MINUTES OF 233rd MEETING OF CENTRAL LICENSING BOARD HELD ON 30TH - 31ST DECEMBER, 2013.

A. LICENSING DIVISION

Item No.	Description
1.	Confirmation of the Minutes of 232nd Meeting
2.	Grant of New Drug Manufacturing Licenses
3.	Grant of Additional Sections
4.	Grant of Renewal of Drug Manufacturing License
5.	Miscellaneous Cases
6.	Any other item with permission of Chair

B. QUALITY CONTROL

Item No.	Description
1.	Quality Control Cases

C. QUALITY ASSURANCE

Item No.	Description
1.	Quality Assurances Cases of GMP

DIVISION OF DRUG LICENSING
DRUG REGULATORY AUTHORITY OF PAKISTAN
ISLAMABAD.

MINUTES OF 233rd MEETING OF CENTRAL LICENSING BOARD HELD ON 30-31st DECEMBER, 2013.

233rd meeting of the Central Licensing Board (CLB) was held on 30-31st December, 2013 in the committee room of Ministry of National Health Services, Regulation & Coordination, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP, Islamabad.

Following members attended the meeting: -

Sr. #	Name & Designation	Status
1.	Mr. Faqeer Muhammad Shaikh, Director, Drug Licensing, DRAP, Islamabad.	Chairman
2.	A.Q Javed Iqbal, Director (QA), as representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad.	Member
3.	Mr. Ayaz Ali Khan, Chief Drug Controller, Department of Health, Govt. of Punjab. (Mr. Muazzam Ali Khan, Secretary, PQCB, Punjab, Lahore attended the meeting on behalf of Ayaz Ali Khan)	Member
4.	Mr. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh.	Member
5.	Mr. Atta-Ur-Rehman, Chief Drug Inspector, Department of Health, Govt. of Baluchistan.	Member
6.	Dr. Syed Jamshed Kazmi	Member
7.	Syed Muid Ahmed	Member
8.	Syed Jawed Yousaf Bukhari	Member
9.	Prof. Dr. Gul Majeed Khan, Chairman, Department of Pharmacy, Quaid-e-Azam University, Islamabad.	Member
10.	Prof. Dr. M. Saeed, Department of Pharmacy, University of Peshawar, KPK.	Member
11.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
12.	Mr. Khawaja Javed Akbar, Representative of PPMA.	Observer
13.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
14.	Mr. Asif Akhai, 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 and the members of the Board briefly introduced themselves.

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. He further added that all the legal and codal formalities regarding convening of the meeting have been fulfilled.

Dr. Ahmed Mehmood Mumtaz, CQC/DDG (E&M), Mr. Khalid Mahmood, DDC (Lic.), Mr. Zaheeruddin M. Baber DDC (Q.C.), Mr. Adnan Faisal Saim, DDC (Q.A.) and Mr. Salateen Waseem Philip ADC (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

2. Secretary CLB presented the agenda and started proceedings of the Board as follows:-

A. LICENSING DIVISION

Item No.1 CONFIRMATION OF THE MINUTES OF 232nd MEETING

The Central Licensing Board confirmed the minutes of 232nd meeting held on 29th & 30th July, 2013.

Item No. 2 GRANT OF NEW DRUG MANUFACTURING LICENSES.

The Board decided the following cases of Grant of Drug Manufacturing License in the light of recommendations by respective panel of experts/inspectors.

S No.	Name of the firm	Type of License	Decision of CLB
1.	M/s Cotton Craft (Pvt) Ltd., Ltd., Plot No. 407- Sunder Industrial Estate, Lahore. (DML No. 000227)	**Formulation**	**Approved the Grant of DML at New Site with same DML No. (DML No. 000227)** subject to cessation of manufacturing operations and surrendering of existing DML to DRAP (CLB-Statutory Body) at present premises situated at 12-KM Multan Road, Canal View Society, Lahore. **Board approved the following Sections: -** **Sections (09)** 1. Absorbent Cotton Wool. 2. Plaster of Paris Bandages. 3. Gauze Swabs/ Ribbon Gauze Section. 4. Gauze Roll / Absorbent Lint Section. 5. Eye Pad Section. 6. Paraffin Gauze Dressing / Para-Tulle Dressing / Poly Grass Dressing. 7. Bandages Section. 8. Cotton Crepe Bandages Section. 9. Lap Sponges Section.
2.	M/s Wellness Pharmaceuticals (Pvt) Ltd., Plot No. 33, Sunder Industrial Estate, Lahore.	**Formulation**	**Approved the Grant of DML with following Sections: -** **Sections (04)** 1. Tablet (General). 2. Capsule (General). 3. Oral Liquid (General). 4. External Preparations.
3.	M/s Stallion Pharmaceuticals, (Pvt) Ltd, Sunder Industrial Estate, Lahore.	**Formulation**	**Approved the Grant of DML with following Sections: -** **Sections (03)** 1. Capsule (Penicillin) 2. Dry Powder Suspension (Penicillin) 3. Dry Powder Injection (Penicillin)

4.	M/s Umema Pharma, Plot No. 28, Hub Industrial Estate, Hub, Balochistan.	**Formulation**	**Approved the Grant of DML with following Sections: -** **Sections: (02)** 1. Tablet (General) 2. Capsule (General)
5.	M/s Hiranis Pharmaceuticals (Pvt) Ltd, Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.	**Formulation**	**Approved the Grant of DML with following Sections: -** **Sections: (16)** 1. Tablet (General) 2. Capsule (General) 3. Dry Powder Suspension (General) 4. Liquid Syrup (General) 5. Mouth Wash (General) 6. Sachet (General) 7. Liquid Sachet (General) 8. Effervescent Tablet (General) 9. Toothpaste (Medicated) 10. Cream/Ointment / Gel (General) 11. Cream/Ointment (Steroid) 12. Tablet (Steroid) 13. Capsule (Steroid) 14. Liquid (Steroid) 15. Capsule (Probiotics) 16. Sachet (Probiotics) The Board desired to get clarification from the firm regarding Liquid Sachet (General) dosage form and its proof of availability in developed countries before issuance of approval letter for this section.
6.	M/s. Cibex (Pvt) Ltd, F-405, SITE, Karachi.	**Formulation**	**Approved the Grant of DML with following Sections: -** **Sections: (09)** 1. Tablet (General) 2. Capsule (General) 3. Sachet (General) 4. Tablet (General Antibiotic) 5. Capsule (General Antibiotic) 6. Dry Syrup (General Antibiotic) 7. Ointment-I (Steroids) 8. Ointment-II (Non Steroids) 9. Liquid Manufacturing
	Mr. Javed Yousuf Bukhari (Memebr CLB) and also member of the inspection panel apprised the Board about unprofessional attitude of Mrs. Roohi Obaid (one of the members of said panel) during inspection proceedings. The Board discouraged such attitude of inspectors during the panel inspections. The Board directed that in case a member intends to write a note of dissent with regard to inspection, the same must be written on the panel report, instead of submitting the note of dissent separately. The Board further decided that in case, if the majority of members of panel recommend the grant of new DML / Renewal of DML / Additional Section(s), the Board may consider such recommendations if deem appropriate, keeping in view the safety of public health at large.		

7.	M/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd, 47-Sunder Industrial Estate, Lahore.	**Formulation**	**Approved the Grant of DML with following Sections: -** **Sections: (03)** 1. Tablet (General) 2. Capsule (General) 3. Injectable General (Ampoule/Vial/Low Volume infusion) The Board directed to get clarification from firm regarding Injectable General Section before issuance of approval.
8.	M/s Lasani Health Care, Plot No.29-A/RI, Industrial Estate, Gadoon Amazai, Sawabi, KPK.	**Formulation**	**Approved the Grant of DML with following Sections: -** **Sections: (03)** 1. Disposable Syringes 2. IV Infusion Set 3. IV Cannula
9.	M/s. Wimits Pharmaceuticals, 129-Sunder Industrial Estate, Lahore.	**Formulation**	**Approved the Grant of DML with following Sections: -** **Human Sections** **Sections: (03)** 1. Syrup (General Human). 2. Tablet (General Human). 3. Capsulation (General Human). **Veterinary Sections** **Sections: (05)** 1. Veterinary Liquid Injection (General) 2. Veterinary Drench General) 3. Veterinary Aerosol (General) 4. Veterinary Oral Powder (General). 5. Veterinary Bolus (General)
10.	M/s Wenovo Pharmaceuticals, Plot No. 31&32, Punjab Small Industrial Estate, Taxila, Rawalpindi.	**Formulation**	**Approved the Grant of DML with following Sections: -** **Sections (05)** 1. Tablet. 2. Capsule. 3. Dry Powder for Suspension (General). 4. Sachet (General). 5. Capsule (Cephalosporin).
11.	M/s Agror Pharma (Pvt) Ltd, Plot No. 4, St No. SS-4 National Industrial Estate, Rawat, Rawalpindi.	**Formulation**	**Approved the Grant of DML with following Sections: -** **Sections (03)** 1. Dry Powder Suspension (Cephalosporin). 2. Capsule (Cephalosporin). 3. Dry Powder for Injection (Cephalosporin).

12.	M/s Nortech Pharmaceuticals, Plot No. 203, Industrial Triangle, Kahuta Road, Islamabad.	**Formulation**	**Approved the Grant of DML with following Sections: -** **<u>Sections (05)</u>** 1. Tablet General 2. Capsule General 3. Dry Powder Suspension 4. Cream/ Ointment /Gel (Non Steroidal)**.** 5. Ampoule/ vial The Board advised to get clarification from firm regarding Ampoule/Vial Section before issuance of approval.
13.	M/s Ravi Medical Supplies (Pvt) Ltd, Pahian Road, Raiwind Distt. Kasur.	**Formulation**	**Approved the Grant of DML with following Section: -** **Section (01)** 1. Disposable Syringes (3cc,5cc&10cc only) The Board also Directed to ask area FID to submit a report on calibration / validation data (both equipment & processes etc) during active production.

Item No.3 GRANT OF ADDITIONAL SECTIONS.

The Board decided the following cases of Grant of Additional Sections in the light of recommendations by respective panel of experts/inspectors.

S No.	Name of the firm	Type of License	Decision of CLB
1.	**M/s Bosch Pharmaceuticals (Pvt) Ltd, Karachi**	**Formulation**	**Approved the Grant of following Additional Sections: -** **Sections (05)** 1. Tablet (Cephalosporin). 2. Dry Powder Suspension (Cephalosporin). 3. Capsule (Cephalosporin). 4. Packing Area (Cephalosporin). 5. Lyophilized Powder Vial Filling
2.	**M/s UDL Pharmaceuticals, Port Qasim, Karachi.**	**Formulation**	**Approved the Grant of following Additional Sections: -** **Sections (02)** 1. Capsule (General). 2. Dry Powder Suspension (General).
3.	**M/s Candid Pharmaceuticals, Opp. Pasrur Sugar Mills, Sialkot**	**Formulation**	**Approved the Grant of following Additional Sections: -** **Sections (03)** 1. Capsule (General). 2. Dry Powder Injectable (Cephalosporin). 3. Dry Powder Suspension (Cephalosporin).
4.	**M/s Mac&Rains Pharmaceuticals (Pvt) Ltd, Manga Mandi, Lahore.**	**Formulation**	**Approved the Grant of following Additional Sections: -** **Sections: (08)** 1. Tablet (General) 2. Capsule (General) 3. Sachet (General) 4. Dry Suspension (General) 5. Liquid Injectable Vial (General) 6. Liquid Injectable Ampoule (General). 7. Cream/Ointment (General) 8. Eye Drops (General)

5.	**M/s Sharooq Pharmaceuticals (Pvt) Ltd, Lahore**	**Formulation**	**Approved the Grant of following Additional Section: -** **<u>Section (01)</u>** 1. Cream/Ointment steroid Section The Board showed its displeasure with respect to casual reporting by the panel by skipping clear rating.
6.	**M/s Mallard Pharmaceuticals (Pvt) Ltd, Lahore**.	**Formulation**	**Approved the Grant of following Additional Sections except repacking for ephedrine HCl & ephedrine sulphate as laid down under Schedule-D: -** **<u>Sections (02)</u>** 1. Powder (Repacking) 2. Liquid (Repacking)
7.	**M/s Medisearch Pharmacal (Pvt) Ltd, Lahore.**	**Formulation**	**Approved the Grant of following Additional Sections: -** **<u>Sections (03)</u>** 1. Dry Powder Suspension (General). 2. Dry Powder Suspension (Cephalosporin). 3. Capsule (Cephalosporin).
8.	**M/s Searle Pakistan Limited, Lahore.**	**Formulation**	**Approved the Grant of Additional Section namely Tablet (General) subject to following conditions that: -** • Newly established QC Laboratory shall be used as in-process QC Laboratory (for products to be manufactured in Block-2) whereas, the already established QC Laboratory of Block-1 shall be used as main laboratory for QC of all the registered products of the firm (for products to be manufactured in Block-1& Block-2) • The Board as per undertaking of the firm endorsed the block-wise arrangement for manufacturing of products. The Board however, did not accede to the undertaking of the firm for surrendering the capsule (General) section (Layout Plan recently approved) and utilizing the said area for tablet section. Board further directed the firm to submit proper application for withdrawal of Capsule (General) section and utilizing the same area for tablet section as per laid down procedure. **The Board authorized its Chairman to dispose-off the case after verification of above conditions /compliance accordingly.**

9.	**M/s Healthtek (Pvt) Ltd, Plot No. 14, Sector 19, Korangi Industrial Area, Karachi**.	**Formulation**	**Approved the Grant of following Additional Section: -** **<u>Section (01)</u>** 1. Liquid ampoule (water for injection with diluents). **Board further approved the verification of changes in the existing building as under: -** 1. Development of Microbiology Laboratory 2. Secondary Packaging area for ampoule and vials. 3. Some changes in personnel and material flow. Addition of air curtains, air lock improved the area classifications.
	Mr. Javed Yousuf Bukhari (Memebr CLB) and also member of the inspection panel apprised the Board about unprofessional attitude of Mrs. Roohi Obaid (one of the members of said panel) during inspection proceedings. The Board discouraged such attitude of inspectors during the panel inspections. The Board directed that in case a member intends to write a note of dissent with regard to inspection, the same must be written on the panel report, instead of submitting the note of dissent separately. The Board further decided that in case, if the majority of members of panel recommend the grant of new DML / Renewal of DML / Additional Section(s), the Board may consider such recommendations if deem appropriate, keeping in view the safety of public health at large.		
10.	**M/s Sunrise Pharma (Pvt) Ltd, A-594, Sunder Industrial Estate, Lahore.**	**Formulation**	**Approved the Grant of following Additional Section: -** **<u>Section (01)</u>** 1. Dry Powder Injectable (Cephalosporin)
11.	**M/s Brookes Pharma (Pvt) Ltd, Karachi**.	**Formulation**	**Approved the Grant of following Additional Sections: -** **<u>Section (2)</u>** 1. Dry Powder Injectable (Cephalosporin) 2. Sterile Liquid Ampoule (expansion)
12.	**M/s. Wise Pharmaceuticals, Rawat, Rawalpindi.**	**Formulation**	**Approved the Grant of following Additional Sections: -** **<u>Sections (02)</u>** 1. Sterile Liquid Ampoule 2. Small Volume Parenteral

13.	**M/s. Decent Pharma, Rawat, Rawalpindi.**	**Formulation**	**Approved the Grant of following Additional Sections: -** **Sections (01)** 1. Liquid Injection General (Vet.)
14.	**M/s Jasons Pharmaceuticals, Plot No. 26, Street No. SS-2, National Industrial Zone, Rawat, Islamabad.**	**Formulation**	**Rejected the grant of additional section of liquid ampoule (General) on the basis of unsatisfactory conditions of the section.**
15.	**M/s Sharooq Pharmaceuticals (Pvt) Ltd, Lahore**	**Formulation**	**Approved the Grant of following Additional Sections: -** **Sections (02)** 1. Injection (General) 2. Vial Infusion Injection (General) Section is not clear whether it is Vial or Ampoule, so Board advised to get clarification from firm/area FID before issuance of approval. The Board showed its displeasure with respect to casual reporting by the panel by skipping clear rating.
16.	**M/s Sanofi Aventis Pakistan Limited Karachi. DML No. ooooo7 (Formulation)**	**Formulation**	**Approved the Grant of following Additional Section: -** **Section (01).** Primary & Secondary Packaging Areas.
17.	**M/s Care Pharmaceuticals 8-KM, Thokar Raiwind Road, Lahore**	**Formulation**	**Approved the Grant of following Additional Section: -** **Section (01)** 1. Oral Liquid (General) The Board showed its displeasure with respect to casual reporting by the panel by skipping clear rating.
18.	**M/s Novartis Pharma (Pakistan) Ltd, West Wharf Road, Karachi DML No.000193 (Formulation).**	**Formulation**	**Approved the Grant of following Section: -** **Section (01)** 1. Capsule (General)

Item No.4 GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE.

The Board decided the following cases of Grant of Renewal of Drug Manufacturing License in the light of recommendations by panel of experts/inspectors subject to confirmation of installation of HVAC system and updated deposition of CRF admissible under the rules.

S No.	Name of the firm	Type of License	Decision of CLB
1	M/s Venus Pharma, Multan Road, Lahore.	Formulation	Approved the Grant of Renewal of DML.
2	M/s Heal Pharmaceuticals (Pvt) Ltd, Peshawar	Formulation	Approved the Grant of Renewal of DML.
3.	M/s Frontier Dextrose Ltd, Hattar	Formulation	Approved the Grant of Renewal of DML.
4.	M/s Global Pharmaceutical, Kahuta Triangle, Islamabad	Formulation	Approved the Grant of Renewal of DML.
5.	M/s Kailgon Agro Industries (Pvt) Ltd District Lasbella Balochistan.	Formulation	Approved the Grant of Renewal of DML except for sterile injection section.
6.	M/s Gelcaps (Pakistan) Ltd, Plot No. B, HITE, District Lasbela Balochistan.	Semi Basic	Approved the Grant of Renewal of DML.
7.	M/s Sultan Cotton & Bandages, Sindh Small Industrial Estate, Mirpurkhas.	Formulation	Approved the Grant of Renewal of DML.
8.	M/s Candid Pharmaceuticals, Opp. Pasrur Sugar Mills, Sialkot. (DML No. 000450)	Formulation	Approved the Grant of Renewal of DML.
9.	M/s Mediways International, 16-KM, Multan Road, Lahore.	Formulation	The Board did not allow the waiver of minimum plot size (i.e. total plot size 1 Kanal and 3 marlas) so deferred the renewal of DML and decided to strictly adhere to the provision of Schedule-B of Drugs (LR&A) Rules, 1976. The Board further decided to issue Show Cause Notice and Personal Hearing in the next meeting of CLB.
10.	M/s BSN Medical (Pvt) Ltd, plot No, A/69, S.I.T.E Karachi.	Formulation	The Board suspended the manufacturing license (Formulation) in all areas for a period of three months under Rule 13 of Drugs (Licensing, Registering and Advertising) Rules, 1976 for rectification of observations made during the inspection by the panel. The Board further decided to issue Show Cause Notice and Personal Hearing in the next meeting of CLB for repeated non-compliance of GMP.

11.	M/s Mallard Pharmaceuticals (Pvt) Ltd, Lahore.	Formulation	Approved the Grant of Renewal of DML.
12.	M/s Attabak Pharmaceuticals, Industrial Area, Islamabad.	Formulation	Approved the Grant of Renewal of DML.
13.	M/s Vetec Laboratory, Industrial Area Kahuta Triangle, Islamabad.	Formulation	Approved the Grant of Renewal of DML.
14.	M/s Legacy Pharmaceutical (Pvt) Ltd, Industrial Estate, Hayatabad.	Formulation	Approved the Grant of Renewal of DML.
15.	M/s Uniferoz (Pvt), Karachi.	Formulation	Approved the Grant of Renewal of DML.
	Mr. Javed Yousuf Bukhari (Memebr CLB) and also member of the inspection panel apprised the Board about unprofessional attitude of Mrs. Roohi Obaid (one of the members of said panel) during inspection proceedings. The Board discouraged such attitude of inspectors during the panel inspections. The Board directed that in case a member intends to write a note of dissent with regard to inspection, the same must be written on the panel report, instead of submitting the note of dissent separately. The Board further decided that in case, if the majority of members of panel recommend the grant of new DML / Renewal of DML / Additional Section(s), the Board may consider such recommendations if deem appropriate, keeping in view the safety of public health at large.		
16.	M/s Healthtek (Pvt) Ltd, Karachi.	Formulation	Approved the Grant of Renewal of DML.
	Mr. Javed Yousuf Bukhari (Memebr CLB) and also member of the inspection panel apprised the Board about unprofessional attitude of Mrs. Roohi Obaid (one of the members of said panel) during inspection proceedings. The Board discouraged such attitude of inspectors during the panel inspections. The Board directed that in case a member intends to write a note of dissent with regard to inspection, the same must be written on the panel report, instead of submitting the note of dissent separately. The Board further decided that in case, if the majority of members of panel recommend the grant of new DML / Renewal of DML / Additional Section(s), the Board may consider such recommendations if deem appropriate, keeping in view the safety of public health at large.		
17.	M/s Macter international (Pvt) Ltd, E-40, S.I.T.E Karachi. (DML No. 000641)	Formulation	Approved the Grant of Renewal of DML.
18.	M/s. Wise Pharmaceuticals, Rawat, Rawalpindi.	Formulation	Approved the Grant of Renewal of DML.
19.	M/s. Zafa Pharmaceuticals Laboratories (Pvt) Ltd., Federal B. Industrial Area, Karachi.	Formulation	Approved the Grant of Renewal of DML.

20.	M/s. Zafa Surgitex, Plot No. A/421, SITE, Nooriabad, Sindh.	Formulation	Approved the Grant of Renewal of DML.
21.	M/s Novartis Pharma (Pakistan) Ltd, West Wharf Road, Karachi DML No.000193 (Formulation)	Formulation	Approved the Grant of Renewal of DML.
22.	M/s Paktex Industries, 2.5 KM, Tatlay Road, Sroya Abad Kamonke, District Gujranwala.	Formulation	Approved the Grant of Renewal of DML.
23.	M/s Risma Laboratories, A-28, S.I.T.E, Karachi DML No. 000053 (Formulation)	Formulation	• The Board suspended the manufacturing license (Formulation) in all areas for a period of three months under Rule 13 of Drugs (Licensing, Registering and Advertising) Rules, 1976 for rectification of observations made during the inspection by the panel. • The Board also did not accede to the recommendations of panel for manufacturing of External Preparations for export purpose in the light of rule 17(2) of Drugs (LR& A) Rules, 1976. • The Board further decided to issue Show Cause Notice and Personal Hearing in the next meeting of CLB.
24.	M/s Nimrall Laboratories, Plot No. 24, St. No. SS-3, National Industrial Estate, Rawat, Rawalpindi.	Formulation	Approved the Grant of Renewal of DML.
25.	M/s Amson Vaccine & Pharma (Pvt) Ltd, Plot No. 113, Industrial Triangle Kahuta Road, Islamabad.	Formulation	Board suspended the manufacturing license (DML No.000638-Formulation) in all areas for a period of one month under Rule 13 of Drugs (Licensing, Registering and Advertising) Rules, 1976 for rectification of observations made during the inspection by the panel. The Board further decided to issue Show Cause Notice and Personal Hearing in the next meeting of CLB.
26.	M/s Hygeia Pharmaceuticals, Plot No. 295, Industrial Triangle, Kahuta Road, Islamabad.	Formulation	Approved the Grant of Renewal of DML.

Item No.5 MISCELLANEOUS CASES.

Case No.1 Establishment of a Pharmaceutical Unit - M/S Pharmedic Chemical, 24-KM, Multan Road, Lahore.

M/s Pharmedic Chemical, Lahore has submitted an application for the Drug Manufacturing License by way of Semi Basic Manufacturing at 24 KM Multan Road, Mohlanwal, Lahore. The proceedings of the above application is as under:-

1. Area FID, Lahore was requested for site inspection on 10th December, 2012.

2. Mr. Ajmal Sohail Asif, Area FID inspected the site on 13th December, 2012, the finding of inspection are as under:

    a. It was observed, astonishingly, that the said site has already been constructed. The pharmaceutical unit to manufacture drugs by way of semi-basic manufacturing has already been established. There was a double story building, having large halls in which the machinery for semi-basic manufacturing has been installed. At few placed some civil work was going on.
    b. The management was inquired about the status of the site. The management was asked that why the building has been constructed prior to the approval of the site and layout as per the Drugs Act, 1976 and rules framed under. Mr. Ejaz Hussain, General Manger informed that they have already got approval of the site and layout few years back but unfortunately the file has been lost by the licensing section of the DRAP Islamabad. He was asked to provide firm's own copies of the said approval so that the lost file may be reconstituted and concerned authority may be approached for further necessary action under the law. He assured to provide the copies to the undersigned on 17-12-2012. But the management of the firm failed to provide the documents as per their claim.
    c. Moreover, it was observed that in front of the site/unit (about 100 meters from the main gate of the unit) there passes a very large sewerage drain (Rajbah/Ganda Nala) that may pose serious environmental hazard to the site/unit.
    d. From the above mentioned situation it appears that the firm has established the pharmaceutical unit without fulfilling the codal formalities as required under the Drugs Act, 1976 and riles frame there under.
    e. Submitted for perusal, further necessary action and direction, please.

3 Mr. Ajmal Sohail Asif, Area FID was again asked on 23rd January, 2013 for clear for clear recommendations regarding approval of site. FID in his letter of 29th January, 2013 furnished following recommendations:

    a. In the light of physical inspection of the site in observations made site is not suitable for established of a pharmaceutical unit as per requirement laid down under paragraph 1 of section 1 of the Schedule "B" (SRO. 470(I)98 dated 15-05-1998. under rule 16(a) for the Drugs(Licensing, registering & Advertising) Rules, 1976.

4 On 3rd April, 2013 another panel comprising of Mr. Jamil Anwar member CLB Lahore and Ms Ayesha Khalil FID, Lahore was requested for re-inspection of the site. Accordingly Ms Ayesha Khalil Area FID conducted inspection on 24-07-2013 alone as

another member of the panel Mr. Jamil Anwar did not join after giving time for the said inspection a no response has bee received from his cell phone even after repeated call.

a. The total area of the land was 26 kanal. A semi basic manufacturing plant was already constructed. In the main building machinery for semi basic manufacturing was installed. Total six buildings comprising of boiler room, raw material store, workshop, compressor room, officer and manufacturing plant i.e. main building were situated in the area.
b. Towards south i.e. in front of the site a sewerage drain passes and the management informed that due to large amount of waste disposal i.e. approximately 25 tons/3 hours owing to semi basic manufacturing this large sewerage drain is very useful as they intend to dispose off their waste in the drain. Moreover, the firm has also provided an environmental monitoring report conducted by the Environmental Services SGS Pakistan (Pvt) Ltd for ambient air quality monitoring, metrological conditions and in door air quality monitoring.
c. On the North, East and West side there were agricultural lands, on the South sewerage drain.
d. Mr. Iftikhar Sheikh informed that he was not aware that a site approval is required for semi-basic manufacturing unit; hence he has done heavy investment in building a semi basic manufacturing facility.
e. Attested copy of sketch of the plot and adjoining areas and other legal documents such as copy of registry etc provided.
f. **Conclusion**: Keeping in view the above facts/observations, M/s Pharmedic Chemicals 24-KM, Multan Road, Mohalanwal, Lahore is a semi basic manufacturing facility built without prior site approval as required under the rules, the firm has also provided report of SGS which shows that the ambient air quality is within the limits, Hence to save huge investment and to encourage semi basic manufacturing the firm may be granted ex-post facto approval for site, for the purpose the case may be referred to Central Licensing Board.

5. Submitted for consideration and order of the Board please.

<u>Decision of CLB</u>: -

The Board after thorough deliberations and keeping in view the rule position rejected the application of Site under Schedule-B (1.2)&(2) of Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No.2 Policy Matter Regarding Grant of Cases / Layout Plans of Additional Sections for Psychotropic / Narcotic Drugs pending / deferred.

The Central Licensing Board in its 232nd meeting held on 29-30 July, 2013 considered the above case and decided as under: -

(*Extracts of 232nd meeting are reproduced as under*)

GRANT OF CASES / LAYOUT PLANS OF ADDITIONAL SECTIONS FOR PSYCHOTROPIC / NARCOTIC DRUGS PENDING / DEFERRED.

The Central Licensing Board in its 227th meeting deferred the approvals of Psychotropic / Narcotic sections of all the firms placed on the agenda till recommendation of the inter-ministerial committee specifically constituted for Psychotropic/Narcotic Drugs. The concerned section of Narcotic / Psychotropic / Controlled Drugs of DRAP has informed that the subject case was placed before the 11th meeting of the committee on allocation of the controlled drugs under Ministry of National Narcotics Control held on 6th May 2013 and forwarded the extract of the minutes of the meeting which is being reproduced as under: -

"The Committee decided that CLB may consider the Licensing and approval of additional sections for manufacture of controlled drugs/substances in the light of ***relevant Act and rules****. The Committee on Allocation of Controlled Drugs will consider matter for allocation of Controlled Drugs in the light of relevant laws and rules after registration".*

DECISION OF CLB.

The Board after taking into consideration all pros and cons of the matter and taking in account decision of meeting of Inter-Ministerial Committee on allocation of the controlled drugs, decided to withheld / defer the cases for approval of layout plans and grant of additional sections for Psychotropic / Narcotics Drugs due to the following reasons: -

- The Board decided to send a reference regarding the above mentioned decision to Director Controlled Drugs, DRAP with the recommendations of CLB to take up the matter with Ministry of National Narcotics Control on following issues as the Central Licensing Board is of opinion that clarification is required to be solicited to proceed further in to the matter.
- There is no provision under the Drugs Act, 1976 and rules framed there under to process the cases for approval of Building Layout plans & sections / additional sections for production of Psychotropic / Narcotic drugs.
- The above mentioned decision of the Inter Ministerial Committee and previous decisions of CLB & DRB need to be revisited as most of the CLB members attending the meeting were of view that as per international practice there is no need of segregated / dedicated facility for manufacturing of Psychotropic / Narcotic products.
- The members of CLB namely Mr. Salim Isharat Husain, Mr. Khalid Yousuf, Syed Jawed Yousaf Bukhari, Dr. Ali Akbar Sial and Mr. Nadeem Iqbal were of view to grant approval of Psychotropic/Narcotic drugs in general sections since: -

  i. No Separate Area is required for manufacturing of Solids or Liquids Psychotropic / Narcotics Dugs in other countries including WHO, FDA USA, FDA India etc., hence why should we put extra burden on our manufacturers for

dedicated areas with dedicated HVACs.

ii. Cross Contamination in the world is handled by Robust Systems and Validation / Cleaning Validation etc. for Psychotropic / Narcotic substances. Even the API's of Psychotropic / Narcotics are manufactured in General Sections in the world.

iii. Only Beta Lactams. Cephalosporin, Anabolic Steroids, etc. requires dedicated facilities.

- However members of CLB, Mr. Ayaz Ali Khan, Chief Drugs Controller, Health Department, Govt. of Punjab, Prof. Gul Majeed Khan, and Mr. Ahmad Din Ansari, Secretary CLB were of view that there must be some more deliberations on the subject issue and policy of dedication / segregation of Psychotropic / Narcotic drugs may not be discontinued with one pen stroke. Furthermore CL&RB in its 184th meeting held on 23-08-2004 "***decided to allow the firms upto 31st December 2005 to establish segregated facilities for Psychotropic / Narcotic Drugs. However, during this period they may manufacture both categories of drugs in their previous facilities but after this period complete shift over to segregated facilities shall be mandatory otherwise they have to surrender their registrations for these drugs".***
- It is further decided that every member of CLB will send his recommendations supported by documentary evidence for revisiting policy decision sent by the Directorate of Controlled Drugs in collaboration with Ministry of National Narcotics Control accordingly.
- The representatives from PPMA and Pharma Bureau also agreed to issue approvals of the deferred cases / sections of Psychotropic/ Narcotic Drugs after receiving the fresh reference from Directorate of Controlled Drugs as stated above.

FURTHER PROCEEDINGS ON THE MATTER

The issue of Psychotropic / Narcotic drugs has witnessed the discussions at various forums. The details of the same are presented here before the Board for its perusal and discussion, so that it can reach an appropriate decision.

1. Decision of Committee on Controlled Drugs dated 6th May, 2013

The Committee on Controlled Drugs decided that:

"The CLB may consider the licensing and approval of additional sections for manufacture of controlled drugs / substances in the light of relevant Act and Rules".

The Drugs Act, 1976 and rules made there under are silent to consider the requests till amendments are made in respective rules.

2. Recommendations of International Narcotics Control Board (INCB)

The delegation of International Narcotics Control Board visited Pakistan on 11th-14th September, 2012 and gave their observations. The major points highlighted by INCB are as under: -

i. Weakness and inadequacies in the control of Narcotics / Psychotropic / precursor chemicals in Pakistan.

ii. Misuse of pharmaceutical preparations containing controlled substances, particularly psychotropic substances, largely due to absence of prescription control at both pharmacy and doctor's level.

iii. Lack of improvement with regard to ensuring adequate availability of opioids for medical purposes.

iv. Increase risk of diversion of precursor chemicals.

v. INCB emphasized the capacity building of Regulatory Authority so that it can discharge its functions as required under the International Drug Control Treaties, i.e.

- **To ensure adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes**,
- To prevent their diversion and abuse
- To ensure full compliance with Pakistan's treaty-based reporting obligations.

vi. Pakistan is among few countries in the world with the highest annual legitimate requirements (ALR) for Ephedrine and Pseudoephedrine.

vii. INCB proposed that UNODC Pakistan and WHO Pakistan may be requested for assistance in conducting study regarding the issued highlighted above.

3. Minutes of 4th Meeting of Policy Board

The Policy Board in its 4th meeting held on 23-10-2013 advised the Director Licensing / Chairman Central Licensing Board to resolve the issue of dedicated facility for the manufacturing of Psychotropic drugs, on priority and if that was not the express requirement of respective rules then the CLB should consider allowing campaign manufacturing as per international practice.

The DRAP is in acute shortage of human resource with respect to Officers and Officials / Staff. The provision of campaign manufacturing to observe specific precautions like validations cannot be ensured with grossly in adequate and rudimentary structure of DRAP. In circumstances where most of the Drug Inspectors have been failed to inspect the License Unit twice in a year for GMP inspections under Rule 4 (1)(a) as laid down under the Drugs (Federal Inspectors, Federal Drugs Laboratory, and Federal Government Analyst) Rules, 1976, how can FIDs ensure validations on campaign manufacturing.

This step may ultimately lead to a discriminatory / unauthorized permission to some manufacturer at one hand and may inhibit the natural right of deserving firms on the other hand. However this provision of campaign manufacturing may be allowed to firms which have their drugs (Psychotropic / Narcotic Drugs) registered in their name if approved otherwise this open ended approval may tantamount to misuse the Narcotic / Psychotropic Drugs.

4. Recommendations of 9th Meeting of DRAP held on 25-11-2013

The DRAP in its 9th meeting considered the observations made by INCB as mentioned above and decided to approve that UNODC and WHO Pakistan may be requested for assistance in conducting study to comply with the observations raised by INCB Mission as above. As such the recommendations of INCB were endorsed by the DRAP.

5. Recommendations of the Members of the CLB

The Central Licensing Board in 232nd meeting desired that every member of CLB may send his recommendations supported by documentary evidence for re-visiting policy decision sent by the Directorate of Controlled Drugs in collaboration with Ministry of National Narcotics Control accordingly.

Only one member of CLB Mr. Javed Yousaf Bukhari has submitted his recommendations supported with the documentary evidence where as remaining members have also submitted their recommendations but without any documentary reference.

Recommendations of Mr. Javed Yousaf Bukhari are as under: -

i. At the initial Phase Grant of Layout plans of Psychotropic Section be allowed after carefully looking proper HVAC System to facilitate regular supply of the Psychotropic Drugs.
ii. He recommended to inspect facilities manufacturing Psychotropic Drugs to review their capabilities and to verify GMP Compliance.
iii. Additional section for Psychotropic Tablet is not economical as low volume of Psychotropic Drugs is manufactured.

6. Some additional grounds and facts

i. The Drugs Act, 1976 and Rules framed there under are silent to decide the fate of Psychotropic / Narcotic Drugs in the light of recommendations of the Committee on the allocation of controlled drugs which is again being reproduced as under: -

> *"The Committee decided that the CLB may consider the licensing and approval of additional sections for manufactured of controlled drugs / substances in the light of relevant Act and Rules".*

ii. An open ended permission of Psychotropic / Narcotic Drugs if granted in General Sections may greatly hamper the efforts of Federal and Provincial Government to check an eye on these Drugs and to curb the menace of misuse potential of Psychotropic / Narcotic Drugs.

iii. Keeping in view of all pros and cons mentioned above, it is proposed that necessary amendments / additions in the rules may be made prior processing the cases for Narcotic / Psychotropic / Precursor Drugs to decide the cases in spirit of the decision of Committee of allocation of Controlled Drugs.

iv. Rule 8(20) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 states as under: -

> "*The Central Licensing Board shall follow the policy guidelines of the Federal Government for the conduct of its business".*

Accordingly, a consensus on the issue of Psychotropic / Narcotic Drugs is necessary and after getting consensus on the issue, the case may be submitted for approval of Federal Government, so that the Federal Government may be on Board for taking any decision by CLB, to avoid any embarrassment.

IN ADDITION TO ABOVE, THE BOARD WAS FURTHER APPRISED OF THE FOLLOWING DELIBERATIONS BEFORE REACHING THE COMPLETE CONSENSUS FOR MAKING DECISION

1. **191st Meeting of Central Licensing & Registration Board held on 30-31 May, 2005.**

The matter of dedicated facilities was placed on the agenda of 191st meeting of CL & RB held on 30th – 31st May, 2005 and it was endorsed by the Board that dedicated / self contained facilities are pre-requisite for the manufacturing of following drugs:-

1. Penicillins
2. Cephalosporin
3. Biologicals
4. Cytotoxic substances
5. Radio Pharmaceuticals
6. Veterinary Immunological Preparations
7. Sterile Preparations
8 Hormonal Preparations.
9. General Antibiotics / Quinolones.
10. Psychotropic / Narcotics.

"The Central Licensing & Registration Board decided to allow the firms up to 31st December, 2005 to establish segregated facilities for "Quinolones" and "Psychotropic / Narcotic" drugs. However, during this period they may manufacture both categories of drugs in their previous facilities but after this period complete shift over to segregated facilities shall be mandatory otherwise they have to surrender their registrations for these drugs".

2. Ministry of Law & Justice Division in its O.M No.2303/97-Law-I, dated 30-03-2010 had opined in a reference sent vide letter No.F.1-1/84-Lic, dated 18-01-2010 by defunct Ministry of Health as under: -

i. We could not find out any provision which enables Central Licensing Board to review its decision in the Drugs Act, 1976 (XXXI of 1976) and the Drugs (Licensing, Registering and Advertising) Rules, 1976".

ii. If anybody is aggrieved against the decision of Central Licensing Board, an appeal may be preferred within sixty days under section 9 of the Drugs Act, 1976(XXXI of 1976).

3. The CLB in its 226th Meeting held on 31st December, 2010 received a report by a committee comprising of Mr. Shahid Nasir, Member, CLB, Mr. Jamil Anwar, DTL, Lahore and Dr. Sheikh Akhtar Hussain DDG, Lahore to analyze the situation and submit their recommendation on Psychotropic/Narcotic Drugs.

The Brief of report submitted by Committee is as under: -

i. 286 companies are found already manufacturing and marketing Psychotropic/Narcotic Drugs in various dosage forms.

ii. 446 products are already in the market.

iii. During one year period i.e. in 2010 these companies have sold 42,547,600 units of various Psychotropic/Narcotic Drugs through retail channels.

4. The Central Licensing Board in its 227th meeting held on 1st & 2nd June, 2011 considered and decided as under: -

i. The Board deferred the approval of Psychotropic Production Areas / Sections under approval by the Licensing Board regarding Capsule, Tablet, Syrup and Injectable etc. till finalization of recommendations of the Inter Ministerial Committee specifically constituted for the Psycho Active Drugs.

ii. The firms already having Psychotropic drugs registered with Ministry of Health can continue with the production of Psychotropic Drugs in segregated areas as requirement of Schedule B (5.2) of the Drugs Act, 1976.

iii. The Board delegated the power to Chairman CLB for converting Psychotropic sections (new) into General Sections if the firm desires so. The firm may submit written request to the Ministry of Health.

5. Recommendations of Committee for Allocation of Controlled Substances/Drugs (Inter-Ministerial Committee)

The Committee for Allocation of Controlled Substances/Drugs (Inter-Ministerial Committee) in its meeting held on 6th May, 2013 decided that:

"Central Licensing Board may consider the licensing and approval of additional sections for manufacture of controlled drugs / substances in the light of relevant Act and Rules. The Committee on Allocation of Controlled Drugs will consider matter for allocation of controlled drugs in the light of relevant laws and rules after registration".

6. Comments of various members of Board made during the proceeding of meeting

Moazzam Ali Khan (Punjab)

b. Pakistan is 4th biggest country in the world declared to be using Psychotropic/Narcotic Drugs.

c. Effective mechanism at manufacturing level needs to be developed.

d. Justification for quota allocation of Psychotropic/Narcotic Drugs needs to be improved.

e. Some mechanism at sale outlets to check the control on these drugs needs to be ensured.

f. Sale of Psychotropic/Narcotic Drugs without prescription should not be allowed.

g. Proper sale record of dispensing of Narcotics / Psychotropic drugs should be maintained.

h. Effective mechanism of controlling Morphine and Pethidine is implemented to prevent their misuse.

i. Manufacturing of Psychotropic / Narcotic Drugs may be allowed in segregated areas as per previous decision of the CLB.

Prof. Dr. Gul Majeed Khan (Islamabad)

He endorsed the proper control on Psychotropic/Narcotic Drugs as suggested by Moazzam Ali Khan (Punjab)

Syed Muid Ahmed (Karachi) also emphasized to develop such mechanism to deal with all matters of Psychotropic/Narcotic Drugs.

Dr. Jamshed Kazmi (Karachi) also supported the justification for controlling / preventing the misuse of Psychotropic/Narcotic Drugs by applying effective checks at the manufacturing level in addition to those exercised at the prescription and sale level especially considering the meager sources of our country. He also supported the opinion of other Board members.

Prof. Dr. M. Saeed (Peshawar) opined to develop stringent control on these drugs.

PPMA and PCDA representatives Mr. Khawaja Javed Akbar and Mr. Asif Akhai respectively also agreed that manufacturing of Psychotropic / Narcotic Drugs may be allowed in segregated areas.

Decision of CLB: -

After thorough deliberations and keeping in view the directions of Policy Board, recommendations of DRAP Authority, recommendations of Committee for Allocation of Controlled Substances / Drugs (Inter-Ministerial Committee), views of honorable members, previous decisions of Central Licensing Board on the said issue, and ensuring adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes as highlighted by INCB, the Central Licensing Board decided: -

- **To continue the previous policy / decisions of Central Licensing Board of segregated facility for manufacturing of Psychotropic / Narcotic Drugs.**
- **To process all pending layout plans / applications accordingly in the light of above decision.**
- **To carryout fresh panel inspections of sections / areas of Psychotropic / Narcotic Drugs considered and deferred in 227th meeting of CLB.**

Case No.3 Acquisition of Licensed Premises of M/s Breeze Pharma (Pvt.) Ltd, DML No. 000659 (formulation) by M/s ICI Pakistan Limited on Lease Hold Rights.

The brief background of the case is as under: -

M/s Breeze Pharma (Pvt) Ltd a Licensed Unit intended to lease out their licensed premises and license to M/s ICI Pakistan Ltd on lease hold rights for a period of ten years. Both the entities are registered with SECP as a Private Limited Company and a Public Limited Company respectively. Since there is no provision under the Drugs Act, 1976 & Rules framed there under to acquire licensed Pharma unit on lease hold rights hence the case was placed before CLB for consideration/decision in its 232nd meeting held on 29-30 July, 2013. The Board accordingly discussed/considered the above case and decided as under: -

"The Board decided to defer the case and desired personal hearing from the owners / directors of M/s ICI Pakistan Ltd and M/s Breeze Pharma (Pvt.) Ltd to update the CLB on their request regarding acquisition of licensed premises on lease agreement rights as there is no provision in Law & Rules to acquire licensed Pharma unit on lease hold rights".

Since the Drugs Act, 1976 & Rules framed there under do not provide any provision/remedy in the instant case. Therefore later on the opinion of Law, Justice & Human Rights Division was solicited in this regard specifically to opine as to whether any licensed unit registered with SECP and DRAP can be acquired by a non licensed unit by DRAP but registered with SECP.

The Law Division has furnished its opinion as under: -

2. The instant case relates to application of sub-rule (6) of rule 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976, which is reproduced as below:-

"[5(6) *For change of the name of a license,* fee as prescribed under Schedule **'F'** for renewal of a license shall be paid]".

3. Brief facts of the case are that M/s. Breeze Pharmaceutical having Drug Manufacturing License have leased out their premises to M/s. ICI Pakistan Limited, which is a non-licensee. Having done that M/s Breeze Pharma and M/s ICI applied for change of name in the license under the above reproduced rule. The issue in hand is as to whether M/s. ICI Pakistan Limited require a fresh license for manufacturing of drugs on the leased premises or license of M/s Breeze Pharmaceutical would be a valid one for manufacturing of drugs.

4. In this regard it is stated that the license issued by the Competent Authority was issued to the drug manufacturing facility/manufacturing plant/premises and the inspection prior to granting license was done for the drugs manufacturing facility, its manufacturing plant, its premises and also of the qualifications of the management under rules 15 and 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. It would, therefore, be wrong to state that the license was only issued to the premises and not the management. The collective view of M/s. Breeze Pharma and M/s. ICI is that only the Board Directors are being changed and not the premises. **Attention of both the companies is invited to section 196 of the Companies Ordinance, 1984, which states that the business of a company is run and managed by the Directors of a company.**

5. In sequel of the above, the Board Directors of a company and the management of a company are as much important as the premises/machinery/manufacturing facility of a company at the time of grant of license for manufacturing of drugs. The lease agreement between M/s. Breeze Pharma and M/s. ICI is more than a mere lease and amounts to transfer of license which is unauthorized under the said Rules.

6. Hence the case does not fall under above reproduced rule 5(6) for change in the name of license. A fresh license would be required by M/s. ICI for manufacturing of drugs. Before parting with the file it is pertinent to point out that the referring Division shall suitably amend the Drugs (Licensing, Registering and Advertising) Rules, 1976 so that such like complications due to silent position of Rules can be averted in future.

Sd/-
(Sheikh Sarfraz Ahmed)
Deputy Draftsman-I
28th November, 2013.

The representatives of both the firms have been called for personal hearing in the light of decision of CLB taken in its 232nd meeting.

Proceedings: -

The firm was called for personal hearing in the light of decision of CLB taken in its 232nd meeting. Mr. Abid Puri, the lawyer of both the firms along with Directors / representatives of both the firms attended the meeting. The point of view of both the firms was heard by the CLB.

The Board was further apprised that: -

1. M/s ICI Pakistan Ltd and M/s Breeze Pharma (Pvt) Ltd are two different entities as both the firms have different Boards of Directors.
2. It is a case of fresh grant of Drug Manufacturing License and not merely a lease agreement, as the Drug Manufacturing License is neither transferable nor heritable.
3. M/s ICI Pakistan Ltd has to apply afresh for grant of DML for which all requirements as per law need to be fulfilled.

Decision of CLB

The Board after hearing the representatives of M/s. ICI Pakistan Ltd and M/s Breeze Pharma (Pvt) Ltd. and their legal counsel, thorough discussion and deliberations, keeping in view the opinion of Law Division and taking in account all pros & cons of the matter, decided as under: -

- **M/s. ICI Pakistan Ltd shall apply afresh for grant of DML after surrendering of License and Inspection Book by M/s Breeze Pharma (Pvt) Ltd.**
- **A fresh resolution in original by the Directors of M/s Breeze Pharma (Pvt) Ltd and M/s ICI Pakistan Ltd shall be submitted to CLB stating that present premises of M/s Breeze Pharma(Pvt) Limited has been acquired/leased out on leased hold rights by M/s ICI Pakistan Ltd.**
- **The fresh agreement of lease (in original) shall be submitted to CLB by the acquiring and ceasing Directors of both firms.**
- **The application already submitted along with prescribed fee by M/s. ICI Pakistan Ltd for grant of fresh DML shall be processed accordingly after fulfillment of legal formalities and no separate fee shall be required.**
- **The Board waived off the condition of site verification and directed for fresh panel inspection.**
- **A new DML with new number shall be granted after approval by the Board.**

Case No.4 **Acquisition of Licensed Premises of M/s Mac & Rains (Pvt.) Ltd, Lahore DML No. 000586 (Formulation) by M/s Searle Laboratories (Pvt.) Limited on Lease Hold Rights.**

The Central Licensing Board in its 232nd meeting held on 29-30 July, 2013 considered the request of M/s Searle Laboratories (Pvt.) Limited Karachi on the subject case and decided as under: -

"The Board decided to defer the case and desired personal hearing from the owners / directors of M/s Mac & Rains (Pvt.) Ltd, Lahore and M/s Searle Laboratories (Pvt.) Ltd to update the CLB on their request regarding acquisition of licensed premises on lease agreement rights as there is no provision in Law & Rules to acquire Licensed Pharma unit on lease hold rights".

M/s Mac & Rains (Pvt) Ltd have submitted their request for withdrawal of their application / NOC of acquisition with M/s Searle Laboratories (Pvt) Limited. The firm has further requested for exemption of personal hearing.

The representatives of both the firms have been called for personal hearing in compliance of decision of CLB taken in its 232nd meeting.

Decision of CLB

Board after hearing the representatives of both the firms that they have requested for withdrawal of their application of acquisition of premises of M/s Mac & Rains (Pvt.) Ltd, Lahore by M/s Searle Laboratories (Pvt.) Ltd on lease hold rights, acceded to their request and approved the applications of withdrawal of both the applicants.

Case No.5 **Closure of Pharmaceutical Unit of M/s. Vetgro Pharmaceutical (Pvt) Ltd., Lahore.**

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

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

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

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

market competitors that the management has closed the firm due to some partnership/family disputes.

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

2. Keeping in view the above, **Show Cause** notice was issued to the firm vide letter dated 8th May 2013. The firm was also asked to appear before the CLB in its next meeting if want to be heard in person.

3. In response Mr. Faiz Rasool Chief Executive of the firm has submitted his reply in which he has denied that the FID has contacted him and written him letters. He has further stated as under:

a. That there are severe financial crises of the country and that there is no gas no electricity no working environment, labor problems business migrations no more investment on business to create jobs. So in this environment everyone is in problem; to meet electricity bills, wages of employees, unsustainable low production volumes, high costs of production and unaffordable circumstances and inevitable expenditures. These are the major factors that we are unable to run the factory at full momentum and capacity and at all levels. In our area light goes from 16-18 hours a day. So how can we work? It is a multimillion investment at stake because of the bad conditions of country.
b. That they have done big investment and are eager to bring up factory in full working position otherwise will shift from Pakistan.
c. That country slams massive power load shedding and all chambers of commerce have expressed serious concerns over the poor response of Government towards unprecedented energy shortage of the industry.
d. That the Show Cause notice has been issued on one and first visit of FID and false report of formal FID. I think they must be friendly with the companies rather to indulge in wrong goings. They try to create easiness to industrials to create problems.
e. That I have done nothing wrong. There is no fault on my part and I am sent show cause notice and not known to reason. I therefore request the competent authority to look into the matter sympathetically and oblige.

3. The firm has been asked to appear before the Board for personal hearing in this meeting and clarify their position on the subject matter.

Decision of CLB

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

Case No.6 **Renewal of DML of M/s Katrina Pharmaceutical Industries (Pvt.) Ltd., Sheikhupura.**

M/s Katrina Pharmaceutical Industries (Pvt) Ltd, Sheikhupura was inspected by a panel of experts on 14.12.2007 for renewal of Drug Manufacturing License wherein panel did not recommend renewal of license. Firm was served with the show cause notice and owner of the firm was given personal hearing in 212th meeting of the board held on 26.05.2008 and undertook before the Board that he will suspend the production with immediate effect and will ready for re-inspection after one month.

The CLB in its 212th meeting decided to grant one month time for improvement of the facility. The FID Lahore conducted inspections on 30.05.2008, 08.07.2008 and then on 15.06.2009 wherein he reported that at the time of inspection the entire manufacturing facility was closed and no production activity was in progress. No technical person was present no compliance of their undertaking regarding rectification and up-gradation was made by the firm even after laps of a period of one year. The FID also recommend that the license of the firm may be suspended as the firm has not done any compliance with reference to previous inspection report and renewal of their DML was also not recommended by the Panel of inspectors. The Board in its 218th meeting held on 30-06-2009 decided to issue final show cause notice and call the management for personal hearing before the next meeting of the Board. The firm was served with show cause notice and advised to appear before CLB for personal hearing in person on 31-07-2009.

The firm applied for renewal of their DML for the period of 14-12-2009 to 13-12-2014 in time. The panel was constituted on 25th February 2011 but the inspection by the panel was not carried out. However, Area FID and ADC Lahore conducted an inspection of the firm on 8th February 2012 and reported that the whole of the plant was dismantled and the installation HVAC was in process and the management informed that they are non-operational from the last three and half years because the financial constraint. Area FID Lahore vide letter dated 28-11-2012 requested for reconstitution of the panel as new members of the CLB have been nominated.

The Federal Inspector of Drugs, Lahore conducted the inspection of M/s Katrina Pharmaceutical Industries (Pvt.) Ltd., Seikhupura on 04-03-2013 to check the status and GMP compliance of the firm. The contents of inspection report of the FID are as under: -

a. That at the time of inspection the firm was closed and no production activity was in process. Only two watchmen were there and one watchman Mr. Ata Ullah has given the statement that the factory is closed for the past many months. It is also pertinent to mention that Dr. Sheikh Akhtar Hussain, Federal Inspect of Drugs at that time, also inspected the fm on 15.6.2009 and at that time the manufacturing facility was also found closed. It was reported that no compliance of the firm's undertaking regarding rectification was made by the firm even after the lapse of one year. He recommended that the license of M/s Katrina Pharma may be suspended as the firm has not done any compliance and the renewal of their DML was also not recommended by the panel
b. The firm was again inspected by Abdul Rashid Sheikh, Federal Inspector Drugs, Lahore as the management has requested for deferment of inspections because of their installation of HVAC system and other renovation and installation of HVAC was in process. The management informed at that time that they are non-operational from the last three and half years because of financial constraints.

c. Mr. Afzal Hameed, Chief Executive of the firm informed telephonically that HVAC system has not been installed yet due to some payment problems.
d. The renewal of DML of the firm was not recommended, however another panel was constituted but now the Board have been reconstituted under Drugs Regulatory Authority of Pakistan, therefore, reconstitution of panel is required. The factory is closed for the last five years; hence the matter may be submitted to Licensing Board for further necessary action, please.

3. Keeping in view the above, show cause notice was issued to the firm vide letter dated 8th November 2013. The firm was also asked to appear before the CLB in its next meeting if want to be heard in person.

4. The firm has been asked to appear before the Board for personal hearing in this meeting and clarify their position on the subject matter. Submitted for consideration of the Board in the light of above background of the case as the renewal of DML of the firm is due last two periods.

Decision of CLB

The representative of the firm was called for personal hearing in the light of previously served Show Cause Notice but no any representative attended the meeting.

Board after through discussion decided to suspend the manufacturing license under Rule 8(14) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till rectification of shortcomings and verification thereof by panel. The Board further decided to give another opportunity of hearing in the light of previous show cause notice.

Case No.7 Cancellation of Drug Manufacturing License No. (000663) (Formulation) of M/s Al-Aju Cotton Industries Mir Pur Khas Sindh.

Federal Inspector of Drugs Dr. Najam-us-Saquib visited M/s Al-Aju Cotton Industries on 28th June 2013 wherein the FID has reported that there was no production activity underway and premises were found closed. He has further informed that letters and reminders to the firms were issued but no reply from the firm was received. The neighboring person informed that there is no production activity since long and this premises alongwith other surrounding land has been purchased by another person namely Mr. Amjad Memon. On contact to Mr. Amjad Memon he has confirmed that he has purchased the whole land and he does not know about running a pharmaceutical unit, nor he is interested in the same. The FID has recommended for cancellation of Drug Manufacturing License of M/s Al-Aju Cotton Industries, Mirpur Khas, Sindh.

Decision of CLB

The Board in light of inspection report of area FID and after thorough discussion and deliberations decided to issue Show Cause notice to M/s Al-Aju Cotton Industries, Mirpur Khas, Sindh and called the firm for personal hearing in next meeting before cancellation of DML. Board further decided to collect the DML and Inspection Book through area FID.

Case No. 8 Renewal of DML unit - M/s Shazal's Pharmaceuticals, Hattar.

M/s Shazal's Pharmaceuticals, Hattar applied for renewal of their DML on 05-05-2011 The brief background of the case is as under: -

The application of renewal of DML of firm, being not on prescribed Form 1A is not tenable and is liable to be rejected as provided under rule 5(2A) of the Drug (Licensing, Registering and Advertising) Rules, 1976. The fact is that the firm did not submit their complete renewal application and did not respond to DRAPs correspondence within thirty days as admissible under above mentioned Rules. Further the management of the licensee/firm has also been changed for which following is submitted for consideration of CLB to take decision in the light of authority forwarded by Law Division as under.

2 The Law Division in the case of M/s Qamar Cotton Industries Okara wherein the comments were solicited as whether the Drug Manufacturing License can be transferred to Legal heirs of the company established under the sole proprietorship. The Law Division opined that the license is a permissive right of an individual and could not be transferable to his son as requested. As the license is neither transferable, assignable and heritable from the previous owner/ seller to Rafi Ul Mulk (purchaser) as requested in receipt as the Drug Manufacturing License. The new management may apply afresh for grant of Drug Manufacturing License under the rules after surrender the DML by the previous owner/ licensee at present being sole proprietor of the firm. Both the persons may be informed about the situation / status accordingly.

Decision of CLB

Board deferred the case for next meeting for want of complete back ground of the case.

Case No.9 Renewal of Drug Manufacturing License of M/s Novartis Pharma Pakistan Ltd, Karachi DML No. 000193 (Formulation)

Proceeding

Decision taken by Board is mentioned under the cases of Renewal of DML and Grant of Additional Section of the said firm.

Case No.10 Application of M/s Abbott Laboratories Pakistan Ltd, Karachi for Cancellation of their DML (No. 000005 Basic Manufacture).

Brief Background:

The Central Licensing Board in its 232nd meeting discussed the case of M/s Abbott Laboratories Pakistan Ltd, Karachi for cancellation of their DML (000005) Basic Manufacture.

After hearing the firm's representative Mr. Anis Shah, Director Plant Operation, and thorough discussion and deliberation among the members of the Board on the issue, the Central Licensing Board did not accede to the request of the firm for cancellation of their DML No. 000005 (Basic Manufacture) being indigenous API manufacturing unit. The following clarification from the firm and the Directorate of PE&R is awaited:

- Documentary evidence supported by relevant documents / information mentioning that why this license has not been feasible to operate.
- The drugs registration directorate shall be asked for clarification regarding approval of change of source of their Aluminum Hydroxide Gel for use in their registered products (i.e. Antacids like Dijex MP and Dijex).
- The firm shall be asked to clarify that how the import of Aluminum Hydroxide Gels had been feasible in spite of enhanced duty structure where said API is approved for local production under the rules?
- The firm shall also be asked how their Formulation Products are being manufactured if they have changed their source after closure of their facility?
- Since, the representative of firm stated that they had been enhancing the capacity of this plant from 500 kg to 1000 kg in the past and now how this plant is suddenly unfeasible to run at once?
- The Drug policy has given different incentives to basic / semi basic manufacture so the firm's request for cancellation of DML No. 000005 (basic manufacture) is absolutely illogical / irrational that tantamount to deprive this country from an API, being manufactured indigenously.

No clarification from the firm as well as from registration directorate received.

Decision of CLB

Board deferred the case till clarification/information by firm and Division of Pharmaceutical Evaluation & Research of DRAP.

Case No.11 M/s The Searle Company Limited, Karachi DML No. (000016) Formulation Manufacturing Nutraceutical Products.

The Central Licensing Board in its 232nd meeting discussed the case of M/s The Searle Company Karachi, regarding using of their premises for manufacture of Drugs. The Board decided to get the facilities of M/s Searle Pakistan Limited, Karachi at Korangi site inspected by a panel as this site is reportedly used for manufacturing nutraceutical products as informed by Mr. Salim Isharat Chief Drug Inspector, Sindh (Member CLB). The Board further decided to get the inspection of two separate premises of M/s Searle Pakistan Limited in Karachi i.e. Korangi Industrial area and S.I.T.E Karachi by panel of experts to ascertain the status of licenses of these Sites and check production activities being carried out at these two sites. In compliance a panel was constituted who submitted its report as under:

i) The panel consisting of Syed Javed Yousaf Bukhar, Mr. Qaiser Muhammad Chief Drug Inspector Sindh, Syed Hakim Masood, Area FID, SITE, Karachi and Abdul Rasool Shaikh FID-III.

Summary of the report of un licensed unit of M/s The Searle Company situated at Plot No.15/1, Sector 15, Korangi Industrial Area, Karachi.

The panel who inspected the premises informed that manufacturing of some food supplements was underway. The panel further informed that their probiotics which are imported and repacked here must be dealt under the uniform policy of the DRAP as probiotics are getting registrations like *Saccharomyces Bouldarii*. The firm was advised to approach DRAP Authorities Islamabad for clarification. The probiotics come under provision of Drugs Act, 1976 and registrations are granted. The case relates to Quality Control and Registration Sections which may give their inputs regarding non compliance / violations of Drug Act, 1976 and Rules framed there under and may accordingly be treated under the ambit of Drug Act, 1976 and Rules framed there under.

Summary of the report of licensed unit of M/s The Searle Company situated at Plot No.F-319, SITE, Karachi DML No.000016 (Formulation).

The panel as above inspected the license premises and observed that the firm is engaged in the manufacturing of registered pharmaceutical products and the firm is still using packaging / labeling components with old company name in few products as was witness during the

inspection. It is worth to mention that the name of the company has been changed with effect from 29&30-07-2013

The panel advised the firm to voluntarily stop the packaging material bearing the name of previous company and such finished products shall be hold for not to be sold till the approval of CLB for utilization of the balance / remaining packaging inventories with old company name. The Management assured the panel that they will get the approval from the Competent Authority to utilize their remaining inventories of few packaging components. Under Schedule B(II) 6.3.4 states that out dated or obsolete primary packaging material or printed packaging material shall be destroyed and its disposal be recorded. M/s Spencer Pharma Karachi was also not permitted to use their old printed packaging material after the change of the name as Rules are very clear to deal with such matters. The firm has violated the said provision of the Rules and a show cause notice / warning as the Central Licensing Board deem appropriate may be issued and the hold stock using old printed packaging material may be destroyed.

Decision of CLB

The Board in the light of panel inspection report of M/s. Searle Company, Plot No.15/1, Sector-15, Korangi Industrial Area, Karachi decided to refer the case for further necessary action to Division of Health and OTC Products (non-drugs) which deals the matters of Probiotics as the said firm is involved in the manufacturing of probiotics.

Whereas, the Board in the light of panel inspection report of M/s. Searle Company, Plot No.F-319, SITE, Karachi (DML No.000016-Formulation) decided to destroy the available packaging /labeling components bearing old company name (The Searle Pakistan Ltd.,) under Schedule-B(II)6.3.4 in the presence of panel. A show cause notice and personal hearing on violation of conditions of Drug Manufacturing License shall be issued to the firm and case shall be presented before CLB in its next meeting.

Case No.12 M/s Brand Pharma International, Karachi. DML No. 000684 (Formulation) - (Case of Non-Compliance of Conditions of DML/cGMP)

The case of M/s Brand Parma International, Karachi was discussed in 232nd meeting of CLB and following decisions were taken.

i). **The Board unanimously decided to suspend the DML No. 000684(Formulation) of the firm for a period of six months**, as the firm had contravened the conditions of DML No. 000684 (Formulation) and due to non-compliance of cGMP under Schedule B of Drugs (L, R & A) Rules 1976 and failed to appear before the Board in spite of five show cause notices / opportunities of personal hearing given to the firm.

ii). The Board further decided to get explanation from the panel for not submitting inspection report in the matter as directed by the Board vide DRAP letter dated 20-05-2013. It was further decided to get the facility inspected by some other panel for facts finding and present the report in the next meeting of the Board.

2. In compliance of the decision of the Board the panel comprising of Dr. Saifu-ur-Rehman Khatak Director, CDL, Karachi. Dr. Najm-us-Saqib Area FID, DRAP, Karachi and Mrs. Ume-e-Lela Area ADC, DRAP, Karachi reiterated their stance and forwarded the report dated 05-11-2013 in response to DRAP's letter dated 02-09-2013 the conclusion of which is reproduced as under:

"based on observations made during the visit, it is evident that the firm is closed for any production and QC activity at present".

3. Further, a legal notice from Mr. Javed Ahmad Chhatari, (claiming to be the Advocate Supreme Court of Pakistan) is received, wherein he has intimated that M/s Brand Pharma International, Karachi bearing DML No. 000684 (Formulation) has been sold by Mr. Muhammad Anees and all rights of proprietor ship has been sold out to Mr. Rizwan Umer Shaikh S/o Manzoor Elahi Shaikh. He has further inform that from now onward you are requested to address your correspondence to new proprietor i.e. Mr. Rizwan Umer Shaikh S/o Manzoor Elahi Shaikh. The request of change of management cannot be acceded to on following grounds.

i) The license is non transferable, non heritable and it is a permissive right issued to the original owners, Directors, Partners etc.
ii) The firm was initially established between two partners and the licensing Directorate neither received any request/statement regarding sale of their factory.

- The Drug manufacturing License is the property of Government of Pakistan (DRAP) and same should be surrendered by the selling party if so.
- In case the DRAP receives the agreement of sale purchase deed accompanied by all documents, dissolution / resolution of partners and surrendering of original license bearing No.000684 to DRAP Authorities, the case for fresh grant may be considered.

4. On the basis of above said ground the request of change of management cannot be acceded to.

Decision of CLB

The Board keeping in view the facts of the case, unanimously decided to extend suspension of DML for further period of six months and decided that the license is non transferable, non heritable, assignable and it is a permissive right issued to the original Owners, Directors, Partners etc.

The Board further decided that in case the DRAP receives agreement of sale/purchase deed executed before the legal forum (Court of Law, Registrar of Firms & SECP) accompanied by all legal documents, dissolution / resolution of partners and surrendering of original DML bearing No.000684 to DRAP Authorities, the case for fresh grant may be considered.

Case No.13 M/s Syntex Pharmaceuticals, Kamra Road, Attock City, DML No. 000290 (Formulation)

Background

The Central Licensing Board in its 232nd meeting was apprised that the Federal Inspector of Drugs along with Mr. Ahmad Mahmood Mumtaz, DDG (E&M) Islamabad visited M/s Syntex Pharmaceuticals, Kamra Road, Attock City, DML (No. 000290) Formulation on 30-05-2013 to check and verify the compliance of firm towards GMP and reported that the firm was found closed for the time being and that the Management had informed further that they intend to open the factory premises within a month. Thereby the firm had violated the condition of Drug Manufacturing License under Drugs (Licensing, Registering & Advertising) Rules, 1976 and taking into consideration the legal provisions as laid down under Section 41 of the Drugs Act, 1976 and the rules framed there under decided as follows: -

a. To issue a show cause notice to the firm as why the firm had been closed without prior permission from or information to the Competent Authority and provide the firm an opportunity of personal hearing in the upcoming meeting of the Board.

b. To get the unit inspected by a larger panel of experts to verify compliance of the firm towards the conditions of DML and cGMP as required under the Drugs (Licensing, Registering & Advertising) Rules, 1976 as reportedly by the FID, the facility had been closed by the management at their own. The inspection report by panel shall be placed before the Board in its next meeting for consideration / decision.

c. The Board also desired to direct the FIDs / Field Officers to inspect such premises in their respective area of jurisdiction for which he/she may take assistance of the law enforcing agencies and that no stone should be left unturned to inspect such units promptly even by follow up visits.

4. Now the management of M/s Syntex Pharma, Attock informs that their CEO has been arrested in case of Ephedrine Quota. In absence of CEO how can firm improve further. However they have trying to improve their facility to comply with GMP as has been identified by Federal Inspector of Drugs.

Decision of CLB

Board deferred the case and decided to get a final report from area FID about the present status of the firm.

Case No.14 M/s Everest Pharmaceuticals, Islamabad, DML No. 000535 (Formulation).

Brief Background

The Central Licensing Board in its 232nd meeting and taking into consideration the legal provisions as laid down under Section 41 of the Drugs Act, 1976 and the rules framed there under was apprised that the Federal Inspector of Drugs, Islamabad-I had informed that he visited M/s Everest Pharmaceuticals (Pvt) Ltd, Plot No.124, Industrial Triangle Kahuta Road, Islamabad on 18-06-2013 for the purpose of GMP inspection. The firm was found closed and that the security supervisor present at the gate informed him that the owner of the property has got the possession of the building through learned Court Order. Thereby the firm had violated the condition of DML.

2 The Central Licensing Board in its 232nd meeting and taking into consideration the legal provisions as laid down under Section 41 of the Drugs Act, 1976 and the rules framed there under decided as follows

a. To issue a show cause notice to the firm as why the firm had been closed without prior permission from or information to the Competent Authority and provide the firm an opportunity of personal hearing in the upcoming meeting of the Board.

b. To get the unit inspected by a larger panel of experts to verify compliance of the firm towards the conditions of DML and cGMP as required under the Drugs (L, R & A) Rules, 1976 as reportedly by the FID, the possession of the building / Licensed Premises has been taken up by Owner of Property through some Court Order. The inspection report by panel shall be placed before the Board in its next meeting for consideration / decision.

c. The Board also desired to direct the FIDs / Field Officers to inspect such premises in their respective area of jurisdiction for which he/she may take assistance of the law enforcing agencies and that no stone should be left unturned to inspect such units promptly even by follow up visits.

3 The firm has now filed an Appeal before Civil Court Lahore, which is lying pending before the Court and Federal Government has directed to plead the case and nominated the defense counsel as well and case is subjudice as para wise comments have been submitted before the Court.

Decision of CLB

Since the case is subjudice before the Honorable Civil Court, Lahore, hence the Board did not take any decision.

Case No.15 Policy Regarding Establishment of Pharmaceutical Units Located in Residential Areas.

Brief Back Ground

The Central Licensing Board in its 228th meeting had decided to issue show cause notices to the firms located in the residential area with the directions to shift their units to the industrial areas. Accordingly as per directions of the Board show cause notices were served to the M/s Bliss Industries Ltd, Karachi, M/s Cresent Cotton, Okara, M/s Soma Laboratories, Lahore and M/s Shamsi Pharmacy, Lahore and opportunities of personal hearing had also been given to the firms. The firms' replies to the show cause notices were discussed in the previous meetings of the Board. The cases were again discussed in 232ndmeeting held on 29th& 30th July 2013 of CLB too in view of decisions taken in 231st meeting of CLB held on 31-01-2013.

The cases of the individual firms in detail and the decision of the Board taken thereof in 232nd meeting are as under: -

S.#	Name of Company / Case background	Decision of CLB
1.	**M/s Bliss Industries Ltd, 225/2, J.M. Sadhu Naval Rai Road, Karachi.** In response to show cause notice bearing No. F. 2-15/95-Lic (Vol-I) dated July 2012. M/s Bliss	The Board in its 232nd meeting discussed the case in the light of decision taken in 231st meeting of the Board in detail. Syed Jawed

	Pharmaceuticals had informed that they had started construction of their facility at new site in Korangi as per approved layout plan. But because of law and order situation in Korangi Karachi they could not completed their construction timely. In compliance to the decision of CLB taken in its 231st meeting a panel comprising Syed Jawed Yousaf Bukhari, Member CLB, Area FID and Area ADC was constituted to conduct the inspection of the firm. Due to delay, a reminder was also issued for timely conduction of inspection of the firm to verify progress made by the firm at the new site so far. In compliance to the decision of CLB taken in its 231st meeting show cause notice/letter for personal hearing dated 25thJuly 2013, was issued and the firm's representative was called before the Board. None of the accused/ representative of the firm appeared before the Board for personal hearing.	Yousaf Bukhari member CLB furnished a panel report which was asked to inspect the new site of the firm in Korangi Industrial area. The Board was apprised by him that Panel tried to contact Mr. Ashraf, representative / spokesman of the firm so that the new site may be inspected to check the progress but the management was not serious and that he did not coordinate and respond for the needful. It was also disclosed by the worthy member that the panel also tried to trace out the location of the new site in Korangi Industrial area, but failed to find out the same. The Board in the light of above said report of the panel and decision taken in 231st meeting of the CLB decided that **(i) To defer the case of firm located in the congested residential area of Karachi.** (ii) **One more but the last opportunity of personal hearing be given to the owner / management of the firm.** (iii) Failing to appear before the CLB, the license of the firm shall be suspended/ cancelled and case shall be forwarded to Registration Board for cancellation / suspension of products registered in the name of firm. IV) Accordingly firm is called for personal hearing before cancelling/suspending DML. **Decision of CLB.** **Mr. Raja Awais Mehmood Janjua Advocate with power of attorney given by M/s Bliss Industries, Karachi appeared and pleaded the case before the Board.** **The Board after hearing the case**

		at length and considering the facts on record decided to suspend the DML of M/s Bliss Industries Ltd, 225/2, J.M. Sadhu Naval Rai Road, Karachi till the firm shifts its premises to an industrial area. The Board further decided to direct the firm to strictly adhere to the provisions of Schedule-B of Drugs (LR&A) Rules, 1976.
2.	**M/s Cresent Cotton, Chowk Depalpur, Okara.** A show cause notice was issued to M/s Cresent Cotton, Okara regarding their unit located in residential area. In response to Show Cause notice the firm has informed that it is located in commercial / industrial area instead of residential area and got NOC from TMA, Okara. 2. The Board in its 230th meeting decided to direct the area FID to inspect the premises again and take the necessary documents as the firm is claiming for verification. The Board also directed to advise the area FID to take and verify the NOC obtained from TMA, Okara and approval from concerned provincial Building Control Authorities (BCA). 3. Subsequently the Area FID reported that the facility is located on Main Adda Road. In front of the factory there is a shop of Fazal Broast, TV repairing shop, a clinic, on left there are furniture making shops, Qamar Cotton Industries is also on same road, and beside the industry one house has been built above the shops. The firm has also produced an attested copy (verified) of a letter of Tehseel Officer TMA Okara certifying that Cresent Cotton Industry situated at Chowk Depalpur Road is a commercial / industrial area. 1. The FID in her report concluded that the firm is located in commercial area. 2. Tehseel Officer (P&C), TMA Okara was also requested vide letter No. F. 1-7/84-Lic (Vol-I) dated 20-05-2013 for verification of a separate Industrial Area in Tehseel Okara but the reply is still awaited. The Board was apprised about the provisions of Schedule "B" of Drugs (Licensing, Registering &	The Board after thorough discussion / deliberation, considering the report of the FID and keeping in view the legal provisions decided as under: - i). The case should be processed and actions shall be taken as per provisions of Schedule B of Drug (L, R & A) Rules 1976. ii). Management of the firm be asked to shift to some Industrial area as there is no provision of Law &Rules that allows Pharma unit in industrial/ commercial area, as per current status of the firm. iii). Renewal of DML of the firm will be decided in the light of commitment of firm for shifting of their unit to some industrial area as per requirement of Law & Rules. The firm was issued DML in 1978, now, the TMA Okara as requested vide letter No. F. 1-7/84-Lic (Vol-I) dated 20-05-2013 for verification of a separate Industrial Area in Tehseel Okara. The TMA, Okara has provided a letter issued by office of TMA, Okara in which the TMA, Okara has informed that the firm is located in commercial/ industrial area as there is no declared industrial in Okara.

	Advertising) Rules, 1976. The case was placed before the Board for its consideration/ decision, keeping in view various industrial incidents/disasters which coasted loss of precious human lives as in case of unfortunate incident of M/s Orient Labs, Lahore.	**<u>Decision.</u>** **The Board decided to get verified the above letter issued by Tehsil Officer, TMA Okara through area Federal Inspector of Drugs. The report shall be submitted before the Board for consideration in its next meeting.**
3.	**M/s Soma Laboratories 692-N, Samanabad, Lahore.** A show cause notice was issued to M/s Soma Laboratories, Lahore regarding their unit located in residential area. In response to Show Cause Notice the firm stated that they are not contravening the section 41 of Drugs Act, 1976 because they got license in 1981 while the rules for condition of location of manufacturing was added in the year 1998. The firm was called for personal hearing in 230th meeting of CLB but they did not appear before the Central Licensing Board. The Board took serious notice regarding manufacturing of drugs in residential area and decided to defer the case till next meeting and one more opportunity for personal hearing was granted. Mr. Mian Ghulam Jelani appeared for personal hearing meeting of the Central Licensing Board in its 231st held on 30-01-2013 and committed that they will shift their unit within one year and has voluntarily stopped the production. The Board decided to suspend the production for a period of three months and verification from Area FID was also advised**.** The area FID has submitted report dated 03-06-2013 stating that the firm was closed and no production activities was observed. The case was placed before the Board for its consideration/ decision, keeping in view various industrial incidents / disasters which coasted loss of precious human lives as in case of unfortunate incident of M/s Orient Labs, Lahore.	The Board after thorough discussion / deliberations, taking into account commitment of the firm before the CLB in its previous meeting and keeping in view the legal provisions decided as under: - **<u>(i). Suspension of DML of the firm with immediate effect for a period of six months</u>** so as to avoid any industrial incident / disaster which may cost loss of precious human lives as occurred in case of M/s Orient Labs Lahore as the firm is located in congested residential area of Samanabad Lahore. The area FID should ensure the closure of unit / stoppage of production and report in this regard be submitted to CLB on monthly basis without fail. ii).The Drug Registration Board is informed about the suspension of DML of the firm for further necessary action. iii). The management be directed to shift their unit in industrial area and to furnish the progress report regarding the shifting of unit as per their commitment made before the CLB in its 231st meeting held on 30-01-2013. iv). Area FID be directed to inspect the new site and submit its progress report. The report of Area FID is awaited.

		Decision of CLB. The Board after considering the facts on record decided as under: - • **The CLB upheld its previous decision of 232nd meeting and extended the Suspension of DML of the firm for further period of six months.** • **Area FID be directed to inspect the new site and submit its progress report which is long awaited.** • **The Board further directed to issue a letter to Area FID and Provincial Govts to verify the availability of stocks of drugs manufactured by firm in market and furnish report.** • **The case is deferred till next meeting of the Board.**
4.	**M/s Shamsi Pharmacy, Samanabad, Lahore.** A show cause notice was issued to M/s Shamsi Pharmacy, Lahore regarding their unit located in residential area. In response to show cause notice the firm has replied that they are not working in old unit since 2010. Area FID as reported that the firm has suspended its production and it is not operational. They also want to postpone the matter because of their father death and some family issues. 2 The firm was called for personal hearing in 230th meeting of CLB but they did not appear before the Central Licensing Board. The Board took serious notice regarding manufacturing of drugs in residential area and decided to defer the case till next meeting and one more opportunity for personal hearing was granted. 3. Mr. Faisal Maqbool the Son of deceased owner appeared before the Board in 231st meeting of CLB who committed that they are ready for inspection at new place. The Board in 231st meeting decided to get the inspection of the premises where firm intends to shift their unit and decided to suspend the production at the congested area of Samanabad. Lahore. The board further decided to get an inspection conducted by Area FID so as to verify the production activity at existing site. 4. The Area FID in response to DRAP letter	The Board after thorough discussion / deliberation, considering the report of the FID, taking into account commitment of the firm before the CLB in its previous meeting and keeping in view the legal provisions decided as under: - **(i). Suspension of DML of the firm with immediate effect for a period of six months** so as to avoid any Industrial incident / disaster which may cost loss of precious human lives as occurred in case of M/s Orient Labs Lahore as the firm is located in congested residential area of Samanabad Lahore. ii). The Drug Registration Board be informed about the suspension of DML of the firm for further necessary action. iii). The management be directed to shift their unit in industrial area and to furnish the progress report regarding the shifting of unit as per their commitment made before the CLB in its 231st meeting held on

	dated 17-05-2013 has reported that she has inspected the facility to check the production status of the firm 20-06-2013 in the presence of Mr. Faisal Maqbool Son of deceased owner of the firm. It has been further reported that no production activity was going on at the time of inspection. However, finished goods were stored in large quantities in two rooms without any temperature control. Bundles of fresh units cottons of different products were also store bearing manufacturing date 2009 & 2010 etc. The FID also took samples of two products i.e. Mag. Sulphate B.P. Batch No. 43 Manufacturing date 06-2011 and Kaolin Light Batch No. 30 Mfg. date 06-2010 for test / analysis purpose. The FID has also stated that as per availability of sample of Mag. Sulphate bearing Manufacturing date 06-2011 and expiry date use within 04 years clearly show that the firm has manufacturing the products after 2010 which is contrary to the reply of firm about the closure of the unit since 2010. FID has also mentioned that the products of M/s Shamsi Pharmacy are also available in the Market bearing manufacturing dates 2009, 2010 and 2011 etc.	30-01-2013. iv). Area FID be asked about the action taken on availability of products manufactured in the period of closure of firm available in the market. The report of FID is awaited. **Decision of CLB.** • **The CLB upheld its previous decision of 232nd meeting and extended the Suspension of DML of the firm for further period of six months.** • **The Area FID be directed to inspect the new site and submit its progress report.** • **The Board directed to issue a letter to Area FID and Provincial Govts to verify the availability of stocks of drugs manufactured by firm in market and furnish report.** • **The case is deferred till next meeting of the Board.**

Case No.16 Renewal of DML of M/s Rex Pharmaceutical Pakistan, Karachi. (DML No. 000536) by way of Formulation.

M/s Rex Pharmaceuticals Pakistan Ltd, Karachi had requested for renewal of their DML on 28th March, 2009 for the period from 01-04-2009 to 31-03-2014.

Accordingly a panel comprising of following members was constituted on 23rd May, 2009: -

1. Mr. M. Moti-ur-Rab, Member, CLB, Karachi.
2. Area, FID, DCA, Karachi.
3. Dr. Obaid Ali, Federal Government Analyst, CDL, Karachi.

Area FID on 27th July, 2009 informed that he has visited the firm and found closed and locked. FID directed the Director of firm for contact and coordination so that renewal inspection may be carried out.

A show cause notice was served to firm on 24th October, 2009 in response of above said letter of FID. A personal hearing was served to firm on 2nd November, 2009 to appear before CLB on 5th November, 2009.

The case was discussed in 219th meeting of the Board. It was decided to issue show cause notice to the firm with the directions to appear before the Board in next meeting. Accordingly a show cause notice was issued and management of the firm was asked to appear before the Board in 220th meeting but the management failed to appear before the Board.

The Board discussed the case in detail and decided to suspend the manufacturing license of the firm for a period of three months.

Accordingly, DML was suspended on 19th December, 2009 for three months.

CLB in its 221st meeting held on 30th December, 2009 further extended the suspension period for three months; the same was informed to the firm on 18th February, 2010.

Background of the Case from QA Section

M/s Rex Pharmaceuticals Pakistan Ltd, Karachi was inspected on 06.03.2013 by Mr. Abdul Rasool Shaikh, FID Karachi with reference to see/verify the GMP compliance. During the inspection the FID pointed out number of serious shortcomings and gross violations in all sections. The FID reported that GMP situation was so critical and the firm cannot be allowed to manufacture life saving drugs under very un-hygienic conditions, without proper quality control department including microbiological lab and lack of necessary technical and quality staff. The FID directed the firm to suspend all kind of production activities initially for 15 days due to severe non-GMP compliance.

Action Taken by DRAP:- Accordingly, a show cause notice was issued to the firm on 23.04.2013 along with the direction to stop production in all sections with immediate effect.
Reply of the firm:- In response of the show cause notice, the firm had submitted that they have worked out on areas of development in compliance to GMP guidelines as advised by the FID in previous inspection and also requested to withdraw the show cause and allow them to continue their production activities. On the request of firm, the Vice Chairman, CLB had constituted following panel to re-inspect the firm for verifying the improvement made by the firm and also to see GMP compliance along with recommendation whether the renewal of DML may be granted or not:

i) Dr. Muhammad Tanweer Alam, DDG (E&M) Karachi
ii) Mr. Qaiser Muhammad, Director DTL, Sindh.
iii) Mr. Saleem Isharat, Chief Drug Inspector, Sindh
iv) Mr. Abdul Rasool Shaikh, Area FID Karachi.

The case was placed before the Central Licensing Board in its 232nd meeting where the firm was also provided personal hearing. After considering all the aspects of the case, *the Board had made following decision which was also conveyed to the firm accordingly:-*

i) The Board decided that the production will remain stopped till the final approval for resumption of production by the Central Licensing Board.

ii) The case was deferred by Central Licensing Board till its next meeting as per request of the firm and also to fulfill legal requirement w.r.t show cause notice and personal hearing.

Present Position: Later on, a aforesaid panel inspection report has been received which was conducted on 04.07.2013 wherein the panel observed major GMP violations and reported that the firm is not in a position to recommended the renewal of DML. The panel further recommended that the firm may be given more time to rectify all the major shortcomings for better compliance till that their production activities may be halted in larger public interest**.**

Decision of CLB

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

======== End ========

B. QUALITY CONTROL

ITEM I: CONFIRMATION OF THE MINUTES OF 232nd MEETING.

The Board confirmed the Minutes without any change.

ITEM II: CASES DEFERRED IN 232nd MEETING

S No	Title of Firm/ Medical Store & Accused Name	Offence	Brief
1	(i) M/s Surat Khan Medical Store, Brewery Road, Opp B.M.C Complex, Quetta (ii) Surat Khan, Proprietor of M/s Surat Khan Medical Store, Brewery Road, Opp B.M.C Complex, Quetta. (iii) Muhammad Aslam Shah, Qualified Person of M/s Surat Khan Medical Store, Brewery Road, Opp B.M.C Complex, Quetta. (iv) Snaullah, (person present at the time of visit at M/s Surat Khan Medical Store,) (v) M/s Medicine Point, Jinnah Road, Quetta (vi) Arshad Mehmood S/O Sultan Mehmood of M/s Medicine Point, Jinnah Road, Quetta. (vii) Mehmood Hassan. Qualified Person of M/s Medicine Point, Jinnah Road, Quetta. (F. No. 3-37/2010-DDC (QC-I)	Manufacture / Sale of Spurious, Drugs Section 23(1)(a)(i), 23(1)(a)(x), 23(1)(c) of Drug Act, 1976,	i. The Board was apprised facts of the case as under:- • Samples of Amoxi-Clave, Batch No AE5475, claimed to be manufactured by M/s Sandoz GmbH Austria, (marketed by Sandoz Division, Novartis Pharma Karachi), drawn from M/s Surat Khan Medical Store, Brewery Road, Quetta, by FID Quetta, on 18-06-2010 were declared **Spurious** by F.G Analyst vide Test Report No.R-646/2010, dated 08-07-2010. M/s Surat Khan Medical Store, could not provide the valid warranties/ bill in respect of the drug • FIR No. 14/2010 dated 06-07-2010 was lodged against accused persons with FIA, Crime Circle, Quetta, with the permission of Chairman Central Licensing Board. The FIA in its Challan has nominated Surat Khan, Muhammad Aslam Shah, Snaullah, Arshad Mehmood as accused in its Challan. The FID later also included name of Mehmood Hassan (Qualified person of Medicine Point) in list of accused and requested permission for lodging prosecution against all the accused. • Show cause notices were issued to accused on 09-05-2013 and they were called for personal hearing before the Board on 29-07-2013 (232nd meeting) but none of the accused appeared before the Board. However, a person namely Asadullah, claimed to be brother of one of the accused Snaullah, appeared before the Board and informed that the Surat Khan Medical Store has already furnished warranty of the Medicine Point in respect of the drug in question to FID Quetta. He further stated that the accused Snaullah could not come for personal hearing because of the hearing of the case in Drug Court on 30th July, 2013. Since Asadullah failed to produce any document / identity in support of his claimed of being representative of the accused Snaullah, so the Board was doubtful about authenticity of his statement and therefore decided to give final opportunity of

			personal hearing to the accused in its next meeting and accordingly defer the case. ii. The accused were again called for personal hearing in the current meeting but no one appeared on behalf of any of the accused nor any intimation was received with regards to their stance. **Decision:** iii. The Board after thorough consideration of the available record/ facts of the case, including the Challan furnished by FIA, decided to allow FID Quetta to prosecute all the accused of the firm viz M/s Surat Khan Medical Store, Brewery Road, Opp B.M.C Complex, Quetta, Surat Khan, Proprietor of M/s Surat Khan Medical Store, Muhammad Aslam Shah, Qualified Person of M/s Surat Khan Medical Store, Snaullah, (person present at the time of visit at M/s Surat Khan Medical Store, M/s Medicine Point, Jinnah Road, Quetta, Arshad Mehmood S/O Sultan Mehmood of M/s Medicine Point, Jinnah Road, Quetta. Mehmood Hassan. Qualified Person of M/s Medicine Point, Jinnah Road, Quetta in Drug Court Quetta for violation of Section 23(1)(a)(i), 23(1)(a)(x), 23(1)(c) of Drug Act, 1976.

Case No. 2 **Manufacturing of Drugs without valid Drug Manufacturing License by M/s Alfalah Pharma (Pvt) Ltd, Sheikhupura Road, Lahore. (F. No. 3-03/2012-QC)**

During proceedings of the case, the Board was informed about background of the case as under:-

i. In January, 2012, when the initial reports of deaths / serious reactions in patients taking medicine from Punjab Institute of Cardiology (PIC), Lahore were received, the FID Lahore drew samples of Alfagrel Tablets 75mg, Batch No.034, from premises of M/s Alfalah Pharmaceuticals Ltd., Lahore on 13-01-2012, for being one of the suspected drug and also an FIR was lodged against the firm on 23rd January, 2011 with allegations that the firm had purchased raw material from open market in violation of Drug (Import & Export) Rules 1976.

ii. Later the FID sealed the firm on 25-01-2012 on finding that it was operating without valid Drug Manufacturing License at that time. The aforementioned sample of Alfagrel Tablets was also declared substandard by Federal Government Analyst, Central Drug Laboratory Karachi, on the basis of description. The firm, in response to FID's letter, calling for explanation, requested Appellate Testing of the sample under Section 22(4) of Drugs Act, 1976. However, since at that time the subject of "Drugs and Medicine" was devolved to the provinces under 18th Constitutional Amendment so, the FID handed over the case along with case property to the Provincial Health Authorities, Punjab. The Provincial Quality Control Board, Punjab later referred back the case to FID, Lahore, pointing out various lacunas and the fact that DRAP had become functional and therefore competent to consider the matter. The FID Lahore, while reporting the aforementioned case also forwarded an incomplete Challan (No 07/2012), furnished by FIA, wherein it is stated that the investigation is yet to be completed.

iii. Though, subsequently, it was learned that the drug Alfagrel Tablet of M/s Alfalah Pharma Lahore, may not be associated with the death incidences relating to PIC, however, from perusal of record, it appears that the firm have indulged in illegal manufacturing of substandard drugs without valid Drug Manufacturing License. The Board was further informed that subsequently the Drug Manufacturing License of was re-granted in 230th meeting of CLB held on 31-08-2012.

iv. The Central Licensing Board in its 231st meeting held on 30-01-2013, while considering the case, inter alia, decided to issue Show Cause notice to the firm. Accordingly show cause notice dated 19th February 2013, was issued and the firm's representative was called for personal hearing before the Board in its 232nd meeting held on 29-07-2013. Since non of the accused/ representative of the firm appeared before the Board in the aforesaid meeting so the Board defered the case till next meeting in order to provide final opportunity of personal hearing to the accused / firm.

2. Mr. Faisal Riaz, claimed to be nephew of the owner Mr. Muhammad Waseem Chaudhry, submitted a written reply to the Board on behalf of the later wherein he has shown his inability to appear before the Board for being out of country (in Canada). Mr. Muhammad Waseem Chaudhry in his written statement stated that the production in their previously / presently licensed premises was done mistakenly which may kindly be regularized since the Drug Manufacturing license was re-granted to M/s Alfalah Pharma.

3. The Board thoroughly scrutinized and discussed record of the case and noted following facts:-

i. The Provincial Quality Control Punjab while referring black the case to DRAP vide its order dated 26-05-2012, inter alia, pointed out following legal flaws and lacunas in the case:

a) Registration of FIR was granted without permission from the concerned Board.
b) Non-availability of complaint (Istagasa) written to the in-charge of the Police Station by FID.
c) Incomplete challan submitted by the investigating officer of FIA.
d) Complete challan has yet to be submitted.

The Board was apprised that at the time of occurrence of the incidence the subject of "Drugs and Medicine" was devolved to provinces under 18th Constitutional Amendment so the then Drug Control Administration was not in a position to take any legal action as the relevant Boards i.e Central Licensing Board and Drug Registration Board were non functional / non existent. Since the required permission of the Board for lodging FIR could not be granted at that time for the obvious reason so the FID was asked to hand over the case along with case property to the Provincial Health Authorities, Punjab. The Board was further informed that the FIA authorities and FID Lahore, during the same period, also made the request for ex post facto approval of the FIR which also could not be processed for the reason mentioned above.

ii. The Challan furnished by the FIA is in-complete which clearly state that the investigation yet to be completed. The Challan mentioned a statement of Mr. Muhammad Waseem Chaudhry, Director of Alfalah Pharma according to which the Production and Quality Control Managers are responsible for the substandard manufacturing but the name of these persons were not mentioned as accused being challaned (column-3 of the Challan) for the reason that the investigation in not yet complete.

iii. It was also noted that the concerned Federal inspector of Drugs forwarded the case alongwith Challan without specifying the nature of contravention, provision of the law being violated, name of accused / responsible persons, conclusion and recommendations.

Decision:-

The Board in view of the available record and facts of the case decided as under:-

i. The FID concerned may be advised to furnish a comprehensive case by clearly specifying the contravention, name of accused / responsible person, conclusion and recommendations at the earliest.
ii. The concerned FID may also pursue the matter with FIA authorities for getting complete Challan at the earliest.
iii. Advise from Law & Justice Division may be sought on the issue of ex post facto approval of the Central Licensing Board for the FIR lodged in this case.

Case No.3 REFERENCE FROM PROVINCIAL QUALITY CONTROL BOARD SINDH FOR CANCELLATION / SUSPENSION OF LICENSE OF FIRMS FOR BEING CONVICTED BY DRUG COURTS UNDER DRUGS ACT, 1976

Giving background of the case the Board was apprised that the Sindh High Court on 14-10-2010, while hearing in Cr. Revision Applications No. 103/2010 to 107/2010 filed by Sindh Government, directed the respondents that, for persons convicted under Drugs Act, 1976, provision of law and rules framed their under, which requires cancellation and or suspension of licenses, be to complied with. The Secretary, Provincial Quality Control Board (PQCB), Sindh forwarded the cases of conviction of M/s Standard Drug Company, M/s Z-Jans and M/s Kamtax by Drug Court Sindh for compliance of the aforementioned High Court's orders. The matter was placed before the Central Licensing Board in its 232nd meeting held on 29-07-2013, where, the then Chief Drug Inspector, Sindh Mr. Saleem Isharat, who was also the member of the Central Licensing Board, apprised the Board that in cases where Drug Courts have awarded lighter sentences to the accused, the PQCB, Sindh, on directions of Supreme Court, approached the Sindh High Court, for enhancing these sentences. The case is at present pending with Sindh High Court, and the Court, in its hearing dated 14-10-2010, gave the directions for cancellation / suspension of licenses of convicts. Since the complete detail of cases, including back ground of the cases, test reports and other relevant documents, required for consideration of the matter and taking decision there off, have not provided by the PQCB, Sindh, so the Board deferred the case with directions to obtain complete details of all such cases from the PQCB, Sindh for consideration of Central Licensing Board in the next meeting.

2. The Board was further informed that subsequently the case (Cr. Revision Applications No. 103/2010 to 107/2010) was again fixed on 15-08-2013 in the Sindh High Court and the Court was informed of the above position with clarification that the requisite information has already been called from the PQCB Sindh, which on receipt, will be placed before the Central Licensing Board for its consideration in accordance with Rule 12 of The Drugs (Licensing, Registering and Advertising) Rules,1976, which require that the Board conduct an inquiry in to the case and provide an opportunity to the Licensee, for being heard, before cancelling or suspending License.

3. Briefing about current status of the case, the Board was informed that the PQCB, Sindh was accordingly requested number of time for providing requisite information, however, complete details were not provided so far. Recently the DDG (E&M) Karachi was asked coordinate with the concerned provincial authorities for obtaining the desired information. The DDG (E&M) Karachi in response obtained details of only one case of M/s Z Jans

Pharmaceuticals, while, for other cases, he was asked by the Secretary Provincial Quality Control Board to get the details of the cases from Drug Court Karachi.

4. On the basis of the record provided by the PQCB so far, brief description of the cases alongwith sentences awarded are given below.

A. **M/s Standard Drug Co., Hyderabad**

S. No	Case No / Product Name	Brief Description	Sentence Awarded
1.	Case No. 61/2011, Counterfeit and Misbranded Drug Linobex-C Syrup, Batch No. LC-062	Sample drawn by Drug Inspector District Dadu from Imran Medical Store, Mehar. The Government Analyst declared the drug counterfeit and misbranded as colour scheme and presentation of outer packing resembles Lederplex Liquid of M/s Wyeth Karachi. Complaint launched for violation of Section 23(1)(a)(ii), 23(1)(a)(iii), 23(1)(a)(x) in Drug Court Sindh on 19-11-2011. The accused pleaded guilty.	Sentence till rising of the Court to Imtiaz Ahmed, Managing partner, Haider Zaidi, Production Incharge, and Miss Sabeen Usman, QC in-charge. Fine of Rs 30,000 to Imtiaz Ahmed and Haider Zaidi and Rs 25,000 to Sabeen Usman. An other accused Mukhtiar Ahmed is absconding
2.	Case No.62/2011 Counterfeit Drug Linobex-C Syrup, Batch No. LC-022 (Resemblance with Lederplex liquid)	Sample drawn by Drug Inspector District Dadu from Hunanin Medical Store, District Dadu. The Government Analyst intimated his inability to carry out test / analysis. The labeling of drug resemble to that of Lederplex Liquid of M/s Wyeth Labs. Complaint launched for violation of Section 23(1)(a)(ii), and 23(1)(a)(x) in Drug Court Sindh on 26-11-2011. The accused pleaded guilty.	Sentence till rising of the Court to Imtiaz Ahmed, Managing partner and Miss Sabeen Usman, QC in-charge. Fine of Rs 30,000 to Imtiaz Ahmed and Rs 25,000 to Sabeen Usman. Other accused Shakeel Ahmed Baloch and Mukhtiar Ahmed are absconding
3.	Case No. 41/2007, Sub-standard Glycodyl Exp Cough Syrup Batch No. GL-033	Sample drawn by Drug Inspector District Thatta from .D.O Health, Thatta on 24-03-2004.The Government Analyst declared the drug sub-standard. After completing	Sentence till rising of the Court to Abdul Ghaffar, Managing Director, and Miss Sabeen Usman, QC in-charge. Fine of Rs 25,000 to

		the legal formalities complaint launched for violation of Section 23(1)(a)(v), 23(1)(a)(x), in Drug Court Sindh on 14-04-2007. The accused pleaded guilty.	Abdul Ghaffar and Sabeen Usman. An other accused Ghulam Murtaza Sheikh is absconding
4.	Case No. 55/2011 Counterfeit Drug Lenobex-C Syrup, Batch No. LC-065 (Resemblance with lederplex liquid)	Sample drawn by Drug Inspector District Umer Kot from E.D.O, Health. The Government Analyst declared the drug counterfeit as colour scheme and presentation of outer packing resembles Lederplex Liquid of M/s Wyeth Karachi. After completing the legal formalities complaint launched for violation of Section 23(1)(i), 23(1)(a)(ii) and 23 (1)(a)(x), in Drug Court Sindh on 10-08-2011. The accused pleaded guilty.	Sentence till rising of the Court to Imtiaz Ahmed, Managing partner, Haider Zaidi, Production Inchage, Fine of Rs 30,000 to Imtiaz Ahmed and Haider Zaidi Other accused Mukhtiar Ahmed and Najum-us-Sehr are absconding
5.	Case No. 41/2011 Counterfeit Drug Staiflic 5mg Tablet (Folic Acid), Batch No. SF-107	Sample drawn by Divisional Drug Inspector Hyderabad from Standard Drug Company, Hyderabad. The Government Analyst declared the drug counterfeit. After completing the legal formalities complaint launched for violation of Section 23(1)(a)(ii) and 23(1)(a)(x), in Drug Court Sindh on 21-05-2011. The accused pleaded guilty.	Sentence till rising of the Court to Imtiaz Ahmed, Managing partner, Haider Zaidi Production In-charge and Najma Perveen Q.C In-charge Fine of Rs 30,000 to all the above accused.
6.	Case No. 32/2008, Sub-standard Linobex-C Syrup, Batch No. 002	Sample drawn by Drug Inspector District Hyderabad from Naeem Medical Store Hyderabad, on 29-09-2000. The Government Analyst declared the drug sub-standard. After completing the legal formalities complaint launched for violation of Section	Sentence till rising of the Court and fine of Rs 25,000 to Miss Sabeen Usman, QC in-charge. An other accused Anees Ahmed is absconding

		23(1)(a)(v), 23(1)(a)(x) and 23(1)(i), in Drug Court Sindh on 01-03-2008. The accused Sabeen Usman pleaded guilty.	
7.	Case No. 31/2008 sub-standard Glycodyl Expectorent Cough Syrup, Batch No. RF 007	Sample drawn by Drug Inspector, District Hyderabad from Naeem Medical Store Hyderabad, on 29-09-2000. The Government Analyst declared the drug sub-standard. After completing the legal formalities complaint launched for violation of Section 23(1)(a)(v), 23(1)(a)(x) and 23(1)(i), in Drug Court Sindh on 01-03-2008. The accused Sabeen Usman pleaded guilty.	Sentence till rising of the Court and fine of Rs 25,000 to Miss Sabeen Usman, QC in-charge. An other accused Anees Ahmed is absconding

B. **M/s Z-Jans Pharmaceuticals Peshawar**

S.No	Case No / Product Name	Brief Description	Sentence Awarded
	Case No. 14/2012 Substandard Lofsin Tablets Batch No. 435	Sample drawn by Provincial Drug Inspector Naushero Feroz, on 23-09-2009, declared substandard by Provincial Government Analyst. The Inspector, after completing the legal formalities, lodged complaint in Drug Court Sindh for violation of Section 23(1)(a)(v),23(1)(i). on 01-01-2012. The accused pleaded guilty	Sentence the three accused Zahid Khan, Muhammad Rafiq and Ghulam Muhammad, till rising of the Court and fine of Rs 25,000 to each accused

C. **M/s Kamtex Cotton Industries, Kamoke**

Details not provided

5. With regards to issue of provision of the detail record of the substandard cases, the Board observed that the Health Department, Government of Sindh, being custodian of record of these cases is the appropriate forum for providing the record. The Board further requested the chief Drug Inspector Sindh, who was representing Sindh Government in the Central Licensing Board, to facilitate for provision of the details/record of these cases in consultation with DDG(E&M) Karachi.

6. The Board also discussed at length the modalities to be adopted for implementation of the aforementioned decision of Sindh High Court. It was noted that as per procedure outlined in Drugs Act, 1976 and Rule framed there under, the Board has to conduct an inquiry in to the case and provide an opportunity to the Licensee, for being heard, before canceling or suspending License. During deliberation a number of question come under discussion which includes;

i. Will it be legally valid that the Central Licensing Board, with out adopting the procedure outlined in Drugs Act, 1976, cancel/suspend Drug Manufacturing License of the firms by relying upon the inquiry conducted and the procedure adopted by the Provincial Drug Inspectors and Quality Control Board in the substandard cases.

ii. Since proceedings of the cases initiated by the Provincial Inspector have already finalized by the Provincial Health authorities and Drug Court has given verdict in these cases, so if the Board has to follow the procedure outlined in Drug Act, 1976, would it not amount to reopening of cases by initiating fresh inquiry, issuance of fresh show cause notices, if required, and giving opportunity of personal hearing to the firms by the Central Licensing Board etc.

iii. Since the Drug Court has already awarded sentences to the firm/accused after finding them guilty of contravention of Drug Act, 1976, so whether the Board, after considering merit of the case, will be in position to take an independent decision which might not be in consistent with the decisions of Courts.

Decision

The Board after detail deliberation was of the view that a number of legal points need to be clarified before proceeding for implementation of decision of Sindh High Court. The Board, therefore, decided that the case may be referred to the Law & Justice Division for legal opinion on how to implement directions of the Sindh High Court. In the mean time relevant authorities of the Health Department Government of Sindh may be pursue for obtaining the relevant detail/document of these cases.

ITEM III: NEW CASES

S No	Title of Firm/ Medical Store & Accused Name	Offence	Brief
1	i). M/s Shahnawaz General Store, Chand Market, Bazar Shaheedan, Mardan ii) Shahnawaz, Owner M/s Shahnawaz General Store, Chand Market, Bazar Shaheedan, Mardan (F. No. 4-02/2013-QC)	Manufacture / Sale of Spurious, Drugs Section 23 (1)(a)(i) of Drug Act, 1976	i. The Board was apprised detail of the case as under:- • On a complaint from M/s Bio Lab Islamabad, the FID Peshawar alongwith ADC Peshawar and FIA team raided the premises of M/s Shahnawaz General Store, Mardan on 27-02-2013, and seized Lazma Cream, Batch No. 473, purported to be manufactured by M/s Bio Labs, Islamabad, on suspicion for being spurious. • The Federal Government Analyst later declared the Lazma Cream as spurious vide test report No. 373/2013 dated 27-03-2013 and M/s Bio Lab has also disowned the product.

			• FIR No. 08/2013 was lodged against Shahnawaz, the owner of Shahnawaz General Store, with FIA, Crime Circle, Peshawar. The Shahnawaz Medical Store failed to provide any evidence in support of its claim that it is not manufacturing the product. • Complete Challan dated 01-08-2013, furnished by the FIA, has nominated, Shahnawaz, the owner of Shahnawa General Store, as accused in the case. • The FID has requested permission for prosecution of accused in Drug Court Peshawar. • Show cause notice issued to accused and the Medical Store on 02-10-2013 and they are called for personal hearing. ii. Mr. Asfandyar Umar, Advocate, appeared before the Board and claimed that Lazma Cream was purchased from Qazi Enterprises, Mardan, but he failed to provide any documentary evidence (invoice/warranty) in support of his claimed. He further denied involvement in any of the illegal activity and also raised questions of jurisdiction of FID and FIA in this case. **Decision:** iii. The Board, in view of personal hearing and thorough consideration of the available record/ facts of the case, including the Challan furnished by FIA, decided to allow FID Peshawar to prosecute all the accused viz M/s Shahnawaz General Store, Mardan and Shahnawaz, the Owner M/s Shahnawaz General Store, in Drug Court Peshawar for violation of Section 23 (1)(a)(i) of Drug Act, 1976.

ITEM IV MISCELLANEOUS CASES

Case No.1 DEATHS INCIDENCES AT LAHORE AND GUJRANWALA AREA ALLEGEDLY ASSOCIATED WITH CONSUMPTION OF COUGH SYRUPS UTILIZING SUB-STANDARD DEXTROMETHORPHAN RAW MATERIAL – RE-CONSTITUTION OF INVESTIGATION COMMITTEE

Giving background of the case the Board was apprised that the recommendations of PQCB, Punjab regarding the cases of manufacturing of cough syrups by M/s Reko Pharmacal & Ethical Lab Lahore, by utilizing substandard Dextromethorphan raw material, was considered by Central Licensing and Drug Registration Boards and following decisions were taken:-

A. The Central Licensing Board in its 231st Meeting held on 30-01-2013 decided as under:-

i. Import of any raw material / drug form M/s Konduskar India is banned forthwith.
ii. WHO Pakistan may be approached with the request to take up the matter with the Indian authorities through WHO India.
iii. Suspension of License of Oral Liquid / Syrup Section of M/s Reko Pharmaceuticals for one year or till completion of investigation and decision by the competent forum, whichever is earlier.
iv. Suspension of License of Oral Liquid / Syrup Section of M/s Ethical Labs for one year or till completion of investigation and decision by the competent forum, whichever is earlier.
v. Recommendations to the Drug Registration Board for Cancellation of Registration of Tyno SF Syrup of M/s Reko Pharmaceuticals and Dextromethorphan Cough Syrup and Cocil Syrup of M/s Ethical Labs
vi. Detail panel GMP inspection of the M/s Reko Pharmaceuticals and M/s Ethical Labs

The Board further decided to take up the matter again after completion of investigation by the relevant quarters

B. The Drug Registration Board in its 237th meeting held on 26-02-2013 took following decisions:-

i. While endorsing the ban on import from M/s Konduskar India, the Board recommended for also involving trade bodies and diplomatic channels for taking up the matter with the Indian authorities.
ii. Ministry of Commerce may be approached with the recommendation that a cautious approach made may be adopted for granting Most Favored Nation (MFN) status to the India in view of the substandard imports.
iii. A committee with following composition is constituted to thoroughly investigate the matter and submit its finding and recommendations to the Board on priority basis.
    a. Representative from DRAP
    b. Representative from the Government of Punjab
    c. Two Experts in Pharmaceutical Sciences
    d. Any other co-optive member the committee may require
iv. Suspension of registration of Tyno SF Cough Syrup of M/s Reko Pharmacal till completion of investigation and decision by the competent forum.

v. Suspension of registration of Dextromethorphan Cough Syrup and Cocil Syrup of M/s Ethical Labs till completion of investigation and decision by the competent forum.

2. In light of the above decisions, the CEO, DRAP vide letter dated 20-03-2013 constituted following Committee in order to investigate / study the tragic incidents allegedly associated with consumption of cough syrups, manufactured by M/s Reko Pharmacal and Ethical Pharma Lahore, by:-

i. Mr. Sultan Ghani, Former Director Health Canada
ii. Syed Shahid Nasir, Ex-Member, Central Licensing Board, Ministry of Health
iii. Prof. Dr. Mahmood Ahmed, Dean, Faculty of Pharmacy & Alternate Medicine, Islamia University, Bahawalpur.
iv. Dr. Mohammad S Iqbal, Professor, Department of Chemistry, Forman Christian College, Lahore
v. Dr. Riaz Bhatti, Head of Pharmacy, Jinnah Postgraduate Medical Graduate Centre, Karachi
vi. Prof. Dr. Muhammad Sualeh, Head of Pharmacognosy, Federal Urdu University, Karachi
vii. Dr. Iftikhar Jaffery, Sr. Director / Head of Technical Division, Pfizer, Pakistan
viii. Dr. Obaid Ali, DDC (Trg & Pharmacy Services) DRAP, Islamabad will be the Secretary / Coordinator of the investigation team / committee

3. However, the Committee could not show any progress after laps of over 06 months. The C.E.O, DRAP, therefore, in consultation with Chairmen, Central Licensing and Drug Registration Boards and with approval of Secretary, NHRS&C, re-constituted the Committee with the following composition:-

i. Syed Shahid Nasir,207-S, Phase–II, DHA, Lahore (Chairman)
ii. Prof. Dr. Mehmood Ahmed, Dean, Faculty of Pharmacy & Alternate Medicine, Islamia University, Bahawalpur.
iii. Prof. Dr. Muhammad S. Iqbal, Professor, Department of Chemistry, Forman Christian College, Lahore
Iv Dr. Saif-ur-Rehman Khattak,Director, CDL, Karachi
v. Prof. Dr. Muhammad Bashir, Ex-Dean, Faculty of Pharmacy, Punjab University, Currently Dean, Faculty of Pharmacy,
University of Lahore.
vi. Dr. Sheikh Akhter Hussain, DDG (E&M), DRAP, Lahore (Coordinator / Secretary Committee)

The main objective of the Committee is to investigate the matter thoroughly, taking in to account all aspects of the issue including scientific, technical, legal etc, and submit its findings with clear and candid recommendations within a period of two months positively for the consideration / decision of DRAP and the Policy Board.

Decision

The Board noted and ratified the decision of reconstitution of Committee and further directed that since two months has already been passed so the Committee be asked to expedite the matter.

Case No. 2:- **REQUEST OF M/S EFROZE CHEMICAL INDUSTRIES FOR RETURN OF SEIZED RAW MATERIALS, PRODUCT SAMPLES AND LOG BOOKS**

Giving background of the case the Board was apprised that M/s Efroze has requested to return the raw materials, product samples and log book seized on 01st February, 2012 by FID Karachi, on the ground that only one batch No. J093 of Isotab 20 tablets was involved in allege contamination/adulteration with Pyrimethmine Moreover, they have been allowed to manufacture specified tablets in the Tablet Section by the Drugs Appellate Board. The brief of the case was submitted before the Board as under:-

i. In January, 2012 on receipt of reports of over hundred deaths / serious reaction in large number of patients receiving medicines from the Punjab Institute of Cardiology, and subsequently, on receipt of information that a foreign Laboratory had reported contamination of antimalarial drug "Pyrimethamine" in samples of Isotab tablets of M/s Efroze Chemical Industries, sent by the Punjab Government, a Joint Investigation team of FIA and Drug Control Administration Karachi inspected M/s Efroze Chemical Industries (Pvt) Ltd., Karachi on 01-02-2012. Seizures were made and not to dispose off orders were passed for stocks of finish drugs, raw materials, equipment, machinery, documents, etc. The Central Licensing Board in its 228th meeting held on 08-06-2012, gave the permission for keeping the seized stocks/materials in safe custody, which includes 11 raw materials, log book for samples, batch documents of Quality Control/ Assurance department (600 pages).
ii. The Provincial Quality Control Board Punjab, in the mean time, also carried out its own investigation and later, vide it's ordered dated 01-02-2012, give recommendations to the Federal Government for cancellation of Registration of the Isotab Tablet and Drug Manufacturing License of M/s Efroze Chemical Industries, Karachi.
iii. The recommendations of PQCB Punjab and the investigation carried out by area Federal Inspector of Drugs was considered by Central Licensing Board in its 231st meetings held on 30-01-2013 and the Board decided as under:-

    a) The License of Tablet Section of M/s Efroze Chemical be suspended for one year
    b) Recommendation to the Registration Board for the cancellation of registration of Isotab Tablet
    c) FID Karachi be directed to launch prosecution against the responsible person(s)/ Director(s) of the firm in Drug Court Karachi

    The FID Karachi accordingly launched prosecution against M/s Efroze Chemical Industry in Drug Court Karachi. The case is still pending before the Drug Court.

2. The request of M/s Efroze Chemical Industries, for return of seized raw materials and record, was referred to the FID Karachi for comments. The FID in response has stated that the materials in question are the case property and therefore it cannot be returned to the firm.

Decision

The Board endorsed the view of the FID that the seized material, being property of the case currently under trial in Drug Court Karachi, cannot be returned to the firm unless directed by the Court.

C. QUALITY ASSURANCE

Cases of firms whose production was stopped due to non-compliance of cGMP and violations of Drugs (Licensing, Registering and Advertising) Rules, 1976

Item No. I
(Old Cases of Quality Assurance)

Case No.1: M/s Oval Pharmaceuticals, Lahore

M/s Oval Pharmaceuticals, Lahore was inspected on 27.02.2013 by Mr. Abdul Rashid Shaikh, FID Lahore with reference to see/verify the GMP compliance of the firm. During the inspection, the FID had pointed out number of shortcomings in all the sections particularly approval of layout plan for new changes and approval of technical staff. The FID had concluded that the firm may stop production till improvements and compliance of their shortcomings. The management also agreed and gave the undertaking to stop their production till upgrading and redesigning their unit. The management claimed that it would take approximately 12-15 weeks and the production shall remain stopped. They will inform to the DRAP office for re-inspection. A show cause notice was issued on 25.03.2013 to the firm along with the direction to stop production in all sections with immediate effect. In response of the show cause notice, the firm had submitted that they have rectified all the shortcomings pointed out by the FID in his inspection dated 27.02.2013.

The case was placed before the Central Licensing Board in its 232nd meeting where the firm was also provided personal hearing. The firm informed the Board that their inspection was conducted on 17.06.2013 and submitted a copy of the report which was not complete to evaluate overall GMP compliance. However the QA Section had not received that inspection report from the concern FID. After considering all the aspects of the case, *the Board had made the following decisions which were also conveyed to the firm accordingly:-*

i) The Board observed that the panel report dated 17.06.2013 was not complete to evaluate overall GMP compliance and rectification of shortcomings etc.

ii) The Board decided to defer the case and place the same in the next meeting of the Central Licensing Board in the light of the detailed report submitted by the panel.

After the CLB 232nd meeting, the panel has submitted complete report of M/s Oval Pharmaceutical, Lahore which is submitted for the appraisal of CLB. The inspection of M/s Oval Pharmaceutical, Lahore was conducted on 17.06.2013 by a panel comprising Dr. Sheikh Akhter Hussain, Director Pharmacy Services Lahore, Mr. Muazzam Ali Khan, Secretary PQCB Punjab, Mr. Asim Rauf, DDG (E&M) Lahore, Mr. Abdul Rashid Shaikh, FID Lahore and Mr. Ihsan-ul-Haq Athar, ADC Lahore to check/verify the rectification of the shortcomings pointed out in the inspection dated 27.02.2013.

The panel observed that most of the shortcomings have been addressed by the firm and recommended the *resume the production activities.*

Decision of CLB:

The case was placed before the Central Licensing Board for consideration/decision.

> ***The Board after* thorough discussion, keeping in view the facts on record & *considering the inspection report of the panel of experts constituted as per decision of the Board taken in its 232nd meeting, agreed to the recommendations of the panel & allowed the resumption of production in all sections of M/s Oval Pharmaceutical, Lahore.***

Case No. 2:- M/s Lawrence Pharma (Pvt) Ltd, Lahore

Background of the Case:

The inspection of M/s Lawrance Pharma (Pvt) Ltd, Lahore was conducted on 11.03.2013 by Mrs. Aisha Khalil, FID Lahore with reference to see and verifying the GMP compliance by the firm. The FID had pointed out number of serious shortcomings and gross GMP violations in all the sections. Accordingly, show cause notice was served by this Authority on 03.04.2013 to the firm with the direction to stop production in all the sections. In the meanwhile, the firm submitted compliance report that they have made improvements as per advice by the FID and was ready for re-inspection. A panel comprising of Mr. Asim Ruaf, DDG (E&M), Lahore, Mr. Muazzam Ali Khan, Secretary PQCB Punjab and Mrs. Aisha Khalil, FID Lahore inspected the firm on 29.05.2013, and recommended to resume production in veterinary vial section and syrup section. The case was placed before the Central Licensing Board in its 232nd meeting held on 29-30th July, 2013 where the firm was also provided opportunity of personal hearing. After considering all the aspects of the case, *the Board had decided the following:*

i) The Board on the recommendations of the panel allowed the provisional resumption of production in veterinary vial (general) section and syrup section only.

ii) The Board also decided to conduct the comprehensive inspection of the entire facility on approved audit Performa as per Schedule B-II of Drugs Act, 1976 for monitoring/evaluation of GMP compliance and conditions by the larger panel within 30 days after resumption of production.

iii) The Board decided to ask the firm to provide copies of approval of technical staff by Licensing Section i.e. Production in charge and QC In charge to QA Section.

Compliance of the Decision of the Board:-

The Central Licensing Board's above mentioned decisions have already been communicated and complied with.

Position Explained:

Another inspection was conducted dated 29.07.2013 by the same panel at its own for verifying the ratification of the shortcomings pointed out in the previous inspection conducted on 29.05.2013. The panel has recommended that the firm may provisionally be allowed production in human Injectable section. The panel of experts However, mentioned that as the building was old hence continuous improvement was required for GMP compliance and Schedule B-II under the Drugs (Licensing, Registering and Advertising) Rules, 1976. The panel also suggested that

the request of the firm for manufacturing steroidal products in general Injectable section till completion of separate area may be placed before CLB. (The copy of said report is annexed with agenda).

The letter for panel as per above decision No. (ii) of CLB was issued but the firm has requested to withdraw that letter of inspection by claiming that there is no need of inspection as they have inspected once by the FID and twice by the panels.

Proceedings:-

The representative of the company was for personal hearing in its 233rd meeting of CLB held on 31.12.2013and the case was placed before the Central Licensing Board for consideration.

Mr. Muhammad Razzaque Asadi, General Manager and Mr. Tariq Javed, QC Manager were appeared before the Board. The representatives of the company informed the Board that the inspection of the firm was conducted dated 29.07.2013 by the panel for verifying the ratification of the shortcomings pointed out in the previous inspection conducted by the panel on 29.05.2013.

The representatives further pleaded that the panel has already allowed provisional production in the human Injectable section. The solution preparation room for steroidal manufacturing will be completed very soon. The representatives are willing to comply the instructions of CLB in letter and spirit in future. The representatives also pleaded before the CLB that the company has already been inspected thrice by various panel and the Board had ordered a Board Based inspection which according to the representative of compliance is unjustified.

Decision of CLB:

i). ***The Board after hearing the views of the Firm, taking in account the deliberations by the board members & considering the inspection report of the panel of experts constituted as per decision of the Board taken in its 232nd meeting, agreed to the recommendations of the panel & allowed the resumption of production in Human Injectable section of the firm.***

ii). The Board did not allow further manufacturing of steroidal preparations in General Human Injectable Section and directed the Firm to apply afresh to Licensing Division for approval of lay out plan & dedicated facility for steroidal section as required under Schedule–B of Drugs (LR&A) Rules 1976. Till such time the production in steroidal section will remain suspended.

iii). The directorate of PE&R shall be informed accordingly.

Case No. 3:- **M/s N.B.S Pharma, Lahore**

Background of the case:

The inspection of M/s N.B.S Pharma, Lahore was conducted on 26.02.2013 by Mrs. Majida Mujahid, FID Lahore with reference to see/verify the GMP compliance of the firm. The FID in her report had pointed out number of serious shortcomings and gross GMP violations in all the sections. Accordingly show cause notice was served on 26.03.2013 to the firm with the **direction to stop production**. The firm had submitted compliance report that they have made improvements and rectified all the shortcomings and now ready for re-inspection. The CEO, DRAP had constituted a panel comprising DDG (E&M) Lahore, Chief Drug Inspector, Punjab/ Director DTL, Punjab or Secretary PQCB, Punjab and area Federal Inspector of Drugs Lahore, to re-inspect the firm to check the GMP condition of the firm. However, the panel inspection could not be carried out before 232nd meeting of CLB held on 29-30th July, 2013. The case was placed before the Central Licensing Board in its 232nd meeting where the firm was also provided personal hearing. After considering all the aspects of the case, the Board decided the following which was conveyed to the firm accordingly:-

i) ***The Central Licensing Board deferred the case till receipt of inspection report.***
ii) ***The production of the firm will remain stopped till the final decision by Central Licensing Board.***

The inspection of M/s N.B.S Pharma, Lahore conducted on 16.08.2013 by a panel comprising Mr. Ayaz Ali Khan, Chief Drug Controller, Punjab, Mr. Nadeem Iqbal, Member CLB and Mrs. Majida Mujahid, FID Lahore with reference to check/verify the improvements made by the firm which were pointed out in previous inspection conducted on 26.02.2013. The panel report has been received according to which the panel had recommended that the firm may resume the production and also directed to comply cGMP strictly on regular basis. (The copy of report is attached with the agenda)

The member of the panel conducted the inspection were not the same as nominated by the CEO, DRAP. A clarification from DDG (E&M) Lahore has been asked in this regard. However, same is awaited.

The case is placed before the Central Licensing Board for consideration.

Decision of CLB:

The Board after thorough discussion and keeping the facts on records has decided as follows:-

i) ***The Board after* thorough deliberations, keeping in view the facts on record & *considering the inspection report of the panel of experts constituted as per decision of the Board taken in its 232nd meeting, agreed to the recommendations of the panel & allowed the resumption of production in all sections of M/s N.B.S Pharma, Lahore.***

ii) ***The Board showed its displeasure on making deliberate changes in the composition of the panel of experts as in instant case by the field offices at their own without seeking prior approval/permission from the Competent Authority constituted for conducting/undertaking inspections of the Firms for specific functions e.g Grant/Renewal of DML, verification of GMP compliance etc. The Board directed the field offices to avoid such practices in future* .The Board desired to convey the said observations to the field offices for compliance.**

Case No. 4. M/s Prime Laboratories (Pvt) Ltd, Lahore

Background of the case :

Inspection of M/s Prime Laboratories (Pvt) Ltd, Lahore was conducted on 06.03.2013 by Mrs. Aisha Khalil, FID Lahore with reference to see/verify the GMP compliance of the firm. During the inspection, the FID had pointed out number of critical and sereous shortcomings in all sections. The FID concluded that the syrup section and in-process quarantine areas were sealed under Section 18(I) of the Drugs Act, 1976. The FID had directed the firm to stop production immediately and re-test all the raw materials as the storage of these materials was done without proper storage requirements for the last two years. Accordingly, a show cause notice was issued on 23.04.2013 to the firm along with the direction to stop production in all sections with immediate effect. On the request of the firm, the Chairman, Central Licensing Board/CEO DRAP had constituted a panel comprising DDG (E&M), Lahore, area FID and Chief Drug Inspector, Punjab/Director DTL, Punjab or Secretary PQCB Punjab to conduct inspection of the firm in order to confirm the improvements made by the firm. However, the inspection report was not received before 232nd meeting of CLB held on 29-30th July, 2013. The case was placed before the Central Licensing Board in its 232nd meeting wherein the firm was also provided opportunity of personal hearing. After considering all the aspects of the case, *the Board had decided the following which were conveyed to the firm & PPMA/Pharma Bureau accordingly:-*

i) The Board decided to defer the case and that production of the firm will remain stopped till rectification of shortcomings verified by the panel.

ii) The Board desired that the decision shall be taken in light of report of panel which will be presented in upcoming meeting of Central Licensing Board.

iii) Board also took extremely serious notice of the harsh, unethical and unprofessional attitude of Sheikh Zubair Iqbal, Director of the firm towards the Board during its proceedings and decided to issue warning to him to refrain from such attitude before the Board and be careful in future.

iv) The Board also directed the representatives of PPMA and Pharma Bureau to communicate, the serious concern and displeasure of all the Board members regarding the un professional, un ethical and harsh attitude of Sheikh Zubair Iqbal, Director of the firm, to all their member companies in general and the firm under reference in particular under intimation to the Central Licensing Board.

Position Explained before the Board:

The inspection report of M/s Prime Laboratories (Pvt) Ltd, Lahore conducted on 23.07.2013 by the following panel was made in QA Section for verifying the rectification of the shortcomings pointed out by the FID in the previous inspection of the firm conducted on 06.03.2013.

i) Mr. Muazzam Ali Khan, PQCB Punjab,
ii) Mrs. Aisha Khalil, FID Lahore
iii) Mr. Ajmal Sohail Asif, FID Lahore

Recommendation of the panel:

The panel was of the view that the firm has done improvements in storage and manufacturing areas. The panel recommended that the production in all sections except syrup section may be resumed. The inspection of syrup section will be conducted after the firm submits compliance.

In the light of decision of 232nd CLB taken in its meeting, a warning letter was issued to Sheikh Zubair, Owner of the firm i.e. M/s Prime Laboratories (Pvt) Lahore. In response of said letter, the owner has regretted and gave the reason of harsh wording mainly due to non-working of microphone.

Later on, the same panel comprising Mr. Muazzam Ali Khan, PQCB Punjab, Mrs. Aisha Khalil, FID Lahore and Mr. Ajmal Sohail Asif, FID Lahore inspected the firm on 05.11.2013 to check/verify the improvements made by the firm in oral liquid section w.r.t the observations pointed out by the panel in its previous inspection dated 23.07.2013.

The panel has reported that the firm has made improvements in Oral Liquid Section and the production in Oral Liquid Section may be resumed.

Decision of CLB:

The Board after thorough discussion and keeping the facts on records has decided as follows:

i) The Board after* thorough discussion, keeping in view the facts on record & *considering the inspection report of the panel of experts constituted as per decision of the Board taken in its 232nd meeting, agreed to the recommendations of the panel & allowed the resumption of production in all sections of M/s Prime Laboratories (Pvt) Ltd, Lahore.

ii) ***The Board showed its displeasure on making deliberate changes in the composition of the panel and conducting inspections /subsequent inspections of experts as in instant case by the field offices at their own without seeking prior approval/permission from the Competent Authority constituted for conducting/undertaking inspections of the Firms for specific functions e.g Grant/Renewal of DML, verification of GMP compliance etc. The Board directed the field offices to avoid such practices in future* .The Board desired to convey the said observations to the field offices for compliance**.

Case No. 5:- **M/s Aptcure (Pvt) Ltd, Lahore**

Background of the Case:-

M/s Aptcure (Pvt) Ltd, Lahore was served with the show cause notice dated 23.04.2013 with the direction to stop production in all sections. On receiving compliance report from the company's management dated 15.09.2013 another inspection was organized by the CEO DRAP comprising of

i) Deputy Director General (E&M) Lahore,
ii) Secretary PQCB
iii) Area FID Lahore.

The said panel conducted inspection of the company on 16.07.2013 before the reply of the company, wherein, the panel reported that GMP compliance of the company was unsatisfactory.

The case was placed before the Central Licensing Board in its 232nd meeting held on 29-30th July, 2013; the Board deferred the case, as the report of the panel was not received in the Board's meeting. The Central Licensing Board however directed the Federal Inspector of Drugs to ensure that the production of the company has been stopped and to keep decision of e production stop upheld.

On the request of the firm, a second panel was constituted by the Chairman, Central Licensing Board comprising of:

i) Mr. Ayaz Ali Khan, Member Central Licensing Board,
ii) DDG (E&M) Lahore,
iii) Mr. Ajmal Sohail Asif, Area FID Lahore
iv) Area ADC Lahore.

Present Position:

During this period Mr. Ajmal Sohail Asif, FID Lahore conducted an inspection on 30.09.2013 for verifying the status of the production. The FID observed that the company was doing active production and operational in respect of manufacturing. The FID seized the documents and BMRs of 5 batches of different products on Form 2 under clause (f) of sub-section (1) of Section 18 as an evidence of the production in violation to the decision and directions of the Central Licensing Board made in its 232nd meeting.

Another show cause notice to the firm has been issued on 12.11.2013 by this Authority with the direction to stop production in all sections immediately. The firm in their reply submitted that they have manufactured some batches and requested for apology on humanitarian ground. The representative of the company was called for personal hearing and the case is placed before the Central Licensing Board for consideration/decision, please.

Proceedings:-

Mr.Muhammad Masood, Chief Executive of the firm and Raja Muhammad Farooq Director Marketing appeared before the Board for personal hearing. Mr.Muhammad Masood, Chief Executive of the Firm tendered his apology before the Board on producing limited batches of their different products for fulfilling the supply orders of hospitals during suspension period of their DML as reported by area FID.

Decision of CLB:

i) ***The Board after considering the inspection report of the panel of experts constituted by competent authority agreed to the recommendations of the panel & allowed the resumption of production in all sections.***
ii) ***The Board directed to issue a strong warning to firm for*** **producing limited batches of their different products for fulfilling the supply orders of hospitals during suspension period of their DML as reported by area FID and confessed by the Firm also.**
iii) ***The board further directed that area FID will collect the details of production of batches and firm is directed to recall the stocks for destruction manufactured during suspension period from market and hospital.***

iv) ***The area FID will submit the compliance report so that a panel be constituted for the destruction of the recalled batches manufactured during suspension period from market and hospital.***

Case No. 6:- M/s Dosaco Laboratories (Pvt) Ltd, Lahore

Background of the case:

GMP inspection of M/s Dosaco Laboratories (Pvt) Ltd, Lahore was conducted on 28.03.2013 by Mrs. Aisha Khalil, FID Lahore verifying the compliance. During inspection the FID had pointed out number of serious shortcomings in all sections. The FID had concluded that:

i) In view of very serious observations, the firm was directed to immediately stop production in all the sections;
ii) The penicillin containing products should be de-registered as dedicated facility is not available.
iii) The segregated area for steroidal products is also required.
iv) Sterile area for eye drops is also not available.

Accordingly, a show cause notice was issued on 29.04.2013 to the firm along with the direction to stop production in all sections with immediate effect. In response of the show cause notice, the firm had submitted that they have started the maintenance work as suggested by the FID and all the pin pointed issues were being worked out. Due to electricity they were facing some delay. As soon as they would rectify all the shortcomings and make improvements, they would inform to this Authority for re-inspection.

The case was placed before the Central Licensing Board in its 232nd meeting where the firm was also provided personal hearing in which the firm had submitted an undertaking to the Board that they would remove all the shortcomings pointed out by the FID in next 6 months and will intimate the Central Licensing Board accordingly and the production will remain stopped. After considering all the aspects of the case, *the Board had made following decisions which were also conveyed to the firm, Federal and Provincial Drug Inspectors,, Registration Section and Licensing Section accordingly:-*

i) *The Board acceded to the request of the firm regarding extension in time period for renovation/upgradation work for a period of 6 months. However, the production of the firm will remain stopped till final decision of CLB.*

ii) *The Central Licensing Board also desired that instruction/information should be issued/conveyed to all FIDs and all provincial Chief Drug Inspectors (Punjab, KPK, Sindh, Baluchistan, Gilgit-Baltistan, ICT) regarding stoppage of production of the firm w.e.f. 29.04.2013 with the advise to ensure that a market/institutional survey should be conducted to check the availability of Drugs of M/s Dosaco Laboratories (Pvt) Ltd, Lahore manufactured after 29.04.2013, and for any action taken under the law/rules shall be presented before the Board.*

iii) *The Board further decided to ask the firm to get layout plan of the building approved for eye drops, penicillin (dedicated) and steroidal products/drugs as required under rules.*

iv) *The Registration Board/Directorate of Registration will also be appraised about the decision of CLB regarding suspension of products/drugs i.e. eye drops, penicillin and steroids containing products manufactured in these sections for immediate action and compliance at their end as firm does not possess manufacturing facilities/areas for these products as required under the rules.*

During this period, Mrs. Aisha Khalil, FID Lahore inspected the firm on 04.09.2013 with reference to check the status of the firm and focused on verification of stoppage of production as per decision of Central Licensing Board dated 03.09.2012. The FID reported that the firm was actively involved in production which is clear violation to decision and directions of the CLB made in its 232nd meeting.

Position Explained:

Another show cause notice to the firm has been issued on 12.11.2013 by this Authority with the strict direction to stop production in all the sections immediately on violating the conditions of License and Good Manufacturing Practice (GMP) as laid down under Drugs (Licensing, Registering and Advertising) Rules, 1976 and had intentionally violated their own commitment/undertaking and the directions of the Central Licensing Board.

Proceedings:-

Mr. Muhammad Azeem, Quality Control In charge and Mr. Humayun Rashid, Production In charge of the firm appeared before the Board for personal hearing. They have stated that they had reprocessed the small quantity of batch. They had not sold any batch in the market.

Decision of CLB:

The Board after considering the request of the representatives of the company and keeping the basic ground of the inspections has decided the following:

i) The Board decided to suspend the production activities till the final approval by CLB.

ii) The company be directed to provide the detail of production and recall the stocks for destruction. The Area FID will submit its report.

iii) The area FID has to watch the destruction of the recalled products.

Case No. 7:- **M/s British Pharma, Lahore**

Inspection of M/s British Pharma, Lahore was conducted on 03.04.2013 by Mrs. Aisha Khalil, FID Lahore for verifying the GMP compliance of the firm. During inspection, the FID had observed number of serious GMP violations. The FID concluded that the firm did not rectify the shortcomings which were pointed out in previous inspection even after the lapse of almost 10 months. At this juncture, company voluntarily stopped their production activities. Accordingly, a show cause notice was issued to the firm on 09.05.2013 along with the **direction to stop production** in all sections with immediate effect. In response of the show cause notice, the firm had submitted that they have completed all the renovation and up-gradation work and requested to resume production activities and are ready for re-inspection.

The Chairman, Central Licensing Board/CEO DRAP had constituted a panel for re-inspection comprising of the following members for confirming the improvements made by the firm.

i) DDG (E&M), Lahore, (Dr. Sheikh Akther Hussain)
ii) Chief Drug Inspector, Punjab/ Director DTL, Punjab or Secretary PQCB Punjab (Mr. Ayyaz Ali Khan)
iii) Mrs. Aisha Khalil, Area FID Lahore

However, the inspection report was not received before 232nd meeting of CLB held on 29-30th July, 2013. The case was placed before the Central Licensing Board in its 232nd meeting where the firm was also provided personal hearing. After considering all the aspects of the case, the Board had decided:

"Deferred the case and decided that the production of the firm will remain stopped till panel inspection and final decision by Central Licensing Board in the light of panel inspection report".

Later on, the inspection report of the firm conducted by the said panel on 22.07.2013 was received. The panel again pointed out number of shortcomings which need improvements. The firm agreed with the suggestions of panel.

The representative of the company was called for personal hearing and the case is placed before the Central Licensing Board for consideration.

Proceedings:-

The representative of the company was for personal hearing in its 233rd meeting of CLB held on 31.12.2013and the case was placed before the Central Licensing Board for consideration.

Mr. Muhammad Akram, Production In charge appeared before the Board wherein he has informed that they have made all improvements as advised by the panel and will be ready for inspection at the mid of January, as the electric transformer is under installation.

Decision of CLB:

The board decided to upheld the decision of 232nd meeting of CLB that the production of the firm will remain stopped till panel inspection and final decision by Central Licensing Board in the light of panel inspection report.

The production of the firm will remain suspended till the approval by the CLB.

The firm will be directed to get approval of technical staff from DRAP.

Case No. 8:- M/s Risma Laboratories (Pvt) Ltd, Karachi

Background of the case:

The show cause notice to M/s Risma Laboratories (Pvt) Ltd, Karachi was served on 16.05.2013 with the direction to stop production in all sections. The company had informed on 25.05.2013 that they had made all the improvements and up-gradation work in all sections and are ready for re-inspection. On the request of firm, the Chairman, CLB/CEO DRAP had constituted following panel to re-inspect the firm for verifying the improvement made by the firm and also to see GMP compliance.

i) Dr. Muhammad Tanweer Alam, DDG (E&M) Karachi
ii) Mr. Qaiser Muhammad, Chief Drugs Inspector, Sindh/Member CLB
iii) Mrs. Muneeza Khan, Area FID Karachi.

The inspection of the firm had not been conducted till 232nd meeting. The case was placed before the Central Licensing Board in its 232nd meeting where the firm was also provided personal hearing. After considering all the aspects of the case, *the Board had made following decision which was also conveyed to the firm accordingly:-*

The Board deferred the case and decided that production of the firm will remain stopped till panel inspection and final decision by Central Licensing Board in the light of panel inspection report.

Present Position:-

Later on, the panel inspection of the company was conducted on 04.11.2013 by the aforesaid panel.

The panel was of the opinion to continue the action taken by the area FID for suspension of the manufacturing operation till further orders by the Board concerned. The panel also passed "Not to dispose off orders" for 149 drums/bags of expired raw material in the raw material store.

The representative of the company was called for personal hearing and the case is placed before the Central Licensing Board for consideration.

Proceedings:-

The representative of the company was for personal hearing in its 233rd meeting of CLB held on 31.12.2013and the case was placed before the Central Licensing Board for consideration.

Mr. Sohail Riaz, Director/GM of the firm appeared before the Board wherein he has requested the Board to allow the production in the re-packing section.

Decision of CLB :

The Board after considering the views of the representatives of the company has decided the following:

- *The Board suspended the manufacturing license (Formulation) in all areas for a period of three months under Rule 13 of Drugs (Licensing, Registering and Advertising) Rules, 1976 for rectification of observations made during the inspection by the panel.*

- *The Board also did not accede to the recommendations of panel for manufacturing of External Preparations for export purpose in the light of rule 17(2) of Drugs (LR& A) Rules, 1976.*

- *The Board further decided to issue Show Cause Notice and Personal Hearing in the next meeting of CLB.*

Case No. 9:- M/s Rex Pharmaceutical Pakistan, Karachi

Background of the Case: M/s Rex Pharmaceuticals Pakistan Ltd, Karachi was inspected on 06.03.2013 by Mr. Abdul Rasool Shaikh, FID Karachi with reference to see/verify the GMP compliance. During the inspection the FID pointed out number of serious shortcomings and gross violations in all sections. The FID reported that GMP situation was so critical and the firm cannot be allowed to manufacture life saving drugs under very un-hygienic conditions, without proper quality control department including microbiological lab and lack of necessary technical and quality staff. The FID directed the firm to suspend all kind of production activities initially for 15 days due to severe non-GMP compliance.

Action Taken by DRAP:- Accordingly, a show cause notice was issued to the firm on 23.04.2013 along with the direction to stop production in all sections with immediate effect.

Reply of the firm:- In response of the show cause notice, the firm had submitted that they have worked out on areas of development in compliance to GMP guidelines as advised by the FID in previous inspection and also requested to withdraw the show cause and allow them to continue their production activities. On the request of firm, the Vice Chairman, CLB had constituted following panel to re-inspect the firm for verifying the improvement made by the firm and also to see GMP compliance along with recommendation whether the renewal of DML may be granted or not:

v) Dr. Muhammad Tanweer Alam, DDG (E&M) Karachi
vi) Mr. Qaiser Muhammad, Director DTL, Sindh.
vii) Mr. Saleem Isharat, Chief Drug Inspector, Sindh
viii) Mr. Abdul Rasool Shaikh, Area FID Karachi.

The case was placed before the Central Licensing Board in its 232nd meeting where the firm was also provided personal hearing. After considering all the aspects of the case, *the Board had made following decision which was also conveyed to the firm accordingly:-*

iii) The Board decided that the production will remain stopped till the final approval for resumption of production by the Central Licensing Board.

iv) The case was deferred by Central Licensing Board till its next meeting as per request of the firm and also to fulfill legal requirement w.r.t show cause notice and personal hearing.

Position Explained:
Later on, a aforesaid panel inspection report has been received which was conducted on 04.07.2013 wherein the panel observed major GMP violations and reported that the firm was not in a position to recommend the renewal of DML. The panel further recommended that the firm may be given more time to rectify all the major shortcomings for better compliance till that their production activities may be halted in larger public interest.

The representative of the company was called for personal hearing and the case was placed before the Central Licensing Board in its 233rd meeting held on 31.12.2013 for consideration.

Decision of CLB:-

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

Case No. 10:- **M/s Avicenna Laboratories (Pvt) Ltd, Lahore**

Background of the Case:

Inspection of M/s Avicenna Laboratories (Pvt) Ltd, Lahore was conducted on 04.03.2013 by Mrs. Aisha Khalil, FID Lahore with reference to see/verify the GMP compliance of the firm. During inspection, the FID had pointed out gross violations in all sections. The FID further reported that the firm had registration of 10 injectable products including penicillin/steroids whereas, the injectable section is not approved by the DRAP, Licensing Section but company had been granted the registration of the same. Accordingly, a show cause notice was issued to the firm on 26.04.2013 along with the direction to stop production in all sections with immediate effect. In response, the firm submitted that they have completed all the renovation and up-gradation work in their manufacturing area. The company had requested to resume production activities, withdraw the show cause notice and ready for re-inspection. The case was placed before the Central Licensing Board in its 232nd meeting wherein the firm was also provided personal hearing.

The Board after giving patient hearing and considering all the aspects had made the following decisions which were conveyed to the firm accordingly:-

i) The Board took serious notice that without prior approval from or intimation to Central Licensing Board (Licensing Section) how the firm involved in renovation of vaccine production area for which the firm should be asked for clarification by QA Section.

ii) The Board further decided to direct the firm to establish a self contained/dedicated facility for production of Penicillin containing products/drugs and no production activity of penicillin containing products shall be conducted till provision of dedicated/self contained facility as per requirement of relevant rules and same approval by the CLB.

iii) The Central Licensing Board decided that the production will remain stopped till the final approval of Central Licensing Board.

iv) The Central Licensing Board also decided for a broad based inspection of unit by a panel as per audit Performa devised as per Schedule B-II of Drugs (Licensing, Registering and Advertising) Rules 1976 framed under Drugs Act, 1976 in order to check/verify the GMP compliance level of the firm.

Position Explained:

The firm did not submit the compliance report for doing needful on the decisions of the Central Licensing Board despite issuance of reminder to the firm on 23.10.2013 in this regard.

The representative of the company has been called for personal hearing and the case is placed before the Central Licensing Board for consideration.

Proceedings:-

The representative of the company was called for personal hearing and the case was placed before the Central Licensing Board in its 233rd meeting held on 31.12.2013 for consideration.

Mr. Muhammad Shafiq, Production Manager appeared before the Board and pleaded that they are not going to manufacture Penicillin products and has improved the general GMP. The representative has not provided any letter of withdrawal of Penicillin products at the time of personal hearing.

Decision of CLB:-

The Board after listening to the representative of the company making thorough discussion and keeping the facts on records has decided as follows:-

i) *The Board decided that the production will remain suspended in all sections till the compliance and good GMP report. Board constituted a panel comprising of Mr. Mouzam Ali Khan, area FID and ADC to inspect the firm. The Board delegated the power to its Chairman for allowing resumption of production in case the panel recommends for resumption of production.*

ii) *The production in the vaccine and penicillin sections will remain suspended. If the company has made any structural changes, they have to get permission from Licensing Section.*

Case No. 11:- **M/s Ardin Pharmaceuticals, Karachi**

The brief of the case is that, the inspection of the firm M/s Ardin Pharmaceuticals, Karachi was conducted on 08.03.2013 by Dr. Shahid Hussain, FID Karachi to check the GMP compliance. The FID pointed out number of serious shortcomings in all sections. Accordingly, a show cause notice was served by this Authority on 25.03.2013 with the direction to stop production. The case was discussed in 232nd meeting of Central Licensing Board held on 29-30th July, 2013, wherein, the Board after detailed discussion/deliberation decided as under:-

> *The CLB after hearing the views of the Director of the firm, acceded to the request of the firm for extension in time period of three months to upgrade/renovate their facility subject to the condition that the production will not be resumed during up-gradation/renovation work and till decision of the CLB after verification of rectification of shortcomings by the panel of experts.*
>
> *The firm will get the layout plan of their building/sections approved in case of up-gradations/improvements of existing facility if any change or alteration is made in the existing/approved layout. The case shall be brought before the notice of Central Licensing Board. In case of failure to rectify the shortcomings and no further time shall be granted and exparte decision shall be taken by the CLB.*

The firm had requested for grant of further three (3) months time for completing their renovation work which is against the decision of the Board.

The case was placed before the Central Licensing Board for consideration.

Decision of CLB:-

The Board after thorough discussion and keeping the facts on records has decided as follows:-

i) *The Board after considering the facts on record and taking the lenient view decided that the company may be allowed one more month for improvement and the directions of suspension of production will continue till the re-inspection by the panel of experts.*

ii) *In case of no reply and after the laps of the grace period, a new show cause notice will be issued for processing of case of cancellation of DML.*

Case No. 12:- **M/s Meredoa Company, Karachi**

M/s Meredoa Company, Karachi was inspected on 08.03.2013 by Dr. Shahid Hussain, FID Karachi with reference to see/verify the GMP compliance of the firm. During the inspection, the FID had pointed out number of serious shortcomings in all sections. The FID directed the firm to stop production immediately and also recommended to cancel the drug manufacturing license of the firm in larger interest of the public. Accordingly, a show cause notice was issued to the firm on 23.04.2013 along with the direction to stop production in all sections with immediate effect.

The case was placed before the Central Licensing Board in its 232nd meeting; the company was provided personal hearing. The owner of the firm informed that he was intending to perform Aitiqaf from the same evening due to which he was unable to travel and could not appear personally before the Board on 30.07.2013, and requested that his case may be deferred for next meeting.,

The Board after considering all the aspects of the case and request of the owner of the company had made following decision which was also conveyed to the firm accordingly:

The Board decided to defer the case till next meeting of CLB and the production will remain stopped till the final decision by Central Licensing Board.

A reminder has been sent to the company by this Authority on 14.11.2013 with the direction to submit the reply of show cause notice along with the current status of the company in the light of their letter dated 25.03.2013 for appraisal of Central Licensing Board. The firm in response has requested to give more time for improvements.

Proceedings:-

The representative of the company was called for personal hearing and the case was placed before the Central Licensing Board in its 233rd meeting held on 31.12.2013 for consideration.

Mr. Amin Motiwala, owner of the firm appeared before the Central Licensing Board and pleaded that they have made all the improvements as advised by the FID and will be ready for re-inspection at the end of January, 2014.

Decision of CLB:-

The Board after thorough discussion and keeping the facts on records has decided as follows:-

The Board acceded to the request of the company and decided to get the firm re-inspected by a panel of experts. The panel has to send a compliance report in this regard to the Chairman, Central Licensing Board.

Agenda Item No. II:

(New Cases of Quality Assurance)

Case No.13:- M/s Munawar Pharma (Pvt) Ltd, Lahore

The inspection of M/s Munawar Pharma (Pvt) Ltd, Lahore was conducted on 25.07.2013 by a panel comprising Mr. Ajmal Sohail Asif, FID Lahore, Mrs. Majida Mujahid, FID Lahore and Dr. Akbar Ali, ADC Lahore with reference to investigate the reported allegric reactions took place at District Head Quarter Hospital, Layyah and to see/verify the GMP compliance of the firm. The panel had pointed out number of shortcomings in all sections. it had been reported that the conditions in the manufacturing unit were not in conformity with the conditions of License and Good Manufacturing Practice (GMP) as laid down under Drugs (Licensing, Registering and Advertising) Rules, 1976.

Recommendation of the Panel: The panel recommended and directed the firm to stop the production in all injectable sections (general, steroids, psychotropic/narcotic and small volume infusion) immediately till further orders.

Action Taken by DRAP: A show cause notice and **direction to stop manufacturing** in the Injectable Sections (general, psychotropic/narcotic and small volume infusion) was served on 02.09.2013. The firm in response has submitted a compliance report and requested for re-inspection of their unit.

Position Explained: On the approval of the Chairman, Central Licensing Board/Director (QA/Lab Testing & Lic) a following panel was constituted for verifying the GMP compliance.

i) Dr. Ahmad Mahmood Mumtaz, Chairman Quality Control, Islamabad,
ii) Mr. Nadeem Iqbal, Member Central Licensing Board,
iii) Mrs. Majida Mujahid,Area FID Lahore and
iv) Mr. Ihsan-ul-Haq instead of Mr. Akbar Ali, Area ADC Lahore

The panel inspected the company on 28.10.2013 to check/verify the improvements made by the company w.r.t the serious shortcomings pointed out by the previous panel in its inspection dated 25.07.2013. The panel dated 28.10.2013 concluded that the company has made improvements in production area, quality control and willing to abide the inspection imparted by the inspection teams. The orders of stop production may be withdrawn at the earliest.

The case was placed before the Central Licensing Board for consideration.

Proceedings:

During the course of the proceeding of the CLB, Mr. Moazzam Ali Khan, Director, PQCB, the representative of the Government of Punjab informed the Board that the company had also been inspected by the Drug Inspector of Health Department of Government of Punjab. The Drug Inspector had ordered for stoppage of production in sterile area. The representative of the Government of Punjab was unable to state regarding the formal report or request by the Provincial, Quality Control Board, Lahore and/or Health Department, Government of Punjab to the Central Licensing Board, Islamabad in this regard. The Board was also informed, the law

position on the coordination between Federal and Provincial Governments under Section 11 of Drugs Act, 1976.

Decision of CLB:-

The Board after thorough discussion and keeping the facts on records has decided as follows:-

The Board after considering the inspection report of the panel of experts constituted by the DRAP, Islamabad agreed the recommendations of the panel to allow the resumption of production of M/s Munawar Pharma (Pvt) Ltd, Lahore.

Case No.14:- **M/s Harmann Pharma (Pvt) Ltd, Lahore**

The inspection of M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, Lahore was conducted on 03.10.2013 and 04.10.2013 by Mr. Ajmal Sohail Asif, FID Lahore to check and verify the GMP compliance by the company. During the inspection, the FID has pointed out a number of major and critical shortcomings and violation GMP under Drugs (Licensing, Registering & Advertising) Rules, 1976.

The FID concluded that the company was considered to be operating at unsatisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under and directed the firm as under:

i) The firm was directed to stop all kinds of manufacturing activities till the rectification of the shortcomings and improvement in GMP compliance level.

ii) The firm was advised to recall all the products which were marketed without conducting the complete test analysis especially the sterile products which were marketed without performing the sterility test.

iii) The firm was advised either to surrender the Narcotic/Psychotropic products registered in tablet section or stop production of these products till the provision of separate section.

iv) The firm was advised either to surrender the Steroidal products registered in tablet section and in ointment/cream section or stop production of these products till the provision of separate sections.

v) The firm was advised either to surrender the Hormonal product registered in injectable section or stop production of this product till the provision of dedicated manufacturing facility.

vi) The firm was advised either to surrender the registrations for manufacturing of eye drops or stop production of these products till the provision of separate section.

vii) The firm was advised to establish a functional, independent and effective Quality Assurance department.

viii) The firm was advised to hire adequate and experienced technical staff to carry out the manufacturing and quality control activities.

ix) The firm was advised to improve the overall conditions of sanitation and hygiene of production areas and general cleanliness of the unit.

x) The firm was advised to review/update and develop the SOPs for each and every process being conducted in the premises in connection to manufacturing and QC of products.

xi) The firm was advised to harmonize the practices and procedures with the SOPs and GMP guidelines and to enforce the strict implementation of the SOPs.

xii) The management of the firm was directed to prepare and submit an action plan in the light of observations of the inspection with clear time schedule for rectification of the shortcomings and improvements in the cGMP compliance.

Action Taken by DRAP: A show cause notice and the direction to stop manufacturing in all sections immediately was served to the company dated 12.11.2013. In response to the inspection report of FID, the firm has submitted annotated reply. The company has filed a writ petition against the show cause notice and stop production order. The Honorable High Court has granted stay to the firm to the extent to stop manufacturing of drugs till next date of hearing against the show cause notice issued by this Authority on 12.11.2013.

The representative of the company has been called for explaining their view point before the Board, please.

Proceedings:

The representative of the firm informed telephonically to the DDC (QA) that the matter is still in the court and they are not able to appear before the Board being a subjudice matter.

Decision of CLB:-

The Board deferred the case as the matter is subjudice before the Honorable Islamabad High Court, Islamabad.

Case No.15:- **The Searle Company Ltd, Lahore**

The inspection of M/s Searle Company Ltd, Lahore was conducted on 21.08.2013 by Mr. Ajmal Sohail Asif, FID Lahore with reference to see/verify the GMP compliance of the firm. The FID has pointed out number of shortcomings in all sections. Whereas, it has been reported that the conditions in the manufacturing unit were not in conformity with the conditions of License and Good Manufacturing Practice (GMP) as laid down under Drugs (Licensing, Registering and Advertising) Rules, 1976. The FID particularly mentioned regarding the tablet section which is as under:

Tablet Section (General):-Manufacturing activities were being conducted in Tablet Section (General) whereas pervious inspection reports were silent about any formal approval of this newly established tablet section. Scrutiny of record available in the office of FID revealed that they had got approval for layout plan expansion to establish Tablet (General), Capsule (general) and Quality Control Laboratory but neither panel inspection had been conducted to verify the facilities nor formal approval of Central Licensing Board was granted for grant of additional sections. They have failed to provide any such approval for allowing them to commence manufacturing in this section.

Action Taken by DRAP: On the approval of the Chairman, CLB, a show cause notice was served on 23.09.2013 with the direction to stop manufacturing in tablet section immediately.

The FID had informed that a panel inspection was conducted on 22.10.2013 which was carried out for the purpose of grant of additional section to the firm.

Reply of the firm:-The firm in their reply to the show cause notice stated that they appreciate and regard the audit procedure and report of FID. The firm further submitted that there was always room for improvement; they will keep on striving to fulfill all shortcomings of their manufacturing facility. They have also requested to facilitate the earliest panel inspection of tablet section.

The representative of the company was called for personal hearing and the case is placed before the Central Licensing Board for consideration, please.

Proceedings:-

The representative of the company was for personal hearing in its 233rd meeting of CLB held on 31.12.2013and the case was placed before the Central Licensing Board for consideration.

Dr. Syed Nadeem Ahmad, CEO and Mr. Muhammad Amir Bashir, Director Technical Operation of the company appeared before the Board and informed that they have established the facilities for the manufacturing of tablets in Block II. The panel of experts in the inspection report dated 22.10.2013 have already recommended for approval of section along with the resumption of production in the tablet section. The panel has commented that the company is GMP compliance. The representative further informed that they are going to withdraw the capsule section and no more interested in the capsule dosage form. They seek permission from the Central Licensing Board for utilizing the facilities for tablet section.

Decision of CLB:

The Board after considering views of the representatives of the company has decided the following:

i) The manufacturing in Tablet Section shall remain suspended.

ii) The resumption of production in the tablet section will be allowed after re-inspection for verification of the cGMP compliance of the company by a panel constituted by competent authority.

Case No.16:- **M/s Hirra Pharmaceutical Labs, Lahore**

The inspection of M/s Hirra Pharmaceutical Labs, Lahore conducted on 27.05.2013 by Mrs. Majida Mujahid, FID Lahore with reference to see/verify the GMP compliance of the firm. During inspection, the FID has pointed out number of serious shortcomings/deficiencies in all sections. The FID had concluded and directed the firm to stop production in vaccine section.

Action taken by the DRAP: A show cause notice was served on 23.09.2013 with the direction to stop manufacturing in vaccine section immediately. The firm has so far not replied the show cause notice. A reminder has been sent to the firm on 12.11.2013.

Reply of the firm: The firm has submitted a reply of reminder of show cause notice in their letter dated 20.11.2013 stating that they are in process of upgradation, renovation in different sections as pointed out by the area FID during inspection. They will be ready within one month for re-inspection. They have also submitted that they will inform in writing to the Central Licensing Board for panel inspection.

The case was placed before the Central Licensing Board for consideration.

Decision of CLB:

The Board after thorough discussion and keeping the facts on records has decided as follows:-

The order of suspension of production in vaccine section will continue till final decision of CLB. A reminder be served to the company as the company has not yet informed the CLB for improvements.

Case No.17:- **M/s Medicare Disposable Industries, Lahore**

The FID, Lahore (Mr. Ajmal Sohail Asif) inspected the M/s Medicare Disposable Industries, Lahore on 28.08.2013, with reference to see/verify the GMP compliance of the firm. The FID, Lahore had pointed out a number of shortcomings in all sections. It had been reported that the conditions in the manufacturing unit were not in conformity with the conditions of License and Good Manufacturing Practice (GMP) as laid down under Drugs (Licensing, Registering and Advertising) Rules, 1976.

Action Taken by DRAP: A show cause notice and direction to stop manufacturing of the Drugs immediately, was served on 19.09.2013. The firm in response vide their letter dated 24.09.2013 has submitted a compliance report and requested for re-inspection of their unit.

Position Explained: On the approval of the Chairman, Central Licensing Board/Director (QA/Lab Testing & Lic) the following panel was constituted for verifying the GMP compliance.

i) Dr. Ahmad Mahmood Mumtaz, Chairman Quality Control, Islamabad,
ii) Mr. Ayaz Ali Khan, Member Central Licensing Board,
iii) Mr. Ajmal Sohail Asif, Area FID, Lahore.

The panel inspected the company on 18.11.2013. The company has made number of improvements, necessary changes and has positive attitude towards the requirements of cGMP, in view of this, the panel of inspectors recommends the resumption of production in all sections.

The case was placed before the Central Licensing Board for consideration.

Proceedings:

The representative of the Government of Punjab, Mr. Moazzam Ali Khan, Provincial, Quality Control Board informed the Central Licensing Board that the company is using corridor for workers to move across the corridor. This practice of moving of workers across the corridor be stopped, immediately. The CLB was informed that the corridor is basically used for transferring of the prepared components of disposable syringes for one building block to the second building block. The Central Licensing Board was further informed that these companies have been granted drug manufacturing license and have now became pharmaceutical companies. The Central Licensing Board was apprised that the Federal Inspector of Drugs have already been advised to make regular inspection of disposable manufacturing companies. The company, M/s Medicare Disposable Industries, Lahore has submitted an undertaking on stamp paper that they will not use the corridor for extra movement of workers.

Decision of CLB:

The Board after thorough discussion and keeping the facts on records has decided as follows:-

i) The Board after considering the inspection report of the panel of experts agreed the recommendations of the panel to allow the resumption of production in all sections of M/s Medicare Disposable Industries, Lahore subject to improvements in corridor as highlighted by area FID.

Case No.18:- **M/s Ahson Drug Company, Tandoadam**

The inspection of M/s Ahson Drug Company, Tandoadam conducted on 25.09.2013 by Dr. Najam-us-Saquib, FID Hyderabad at Karachi with reference to see/verify the GMP compliance of the firm. During inspection, the FID has pointed out number of serious shortcomings/deficiencies in all sections. The FID concluded that the firm was not operational at an acceptable level of compliance with GMP guidelines. The FID has recommended that it is quite dangerous and health hazardous for the public, that is why the firm was directed to **stop production in all sections** immediately.

Action taken by the DRAP: A show cause notice was served on 01.11.2013 by this Authority with the **direction to stop manufacturing** of drugs immediately.

Reply of the firm: The firm has submitted a reply in response of show cause notice stated that they have made improvements as suggested by the FID and requested for re-inspection.

The case was placed before the Central Licensing Board for consideration.

Proceedings:-

The representative of the company was for personal hearing in its 233rd meeting of CLB held on 31.12.2013and the case was placed before the Central Licensing Board for consideration.

Mr. Abdul Wahab Ansair, Managing Partner and Mr. Manohar Lal, Chief Executive of the company appeared before the Board and requested that they have made improvements as advised by the FID. They pleaded that they are ready for inspection.

Decision of CLB:

The Board after thorough discussion and keeping the facts on records has decided as follows:-

> *The company, M/s Ahson Drug Company, Tandoadam be re-inspected by a panel of experts within one month. The production of the company shall remain suspended and the report will be submitted before CLB for approval.*

Case No.19: M/s Epoch Pharmaceuticals, Karachi

The inspection of M/s Epoch Pharmaceuticals, Karachi conducted on the directions of 239th meeting of Drug Registration Board vide letter No.F.3-2/2013-Reg-II (M-328) dated 07.10.2013 for the purpose of grant of registrations of certain drugs. A panel comprising of Mr. Amanullah Khan, Director DTL Quetta/Member DRB and Mr. Abdul Rasool Shaikh, FID Karachi conducted the inspection on 01.11.2013. The panel rejected the recommendations for registration of the products applied by the company. The panel also observed serious shortcomings/deficiencies and GMP violations in all sections. The matter was referred to QA Section for evaluation/verification of the GMP compliance by the company.

Action taken by the DRAP:

i) A show cause notice was served on 19.11.2013 by this Authority with the direction to **stop production** in tablet, capsule and sterile injection section with immediate effect.

ii) A following panel was constituted on 19.11.2013 for conducting the inspection of the firm in all sections excluding tablet, capsule and sterile injection sections mentioned in the show cause notice dated 19.11.2013.

a) Syed Jawed Yousaf Bukhari, Member Central Licenisng Board.
b) Dr. Muhammad Tanweer Alam, DDG (E&M) Karachi.
c) Mr. Abdul Rasool Shaikh, Area FID, Karachi.
d) Dr. Shoaib Ahmad, ADC Karachi

The aforesaid panel inspected the company on 11.12.2013 and concluded as under:

The panel identified some serious GMP lapses mentioned under each heading and critical observations of high risk. The panel unanimously decided that the firm should voluntarily discontinued their production activities till compliance of all the critical observations in following production areas.

Sterile cephalosporin
Oral cephalosporin,
Oral penciling and
Ophthalmic sections

In other sections, the company may continue their manufacturing processes as those were minor shortcomings which the management agreed to rectify within 15 days. The panel also observed that the other sections (tablet, capsule and sterile injection sections) were under renovation and overhauling and no production was seen during their visit.

The representative of the company was called for personal hearing and the case is placed before the Central Licensing Board for consideration, please.

Proceedings:

The representative of the company was called for personal hearing in its 233rd meeting of CLB held on 31.12.2013. Mr. Saleem Managing Director appeared before the Board. The representative submitted that they have made improvements and ready for inspection. The Board was informed that the company is involved in the manufacturing of sterile cephalosporin and other sensitive

products and at the time of inspection by the panel, tablet, capsule and sterile injection sections were under renovation and overhauling and no production was seen during their visit. The panel identified some serious GMP lapses in the Sterile cephalosporin, Oral cephalosporin, Oral penicillin and Ophthalmic sections.

Decision of CLB:-

The Board after considering views of the representatives of the company has decided the following:

> *The production of the company will remain suspended till the final approval of CLB. In the meanwhile the FID has to verify the production activities and progress made by the company by making frequent inspections/visits at a practicable time intervals.*

Case No.20: M/s Nawan Laboratories (Pvt) Ltd, Karachi

The inspection of M/s Nawan Laboratories (Pvt) Ltd, Karachi was conducted on 01.11.2013 on the directions of Drug Registration Board in its 239th meeting for investigating the reasons manufacture and sale of substandard, "Paemactin Drench" and to identify the problems and confirm the actions take by the firm. A panel comprising of Mr. Amanullah Khan, Member DRB/Director DTL Quetta, Dr. Tanweer Alam, DDG (E&M) Karachi and Mr. Abdul Rasool Shaikh, FID Karachi had also observed the GMP compliance level of the firm. During the inspection, the panel pointed out number of gross violations of GMP. The matter was referred to QA Section for evaluation/verification of the GMP compliance by the company.

Recommendations of the panel:-

The panel had reported that the overall GMP compliance of the firm was non-compliant. Around 115 bottles of suspension Paemactin were recovered/recall from the market and seen kept in finished good stores. The root-caused still has not been identified. The panel recommended that due to gross GMP violation of the firm, the production in all solid/dosage and liquid veterinary section be stopped. The panel also sealed the veterinary production area of the firm for public interest.

The FID telephonically confirmed that the veterinary production area and only non-sterile area was sealed because the scope of the inspection was specific/limited, so other manufacturing areas could not been inspected.

Action taken by the DRAP:

i) A show cause notice was served on 19.11.2013 by this Authority with the direction to **stop production** in solid dosage form of veterinary production area including liquid veterinary section with immediate effect.

ii) A following panel was also constituted on 19.11.2013 conducting the inspection in other areas which were not inspected in previous inspection to check the overall GMP compliance:

a) Syed Jawed Yousaf Bukhari, Member Central Licensing Board.
b) Director CDL, Karachi.
c) Chief Drug Inspector, Sindh.
d) Area FID, Karachi.

On the request of the company, the aforesaid panel has not yet inspected the company. The company in their reply however, has submitted that:

i) To de-seal/re-open the area so as to remove the manageable inadequacies which has been overlooked inadvertently.

The company further stated that it is only possible that the area may be opened so that they may start upgrading and rectify the deficiencies.

ii) To extend the panel inspection since they are in the phase of biannual internal cGMP audit by their internal inspection team, the inspection may be extended till late December, 2013 or early January, 2014.

Proceedings:

The representative of the company was called for personal hearing in its 233rd meeting of CLB held on 31.12.2013. Mr. Naseer Ahmad Awan, Managing Director appeared before the Board. The representative submitted that they have made lot of improvements and ready for inspection. The representative further submitted that the section which was sealed by the team constituted by Drug Registration Board may be de-sealed so that changes and up-gradation at par with cGMP compliance be carried out. The representative has explained that he himself requested the panel of inspector for the grant of time so that the inspection of the company be carried out after they completed all the renovation and up-gradation.

Decision of CLB:

The Board after considering views of the representatives of the company has decided the following:

i) The directions to FID to de-seal the area sealed by the panel of inspectors constituted by Drug Registration Board, so that the company may make appropriate up-gradation/improvements.

ii) On getting the compliance report from the company within one month, the same panel already constituted for other areas will inspect all the sections including the area de-sealed for verification of improvements made by the company.

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