appeared on behalf of the firm the Board decided to seek clarification from the Federal Inspector of Drugs, Drug Regulatory Authority, Quetta @ Karachi and to serve final opportunity to firm before taking final decision.

The reply of the firm is received in which firm has stated that no show cause notice has been received to this office as mentioned in proceeding and Decision paras of the minutes issued. Representative of the firm visited DRAP office Islamabad on 1st July 2019 and during the visits it was communicated that certain clarification regarding manufacturing plant location has been asked from the area FID.

With regard to the location of M/s Kalgon Agro Industries is located in general area HITE, Baluchistan, where certain other manufacturing facilities are also constructed and operational (Google image is attached vide Annexure A)

All basic industrial amenity connections have been provided by the Government Department i.e, Electricity, Water, Gas, Road infrastructure and Sanitation/Sewerage.

The situation adjacent with the factory premises is clear from the populated area as construction of the manufacturing facility is in the center of the available space of 16940 Square yards Area (approximately 3.5 Acres). (Google image is attached vide Annexure B)

It is highlighted that No Objection Certificate for establishment of Manufacturing Plant was issued from Government of Baluchistan, Industries Department vide BOI (IND) 3-10-75 Dated 25 Feb 1981 (Copy enclosed). Subsequently, Drug Manufacturing license was issued from Ministry of Health, Pakistan on fulfilling all departmental requirements vide DML

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

Decision by the Central Licensing Board in 273rd meeting

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

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

Decision of the Central Licensing Board in 276th meeting

Mr. Shahab Hashmi Director of the firm appeared before the Board. He contended that when Unit was established in 1981 there was no residential area but two different industrial units of Garment and other Industrial Units were located alongwith this Unit. Those unit has been sold out and since last five years peoples have started converting those areas into rersidential buildings. He further contented that he is law abiding citizen and he may be given reasonable time to shift this unit to industrial area.

The Board after hearing the represetattive of the firm decided to approve the renewal of Drug Manufacturing License No. 000277 by way of Formulation in the name of M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Hub Chowki Road (RCD), Lasbella, Baluchistan on the recommendations of the panel of experts for following sections ;

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

The Central Licensing Board also decided to grant four (04) years time frame to the firm for shifting of Pharmaceutical manufacturing facility from the current location to any designated industrial area as per applicable law. However, firm shall submit detailed working plan with time line for shifting to industrial area.

Case No. 23 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MYRTLE PHARMA, KARACHI**

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

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

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

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

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

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

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

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

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

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

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

Decision by the Central Licensing Board in 273rd meeting

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

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

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

No Person appeared before the Board on behalf of the firm. The Board decided to suspend the Drug Manufacturing license No. 000722 by way of formulation of M/s Myrtle Pharma Karachi Plot No. E-100, North Western industrial Zone,Bin Qasim Karachi, for the period of six (06) months. Production shall be resumed after approval by the Central Licensing Board.

Case No. 24. <u>GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S. SPENCER & COMPANY (PVT) LTD, KARACHI</u>

	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: -

<u>Conclusion:-</u>

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.

<u>Recommendations:-</u>

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. **<u>Renewal not recommended</u>**.

<u>Decision by the Central Licensing Board in 267th meeting</u>

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 recived on the date meeting from the Company wherein it was requested that they may be called in next meeting to resond 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 brfore the Board. After thorough discussion and deliberations, considering the background of the case and facts on record, the Board decied 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 recipt 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.

Case No. 25. APPROVAL OF LAYOUT PLAN FOR REGULARIZATION OF PENDING DRY POWDER INHALER (GENERAL) SECTION UNDER DRUG MANUFACTURING LICENSE NO.000141 (FORMULATION) OF M/S MACTER INTERNATIONAL LTD, PLOT NO. F-216, S.I.T.E, KARACHI.

The Central Licensing Board in its 272nd meeting approved the regularization of master layout plan of M/s Macter International Ltd, Plot No. F-216, S.I.T.E, Karachi, under DML No. 000141 (Formulation), and decided as under:

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

Ground floor:

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

First Floor:

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

Second floor (A and B):

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

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

The decision of the CLB was communicated to the firm.

Now the area FID Mr. Hakim Masood has submitted report regarding availability of required equipments and machinery for General Dry Powder Inhaler. The recommendations of the area FID are mentioned below:

Recommendations:-

In conclusion it is confirmed that the firm has requisite facilities for the manufacturing & testing of the DPI Capsule (General) & accordingly recommended for the grant of additional section namely Encapsulation (General) including Dry Powder Inhaler as per recommendations of renewal of DML panel inspection dated 10-10-2019.

Decision of the Central Licensing Board in 275th meeting:

The Board considered the case and decided to call the company in the next meeting of the Board regarding seeking clarification for manufacturing of General as well as DPI in one and same Section.

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

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

Dr. Salman Ahmed Technical Director of the firm and Mr. Fakhruddin Ahmad Director Regulatory affairs appeared before the Board. They contended that they are ready to abide by law and would address the matter. The Board decided to advise the firm to regularize the layout plan and establish separate sections for Capsule (General) and Capsule (DPI). Meanwhile, till regularization, manufacturing shall remain stopped in the section which needs regularization.

CASE NO. 26. M/S MEDIWAYS INTERNATIONAL, LAHORE

Background:-

M/s Mediways International, Multan Road, Lahore was inspected on 09.02.2015 by Mr. Ajmal Sohail Asif, FID Lahore to see/verify the GMP compliance. During inspection the FID pointed out a number of serious shortcomings and gross violations including the following:-

Change Rooms:

- Air curtains were installed but were not functional at the time of inspection.
- No Separate change room was provided for visitors or executives.
- Change rooms were very small and need to be reorganized in respect of outside doors.
- The firm was also advised to provide cabinets in the change rooms for keeping the workers belongings etc.
- It was also noticed that at the time of inspection the change rooms were not maintained and were not neat and clean.

Storage Areas:

- Quarantine area not properly demarcated and separated from the de-dusting area.
- The firm has provided a dispensing hood which was placed in the raw material store for recipients. But it seemed not to be in use, since there were no accessories like balance, scoops etc inside the dispensing booth.
- Balances and other accessories for dispensing were available on one of the racks of raw materials.
- No separate facility for sampling of the materials was available; the firm was advised to provide proper sampling facility.

- The firm was also advised to rearrange the placement of dispensing hood providing separate cabin and proper flow of pre and post dispensed materials
- However packing material store was congested the firm was advised to expand the storage area for packing materials.

Production Areas:

- HVAC was not functional at the time of inspection due to load shedding as informed by management of the firm.
- The firm was advised to partition this room for separation of de-cartooning and bottle blowing functions.
- It was also noticed that all the doors in production area were wooden and the firm was advised to replace all the wooden doors.

Quality Control Laboratory:

- It was noticed that QC lab was accessed through the de-dusting/ quarantine area of raw material store; the firm was advised to provide some other entrance to QC laboratory in order to avoid unnecessary movements QC of staff in stores.

Quality Assurance:

- During the last inspection the firm has presented a QA officer but at the time of this inspection no QA personnel was present.
- From ware houses to production and quality control no prevalence/involvement of quality assurance was observed.
- The management of the firm was also advised during previous inspection to strengthen the QA department but no improvement was seen in this department.
- Due to lack of QA system, deviations from SOPs, GMP, GSP etc, were observed in stores, manufacturing areas and quality control.
- Non existence of an independent check and balance system may result in compromises, by manufacturing and QC personnel, for routine deviations from practices and procedures. Such a situation may pose a great potential of compromises on overall quality of the products being manufactured.

Sanitation and Hygiene:

- The equipments in QA laboratory and different gauges, matters and equipment in manufacturing areas were not calibrated.
- There was no system for qualification and validation of machines, procedures and practices.
- The firm has no procedures for cleaning validation and was advised to develop.

Products Recalls:

- The firm was advised to assign a separate area for recall products and demark it well

Self Inspection and Quality Audit:

- No record was available for any audit.

Personnel:

- However, there was no technical person to look after the QA.
- The firm was advised to establish proper QA department and to hire appropriate personnel to strengthen the QA

Training:

- However, It was not being implemented as no record was available

Equipment & Machinery:

- However, the firm was advised to upgrade the syrup filling machine.
- The machines/equipments were not properly labeled regarding the status.
- However, the firm was advised to purchase the FTIR on priority basis.

Materials:

- The firm was advised to purchase the materials from manufacturers or authorized suppliers.
- The firm was also advised to conduct vendor qualification.
- The firm has not developed a proper material management system.
- The materials were not properly labeled.
- The firm was advised to affix the label on each and every container / bag of a lot of material.
- The firm was also advised to develop and implement the procedures for safety and security of the workers/personnel handling the materials in stores and also to mark the racks and allocate locations of the materials.
- In packing materials store the firm was advised for safe storage of printed materials and unit cartons under lock and key.

Documentation:

- It was found that some of the SOPs and BMRs needed review, improvement and updating regarding the actual practices.
- The log books for QC equipment were not maintained.
- The firm was advised to prepare procedure for OOS, cleaning validation etc.

Good Practices in Production:

- In general the practices were observed not to be in accordance with the prescribed procedures.
- The firm was asked to present the BMR for the last batch of a product namely “Antizile Syrup” but the management failed to produce any documentation.

Good Practices in Quality Control:

- There were procedures for QC analysis but they needed to be updated.
- The log books for instruments and equipments were not maintained.
- In General the practices were observed not to be in accordance with the prescribed procedures.

Utilities

Water Purification System:

- The firm was advised to install transfer pipes for supply of purified water to manufacturing area to minimize the exposure to external environment during manual transfer.

HVAC System:

- The firm was advised to repair the manometer so that the pressure gradients in buffer and manufacturing areas may be checked.

The FID further concluded that: The non compliant behavior of the firm towards advises made during previous panel inspection; the firm was considered to be operating at unsatisfactory level of the compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under.

Action Taken by DRAP: - Accordingly, a show cause notice and suspension of production order in all section was issued to the firm on 20.03.2015 with immediate effect.

Reply of the firm: - In response to show cause notice the firm vide letter No. Nil dated 15.06.2015 submitted their reply and requested to verify the shortcomings through area FID.

Proceedings of 245th meeting of CLB held on 30.12.2015

Mr. Jamil Ahmad, CEO of the firm appears before the Board. He informed that the observations given by the FID were given attention and most of the observations have been rectified and compliance report was also submitted. The firm is ready for inspection.

Decision of 245th meeting of CLB held on 30.12.2015

The case was placed before the Central Licensing Board for consideration. The Board after thorough discussion, keeping in view the available record, compliance report and request from CEO of the firm, decided to conduct panel cGMP inspection of the firm, on approved Schedule B-II cGMP format and panel will also submit report in tabulated form identifying the previous observations and the current status, by the following members:-

i. Dr. Ikram ul Haq, Member, CLB
ii. Dr. Zaka ur Rehman, Member, CLB
iii. Mr. Ajmal Sohail Asif, Area FID.

Accordingly decision of 245th meeting of CLB was conveyed to the firm on 10.02.2016

Letter of Secretary PQCB, Lahore:-

Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab informed that Deputy Drug Controller Allama Iqbal Town Lahore alongwith other members inspected the premises on 16.06.2016. The team observed that:-

i. Manufacturing of Drugs was being carried out under unhygienic conditions.

ii. Improper storage of drugs (at 40 degree Centigrade).
iii. Illegal or unauthorized import of raw materials without label (misbranded).

The case was placed in 249th meeting of CLB held on 29.08.2016.

Proceedings of the 249th meeting of CLB

The Board was informed that Mr. Ajmal Sohail Asif, FID conducted inspection of the firm on 09.02.2015. The firm was issued order for suspension of production activities and issued showcause notice / Suspension of production order No.F.4-4/2001-QA on 20.03.2015. Accordingly, the case was discussed in 245th Meeting of CLB, wherein the CLB had constituted following panel of experts to verify the improvements:-

a. Dr. Ikram ul Haq
b. Dr. Zaka ur Rehman
c. Mr. Ajmal Sohail Asif

Inspection report of the firm is still awaited. The Board also discussed and evaluated the reports / cases forwarded by the Secretary, PQCB, Punjab, Lahore and Chief Drug Controller, Punjab for cancellation / suspension of DML of the firm M/s Mediways, Lahore. The Board also consider sub Rule 3 of Rule 5 of Punjab Drugs Rules, 2007 which categorically stated that *"The provincial and district Board shall examine a case referred to it by an inspector and shall , if an action is proposed to be taken against a person under the Act or the rule, issue a showcause notice to the personal and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."*

Decision of the 249th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, the Board considered the recommendations of the Secretary, PQCB, Punjab and took a serious notice on illegal / unauthorized manufacturing and violation of the orders of the DRAP's letter No. No.F.4-4/2001-QA dated 20.03.2015. The Board decided to issue a showcause notice to the firm M/s Mediways, Lahore on illegal / unauthorized production activities and disobeying the orders of DRAP.

Accordingly showcause notice was issued to the firm on 03.10.2016.

Proceedings of the 250th Meeting of CLB

Mr. Jamil Ahmed, Chief Executive of the firm M/s Mediways International, Lahore appeared before the Board for personal hearing. He informed that the production is suspended since March, 2015, as per direction of the Division of QA&LT. The provincial government during the raid sealed the premises, which was later on de-sealed on the order of the Drug Court, Lahore. He also informed that inspection book is also in the custody of

provincial drug inspector, which has not been handed over to him till date, despite number of requests. Dr. Ikram ul Haq, Member CLB informed the Board that he along-with other members of the panel visited the firm, in compliance to decision of 245th Meeting of CLB, but the firm was found closed and the inspection could not be carried out.

Decision of the 250th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, non serious and non-professional attitude of the firm, , the Board decided to:-

i. Suspend the Drug Manufacturing License of the firm M/s Mediways International, Lahore for a period of six months under Section 41 of the Drugs Act, 1976 read with Rule 12 (1) of the Drugs (LR&A) Rules, 1976.
ii. Direct the area FID to visit the firm on alternate months to verify the suspension of production and submit report.
iii. Resumption of production shall only be allowed after completion of suspension of DML period, verification by the panel of experts and subsequent approval from the Competent Authority.

Updated status:-

The panel constituted by the Director QA&LT conducted inspection of the firm on 26.12.2017 (received on 17.04.2018). The panel submitted detailed inspection report including previous observations and updated status on Schedule B-II format and recommended as under:-

"Based on the areas inspected, the people met and the documents reviewed, and considering the finding of the inspection in comparison with the observations of the previous inspection, the panel of inspectors does not consider the firm to be at a satisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under. The plot size is smaller than the prescribed requirement. However, CLB in its 241st meeting held on 15.5.2015 decide "to allow two years time for shifting of unit / enhancement of plot size according to rules"; and that two years period. Therefore, the panel of inspectors does not recommend M/s Mediways International, 16KM Multan Road, Lahore, for resumption of production. The report is forwarded herewith for further consideration and necessary action".

Proceedings of the 261st meeting of the CLB

The case was placed before the board for appraisal in the light of recommendations of the panel of experts in its report dated 26.12.2017.

Decision of the 261st Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendation of the panel of experts in its report dated 26.12.2017, the Central Licensing Board decided to:-

i. Further extend Suspension of DML period for next six months from the date of issuance of decision of 261st meeting of CLB.

ii. The Licensing Division Shall place the case in forthcoming meeting of CLB in the light of decision of 241st meeting of CLB.

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

The Central Licensing Board in its 241st meeting held on 15th May, 2015 has considered the case of M/S Mediways International, Lahore and decided as under:

- *"To allow two years time for shifting of unit / enhancement of plot size according to the rules.*
- *To scrutinize the application of the renewal of DML of the firm for the period 09-02-2015 to 09-02-2020 and inform the applicant the status of the application according to Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rules 1976 and conduct inspection of the firm after completion of application of renewal of DML."*

The same decision was conveyed to the firm vide letter issued on 24th August, 2015 but till date no application is received from the firm for shifting of their existing facility and application for renewal of DML No. 000468 (Formulation) for period of 09-02-2015 to 08-02-2020 is incomplete with following documents being deficient:

i. Nothing due certificate regarding CRF (Updated).
ii. Approval letters of Production Incharge and Quality Control Incharge, if not approved, complete set of duly attested documents (as per checklist) of qualified staff alongwith prescribed fee of Rs.10,000/-
iii. Detail of management at the time of previous renewal and at present renewal, if any change, prescribed fee of Rs.50, 000/- for change in management.
iv. CNIC copies of owner/partners.
v. Proof of CLB approved sections.
vi. Legal status of the firm.

Proceedings and Decision of Central Licensing Board in 265thmeeting

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 19,Schedule B-II and Rule 20 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/sMediways International, Multan Road, Lahore, under Drug Manufacturing Licence No. 000468 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 27thSeptember, 2018 was issued to the M/sMediways International, Multan Road, Lahore which was returned back. Then The Additional Director (E&M),DRAP, Lahore requested to ensure delivery and receiving of show cause notice to the firm.

The firm replied to the show cause notice and the application for renewal of DML is incomplete till date with following short comings.

i. Nothing due certificate regarding CRF (Updated).
ii. Proof of CLB approved sections.
iii. Undertaking as sole proprietor on stamp paper.

Furthermore, the firm requested to allow three year for shifting unit after earning some revenue as the production has remained suspended for two years.

Proceedings and Decision of Central Licensing Board in 267thmeeting

The Board considering the facts on the record and after thread bare deliberation decided to call the firm M/s Mediways International, Multan Road, Lahore for personal hearing in forthcoming meeting of the Central Licensing Board.

Proceedings and Decision of Central Licensing Board in 267thmeeting

The Board considering the facts on the record and after thread bare deliberation decided to call the firm M/s Mediways International, Multan Road, Lahore for personal hearing in forthcoming meeting of the Central Licensing Board.

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

A letter of Personal hearing has been issued on 19-02-2019

Decision by the Central Licensing Board in 269th meeting

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

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

M/s Mediways International, Multan Road, Lahore had applied for renewal of DML No. 000468 by way of formulation on 07-02-2020.The application for the renewal of DML of the firm was evaluated and following documents still shortcomings / deficiencies:-

i. Proof of sections / Section approval letter approved by CLB.

ii. Duly attested CNIC copy of owner.

Now M/s Mediways International, Lahore has requested for exemption in area of 4-Kanal and stated as under:-

> *"It is stated that I, Jamil Ahrnad Proprietor of Mediways International Lahore being a Pharmacist belong to an honorable family, got Drug Manufacturing License in 2000 and fulfilled all the coda1 formalities prevailed at that time.*
>
> *I have only one section (Oral Liquid) in an area of 1-kana1 3-marala duly approved by the competent authority as per existing law at that time. In August, 20 15 a notice was given for expansion in area to 4-kanal. The DRAP very kindly gave me exemption in 4-kana1 arca for 2 years with the directions to extend meanwhile up to 4-kana1 vide Letter No. F.1-42/92-Lic (Vol-1).*
>
> *But Unfortunately the Federal Inspector of Drugs stopped the production before grant of exemption period by the Drug Regulatory Authority of Pakistan (DRAP), Therefore the factory remained closed up till now. I deposited the Renewal fee and relevant documents as per law,*
>
> *Sir, in the above mentioned circumstances I was unable to purchase 4-kanal plot and build a new factory due to severe upset in my financial position. I have been damaged very badly even education of my children have to be suspended. There is no case pending in the court of law.*
>
> *Respected Sir, kindly grant me exemption from area of 4-kanal for at least a period of 3 years on sympathetic grounds with the permission to start manufacturing simultaneously. I have only one liquid section for which 1-kanal 3-marala is sufficient to, meet out the requirements.*
>
> *I **assure** you sir, I will abide by the law **and** establish a new unit on 4-kana1 within 3 years. This act of kindness will save my family along with continuity in education of my children".*

A letter of Personal Hearing was issued to the firm on 28th August, 2020.

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

Mr. Jameel Ahmed, Chief Executive of the firm appeared before the Board and requested to give further time of three years for shifting to industrial area as exisiting facitility do not comply minimum area of plot under the Rules. He also contended that he wanted to generate resources from this unit to shift to new area which comply

the provision of law. He also stated that it is also difficult to maintain the GMP compliance in existing building therefore, unit has remain non operational for last three years. The Board also considered the previous GMP inspection report which noted number of serious observations noted by the Inspector. The Board also noted shortcomings in the application for renewal of Drug Manufacturing Licence.

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 19,Schedule B-II and Rule 20 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976, as to why their application for renewal of M/s Mediways International, Multan Road, Lahore, under Drug Manufacturing Licence No. 000468, by way of formulation, may not be rejected or Drug Manufacturing Licence may not be cancelled by Central Licensing Board.

Case No. 27 <u>RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S JAWA PHARMACEUTICALS (PVT) LTD, LAHORE.</u>

M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore had applied for renewal of DML No. 000150 by way of Formulation for the period of 24-12-2019 to 23-12-2024 on 17-10-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 04thFebruary, 2020 under 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 all Directors.
iii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).

The firm replied to this letter on 24thFebruary 2019 but application was incomplete with following shortcomings and reminder letter was issued on 29thApril, 2020 to the firm for completion of application:

i. Latest certified true copy of Form-29 mentioning names of all Directors duly attested by SECP.

The firm submitted documents on 06thMay, 2020 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest certified true copy of Form-29 mentioning names of all Directors duly attested by SECP.

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, Drug Manufacturing Licence No 000150 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The show cause notice dated 6thJuly, 2020 was issued to M/sJawa Pharmaceuticals (Pvt) Ltd, 112/10-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.

The firm has replied to show cause notice on22-07-2020. The firm has submitted all deficient documents and application of renewal of Drug Manufacturing Licensing is complete.

A letter of Personal Hearing was issued to the firm on 28th August, 2020.

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

Mr. Raza Jawa Director of M/ Jawa Pharmaceuticals (Pvt) Ltd, 112/10-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore appeared before the Board. He submitted that since legal and codal formalities has been complied therefore showcause may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of the showcause Notice. The Board also decided to issue warning to the firm to be careful in future for compliance of the law.

Case No. 28 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S DRUGPHARM (PVT) LTD, LAHORE

M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore had applied for renewal of DML No. 000366 by way of formulation for the period of 24-04-2016 to 23-04-2021 on 15-04-2016.

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 23th August, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Classes of Drugs.
2. Dosage forms of drugs.
3. Change (s) in name of proprietor / directors / partners.
4. Detail of premises including approved layout plan of the factory / proof of section from CLB.
5. Copy of approval production and QC Incharge
6. Noting due certificate regarding CRF from STO.
7. Form-29 from S.E.C.P and CNIC of partners

The firm submitted their reply on 8th September, 2016 After evaluation of the submitted documents, a letter was issued on 30th January, 2017 to the firm with following shortcomings: -

1. Attested Form-29 from S.E.C.P along with copies of CNIC of all directors.
2. Any change in directors from last renewal along with Form-29 at previous renewal.
3. N.O.C for C.R.F (attested up to 2015).
4. Approved copy of Layout Plan.
5. Approved of technical staff or application / documents.
6. All documents should be duly attested.

The firm submitted their reply on 23th February, 2017 After evaluation of the submitted documents, Final Reminder was issued on 19th June, 2017 to the firm with following shortcomings: -

1. Attested Form-29 from S.E.C.P along with copies of CNIC of all directors.
2. Any change in directors from last renewal along with Form-29 at previous renewal.
3. N.O.C for C.R.F (attested up to 2016).
4. Approved copy of Layout Plan.
5. Approved of technical staff or application / documents.
6. All documents should be duly attested.

Firm did not submit their reply to Final Reminder and following documents are still deficient /short and application for renewal of DML is still incomplete.

1. Attested Form-29 from S.E.C.P along with copies of CNIC of all directors.
2. Any change in directors from last renewal along with Form-29 at previous renewal.
3. N.O.C for C.R.F (attested up to 2016).
4. Approved copy of Layout Plan.
5. Approved of technical staff or application / documents.
6. All documents should be duly attested.

Moreover, The Hon'ble Chairman, Drug Court, Balochistan Quetta has passed an order whereby it is stated that a case No. 37/17 is filed before Hon'ble Drug Court, Quetta in respect of M/s DrugPharm (Pvt) Ltd, 28-Km,

Lahore Sheikhupura Road, Lahore. Accused are not appearing before the Court despite issuance of Non bailable warrants repeatedly. Therefore, Chairman Drug Court, Balochistan, Quetta has ordered to cancel the Drug Manufacturing Licence of said firm and report in this regard may be forwarded to Chairman Drug Court, Balochistan, Quetta.

Proceedings and Decision of Central Licensing Board in 256th 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 Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore Drug Manufacturing Licence No. 000366 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 05th January, 2018 was issued to the M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore

A letter of Personal hearing has been issued on 17th January,2018.

Proceedings and Decision of Central Licensing Board in 257th meeting

No representative of the of the firm appeared before the Board. The Board considering the facts on the record and after thread bare deliberation decided to cancel Drug Manufacturing Licence No. 000366 by way of formulation issued in the name of M/s Drugpharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahoreon the orders of the Court 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.

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

The Central Licensing Board in its 257th meeting held on 24-25th January, 2018 cancelled the Drug Manufacturing Licence No. 000366 (Formulation)M/s Drugpharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore and the same decision was conveyed to the firm vide letter dated 20th March, 2018.

The firm filed appeal in Appellate Board against the decision of CLB. Appellate Board in its 151st sitting held on 16th January, 2019" considered the appeal of the firm and decided as under:-

"The Board, after hearing arguments and perusing record if the case, decided to remand the case back to the Central Licensing Board with direction to decide a fresh the application for renewal of DML No. 000336 submitted by M/s DrugPharm (Pvt) Ltd, Lahore in forthcoming meeting.

The Licensing Division shall constitute panel for inspection of the firm to be carried out after two months of the communication of this decision. Dr. Farzana Chaudhary and Mr. Shahid Nasir (Member, Appellate Board) are to be included in the Panel. The panel so constituted may allow production if the firm is complying with Good Manufacturing Practices (GMP) guidelines".

Licensing Division then afresh evaluate the application of the firm and following shortcoming in the application were conveyed to the firm vide letter dated 3rdJuly 2019.

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of 50,000/-.
iii. Latest certified true copy of Form-29 (duly attested by S.E.C.P).
iv. Duly attested CNIC copies of all directors.
v. Section approval letters of all sections issued by Central Licensing Board, if not available, apply for regularization of layout plan.
vi. Complete set of duly attested documents of proposed Production Incharge and Quality Control Incharge (as per checklist) along with prescribed fee of Rs. 10,000/-.

Firm did not submit their reply till date and application for renewal of DML is still incomplete. File forwarded to Legal Affairs Division, DRAP for legal opinion whether the Drug Manufacturing Licence of the firm is valid or the decision of Central Licensing Board is intact.

Reply of the Legal Affair Division

Appellate Board in its 151st meeting held on 16th January, 2019 decided to remand back the case to Central Licensing Board with direction to decide afresh the application of renewal of DML No. 000336 submitted by M/s Drugpharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore in its forthcoming meeting. The Licensing division the afresh evaluate the renewal application of the firm and shortcoming were conveyed to firm but the firm did not reply yet. In the light of above available facts, Legal Affairs Division is opined that the decision of the Appellate Board is still intact and Central Licensing Board may finally decide the renewal application of the firm according to its procedure.

Proceedings and Decision by the Central Licensing Board in 275th 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), 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore Drug Manufacturing Licence No. 000366 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The show cause notice dated 06thJuly, 2020 was issued to M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore.

The firm has replied to show cause notice on 24-8-2020 but following documents are still deficient in the application

1. Prescribed fee of Rs. 50,000/- (change of management).
2. Prescribed fee of Rs. 5,000/- (Quality Control Incharge).
3. Prescribed fee of Rs. 5,000/- (Production Incharge).
4. Prescribed fee of Rs. 35,000/- (Regularization of Layout plan).
5. Updated Nothing due certificate regarding CRF from STO.
6. Duly attested legible copies of CNIC of all Directors.
7. Duly attested legible copies of CNIC of Quality Control Incharge.
8. Registration certificate from Pharmacy Council of Production Incharge.

A letter of Personal Hearing was issued to the firm on 28th August, 2020.

Decision by the Central Licensing Board in 276th meeting

Mr. Shoaib Butt CEO and Mr. Waqas Butt Director HR of the company appeared before the Board and contended that almost most of the shortcomings have been rectified. The Board after hearing the representative of the firm and considering the facts on the record and after thread bare deliberation decided to suspend the Drug Manufacturing Licence No. 000366 by way of formulation for three (03) months issued in the name of M/s Drugpharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore 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, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 29 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FILIX PHARMACEUTICALS (PVT) LTD, RAWAT, ISLAMABAD.**

M/s Filix Pharmaceuticals (Pvt) Ltd, Plot No. 4-A, Main Road, R.C.C.I, Rawat, Islamabad had applied for renewal of DML No. 000779 by way of Formulation for the period of 30-08-2018 to 29-08-2023 on 10-08-2018.

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 7thSeptember, 2018 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form 1A alongwith enclosure / annexure / flags.
ii. Classes of Drugs.
iii. Dosage form of drugs.
iv. Detail of management at the time of previous renewal and present renewal.
v. In case if firm is Private Limited then Certificate of incorporation with SECP, Memorandum and Article of Association, Form-A and Form-29 may also be furnished.
vi. Declaration of firm on stamp paper in case of sole proprietorship company alongwith CNIC.
vii. Partnership deed attested in case of partnership deed alongwith CNICs.
viii. Detail of premises including layout plan
ix. Proof of licensed sections from CLB.
x. Approval letter of Production / Quality Control Incharge in case of change than submit required documents as per check list.
xi. All documents duly should be attested.

The firm replied to this letter on 19thNovember, 2018 but application was incomplete with following shortcomings and reminder letter was issued on 21st May, 2019 to the firm for completion of application:

For Renewal of DML.

i. Detail of management at the time of previous renewal and present renewal.

ii. In case if firm is Private Limited then Certificate of incorporation with SECP, Memorandum and Article of Association, Form-A and Form-29 may also be furnished.

For Production Incharge (Amjad Ikram).

i. Experience Certificate as under Drug (Licensing, Registering and Advertising) Rules, 1976 not less than 10 years.
All documents duly should be attested.

The firm submitted documents on 16th July, 2019 in reply to Reminder but application was incomplete with following shortcomings and final reminder letter was issued on 26th February, 2020 to the firm for completion of application:

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 (duly attested by SECP).
iii. Updated Nothing Due Certificate regarding CRF from STO (R&D),DRAP.

The firm submitted documents on 02nd April, 2020 in reply to final reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 (duly attested by SECP).
iii. Updated Nothing Due Certificate regarding CRF from STO (R&D),DRAP.

Proceedings and Decision by the Central Licensing Board in 275th 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), 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Filix Pharmaceuticals (Pvt) Ltd, Plot No. 4-A, Main Road, R.C.C.I, Rawat, Islamabad Drug Manufacturing Licence No. 000779 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The show cause notice dated 6thJuly, 2020 was issued to M/sFilix Pharmaceuticals (Pvt) Ltd, Plot No. 4-A, Main Road, R.C.C.I, Rawat, Islamabad.

The firm has replied to show cause notice on29-07-2020 and submitted all deficient documents.Theapplication of renewal of Drug Manufacturing Licensing is complete.

A letter of Personal Hearing was issued to the firm on 28th August, 2020

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

Mr. Zeeshan Shahzad Director of M/s Filix Pharmaceuticals (Pvt) Ltd, Plot No. 4-A, Main Road, R.C.C.I, Rawat, appeared before the Board. He submitted that since legal and codal formalities has been complied therefore showcause may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of the showcause Notice. The Board also decided to issue warning to the firm to be careful in future for compliance of the law.

Case No. 30 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AGROR PHARMA (PVT) LTD, RAWAT, ISLAMABAD.

M/s Agror Pharma(Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat, Islamabad had applied for renewal of DML No. 000791 by way of Formulation for the period of 03-02-2019 to 02-02-2024 on 23-01-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 29th May, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

1. Detail of management at the time of previous renewal and present renewal.
2. Attested Form 29 from SECP alongwith CNICs of all Directors.
3. Proof of sections approved by the Central Licensing Board.
4. Nothing due certificate regarding CRF from STO DRAP updated.

For Production Incharge (Mr. Abid Maqsood).

i. Appointment letter and job acceptance letter
ii. Resignation of the earlier production Incharge.
iii. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

For Quality Control Incharge (Mr. Salah ud Din).

i. Appointment letter and job acceptance letter
ii. Resignation of the earlier Quality Control Incharge
iii. Resignation / retirement of earlier approved QC Incharge.
iv. All documents should be duly attested.

The firm filed new application for approval of new Production Incharge on 24th May, 2019 but application was incomplete with following shortcomings and reminder letter was issued on 8th November, 2019 to the firm for completion of application:

For Renewal of DML.

1. Detail of management at the time of previous renewal and present renewal.
2. Attested Form 29 from SECP alongwith CNICs of all Directors.
3. Proof of sections approved by the Central Licensing Board.

For Quality Control Incharge (Mr. Salah ud Din).

1. Appointment letter and job acceptance letter of appointee.
2. Resignation / retirement of earlier approved QC Incharge.
3. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
4. All documents should be duly attested.

For Production Incharge (Khalid Rehman Khattak).

1. Appointment letter.
2. Job acceptance letter by the appointee.
3. Copy of CNIC of appointee.
4. Resignation / retirement of earlier approved Production Incharge.
5. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
6. All documents should be duly attested.

The firm submitted documents on 18th December, 2019 in reply to final reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Prescribed fee of Rs. 50,000/- for change of management as there is change in management of the firm.
ii. Latest certified true copy of Form-29 duly attested by SECP mentioning detail / name of all Directors / CEO.

iii. Duly attested CNIC copies of all Directors.

iv. Duly attested CNIC copy of proposed Production Incharge.

Proceedings and Decision by the Central Licensing Board in 275th 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), 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Agror Pharma(Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat Drug Manufacturing Licence No. 000791 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The show cause notice dated 06thJuly, 2020 was issued to M/s Agror Pharma(Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat, Islamabad.

The firm has replied to show cause notice on2207-2020 and submitted all documents except certified true copy of form-29.

A letter of Personal Hearing was issued to the firm on 28th August, 2020.

Decision by the Central Licensing Board in 276th meeting

Mr. Asad ullah, Chief Executive and Mr. Khalil Rehman Khattak respresenatative of the company appeared before the Board and contended that almost most of the shortcomings have been rectified. The Board after hearing the representative of the firm and considering the facts that some shortcomings still exists on the record and after thread bare deliberation decided to suspend the Drug Manufacturing Licence No. 000791 by way of formulation for three (03) months issued in the name of M/s Agror Pharma(Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat, 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 19 and Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 31 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S BAJWA PHARMACEUTICALS (PVT) LTD, DISTRICT SHEIKHUPURA.**

M/s Bajwa Pharmaceuticals (Pvt) Ltd, 36-Km, Lahore-Gujranwala Road, Khori, District Sheikhupura had applied for renewal of DML No. 000805 by way of Formulation for the period of 02-12-2019 to 01-12-2024 on 20-09-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 25thFebruary, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 (duly attested by SECP).
iii. Duly attested CNIC copies of all Directors.
iv. Detail of management at the time of grant of DML & at present, if any change, apply for change of management.
v. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.
vi. Approval letter of Production Incharge and Quality Control Incharge, if not approved, apply for approval of technical staff.

The firm replied to this letter on 10th March, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 8th April, 2020 to the firm for completion of application:

i. Complete set of duly attested documents (except appointment and job acceptance letters) of proposed Production Incharge and quality Control Incharge alongwith prescribed fee of Rs. 10,000/-.

The firm submitted documents on 22nd April, 220 in reply to final reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Registration certificate from Pharmacy Council of Quality Control Incharge and Production (valid / renewed).

ii. Resignation / retirement of earlier Production Incharge.

iii. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Production Incharge).

Moreover, It is pertinent to mention here that proposed Quality Control Incharge Mr. Ammar Yasir Bhutta Joined the firm w.e.f. 26-05-2016 and proposed Production Incharge Mr. Abdul Khaliq Joined the firm w.e.f. 26-06-2015 and the firm filled their application on 21-04-2020. Upon inquiring the firm regarding carrying out production activities without approved technical staff the firm has stated that they have intimated DRAP Lahore regarding appointment of technical staff.

Proceedings and Decision by the Central Licensing Board in 275th 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 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing Licence No. 000805 by way of formulation in the name of M/s Bajwa Pharmaceuticals (Pvt) Ltd, 36-Km, Lahore-Gujranwala Road, Khori, District Sheikhupura may not be suspended or cancelled.

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

The show cause notice dated 6thJuly, 2020 was issued to M/sBajwa Pharmaceuticals (Pvt) Ltd, 36-Km, Lahore-Gujranwala Road, Khori, District Sheikhupura.

The firm has replied to show cause notice on24-07-2020. The firm has submitted all deficient documents and application of renewal of Drug Manufacturing Licensing is complete.

A letter of Personal Hearing was issued to the firm on 28th August, 2020

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

Mr. Faisal, Field Manager of M/s Bajwa Pharmaceuticals (Pvt) Ltd, 36-Km, Lahore-Gujranwala Road, Khori, District Sheikhupura appeared before the Board. He submitted that since legal and codal formalities has been complied therefore showcause may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of the showcause Notice. The Board also decided to issue warning to the firm to be careful in future for compliance of the law.

Case No. 32 **RENEWAL OF DML OF M/S KATRINA PHARMACEUTICAL INDUSTRIES (PVT.) LTD., SHEIKHUPURA.**

The case was placed the Board as under: -

The renewal of DML # 000344 (Formulation) of M/s Katrina Pharmaceutical Industries (Private) Limited located at 10-km Sheikhupura Road, Sheikhupura was not recommended by the panel who conducted inspection on 14-12-2007 for renewal of DML for the period 14-12-2004 to 13-12-2009.

Firm was then issued a show cause notice on 23-05-2008 and directed to appear before the Board on 26-05-2008.

Firm appeared before the Board in its 212th meeting held on 26-05-2008, to avail opportunity of personal hearing wherein Chief Executive of the firm Mr. Afzal Hameed submitted undertaking for voluntary stoppage of production with immediate effect and stated that they will be ready for inspection after one month.

Firm was again inspected by the then area FID on 15-06-2009 and inspection report he stated that firm had not done any compliance with reference to previous inspection report and renewal of DML was also not recommended by the panel.

Firm was again served a show cause notice dated 29-07-2009 and advised to appear before the Board for personal hearing on 31st July 2009. However firm did not appear before the Board for personal hearing.

Afterwards, firm submitted application of renewal of DML for the period of next five years **i.e. 14-12-2009 to 13-12-2014** for which a panel was constituted on 25-02-2011 but no inspection report received from that panel yet.

Meanwhile, Area Federal Inspector of Drugs, DRAP, Lahore visited firm on 06-03-2013 for routine GMP inspection and reported that firm was closed for the past many years and firm has not done any improvements in their premises.

Firm was then again served show cause notices on 23rd December 2013, 24th February 2014 with advise to appear before CLB for personal hearing but firm failed to appear in any of the meetings of the Board for personal hearing.

The case was then again discussed in 234th meeting held on 27th February, 2014 wherein the Board decided as under; -

Decision of CLB in its 234th meeting

The Board after thorough discussion / deliberations and facts on grounds considered and decided as under:-

- Fresh status report by panel comprising of Dr. Ikram ul Haq, Member CLB, Ahmad Mehmood Mumtaz, CQC, DDG (E&M), Lahore and Area FID, Lahore.

- Opinion from Law Division that the firm has been called twice for personal hearing but did not attended for personal hearing so whether CLB can decide for suspension / cancellation of Drug Manufacturing License ex-parte under section 41 of Drugs Act, 1976.
- Last and final opportunity of personal hearing in the forthcoming meeting of CLB and letter shall be sent through Registered Post and receipt of same shall be retained

With respect to the decision of the Board in its meeting, the panel inspection report is still awaited.

Opinion from Division of Legal Affairs, DRAP, has been taken with respect to failure of the firm to appear before the Board for personal hearing. In this regard, the comments of Division of Legal Affairs, DRAP are as under:-

"***Section 41 of the Drugs Act, 1976 and Rule 12 of the Drugs (Licensing, Registering & Advertising) Rules 1976 are clear that an opportunity of being heard is to be provided to the licensee and obviously he cannot be forced physically for such appearance. Similarly the licensee cannot be allowed to defeat the law and the rules by his non appearance. Therefore, if all conditions given in the respective provisions of law and rules have been satisfied in a bonafide manner, the Board may go ahead in taking the decision***"

Current status of the license of the firm:-

As per record of Licensing Division, DRAP, Islamabad, the both previous tenure of renewal of DML of the firm i.e. **14-12-2004 to 13-12-2009 and 14-12-2009 to 13-12-2014** has been expired. Firm has now submitted application for renewal of DML of the firm for the period of next five years **i.e. 14-12-2014 to 13-12-2019** which is well before the expiry of the period of validity of the license therefore license of the firm shall continue in force till any further orders passed on such application according to Rule 5 of the Drugs (Licensing, Registering & Advertising) Rules 1976.

The firm was called for availing last opportunity of personal hearing.

Proceedings of the case:-

Mr. Shoib Afzal S/O Mr. Afzal Hameed appeared before the Board as representative of the firm on behalf of his father (the owner of the firm). He stated that firm is closed since year 2008 because HVAC system installation is not completed due to financial constraint. He further added that their firm has made some modifications in the existing building by addition of more sections and accordingly got approval of layout plan from Central Licensing Board. Previously, firm possess very low number of registered products in tablet section due to which survival in the market was very difficult. The representative of the firm informed that they have submitted application for renewal of DML for the period 14-12-2014 to 13-12-2019 and their license is valid and further informed that their unit will be ready for inspection after 05 months.

Decision by the Central Licensing Board in 241st meeting:

The Board after hearing the representative of the firm and on the basis of the commitment decided to allow 05 month time to the firm for completing the installation of HVAC system according to the approved layout plan and also directed the firm to not start production unless inspected and granted permission by Central Licensing Board.

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

The letter was issued vide letter dated 20th August, 2015 to M/s Katrina Pharmaceutical Industries (Pvt) Ltd, Sheikhupura.

The Firm has filled new application on 06-12-2019 for renewal of DML for period of 14-12-2019 to 13-12-2024. The application for the renewal of DML of the firm was evaluated. Following documents being shortcoming / deficient.

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Updated NDC regarding CRF from STO, DRAP.
iii. Latest certified true copy of Form-29 duly attested 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. Name and qualification of qualified staff.
vii. Approval letters of Production Incharge and Quality Control Incharge.
viii. Classes of Drugs.
ix. Section wise detail of machinery in Production and Quality Control.

A letter has been issued to QA & LT Division, DRAP, Islamabad to provide the current GMP status of the firm vide letter dated 06th March, 2020.

QA & LT Division, DRAP, Islamabad replied this letter on 16th March, 2020 and stated as under:

> As per the available record. It is submitted that Ms. Aisha Irfan the than FID conducted inspection of the firm M/s Katrina Pharmaceutical Industries (Pvt) Ltd, 10-Km, Sheikhupura Faisalabad Road, Sheikhupura on 09-05-2016. The FID informed that *"The Central Licensing Board in its 241st meeting held on 15-05-2015, have decided to allow 05 months time period of the firm for completing the installation of HVAC system. However, even after lapse of one year, the firm failed to submit any progress and compliance in this regard. The factory is not in working condition for the last many years. The undersigned have visited the factory almost thrice and all the time it was found closed and non-*

functional. Apparently it seemed that no renovation work / installation of HVAC has been done. The unit is not functional for the last seven years approximately and renewal of Drug Manufacturing License has not been granted. Hence, under these circumstances it is proposed that DML of the firm M/s Katrina Pharmaceutical Industries (Pvt) Ltd, 10-Km, Sheikhupura Faisalabad Road, Sheikhupura may be cancelled under Rule 12 of (Licensing, Registering and Advertising) Rules 1976 in order to avoid any illegal activities in the firm. "

Proceedings and Decision by the Central Licensing Board in 275th 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), 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Katrina Pharmaceutical Industries (Private) Limited located at 10-km Sheikhupura Road, Sheikhupura Drug Manufacturing Licence No. 000344 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board

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

The show cause notice dated 20thJuly, 2020 was issued to M/sKatrina Pharmaceutical Industries (Private) Limited located at 10-km Sheikhupura Road, Sheikhupura.

The firm did not replythe show cause notice.

A letter of Personal Hearing was issued to the firm on 28th August, 2020

Proceedings and Decision of Central Licensing Board in 276thmeeting

No representative of the of the firm appeared before the Board. The Board considering the facts on the record and after thread bare deliberation decided to cancel Drug Manufacturing Licence No. 000344 by way of formulation issued in the name of M/s Katrina Pharmaceutical Industries (Private) Limited located at 10-km Sheikhupura Road, Sheikhupura 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 33 APPROVAL OF QUALITY CONTROL INCHARGE OF M/S CURE LABORATORIES (PVT) LTD, RAWAT, RAWALPINDI.

Mr. Ameer Hussain, approved Quality Control Incharge of M/s Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi, under Drug Manufacturing Licence No. 000897 by way of formulation had resigned w.e.f, 06-03-2019. The firm filed application for approval of new Quality Control Incharge on 13-11-2019.The application was evaluated and letter for following shortcomings / deficiencies was issued to the firm on 22nd January, 2020.

i. It has been noticed that there is duplication in dates of experience certificates of proposed Quality Control Incharge i.e Ambrosia Pharmaceutical, Islamabad 16th August, 2004 to 9th January, 2007 and Goodman Laboratories, Islamabad 1st December, 2006 to 12th February, 2014, the said person was working at two different organizations at the same time. Moreover, the previous Quality Control Incharge resigned on 6th March, 2019 from your firm and Quality Control testing has been continued without the supervision of approved Quality Control Incharge.

ii. You are therefore required to justify your position in writing regarding said experience and for violating the Rule 16 and 19 of Drugs (Licensing, Registering & Advertising) Rules 1976.

The firm submitted their reply on 6thFebruary, 2020. The application was complete and propose Quality Control Incharge was approved.

The firm carried production activity without approved Quality Control Incharge which is violation of Rule 16 of the Drugs (Licensing, Registering and Advertising) Rule, 1976.

Proceedings and Decision by the Central Licensing Board in 275th 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 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing Licence No. 000897by way of

formulation in the name of M/s Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2, National Industrial Zone, Rawat may not be suspended or cancelled.

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

The show cause notice dated 6thJuly, 2020 was issued to M/sCure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2, National Industrial Zone, Rawat.

The firm has replied to show cause notice on17-07-2020 and stated that they were in the process of hiring a Quality Control Incharge and during this period, no production activities were carried out because of the fact that the product registrations were in the process of approval in the DRAP and the registration certificates were issued on 22nd August and 25th September, 2019. The production activities at Cure Laboratories were started in the month of November 2019 after the hiring of Quality Control Incharge on 13th October, 2019.

A letter of Personal Hearing was issued to the firm on 28th August, 2020

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

No person appeared on behalf of the firm. The Board after considering the facts decided to defer the case to give final opportunity to the firm to plead his case. Moreover, the Board decided to verify the start of production activities from Batch Manufacturing Record through Area Federal Inspector of Drugs.

Case No. 34. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MTI MEDICAL (PVT) LTD, LAHORE.

M/s MTI Medical (Pvt) Ltd, Plot No. 586, Sunder Industrial Estate, Lahore had applied for renewal of DML 000801 by way of (Formulation) for the period of 19-09-2019 to 18-09-2024. 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 30th September, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed and stamped Form-1A (as per format)
ii. Updated Nothing Due Certificate regarding CRF from STO (R&D) DRAP, Islamabad.
iii. Detail of management at the time of grant of DML and at present, if any change, apply for change of management.
iv. Latest Certified true copy of Form-29. (Attestation by SECP).
v. Duly attested CNIC Copy of all Directors / CEO.

vi. Approval letters of Production Incharge and Quality Control Incharge, if not approved, submit application with prescribed fee to Licensing Division.

The firm submitted their reply on 6th November. 2019 After evaluation of the submitted documents, final reminder was issued on 12thFebruary, 2020to the firm with following shortcomings: -

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 attested by SECP.
iii. Duly attested copies of experience certificates of Quality Control Incharge.
iv. Duly attested copies of resignation of earlier Production Incharge and Quality Control Incharge.
v. Duly attested copies of resignation /retirement of proposed Production Incharge and Quality Control Incharge from previous firms.

Firm has submitted their reply in response to this Division's Final Reminder on 09th March, 2020 and following documents are still deficient /short and application for renewal of DML was incomplete:-

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 attested by SECP.

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s MTI Medical (Pvt) Ltd, Plot No. 586, Sunder Industrial Estate, Lahore Drug Manufacturing Licence No. 000801 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board

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

The show cause notice dated 6thJuly, 2020 was issued to M/sMTI Medical (Pvt) Ltd, Plot No. 586, Sunder Industrial Estate, Lahore.

The firm has replied to show cause notice on10-07-2020. The firm has submitted all deficient documents and application of renewal of Drug Manufacturing Licensing is complete.

A letter of Personal Hearing was issued to the firm on 28th August, 2020

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

Mr. Nadeem Anwar of M/s MTI Medical (Pvt) Ltd, Plot No. 586, Sunder Industrial Estate, Lahore appeared before the Board. He submitted that since legal and codal formalities has been complied therefore showcause may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of the showcause Notice. The Board also decided to issue warning to the firm to be careful in future for compliance of the law.

Case No. 35 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HOOVER PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Hoover Pharmaceuticals (Pvt) Ltd, Plot No. 16, Zain Park Industrial Area, Saggain Bypass Road, Lahore had applied for renewal of DML No. 000676 by way of Formulation for the period of 09-12-2019 to 08-12-2024 on 15-10-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 10thFebruary, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Proof of sections approved by CLB, if not available, apply for regularization of layout plan.
iii. Latest certified true copy of Form-29 (duly attested by SECP).
iv. Duly attested CNIC copies of all Directors.
v. Prescribed fee of Rs. 50,000/- for change of management as there is change in management of the firm.

The firm replied to this letter on 27th February, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 29th April, 2020 to the firm for completion of application:

i. Prescribed fee of Rs. 50,000/- for change in management of the firm.
ii. Latest certified true copy of Form-29 duly attested by SECP (original)
iii. Proof of sections approved by Central Licensing Board / Section approval letters, if not available then apply for regularization of layout plan.

The firm submitted documents on 20th May, 220 in reply to final reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest certified true copy of Form-29 duly attested by SECP (original).

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Hoover Pharmaceuticals (Pvt) Ltd, Plot No. 16, Zain Park Industrial Area, Saggain Bypass Road, Lahore Drug Manufacturing Licence No. 000676 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board

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

The show cause notice dated 06thJuly, 2020 was issued to M/s Hoover Pharmaceuticals (Pvt) Ltd, Plot No. 16, Zain Park Industrial Area, Saggain Bypass Road, Lahore.

The firm has replied to show cause notice on 30-07-2020. The firm has submitted all deficient documents and application of renewal of Drug Manufacturing Licensing is complete.

A letter of Personal Hearing was issued to the firm on 28th August, 2020.

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

Mr. Mir Anjum Ishaq Director of M/s Hoover Pharmaceuticals (Pvt) Ltd, Plot No. 16, Zain Park Industrial Area, Saggain Bypass Road, Lahore appeared before the Board. He submitted that since legal and codal

formalities has been complied therefore showcause notice may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of the showcause Notice. The Board also decided to issue warning to the firm to be careful in future for compliance of the law.

Case No. 36 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AXIS PHARMACEUTICALS, FAISALABAD.

M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad. DML No. 000667(Formulation). **Name of Sections (01)** 1. Topical Semisolid (Cream / Ointment / Gel) Section (New section).	09-06-2020	**Good**	1. Dr Munawar Hayat, Chief Drugs Controller, Punjab 2. Dr. Farzana Chaudhary, Expert Member. 3. Mr Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore

Recommendations of the panel: -

" Based on the areas inspected, the technical people met and the documents reviewed and considering the findings of the inspection the panel verified a satisfactorily maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirement of DML as per Drug (Licensing , Registering and Advertising) Rules, 1976 and capacity & capability of the firm in respect of manufacturing and quality control of all registered products and approved sections and newly applied section as per following list.

1. Tablet Section (General).
2. Capsule Section (General).
3. Dry Powder Sachet Section (General).
4. Oral Liquid Section (General).
5. Topical Semisolid (Cream / Ointment / Gel) Section (New section).

The Panel of Inspectors **recommends** the renewal of Drug Manufacturing License No. 000667and grant of new manufacturing section in favour of M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City,

1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad"

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of Additional sections/ facilities/ amendments in the name of M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad

Name of Sections (01)

Topical Semisolid (Cream / Ointment / Gel) Section (New section).

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

The title of the firm was mistakenly written as "M/s Axis Pharmaceuticals (Pvt) Ltd" instead of "M/s Axis Pharmaceuticals" and Drug Manufacturing License had been issued with the same title. Now, the firm has returned the original Form-2 with the request to correct the title.

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

The Board considered and approved the correction.

Case No. 37 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDISAVE PHARMACEUTICALS, LAHORE.

M/s Medisave Pharmaceuticals. Plot No. 578,579 Sunder Industrial Estate, Lahore had applied for renewal of DML No. 000681 by way of Formulation for the period of 26-01-2020 to 25-01-2025 on 17-01-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 18thFebruary, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Duly attested CNIC Copies of all partners.
iii. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm replied to this letter on 03rd March, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 27thApril, 2020 to the firm for completion of application:

i. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm submitted documents on 04thJune, 2020 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

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 of M/s Medisave Pharmaceuticals. Plot No. 578,579 Sunder Industrial Estate, Lahore Drug Manufacturing Licence No. 000681 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No.38. SURRENDER OF DRUG MANUFACTURING LICENSE NO.000254 (FORMULATION) OFM/S KARIM INDUSTRIES, LAHORE.

Drug Manufacturing License No.000254 (Formulation) was issued to M/s Karim Industries, Lahore. Original files of the firm were handed over of Medical Devices & Medicated Cosmetics, Division, DRAP, Islamabad after S.R.O 824(i) / 2018. Now M/s Karim Industries, Lahore, has intimated that they have been shifted from Pharmaceutical Division to Medical Devices Division as per the directions of DRAP and the firm have also been granted Drug Manufacturing License from Medical Devices, Division of DRAP, Islamabad. Therefore, the firm has surrendered their Drug Manufacturing License No. 000254 (Formulation).

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

The Board considered and acceded the request of the firm. The Board also decided to seek current status of similar firms from MDMC and submit the report to Central Licensing Board for consideration.

Case No. 39 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HIGHNOON LABORATORIES LTD, LAHORE.

M/s Highnoon Laboratories Ltd, 17.5-Km, Multan Road, Lahore had applied for renewal of DML No. 000155 by way of Formulation for the period of 21-08-2020 to 20-08-2025 on 28-11-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 26thFebruary, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Section approval letters of Tablet (General) section & Capsule (General) section approved by CLB.
ii. Duly attested CNIC copies of all Directors.
iii. Prescribed fee of Rs. 50,000/- for change in management of the firm as there has been change in management of the firm.

The firm replied to this letter on 18thMarch, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 19thMay, 2020 to the firm for completion of application:

i. Section approval letters of Tablet (General) section & Capsule (General) section approved by CLB.

The firm submitted documents on 08thJune, 2020 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

ii. Section approval letters of Tablet (General) section & Capsule (General) section approved by 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 of M/s Highnoon Laboratories Ltd, 17.5-Km, Multan Road, Lahore Drug Manufacturing Licence No. 000155 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 40. CHANGE OF MANAGEMENT OF M/S. ICI PAKISTAN LTD, UNDER DRUG MANUFACTURING LICENSE NO. 000006(FORMULATION), KARACHI.

M/s. ICI Pakistan Ltd, Plot No. S-33 Hawkes Bay Road, S.I.T.E, Karachi under DML No.000006 (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:-

Previous Management as approved by the CLB in its 259th meeting	Current Management as per form-29 (Year 2020)
1. Asif Jooma S/o Umer Wali Jooma CNIC No.42301-3175078-7. 2. Kamal A Chinoy S/o Amir S Chinoy CNIC No.42301-1401852-5. 3. Muhammad Abid Ganat S/o Moosa Ganatra CNIC No.42201-5355492-7. 4. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No.42000-0568372-5 5. Muhammad Ali Tabba S/o Abdul Razzak Tabba CINC No.42201-6464247-3 6. Jawed Yunus Tabba S/o Muhammad Yunus CNIC No.42201-2111104-7 7. Amina Abdul Aziz Bawany W/o Abdul Aziz Bawany CNIC No.42000-3004991-0. 8. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No.42301-8986425-7	1. Asif Jooma S/o Omar Valli Jooma CNIC No.42301-3175078-7. 2. Syed Muhammad Shabbir Zaidi S/o Syed Muhammad Tehwar Zaidi CNIC No. 42301-1740521-7 3. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No.42201-5355492-7. 4. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No.42000-0568372-5 5. Muhammad Ali Tabba S/o Abdul Razzak Tabba CINC No.42201-6464247-3 6. Jawed Yunus Tabba S/o Muhammad Yunus CNIC No.42201-2111104-7 7. Amina Abdul Aziz Bawany W/o Abdul Aziz Bawany CNIC No.42000-3004991-0. 8. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No.42301-8986425-7

Submitted for consideration of the board, please.

<u>Decision of the Central Licensing Board in 276th meeting:</u>

The Board considered and endorsed the change of management of M/s. ICI Pakistan Ltd, Plot No. S-33 Hawkes Bay Road, S.I.T.E, Karachi under DML No.000006 by way of formulation as under;

Previous Management as approved by the CLB in its 259th meeting	Current Management as per form-29 (Year 2020)
1. Asif Jooma S/o Umer Wali Jooma CNIC No.42301-3175078-7. 2. Kamal A Chinoy S/o Amir S Chinoy CNIC No.42301-1401852-5. 3. Muhammad Abid Ganat S/o Moosa Ganatra CNIC No.42201-5355492-7. 4. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No.42000-0568372-5 5. Muhammad Ali Tabba S/o Abdul Razzak Tabba CINC No.42201-6464247-3 6. Jawed Yunus Tabba S/o Muhammad Yunus CNIC No.42201-2111104-7 7. Amina Abdul Aziz Bawany W/o Abdul Aziz Bawany CNIC No.42000-3004991-0. 8. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No.42301-8986425-7	1. Asif Jooma S/o Omar Valli Jooma CNIC No.42301-3175078-7. 2. Syed Muhammad Shabbir Zaidi S/o Syed Muhammad Tehwar Zaidi CNIC No. 42301-1740521-7 3. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No.42201-5355492-7. 4. Muhammad Sohail Tabba S/o Muhammad Yunus Tabba CNIC No.42000-0568372-5 5. Muhammad Ali Tabba S/o Abdul Razzak Tabba CINC No.42201-6464247-3 6. Jawed Yunus Tabba S/o Muhammad Yunus CNIC

	No.42201-2111104-7 7. Amina Abdul Aziz Bawany W/o Abdul Aziz Bawany CNIC No.42000-3004991-0. 8. Khawaja Iqbal Hassan S/o Khawaja Zafar Hassan CNIC No.42301-8986425-7

Case No. 41. **RENEWAL OF DRUG MANUFACTURING LICENCE AND CHANGE OF TECHNICAL STAFF APPLICATION OF M/S NEOMEDIX, PLOT NO. N/5, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD.**

M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, had applied for renewal of DML 000539 by way of (Formulation) for the period of 02-04-2019 to 01-04-2024. 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 11th September, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Form-1A duly signed & stamp by CEO.
ii. Classes of Drugs.
iii. Dosage forms of drugs.
iv. Name(s) of drugs registered / approved.
v. Detail of management at the time of previous and present renewal
vi. Partnership Deed alongwith CNIC's of all partners.
vii. Proof of Licensed Section from CLB.
viii. Up to date nothing due certificate regarding CRF from STO.
ix. All documents should be duly attested.

The firm submitted their reply on 15th October, 2019 after evaluation of the submitted documents, final reminder was issued on 15th October, 2019 to the firm with following shortcomings: -

For Quality Control Incharge.

1. Appointment letter.
2. Job acceptance letter by the appointee.
3. Copy of CNIC of appointee.
4. Copy of academic degrees.
5. Registration certificate from Pharmacy Council.
6. Experience Certificate.
7. Resignation of earlier Q.C Incharge.
8. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Attested).
9. Undertaking as whole time employee on stamp paper as per check list.

For Production Incharge.

i. Job acceptance letter by the appointee.
ii. Resignation / retirement of earlier approved Production Incharge.
iii. Undertaking as whole time employee on stamp paper as per check list.

Firm has submitted their reply in response to this Division's Final Reminder and following documents are still deficient /short and application for renewal of DML was incomplete:-

For Renewal of DML.

i. Name(s) of drugs registered / approved.
i. Detail of management at the time of previous and present renewal.
ii. Partnership Deed alongwith CNIC's of all partners.
iii. Detail of premises including layout plan.
iv. All documents should be duly attested.

For Prod. Incharge.

iv. Job acceptance letter by the appointee.
v. Resignation / retirement of earlier approved Production Incharge.
vi. Undertaking as whole time employee on stamp paper as per check list.
vii. All documents should be duly attested

For Q.C. Incharge.

i. Job acceptance letter by the appointee.
ii. Copy of CNIC of appointee.
iii. Copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
iv. Registration certificate from Pharmacy Council (in case of Pharmacist).
v. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
vi. Resignation / retirement of earlier QC Incharge.
vii. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
viii. Undertaking as whole time employee.

Proceedings and Decision by the Central Licensing Board in 276nd 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad, Drug Manufacturing Licence No 000539 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board

Case No. 42. SITE VERIFICATION OF M/S SIDDIQUI PHARMACEUTICAL, MULTAN..

Site verification report of M/s Siddiqui Pharmaceutical, Khewat No. 101/98, Khatooni No. 259/264, Behind Rescue 1122 Station, China Chowk, Phase-II Multan Industrial Estate, Multan. The inspection was conducted by Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore on 27-02-2020, in response to this office letter dated 18th May, 2018. The recommendations of the inspection report are as under:-

i. **Location** : The proposed site is located at Khewat No. 101/98, Khatooni No. 259-264, behind Rescue 1122 Station, China Chowk, Phase-II, Multan Industrial Estate, Multan (out side of estate).

ii. **Surrounding** : The dimensions of the plot are as follow:-

On the front side of the site there was 30 ft wide road.
On the left side of the site there was 30 ft wide road and their was also two functional klint at about 300-400 meters.
On the right side of the site there was open field.
On the back side of the site there was also open field.

iii. **Recommendations** : "**It was observed that at the distance of 300-400 meter away from the site their were two heavy functional klints.**

The above observation led to the conclusion that the site is as per requirements, laid down under paragraph 1 of section 1 of schedule "B" (SRO 470 (1)/98 dated 15-05-1998) under rules 16 (a) of the Drugs (Licensing, Registration and Advertising) rules 1976". Hence the proposed site is **not suitable** for establishment a pharmaceutical unit as of today.

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

The Board considering the case and decided to serve Show Cause Notice to the firm as to why their site for establishment of pharmaceutical unit may not be rejected on the recommendations of the Federal Inspector of Drugs. Board further decided that area Federal Inspector of Drugs may be called for clarification regarding recommendations by him about suitability of proposed site.

Case No. 43. RENEWAL OF DRUG MANUFACTURING LICENCE UNDER DML NO. 000255 OF M/S PHARMACARE LABORATORIES (PVT) LTD, PLOT NO. 129/1, INDUSTRIAL ESTATE, KOTLAKHPAT, LAHORE.

Case background. M/s Pharmacare Laboratories (Pvt) Ltd, Lahore, had applied for renewal of DML 000255 by way of (Formulation) for the period of 13-06-2019 to 12-06-2024. 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 18th July, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

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

ii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee.
iii. CNIC copies of all Directors.
iv. Latest certified true copy of Form-29 (attestation by SECP).
v. Section approval letter of all sections approved by Central Licensing Board.
vi. List of technical staff working in Production & Quality Control department.
vii. All documents should be duly attested.

2. The firm submitted their reply on 6th August. 2019 After evaluation of the submitted documents, final reminder was issued on 14th October, 2019 to the firm with following shortcomings: -

i. Nothing-due certificate regarding CRF from STO (updated).
ii. Latest certified true copy of Form-29 (Attestation by SECP Without the phrase of (SECP) to not take responsibility of contents of form.
iii. Section approval letter of all sections approved by Central Licensing Board, if not available, apply for regularization of layout plan.

3. Firm has submitted their reply in response to this Division's Final Reminder and following documents are still deficient /short and application for renewal of DML was incomplete:-

i. Nothing-due certificate regarding CRF from STO (updated).
ii. Latest certified true copy of Form-29 (Attestation by SECP Without the phrase of (SECP) to not take responsibility of contents of form.
iii. Section approval letter of all sections approved by Central Licensing Board, if not available, apply for regularization of layout plan.

4. Meanwhile inspection report by the panel constituted 2017 for the term 13-06-2014 to 12-06-2019 is received which was conducted on 16-1-2020 as blow:

	M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore. DML No.000255 (Formulation). **Period**: 13-06-2014 to 12-06-2019	16-01-2020	Good	1. Dr. Farzana Chowdhary, Member, CLB, DRAP, Islamabad. 2. Syed Shahid Nasir, Expert, Member. 3. Aisha Irfan, FID, DRAP, Lahore.
	Recommendations of the panel: - "The panel of inspectors **do not recommend** the renewal of Drug Manufacturing License to M/s Pharmacare Labs (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore".			

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Central Licensing Board considered the case and noted with serious observations for delays in coordinating and conducting of panel Inspections by the Federal Inspector of Drugs. The Board perused the inspection report

of the panel on record where serious observations are recorded in terms of GMP non Compliance. The Board, therefore, decided to stop production of the firm with immediate effect in public interest.

The Board considering the facts on the record in respect of renewal application for the period 13-06-2019 to 12-06-2024 and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Pharmacare Labs (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore Drug Manufacturing Licence No. 000255 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Reply of the firm.

M/s Pharmacare Laboratories (Pvt) Ltd, Plot No. 129/1, Industrial Estate, Kotlakhpat, Lahore wherein the firm has submitted reply in response to this Division's Show Cause Notice dated 15th July, 2020 for renewal of Drug Manufacturing License application as under;

i. Under Drug Manufacturing License No.000255 dated 13-06-1985, we were licensed to manufacture all such drugs, which initially and from time to time, we were permitted to manufacture. Ever since 1985 there has NOT been one instance where we have ever deviated from the requirements of Drug Licensing and Registration Rules. However there is always ROOM FOR IMPROVEMENT, which we have and will always abide you.

ii. Regarding the deficiencies conveyed to us through your above referred letter No.F.1-72/84-Lic (Vol-III) dated 15-07-2020 which we received on dated 23-07-2020, it is to submit that some have been rectified and other remaining will be rectified within month or so. So the panel can visit the manufacturing facility for the verification of compliance.

The case was placed in 276 meeting of the CLB. The firm was issued letter for personal hearing on 28th August, 2020.

Decision by the Central Licensing Board in 276th meeting

Mr. Babar Mehmood Ch. CEO of the company appeared before the Board and contended that almost most of the shortcomings have been rectified. He further argued that he needs one month time for rectifications of all the observations of the Inspection.

The Board after hearing the representative of the firm and considering the facts on the record and after thread bare deliberation decided to suspend the Drug Manufacturing Licence No. 000255 by way of formulation for three (03) months issued in the name of M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore 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 and Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No. 44. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S TRISON RESEARCH LABORATORIES (PVT) LTD, SARGODHA.

M/s Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, P.S.I.E Sargodha had applied for renewal of DML No. 000529 by way of Formulation for the period of 27-01-2019 to 26-01-2024 on 15-01-2019. The application for the renewal of DML was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 21st February, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

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

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

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

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

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

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

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, P.S.I.E Sargodha, Drug Manufacturing Licencee No 000529 by way of formulation may not be rejected or Drug Manufacturing Licencee may not be suspended or cancelled by Central Licensing Board.

The case was placed in 276 meeting of the CLB. The firm was issued letter for personal hearing on 28th August, 2020.

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

Mr. Mubbashir Javaid CEO of M/s Trison Research Laboratories (Pvt) Ltd, Plot No. 27-A, P.S.I.E Sargodha appeared before the Board. He submitted that since legal and codal formalities has been complied therefore showcause may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of the showcause Notice. The Board also decided to issue warning to the firm to be careful in future for compliance of the law.

Case No. 45. GRANT OF ADDITIONAL API's UNDER DRUG MANUFACTURING LICENCE NO. 000325 (SAMI BASIC) OF M/S PHARMAGEN LIMITED, LAHORE.

M/s Pharmagen Limited, 34-KM, Ferozepur Road, Lahore had applied for grant of API's under DML No. 000325 (by way of Sami Basic) and the case was placed before 275th meeting of Central Licensing Board held on 25th June, 2020 and decided as under:-

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of Additional API in the name of M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore on the recommendations of the panel of experts:

Name of API's (01)

1. Moxifloxacin (USP/BP/EP).

The Board also decided to call the representative of the firm in the next meeting of the Board for seeking clarification for manufacturing of Ciprofloxacin base instead of Ciprofloxacin HCL

The case was placed in 276th meeting of the CLB. The firm was issued letter for personal hearing on 28th August, 2020.

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

Mr Sarfraz, Quality Control Manager of the firm the firm appeared before the Board. He could not present any document in his support for seeking approval of Ciproflozacin Base. The Board after considering the facts decided to defer the case to get more evidence from the firm regarding need of Ciprofloxacin base.

Case No. 46. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S PANACEA PHARMACEUTICALS, PLOT NO. 4, STREET NO. S-6, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD.

Case background: Mr. Hasan Afzaal, FID-III, DRAP, Islamabad he has submitted inspection report for Renewal of Drug Manufacturing License No. 000600 by way (Formulation) of M/s Panacea Pharmaceuticals,

Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad. The conclusion of inspection report is as under:-

"Keeping in view the above facts, detailed visit of facility as of today and review of documents the panel unanimously **Recommended** M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad for the Renewal of Drug Manufacturing License No. 000600 (Formulation) for the following sectio0ns namely;

1. Tablet Section (General).
2. Capsule-I Section (General).
3. Capsule-II Section (General).
4. Tablet Section (Psychotropic).
5. Cream / Ointment Section (General).
6. Dry Suspension Section (General).
7. Sachet Section (General).
8. Sterile Ophthalmic (General).

The panel has also verified the amendments in the Layout of the following sections;

9. Capsule (Ceph).
10. Dry Powder for Suspension (Ceph).

2. The case was placed in 276th meeting of the Central Licensing Board held on 25th June, 2020 and decided as under:-

Decision of the Central Licensing Board in 275th meeting

The Board considered and deferred the grant of renewal in the name of M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad as panel of inspectors has rated it as satisfactory / average while Board has clear recommendations time and again that firms of at least good or very good rating may be recommended. The Board, therefore, decided to get the facility re-inspected by the following panel:

1. Mr. Manzoor Ali Bozdar, Secretary, Central Licensing Board.
2. Ms Mahvash Ansari, Deputy Director (QC).
3. Area Federal Inspector of Drugs, DRAP, Islamabad.

3. Mr. Manzoor Ali Bozdar, Secretary Central Licensing Board has declined to proceed due to work load official assignments. Therefore, panel may be re-constituted.

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

The Board after considering the facts decided to re-constitue the panel of experts as under:-

1. Prof. Dr. Gul Majeed, Professor , QAU
2. Ms Mahvash Ansari, Deputy Director (QC).
3. Area Federal Inspector of Drugs, DRAP, Islamabad.

Case No. 47 **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: -

7. Form-1A dully signed and attested by the management of firm alongwith all enclosures.
8. 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).
9. 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).
10. 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.
11. 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 duly 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.

Case No. 48 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S IRZA PHARMA (PVT) LTD, DISTRICT SHEIKHUPURA.

M/s Irza Pharma (Pvt) Ltd, 10/2-Km, Lahore Sheikhupura Road, P.O Kot Abdul Malik, District Sheikhupura had applied for renewal of DML No. 000108 by way of Formulation for the period of 12-07-2019 to 11-07-2024 on 15-07-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 23rd August, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Detail of management at the time of previous renewal and at present, if any change, apply for change of management.
iii. Duly attested job acceptance letter by Quality Control Incharge.
iv. Latest certified true copy of Form-29 mentioning all Directors (Attestation by SECP).
v. Duly attested CNIC copies of all Directors.

The firm replied to this letter on 18th September, 2019 and the deposited balance fee of Rs. 15,000/-for late submission of application on 14th February, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 27thApril, 2020 to the firm for completion of application:

i. Latest certified true copy of Form-29 duly attested by S.E.C.P without phrase that S.E.C.P does not take any responsibility of the correctness of the contents of Form.

The firm submitted documents on 12th May, 2020 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest certified true copy of Form-29 duly attested by S.E.C.P without phrase that S.E.C.P does not take any responsibility of the correctness of the contents of Form.

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 of M/s Irza Pharma (Pvt) Ltd, 10/2-Km, Lahore Sheikhupura Road, P.O Kot Abdul Malik, District Sheikhupura Drug Manufacturing Licence No. 000108 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 49 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDI-VET (PVT) LTD, LAHORE.

M/s Medi-Vet (Pvt) Ltd, 16-Km, Sheikhupura Road, Lahore had applied for renewal of DML No. 000269 by way of Formulation for the period of 22-12-2019 to 21-12-2024 on 24-10-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 19th February, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Classes of drugs & dosage forms of drugs.
iii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).
v. Duly attested CNIC copies of all Directors.
vi. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm replied to this letter on 11th March, 2020but application was incomplete with following shortcomings and reminder letter was issued on 8th May, 2020 to the firm for completion of application:

i. Properly filled, signed & stamped Form-1A (as per format) signed by management.
ii. Classes of drugs & dosage forms of drugs.

iii. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).
v. Duly attested CNIC copies of all Directors.
vi. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm submitted documents on 28th July, 2020 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Properly filled, signed & stamped Form-1A (as per format)filled by Mr. Saeed Iqbal and signed by Mr. Haris Saeed.
ii. Prescribed fee of Rs. 50,000/- as there is change in management of the firm.
iii. Latest certified true copy of Form-29 duly attested by SECP.
iv. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

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 of M/s Medi-Vet (Pvt) Ltd, 16-Km, Sheikhupura Road, Lahore Drug Manufacturing Licence No. 000269 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 50. AMALGAMATION OF LAND IN ALREADY EXISTING UNIT M/S SAPIENT PHARMA, 123/S INDUSTRIAL AREA KOT LAKHPAT, LAHORE.

M/s Sapient Pharma, 123/S Industrial Area, Kot Lakhpat, Lahore. Drug Manufacturing License No. 000207 (Formulation)	**19-09-2019** **&** **18-11-2019**	**Good**	1. Dr. Farzana Chowdhary, Member. 2. Ms. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP,

Period: Commencing on 09-02-2016 ending on 08-02-2021.			Lahore.

Recommendations of the panel: -

In view of above inspection proceedings and facilities checked such as company, profile building machinery material, management, personnel, documentation and quality control testing, etc, the panel **recommends** the renewal of Drug Manufacturing License to M/s Sapient Pharma, 123/S, Industrial Estate, Kot Lakhpat, Lahore by way of formulation for the following sections only:-

1) Oral Liquid Section.
2) General Tablet Section.
3) Cream/Ointment Section.
4) External Preparation Section.
5) Ear Drop Section.
6) Suppository Section".

In addition to this it was observed that the area of the firm was 2 Kanal 4 Marlas, however the management of the firm informed that the adjacent land of 2 Kanal 1 Marla was purchased by the firm and now the total area is 04 Kanal 05 Marla as per requirement of Drugs Act 1976/DRAP Act 2012,. The panel advised the firm to submit documents of acquired land for regularization to Licensing Division, DRAP, Islamabad.

Decision by the Central Licensing Board in 273rd meeting

The Board considered and defferred the renewal of Drug Manufacturing Licence No. 000207 (Formulation) in the name of M/s Sapient Pharma, 123/S Industrial Area, Kot Lakhpat, Lahore.for seeking clarification from the firm regarding minimum area of establishment in the light of observation of the panel.

Proceedings of Licensing Divison:

Site verification report of M/s Sapient Pharma, 123/S, Industrial Estate, Kot Lakhpat, Lahore. The inspection was conducted by Mrs. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore on 02-09-2020 in response to this office letter dated 1st September, 2020. The recommendations of the inspection report are as under:-

Location:	The proposed site is located at 104/S, Industrial Area, Kot Lakhpat, Lahore.
Surrounding:	On the front side of the site there was a wide road. On the left side of the site there was an empty small building on plot No. 105/S. On the right side of the site there was an empty shed. On the back side of the said site was linked with 123/S plot which is the existing facility of M/s Sapient Pharma.
Size:	The size of plot was 02 kanals 01 marla. The dimension of the plot is annexed with the report. On the site a large hall alongwith some small rooms were constructed.
Recommendations:	The above observation led to the conclusion that the site is as per requirement, laid down under paragraph 1 of section 1 of schedule "B" (SRO 470 (1)/98 dated 15-05-1998) under rules 16 (a) of the Drugs (Licensing, Registration and Advertising) rules 1976. Hence the proposed site is suitable, and is recommended for the extension of M/s Sapient Pharma, Kot Lakhpat, Lahore.

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

The Board after considering the facts on the record and after thread bare deliberation decided to approve the site for amalgamation of land in already existing unit M/S Sapient Pharma, 123/S Industrial Area Kot Lakhpat, Lahore and now firm meet the minimum area requirement of the plot as required under the rules. The Board also approved renewal of Drug manufacturing Licence in the name of of M/S Sapient Pharma, 123/S Industrial Area Kot Lakhpat, Lahore commencing on 09-02-2016 ending on 08-02-2021 on the recommendation of the panel of experts.

QUALITY ASSURANCE CASES

Case No. I **M/s Rex Pharmaceutical Pakistan, Karachi**

Background of the case

Mr. Abdul Rasool Sheikh, FID, Karachi conducted inspection of the firm M/s Rex Pharmaceutical Pakistan, Karachi on 06.03.2013. During inspection the FID pointed out number of serious/critical shortcomings in all sections. Accordingly show cause notice/stop production order was issued on 23.04.2013. The case was presented before CLB in its 232nd meeting held on 29&30th July 2013. The Board had decided as under:-

i) The case was deferred by Central Licensing Board till its next meeting as per your request that the Director of the firm had gone to Saudi Arabia for performing Umrah and requested to defer the case till next meeting of CLB.

ii) The production will remain stopped / suspended till the final approval for resumption of production by the Central Licensing Board.

2. The case was presented before the 233rd Meeting of CLB, wherein the CLB had decided as under:-

Decision of 233rd Meeting of CLB:

After thorough discussion and deliberations, considering the background of the case and facts on record, Board unanimously decided to suspend the DML of the firm for period of three months under Rule 13 of Drugs (Licensing, Registering and Advertising) Rules, 1976. The Board further decided to issue show cause notice and personal hearing to the firm and advised for market survey of production manufactured by firm.

3. Decision of the CLB was conveyed to the firm on 24.02.2014.The firm vide letter No. Nil dated 02.04.2014 replied that they have removed all the shortcomings and ready for inspection. The Area FID visited the firm on 18.11.2014 and recommended for cancellation of DML. The case was placed before the CLB in its 245th Meeting held on 30.12.2015.

4. The case was again presented before the 245th Meeting of CLB, wherein the CLB had decided as under:-

Decision of 245th Meeting of CLB:

The Board after thorough discussion, keeping in view the available record, observations of the FID in its inspection conducted on 06.03.2013, track record and non-serious attitude of the firm, and report of the FID dated 18.11.2014 which categorically stated that "The DML of the firm may be cancelled in larger public interest", has decided to suspend the DML of the firm M/s Rex Pharmaceuticals Pakistan, Karachi for a period of 06 months, under Rule 12 of the Drugs (LR&A) Rules, 1976.

5. The decision of the CLB was conveyed to the firm on 09.02.2016.

Recommendations of FID

Mr. Abdul Rasool Shaikh, FID, Karachi vide letter dated 24.01.2017 informed that the firm was inspected on 06.01.2017 and found non-operational, no one was there except watchman who told that factory is closed since 2011 and owners are reported to be living in USA now days. Based on the current conditions of the firm it is recommended that their DML by way of formulation may be cancelled in larger public interest.

6. The recommendations of FID were presented before the 252nd Meeting of CLB, wherein the CLB had decided as under:-

Decision of the 252nd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the Federal Inspector of Drugs in its letter dated 24.01.2017, in which the FID recommended to cancel the DML of the firm in the larger public interest, casual attitude of the firm towards GMP compliance, track record of the firm and nonappearance of representatives of the firm before the Board to defend the case, the Board decided to *cancel the Drug Manufacturing License of the firm M/s Rex Pharmaceutical Pakistan, Karachi*, under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (L,R&A) Rules, 1976, from the date of issuance of decision of the 252nd meeting of CLB.

7. The firm file appeal in Appellate Board under section 9th of the Drugs Act, 1976 147th. The Board decided as under:-

Decision of Appellate Board in its 147th Meeting

M/s Rex Pharmaceutical Pakistan, Karachi filed an appeal against the decision of the CLB regarding cancellation of DML. The case was considered in 147th meeting of the Appellate Board held on 28.08.2017, wherein the appellate board decided to suspend the operation of impugned order of CLB dated 15.03.2017 communicated on 24.04.2017 and remand the appeal back to the CLB. The appellate board constituted a panel of following panel to inspect the premises of the appellant who shall submit its report within 30 days from the date of communication:-

a. Dr. KifayatUllah, CDC, Gilgit, Baltistan
b. Prof. Dr. Maqsood Ahmed, Riphah International University, Lahore
c. Syed Muied Ahmed, Expert in Manufacturing, Karachi

Report of the panel will be placed before the CLB in its forthcoming meeting. Meanwhile the production of the firm will remain suspended till recommendations by the panel for the resumption of production and approval thereof by the CLB.

8. The panel inspected the firm on 12.12.2017 and noticed observation which still needs rectification:-

The panel further concluded and recommended that:-

The panel observed a number of shortcomings in building, production machinery, HVAC system, documentation etc. Therefore, based on the areas inspected, the people met and documents reviewed and considering the findings of inspection the panel recommends that the Drug Manufacturing License may be granted to M/s Rex Pharmaceuticals Pakistan, Karachi, for two sections only namely Oral Liquids and Tablet (after addressing the observations in this report).

9. The panel inspection report was placed before 257th meeting of CLB. Wherein the Board decided as under:-

Decision of 257th Meeting of CLB:-

The case was placed before the Central Licensing Board in its 257th Meeting held on 24-25 Jan, 2018 and decided as under:-

"After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the panel of experts in its report dated 12.12.2017 decided to

i. Re-inspect the firm M/s Rex Pharmaceutical Pakistan, Karachi by following panel of experts, constituted by the Appellate Board in its 147th Meeting:-

a. Dr. KifayatUllah, CDC, Gilgit, Baltistan
b. Prof. Dr. Maqsood Ahmed, Riphah International University, Lahore
c. Syed Muied Ahmed, Expert in Manufacturing, Karachi

ii. The panel shall submit the detailed report along with rectification status of the observations in the Tablet Section and Liquid Syrup Section noted by the panel in the report dated 12.12.2017. Furthermore the panel will also submit detailed report regarding the quality control laboratory and storage facilities of the firm. The report shall be placed in the forthcoming meeting of Central Licensing Board for consideration.

10. The Decision of the 257th meeting of CLB was conveyed to the firm and quarters concerned on 06.03.2018.

11. The firm vide letter No. Nil dated 20.03.2018 received on 27.03.2018 informed that they have rectified the observations recommended by the panel. In the mean while one of the respected panel member Dr. KifayatUllah, CDC, Gilgit passed away.

12. The case was placed before 259th meeting of CLB. The Board decided as under:-

Decision of the 259th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case and intimation of the firm regarding death of the worthy panel member Dr. Kifayatullah, Chief Drug Controller, Gilgit Baltistan, the Central Licensing Board decided to replace name of deceased member Dr. Kifayatullah, Chief Drug Controller, Gilgit Baltistan with Additional Director, Karachi, other members of the panel shall remain same.

13. Mr. Syed Muied Ahmad, Member, CLB vide letter dated 25.04.2019 addressed to Chairman CLB informed that he could not conduct regulatory inspections due to illness of his mother.

14. Request of Mr. Syed Muied Ahmad, Member, CLB was placed before 270th meeting of CLB. The Board decided as under:-

Decision of the 270thMeeting of CLB

After thorough discussion/deliberations and keeping in view the request of Mr. Syed Muied Ahmad. The board decided to nominate Dr. Abdullah Dayo, Member, CLB in lieu of Mr. Syed Muied Ahmad.

15. Decision of 270th meeting was conveyed to the quarters concerned. The panel conducted inspection of the firm on 12.07.2019 submitted comparison of observations noted on 12.12.2017 and 12.07.2019. The panel concluded as under:-

"Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, it was noticed that no technical person (in Quality Control laboratory, Production sections and ware house) was available in the firm to represent and answer, technically, the observations of the panel. The firm was being represented by Mr. Muhammad Amin along with his son and daughter. Moreover, Quality Control Laboratory required to be upgraded in terms of equipment and testing procedures. Management also couldn't display the equipment in working condition as no power supply was seen in the QC Laboratory and re-calibration was also due for available equipments. HVAC system, in general, requires to be commissioned and qualified and air balancing to be performed to avoid any chance of contamination and cross-contamination. Power supply was also seen inadequate and insufficient to run the production operations smoothly including HVAC system. The management of M/s. Rex Pharmaceutical Pakistan couldn't improve / upgrade the production and testing facility as identified by the panel during inspection on dated 12.12.2017.

Keeping in view the above stated facts, Panel does not recommend the commencement of the production in these sections in larger public interest."

16. The case was placed in 271st meeting of CLB.

Proceedings of 271st meeting:-

Quality Assurance Division presented the case before the Board keeping in view the recommendations of panel in its report dated 12.07.2019. The board discussed the case in detail including decision of 252nd meeting of CLB, wherein the Board decided to cancel the DML of the firm. The Board also go through the decision of 147th meeting of Appellate Board and subsequent recommendations of the panel in its report dated 12.07.2019, in compliance to 270th meeting of CLB.

Decision of the 271stMeeting of CLB

After thorough discussion/deliberations, the Board considered the report of the panel of experts dated 12.07.2019 and recommendations of the panel of experts. The Board also considered the background history of the case and failure on the part of the firm for complying the conditions of License as enumerated under Rule, 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 and Schedule B framed under the Drugs Act, 1976. The Board, therefore decided to serve Show Cause Notice under Section 41 of the Drugs Act, 1976

read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 to the firm M/s Rex Pharmaceuticals Pakistan, DP-3, Sector 12-D, North Karachi Industrial Area, Karachi as to why their Drug Manufacturing License No. 000536 by way of formulation may not be suspended or cancelled for failure to maintain conditions of License as enumerated under Rule, 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 and Schedule B framed under the Drugs Act, 1976 and reported by the panel of experts in their inspection report dated 12.07.2019.

17. The firm was issued show cause No. F. 8-3/2019-QA (CLB-M-271) on 01.10.2019 in compliance to decision of 271st meeting of CLB.

18. The case was placed before the 273rd meeting of CLB.

Proceedings of 273rd Meeting of CLB

Division of QA&LT presented the case before the CLB. Mr. Amin Akhai (Owner of the firm) and his Son Mr. Zaid Akhai of the firm M/s. Rex Pharmaceuticals Pakistan, Karachi appeared before the Board. Mr. Amin Akhai stated that they did not receive show cause notice or personal hearing letter. On query raised by Board regarding information of meeting. He stated that one of his friends told him about the personal hearing so he reached Islamabad. Accordingly copy of show cause notice and personal hearing letter was handed over to Mr. Amin Akhai in the Board. Secretary, CLB and Deputy Director (QA) inform to the Board that the firm also file a writ petition No D-6473/2019 in the High Court of Sindh at Karachi. Mr. Amin Akhai requested that the correspondence may also be made on the address *"A-35, Muhammad Ali Jinnah Society, Karachi"* in addition to the factory Address.

Decision of 273rdMeeting of CLB

Without prejudice any order of any court including High Court & Supreme Court and after thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view available record and request of the firm, the Board decided to provide:-

i. Final opportunity to submit reply of Show Cause notice dated 01.10.2019 within 15 days.
ii. Last chance of personal hearing in the forthcoming meeting of CLB.

19. The firm vide letter dated 29.01.2020 submitted reply of show cause notice and submitted para wise reply as under:

"Inspection conducted by Area FID, Karachi on 06.01.2017

The inspection report submitted by Abdul Rasool Sheikh' FID Karachi' vide letter, dated 24.01.2017, informed that, the firm was inspected on 06.01.2017 and found non-operational, no one there except watchman who told that factory is closed since 2011 and owners are reported to be living USA now days. Based on the current conditions, of the firm it is recommended that, the DML by way of formulation may be cancelled in larger public interest. It is pertinent to mention here that, the FID had submitted a fake report and even otherwise, if consider the same, how come it be possible that, when a factory which was initially inspected on 06.03.2013, now declared as a close factory since from the year 2011 and mentioning about the living of owners abroad in

USA now a days. Even otherwise, the factory was / has to remain in operative due to the decision of suspension of DML by the CLB.

10. That the contents of Paragraph No. 12, are denied. There was no inspection was ever conducted on 12.07.2019, by the panel of three members and the inspection report is a fake report. It is pertinent to mention here that, the team of members reached at the factory / firm on 12.07.2019, but they left from there within a time of 10-15 minutes, without even conducting a proper inspection and visiting the premises and area of productions, as is evident, from the report of inspection submitted by the three members panel in which there is no signature of mine and the only signatures are placed by the three members panel. It is submitted here that, the copy of the inspection report, dated 12.07 .2019 ' was delivered to me by hand when on 15.01 2020, I personally appeared before you in 273rd meeting held in Islamabad, without receiving a notice of personal hearing and intimation from your end. The information of the above referred meeting was gathered by us from a reliable source, which l informed you as well and in lieu of the same you have forced me to receive a back dated show cause notice, dated 10.10.2019 alongwith the inspection report, dated 12.07.2019 (not signed by me / only signed by three members panel) with an instruction given on the said show cause notice to reply the same in writing within 15 days of issuance of this letter (which was expired much earlier), but the same is now replied by me, due to show a gesture that, I was and still trying to get a positive reply from your end, keeping in mind that, I was not Provided any equal opportunity of personal hearing and all the decisions were taken against me one sided.

11. That the contents of Paragraph No 13' are replied as unclear

Proceedings of 271st Meeting

The proceeding of the 271st meeting conducted for the purpose of taking decision on the recommendations of the three members panel for cancellation of DML of firm is based on a fake report dated 12.072019 and I totally disagree with a same.

Decision of the 271st Meeting of CLB

The decision of serving a Show Cause Notice Under Section 41 of the Drugs Act, 1976 Read With Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 to our firm M/s Rex Pharmaceuticals Pakistan, DP-3, Sector 12-D' Area, Karachi, as to why our Drug Manufacturing License No. 000536 by way of formulation may not be suspended or cancelled for failure to maintain conditions of License as enumerated under Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 and Schedule B framed under the Drugs Act, 1976 and reported by the panel of experts in their Inspection report, dated 12.07.2019. It is pertinent to mention here that, the three member panel have not conducted a proper inspection and they have only visited the site for 5-10 minutes and submitted a fake report, reason better known to them. I was not provided any equal opportunity of personal hearing and when I personally appeared before the board on 15.01.2020 in its 273rd meeting and I personally informed the committee about the non-delivery of the notices and same was also acknowledged by the staff of your own department that, all the notices were returned unserved on me and were available in their possession alongwith unserved reports of courier companies, which is an evidence that, I was never been provided an opportunity of personal hearing for just and proper decision.

12. That the contents of Paragraph No. 14 are related with the show cause, dated 01.10.2019 which l was supposed to reply within a period of 15 days. How it was possible, as I received a show cause, dated 10.10.2019 on 15.01.2020, at the time of my Personal appearance in a 273rd meeting, which was once again not informed by you to me from your end and the information regarding the same was gathered by me to my own personal sources and I appeared before you on a very short period of time and on my personal hearing, I disclosed the true facts and circumstances related with my case with a request kindly consider my case as special one, due a reason that, I was not provided any equal opportunity of personal hearing in past and whatever, the decisions taken earlier by your authority was due to a reason that, the FID and the nominated panel of members have submitted fake reports against my firm and all those misstatements were clarified by me personally and am still ready to cooperate further, so as to enable you, to consider my request and to allow me to resume my production, at least in two sections at this stage as Per the recommendation of the three members inspection team. All the recommendations are already rectified.

13. That in the reply of the contents of Paragraph No. 15, it is submitted that, I have availed already and personally appeared before you on 15.01.2020 at the time when I received this show cause notice, dated 01.10.2019 and also sought time to reply which was granted. In the light of the above stated true facts, circumstances and grounds, I would like to once again request you to kindly consider my case as a special case and not an ordinary one, reason behind, there are multiple discrepancies from your end in the delivery of notices of personal appearance through courier services, which were returned unserved and also fake inspection reports where your three members inspection panel did not obtain my signatures and submitted the same without conducting any proper inspection. In the end, it is once requested, to consider my request of renewal my DML on an urgent basis as a same is suspended since last many years. An early and prompt reply from your end shall be highly appreciated".

20. Representatives of the firm were called upon for personal hearing vide letter No. F.8-3/2020-QA (M-276-CLB) dated 27-08-2020. The case is placed before the CLB in compliance to the orders of 273rd meeting of CLB, please.

Proceedings of 276th Meeting of CLB.

The case was presented by the Division of QA&LT. It was informed to the Board that the firm M/s Rex Pharmaceuticals Pakistan vide No. Nil dated 01-09-2020 received today on 03-09-2020 inform that they cannot appear in the meeting due to heavy rains in Karachi. The firm had requested to re-schedule the Central Licensing Board Meeting until further notice.

Decision of 276th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the panel of experts in their report dated 12.12.2017 and 12.07.2019 for cancellation of Drug Manufacturing Licence and casual attitude of the firm towards GMP compliance and track record of the firm, the Board decided to *cancel the Drug Manufacturing License of the firm M/s Rex Pharmaceutical*

Pakistan, Karachi, under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (L,R&A) Rules, 1976, from the date of issuance of decision of the 276th meeting of CLB.

Case No. II: - M/S TAS PHARMACEUTICALS, ISLAMABAD (DML NO. 000375)

Following panel of members conducted inspection of the firm M/s Tas Pharmaceuticals, Plot No. 209, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000375) on 06.02.2020 to verify GMP compliance and verification of consumption of narcotics.

i. Mr. Babar Khan, area FID, DRAP, Islamabad.
ii. Dr. QurratulAin Jamil Rana, Assistant Director I&E, DRAP Islamabad.

2. The panel during inspection noticed following critical observations:-

Observations

i. There was no approval of section by the licensing Board.

Change Rooms (Premises)

ii. In general the room was very dusty.
iii. Air Curtains provided at entrance were in very poor condition.
iv. The cross-over bench was not of appropriate dimensions.
v. The Rack for holding shoes was present bit full of dust.
vi. Mirror is in the change room but in very dirty condition.
vii. Light was inadequate in the room even SOP hanged in the room couldn't be read.
viii. There was dust on the cupboard, wall and doors.
ix. There were no hand wash and dryer in the change room.
x. Many cobwebs were noticed in the change room.
xi. There was no water supply in the sink.
xii. There were gaps in the door.
xiii. The paint was shedding at some places.
xiv. Pipe work, light fittings, ventilation points and other services have not been designed to avoid the creation of recesses. There were cracks seen at some points.
xv. Though insect killer were present but it was not maintained for cleanliness.
xvi. There were male clothes seen in the cupboard in the female change room.
xvii. The exhaust was installed but not working
xviii. There was a room adjacent to change room in which electric panel was installed. The room was in very poor condition due to non-maintenance.
xix. The changeover facilities were inadequate as not complying with GMP requirements.
xx. There was a space/room between change room and manufacturing/production area which was according to the GM a buffer room while one the door of this room opens to the roof through stairs. Hence, the purpose of the buffer couldn't be achieved.

Storage area/ Ware houses (Premises)

i. There was not a single material present in all stores.
ii. No pharmacist was hired to look after the activities of the stores as recommended in GMP (Schedule B-II of the Drugs (Licensing, Registering and Advertising) Rules, 1976.
iii. There was no evidence of clearance of import of any raw material by DRAP as required under the rules for last three years.

Production Area (Premises)

i. There was no pharmacist under supervision of Production Manager
ii. Walls and floors were not in good condition. The surfaces were in rough condition.
iii. There were gaps in doors.
iv. The alignments of doors were also not in good condition. Many surfaces were in rough condition.
v. There was no pressure maintenance/ balancing in the rooms.
vi. The temperature and humidity conditions were not proper as in some areas like Psychotropic Tablet it was 18°C and 37% RH.
vii. The grills in the return were very dusty. The GM, PM and QCM could not tell about the filters present in return.
viii. There was fresh paint giving nauseous/ pungent smell.
ix. In the mixer, sticky material was seen while cleaned label was mentioned on the mixer.
x. The white sticky material present on granulator in the Psychotropic section was referred as Paracetamol by GM and PM. It means that firm has not followed concept of segregation as per GMP requirement during manufacturing.
xi. Some expired calibration stickers were seen on equipment mentioning the date of 20-09-2019
xii. Labels about cleaning status mentioned date 02-01-2018.
xiii. There was no temperature measuring equipment in the mixing area.
xiv. There were steel nails fixed on the walls.
xv. In compression area, the placement of compression machine ZP-19 was questionable since it was causing hindrance in flow air thus producing the dead ends. The floor was very dirty, full of powder, paint and rust.
xvi. Hopper of ZP-19 compression machine was found stick with powder.
xvii. Though the tablet machine was labeled as "Clean" but there was sticky powder in lumps seen in the machine. The temperature in the tablet (General) area where ZP-25 was present was 14.1°C while relative humidity was 54%. The pieces of papers were found on the floor.
xviii. There was no operator/technician seen.
xix. There was no log book available in the compression machine area.
xx. The electrical balance in the IPQC was not operative. The calibration sticker mentions the date 29-08-2018. There was no other equipment in IPQC lab.
xxi. In coating area, the door could not be closed properly.
xxii. The pressure differential measurement devices were not in working condition.
xxiii. The surface of the coating pan was not smooth.
xxiv. In packaging area, the blistering machine was in very rusty condition.
xxv. There was no pest and rodent control system noticed to be existed in the firm.
xxvi. The drainage system does not seem proper for cleaning of area.
xxvii. Some primary packaging rolls found uncovered
xxviii. In packaging area, the glass of the door found in broken condition.
xxix. The cleanliness in the cream/ointment semisolid area was also very poor. Floor was not clean. Water was leaking and sticky material was present on floor.
xxx. Cleaning tag mentioned date 02-01-2018
xxxi. In packing hall, smell of fresh paint was present.
xxxii. There were cobwebs in Finished goods store.
xxxiii. There was no product in the Finished Goods Store. No temperature and humidity control device was present as well.
xxxiv. No proper proper dispensing booth present in RMS, hence dispensing practices were questionable with regard to GMP code. The dispensing tools were also not in accordance with GMP hence may cause source of contamination.
xxxv. There were gaps in the duct of A/C installed in the store.

xxxvi. Broken balance was present in RMS
xxxvii. In capsule section, log boojk of period of May 2019- may 2019 shows no manufacturing of any product. Dust was present on the mixer.
xxxviii. There was no temperature/ humidity control and differential pressure monitoring in capsule section.
xxxix. There was no temperature/humidity control or monitoring in the retained samples area.

Quality Control (Premises)

i. Condition of QC lab was very poor and it seemed that it was not functional since long.
ii. The sink was full of dust.
iii. The equipment like Friabilator, Disintegration Apparatus, Dissolution Apparatus, Moisture Analyzer were checked and found out of order or not in operative condition.
iv. Some reagent (Tryptone Lot No. 10P010 expiry date 19.02.20) were checked and found expired.
v. No primary reference standard was available.
vi. The firm has no operational microbiology laboratory.
vii. Calibration of Oven mentioned date 29-08-2018. (Calibration expired)
viii. No FTIR/IR for identification of API or by any other method.
ix. There was no Validation Master Plan (VMP) and Stability Programme.
x. There was one stability chamber that was not operational. No product was present in the chamber.
xi. An isocratic HPLC was present but not in a functional state hence analysis of products became under question.

HVAC System (Utilities)

i. There was no person who could demonstrate HVAC System. The filters like pre-filter (Like G-4), Bag filters (Like F-6, F-9) and HEPA couldn't be ascertained at their respective. The preventive and maintenance system for HVAC is not in place.
ii. Since there is no microbiology laboratory, hence microbiological standards of water remains questionable.

Water Treatment System (Utilities)

There is no water system shown by GM and since there is no microbiology lab, hence microbiological standards of water remains questionable.

Quality Assurance

There is no QA Manager appointed in the firm. The firm has very poor QA system and hence has no Pharmaceutical Quality System.

Sanitation and Hygiene

i. Overall, sanitation and hygiene was observed to be maintained at highly unsatisfactory level.
ii. There was no Sanitization and Hygiene System and Record.

Medical Checkups

There is no record of routine medical checkups available.

Qualification and Validation

Calibration of all equipment is not upto date, hence remains questionable. No validation master plan was available. No validation of process and analytic methods were performed.

Complaints

No SOP exists to deal with complaints.

Product Recalls

There is no SOP for recall.

Contract Production and Analysis

According to GM, there is no contract manufacturing and analysis by the firm and for the firm.

Self-Inspection and Quality Audit

There is no SOP for self-inspection.

Training

There is no SOP for training of personnel.

Equipment & Machinery

The firm does not have sufficient machinery/equipment in every section and their qualification and calibration status is questionable.

Documentation

i. There was no concept of documentation as SOPs seen during the visit were without any date, approval, authorization and date of revision.
ii. Overall the pharmaceutical Quality Management System is very poor.

3. The Panel concluded and recommended as under:-

Conclusion:

Based on the areas inspected, the people met, the documents reviewed, and assessment made on-site, the panel of inspectors concluded that the firm is operating at a very poor level of GMP compliance. The firm hence is working at a very high risk since violations of GMP (which is also the violation of condition of license) have been assessed/noticed are of critical nature like no Pharmaceutical Quality System, validated HVAC system, water treatment system and microbiology laboratory exists and further poor Production and Quality control practices were being undertaken as indicated above in the production from the date of inspection till compliance of GMP duly verified by a panel approved by competent authority.

Recommendations:

Considering the risk-based approach, it is therefore recommended that the DML of firm should be suspended, as the firm has violated the condition of license by which they were required to comply with requirements of GMP, till compliance of GMP since public health is endangered due to high risk quality issues.

Action Taken by DRAP: -

4. Accordingly show cause notice and suspension of production order was issued to the firm on 04.05.2020 with immediate effect.

5. In response to Show Cause Notice the firm M/s TAS Pharmaceuticals, Plot No. 209, Industrial Triangle Kahuta Road Islamabad (DML No. 000375) submitted two (2) replies. One was submitted on 18.05.2020 and other on 28.05.2020.

6. The Response submitted on 18.05.2020 was presented before the board and is reproduced below;

"1. That the show cause notice dated 04.05.2020 is based on the chain if malafides and ulterior motives because the enmity of three officers of the department is instrumental in the issuance of notice under reply. The said officers have been carrying serious grudge for submission of a complaint to the Chief Executive Officer of Drug Regulatory Authority of Pakistan (DRAP). Before that complaint the matter was also verbally referred that the said officers have been extending threats blackmailing and maligning the respondent. The company reserves its right to initiate civil, criminal and other proceeding against the said officers before all the competent forums

2. That brief facts of the matter are that the respondent's company applied for issuance of Consumption Certificate on 2nd day of September 2019 upon which Dr. Qurat ul Ain visited the company to check the records and everything was satisfactory and the company was directed to collect the Consumption Certificate, where after the company representative visited the office almost on daily basis, but all in vain. Thereafter having no other option the CEO of the company met Dr. Qurat ul Ain and complaint that despite lapse of 3-4 months, the Consumption certificate was not issued to the company due to whioch the company is suffering financial losses as well as mental torture, whereas on the other hand this complaint displeased the Dr. Qurat ul Ain upon which she was

showed that certificate was required out of quota, otherwise the company will suffer great loss. The quota control was required for drug titled as "Alprazolam, the fee whereof Rs. 20,000/- was already paid. Its meeting was about to take place but even then the company was not issued Consumption Certificate even after the meeting due to which quota was not allocated to the company. The entire responsibility of non-issuance of Consumption Certificate lies on Dr. Qurat ul Ain, Madam Hafsa and Federal inspector of Drugs Babar. All these persons inordinately delayed the matter without any lawful justification. The complaint the above referred officials was submitted to the CEO of DRAP, who took cognizance of the matter and directed all the concerned officials for issuance of Consumption Certificate, which further annoyed the said officers and extended serious threats to the ready to see consequences of complaining to CEO. It is very important to mention here that above said officers were called by the CEO and verbal orders were passed and further asked FID Babar that he has no concern with the Consumption Certificate to be issued to the respondent's company. Issuance of Consumption certificate and inspection are separate subjects, Madam Hafsa was ordered to issue Consumption Certificate, but she failed to comply with despite clearly express orders/direction. The Consumption Certificate was issued on 16.03.2020 after 4 to 5 times visits to the office of CEO DRAP and long struggle of seven months. During that period three meetings of control drugs were held and the respondent factory's case file couldn't be included in those meetings due to which the company suffered huge financial losses for which the company reserves its rights to take up the matter before all the legal competent forums

3. That the company is in operation since the year 1994 carrying good report regarding its premises. The last report was issued on 27th day of April 2018 that too carries good remarks. For the facts, attitude of the said officers and circumstances stated above the respondent's company was not

informed in any manner and FID Babar along with Dr. Qurat ul Ain Inspected the site and malafidely raised 27 observaions. Actually all these officials were adamant to take revenge of their insult at the hands of CEO on the complaint of respondent's company.

4. That initially only 27 observations was raised but subsquentlythe observation was increased to 89 on the basis of malafides, whereas on the day of inspection the factory was not producing anything, rather the work of cleanliness was being carried out which was notified to FID Babar, therefore despite these aspects of the matter carrying inspection of the company was totally against the rules.

PARAWISE COMMENTs (Observations)

i. That the observation No. 1 is scribed that "There was no approval by licensing board" this observation is made without perusal of record because through the letters dated 17.01.2019 and 04.07.2018 the approval of licensing board was given. Copy of the letter is attached herewith.

ii. The observation clearly shows that both the above mentioned persons violated all the rules and regulations despite having perusal of both the above mentioned letters.

5. Most of the objections listed (e.g. Sr. No. 5, Sr. No. 6, SrNo. 8, sr. No. 16, sr. No. 20, sr. No. 35, sr. No. 30, Sr. No. 32, Sr. No. 38, Sr. No. 52, Sr. No. 60) are pointing towards presence of dust, rough surfaces, and mess in the unit.

In response to these objections, the unit was undergoing minor renovations due to which there was dust. In addition to that, there was no production going on at the time of renovation. As there was no production so raw material was not present in the unit (ref: Sr. No. 21).During renovation we placed the temperature balance aside (ref: Sr. No. 28) and S.S. nails was present as SOPs are hanged on them, but due to cleaning purposes they put the SOPs board aside (ref: Sr. No. 37). This is the reason SOPs were not present (ref: Sr. No. 81; Sr. No. 82).Also the books and documents were placed in the cupboard (ref: Sr. No. 41; Sr. No. 87). Furthermore Sr. No. 30 shows that FID was well-aware that renovation in the unit was taking place; still such objections were raised by him.

6. Referring to Sr. No. 1 which states no approval of section, even though there are four sections i.e. Psychotropic Tablet section, General tablet section, Capsule Section, and Cream ointment section including complete Quality

Control (QC) Lab consisting of Microbiology lab.

7. The objections rose in the recent inspection(ref: Sr. No. 3, Sr. No. 4, Sr. No. 11, and Sr. No. 57) were not raised in inspection that took place in 2018. FID checked and appreciated the presence of air curtain, the cross over bench, and dispensing booth at the time of 2018 inspection. The same FID rose objections over air curtain, cross over bench, and dispensing booth in the recent inspection, even though these were not changed and were the same from that time till date. Same goes with the presence of water supply.

8. There is a great contradiction in Sr. No. 9 and Sr. No. 10, as Sr. No. 9 says no hand wash was present and in Sr. No. 10 it states no water supply in 'sink'. This shows that the water system is present, negating the objection raised in Sr. No. 9. Though, we accept that dryer was not present, so will install it.

9. In last inspection that took place in 2018, all the requirements were fulfilled as stated. No objection or suggestion was given (ref: Sr. No. 19). New labels have to be mentioned after the cleaning process (ref: Sr. No. 35).

10. During the process of making of granule by granulator in the General Tablet Section, meanwhile the belt was broken, therefore, it was granule with the other granulator, so that the batch may not rot.

11. In response to Sr. No. 48, the entire area gets cleaned with disinfectant. After every four months, fumigation in the unit also takes place. As summers are approaching, so Air-Conditioner was being cleaned/ serviced, so gaps were present (ref: Sr. No. 58). In reference to Sr. No. 59, the balance broke the day before the inspection. Though, temperature/ humidity control was present in samples area (ref: Sr. No. 62).

12. Referring to Sr. No. 63 and Sr. No. 64, after every four months thorough cleaning takes place in QC and production area, but no record is kept as it is a routine matter not solely for inspection purposes. Likewise sanitization and hygiene standards are strictly followed by GM but not recorded (ref: Sr. No. 78). The sink was found dirty as cleaning was being done.

13. In response to Sr. No. 65, the equipment was partially operative but still given for repair. Moreover, reagents were yet to be removed as cleaning was taking place (ref:Sr. No. 66). Unfortunately, primary reference standard was misplaced, but as an alternative USP/B.P was used as reference point. Reference standard would be bought (ref: Sr. No. 67).

14. In response to Sr. No. 68, the lab is well-equipped and operational but microbiology lab is not present as none of the products require this lab. Same for HPLC, as it is in working condition. However, we use spectrometer for testing purposes (ref: Sr. No. 73). Calibration is being done (ref: Sr. No. 69).

15. There is again a condition in Sr. No. 68 and Sr. No. 74. In Sr. No. 68 it mentioned that microbiology lab was not 'operational', but in Sr. No. 74 it says 'no' microbiology lab. This shows that the inspector is accepting that microbiology lab is present but not functional. Thus, it shows ambiguous statements.

16. Referring to Sr. No. 22, to Sr. No. 23, and to Sr. No. 77, as there is limited production so QC looks after QA matter and there is no pharmacist. But we assure you that we will hire them. Also due to limited product, we borrow raw material from other companies.

17. It would be assured that next time routine medical checkups would be available (ref: Sr. No. 79). Contract manufacturing is not done by the firm (ref: Sr. No. 83). According to the self-inspection SOPs, the unit was undergoing maintenance (ref. Sr. No. 84). In response to Sr. No. 86, more than sufficient equipment are present and are in proper working condition. FID checked all the machinery in the presence of GM and other staff members.

18. Fire extinguishers have been given for refill (ref: Sr. NO. 88). In response to Sr. No. 89, the location of emergency exits are exactly according to what is mentioned and approved in the map (the map is attached and the exits are highlighted).

19. That it is the historical aspect of the matter are that 89 observations are raised against any company with clearly show the ill-will of the above named officers whereas the CEO of DRAP was already informed of the prejudicial attitude of these officers.

20. That the allegation mentioned in the above captioned show cause notice are without explanation.

21. That all the allegations leveled against me in above referred show cause notice are baseless, frivolous and without any evidence

22. That above captioned show cause notice is illegal against the facts and circumstances, hence the same is liable to be withdrawn forthwith. In these circumstances, it is therefore most humbly prayed that the show cause notice may kindly be withdrawn and a honest, intelligent and impartial officers may be appointed to inquire the matter through a transparent, fair and just inquiry in order to reach at the truth.

The respondent's company is ready to remove their observation, so that the company can restart its The company is ready to given an undertaking in this regard. It is therefore respectfully submitted that the company's bore huge costs and has already removed almost all the so-called objections/observations which can be anytime.

It is further submitted that CEO of the respondent may kindly be granted an opportunity of personal order to explain each and everything in deal in accordance law."

7. The response of firm dated 28.05.2020 was also presented before the board. It is reproduced below;

S. No.	Observations	Rectification Status
1.	There was no approval of section by the licensing Board.	We have the Approval of Sections by Licensing Board issued on 4th July, 2018 & 17th January 2019 (Copy Attached)
Change Rooms (Premises)		
2.	In general the room was very dusty.	The room has been cleaned as per set standards.
3.	Air Curtains provided at entrance were in very pathetic condition.	Air Curtains have been repaired and are in good condition now.
4.	The cross-over bench was not of appropriate dimensions.	Cross over bench is now fixed, cleaned and is in appropriate dimension.
5.	The Rack for holding shoes was present bit full of dust.	We have cleaned the Racks of male and female change room.
6.	Mirror is in the change room but in very dirty condition.	We have cleaned the mirror of male and female change room.
7.	Light was inadequate in the room even SOP hanged in the room couldn't be read.	Proper light has been placed, so SOP can easily be read.
8.	There was dust on the cupboard, wall and	Cupboard, walls and doors have been

	doors.	cleaned.
9.	There were no hand wash and dryer in the change room.	There was already hand wash but now new dryer has been bought and placed.
10.	Many cobwebs were noticed in the change room.	Cobwebs have been cleaned.
11.	There was no water supply in the sink.	Water supply was already there but now new dryer has been bought and placed.
12.	There were gaps in the door.	Gaps in the doors have been properly filled.
13.	The paint was shedding at some places.	Where ever the paint was shedding, it has been fixed.
14.	Pipe work, light fittings, ventilation points and other services have not been designed to avoid the creation of recesses. There were cracks seen at some points.	The cracks and gaps have been filled and now cracks can be seen now.
15.	Though insect killer were present but it was not maintained for cleanliness.	The insect killer has been maintained.
16.	There were male clothes seen in the cupboard in the female change room.	Now male clothes have been removed from the female cupboard.
17.	The exhaust was installed but not working	Exhaust is now repaired and in working condition.
18.	There was a room adjacent to change room in which electric panel was installed. The room was in very pathetic condition due to non-maintenance's	Electric Panel room has been cleaned and maintained.
19.	The changeover facilities were inadequate as not complying with GMP requirements.	All the changeover facilities provided according to the GMP requirements.
20.	There was a space/room between change room and manufacturing/production area which was according to the GM a buffer room while one the door of this room opens to the roof through stairs. Hence, the purpose of the buffer couldn't be achieved.	The door is permanently closed.
Storage area/ Ware houses (Premises)		

21.	There was not a single material present in all stores.	There were no production going on at the time of renovation, as there was no production so Raw Material was not present in the unit.
22.	No pharmacist was hired to look after the activities of the stores as recommended in GMP (Schedule B-II of the Drugs (Licensing, Registering and Advertising) Rules, 1976.	Pharmacist is now appointed to look after the stores.
23.	There was no evidence of clearance of import of any raw material by DRAP as required under the rules for last three years.	Due to limited production we borrow the Raw Material from other companies. Next time, we will import all the Raw Material.
Production Area (Premises)		
24.	There was no pharmacist under supervision of Production Manager	Pharmacist is appointed for supervision of Production Manager.
25.	Walls and floors were not in good condition. The surfaces were in rough condition.	Walls and floor has been cleaned.
26.	There were gaps in doors.	Gaps in the door were removed.
27.	The alignments of doors were also not in good condition. Many surfaces were in rough condition.	The alignment of doors is in good condition, many surfaces have been smoothened.
28.	There was no pressure maintenance/ balancing in the rooms.	Now pressure has been maintained and balanced.
29.	The temperature and humidity conditions were not proper as in some areas like Psychotropic Tablet it was 18°C and 37% RH.	It has been maintained.
30.	The grills in the return were very dusty. The GM, PM and QCM could not tell about the filters present in return.	New filters have been installed in return.
31.	There was fresh paint giving nauseous/ pungent smell.	The renovation work was going due to which pungent smell of fresh paint was there.
32.	In the mixer, sticky material was seen while cleaned label was mentioned on the mixer.	Sticky material has been washed
33.	The white sticky material present on granulator	Sticky material has been washed.

	in the Psychotropic section was referred as Paracetamol by GM and PM. It means that firm has not followed concept of segregation as per GMP requirement during manufacturing.	
34.	Some expired calibration stickers were seen on equipment mentioning the date of 20-09-2019	All machinery has been caliberated abd stickers have been placed.
35.	Labels about cleaning status mentioned date 02-01-2018.	New label has been placed.
36.	There was no temperature measuring equipment in the mixing area.	It has been placed.
37.	There were steel nails fixed on the walls.	SOP's were removed form cleanliness purpose now it has been hanged on the same steel nails.
38.	In compression area, the placement of compression machine ZP-19 was questionable since it was causing hindrance in flow air thus producing the dead ends. The floor was very dirty, full of powder, paint and rust.	All deficiencies have been removed.
39.	Hopper of ZP-19 compression machine was found stick with powder.	It has been cleaned.
40.	Though the tablet machine was labeled as "Clean" but there was sticky powder in lumps seen in the machine. The temperature in the tablet (General) area where ZP-25 was present was 14.1°C while relative humidity was 54%. The pieces of papers were found on the floor.	During cleanliness it has been cleaned properly.
41.	There was no operator/technician seen.	Due to renovation process the operators were on leave. Now they are back.
42.	There was no log book available in the compression machine area.	Was available, but –placed aside for cleanliness now placed there.
43.	The electrical balance in the IPQC was not operative. The calibration sticker mentions the date 29-08-2018. There was no other equipment in IPQC lab.	Electric balance has been repaired and calibrated.
44.	In coating area, the door could not be closed	The door is properly closed.

	properly.	
45.	The pressure differential measurement devices were not in working condition.	All the devices are in working conditions,
46.	The surface of the coating pan was not smooth.	It is now smoothened.
47.	In packaging area, the blistering machine was in very rusty condition.	Blistering machine has been cleaned as per the requirement.
48.	There was no pest and rodent control system noticed to be existed in the firm.	The entire area gets cleaned through fumigation after every four months. The fumigation team comes to do so. Furthermore the area gets cleaned twice a day.
49.	The drainage system does not seem proper for cleaning of area.	Drainage system maintained properly.
50.	Some primary packaging rolls found uncovered	Machine testing rolls was present but removed now.
51.	In packaging area, the glass of the door found in broken condition.	The broken glass pieces was removed and placed with expensive glass.
52.	The cleanliness in the cream/ointment semisolid area was also very pathetic. Floor was not clean. Water was leaking and sticky material was present on floor.	Everything has been cleaned,
53.	Cleaning tag mentioned date 02-01-2018	New cleaning tag has been placed.
54.	In packing hall, smell of fresh paint was present.	Due to renovation process the packing hall was newly painted so the fresh paint smell was there.
55.	There were cobwebs in Finished goods store.	It has been cleaned.
56.	There was no product in the Finished Goods Store. No temperature and humidity control device was present as well.	Due to renovation there was no product in the finished Goods Store.
57.	No proper dispensing booth present in RMS, hence dispensing practices were questionable with regard to GMP code. The dispensing tools were also not in accordance with GMP hence may cause source of contamination.	HEPA filter is installed there; the dispensing tools were purchased with accordance of GMP.

58.	There were gaps in the duct of A/C installed in the store.	Gap has been removed.
59.	Broken balance was present in RMS	Balance has been repaired and is now in working condition.
60.	In capsule section, log boojk of period of May 2019- may 2019 shows no manufacturing of any product. Dust was present on the mixer.	No manufacturing was taking place of any product due to no order, and mixer is cleaned.
61.	There was no temperature/ humidity control and differential pressure monitoring in capsule section.	Pressure maintenance equipment has been placed now.
62.	There was no temperature/humidity control or monitoring in the retained samples area.	Pressure maintenance equipment has been placed now.
Quality Control (Premises)		
63.	Condition of QC lab was very pathetic and it seemed that it was not functional since long.	QC lab was functional but due to dust it seemed that it was not in working condition.
64.	The sink was full of dust.	It has been cleaned.
65.	The equipment like Friabilator, Disintegration Apparatus, Dissolution Apparatus, Moisture Analyzer were checked and found out of order or not in operative condition.	The equipment like friabilator, disintegration apparatus, dissolution apparatus, moisture analyzer are operative and calibrated.
66.	Some reagent (Tryptone Lot No. 10P010 expiry date 19.02.20) were checked and found expired.	Reagents with near expiry dates were removed.
67.	No primary reference standard was available.	We follow the books to make the assay and identify the Raw material.
68.	The firm has no operational microbiology laboratory.	The firm has Operational Microbiology Laboratory, in 2018 it was seen too (copy of last inspection report is attached)
69.	Calibration of Oven mentioned date 29-08-2018. (Calibration expired)	It has been caliberated.
70.	**No FTIR/IR for identification of API or by any other method.**	**Other methods of API identification are available.**

71.	There was no Validation Master Plan (VMP) and Stability Programme.	Validation master plan is available and in future we have the plan of stability.
72.	There was one stability chamber that was not operational. No product was present in the chamber.	Electric Switch of Stability Chamber was replaced and is in working condition now.
73.	An isocratic HPLC was present but not in a functional state hence analysis of products became under question.	HPLC is in working condition and calibrated.
HVAC System (Utilities)		
74.	There was no person who could demonstrate HVAC System. The filters like pre filter (Like G-4), Bag filters (Like F-6, F-9) and HEPA couldn't be ascertained at their respective. The preventive and maintenance system for HVAC is not in place.	We hire on call person for demonstration and maintenance of HVAC. At the time of inspection he will be available for demonstration. The filters are present in HVAC unit.
75.	Since there is no microbiology laboratory, hence microbiological standards of water remains questionable.	Microbiology Laboratory is well-equipped.
Water Treatment System (Utilities)		
76.	There is no water system shown by GM and since there is no microbiology lab, hence microbiological standards of water remains questionable.	Water system is available and calibrated. It is also in working condition.
Quality Assurance		
77.	There is no QA Manager appointed in the firm. The firm has very poor QA system and hence has no Pharmaceutical Quality System.	QA Manager has been appointed.
Sanitation and Hygiene		
78.	Overall, sanitation and hygiene was observed to be maintained at highly unsatisfactory level. There was no Sanitization and Hygiene System and Record.	Sanitation and hygiene has been maintained.
Medical Checkups		

79.	There is no record of routine medical checkups available.	Record will be maintained from now.
Qualification and Validation		
80.	Calibration of all equipment is not upto date, hence remains questionable. No validation master plan was available. No validation of process and analytic methods were performed.	All the issues raised have been rectified.
Complaints		
81.	No SOP exists to deal with complaints.	SOPs are available to deal with complaints.
Product Recalls		
82.	There is no SOP for recall.	SOPs are available to deal with complaints.
Contract Production and Analysis		
83.	According to GM, there is no contract manufacturing and analysis by the firm and for the firm.	We do not do any kind of contract manufacturing for any firm.
Self-Inspection and Quality Audit		
84.	There is no SOP for self-inspection.	SOPs are available to deal with self inspection.
Training		
85.	There is no SOP for training of personnels	SOPs are available to deal with training of personnel.
Equipment & Machinery		
86.	The firm does not have sufficient machinery/equipment in every section and their qualification and calibration status is questionable.	Sufficient machinery is available in every section. Qualification and calibration has been updated.
Documentation		
87.	There was no concept of documentation as SOPs seen during the visit were without any date, approval, authorization and date of	Now all the SOPs are there with date, approval, authorization, and date of revision are available. Pharmaceutical quality management system has been

	revision. Overall the pharmaceutical Quality Management System is very poor.	improved.
Fire Fighting System		
88.	All fire extinguishers were expired with date 18-09-2018	Fire extinguisher has been filled and new expiry has been mentioned.
89.	There were no proper emergency exists.	As per layout plan the emergency exits are available. The copy of layout plan is attached.

Proceedings of 276th meeting of CLB:

Division of QA&LT presented the case before the Board. Syed Muhammad Tayyab (Son of CEO M/s TAS Pharma/Representative) and Mr. M. Saleem Shahzad (General Manager) appeared before the board with authority letter from Syed Tariq Ahmed CEO M/s TAS Pharmaceuticals (Pvt.) Ltd. Islamabad. Mr. Saleem Shahzad submit that they have rectify all the observations noted in the inspection dated 06.02.2020. The Board enquire about the two letters dated 18.05.2020 & 28.05.2020. submitted by the firm. Mr. Saleem Shahzad stated that their letter dated 18.05.2020 may please be considered as withdrawn and their detailed reply dated 28.05.2020 mentioned at para 7 of the case, may please be considered as reply of show cause notice.

Decision of 276th meeting of CLB:

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

i. Constitute following panel of experts for verification of rectification status of the observations noted by the panel in their report dated 06.02.2020: -

   a) The Deputy Director (QA-III), DRAP Islamabad.
   b) Area FID, DRAP, Islamabad
   c) Mr. Rao Abdul Hameed, Drug Controller, Rawalpindi

ii. The panel shall submit detailed inspection report including rectification status of the observations noted by the panel in their report dated 06.02.2020, with clear and candid recommendations.

iii. Production of the firm M/s TAS Pharmaceuticals (Pvt.) Ltd. Plot No. 209-Sihala Triangle, Kahuta Road Islamabad (DML No. 000375) shall remain suspended till recommendation by panel and subsequent approval by the CLB.

Case No. III M/S. OVAL PHARMACEUTICALS

Inspection of the firm M/s. Oval Pharmaceuticals, Lahore was conducted on 12.09.2019 by following panel.

iii. Ms. Aisha Irfan, FID, DRAP, Lahore
iv. Mr. AjmalSohail Asif, FID, DRAP, Lahore

2. The panel during inspection submitted comparison of the observations noted in inspection 28.02.2018, noticed following improvements / observations:-

Previous Inspection Dated: 28-02-2018	Inspection Dated: 12-09-2019
Entries: The firm had provided separate entries for male and female workers and both were lack of changeover facilities. Executive entrance was demolished as many areas of the firm were under construction at the time of inspection. The overall cleanliness and hygienic conditions were found unsatisfactory.	**Entries:** Proper training of workers required regarding cleanliness, maintenance of changing rooms & implementation changing SOPs.
Stores: **Raw Material Store:** The firm had provided receiving and De-Dusting bay but no demarcation between, Quarantine and Released area. No separate Rejected area was seen the store was provided with different racks where active and inactive materials, Pharmacopoeias and Quality Control files were placed in haphazard manner. Stearic acid, Chlorbutanol, Synthetic Camphor, Zinc Oxide, Refined Sugar were placed on the racks without any status and identification slips. Sampling hood was placed inside the store but no weighing balance was seen there. Dispensing room was separate with Dispensing Hood inside and balance without calibration was placed outside the hood.	Stores: Raw Material Store: The firm was advised to provide partition between de-dusting area and main store. It was advised to provide proper rejection area under lock and key. The traceability of raw materials with documents was not satisfactory. The firm was directed to conduct vender qualification, and follow I&E Rules 1976, for imported raw materials. It was advised to install air conditioner in dispensing area as temperature / humidity was not controlled. Store Incharge was not present, and the store was being run by production pharmacist. The firm was advised to hire Store Incharge, implement store SOPs regarding sampling, dispensing and material management. The store data should be computerized.
Packing Material Store: Firm was manufacturing plastic bottles for all of their registered products even for Ear Drops inside the building on 1st floor in very poor condition. Machinery was installed and workers were working there in unsanitary conditions. Firm was also selling those plastic bottles in commercial	**Packing Material Store:** The firm was advised to segregate primary and secondary packing materials.

market as informed by the management. Many rooms were seen on the back side of the corridor where printed material, outer cartons, unit cartons, Glass bottles, and plastic bottles were stored. Hydrogen peroxide was stored in drums in another room in the corridor along with Boric Acid &Bentonite without any status and identification slips.	
Finished Goods Store: Finished Goods Store was provided in the outer corridor where many Finished Product cartons were placed in haphazard manner on the floor. The management informed that their production activities were stopped from almost 02 months, but the products manufactured in November, 2018 and October, 2018 were seen in packed form inside the store in large quantity e.g. Glycerin Suppositories Batch No. DS013 Mfg. Date: 11-2018, Expiry Date: 10-2020, Glycerin Pure Batch No. GLY008, Mfg. Date: 11-18 Expiry Date: 11-20.	**Finished Goods Store:** **Finished Goods were placed on racks in the store. The firm was advised to maintain storage condition.**
Production Areas: **Oral Liquid Section:** The section was comprised of two rooms. One Mixing and the other Filling and Sealing room. Silverson Mixer, Suspension Filling Machine and Storage tanks were seen in the Mixing room while Filling room was provided with Filling and sealing machine along with the Blowing machine without any segregation. **No** separate Decartoning and Bottle Blowing area was provided. Large number of cans / containers of Hydrogen peroxide preparation were seen in the Mixing room. Upon asking, the Production Incharge informed that they are only engaged in diluting the purchased Hydrogen peroxide with RO Water with a plastic jug placed there. No written document and no proper SOP was provided for that.	**Production Areas:** **Oral Liquid Section:** Same as before, separate decartoning and bottle blowing area required as bottle blowing area for repacking was being used for oral liquids. HVAC system required validation.
Aural Section: The section was provided with the Filling Machine only while sealing and capping was manual. Filled Soda Glycerin Ear Drops Bottles Batch No. SG-007, without labels, were placed inside the room on trays.	**Aural Section:** HVAC system was not functioning properly.
Suppository Section: The section was provided with the Moulds and Fridge for solidifying suppositories. Raw materials were seen placed in the plastic bowls and saucepan. The firm was in a practice of heating the components in a pan and transferring in a mould	**Suppository Section:** The firm was directed to install S.S. pipes for R.O Water supply. Ceiling fan was seen. HVAC system not functional**.**

where the suppositories would solidify. No written document and no proper SOP was provided for that.	
Quality Control Laboratory: Quality Control Laboratory was newly established on the First Floor of the premises. Isocratic HPLC and Double Beam Spectrophotometer was seen which were not in working condition. The staff informed that Assay and Identification tests were performed by Titration method. All the equipment in Quality Control were found out of calibration at the time of inspection**.** Many testing SOPs and certificate of Analysis were evaluated. SOPs were not upgraded and were not followed as well in both production and testing. Microbiology Laboratory was not established yet and no separate stability chamber room was provided.	**Quality Control Laboratory:** Log books were not maintained. Microbiology laboratory was not fully developed yet. SOPs were developed however the firm was directed to perform tests as per pharmacopoeial requirements.
Personnel: The firm was having shortage of Technical staff. In production, there was only one pharmacist for all the sections. In Quality Control, Quality Control Manager was constantly absent and the Quality Control Analyst was working as Quality Control Manager without any approval from DRAP. There was no separate Quality Assurance Department.	**Personnel:** The firm was advised to hire pharmacist for every section. Technical person for material management was also required.
Sanitation & Hygiene: Sanitary and Hygienic conditions were found un-satisfactory at the time of inspection. Change rooms were having very poor condition as well.	**Sanitation & Hygiene:** The firm was advised to develop waste disposal SOPs and implement it. The worker's change rooms required improvement.
Documentation: Documentation practices were found poor. SOPs were not upgraded. Production and testing procedures were not followed and documented properly. HVAC was found non-functional at the time of inspection.	**Documentation:** Documentation with respect to manufacturing SOPs, BMRs, and testing procedures were available, however improvement required in certain areas such as deviation in processes, rework / batch reprocessing, recall, testing procedures etc. The implementation of SOPs required improvement. HVAC system required improvement with respect to number of air changes, differential pressures etc. The firm was advised to validate the system.
Fire Extinguishers were installed. Firm was asked for the training record but not provided.	Firm was advised to install smoke detector, fire alarms and provide proper emergency exit. Training of workers required.

3. In addition to this comparative analysis, following observations were also noted by the panel:

- Double RO Water Treatment plant was required. Single RO was installed. It was also advised to conduct sanitization process for cleaning / validation of the plant.
- The firm did not have in-process quarantine area, for storage of under test products. In process quality control laboratory was also required.
- HVAC system required validation as in some sections, HVAC was not functioning properly.
- Firm was advised install generator for backup electricity.

Action taken by DRAP:

4. Accordingly the firm was issued show cause notice and suspension of production order letter No.F.4-121/89-QA on 16.10.2019.

Reply of the firm:

5. The firm M/s. Oval Pharmaceuticals, Lahore submitted compliance report and requested for resumption of production vide letter dated 15th November, 2019.

6. Request of the firm was placed before the Director (QA & LT) Division. The Director (QA & LT) constituted following panel of experts for verification of improvements made by the firm.

i. Ms. Aisha Irfan, FID (VII), DRAP, Lahore
ii. Ms. MahamMisbah, AD, DRAP, Lahore
iii. Mr. Akbar Ali, AD, DRAP, Lahore

7. The panel conducted inspection of the firm M/s. Oval Pharmaceuticals, Lahore 07.01.2020. The panel after detailed inspection concluded as under;

"*In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 for GMP compliance."*

8. Recommendations of the panel were placed before the Director (QA&LT). The Director (QA&LT) allow resumption of production activities on recommendations of panel of experts. Resumption was allowed on 03.02.2020.

Proceedings of 276th meeting:-

Quality Assurance Division presented the case before the Board for revocation of show cause notice No. F.4-121/89-QA dated 16.10.2020. The Division informed the Board about decision of the Director (QA&LT) regarding resumption of production of the firm M/s. Oval Pharmaceuticals, 112/11, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore in the light of decision of 273rd meeting of CLB, under the head of power delegation.

Decision of the 276th Meeting of CLB

The Central Licensing Board considered the proposal and decided to seize the enforcement of Show Cause Notice No. F.4-121/89-QA dated 16.10.2019.

Item No. II PERSONAL HEARING IN COMPLIANCE TO DECISION OF 275TH MEETING OF CLB

Case No. I:- M/S MEDIWAYS INTERNATIONAL, LAHORE

Background:-

M/s Mediways International, Multan Road, Lahore was inspected on 09.02.2015 by Mr. AjmalSohail Asif, FID Lahore to see/verify the GMP compliance.

2. During inspection the FID pointed out number of serious shortcomings and gross violations.

Action Taken by DRAP: -

3. Accordingly, a show cause notice and suspension of production order in all section was issued to the firm on 20.03.2015 with immediate effect.

Reply of the firm: - In response to show cause notice the firm vide letter No. Nil dated 15.06.2015 submitted their reply and requested to verify the shortcomings through area FID.

4. The case was placed before the 245th meeting of CLB. Wherein the Board decided as under:-

Decision of 245th meeting of CLB held on 30.12.2015

The case was placed before the Central Licensing Board for consideration. The Board after thorough discussion, keeping in view the available record, compliance report and request from CEO of the firm, decided to conduct panel cGMP inspection of the firm, on approved Schedule B-II cGMP format and panel will also submit report in tabulated form identifying the previous observations and the current status, by the following members:-

iv. Dr. IkramulHaq, Member, CLB
v. Dr. ZakaurRehman, Member, CLB
vi. Mr. AjmalSohail Asif, Area FID.

5. Accordingly decision of 245th meeting of CLB was conveyed to the firm on 10.02.2016

Letter of Secretary PQCB, Lahore:-

6. Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab informed that Deputy Drug Controller Allama Iqbal Town Lahore alongwith other members inspected the premises on 16.06.2016. The team observed that:-

iv. Manufacturing of Drugs was being carried out under unhygienic conditions.
v. Improper storage of drugs (at 40 degree Centigrade).
vi. Illegal or unauthorized import of raw materials without label (misbranded).

7. The case was placed in 249th meeting of CLB held on 29.08.2016. Where in the Board decided as under:-

Decision of the 249th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, the Board considered the recommendations of the Secretary, PQCB, Punjab and took a serious notice on illegal / unauthorized manufacturing and violation of the orders of the DRAP's letter No. No.F.4-4/2001-QA dated 20.03.2015. The Board decided to issue a showcause notice to the firm M/s Mediways, Lahore on illegal / unauthorized production activities and disobeying the orders of DRAP.

8. Accordingly show cause notice was issued to the firm on 03.10.2016. The case was placed before the 250th meeting of CLB. Wherein the Board decided as under:-

Decision of the 250th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, non serious and non-professional attitude of the firm, , the Board decided to:-

i. Suspend the Drug Manufacturing License of the firm M/s Mediways International, Lahore for a period of six months under Section 41 of the Drugs Act, 1976 read with Rule 12 (1) of the Drugs (LR&A) Rules, 1976.

ii. Direct the area FID to visit the firm on alternate months to verify the suspension of production and submit report.

iii. Resumption of production shall only be allowed after completion of suspension of DML period, verification by the panel of experts and subsequent approval from the Competent Authority.

9. The panel constituted by the Director QA&LT conducted inspection of the firm on 26.12.2017 (received on 17.04.2018). The panel submitted detailed inspection report including previous observations and updated status on Schedule B-II format and recommended as under:-

"Based on the areas inspected, the people met and the documents reviewed, and considering the finding of the inspection in comparison with the observations of the previous inspection, the panel of inspectors does not consider the firm to be at a satisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under. The plot size is smaller than the prescribed requirement. However, CLB in its 241st meeting held on 15.5.2015 decide "to allow two years' time for shifting of unit / enhancement of plot size

according to rules"; and that two years period. Therefore, the panel of inspectors does not recommend M/s Mediways International, 16KM Multan Road, Lahore, for resumption of production. The report is forwarded herewith for further consideration and necessary action".

10. The case was placed in 261st meeting of CLB. Wherein the board decided as under:-

Decision of the 261st Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendation of the panel of experts in its report dated 26.12.2017, the Central Licensing Board decided to:-

iii. Further extend Suspension of DML period for next six months from the date of issuance of decision of 261st meeting of CLB.

iv. The Licensing Division Shall place the case in forthcoming meeting of CLB in the light of decision of 241st meeting of CLB.

Request of the Firm

Mr. Jamil Ahmad, Chief Executive, Mediways International, Lahore vide letter dated 08.02.2020 has requested that "*the suspension period of six months has expired on 14.11.2018, we may be allowed to resume production".*

Proceedings of 275th meeting:-

Quality Assurance Division place the case before the Board in the light of the request of the firm dated 08.02.2020 and decision of 261st meeting of CLB.

Decision of the 275thMeeting of CLB

After thorough discussion/deliberations, the Central Licensing Board decided to provide personal hearing to the firm M/s Mediways International, Lahore in the forthcoming meeting of CLB to reach at the right decision.

11. Decision of 275th meeting of CLB was conveyed to FID vide letter dated 02.07.2020.

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

Mr. Jameel Ahmed, Chief Executive of the firm appeared before the Board and requested to give further time of three years for shifting to industrial area as existing facility do not comply minimum area of plot under the Rules. He also contended that he wanted to generate resources from this unit to shift to new area which comply the provision of law. He also stated that it is also difficult to maintain the GMP compliance in

existing building therefore, unit has remained non-operational for last three years. The Board also considered the previous GMP inspection report which noted number of serious observations noted by the Inspector. The Board also noted shortcomings in the application for renewal of Drug Manufacturing License. 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 19,Schedule B-II and Rule 20 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Mediways International, Multan Road, Lahore, under Drug Manufacturing License No. 000468 by way of formulation may not be rejected or Drug Manufacturing License may not be cancelled by Central Licensing Board.

Case No. II:-M/s Helix Pharma (Pvt.) Ltd. Karachi (DML No. 000030)

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.

2. 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.

3. 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:

4. 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.

Non-compliance of the firm:

5. 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.

6. The FID reported that the firm had suspended production activities in sterile area and ***production was underway in other sections.***

7. 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 the firm to Explanation letter:

8. The firm meanwhile submitted reply to this office explanation letter dated 12-02-2020 and stated that they have rectified the observations and are ready for inspection.

Panel Constituted:

Request of the firm was placed before the Director QA&LT. the Director QA&LT constituted following panel of experts to conduct inspection of firm M/s Helix Pharma Karachi.

i. Dr. Najam us Saqib Additional Director DRAP Karachi.
ii. Mr. Awais Ahmed, area FID, DRAP Karachi.
iii. Ms. MehwishTanveer, Assistant Director, DRAP Karachi.

Panel Report:

9. The panel inspected the firm M/s Helix Pharma (Pvt.) Ltd. A-56. S.I.T.E., Karachi (DML No. 000030 on 06-05-2020 and concluded the report as under;

"Keeping in view above mentioned rectification status in OSD and Oral Liquid section of the firm and positive intention towards improvements, panel unanimously recommends the ***resumption of production in OSD and Oral Liquid section only****, However, construction work including HVAC ducting, installation of Air Showers etc. was in process in Liquid Sterile Ampoules/Infusion/Ophthalmic/Otic section, which need some time to be completed.* ***Firm is also advised to provide segregated section for Psychotropic products and submit compliance report to QA&LT, Islamabad."***

10. Based on recommendations of panel, the Director QA&LT granted permission for **resumption of production activities in Oral Solid Dosage Form Section and Oral Liquid Sectiononly.** The production activities in Liquid Sterile Ampoules/ Infusion/Ophthalmic/Otic section are still suspended.

11. The same panel has been asked to verify firm's compliance and give clear & candid recommendations whether resumption of production activities in remaining sections of M/s Helix Pharma (Pvt.) Ltd, A-56, S.I.T.E, Karachi (DML No. 000030) shall be granted or otherwise based on condition and facilities of the firm. The report from the panel is still awaited.

Detailed investigation report from FID on illegal manufacturing by M/s Helix Pharma Karachi.

Reply of FID:

12. 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 (annex-A). 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.

13. *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.*

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.

14. Decision of 275th meeting of CLB was conveyed to FID vide letter dated 02.07.2020.

Reply of FID:-

15. 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 NabiMirza, Director Quality Assurance & Regulatory Affairs.*
      - *Mr. Abu Sagheer, General Manager Production.*

   ii. *Any other directions as may be passed by the Central Licensing Board."*

Proceeding of 276th Meeting of CLB

The Division of QA & LT presented the recommendations of the FID before the Board in the light of the decision of 275th meeting of CLB.

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).

Item No. III GMP Non-Compliance Cases (New)

Case No. I:-M/s Epoch Pharmaceutical (Pvt.) Ltd. Karachi.

Background:-

Mr. Abdul Rasool Shaikh, FID DRAP Karachi inspected M/s Epoch Pharmaceuticals (Pvt.) Ltd. Karachi on 02-12-2019 and recovered *Fenacold Injections, Batch No. 039* with apparent discoloration of half of ampoule. The Product was ordered not to dispose off on Form-I. The Director QA&LT constituted following panel of experts for Product Specific Inspection (PSI).The inspection was conducted on 07-05-2020 & 11-05-2020 by following panel;

i. Mr. Awais Ahmed, Assistant Director/ Federal Inspector of Drugs DRAP Karachi.
ii. Mrs. Hira Bhutto, Assistant Director DRAP Karachi.

2. The observations reported by the panel are mentioned below;

i. **Meeting / Discussion with technical Staff:**

a. The single batch was being autoclaved in 4 lots and last lot of 3125 ampoules was mistakenly exposed for prolonged time in autoclave after completion of autoclave cycle. The same lot showed discoloration.

b. No CAPA was available with the firm regarding this matter.

ii. **Raw Material Store:**

a. The RMS was uncontrolled having HVAC system instead fresh air system was installed, which was not working at the time of inspection. Temperature was observed 27°C and RH 60% and the material with storage condition of below 25°C were placed.

b. Cleaning condition of RMS was unsatisfactory and powder on drums and floor was seen, looks like material might be sampled in same area.

c. Job description of dispensing pharmacist was not available, when inquired they informed that Dispensing Pharmacist is directly reporting to CEO

d. Dispensing of material was being done without QA officer. Weight of raw material was not noted on dispensing slips.

e. Dispensing booth calibration is due by 30-12-2019, no further correspondence available.

f. Sampling booth used for raw material sampling is not adequate to perform sampling operations due to space constraints.

g. Raw material was not assigned unique identity code at the time of arrival. Raw material details could not be traced from material issuance note as no unique code assigned.

iii. **Quality Control Department:**

a. The record showed that product was tested as per in-house specifications, however no record of product retesting after complaint of apparent discoloration was shown to the panel.

b. COA of diclofenac sodium from manufacturer and testing record of raw material used in batch was checked. Reference standard and batch testing record was verified.

c. Calibration of most of the equipment in quality control lab was due for which no update schedule was available.

d. Document record/ log sheets and record of relevant raw calculation was found to be un-satisfactory and non-traceable.

iv. **Production Section:**

a. Chart of autoclave could not be interpreted as the graph was not clear and no reference scale was mentioned in SOP, however temperature was noted in hand writing as 117.6 °C and taken as equivalent to 121°C by firm. For which firm informed that, autoclave is placed in production and display of autoclave in Quality Control lab, that's why the difference in actual temperature of Autoclave is shown, which seems unjustifiable.

v. **Documentation:**

a. During document verification, it was observed that firm does not have standard validated Batch Size. Batch manufacturing record for 150 liter was available which is used for manufacturing of 275 liter batch.

b. Batch scale up studies was not available.

c. Most part of the Bach Document of Fenaclod injection B# 039 was not signed.

d. Batch validation documents were not available. Apparently no batch validation was performed as there is no standard batch size followed.

e. Batch size is dependent on availability of pre-printed (Batch No.: and Expiry Date printed) ampoules. B#038 has not been manufactured because of unavailability of pre-printed ampoules for which quality assurance finding report was raised, but no deviation form was and CAPA performed.

f. Autoclave qualification documents not available.

g. Autoclave batch lot validation documents were not provided.

h. Production steps time was not recorded in Batch documents, therefore autoclave cycle time and other step of manufacturing could not be traced from batch documents.

i. Incident report, deviation form and CAPA were not raised for this incident.

j. SOP of CAPA SOP# EP/QA/SOP-010/002 was implemented on 11-11-2019 having no description of CAPA investigation committee; firm is advised to review the SOP.

k. SOP of deviation available SOP# EP/QA/SOP-015/02 effective date 02-08-2018. However, not being implemented as no deviation of incident was raised.

l. Fenaclod injection B# 039 manufactured on 17-10-2019 and released by QA on 09-11-2019 with a note that 3125 quanitity of ampoules are hold. However, QA release certificate is issued for complete release of batch without description of partial release and reason of hold quantity as per their written SOP of Product release. Firm did not follow the SOP of product.

m. Reconciliation on batch packaging record of fenaclod injection B#039 shows that batch is under process however Batch is released by QA on 09-11-2019 without investigation the reason of hold quantity and performing its destruction.

n. Destruction certificate of batch documents have description "damage ampoules for Destruction / Reprocessing" apparently it shows that reprocessing of ampoules couldn't be performed which is very critical looking into sterile products.

o. On investigating the subsequent batches it's been observed that firm is continuously facing the yield loss in batches more than their prescribed limit of loss (92-108% as per approved batch documents), but so far no investigation for increased loss performed in any of the batches.

5. The conclusion of panel PSI is reproduced below;

"In the light f the meeting with staff, area visited, documents review including manufacturing, testing and ware-house record and findings of the inspection, the firm is found non-compliant in manufacturing of the Fenaclod Injection in sterile area. It is further recommended that the said product may be suspended till rectification of above noted observations or any appropriate decision by the Director Registration Board."

Action Taken by DRAP:

6. Keeping in view recommendations of the panel in its report dated 11.05.2020, it was proposed to suspend production activities in Liquid Injectable/Sterile area till rectification of all observations, verification of rectification of all observations by a panel of experts and subsequent approval by the competent authority.

7. The CLB in its 273rd meeting has delegated following powers to the Director QA<

i. Advisory letters, explanation letters or any other action as deems fit for the purpose of improvement (in case of GMP matters)
ii. Suspensions of Production (in case of GMP and Quality Control matters)

Updated Status:

8. At present post of Director QA&LT is vacant. The matter is of the urgent nature and need immediate action for suspension of production in the Liquid Injectable/Sterile area, as recommended by the panel in its report dated 11.05.2020.

Proceeding of 276th Meeting of CLB

The Division of QA & LT presented the recommendations of the panel before the Board for suspension of production in Liquid Injection Section.

Decision of 276th Meeting of CLB.

After thorough discussion and deliberation, the Board decided to serve show cause notice to the firm M/s Epoch Pharmaceuticals, Plot No.83-85, Sector 15, Korangi Industrial Area, Karachi under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (L, R&A) Rules 1976 for GMP violations as envisaged in Schedule "B" Rule 16 (a) of the Drugs (L,R&A) Rules, 1976 in ***Liquid Injectable/Sterile area***.

Item No. IV RE-CONSTITUTION OF PANEL

Case No. I: **M/S. RAAZEE THERAPUTICS (PVT.) LTD, KASUR.**

Background:

Inspection of the firm M/s. Raazee Therapeutics (Pvt.) Ltd., 48-KM, Lahore-Kasur Road, Kasur was conducted in compliance to letter No. F. 03-41/2019-QC (291-RB) dated 19.09.2019. The following panel conducted inspection on 03.10.2019.

i. Mr. AjmalSohail Asif, FID, DRAP, Lahore
ii. Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore
iii. Ms. MahamMisbah, AD, DRAP, Lahore

Action taken by DRAP:

2. The firm M/s. Raazee Therapeutics (Pvt.) Ltd, Kasur was served Show Cause Notice /Suspension of Production activities in Liquid Injectable Section order No.F.4-17/2002-QA (Vol-I) on 05.12.2019.

3. The case was placed before 273rd meeting of Central Licensing Board. Wherein the Board decided as under:-

Decision of 273rd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view available record and submission of the firm, the Board decided to :-

i. Constitute following panel of experts for detailed GMP inspection of the firm,:-

- Dr. Munawar Hayat, CDI, Punjab.
- Mr. AjmalSohail Asif, FID, Lahore
- Area FID, Lahore

ii. Direct the panel to submit detailed report with clear and candid recommendations.

iii. Production in the Liquid Injectable Section shall remain suspended till verification by panel of experts and subsequent approval by the Central Licensing Board.

iv. Refer the case to Drug Registration Board for necessary action at their end regarding manufacturing and sale of substandard Narobe Infusion, Batch No. 104092.

4. The decision was conveyed to the quarter concerned vide letter dated 06.02.2020 and reminder was issued on 13.05.2020.

Updated Status

5. Dr. Syed Zia Husnain, FID, DRAP, Lahore vide letter dated 04.08.2020 informed that Dr. Munawar Hayat, CDI Punjab has been transferred from the post of CDI, Punjab. He requested for reconstitution of panel of experts to carry out the said inspection.

Proceeding of 276th Meeting of CLB

The Division of QA & LT presented request of the FID before the Board for reconstitution of panel after the transfer of Dr. Munawar Hayat, CDI.

Decision of 276th Meeting of CLB

The Board considered the proposal and decided to replace Dr. Munawar Hayat, Chief Drug Controller, Punjab with Chief Drug Controller Punjab in panel already constituted in 273rd meeting of CLB.

Item No. V RESUMPTION OF PRODUCTION

Case No. i: M/S LIBRA PHARMA (PVT) LTD, PESHAWAR

Background:

Muhammad Arif Chaudhary, FID, DRAP, Peshawar conducted inspection of the firm M/s Libra Pharmaceuticals, Peshawar on 24.04.2018, to verify the GMP compliance and production activities.

2. The FID noticed number of observations which need urgent attention and rectification.

Action taken by DRAP:-

The case was placed for the approval of show cause notice and suspension of production activities on the critical observation noted by the FID. It was advised to place the case before the central licensing board for taking further necessary action in this regard.

3. The case was placed in 265th meeting of CLB. The Central Licensing Board decided as under:-

Decision of the 265thMeeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to serve show cause notice to the firm M/s. Libra Pharmaceuticals, Peshawar on the observations noted by the FID in its inspection conducted on 24.04.2018.

Show Cause Notice:-

As per decision of 265th meeting of CLB held on 10.08.2018, show cause notice was issued to the firm M/s. Libra Pharmaceuticals, Peshawar on 31.08.2018.

4. The case was again placed in 266th meeting of CLB. Wherein the CLB decided as under:-

Decision of the 266thMeeting of CLB

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

i. Conduct GMP inspection of the firm M/s. Libra Pharmaceuticals, Peshawar by following panel of experts:-

   a. Prof. Dr. Jamshaid Ali Khan, Member, CLB
   b. The Additional Director, DRAP, Peshawar
   c. The Area Federal Inspector of Drugs, Peshawar

ii. Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB.

iii. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 24.04.2018, with clear and candid recommendations.

Updated Status:-

The panel conducted inspection of the firm 25.02.2019 and submitted compliance report. The panel concluded as under:-

"Panel of experts unanimously recommends restoration of production activities of the firm M/s Libra Pharmaceuticals, Peshawar in the following sections.

i. Tablet (General/Quinolones)
ii. Sachet (General)
iii. Liquid Syrup (General)
iv. Tablet (Ceph)
v. Capsule (Ceph)
vi. Dry Syrup (Ceph)
vii. Tablets (Hormones)
viii. Capsules (Hormones)

However the firm needs some further improvements in the following sections and production will remain suspended in these sections till the rectification of shortcomings mentioned against;

S. No	***Section***	***Shortcomings***
1	*Dry Powder Injectable (Ceph)*	*HVAC needs revalidation and firm has also needs microbiological lab for testing of microbial testing like area monitoring, sterility testing etc.*
2	*Capsule (General)*	*No HVAC installed*
3	*Cream/Ointment (General)*	*Civil work is undergoing, and HVAC need up gradation.*

5. Inspection report was placed in 270th meeting of CLB. Wherein the CLB decided as under:-

Decision of the 270thMeeting of CLB

After thorough discussion/deliberations and recommendation of the panel of experts dated 25.02.2019, the Central Licensing Board decided to:-

I. Resume production activities in the following section, from the date of issuance of decision of 270th meeting of CLB.

i. Tablet (General/Quinolones)
ii. Sachet (General)
iii. Liquid Syrup (General)
iv. Tablet (Ceph)
v. Capsule (Ceph)
vi. Dry Syrup (Ceph)
vii. Tablets (Hormones)
viii. Capsules (Hormones)

II. However production will remain suspended in the following sections, till the improvements suggested by the panel, verification by the panel of experts and subsequent approval by the CLB.

i. Dry Powder Injectable (Cephalosporin)
ii. Capsule (General)
iii. Cream/Ointment (General)

Panel Report dated 12.08.2020

6. The panel in compliance to the decision of 270th meeting of CLB conducted inspection of the firm M/s Libra Pharma (pvt) Ltd on 12.08.2020 and concluded as under:-

"Based on various inspections of the areas, documents, corrective and preventive actions taken, cleaning and process validation, calibrations and training of works and technical staff, it is concluded that the firm adheres to cGMP and DRAP regulations. As per findings of the inspection recorded and keeping in view the overall all cGMP compliance status of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and calibration record evaluation, the panel unanimously recommends the resumption of production in the following three (03) sections".

(i) Dry Powder Injection (Cephalosporin)
(ii) Capsule (General/antibiotic)
(iii) *Cream/Ointment (General/antibiotic)*

Proceeding of 276th meeting of CLB

The Division of QA&LT presented the case before the Board. QA division presented the panel inspection report and its recommendation dated 12.08.2020.

Decision of 276th Meeting of CLB

Keeping in view the recommendations of panel in their inspection conducted on 12.08.2020, in compliance of decision of 270th meeting the board decided to;

i. Allow resumption of production in following three (03) sections;

   a. Dry Powder Injection (Cephalosporin)
   b. Capsule (General/antibiotic)
   c. Cream/Ointment (General/antibiotic)

ii. Seize the enforcement of Show Cause Notice dated 31.08.2018 from the date of issuance of decision of 276th meeting of CLB.

QUALITY CONTROL CASES

[F. No. 13-200/2019-QC]

Case No. 01 **SEIZURE OF DRUGS UNDER DRAP ACT, 2012. PERMISSION FOR SAFE CUSTODY OF SEIZED DRUGS – M/S WALTON PHARMACY, SHOP NO. 12, SHAQUIT PLAZA, I-10 MARKAZ, ISLAMABAD.**

That FID-IV, Islamabad vide reference No.F.4-1/2018-FID-IV (ISD) dated 22nd Nov, 2019 received on 10-12-2019 addressed to The Chairman, Central Licensing Board, DRAP, Islamabad informed that she inspected the premises of M/s Walton Pharmacy, Shop No. 12, Shaquit Plaza, I-10 Markaz, Islamabad on 06-11-2019, wherein following batch of unregistered drug Viagra 100mg Sildenafil citrate film coated tablets having different manufactured & expiry date exhibited/ offered for sale, recovered from M/s Walton Pharmacy, Shop No. 12, Shaquit Plaza, I-10 Markaz, Islamabad, which of some stocks was stored in nearby basement of un-licensed premises shop no. 14, owned by owner/proprietor of M/s Walton Pharmacy, Shop No. 12, Shaquit Plaza, I-10 Markaz, Islamabad as per his claim but owner ship document for same could not be provided by owner/proprietor at the time of inspection. The stocks recover were seized under section 18(1)(f) of the Drugs Act, 1976 and same was sampled for test analysis under section 18(1)(c) of Drugs Act, 1976 and unlicensed premises from where stocks was being delivered i.e. basement of un-licensed premises shop no. 14 was sealed under section 18(1)(h) of Drugs Act, 1976 and seized key was handed over to the owner/proprietor/qualified person of M/s Walton Pharmacy, Shop No. 12, Shaquit Plaza, I-10 Markaz, Islamabad in the presence of witnesses. The detail of unregistered drug seized is mentioned below:-

S.#	Name of Drug	Batch No. & Quanitity	Manufacturer	Reason for Seizure
1	Viagra 100mg Sildenafil Citrate film coated tablets Reg. No. Nil Mfg. Date: Oct-17 Exp. Date: Oct-23	MALL 19990544AG (6 X 9 Packs)	M/s Pfizer Brooklyn, Packed by M/s Pfizer, Australia, Under Authority Pfizer, USA	Un-registered
2	Viagra 100mg Sildenafil Citrate film coated tablets Reg. No. Nil Mfg. Date: Feb-18 Exp. Date: Feb-22	MALL 19990544AG (6 X 3 Packs)	M/s Pfizer Brooklyn, Packed by M/s Pfizer, Australia, Under Authority Pfizer, USA	Un-registered

02. The FID requested for the grant of permission for keeping the above mentioned seized material in safe custody till the decision of the case and extension of sealing of un-licensed premises till decision of the case,

under clause (b) of heading (5) of procedure for inspector in of Schedule-V of DRAP Act, 2012 read with Section 19(5)(b) of the Drugs Act, 1976.

03. In the light of request of FID, Islamabad the permission to continue the safe custody of seized material was granted till decision of the case vide letter no. 13-200/2019-QC dated 30.12.2019 after due approval from Director QA&LT being authorized by CLB in its 237th meeting held on 01-10-2014.

04. Meanwhile, request for "De-sealing of Store of Walton Pharmacy" is received in this Division from accused Fakhir Raza (B.Pham, BZU) [CNIC No.: 32304-1650108-1, Cell No.: 0300-6862448] vide letter no. Nil dated December 18, 2019. The contents of request for De-sealing are reproduced as under:

> *"Distinguished Sir,*
>
> *I hope this humble request letter find you in good health. With utmost regard it is stated that* ***Store of Walton Pharmacy*** *located at* ***Basement number 14, Shoukat Plaza, I-10/3 Islamabad",*** *has been sealed by Area Drug Inspector(FID) on November 6th, 2019. Sir as my store has been sealed, it is going to cost me unbearable financial losses as there are different products which are going to expire very soon.*
>
> *I humbly pray to your office that kindly de-seals the store of Walton Pharmacy so that we may continue our operations in a smooth manner and serve our local community in optimal capacity. I further request your esteemed office to serve us from financial losses, as delay in de-sealing will smoother us economically. We will really appreciate your cooperation in this regard."*

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

Board after detailed discussion and deliberations considering the facts of the case including the request of area FID-IV, Islamabad for extension in the sealing period of unlicensed Store of Walton Pharmacy located at Basement number 14, Shoukat Plaza, I-10/3 Islamabad decided to extend the sealing period of aforesaid sealed unlicensed premises till decision of the case and regretted the request of De-sealing of Store of Walton Pharmacy received from the accused Fakhir Raza (proprietor and qualified person) of M/s Walton Pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad.

Board further directed the area FID-IV, Islamabad, to complete the investigation of the case as the earliest after fulfilling all legal/codal formalities and submit complete case for consideration of the Board.

06. Decision of 273rd meeting of CLB was communicated to area FID Islamabad vide letter No. F. 03-01/2020-QC (273-CLB) dated 04-03-2020 wherein granting extension in the sealing period of the unlicensed premises to FID till decision of the case and instructing FID to complete the investigation of the case.

07. FID submitted the complete case as under;

*"Upon receipt of complaint from Dr. Minhaj us-Siraj, Deputy Director General, Health, undersigned inspected the premises of M/s Walton Pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad on 06-11-2019, wherein following batch of un-registered drug Viagra 100mg Sildenafil citrate film coated tablets having different manufacturing & expiry date exhibited / offered for sale, recovered from M/s Walton Pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad, which of some stocks were stored in near by basement of un-licensed premises shop no. 14, owned by owner/ proprietor of M/s Walton Pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad as per his clam but owner ship document for same could not be provided by the owner/ proprietor at the time of inspection. The stocks recovered were seized under section (18) (1)(f) of the Drugs Act, 1976 and same was sampled for test analysis under section 18(1)(c) of Drugs Act, 1976 and unlicensed premises from where stocks were being delivered i.e. basement of un-licensed premises shop No. 14, was sealed under section 18 (1) (h) of Drugs Act, 1976 and sealed key was handed over to the owner/ proprietor / qualified person of M/s Walton Pharmacy, Islamabad in the presence of witnesses. The details of unregistered drug seized are mentioned below (**Annexed-I**):-*

S.#	***Name of Drug***	***Batch No & Quantity***	***Manufacturer***	***Reason of Seizure of***
1.	*Viagra 100mg Sildenafil citrate film coated tablets Reg, No. Nil* *Mfg. Date: Oct-17* *Exp. Date: Oct-23*	*MALL* *19990544AG* *(6 x 9 Packs)*	*M/s Pfizer Booklyn Packed by M/s Pfizer, Australia, Under Authority Pfizer, USA.*	***-registered.***
2	*Viagra 100mg Sildenafil citrate film coated tablets Reg, No. Nil* *Mfg. Date: Feb-18* *Exp. Date: Feb-22*	*MALL* *19990544AG* *(6 x 3 Packs)*	*M/s Pfizer Booklyn Packed by M/s Pfizer, Australia, Under Authority Pfizer, USA.*	***-registered.***

*2. The case was submitted for the grant of permission for keeping the above mentioned seized material in safe custody till the decision of the case, under clause (b) of heading (5) of procedure for inspector in of schedule –V of DRAP Act 2012 read with Section 19 (5)(b) of the Drugs Act, 1976(**Annexed-II**)*

*3. The sealed samples of drug was sent to the Government Analyst, Central Drugs Laboratory Karachi for test & analysis on 12th November, 2019 and other sealed portion of the said samples were dispatched/ delivered as per of DRAP Act, 2012 read with section of the Drugs Act, 1976 (**Annexed-III**).*

*4. Federal Govt. Analyst under section 22 of the Drugs Act, 1976 had submitted the test report of the sample. Copy of the test report was sent to Mr. Fakhar Raza, the proprietor/ Qualified person of said pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad under section 22 (3) of the Drugs Act, 1976 (**Annexed-IV**).*

5. The detail of the test report is as under: -

S. No.	***Name of Drug/Regn No.***	***Batch No.***	***Manufacturer***	***Test/Analysis Report No. & dated***	***Results declared by Govt. Analyst***
1	*Viagra 100mg Tablets* *Nil*	*MALL 19990544AD*	*M/s Pfizer Booklyn NE.* *Packed by M/s Pfizer Australia, under Authority Pfizer.*	*T.R.No. R.IP.118/2019* *dated:06-01-2019.*	*Un-Registered Drug Product.*

*6. Keeping in view of the test report of Federal Government Analyst, Central Drugs Laboratory, Karachi the proprietor/ Qualified person of said pharmacy has violated Section Schedule-II (A) (I) (a) (vii) (x), (b), (c), (d) (i) of DRAP Act, 2012 read with Section 23(1)(vii)(x), (b), (c), (d), (i) of Drugs Act, 1976 which is cognizable offence under Schedule IV (2) (a) of DRAP Act, 2012 and Section 30 (2) (a) and punishable under Schedule-III(1)(a)(b)(c) and (2) (4) (6) read with Section 27(1)(a)(b)(c) and 27(2)(4) of Drug Act, 1976. The proprietor/ Qualified person of said pharmacy were already directed vide letter of even number dated 04-12-2019 and 07-01-2020 to provide the bill invoice with warranty as required under section 32(3)(b)(i), to present proprietor / qualified person as required under section 18(1)(g) of Drugs Act, 1976 including the explanation but they have failed to do the needful (**Annexed-V**).*

*7. The letter had been received from Assistant Director (QC-I)/ for Secretary, Central Licensing Board, wherein it had been conveyed for grant of permission for keeping the above mentioned seized material / un-registered therapeutic goods in safe custody under the prescribed law and procedure whereas the permission for un-licensed premises as granted in the same case of M/s Shaheen Chemist, Islamabad till decision of the case had not been granted. The competent forum of CLB was requested to grant the same as per law and procedure (**Annexed-VI**).*

*8. For Secretary, CLB has conveyed for extension of sealing period of afore said sealed un-licensed premises and regretted the request of de-sealing of un-licensed store, received from the accused Mr. Fakhar Raza, the proprietor/ Qualified person of said pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad (**Annexed-VII**).*

*9. As already mentioned that the proprietor/ Qualified person of said pharmacy was directed vide letter of even number dated 04-12-2019, 07-01-2020, 20-012020 and 25-02-2020 to provide the bill invoice with warranty as required under section 32(3)(b)(i), to present proprietor / qualified person as required under section 18(1)(g) of Drugs Act, 1976 including the explanation on selling of un-registered drug with out bill invoice with warranty, storing of un-registered drug in un-licensed premises and other contraventions etc. but has failed to provide any evidence/ reasons in the case (**Annexed-VIII**).*

10. Keeping in view of the test report of Federal Government Analyst, Central Drugs Laboratory, Karachi and the investigation conducted so for , the proprietor/ Qualified person of said pharmacy has violated Section Schedule-II (A) (I) (a) (vii) (x), (b), (c), (d) (i) of DRAP Act, 2012 read with Section 23(1)(vii) (x) (b) (c) (d) (i) of Drugs Act, 1976 which is cognizable offence under Schedule IV (2) (a) of DRAP Act, 2012 read with Section 30 (2) (a) and punishable under Schedule-III (1)(a)(b) (c) and (2)(4)(6)/ read with Section 27(1)(a)(b)(c) and 27(2)(4) of Drug Act, 1976. The proprietor/ Qualified person of said pharmacy were directed vide letter of even number dated 04-12-2019, 07-01-2020, 20-012020 and 25-02-2020 to provide the bill invoice with warranty as required under section 32(3)(b)(i), to present proprietor / qualified person as required under section 18(1)(g) of Drugs Act, 1976 including the explanation on selling of un-registered drug without bill invoice with warranty, having valid licensed of the un-licensed premises and other contraventions etc. but they have failed to provide any evidence/ reasons in the case. Hence, it is requested to grant the permission to prosecute the following accused in the Drug Court, Islamabad.

i. *M/s Walton Pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad for using Un-licensed premises as store/ godown to stock/sale the un-registered drugs.*
ii. *Mr. Fakhar Raza, the proprietor of M/s Walton pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad.*
iii. *Mr. Fakhar Raza, the Qualified person of said pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad*

*11. The Case is submitted for further necessary action/ direction as per clause (7) under heading "**procedure for inspectors**" Schedule-V of DRAP Act, 2012 read with Section 19(7) of the Drugs Act, 1976, please."*

08. Show cause notice was issued to the accused vide F. No. 13-200/2019-QC dated 14-05-2020 to the accused as mentioned by Area FID in her report contents of which are as under;

"I am directed to refer to the subject cited above and to say that FID-IV Islamabad vide letter No. 4-1/2018-FID-IV (ISD) dated 12th March 2020 wherein FID Islamabad informed that upon receipt of complaint from Dr. Minhaj us-Siraj, Deputy Director General, Health; the FID-IV Islamabad inspected the premises of M/s Walton Pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad on 06-11-2019, wherein following batch of un-registered drug Viagra 100mg Sildenafil citrate film coated tablets having different manufacturing & expiry date exhibited / offered for sale, were recovered from M/s Walton Pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad, some of stocks were stored in nearby basement of un-licensed premises shop no. 14, owned by owner/ proprietor of M/s Walton Pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad as per his clam but owner ship document for same could not be provided by the owner/ proprietor at the time of inspection. The stocks recovered were seized under section (18) (1)(f) of the Drugs Act, 1976 and same was sampled for test analysis under section 18(1)(c) of Drugs Act, 1976 and unlicensed premises from where stocks were being delivered i.e. basement of un-licensed premises shop No. 14, was sealed under section 18 (1) (h) of Drugs Act, 1976 and sealed key of aforesaid unlicensed premises was handed over to the owner/ proprietor / qualified person of M/s Walton Pharmacy, Islamabad in the presence of witnesses. The details of seized unregistered drug are mentioned below:-

S.#	***Name of Drug***	***Batch No & Quantity***	***Manufacturer***	***Reason of Seizure of***
1.	*Viagra 100mg Sildenafil citrate film coated tablets Reg, No. Nil* *Mfg. Date: Oct-17* *Exp. Date: Oct-23*	*MALL* *19990544AG* *(6 x 9 Packs)*	*M/s Pfizer Booklyn Packed by M/s Pfizer, Australia, Under Authority Pfizer, USA.*	***Un-registered.***
2	*Viagra 100mg Sildenafil citrate film coated tablets Reg, No. Nil* *Mfg. Date: Feb-18* *Exp. Date: Feb-22*	*MALL* *19990544AG* *(6 x 3 Packs)*	*M/s Pfizer Booklyn Packed by M/s Pfizer, Australia, Under Authority Pfizer, USA.*	***Un-registered.***

2. FID Islamabad IV informed that the case was submitted for the grant of permission for keeping the above-mentioned seized material in safe custody till the decision of the case, under clause (5)(b) of heading procedure for inspector in schedule –V of DRAP Act 2012 read with Section 19 (5)(b) of the Drugs Act, 1976. The sealed samples of drug was sent to the Government Analyst, Central Drugs Laboratory Karachi for test & analysis on 12th

November, 2019 and other sealed portion of the said samples were dispatched/ delivered as per of DRAP Act, 2012 read with the Drugs Act, 1976.

3. The FID Islamabad further informed that Federal Govt. Analyst under section 22 of the Drugs Act, 1976 submitted the test report of the sample. Copy of the test report was sent to Mr. Fakhar Raza, the proprietor/ Qualified person of M/s Walton pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad under section 22 (3) of the Drugs Act, 1976.

4. The FID submitted the detail of the test report as under: -

S. No.	***Name of Drug/Regn No.***	***Batch No.***	***Manufacturer***	***Test/Analysis Report No. & dated***	***Results declared by Govt. Analyst***
1	*Viagra 100mg Tablets* *Reg. No.: Nil* *Mfg Date: Oct 17* *Exp Date: Oct 23*	*MALL 19990544AD*	*M/s Pfizer Booklyn Ne.* *Packed by M/s Pfizer Australia, under Authority Pfizer.*	*T.R.No. R.IP.118/2019* *dated:06-01-2020.*	*Un-Registered Drug Product.*

5. The FID IV Islamabad submitted that in light of test report of Federal Government Analyst, Central Drugs Laboratory, Karachi and investigation conducted so far, the proprietor/ Qualified person of M/s Walton pharmacy Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad has violated Schedule-II (A) (1) (a) (vii) (x), (b), (c), (d) (i) of DRAP Act, 2012 read with Section 23(1)(vii) (x) (b) (c) (d) (i) of Drugs Act, 1976 which is cognizable offence under Schedule IV (2) (a) of DRAP Act, 2012 read with Section 30 (2) (a) and punishable under Schedule III (1) (a) (b) (c) and (2) (4) (6)/ Section 27(a) (b) (c) and (2) (4) of Drug Act, 1976. The proprietor/ Qualified person of said pharmacy was already directed vide letter of even number dated 04-12-2019 and 07-01-2020 to provide the bill invoice with warranty as required under section 32 (3) (b) (i), to present proprietor / qualified person as required under section 18 (1) (g) of Drugs Act, 1976 including the explanation but they failed to do needful. FID Islamabad added that approval was conveyed for grant of permission for keeping the above-mentioned seized material/un-registered therapeutic goods in safe custody vide letter No. 13-200/2019-QC dated 30-12-2019. The extension of sealing period of afore said sealed un-

licensed premises was conveyed vide letter NO.03-01/2020-QC (273-CLB) dated 04th March 2020 and regretted the request of de-sealing of un-licensed store, received from the accused Mr. Fakhar Raza, the proprietor/ Qualified person of said pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad.

6. FID Islamabad further informed that the proprietor/ Qualified person of M/s Walton Pharmacy was already directed vide letter of even number dated 04-12-2019, 07-01-2020, 20-012020 and 25-02-2020 to provide the bill invoice with warranty as required under section 32(3)(b)(i), to present proprietor / qualified person as required under section 18(1)(g) of Drugs Act, 1976 including the explanation on selling of un-registered drug without bill invoice with warranty, storing of un-registered drug in un-licensed premises and other contraventions etc. but has failed to provide any evidence/ reasons in the case.

7. FID Islamabad reported that according to the test report of Federal Government Analyst, Central Drugs Laboratory, Karachi and the investigation conducted so for, the proprietor/ Qualified person of said pharmacy has violated Section Schedule-II (A) (I) (a) (vii) (x), (b), (c), (d) (i) of DRAP Act, 2012 and Section 23(1)(vii) (x) (b) (c) (d) (i) of Drugs Act, 1976 which is cognizable offence under Schedule IV (2) (a) of DRAP Act, 2012 and Section 30 (2) (a) and punishable under Schedule III (1) (a) (b) (c) and (2) (4) (6)/ Section 27(a) (b) (c) and (2) (4) of Drug Act, 1976. The proprietor/ Qualified person of said pharmacy were directed vide letter of even number dated 04-12-2019, 07-01-2020, 20-01-2020 and 25-02-2020 to provide the bill invoice with warranty as required under section 32(3)(b)(i), to present proprietor / qualified person as required under section 18(1)(g) of Drugs Act, 1976 including the explanation on selling of un-registered drug without bill invoice with warranty, having valid licensed of the un-licensed premises and other contraventions etc. but they have failed to provide any evidence/ reasons in the case. Hence, it is requested to grant the permission to prosecute the following accused in the Drug Court, Islamabad.

i. M/s Walton Pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad for using Un-licensed premises as store/ godown to stock/sale the un-registered drugs.
ii. Mr. Fakhar Raza, the proprietor of M/s Walton pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad.
iii. Mr. Fakhar Raza, the Qualified person of said pharmacy, Shop No. 12, Shoukat Plaza, I-10 Markaz, Islamabad

08. You are, hereby required to show cause in writing within 15 (fifteen days) of the receipt of this letter so that why the following actions(s) should not be initiated against you, at the same time you are required to indicate whether you desire to be heard in person/through authorized legal counsel or not?

i. Prosecution in Drug Court.

ii. Any other action the Board may deem fit.

09. In case no reply is received within the specific period, it would be presumed that you have no defense to offer or you have declined to offer the same & accepted the charges and in that case action against you shall be taken ex-parte on the basis of available record."

09. Reply of the accused in response to the mentioned show cause notice is as under;

"Dear Sir,

Very respectfully, undersigned replies/states as under:-

1. That it is correct to the extent of that undersigned's pharmacy M/S Walton Pharmacy DSL#(413-ICT/2013) .shop No.12,Shoukat plaza ,1-10 Markaz Islamabad was inspected by the learned FID on 6-11-2019,but the alleged unregistered drugs were not recovered from the said premises.

2. That as per record, it is evident that the alleged recovery of drugs was made from a nearby unlicensed premises and the same was sealed by the learned FID.

3. That the report produced by learned FID in no way establishes, ,any nexus of unlicensed premises with the undersigned or with the undersigned's pharmacy under any lease agreement, nor any receipt regarding sale of alleged unregistered drug was produced by the undersigned's pharmacy.

4. That sealing of the said unlicensed premises by itself reveals that the alleged recovery has no connection with undersigned or with the undersigned's pharmacy.

5. That as being the fact of unlicensed premises the instant case falls out of the jurisdiction of Federal subject as per law.

6. That the signatures on recovery memo were taken under duress and undue influence as no neutral witnesses were taken by the learned FID in spite of the fact that locality was situated in a highly populated area, which is mandatory under the law.

7. That the undersigned was made by the concerned officials to put a de-sealing application for the unlicensed premises before the QC board under the directions and promise for the discharge of undersigned from the charges level against which clearly manifests malafide on the part of said officials ,for the purpose of extracting false incriminating material against the undersigned.

8. That there is sufficient proof on record which shows that the undersigned is falsely implicated in the said case and there is no sufficient incriminating material on record against the undersigned.

In the light of forgoing, it is prayed that the instant show cause notice may kindly be withdrawn and undersigned be exonerated of the charges leveled against on the basis of factual and legal grounds.

Undersigned shall remain obliged forever."

10. A personal hearing notice was issued to the accused to appear before the board vide F. No. 03-36/2020-QC (276-CLB) dated 27-08-2020.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

11. The accused, Fakhar Raza, Proprietor and Qualified person of M/s. Walton Pharmacy, Shop No 12, Shoukat Plaza, I-10 Markaz, Islamabad, appeared neither himself, nor through any counsel before the Board.

12. Board after considering the facts of the case and the reply of accused decided as under;

Board granted permission to the area FID Islamabad for prosecution in the court of competent jurisdiction against following accused for the contraventions of the DRAP Act 2012 and The Drugs Act 1976 as given under;

i. **M/s. Walton Pharmacy, Shop No. 12, Shoukat Plaza, I-10 markaz, Islamabad through its owner/qualified person, Fakhar Raza S/o Chaudhry Muhammad Ashraf CNIC No. 32304-1650108-1, R/o**
    a. **House No. 132, Street No. 31, I-10/4, Islamabad.**
    b. **Flat No.4, 2nd Floor, Rehman Plaza, I-10 Markaz, Islamabad.**
ii. **Fakhar Raza S/o Chaudhry Muhammad Ashraf, CNIC No. 32304-1650108-1 R/o**
    a. **House No. 132, Street No. 31, I-10/4, Islamabad.**
    b. **Flat No.4, 2nd Floor, Rehman Plaza, I-10 Markaz, Islamabad.**

Case No. 02: **MANUFACTURING AND SALE OF SUBSTANDARD INJECTION HEPAFERON (INTERFERON) B. NO. 85 BY M/S PHARMEDIC LAB, LAHORE.**

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

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

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

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

03. Proceeding and Decision of 291st meeting of Registration Board.

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

- Case forwarded by the FID, DRAP, Peshawar.
- Inspection report of M/s Pharmedic laboratories by FID, DRAP, Lahore and ADC, DRAP, Lahore dated 20-03-2014.
- Test reports by the Federal Government Analyst, NCLB, Islamabad.
- Show cause notice issued to the M/s Pharmadic and accused persons.
- Reply to the show cause notice as well as correspondence by the firm.
- Personal hearing in different meetings of Registration Boards (286th , 289th)

Decision of Registration Board in its 291st Meeting:

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

i. **The firm failed to comply with the condition of registration prescribed under the law. At the time of inspection dated 20-03-2014 it was revealed that requisite storage facilities (2-8 ºC) were not sufficient to store the manufacture stocks at the recommended temperatures and humidity. The stocks were kept in the corridors at room temperature. This reveals manufacturing and storage conditions do not corresponds in terms of capacity.**
ii. **That the FID recorded the temperature at the time of sampling, which revealed the samples picked up at the controlled temperature (2-8 ºC) were also, declared of substandard quality.**
iii. **On the basis of above findings, the Board decided to cancel the registration of the product i.e. (Hepaferon Injection 3 MIU) Interferon Alpha 2a Registration No.029537 due to failure of the registration holder to meet the conditions for registration of drugs prescribed under the rules.**
iv. **The Board also decided to recommend the cancellation of the section to the central licensing board approved for manufacturing of biological products.**

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

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

04. In compliance to the decision of 273rd meeting of CLB, the accused was served show cause notice of which no reply has been received till date. The accused are called before the Board for personal hearing.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

05. The firm was issued show cause and personal hearing notice as mentioned above but no representative of the firm appeared before the Board nether neither himself nor through representative. Moreover, firm did not reply to to show cause notice in writing.

06. The Central Licensing Board after thorough delibration, considering the facts of the case that company have been found continuously manufacturing of substandard drugs and in the light of the recommendations of the 291st meeting of Registration Board held on 04th September, 2019 decided to Cancel the license of Biological Section of M/s. Pharmedic Laboratories (Pvt.) Ltd., 16-KM Multan Road, Lahore under section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (LRA) Rules 1976 for not complying the provisions of rule 20(a) of the Drugs (LRA) Rules, 1976.

Case No. 03: **STOCKING FOR SALE & SELLING OF UN-REGISTERED DRUGS – M/S AL-TAWAKAL MEDICOS, SHOP NO. B-2, TAJ COMPLEX, M. A. JINNAH ROAD, KARACHI.**

That FID-V, Karachi vide reference No.SAA-07-15/2018-FID-V(K) dated 26th April, 2019 received on 08-05-2019.

02. The FID informed that he along with Mr. Abdul Rasool Shaikh, FID(DRAP), Karachi, inspected the premises of M/s Al-Tawakal Medicos, Shop No.B-2, Taj Complex, M. A. Jinnah Road, Karachi on 28.01.2019 at around 02:00 pm in a routine market survey. During visit 31 different un-registered drugs were found available in a carton placed under cash counter of said premises. The FID `took the following three samples from said un-registered drugs on form-3 for the purpose of test analysis and remaining stocks of all un-registered drugs were seized on Form-2 under Section 19(f) of the Drugs Act, 1976

Form-3							
S.#	**Name of Drug**	**Reg. No.**	**Batch No.**	**Quantity**	**Mfg. Date**	**Expiry Date**	**Manufacturer by**
1	Tab Viagra 50mg	Nil	Nil	6 x2	Nil	Nil	Pfizer Brooklyn, USA
2	Tab Erectal Gold	Nil	1325502	1x10x3	10/17	09/20	WBB Tech Co. Ltd, USA
3	Tab Penegra 100mg	Nil	G70534	1x4x2	Nil	Nil	Cadila Healthcare, India

Sr. No.	**NAME OF DRUG**	**BATCH No**	**QUANITY**	**MFG DATE**	**EXP DATE**	**MANUFACTURED BY**
1.	Novomix 30 Plexpen 100U/ml	GT 6B642	3ml X 3	09/2017	08/2019	M/s Novo Nardisk France
2.	Novomix 30 Plexpen 100U/ml	GT 6C770	3ml X1X 5	11/2017	10/2019	M/s Novo Nardisk France
3.	Tabs. Centrum Silver	T 93992	125 Tabs X1X 4	NIL	12/2019	Made in Canada
4.	Tabs. Centrum Silver	W 11011	125 Tabs X 1X1	NIL	12/2019	Made in Canada
5.	Tabs. Viagra 50mg	MAL19990545AG	6 Tabs X1X9	07/2016	07/2020	M/s Pfizer USA

6.	Questran 4g	1994	12 Bustine X 1	NIL	06/2020	M/s Bristol Myers Squib Roma
7.	Questran 4g	1985	12 Bustine X 1	NIL	06/2020	M/s Bristol Myers Squib Roma
8.	Questran 4g	1979	12 Bustine X 2	NIL	06/2020	M/s Bristol Myers Squib Roma
9.	Tabs. YTiG	T0606	2 Tabs X 2	12/2018	12/2020	M/s Trends Pharmaceuticals (Pvt) Ltd; Lahore
10.	Tabs. Caltrate	PF18-008	60 Tabs X1X 5	NIL	12/2019	Marketed by M/s Pfizer USA
11.	Tabs. Centrum Silver	T93988	80 Tabs X 1	NIL	10/2019	Made in Canada
12.	Tabs. Centrum Adult	W94625	130 Tabs X 1	NIL	12/2019	Marketed by M/s Pfizer USA
13.	Caps. Epanutin 100mg	171797103	70 Caps	NIL	01/2020	M/s Pfizer Instanbul
14.	Tabs. Sinemet Plus	W170190	20 Caps	NIL	02/2022	M/s Merck Shop dohm, Haosten
15.	Tabs. Imuran 50mg	810943	100 Tabs X1X 3	NIL	06/2023	M/s Aspen Pharma, Ireland
16.	Tabs. Imuran 50mg	611160	75 Tabs.	NIL	09/2021	M/s Aspen Pharma, Ireland
17.	Inj. Ipraton 500mcg/2ml	G72200831	20 Inj X 2	NIL	08/2020	Made in Turkey
18.	Tabs. Penegra	Different batches	4 Tabs X 28	02/2017	08/2020	M/s Cadila Healthcare India
19.	Tabs. Metrex	18001	100 Tabs	20.03.2018	19.03.2021	M/s Daehan New Pharma Korea
20.	Tabs. Sorafenib 200mg	6J80745	30 Tabs X 1	6/2018	05/2020	M/s Cipla Ltd; India
21.	Tabs. Sorafenib 200mg	6J80967	30 Tabs X 1	9/2018	08/2020	M/s Cipla Ltd; India
22.	Tabs. Sorafenib 200mg	6J80746	30 Tabs X 1	6/2018	05/2020	M/s Cipla Ltd; India
23.	Caps. Temosido 100	6J70925	5 Caps X1x 3	10/2017	09/2019	M/s Cipla Ltd; India

24.	Caps. Kreon 10,000IU	55625	100 Caps X1x2	NIL	09/2019	M/s Abbott Labs, Almanya
25.	Tabs. Marevan 5mg	A526846	100 Tabs X 2	03/2018	09/2020	M/s GSK
26.	Tabs. Lioresal 10mg	KD 527	100 Tabs	NIL	11/2020	M/s Novartis Istanbul
27.	Tabs. PTU 100	1171003	1000 Tabs	19/02/2018	19/02/2021	M/s T. O. Chemical Bankok
28.	Tabs, Furotin 100mg	1805422	30 Tabs X 2	Nil	Nil	M/s IASIS Pharma, Greece
29.	Tabs. Florinef 100mcg	7F5332	100 Tabs	05/2017	05/2020	M/s Aspen Pharma Austria
30.	Inj. Konakion 10mg/ml	F3261F03	5 Amps X 1	05/2017	05/2020	M/s F. Hoffman Roche France
31.	Tabs. Endoxan	G803069	100 Tabs	05/2018	04/2020	M/s Baxler, Germany

03. The FID informed that the Division of QA&LT was intimated regarding the seizure of drugs with request of permission for safe custody of the seized stock vide this office letter dated 29-01-2019. The same was received on 13-02-2019 in concerned section.

04. The FID further informed that the sample of the drugs (suspected to have sildenafril citrate) were sent to the Central Drugs Laboratory, Karachi on prescribed form-4 dated 29.01-2019. The Show case notice was served by FID to M/s Al-Tawakal Medicos vide letter dated 29-01-2019 for stocking/sale of un-registered drugs. The M/s Al Tawakal medicos Taj Complex Karachi submitted its reply dated 04-02-2019 which was incomplete and un-satisfactory. The FID informed that *M*/s Al Tawakal Medicos Karachi was asked to appear in person in the office of FID on 15th February 2019 under Section 18(1)(g) of the Drugs Act 1976 to explain its position with clear/satisfactory submission of their reply.

05. The CDL Karachi vide test report No. RKQ 119/2019 dated 04-03-2019 issued the report for tablet Erectal Gold batch no. 1325502 in which the suspected ingredient "sildenafil citrate" was not identified.

06. The FID informed that the Division of QA&LT vide letter No. F13-44/2019-QC dated 28-02-2019, received to FID on 05th March 2019 granted the permission for safe custody of the seized. The reminder letter of dated 11-03-2019 was sent to M/s Al-Tawakal Medicos Karachi to appear in person in the FID office to explain its position and submission of satisfactory reply.

07. The CDL Karachi vide report no. **RKQ 120/2019 dated 04-03-2019 declared the sample of Tab penegra batch no. G705345 as unregistered drug product**. The M/s Al-Tawakal Medicos Karachi was asked to explain its position and submit the bill warranty purchase record or any document in the defense for stocking sake of unregistered drug vide office letter No. SAA-07-12/2019 FID V K dated 12-03-2019.

08. **The CDL vide report no. RKQ118/2019 dated 01-04-2019 declared the sample of Tab .Viegra 50mg batch no MAL 199905 as unregistered drug product**. M/s Al Tawakal Medicos Karachi was asked again to explain its position and submit the bill/warranty purchase record or any document in their defense for stocking/sale of unregistered drugs vide letter no. SAA-07-12/2019-FID-V K dated 09-04-2019.

09. The FID further informed that Mr. Naveed Ahmed S/o Abdul Hameed Proprietor of M/s Al-Tawakal Medicos Karachi appeared in person in the office of FID on dated 22-04-2019 along with his submission vide letter dated 15th April 2019 along with explanation about the proprietorship of the shop with supporting copy of agreement.

10. The FID submitted regarding the submissions/stated facts M/s Al-Tawakal Medicos Karachi is involved in stocking/sale of un-registered drugs which is violation of Section 23(1)(a) (vii) punishable under section 27 (1) (a) of the Drug Act 1976 and Schedule-II A. (1) (a)(vii) punishable under Schedule-III (1) (a) of the DRAP Act 2012

11. The FID submitted the names of accused persons of the firm:-

a. M/s Al-Tawakal Medicos Shop No.B-2 Taj Complex M.A Jinnah Road Karachi.
b. Mr. Naveed Ahmed S/o Abdul Hameed (Propretor of M/s Al-Tawakal Medicos).

10. The FID requested on the facts personal appearance and submission of replies by M/s Al-Tawakal Medicos Taj Complex Karachi the permission for prosecution of the accused persons may kindly be granted to initiate the trial before the Drug Court Karachi.

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

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

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

below in para 2:

a. **M/s Al-Tawakal Medicos Shop No.B-2 Taj Complex M.A Jinnah Road Karachi.**
b. **Mr. Naveed Ahmed S/o Abdul Hameed (Proprietor of M/s Al-Tawakal Medicos).**

2. **The mentioned accused persons are involved in stocking / sale of un-registered drugs which is violation of Section 23(1)(a) (vii) punishable under section 27 (1) (a) of the Drug Act 1976 and Schedule-II A. (1) (a)(vii) punishable under Schedule-III (1) (a) of the DRAP Act 2012.**

12. In the light of decision of Board, show cause notice was issued to the accused persons vide No. F. 03-33/2019-(QC) (270-CLB) dated 02-01-2020.

13. Proceedings and decision of 273rd Meeting held on 15th January, 2020:

No person appeared before the Board. The Board after considering the facts decided to defer the case for giving final opportunity to the accused to plead their case

14. As per directions of the Board, the accused were served one final opportunity of Personal Hearing vide F. No. 03-01/2020-QC (273-CLB) dated 27-08-2020 to appear before the Board.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

15. The accused, M/s Al-Tawakal Medicos Shop No. B-2 Taj Complex M.A Jinnah Road and Naveed Ahmad S/o Abdul Hameed (owner / proprietor) M/s. Al-Tawakal Medicos Shop No. B-2 Taj Complex M.A. Jinnah Road did not appear neither himself nor through any counsel before the Board.

16. Board after thorough delibration and considering the facts of the case decided as under;

Board granted permission to the area Federal Inspector of Drugs, Karachi for prosecution in the court of competent jurisdiction against the following accused for the contraventions of the DRAP Act 2012 and The Drugs Act 1976 as given under;

i. M/s Al-Tawakal Medicos Shop No. B-2 Taj Complex M.A Jinnah Road through its owner, Naveed Ahmed S/o Abdul Hameed.

ii. Naveed Ahmad S/o Abdul Hameed (owner / proprietor) M/s. Al-Tawakal Medicos Shop No. B-2 Taj Complex M.A. Jinnah Road, Karachi.

Case No. 04: **MANUFACTURE AND SALE OF SPURIOUS AND SUB-STANDARD DRUG RECOVERED FROM M/S NEHAL MEDICOS LANDHI NO. 06 GHOUSIA REHMANIA MASJID LANDHI KARACHI AND PERMISSION OF SHOW CAUSE FOR PROSECUTION THEREOF.**

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

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

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

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

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

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

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

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

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

2.	Chlorpheniramine Syrup	009071	113	May - 2017	April-2019	M/s Gaba Pharmaceuticals	Spurious	KQ.75/2019 Dated 18th March, 2019

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

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

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

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

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

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

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

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

In the light of above test report of Federal Government Analyst, Central Drug Laboratory, Karachi an explanation letters of even number dated 11th March 2019 alongwith test report No.R.KQ.76/2019 dated 06th March 2019 was accordingly issued to M/s Gaba Pharmaceuticals Lab: S/76, S.l.T.E,

Mauripur Road. Karachi & M/s Nehal Medicos. Landhi No.06. Ghousia Rehmania Masjid. Landhi Karachi for explaining their position in the matter of manufacturing/selling of above mentioned Spurious and Sub-Standard drug.(Annexure-G & H).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

S.No.	***Name of Drugs***	***Reg.No.***	***Batch No.***	***Mfg Date***	***Expiry Date***	***Purported to be Mfg by***

1.	*Chlorpheniramine Syrup*	*009071*	*113*	*May - 2017*	*April-2019*	*M/s Gaba Pharmaceuticals*

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

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

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

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

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

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

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

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

Undersigned vide this office letter of even number dated 28th May 2019 informed M/s Nehal Medicos Landhi No.06 Ghousia Rehmania Masjid Landhi Karachi that bill warranty for Chlorpheniramine

Syrup B.No.113 provided by you is not acceptable as the date of bill warranty is 06th February 2019 while the then FID took the sample from his premises on 16th January 2019.

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

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

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

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

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

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

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

08. Recommendations by FID, Karachi:

In the light of above stated facts it is submitted that M/s Nihal Medical Store Shop No. 4 Ghousia Rehmania Masjid Landhi No.06 Karachi and above said owner and qualified person were found involved in selling of

spurious Chlorpheniramine Syrup Batch No. 113 and Spurious and Sub-standard Galtran Tablet Batch no. 185 and contravened the provision of section 23(1)(a)(i), 23(1)(a)(v), 23(1)(a)(x), & 23(1)(f) punishable under section 27(1)(a) of the Drug Act 1976 read with schedule-II (A)(1)(a)(i), schedule-II (A)(1)(a)(v), & schedule II (A)(1)(f) punishable under schedule-III (1)(a) and schedule III(6) of the DRAP Act 2012 Therefore grant permission for prosecution in Drug Court.

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

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

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

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

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

10. In compliance to the directions of the Board, the accused were served show cause notice vide No. F. 03-014/2020-QC (273-CLB) dated 04-03-2020 reply of which has not been received till date. The accused are called before the Board for personal hearing.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

11. The accused, Mr. Nihaluddin Khan (Proprietor) M/s Nehal Medial Store Shop No. 4 Ghousia Rehmanida Masjid Landhi Karachi H.No.1 Gali No.3 Area A-2 Landhi No.3 Karachi and Mr. Abdul Majid

Shaikh (Qualified person) M/s Nihal Medical Store shop No. 4 Ghousia Rehmania Masjid Landhi No. 6 Karachi did not appear before the Board neithr themselves nor through any Counsel/representative.

12. **The Board after considering the facts of the case and thorugh delibration decided to give one final opportunity of personal hearing to the accused namely;**

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

Moreover, to meet the ends of justice, the Board decided to remand back the area Federal Inspector of Drugs to establish/trace the bill warranty/invoice from supplier/distributor and the manufacturer and provide a comprehensive report for the consideration of the Board in its forthcoming meeting.

Case No. 05: **MANUFACTURE & SALE OF SPURIOUS PENRO 1000MG INJECTION, REG. NO. 042107, BATCH NO. PO200030, MFG. DATE 10-2019, EXP. DATE 09-2022 MANUFACTURED BY M/S BOSCH PHARMACEUTICALS (PVT.) LTD., KARACHI.**

Brief facts of the case are as under;

02. A copy of test/analysis reports No.R.KQ.179/2020 dated 07th July, 2020 from the Federal Government Analyst, CDL, Karachi was received in the divison of QA&LT wherein, the Federal Government Analyst has declared samples of PENRO 1000mg Injection, Reg. No. 042107, Batch No. PO200030, Mfg. Date 10-2019, Exp. Date 09-2022 Manufactured by M/s Bosch Pharmaceuticals (Pvt.) Ltd., Karachi received in CDL, Karachi vide memorandum No.ARS-73/2020-FID-VI-(K) dated 01-07-2020 as of ***"Spurious drug"***.

03. Results of CDL on the basis of which sample under reference has been declared as Spurious are reproduced as under:-

"Description: *Off white powder in clear glass vial.*

Identification:

i. *Meropenem **Not** identified. (By FTIR and HPLC)*
ii. *Ceftriaxone Sodium identified. (By FTIR and HPLC)*

Note:- *The sample has been referred with remarks "Sample is suspected to contain Ceftiaxone Sodium"*

Remarks:-

i. *The label claim Meropenem, however, it could not be identified in identification test.*
ii. *Ceftriaxone Sodium identified as suspected by the Federal Inspector of Drugs.*
iii. *The sample does not contain the drug as claimed in the labeland contains another drug, therefore, the sample is declared as **"spurious drug"** under section 3 (z-b) (iii) of the Drugs Act, 1976.*

Section 3 (Definition): In this Act unless there is anything repugnant in the subject or context:

3 (z-b): Spurious drug means a drug:

iii) Which is imported or exported or sold or exposed for sale under a particular name while actually it is another drug"

04. The FID-VI, DRAP, Karachi was requested to complete the investigation of the case at the earliest and submit a comprehensive report covering full details of the case including nature of contravention, views/comments on the manufacturer, name(s) of responsible persons committing the offence and recommendations for further processing the case and its consideration by the Central Licensing Board.

05. In response to the instruction of the division of QA&LT, FID VI Karachi vide letter No. F. ARS-73/2020-FID-VI (K) dated 14-07-2020 on the subject "**SALE OF SPURIOUS DRUG.**" and submitted as under;

"I have the honor to refer to the subject mentioned above and to submit that undersigned inspected M/s. Abbasi Shaheed Chemist, 3-8/39, Nazimabad, Opposite Abbasi Shaheed Hospital, Karachi on 01-07-2020 in light of NTF. Wherein following sample of drug was taken for the purpose of test/analysis on prescribed Form-3 (Annexure-A).

Name of Drug	Batch No.	Mfg. Date	Exp. Date	Claimed to be Mfg. By
Penro 1000 mg Injection (R. No. 042107)	**P0200030**	**10-2019**	**09-2020**	**M/s. Bosch Pharma (Pvt.) Ltd., Karachi**

The remaining suspected stock of aforesaid drug was seized on Form-2 under Section 18(1) of the Drug Act, 1976 (Annexure-B).

The sealed sample of above drug was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for the test/analysis vide this office memorandum No. ARS-73/2020-FID-VI (K) dated 01-07-2020 (Annexure-C).

The sealed sample (manufacturer portion) of under reference drug was sent to M/s. Bosch Pharma (Pvt.) Ltd., 221, Sector 23, Korangi Industrial Area, Karachi vide this office letter No.ARS-73/2020-FID-VI(K) dated 1st July 2020 as required under the provision of clause (c) (3) Schedule-V (Procedure for Inspector) of DRAP Act, 2012 (Annexure-D).

M/s. Bosch Pharma (Pvt.) Ltd., 221, Sector 23, Korangi Industrial Area, Karachi vide letter No. GMQO&RA/BOSCH/221-223/020720 dated 02nd July 2020 verified that the drug is spurious in the light of comparison with quality control reference pack. Their findings is annexed as (Annexure-E).

The report was forwarded to the Director (QA&LT) DRAP, Islamabad for information including permission for safe custody of seized stock under Drugs Act, 1976/D RAP Act 2012 was requested vide this office letter No.F.01-21/2019-FID-VI(K)-NTF dated 06-07-2020 (Annexure-F). The permission is still awaited.

M/s. Abbasi Shaheed Chemist, 3-8/39, Nazimabad, Opposite Abbasi Shaheed Hospital, Karachi was directed to provide the bill warranty/invoice of aforesaid drug as required under Section 23(l)(i) of Drug Act, 1976 vide this office letter of even number dated 1st July 2020 but bill warranty/invoice not provided yet (Annexure-G).

The Government Analyst, Central Drugs Laboratory, Karachi vide test report No. R.KQ. 179/2020 dated 07th July 2020 declared the sample of the above named drug as "Spurious

Drug" under Section 3 (z-b) of the Drugs Act, 1976, which is violation of Section 23(1) (a) (i) of Drugs Act, 1976 and rules framed there under (Annexure-H).

In the light of spurious test report of CDL, Karachi, the show cause notice of even number dated 09th July 2020 was accordingly issued to M/s. Abbasi Shaheed Chemist, 3-8/39, Nazimabad, Opposite Abbasi Shaheed Hospital, Karachi for explaining their position in the matter for manufacturing and selling of above mentioned Spurious Drug (Annexure-I).

M/s. Abbasi Shaheed Chemist, 3-8/39, Nazimabad, Opposite Abbasi Shaheed Hospital, Karachi vide letter dated 14-07-2020 submitted unsatisfactory reply wherein, Muhammad Siddique denied all the facts, however, necessary Form-2 & Form-3 were signed by his son Anjum Ali who disclosed himself as Proprietor at the time of inspection and did not provided the bill warranty/invoice (Annexure-T).

Keeping in view of above, it is established that the M/s. Abbasi Shaheed Chemist, 3-8/39, Nazimabad, Opposite Abbasi Shaheed Hospital, Karachi was found involved in Selling of Spurious Drug and has not provided the bill warranty/warranty hence violated the Section 23(1)(a)(i), 23(l)(i) of Drug Act, 1976, which is punishable under Section 27 of Drug Act, 1976 therefore, it is recommended :-

That the permission to lodge the FIR against below mentioned accused persons may kindly be granted for selling of spurious drug and non- submission of bill warranty/invoice and for further investigation to find out the names of main culprits who are actually manufacturing these kinds of fake drugs in the market:-

1. *M/s. Abbasi Shaheed Chemist, 3-8/39, Nazimabad, Opposite Abbasi Shaheed Hospital, Karachi Drug Sale License No. 3761.*
2. *Muhammad Siddique S/O Muhammad Yaqoob, Proprietor (CNIC No. 42101-1580019-1)*
3. *Anjum Ali, Proprietor who signed the Form-2 & Form-3*
4. *Muhammad Naeem S/O Muhammad Ahsan, Qualified Person.*

The complete case along with annexure is submitted for your kind information and further necessary action into the matter, please."

06. In his report, the FID VI Karachi had requested for the permission to lodge FIR against following accused persons;

i. M/s. Abbasi Shaheed Chemist, 3-8/39, Nazimabad, Opposite Abbasi Shaheed Hospital, Karachi Drug Sale License No. 3761.
ii. Muhammad Siddique S/O Muhammad Yaqoob, Proprietor (CNIC No. 42101-1580019-1)
iii. Anjum Ali, Proprietor who signed the Form-2 & Form-3
iv. Muhammad Naeem S/O Muhammad Ahsan, Qualified Person.

07. Moreover, Area FID Karachi has asked for the permission of for safe custody of seized stock till the decision of case.

08. The Central Licensing Board in its 273rd meeting held on 15-01-2020 delegated it's power of granting permission to lodge FIR against the accused persons and permission for safe custody of seized drugs to The Director, QA&LT. Currently charge of The Director QA&LT is vacant and therefore the case is being presented before the Central Licensing Board for grant of permission to lodge FIR against the above mentioned accused persons and grant for permission of safe custody of seized stock till the decision of the case.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

09. The Board after considering the facts of the case and thororugh delibration decided as under;

a. **Granted permission of safe custody of the seized stock till the decision of the case**

b. **Granted permission to lodge FIR against the following accused for selling of spurious drugs and non-submission of bill warranty/invoice and for further investigation to find out the names of main culprits who are actually manufacturing these kinds of fake drugs in the market;**

   i. **M/s. Abbasi Shaheed Chemist, 3-8/39, Nazimabad, Opposite Abbasi Shaheed Hospital, Karachi Drug Sale License No. 3761.**
   ii. **Muhammad Siddique S/O Muhammad Yaqoob, Proprietor (CNIC No. 42101-1580019-1)**
   iii. **Anjum Ali, Proprietor who signed the Form-2 & Form-3**
   iv. **Muhammad Naeem S/O Muhammad Ahsan, Qualified Person.**

Case No. 06: **REQUEST OF SHIFA INTERNATIONAL HOSPITAL REGARDING PURCHASE AND USE OF DRUG COMPOUNDED BY A LOCAL PHARMACEUTICAL COMPANY FOR THEIR HOSPITAL USE.**

Brief facts of the case are under;

02. Mrs. Salwa Ahmed, Chief of Pharmacy, Shifa International Hospital Ltd; H-8/4, Islamabad has forwarded a letter regarding no objection certificate (NOC) for purchase and use of drugs compounded by a local pharmaceuticals company, for their hospital use. She has added that M/s. Wilshire Laboratories (Pvt) Ltd; Quaid-e-Azam Industrial Estate, Kotlakhpat, Lahore are compounding some clinically needed (both registered and unregistered) drugs under license # 05-352-0070039102P (under form 9, Rule # 16) valid until 09th June, 2021 issued by competent authority of Chief Drug Controller Punjab Licensing Authority, Lahore.

03. The Routine procedure of such license holder pharmacies usually is; they compound and sell medicines directly to patients according to proper physician prescription. But here being a pharmaceutical company, they are also offering these compounded products to hospitals under warranty and invoice to that hospital can further dispense these to patients according to perception. As M/s. Wilshire is offering products that are either chronically short in market or not yet registered, and are of high clinical importance for treating patients.

04. They therefore, requested for No Objection Certificate, if their hospital procures the stock to facilitate their patients. The case was dicussed in 85th Meeting of the policy Board wherein the policy board decided as under;

> *"The Authority directed the Division of QA&LT to initiate the legal proceedings against M/s Wilshire Laboratories (Pvt.) Ltd, Lahore on account of manufacturing and selling unregistered drugs with unapproved MRP under the umbrella of MRP."*

05. The decision of the Authoriy was forwarded to the Area FID vide letter F. No. 04-11/2020-QC dated 28-07-2020 for investigation of the matter and to take appropriate action under the law in the matter and report to the division of QA&LT for further necessary action in the matter.

06. In response to the above-mentioned letter, Area FID Lahore conducted an inspection of M/s. Wilshire Laboratories and submitted report vide letter No. 10919/2020-DRAP (L-VII) dated 07-08-2020 contentes of which are as under;

> *"The inspection of M/s. Wilshire Laboratory (Pharmacy) was conducted on 29-07-2020, with reference to DRAP, Islamabad letter No. 04-11/2020-QC dated, 28-07-2020 .*
>
> *M/s. Wilshire Laboratory (Pharmacy) was issued Form 9 License No. 05-352-0070-039102P dated, 19-01-2019, by Chief Drugs Controller, Punjab Licensing Authority, Lahore. Hence the firm is hereby licensed to sell/compound or prepare on prescriptions the drugs and sell or distribute all types of registered drugs on the premises situated at plot No. 124/1, Quaid-e-Azam Industrial Estate Kot Lakhpat, Lahore.*
>
> *The pharmacy is situated in a separate block with separate entry from the pharmaceutical manufacturing plant, which was also located on the same plot i.e., 124/1,*

Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore. At the time of inspection, the following products were displayed for sale in Wilshire Labs (Pvt.) Ltd., (Pharmacy) and were Not to Dispose off Under Section 18 (1) of the Drug Act, 1976 and DRAP Act, 2012 (copy of Form-1 attached):-

S. No.	*Name of Drugs/Articles*	*Batch No./Lot No.*	*Mfg. Date*	*Exp. Date*	*Manufactured/Dispensed by*	*Quantity*
01	*Cabergoline 0.5mg Tablets*	*001*	*Jan.2020*	*Jan. 2021*	*M/s. Wilshire Labs (Pharmacy), Quaid-e-Azam, Industrial Estate, Kot Lakhpat, Lahore*	*1x8x5*
02	*Acetazolamide 250mg Tablets*	*001*	*April 19*	*April 2020*	*-do-*	*1x10x6*
03	*Phenytoin Sodium 100mg Capsule*	*001*	*07/19*	*06-2020*	*-do-*	*1x20x5*
04	*Mesalamine (USP) 4g/100ml Rectal suspension Enema*	*006*	*Oct.2019*	*Sep. 2020*	*-do-*	*1x5*
05	*Fludrocortisone 0.1mg Tablets*	*001*	*Dec.2019*	*Dec. 2020*	*-do-*	*1x30x5*
06	*Purcalopride 2mg Tablets*	*002*	*Dec. 2019*	*Dec. 2020*	*-do-*	*1x10x4*
07	*Hydrocortisone 10mg Tablets*	*001*	*Nov. 2019*	*Nov. 2020*	*-do-*	*1x30x5*

The above-mentioned drugs were Not to Dispose off in the presence of Mr. Muhammad Faisal Javed, Qualified person (person present) and Mr. Saqlain Arshad, Manager Regulatory (Person present). The witnesses were also recorded on the form. The reasons for Not to Dispose off are:

i) The drugs at S. No. 2-3 were expired.

ii) The products were compounded drugs as per firm's claim and were meant for immediate patient use on prescription. However, the drugs were compounded in January 2020 and in the year 2019 and were placed on the shelves of pharmacy for sale. The prescriptions of patients were also not available.

iii) The drugs were not registered, brand names were printed, prices were also mentioned on the unit cartons.

iv) The compounded drugs were also supplied to different hospitals such as Shifa International Hospital Islamabad, Aga Khan Hospital, Karachi etc., The record of patients were not available at the time of inspection.

The firm was directed to explain its position in this regard.

The Competent Authority i.e. Chairman Registration Board is requested to grant permission to keep the stock as evidence of offense for further three months or till the decision of case under section 18(1) of the Drugs Act, 1976, and rule framed thereunder.

The case is being referred to the Competent Authority under Section 18(1) of the DRAP Act, 2012 and DRAP Act,. 2012 to seek further orders as to the action to be taken in this regard. The complete case will be submitted after completion of investigation and other codal formalities in this regard please."

07. In the above-mentioned report, area FID Lahore has requested to grant the permission to keep the stock ordered not to dispose. In this regard, the Director QA&LT is empowered to grant extension in period not to dispose of for a period of 3 months by the Central Licensing Board in its 273rd meeting held on 15th January, 2020. Since the post of Director QA&LT is vacant, the case is presented before the Central Licensing Board for grant of extension in order not to dispose of to FID VII Lahore for further processing of the case.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

08. **The Board after considering the facts of the case and thororugh delibration aceeded the request of are FID Lahore and decided to grant permission of safe custody of the seized stock till the decision of the case.**

09. **The Board also decided to direct Federal Inspector of Drugs to complete the investigation and submit comprehensive report with recommendations without further delay for consideration of the Board.**

Case No. 07: **APPROVAL OF APPELLATE TESTING OF ESOMEPRAZOLE MAGNESIUM RAW MATERIAL, BATCH NO.ESM/1911481, IMPORTED BY M/S SAAKH PHARMA KARACHI.**

Assistant Director-VI/FID, DRAP, Karachi visited the premises of M/s Saakh Pharma Private Limited Plot No.C-7/l, North West Industrial Zone, Port Qasim, Karachi on 30th December 2019, wherein subject mentioned drug was drawn for the purpose of test analysis on prescribed Form-3.

02. The sealed sample of above drug was sent to Federal Government Analyst Central Drugs Laboratory. Karachi by the Assistant Director-VI/FID, DRAP, Karachi for the purpose of test/analysis vide memorandum No.DMT-25-30/2019-AD-(VI) (K) Dated 30th December 2019.

03. A portion of sealed sample was sent to DRAP Islamabad vide letter of even number dated 30th December 2019.

04. M/s Saakh Pharma Private Limited, Plot No.C-7/1, North West Industrial Zone, Port Qasim Karachi provided the copy of invoice bearing No. AE/19/334 dated 23-11-2019 in connection with purchase of above said raw material.

05. Federal Government Analyst, Central Drugs Laboratory. Karachi declared the above said sample as **"Sub-Standard"** quality under the Drugs Act 1976 vide their test report No.RM.93/2019 dated 18th February 2020. Results of the test report are reproduced as under:-

Description:	*Off white powder.*
Identification:	Esomeprazole Magnesium *identified.*
Solubility:	*Complies.*

Assay for Esomeprazole Magnesium.

Determined %.	*93.19%*
Limits:	*98.0% to 102% (anhydrous substance)*

(Does not comply with European Pharmacopoeia-9)

Remarks:- *The sample is of* ***substandard quality*** *under the Drugs Act. 1976.*

06. As per test report of Federal Government Analyst, CDL, Karachi M/s Saakh Pharma Private Limited, Plot No.C-7/l, North West Industrial Zone, Port Qasim, Karachi was asked by the Assistant Director-VI/FID, DRAP, Karachi to explain their position vide letter No.DMT.2 l/2-2020-FID-VII (DRAP) (K) dated 21st February 2020.

07. M/s Saakh Pharma Private Limited Plot No.C-7/1, North West Industrial Zone Port Qasim, Karachi vide their letter number nil dated 26th February explain their position and deny the contents of test report and challenged for retesting from Appellate testing of the Sub-Standard Drug Esomeprazole Magnesium (R.M) batch No.ESM 1911481

08. The Assistant Director-VI, DRAP, Karachi further submitted that in the light of firms reply portion lying with the Board may kindly be retested from the Appellate Laboratory, N.I.H Islamabad under the rules.

09. It is submitted that the sample was drawn from M/s Saakh Pharma (Pvt.) Ltd., Karachi and the firm is licensed to manufacture by the way of Semi Basic DML # 000588. The sample is raw material and purported to

be used for API manufacturing i.e. Lansoprazole which was approved by Central Licensing Board via letter No.F.2-5/2001-Lic (Vol-II) dated 30th July, 2018.

10. Central Licensing Board in its 273rd meeting held on 15-01-2020 delegated its power for sending Boards portion of the sample for appellate testing to the Director QA&LT, DRAP, Islamabad.

11. Since the post of Director QA&LT, DRAP, Islamabad is vacant, the matter is placed for consideration of the Board for granting approval for Appellate testing from NIH, Islamabad on the request of the firm.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

12. **As per request of the firm, the Board, after considering the facts of the case decided to grant approval for appellate testing from NIH, Islamabad.**

Case No. 08: **APPROVAL OF APPELLATE TESTING OF LANSOPRAZOLE RAW MATERIAL, BATCH NO.LSA/1911109, IMPORTED BY M/S SAAKH PHARMA KARACHI.**

Assistant Director-VI/FID, DRAP, Karachi visited the premises of M/s Saakh Pharma Private Limited Plot No.C-7/l, North West Industrial Zone, Port Qasim, Karachi on 30th December 2019, wherein subject mentioned drug was drawn for the purpose of test analysis on prescribed Form- 3.

02. The sealed sample of above drug was sent to Federal Government Analyst Central Drugs Laboratory. Karachi by the Assistant Director-VI/FID, DRAP, Karachi for the purpose of test/analysis vide No.DMT-25-30 2019-AD-VI (K) Dated 30th December 20I9.

03. A portion of sealed sample was sent to DRAP Islamabad by Assistant Director-VI/FID, DRAP, Karachi vide letter of even number dated 30th December 2019.

04. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as **"Sub-Standard"** quality under the Drugs Act 1976 vide their test report No.RM.94/2019 dated 26th February 2020. Results of the test report are reproduced as under;

Description:	*Off white powder.*
Identification:	*Lansoprazole identified.*
Assay for Lansoprazole.	
Determined %:	*92.8%*
Limits:	*98.0-102.0%.* ***Does not comply with USP 42.***

Remarks:- *The sample is of* ***substandard quality*** *under the Drugs Act. 1976.*

05. As per test report of Federal Government Analyst, CDL, Karachi M/s Saakh Pharma Private Limited, Plot No.C-7/l, North West Industrial Zone, Port Qasim, Karachi was asked by Assistant Director-VI/FID, DRAP, Karachi to explain their position vide letter of even number dated 03-03-2020.

06. M/s Saakh Pharma Private Limited, Plot No.C-7/1, North West Industrial Zone, Port Qasim, Karachi vide their letter number nil dated 11th March, 2020 explain their position and deny the contents of test report and challenged for retesting from Appellate testing of the Sub-Standard Drug Lansoprazole (R.M) batch No.LSA/1911109.

07. The Assistant Director-VI, DRAP, Karachi further submitted that in the light of firms reply portion lying with the Board may kindly be retested from the Appellate Laboratory, N.I.H Islamabad under the rules.

08. It is submitted that the sample was drawn from M/s Saakh Pharma (Pvt.) Ltd., Karachi and the firm is licensed to manufacture by the way of Semi Basic DML # 000588. The sample is raw material and purported to be used for API manufacturing i.e. Lansoprazole which was approved by Central Licensing Board via letter No.F.2-5/2001-Lic (Vol-II) dated 30th July, 2018.

09. Central Licensing Board in its 273rd meeting held on 15-01-2020 delegated its power for sending Boards portion of the sample for appellate testing to the Director QA&LT, DRAP, Islamabad.

10. Since the post of Director QA&LT, DRAP, Islamabad is vacant, the matter is placed for consideration of the Board for granting approval for Appellate testing from NIH, Islamabad on the request of the firm.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

11. **As per request of the firm, the Board, after considering the facts of the case decided to grant approval for appellate testing from NIH, Islamabad.**

Case No. 09: **PERMISSION FOR PROSECUTION AGAINST THE MANAGEMENT OF M/S EVEREST PHARMACEUTICALS FOR THE ILLEGAL IMPORT OF PHARMACEUTICAL RAW MATERIAL THROUGH FORGED IMPORT CLEARANCE CERTIFICATE WITHOUT ANY DRUG IMPORT LICENSE.**

09.1 Incomplete Challan for FIR No. C-69/2018 dated 16/05/2018:

The Federal Inspector of Drugs DRAP Lahore vide letter No. 6246/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Colleotorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Deciaration-GD-i, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity

M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore	SPKGC15001	02-04-2015	Xanthan Gum Pharma Grade Mesh	3000 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

04. As the records show that the import authorizations is forged, bearing the fake Diary and Issue Nos. of DRAP Office, Lahore, and used for the illegal import of pharmaceutical raw material, without any requisite Drug Import License, hence, the management of M/s. Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1) (e) of the paragraph A of the Schedule-ll of the DRAP Act, 2012, read with Section 23 (1) (e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30 (2) (a) of the Drugs Act, 1976, and is punishable under Clause (1) (c) of the Schedule-Ill of the DRAP Act, 2012, read with Section 27 (1) (c) of the Drugs Act, 1976.

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore , through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

1. To issue Show Cause Notices for prosecution in the Drug Court of competent jurisdiction to the following accused persons for the offences committed by them as stated herein below in para 2:

i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman
ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

10. Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

11. In compliance to the decision of 273rd meeting of CLB, the accused were once again show caused vide letter No. F. 03-01/2020-QC (CLB-273) dated 07-04-2020 and till date no reply has yet been received in this office. The accused are once again called before the Board for one final opportunity of personal hearing.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

12. The accused, M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore and Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore did not appear himself nor through any counsel before the Board.

13. **The Board considered the records and reports regarding the case and granted permission to the area Federal Inspector of Drugs, Lahore for prosecution of case in the court of competent jurisdiction against the following:**

i. **M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

ii. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

14. The FID shall submit the complete case with original forms, permission for registration of FIR, original show cause notice, original permission for prosecution, original records & all other related documents etc and list of witnesses before the court of competent jurisdiction. Copy of the complaint filed in the court shall also be forwarded for further necessary action and record.

09.2. <u>Incomplete Challan for FIR No. C-70/2018 dated 16/05/2018:</u>

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6246/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Colleotorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Deciaration-GD-i, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity

M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore	SPKGC15003	02-04-2015	Xanthan Gum Pharma Grade Mesh	3000 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

04. As the records show that the import authorizations is forged, bearing the fake Diary and Issue Nos. of DRAP Office, Lahore, and used for the illegal import of pharmaceutical raw material, without any requisite Drug Import License, hence, the management of M/s. Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1) (e) of the paragraph A of the Schedule-ll of the DRAP Act, 2012, read with Section 23 (1) (e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30 (2) (a) of the Drugs Act, 1976, and is punishable under Clause (1) (c) of the Schedule-Ill of the DRAP Act, 2012, read with Section 27 (1) (c) of the Drugs Act, 1976.

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

1. To issue Show Cause Notices for prosecution in the Drug Court of competent jurisdiction to the following accused persons for the offences committed by them as stated herein below in para 2:

i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman
ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

10. Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

11. In compliance to the decision of 273rd meeting of CLB, the accused were once again show caused vide letter No. F. 03-01/2020-QC (CLB-273) dated 07-04-2020 and till date no reply has yet been received in this office. The accused are once again called before the Bord for one final opportunity of personal hearing.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

12. The accused, M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore and Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore did not appear himself nor through any counsel before the Board.

13. **The Board considered the records and reports regarding the case and granted permission to the area Federal Inspector of Drugs, Lahore for prosecution of case in the court of competent jurisdiction against the following:**

i. **M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

ii. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

14. The FID shall submit the complete case with original forms, permission for registration of FIR, original show cause notice, original permission for prosecution, original records & all other related documents etc and list of witnesses before the court of competent jurisdiction. Copy of the complaint filed in the court shall also be forwarded for further necessary action and record.

09.3. <u>Incomplete Challan for FIR No. C-100/2018 dated 25/05/2018:</u>

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6261/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Collectorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s. Everest Pharmaceuticals, Office No.13, 3rd Floor, Gohar Centre, Wahdat Road, Lahore	N15AS23387	15.06.2015	1) Phloroglucinnol Dihydrate 2) 1) Phloroglucinnol Trimethyl	1) 100 kg 2) 100kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

04. As the records show that the import authorizations is forged, bearing the fake Diary and Issue Nos. of DRAP Office, Lahore, and used for the illegal import of pharmaceutical raw material, without any requisite Drug Import License, hence, the management of M/s. Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1) (e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23 (1) (e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30 (2) (a) of the Drugs Act, 1976, and is punishable under Clause (1) (c) of the Schedule-Ill of the DRAP Act, 2012, read with Section 27 (1) (c) of the Drugs Act, 1976.

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

1. To issue Show Cause Notices for prosecution in the Drug Court of competent jurisdiction to the following accused persons for the offences committed by them as stated herein below in para 2:

i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman
ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

10. Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

11. In compliance to the decision of 273rd meeting of CLB, the accused were once again show caused vide letter No. F. 03-01/2020-QC (CLB-273) dated 07-04-2020 and till date no reply has yet been received in this office. The accused are once again called before the Bord for one final opportunity of personal hearing.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

12. The accused, M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore and Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore did not appear himself nor through any counsel before the Board.

13. **The Board considered the records and reports regarding the case and granted permission to the area Federal Inspector of Drugs, Lahore for prosecution of case in the court of competent jurisdiction against the following:**

i. **M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

ii. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

14. The FID shall submit the complete case with original forms, permission for registration of FIR, original show cause notice, original permission for prosecution, original records & all other related documents etc and list of witnesses before the court of competent jurisdiction. Copy of the complaint filed in the court shall also be forwarded for further necessary action and record.

09.4. <u>Incomplete Challan for FIR No. C-107/2018 dated 30/05/2018:</u>

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6256/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Collectorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s. Everest Pharmaceuticals, 86-G, Model town Lahore	16IXTXI-0842	21.07.2016	Vitamin B6 HCl	100 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

04. As the records show that the import authorizations is forged, bearing the fake Diary and Issue Nos. of DRAP Office, Lahore, and used for the illegal import of pharmaceutical raw material, without any requisite Drug Import License, hence, the management of M/s. Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1) (e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23 (1) (e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30 (2) (a) of the Drugs Act, 1976, and is punishable under Clause (1) (c) of the Schedule-Ill of the DRAP Act, 2012, read with Section 27 (1) (c) of the Drugs Act, 1976.

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch

Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

1. To issue Show Cause Notices for prosecution in the Drug Court of competent jurisdiction to the following accused persons for the offences committed by them as stated herein below in para 2:

i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman
ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

10. Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

11. In compliance to the decision of 273rd meeting of CLB, the accused were once again show caused vide letter No. F. 03-01/2020-QC (CLB-273) dated 07-04-2020 and till date no reply has yet been received in this office. The accused are once again called before the Bord for one final opportunity of personal hearing.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

12. The accused, M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G,

Model Town, Lahore and Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore did not appear himself nor through any counsel before the Board.

13. **The Board considered the records and reports regarding the case and granted permission to the area Federal Inspector of Drugs, Lahore for prosecution of case in the court of competent jurisdiction against the following:**

i. **M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

ii. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

14. The FID shall submit the complete case with original forms, permission for registration of FIR, original show cause notice, original permission for prosecution, original records & all other related documents etc and list of witnesses before the court of competent jurisdiction. Copy of the complaint filed in the court shall also be forwarded for further necessary action and record.

09.5. <u>Incomplete Challan for FIR No. C-81/2018 dated 17/05/2018:</u>

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6249/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Collectorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s. Everest Pharmaceuticals, 86-G, Model town Lahore	DE14W004	31.12.2014	Clotrimazole	100 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization

was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

04. As the records show that the import authorizations is forged, bearing the fake Diary and Issue Nos. of DRAP Office, Lahore, and used for the illegal import of pharmaceutical raw material, without any requisite Drug Import License, hence, the management of M/s. Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1) (e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23 (1) (e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30 (2) (a) of the Drugs Act, 1976, and is punishable under Clause (1) (c) of the Schedule-Ill of the DRAP Act, 2012, read with Section 27 (1) (c) of the Drugs Act, 1976.

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under

section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

1. To issue Show Cause Notices for prosecution in the Drug Court of competent jurisdiction to the following accused persons for the offences committed by them as stated herein below in para 2:

i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman
ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

10. Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

11. In compliance to the decision of 273rd meeting of CLB, the accused were once again show caused vide letter No. F. 03-01/2020-QC (CLB-273) dated 07-04-2020 and till date no reply has yet been received in this office. The accused are once again called before the Bord for one final opportunity of personal hearing.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

12. The accused, M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore and Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore did not appear himself nor through any counsel before the Board.

13. **The Board considered the records and reports regarding the case and granted permission to the area Federal Inspector of Drugs, Lahore for prosecution of case in the court of competent jurisdiction against the following:**

i. **M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

ii. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

14. The FID shall submit the complete case with original forms, permission for registration of FIR, original show cause notice, original permission for prosecution, original records & all other related documents etc and list of witnesses before the court of competent jurisdiction. Copy of the complaint filed in the court shall also be forwarded for further necessary action and record.

09.6. <u>Incomplete Challan for FIR No. C-85/2018 dated 23/05/2018:</u>

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6244/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Collectorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s. Everest Pharmaceuticals, 86-G, Model town Lahore	MT-1505115	07.02.2015	Microcrystalline cellulose	2000 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

04. As the records show that the import authorizations is forged, bearing the fake Diary and Issue Nos. of DRAP Office, Lahore, and used for the illegal import of pharmaceutical raw material, without any requisite Drug Import License, hence, the management of M/s. Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1) (e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23 (1) (e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30 (2) (a) of the Drugs Act, 1976, and is punishable under Clause (1) (c) of the Schedule-Ill of the DRAP Act, 2012, read with Section 27 (1) (c) of the Drugs Act, 1976.

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch

Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

1. To issue Show Cause Notices for prosecution in the Drug Court of competent jurisdiction to the following accused persons for the offences committed by them as stated herein below in para 2:

i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman
ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

10. Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

The accused persons neither by themselves, nor through any authorized legal counsel appeared before the Board. To meet the ends of justice, the Board decided to ensure the service of show cause and personal hearing notice upon the accused through registered AD.

11. In compliance to the decision of 273rd meeting of CLB, the accused were once again show caused vide letter No. F. 03-01/2020-QC (CLB-273) dated 07-04-2020 and till date no reply has yet been received in this office. The accused are once again called before the Bord for one final opportunity of personal hearing.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

12. The accused, M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G,

Model Town, Lahore and Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore did not appear himself nor through any counsel before the Board.

13. **The Board considered the records and reports regarding the case and granted permission to the area Federal Inspector of Drugs, Lahore for prosecution of case in the court of competent jurisdiction against the following:**

i. **M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

ii. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

14. The FID shall submit the complete case with original forms, permission for registration of FIR, original show cause notice, original permission for prosecution, original records & all other related documents etc and list of witnesses before the court of competent jurisdiction. Copy of the complaint filed in the court shall also be forwarded for further necessary action and record.

09.7. <u>Incomplete Challan for FIR No. C-86/2018 dated 23/05/2018:</u>

01. Brief facts of the case are as under;

Istighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6241/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.I.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons, namely:-

1. Ch Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals)
3. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals)
4. Muhammad ishtiaq (QC incharge), M/s. Everest Pharmaceuticals

02. Accordingly, a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (West), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (l&E), DRAP, stamped invoices submitted by the firm. The Customs Collectorate, amongst other, has provided the invoice, detailed below, purportedly singed and stamped by the Assistant Director (l&E), DRAP, Lahore, alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-Il),imported by M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-Ill).

Name of Importer	Invoice No.	Dated	Name of raw material	Quantity
M/s. Everest Pharmaceuticals, 86-G, Model town Lahore	4182-01	31.05.2015	Lactose Monohydrate	3000 kg

03. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation bf Drug (Import & Export) Rules, 1976, framed under the Drugs Act, 1976.

04. As the records show that the import authorizations is forged, bearing the fake Diary and Issue Nos. of DRAP Office, Lahore, and used for the illegal import of pharmaceutical raw material, without any requisite Drug Import License, hence, the management of M/s. Everest Pharmaceuticals, has committed offence under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1) (e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23 (1) (e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30 (2) (a) of the Drugs Act, 1976, and is punishable under Clause (1) (c) of the Schedule-Ill of the DRAP Act, 2012, read with Section 27 (1) (c) of the Drugs Act, 1976.

05. The direction to lodge FIR against the responsible accused persons has been received vide letter No. F. 13-8/18-QC, dated 17-04-2018, of the DRAP, Islamabad (Annex-IV).

06. It is, therefore, requested to register F.I.R for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the Officer of DRAP, Lahore, in her official capacity:-

1. M/s. Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road Lahore, through its Managing Partner.
2. Ch. Muhammad Lisman (Owner of M/s. Everest Pharmaceuticals).
3. Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals).
4. Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals).
5. Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals.

07. Furthermore, in the Urdu language part of the incomplete challan, IO FIA has stated that Ch Muhammad Usman S/o Zaheer Ahmad Chaudhary R/o 86-G Model Town Lahore (Owner of M/s. Everest Pharmaceuticals, Islamabad) has been arrested in this case and was declared guilty after investigation of the matter whereas, investigation regarding other nominated accused persons is ongoing. Therefore, IO FIA has submitted the incomplete challan.

08. In the light of investigation and findings of the IO, FIA, Lahore, the accused person namely Ch

Muhammad Usman (Owner of M/s. Everest Pharmaceuticals, Islamabad) have been declared guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. It is therefore submitted that the mentioned accused person may be show caused for the offences committed by him as stated herein above in this para.

Proceedings and Decision of 270th meeting of CLB:

The CLB examined record/documents of the case file, FID report and in-complete challan submitted by IO, FIA and decided as under:

1. To issue Show Cause Notices for prosecution in the Drug Court of competent jurisdiction to the following accused persons for the offences committed by them as stated herein below in para 2:

i. M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman
ii. Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)

2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.

3. Personal Hearing may be given before the CLB to the accused persons.

09. Show cause notice was sent to the accused vide letter F. No.03-33/2019 (QC) (270 CLB) dated 30-09-2019 and the accused are called before the Board for personal hearing.

10. Proceeding & Decision of the 273rd Meeting held on 15th January, 2020:

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11. In compliance to the decision of 273rd meeting of CLB, the accused were once again show caused vide letter No. F. 03-01/2020-QC (CLB-273) dated 07-04-2020 and till date no reply has yet been received in this office. The accused are once again called before the Bord for one final opportunity of personal hearing.

Proceedings and decision of 276th meeting of CLB held on 03-09-2020:

12. The accused, M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G,

Model Town, Lahore and Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore did not appear himself nor through any counsel before the Board.

13. **The Board considered the records and reports regarding the case and granted permission to the area Federal Inspector of Drugs, Lahore for prosecution of case in the court of competent jurisdiction against the following:**

i. **M/s Everest Pharmaceuticals, Office No. 13, 3rd Floor Gohar Center, Wahdat Road, Lahore through its CEO/Owner/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

ii. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore**

14. The FID shall submit the complete case with original forms, permission for registration of FIR, original show cause notice, original permission for prosecution, original records & all other related documents etc and list of witnesses before the court of competent jurisdiction. Copy of the complaint filed in the court shall also be forwarded for further necessary action and record.

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