DRAFT MINUTES OF 244th MEETING OF CENTRAL LICENSING BOARD HELD ON WEDNESDAY 28th OCTOBER, 2015

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244th meeting of the Central Licensing Board (CLB) was held on Wednesday, 28th October, 2015 in the Committee Room of M/o NHSR&C, 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. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh.	Member
4.	Mr. Afrasiyab, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa.	Member
5.	Mr. Atta-ur-Rehman, Chief Drug Inspector, Department of Health, Govt. of Balochistan.	Member
6.	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
7.	Dr. Ikram-ul-Haq, QC/QA Expert	Member
8.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
9.	Prof. Dr. Gul Majeed Khan, Professor of Pharmacy	Member
10.	Prof. Dr. Muhammad Saeed, Professor of Pharmacy	Member
11.	Mr. Khurram Shahzad Mughal, Consultant M/o Law, Justice and Human Rights, as representative of M/o Law, Justice and Human Rights, Islamabad.	Member
12.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
13.	Mr. Khalid Munir, Chief Executive, Trigon Pharmaceuticals (Pvt) Ltd., & Ms. Mahvash Siddiqi, Chief Operating Officer Epla Laboratories (Pvt) Ltd., as Representative of PPMA	Observer
14.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
15.	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), Mr. Adnan Faisal Saim DDC (QC) & 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 243rd MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 243rd meeting held on Wednesday 9th September, 2015.

Item-II: **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 & Address of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s GT Pharma (Pvt) Ltd, Plot No. 713, Punjab Industrial Estate, Sunder Industrial Estate, Lahore.	24-08-2015 Formulation	**Approved the grant of DML with following four sections:** **Sections (04)** 1. Liquid Injectable (General) for Ampoule & Vial (SVP). 2. Oral Dry Suspension (General). 3. Sachet (General) 4. Capsule (General).
2.	M/s 3 N-Lifemed Pharmaceuticals, 45 S.B, Abdullah Colony, Sargodha.	27-08-2015 Formulation	**Approved the grant of DML with following two sections:** **Sections (02)** 1. Dialysis Solution Section. 2. Sachet (General).
3.	M/s Skims Pharmaceuticals, 10-B, Value Addition City, Khurrianwala, Faisalabad.	08-10-2015 Formulation	**Approved the grant of DML with following two sections:** **Sections (02)** 1. Oral Liquid (General) by way of formulation. 2. Oral Liquid by way of repacking.

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

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

S #	Name & Address of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s. Genix Pharma (Pvt) Ltd, 44, 45-B, Korangi Kreek Road, Karachi. DML No. 000351	**13-10-2015 (Formulation)**	**The Board approved the grant of one additional sections as under:-** **Section(01)** 1. Beta-Lactam (Penems) non-penicillin

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 UDL Pharmaceuticals (A division of first UDL Modaraba) E-44-45, Karachi. DML No.000693	**20-8-2015** (Formulation)	The Board perused the recommendations of panel as under: Recommendations of the panel: Based on the strong commitment of the firm's management and comprehensive action plan for further improvements (copy enclosed) the panel unanimously recommends the following. • Renewal of the drug manufacturing license No. 000693 may kindly be made by the licensing board for further periods of five years. • Further improvements for better GMP compliance may be made by the firm in the areas of validation / qualification, revision of existing SOPs, training personnel, addition of technical staff, QA system, sampling procedures, equipment and monitoring of climatic conditions etc. The Board observed that the panel inspection report is deficient of evaluation proforma and details of sections which panel has inspected. The report does not reveal which dosage forms/sections have been inspected by the panel. 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 and complete report along with details of sections on the prescribed evaluation proforma from panel.**
2.	M/s Jfrin Pharmaceutical Laboratories, Plot No. 16, 17 & 20, Hub Industrial Trading Estate Hub Balochistan.	**12-10-2015 (Formulation)**	**The Board approved the renewal of DML** **<u>Sections (04)</u>** 1. Oral Liquid 2. Dry Powder Oral 3. Sterile Dry Injection 4. Sterile Liquid Injection
3.	M/s Genix Pharma (Pvt) Ltd, 44,45-B, Korangi Kreek Road, Karachi. DML No. 000351	**13-10-2015** (Formulation)	**The Board approved the renewal of DML**
4.	M/s Abbott Laboratories Pakistan Ltd, Plot No. 13 Sector 20, Korangi Industrial Area, Karachi. DML No. 000004	**15-10-2015** (Formulation)	**The Board approved the renewal of DML for following section:** **<u>Section (01)</u>** 1. Liquid Syrup

Item No. V Miscellaneous Cases.

Case No.1 **APPROVAL OF MASER LAYOUT PLAN / AUTHENTICATION / REGULARIZATION OF EXISTING FACILITY & RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000335 (FORMULATION) ADDITIONAL SECTION AND REGULARIZATION OF MATER LAYOUT PLAN.**

The case placed before the Board as under:

M/s Semos Pharmaceuticals (Pvt) Ltd, Plot No. 11-B, Sector 12/A North Karachi Industrial Area, Karachi DML No. 000335 (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.	Capsule (General)
3.	Oral Dry Powder Suspension (General)
4.	Liquid Syrup (General)
5.	Cream/ Ointment / Gel (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. Dr. Muhamamd Tanweer Alam, Director, CDL, Karachi.
2. Syed Muied Ahmed, Member CLB.
3. Mr. Qaiser Muhammad Chief Drug Inspector Sindh,
4. Abdul Rasool Shaikh, Area FID, DRAP Karachi.

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

Recommendations: -
In compliance to DRAP Islamabad direction; the panel inspected in detail the area under scope and found those sections given as per approved layout plan along with necessary machineries installed, HVAC & other utilities and appropriate GMP conditions at the time of inspection. Keeping in view the above stated observations the panel unanimously recommends the grant of regularization / authentication of all the above mentioned sections.

Decision of CLB:

Keeping in view of the recommendations of panel, the Board approved the regularization/authentication of following sections of the firm:

S. No.	Sections
1.	**Tablet (General)**
2.	**Capsule (General)**
3.	**Oral Dry Powder Suspension (General)**
4.	**Liquid Syrup (General)**
5.	**Cream/ Ointment / Gel (General)**

Case No. 2. M/S CORTEX PHARMACEUTICALS, PLOT NO. 16-A STREET NO. SS-4 NATIONAL INDUSTRIAL ZONE, RCCI, RAWAT RAWALPINDI.

The case placed before the Board as under:

M/s Cortex Pharmaceuticals Rawat, Rawalpindi Drug Manufacturing License No.000826 (Formulation) has requested for following items for repacking. The firm has following two sections: -

1. Liquid External Preparation (General)
2. Liquid Repacking

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

S No.	Name of Item	Remarks
1.	Glycerin	Falls under Schedule-D
2.	Castor Oil	-do-
3.	Liquid Paraffin (Heavy)	-do-
4.	Gentian violet	-do-
5.	Ichthammol	-do-
6.	Magnesium Sulphate	-do-
7.	Petroleum Jelly	Does not fall under Schedule-D
8.	Glycerin Suppositories	-do-
9.	Formulize	-do-
10.	Liquid Prafin	-do-
11.	Olive 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.	Castor Oil
3.	Liquid Paraffin (Heavy)
4.	Gentian violet
5.	Ichthammol
6.	Magnesium Sulphate

The Board further did not approve the following items as these do not fall under Schedule-D of the Drugs (Licensing, Registering & Advertising) Rules, 1976:

S No.	Name of Item
1.	Petroleum Jelly
2.	Glycerin Suppositories
3.	Formulize
4.	Liquid Prafin
5.	Olive Oil

Case No.3 CHANGE OF THE MANAGEMENT OF STATUS OF M/S CCL PHARMACEUTICALS, 62- INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE DML NO.000052 (FORMULATION).

The case placed before the Board as under:

M/s. CCL Pharmaceuticals, Lahore, DML No.000052 (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 29 issued by Security Exchange Commission of Pakistan where this company is registered under:-

Current Management as per Form 29	Proposed Management as per Form 29
1. Kashif Sajjad Sheikh **CNIC:** 35201-8114696-9 2. Hassan Zubair Shaikh **CNIC:** 35201-1670274-7 3. Kashif Sajjad Sheikh **CNIC:** 35201-8114696-9 4. Nadeem B.J. Sheikh **CNIC:** 35201-1492726-3 5. Asim Dilwar Sheikh **CNIC:** 35201-1739536-5 6. Fouzia Zubair Sheikh **CNIC:** 35201-1538777-8 **7.** Saeeda Javid Shaikh **CNIC:** 35201-4972972-0	1. Kashif Sajjad Sheikh **CNIC:** 35201-8114696-9. 2. Hassan Zubair **CNIC:** 35201-1670274-7. 3. Asim Dilwar Sheikh **CNIC:** 35201-1739536-5 4. Nadeem B.J. Sheikh **CNIC:** 35201-1492726-3

Decision of CLB:

Keeping in view the approval by SECP and as per Form-29 issued by SECP, the Board considered and approved the change of management from old management to new management as under: -

Old Management as per Form 29	Retiring/Leaving Management	New Management as per Form 29
1. Kashif Sajjad Sheikh CNIC: 35201-8114696-9 2. Hassan Zubair Shaikh CNIC: 35201-1670274-7 3. Kashif Sajjad Sheikh CNIC: 35201-8114696-9 4. Nadeem B.J. Sheikh CNIC: 35201-1492726-3 5. Asim Dilwar Sheikh CNIC: 35201-1739536-5 6. Fouzia Zubair Sheikh CNIC: 35201-1538777-8 7. Saeeda Javid Shaikh CNIC: 35201-4972972-0	1. Fouzia Zubair Sheikh CNIC: 35201-1538777-8 2. Saeeda Javid Shaikh CNIC: 35201-4972972-0	1. Kashif Sajjad Sheikh CNIC: 35201-8114696-9. 2. Hassan Zubair CNIC: 35201-1670274-7. 3. Asim Dilwar Sheikh CNIC: 35201-1739536-5 4. Nadeem B.J. Sheikh CNIC: 35201-1492726-3

Case No.4 **Manufacturing of Active Pharmaceutical Ingredients (APIs) by way of Semi Basic Manufacture under DML No. 000429 of M/s Citi Pharma (Pvt) Ltd, Phool Nagar Kasur.**

The case placed before the Board as under:

Brief History: The case was placed in agenda of 241st meeting of CLB held on 15th May, 2015 as under:

Name of the firm	**Date of Inspection**	**Ranking/ Evaluation**	Inspection Panel Members
M/s Citi Pharma (Pvt) Ltd, 3.5 KM Head Baloke Road, Phool Nagar, District Kasur. DML No.000429 (Semi-Basic) Sections: (01) Penicillin by way of semi-basic manufacture	20-04-2015	Good	1. Dr. Ikram ul Haq, Member CLB. 2. Dr. Sheikh Akhter Hussain, DDG, DRAP, Lahore. 3. Mr. Tallat Farooq, Secretary PCQB, Punjab. 4. Abdul Rashid Shaikh, FID, DRAP Lahore.
Recommendations of the Panel:- In the light of above, the panel is of the opinion to recommend the manufacturing facilities of the firm for the manufacturing of "Penicillin drugs by way of semi basic manufacturing.			

Decision of 241st Meeting: The Board decided as under:-

Name of the Firm	**Type of License**	**Decision of CLB**
M/s Citi Pharma (Pvt) Ltd., 3.5 KM Head Baloke Road, Phool Nagar, District Kasur.	DML No.000429 (Semi-Basic)	The Board approved the following one additional section Section: (01) Penicillin by way of Semi-Basic Manufacture The Board further advised the members of the panel to sign the flow chart /diagram / process of the APIs intended to be manufactured at penicillin facility.

It is submitted that the panel was given two mandates as under:-

i. Inspection for grant of additional section i.e. Penicillin by way of Semi-basic manufacture.
ii. Inspection for verification of manufacturing of APIs i.e. Ampicillin and Amoxicillin

The recommendations for APIs were not mentioned clearly in the report so could not be made part of agenda. Later, concerned FID was requested to clarify the same. The FID has clarified that firm has facilities for manufacturing of Ampicillin and Amoxicillin APIs.

Accordingly, case is submitted for the consideration of Board for two APIs i.e Ampicillin and Amoxicillin, please.

Decision of CLB:

Keeping in view the facts of the case and above situation, the Board considered and approved the following APIs in the name of M/s Citi Pharma (Pvt) Ltd, 3.5 KM Head Baloke Road, Phool Nagar, District Kasur DML No.000429 by way of semi basic manufacture: -

S No.	**Name of API**
1.	Amoxicillin
2.	Ampicillin

Case No.5 THE STATE VERSUS M/S ANKAZ PHARMAX, KARACHI.

The case placed before the Board 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 / cancelled 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.**

Item No. 6 Any other item with the permission of Chair.

The following additional agenda could not be discussed due to paucity of time.

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

Following cases have been recommended by the respective panel of experts for grant of additional sections. The same are placed before the Board for its consideration/decision, please.

S No.	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Lotus Pharmaceuticals (Pvt) Ltd, Plot No. 118-A, Street No. 8, I-10/3, Industrial Area, Islamabad. Section (02) 1. Capsule (Cephalosporin) 2. Dry Powder Suspension (Cephalosporin)	26-10-2015	Good	1. Manzoor Ali Bozdar, Director FDSL, Islamabad. 2. Muhammad Amin, DDC, DRAP Islamabad. 3. Dr. Fakhruddin Aamir, Area FID, DRAP, Islamabad. 4. Sardar Shabbir, Drug Inspector ICT.
	Recommendations of the panel: - Cephalosporin Production facility was developed on 1st floor with capsule and dry powder for suspension section, raw material store, packing material store, packing hall already existing QC Lab will be used for the testing of registered products. Air handling unit installed (require strict monitoring) one pharmacist for Cephalosporin production facility. It is directed facility with separate entrance for which the training of worker is needed. View the facts the panel unanimously recommended the grant of Capsule (Cephalosporin) and Dry Powder Suspension (Cephalosporin).			

Item-II: GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE.

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

S No.	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Werrick Pharmaceuticals 216-217, I-10/3 Industrial Area, Islamabad. DML No.000489 (Semi Basic)	08-10-2015	Good	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.
	Recommendations of the panel: - Viewing the facts the facilities provided M/s Werrick Pharmaceuticals 216-217, I-10/3 Industrial Area, Islamabad DML No. 000489 Semi Basic the panel unanimously decided to recommend for the grant of renewal of DML for Biotech section and Chemical Manufacturing. *However for commercial manufacturing, they will have to get separate approval from the DRAP. (Muhammad Arif Ch. DDC DRAP Islamabad)			
2.	M/s Aims Pharmaceuticals Plot No. 291, Industrial Triangle Kahuta Road, Islamabad. DML No.000608 (Formulation)	16-10-2015	Good	1. Prof. Dr. Gul Majeed Khan, Member CLB. 2. Mr. Zaheeruddin M. Babar, DDC, DRAP Islamabad. 3. Dr. Muhammad Fakhruddin Aamir Area FID, DRAP Islamabad.
	Recommendations of the panel: - The company has two story building, production and QC lab on 1st floor and stores at ground floor. Tab, Capsule, Cream/Ointment and cephalosporin (Capsule and dry powder) section are provided. HVAC installed QC Lab maintained. The company has pharmacists and the panel suggested to verify the presence of pharmacists at random. Viewing the facts facilities the panel unanimously recommends the grant of Renewal of DML by way of formulation.			
3.	M/s Benson Pharmaceuticals Plot No. 119, Street No. 8 Sector I-10/3 Industrial Area Islamabad. DML No.000447 (Formulation)	16-09-2015	Good	1. Prof. Dr. Gul Majeed Khan, Member CLB. 2. Sardar Shabbir, Drug Inspector ICT. 3. Dr. Muhammad Fakhruddin Aamir Area FID, DRAP Islamabad.
	Recommendations of the panel: - Viewing the facts and the facilities provided in M/s Benson Pharmaceuticals Plot No. 119, Street No. 8 Sector I-10/3 Industrial Area Islamabad the panel unanimously decided to recommend for the grant of renewal of DML No.000447-Formulation.			

= = = = = End of Licensing Division = = = = =

Quality Control Cases

Case No. 01

Subject: - **MANUFACTURING OF SPURIOUS DRUGS AND MANUFACTURING OF DRUGS WITHOUT DRUGS MANUFACTURING LICENSE-RAID AT MUSTAFA COLONY, LAHORE (No.F.4-11/2014-QC)**

Mr. Abdul Rashid Sheikh, FID, Lahore with Ms. Majida Mujahid (FID), Mr. Asif Ali Mian (Assistant Director, FIA), Mr. Ejaz Ahmed (Inspector, FIA), Mr. Muhammad Khan Niazi (ASI, FIA), Mr. Muhammad Hassan (Constable, FIA), Mr. Babar Ali (Constable, FIA) and Syed Mehran Hussain Shah (Constable FIA) on 09.12.2014 had conducted a raid on the premises situated at Main Street No.1, Choti Gali No. 3, Malik Chowk, Mustafa colony, Chand Rai Road, Kot Lakhpat, Lahore from where following drugs / items were recovered.

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Sr. #	Name of Drug/Material/Article	Quantity
1.	Blue Coloured coated diamond shaped tablets. One side engraved with "VGR 100" and other side with "Pfizer", in two plastic bags. Suspected to be spurious Viagra 100 mg tablets of M/s Pfizer.	16 KG + 17 KG Total 33 Kg
2.	Golden coloured elongated tablets in two drums.	15 KG + 15 KG Total 30 Kg
3.	Brown coloured elongated tablets in one drum	22 KG
4.	White elongated tablet cores having line of bisection on one side in three drums.	82 KG
5.	One drum of brown coloured mix powder.	25 KG
6.	One drum of HOMC Batch # 201402025, Mnfd. By: China (as per label claim)	8 KG
7.	One drum of PVP K 30 USP, BATCH # 114030901. Importer: Al Mamoon Trader, Source China (as per label claim)	8 KG
8.	One drum containing white powder (unidentified)	15 KG
9.	One electric air heater for tablet coating machine	1 No.
10.	Coating blower for tablet coating machine	1 No.
11.	Spray gun for tablet coating machine	1 No.

2. At the time of the raid Muhammad Nasir S/o Muhammad Rafique Lodhi, R/o Mustafa Colony, Lahore and Muhammad Jamil Anjum s/o Shah Muhammad, R/o Awan Chowk, Baba Farid Colony, Lahore were present in the premises.

3. During investigation the accused gave information about another premises situated at Quaid-e-Millat colony new Jail Road, Lahore. The party had conducted another raid on that premises from where following drugs / items were recovered.

Sr. #	Name of Drug/Material/Article	Quantity
1.	Light pink coloured elongated biconvex tablets/powder. One side engraved with Xanax in a polythene bag. Suspected to be spurious Xanax of M/s Pfizer	800 gm
2.	One paper bag containing lactose B 200, Mnfd By. Germany (as per label claim)	12 KG
3.	One polyester bag containing mixed/crushed brownish yellow powder with pungent smell.	22 KG
4.	One polyester bag containing Magnesium Sterate, Batch No. 1010123 F, Mnfd by Adil Chemicals, Lahore. (as per label claim)	3 KG
5.	One poly bag containing white powder (unidentified)	1 KG
6.	One polyester bag containing powder Talcum purified, Batch No. 24820096 Mnfd By: Karachi. (as per label claim)	20 KG
7.	Buffering Machine for dyes and punches	1 No.
8.	Different dyes and punches of miscellaneous sizes for tablet compression machines	Approx. 100 sets
9.	Stain less steel buckets	2 Nos.
10.	Electric weighing balance	1 No.

3. The seizure was made on Form-2 under section 18(1)(f) of the Drugs Act, 1976. The premises was sealed under Section 18 (1)(h) of the Drugs Act, 1976 and the sealed keys were handed over to Muhammad Jamil Anjum in the presence of witnesses.

4. Accordingly permission for FIR was granted to the concerned FID under section 23/27 of the Drugs Act, 1976. The FIR No 98/2014 was lodged in the Police Station FIA/ACC Lahore on 09.12.2014 against accused persons in for violation of the section 23 of the Drugs Act, 1976 which is punishable under Section 27 of the said Act.

5. The FIA has submitted incomplete challan on 16.03.2015 in the office of the FID, Lahore and has held responsible for the aforesaid offences to the following accused persons.

a. Shahid Lodhi S/o Muhammad Rafique Lodhi, R/o Quaid-e-Millat Colony, new Jail Road, Lahore

b. Muhammad Nasir S/o Muhammad Rafique Lodhi, R/o Mustafa Colony, Lahore

c. Muhammad Jamil Anjum s/o Shah Muhammad, R/o Awan Chowk, Baba Farid Colony, Lahore.

6. The FID has requested to grant the permission for prosecution in the Drug Court, Lahore on contravention of the Section 23 punishable under section 27 of the Drugs Act, 1976.

7. Accordingly on 10th April 2015 the FID was asked to coordinate with the FIA officers for completion of investigation by visiting their offices and prepare the case against the accused as per Drug Act 1976. The FID was requested to submit report along with recommendation.

8. The FID on 15th may 2015 has submitted the copies of the test reports of the samples drawn and also enclosed written reply of the accused persons.

9. On 30th June 2015 FID has requested for the grant of permission to keep the seized drug in the safe custody under Section 19(5) of the Drugs Act 1976.

10. Permission to keep the seized stock in the safe custody was granted on 19th August 2015.

11. On 09th October 2015 Mr. Abdul Rashid Sheikh, FID, Lahore has informed that he has appeared before the honorable Drug Court, Lahore in the said case. The Honorable Chairman, Drug Court, Lahore show displeasure on non submission of the challan of the case, even after passing several months. The Chairman, Drug Court, Lahore has directed the FID to submit the report before the Court within 10 days, if he failed then Sheikh Faqeer Muhammad, Chairman, Central Licensing Board appeared himself before the Court and adjourned the case to 19.10.2015.

12. Accordingly the case was processed to fulfill the legal requirements, and after approval from the Director QA/LT, a Show cause notice served to the accused persons on 15th October 2015 to submit their replies within 07 days and offering them opportunity of personal hearing before the CLB.

13. The FID has informed that the show cause notices has been served to the accused persons.

14. The FID Lahore on 19-10-2015 has informed that the Honorable Judge Drug Court Lahore has directed to submit the challan on 06-11-2015.

15. As per challan and investigation of the FIA and FID recommended that the following accused persons are held responsible in the manufacturing of spurious drugs.

a. Shahid Lodhi S/o Muhammad Rafique Lodhi, R/o Quaid-e-Millat Colony, new Jail Road, Lahore

b. Muhammad Nasir S/o Muhammad Rafique Lodhi, R/o Mustafa Colony, Lahore

c. Muhammad Jamil Anjum s/o Shah Muhammad, R/o Awan Chowk, Baba Farid Colony, Lahore

16. The FID has requested to grant the permission of prosecution of the above mentioned persons in the Drug Court Lahore under Section 23, which is punishable under Section 27 of the Drugs Act 1976 and is cognizable under Section 30(2) of the Drugs Act 1976.

The Case is submitted for perusal please.

Case No.02.

Sale of Un-Registered Drugs- Raid on M/s Khalid Pharmacy Liberty Market Lahore with FIA Team

The FID Lahore Mr. Ajmal Sohail Asif raided M/S Khalid Pharmacy 90-A, C-II, Liberty Market Near Soneri Bank, Lahore on 01.12.2014 along with Mr. Zia Husnain FID (V) and FIA raiding party headed by Mr. Asif Ali Mian, Assistant Director, Mr. Ijaz Ahmad Inspector and Mr. Muhammad Khan Niazi, ASI.

At the time of inspection Mr. Sohail Mehmood S/o Khalid Mehmood Butt (son of proprietor) was present.

During inspection huge quantity of un-registered (smuggled/unwarranted) drugs including different brands of sexual drugs and many other branded drugs were found at the premises. These different un-registered drugs were recovered and seized on form No. 2, (copy handed over to Mr. Sohail Mehmood S/o Khalid Mehmood Butt) as case property under Section 18(f) of the Drugs Act, 1976. All the materials were recovered in the presence of Mr. Sohail Mehmood S/o Khalid Mehmood Butt (son of proprietor) and FIA team.

After the seizure of above said material the premises comprising a shop on ground floor and a godown (unauthorized) on first floor were sealed under section 18(1)(h) in front of above mentioned witnesses.

The FID Mr. Ajmal Sohail Asif informed vide his letter dated 22-12-2014 that in compliance to the orders of Honourable Drug Court, Lahore dated 19-12-2014, the premises was de-sealed on 19-12-2014 in the presence of Mr. Khalid Mehmood Butt s/o Mr. Yasin Butt (Proprietor), and other witnesses.

Since the sale of un-registered drugs is prohibited under Section 23(1), which is punishable under Section 27(1)(a) of the Drugs Act 1976 and is cognizable offence under section 30 (2) of the Drug Act 1976.

The FIA has submitted the complete challan in connection with FIR lodged vide No. C-95/14 dated 01-12-2014 to FID Mr. Ajmal Sohail Asif.

The FID and the FIA have concluded as a result of investigation that following persons have been found contravening the provisions of the DRAP ACT, 2012 and the Drug Act, 1976.

i) Mr. Sohail Mehmood S/o Khalid Mehmood Butt (son of proprietor/present), resident of H# 34, Krishna Gali Bansawala bazar, Lahore, Cantt.	ii) Mr. Khalid Mehmood Butt S/o Yasin Butt (Proprietor/Absent), resident of H# 34, Krishna Gali Bansawala bazar, Lahore (Proprietor/Absent).
iii) Mr. Usama Siddique S/o Muhammad Siddique (Qualified Person/absent) R/o House No. 288/B P.C.H.S Cantt Ghazi road, Lahore. Address No. 2: Nazim-ud-din Road, A-1, F-10/1, Islamabad.	

Since the sale of un-registered drugs is prohibited under Section 23(1), which is punishable under Section 27(1) (a) of the Drugs Act 1976 and is cognizable offence under section 30 (2) of the Drug Act 1976

Submitted for consideration of the Board

Case No 03

Inspection of Al-Farid Traders Khuda Bakhash Plaza Qutub-ud-Aeibek Road, Lahore along with FIA Lahore.

The FID Lahore-V, Mr Zia Husnain and Mr. Ajmal Sohail Asif, FID (F) inspected Al Farid Taders Khuda Bakhash Plaza Aeibek Road Lahore on 27-11-2014 along with Mian Asif Assistant Director FIA Lahore. During the inspection huge quantity of printing material/printed labels etc were recovered and seized under section 18 (1)(f) of Drugs Act 1976 which may be used for production of spurious drugs. For further investigation in this regard, FIR was lodged at FIA/ACC, Lahore vide No.91/14 dated 27-11-2014

The FID Mr. Zia Husnain has submitted the copy of complete challan presented to him by the FIA crime circle, Lahore, wherein the FIA has concluded in connection with FIR lodged vide No.C-95/14 dated 01-12-2014 that as a result of investigation that following persons have been found contravening the provisions of the DRAP Act 2012 and the Drugs Act 1976.

1.Muhammad Arshad S/o Ch. Khuda Buksh, R/o H# DI 2436, Koocha Dogran, Nia Bazar, Shama	2.Hafiz Muhammad Jameel Anjum S/O Eid Muhammad R/o Junnah Town Harrappa District Sahiwal Current address: Hall Road House No.214 Sector F-3 Meerpur Azzad Kashmir

Since manufacturing and sale of spurious drugs contravention of section 23(1) (a) (i) of Drugs Act 1976 and Section A(1)(a) (i) of Schedule-II of the DRAP Act 2012, which is punishable under Section (1) (a) of schedule-III of DRAP Act 2012 and cognizable offence under schedule-IV of DRAP Act 2012,

Submitted for consideration of the Board

Quality Assurance Cases (GMP)

Case No. 1 M/S PARAMEDIC LABS, LAHORE

Background of the case

i. In 2012- 2013, the firm M/s Paramedic Labs, Lahore supplied a huge quantity of Hepaferon Injection 3.0MIU to Health Department of KPK Government.

ii. Samples of said supply were drawn from Peshawar in 2013 by Provincial Drug inspector, which were declared substandard/adulterated by DTL due to presence of particulate matter.

iii. Honorable High Court of Peshawar took the *suo moto* notice for supplying the substandard/adulterated drugs.

iv. The matter was investigated by anti corruption department, NAB and DRAP. Later on the case was prosecuted by Provincial Health Department in the Drug Court, Peshawar, wherein the Honorable Court dismissed the case for being devoid of merits.

v. In may, 2014 the firm intimated that they have voluntarily stopped the production in biological section for up-gradation of the biological section and requested to allow them to resume the production as they have renovated the section.

The case was placed in 236th Meeting of CLB held on 27.06.2014. The board had decided as under:-

"Following panel will conduct the GMP inspection of the Biological Section of the firm and will submit conclusive report with clear and candid recommendations on the subject matter for the consideration of Central Licensing Board before resumption of production:

a. Shaikh Ansar Ahmad, Director Biological
b. Dr. Ikram-ul-Haq, Member CLB
c. Mr. Ayaz Ali Khan, Chief Drug Controller, Punjab
d. Mr. Abdul Samad Khan, Director NCLB
e. Mr. Zafar Minhas, Deputy Director NCLB
f. Area FID, Lahore"

vi. The panel inspected the firm on 25.11.2014 but did not recommend allowing the firm to resume production in the section for certain deficiencies/shortcomings in manufacturing facility and QC laboratory.

vii. The firm was directed to rectify the shortcomings and submit the compliance report.

viii. Re-inspection of the firm was conducted on 20.08.2015 vide this office letter dated 10.06.2015. The panel has physically verified improvements made by the firm and concluded as under:-

Sr. No	Observations of the panel	Improvements made by the firm
1.	The firm was advised to hire experienced trained and conscientious technical personnel to run and supervise the biological section and Quality control	The firm has hired a highly qualified person having more than 30 years of experience in multinational pharmaceutical companies as Technical Advisor.
2.	The firm was advised to shift the microbiology laboratory from within the injectable manufacturing area and to establish an appropriate microbiology laboratory equipped with proper equipment and instruments	The firm has shifted the microbiological laboratory from injectable area. A new microbiological laboratory has been established within Quality Control laboratory.
3.	The firm was advised to upgrade optical checking apparatus as per WHO guidelines and preferably purchase some digital particle counter	An optical checking table was also provided within the packing room.
4.	The firm was advised to upgrade bioactivity laboratory regarding provision of gowning and de-gowning facility and bio-safety cabinet	The Biological Laboratory to evaluate the bioactivity of the product was established on third floor.
5.	The firm was advised to establish a functional, independent and effective quality assurance department.	The firm has now established an independent QA department and revised the organizational structure. The firm has hired a QA manager, having 13 years experience and two QA officers.
6.	Validate the manufacturing and quality control procedures for interferon and also to validate HVAC system	The firm has validated its HVAC system through external source in December, 2014. Validation reports were seen. The firm informed that they have developed validation master protocol and validation of manufacturing process will be conducted when production will be allowed. The equipments in QC laboratory and different gauges, meters and equipment in manufacturing areas were found calibrated.
7.	To Approach directorates of registration and licensing of DRAP for regularization of any change in master formulation of Interferon Injection and layout of biological section.	The panel has confirmed that the firm already approached the directorates of registration and licensing for regularization of change in master formula and lay out for new microbiological laboratory.

"Panel noted that the firm has shown good compliance towards the recommendations given during previous inspection and has almost rectified all the shortcomings pointed out during previous inspection. Based on the areas inspected, the technical people met and the documents reviewed, and considering the findings of the inspection the panel was of the opinion that the biological section the firm meets the requirements of GMP for manufacturing the interferon. ***The panel recommends that the firm may be allowed to resume the production in biological section."***

The case is presented before the Board before as per its decision in 236th meeting for resumption of production.

Case No. 2 M/S Euro Pharma, Karachi

Background of the case

i) Inspection of the firm 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.

ii) Accordingly a showcause notice/stop production order was issued on 23.04.2013.

iii) 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 performa 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.

iv) The decision of the CLB was conveyed to the firm on 03.09.2013.

v) The firm vide letter No. Nil dated 25.11.2013 replied that they have removed all the shortcomings and ready for inspection.

vi) 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.

vii) 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.

viii) 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. Naushad 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.

ix) The decision of the CLB was conveyed to the firm on 14.10.2014.

x) Area FID issued a letter to the company on 12.03.2015 with the direction to surrender all the documents issued by the DRAP.

Now the firm has requested that the significant changes, improvement in the factory for better compliance of GMP has been made. The management of the company has requested for the panel inspection of the firm.

The case is presented before the Board keeping in view the non-appearance of the owner before the CLB as per decision of 237th meeting of CLB.