MINUTES OF 252nd MEETING OF CENTRAL LICENSING BOARD HELD ON WEDNESDAY 15TH MARCH, 2017

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252nd meeting of the Central Licensing Board (CLB) was held on Wednesday 15th March, 2017 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, Drug Regulatory Authority of Pakistan.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Dr Sheikh Akhter Hussain, Director, Quality Assurance and Laboratory Testing Representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad	Member
2.	Mr. Akbar Jan, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa, Peshawar	Member
3.	Syed Saleem Shah, Chief Drug Inspector, Department of Health, Govt. of Balochistan, Quetta	Member
4.	Mr. KhurramShahzad Mughal, Consultant M/o Law, Justice and Human Rights, as representative of M/o Law, Justice and Human Rights, Islamabad.	Member
5.	Syed Tariq Masud Shah, Drug Controller Primary and Secondary Health Care Department, Govt. of Punjab, Lahore	Member
6.	Dr.Ikram-ul-Haque , Expert inQC/QA of drugs.	Observer
7.	Syed Muied Ahmed, Expert in manufacturing of drugs.	Observer
8.	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
9.	Ms. Mahwsish Siddiqui, Director, Epla Laboratories (Pvt) Ltd., and Mr. Arshad Mehmood, Managing Partner, Welwrd Pharmaceuticals as Representatives of PPMA	Observer
10.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
11.	Mr. Shafiq Ahmed Abbasi , representative of PCDA	Observer

The meeting started with the recitation of verses from the Holy Qura'an. The Chairman CLB welcomed the honorable members and participants of the meeting. The Chairman briefed the Board that after approval of Competent Authority Dr. Ikram-ul-Haque , Expert in QC/QA of drugs

and Syed Muied Ahmed, Expert in manufacturing of drugs were invited as observer in meeting due to their active participation in previous meetings. The Board endorsed the participation of the said experts as observer. He further added 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. Dr. Abdur Rashid, Addl. Director (QA/LT), Mr. Zeeshan Bajar, Deputy Director (QA/LT), Mr. Adnan Faisal Saim DD(QC) & Dr. Akbar Ali, AD (Lic.), Dr. Muhammad Usman, AD (Lic), Dr. Muhammad Ashfaq, AD (Lic) and Dr. Muhammad Yaqoob, AD (Lic) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

LICENSING DIVISION

Item-I **CONFIRMATION OF THE MINUTES OF 251st MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 251st meeting held on 6th December, 2016.

Item-II(A): **GRANT OF NEW DRUG MANUFACTURING LICENSES.**

The Board considered the following cases of grant of new drug manufacturing licenses in the light of recommendations of respective panel of experts/inspectors and decided as under:

S#	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s Walt Danzay Pharmaceuticals, Plot No.35-A, Small Industrial Estate, Taxila.	**15-02-2017 Formulation**	The Board approved the grant of DML by way of formulation with following sections: **Sections (10)** 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointment/Gel Section (General) 4. Liquid Injection Ampoule (General) 5. Dry Powder Injection Vial (General) 6. Dry Powder Injection Vial (Steroid) 7. Ear/Eye Drops (General) 8. Tablet Section (Hormone) 9. Liquid Injection Ampoule (Hormone) 10. Dry Powder Injection (Hormone)

2.	M/s Apsis Pharmaceuticals, Eminabad Road Khan Payara, 1.3-KM GT Road, Gujranwala.	**06-01-2017 Formulation**	The Board approved the grant of DML by way of formulation with following sections: **Section (01)** 1. Infusion Section (LVP)
3.	M/s Karsons Pharmaceuticals, Plot No. 01, Street No. SS-3, National Industrial Zone, Rawat, Rawalpindi	**10-03-2017 Formulation**	The Board approved the grant of DML by way of formulation with following sections: **Sections (04)** 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointment/Gel Section (General) 4. Dry Powder for Suspension Section (General)

Item-II(B): **GRANT OF DRUG MANUFACTURING LICENSES AFRESH (RE-GRANT).**

The Board considered the following cases of grant of drug manufacturing licenses afresh which were previously declared invalid due to late submission of application for the purpose of renewal of Drug Manufacturing Licence. The applications were processed afresh under Rule 5 (3) of the Drugs (Licensing, Registering and Advertising) Rues, 1976 and the Board considered recommendations of respective panel of experts/inspectors and decided as under:

S#	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1	M/s Chemiworld (Pvt) Ltd, Plot No.97-J, Industrial Estate, Hayatabad, Peshawar .	**29-11-2016 Basic Manufacturing**	The Board approved afresh the grant of DML by way of Basic Manufacture for the following Active Pharmaceutical Ingredients.- **Iron Polymaltose Complex**
2	M/s Zaynoon Pharmaceuticals (Pvt) Ltd, 27-28-B, Industrial Estate, Hayatabad, Peshawar.	**30-12-2016 Formulation**	The Board approved afresh the grant of DML by way of formulation with following sections: **Sections (01)** Liquid Syrup Section.

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

The Board considered following cases of Grant of Additional Sections & Expansion/Amendments of already licensed units in the light of recommendations by respective panel of experts/inspectors and decided as under: -

S#	Name of the firm / DML No.	Date of Inspection	Decision of CLB
1	M/s Aulton Pharmaceuticals, Plot No.84/1, Block A, Phase-V, Industrial Estate, Hattar. DML No. 0000828 (Formulation)	**17-02-2017**	The Board approved the grant of following additional sections /amendment as under:- **Section (03)** 1. Capsule Section (Cephalosporin) 2. Dry Powder Suspension Section (Cephalosporin) 3. Dry Powder Injection Section (Cephalosporin)
2	M/s Roryan Pharmaceutical Industries (Pvt) Ltd, 85/B, Hayatabad Industrial Estate, Peshawar. DML No. 0000566 (Formulation)	**24-02-2017**	The Board approved the grant of following additional sections /amendment as under:- **Section (01)** 1. Dry Powder Suspension Section (General/Antibiotic)
3	M/s Welmed Pharmaceutical Industries (Pvt) Ltd, 108-R-2, Industrial Estate, Gadoon, Swabi. DML No. 0000546 (Formulation)	**04-03-2017**	The Board approved the grant of following additional sections /amendment as under:- **Sections (04)** 1. Oral Liquid Section 2. Cream/Ointment Section 3. Sachet Section 4. Dry Powder Suspension Section (General)
4	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. DML No. 0000565 (Formulation)	**10-03-2017**	The Board approved the grant of following additional sections /amendment as under:- **Sections (10)** 1. Tablet (General / General Antibiotics)-II 2. Oral Liquid (General)-I 3. Oral Liquid (General)-II 4. Additional Warehouses 5. Dry Powder Injection (General) 6. Liquid Ampoule Injectable (General)

			7. Liquid Infusion/Vials (General) 8. Tablet (Hormone) 9. Liquid Injection Section (Psychotropic) 10. Microbiology Lab (Extension)
5	M/s Leads Pharma (Pvt) Ltd., Plot No. 81-A, Street No. 6, I-10/3, Industrial Area, Islamabad. DML No. 000392 (Formulation)	**06-01-2017**	The Board approved the grant of following additional sections /amendment as under:- **Section (02)** 1. Penicillin Dry Powder (Veterinary). 2. Penicillin Liquid Injection (Veterinary)
6	M/s Crest Pharmaceuticals, Plot No. 43, Industrial Triangle, Kahutta Road, Islamabad. DML No. 000694 (Formulation)	**16-12-2016**	The Board approved the grant of following additional sections /amendment as under:- **Section (07)** 1. Dry Powder (Injection Vials (General). 2. Capsule (General). 3. Q.C Lab (II). 4. Oral Dry Powder Suspension (General). 5. Eye / Ear Drops. 6. Liquid Injection Ampoule (General). 7. Warehouse. **However, Board did not approve Tablet (Hormone) Section on the recommendations of the panel.**
7	M/s Crystolite Pharmaceuticals, Plot No. 1 & 2, Street No. S-2, National Industrial Zone, Rawat, Rawalpindi. DML No. 000778 (Formulation)	**01-02-2016**	The Board approved the grant of following additional sections /amendment as under:- **Section (02)** **1.** Soft Gelatin Capsule Section. 2. Syrup Section (General)
8	M/s Ipram International, Plot No. 26, Street No. SS-3, National Industrial Zone, Rawat, Rawalpindi. DML No. 000551 (Formulation)	**16-02-2017**	The Board approved the grant of following additional sections /amendment as under:- **Sections (02)** 1. Dry Powder Injection (Carbapenem). 2. Capsules (General).

9	M/s Don Valley Pharmaceuticals (Pvt) Ltd, 31-KM, Ferozepur Road, Lahore. DML No. 000395 (Formulation)	**10-11-2016** **&** **22-12-2016**	The Board approved the grant of following additional sections /amendment as under:- **Sections (02): -** 1. Dry Powder Oral Suspension (Cephalosporin) 2. Capsule (Cephalosporin)
10	M/s Intervac (Pvt) Ltd, 18-KM Lahore Sheikhupura road, Sheikhupura DML No. 000623	**02-12-2016** (Formulation)	The Board approved the grant of following additional sections /amendment as under:- **Sections (05): -** 1. Veterinary Oral Dry Powder Suspension (Penicillin) 2. Warehouses. 3. Veterinary Liquid Vials Injection (Hormone) 4. Veterinary Liquid (Re-packing) 5. Veterinary Powder (Re-packing) **However, the Board did not approve renewal for Penicillin Dry Powder Injectable and Penicillin Liquid Injectable on the recommendations of the panel.**
11	M/s MTI Medical (Pvt) Ltd Plots No. 586-587, Sunder Industrial Estate, Lahore. DML No. 000801 (Formulation)	**22-11-2016**	The Board approved the grant of following additional sections /amendment as under:- **Sections (02)** 1. Lyophilized Vials Injectable (General). 2. Dry Powder Injectable (Cephalosporin).
12	M/s Rehmat Pharma, 10-KM, Sheikhupura Road, Lahore. DML No. 000476 (Formulation)	**23-11-2016**	The Board approved the grant of following additional sections /amendment as under:- **Section (01)** Syrup (General) **The Board decided to direct the firm for submitting the Lay Out plan for regularization of sections and firm may also be directed to follow the codal formalities for regularization of sections.**

13	M/s NovaMed Pharmaceuticals (Pvt) Ltd, 28-KM, Ferozepur Road, Lahore. DML No. 000590 (Formulation)	**08-02-2017**	The Board approved the grant of following additional sections /amendment as under:- **Sections (03)** 1. Cream / Ointment / Gel (General). 2. Eye Drops (General). 3. Tulle Dressing.
14	M/s Ankaz Pharmex (Pvt) Ltd, Plot No. 24, Sector 12-A, North Karachi Industrial Area, Karachi DML No. 000247 (Formulation) **Section (02)** 1. Capsule (General) 2. Dry Powder Suspension (General)	**22-12-2016**	The Board considered the case and it was apprised from QA/LT Division that a number of GMP non compliance complaints are pending with them. The Board deferred the case till next meeting of the Board. Meanwhile comprehensive report would be obtained from the QA/LT Division regarding updated GMP status of the firm for consideration of the Board.
15	M/s Vetz Pharmaceuticals (Pvt) Ltd, Plot No. Q-1, SITE, Kotri Sindh. DML No. 000813 (Formulation)	**10-02-2017**	The Board approved the grant of following additional sections /amendment as under:- **Section (03)** 1. Oral Powder (Penicillin Veterinary) 2. Sterile Dry Powder Vials Injectable (Penicillin Veterinary) 3. Sterile Liquid Vials Injectable (Penicillin Veterinary)
16	M/s Atco Laboratories Ltd, B-18. S.I.T.E. Karachi. DML No. 000188 (Formulation)	**28-02-2017**	The Board approved the grant of following additional sections /amendment as under:- **Section (02)** 1. Ointment (Steroid) Section. 2. Oral Liquid (General) Section
17	M/s Akhai Pharmaceuticals, Plot No. A-248 to A-259, Hub Industrial Triangle Estate, Hub Balochistan DML No.000640 (Formulation)	03-03-2017	The Board approved the grant of following additional sections /amendment as under:- **Section (01)** 1. Tablet (Psychotropic).

18	M/s Nawan Laboratories (Pvt) Ltd, Plot No. 136-138, Sector 15, Korangi Industrial Area, Karachi. DML No. 0000442 (Formulation)	**10-12-2016**	The Board approved the grant of following additional sections /amendment as under:- **Section (01)** Sachet (General).
19	M/s GSK (OTC) (Pvt) Ltd, Petaro Road, Jamshoro, Sindh. (Formerly M/s Novartis Pharma, PetaroRaod, Jamshoro, Sindh.) DML No. 000010 (Formulation)	**06-02-2017** **07-02-2017**	The Board approved the grant of following additional sections /amendment as under:- **Section (01)** 1. CapsuleSection (General). 2. Tablet Section (Vitamin) with one production line. However, remaining two lines of tablet Section have been deffered on the recommendations of the panel. Firm shall submit Lay Out Plan for approavl of Psychotropic drugs.
20	M/s Winbrains Research Laboratories, Plot No.69/1, Block B, Phase-I&II, Industrial Estate, Hattar. DML No. 0000725 (Formulation)	**03-02-2017**	The Board approved the grant of following additional sections /amendment as under:- **Sections (04)** 1. Eye Drop (General) 2. Liquid Injection (General) 3. Dry Powder Injection (General) 4. Cream/Ointment/Gel (General)
21	M/s Hoover Pharmaceuticals (Pvt) Ltd, Plot No.16, Zain Park IndustrialArea Saggian Bypass Road, Lahore. DML No. 0000676		The Board approved the grant of following additional sections /amendment as under:- **Sections (04)** 1. Oral Dry Powder Suspension Section (General) 2. Oral Liquid Section (General) 3. External Liquid Section (General) 4. Sachet Section (General)

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

The Board considered the following cases of Grant of Renewal of Drug Manufacturing Licenses in the light of recommendations by panel of experts/inspectors subject to confirmation of deposition of CRF as admissible under the rules and decided as under: -

S. No	Name of the firm/ Type of License	Date of Inspection	Decision of CLB
1.	M/s Navegal Laboratories, 41/1-A-2, Phase-I, Industrial, Hattar. DML No. 000591 (Formulation)	**31-12-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **05-05-2016 to 04-05-2021**
2	M/s Rock Pharmaceutical Laboratories (Pvt) Ltd, Plot No.134&135-B, Nowshera Industrial Estate, Risalpur. DML No. 000691 (Formulation)	**21-12-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **03-08-2015 to 02-08-2020**
3	M/s LeamaChemi Pharma (Pvt) Ltd, Industrial Estate, Jamrud Road, Peshawar. DML No. 000404 (Formulation)	**13-01-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **03-04-2015 to 02-04-2020**
4	M/s Hizat Pharmaceutical Industry, Industrial Estate, Hayatabad, Peshawar. DML No. 000315 (Formulation)	**02-12-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **11-12-2014 to 10-12-2019**
5	M/s Roryan Pharmaceutical Industries (Pvt) Ltd, 85/B, Hayatabad Industrial Estate, Peshawar. DML No. 0000566	**24-02-2017** (Formulation)	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **31-12-2014 to 30-12-2019**
6	M/s Welmed Pharmaceutical Industries (Pvt) Ltd, 108-R-2, Industrial Estate, Gadoon, Swabi. DML No. 0000546 (Formulation)	**04-03-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f**17-07-2014 to 16-07-2019**

7	M/s Goodman Laboratories, Plot No. 5, Street No. S-5, National Industrial Zone, RCCI, Rawat, Rawalpindi. DML No. 000613 (Formulation)	**27-01-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f**21-03-2012 to 20-03-2017** The Board also took serious note of the observations of the panel regarding management of the firm which was not their mandate. The Board also noted that Mr. Khalid Mehmood, Federal Inspector of Drugs is working since last two (02) years in the same area of jurisdiction. If facts regarding management were in his knowledge then why they were not submitted before the Board previously. The Board also recalled that he has been previously served the note of displeasure by the Board in the case of Crystolite Pharmaceuticals, Plot No. 1 & 2, Street No. S-2, National Industrial Zone, Rawat, Rawalpindi but had repeated his same conduct. Board also noted neglect and malafide on the part of Mr. Khalid Mehmood, Federal Inspector of Drugs in this effect and decided to bring the facts into the knowledge of Chief Executive Officer, DRAP for taking decision in this regard.
8	M/s Werrick Pharmaceuticals, Plot No. 216-217, Industrial Area, I-10/3, Islamabad. DML No. 000340 (Formulation)	**02-02-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f**16-10-2014 to 15-10-2019.**
9	M/s Rehmat Pharma, 10-KM, Sheikhupura Road, Lahore. DML No. 000476 (Formulation)	**23-11-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f**12-05-2015 to 11-05-2020**

10	M/s Nawabsons Laboratories (Pvt) Ltd, JiaBagga off Raiwind Road, Lahore. DML No. 000493 (Formulation)	**20-12-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f**27-02-2012 to 26-02-2017**
11	M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Addition City, 1.5KM Khurrianwala-Sahinwala Road, Faisalabad. DML No. 000667 (Formulation)	**15-02-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f**10-06-2014 to 09-06-2019**
12	M/s Medi-Vet (Pvt) Ltd, 16-KM Sheikhupura Road (Link Pindi Das) Lahore. DML No. 000269 (Formulation)	**14-12-2016 & 23-12-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f**26-02-2012 to 25-02-2017**for the following sections; i. Oral Powder Section (Vet). ii. Oral Liquid Section (Vet). iii. Bolus Section Only (Vet). **The Board did not approve renewal of liquid Injectable section (Vet)** to the firm on the recommendations of the panel of experts.
13	M/s Perfect Pharma (Pvt) Ltd., 5KM Manga Raod, Raiwand, Lahore. DML No. 000469 (Formulation)	**24-10-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 01-03-2015 to 28-02-2020 for the following sections (i) External Preparation Section (Re-Packing) Ground Floor. (ii) Cream/Ointment (General) First Floor. The Board also allowed resumption of production on the recommendations of the panel for the above sections. The Board however, deferred the renewal of Drug manufacturing Licence of following sections on the recommendations of the panel • Tablet General • Tablet (Psychotropic) (

			Ground Floor) • Capsule (General) (Ground Floor) The Board also authorized same panel for the purpose of verification of improvements and recommendations for resumption and renewal of deferred sections.
14	M/sUni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21 Korangi Industrial area, Karachi. DML No. 000356 (Formulation)	**24-02-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 4-10-2014 to 3-10-2019
15	M/s ISIS Pharmaceuticals & Chemical Works, Plot No. 25/1-3 Sector 12-C North Karachi Industrial Area, Karachi. DML No. 000126 (Formulation)	**30-12-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 02-10-2015to 01-10-2020
16	M/s Geofman Pharmaceuticals 20/23, Korangi Industrial Area, Karachi DML No. 000090 (Formulation)	**01-12-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 05-03-2016 to 04-03-2021 **except Veterinary Injectable (Vials)** Section.
17	M/s Nawan Laboratories (Pvt) Ltd, Plot No. 136, Sector 15, Korangi Industrial Area, Karachi. DML No. 0000442 (Formulation)	**10-12-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **28-06-2016 to 27-06-2021 except liquid vial injection (General) and Cephalosporin liquid injection (veterinary) Section.**
18	M/s Atco Laboratories Ltd, B-18. S.I.T.E. Karachi. DML No. 000188 (Formulation)	**28-02-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 11-04-2016 to 10-04-2021

19	M/s Amros Pharmaceuticals (Pvt) Ltd, Plot No. A-96, S.I.T.E., North Karachi. DML No. 000406 (Formulation)	**27-02-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **19-06-2015 to 18-06-2020**
20	M/s GSK (OTC) (Pvt) Ltd, Petaro Road, Jamshoro, Sindh. (Formerly M/s Novartis Pharma, PetaroRaod, Jamshoro, Sindh.) DML No. 000010 (Formulation)		The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **31-03-2015 to 30-03-2020.** Board also decided that firm may not manufacture psychotropic drugs till formal approval of the facility for manufacturing of Psychotropic drugs from the Central Licensing Board. Firm is also directed to submit lay out Plan for regularization of Sections.
21	M/s Martin Dow Ltd, Plot No.37, Sector 19, Korangi Industrial Area, Karachi. DML No. 000267 (Formulation)	**16-02-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 09-02-2016 to 08-02-2021
22	M/s Winbrains Research Laboratories, Plot No.69/1, Block B, Phase-I&II, Industrial Estate, Hattar. DML No. 0000725 (Formulation)	**03-02-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 24-06-2016 to 23-06-2021
23	M/s Fedro Pharmaceutical Labs (Pvt) Ltd, 149-Industrial Estate, Hayatabad, Peshawar. DML No. 0000238 (Formulation)	**03-03-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 09-02-2016 to 08-02-2021
24	M/s Festel Laboratories, Link Katar Bund Road, ThokarNiazBaig, Lahore DML No. 000556 (Formulation)	**24-10-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 02-11-2014 to 01-11-2019

Item No. V Miscellaneous Cases.

Case No. 1 CHANGE OF MANAGEMENT OF M/S 3S PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s 3S Pharmaceuticals (PVT) Ltd. Lahore, DML No. 000665by 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/- as under;

Existing Management as per Form-29	**Retiring Management as per Form-29/Form-A**	**New Management as per Form-29/Form-A**
1. Mr. Naveed Ahmad S/o Muhammad Shafique CNIC No.35202-4480325-7. 2. Mr. Muhammad Shafique S/o Muhammad Siddique, CNIC No. 35202-3035267-3.	1. Mr. Naveed Ahmad S/o Muhammad Shafique CNIC No.35202-4480325-7	1. Dr. Mahmood Ahmad S/o Muhammad Sharif, CNIC No. 42000-0446366-5. 2. Abdul Wahid Qureshi S/o Abdul Majeed CNIC No. 35202-5182936-5. 3. Zafar SuroorQidwai S/o Mehmood Ali SuroorQidwai CNIC No. 42101-1847071-7 4. Mr. Muhammad Shafique S/o Muhammad Siddique, CNIC No. 35202-3035267-3.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management of M/s 3S Pharmaceuticals (PVT) Ltd. Lahore, DML No. 000665by way of formulation as per Form -29 as under;

Existing Management	**Retiring Management**	**New Management**
1. Mr. Naveed Ahmad S/o Muhammad Shafique CNIC No.35202-4480325-7. 2. Mr. Muhammad Shafique S/o Muhammad Siddique, CNIC No. 35202-3035267-3.	1. Mr. Naveed Ahmad S/o Muhammad Shafique CNIC No.35202-4480325-7	1. Dr. Mahmood Ahmad S/o Muhammad Sharif, 2. CNIC No. 42000-0446366-5. 3. Abdul Wahid Qureshi S/o Abdul Majeed CNIC No. 35202-5182936-5. 4. Zafar SuroorQidwai S/o Mehmood Ali SuroorQidwai CNIC No. 42101-1847071-7 5. Mr. Muhammad Shafique S/o Muhammad Siddique, CNIC No. 35202-3035267-3.

Case No.2. CHANGE OF MANAGEMENT OF M/S REKO PHARMACAL (PVT) LTD., 13-KM, MULTAN ROAD, LAHORE

M/s Reko Pharmacal (Pvt) Ltd., 13-kM, Multan Road, Lahore, License No. 000037 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/- as under;

Existing Management as per Form-29	Retiring Management as per Form-29	New Management as per Form-29
1. Mr. Khalid S. Mian S/o Lt Gen S.A Munir CNIC No.35201-1355946-5. 2. Mrs. Sadiqa Mansur W/o Khaldi S. Mian CNIC No. 35201-1290954-6 3. Mr. Abdul Majeed Chaudhary 4. Ms. Sumera Ahmad 5. Mr. Azhar Mehmood	1. Mrs. Sadiqa Mansur W/o Khaldi S. Mian CNIC No. 35201-1290954-6	1. Mr. Khalid S. Mian S/o Lt Gen S.A Munir CNIC No.35201-1355946-5. 2. Mrs. Shazah Khali D/o Khalid S. Mian CNIC No. 35201-7755586-2. 3. Mrs. Seemal Khalid Mian W/o Khalid S. Mian CNIC No. 35201-1290954-8

Decision of CLB:

The Board considered and endorsed the change of management from old to new management of M/s Reko Pharmacal (Pvt) Ltd., 13-kM, Multan Road, Lahore, Drug Manufacturing License No. 000037 by way of formulation as per Form -29 as under;

Existing Management	Retiring Management	New Management
1. Mr. Khalid S. Mian S/o Lt Gen S.A Munir CNIC No.35201-1355946-5. 2. Mrs. Sadiqa Mansur W/o Khaldi S. Mian CNIC No. 35201-1290954-6 3. Mr. Abdul Majeed Chaudhary 4. Ms. Sumera Ahmad 5. Mr. AzharMehmood	1. Mrs. Sadiqa Mansur W/oKhaldi S. Mian CNIC No. 35201-1290954-6	1. Mr. Khalid S. Mian S/o Lt Gen S.A Munir CNIC No.35201-1355946-5. 2. Mrs. Shazah Khali D/o Khalid S. Mian CNIC No. 35201-7755586-2. 3. Mrs. Seemal Khalid Mian W/o Khalid S. Mian CNIC No. 35201-1290954-8

Case No.3. CHANGE OF MANAGEMENT OF M/S SUNRISE PHARMA (PVT) LTD,LAHORE

M/s Sunrise Pharma (Pvt) Ltd., Plot No. 594-A, Sunder Industrial Estate, Sunder Raiwind Road, Lahore, DML No. 000712 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/- as under;

Existing Management as per Form-29	Retiring Management as per Form-29	New Management as per Form-29
1. Mr. Muhammad MansoorDilawar S/o Muhammad Maqsood CNIC No.35202-6194911-3. 2. Khawaja Mushtaq Ahmad S/o Khawaja Noor Elahi CNIC No. 38403-5384555-5 3. Khawaja Abdul Rauf S/o Muhammad Zahoor CNIC No. 12101-6871164-9. 4. Muhammad MatloobKhawar S/o Muhammad Maqsood CNIC No. 35202-1983664-5.	1. Muhammad Matloob Khawar S/o Muhammad Maqsood CNIC No. 35202-1983664-5.	1. Mr. Muhammad Mansoor Dilawar S/o Muhammad Maqsood CNIC No.35202-6194911-3. 2. Khawaja Mushtaq Ahmad S/o Khawaja Noor Elahi CNIC No. 38403-5384555-5 3. Khawaja Abdul Rauf S/o Muhammad Zahoor CNIC No. 12101-6871164-9.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management of M/s Sunrise Pharma (Pvt) Ltd., Plot No. 594-A, Sunder Industrial Estate, Sunder Raiwind Road, Lahore, DML No. 000712 by way of formulation as per Form -29 as under;

Existing Management	Retiring Management	New Management
1. Mr. Muhammad MansoorDilawar S/o Muhammad Maqsood CNIC No.35202-6194911-3. 2. Khawaja Mushtaq Ahmad S/o Khawaja Noor Elahi CNIC No. 38403-5384555-5 3. Khawaja Abdul Rauf S/o Muhammad Zahoor CNIC No. 12101-6871164-9. 4. Muhammad MatloobKhawar S/o Muhammad Maqsood CNIC No. 35202-1983664-5.	1. Muhammad Matloob Khawar S/o Muhammad Maqsood CNIC No. 35202-1983664-5.	1. Mr. Muhammad Mansoor Dilawar S/o Muhammad Maqsood CNIC No.35202-6194911-3. 2. Khawaja Mushtaq Ahmad S/o Khawaja Noor Elahi CNIC No. 38403-5384555-5 3. Khawaja Abdul Rauf S/o Muhammad Zahoor CNIC No. 12101-6871164-9.

Case No.4. **CHANGE OF MANAGEMENT OF M/S SOMA LABORATORIES, LAHORE.**

M/s Soma Laboratories, 43-D, Sunder Industrial Estate, Raiwind Road, Lahore, DML No. 000225 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/- as under;

Existing Management as per sale agreement	Retiring Management as per agreement	New Management as partnership deed
1. Mian Ghulam Jillani S/o MianFazal Din CNIC No.35202-2343495-1.	1. Mian Ghulam Jillani S/o MianFazal Din CNIC No.35202-2343495-1.	1. Mr. NajeebMansoor Malik S/o Manzoor Ahmad CNIC No.35202-2986391-7. 2. Mr. Ahmad Raza Jillani S/o MianghulamJillani CNIC No.35202-2343508-7.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management of M/s Soma Laboratories, 43-D, Sunder Industrial Estate, Raiwind Road, Lahore, DML No. 000225 by way of formulation as per Form -29 as under;

Existing Management	Retiring Management	New Management
1.Mian Ghulam Jillani S/o MianFazal Din CNIC No.35202-2343495-1.	1. Mian Ghulam Jillani S/o MianFazal Din CNIC No.35202-2343495-1.	1. Mr. NajeebMansoor Malik S/o Manzoor Ahmad CNIC No.35202-2986391-7. 2. Mr. Ahmad Raza Jillani S/o MianghulamJillani CNIC No.35202-2343508-7.

Case No.5. **CHANGE OF MANAGEMENT OF M/S IZFAAR PHARMACEUTICALS INDUSTRIES, LAHORE.**

M/s Izfaar Pharmaceutical Industries, 542-A, Sunder Industrial Estate, Lahore, DML No. 000800 by way of formulation has submitted request for change in management of the firm as per Form-IA with prescribed Fee Challan of Rs. 50,000/- as under;-

Existing Management as per Form.V	Retiring Management as per Form.V	New Management as per Form.V
1. Mr. M. Iqbal Khan S/o Mr. Faqir Ahmed Khan CNIC No.35202-2482319-1. 2. Mr. Muhammad Zeeshan Iqbal Khan S/o Mr. M. Iqbal Khan CNIC No. 35202-2384712-7	1. Mr. M. Iqbal Khan S/o Mr. Faqir Ahmed Khan CNIC No.35202-2482319-1. 2. Mr. Muhammad Zeeshan Iqbal Khan S/o Mr. M. Iqbal Khan CNIC No. 35202-2384712-7	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

Decision of CLB:

The Board considered and endorsed the change of management from old to new management of M/s Izfaar Pharmaceutical Industries, 542-A, Sunder Industrial Estate, Lahore, DML No. 000800 by way of formulation as per Form -29 as under;

Existing Management	Retiring Management	New Management
1.Mr. M. Iqbal Khan S/o Mr. Faqir Ahmed Khan CNIC No.35202-2482319-1. 2.Mr. Muhammad Zeeshan Iqbal Khan S/o Mr. M. Iqbal Khan CNIC No. 35202-2384712-7	1. Mr. M. Iqbal Khan S/o Mr. Faqir Ahmed Khan CNIC No.35202-2482319-1. 2. Mr. Muhammad Zeeshan Iqbal Khan S/o Mr. M. Iqbal Khan CNIC No. 35202-2384712-7	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

Case No.6. **CHANGE OF TITLE OF THE FIRM&CHANGE IN MANAGEMENT OF THE FIRM.**

AJ M Pharma (Pvt) Ltd, Plot No. 44, Sector 27, Korangi Industrial Area, Karachi, has submitted request for change of firms title/Status as per Form-29 from S.E.C.P along with prescribed fee Challan of Rs. 50000/- as under:-

Present Name/Title /Status of Firm	New Name/Title/Status of Firm (as per Form-29)
Meredoa Company, Plot No. 44, Sector 27, Korangi Industrial Area, Karachi	AJM Pharma (Pvt) Ltd, Plot No. 44, Sector 27, Korangi Industrial Area, Karachi

The Company has also submitted request for change in management of the firm as per Form-29 from S.E.C.P along with prescribed Fee Challan of Rs. 50000/- as under:-

Existing Management as per partnership deed	Retiring Management as per partnership deed	New Management As per Form-29
1. Mr. Muhammad SiddiqMotiwala S/o Abdul GhaffarMotiwala CNIC No. 42201-5825486-9. 2. Mrs. Fatima Motiwala W/o Abdul GhafforMotiwala CNIC No. 42201-1236820 3. Mr.Muhammad Amin Motiwala S/o Abdul GhaffarMotiwala CNIC No. 42201-2228262-3.	1.Mr. Muhammad SiddiqMotiwala S/o Abdul GhaffarMotiwala CNIC No. 42201-5825486-9. 2.Mrs. Fatima Motiwala W/o Abdul GhafforMotiwala CNIC No. 42201-1236820- 3.Mr.Muhammad Amin Motiwala S/o Abdul GhaffarMotiwala CNIC No. 42201-2228262-3.	1. Mr. Adnan Hussain S/o Ikhlaq Hussain CNIC No. 42301-8282999-1. 2. Mrs. Ayesha Adnan W/o Adnan Hussain CNIC No. 42301-7967348-0. 3. Miss. Dina Jamal D/o Ahmed Jamal Mirza CNIC NO.42000-0466594-4.

Decision of CLB:

The considered request of M/s AJM Pharma (Pvt) Ltd, Plot No. 44, Sector 27, Korangi Industrial Area, Karachi and accorded approval for change of title/ name of firms/ company as under:-

Present Name/Title of Firm/Company	**New Name/Title of Firm/ Company (as per Form-29)**
Meredoa Company, Plot No. 44, Sector 27, Korangi Industrial Area, Karachi	AJM Pharma (Pvt) Ltd, Plot No. 44, Sector 27, Korangi Industrial Area, Karachi

The Board also considered and acknowledged the change of management from old to new management of M/s AJM Pharma (Pvt) Ltd, Plot No. 44, Sector 27, Korangi Industrial Area, Karachi, as per Form -29 as under;

Existing Management	**Retiring Management**	**New Management**
1. Mr. Muhammad SiddiqMotiwala S/o Abdul GhaffarMotiwala CNIC No. 42201-5825486-9. 2. Mrs. Fatima Motiwala W/o Abdul GhafforMotiwala CNIC No. 42201-1236820 3. Mr.Muhammad Amin Motiwala S/o Abdul GhaffarMotiwala CNIC No. 42201-2228262-3.	1.Mr. Muhammad SiddiqMotiwala S/o Abdul GhaffarMotiwala CNIC No. 42201-5825486-9. 2.Mrs. Fatima Motiwala W/o Abdul GhafforMotiwala CNIC No. 42201-1236820- 3.Mr.Muhammad Amin Motiwala S/o Abdul GhaffarMotiwala CNIC No. 42201-2228262-3.	1.Mr. Adnan Hussain S/o Ikhlaq Hussain CNIC No. 42301-8282999-1. 2.Mrs. Ayesha Adnan W/o Adnan Hussain CNIC No. 42301-7967348-0. 3.Miss. Dina Jamal D/o Ahmed Jamal Mirza CNIC NO.42000-0466594-4.

Case No.7. **CHANGE OF MANAGEMENT OF M/S CIRIN PHARMACEUTICALS (PVT) LTD, 32/2A, PHASE-III, INDUSTRIAL ESTATE,HATTAR.**

M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase-III, Industrial Estate, Hattar Drug Manufacturing License No. 000363 by way of formulation has submitted request for change in management of the firm as per Form -29 with prescribed Fee Challan of Rs. 50,000/- as under;

Existing Management as per Form-29	Retiring Management as per Form-29	New Management as per Form-29
1. Mr. Muhammad Yousaf S/o Muhammad Rasool, CNIC No. 17301-4724873-9 2. Mr. Munim Sultan Mir S/o Mir Naeemullah, CNIC No. 17301-5559109-7	1. Mr. Muhammad Yousaf S/o Muhammad Rasool, CNIC No. 17301-4724873-9 2. Mr. Munim Sultan Mir S/o Mir Naeemullah, CNIC No. 17301-5559109-7	1. Mr. Asif Jooma S/o O V Jooma, CNIC No. 42301-3175078-7 2. Mr. Muhammad Ali Tabba S/o Abdul RazzakTabba CNIC No.42201-6464247-3 3. Mr. Muhammad SohailTabba S/o Muhammad YounusTabba CNIC No.42000-0568372-5 4. Mr. Muhammad AbidGanatra S/o MoosaGanatra CNIC No.42201-5355492-7 5. Mr. M.A. SamieCashmiri S/o Abdul Rauf Moosa CNIC No.35201-8722191-7

Decision of CLB:

The Board considered and endorsed the change of management from old to new management of M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase-III, Industrial Estate, Hattar Drug Manufacturing License No. 000363 by way of formulation as per Form -29 as under;

Existing Management	Retiring Management	New Management
1. Mr. Muhammad Yousaf S/o Muhammad Rasool, CNIC No. 17301-4724873-9 2. Mr. Munim Sultan Mir S/o Mir Naeemullah, CNIC No. 17301-5559109-7	1. Mr. Muhammad Yousaf S/o Muhammad Rasool, 2. CNIC No. 17301-4724873-9 3. Mr. Munim Sultan Mir S/o Mir Naeemullah, 4. CNIC No. 17301-5559109-7	1. Mr. Asif Jooma S/o O V Jooma, CNIC No. 42301-3175078-7 2. Mr. Muhammad Ali Tabba S/o Abdul Razzak Tabba CNIC No.42201-6464247-3 3. Mr. Muhammad Sohail Tabba S/o Muhammad YounusTabba CNIC No.42000-0568372-5 4. Mr. Muhammad Abid Ganatra S/o Moosa Ganatra CNIC No.42201-5355492-7 5. Mr. M.A. SamieCashmiri S/o Abdul Rauf Moosa CNIC No.35201-8722191-7

Case No.8. **CHANGE OF MANAGEMENT OF M/S NEUTRO PHARMA (PVT) LTD, 9.5-KM, SHEIKHUPURA ROAD LAHORE.**

M/s Neutro Pharma (Pvt) Ltd, 9.5-KM, Sheikhupura Road, Lahore, DML No. 000576 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/- as under;-

Existing Management as per Form-29 (Page 174-180/Corr)	Retiring Management Form-29 (Page 341-342/Corr)	New Management as per Form-29 (Page 341-342/Corr)
1. Mr. Hamid Raza S/o Abdul Jabbar CNIC No.35202-9569392-7. 2. Mr. Amir Raza S/o Abdul Jabbar, CNIC No. 35202-8669057-9. 3. Mrs. Sarwat Hamid W/o Hamid Raza, CNIC No. 35202-1174393-4.	1. Mr. Hamid Raza S/o Abdul Jabbar CNIC No.35202-9569392-7. 2. Mr. Amir Raza S/o Abdul Jabbar, CNIC No. 35202-8669057-9. 3. Mrs. Sarwat Hamid W/o Hamid Raza, CNIC No. 35202-1174393-4.	1. Mr. Zia ud Din Zia S/o Fazal Din, CNIC No. 35202-2788744-7. 2. Mr. Bilal Javed S/o Abdul Majeed CNIC No. 35201-5070788-7.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management of M/s Neutro Pharma (Pvt) Ltd, 9.5-KM, Sheikhupura Road, Lahore, DML No. 000576 by way of formulation as per Form -29 as under;

Existing Management	Retiring Management	New Management
1. Mr. Hamid Raza S/o Abdul Jabbar CNIC No.35202-9569392-7.	1.Mr. Hamid Raza S/o Abdul Jabbar CNIC No.35202-9569392-7.	1.Mr. Zia ud Din Zia S/o Fazal Din, CNIC No. 35202-2788744-7.
2. Mr. Amir Raza S/o Abdul Jabbar, CNIC No. 35202-8669057-9.	2.Mr. Amir Raza S/o Abdul Jabbar, CNIC No. 35202-8669057-9.	2.Mr. Bilal Javed S/o Abdul Majeed CNIC No. 35201-5070788-7.
3. Mrs. Sarwat Hamid W/o Hamid Raza, CNIC No. 35202-1174393-4.	3.Mrs. Sarwat Hamid W/o Hamid Raza, CNIC No. 35202-1174393-4.	

Case No.9. M/S HERBION PAKISTAN (PVT) LTD., INDUSTRIAL TRIANGLE KAHUTA ROAD, HUMAK, ISLAMABAD, DML NO. 000795(FORMULATION)

Case Background;

S No.	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle Kahuta Road, Humak, Islamabad DML No. 000795 (Formulation) **Additional Sections:** i. Oral Syrup (General) (Revised/ Amended) ii. Cream/Ointment Syrup (General) (Revised/ Amended) iii. Quality Control/ Microbiology Laboratory (Revised/ Amended)	**17-11-2016**	-	1. Prof. Dr. Gul Majeed Khan, Dean, Quaid-e-Azam University, Islamabad. 2. Dr. HafsaKaramElahi, Deputy Director DRAP, Islamabad. 3. Area Federal Inspector of Drugs, DRAP, Islamabad.

Proceedings of 251st Meeting.

The case was placed in 251st meeting of CLB for grant of following additional sections;

i. Oral Syrup (General) (Revised/ Amended)
ii. Cream/Ointment Syrup (General) (Revised/ Amended)
iii. Quality Control/ Microbiology Laboratory (Revised/ Amended)

Decision of the CLB in 251st Meeting

The Board observed that as Microbiology Laboratory is important in testing of water and environment control besides testing of drugs which is under renovation. Therefore, the Board decided to defer grant of additional / amendment of Sections with the remarks that clear and candid report on the format be obtained.

Further proceeding:

Now panel has again inspected the facility and submitted the recommendation as under;
In continuation to the inspections dated 17-11-2016 and 02-01- 2017 of premises of M/s. Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahutta Road, Islamabad. The company was inspected to verify the up gradation of compliance of amendments approved in the lay out plan of syrup section, cream / ointment and microbiology in reference to the DRAP letter F.1-21/2012-Lic. The evaluation form as per instructions has been filled and being submitted with the recommendations of resumption of production in the said sections after the completion and up gradation according to the revised layout plan approved.

Decision by CLB in 252nd Meeting.

The Board approved the grant of following additional sections /amendment as under:-

Sections (04)

1. Oral Syrup (General) (Revised/ Amended)
2. Cream/Ointment Syrup (General) (Revised/ Amended)
3. Quality Control/ Microbiology Laboratory (Revised/ Amended)

Case No.10. **APPROVAL OF MASTER LAYOUT PLAN / AUTHENTICATION / REGULARIZATION OF EXISTING FACILITY, DRUG MANUFACTURING LICENSE NO.000071 (FORMULATION) OF M/S EPLA LABORATORIES (PVT.) LTD. KARACHI**

M/s Epla Laboratories (Pvt) Ltd, D-12, Estate Avenue S.I.T.E, Karachi , DML No. 000071 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

Regularization / Authentication / Amendment of Already existing Sections.			
1.	Liquid Section Oral (General)	2.	TabletSection (General)
3.	Dry Powder Section (General)	4.	Capsule Section (General).
5.	Ointment / Cream Section (General)	6.	Nasal Solution Section (General)
7.	Beta Lactum Section Capsule	8.	Liquid Section (Veterinary)
9.	Powder Section (Veterinary)	10.	Beta Lectum Dry Powder

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

i. Syed Jawed Yousaf Bukhari, Expert in QC, Karachi.
ii. Abdul SattarSoomro, Director, Drug Testing Laboratory, Sindh.
iii. Mrs. Muneeza Khan, Area Federal Inspector of Drugs-II Karachi

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

Recommendations: -

The panel observed that all manufacturing areas, stores and QC labs are constructed in accordance with the approved layout plan by the DRAP, Islamabad, with all necessary equipments and machinery installed, HVAC operating in good working condition and as per layout plan installed, therefore the panel recommends authenticates the regularization of master layout plan of M/s Epla Laboratories (Pvt) Ltd, D-12, Estate Avenue S.I.T.E, Karachi, DML No. 000071 (Formulation).

Decision of CLB in 252nd meeting.

The Board considered the facts on record, report of the panel and approved the regularization of Lay out Plan of M/s Epla Laboratories (Pvt) Ltd, D-12, Estate Avenue S.I.T.E, Karachi for the sections mentioned above.

Case No.11. **M/S ZINTA PHARMACEUTICAL INDUSTRY, 168, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.**

M/s Zinta Pharmaceutical Industry, Industrial Estate, Hayatabad, Peshawar submitted the application for renewal of DML No. 000570 by way of formulation on 15-05-2015 for the period of 14-05-2015 to 13-05-2020, which was two (02) days late as due date of renewal of said DML was 13-05-2015.

After evaluation of the renewal application of the firm,a letter for completion of application for renewal of DML was issued for following shortcomings: -

i) The renewal application was two days late, due date was 13-05-2015 where as application for DML Renewal was submitted on 15-05-2015, accordingly late fee of Rs.10,000/- is required.

ii) No Objection Certificate for Central Research Fund (CRF) by Statistical Officer DRAP, Islamabad

iii) The experience of technical person (proposed) Mr. Mudassir Iqbal after M.Sc Chemistry (2008) is less than 10 years.

iv) Proof of approved / licensed sections.

With reference to above letter, it is mentioned that as per available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. Licensing Division again issued reminder for completion of application of renewal of DML to the firm for information / documents as under;

i) The renewal application was two days late, due date was 13-05-2015 where as application for DMl Renewal was submitted on 15-05-2015, accordingly late fee of Rs.10,000/- is required.

ii) No Objection Certificate for Central Research Fund (CRF) by Statistical Officer DRAP, Islamabad

iii) The experience of technical person (proposed) Mr. Mudassir Iqbal after M.Sc Chemistry (2008) is less than 10 years.

iv) Proof of approved / licensed sections.

The firm replied to the above mentioned reminderas under:-

i. Late fee amounting to Rs.10,030.00 (Ten Thousand thirty only) has been deposited in Allied Bank Limited, PDA Building Branch Hayatabad, Peshawar through deposited slip #0585606 dated 26-12-2016. Copy of deposit slip attached.

ii. Rs.14610.00 (Fourteen Thousand six hundred ten only) has been deposited online in Allied Bank Limited, PDA Building Branch Hayatabad, Peshawar through deposited slip #2033714 dated 26-12-2016 as CRF for the year 2015-2016. Copy of deposit slip attached. We have applied for NOC from Statistical Officer DRAP.

iii. We have appointed Mr. ShabirHausain as Q.C Incharge and his documents have been sent earlier for your kind approval alongwith deposit slip of Rs.5000.00.

iv. Copy of our approved sections also attached.

Upon evaluation of reply received from the firm, shortcomings were still present in the application for renewal of DML. Licensing Divisionissued final reminder for completion of application of renewal of DML to the firmfor information / documents as under: -

i). Up-to-date nothing due certificate (CRF) from Statistical Officer, DRAP, Islamabad.

ii). The experience of proposed QC Incharge, Mr. Shabir Hussain is less than prescribed experience of ten (10) years after academic qualification.

iii). Deposited fee challan of Rs.5000/- for change of technical staff.

The firm has replied to final reminder as under;

i). According to M.Sc degree and Experience certificates provided by our proposed Q.C Incharge, he bears an experience of ten years.

ii). We have deposited fee of Rs.5000/- for change of technical through deposit slip #058612 dated 05-12-2016 and sent to your office through OCS Courier (slip #0407280 dated 06-12-2016). Photocopy attached.

iii). Please receive our up to date NOC for (CRF) clearance from STO (R&D), DRAP, Islamabad.

Upon evaluation of submitted documents following shortcomings have still been observed in the DML renewal application;

i. The experience of proposed QC Incharge Mr. Shabir Hussain is less than prescribed experience of ten (10) years after academic qualification. The detail of experience as per provided certificates is as under;

Ser	**Name of Firm**	**Designation**	**Period**	**Duration**
1.	M/s Hizat Pharmaceutical Industry, Peshawar	Senior QC Analyst	01 Oct, 2006 to 31 Dec, 2009	03 years and 03 Months
2.	M/s Fozan Pharmaceutical Industries (Pvt) Ltd, Peshawar	Senior QC Analyst and QA Inspector	Dec 2009 to Aug 2010	09 Months
3.	M/s Alliance Pharmaceuticals (Pvt) Ltd, Peshawar	Assistant QCM and QCM	Aug 2010 to 03 April 2015	04 Years 08 Months
			Total Experience	**08 Years 08 Months**

ii. The fee challan provided has already been considered for approval of proposed Production Incharge.

Decision of CLB.

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) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of Drug Manufacturing Licence No. 000570 by way of formulation of M/s Zinta Pharmaceutical Industry, Industrial Estate, Hayatabad, Peshawar may not be rejected by Central Licensing Board.

Case No.12. <u>M/S NENZA PHARMACEUTICALS (PVT) LTD, 33-A, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.</u>

M/s Nenza Pharmaceuticals, Industrial Estate, Hayatabad, Peshawar submitted the application for renewal of DML No. 000474 by way of formulation on 21-04-2015 for the period of 05-05-2015 to 04-05-2020, which was well on time as due date of renewal of said DML was 04-05-2015.

After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. Job acceptance letter by the newly appointed QC Incharge.
ii. Undertaking by the newly appointed QC Incharge, who is whole time employee in the firm and is not working anywhere else.
iii. Updated nothing due certificate (CRF) from STO (R&D) DRAP Islamabad.
iv. Attested copies of Form-29 (current & previous) from SECP with company letter head.
v. Requisite fee for change of technical staff (QC Incharge & Production Incharge).
vi. Total sections with approval letters issued by Central Licensing Board.
vii. Updated and attested copy of certificate of registration from pharmacy council for QC Incharge and Production Incharge.

With reference to above letter, the firm replied as under;

i. Job Acceptance letter by newly appointed QCM.
ii. Undertaking by newly appointed QCM.
iii. Updated CRF certificate.
iv. Attested copies of Form-29.
v. Requisite fee for change of QC and Production Incharge.
vi. Approval letter of total sections issued by Central Licensing Board.
vii. Updated and attested copies of certificates of registration from Pharmacy Council for QC and Production Incharge.

Upon evaluation of reply received from the firm, shortcomings were still present in the application for renewal of DML. Licensing Division issued reminder for completion of application to the firm for information / documents as under: -

i. Form-29 and Form-A mentioning the names of Directors.
ii. Attested copies of CNIC of all Directors.

With reference to above reminder, the firm replied as under;

i. Form-29 and Form-A.
ii. Attested copies of CNIC of all Directors.

Upon evaluation of reply received from the firm, shortcomings were still present in the application for renewal of DML. Licensing Division issued final reminder on 27th December, 2016 for completion of application to the firm for information / documents as under: -

i. Nothing due certificate regarding CRF issued from STO office.
ii. Complete information of management
iii. Proof of approved sections.

The response of final reminder is still awaited.

Decision of CLB.

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) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of Drug Manufacturing Licence No.000474 by way of formulation M/s Nenza Pharmaceuticals, Industrial Estate, Hayatabad, Peshawar may not be rejected by Central Licensing Board.

Case No.13. <u>M/S FASSGEN PHARMACEUTICALS, PLOT NO.67/1-A, PHASE-III, INDUSTRIAL ESTATE, HATTR – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.</u>

M/s Fassgen Pharmaceuticals, Industrial Estate, Hattarsubmitted the application for renewal of DML No. 000646 by way of formulation on 06-12-2013 for the period of 12-12-2013 to 11-12-2018, which was well on time as due date of renewal of said DML was 11-12-2013.

After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. You are required to provide copy of previous Drug Manufacturing License issued to your firm and Nothing Due Certificate issued by Statistical Officer,

DRAP, Islamabad regarding deposition of Central Research Fund upto 31-12-2014.

ii. You are also required to furnish approval letter of proposed technical experts from competent authority, in case if nt approved, you are required to furnish documents of proposed technical experts as per checklist (attached).

With reference to above letter, it is mentioned that as per available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. Licensing Division again issued reminder for completion of application of renewal of DML to the firm for information / documents as under;

i. Updated Nothing Due Certificate (CRF).

ii. To provide approval letter of technical staff, if technical staff is changed than provide attested documents according to Rule 16 of Drugs (Licensing, Registering & Advertising) Rules, 1976 and requisite fee.

iii. Copy of Drug Manufacturing License.

The firm submitted documents of technical staff for approval. Upon evaluation of reply received from the firm, shortcomings were still present in the application for renewal of Drug Manufacturing License. Licensing Division issued final reminder for completion of application to the firm for information / documents as under: -

For Renewal of DML No. 000646

i. Attested copy Nothing due certificate from statistical officer, is not attached.

ii. Attested Copy of DML, is not attached.

iii. Attested Copy of approved Layout Plan alognwith approval letter (s) for all approved sections, is not attached.

iv. Attested Copy of Partnership Deed, is not attached.

For Production Incharge

v. Attested copy of job acceptance letter of proposed Production Incharge (Mr. Sajjad Ali), is not attached.

vi. Attested copy of appointment letter of proposed Production Incharge, is not attached.

vii. Experience of proposed Production Incharge, is less than ten (10) years.

viii. Attested copy of resignation letter of / promotion letter of previous Production Incharge, is not attached.

ix. Attested copy of resignation of proposed Production Incharge from previous firm, is not attached.

For QC Incharge

x. Attested copy of appointment letter of proposed QC Incharge (Mr. Mukhtar Ahmad), is not attached.

xi. Attested copy of job acceptance letter of proposed QC Incharge, is not attached.

With reference to above final reminder, the firm has submitted reply as under;

For Renewal of DML No. 000646

i. Attested copy of NOC of CRF (As we have furnished al the requirements in the statistical department of yours organization & we except for the earliest execution of this NOC. And then we will immediately provide to yours department.

ii. Attested Copy of DML.

iii. Attested Copy of approval letter (s) for all approved sections.

iv. Attested Copy of Partnership Deed.

For Production Incharge

v. As per our non-awareness for the legal eligibility for Technical staff with experience of 10 years, we hereby declare that as our already approved Production Incharge (Mr. Kamran Naveed) is alos working as Plant Manager after the appointment of Mr. Sajjad Ali at this post. Now the management has decided to restore the position of already approved Production Incharge (Mr. Karman Naveed) & Mr. Sajjad Ali will work at the post of Assistant Production Incharge till the complete eligibility time. So it is hereby requested to freeze our request of approval of new Production Incharge till our further intimation.

For QC Incharge

vi. Attested copy of appointment letter.

vii. Attested copy of job acceptance letter.

Upon evaluation of documents following shortcomings have still been observed;

i. Nothing Due Certificate from STO, DRAP, Islamabad, has not been attached.

ii. Complete set of documents alonwith requisite fee for approval of Proposed Production Incharge, has not been attached.

Decision of CLB.

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) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of Drug Manufacturing Licence No. 000646 by way of formulation M/s Fassgen Pharmaceuticals, Industrial Estate, Hattar may not be rejected by Central Licensing Board.

Case No.14. **M/S POLYFINE CHEMPHARMA, 51-HAYATABAD INDUSTRIAL ESTATE, PESHAWAR – VIOLATION OF RULE 5(2A)& RULE 16 OF DRUGS (L,R&A) RULES, 1976.**

M/s Polyfine Chempharma, Peshawar submitted the application for renewal of DML No. 000216 by way of formulation on 16-02-2016 for the period of 14-03-2016 to 13-03-2021, which was well on time as due date of renewal of said DML was 13-03-2016.

After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. To provide name of registered drugs.
ii. To provide details of premises including approved layout plan of the factory.
iii. Proof of approval of all licensed sections.
iv. No Objection Certificate for Central Research Fund (CRF) by Statistical Officer DRAP, Islamabad.

With reference to above letter, it is mentioned that as per available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. Licensing Division again issued reminder for completion of application of renewal of DML to the firm for information / documents as under;

i. To provide name of registered drugs.
ii. To provide details of premises including approved layout plan of the factory.
iii. Proof of approval of all licensed sections.
iv. No Objection Certificate for Central Research Fund (CRF) by Statistical Officer DRAP, Islamabad

The firm submitted shortcoming documents as under;

i. List of names of registered drugs.
ii. Details of premises including approved layout plan of the factory.
iii. Proof of approval of all licensed sections.
iv. No Objection Certificate for Central Research Fund (CRF) by Statistical Officer DRAP, Islamabad.

Meanwhile, M/s Oakdale Pharmaceuticals, Peshawar submitted application for approval of Mr. Subhash Chandar as QC Incharge wherein they submitted experience letter purported to be issued by M/s Polyfine Chempharma, Peshawar mentioning that Mr. Subhash Chandar has resigned on 31st August, 2015 from M/s Polyfine Chempharma, Peshawar. But M/s Polyfine Chempharma, Peshawar in their DML renewal application dated 15-02-2016 claimed that they have not changed their QC Incharge since the previous renewal (14-03-2011 to 13-03-2016) and Mr. Subhash Chandar who was their approved QC Incharge at the time of previous renewal is still working with them.

A letter was issued to M/s Polyfine Chempharma, Peshawar to clarify their position regarding the resignation of their QC Incharge. Now the firm has declared that their QC Incharge Mr. SubhashChandar resigned on 31-08-2015 and submitted documents of new QC Incharge in which following shortcoming has been observed;

i. The experience of proposed QC Incharge is less than prescribed experience of ten (10) years.

Decision of CLB.

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) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of Drug Manufacturing Licence No. 000216 by way of formulation M/s Polyfine Chempharma, Peshawar may not be rejected by Central Licensing Board.

Case No.15. <u>CHANGE OF TECHNICAL STAFF OF CKD PHARMACEUTICALS PAKISTAN (PVT) LTD, KARACHI.</u>

M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd, Plot No 50, Sector 28, Korangi Industrial Area, Karachi, applied for approval of production incharge. A letter regarding shortcomings in documents of proposed production incharge was issued to the firm. Later on, Reminder letter was issued to the firm to submit the deficient documents of proposed production incharge as the firm was carrying out production activities for many months without the approval of production incharge as under Rule(16) of Drugs(Licensing, Registration and Advertisement) Rules,1976. .Firm again failed to rectify the shortcomings in documents and again firm requested to be granted a period of 3-4 weeks for appointment of production incharge.

2. Now firm has submitted the documents of new proposed Production Incharge and following document are still deficient.

i. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not less than 10 years).

Decision of CLB.

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 their Drug Manufacturing Licence No. 000144 (Formulation) M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd, Plot No 50, Sector 28, Korangi Industrial Area, Karachi may not be suspended or cancelled by Central Licensing Board.

Case No.16. CHANGE OF TECHNICAL STAFF (PRODUCTION INCHARGE AND QC INCHARGE) OF M/S NABIQASIM INDUSTRIES (PVT) LTD,KARACHI

M/s Nabi Qasim Industries (Pvt) Ltd, Plot No. 17, Sector 24, Korangi Industrial Area, Karachi, applied for approval of production incharge and Quality Control incharge. A letter regarding shortcomings in documents of proposed production incharge and Quality Control incharge was issued to the firm. Later on, Reminder letter was issued to the firm to submit the deficient documents of proposed technical staff as the firm was carrying out production activities for many months without the approval of production incharge and QC incharge as under Rule(16) of Drugs(Licensing, Registration and Advertisement) Rules,1976.

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Firm failed to provide the required documents and a **Final Reminder** was issued to the firm for submission of required documents. Firm again failed to provide the documents required for approval of production incharge and Quality control incharge. Following document is still deficient.

1. Firm has only submitted the prescribe fee of new proposed Quality Control Incharge and Production Incharge and firm has not submitted any document for the said technical persons as per check list.

Decision of CLB.

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 their Drug Manufacturing Licence No. 000105 Formulation M/s Nabi Qasim Industries (Pvt) Ltd, Plot No. 17, Sector 24, Korangi Industrial Area, Karachi, may not be suspended or cancelled by Central Licensing Board.

Case No.17. RESTORATION OF DRUG MANUFACTURING LICENSE NO.000158 (FORMULATION) OF M/S QAMAR COTTON INDUSTRIES, DIPALPUR CHOWK OKARA.

Summary of the Case:-

- Drug Manufacturing License (DML) of M/s Qamar Cotton, Dipalpur Chowk, Okara was cancelled by the Central Licensing Board on 10-07-1999 due to continuous non-compliance of Good Manufacturing Practices (GMP) by the firm.

- The firm filed an appeal against the decision of cancellation of DML which was heard on 06-10-1999 in the 98th sitting of the Appellate Board where the decision of the Central

Licensing Board was upheld and the order of the Appellate Board was conveyed to the Appellant on 15-11-1999.

- The firm filed a writ petition in the Lahore High Court, Lahore on 06-12-1999 against the decision of Appellant Board.

- The Hon'rable Lahore High Court set aside the decision of the Appellate Board with its orders dated 08-02-2000 and directed that the appeal filed by the petitioner shall be deemed pending with the Appellant Board which shall be considered and decided afresh by affording a reasonable opportunity of hearing to the petitioner in accordance with law with in a period of one month.

- Accordingly, the Appellant was called for personal hearing in the 100th sitting of the Appellant Board held on 08-04-2000. Mr. Manzoor Hussain, Mr. Ahsan and Mr. Bashir Ahmad appeared on behalf of the firm. During proceedings of the Board, it was transpired that Mr. Qamar-ud-din, the sole proprietor of the firm, had expired on 06-12-1999.

- The Appeal was deferred for want of legal opinion on the matter from Ministry of Law and Justice and Human Rights, Which opined as under:

  "*Mr. Qamar-ud-din was the sole proprietor of the firm as is evident from proforma"A" on the record by Qarmar-ud-din himself. On his death the firm stood automatically dissolved. The drug-manufacturing license was issued to Mr. Qamar-ud-din and with the death of licensee the said license seized [sic] to exist. The license to a sole partnership was a personal and permissive right which was neither assignable nor heritable".*

- Based on the opinion of Ministry of Law Division, the Appellant Board dismissed the Appeal in its 101st sitting held on 28-06-2000.

- The firm again filed the writ petition in the said Court against the decision of Appellate Board, where the Hon'rable Court directed the Board to hear and decide the Appeal afresh by affording personal hearing to the firm.
- Accordingly, the Appellate Board in its 126th sitting held on 01-06-2006 heard the Appellant, where the Appellant informed that they were already carrying on manufacturing activates assuming that the Lahore Court vide its orders dated 20-11-2000 had suspended the orders of Central Licensing Board dated 10-07-1999 meaning, thereby, that their DML was valid whereas the Appellant Board was of opinion that firm should have not start the manufacturing activities till final decision by the Appellant Board as per orders of the Hon'rable Court dated 06-02-2006.
- The case was accordingly, referred for legal opinion to the Law Division in view of Appellate Boards observation. *The Law Division opined that the firm should stop manufacturing of drugs and apply afresh for grant of MDL and registration of drugs if so desired.*
- The case was again taken up in the 130th sitting of the appellate Board held on 22-11-2006. After deliberation on the matter and taking into account the orders of the Hon'rable Lahore High Court, Lahore the Board decided to accept the Appeal subject to verification of compliance of the firm towards cGMP by the following panel of inspector within a period of one month:
  - Pro. Mumtaz Hassan (Member, Appellate Board)
  - Mr. Faqeer Muhammad Sheikh (Chairman, Quality Control)
  - Mr. HyderBuxBozdar DDG (E&M), Lahore
  - Mr. Obaid Ali Assistant Drugs Controller Karachi

- The Appellant later informed, vide its letter dated 25-01-2007, that it was not ready for inspection and requested that the said inspection be deferred for a period of 15 days.

- The matter could not be taken up due to the 18th Constitutional Amendment and remained pending. After the reconstitution of the Appellate Board a letter was received from the Appellant dated 19-06-2013 and 19-09-2013 requested for reconstitution of panel of inspectors for appellate re-inspection of their manufacturing unit in light of the decision of the Appellate Board taken in its 130th sitting held on 22-11-2006.

- Consequently, the following panel was reconstituted by the Chairman, Appellate Board:
    - Dr. Farzama Chaudhary (Member Appellate Board).
    - DDG-E&M, Lahore.
    - Area Federal Inspector of Drugs, Lahore.
    - Chief Drugs Inspector, Punjab or his nominee

- The reconstituted panel conducted the inspection on 8th May, 2014 and has informed that:

  "*An inspection was ordered by the Appellate Board which was conducted on 04-03-2007 by the panel comprising Mr. Khadim Hussain Drugs Controller (QA) / CQCA, Islamabad, Prof Dr. Shabbir Ali Bhatti, Head Department of Pharmacology, King Edward Medical University , Lahore, Mr. HyderBuxBozdar, Deputy Director General (E&M), Lahore and Mr. Obaid Ali, Assistant Drugs Controller, Karachi. The Panel did not recommended the restoration of DML at that time".*

- The Panel has passed the following recommendations:

  " *In view of the observation noted during the inspection, the panel recommended restoration / re-grant of the Drug Manufacturing License of M/s Qamar Cotton Dipalpur Chowk subject to the fulfillment of codal requirements".*

- However, one member of the panel i.e. Mr. Hafiz Faisal (Nominee of CDI, Punjab) has submitted that the DML of the said firm may be renewed subject to fulfilling the minimum area requirements as per SRO 470 (I) / 98 dated 15-05-1998. However, the management of the firm , as mentioned in the report, informed that their unit had been granted the DML when this condition was not imposed. Many other old units, granted license at that time, were constructed on area less than 04 Kanals and were also working presently.

Appellant Represented By:

- Mr. Muhammad Aslam Javed, Advocate.
- Mr. Muhammad Qamar Ilyas, Manager.
- Mr. Muhammad Irfan Qamar, Proprietor.

Decision of the 142nd Sitting of Appellate Board held on 24th June, 2014:-

The Appellate Board in light of the recommendation of the panel and the clarification that the license was granted before the notified of S.R.O 470 (I) / 98 dated 15-05-1998, after detailed discussion, decided by majority vote that the Central Licensing Board restore the license of the firm after fulfillment of codal formalities including submission of legal papers regarding ownership of the firm.

Decision of the CLB

The Board after detailed discussion, making deliberations, taking into account all pros and cons and considering facts on record decided to call the representative of the firm for personal hearing before next meeting of the Board to ascertain the facts regarding codal formalities specially plot size of the unit as well as location of the firm as per prevailing laws.

Case No.18. M/S CRESENT COTTON, CHOWK DEPALPUR OKARA.

Background of the case:

A show cause notice was issued to M/s Cresent Cotton, Okara regarding their unit located in residential area. In response to Show Cause notice the firm had informed that it was located in commercial / industrial area instead of residential area and got NOC from TMA, Okara.

2. The Board in its 230th meeting decided to direct the area FID to inspect the premises again and take the necessary documents as the firm was claiming for verification. The Board also directed the area FID to take and verify the NOC obtained from TMA, Okara and approval from concerned provincial Building Control Authorities (BCA).

3. Subsequently the Area FID reported that the facility was located on Main Adda Road. In front of the factory there was a shop of FazalBroast, TV repairing shop, a clinic, on left there are furniture making shops, Qamar Cotton Industries was also on same road, and beside the industry one house had been built above the shops. The firm had also produced an attested copy (verified) of a letter of Tehseel Officer TMA Okara certifying that Cresent Cotton Industry situated at ChowkDepalpur Road is a commercial / industrial area.

1. The FID in her report concluded that the firm was located in commercial area.

2. Tehseel Officer (P&C), TMA Okara was also requested vide letter No. F. 1-7/84-Lic (Vol-I) dated 20-05-2013 for verification of a separate Industrial Area in Tehsil Okara but the reply is still awaited.

The case was placed before the Board in its 232nd meeting held on 29th & 30th July 2013 for its consideration/ decision, keeping in view along with legal provision of Schedule "B" of Drugs (Licensing, Registering & Advertising) Rules, 1976, also of various industrial incidents/disasters which costed loss of precious human lives as in case of unfortunate incident of M/s Orient Labs, Lahore.

Decision of 232nd meeting

The Board after thorough discussion / deliberation, considering the report of the FID and keeping in view the legal provisions decided as under: -

i. The case should be processed and actions shall be taken as per provisions of Schedule B of Drugs (L, R & A) Rules 1976.
ii. Management of the firm be asked to shift to some Industrial area as there is no provision of Law &Rules that allows Pharma unit in industrial/ commercial area, as per current status of the firm.
iii. Renewal of DML of the firm would be decided in the light of commitment of firm for shifting of their unit to some industrial area as per requirement of Law & Rules.

The decision of the Board was accordingly communicated to the firm and area FID for compliance.
The case was again placed before Board in its 233rd meeting for consideration/decision as under:-

The firm was issued DML in 1978, now, the TMA Okara as requested vide letter No. F. 1-7/84-Lic (Vol-I) dated 20-05-2013 for verification of a separate Industrial Area in TehseelOkara. The TMA, Okara has provided a letter issued by office of TMA, Okara in which the TMA, Okara has informed that the firm is located in commercial/ industrial area as there was no declared industrial area in Okara.

Decision of 233rd meeting of CLB.

The Board decided to verify the letter issued from Tehsil Officer, TMA Okara through Federal Inspector of Drugs. The report shall be submitted before the Board.
The decision of the Board was accordingly communicated to area FID for compliance.

Report of FID in the light of CLB Decision

FID had verified the above said letter from Tehsil Municipal Officer TMA, Okara who had submitted as under: -

"It is clarified that Tehsil Municipal Officer, Okara has no separate industrial area in Tehsil Okara. The office letter No. 302/TO (P&C) dated 05-09-2013 is issued by Tehsil Municipal Administration, Okara".

Accordingly, the case along with its complete background was presented before the Board in its 235th meeting held on 15th May 2014 for consideration/decision.

Decision of CLB in 235th meeting held on 15-05-2014

The Board after thorough discussion/deliberations and in view of facts on ground as narrated above decided to defer the case and provided opportunity of personal hearing to the firm in next meeting of CLB.

Proceedings

Mr. Ch. Shahid Hameed on behalf of Ch. Abdul Hameed Managing Partner / Director appear before the Board and stated his point of view that they may be given 10-15 years period to shift their industry to an industrial area, however, realizing that his request was impracticable, he himself offered that they should be given 03 years period for shifting.

Decision of CLB

The Board considered and deferred for the case with following decisions: -

- **The company shall be directed to submit an undertaking on judicial paper that they will shift their unit to an industrial area within a period of two years.**
- **Environmental Protection Agency shall be requested for inspection of the area surroundings of the firm with regard to the environmental pollution and air particle count.**

M/s Crescent Cotton, Chowk DepalpurOkara has submitted the following documents / information:

a) Environmental Monitoring report.
b) Pak Green Laboratories reports.
c) Stability certificate from District Officer Buildings Division, Okara.
d) Copy of letter of District Officer (environment), Okara.

e) Copy of certificate issued by District Officer Civil Defense Okara.
f) Undertaking from Ch. Abdul Hameed, Proprietor of M/s Crescent Cotton Factory, Okara which states that:-
   - I undertake that I am the Director of M/s Crescent Cotton Factory, Okara.
   - I undertake that M/s Crescent Cotton Factory, Okara located at Depalpur Chowk, Okara where many other factories are also located.
   - I undertake that as soon as Industrial Area is declared in Okara City I will shift my factory in the respective industrial area.
   - I undertake that all above information is to my best knowledge and there is nothing kept hidden.

Decision of CLB.

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 Schedule B-II of Rule, 20 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug Manufacturing Licence No. 000517 (Formulation) of M/s Cresent Cotton, Okara may not be suspended or cancelled by Central Licensing Board.

Case No.19. <u>M/S CAYLEX PHARMACEUTICALS (PVT) LTD, LAHORE.</u>

The area Federal Inspector of Drugs, Mr. Zia Hussnain visited the firm on 08-11-2016 and submitted the report the report contains some observations related to Licensing divisions which are as under:

> **"The production of the firm was stopped by the area F.I.D till the appointment of production and Quality Control Incharge and submission of their documents to CLB for approval. However when on 08-11-2016 F.I.D visited the firm to verify the production status it was found that firm was manufacturing the capsule ,rests of all section were not operational, QC Incharge was absent and Mr. Akbar Malhi was claiming as Production Incharge was present in firm could not provide any document regarding appointment and approval of production and QC Incharge."**

It is submitted that the manufacturing of Drugs without approved technical staff is violation of Rule 16 of the Drugs (Licensing, Registering and Advertising) Rule, 1976. Proceeding may be initiated for suspension or cancellation of Drug Manufacturing License under section 41 of the Drugs Act, 1976 and rules framed there under.

Decision of CLB.

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 their Drug Manufacturing Licence No. 000451 (Formulation) M/S Caylex Pharmaceuticals (Pvt) Ltd, Lahore, may not be suspended or cancelled by Central Licensing Board.

Case No.20. DELEGATION OF FUNCTIONS / POWERS.

The Central Licensing Board approved and delegated its powers retrospectively with certain modifications to its Chairman and Secretary under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) rules, 1976 in order to facilitate timely disposal of routine and day to day business of Central Licensing Board.

Function	Previous power delegated in 237th meeting	Proposed Delegation
Site Approval & Rejection	Secretary CLB	Chairman CLB

Decision of CLB

The Board approved the above proposal.

Case No.21. SITE VERIFICATION OF M/S HUSSSAIN PHARMACEUTICALS, 41-KM, FEROZEPUR ROAD DISTRICT KASUR.

M/s Hussain Pharmaceuticals have applied for the site verification of their proposed site located at 41-Km,Ferozepur Road , District Kasur , The area F.I.D Mr. Abdul Rashed sheikh visited the proposed site and submitted his recommendations as under;

Location: -
The proposed site is located at firms 700 meters inside from main 41-KM main Ferozepur Road, then 18 feet vide passage leads to the site behind the Bismillah Dyeing factory.

Recommendations: -
As the Bismillah Dyeing factory has a boiler where the dyeing factory is using wood for steam generation which is causing the smoke and the same time the Madinah Steel Industry and the nearby residential houses and the only a 18 feet wide passage which cannot fulfill the emergency conditions of any accident, from where fire-tenders cannot cross each other. The above observations led to the conclusion that the site is not suitable as of today for establishing a pharmaceutical unit.

Decision of CLB.

The Board on the recommendations of the Federal Inspector of Drugs decided to reject the proposed site of M/s Hussain Pharmaceuticals located at 41-Km,Ferozepur Road , District Kasur for establishment of Pharmaceutical unit.

Case No.22. CLOSURE OF PHARMACEUTICAL UNIT OF M/S VETGRO PHARMACEUTICAL (PVT) LTD, LAHORE.

Background of the Case.

The case of M/s Vetgro Pharmaceutical (Pvt) Ltd, Lahore was placed in agenda of 233rd meeting of CLB held on for consideration of the Board as under: -

Inspector Drugs, Lahore, has visited M/s Vetgro Pharmaceuticals (Pvt) Ltd, Multan Road, Lahore on 14-03-2013 and he has stated that firm was found closed. The FID has reported the following points in its report: -

i) The firm's three security guards were present at the main gate of the firm. They did not allow to undersigned to enter the main gate. They stated that they do not have the keys of the main building (production area). One of them Mr. Zulqarnain informed that they are employees of a security company and he is appointed here for the last seven months. He further informed that he does not know about the owners of the firms and since his duty here the firm was close and no production activity is seen.

ii) Ex Area FID Mr. Asim Rauf had also visited the firm on 01-03-2012 and found the same status. Letters have also been written to the firm to explain its position in this regard on 01-03-2012 and 17-05-2012. However, neither any reply received nor any person contacted even after the lapse of one year.

iii) Undersigned also tried best to contact the Chief Executive of the firm or any other person responsible but to vain. All the contact numbers landline/mobile as per office record is either unattended or disconnected. However, it is learnt from some other market competitors that the management has closed the firm due to some partnership/family disputes.

iv) As it appears from the above submission that the firm is not functional for more than one year and as non of the owner or any other responsible person is available and as the premises is not accessible to area FID and as the conditions of the license as per the Drug (Licensing, Registering and Advertising) Rules, 1976 are not being maintained. **It is recommended that the Drug Manufacturing License bearing No. 000650 dated 30-01-2009 issued in favor of M/s VetgroPharmaceuticals (Pvt) Ltd may be cancelled/ suspended under rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.**

2. Keeping in view the above, **Show Cause** notice was issued to the firm vide letter dated 8th May 2013. The firm was also asked to appear before the CLB in its next meeting if want to be heard in person. 3. In response Mr. FaizRasool Chief Executive of the firm has submitted his reply in which he has denied that the FID has contacted him and written him letters. He has further stated as under:

a) That there are severe financial crises of the country and that there is no gas no electricity no working environment, labor problems business migrations no more investment on business to create jobs. So in this environment everyone is in problem; to meet electricity bills, wages of employees, unsustainable low production volumes, high costs of production and unaffordable circumstances and inevitable expenditures. These are the major factors that we are unable to run the factory at full momentum and capacity and at all levels. In our area light goes from 16-18 hours a day. So how can we work? It is a multimillion investment at stake because of the bad conditions of country.

b) That they have done big investment and are eager to bring up factory in full working position otherwise will shift from Pakistan.

c) That country slams massive power load shedding and all chambers of commerce have expressed serious concerns over the poor response of Government towards unprecedented energy shortage of the industry.
d) That the Show Cause notice has been issued on one and first visit of FID and false report of formal FID. I think they must be friendly with the companies rather to indulge in wrong goings. They try to create easiness to industrials to create problems.
e) That I have done nothing wrong. There is no fault on my part and I am sent show cause notice and not known to reason. I therefore request the competent authority to look into the matter sympathetically and oblige.

Keeping in view the above, **Show Cause** notice was issued to the firm vide letter dated 8th May 2013. The firm was also asked to appear before the CLB in its next meeting if want to be heard in person. 3. In response Mr. FaizRasool Chief Executive of the firm has submitted his reply in which he has denied that the FID has contacted him and written him letters. He has further stated as under:-

a. That there are severe financial crises of the country and that there is no gas no electricity no working environment, labor problems business migrations no more investment on business to create jobs. So in this environment everyone is in problem; to meet electricity bills, wages of employees, unsustainable low production volumes, high costs of production and unaffordable circumstances and inevitable expenditures. These are the major factors that we are unable to run the factory at full momentum and capacity and at all levels. In our area light goes from 16-18 hours a day. So how can we work? It is a multimillion investment at stake because of the bad conditions of country.

b. That they have done big investment and are eager to bring up factory in full working position otherwise will shift from Pakistan.

c. That country slams massive power load shedding and all chambers of commerce have expressed serious concerns over the poor response of Government towards unprecedented energy shortage of the industry.

d. That the Show Cause notice has been issued on one and first visit of FID and false report of formal FID. I think they must be friendly with the companies rather to indulge in wrong goings. They try to create easiness to industrials to create problems.

e. That I have done nothing wrong. There is no fault on my part and I am sent show cause notice and not known to reason. I therefore request the competent authority to look into the matter sympathetically and oblige.

The firm was asked to appear before the Board in its last meeting for personal hearing to clarify their position on the subject matter.

CLB taken in 233rd meeting held on 30-31 December, 2014 considered and decided as under:

"The representative of the firm was called for personal hearing in the light of previously served Show Cause Notice but no any representative attended the meeting, so Board deferred the case for final opportunity of personal hearing".

Decision in 234th meeting of CLB

The Board after thorough discussion / deliberations and facts on grounds deferred the case for: -

- **Obtaining latest status of firm by panel comprising of Dr. IkramulHaq Member CLB, Ahmad MehmoodMumtaz CQC, DDG (E&M) Lahore and Area FID, Lahore.**
- **Opinion from Law Division that the firm has been called twice for personal hearing before CLB but did not appear for personal hearing so whether CLB can decide for suspension / cancellation of Drug Manufacturing License of firm ex-parte under section 41 of Drugs Act, 1976.**
- **Last and final opportunity of personal hearing in the forthcoming meeting of CLB and personal hearing letter shall be sent through Registered Post and receipt of same shall be retained.**

Proceedings

Accordingly, the above panel visited the firm on 08-04-2014 and submitted its report as under: -

a. Owner of the company Mr. FaizRasool was tried to be contacted telephonically but in vain, as all phone numbers as per office record were either unattended or disconnected.

b. The firm was inspected physically on 08-04-2014 at about 10:45 am. The main gate of the firm was closed. No person (gate keeper, security guard etc) was present at the gate. The gate was knocked may times but no response was received from inside.

c. The panel members tried to contact the neighbors for getting some witness. On the left side of the firm was a goods company namely M/s Al-Sheikh Goods Transport Company, but that company was also closed and gate was locked and there was no gatekeeper. On the right side of the firm was an empty land.

d. As per inside view from the gate it appeared that the was no activity in the main building at the tie of inception. The drive way on outside and inside of the gate seemed to be rarely used as grass was grown. Some photo graphs were also taken as a witness of physical situation.

e. One member of the panel Dr. Ahmad Mahmood Mumtaz, CQC informed that he has contacted the owner of the firm Mr. FaizRasool on 07-04-2014 telephonically through mobile number (0300-8416524) obtained from market. The owner Mr. FaizRasool informed the Chairman QC/member of the panel that he has voluntarily closed the firm because of number of personal reasons including financial constraints.

Current Status of Firm

Letter received from Mr. AjmalSohail Asif (Federal Inspector of Drugs Lahore) dated 14-04-2016 in which the FID has submitted a surprise inspection report to check the latest status of M /s Vetgro Pharmaceuticals (Pvt) Ltd, 38-Km, Multan Road, Lahore as under: -

"The main gate of the firm was found closed. No person (gatekeeper, security guard etc.) was present at the gate. The gate was knocked many times but no response was received from outside. Undersigned also visited the other side of the premises to check the presence of any other gate / entrance but it was surrounded by agricultural land and there was no other gate / entrance except the front main gate. As per inside view from the gate it appeared that there was no activity in the main building at the time of inspection. The driveway on outside and inside of the gate seemed to be rarely used, as grass was grown.

In the light of previous inspections conducted on 14-03-2013 and 01-03-2016 (by area FIDs) and 08-04-2014 (by a panel on the directions of CLB) and considering the observations of instant visit, it appears that the firm is not functional for more than four years and as none of the owner or any other responsible person is available and as the premises is not accessible to area FID and as the conditions of the license as per the Drug (Licensing, Registering and Advertising) Rules, 1976 are not being maintained, it is therefore, recommended that the Drug Manufacturing Licensing bearing No.000650 dated 30-01-2009 issued in favor of M/s Vetgro Pharmaceuticals (Pvt) Ltd, 38-Km, Multan Road, Lahore may be cancelled / suspended under rule 12 of the Drug (Licensing, Registration and Advertising) Rules, 1976".

Decision of CLB.

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, 19 and 20 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug Manufacturing Licence No. 000650 M/s vetgro Pharmaceuticals (Pvt) Ltd, 38-Km, Multan Road, Lahore may not be suspended or cancelled by Central Licensing Board.

Case No.23. RENEWAL OF DRUG MANUFACTURING LICENCE M/S HUMAYUN INTERNATIONAL PHARMA (PVT) LTD, FAISALABAD.

M/s Humayun International Pharma (Pvt) Ltd, 20-KM Satiana Road, Faisalabad has applied for renewal of DML No. 000443 by way of formulation for the period of 26-11-2014 to 25-11-2019 on 14th November, 2014.

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 12th December, 2014 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Nothing Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of CRF valid upto 31-12-2014.

ii. List of total sections f the firm as per approved layout plan by the competent authority.

iii. List of sections under construction / not constructed as per approved layout plan by the competent authority.

iv. As per available record of licensing Division, DRAP, Islamabad, CLB in its 130th meeting held on 10th November, 19897 approved the grant of DML No. 000443 (formulation) to your firm for manufacturing of Injectable (ampoule only). I t has been noticed in your application for renewal of DML that firm also possess registrations of products for (i) Sterile Dry Powder Injectable Vials (General) (ii) Injectable Dry Powder Vials (Cephalosporin) (iii) Sterile Liquid Vials/Infusion (General) therefore you are required to furnish proof of grant of above mentioned sections form CLB.

v. Copy of latest Form-29 issued and attested by Security Exchange Commission of Pakistan along with attested photocopies of CNICs of all the Directors as per Form-29.

Later on with reference to above shortcomings / deficiencies a reminder letter was issued on 3rd November, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976. The firm has submitted their reply on 22nd November, 2016 which is evaluated and still found following shortcomings / deficiencies:-

i. Updated Nothing Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of CRF.

ii. Proof of sections from CLB.

Decision of CLB.

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) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of Drug Manufacturing Licence No. 000443 by way of formulation M/s Humayun International Pharma (Pvt) Ltd, 20-KM Satiana Road, Faisalabad may not be rejected by Central Licensing Board.

Case No. 24. <u>DEMOLITION OF PREMISES OF M/S GUYTON PHARMACEUTICALS, 25.5 KM, RAIWAND ROAD, LAHORE</u>.

BACKGROUND:

M/s Guyton Pharmaceuticals, 25.5 KM, Raiwand Road, Lahore bearing Drug Manufacturing Licence No. 000548 (Formulation) was granted licence on 26 October,2004. Now, Federal Inspector of Drugs, Lahore has forwarded an inspection report whereby he has mentioned that Guyton Pharmaceuticals, 25 .5 KM, Raiwand Road, Lahore has been acquired by the Government of Punjab. Firm is under process of demolishing and machinery is being shifted to ware house under the explained circumstances by firm and physical verification M/s Guyton Pharmaceuticals, 25.5 KM, Raiwand Road, Lahore does not exist as per Drugs Act, 1976 including rules framed there under.

2. It is also submitted that M/s Guyton Pharmaceuticals, has informed that they have purchased a plot measuring 16 kanal& 13 Marlas for shifting of their already existing registered pharmaceutical company, Gyton Pharmaceutical (DML No. 000548) due to the acquisition of Land by Ring Road Authority Govt of Punjab. They have made an application for verification of site at 4 KM, Raiwand-Manga Road, near addaKharaKhoh, Lahore. Site has been verified and Building Lay out Plan is under approval.

DECISION OF 250TH MEETING OF CLB:

The Central Licensing Board deliberated and decided as under:

i. The firm may be issued show cause notice for suspension / cancellation of Drug manufacturing License.

ii. Report from Government of Punjab may be obtained regarding inspection of the said firm carried by the task force constituted by the Government of Punjab, as informed by one of the member of Central Licensing Board during the meeting.

iii. Panel including Dr. IkramulHaq, Member CLB, Additional Director (E&M), Lahore and area Federal Inspector of Drugs to re- verify the current status with reference to previous inspections of the facility with clear and candid recommendations for consideration of Board

PROCEEDINGS OF THE BOARD IN ITS 251ST MEETING.

Letters in the light of the decision of the Board has been issued. Show cause notice has also been issued to the firm. Firm has been called for personal hearing.

DECISION OF THE CLB IN 251ST MEETING

The Board deliberated on the facts mentioned above and latest inspection report of the Federal Inspector of Drugs, Lahore decided to cancel the Drug Manufacturing License No. 000548 by way of Formulation of M/s Guyton Pharmaceuticals, 25.5 KM, Raiwand Road.

The Orders of Honorable Court were received before convene of order of Central Licensing Board.

WRIT PETITION NO. 4067/2016 OF M/S GUYTON PHARMACEUTICALS VS FEDERATION OF PAKISTAN.

M/s Guyton Pharmaceuticals, Lahore has filed a writ petition No.4067/2016 in honorable Lahore High Court Lahore in which they pray to Court that proceedings against the petitioner by the respondents, show cause notice and all further proceedings may very graciously be declared as without lawful authority, unlawful; unconstitutional; against the well settled principle of law laid down by the Apex Court of Pakistan; and also against the well settled principles of Natural Justice as such are of no legal effect, to meet the ends of justice.

It is further prayed that in the meanwhile the respondents may very kindly be directed that they shall not pass and issue any adverse order against the petitioner and further proceedings may very graciously be stayed against the petitioner, in the interest of justice.

Court Orders

Learned counsel for the petitioner feels satisfied if a direction is given respondent No. 2 to look into the grievance of the petitioner and decide the same in accordance with law. Learned Standing Counsel on Court call has no objection in this regard.

Let a copy of this petition along with its annexure be remitted to respondent No. 2 to treat it as well as written reply submitted by the petitioner on 20-12-2016 as reply to the show cause notice dated 25-11-2016 issued to the petitioner and decide the same in accordance with law after giving opportunity of hearing to the petitioner. Needful shall be done within six weeks commencing from the date of receipt of certified copy of this order. In the meanwhile, no adverse order shall be passed against the petitioner. **Disposed off.**

Proceedings of Licensing Division.

In compliance of above Court Orders, the Licensing Division has issued letter to the firm for personnel hearing before Central Licensing Board. Mr. Bilal Khurshid Siddiqui, Chief Executive Officer of M/s Guyton Pharmaceuticals, 25.5 KM, Raiwand Road, Lahore appeared before the Board. He made verbal statement before the Board that his factory premises has been acquired by the Government of Punjab for Ring Road Project. Building of Factory has been demolished by the Government of the Punjab. His case may be considered on humanitarian ground and he may be

allowed products on toll manufacture by any other firm as he may continue his survival and livelihood of family.

Decision of CLB.

The Board after hearing the representative of the firm M/s Guyton Pharmaceuticals, 25.5 KM, Raiwand Road, Lahore and facts on record decided to:

i. Cancel the Drug manufacturing Licence No. 000548 of M/s Guyton Pharmaceuticals, 25.5 KM, Raiwand Road, Lahore.

ii. Refer the case to the Drug Registration Board for considering the request of M/s Guyton Pharmaceuticals, 25.5 KM, Raiwand Road, Lahore for toll manufacturing as per law.

Case No. 25. <u>ORDERS OF HONORABLE LAHORE HIGH COURT, LAHORE REGARDING WRIT PETITION NO. 10988/2007 FILED BY M/S MICKOINDUSTRIAL CHEMICALS CO. (PRIVATE) LIMITED, 28-KM FEROZEPURROAD, LAHORE.</u>

The complete case background is narrated in chronological order as follows:

1. M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore submitted application for renewal of Drug Manufacturing Licence (DML) # 000183 (Formulation) for the period 17-11-2005 to 16-11-2010 for which a panel was constituted on 23-09-2005. The panel conducted inspection on 20-07-2006 of the Company for renewal of DML and submitted report on 17-08-2006 wherein a number of observations/shortcomings were reported. The Company submitted an undertaking that it would remove the shortcomings as pointed out by the panel within 15 days.

2. The Licensing section of Ministry of Health (Defunct) issued a letter to Federal Inspector of Drugs, Drugs Control Administration (now DRAP), Lahore, wherein it was stated that the firm has submitted an under taking to the panel stating that it will rectify the shortcomings as pointed out by the panel dated 20-07-2006, but the compliance report concerning the same was not been received, therefore, the Area FID was requested to verify the same and submit report within 07 days positively.

3. The Area Federal Inspector of Drugs (FID), inspected the premises on 30-10-2007, along with Mr. Ghazanfar Ali Khan, Assistant Drug Controller (ADC), Lahore to check the rectification of shortcomings as pointed out by the panel during its inspection dated 20-07-2006. The Area FID submitted inspection report wherein a number of serious GMP non-compliance were observed and it was suggested by the Area FID, that production of the firm be stopped and renewal of DML may not be considered in the light of critical shortcomings observed and due to failure of the commitment given by the Company to remove the deficiencies as pointed out by the panel during its previous inspection.

4. During the inspection, Area F.I.D took the samples of drugs, for the purpose of test and analysis and reported that the owner of company snatched the box of samples along with form- 3 from the driver (Mr. Ismail) of Area FID. Area F.I.D along with ADC, Mr Ghazanfar Ali Khan launched a F.I.R in the concerned police station (Khana) and also sealed the premises on the violation of provisions of Drug Act, 1976 and rules framed there under, with the assistance of police.

5. The Company was then served a Show Cause Notice on 19th November 2007 by the Central Licensing Board (CLB) and was directed to submit reply to the Show Cause within 15 days.

6. However, in the meanwhile, Mr. Khurshid Alam Sheikh filed a Writ Petition No. 10988/2007 in Honorable Lahore High Court, Lahore through his counsel against the sealing of his premesis of M/s Micko Industrial Chemicals Co. (Private) Limited located

at 28-km Ferozepur Road, Lahore requesting the Court to declare the **sealing order illegal and for award of cost incurred on this petition**. The Court issued Order dated 07-11-2007 wherein the Court suspended the sealing order of the Area FID till next date of hearing without hearing the respondent (Area FID). The Court also ordered for submission of reply and para-wise comments.

7. In compliance to the Court Order dated 07-11-2007, Area FID along with Mr. Ghazanfar Ali Khan ADC visited the premises on 14-11-2007 to de-seal the factory but surprisingly found that the seals were already broken and production of drugs was already in process. The Area F.I.D reported the same to the honorable High Court, Lahore and to the Central Licensing Board.

8. The Secretary Licensing Section of the Central Licensing Board, issued a letter on 05th December 2007, to the Company wherein it was stated that the Board has been informed by the Area FID about the unlawful de-sealing of premesis and resumption of production by the Company upon its inspection dated 14-11-2007. The same is a violation of Rule 13 of the Drugs (Licensing, Registering & Advertising) Rules 1976. therefore, the Company was directed to suspend the production with immediate effect till removal of the deficiencies and re-inspection by the panel and approval of Central Licensing & Registration Board.

9. Meanwhile, M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore filed another Writ petition No. 11889/2007 whereby orders for suspension of production by the Central Licensing Board were challenged.

10. The honorable Lahore High Court, Lahore passes an Order dated 23-04-2015 in Writ Petition # 10988/2007 & 11839/2007 which is reproduced as under :

Mr. Bashir Ahmad Tariq, Advocate for the Petitioner.
Ms. Saadia Malik, learned Standing Counsel for Pakistan along with Ayesha Irfan, Federal Inspector Drugs.
Through this single order I intend to dispose of writ petition Nos. 10988 and 11889 of 2007 as both are based on common facts.
2. In W.P NO. 10988/2007 order dated 30-10-2007 is challenged whereby the factory of the petitioner was sealed for violation of Section 27 (3) and other provisions of the Drugs Act, 1976 and also for the reason that owner of the factory namely Khurshid Alam Sheikh had snatched samples taken from the factory premises by the Federal Drug Inspector.
3. Facts, which have surfaced after arguments from both sides, are that he inquiry report was being prepared by the Federal Drug Inspector when samples of some illegal drugs were allegedly snatched by the owner of the factory. Stately, due to violation of the statutory provisions and the illegal act by the owner, the factory premises were sealed. As per learned Standing Counsel's assertions, the factory was de-sealed illegally and production was commenced by the petitioner, therefore, another order for suspension of production was passed.
1. Due to multiplicity of litigation, facts of the case are confused. It is asserted by the petitioner that its factory is sealed and production is suspended whereas learned Standing Counsel submits that the production is being carried out illegally at the sealed premises.

5. Be that as it may, it is settled proposition that this Court cannot look into factual

controversies in exercise of its constitutional jurisdiction. For resolution of dispute on facts as well as on legal side, this matter is referred to Central Licensing Board, before which report has already been filed by the Federal Drugs Inspector. The Board shall provide opportunity of being heard to the petitioner and shall pass a speaking order within 45 days positively under intimation to the Deputy Registrar (Judicial) of this Court.
Till decision no coercive measures shall be taken

11. Against the aforementioned order of the honorable High Court, M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore filed Inter Court Appeal.

The Orders of the Honorable Court in Intra Court Appeal are as under: -

"For what has been discussed above this Court is of the view that present appeals have not been filed by an authorized person therefore they being incompetently filed are not maintainable and are thus dismissed".
"For the reasons recorded in judgment of even dated passed in ICA No. 653-2015, this Intra Court appeal is dismissed". (Announce Date 26-01-2016)

12. <u>Proceedings of Licensing Division:</u>

Licensing Division placed the case before the Central Licensing Board and the Board deliberated the case in its 241st, 243rd, 247th, 250th , 251st and 252nd meetings. The Board deliberated the case in detail and issued notice for personnel appearance/hearing to the petitioners, Federal inspector of Drugs and witnesses Mr. Ghazanfar Ali Khan (ADC), and Mr. Ismail (Driver).

13. <u>The statement of Mrs. Aisha Irfan, Federal Inspector of Drugs is reproduced as under</u>*;*

"The inspection of M/s. Micko Chemical Industries (Pvt.) Ltd., was conducted on 30-10-2007 alongwith Mr. Ghazanfar Ali Khan, Assistant Drugs Controller, Lahore vide the defunct Ministry of Health, Islamabad letter No. F.1-16/85-Lic (Vol-II), dated 29-07-2007 to check the rectifications of shortcomings pointed-out in previous inspection conducted for the renewal of DML.

It was noticed at the time of inspection that the firm did not rectify the shortcomings and overall condition of the firm was very deplorable, hence clear violations of GMP were observed.

Meanwhile, the samples of the drug Gentian Violet Paint Batch No. G/000404, Wax Aid, Batch No. SG/0142 and Tincture Iodine Batch No. TID/003156, were taken for test / analysis purpose. Mr. Khurshid Alam the owner of the firm behaved in a very harsh manner and snatched the samples alongwith form-3 from the driver of the undersigned. He created obstruction in the official duty of the Federal Inspector of Drug, and took away the box of samples and Form-3 with him and left the factory with his wife Mrs. Rubina Khursheed, Chief Pharmacist of the factory. He did not provide the inspection book on demand. The Drugs Controller and Deputy Director General (E&M), Lahore at that time were informed and the Drugs Controller directed, to lodge FIR immediately and seal the factory.

FIR No. 1257/07 dated 30-07-2007 was lodged against Mr. Khurshid Alam, under section 27(3) of Drug Act, 1976 with section 186/506PPC at Police Station, Khana. The factory was sealed in the presence of Assistant Sub Inspector and Head Constable.

The firm had taken interim order from High Court for de-sealing of premises. The undersigned visited the factory on 12-11-2007 as per High Court order in writ petition No. 10988/2007 to de-seal the factory. It was noticed that the seals were already broken and the factory was already opened and illegal production was going on. The order of the court was just to de-seal the factory and the production of the factory was not allowed. The undersigned informed the High Court and the Chairperson, Central Licensing and Registration Board of the above position. The case was referred to Chairperson Central Licensing & Registration Board.

The show cause notice to the firm was issued vide Ministry's letter No. 1-16/85-Lic (Vol-II) dated 19th November, 2007. The production of M/s. Micko Chemical Industries (Pvt.) Ltd. was suspended vide Ministry's letter No. F.1-16/85-Lic (Vol-II) dated 30th November, 2007.

The owner of the firm Mr. Khursheed Alam filed Writ Petition No. 10988/2007 in the High court and three cases of damages against the undersigned in the civil court just to create harassment. The cases are still at different stages in courts as cited below.

S.No.	Name of Court.	Title of Case	Nature of case
01	In the Court of Qazifi Bin Zair Civil Judge, Lahore.	Mrs. Rubina Khurshid Wife of Khurshid Alam, Chief Pharmacit, Micko Indu. Chemical Co., (Pvt.) Ltd., Ferozepur Road, Lahore Vs. Mst. Aisha Khalil, FID, Lahore.	For damages Rs. Ten Million.
02	In the Court of Mr. Khalid Mehmood, Civil Judge, Lahore.	Khurshid Alam, Sh. R/o/ 50-C, F.C.C., Ch Zahoor Elahi Road, Gulberg, Lahore Vs. Mst. Aisha Khalil, FID, Lahore.	For damages Rs. 150,40,000/-
03	In the Court of Mr. Hymoon Pervaiz, Civil Judge, Lahore.	Khurshid Alam, Sh. R/o/ 50-C, F.C.C., Ch Zahoor Elahi Road, Gulberg, Lahore Vs. Mst. Aisha Khalil, FID, Lahore.	For damages Rs. 130,40,000/-

One case of complaint was filed by Mr. Khursheed Alam in Special Judicial Magistrate Lahore, Cantt which the undersigned won and acquitted, the judge gave 08 page judgment in the favor of undersigned stating that the acquittal of the accused is accepted as being on merit and complaint is herby dismissed.

It is pertinent to mention here that the firm is involved in the illegal manufacturing of drugs to date, as the production of the firm was suspended and the firm's Drug Manufacturing License was not renewed as two times the panel inspected the firm for the Renewal of DML in year 2007 and 2011 and in both the inspections serious short comings were pointed out by the panel. Moreover, it is asserted by the petitioner in the High Court that his factory is sealed and production is suspended, where as learned standing counsel submits that the production is being carried out illegally at the premises, as mention in the Lahore High Court order dated 23-04-2015. Moreover, the drugs manufactured by M/s. Micko Industries are freely available in the market.

It is submitted that all the actions were taken on the directions of the Central Licensing & Registration Board as per Drugs Act, 1976 and rules framed there under, hence no malafide intentions were involved, and the actions were taken in Good Faith by

the undersigned. The undersigned was not given counsel in the damages cases and in the case of complaint filed by Mr. Khursheed Alam in Special Judicial Magistrate Lahore, Cantt and the lawyers were hired by the undersigned personally and fees paid to them from own pocket. The purpose of Mr. Khursheed Alam owner of M/s. Micko Industries is being fulfilled by creating harassment to the undersigned for the last 09 years, while he is doing illegal business without any fear, hence endangering public life.

It is therefore humbly requested that strict action against Mr. and Mrs. Khurseed Alam owner/Chief Pharmacist of M/s. Micko Industrial Chemical Co., be taken such as the plaintiff be given due punishment under provision of Section 27 (3) and (4) of Drugs Act, 1976 with imprisonment of five years and fine, his DML be cancelled as he is involved in the illegal manufacturing of drugs. Hence in order to curtail these type of illegal practices in future such as taking law in their own hands by creating harassment and hurdles in the official duties of FIDs stringent action is required. Moreover, it is also requested to give counsel to the undersigned in all the damages cases filed by Mr. Khurseed Alam as the actions were taken in official capacity and in good faith. The damages suits are barred under Section 38 of Drugs Act, 1976 and also liable to be dismissed under Section 07 Rule 11 of the CPC and the compensation of Rs: 200,000/- be given to the undersigned for the fees already paid to lawyers in the last 09 years till to date."

14. **The statement of *M/s. Micko Chemical Industries (Pvt.) Ltd., which was represented by the following persons.***

1. Mr. Khursheed Alam, Director Admn

2. Mr. Shahyar Alam, Assistant Production Manager

Mr. Khursheel Alam, (Director Admin) in his verbal statement before the Board stated that he did not snatched the box of samples but has voluntarily provided same to the Federal Inspector of Drugs, however later he asserted that the Federal Inspector of Drugs was not authorized to inspect his factory and the action of Federal Inspector of Drugs was totally unlawful and illegal.

Mr. Khursheed Alam further stated that he has obtained a suspension Order against the decision of the Central Licensing Board from the High Court, Lahore. However, he was unable to provide the copy of the said Order but committed that same will be provided upon his return to Lahore. The Board advised that he may submit the copy of the Order within 07 days. He also admitted before the Board that the production in his factory is continued till date.

The Board requested to submit his asserted facts in writing but he has refused to accede to Board's request. Further, he has not provided such orders of the High Court till date.

15. **<u>Statement of Mr. Ghazanfar Ali Khan is as under:-</u>**

With reference to Secretary, Central Licensing Board (CLB) letter No. F.1-16/85-Lic (Pt) dated 08-03-2016, the undersigned appeared before the CLB for recording statement in subject mentioned case. Accordingly, the written statement is as under:-

1) That the undersigned being ADC, Lahore accompanied Mrs. Aisha Irfan, FID, Lahore to assist her in inspection of M/s Micko Industrial Chemicals Company (Pvt) Ltd, 28-KM Ferozepur Road, Lahore on 30-10-2007.
2) That during inspection of the manufacturing unit critical MP non-compliance of the firm was observed for which a detailed report was written / forwarded by FID.
3) That the FID, took drug samples for test / analysis from the premises of the company and Mr. Muhammad Iqbal (Naib Qasid) handed over them to Mr. Muhammad Ismail, Driver to keep them in the official jeep parked nearby the manufacturing area.
4) That the FID and the undersigned asked the owner / management namely, Mr. Khurshid Alam to provide the inspection book so as to write the inspection report in the premises but he flatly refused to accede t despite repeated requests.
5) Meanwhile Mr. Ismael, driver rushed in to the premises where the undersigned and the FID were standing and informed that the owner Mr. Khurshid Alam took the samples from him on the pretext to see the stamp on the samples and on handing over the drug samples, Mr. Khursheed Alam fled away in his car from the premises of the manufacturing unit.
6) Later, on the same day, an application was given in Police Station Kahna Nau and subsequently an FIR was lodged and the factory was sealed with the assistance of the police at around 9:00 pm.
7) After few days the undersigned accompanied the Area FID to the premises of aforementioned company for de-sealing and found out that the sealed were already broken and the production was in progress.

16. <u>Statement of driver Ismail is as under: -</u>

1) That the undersigned being driver of the FID, Lahore, namely, Mrs. Aisha Irfan accompanied her along with Dr. Ghazanfar Ali Khan, ADC to M/s Micko Industrial Chemicals Company (Pvt) Ltd, 28-KM Ferozepur Road, Lahore on 30-10-2007.
2) That the FID, took drug samples from the premises of the company. Mr. Muhammad Iqbal (Naib Qasid) brought the samples and handed over to me for keeping the same in the official jeep.
3) While FID and ADC were busy in inspection in the Production Area, the owner Mr. Khurshid Alam in the presence of Mr. Muhammad Iqbal asked the undersigned to handover the drug samples to him in order to see the stamp on the drug samples. I handed over the drug samples and he kept them in his car and fled away from the premises of the company.
4) I rushed inside to inform the FID and ADC.
5) Later on FIR was lodged in Kahna Nau Thana and factory was sealed with the assistance of the police.

Decision of 252nd meeting of CLB :

The Board provided a fair opportunity of being heard in person to both the Parties i.e M/s. Micko Chemical Industries (Pvt.) Ltd. represented by Mr Khurshid Alam (Director Admin) and the Area Federal Inspector of Drugs (FID) Mrs. Aisha Irfan along with their witnesses. After a great deal of deliberations on the facts and in the light of the statements made by the Parties and their witnesses, the Board concludes as follows:

i) That the allegation leveled by the Area FID against Mr. Khurshid Alam, Director Admin / owner of the firm that he has behaved in a very harsh manner and snatched the samples along with form-3 from the driver (Mr. Ismail) at the time of inspection.

ii) This fact is corroborated by the verbal as well as written statement of the Driver (Ismail) who has confirmed that Mr. Khurshid Alam, took away the box of samples along with Form 3 from him by deceptive means by saying that he only wants to check the stamp on the samples.

iii) Mr Ghazanfar Ali Khan ADC, who accompanied FID at the time of inspection, also confirmed in his statement that after the samples were taken away by Mr. Khurshid Alam, the driver (Ismail) came rushing to FID and informed her that Mr. Khurshid Alam took away the samples from him on the pretext to see the stamps but did not return and took them away.

iv) Mr. Khurshid Alam in his verbal statement admitted before the Board that he got the box of samples along with form 3 from the Driver. His refusal to narrate the facts and his verbal statement into writing, confirms the fact that he got hold of the box of samples along with Form 3 without any lawful cause which tantamount to causing resistance in the lawful authority of the public servant in the discharge of public functions. Further the refusal to give statement in writing, leaves the Board with no option except to draw a negative inference against Mr. Khurshid Alam.

v) The other allegations that the seals of the factory were unlawfully broken and production was in progress at the time the Area FID visited to de-seal the factory in compliance with the order of the Honorable High Court. Mr. Khurshid Alam admitted verbally during the course of personal hearing that the production was in progress when the Area FID visited the factory.

vi) Moreover, there are no orders as to the resumption of production passed by the Board after same was suspended. Resumption of production without orders by competent authority amounts to violations of the provisions of the Drug Act, 1976 and Rules framed thereunder.

vii) In consideration to the foregoing facts the Board is of unanimous view that violations of the provisions of the Drugs Act 1976 and the Rules framed there under have been committed. So, a SHOW CAUSE NOTICE should be issued to provide an opportunity of being heard as required by the Drugs Act 1976 and the Rules framed there under.

Case No.26. M/S ELIXIR LABORATORIES (PVT) LTD, 26-S, INDUSTRIAL AREA, KOTLAKHPAT, LAHORE.

Background of the Case: -

The Area FID, Lahore visited the firm M/s Elixir Laboratories (Pvt) Ltd, 26-S, Industrial Area Kot Lakhpat, Lahore, on 12-03-2013 to check the GMP compliance and observed severe shortcomings and management was advised to improve their manufacturing and testing SOPs along with their strict compliance and improve the condition of manufacturing area till shifting, to their new premises which was already under completion, at the earliest because no further structural changes can be advised in this premises due to space constraint.

Later on DRAP, Islamabad issued Show Cause Notice / Stop Production order vide DRAP, Islamabad letter No. F4-9/2001-QC, dated 06-05-2013. The firm in response instead of replying to the Board, preferred to file a writ petition in the Honourable Islamabad High Court, Islamabad. The Honourable Court in its order dated 27-05-2013 suspended the show cause notice to the extent to stop manufacturing of drugs till next date of hearing.

The panel comprising of following experts / inspectors visited in compliance to the order dated 11-01-2017 of Honourable Islamabad High Court, Islambad by a team constituted by the Honourable Court.

1. Mr. Faqeer Muhammad Sheikh, Chairman CLB, DRAP, Islamabad.
2. Dr. IkramulHaq, Ex Director DTL, Lahore / Ex member CLB.
3. Dr. Abdul Rasheed, Additioanl Director, QA, DRAP, Islamabad.
4. Mr. Abdul Rashid Shaikh, Area FID, DRAP, Lahore.

Observations:

The panel observed that there was no building, machinery/ equipment and technical staff and workers at the licensed site situated at 26-s, Industrial Rea Kot Lakhpat Lahore. At the time of inspection, it was only a plot. It was noted that the building has been demolished and the machinery / equipment removed.
The panel tried to contact CEO of the said firm, Dr. Col (R) Ishtiaq Ahmed Khan on his mobile phone No. 0333-4249402, but his mobile phone was found to be switched off. As such M/s Elixir Laboratories (Pvt) Ltd, 26-S, Industrial Area Kot Lakhpat Lahore, does not full fill the requirements of building, machinery / equipment, technical personnel, and conditions of license to manufacture drugs by way the formulation.

Conclusion:

Considering the findings of he inspection, the tam of inspectors was of the opinion that M/s Elixir Laboratories (Pvt) Ltd, 26-S, Industrial Area Kot Lakhpat Lahore did not physically exist at that site thus was not maintaining the conditions of license as required under Rule 16,19& 20 of Drugs (Licensing, Registering & Advertising) Rules, 1976.

Recommendations:

Keeping in view the findings of the inspection and conlusion, the team of inspectors recommends that Drug Manufacturing License bearing No. 000288 issued in favour of M/s Elixir Laboratories (Pvt) Ltd, 26-S, Industrial Area Kot Lakhpat Lahore may be cancelled.

In view of above report, case was presented before the Honourable Islamabad High Court and Honourable Islamabad High Court passed orders dated 14-02-2017 as under: -

ORDER
"In terms of order even date passed in Writ Petition No. 4328 of 2013, instant Writ Petition also stands dismissed."

Orders of Honorable Court in Writ Petition No. 4328 of 2013 is reproduced as under: -

> "At the very outset this court inquired from the learned counsel for petitioner, as to whether petitioner filed reply to show cause notice dated 12-11-2013, learned counsel answered in negative and when asked that how writ petition is maintainable against the show cause notice, learned counsel submits that he shall file reply to the show cause notice, therefore instant petition may be dismissed as withdrawn but respondent be restrained from taking any action besides the law.

Accordingly, Writ Petition is dismissed. However, respondent are directed to perform their statutory obligations without fear and favor and must take all the steps which fall within the ambit of applicable law. Since in compliance of the order of this court fresh inspection has been carried out and report dated 08-02-2017 has also been submitted, therefore, respondents may take necessary legal measures. Since restraining orders has already been vacated; therefore, respondents are at liberty to proceed in the matter in requirement of law.

The respondents shall submit report through learned Registrar of this Court for perusal in chamber".

Proceedings of the Licensing Division
As per the conclusion of the above report submitted by panel of experts constituted by Islamabad High Court, Islamabad and after the disposal of the writ petition no. 4328/2013 by the Islamabad High Court, Islamabad the Licensing Division taken up the case and as already show Cause Notice has been issued by QA/LT Division on 06-05-2013. Accordingly, personnel hearing has been issued to the firm through Director QA/LT Division and case is placed before the CLB for consideration, please.

Proceeding of the Central Licensing Board

Dr. Ishtiaq Khan, Chief Executive Offcier M/s Elixir Laboratories (Pvt) Ltd, 26-S, Industrial Area Kot Lakhpat Lahore apeared before the Board and contended that he was shifting from present site to new site where he has established a firm with the name of M/s Navartana. He also informed the Board that he has taken all machinery from present site to new site of M/s Navartana. He also informed the Board that he is in process of merging the two firms thereby all assets would be property of one firm.

Decision of the Central Licensing Board in 252nd meeting
The Board considered the view point of Dr. Ishtiaq Khan, Chief Executive Offcier and delibrated on the facts and recommendations of the panel as mentioned above and Order of the Court and

ground reality as no building exists for which Licence to Manufacture Drugs was granted as of today and no condition exists for the purpose of Licence. Therefore, the Board decided to cancel the Drug manufacturing Licnece No. 000288 issued in favour of M/s Elixir Laboratories (Pvt) Ltd, 26-S, Industrial Area Kot Lakhpat Lahore.

Case No.27. M/S RAYMOND PHARMACEUTICALS, 16-KM, MULTAN ROAD, LAHORE.

Brief History of Case:

1. Production of the firm was stopped by CLB due to GMP non-compliance as reported during an inspection by FID conducted on 13.04.2013. Firm was served a show cause notice and case was placed in 232nd meeting of the Board, wherein the Board decided that the production of the firm will remain stopped till the final decision of the Board and firm will be re-inspected by a panel. A panel was constituted accordingly to re-inspect the firm. But firm informed that they were not ready and requested more time for rectification of shortcomings.

2. FID then again visited the firm on 07.05.2014 to check the status of the firm. The firm was found closed. Mr. Kashif, Son of Mr. Asif Chaudhary CEO was present at the premises and informed that they were renovating the firm and will intimate for panel inspection when ready. The firm also submitted an undertaking in this regard.

3. The firm informed the licensing section on 21.09.2015 that they were ready for inspection and Directorate of QA constituted a new panel to conduct inspection. Accordingly, panel inspection was scheduled on 15.12.2015 and the firm was also intimated. However, Mr. Muhammad Asif, CEO of the firm submitted a request to defer the inspection as the renovation work was not completed and they were not ready for inspection.

4. FID again made a surprise inspection of the firm on 07.04.2016 to check the status of the firm. It was reported that the firm was closed. Main gate was locked and no person was seen inside the premesis. Mr. Muhammad Asif, CEO, was contacted on his mobile No. but no response was received. Later on son of Mr. Muhammad Asif, CEO was contacted who arrived at the premises and informed that his father Muhammad Asif, CEO of the firm was severely ill and the firm was closed and they were not yet ready for panel inspection

Findings of Instant Inspection (07-11-2016):

5. Keeping in view the above situation and unwillingness of the management of the firm for panel inspection, the panel decided to make a surprise inspection, therefore the panel visited the firm on 07.11.2016. At the time, it was found that Mr. Akif (son of Mr. Asif, CEO) was

present at the premises. He informed the panel that the firm was non-functional since 2013 and his father, CEO of the firm was severely ill and did not come to factory.

6. The panel visited the production areas along with Mr. Akif. The firm possessed two sections namely Tablet section and Oral liquid section. Both the sections were closed. There was no production and there were no signs for any kind of production activities since long. Both the sections for production were very dirty. There was dust, cobwebs everywhere in these areas. Machines in tablet section were not cleaned. In oral liquid section the mixing tanks were dirty having remains of previously manufactured batches and not cleaned. Both the areas were not maintained and sanitation & hygienic conditions were worst. Some of the machines were dismantled.

Conclusion:

7. Keeping in view the brief history of the manufacturing activities and GMP status of the firm since 2013, and findings of this inspection and apathy and non-serious attitude of the management of the firm, the panel was of the opinion that firm did not maintain the GMP requirements and licensing conditions as required under Rule 16, 19 & 20 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

Recommendations:

8. As the firm is non-functional since 2013 and failed to meet the requirements of drug manufacturing license (DML) in spite of the repeated directions and show cause notice issued by DRAP and commitments given by management of firm from time to time. In the light of observations and above submission the panel recommends that the Drug Manufacturing License of the firm bearing No. 000201 may be cancelled in accordance with the law.

Decision of CLB.

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, 19 & 20 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of Drug Manufacturing Licence No. 000201 by way of formulation M/S Raymond Pharmaceuticals, 16-Km, Multan Road, Lahore may not be suspended or cancelled by Central Licensing Board.

Case No.28. **RECOMMENDATIONS FOR CANCELLATION / SUSPENSION OF DRUG MANUFACTURING LICENSES OF M/S KLIFTON PHARMA, PLOT NO. D-2, SITE, KOTRI JAMSHORO UNDER DML NO 000666 BY WAY OF FORMULATION.**

The Case Background

M/s Klifton Pharma, Jamshoro, applied for renewal of DML # 000666 (Formulation). The applicant for renewal of DML was 05 months delayed. Hence, according to Rule 5 (3) of Drugs (L,R&A) Rules, 1976 the license of the firm was declared invalid and a letter regarding invalidation of DML#000666 (Formulation). The firm was also directed to immediately stop production via same letter dated: 13-03-2015.

A letter No. 2-9/2006-Lic (Vol-1) dated 13-03-2015 was received from Mr. Hakim Masood, Federal Inspector of Drugs Hyderabad stated that he visited the premises of M/s Klifton Pharma, Jamshoro on 11-04-2015 and he found the premises of said firm closed and no person was available at premises to open the gate.

Decision of CLB:

The Board deliberated on the case and decided as under:

i. Drug Manufacturing License No. 000666 by way of Formulation of M/s Klifton Pharma, Plot No. D-2, SITE, Kotri, District Jamshoro, is not valid and same shall be conveyed to firm.

ii. The decision of the central Licensing Board will be conveyed to Drug Registration Board and QA/LT Division for the necessary actions at their end.

Case No.29. **RENEWAL OF DRUG MANUFACTURING LICENSE NUMBER 000499 - BY WAY OF FORMUALTION OF M/S AGS PHARMA AND CHEMICAL INDUSTRIES (PVT) LTD, 58-A, INDUSTRIAL ESTATE, JAMRUD ROAD, PESHAWAR.**

The renewal of Drug Manufacturing License No.000499 (Formulation) of M/s AGS Pharma and Chemical Industries (Pvt) Ltd, Industrial Estate, Jamrud Road, Peshawar was due on 22-06-2012. The firm has not submitted the application for renewal of said Drug Manufacturing License till to date. Under Rule 6 of Drugs (Licensing, Registering & Advertising) Rules, 1976, a license is valid for a period of 5 years and may be renewed for further period of five years, if application is made before the expiry of validity or within sixty days after period of expiry with payment of additional surcharge of Rupees five thousand for each day.

As renewal application of said Drug Manufacturing License is not submitted till to date, the said Drug Manufacturing License is not valid under the Drugs Act 1976 and rules frame there

under. However as per Rule 5(3) "if the application for Renewal of License is made after the expiry of validity of License, it shall be treated as a fresh application."

Licensing Division has already conveyed the status of said Drug Manufacturing License to Area FID on 03rd February, 2017 under intimation to the firm that manufacture of drugs in the name of said license at said premises is prohibited and punishable offence under section 23 read with section 27 of the Drugs Act 1976 and rules frame there under.

Report of Area FID

In response to Licensing Division's letter dated 03rd February, 2017 the area FID Mr. Rehmat Ullah BaigAlvi has submitted the inspection report of M/s AGS Pharma and Chemical Industries (Pvt) Ltd, Industrial Estate, Jamrud Road, Peshawar as under;

i. The undersigned visited M/s AGS Pharma and Chemical Industries (Pvt) Ltd, Industrial Estate, Jamrud Road, Peshawar on 13-02-2017 and found the factory closed. The undersigned again visited M/s AGS Pharma and Chemical Industries (Pvt) Ltd, Industrial Estate, Jamrud Road, Peshawar on 24-02-2017 and observed that Aquapura Tablet Batch No. DF004 was under stripping and packing process. The technical staff was not there and only operators were working. GMP and Test report was maintained.

ii. As the firm did not submit their renewal of Drug Manufacturing License Fees in time therefore, the undersigned directed the firm M/s AGS Pharma and Chemical Industries (Pvt) Ltd, Industrial Estate, Jamrud Road, Peshawar to stop their production and submit the Renewal feed of DML as soon as possible for further necessary action.

Concurrence of Central Licensing Board is solicited for formally issuance of letter for invalid status of said license. Moreover, the firm may be informed that drug manufacturing license is no more valid, however there is no bar on filing fresh application as per Rule 5(3) for grant of Drug Manufacturing License.

Decision of the Central Licensing Board

The Board deliberated on the case and decided as under:

i. Drug Manufacturing License No. 000499 by way of Formulation M/s AGS Pharma and Chemical Industries (Pvt) Ltd, Industrial Estate, Jamrud Road, Peshawar, is not valid and same shall be conveyed to firm.

ii. The decision of the central Licensing Board will be conveyed to Drug Registration Board and QA/LT Division for their necessary actions at their end.

iii. The Board took serious note of the lapse on the part of the Federal Inspector of Drugs, Peshawar and decided to issue directions to the Federal Inspector of Drugs, Peshawar to investigate manufacturing of unregistered Aquapura Tablet and submit report with recommendations for prosecution of the accused.

Case No.30. CANCELLATION OF DRUG MANUFACTURING LICENSE NO.000078 (FORMULATION) OF M/S REDEX PHARMACEUTICALS INDUSTRIES (PVT) LTD, 12.8 KM, SATIANA ROAD, FAISALABAD ON FIRM REQUEST AND GRANT OF DRUG MANUFACTURING LICENSE BY WAY OF RE-PACKING ON SAME PREMISES.

M/s Redex Pharmaceuticals Industries (Pvt) Ltd, 12.8 KM, Satiana Road, Faisalabad DML No.000078 by way of formulation wherein the firm has submitted a request to cancellation of DML by way of formulation and issuance of DML by way of re-packing on the same premises.

Decision of the Central Licensing Board

The Board deliberated on the voluntarily surrendering of the Drug Manufacturing Licence No.000078 by way of formulation by M/s Redex Pharmaceuticals Industries (Pvt) Ltd, 12.8 KM, Satiana Road, Faisalabad and acceded the request for surrendering the Licence. Hence, the Drug Manufacturing Licence No.000078 in the name of M/s Redex Pharmaceuticals Industries (Pvt) Ltd, 12.8 KM, Satiana Road, Faisalabad stands cancelled. The Board further decided to convey the same to Drug Registration Board and QA/LT Division for necessary action at their end. The Board also considered the request of M/s Redex Pharmaceuticals Industries (Pvt) Ltd, 12.8 KM, Satiana Road, Faisalabad for garnt of Drug Manufacturing Licence by way of Repacking and decided that request of the firm may be processed for fulfillment of codal formalities.

Case No.31. <u>ANNUAL PAYMENT OF CENTRAL RESEARCH FUND (CRF) OF M/S GETZ PHARMA (PVT) LTD</u>

M/s Getz Pharma (Pvt) Ltd, Karachi,has sent a letter whereby they have stated that annual payment of Central Research Fund (CRF) for the year 2015 that is required to be made by Getz Pharma. They have further stated that Sub-Rule 14 of Rule 19 of the Licensing Registering and Advertising Rule, 1976 (LR&A Rules), requires a pharmaceutical company to contribute one percent of its gross profit before deduction of income tax towers the Central Research Fund to be maintained by the Federal Government, However, under the provision to this Sub Rule 14 of Rule 19, the Central Research Board may allow portion of such contribution to be spent by the Firm / Pharmaceutical Company itself for research and development of new drugs or for establishing research laboratories, when it is satisfied that such expenditure is being utilized for the said purpose effectively and properly.

- In accordance with Sub-Rule 14 of Rule 19 of the Licensing Registering and Advertising Rule, 1976 (LR&A Rules), Getz Pharma has stated that it may kindly be allowed to retain a substantial portion out of one percent CRF annual contribution on the grounds that it has already made substantial laboratories / facilities and is willing to provide details of such continuous and future investment, as and when required (Subject to requirements of business and trade confidentiality).
- It is submitted that M/s Getz Pharma (Pvt) Ltd, Karachi has also filed a Constitution petition No. D-3896 of 2016 in the High Court of Sindh, Karachi on the instant matter. Parawise comments have already been submitted in the Hon'rable Sindh High Court Karachi.
- Submitted before the board that firm may be advised to submit proper application for availing benefit in the light of Rule 19(14).Firm may also be advised to submit documents /information along with the application including but not limited to the following.

    1. Details of proposed research Projects.
    2. Details of investigators.
    3. Details of equipments and chemicals.
    4. Estimated Cost of the research Project.
    5. Duration of the research Project.
    6. Expected outcomes / benefits of the research Project.
    7. Details of the research facility.
    8. Details of new drugs previously developed.
    9. Details of firm's investment and contribution of CRF required for the proposed research project.
    10. Details of research Laboratories (Scope, Objective).

Decision of the central Licensing Board.

The Board considered the facts decided to defer the case for want of more data and relevant information on the subject matter for framing the format of application.

Case No. 32. RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S MARION LABORATORIES (PRIVATE) LIMITED, D-43, TEXTILE AVENUE, S.I.T.E, KARACHI.

The case was included in the agenda as under: -

BACKGROUND OF THE CASE: -

The case was placed in 241st meeting of CLB held on 15th May, 2015: -

- M/s Marion Laboratories (Private) Limited was initially granted Drug Manufacturing License (DML) for the manufacturing of Drugs in **LVPs (Infusion)** at premises located at D-43, Textile Avenue, S.I.T.E, Karachi, in 199th meeting of Central Licensing Board held on 23rd – 24th August 2006.
- Accordingly, Firm was issued DML # 000599 (Formulation) for the period of five years w.e.f. 16th September 2006.
- Afterwards, firm submitted application for renewal of DML for the period 16-09-2011 to 15-09-2016 which was well before the period of expiry of validity period of the license. Therefore, license of the firm is continue in force till further orders passed by Central Licensing Board according to Rule 6 of the Drugs (Licensing, Registering & Advertising) Rules 1976 which reproduced as under:-
  "Provided that if application for renewal is made before the expiry of the period of the validity of a license, the license shall continue in "force until" orders are passed on such application"
- The application of renewal of the license dated 08th September 2011 was not entertained at the time of submission, due to devolution of the then Ministry of Health.
- After the establishment of the Drug Regulatory Authority of Pakistan in November 2012, the application of renewal of the firm was scrutinized by Licensing Division and shortcomings in the application of renewal of DML were conveyed to the firm on 05th March 2015 according to Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rule 1976 which reproduced as under:-
  "On receipt of an application of renewal of a license any objection or shortcoming in the application observed by the Central Licensing Board may be notified to the applicant and he shall be given a time period of thirty days for rectification or completion of the application. In case he fails to rectify or complete the application within the specified period, the application may be rejected"

- The shortcomings in the application of renewal of DML conveyed to the firm vide letter dated 05th March 2015, are as under:-
-
  (i) Differential fee of Rs. 32,500/- for renewal of Drug Manufacturing License, as fee revised for renewal of DML is 50,000/-
  (ii) Names / List of total licensed sections of the firm and proof of grant/approval of sections from Central Licensing Board.
  (iii) Details of premises including copy of approved layout plan by competent Authority.
  (iv) Details of proposed production and Q.C Incharge as per checklist enclosed herewith. The technical experts shall possess minimum 10 years experience in the relevant fields after academic qualification according to Rule 16 of Drugs (Licensing, Registering & Advertising) Rules 1976 after promulgation of S.R.O 470 (I)/98 dated 15-05-1998.
  (v) Copy of latest form 29 issued and attested by Security Exchange commission of Pakistan along with CNIC photocopies of all directors.

(vi) An undertaking on letter head of the firm signed by all directors of the firm stating that all information/ documents provided with application of renewal of Drug Manufacturing License is complete and correct and management of firm shall be responsible for hiding or providing wrong information.
(vii) Nothing Due certificate issued by Statistical Officer , DRAP, Islamabad, regarding deposition of Central Research fund up to 31-12-2015.

- On 01-04-2015, firm has submitted reply with respect to the letter issued from this Division regarding shortcomings in their application for renewal of DML.

- In the reply, firm stated that all liable requirements were submitted to Licensing Division in liable period and only liable inspection was supposed to be conducted.

- According to record of Licensing Division DRAP, Islamabad, the application of renewal of DML of the firm is still incomplete and firm fails to rectify or complete the application within the specified period of 30 days under Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rules 1976. Therefore the application of the firm is liable to be rejected.

The case was presented in 241st meeting of the Board wherein the Board decided as under:-
Decision of the Board (M-241):

The Board decided to issue a Show Cause Notice with personal hearing to the firm

Accordingly, Show Cause Notice with personal hearing was issued to the firm and firm was called for personal hearing, please.

Proceedings:
Mr. Amjad Ali, Manager Regulatory Affairs appeared before the Board for personal hearing. He informed that the firm has not received the letter of personal hearing of the instant meeting. However, if a copy of said letter is provided then they will provide the requisite information / documents.

Licensing Division apprised the Board that the statement of firm's representative was not correct as the firm has received the Show Cause notice and also submitted but the information desired is skill lacking. It was added that the letter for personal hearing of the instant meeting of the Board was not sent through ordinary mail but dispatched to the firm through TCS.
Decision of CLB (M-243):
The Board after thorough discussion of the said situation unanimously decided and deferred the matter with final opportunity of Personal Hearing. Board further advised to obtain the tracking of TCS as to verify the claim of firm's representative.
Decision of CLB:
Keeping in view the facts of the case, the Board considered and deferred the matter with final opportunity of Personal Hearing. Board further directed to deliver personal hearing letter through area FID and Courier before one week of CLB meeting.

Accordingly, firm was called for personal hearing.
Proceedings of CLB:
Mr. Imran Saboor, CEO of the firm and Mr. Amjad Manager Regulatory Affairs of the firm's appeared before the Board and presented their point of view that they have already provided the requisite information and obtain acknowledgment of application.

The Board explained then that the firm has not provided requisite information / documents that's why they were issued reminder again.

After such explanation the representative of the firm submitted that their factory is officially closed and they will provide the requisite information / documents after the access to record / documents.

The Law Expert (Member of Board) clarified them that they can access to their record and provide the required information to CLB.

Decision of CLB

Keeping in view the above, the Board considered and decided for final opportunity to provide the requisite information / documents under Rule 5(2A) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

The Board further directed to inform the firm complete background of the case while communicating decision of CLB.

Proceedings

The above decision of the Central Licensing Board was conveyed to the firm on 22 June, 2016 and asked to provide the remaining documents to complete application of renewal of Drug Manufacturing Licence. The firm has not provided documents Now firm has been called in person for hearing.

The firm has leveled allegations against Mr. Faqeer Muhammad Shaikh, Chairman, central Licensing Board being partisan. Therefore, Mr. Faqeer Muhammad Shaikh separated himself from the proceedings of the instant case. The Board authorized Dr.Ikram-ul-Haque, Member, Central Licensing Board to chair the proceedings.

Mr. Imran Saboor, CEO of the firm and Mr. Amjad Manager Regulatory Affairs of the firm's appeared before the Board. He admitted that they have access to Factory premises and all record as manufacturing of the their company / Firm is suspended but not sealed. On query regarding submission of required documents, Mr. Imran Saboor replied that he could not make any commitment but would submit written reply within 15 days after consulting his Legal Counsel.

Decision of 251st meeting of CLB

After hearing the representatives of the Company/ firm the Board decided to defer the case for giving last opportunity for fulfillment of commitment by the Company / form.

Proceeding of Licensing Division :

Accordingly the Licensing Division has issued letter for last opportunity for fulfillment of commitment by company to complete DML renewal Application. The firm submitted the reply, however following documents/information is still short as under :

(i) Names / List of total licensed sections of the firm and proof of grant/approval of sections from Central Licensing Board.
(ii) Details of premises including copy of approved layout plan by competent Authority.
(iii) Details of proposed production and Q.C Incharge as per checklist enclosed herewith. The technical experts shall possess minimum 10 years' experience in the relevant fields after academic qualification according to Rule 16 of Drugs (Licensing, Registering & Advertising) Rules 1976 after promulgation of 1134(I)/2014.
(iv) Copy of latest form 29 issued and attested by Security Exchange commission of Pakistan along with CNIC photocopies of all directors.

(v) An undertaking on letter head of the firm signed by all directors of the firm stating that all information/ documents provided with application of renewal of Drug Manufacturing License is complete and correct and management of firm shall be responsible for hiding or providing wrong information.
(vi) Nothing Due certificate issued by Statistical Officer, DRAP, Islamabad, regarding deposition of Central Research fund (updated).

In view of above, letter for personal hearing has been issued to the firm and case is placed before Board for consideration.

Proceedings of the Board.

Mr. Faqeer Muhammad Shaikh, Chairman, Central Licensing Board voluntarily separated himself from the proceedings of the instant case. The Board authorized Muhammad Saleem Shah, Member, Central Licensing Board to chair the proceedings.

Mr. Imran Saboor, CEO of the firm and Mr. Amjad Manager Regulatory Affairs of the firm's appeared before the Board. On query regarding non submission of required documents as per commitment in 251st meeting of the Central Licensing Board, Mr. Imran Saboor could not give satisfactory answer as he has submitted some of the documents as mentioned above and still following documents are required to be submitted by the firm for completion of their application for the renewal of Drug Manufacturing License.

(i) Names / List of total licensed sections of the firm and proof of grant/approval of sections from Central Licensing Board.
(ii) Details of premises including copy of approved layout plan by competent Authority.
(iii) Details of proposed production and Q.C Incharge as per checklist enclosed herewith. The technical experts shall possess minimum 10 years' experience in the relevant fields after academic qualification according to Rule 16 of Drugs (Licensing, Registering & Advertising) Rules 1976 after promulgation of 1134(I)/2014.
(iv) Copy of latest form 29 issued and attested by Security Exchange commission of Pakistan along with CNIC photocopies of all directors.
(v) An undertaking on letter head of the firm signed by all directors of the firm stating that all information/ documents provided with application of renewal of Drug Manufacturing License is complete and correct and management of firm shall be responsible for hiding or providing wrong information.
(vi) Nothing Due certificate issued by Statistical Officer, DRAP, Islamabad, regarding deposition of Central Research fund (updated).

Decision of the CLB in its 252nd meeting

The Board considered the facts on record, Show Cause served and number of opportunities provided 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) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for completion of

application for the purpose of the renewal of Drug manufacturing Licence which the firm/ company failed to complete despite of number of opportunities. The Board took notice of callous attitude of the firm/ company and opportunities provided and decided to reject the application of M/s Marion Laboratories (Private) Limited, D-43, Textile Avenue, S.I.T.E, Karachi for renewal of Drug Manufacturing Licence No. 000599 by way of Formulation under Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

QUALITY ASSURANCE CASES (GMP NON-COMPLIANCE)

Item No. I GMP Non-compliance Cases (Old)

Case No. i. **M/s Euro Pharma, Karachi**

Background of the case

Inspection of the firm M/s Euro Pharma, Karachi was conducted on 05.03.2013 by a panel comprising of Area FID and Area ADC. During inspection the panel pointed out a number of serious/critical shortcomings in all sections. Accordingly a showcause 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:-

a. ***To stop the production till the rectification of the shortcomings after approval by the Central Licensing Board.***

b. ***After two months, a larger panel will inspect the firm on audit proforma Schedule -II to verify the improvements made by the firm.***

c. ***The Board has also directed the firm to provide the status of the matter decided by the Custom Authorities to QA Section immediately and a letter to firm in this regard shall be issued with complete background.***

2. Decision of the CLB was conveyed to the firm on 03.09.2013.The firm vide letter No. Nil dated 25.11.2013 replied that they have removed all the shortcomings and ready for inspection. The Chairman, CLB had constituted a larger panel comprising of CDI (Sindh), Director (CDL), Area FID and Area ADC, Karachi to conduct the inspection of the firm in compliance to the orders of CLB on 11.12.2013. Mr. Abdul Rasool Sheikh, Area FID vide office letter No. F.ARS.000172/2014-FID(III) dated 09.04.2014 informed that he alongwith other members of the panel went for inspection of the company but the company was found closed and only one person, who introduced himself as chowkidar of the company, was present. The panel unanimously decided to recommend the cancellation of the DML of the company. The case was presented before CLB in its 237th meeting held on 01.10.2014. Wherein the Board had decided as under:-

a. ***The License of the firm is suspended for three months as the firm has been served show cause notice, which was not replied.***

b. ***Taking into consideration the report of the panel and also information provided by the Chief Drugs Inspector, Sindh (Member CLB) that the company when was visited always gave a deserted look and only a family of Chowkidar was living/presented there. However, the Owner/CEO of the company Mr. Nashad Akhai has given the one or other reasons at two different times through emailed with the excuse of not attending the personal hearing before the CLB.***

c. ***Final notice be sent to the Owner that in case if personal appearance will not be made by CEO/Owner or through legal representative before the CLB in the next meeting, the License may be treated as cancelled.***

3. Decision of the CLB was conveyed to the firm on 14.10.2014. Area FID issued a letter to the company on 12.03.2015 with the direction to surrender all the documents issued by the DRAP. The firm requested that the significant changes, improvement in the factory for better compliance of GMP has been made. The management of the company requested for the panel inspection of the firm. The case was placed before the CLB in its 244th Meeting held on 28.10.2015.

Proceedings of the 244th Meeting of CLB:

Mr. Asif Iqbal S/o Muhammad Rafiq appeared before the Board. He has presented scanned copy of the authority letter issued by Mr. Noshad Akhai and copy of deed of working partnership between Muhammad Asif Iqbal and Mr. Noshad Akhai on stamp paper. He has informed that Mr. Noshad Akhai is in America. Asif Iqbal informed that all the observations noted during the last inspection have been given due attention and are rectified. He added that the firm was given on rent to Mr. Imtiaz Ahmad, owner of M/s Standard Drug Company, Hyderabad from 2009 to 2013. Moreover he informed that the firm is ready for inspection and requested for inspection.

Decision of CLB:

Keeping in view the request of Mr. Asif Iqbal S/o Muhammad Rafiq appeared on behalf of the firm *M/s Euro Pharma International, the Board has decided:-*

" i. To conduct the inspection of the firm with a larger panel, comprising of following members.

i. Syed Muid Ahmad, Member CLB
ii. Mr. Qaiser Muhammad, Chief Drug Inspector, Karachi
iii. Dr. Saif ur Rehman Khattak, FGA, CDL, Karachi
iv. Mr. .Abdul Rasool Sheikh, Area FID

ii. The panel shall submit the report on prescribed GMP format.

iii. The panel inspection report shall be placed in the next forthcoming meeting of CLB for appraisal and its decision.

The decision of the 244th meeting of CLB was conveyed to the firm and panel on 18.12.2015

Updated Status

The panel conducted inspection of the firm on 06.01.2017 and informed as under:-

1. The panel had serious observation on the legal status of Mr. Asif Iqbal as there was no any DRAP approved documentary evidence which could declare him as partner of the firm. Keeping in view the background of the firm the panel recommends that this matter may be solved by the Board concerned so the future course of action may be ascertained in case of any violations.
2. It was told that the QA manager is working under QC manager, it will be a sheer compromised condition, the panel also observed some major QA non-compliance like there was no proper job description given to the technical persons; even appointment letters were not given.
3. The existing layout was not approved and the total plot size is around 900 square yards which is less than the required legal size of the plot.
4. It was informed that the firm has registration in seven sections including penicillin Dry Powder suspension and capsules but currently they wish to be inspected in general areas as other areas were not ready for inspection. The DRAP Islamabad does not have information in this regard.
5. The firm has total 47 registered products in all seven sections and the renewal status of all there registrations were not confirmed as the firm was closed since 2013 and new management had not applied for renewal of there registrations.
6. It was further informed that around seven million has been spent on overall renovation of the plant in HVAC and plant upgradation.

7. During inspection it was observed that there was no APIs, Excipients and finish good stocks available with the firm. The keeping samples and the relevant records have been removed from the premises that could not be traced out.
8. There was no filtration system installed in the HVAC system, no air balancing has been carried out, monitoring devices were noted merely installed but not in working order.
9. None of equipment was qualified, no validation master plan was found in place, none of analytical method was validated, water system was not validated.
10. No training record was in place, the firm was found deficient of technical persons
11. In QC Lab the firm does not have any reagent or chemical / media.
12. In production area the panel observed wooden painted doors, floors and ceiling were found cracked at different places of production, FB dryer was rusted with uneven trolley sides likewise other machines were also found not in working conditions, exhaust dust was noticed without dust collector and panel noted open electric wires with wooden Boards. In compression area doors were of wooden, machines were old and not well installed, HVAC noted not in order/ function, out of use equipment could be main source of contamination and same critical situation was noted in rest of the production areas. Sampling and dispensing booths were found un-qualified.
13. In short the panel observed very critical non-compliances in production, QA and QC Lab and based on the above critical observations the firm was advised not to start production amid such critical observations, the Board / Authority concerned is appraised the keep the contents of the report on the upcoming agenda of CLB meeting to decide the future course of action as recommended in earlier inspection of this Authority.

Proceedings of the 252nd Meeting of CLB

The Board was informed by the Deputy Director (QA) that the firm was served letter for personal hearing on 08.03.2017 and the area FID was also informed to send the letter to the firm. But no representative of the firm appeared before the Board for personal hearing under section 41 under the Drug Act 1976, read with rule 12 of the Drugs (L, R & A) Rules 1976.

Decision of the 252nd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the panel of experts in its report dated 06.01.2017, 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 Euro Pharma International, 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.

Case No. ii. **M/s Rex Pharmaceuticals, Karachi**

Background of the case

Inspection of the firm M/s Rex Pharmaceutical Pakistan, Karachi was conducted on 06.03.2013 by Mr. Abdul Rasool Sheikh, FID, Karachi. During inspection the FID pointed out a number of serious/critical shortcomings in all sections. Accordingly showcause 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 again presented before the 233rd Meeting of CLB, wherein the CLB had decided as under:-

"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. The 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.

Proceedings of the 245th Meeting of CLB:

The firm was provided opportunity of personal hearing before the Board, but no representative appeared before the CLB, on behalf of firm. The Board showed displeasure on such non serious attitude of the company.

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.

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

Updated status

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.

Proceedings of the 252nd Meeting of CLB

The Board was informed by the Deputy Director (QA) that the firm was served letter for personal hearing on 08.03.2017 and the area FID was also informed to send the letter to the firm. But no representative of the firm appeared before the Board for personal hearing under section 41 under the Drug Act 1976, read with rule 12 of the Drugs (L, R & A) Rules 1976.

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.

Item No. II (GMP Non-compliance Cases New)

Case No. i. M/S ALKEMY PHARMACEUTICAL (PVT) LTD, HYDERABAD

Background of the case:

Dr. Abdur Rashid, Additional Director (QA&LT) along-with Syed Hakim Masood, Area FID, Karachi conducted inspection of the firm M/s Alkemy Pharmaceutical, Hyderabad on 16.11.2016 in connection to Quality Control letter dated 27.05.2016, wherein the firm was found in manufacturing and sale of sub-standard drug Azofin suspension, Kemycone suspension and to verify GMP compliance / production activities of the firm.

2. The panel noticed number of critical observations, which need urgent attention and rectification. The observations includes:-

i. No traceability of Raw Materials was available. No proper records were available. No thermometer and hygrometer were found for recording of temperature and humidity in the warehouse.

ii. Dispensing Areas needs renovation and additional calibrated weighing balance required.

iii. Old silverson mixers are rusted/old and required to be placed with new ones.

iv. Storage tanks required to be replaced with new ones.

v. Floor, walls and ceiling are cracked/old and needs overall, renovation required.

vi. The rodents and insects can enter from drainage in the production of syrup section and so requires better drainage system.

vii. Vessels need to be replaced.

viii. Liquid filling machine is old and rusty and must be replaced with semi- automatic filling machine with conveyor belt.

ix. Water System needs to be upgraded with new one.

x. Batch Manufacturing instructions were missing from batch manufacturing records.

xi. Iron racks are required to be placed in the warehouse. Iron and plastic pellets maybe further added in the warehouse and wooden pellets should be removed from the area.

xii. There are no racks in the finished goods store and medicines are placed on the floor. Few wooden pellets and plastic pellets are also seen in one room. There is a need that iron racks and plastic pellets maybe provided along with hygrometers to monitor the humidity of the finished goods store. Floor walls and ceiling needs renovation paint and up gradation.

xiii. Dust can enter from the open exhaust, therefore an exhaust is required.

xiv. There is overall need to upgrade the facility in the chemical and microbiological sections of the QC laboratory. No HPLC is available, so one HPLC may be provided.

xv. There is lacking of proper log book of the equipments, calibration, and validation of the analytical methods.

xvi. Viscometer is no more available to measure the viscosity of suspension.

xvii. In microbiological section, autoclave, colony counter and refrigerator are no more available. It is recommended to provide the same.

xviii. The qualified person in chemical and microbiological section needs training and has lack of latest knowledge. It is recommended that the technical personnel may be sent to Karachi for proper training.

xix. Qualified persons documents were submitted in 2013, but have not been approved by the concerned division.

xx. Packaging materials and labels are not properly stored and documented.

The panel concluded that:- The observations were discussed with the management and the management of the firm voluntarily stopped production in the liquid syrup section for maintenance and renovation. The panel recommended to issue a show cause notice for Liquid Section and personal hearing be given to the representative of the firm for cancellation and suspension of DML.

Action taken by DRAP: Accordingly show cause notice / suspension of production activities in liquid syrup section was issued to the firm on 09.01.2017.

Reply by the firm: The firm vide letter dated 17.01.2017 submitted reply, requested that the facility has been maintained and requested for the constitution of the panel to visit the firm and to provide opportunity for personal hearing.

Proceedings of the 252nd Meeting of CLB

The Board was informed by the Deputy Director (QA) that the samples of Azofin Suspension and Kemycone Suspension were declared as of substandard quality by the Central Drugs Laboratory, Karachi. Accordingly the case was placed in 258th meeting of Registration Board held on 25th and 26th April, 2016. The Registration Board constituted panel of experts comprising of Dr. Abdur Rashid, Additional Director (QA&LT) and Syed Hakim Masood, Area FID to conduct PSI. The panel conducted inspection of the firm on 16.11.2016 and observed gross violations in Liquid syrup Section. Accordingly show cause notice / suspension of production activities in liquid syrup section was issued to the firm on 09.01.2017. The firm was served letter for personal hearing on 08.03.2017. Mr. Faraz Ahad Shaikh, Managing Director and Mr. Asif Najeeb Laghari, QC In-charge appeared before the Board. Managing Director inform the Board that they voluntarily stop the production in liquid section. He added that the observations noted by the panel have been rectified and they are ready for inspection. The Board inquired regarding availability of FTIR, Viscometer and Polarimeter in the Quality Control Lab. The QC In-charge replied in negative. The Board took serious notice of non-availability of most important equipments used for testing of liquid products, in QC Lab.

Decision of the 252nd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the panel of experts in its report dated 16.11.2016, casual attitude of the firm towards GMP compliance in liquid syrup section, the Board decided to:-

i. *Suspend the Drug Manufacturing License of liquid syrup section of the firm M/s Alkemy Pharmaceutical Laboratories (Pvt) Ltd, Karachi, for a period of 03 months under section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (LR&A) Rules, 1976, from the date of issuance of decision of the 252nd meeting of CLB.*

ii. Conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976, after submission of compliance report by the firm, by the following members:-

- *Syed Muid Ahmad, Member CLB*
- *Dr. Abdur Rashid, Additional Director (QA&LT), Islamabad.*
- *Syed Hakim Masood, Area FID, Hyderabad / Karachi*

iii. The Board also decided to direct the panel to submit brief report in tabulated form identifying the previous observations and the current status with clear and candid recommendations.

iv. The report shall be presented in the meeting of Central Licensing Board for perusal and approval.

Case No. ii. **M/S WARRIA BROTHERS, FAISALABAD**

Background of the case:

Inspection of M/s Warria Brothers, Faisalabad was conducted on 28.11.2016 by a panel comprising of Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore and Mr. Ajmal Sohail Asif, FID (F), Lahore, with reference to QA Division letter dated 23.09.2014.

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

i. All the doors of the production area were wide open.

ii. There was no activity in production area (Bandage rolling, cutting and packing)

iii. There was no material in raw material and packing material stores.

iv. There were no finished products in the FG store or elsewhere in the firm.

v. Production area was dirty and not maintained. There was dust, cobwebs everywhere in these areas. Floor was broken at some places and covered with plastic sheets. The ceiling was made of iron girders and bricks and was covered with plastic sheets which were fallen at many places.

vi. Proper change over facility was not provided for workers

vii. Other door of the production corridor was opening into backyard connected with a house informed to be of the owner of premises (premises of unit was on rent and owner was residing in a house at the back side of the unit.)

The panel concluded that:-

Keeping in view history of the manufacturing activities and GMP status of the firm since 2013 and findings of this inspection and apathy and non-serious attitude of the management of the firm, the panel is of the opinion that the firm did not maintain the GMP requirements and licensing conditions as required under rule 16, 19 & 20 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

3. The panel further recommended that the Drug Manufacturing License of the firm bearing No. 000345 may be cancelled/ suspended till the firm shifts its unit to some other place as committed by the management of your firm.

Action taken by DRAP: Accordingly showcause notice / suspension of production was issued to the firm on 19.01.2017

Reply by the firm: The firm vide letter dated 28.01.2017 submitted reply, denied the observations and informed that the premises was under renovation at the time of inspection.

Proceedings of the 252nd Meeting of CLB

The Board was informed by the Deputy Director (QA) that Mr. Ajmal Sohail Asif, Area FID, Lahore conducted inspection of the firm on 16.06.2014 and noted gross violations in the GMP compliance. The FID recommended to stop production in the public interest and constitution of panel for grant of renewal of DML and evaluation of GMP conditions of the firm. Accordingly show cause notice and suspension of production order was issued to the firm on 21.07.2014. The firm submitted compliance report on 05.08.2014 and requested for inspection of the firm. The Director QA&LT constituted panel of experts comprising of DDG (E&M), Lahore, Area ADC, Lahore and Area FID, DRAP, Lahore to verify the improvements made by the firm. In response the panel conducted inspection of the firm on 28.11.2016 and observed gross violations. The panel

recommended for the cancellation of DML in accordance with the law. Accordingly show cause notice and suspension of production order was again served to the firm on 19.01.2017.

The firm was served letter for personal hearing on 08.03.2017. Mr. Muhammad Alam, Proprietor of the firm M/s Warria Brothers, Faisalabad appeared before the Board. Proprietor of the firm informs that he purchased a new plot and site verification was conducted on 06.10.2016 and requested for suitable time for completion of project at new site.

Decision of the 252nd Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the panel of experts in its report dated 28.11.2016, with law and poor compliance of the firm towards GMP compliance since 2014, wherein the panel recommended to cancel the DML of the firm M/s Warria Brothers, Faisalabad in accordance with law. The Board, in the light of poor compliance of the firm towards GMP compliance since 2014, decided to *cancel the Drug Manufacturing License of the firm M/s Warria Brothers, Faisalabad*, 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.

Case No. iii. M/S HARMANN PHARMACEUTICAL LABORATORIES (PVT) LIMITED, LAHORE

Background of the case:

Mr. Ajmal Sohail, FID conducted inspection of firm on 3rd and 4th October, 2013 to check the GMP compliance of the firm. The FID reported that the firm was operating at unsatisfactory level of compliance with GMP guidelines as per the Drugs Act, 1976 and rules framed there under and recommended that the firm may be directed to stop all kinds of manufacturing activities till rectification of the shortcomings and improvement of GMP compliance level. Accordingly, show cause notice was issued to the firm and directed to stop manufacturing of drugs in all sections immediately.

2. The firm in response, instead of replying to the Show Cause Notice issued by CLB, preferred to file a writ petition in Honorable Islamabad High Court Islamabad. The Honorable Court in its order dated 26.11.2013 suspended the show cause notice to the extent to stop manufacturing of drugs till next date of hearing. The Honorable Court while hearing the case on 11.01.2017 constituted a team to be headed by Chairman, CLB (Official in attendance) consisting of Area Federal Inspector of Drugs Lahore, Additional Director Quality Assurance, Islamabad and Dr. Ikram ul Haq Ex-Director of Drugs Testing Laboratory/Ex- Member of CLB and directed to visit the premises of the petitioner and submit report.

3. It is also worthwhile to mention here that renewal of Drug Manufacturing License (DML) of the firm is also due w.e.f. 09.01.2011. A panel was constituted on 24.01.2013 but the firm showed some reservations on panel members and applied for reconstitution of panel . Another panel was constituted by competent authority on 26.11.2014 but the firm raised reservations on panel members and gave a legal notice to Licensing Division . Another letter was issued for renewal of DML of the firm on 31.07.2015 , but the firm again sent a legal notice to Licensing Division . Hence, inspection of firm for renewal of DML could not be conducted yet.

Observations of the panel:

The team visited the firm on 24.01.2017 at about 12:30 PM. At the time of visit a person namely Mr. Luqman Ali, who introduced himself as production manager of the firm, was present. A lady, who introduced herself as QC In-charge of the firm, was also present but left the premises before inspection was started.

Mr. Luqman, production In-charge was informed that the team has to conduct inspection of firm on the directions of Honorable Court. He told the team that none of owners/Directors of the firm was present at premises and Mr. Haseeb Khan, director of the firm had left just 10 minutes before the arrival of team. He was asked to call Mr. Haseeb Khan, Director and request him to come back so that inspection may be conducted in his presence. Accordingly, Mr. Luqman contacted him on his mobile phone and area FID (Ajmal Sohail Asif) also talked to him and informed about the purpose of inspection and requested him to be present during the course of inspection. Mr. Haseeb Khan told that he was coming, so the team decided to wait for his arrival.

Upon inquiring about production status; Mr. Luqman told the team that at that time two batches of syrups namely "No–All and Ammo Plus" were under manufacturing in oral liquid section. He further told that firm was also under maintenance and paint work was being done. Team noted that paint work was being done on the outer side of the building.

While waiting in the lobby of production areas (outside the executive entrance) team saw through the glass door that the workers were walking/running in the production corridor. After

about 10 minutes, Mr. Luqman informed the team that Mr. Haseeb Khan, Director/owner of the firm has directed him not to allow the team to visit the firm.

While standing in the lawn of the firm team noted that the workers of the firm were leaving the premises. In the meanwhile, a person namely Mr. Asif Khan, who told himself to be the security guard/supervisor (without any uniform), also conveyed the team that Mr. Haseeb Khan Director/owner has directed that team may not be allowed to inspect the firm and asked the team to leave the premises (it is worth mentioning here that he had a naked pistol (without holster) in his hand while talking to the team and moving here and there – there was no need to exhibit weapon in their own premises .

Team asked Mr. Luqman that he being production manager is a responsible person for manufacturing and he should let the team to inspect the firm as he is bound under section 20 of the Drugs Act, 1976 which is read as:

"20. Persons bound to disclose place where drugs are manufactured or kept:
Every person for the time being in charge of any premises whereon any drug is being manufactured or is kept for sale or distribution shall, on being required by an Inspector so to do, disclose to the Inspector the place where the drug is being manufactured or is kept, as the case may be."

But he refused and told that as per owner's direction he could not allow the team to inspect the premises. However, considering the persistent denial of the firm regarding inspection, the team suspecting the possibility of GMP violations (that may endanger the public health) decided to enter the production areas to fulfill the duty in compliance to Honorable Court's orders and as empowered by the Drugs Act, 1976 and rules framed there under.

Team then entered the production area along with Mr. Luqman, Production manager and noted that the firm has locked many of the rooms such as raw materials store, finished goods store, packing materials store and entrance doors leading to first floor (injection section/cream ointment section/capsule section & quality control/microbiology laboratory). Team of inspectors asked Mr. Luqman to open the locks of all the manufacturing sections but he denied and told that the person with keys has left the premises. Only areas open/accessible were tablet section, oral liquid section and workers change rooms. Thus, the team could only inspect the open areas with the help of mobile phone flash lights as the firm also shut down the electricity supply few minutes after the team entered the production areas. The observations were as follows:

i. Change rooms:

The firm has provided separate change rooms for male and female workers. Separate entrance for executives was provided.

The change rooms were not neat and clean. The cabinets were dirty and rusty. The fixtures for tube lights were not properly affixed and were loose producing recesses and staying area for dust and dirt. There was water seepage on walls. The change rooms were stinking; no means of fresh air/air conditioning was provided.

ii. Oral liquid section, it was comprised of:

a. A room for solution preparation containing storage and manufacturing vessels of different sizes and mixers. The room was not neat and clean. A small room connected to this room was very dirty, having seepage on walls, the sanitary conditions of this room were very unhygienic .

The team noted that firm was involved in active manufacturing in this section at the time of inspection and it was evident that the firm after arrival of the inspection team let the workers to leave the premises and the batches of drugs under manufacturing were left as they were. It was noted that a batch of syrup namely "Ammo Plus, Batch No.3481, batch size 1000 liter" was present in a manufacturing tank. On the window of the room a label "Line Clearance Certificate" was fixed by adhesive tape showing that area was being used for manufacturing of Ammo Plus, Batch No. 3481 on 24.01.2017. A container was containing some liquid material bearing a label "Zofen Tab,

Coating material" showing that this syrup manufacturing area was also being used for other purposes such as for preparation of coating solutions for tablets, which is also a severe GMP non-compliance and may lead to cross-contamination.

b. A room for oral liquid filling having two filling machines and an attached small room having a bottle blowing machine. Liquid filling room was connected to packing room through conveyor belt. This area was not provided with HVAC system which is required for environmental control and to avoid cross-contaminations.

Team noted that a batch of syrup No-All, Batch No. 3480 was being packed and some quantity of packed/unpacked filled bottles were left on the packing table when the workers left the premises.

iii. **Tablet Section,** it was comprised of:

a. A room for dry and wet granulation, drying & final mixing. This room was not neat and clean. There was powder and dust on floor, walls, and electrical panels. The fluidized bed dryer in section was very dirty. It was rusty and its bottom air duct for supply of hot air was full of powder. Even cobwebs were seen in the airway .

There were about 9 drums full of different tablets of different colours in polythene bags of different sizes and powder/granules of some unidentified materials. Some of the bags were labeled with marker, whereas, majority were unidentified. Storage/stocking of these different loose tablets and powder/granules in this manufacturing area could not be justified by the production manager. Presence of such different unidentified tablets/powder/granules is a serious violation of GMP as it has potential for cross-contamination and mix-ups .

b. A compression room, accessed through a buffer that opened into a lobby having three cubicles with compression machines. The compression cubicles were provided with HVAC. The lobby was not provided with HVAC, suggesting that it was not possible to maintain the negative pressure of compression cubicles that may pose a great risk of cross contamination. The doors and cubicles of this area were made of aluminum and glass and were not properly maintained. There were open drainage holes in the compression cubicles.

c. A coating room having entry through a buffer and a solution preparation room was provided. This area was not provided with HVAC. There was water seepage on walls. There was no equipment for preparation of coating solution.

d. A blistering room; this room was not provided with HVAC. The room was dirty. Open electrical wires were hanging, filled with dust and powder at the connection point of ceiling fan.

iv. **Capsule section:** could not be inspected because entrance door to this section was locked by the firm and was not opened even when asked.

v. **Ointment/Cream/Gel section:** could not be inspected because entrance door to this section was locked by the firm and was not opened even when asked.

vi. **Injectable section:** could not be inspected because entrance door to this section was locked by the firm and was not opened even when asked.

vii. **Raw material store:** could not be inspected because entrance door was locked by the firm and was not opened even when asked.

viii. **Packing material store:** could not be inspected because entrance door was locked by the firm and was not opened even when asked.

ix. **Finished goods store:** could not be inspected because entrance door was locked by the firm and was not opened even when asked.

x. **Quality Control:** could not be inspected because entrance door was locked by the firm and was not opened even when asked.

Conclusion:

Based on the areas inspected, and considering the findings of the inspection, the team of inspectors was of the opinion that M/s Harmann Pharmaceutical Laboratories (Pvt) Limited, situated at 16 Km, Multan Road, Lahore was Not Complying with GMP requirements as per Schedule B-II required under Rule 20 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

The team of inspectors also observed that the firm was Not Complying with the conditions of license as required under Rule 16, 19 & 20 of Drugs (Licensing, Registering & Advertising) Rules, 1976.

The management of the firm created resistance and obstruction in the inspection of the team by shutting down the electricity and not opening the locked areas as mentioned above, which is a clear violation of Rule 19(8) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is read as:

*"**19. Conditions of licence to manufacture, by way of basic manufacture, semi-basic manufacture formulation and repacking of drugs:***

(8) The licensee shall allow any member of the Central Licensing Board or of a Provincial Quality Control Board or an Inspector to enter, with or without prior notice, any premises and to inspect the plant and the process of manufacture & the means employed in standardising and testing the drugs and to take samples for test and analysis."

And is also an offence under Schedule III of the DRAP Act, 2012, which is read as:

"(3) Obstruction of Inspector - Whoever obstructs an Inspector in the exercise of any power conferred upon him by or under this Act, or disobeys the lawful authority of any Inspector, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one lakh rupees, or with both."

Recommendations:

Keeping in view the findings of the inspection and conclusion, the team of inspectors recommends that:

i. The firm may be directed to stop all kinds of manufacturing activities immediately, because of GMP non-compliance, in greater public interest.
ii. The Drug Manufacturing License of the firm may be cancelled for not complying with the licensing conditions.
iii. Legal action may be taken against the firm for obstructing the lawful authority of inspectors.

Updated Status:

The case was fixed to be heard on 14.02.2017 in the Honorable Justice Islamabad High Court, Islamabad. Wherein the Honorable Justice dismissed the Writ Petition No. 4328/2013 and directed the respondents to perform their statutory obligations without fear and favor and must take all the steps which fall within the ambit of applicable law. The respondents are at liberty to proceed in the matter in requirement of law. The respondents shall submit report through learned registrar of this court for perusal in chamber.

Reply by the firm: The firm vide letter dated 03.03.2017 submitted reply of showcause notice dated 12.11.2013 and requested for the personal hearing and constitution of panel of experts to inspect the production and Quality Control section.

Proceedings of the 252nd Meeting of CLB

The Board was informed that Mr. Ajmal Sohail Asif, FID, Lahore conducted routine GMP inspection of the firm on 03-04.10.2013 and noticed gross violations in the GMP compliance. The FID informed that firm is operating at unsatisfactory level of compliance with GMP guidelines. The FID directed to stop manufacturing activities. Accordingly QA&LT Division issued showcause notice and suspension of production activities to the firm on 12.11.2013. The firm filed a writ petition in Honorable Islamabad High Court, Islamabad, whereby showcause notice and suspension

of production order was challenged. The Honorable Court in its order dated 26.11.2013 suspended the showcause notice / suspension of production order till next date of hearing. The case was heard on 11.01.2017 and the Honorable, Islamabad High Court, Islamabad vacated the stay order and constituted followng panel of experts to conduct the inspection of the firm:-

i. Mr. Faqeer Muhamamd Shaikh, Chairman CLB
ii. Dr. Abdur Rashid, Additional Director (QA&LT)
iii. Dr. Ikram-ul-Haq Member CLB
iv. Area FID, Lahore

The panel inspected the firm on 24.01.2017 and concluded as under:-

a. *" Based on the areas inspected, and considering the findings of the inspection, the team of inspectors was of the opinion that M/s Harmann Pharmaceutical Laboratories (Pvt) Limited, situated at 16 Km, Multan Road, Lahore was Not Complying with GMP requirements as per Schedule B-II required under Rule 20 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.*

b. *The team of inspectors also observed that the firm was Not Complying with the conditions of license as required under Rule 16, 19 & 20 of Drugs (Licensing, Registering & Advertising) Rules, 1976.*

c. *The management of the firm created resistance and obstruction in the inspection of the team by shutting down the electricity and not opening the locked areas as mentioned above, which is a clear violation of Rule 19(8) of the Drugs (Licensing, Registering & Advertising) Rules, 1976."*

Letter for personal hearing was issued to the firm on 08.03.2017. Mr. Haseeb Khan, Director and Prof. Dr. Hafeez Khan of the firm M/s Harmann Pharmaceutical, Lahore appeared before the Board for personal hearing. Mr. Haseeb Khan informed the Board that reply of the show cause notice dated 12.11.2013 has been submitted in the QA&LT Division on 03.03.2017, in compliance to the orders of the Honorable, Islamabad High Court, Islamabad dated 14.02.2017. He added that request for panel inspection to verify the GMP and constitution of panel of experts was also submitted on 03.03.2017. He also added that observations noted during the inspection conducted on 03 & 04.10.2013 and 24.01.2017 has been rectified and the firm is ready for the inspection. The Board enquired regarding status of the production activities of the firm. Director of the firm informed that the production has been suspended after decision of the Honorable, Islamabad High Court. The Board also enquired regarding approval of layout plan in connection with the approved products. Director of the firm informed to the Board that new layout plan in accordance with the registered products shall be submitted in the Licensing Division for necessary approval.

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 inspection dated 03 & 04.10.2013, poor compliance of the firm towards GMP compliance, a Show Cause Notice dated 12-11-2013 and reply of the firm dated 03-03-2017 and orders of the Honorable Islamabad High Court, Islamabad in its Writ Petition No. 4328/2013 dated 14.02.2017, the Board decided to:-

i. Suspend the Drug Manufacturing License of the firm M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, Lahore for a period of (06) six months, under Section 41 of the Drugs Act, 1976 read with Rule 12 (1) of the Drugs (L, R&A) Rules, 1976, from the date of issuance of decision of the 252nd meeting of CLB.

ii. If the management of the firm wants to continue the manufacturing of registered products, the firm shall submit revised layout plan in accordance with the prevailing law, with respect to the registered products and get approval from the Licensing Division.

iii. Re-inspection shall be conducted after completion of suspension period of DML and approval of revised layout plan from the Licensing Division. The CLB authorized Chairman CLB to constitute panel of experts to verify the rectification status of the observations noted during the inspections dated 03&04.10.2013 and 24.01.2017.

iv. The Panel should submit the report on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976. The panel shall also submit brief report in tabulated form identifying the previous observations and the current status with clear and candid recommendations.

v. The report shall be presented in the meeting of Central Licensing Board for perusal and approval.

Item No. III (Misc. Cases)

Case No. i: - Recommendations for Cancellation / Suspension of Drug Manufacturing Licenses of Pharmaceutical Manufacturing Units.

Background of the case:

The Secretary, P&SHD, Punjab, Lahore vide letter dated 09.08.2016 informed that the department has stopped the dispensation of products of some of the companies, due to poor quality issues of the products mentioned against each firms/suppliers. He had recommended for the immediate GMP inspection by DRAP and initiation of exemplary action as per law, in case of non compliance of the premises outside the territory of Punjab.

2. Accordingly, panel of experts were constituted to verify the GMP compliance of the firm located outside the territory of Punjab. Inspection of the following firms located at Karachi, Sindh were conducted by panel comprising of Dr. Najam-us-Saquib, Additional Director (E&M), Syed Muid Ahmed, Member CLB and Mr. Abdul Rasool Shaikh, FID, Karachi and concluded as under:-

Cases referred by the PQCB, Punjab to conduct GMP / PSI of the firms located outside of the territory of the Punjab

S. No.	Product Name	Active Ingredient	Manufacturer.	Conclusion	Action Taken
i.	Kleen Enema		M/s Nabiqasim, Karachi	The firm is found complying GMP as of today. The manufacturing of the product in question was found satisfactory in accordance with the SOP and approved procedure.	No action required. Copy of report sent to the quarter concerned.
ii.	Inhaler Salbo HFA	Salbutamol	M/s Getz, Karachi	The product in question is imported from China. However, the firm should conduct test analysis of this product at there premises.	Accordingly, the firm was directed vide letter dated 28.12.2016 to do the needful as per directions of the panel.
iii.	Susp. Maxil	Amoxicillin	M/s Macter, Karachi	Overall compliance level is rated as good.	No action required. Copy of report sent to the quarter concerned.
iv.	Tab. Augmiclave-DS	Amoxicillin Calvolaunic	M/s Lisko, Karachi	The firm is found complying GMP as of today. The manufacturing of the product in question was found	No action required. Copy of report sent to the quarter concerned.

		Acid		satisfactory in accordance with the SOP and approved procedure.	
v.	Tab. Dirite 500 mg	Valproic Acid	M/s Genome Pharma, Hattar	After thorough inspection the panel concluded that the firm is following GMP guidelines as per Drugs Act, 1976. The firm has also assured not to compromise on the quality and will follow their GMP.	No action required. Copy of report sent to the quarter concerned.

Proceedings of the 252nd Meeting of CLB

The DD (QA) informed to the Board that GMP inspections of the firm were conducted on the request of the Secretary, PQCB, Govt. of Punjab, Lahore. However despite request Government of Punjab did not provided any evidence in support of their recommendations. The reports were presented before the Board for perusal. The Board is of the view that remedy is available under the Provincial Drug Rules. Moreover the Provincial Quality Control Board has their own legal frame work to take action under the prescribed rules. Prequalification inspections are also conducted by the provincial governments prior to purchase of medicines / drugs, which may look into such matters.

Decision of the 252nd Meeting of CLB

After thorough discussion/deliberations and considering all the pros and cons of the case, the Board has decided to ask the Secretary, PQCB, Government of Punjab, Lahore to take action under the prevailing Punjab Drug Rules, 2007.

QUALITY CONTROL CASES

Case No. 01:

Subject: **Manufacture & Sale of Sub-Standard Drugs by M/S Standard Drug Company, Hyderabad. –Recommendation of Cancellation of Drug Manufacturing License (DML) of 12 Samples of M/S Standard Drug Company, Hyderabad, "Under Section 41 of Drugs Act, 1976".**

It is submitted that 12 samples of drugs Manufactured by M/s Standard Drug Company, Hyderabad drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, were declared Substandard by CDL Karachi. On explanation letter issued by the FID, the firm challenged the CDL reports and requested for Appellate Testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the 12 samples as Substandard.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

The Case placed before the Central Licensing Board on recommendations of Registration Board in its 255th meeting held on17-18th December 2015

The Registration Board decided to cancel the registration of following twelve (12) products of M/s Standard Drug Company Hyderabad and recommended the Central Licensing Board for cancellation of DML of M/s Standard Drug Company Hyderabad as 12 samples drugs product of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate Lab NIH Islamabad

Details of Drugs declared Substandard by Both the Labs:

S.No.	Name of the Product Batch No. & M/s	Remarks	Decision of DRB in its 255th meeting held on 17-18th December 2015
1.	Netrozole (Metronidazole) Suspension Batch No.NZ10-A M/s Standard Drug Company Hyderabad (***Reg. No. 057829***)	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of*** **Netrozol Suspension Batch No. NZ 10-A** ***Reg. No. 057829 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as many samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
2.	Netrozole (Metrinidazole) Suspension Batch No.NZ.08-A M/s Standard Drug	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of*** **Netrozol Suspension** ***Batch No. 08-A Reg. No. 057829 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared***

	Company Hyderabad (***Reg. No. 057829)***		***substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
3.	Staifaminc(Mefanimic Acid) Suspension Batch No.SF.07A M/s Standard Drug Company Hyderabad (***Reg. No. 057826)***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of Staifaminc*** **Suspension** ***Reg. No. 057826 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
4.	Linobex-C (Multivitamins) Syrup Batch No. LC.09-A M/s Standard Drug Company Hyderabad ***Reg. No.004077***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of Linobex C Syrup*** **Suspension** ***Reg. No.004077 decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
5.	Rehu-K 50mg Tablets (Diclofenic Potassium) Batch No. RK.01A M/s Standard Drug Company Hyderabad ***Reg. No. 066937***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of Rheu-K 50mg Reg. No. 066937 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
6.	Rheudic-50 Tablets (Diclofenic Sodium) Batch No.RD.04-A M/s Standard Drug Company Hyderabad ***Reg. No.066939***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of Rheudic-50 Tablets Reg. No.066939 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
7.	Sodamint Tablets (Sodium Bicarbonate) Batch No. SM.09-A M/s Standard Drug Company Hyderabad (***Reg. No.008879)***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of*** **Sodamint Tablets** ***Reg. No.008879 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
8.	Staiflic Tablets (Folic Acid) Batch No.SF.03-A M/s Standard Drug Company Hyderabad ***Reg. No.57828***	Substandard (CDL/NIH)	***The Board decided to Cancel the registration of*** **Staiflic Tablets (Folic Acid)** ***Reg. No.57828 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***

9.	Montilu 10mg Tablets (Montilukast Sodium) Batch No.B01A M/s Standard Drug Company Hyderabad ***Reg. No.067688***	Substandard (CDL/NIH)	***The Board decided to Cancel the registration of* <u>Montilu 10 mg Tablets (Mountelukast Sodium)</u> *Reg. No.067688 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
10.	Stabru Suspension (Ibuprofen) Batch No.SB.22A M/s Standard Drug Company Hyderabad ***Reg. No.057827***	Substandard (CDL/NIH)	***The Board decided to Cancel the registration of* <u>Stabru Suspension Ibuprofen</u> *Reg. No.057827 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
11.	Stamelox 15mg Tablets (Meloxicam) Batch No.SA01-A M/s Standard Drug Company Hyderabad ***Reg. No.067648***	Substandard (CDL/NIH)	***The Board decided to Cancel the registration of* <u>Stamelox 15 mg Tablets (</u>Meloxicam)** ***Reg. No.067648 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
12.	Standlo 500mg Tablets (Levofloxacine) Batch No.SO-03-A M/s Standard Drug Company Hyderabad ***Reg. No.066934***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of* <u>Standlo 500mg Tablets (Levofloxicine)</u>** ***Reg. No.066934 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***

M/s Standard Drug Company Hyderabad has filed Constitutional Petition No.971 of 2016 (MA 6205/2016) through Mr. Imtiaz Ahmed Vs Federation of Pakistan in the High Court of Sindh, Karachi, Circuit Court, Hyderabad against the decision of the Drug Registration Board in its 255th meeting held on 17-18th December 2015for cancellation of registration of twelve registered products of M/s Standard Drug Company Hyderabad. However no directions for Central Licensing Board have been received from Honorable Sindh High Court Karachi, Circuit Court, Hyderabad.

The FID Hyderabad at Karachi vide his letter No.10-02-2016-DRAP(K) dated 01-08-2016 has requested to send the Parawise comments and appointment of Standing Council.

Parawise comments and nomination of standing council are under processed/approval in the Division of legal Affairs, DRAP, Islamabad.

Decision:

The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"*The Board decided to issue show cause notice for cancellation of DML of the firm M/s Standard Drug Company Hyderabad as recommended by Registration Board in its 255th meeting held on 17-18th December 2015".*

Current Status:

As per decision of the Central Licensing Board in its 250th meeting held on 27th October, 2016 the firm was issued a show cause notice for cancellation of Drug Manufacturing License (DML). The firm has submitted its reply in response to show cause notice regarding cancellation of Drug Manufacturing License (DML) as 12 samples of the said firm has been declared substandard by both the Laboratories.

The M/s Standard drug company Hyderabad has filed constitution petition in the High Court of Sindh Circuit Bench at Hyderabad vide C.P. D-971/16 which is graciously being dismissed. The judgment of the Honorable High Court Sindh dated 13-02-2017 is as under:-

> ***"the impugned orders are within the jurisdiction as such extraordinary remedy may be pursued/availed by the petitioner. Accordingly, petition is dismissed. Parties shall bear their own costs. However it is clarified that in order to redress his grievance the petitioner may adopt appropriate remedy available to him under the relevant law which shall be dealt with strictly in accordance with law"***

They have requested for personal hearing before the Central Licensing Board.

They have been called for personal hearing.

Proceedings:

Personal hearing letters were issued to the accused persons of the firm but no person appeared before the board. The board was informed that the letter has been received from the Managing Director of the firm, Mr. Imtiaz Ahmad dated 14th March, 2017. He submitted that He is unable to attend the meeting as He is suffering from high fever due to which doctor had suggested him to take complete bed rest and not to travel somewhere with this condition. He requested to call him for personal hearing in next meeting of the Board.

Decision:

The Board after detailed discussion, deliberation and keeping in view the facts of the case including the information provided, the Board decided to cancel the Drug Manufacturing License of the Firm M/s. Standard Drug Company, Hyderabad.

Case No. 02:

Subject: **Seizure of Un-Registered Drugs under Section 18(1) of the Drug Act 1976.**

The FID Lahore Mr. Syed Zia Husnain visited the premises of M/s Mahmood Pharmacy S-77-R/85/C, Jail Road, opposite Services Hospital Lahore on 26th August, 2016. The FID forwarded the case to the Director, QA&LT, DRAP, Islamabad vide letter No.12406/2016-DRAP (L-V) dated 29th August, 2016.

At the time of raid Mr. Sana ullah S/o Muhammad Suleman R/o H. No.05 St. No.05, mohallah Amin park Ravi road Lahore who is manger was present. Mr. Atif Ejaz S/o Ejaz pervaz R/o 67/C Punjab Co-operative housing Society, defense Lahore (Qualified person as per drug sale license) was gone for jumma prayer as informed by the manager Mr. Daud Tareen s/o Muhammad Aslam Tareen R/o B-42, GOR-III Shadman, Lahore (Proprietor) was absent.

The FID Lahore seized the following drugs on form-2 under section 18 (1) (f) of Drug Act, 1976:

S. No.	Name Of Product(s)	Batch/Lot No.	Mfg Data	Exp. Date	Manufactured by	Quantity
01.	Marevan 5mg Tablets	A520518	11-15	05-18	Mfd By. GSK (Detail address not mentioned in English)	(13) Thirteen jars
02.	Marevan 5mg Tablets	A521058	03-16	09-16	-do-	(11) Eleven jars
03.	Marevan 5mg Tablets	A520917	02-16	08-18	-do-	(04) Four jars
04.	Marevan 5mg Tablets	A520916	02-16	08-18	-do-	(15) Fifteen jars
05.	Marevan 5mg Tablets	A520917	02-16	08-18	-do-	(03) Three jars
06.	Centrum Silver	M25939	-	Sep-17	Marked by. Pfizer Madison, NJ07940 USA 2015 Pfizer Inc Made in Canada	(03) Three Packs
07.	Centrum Silver	M87735	-	Dec-17	2014 Pfizer Inc Made in Canada	(02) Two Packs
08.	Centrum Silver	N43989	-	01-18	2014 Pfizer Inc marked by M/s Pfizer Madison, NJ07940	(02) Two Jars
09.	Colomycin Injection	11393	10-2014	10-2017	M/s Forest Laboratories UK, Ltd, Whiddon Valley, Branstaple,	02 Packs×10 Vials

					North Devon Ex 32 8NS, United Kingdom.	
10.	Viagra 100mg Tablets	MALL 19990544G	Dec-2013	01-Apr-2018	Mfd by. Brooklyn, Ne Packed by: Pfizer Ply Ltd, Australia	(03) Three Packs× 06 Tablets
11.	Cialis 20mg Tablets	Control No. 0674654099	-	April-04/2018	Made in USA	(02) Two Packs× 03 Tablets
12.	Centrum Tablets	M877733	-	Dec-17	Mfd. Pfizer Inc. Canada	(02) Packs
13.	Neurobion Injection	213371	12-2015	112017	Mfd. Merck kGaA, Darmstadt, Germany	(03) Three Packs
14.	Pirfenex 200mg Tablets	BA60218	Dec-15	Nov-17	Mfd. Cipla Malpur, Solan 173205 India	(01) One Pack

The FID seized these unregistered drugs in contravention to section 23 of Drugs Act, 1976 and also contravention to DRAP Act, 2012 and the room was locked and sealed under section 18 (i) (h) of Drugs Act, 1976.

Samples of drugs which were available in sufficient quantities were also sent to Federal Government Analyst for test/ analysis.

The details of test/analysis results of said drugs by Federal Government Analyst, Central Drug Laboratory are as under:-

S.No.	**Test Report No.& date**	**Name of Drug with batch No.**	**Mfg by**	**Remarks of CDL**
1.	Test Report No. R.LHR.403/2016 dated 01-11-2016	Marevan 5mg Tablets Batch No.A521058	M/s GSK	Declared **Unregistered** report no.R.LHR.403/2016 dated 01-11-2016
2.	Test Report No. R.LHR.404/2016 dated 01-11-2016	Centrum Sliver Batch No.M30477	M/s Pfizer Inch, Canada	Declared **Unregistered** report no.R.LHR.404/2016 dated 01-11-2016
3.	Test Report No. R.LHR.405/2016 dated 02-11-2016	Cialis 20mg Batch No.0674654099	M/s GSK	Declared **Unregistered** test report no. R.LHR.405/2016 dated 02-11-2016
4.	Test Report No. R.LHR.406/2016 dated 02-11-2016	Pirfenex Tablets Batch No.BA60218	M/s Cipla Ltd India	Drug is not included in any Pharmacopoeia, test report no. R.LHR.406/2016, dated 02-11-2016

The FID requested to allow to keep the safe custody of the seized drugs mentioned on Form-2 under Section 19(5) of the Drug Act 1976 as the firm is involved in illegal and unregistered manufacturing of drugs.

Permission of safe custody of the stock was granted to the FID on 16th September 2016. Meanwhile M/s Mehmood Pharmacy S-77-R/85/C, Jail Road Opposite Services Hospital Lahore filed application in the **Drug Court**, Lahore in connection with case under reference. On the order of Drug Court Lahore, premises (room) under reference was de-sealed on 17-11-2016.

Recommendations of FID

Since the sale and stock of un registered drugs in prohibited under section 23 (1) and section A(1) (a)(vii) of schedule II of Drugs Regulatory Authority of Pakistan Act 2012 which is punishable under section 27(1) (A) of the Drug Act 1976 and schedule III of DRAP Act 2012 . sale of un registered drug is cognizable offence under section 30(2) of the Drug Act 1976 and schedule IV(1) (a) of Drug regulatory authority of Pakistan Act 2012. As pharmacy is not explaining their position in response to the letters of FID. The FID further informed that all four reports of Federal Government Analyst have also been received, therefore under the explained circumstances mentioned above case is being forwarded under section 19(7) of Drugs Act 1976 and section 7 of schedule V of Drugs Regulatory Authority of Pakistan Act 2012 to seek further orders of central licensing Board as to action to be taken against the following accused persons in respect of contravention of Drug Act 1976 and Drug Regulatory Authority of Pakistan Act 2012.

The Show cause notice was issued to the following accused persons on 25th January 2017.

M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital, Lahore.	**Mr. Sana Ullah** S/O M Suleman House No. 05, Street No.05 Mohellah Amin Park Ravi Road, Lahore
Mr. Atif Ejaz S/O Ejaz Perves R/O67/C Punjab Co-Operative Housing Society Defense Lahore.	**Mr. Daud Tareen** S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore (Proprietor).

However, the accused persons had not submitted the reply of the show cause notice.

The above mentioned accused persons have been called for personal hearing before the central Licensing Board.

Proceedings:

The accused persons were called for personal hearing but no person appeared before the Board. The Board was informed that an unsigned letter is received addressed to Secretary Licensing Board from the Sami Ullah, ADV For Asmar Law Associates dated 14th March, 2017 Ref:DRAP/Civil-1297 stating that,

"Mr. Daud Tareen son of Mr. Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore requiring him to "Appear in Person" before the Central Licensing Board, Drug Regulatory

Authority, Islamabad on 15-03-2017 at 11:00 AM in the TF complex, 4th Floor, Sector G-9/4, Islamabad, our elucidations in this regard are as under:-

1. I have been engaged by said Daud Tareen telephonically, formel power of attorney & the necessary relevant record/ documents are still awaited, whereas as per instructions , he is leaving for performing Umrah and is expected back within one month.

2. We are therefore, requested to fix the future date keeping in view the above stated situation within advance intimation to the undersigned."

On query of delivery of Show cause notice, the Board was informed that the Show cause notice were delivered to all accused persons on their own addresses as given by the Federal inspector of Drugs but the enclosed envelops of Show Cause notice dated 25th January, 2017 and personal hearing dated 09th march, 2017 of Mr. Daud Tareen S/O M. Aslam Tareen R/O B-42, GOR-III (Proprietor) is received as returned back with the remarks, " They have left".

Decision:

The Board after detailed discussion, deliberation and keeping in view the facts of the case including the information provided, the Board deferred the case and directed the FID to make sure delivery of show Cause notice and submit the report alongwith clear recommendations including all the provisions of Act and Rules and also to provide copies of Identity Card and Mobile Numbers of all accused persons and the copy of the Drug sale License of the premises.

The meeting ended with the vote of thanks to and by the Chair.