MINUTES OF 245th MEETING OF CENTRAL LICENSING BOARD HELD ON WEDNESDAY 30th DECEMBER, 2015

=*=*=*=

245th meeting of the Central Licensing Board (CLB) was held on Wednesday, 30th December, 2015 in the Committee Room of National Control Laboratory for Biologicals (NCLB), Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad. (Dr. Abdul Rashid CQC attended as representative of QA/LT Division)	Member
2.	Dr. Zaka-ur-Rehman, Chief Drug Controller, Department of Health, Govt. of Punjab.	Member
3.	Mr. Afrasiyab, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa.	Member
4.	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
5.	Dr. Ikram-ul-Haq, QC/QA Expert	Member
6.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
7.	Prof. Dr. Gul Majeed Khan, Professor of Pharmacy	Member
8.	Prof. Dr. Muhammad Saeed, Professor of Pharmacy	Member
9.	Mr. Khurram Shahzad Mughal, Consultant M/o Law, Justice and Human Rights, as representative of M/o Law, Justice and Human Rights, Islamabad.	Member
10.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
11.	Mr. Khalid Munir, Chief Executive, Trigon Pharmaceuticals (Pvt) Ltd., & Ms. Mahvash Siddiqi, Chief Operating Officer Epla Laboratories (Pvt) Ltd., as Representative of PPMA	Observer
12.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
13.	Mr. Kamran Anwar, Secretary General PCDA , representative of PCDA	Observer

The Chairman CLB welcomed the honorable members of this Apex Forum & participants of the meeting. The meeting started with the recitation of verses from the Holy Quran.

The Chairman apprised the members of the Board that proceedings of CLB shall be conducted in an amicable and responsible way to deliver to the public and stake holders in a transparent and efficient manner. Quality shall be given priority and there shall be zero tolerance. He further added that all the legal and codal formalities regarding convening of the meeting have been fulfilled. Mr. Zeeshan Nazir DDC (QA) & Dr. Akbar Ali ADC (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

A. LICENSING DIVISION

Item-I **CONFIRMATION OF THE MINUTES OF 244th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 244th meeting held on Wednesday, 28th October, 2015.

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

The Board considered the following cases of grant of new drug manufacturing license 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 Zoic International, Plot No. 573, Sunder Industrial Estate, Lahore.	**10-12-2015**	**Approved the grant of DML by way of formulation with following two sections:** **Sections (02)** 1. Oral Dry Powder (General) Veterinary 2. Oral Liquid (General) Veterinary

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

The Board considered following cases of Grant of Additional Sections & Expansion/Amendments in Layout Plans (LOPs) etc of already licensed units in the light of recommendations by 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 Lotus Pharmaceuticals (Pvt) Ltd, Plot No. 118-A, Street No. 8, I-10/3, Industrial Area, Islamabad. DML No. 000661	**26-10-2015 Formulation**	**The Board approved the grant of two additional sections as under:-** **Section (02)** 1. Capsule (Cephalosporin) 2. Dry Powder Suspension (Cephalosporin)
2.	M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase-III, Industrial Estate, Hattar. DML No.000363	**07-11-2015 (Formulation)**	**The Board approved the grant of one additional section as under:-** **Section (01)** 1. Injectable Vial (Carbapenem)
3.	M/s Bosch Pharmaceuticals (Pvt) Ltd, Plot No. 221, Sector 23-Korangi Industrial Area, Karachi. DML No.000350	**26-10-2015 (Formulation)**	**The Board approved the grant of two additional sections as under:-** **Sections (02)** 1. Dry Powder Injectable (Carbapenem) with warehouse 2. Sachet (General)

4.	M/s Nexus Pharma (Pvt) Ltd, Plot No. 4/19-4/36 Sector 21 Korangi Industrial Area Karachi. DML No. 000421	**10-12-2015 (Formulation)**	**The Board approved the grant of two additional sections as under:-** **Sections (02)** 1. Dry Powder Suspension (General) 2. Sachet (General)
5.	M/s Gallop Water Sciences, Plot No. 404, Sunder Industrial Estate, Lahore. DML No. 000	**09-11-2015 (Formulation)**	**The Board approved the grant of two additional sections and amendment of LOP in one section as under:-** **Sections (02)** 1. Small Volume Parenteral (SVP)-New section. 2. Ampoules Section (Liquid Injection LDPE Packing)-New section. **Amendments in LOP(01) Section** 1. Large Volume parenteral (LVP)-Amended section.
6.	M/s Stallion Pharmaceuticals (Pvt) Ltd Plot No. 581, Sunder Industrial Estate, Lahore. DML No. 000783	**26-10-2015 (Formulation)**	**The Board approved the grant of one additional sections as under:-** **Section (01)** 1. Dry Powder Injection Vial (Carbapenem)
7.	M/s Kohinoor Industries, 159-160/B, Industrial Estate, Sahiwal. DML No. 000197	**18-09-2015 (Formulation)**	**The Board approved the grant of two additional sections and one Warehouse General as under:-** **Sections (02)** 1. Veterinary Oral Dry Powder (General) 2. Veterinary Oral Liquid (General)
8.	M/s Global Pharma (Pvt) Ltd, Plot No. 204-205, Industrial Area, Kahuta Triangle, Islamabad DML No. 000417	**21-12-2015 (Formulation)**	**The Board approved the amendments /expansions in existing sections as under:-** **Sections (03)** 1. Dry Powder (Suspension) 2. Capsule (Cephalosporin) 3. Dry Powder Injection Vial
9.	M/s Selmore Pharmaceuticals (Pvt) Ltd, 36-KM, Multan Road, Lahore. DML No. 000507	**19-11-2015 (Formulation)**	**The Board approved the grant of seven additional sections as under:-** **Sections (07)** 1. Oral Powder dedicated for penicillin. (Veterinary) 2. Liquid injectable dedicated for penicillin. (Veterinary) 3. Dry powder injectable dedicated for penicillin. (Veterinary) 4. Liquid injectable dedicated for Hormone. (Veterinary) 5. Capsule dedicated for penicillin. (Human) 6. Dry Powder Oral Suspension dedicated for penicillin (Human) 7. Dry powder injectable dedicated for penicillin. (Human)

10.	M/s Fynk Pharmaceutical (Pvt) Ltd, 19-kM GT Road, Kala Shah Kaku District Sheikhupura DML No. 000494	**03-12-2015 (Formulation)**	**The Board approved the grant of two additional sections as under:-** **Sections (02)** 1. Dry Powder Injection (General) 2. Sachet (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	Date of Inspection / Type of License	Decision of CLB
1.	M/s Werrick Pharmaceuticals 216-217, I-10/3 Industrial Area, Islamabad. DML No.000489	**08-10-2015 (Semi Basic)**	The Board was apprised that: • The panel unanimously decided to recommend for the grant of renewal of DML for Biotech section and Chemical Manufacturing with following additional remarks by one panel member Muhammad Arif Ch. DDC DRAP Islamabad as under: "However for commercial manufacturing, they will have to get separate approval from the DRAP." • The panel has not mentioned names of APIs manufactured by firm by way of semi basic. However, firm has provided a separate list of APIs being manufactured in Biotech and Chemical Section which include Interferon Alpha 2a long acting & Interferon Alpha 2b long acting in Biotech Section and Sertraline Citrate, Quetiapine Citrate, Olanzapine Citrate and Cerivastatin Sodium in chemical section. As per available record, the firm has more APIs enlisted in their name which are also not mentioned in the panel inspection report. The Board accordingly observed that panel has not furnished proper report with complete list of APIs being manufactured and list of APIs discontinued and further that the firm is manufacturing biological APIs also, but in panel there is no member from biological side. **Decision of CLB:** **Keeping in view the foregoing narrated facts, the Board unanimously considered and deferred the renewal of DML for re-inspection by same panel with inclusion**

			of Mr. Abdul Samad Director NCLB. The new composition is as under: **1. Mr. Abdul Samad, Director NCLB** **2. Prof. Dr. Azhar Husain, DG/Director HIPS Hamdard University Islamabad.** **3. Muhammad Arif Ch. DDC, DRAP Islamabad.** **4. Zeeshan Nazir Bajar, DDG, DRAP Islamabad.** **5. Dr. Muhammad Fakhruddin Aamir Area FID, DRAP Islamabad.** **The Board further directed the panel to furnish report with clear and candid recommendations for APIs being manufactured and APIs discontinued by the firm.**
2.	M/s Aims Pharmaceuticals Plot No. 291, Industrial Triangle Kahuta Road, Islamabad. DML No.000608	**16-10-2015 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **<u>Sections (05)</u>** 1. Tablet 2. Capsule 3. Cream/Ointment 4. Capsule (Cephalosporin) 5. Dry Powder Suspension (Cephalosporin)
3.	M/s Benson Pharmaceuticals Plot No. 119, Street No. 8 Sector I-10/3 Industrial Area Islamabad. DML No.000447	**16-09-2015** (Formulation)	The Board approved the renewal of DML for following sections as per recommendations of panel: **<u>Sections (05)</u>** 1. Tablet 2. Capsule 3. Tablet (Cephalosporin) 4. Capsule (Cephalosporin) 5. Dry Powder Suspension (Cephalosporin)
4.	M/s. Schazoo Pharmaceutical Laboratories (Pvt) Ltd, 20, Jaranwala Road, Kalawala Stop, Tehsil Ferozewala, District Sheikghupura. DML No.000019	**15-10-2015** (Formulation)	The Board approved the renewal of DML for following sections as per recommendations of panel: **<u>Sections (08)</u>** 1. Tablet General 2. Capsule General 3. Oral Liquid Syrup 4. Liquid Ampoule 5. Eye / Nasal drop 6. Tablet Cephalosporin 7. Capsule Cephalosporin 8. Dry Powder Suspension Cephalosporin

5.	M/s. Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase-III, Industrial Estate, Hattar. DML No.000363	**07-11-2015** (Formulation)	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (14)** 1. Tablet (General) 2. Sachet (General) 3. Capsule (General) 4. Dry Powder Suspension (General) 5. Liquid Injectable (General) Ampoule 6. Capsule (Cephalosporin) 7. Dry Powder Suspension (Cephalosporin) 8. Dry Powder Injection (Cephalosporin) 9. Capsule (Penicillin) 10. Tablet (Penicillin) 11. Dry Powder Suspension (Penicillin) 12. Dry Powder Injection Vial (Penicillin) 13. Tablet (Psychotropic) 14. Dry Powder Injection (Steroid)
6.	M/s Dyson Research Laboratories (Pvt) Ltd, 28-KM Ferozepur Road, Lahore. DML No.000559	**14-10-2015 & 03-11-2015** (Formulation)	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (05)** 1. Tablet (General) 2. Tablet (hormone) 3. Capsule (General) 4. Oral Liquid (General) 5. Dry Powder Suspension (General)
7.	M/s Pharmatec Pakistan (Pvt) Ltd, D-86/A, SITE, Karachi DML No.000024	**21-10-2015** (Formulation)	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (04)** 1. Tablet 2. Liquid 3. Cream / Ointment / Gel (General) 4. Capsule The Board was apprised of the observation of the panel that the firm is manufacturing the hormonal sterile products (androgens and anabolic steroids) in the area for sterile ampules for general products. Therefore the firm was directed to immediately stop the production of hormonal products in the aforesaid area and all previous approvals for hormone production are henceforth, stand cancelled till further approval by the DRAP Islamabad. The Board deferred the renewal of Sterile Liquid Ampoule section due to Sub-Judice nature of case. The Board further directed to forward the observations of panel to Registration Board related to Sterile Liquid Ampoule Section.

8.	M/s Mediate Pharmaceuticals (Pvt) Ltd, Plot No.150-151, Sector 24, Korangi Industrial Area, Karachi. DML No.000167	**26-11-2015** (Formulation)	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (14)** 1. Tablet (General) 2. Tablet (Quinolone) 3. Tablet Psychotropic (oral) 4. Liquid / syrup 5. Ointment 6. Liquid ampoule (general) 7. Liquid Injection (Psychotropic) 8. Infusion (general antibiotic) 9. Dry powder injection (cephalosporin) 10. Capsule (cephalosporin) 11. Dry powder oral (cephalosporin) 12. Capsule (general) 13. Antibiotic (general) Oral 14. Dry powder (general) Injection
9.	M/s Jassh Pharma, 19-KM Ferozepur Road, Lahore. DML No.000601	**07-09-2015 & 15-10-2015** (Formulation)	The Board approved the renewal of DML for following section as per recommendations of panel: **Sections (01)** 1. Hemodialysis
10.	M/s Wahabsons Pharma (Pvt) Ltd, plot No. 402, Settlement No. 184, Bari Kot, Sawat. DML No.000533	**29-08-2015 & 02-11-2015** (Formulation)	The Board approved the renewal of DML for following section as per recommendations of panel: **Sections (01)** 1. Liquid syrup The Board further deferred the renewal of Dry powder suspension (cephalosporin) due to following observations of panel: • Since the unit was granted DML about fifteen years ago, therefore, panel observed that existing layout plan of cephalosporin is not up to the mark as per cGMP requirements. The panel is of opinion that cephalosporin section (dry syrup) may be modified / upgraded. The Board directed the firm to address the observations of panel and rectify the same and inform CLB accordingly.

11.	M/s Nexus Pharma (Pvt) Ltd, Plot No. 4/19-4/36 Sector 21 Korangi Industrial Area Karachi DML No. 000421	**10-12-2015 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (09)** 1. Tablet (General). 2. Capsule (General) 3. Liquid (General) 4. Ointment (General) 5. Dry Powder (Cephalosporin) 6. Capsule (Cephalosporin) 7. Dry Powder Injectable (Cephalosporin) 8. Injectable (Liquid General) 9. Eye Drops (Sterile).
12.	M/s Universal Pharmaceuticals (Pvt) Ltd, 131-A, Industrial Estate, Hayatabad, Peshawar. DML No. 000545 (Formulation)	**15-10-2015 & 05-11-2015**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (06):** 1. Tablet General /Antibiotic 2. Tablet Psychotropic 3. Liquid Syrup General 4. Capsule Cephalosporin 5. Oral Dry Powder Suspension Cephalosporin 6. Capsule General
13.	M/s Renacon Pharma (Pvt) Ltd, 18-KM, Ferozepur Road, Opp. Nishter Colony, Lahore. DML No. 000458 (Formulation)	**29-09-2015 & 07-10-2015**	Keeping in view the recommendations of the panel of experts; the Board thoroughly considered/discussed the case and decided as under: - The Board approved the renewal of DML of the firm for following section as per recommendations of panel: **Section (01)** 1. Hemodialysis Board further directed the firm to shift at new premises after obtaining license within 03 years after fulfilment of legal/codal formalities. The firm shall submit layout plan within 03 months for new premises.
14.	M/s Selmore Pharmaceuticals (Pvt) Ltd, 36-KM, Multan Road, Lahore. DML No. 000507 (Formulation)	**19-11-2015**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (05):** 1. Bolus veterinary 2. Oral Powder veterinary 3. Oral Liquid veterinary 4. Aerosol veterinary 5. Liquid Injectable veterinary

15	M/s Genome Pharmaceuticals (Pvt) Ltd, Plot no. 16/1, Phase-IV, Industrial Estate, Hattar. DML No. 000454 (Formulation)	**19-12-2015**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (07):** 1. Tablet (General) 2. Tablet (Antibiotic/Quinolone) 3. Capsule (General) 4. Dry Powder Suspension (General) 5. Sachet (General) 6. Capsule (Cephalosporin) 7. Dry Powder Suspension (Cephalosporin)
16	M/s Pharmawise Labs (Pvt) Ltd, 25-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore DML No. 000182	**30-10-2015** (Formulation)	The Board was apprised about the background of the previous inspections of the firm and observations of the respective panels. Board further observed that firm's understanding of merely submission of LOP as its approval is not correct. Keeping in view the facts on ground, the Board discussed the case and deferred the renewal of drug manufacturing license due to following observations: - 1. Installation of proper HVAC system as per cGMP requirements; 2. Renovation / upgradation of manufacturing sections and warehouse by getting approval of revised layout plan; 3. Establishment of a separate, independent quality assurance department under additional senior qualified person and also appointment of qualified / technical staff as per requirements; 4. Improvements of flow pattern in the manufacturing and packing section as per requirements; Board further directed the firm to comply the above observations within period of 03 months.
17	M/s Surge Laboratories (Pvt) Ltd, 14-KM, Sheikhupura Faisalabad Road, Bhikhi, District Sheikhupura. DML No. 000484	**27-10-2015** **&** **01-12-2015** (Formulation)	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (02):** 1. General liquid Injectable (including blow fill seal area). 2. Cephalosporin Dry Powder Injectable

Item No. V Miscellaneous Cases.

Case No.1 CHANGE OF THE MANAGEMENT OF M/S HISUN PHARMACEUTICAL INDUSTRIES, 6237-A, R-2 INDUSTRIAL ESTATE GADOON AMAZAI SWABI, DML NO.000624 (FORMULATION).

The case was placed in the agenda as under: -

M/s. Hisun Pharmaceutical Industries, Swabi, DML No.000624 (Formulation) has applied for change of management with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad.

The management of the firm has been partially changed as per Form-H as under:-

Old Management	Retiring Management	New Management (Form-H)
Mr. Altaf-Ur-Rahman S/o Abdul Wadood. CNIC No. 13503-1365319-9. Zia-ur-Rahman S/o Abdul Wadood. CNIC No. 16101-1751185-5. Rashid Ahmad S/o Abdul Wadood. CNIC No. 15602-8456636-7. Shafiq-ur-Rahman S/o Abdul Wadood. CNIC No. 16101-8654128-5	Mr. Alataf-Ur-Rahman S/o Abdul Wadood. CNIC No. 13503-1365319-9. Zia-ur-Rahman S/o Abdul Wadood. CNIC No. 16101-1751185-5. Rashid Ahmad S/o Abdul Wadood. CNIC No. 15602-8456636-7.	Rana Muhammad Nawaz S/o Rana Muhammad Aslam. CNIC No. 34601-9588618-1. Muhammad Burhan-ud-Din S/o Haji Yousaf Sghah. CNIC No. 15602-823622-9. Shafiq-ur-Rahman S/o Abdul Wadood. CNIC No. 16101-8654128-5

Decision of CLB:

The Board considered and approved the change of management of M/s. Hisun Pharmaceutical Industries, Swabi, DML No.000624 (Formulation) from old management to new management as under: -

Old Management	Retiring Management	New Management (Form-H)
1. Mr. Altaf-Ur-Rahman S/o Abdul Wadood. CNIC No. 13503-1365319-9. **2. Zia-ur-Rahman S/o Abdul Wadood. CNIC No. 16101-1751185-5.** **3. Rashid Ahmad S/o Abdul Wadood. CNIC No. 15602-8456636-7.** **4. Shafiq-ur-Rahman S/o Abdul Wadood. CNIC No. 16101-8654128-5**	**1. Mr. Alataf-Ur-Rahman S/o Abdul Wadood. CNIC No. 13503-1365319-9** **2. Zia-ur-Rahman S/o Abdul Wadood. CNIC No. 16101-1751185-5** **3. Rashid Ahmad S/o Abdul Wadood. CNIC No. 15602-8456636-7**	**1. Rana Muhammad Nawaz S/o Rana Muhammad Aslam. CNIC No. 34601-9588618-1** **2. Muhammad Burhan-ud-Din S/o Haji Yousaf Sghah. CNIC No. 15602-823622-9** **3. Shafiq-ur-Rahman S/o Abdul Wadood. CNIC No. 16101-8654128-5**

Case No.2 CHANGE OF THE MANAGEMENT OF STATUS OF M/S A'RAF (PVT) LTD, 23-KM, RAIWIND ROAD, LAHORE DML NO.000685 (FORMULATION).

The case was placed in the agenda as under: -

M/s. A'raf (Pvt) Ltd, Lahore, DML No.000685 (Formulation) has applied for change of management with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad.

The management of the firm has been changed as per Form 29 issued by Security Exchange Commission of Pakistan where this company is registered under:-

Current Partners as per Form 29	Proposed Management as per Form 29
1. Mr. Shahid Munir, **CNIC:** 35202-2938966-1.	1. Mr. Muhammad Zeeshan, **CNIC:** 35202-9611591-7.
2. Mr. Khalid Munir, **CNIC:** 35202-6378136-7.	2. Mrs. Farah Naz Saleem Qureshi, **CNIC:** 35202-9830108-0.

Decision of CLB:
The Board considered and approved the management of M/s. A'raf (Pvt) Ltd, Lahore, DML No.000685 (Formulation) from old management to new management as under: -

Old Management as per Form 29	Retiring/Leaving Management	New Management as per Form 29
1. Mr. Shahid Munir, CNIC: 35202-2938966-1	**1. Mr. Shahid Munir, CNIC: 35202-2938966-1**	**1. Mr. Muhammad Zeeshan, CNIC: 35202-9611591-7**
2. Mr. Khalid Munir, CNIC: 35202-6378136-7	**2. Mr. Khalid Munir, CNIC: 35202-6378136-7**	**2. Mrs. Farah Naz Saleem Qureshi, CNIC: 35202-9830108-0**

Case No.3 CHANGE OF THE MANAGEMENT OF STATUS OF M/S SYNCHRO PHARMACEUTICALS, 77 INDUSTRIAL ESTATE KOT LAKHPAT LAHORE DML NO.000575 (FORMULATION).

The case was placed in the agenda as under: -

M/s Synchro Pharmaceuticals, 77 Industrial Estate Kot Lakhpat Lahore, DML No.000575 (Formulation) has applied for change of management with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad.

The management of the firm has been partially changed as per partnership deed:-

Current Partners as per Partnership Deed	Proposed Management as per Form 29
1. Dr. Mahmood Alam Sadana 2. Mr. Shams Mahmood Sadana.	1. Mr. Muhammad Shams Mahmood Sadana CNIC No. 35202-7439673-5. 2. Sheikh Mahmood Alam CNIC No. 35202-4590611-7. 3. Mrs. Anood Shams CNIC No. 35202-0895802-0.

Decision of CLB:

The Board considered and approved the management of M/s Synchro Pharmaceuticals, 77 Industrial Estate Kot Lakhpat Lahore, DML No.000575 (Formulation) from old management/partners to new management/partners as under: -

Old Partners/Management as per Partnership Deed	Retiring Management	New Partners/ Management as per Partnership Deed
1. Dr. Mahmood Alam Sadana 2. Mr. Shams Mahmood Sadana.	-Nil-	1. Sheikh Mahmood Alam CNIC No. 35202-4590611-7 2. Mr. Muhammad Shams Mahmood Sadana CNIC No. 35202-7439673-5 3. Mrs. Anood Shams CNIC No. 35202-0895802-0

Case No.4 **APPROVAL OF MASER LAYOUT PLAN / AUTHENTICATION / REGULARIZATION OF EXISTING FACILITY & RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000363 (FORMULATION) ADDITIONAL SECTION AND REGULARIZATION OF MATER LAYOUT PLAN.**

The case was placed in the agenda as under: -

M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase-III, Industrial Estate, Hattar DML No. 000363 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were being licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

S.#	Sections	S.#	Sections
1.	Tablet (General)	2.	Sachet (General)
3.	Capsule (General)	4.	Dry Powder Suspension (General)
5.	Liquid Injectable (General) Ampoule	6.	Capsule (Cephalosporin)
7.	Dry Powder Suspension (Cephalosporin)	8.	Dry Powder Injection (Cephalosporin)
9.	Capsule (Penicillin)	10.	Tablet (Penicillin)
11.	Dry Powder Suspension (Penicillin)	12.	Dry Powder Injection Vial (Penicillin)
13.	Tablet (Psychotropic)	14.	Dry Powder Injection (Steroid)

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

1. Prof. Dr. Muhammad Saeed, Member CLB.
2. Mr. Sardar Afrasiab, Chief Drug Inspector, KPK
3. Mr. Rehmatullah Baig Alvi FID, DRAP Peshawar.
4. Mr. Adnan Shahidullah, ADC DRAP Peshawar.

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

Recommendations: -

Based on the findings of the inspection M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase-III, Industrial Estate, Hattar was considered to be operating at a very good level of compliance with cGMP guidelines as per Drug Act 1976 and rules framed there under.

Therefore the panel recommends the grant of approval of master layout plan/ authentication / regularization of existing facility, grant of additional section i.e. Injectable vial (Carbapenem) and renewal of DML No. 000363 (formulation).

Decision of CLB:

The Board considered the case and approved regularization of following sections of M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase-III, Industrial Estate, Hattar DML No. 000363 (Formulation) as per recommendations of panel of experts: -

S.#	Sections	S.#	Sections
1.	Tablet (General)	2.	Sachet (General)
3.	Capsule (General)	4.	Dry Powder Suspension (General)
5.	Liquid Injectable (General) Ampoule	6.	Capsule (Cephalosporin)
7.	Dry Powder Suspension (Cephalosporin)	8.	Dry Powder Injection (Cephalosporin)
9.	Capsule (Penicillin)	10.	Tablet (Penicillin)
11.	Dry Powder Suspension (Penicillin)	12.	Dry Powder Injection Vial (Penicillin)
13.	Tablet (Psychotropic)	14.	Dry Powder Injection (Steroid)

Case No.5 APPROVAL OF MASER LAYOUT PLAN / AUTHENTICATION / REGULARIZATION OF EXISTING FACILITY OF M/S GENOME PHARMACEUTICALS (PVT) LTD, PLOT NO. 16/1, PHASE-IV, INDUSTRIAL ESTATE, HATTAR. DML NO. 000454 (FORMULATION)

The case was placed in the agenda as under: -

M/s Genome Pharmaceuticals (Pvt) Ltd, Plot no. 16/1, Phase-IV, Industrial Estate, Hattar. DML No. 000454 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were being licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

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

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

1. Prof. Dr. Muhammad Saeed, Member CLB.
2. Mr. Sardar Afrasiab, Chief Drug Inspector, KPK.
3. Rana Ihsanul Haq Athar ADC (Reg-PEC), DRAP Islamabad
4. Mr. Rehmatullah Baig Alvi FID, DRAP Peshawar.
5. Mr. Adnan Shahidullah, ADC DRAP Peshawar.

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

Recommendations: -

In reference to DRAP letter No.F.3-7/95-Lic (Vol-I) dated December, 10, 2015, the constituted panel conducted detail inspection of the firm M/s Genome Pharmaceutical (Pvt) Ltd, Plot no. 16/1, Phase-IV, Industrial Estate, Hattar on 19-12-2015 regarding renewal of DML No. 000454 (by way of formulation) and regularization of existing sections.

The constituted panel observed that the firm has 7 approved sections as per approved layout plan i.e.

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

However, dry powder injection (cephalosporin) section does not exist. All the existing sections are separate from each other and the entire machines / equipments found placed in

separate rooms with proper HVAC system. HVAC found in proper conditions, validated and humidity record was properly experienced technical staff in QA, QC & Production. The firm has also provided separate rooms for raw material, packing materials and finished goods. In dispensing room they have provided weighing balances, dehumidifier with proper HVAC facilities. Area found properly maintained.

In quality control the firm has provided all the latest equipments i.e. HPLC gradient and isocratic, FTIR, Atomic Absorption and stability chambers etc. all the equipments found calibrated and validated. Some of the test reports of raw material, finished product checked an well maintained.

Therefore, the panel recommends the renewal of DML No.000454 and regularization of existing sections as mentioned above.

Decision of CLB:

The Board considered the case and approved regularization of following sections of M/s Genome Pharmaceuticals (Pvt) Ltd, Plot no. 16/1, Phase-IV, Industrial Estate, Hattar DML No. 000454 (Formulation) as per recommendations of panel of experts: -

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

Case No.6 **APPROVAL OF MASER LAYOUT PLAN / AUTHENTICATION / REGULARIZATION OF EXISTING FACILITY OF M/S PHARMATEC PAKISTAN (PVT) LTD, D-86/A, SITE, KARACHI DRUG MANUFACTURING LICENSE NO. 000024 (FORMULATION)**

The case was placed in the agenda as under: -

M/s Pharmatec Pakistan (Pvt) Ltd, D-86/A, SITE, Karachi DML No. 000024 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were being licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

S.#	Sections
1.	Tablet General
2.	Liquid General
3.	Capsule General
4.	Cream / Ointment & Gel (General)
5.	Sterile Liquid Ampoules (General)

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

1. Syed Muied Ahmed, Member CLB, Lahore.
2. Mr. Qaiser Muhammad, Chief Drug inspector, Sindh.
3. Dr. Saif ur Rehman Khattak, Government Analyst CDL, Karachi.
4. Muneeza Khan, FID, DRAP, Karachi.
5. Mr. Farman Ali Bozdar, ADC, CDL, Karachi.

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

Recommendations: -

Keeping in view good facilities made available and over all well maintained manufacturing operations, the panel recommends the renewal of firm's Drug Manufacturing License by way of formulation bearing No. 000024.

Since the plant has been constructed in accordance with the approved layout plan, the panel verifies and recommends the approval of master layout plan / authentication / regularization of existing facility of the firm bearing Drug Manufacturing License by way of formulation No. 000024 having dedicated HVAC and as per approved layout plan.

Inspection report was also prepared on the evaluation Performa that is attached herewith for the submission to Central Licensing Board, DRAP Islamabad for its consideration and further necessary action in the mater.

Decision of CLB:

The Board considered the case and approved regularization of following sections of M/s Pharmatec Pakistan (Pvt) Ltd, D-86/A, SITE, Karachi DML No. 000024 (Formulation) as per recommendations of panel of experts: -

S.#	Sections
1.	**Tablet General**
2.	**Liquid General**
3.	**Capsule General**
4.	**Cream / Ointment & Gel (General)**

The Board deferred the regularization of Sterile Liquid Ampoule section due to Sub-Judice nature of case.

Case No.7 APPROVAL OF MASER LAYOUT PLAN / AUTHENTICATION / REGULARIZATION OF EXISTING FACILITY OF M/S WILSON'S PHARMACEUTICALS, PLOT NO. 366,387-388, I-10 INDUSTRIAL AREA, ISLAMABAD. DML NO. 000239 (FORMULATION)

The case was placed in the agenda as under: -

M/s Wilson's Pharmaceuticals, Islamabad DML No. 000239 (Formulation), has applied for regularization of layout plan of running facility for their following existing section which was being licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

S.#	Section
1.	Tablet (Psychotropic)

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

1. Prof. Dr. Gul Majeed Khan, Member CLB.
2. Muhammad Arif Chaudhary, DDC DRAP Islamabad.
3. Dr. Muhammad Fakhruddin Aamir FID, DRAP, Islamabad.
4. Dr. Akbar Ali, ADC(Lic), DRAP Islamabad.

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

Recommendations: -

Inspection was conducted on 28-12-2015 and rated Good by the panel.

The company has developed and renovated the existing psychotropic section as per the approve layout plan. The machines were installed. The section has separate independent change room facility. HVAC system was installed. As per the scope of letter of DRAP, the panel unanimously verify and recommend the amended psychotropic tablet section.

Decision of CLB:

The Board considered and approved the amendments in layout plan and further approved regularization of the Tablet Psychotropic section of M/s Wilson's Pharmaceuticals, Islamabad DML No. 000239 (Formulation) as per recommendations of panel of experts.

Case No.8 THE STATE VERSUS M/S MEDI MARKER'S PHARMACEUTICALS (PVT) LTD., PLOT NO. A-104, S.I.T.E., HYDERABAD.

The case was placed in the agenda as under: -

Division of Drug Licensing has received following Court Orders from Drug Court, Lahore. The same are placed for the consideration of Board, please.

THE STATE VERSUS MEDI MARKER'S PHARMACEUTICALS (PVT) LTD

Present: DDPP for the State
Accused Absent.

On the last date of hearing N.B.W were issued and the same be forwarded to Deputy Inspector General Hyderabad. The reply from the DIG is received, further marked to the Superintendent of Police Hyderabad, but no reply from the S.P Hyderabad is received as yet.

Let us issued N.B.W of arrest of the accused for 20-11-2015 and again forwarded to the DIG Hyderabad with the direction that the previous warrant were not returned back yet. In these circumstances the attitude of the Sindh Police is highly objection. The copy of the order be sent to the DIG and S.P Hyderabad along with warrants with the direction to get execute the warrant and produce the accused before the court, if he failed then a responsible officer not below the rank of Sub Inspector is directed to appear before.

The N.B.W of arrest of the accused forwarded to the Drug Regulatory Authority of Pakistan through Federal Drug Inspector Lahore with the direction to get execute the warrant of the accused and till the arrest of the accused their license may immediately be suspended and the factory premises of the accused shall be scaled under intimation to this Court.

Announced

03-11-2015

S/d
Ch. Muhammad Jahangir
Chairman

S/d
Dr. Mubashar Ahmed Butt
Member

S/d
Farooq Bashir Butt
Member

Proceedings:

The Board was apprised that in pursuance of orders of Honorable Drug Court; Licensing Division has written a letter to DDG (E&M) Lahore for obtaining complete case details from Honorable Drug Court so that case may be processed further.

Decision of CLB:

Keeping in view the facts of the case, proceeding of the Board and opinion of law expert; the Board considered and decided as under: -

- **The Board adopted and endorsed the actions taken by Licensing Division.**
- **The Board decided to issue a Show Cause notice with personal hearing to the M/s. Medi Marker's Pharmaceuticals (Pvt) Ltd that why their drug manufacturing license may not be suspended in pursuance of the orders of Honorable Drug Court.**
- **Orders of Honorable Drug Court for sealing of factory premises shall be executed by QA/LT Division through concerned FID.**
- **The Board directed to send an interim report to the Honorable Drug Court Lahore.**

Case No. 9 **State Versus 1. Saif Islam M.D 2. Roohullah production incharge 3. Miss Nosheen Raza Quality control incharge of M/s. Alson Pharmaceuticals 169-7th Road Industrial Estate Hayatabad Peshawar Pakistan. (Accused)**

The case was placed in the agenda as under: -

Division of Drug Licensing has received following Court Orders from Drug Court, Gilgit Baltistan. The same are placed for the consideration of Board, please.

IN THE COURT OF CHAIRMAN DRUG COURT/SESSIONS JUDGE, GILGIT.

S.C. No. 117/2014

State ……

Versus.

1. Saif Islam M.D 2. Roohullah production incharge 3. Miss Nosheen Raza Quality control incharge of M/s. Alson Pharmaceuticals 169-7th Road Industrial Estate Hayatabad Peshawar Pakistan. (Accused)

OFFENCE UNDER SECTION 27/23 DRUG ACT, 1976.

To,

The CEO,
Drug Regulatory Authority of Pak (DRAP),
Pak Secretariat Block-C Islamabad.

Subject: - SUSPENSION OF LICENSE OF M/S ALSON PHARMACEUTICALS, 169-7 ROAD, INDUSTRIAL ESTATE HAYATABAD PESHAWAR PAKISTAN FIXIL REG. NO. 031652 BATCH NO. 03. MANUFACTURE DATE 11/2004 EXPIRE DATE 11/2006.

Whereas, this court had issued show cause notice against the accused/respondents above on 26-06-2015 in offences under section 27/23 Drug Act 1976 pending trial before this court with direction to contest the show cause notice which is not interested in contesting the show cause notice.

Since DRA is the only authority in Pakistan to issue the manufacturing license and registration of the drugs the provision has already given this mandate to the federal government to established the DRA at federal level.

You are therefore directed to suspend the manufacturing license of manufacturing company MS Alson pharmaceuticals 169 7th Road Industrial Estate Hayatabad Peshawar Pakistan to the extent of product fixil suspension Reg. No. 031652 batch No. 3 and communicate your action taken to this court on or before 26-11-2015.

Given under my hand and seal of the court this 27th October, 2015.

Sd/-
Chairman Drug Court
Gilgit Baltistan
Session Judge
Gilgit

Decision of CLB:

Keeping in view the facts of the case, proceeding of the Board and opinion of law expert; the Board considered and decided as under: -

- **The case shall be referred to Registration Board for suspension of registration of Fixil Suspension Reg. No. 031652 in the light of orders of Honorable Drug Court Gilgit Baltistan.**
- **A Show Cause notice with personal hearing to M/s. Alson Pharmaceuticals 169-7th Road Industrial Estate Hayatabad Peshawar Pakistan be issued that why their drug manufacturing license for Dry Suspension Section in which Fixil Suspension is manufactured may not be suspended in pursuance of the orders of Honorable Drug Court, Gilgit Baltistan.**
- **The Board directed to send an interim report to the Honorable Drug Court Gilgit Baltistan accordingly.**

Case No. 10 **State through Drug Inspector District Skardu Gilgit Baltistan**

Versus

1. Imtiaz Ahmed Managing Director 2. Hameed Shuja production incharge 3. Abdul Rub Quality Control Incharge of M/s. Medicraft Pharmaceuticals 126-B Industrial Area Hayatabad Peshawar (Accused)

The case was placed in the agenda as under: -

Division of Drug Licensing has received following Court Orders from Drug Court, Gilgit Baltistan. The same are placed for the consideration of Board, please.

IN THE COURT OF CHAIRMAN DRUG COURT/SESSIONS JUDGE, GILGIT.

Complaint No. 119/2014 Dated 26th October, 2015

To,

The Chief Executive Officer,
Drug Regulatory Authority
C block, Pak Secretariat,
Islamabad.

Title: State through drug inspector District Skardu, Baltistan.

Versus

1. Imtiaz Ahmed Managing Director 2. Hameed Shuja Produciton Incharge 3. Abdul Rub quality control incharge M/s Medicraft Pharmaceutical 126-B Industrial Area Hayatabad Peshawar.

Subject: - COMPLAINT UNDER SECTION 23/27 DRUG ACT, 1976.

The above mentioned complaint has been registered in this court under the provision of Drugs Act 1976 and trial against the respondent/Company is hampered due to non attendance of the accused/ manufacturers despite issuance of legal notice/information to them by the Court. This willful absence of the respondents shows that the company respondents / accused have nothing to say in their defense.

Allegation/accusation against the accused/ company (M/s Medicraft pharmaceuticals 126-B Industrial Area Hayatabad Peshawar) are manufacturing of substandard drugs i.e inj. Rocimed 1 mg Bach No. RMO19.

The Ministry of National Regulations Coordinations and Services (DRAP) is the only Authority for issuance for drugs the country there for it is required of the DRAP to suspend and cancel the license and registration of the above said company medicine and the result of the action taken may be communicated to this court on or before 25-11-2015.

Given under my hand and seal of the court this 26th October, 2015.

Sd/-
Chairman Drug Court
Gilgit Baltistan
Session Judge
Gilgit

Decision of CLB:

Keeping in view the facts of the case, proceeding of the Board and opinion of law expert; the Board considered and decided as under: -

- **The case shall be referred to Registration Board for suspension / cancellation of registration of Injection Rocimed 1mg in the light of orders of Honorable Drug Court Gilgit Baltistan.**
- **A Show Cause notice with personal hearing to M/s. M/s Medicraft pharmaceuticals 126-B Industrial Area Hayatabad Peshawar be issued that why their drug manufacturing license for Injection Section in which Injection Rocimed 1mg is manufactured may not be suspended / cancellation in pursuance of the orders of Honorable Drug Court.**
- **The Board directed to send an interim report to the Honorable Drug Court.**

Case No. 11 **State through Drug Inspector District Skardu Gilgit Baltistan**
Versus

1. Aftab Ahmed Managing Director 2. Muhammad Iqbal Somoroo Production Incharge 3. Muhammad Yousaf Qureshi quality control incharge M/s Regent Laboratory C-20, SITE, Super Highway Karachi. (Accused)

The case was placed in the agenda as under: -

Division of Drug Licensing has received following Court Orders from Drug Court, Lahore. The same are placed for the consideration of Board, please.

IN THE COURT OF CHAIRMAN DRUG COURT/SESSIONS JUDGE, GILGIT.

Complaint No. 30/2014 Dated 26th October, 2015

To,

The Chief Executive Officer,
Drug Regulatory Authority
C block, Pak Secretariat,
Islamabad.

Title: State through drug inspector District Skardu, Gilgit Baltistan.

Versus

1. Aftab Ahmed Managing Director 2. Muhammad Iqbal Somoroo Production Incharge 3. Muhammad Yousaf Qureshi quality control incharge M/s Regent Laboratory C-20, SITE, Super Highway Karachi.

Subject: - COMPLAINT UNDER SECTION 23/27 DRUG ACT, 1976.

The above mentioned complaint has been registered in this court under the provision of Drugs Act 1976 and trial against the respondent/Company is hampered due to non attendance of the accused/ manufacturers despite issuance of legal notice/information to them by the Court. This willful absence of the respondents shows that the company respondents / accused have nothing to say in their defense.

Allegation/accusation against the accused/ company (M/s Regent Laboratory C-20, SITE, Super Highway Karachi) are manufacturing of substandard drugs i.e Tablet Capsule Remoxy 250 mg batch No. 901.

The Ministry of National Regulations Coordinations and Services (DRAP) is the only Authority for issuance for drugs the country there for it is required of the DRAP to suspend and cancel the license and registration of the above said company medicine and the result of the action taken may be communicated to this court on or before 25-11-2015.

Given under my hand and seal of the court this 26th October, 2015.

Sd/-
Chairman Drug Court
Gilgit Baltistan
Session Judge
Gilgit

Decision of CLB:

Keeping in view the facts of the case, proceeding of the Board and opinion of law expert; the Board considered and decided as under: -

- **The case shall be referred to Registration Board for suspension / cancellation of registration of Tablet Capsule Remoxy 250mg in the light of orders of Honorable Drug Court Gilgit Baltistan.**
- **A Show Cause notice with personal hearing to** M/s Regent Laboratory C-20, SITE, Super Highway Karachi **be issued that why their Table & Capsule Section in which Tablet/Capsule Remoxy 250mg is manufactured may not be suspended / cancellation in pursuance of the orders of Honorable Drug Court.**
- **The Board directed to send an interim report to the Honorable Drug Court.**

Case No.12. M/S ABBOTT LABORATORIES (PAKISTAN) LTD, KARACHI.

- **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000001 (FORMULATION) OF**
- **GRANT OF ADDITIONAL SECTIONS / EXPANSION / AMENDMENTS (CAPSULE GENERAL)**
- **REEGULARIZATION OF MASTER LAYOUT PLAN**

The case was placed in the agenda as under: -

Brief Background:-
The case was placed in 243rd meeting of CLB held on 9th September, 2015 as under: -

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Abbott Laboratories (Pakistan) Ltd, Karachi. DML No.000001 (Formulation) **Sections (01)** 1. Capsule (General)	**3-6-2015 & 4-6-2015**	**Panel also recommends renewal of DML by way of formulation. Panel also recommends capsule section intended for filling of Dry pellets.**	1. Mr. Muied Ahmad, Member CLB. 2. Dr. Muhammad Tanweer Alam, Director CDL, Karachi. 3. Mr. Qaiser Muhammad Chief Drug Inspector, Sindh. 4. Obaid Ali, Ph.D, Area FID, DRAP Karachi. 5. Dr. Shoaib Ahmed, ADC, DRAP, Karachi.
	Recommendations of the Panel:- Two days pre-announced 10 hour visit of M/s Abbott Laboratories (Pakistan) Ltd, Karachi was conducted by the constituted panel. Visit included walk through inspection of manufacturing facilities, on site and off site discussion with inspected from Director to Operator and quick review of documents. The objective of the inspection in the shortest time was limited to verification of manufacturing site in accordance with the approved layout plan and assessment of suitability with regard to equipment, HVAC and Personnel to give recommendation for renewal of Drug Manufacturing License (DML). However, total GMP compliance inspection in 10 hours for such a wide manufacturing facility (aseptic and terminal sterilization manufacturing process of Injectables, multiple oral solid dosage from manufacturing facility, oral liquid manufacturing facility, ointment / cream manufacturing facility, facility of sachet dosage form, warehouse, quality control laboratory, microbiological laboratory, HVAC, water system and over and above quality system etc.) was a challenge and hard to conclude. During			

	inspection, temperature control of the huge raw and packaging material warehouse divided into several segregated portion was found not controlled for temperature and humidity, few portions were designated as "controlled temperature" where temperature was found 25◦C, some portions had no facilities of temperature control and bear the natural temperature that may go up to scorching and the only intercepting hindrance is the concrete wall and roof that ma significantly absorb heat and take time to come back on ground state sometimes. M/s Abbott Laboratories (Pakistan) Ltd, Karachi assured their level of compliance moving towards improvement and maintains consistency in addressing the potential observations discussed. M/s Abbott Laboratories (Pakistan) Ltd, Karachi bearing Drug Manufacturing License (DML) No. 000001 by way of formulation was concluded up to reasonable level of GMP compliance with regard to competitive environment. Panel also verified the layout plan with shown plan that was already approved by the Islamabad through stamp and signature. Panel also recommends renewal of DML by way of formulation and capsule section intend for filling of dry pellets. However, a detail inspection of at least 10 working days is required to assess the compliance of good Manufacturing Practices that will be done by the FID in coming months. The case is submitted for consideration of the Board, please.

Decision of CLB (243rd Meeting) The Board in above three cases decided as under:-

Decision of CLB
The Board was apprised that panel inspection report comprises of two pages and lacks evaluation proforma to be filled separately for each section. The Board reiterated that panel inspection report and recommendations shall be clear and candid and on prescribed proforma which is in practice and implemented by all FIDs of Pakistan. The Board further discussed that evaluation report on prescribed proforma provides information in detail with regard to firm and its running sections. **Keeping in view the above situation the Board unanimously decided and deferred the case for comprehensive report on the prescribed evaluation proforma.**

Accordingly, the decision of CLB was conveyed to the members and FID

Subject:- **Duty Bound To Protect And Promote The Public Health Within The Norms & Science Of Pharmaceutical Regulation.**

Dear Sir,

This refers to letter No. F.2-6/2003 & F.2-3/92-Lic (Vol-II) dated 21st October, 2015 received to your office on 09 November, 2015 addressing your kind good self. I am very thankful to receive at least first indirect communication on the issue related to the subject. The tools and approaches for which I am forced to use in compliance and enforcement were proven inappropriate for example the same did not catch visible signals of high risk and took over 100s of innocent patients life in PIC tragedy. The similar practice of inspection is going on which is neither trustable nor fulfils the required purpose.

I wish to respect the decisions of worthy Board but I have no reason to do so. Since, my posting as FID I am constantly seeking to request meeting before the both Boards so that I can communicate my concerns for open debate and record. My request of March 2015 reminded in

April, May and June 2015 (emailed too) is hereby attached (04 Pages) to see the disregard of the Authority towards written communication of a Ph.D, 20 years experienced Civil Services Officer, as none of the one have been responded so far.

I strongly believe that we are here to protect and promote public health not vice versa in any case. I have a lot of real cases that reveal the ongoing victimization of patients or consumers that can be resolved without adding any cost but with sincere willingness consistent with the science of modern world. It is again requested to give me considerable time to present my concerns and progressive solutions. It is up to the Board what consensus or agreement the Board develops but to make record accurate, precise, accountable and transparent my concerns may be narrated in minutes.

Attached: 04 pages of letters on the subject under discussion.

Sd/-

Obaid Ali, R.Ph, Ph.D
FID, Karachi.

Proceedings:

The Board observed that the directions of Board given in its 243rd meeting have not been followed wherein it was directed for submission of comprehensive report on the prescribed evaluation proforma which is in practice by all FIDs for more than a decade for submission of panel inspection reports for the purpose of grant/renewal of DML etc.

Board further observed that the concerned FID has responded the letter with his concerns regarding the said prescribed proforma whereas the other panel members have not responded to the said letter. The Board further showed its displeasure on such practices.

Decision of CLB:

Keeping in view the above situation, Board thoroughly discussed the matter taking into account the all pros & cons of the case and decided as under:

- **The panel be asked again to furnish the report on the prescribed proforma. In case FID does not prepare the report on prescribed proforma; the panel members may prepare report on the prescribed proforma and submit to the CLB.**
- **Board further directed the area FID to propose a new proforma based on technical grounds for consideration of CLB if he considers existing proforma not addressing inspection requirements / findings appropriately for consideration/decision of the CLB.**

Case No.13. M/S AGP (PVT) LTD, B-23, SITE, KARACHI.

- **Grant of Renewal of Drug Manufacturing license No.000348 (Formulation).**
- **Regularization of Master Layout Plan of M/s AGP (Pvt) Ltd, B-23, SITE, Karachi. DML No.000348 (Formulation).**

The case was placed in the agenda as under: -

Brief Background:-
The case was placed in 243rd meeting of CLB held on 9th September, 2015 as under: -

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
8.	M/s AGP (Pvt) Ltd, B-23, SITE, Karachi. DML No.000348 (Formulation)	**9-6-2015 & 10-6-2015**	**Panel recommends renewal of DML by way of Formulation**	1. Syed Muied Ahmad, Member CLB. 2. Hyder Bux Bozdar, DDG, DRAP, Karachi. 3. Dr. Riaz Bhatti. Chief Pharmacist, JPMC, Karachi. 4. Obaid Ali, Ph.D, Area FID, DRAP Karachi. 5. Dr. Shoaib Ahmed, ADC, DRAP, Karachi.

Recommendations of the Panel:-

Establishment of manufacturing site in 1994 at B-23, SITE, Karachi.

- Solid oral dosage forms tablets.
- Solid oral dosage forms capsules.
- Liquid injection in 1994.
- Liquid syrup / suspension in 1994.
- Semi solid preparations in 1994.
- Sachet filling area.

- ✓ Total number of products registered till date:287 Products
- ✓ Total number of molecules registered till date: 148 molecules
- ✓ Total number of products registered but not manufactured yet: 124 Products
- ✓ Total number of molecules registered but not manufactured yet: 65 molecules
- ✓ Total number of products not manufactured since more than 1 year: 02 products
- ✓ Total number of molecules not manufactured since more than 1 year: 01 molecule
- ✓ Total number of panel inspections conducted so far: 09 panel inspections since 1994

[Extracted from the information of M/s. AGP]

Two days pre-announced 10 hour visit M/s AGP (Pvt) Ltd, B-23, SITE, Karachi was conducted by the constituted panel. Visit included walk through inspection of manufacturing facilities, on site and off site discussion with inspectee from Director to Operator and quick review of documents. The objective of the inspection in the shortest time was limited to verification of manufacturing site in accordance with the approved layout plan and assessment of suitability with regard to equipment, HVAC and Personnel to give recommendation for renewal of Drug Manufacturing License (DML). However, total GMP compliance inspection in 10 hours for such a wide manufacturing facility (aseptic and terminal sterilization manufacturing process of Injectables, multiple oral solid dosage from manufacturing facility, oral liquid manufacturing facility, ointment / cream manufacturing facility, facility of sachet dosage form, warehouse, quality control laboratory, microbiological laboratory, HVAC, water system and over and above quality system etc.) was a challenge and hard to conclude.

	M/s AGP (Pvt) Ltd, B-23, SITE, Karachi assured their level of compliance moving towards improvement and maintain consistency in addressing the potential observations discussed. M/s AGP (Pvt) Ltd, B-23, SITE, Karachi bearing Drug Manufacturing License (DML) No. 000348 by way of formulation was found up to reasonable level of GMP compliance with regard to competitive environment. **Panel recommends renewal of DML by way of formulation and verified the layout plan with shown map that was already approved by the Islamabad.** However, a detail inspection of at least 10 working days is required to assess the compliance of Good Manufacturing Practices that will be done by the FID in coming months.

Decision of CLB (243rd Meeting) The Board in above three cases decided as under:-

Decision of CLB
The Board was apprised that panel inspection report comprises of two pages and lacks evaluation proforma to be filled separately for each section. The Board reiterated that panel inspection report and recommendations shall be clear and candid and on prescribed proforma which is in practice and implemented by all FIDs of Pakistan. The Board further discussed that evaluation report on prescribed proforma provides information in detail with regard to firm and its running sections. **Keeping in view the above situation the Board unanimously decided and deferred the case for comprehensive report on the prescribed evaluation proforma.**

Accordingly, the decision of CLB was conveyed to the members and FID

Subject:- **Duty Bound To Protect And Promote The Public Health Within The Norms & Science Of Pharmaceutical Regulation.**

Dear Sir,

This refers to letter No. F.2-6/2003 & F.2-3/92-Lic (Vol-II) dated 21st October, 2015 received to your office on 09 November, 2015 addressing your kind good self. I am very thankful to receive at least first indirect communication on the issue related to the subject. The tools and approaches for which I am forced to use in compliance and enforcement were proven inappropriate for example the same did not catch visible signals of high risk and took over 100s of innocent patients life in PIC tragedy. The similar practice of inspection is going on which is neither trustable nor fulfils the required purpose.

I wish to respect the decisions of worthy Board but I have no reason to do so. Since, my posting as FID I am constantly seeking to request meeting before the both Boards so that I can communicate my concerns for open debate and record. My request of March 2015 reminded in April, May and June 2015 (emailed too) is hereby attached (04 Pages) to see the disregard of the Authority towards written communication of a Ph.D, 20 years experienced Civil Services Officer, as none of the one have been responded so far.

I strongly believe that we are here to protect and promote public health not vice versa in any case. I have a lot of real cases that reveal the ongoing victimization of patients or consumers that can be resolved without adding any cost but with sincere willingness consistent with the science of modern world. It is again requested to give me considerable time to present my concerns and

progressive solutions. It is up to the Board what consensus or agreement the Board develops but to make record accurate, precise, accountable and transparent my concerns may be narrated in minutes.

Attached: 04 pages of letters on the subject under discussion.

Sd/-

Obaid Ali, R.Ph, Ph.D
FID, Karachi.

Proceedings:

The Board observed that the directions of Board given in its 243rd meeting have not been followed wherein it was directed for submission of comprehensive report on the prescribed evaluation proforma which is in practice by all FIDs for more than a decade for submission of panel inspection reports for the purpose of grant/renewal of DML etc.

Board further observed that the concerned FID has responded the letter with his concerns regarding the said prescribed proforma whereas the other panel members have not responded to the said letter. The Board further showed its displeasure on such practices.

Decision of CLB:

Keeping in view the above situation, Board thoroughly discussed the matter taking into account the all pros & cons of the case and decided as under:

- **The panel be asked again to furnish the report on the prescribed proforma. In case FID does not prepare the report on prescribed proforma; the panel members may prepare report on the prescribed proforma and submit to the CLB.**
- **Board further directed the area FID to propose a new proforma based on technical grounds for consideration of CLB if he considers existing proforma not addressing inspection requirements / findings appropriately for consideration/decision of the CLB.**

Case No. 14. M/S SKIMS PHARMACEUTICALS, VALUE ADDITION CITY, KHURRIANWAL FAISALABAD.

The case was placed in the agenda as under: -

M/s Skims Pharmaceuticals Faisalabad, Drug Manufacturing License No.000830 (Formulation) has requested for following items for repacking. The firm has following two sections: -

1. Oral Liquid General by way of formulation.
2. Oral Liquid General by way of Re-packing.

Firm has now applied and requested for enlistment and approval of following repacking items as under: -

S No.	Name of Item	Remarks of Licensing Division
1.	Glycerin	Falls under Schedule-D
2.	Liquid Paraffin (Heavy)	-do-
3.	Castor Oil	-do-

Decision of CLB:

The Board considered and approved the following items for repacking as per Schedule-D of the Drugs (Licensing, Registering & Advertising) Rules, 1976: -

S No.	Name of Item
1.	Glycerin
2.	Liquid Paraffin (Heavy)
3.	Castor Oil

Case No. 15. M/s. Obsons Pharmaceuticals, 209-S, Industrial Estate, Kot Lakhpat, Lahore. DML No. 000416 (Formulation)

The case was placed in the agenda as under: -

Background of the case:-
The case was placed in 243rd meeting of CLB held on 9th September, 2015 as under: -

S No.	Name of the firm	Date of Inspection / Type of License	Decision of CLB
	M/s. Obsons Pharmaceuticals, 209-S, Industrial Estate, Kot Lakhpat, Lahore. DML No. 000416 (Formulation)	**04-06-2015** (Formulation)	**The Board was apprised of the back ground of the case and reply of the panel as under:** **Background:** The case was previously considered in 242nd meeting of CLB held on 8th July, 2015. Previous recommendations of panel. As per current policy and the SRO No.470(1)/98, dated 15-05-1998 and schedule B to the Drug Act 1976, the firm does not full fill the requirement of area land i.e. of 2000 sq. yards so the panel of experts is not in a position to recommend the renewal of Drug Manufacturing License No. 000416 (by way of formulation) to M/s. Obsons Pharmaceuticals, 209-S, Industrial Estate, Kot Lakhpat, Lahore and suggests that the case may be referred to the Honorable Drug Licensing board for further decision in this regard the management may be directed to full fill the requirement of area as per SRO No.470(1)/98, dated 15-05-1998 within a shortest period of time. In the meantime, they may be allowed to carry on production at the present premises by maintaining the cGMP conditions. DML was granted to them before promulgation of SRO No.470(1)/98, dated 15-05-1998 Decision of CLB of 242nd meeting held on Wednesday, 08th July, 2015 Deferred the renewal of DML for want of following information from panel: 1. Rating of the firm with regard to inspection as same is not mentioned. 2- Deficient area/plot of the firm as same is not mentioned. 3- Compliance of GMP with regard to renewal of DML. The panel was conveyed above decision of CLB on 4th August, 2015. In reply the panel has furnished as under: - 1. I have the honour to refer to DRAP,

			Islamabad letter No.F.1-84 (Vol-III), dated 04-08-2015 on the subject cited. 2. The panel inspection report of M/s Obsons Pharmaceutical (Pvt) Ltd, Lahore has already been sent to your good office vide this office letter No. 9319/2015-DRAP (Lic), dated 07-07-2015. 3. The detailed section wise evaluation proforma is attached herewith for ready reference, duly signed by the members of the panel. 4. So far as the plot size is concerned the firm has total land / area, 1295 sq. yards. However, as per SRO.470 (1)/98, dated 15-05-1998 Schedule B to the Drugs (Licensing, Registering & Advertising) Rules, 1976, the minimum area of 2,000 sq. yard is required. In this way, the firm is deficient of 705 sq. yards as per the requirement. 5. The firm fulfills the basic requirements for manufacturing of their registered products. As per GMP requirements, however, some points for further improvements were discussed with the management. **Keeping in view the above situation, the Board decided and deferred the case for personal hearing of the firm. Board further directed that the firm shall be informed about the observations of inspection panel.**

Accordingly, firm was called for personnel hearing before the Board, please.

Proceedings:

Mr. S.M. Naeemullah CEO M/s Obsons Pharmaceuticals appeared before the Board. He submitted that they were granted license in 1996 and subsequent renewals have been made from time to time. At present, firm have four sections having the prescribed area however the overall size of the plot is less than 2000 sq. yards as the license was granted before the promulgation of SRO 470(I)/98. Mr. Khurram Shahad Mughal representative of M/o Law, Justice and Human Rights, Islamabad informed the Board that it is mandatory to fulfill the conditions of SRO 470(I)/98 i.e. plot size should not be less than 2000 sq. yards. Mr. S.M. Naeemullah admitted the condition of 2000 sq. yards of plot size and submitted an undertaking to Board stating that they will arrange the required area as per SRO 470(I)/98 dated 15-05-1998 within the period of three years i.e. 30-12-2018.

Decision of CLB:

- **In the light of undertaking by the firm that they will arrange the required area as per SRO 470(I) /98 dated 15-05-1998 with in the period of three years i.e. 13-12-2018, the Board approved the renewal of DML of the firm**

- **Board further decided and directed the firm to develop new premises with plot size of not less than 2000 sq. yards as per given undertaking within 03 years.**

Case No.16 THE STATE VERSUS M/S ANKAZ PHARMAX, KARACHI.

The case was placed in the agenda as under: -

Background of the case:

The case was considered and decided in 244th meeting of CLB held on 28th October, 2015 as under:-

Division of Drug Licensing has received following Court Orders from Drug Court, Lahore. The same are placed for the consideration of Board, please.

The State versus Ankaz Pharmex

Present: DDPP for the State
Accused Absent.

On the last date of hearing N.B.W of arrest of the accused was issued and the same be forwarded to the Chairman Drug Court Karachi, but no report received yet.

Let us issued N.B.W of arrest of the accused and same be forwarded to Drug Regulatory Authority who is directed to get execute the warrant.

Meanwhile, the Drug Regulatory Authority is directed to suspend the license of M/s Ankaz Pharmex till the arrest of the accused and submit his report on 23-11-2015.

Announced
21-10-2015

S/d
Ch. Muhammad Jahangir
Chairman

S/d	S/d
Dr. Mubashar Ahmed Butt	Farooq Bashir Butt
Member	Member

Proceedings:

The Board was apprised of the above court case. The Board was further apprised that Division of Legal Affairs has directed to Licensing & QA/LT Division for implementation of said order as under:

1. Orders for suspension of the drug manufacturing license of M/s. Ankaz Pharmax (Pvt) Ltd., Karachi – Action to be taken by Director (Licensing)

2. Four arrest warrant of M/s. Ankaz Pharmax (Pvt) Ltd., Karachi, in original, for service through Karachi office / Area Federal Inspector of Drugs, Karachi and submission of the report to the Drug Court Lahore on 23-11-2015 – Action to be taken by Director (Q.A)

The Board was apprised that in pursuance of orders of Honorable Drug Court and Division of Legal Affair, DRAP; the Licensing Division has written a letter to DDG (E&M) Lahore for obtaining complete case details from Honorable Drug Court and Provincial Drug Inspector so that case may be processed further.

The Board further discussed with the Law Expert Mr. Khurram Shahzad Mughal, Consultant M/o Law, Justice and Human Rights, as representative member of CLB from M/o Law, Justice and

Human Rights, Islamabad. He opined that the Orders of Honorable Drug Court has been brought before the Board and the Board shall follow the procedure as prescribed under the Drugs Act, 1976 and Rules framed there under.

Decision of CLB:

Keeping in view the facts of the case, proceeding of the Board and opinion of law expert; the Board considered and decided as under: -

- The Board adopted and endorsed the actions taken by Licensing Division.
- The Board decided to issue a Show Cause notice with personal hearing to the M/s. Ankaz Pharmex that why their drug manufacturing license may not be suspended in pursuance of the orders of Honorable Drug Court.
- The Board directed to send an interim report to the Honorable Drug Court.
- The Board advised the Chief Drug Controller, Punjab (Member CLB) to support in providing the case details from provincial drug inspector.

In the light of above decision of CLB an interim report was sent to Honorable Drug Court. The firm was issued show cause notice with personal hearing. Accordingly the firm has been called for personal hearing, please.

Response of M/s Ankaz Pharmex (Pvt) Ltd, Karachi

Firm has submitted that Mr. Ali Abbas attended the Drug Court Lahore dated 10-12-2015 as desired by the Lahore Drug Court, In this context the decisions made by the Court is as under:-

The state V/s M/s Ankaz Pharmex

Present DDPP for the State.
Accused Ali Abbas with Counsel.
Accused Naveed Mustafa and Rukhsana Khan absent.

Accused Ali Abbas is present and informed that co-accused were employees at his business and now have left the job and are not in his contact. Let us issue NBW of both the absentee accused for 07-01-2016 and same be handed over to the process server Yaseen immediately who is directed to approach office of the inspector general of police Sindh and hand over the warrants to the IG who is directed to depute any responsible police officer for execution of the warrants. In case of non-service, the executing officer shall appear on the next date.

Meanwhile, accused present in the Court is directed to submit surely bonds in the sum of Rs. 500,000/- with one surety in the like amount to the satisfaction of this Court within 7-days.
Announced
10-12-2015

Sd/-
Ch. Muhammad Jahangir
Chairman

Sd/-	Sd/-
Dr. Mubashar Ahmed Butt	Farooq Bashir Butt
Member	Member

Proceedings:

Muhammad Ishtiaq Javed Advocate on behalf of M/s. Ankaz Pharmax appeared before the Board. He submitted that their client has already appeared before the Honorable Drug Court, Lahore. Recently Honorable said Drug Court has passed the orders on 22-12-2015 with the directions to the DRAP to drop the proceedings of suspension of DML of the firm. He assured that the copy of said court orders would be provided to the Board shortly. He further submitted that the current mailing addresses of technical staff which of their firm who are also accused have also been provided to Honorable Drug Court.

Decision of CLB:

Keeping in view the proceedings of the case and facts on ground the Board unanimously decided to drop the proceedings of suspension of DML subject to submission of referred to Court Orders passed on 22-12-2015.