MINUTES OF 246th MEETING OF CENTRAL LICENSING BOARD HELD ON MONDAY 22nd FEBRUARY, 2016

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246th meeting of the Central Licensing Board (CLB) was held on Monday 22nd February, 2016 in the Division of Drug Licensing, Drug Regulatory Authority of Pakistan, 3rd Floor, TF Complex, G-9/4, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP.

Following members attended the meeting: -

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

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

The Chairman apprised the members of the Board that proceedings of CLB shall be conducted in an amicable and responsible way to deliver to the public and stake holders in a transparent and efficient manner. Quality shall be given priority and there shall be zero tolerance.

He further added that all the legal and codal formalities regarding convening of the meeting have been fulfilled. Mr. Adnan Faisal Saim DDC (QC) & Dr. Akbar Ali ADC (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

LICENSING DIVISION

Item-I **CONFIRMATION OF THE MINUTES OF 245th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 245th meeting held on Wednesday 30th December, 2015.

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

The Board considered the following cases of grant of new drug manufacturing license in the light -8/of recommendations of respective panel of experts/inspectors and decided as under:

S#	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s Moon Pharmaceuticals, Plot No. S-5, Street No. SS-4, National Industrial Zone, RCCI, Rawat, Rawalpindi.	**29-12-2015 Formulation**	**The Board approved the grant of DML by way of formulation with following six sections:** **Sections (06)** 1. Tablet (General) 2. Capsule (General) 3. Topical (General) 4. Sachet (General) 5. Liquid Syrup (General) 6. Oral Dry Powder for Suspension (General)
2.	M/s. Jupiter Pharma, Plot No. 25, Street No. S-6, National Industrial Zone, RCCI, Rawat, Rawalpindi. **Sections (03)** 1. Tablet (General) 2. Capsule (General) 3. Dry Powder for Suspension (General)	**17-02-2016 Formulation**	**The Board observed that the instant case was of grant of new DML and three out of five panel members have inspected the premises; which is inappropriate practice especially in cases of new grant of DML.** **Keeping in view the above situation, Board considered and deferred the grant of DML and decided for re-inspection by following panel: -** 1. Prof. Dr. Gul Majeed Khan, Member CLB. 2. Khalid Mahmood, FID-II, DRAP Islamabad. 3. DDG-Lic, DRAP, Islamabad. 4. Mrs. Tehreem Sara, DDC (Reg) 5. Mr. Zeeshan Nazir, DDC, QA, DRAP, Islamabad. **The Board further directed the FID to avoid such practices in future.**

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

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

S#	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s MTI Medical (Pvt) Ltd, Plot No. 586-587,Sunder Industrial Estate, Raiwind Road, Lahore. DML No. 000801.	**15-10-2015** (Formulation)	**The Board approved the grant of one additional section as under:-** **Section (01)** 1. Liquid Vial Injectable (General)
2.	M/s Seatle (Pvt) Ltd, 45-KM, Multan Road, District Kasur.	**21-09-2015** **&** **23-11-2015** **(Formulation)**	**The Board approved the grant of one additional section as under:-** **Section (01)** 1. Ointment / Cream (Steroidal Topical)
3.	M/s Searle IV Solutions (Pvt) Ltd, 1.5KM, Manga Raiwind Road, Manga Mandi, District Lahore. DML No. 000586 (Formulation)	**04-02-2016** **(Formulation)**	**The Board approved the grant of two additional sections as under:-** **Sections (02)** 1. Tablet (Psychotropic) 2. Aerosol (General)
4.	M/s Getz Pharma (Pvt) Ltd, 29-30 Sector 27, Korangi Industrial Area, Karachi.	**03-02-2016** **(Formulation)**	**The Board approved the grant of one additional section as under:-** **Section (01)** 1. Metered Dose Inhalers (MDIs).
2.	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14-KM, Adyala Road, Rawalpindi. **Section (09)** 1. Pelletization Section (for in house use only) 2. Cream / Ointment / Gel (Steroidal) 3. Sterile Eye Drops (Steroidal) 4. Tablet (Hormone) 5. Cream / Ointment / Gel (Hormone) 6. Lyophilized Injectable Vials (Hormone) 7. Liquid Injection Ampoule (Hormone) 8. Oral Liquid Section (Relocation) 9. Tablet Section (general) (Extension) (Relocation)	**27-01-2016** **(Formulation)**	**The Board observed that the instant case was of grant of new additional sections and three out of five panel members have inspected the premises; which is inappropriate practice especially in cases of grant of new additional sections.** **Keeping in view the above situation, Board considered and deferred the grant of new additional sections and decided for re-inspection by following panel: -** 1. Dr. Gul Majeed Khan, Member CLB. 2. Mr. Manzoor Ali Bozdar, Director FDSL, Islamabad. 3. Mr. Khalid Mahmood, FID, DRAP, Islamabad. 4. Dr. Ikram-ul-Haq Member, CLB 5. Syed Muid Ahmed, Member, CLB **The Board further directed the FID to avoid such practices in future.**

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

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

S. No	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s Seatle (Pvt) Ltd, 45-KM, Multan Road, District Kasur. DML No. 000481	**21-09-2015 & 23-11-2015** (Formulation)	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (06)**: 1. Tablet (General) 2. Capsule (General) 3. Ointment / Cream (General Topical) 4. Tablet (Cephalosporin) 5. Capsule (Cephalosporin) 6. Dry Powder for Suspension (Cephalosporin)
2.	M/s. Ambrosia Pharmaceuticals, Plot No. S-5, Street No. 18, Street No. 9 National Industrial Zone, Rawat, Rawalpindi. DML No. 000561.	**27-01-2016 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (04)**: 1. Tablet (General). 2. Capsule (General). 3. Cream / Ointment (General). 4. Liquid Syrup (General).
3.	M/s. Seagull Surgical Cotton Bandge Industry, Tower Point, Beg Colony, Gojra Road, Jhang. DML No. 000482.	**24-11-2015 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (03)**: 1. Bandage section (open wove bandage cotton crepe bandage, surgical swabs, absorbent gauze roll). 2. Absorbent cotton wool section. 3. Grass tulle section.
4.	M/s. Guyton Pharmaceuticals, 25.5-KM Raiwind Road, Lahore. DML No. 000548.	**01-12-2015 (Formulation)**	The Board observed that the panel in its inspection report has pointed out the following observations: • That the firm did not provide segregated facility for manufacturing of human and veterinary products. • The raw material stores, dispensing facility, was common for both human and veterinary products. Manufacturing areas were not physically segregated having common utilities. • Panel noted that most of the observations of previous inspection were not properly rectified.

			• Panel also noted that though the firm has provided a dedicated section for manufacturing of cephalosporin products but the change rooms, raw material storage and dispensing facility was not proper. • It was also noted that QC laboratory was lacking some instruments / equipment required to carry out routine compendia test / analysis of registered rugs such as FTIR, Liquid Particle Counter, Karl Fischer etc. Microbiology Laboratory for testing of sterile products was also not properly equipped. • Unsatisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under in respect of: a. Liquid Injectable Section (General and Antibiotic) for human. b. Oral liquid syrup section for human. c. Cephalosporin section (dry powder injection, capsule and oral suspension) for human. d. Liquid injectable section (General and Antibiotic) for veterinary. • Over all evaluation of the inspection report rated as "un-satisfactory". Keeping in view the above observations, the Board considered, discussed and unanimously decided and deferred the renewal of DML due to above observations and suspended the production operations under Rule 13 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 in all areas of the premises for a period of three months and directed to rectify the observations of panel of inspectors. Board further constituted the following panel for inspection after intimation of rectification of above observations by the firm: 1. Dr. Ikram-ul-Haq Member CLB 2. Dr. Farzana Choudhary, Dean, UVAS, Lahore. 3. Chief Drug Controller, Punjab (Member CLB) 4. Area FID, DRAP, Lahore. 5. Ms. Saira Naeem, ADC, Lahore.

5.	M/s Star Laboratories (Pvt) Ltd, 23-KM Multan Road, Lahore. DML No. 000130.	**14-12-2015 (Formulation)**	The Board approved the renewal of DML as per recommendations of panel.
6.	M/s Intervac (Pvt) Ltd, 18-KM Sheikhupura Road, District, Sheikhupura. DML No. 000623.	**09-12-2015 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (05)**: 1. General Powder Section. 2. General Antibiotic Powder Section. 3. General Liquid section. 4. General Antibiotic Liquid Section 5. Bolus Section. Board deferred the renewal of DML for Injectable section as it was not granted at that stage. Moreover, the firm was also advised to improve GMP conditions and remove shortcomings pointed out. Board further deferred the renewal of DML for Vaccine section as panel constituted for inspection was not accompanying any Biological Expert. Board directed for re-inspection of injectable section & vaccine section after inclusion of expert in biologicals in panel of inspectors/experts. Board further directed to refer the remarks of panel regarding penicillin products to Registration Board as under: - • It was also observed that the firm has registrations of following penicillin containing products. i. Vetcolimox Powder (Reg. No. 046640) ii. Amoxy-Co Water solube powder (Reg. No. 0466541) iii. Ultra Glow Powder (Reg. No. 071034) • However, the dedicated section for penicillin was not provided, hence the firm is directed to stop manufacturing of penicillin containing products and the matter may be referred to registration Board for de-registration of products.

7.	M/s Reckitt Benkiser Pakistan Ltd, Karachi. DML No. 000022	**21-12-2015 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (03)** 1. Tablet (General). 2. Oral Liquids / Syrups (General). 3. External preparation.
8.	M/s Hisun Pharmaceutical Industries, 37-A, R-2, Industrial Estate, Gadoon Amazai, Swabi. DML No. 000624	**02-02-2016 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (06)** 1. Tablet General/ Antibiotic 2. Capsule General 3. Liquid Syrup General 4. Ointment General 5. Cephalosporin Capsule 6. Cephalosporin Dry Powder Suspension.
9.	M/s Ameer Pharma (Pvt) Ltd, 23-KM, Sheikhupura Road, Lahore. DML No. 000604	**11-01-2016 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (07)** 1. Liquid Injectable General 2. Liquid Injectable Antibiotic 3. Liquid Injectable Narcotic 4. Liquid Injectable Steroids 5. Oral Liquid General 6. Tablet General 7. Dry Powder Injectable Cephalosporin
10.	M/s Bloom Pharmaceuticals (Pvt) Ltd, Phase I&II Hattar Industrial Estate, Haripur. DML No. 000374	**13-02-2016 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (09)** 1. Capsule General 2. Tablet General 3. Tablet Psychotropic 4. Dry Powder Suspension Cephalosporin 5. Capsule Cephalosporin 6. Injectable Vial Cephalosporin 7. Sachet General 8. Cream/Ointment General 9. Liquid Syrup General
11.	M/s Searle IV Solutions (Pvt) Ltd, 1.5KM, Manga Raiwind Road, Manga Mandi, District Lahore. DML No. 000586	**04-02-2016 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (10)** 1. Large Volume Parenterals 2. Oral Liquid Syrup/Suspension 3. Tablet (General) 4. Capsule (General) 5. Sachet (General) 6. Dry Suspension (General) 7. Liquid Injectable Vial (General) 8. Liquid Injectable Ampoule (General). 9. Cream/Ointment (General) 10. Eye Drops (General)

11.	M/s Searle Company Ltd, SITE, Karachi. DML No. 000016	**11-01-2016 To 14-01-2016 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (05)**: 1. Tablet general 2. Capsule General 3. Injection Liquid Ampoule General 4. Sachet General 5. Oral Liquid General
12.	M/s Sayyed Pharmaceutical Industries (Pvt) Ltd, Hattar. DML No. 000697	**10-02-2016 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (06)** 1. Tablet General 2. Capsule General 3. Dry Powder Suspension General 4. Liquid Syrup General 5. Capsule Cephalosporin 6. Dry Powder Suspension Cephalosporin
13.	M/s Brooks Pharma (Pvt) Ltd, Plot No. 58-59,Sector 15, Korangi Industrial Area, Karachi. DML No. 000275	**02-02-2016 (Formulation)**	The Board approved the renewal of DML for following sections as per recommendations of panel: **Sections (15)** 1. Tablet General 2. Tablet Psychotropic 3. Capsule General 4. Capsule Psychotropic 5. Liquid Syrup 6. Cream/Ointment/ Gel. 7. External Preparation. 8. Sterile Liquid Injection (SVP). 9. Sterile Liquid Injection (LVP). 10. Sterile Solution (Topical) 11. Sterile Dry Powder Injection (Cephalosporin) 12. Sterile Dry Powder Injection (General) 13. Dry Powder Suspension (General) 14. Sachet (General) 15. Pellets Manufacturing Section.

Item No. V Miscellaneous Cases.

Case No.1 **INCREASE OF TECHNICAL PERSON'S EXPERIENCE FROM 3 TO 10 YEARS.**

The case was placed before the Board as under: -

Brief History:

It is submitted that the Drugs (Licensing, Registering & Advertising) Rules, 1976 were notified under S.R.O No. 145(1)/76, dated 12th February, 1976. It is further submitted that: -

- Rule 15 (c) & (e) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 provides for provisions for qualification and experience of technical staff (Production Incharge and Quality Control Incharge) for Grant or Renewal of a licence to manufacturing drugs by way of basic or semi-basic manufacture. Previously these rules required two years experience in basic or semi basic manufacturing.
- Rule 16 (c)(i)(ii)&(e) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 provides for provisions for qualification and experience of technical staff (Production Incharge and Quality Control Incharge) for Grant or Renewal of a licence to manufacturing drugs by way of Formulation. Previously these rules required three years experience for Pharmacy Degree holders and Ten years for Chemistry Degree holders.

4th meeting of DRAP Authority held on 25th April, 2013

It is submitted that previously Authority in its 4th meeting held on 25th April, 2013 has considered the said matter and decided accordingly as under:

Decision of Authority: The Authority approved the following amendment under Rule 15(C) & (e) and Rule 16 (c) & (e) of the Drugs (Licensing, Registering & Advertising) Rules, 1976:-

1. The qualification and experience of Production Incharge for semi basic and basic manufacture under rule 15(C) may be increased from **two** years to **ten** years.
2. The qualification and experience of Quality Control Incharge for semi basic and basic manufacture under rule 15(e) may be increased from **two** years to **ten** years.
3. The qualification and experience of Production Incharge for manufacturing by way of formulation as laid down under Rule 16(c) may be increase as under:-

    i. Under rule 16 (c) (i), the required experience may be increased form **three** years to **ten** years.
    ii. Under Rule 16 (c) (ii) the required experience may be increased from **ten** to **fifteen** years.
    iii. Under Rule 16 (c) (iii) the required experience may be increased from **three to ten** years.
    iv. Under Rule 16(c)(iii) the required experience for section incharge may be increased from **sufficient experience** to **not less than three years** experience.

4. The qualification and experience of Quality Control Incharge for manufacture by way of formulation under rule 16(e) may be increased from **three** years to **ten** years and in the proviso of said rules from **sufficient experience** to **ten** years.

5. Provision for availability of alternative staff in the absence of qualified staff shall also be placed in rules."

Accordingly, SRO No. 1134 (I) / dated 17th July, 2014 was notified in the light of decision of 4th DRAP Authority meeting which is in practice at present.

Request of PPMA

The above matter has been taken up by the Licensing Division on the request of PPMA and placed in 30th meeting of DRAP Authority held on 23rd December, 2015 for its consideration.

The complete case which was placed in Agenda is as under: -

Chairman, Pakistan Pharmaceutical Manufacturers Association (PPMA) in letter addressed to CEO DRAP has submitted as under: -

> "We are obliged indeed for your patient hearing to the genuine grievances / hardships of the industry facing since long presented by our delegation which met you in your office on 6th November, 2015.
>
> According to the Policy 10 years' experience personnel's are mandatory. We would like to draw your kind attention that there are more than 700 pharmaceutical units in Pakistan and industry cannot have persons with such vast experienced and it is hardly to find out.
>
> Therefore, it is humbly requested to kindly reduce the experience from 10 years to 5 years."

Decision of Authority taken in its 30th meeting:

> "Division of Licensing was advised to prepare a working paper on the matter of experience required for appointment of technical person in the pharmaceutical industry; keeping in view of the reservations of the PPMA on the subject issue regarding difficulties for finding a pharmacist with ten years' experience; which is leading to non-compliance and court cases and according to them that may ultimately cause shortages of drugs. The subject agenda items shall be placed before the Licensing Board for its evaluation and recommendation and thereafter shall be brought before the Authority, as required. The agenda item may be evaluated in line with practices followed in regional countries and WHO guidelines / recommendations, if available in the subject matter".

The minutes of the 30th meeting of the Authority have been received in the Licensing Division on 30-12-2015 and the action has been initiated accordingly.

Recommendations of Senate Standing Committee on National Health Services Regulations and coordination: The said committee in its meeting held on 06th January, 2016 has given following recommendation:

"The Committee recommended that requirement of experience for appointment of technical persons in licensed pharmaceutical industries should be five to six years."

A meeting of PPMA with Honorable Minister of State was held 10-02-2016 in which following instructions were passes on:

"The decrease in required experience for qualified person for license from 10 years to 5 years to be implemented as already decided."

Decision of CLB:

Keeping in view the back ground of case, directions of DRAP Authority and recommendations of Senate Standing Committee on National Health Services Regulations and Coordination; the Board approved following recommendations for consideration of Authority and onward amendments in relevant rules accordingly: -

Existing Rules/Experiences	Recommendations of CLB
The experience of Production Incharge for semi basic and basic manufacture under rule 15(c) is **ten** years.	The experience of Production Incharge for semi basic and basic manufacture under rule 15(c) may be decreased from **ten** years to **eight** years.
The experience of Quality Control Incharge for semi basic and basic manufacture under rule 15(e) is **ten** years.	The experience of Quality Control Incharge for semi basic and basic manufacture under rule 15(e) may be decreased from **ten** years to **eight** years.
The experience of Production Incharge for manufacturing by way of formulation as laid down under Rule 16(c)(i) is **ten** years.	The experience of Production Incharge for manufacturing by way of formulation as laid down under Rule 16(c)(i) may be decreased from **ten** years to **six** years.
Rule 16 (c)(ii): a masters degree in science with chemistry or pharmaceutical chemistry as the principal subject who has not less than **fifteen** years practical experience in the manufacture of drugs intended to be manufactured, knowledge of pharmacy which, in the opinion of Central Licensing Board, is adequate for the purpose; or	Rule 16 (c)(ii) shall be omitted.
Under Rule 16 (c) (iii) the required experience is **ten** years.	Under Rule 16 (c) (iii) the required experience may be decreased from **ten** years to **six** years. In sub-clause (iii) of Rule 16 (c), for the word "medicine", the words "pharmacy or microbiology or biotechnology" shall be substituted;
The experience of Quality Control Incharge for manufacture by way of formulation under rule 16(e) is **ten** years.	The experience of Quality Control Incharge for manufacture by way of formulation under rule 16(e) may be decreased from **ten** years to **six** years.
"Provided further that there shall be a separate incharge for the in process control of the drugs being manufactured who shall possess a degree in pharmacy or a masters degree in chemistry, with sufficient experience."	"Provided further that there shall be a separate **Quality Assurance** incharge for the in process control of the drugs being manufactured who shall possess a degree in pharmacy or a masters degree in chemistry, with **eight years** experience."

Case No.2 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000481 (FORMULATION) ADDITIONAL SECTION AND REGULARIZATION OF MATER LAYOUT PLAN.**

QC LABORATORY SHIFTED FROM GROUND FLOOR TO FIRST FLOOR, DEDICATED PACKING HALL FOR CEPHALOSPORIN AND SEPARATE ENTRY TO CEPHALOSPORIN SECTION.

The case was placed in the agenda as under: -

M/s Seatle (Pvt) Ltd, 45-km, Multan Road, District Kasur DML No. 000481 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were being licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

S.#	Sections	S.#	Sections
1.	Tablet (General)	2.	Capsule (General)
3.	Ointment / Cream (Steroidal Topical)	4.	Ointment / Cream (General Topical)
5.	Tablet (Cephalosporin)	6.	Capsule (Cephalosporin)
7.	Dry Powder for Suspension (Cephalosporin)		

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

1. Mr. Ayyaz Ali Khan, Chief Operating Officer, PDTRC, Sunder Industrial Estate, Lahore.
2. Dr. Zaka-ur-Rehman, Chief Drug Controller, Punjab.
3. Miss Aisha Irfan, FID, DRAP, Lahore.
4. Abdul Rashid Shaikh, FID, DRAP, Lahore

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

Recommendations: -

For regularization;

In the light of above, the panel experts is of the opinion to recommend the grant of Cream/ Ointment Steroidal (Topical) Section as an additional section to the M/s Seatle (Pvt) Ltd, 45-KM, Multan Road, District Kasur. The panel also recommends the renewal of Drug Manufacturing License by way of formulation and regularization of the layout plan for the above sections:-

For QC Laboratory;-

The firm has established Quality Control and Quality Assurance Department on the first floor of the premises. The QC department is newly constructed.

Decision of CLB:

The Board considered and approved the regularization of above sections of M/s. Seatle (Pvt) Ltd, 45-KM, Multan Road, District Kasur and QC Laboratory on first floor of the premises.

Case No.3 **CHANGE OF THE MANAGEMENT OF M/S. EPLA LABORATORIES (PVT) LTD, D-12, ESTATE AVENUE SITE, KARACHI, DML NO.000071 (FORMULATION).**

The case was placed in the agenda as under: -

M/s. Epla Laboratories (Pvt) Ltd, D-12, Estate Avenue SITE, Karachi, DML No.000071 (Formulation) has applied for change of management with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad.

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

Old Management	Retiring Management	New Management
1. Dr. Muhammad Haroon Siddiqi S/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-8277304-9. 2. Dr. Muhammad Tariq Siddiqi S/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-0170196-5. 3. Mrs. Farhat Haroon Siddiqi W/o Dr. Muhammad Haroon Siddiqi. CNIC No.42301-0835333-2. 4. Dr. (Mrs.) Ghazala Tariq Siddiqi W/o Dr. Muhammad Tariq Siddiqi. CNIC No.42301-6657966-8. 5. Ms. Mahvash Tariq Siddiqi D/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-099766-4. 6. Mr. Adil Haroon Haroon S/o Dr. Muhammad Haroon Siddiqi. CNIC No.42301-0957938-7.	1. Dr. (Mrs.) Ghazala Tariq Siddiqi W/o Dr. Muhammad Tariq Siddiqi. CNIC No.42301-6657966-8. 2. Mrs. Farhat Haroon Siddiqi W/o Dr. Muhammad Haroon Siddiqi. CNIC No.42301-0835333-2. 3. Mr. Adil Haroon Haroon S/o Dr. Muhammad Haroon Siddiqi. CNIC No.42301-0957938-7.	1. Dr. Muhammad Haroon Siddiqi S/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-8277304-9 2. Dr. Muhammad Tariq Siddiqi S/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-0170196-5 3. Ms. Mahvash Tariq Siddiqi D/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-0997066-4

Decision of CLB:

The Board considered and approved the change of management from old management to new management as under: -

Old Management	**Retiring Management**	**New Management**
1. Dr. Muhammad Haroon Siddiqi S/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-8277304-9. **2. Dr. Muhammad Tariq Siddiqi S/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-0170196-5.** **3. Mrs. Farhat Haroon Siddiqi W/o Dr. Muhammad Haroon Siddiqi. CNIC No.42301-0835333-2.** **4. Dr. (Mrs.) Ghazala Tariq Siddiqi W/o Dr. Muhammad Tariq Siddiqi. CNIC No.42301-6657966-8.** **5. Ms. Mahvash Tariq Siddiqi D/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-099766-4.** **6. Mr. Adil Haroon Haroon S/o Dr. Muhammad Haroon Siddiqi. CNIC No.42301-0957938-7.**	**1. Dr. (Mrs.) Ghazala Tariq Siddiqi W/o Dr. Muhammad Tariq Siddiqi. CNIC No.42301-6657966-8.** **2. Mrs. Farhat Haroon Siddiqi W/o Dr. Muhammad Haroon Siddiqi. CNIC No.42301-0835333-2.** **3. Mr. Adil Haroon Haroon S/o Dr. Muhammad Haroon Siddiqi. CNIC No.42301-0957938-7.**	**1. Dr. Muhammad Haroon Siddiqi S/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-8277304-9** **2. Dr. Muhammad Tariq Siddiqi S/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-0170196-5** **3. Ms. Mahvash Tariq Siddiqi D/o Dr. Ehtisham Ali Siddiqi (Late). CNIC No.42301-0997066-4**

Case No.4 **CHANGE OF THE MANAGEMENT OF M/S PDH LABORATORIES (PVT) LTD, 9.5-KM, SHEIKHUPURA ROAD (KHAKI) LAHORE, DML NO.000039 (FORMULATION).**

The case was placed in the agenda as under: -

M/s. PDH Laboratories (Pvt) Ltd, 9.5-KM, Sheikhupura Road (Khaki) Lahore, DML No.000039 (Formulation) has applied for change of management with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad.

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

Old Management	Retiring Management	New Management (As per Form 29 of S.E.C.P)
1. Mr. Sheikh Muhammad Ilyas. 2. Mr. Mohsin Ilyas. 3. Mr. Ghulam Mustafa. 4. Mr. Gohar ellahi. 5. Mr. Aftab Altaf. 6. Mr. Jamil Altaf.	1. Mr. Gohar Ellahi 2. Mr.Aftab Altaf. 3. Mr. Jamil Altaf.	1. Mr. Sheikh Muhammad Ilyas CNIC No.35202-4809282-7. 2. Mr. Mohsin Ilyas CNIC No.35202-9998661-7. 3. Mr. Ghulam Mustafa CNIC No.35202-8602732-3.

Decision of CLB:

The Board considered and approved the change of management from old management to new management as under: -

Old Management	**Retiring Management**	**New Management (As per Form 29 of S.E.C.P)**
1. Mr. Sheikh Muhammad Ilyas. **2. Mr. Mohsin Ilyas.** **3. Mr. Ghulam Mustafa.** **4. Mr. Gohar ellahi.** **5. Mr. Aftab Altaf.** **6. Mr. Jamil Altaf.**	**1. Mr. Gohar Ellahi** **2. Mr.Aftab Altaf.** **3. Mr. Jamil Altaf.**	**1. Mr. Sheikh Muhammad Ilyas CNIC No.35202-4809282-7.** **2. Mr. Mohsin Ilyas CNIC No.35202-9998661-7.** **3. Mr. Ghulam Mustafa CNIC No.35202-8602732-3.**

Case No.5 **CHANGE OF THE MANAGEMENT OF M/S PDH PHARMACEUTICALS (PVT) LTD, 19-KM, FEROZEPUR ROAD LAHORE, DML NO.000459 (FORMULATION).**

The case was placed in the agenda as under: -

M/s. PDH Pharmaceuticals (Pvt) Ltd, 19-KM, Ferozepur Road Lahore, DML No.000459 (Formulation) has applied for change of management with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad.

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

Old Management	Retiring Management	New Management (as per Form-29 of S.E.C.P)
1. Mr. Aftab Altaf. 2. Mr. Jameel Altaf. 3. Mr. Gohar Ellahi. 4. Sh. Muhammad Ilyas 5. Mr. Mohsin Ilyas 6. Mr. Ghulam Mustafa.	1. Mr. Muhammad Ilyas. 2. Mr. Muhsin Ilyas 3. Mr.Ghulam Mustafa 4. Mr.Jameel Altaf	1. Mr. Aftab Altaf CNIC No.35202-3977191-7. 2. Gohar Ellahi CNIC No.35202-6003549-5.

Decision of CLB:

The Board considered and approved the change of management from old management to new management as under: -

Old Management	**Retiring Management**	**New Management (as per Form-29 of S.E.C.P)**
1. Mr. Aftab Altaf. **2. Mr. Jameel Altaf.** **3. Mr. Gohar Ellahi.** **4. Sh. Muhammad Ilyas** **5. Mr. Mohsin Ilyas** **6. Mr. Ghulam Mustafa.**	**1. Mr. Muhammad Ilyas.** **2. Mr. Muhsin Ilyas** **3. Mr.Ghulam Mustafa** **4. Mr.Jameel Altaf**	**1. Mr. Aftab Altaf CNIC No.35202-3977191-7.** **2. Gohar Ellahi CNIC No.35202-6003549-5.**

Case No.6 **CHANGE OF THE MANAGEMENT OF M/S SAYYED PHARMACEUTICALS (PVT) LTD, PLOT NO. 72/3 PHASE-3, INDUSTRIAL ESTATE, HATTAR DML NO.000697 (FORMULATION).**

The case was placed in the agenda as under: -

M/s. Sayyed Pharmaceuticals (Pvt) ltd, Plot No. 72/3 Phase-3, Industrial Estate, Hattar, DML No.000697 (Formulation) has applied for change of management with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad.

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

Old Management	Retiring Management	New Management (As per Form -29 of S.E.C.P)
1. Syed Muhammad Tahir CNIC NO. 17301-4464026-7. 2. Syed Muhammad Qasim CNIC No. 17301-1250801-5 3. Syed Muhammad Zahid CNIC No. 17301-11250803-3 4. Mr. Nasim Mohammad CNIC No. 161016-350877-5	1. Mr. Nasim Muhammad	1. Syed Muhammad Tahir CNIC No. 17301-4464026-7. 2. Syed Muhammad Qasim CNIC No. 17301-1250801-5. 3. Syed Muhammad Zahid CNIC No. 17301-1250803-3.

Decision of CLB:

The Board considered and approved the change of management from old management to new management as under: -

Old Management	Retiring Management	New Management (As per Form -29 of S.E.C.P)
1. Syed Muhammad Tahir CNIC NO. 17301-4464026-7. **2. Syed Muhammad Qasim CNIC No. 17301-1250801-5** **3. Syed Muhammad Zahid CNIC No. 17301-11250803-3** **4. Mr. Nasim Mohammad CNIC No. 161016-350877-5**	**1. Mr. Nasim Muhammad**	**1. Syed Muhammad Tahir CNIC No. 17301-4464026-7.** **2. Syed Muhammad Qasim CNIC No. 17301-1250801-5.** **3. Syed Muhammad Zahid CNIC No. 17301-1250803-3.**

Case No.7 **CHANGE OF THE MANAGEMENT OF M/S HIGHNOON LABORATORIES LTD, 17.5, KM, MULTAN LAHORE , DML NO.000155 (FORMULATION).**

The case was placed in the agenda as under: -

M/S Highnoon Laboratories Ltd, 17.5, KM, Multan Lahore, DML No.000155 (Formulation) has applied for change of management with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad.

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

Old Management	Retiring Management	New Management
1. Mr. Jawaid Tariq Khan (Chairman) 2. Mir Tausif Ahmad Khan (Vice Chairman) 3. Mr. Anees Ahmad Khan (Vice Chairman) 4. Mr. Aslam Hafiz (MD) 5. Mr. Ghulam Hussain Khan 6. Mian Muhammad Ashraf 7. Mrs Nosheen Riaz Khan 8. Mrs. Zainub Abbas	1. Mr. Jawaid Tariq Khan 2. Mr. Aslam Hafiz 3. Mian Muhammad Ashraf 4. Mrs. Nosheen Riaz	1. Mr. Tausif Ahmad Khan CNIC No. 35202-5478882-7. 2. Mrs. Zainub Abbas CNIC No. 35202-2649546-6. 3. Mr. Adeel Abbas Haideri CNIC No. 35201-9490548-1. 4. Mr. Anees Ahmad Khan CNIC No. 35202-2392890-5. 5. Mr. Ghulam Hussain Khan CNIC No. 35201-3787935-7. 6. Mr. Shazib Masud CNIC No. 35202-0873913-7. 7. Mr.Taufiq Ahmad Khan CNIC No.35201-9273258-3

Decision of CLB:

The Board considered and approved the change of management from old management to new management as under: -

Old Management	Retiring Management	New Management
1. Mr. Jawaid Tariq Khan (Chairman) **2. Mir Tausif Ahmad Khan (Vice Chairman)** **3. Mr. Anees Ahmad Khan (Vice Chairman)** **4. Mr. Aslam Hafiz (MD)** **5. Mr. Ghulam Hussain Khan** **6. Mian Muhammad Ashraf** **7. Mrs Nosheen Riaz Khan** **8. Mrs. Zainub Abbas**	**1. Mr. Jawaid Tariq Khan** **2. Mr. Aslam Hafiz** **3. Mian Muhammad Ashraf** **4. Mrs. Nosheen Riaz**	**1. Mr. Tausif Ahmad Khan CNIC No. 35202-5478882-7.** **2. Mrs. Zainub Abbas CNIC No. 35202-2649546-6.** **3. Mr. Adeel Abbas Haideri CNIC No. 35201-9490548-1.** **4. Mr. Anees Ahmad Khan CNIC No. 35202-2392890-5.** **5. Mr. Ghulam Hussain Khan CNIC No. 35201-3787935-7.** **6. Mr. Shazib Masud CNIC No. 35202-0873913-7.** **7. Mr.Taufiq Ahmad Khan CNIC No.35201-9273258-3**

Case No.8 **CHANGE OF STATUS OF M/S SEATLE PHARMA PAKISTAN (PVT) LTD, LAHORE, DML NO.000481 (FORMULATION).**

The case was placed in the agenda as under: -

M/s Seatle Pharma Pakistan (Pvt) Ltd, 45-KM Multan Road, Lahore, DML No.000481 (Formulation) has applied for change of status with a fee of Rs.50,000/- duly retained by Statistical Officer DRAP Islamabad as under:-

Present name (AS PER FORM-29)	New name (AS PER FORM-29)
M/s. Seatle Pharma Pakistan (Pvt) Ltd, 45-KM Multan Road, Lahore	M/s. Seatle (Pvt) Ltd, 45-KM Multan Road, Lahore

Decision of CLB:

The Board considered and approved the change of name/title of the firm from M/s. Seatle Pharma Pakistan (Pvt) Ltd. 45-KM Multan Road, Lahore to M/s. Seatle (Pvt) Ltd. 45-KM Multan Road, Lahore.

Case No. 9 RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S MARION LABORATORIES (PRIVATE) LIMITED, D-43, TEXTILE AVENUE, S.I.T.E, KARACHI.

The case was included in the agenda as under: -

BACKGROUND OF THE CASE: -

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

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

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

(v) Copy of latest form 29 issued and attested by Security Exchange commission of Pakistan along with CNIC photocopies of all directors.
(vi) An undertaking on letter head of the firm signed by all directors of the firm stating that all information/ documents provided with application of renewal of Drug Manufacturing License is complete and correct and management of firm shall be responsible for hiding or providing wrong information.
(vii) Nothing Due certificate issued by Statistical Officer , DRAP, Islamabad, regarding deposition of Central Research fund up to 31-12-2015.

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

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

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

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

Decision of the Board (M-241):

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

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

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

Licensing Division apprised the Board that the statement of firm's representative was not correct as the firm has received the Show Cause notice and also submitted but the information desired is skill lacking. It was added that the letter for personal hearing of the instant meeting of the Board was not sent through ordinary mail but dispatched to the firm through TCS.

Decision of CLB (M-243):

The Board after thorough discussion of the said situation unanimously decided and deferred the matter with final opportunity of Personal Hearing. Board further advised to obtain the tracking of TCS as to verify the claim of firm's representative.

Decision of CLB:

Keeping in view the facts of the case, the Board considered and deferred the matter with final opportunity of Personal Hearing. Board further directed to deliver personal hearing letter through area FID and Courier before one week of CLB meeting.

Case No. 10 ORDERS OF HONORABLE LAHORE HIGH COURT, LAHORE REGARDING WRIT PETITION NO. 10988/2007 FILED BY M/S MICKO INDUSTRIAL CHEMICALS CO. (PRIVATE) LIMITED, 28-KM FEROZEPUR ROAD, LAHORE.

The case was included in the agenda as under: -

Background of the case: -

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

M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore submitted application for renewal of DML # 000183 (Formulation) for the period 17-11-2005 to 16-11-2010 for which a panel was constituted on 23-09-2005 for inspection of the firm comprising of following experts / inspectors:-

1. Dr. Ijaz Ahmad, Associate Professor, University of Veterinary and Animal Sciences, Lahore.
2. Area Federal Inspector of Drugs, DCA, Lahore
3. Area Assistant Drugs Controller, DCA, Lahore

The above mentioned panel conducted inspection of the firm for renewal of DML and submitted report on 17-08-2006 wherein panel stated that overall condition of the firm was good. The firm had given undertaking that they would remove the shortcomings pointed out within 15 days. Therefore, the panel is of the opinion that firm may be granted renewal of their Drug Manufacturing License by way of formulation and re-packing.

After receipt of inspection report in this office, the then ADC (L & A) issued a letter to Federal Inspector of Drugs, DCA, Lahore, he stated that firm had submitted an under taking to the panel to rectify the shortcomings as pointed out by the panel, but the compliance report concerning the same had not been received so far therefore area FID was requested to verify the same and submit report within 07 days positively.

The area Federal Inspector of Drugs inspected the premises on 31-10-2007, along with Mr. Ghazanfar Ali Khan, ADC, Lahore to check the rectification of shortcomings pointed out during inspection dated 20-07-2006. The area FID submitted inspection report wherein a number of serious GMP non-compliance were reported and she suggested that production of the firm be stopped and renewal of DML may not be considered in light of critical shortcomings and failure of commitment given by the firm to remove the deficiencies pointed out by the panel during previous inspection.
The area FID sealed the factory and on the form of sealing of the factory she stated that *M/s Micko Industrial Chemicals , 28-km Ferozepur Road, Lahore is sealed due to the violation of Section 27(3) of the Drugs Act, 1976 and various other provisions of the Drugs Act, 1976 and rules framed there under . The owner Mr. Khursheed Alam snatched the samples of drugs taken for the purpose of test analysis from driver Ismail with Form 3. FIR was launched in police station, Kahana and the factory is sealed in the presence of Mr. Ghazanfar, ADC, Javed Iqbal, ASI and Tahir Iqbal, Head Constable .*

The firm was then served a Show Cause Notice on 19th November 2007 by the then Secretary CLB and directed to submit reply of the show cause within 15 days.

A letter dated 17-11-2007 was again received from Ms. Aisha Khalil, the then area FID wherein she informed that owner of the firm had challenged the legal process of panel and the accused Mr. Khurshid Alam Sheikh filed a writ petition No. 10988/2007 in Honorable Lahore High Court Lahore through his counsel requesting the Court to declare the sealing order illegal and for award of cost incurred on this petition. Mr. Justice Syed Hamid Ali Shah issued a one sided interin order dated 07-11-2007 hence suspended the sealing order of panel without hearing the panel, till next hearing and ordered for submission of reply and parawise comments in this regard.
In compliance of court order dated 07-11-2007 she along with Mr. Ghazanfar Ali Khan ADC visited the premises on 14-11-2007 to de-seal the factory and found that the seals were broken by the owner and production of drugs was in process. The position was also brought in to the kind notice of Honorable Court vide etter No. 9067/2007-DCA (L-II) dated 14-11-2007.
On 05th December 2007, a letter was issued to the firm from this office by the then Secretary CLB wherein it was stated that refer to the panel inspection report of the firm conducted by area FID Lahore on 14-11-2007 wherein it was reported that production was in-progress while the conditions of renewal of DML have not been fulfilled as reported by the panel during inspection conducted on 30-10-2007. As this is an offence under Rule 13 of the Drugs (Licensing, Registering & Advertising) Rules 1976, therefore, firm was directed to suspend the production with immediate effect till removal of the deficiencies and re-inspection by a panel and approval of Central Licensing & Registration Board.

Recently, On 23-04-2015, a letter was received from Assistant Registrar , wherein he forwarded the order sheet of Honorable Lahore High Court, Lahore for the Writ Petition # 10988/2007 & 11839/2007. The contents of the order sheets are as under:-

Mr. Bashir Ahmad Tariq, Advocate for the Petitioner.
Ms. Saadia Malik, learned Standing Counsel for Pakistan along with Ayesha Irfan, Federal Inspector Drugs.

Through this single order I intend to dispose of writ petition Nos. 10988 and 11889 of 2007 as both are based on common facts.

2. In W.P NO. 10988/2007 order dated 30-10-2007 is challenged whereby the factory of the petitioner was sealed for violation of Section 27 (3) and other provisions of the Drugs Act, 1976 and also for the reason that owner of the factory namely Khurshid Alam Sheikh had snatched samples taken from the factory premises by the Federal Drug Inspector.
In other writ petition No. 11889/2007 order for suspension of production is challenged.

3. Facts, which have surfaced after arguments from both sides, are that he inquiry report was being prepared by the Federal Drug Inspector when samples of some illegal drugs were allegedly snatched by the owner of the factory. Statedly, due to violation of the statutory provisions and the illegal act by the owner, the factory premises were sealed. As per learned Standing Counsel's assertions, the factory was de-sealed illegally and production was commenced by the petitioner, therefore, another order for suspension of production was passed.

4. Due to multiplicity of litigation, facts of the case are confused. It is asserted by the petitioner that its factory is sealed and production is suspended whereas learned Standing Counsel submits that the production is being carried out illegally at the sealed premises.

5. Be that as it may, it is settled proposition that this Court cannot look into factual controversies in exercise of its constitutional jurisdiction. For resolution of dispute on facts as well as on legal side, this matter is referred to Central Licensing Board, before which report has already been filed by the Federal Drugs Inspector. The Board shall provide opportunity of being heard to the petitioner and shall pass a speaking order within 45 days positively under intimation to the Deputy Registrar (Judicial) of this Court.
Till decision no coercive measures shall be taken

RECORD AND STATUS OF FIRM IN LICENSING DIVISION

The five years tenure of renewal of DML of the firm for the period 17-11-2005 to 16-11-2010 has been expired without any further orders by Central Licensing Board.
Afterwards, firm submitted application for renewal of DML of the firm for the next five years i.e. from 17-11-2010 to 16-11-2015 for which a panel of experts/inspectors was constituted on 10th March 2011 comprising of following members:-

1. Dr. Farzana Chaudhary, (Member DRB) Director IPS University ad Animal Sciences, Lahore
2. Dr. Noor Muhammad Shah, Deputy Director General (L & A), Islamabad.
3. Dr. Sheikh Akhtar Hussain, Deputy Director General (E & M), DCA, Lahore
4. Area Federal Inspector of Drugs, DCA, Lahore.

The report of the above mentioned panel is still awaited.

It is also submitted here that Ms. Aisha Irfan, Area Federal Inspector of Drugs also updated Licensing Division about the recent orders passed by Honorable Court and case background. she stated that all the action taken by her on the directions of the Central Licensing & Registration Board and as per the Drugs Act, 1976 and rules framed there under, hence, no malafide intentions were involved, and the actions were taken in Good Faith by her. She also requested that she may also be provided with an opportunity to present this case in Central Licensing Board personally.

Therefore, the case is placed before the Licensing Board as per orders of the High Court for further directions in the matter.
The firm, M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore and Ms. Aisha Irfan, FID, DRAP, Lahore were called for personal hearing.

Proceedings of the case:

Licensing Division, DRAP apprised the Board that the order sheet of the Honorable Court was received in the Secretariat of the Licensing Division in late hours at Friday on 08th May 2015.

After receipt of the orders of the Honorable Court, Licensing Division processed the case on 11th May 2015 and after approval from competent Authority, letter for personal hearing was issued through Courier to the firm on 13th May 2015.

Area Federal Inspector of Drugs, DRAP, Lahore was contacted telephonically to deliver the copy of the letter of personal hearing to the firm in person but she informed that she couldn't deliver letter because she was at hospital for treatment of illness of his father and her assistant may also not deliver the letter to the firm in person because she is a female. After that, Deputy Director General (E&M), DRAP, Lahore was requested on 14th May 2015 to depute a person from his

office who shall deliver letter to the management of the firm by hand. Accordingly, Mr. Shahid Mehmood, LDC, DRAP, Lahore was sent to deliver the letter of personal hearing to the firm, by hand.

When he reached the location of the firm and contacted the person, Mr. Shoib (son of the owner of the firm) opened the gate and viewed the letter and requested him to be seated so that he may contact his father (Owner of the firm) before receiving the letter.

After half an hour, he came and refused to receive letter of personal hearing from him and stated that his father is not in the factory and currently outside the city. Mr. Shahid Mehmood also given in writing the conversation.

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

Decision of the Board:
The Board after thorough discussion and deliberation decided:-

1. *To provide another opportunity of personal hearing to the firm.*
2. *To deliver letter of personal hearing to the firm by registered post/UMS/ through courier.*
3. *To submit an interim report for the appraisal of Honorable Court, regarding current status of the case in the Central Licensing Board.*

Accordingly, above decision of the Board was conveyed to the firm and letter for personal hearing was issued, please.

Proceedings:
The Board was apprised that the letter for personal hearing was sent to the firm via TCS but no any representative of firm is present for personal hearing.

Decision of CLB (M-243):

Keeping in view the facts of the case, the Board unanimously decided for final opportunity of personal hearing. The Board further directed that letter of personal hearing be sent through TCS, Registered AD, Area FID and also email (if email available). The Honorable Court may again be apprised of the status of the case.

Further Proceedings.
Mr. Khurshid Alam Sheikh, Director Admin for M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore informed the Licensing Division vide letter No. 37/Micko-Lahore dated 01-11-2015 that the orders of single judge in chamber of Lahore High Court dated 23-04-2015 have been challenged before the Division Bench by way of filing inter Court No. 653 & 655, of 2015 and informed that there is hardly any need for personal hearing of the above cases. It is therefore, requested that the matter may be please be protracted till the final disposal of said appeals.

M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore has filed Inter Court Appeal against the judgment passed on W.P. NO. 10/988/2007 in the Honorable Lahore High Court Lahore. The orders of the Honorable Court is as under: -

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

Proceedings:

The Board was apprised of the background of the case and further apprised that M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore had filed Intra Court Appeal against the judgment passed on W.P. NO. 10/988/2007 in the Honorable Lahore High Court Lahore. The orders of the Honorable Court are as under: -

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

The Board was further apprised that after the decision of Intra Court Appeal, M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore has requested for processing the case in the light of previous decision of Honorable Court against writ petition Nos. 10988 and 11889 of 2007.

Decision of CLB:

Keeping in view the facts of the case, the Board unanimously considered and decided for personal hearing of the firm in the light of decision of Honorable Court against writ petition Nos. 10988 and 11889 of 2007.

Case No.11 RENEWAL OF M/S SAFINA PHARMACEUTICALS (PVT) LTD, 17-KM, LAHORE SHEIKHUPURA ROAD, LAHORE.

The case was included in the agenda as under: -

M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km Lahore Sheikhupura Road, Lahore has applied for Renewal DML No. 000654 (Formulation) for the period of 30-01-2014 to 29-01-2019. On scrutiny of documents, it has been noticed that firm has submitted the prescribed fee of Rs.50,000/- for renewal of DML on 11-02-2014. The due date for renewal of DML was 29-01-2014 as verified from previous copy of DML. According to date of submission of prescribed fee i.e. 11-02-2014, the application is delayed by 13 days with regard to period of validity of the license. Thus according to Rule 6 of Drugs (Licensing, Registering & Advertising) Rules 1976, firm is required to pay a total surcharge of Rs.65000/- with respect to 5000/- surcharge for each day the application is delayed.

It is further submitted that firm was also informed to deposit additional surcharge of Rs.65000/- (sixty five thousand) for submitting application of renewal for DML 13 days delayed from the due date of renewal but firm has not yet deposited the required fee of additional surcharge.

The application for renewal of DML is still incomplete with respect to the following shortcomings:

i). Noting Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of Central Research Fund valid up to 31-12-2015.

ii). Deposit additional surcharge of Rs.65000/- for submitting application of renewal of DML delayed by 13 days from due date of renewal.

iii). Documents of proposed Production are still incomplete as not according to checklist.

a. The experience of production in-charge is less than 10 years and does not meet the rules 16 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

Decision of CLB (M-243):

The Board after considering all facts on record, decided to issue a Show Cause Notice with personal hearing to the firm.

Proceedings:
Mr. Muhammad Nadeem, Chief Executive of the firm and his assistant Muhammad Waqas Afzal appeared before the Board for presenting their case before the Board. Chief Executive said that he will be complying the above shortcomings by today i.e. 22nd Feb, 2016.

Decision of CLB:

Keeping in view the above situation, the Board discussed and decided for further processing of the application of firm for renewal of DML by Licensing Division after fulfilment of shortcomings as committed by firm's Chief Executive Mr. Muhammad Nadeem.

Case No. 12 M/S ELIXIR LABORATORIES (PVT) LTD., 26-S, INDUSTRIAL AREA, KOT LAKHPAT, LAHORE AREA SHORT.

The case was placed in the agenda as under: -

The case was placed the Board as under: -

M/s Elixir Laboratories (Private) Limited located at 26-S, Industrial Area, Kot Lakhpat, Lahore submitted application for renewal of DML # 000288 (Formulation) of their firm for the period 07-09-2014 to 06-09-2019 which was received in this Secretariat of Licensing Division DRAP on 18-09-2014. The application of renewal of DML was 11 days delayed from its due date of renewal of DML.

Following shortcomings were noticed in application of renewal of DML of the firm which were conveyed to the firm vide letter dated 14th January 2015.

i. To deposit additional surcharge of Rs. 55000/- according to Rule 6 of Drugs (Licensing, Registering & Advertising) Rules 1976 for submitting application for renewal of Drug Manufacturing License of your firm on 18th September 2014, which is delayed by 11 days from the due date i.e. 07th September 2014.

ii. To furnish documents/ information of production and Q.C Incharge as per checklist enclosed herewith. The experience and qualification of proposed technical experts shall meet the requirement of Rule 16 of Drugs (Licensing, Registering & Advertising) Rules 1976. *All documents/information should be attested by gazette officer or notary public and shall be signed by authorized person of the firm also.*

iii. In inspection report of firm dated 26-03-2011, the management of the firm reiterated that they are under the active process of shifting the unit to Sunder Industrial Estate and the construction of the basement has been completed. In this regard firm was directed to furnish Plot Allotment, Plot possession letter, plot demarcation, site verification report of area Federal Inspector of Drugs, Site approval letter from competent authority, layout plan approval from competent authority & necessary supported documents for the plot in Sundar Industrial Estate for the purpose of shifting of licensed unit

iv. It has been further noticed during scrutiny of application of renewal of DML that firm has included 03 more directors in management and one of the existing director i.e. Mrs. Ayesha Nadeem has resigned from directorship as reflected from Form 29 issued by SECP. Therefore firm was required to furnish application of change of management of the firm with following information/documents.
    a) To deposit prescribed fee of Rs. 50,000/- and submit the retained copy of challan in this division.
    b) To furnish the photocopies Form A, Form 29, Form 21, Certificate of Incorporation and Memorandum of Association issued and attested by Security Exchange Commission of Pakistan.
    c) To furnish copy of agreement/deed of 03 new directors with the existing directors.

Firm submitted the reply of the letter issued from this Division on 14th January 2015 where in shortcomings in the application for renewal of DML of the firm were conveyed according to Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rules 1976.

It was advised to the firm in the letter of this Division according to Rule 6 of the Drugs (Licensing, Registering & Advertising) Rules 1976, to deposit additional surcharge of Rs.

55000/- for submission of application of renewal of DML, addressed to Secretary CLB on 18th September 2014 which was 11 days delayed from due date of renewal i.e. 07th September 2014. But firm in their reply stated that renewal fee was deposited on 2nd September 2014 within the stipulated time and receipt deposit slip (DRAP) enclosed with renewal application was subsequently dispatched to DRAP (Licensing Board) through Courier (TCS) on 09th September 2014. Copy of Courier slip is enclosed and at (Page 249/Corr.).

It is pertinent to mention here that it is clear in Rule 5 of the Drugs (Licensing, Registering & Advertising) Rules 1976 that application for renewal of DML shall be made on prescribed For 1A to the Central Licensing Board through its Secretary.

In this regard, the application of renewal of DML of the firm on prescribed Form 1-A, was received in DRAP via Diary No. 94 R & I dated 18-09-2014 which is the actual date of receipt of application, delayed by 11 days from the due date.

Furthermore, in the letter issued from this Division, firm was also advised to deposit prescribed Fee of Rs. 50,000/- along with other documents, for change in management of the firm but firm has not deposited the prescribed fee and stated in their reply that firm has informed to Security Exchange Commission of Pakistan and accordingly Form A and Form 29 were initiated and forwarded to SECP with required fee as per law.

Firm was also advised to provide details of the documents for their new plot to fulfill the requirement of the rules because existing unit is of 01 kanal and 04 marlas area which is less than the minimum area i.e. 2000 square yards. In their reply, it is stated that for the time being it is not possible to shift the unit to their new plot due to change in management and handing over to the said property to relieving partner. Firm stated that they are working on various alternate options and soon apprise this office about the actual schedule.

It is to bring in notice that firm has committed for shifting of their unit since March 2011 and now more than 04 years have been passed but still firm is in strategy to delay it further.

Decision of CLB (M-241)

The Board after thorough discussion and deliberations decided for Show Cause with Personal Hearing.

Proceedings of meeting:

Mr. Ishtiaq Khan, Chief Executive of the firm appeared for presenting their case before the Board. Chief Executive said that he will be complying the above shortcomings at the earliest.

Board reiterated that firm shall continue its activities but under the rules.

Decision of CLB:

Keeping in view the above situation, the Board discussed and decided for further processing of the application of firm for renewal of DML by Licensing Division after fulfilment of shortcomings as committed by firm's Chief Executive Mr. Ishtiaq Khan.

Case No.13 THE STATE VERSUS M/S MEDI MARKER'S PHARMACEUTICALS (PVT) LTD., PLOT NO. A-104, S.I.T.E., HYDERABAD.

The case was placed in the agenda as under: -

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

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

Present: DDPP for the State
Accused Absent.

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

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

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

Announced
03-11-2015

S/d
Ch. Muhammad Jahangir
Chairman

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

Proceedings:

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

Decision of CLB (M-245):

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

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

Proceedings:

Accordingly, a Show Cause Notice with Personnel Hearing issued to the firm and a letter for taking further action by Registration Board is conveyed for information / compliance as per the directions of the Honorable Chairman Drug Court, Gilgit Baltistan.

Proceedings of meeting:

The Board was apprised of the case that Honorable Drug Court has passed following orders dated 08-02-2016 as under: -

Present: DDPP for the State.

Accused Munsif Qureshi, Shakoor Sheikh and Raheela Saleem with their counsel.

The accused Raheela Saleem declared as P.O today the learned moved an application and argued that the accused were not properly served and as and when she informed about the N.B.W. she voluntarily surrender himself to appear before the court and ready to furnishing surety bonds. Remaining accused namely Munsif Qureshi and Shakoor Sheikh was regularly appeared before the court, but all of sudden both are seriously ill and it is difficult to travelled from Karachi to Lahore and informed that in future they will careful and appear before the court on each and ever date and requests for withdrawal of warrant of arrest.

Reason seems to be genuine and in the interest of justice the warrants of arrest of the accused already issued by this court is hereby withdrawn and proclamation issued by this court against the accused Raheela Saleem is also withdrawn subject to furnishing surety bonds in the sum of Rs.200,000/- with one surety in the like amount to the satisfaction of this Court.

Copies delivered to the accused. Now to come up for framing of charge on 17-02-2016.

ANNOUNCED

08-02-2016

Ch. Muhammad Jahangir
CHAIRMAN

Dr. Mubashar Ahmed Butt
Member

Farooq Bashir Butt
Member

Decision of CLB:

Keeping in view the above situation and latest court orders, the Board considered and deferred the case till next meeting. Board further directed to ask firm, for the reasons of not appearing before the Board for personal hearing.

Case No. 14 **State Versus 1. Saif Islam M.D 2. Roohullah production incharge 3. Miss Nosheen Raza Quality control incharge of M/s. Alson Pharmaceuticals 169-7th Road Industrial Estate Hayatabad Peshawar Pakistan. (Accused)**

The case was placed in the agenda as under: -

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

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

S.C. No. 117/2014

State ……

Versus.

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

OFFENCE UNDER SECTION 27/23 DRUG ACT, 1976.

To,

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

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

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

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

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

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

Sd/-
Chairman Drug Court
Gilgit Baltistan
Session Judge
Gilgit

Decision of CLB (M-245):

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

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

Proceedings:

Accordingly, a Show Cause Notice with Personnel Hearing issued to the firm and a letter for taking further action by Registration Board is conveyed for information / compliance as per the directions of the Honorable Chairman Drug Court, Gilgit Baltistan.

Proceedings of meeting:

Mr. Saif-ul-Islam, Director appeared before the Board. He said that firm has not received any communication from the Drug Court Gilgit-Baltistan. However, they have taken information for next date of hearing which is fixed on 25-02-2016.

Decision of CLB:

Keeping in view the hearing of the case, the Board considered and deferred the case till next meeting. Board further directed to send an interim report of the case to the Honorable Court.

Case No. 15 **State through Drug Inspector District Skardu Gilgit Baltistan**

Versus

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

The case was placed in the agenda as under: -

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

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

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

To,

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

Title: State through drug inspector District Skardu, Baltistan.

Versus

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

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

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

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

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

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

Sd/-
Chairman Drug Court
Gilgit Baltistan
Session Judge
Gilgit

Decision of CLB (M-245):

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

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

Proceedings:

Accordingly, a Show Cause Notice with Personnel Hearing issued to the firm and a letter for taking further action by Registration Board is conveyed for information / compliance as per the directions of the Honorable Chairman Drug Court, Gilgit Baltistan.

Proceedings of meeting:

Mr. Mushtaq Ahmed, Production Manager of the firm appeared before the Board. He said that firm has taken information for next date of hearing which is fixed on 24-02-2016 and firm will appear before the Honorable Drug Court on the said date.

Decision of CLB:

Keeping in view the hearing of the case, the Board considered and deferred the case till next meeting. Board further directed to send an interim report of the case to the Honorable Court.

Case No. 16 **State through Drug Inspector District Skardu Gilgit Baltistan**
Versus

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

The case was placed in the agenda as under: -

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

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

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

To,

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

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

Versus

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

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

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

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

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

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

Sd/-
Chairman Drug Court
Gilgit Baltistan
Session Judge
Gilgit

Decision of CLB (M-245):

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

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

Proceedings:

Accordingly, a Show Cause Notice with Personnel Hearing issued to the firm and a letter for taking further action by Registration Board is conveyed for information / compliance as per the directions of the Honorable Chairman Drug Court, Gilgit Baltistan.

Proceedings of meeting:

Mr. Ikhlaque Ahmed, CEO of the firm appeared before the Board. He said that previously they received a letter from the Honorable Court and replied accordingly. After that they have not received any communication from the Honorable Drug Court. He further said that he will approach the Honorable Drug Court and obtain information of the said case and then act accordingly. He further informed the Board that Aftab Ahmed Managing Director and Muhammad Iqbal Somoroo Production Incharge have passed away.

Decision of CLB:

Keeping in view the hearing of the case, the Board considered and deferred the case till next meeting. Board further directed to send an interim report of the case to the Honorable Court.

Case No. 17 **M/S VISION PHARMACEUTICALS, PLOT NO. 22-23, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD DML NO. 000806 BY WAY OF SEMI BASIC MANUFACTURER.**

The Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad has requested with a fee of Rs.5000/- that they have received approval letter of Active pharmaceutical Ingredients with the name of Tamsulosin SR Pellets which is not correct, whereas in application dossier firm applied for Tamsulosin HCL SR Pellets which is correct so they have requested for correction of name of API from Tamsulosin SR Pellets to Tamsulosin HCL SR Pellets

The firm in its application has written as "Tamsulosin HCL SR Pellets (Tamsulosin HCL 0.2%)

Case Background;

API Tamsulosin SR Pellets were approved in 243rd meeting of CLB held on 9th September, 2015 with following nomenclature.

SUSTAINED RELEASE / EXTENDED RELEASE PELLETS	
S. No	**Name of Drug**
1	Tamsulosin SR Pellets

Decision of CLB:

The Board considered and approved the request of the firm for correction of name of API from Tamsulosin SR Pellets to Tamsulosin HCL SR Pellets.

Case No. 18. M/S ABBOTT LABORATORIES (PAKISTAN) LTD, KARACHI.

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

The case was placed in the agenda as under: -

Brief Background:-

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Abbott Laboratories (Pakistan) Ltd, Karachi. DML No.000001 (Formulation) **Sections (01)** 1. Capsule (General)	**3-6-2015 & 4-6-2015**	**Panel also recommends renewal of DML by way of formulation. Panel also recommends capsule section intended for filling of Dry pellets.**	1. Mr. Muied Ahmad, Member CLB. 2. Dr. Muhammad Tanweer Alam, Director CDL, Karachi. 3. Mr. Qaiser Muhammad Chief Drug Inspector, Sindh. 4. Obaid Ali, Ph.D, Area FID, DRAP Karachi. 5. Dr. Shoaib Ahmed, ADC, DRAP, Karachi.

Recommendations of the Panel:-

Two days pre-announced 10 hour visit of M/s Abbott Laboratories (Pakistan) Ltd, Karachi was conducted by the constituted panel. Visit included walk through inspection of manufacturing facilities, on site and off site discussion with inspected from Director to Operator and quick review of documents. The objective of the inspection in the shortest time was limited to verification of manufacturing site in accordance with the approved layout plan and assessment of suitability with regard to equipment, HVAC and Personnel to give recommendation for renewal of Drug Manufacturing License (DML). However, total GMP compliance inspection in 10 hours for such a wide manufacturing facility (aseptic and terminal sterilization manufacturing process of Injectables, multiple oral solid dosage from manufacturing facility, oral liquid manufacturing facility, ointment / cream manufacturing facility, facility of sachet dosage form, warehouse, quality control laboratory, microbiological laboratory, HVAC, water system and over and above quality system etc.) was a challenge and hard to conclude. During inspection, temperature control of the huge raw and packaging material warehouse divided into several segregated portion was found not controlled for temperature and humidity, few portions were designated as "controlled temperature" where temperature was found 25◦C, some portions had no facilities of temperature control and bear the natural temperature that may go up to scorching and the only intercepting hindrance is the concrete wall and roof that ma significantly absorb heat and take time to come back on ground state sometimes.

M/s Abbott Laboratories (Pakistan) Ltd, Karachi assured their level of compliance moving towards improvement and maintains consistency in addressing the potential observations discussed. M/s Abbott Laboratories (Pakistan) Ltd, Karachi bearing Drug Manufacturing License (DML) No. 000001 by way of formulation was concluded up to reasonable level of GMP compliance with regard to competitive environment. Panel also verified the layout plan with shown plan that was already approved by the Islamabad through stamp and signature. Panel also recommends renewal of DML by way of formulation and capsule section intend for filling of dry pellets. However, a detail inspection of at least 10 working days is required to assess the compliance of good Manufacturing Practices that will be done by the FID in coming months.

The case is submitted for consideration of the Board, please.

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

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

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

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

Dear Sir,

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

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

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

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

Sd/-

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

Proceedings:

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

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

Decision of CLB (M-245):

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

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

Proceedings of the Meeting: The Board was apprised that the panel has furnished evaluation proforma of the sections of the firm as per decision of 245th meeting of CLB held on Wednesday, 30th December, 2015.

Decision of CLB:

Keeping in view the facts of the case and submission of report by panel on prescribed evaluation proforma, the Board considered and decided as under: -

- **Approved the renewal of Drug Manufacturing License No. 000001 (formulation).**
- **Approved the grant of additional section "Capsule General".**
- **Approved the regularization of master layout plan for sections namely Tablet, Granules, Liquids, Cream / Gel and Injectable.**

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

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

The case was placed in the agenda as under: -

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

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

Recommendations of the Panel:-

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

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

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

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

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

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

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

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

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

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

Dear Sir,

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

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

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

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

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

Sd/-

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

Proceedings:

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

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

Decision of CLB:

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

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

Proceedings of the Meeting:
The Board was apprised that the panel has furnished evaluation proforma of the sections of the firm as per decision of 245th meeting of CLB held on Wednesday, 30th December, 2015.

Decision of CLB:

Keeping in view the facts of the case and submission of report by panel on prescribed evaluation proforma, the Board considered and decided as under: -

- **Approved the renewal of Drug Manufacturing License No. 000348 (Formulation).**
- **Approved the regularization of master layout plan for sections namely Tablet, Capsule, Oral Liquid, Semi Solid (Cream/Ointment), Liquid Parental & Sachet.**

Case No.14. **PROVISION OF INFORMATION AND ENDORSEMENT OF MANUFACTURING PROCESS FLOW / PROTOCOL OF MANUFACTURING AND TESTING OF APIs/ BULK DRUGS.**

Rule 10 of Drug (Licensing, Registration, Advertising) rules 1976; Procedure Of Central Licensing Board as under :-

"The Central licensing Board may, Before issuing a license, cause the premises in which the manufacture is proposed to be conducted to be inspected by itself or by its sub-committee or by panel of inspectors or experts appointed by it for the purpose , which may examine all portions of premises and the plant and appliances**, inspect the process of manufacture intended to be employed** and the means to be employed for standardizing, if necessary and testing and analysis substances to be manufactured and enquire into the professional qualifications of the technical staff employed."

Current Practices:-

As per practice in vogue CLB receives applications for enlistment of APIs and then constitutes a panel for the inspection of Manufacturing Facility. After satisfactory report CLB approves the APIs in the same applicant. Recently, various APIs manufacturer demand for approval of Manufacturing Process flow by CLB.

In this regard it is submitted that as per provision of above rule, the panel of experts may be directed to inspect thoroughly the process of manufacturing of every specified APIs/Bulk Drugs and furnish the manufacturing process flow with complete manufacturing and testing process/protocol dully attested /Endorsed by the inspecting panel along with the inspection report. Accordingly the same would be presented before the Board for consideration and the same list of Manufacturing Process flow would be provided to applicant/ Firm along with approval of APIs and copy of the same would be conveyed to Area DDG/ADC. In order to regularize the existing approvals of APIs a panel may be constituted to verify/endorse the manufacturing process flows of already granted APIs by CLB.

Proceedings of the Meeting: The Board was apprised that at present following firms are requesting for attestation of manufacturing process flow for their approved / enlisted API's as under: -

S No.	Names of Firm	APIs
1	M/s Alpha chemical (Pvt) Ltd, 65-km Lahore-multan National Highwar, Industrial Zone, Chunian, Kasur. DML No. 000373 By way of Basic Manufacture	1. Santonin Powder BP/USP 2. Monoammonium Glyceyrrhizinate 3. Ephedrine HCL & other salts 4. Dipotassium Glyeyrrhizinate 5. Pseud- Ephedrine HCL & other salts 6. 18-Beta Glyeyrretinic Acid 7. Liquorice Extract 8. Crude Disogenin 90 to 95% 9. Crude Glyeyrrhizi Acid 10. Berberine Hydrochloride 11. Acscin 12. Amonium Chloride 13. Aluminium Chloride Liquid /Gel 14. Sodium Acid Citrate 15. Caffein Citrate 16. Furazolidone 17. Sulphamethoxazole 18. Pyrazinamide
2	M/s Pharmagen Ltd, Kot Nabi Baksh Wala, Ferozpur Road, Lahore. DML No. 000325 by way of Semi Basic Manufacture	1. Ampicillin Trihydrate 2. Ampicillin Anhydrous 3. Amoxycillin Trihydrate 4. Cloxacillin Sodium 5. Flucloxacillin Sodium 6. Cephradin 7. Cephalexin Hydrate 8. Cefadroxil 9. Cefaclor 10. Cefixime 11. Cefuroxime Axetil 12. Cephradine L-Arginine 13. Cefixime Sodium 14. Ceftriaxone Sodium 15. Cephalexin Sodium 16. Cefazoline Sodium 17. Cefoperazone Sodium 18. Ceftazidime Pentahydrate 19. Cefuraxime Sodium 20. Ciprofloxacin Hydrochloride 21. Moxifloxacin Hydrochloride 22. Pefloxacin Mesylate 23. Levofloxacin 24. Norfloxacin 25. Azithromycin 26. Clarithromycin 27. Sulfamethoxazole 28. Omeorazole 29. Esomeprazole Magnesium Trihydrate 30. Paracetamol 31. Parazinamide 32. Naproxen Sodium 33. Ibuprofen 34. Simvastatin 35. Atovastatin Calcium Trihydrte 36. Amlodipine Besyalte 37. Montelukast Sodium 38. Mefenamic Acid 39. Dexamethasone Sodium Phosphate 40. Dexamethasone Acetate 41. Betamethasone Sodium 42. Betamethasone Valerate 43. Betamethasone Dipropionate 44. Sofosbuvir XXXXXXXXXXXXXXX
3	M/s Zafa Chemie, Raiwind Manga Bypass, Mouza Bahikot, Distt: Lahore. DML No. 000589 by way of Basic Manufacturer	1. Ibuprofen 2. Sulphmethoxazole 3. Ampicillin Trihydrate 4. Amoxicillin Trihydrate 5. Cloxacillin Sodium 6. Ciprofloxacin HCL 7. Norfloxacin 8. Pyrazinamide 9. Paracetamol 10. Amlodipine Besylate 11. Alendronate Sodium XXXXXXXXXXXXXXXXXXX
4	M/s Zenith Chemical Industries (Pvt) Ltd., Lahore. DML No 000733 by way of Semi Basic Manufacture	1. Paracetamol. 2. Ibuprofen 3. Citrizine Dihydrochloride 4. Montelukast 5. Ciprofloxacin 6. Ofloxacin 7. Levofloxacin 8. Moxifloxacin HCL
5.	M/s Citi Pharma (Pvt) Ltd, 3-KM Head Baloki Road, Phool Nagar Kasur. DML No. 000429 by way of Semi Basic Manufacture	1. Aspirin Raw Material 2. Paracetamol Raw Material 3. Quinolone (Norfloxacin) 4. Ciprofloxacin, Levofloxacin) 5. Ibuprofen xxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Decision of CLB:

Keeping in view the above situation, the Board considered, discussed and unanimously decided for panel inspection of the above firms by following panel: -

1. **Prof. Dr. Saeed Sb. Member CLB**
2. **Dr. Ikram-ul-Haq, Member CLB**
3. **Syed Muid Ahmed, Member CLB**
4. **Syed Javed Yousuf Bukhari, Member CLB**
5. **Area FID, DRAP, Lahore**

The Board further directed the panel: -

- **to verify the complete process of manufacturing of every API as per requirement of Rule 10 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.**
- **to sign / endorse the complete report and their manufacturing process flows of APIs.**

The Board further decided that in future above procedure shall be followed for approval any new API.

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

Quality Assurance Cases (GMP)

S. No.	Name of firm
1.	**Item No. I GMP Cases (Old)**
i.	M/s Nawabsons Laboratories, Lahore
ii.	M/s Redex, Faisalabad
2.	**Item No. II GMP Cases (New)**
i.	Avicenna, Lahore
ii.	Ideal, Lahore
iii.	Albro, Lahore
iv.	Ali Industries, Lahore
v.	Inshall, Rawat
vi.	My Labs, Lahore
vii.	Medisave, Lahore
viii.	Surgitex Rehman Rainbow, Lahore
ix.	Rehmat Pharma, Lahore

Item No. I (GMP Cases old)

Case No. i:- M/s Nawabsons Laboratories, Lahore

The case was presented before the Central Licensing Board as under:

Background of the case

Inspection of company was conducted on 14.09.2015 by Mr. Ajmal Sohail Asif, area FID, Lahore to verify the GMP compliance and production activities of the firm.

The FID has noticed a number of major and critical observations, which needs urgent attention and rectification. The observations include:-

Ground floor

Change Rooms:

- The firm was advised to replace the wooden cabinets in the change rooms and also to rearrange the placement of cross over bench as they were fixed outside the doors of the change rooms towards production area.

Storage areas:

- The firm was advised to provide proper dispensing booth along with GMP compliant scoops to avoid cross contamination. The firm was also advised to provide a sampling area having sampling booth with accessories.
- The firm was advised to improve the floors of the old area of RM stores. The pellets in the quarantine area need to be painted. The firm was also advised to install thermometers to monitor the temperature of the stores. The firm was advised to replace the coil shaped light bulbs with concealed type lights to ease the cleanliness.
- The firm was advised to store the primary packing materials such as aluminum foils PVC at proper temperature.

Production Areas

Oral Liquid Section:

- The firm was advised to tag/label different pipes in the area. The firm was also advised to prepare SOP for cleaning of these pipes.
- There was a bottle blowing machine within the filling room. The firm was advised to segregate bottle de-cartooning and blowing area.

- Oral liquid section of the firm was not provided with HVAC. Ceiling fans were installed and functional at the time of inspection. The firm was advised to remove the fans at once and provide HVAC in the area.

General tablet section:

- The firm was advised to remove the coil shaped light bulbs and provide concealed lights in the area.
- The firm was advised to remove all wooden materials from the area. HVAC was installed but it seemed to be insufficient, pressure gradients were not satisfactory.
- The firm was advised to improve and validate the HVAC system in this area. The firm was also advised to remove the coil shaped light bulbs and provide concealed light in the area.
- The area was not well maintained. The firm was advised to remove all the wooden materials from there and improve the general cleanliness. The firm was also advised to do overhauling of coating pans. The firm was also advised to remove the coil shaped light bulbs and provide concealed light in the area.
- HVAC was not provide in the area and ceiling fans were installed and functional at the time of inspection. The firm was advised to remove the ceiling fans and provide HVAC to blistering area on priority basis. The firm was advised to remove coil shaped light bulbs and provide concealed light in the area

Sachet Section

- It was noticed by the FID that this room was devoid of any type of ventilation, HVAC was not provided in this room. Process / material flow for mixing, granulation, drying and filling was not satisfactory. It was observed by the FID that the firm was not having proper manufacturing facility for sachet. The firm was advised to provide proper manufacturing facility for sachet with proper flow and HVAC.

External Preparation Section:

- The firm was advised to install split air conditioner in the day store of the section to control the temperature.

Change Rooms:

- The firm was advised to replace the wooden cabinets in the change rooms and also to rearrange the placement of cross over bench. The firm was also advised to provide supply for fresh air in the change rooms.

Storage areas:

- The firm was advised to provide proper dispensing booth and other accessories for dispensing.

Production Areas:

Antibiotic tablet & Capsule Section:

- The firm was advised to provide HVAC in the blistering room and to install double door transfer hatch in between the blistering and packing hall. The firm was also advised to repair the HVAC ducts in granulation and capsulation areas.

Oral Dry Powder Suspension:

- The firm was advised to replace the window with a double door transfer hatch.

Quality Assurance:

- The firm was advised to hire some experienced person as QA manager and strengthen the section by making it independent and fully effective.

Sanitation and Hygiene:

- The firm was advised to improve the general cleanliness of RM stores, oral liquid section and tablet coating sections.

Qualification and Validation:

- The firm was advised to validate the manufacturing and QC procedures and perform cleaning validations.

Product Recalls:

- The firm was advised to perform a mock recall to evaluate the effectiveness of the recall system.

Self Inspection and Quality Audit:

- The firm was advised to elaborate the report and maintain the record of CAPA.

Personnel:

- The firm was advised to strengthen the QA section by hiring some experienced person as QA manager.

Training:

- The firm was advised to implement it in true letter and spirit and maintain the records.

Equipment and machinery:

- The tablet coating pans need overhauling or replacement.
- The firm was advised to purchase FTIR for identification of the raw materials and other equipments necessary to carry out the compendia tests, such as Karl Fischer, Digital polarimeter etc

Materials:

- The firm was advised to further improve the material management system. The labels were not having complete information of the product as required to have. The firm was advised to improve the labels by incorporating the essential information of the materials.

Good Practices in Quality Control:

- The firm was advised to maintain the log books properly and keep the raw data for analysis. The firm was using in house working standards for testing and was advised to purchase reference standards.

Utilities

Water Purification System:

- The firm was advised to prepare procedure for sanitization of water supply pipe lines

HVAC System

- There was no provision of HVAC in oral liquid section and tablet blistering areas. The firm was advised to install HVAC in all production areas and to validate the existing HVAC facility.

The FID further Recommended that

- The management of the firm was advised to prepare and submit an action plan in the light of the observations of the inspection report with clear time schedule for rectification of the shortcomings and improvements in the cGMP compliance. The management of the firm was also advised to provide dedicated facility for production of Penicillin and Cephalosporin products as required under sub-section 5.2 of Section 1 of Schedule B of the Drugs (LR&A) Rules, 1976. The firm was also advised to remove wooden doors and other wooden items from the production areas.

Action Taken by DRAP: - After receiving inspection report, a show cause notice / stop production order in all production areas was issued to the firm on 30.10.2015.

Reply of the firm:- In response of the show cause notice / stop production order, the firm vide letter No. Nil dated 14.11.2015 informed that all the critical observations have been rectified.

Proceedings of the 245th Meeting of CLB

The firm was given opportunity of personnel hearing before the Board. But no person appears before the board on behalf of firm. The Board shows displeasure on non serious attitude of the company.

Decision of the 245th Meeting of CLB

The case was placed before the Central Licensing Board for consideration. The Board after thorough discussion has decided to:-

- Provide a last opportunity for personnel hearing and a final notice shall be served to the firm in the next meeting.
- In case of failure to appear before the Board in the forthcoming meeting, ex-parte decision shall be taken.

Proceedings of the 246th Meeting of CLB

Mr. Nadeem Akhtar, Quality Control Manager/Director and Mr. Arjumend Akhter, Production Manager/Director of the firm M/s Nawabasons Laboratories, Lahore appeared before the Board for personal hearing. They informed the board that all the observations identified by FID during his inspection conducted on 14.09.2015 have been rectified includig ceiling fan installed in the syrup section have also been removed. In blister room both HVAC and Air Conditioners are installed. When Mr. Javed Bukhari, Member inquired about the static pressure and air changes of HAVC, in the production area, representatives of the firm failed to satisfy the Board. They further informed that the firm M/s Nawabasons Laboratories, Lahore will be ready for inspection in one week time for the verification of improvements made by them.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberation, considering all the pros and cons of the case, keeping in view the available record, compliance report of the firm and request from Directors of the firm, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members.

i. Prof. Dr. Saeed Member CLB
ii. Dr. Muid Ahmed, Member CLB
iii. Mr. Ajmal Sohail Asif, FID, Lahore

The Board further directed to ask the panel to also submit report in tabulated form identifying the previous observations and the current status. The production will remain stop till recommendation by the panel for resumption of production and accordingly approval from the Board.

Case No. ii: - **M/s Redex Pharmaceuticals, Faisalabad**

The case was presented before the Central Licensing Board as under:

Background of the case

Mr. Ajmal Sohail Asif, FID Lahore conducted inspection of the company on 14.05.2015 to verify GMP compliance and production activities. Following critical observations were noticed by the FID:-

i) The firm has two premises, one having DML and other adjacent (attached) to licensed premises, unlicensed purported for manufacturing of neutraceuticals / herbal products.

Licensed Premises

ii) The licensed premises was found non functional and all manufacturing sections were found closed except oral liquid section (human) where some bottles were placed on filling / packing table and in finish good some products were found.

iii) General cleanliness, sanitation / hygienic conditions, temperature and humidity control were not maintained and unsatisfactory.

iv) The FID directed the firm to stop manufacturing / production immediately as the GMP and licensing requirements were not maintained.

Unlicensed Premises

v) In unlicensed premises various facilities for manufacturing for **herbal** and **registered** products were found including labels, unit cartons, aluminum foils of different pharmaceutical products alongwith various herbal products were found.

vi) In unlicensed area varied quantity of products such as Felrosol suspension and Broncho MED syrup alongwith herbal products of tablets and syrups were placed.

vii) **Broncho MED syrup was being filled under a tree by workers** (male and female) who were busy in filling, labeling and packing activities under trees and inside the room.

viii) **The FID seized the material** (raw, packing, printed) and finish products alongwith syrup filling machine and filled bottles under section 18(1) F of the Drugs Act, 1976 and Schedule V of DRAP Act, 2012. The FID seized and sealed all the material in the presence of Mr. Deedar Ali (Production Incharge)

ix) The FID has reported that **firm is involved in violation of the provisions of Drugs Act, 1976 and rules framed there under** as the firm is involved in the illegal/unauthorized manufacturing of its registered products at an unlicensed premises under extremely unhygienic conditions.

x) The FID emphasized that the firm is not only violating the provisions of the Drugs Act, 1976 but also **put the lives of innocent patients in danger**.

xi) The FID directed the management of the firm to stop all the operations in the licensed/unlicensed premises immediately.

Action Taken by DRAP:- After receiving inspection report, a show cause notice / stop production order in all sections was issued to the firm on 24.06.2015.

Reply of the firm:- In response of the show cause notice, the firm vide letter No. Nil dated 17.11.2015 informed that the FID has made the observation in the neutraceutical site, not in the human site because human site was closed at the time of inspection. The firm further requested for resumption of production.

Proceedings of the 245th Meeting of CLB

The firm was given opportunity of personnel hearing before the Board. But no person appears before the board on behalf of firm. The Board shows displeasure on non serious attitude of the company.

Decision of the 245th Meeting of CLB

The case was placed before the Central Licensing Board for consideration. The Board after thorough discussion has decided to

- Provide a last opportunity for personnel hearing and a final notice shall be served to the firm in the next meeting.
- In case of failure to appear before the Board in the forthcoming meeting, ex-parte decision shall be taken.

Proceedings of the 246th Meeting of CLB

Mr. Ishfaq Ahmad, CEO of the firm M/s Redex Pharmaceuticals, Faisalabad appeared before the Board for personnel hearing. He informed that at the time of visit of FID on 14.05.2015, the factory was closed due to short-circuit of electricity; all the finished goods were shifted in the open area under a tree. On query raised by Director (QA&LT), the CEO of the firm informed that he is metric passed, Mr. Deedar Ali is production manager and Ms. Sadia Ashraf is QCM. He further informed that all the observations identified by FID during his inspection have been rectified and they are ready for inspection for verification of the improvement made by them.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberation, considering all the pros and cons of the case, keeping in view the available record and request from CEO of the firm M/s Redex Pharmaceuticals, Faisalabad, the Board decided to conduct panel cGMP inspection on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976, by the following members:-

i. Prof. Dr. Saeed Member CLB
ii. Dr. Muid Ahmed, Member CLB
iii. Mr. Ajmal Sohail Asif, FID, Lahore

The production will remain stop till recommendation by the panel for resumption of production and accordingly approval from the Board.

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

i.	Avicenna, Lahore
ii.	Ideal, Lahore
iii.	Albro, Lahore
iv.	Ali Industries, Lahore
v.	Inshall, Rawat
vi.	My Labs, Lahore
vii.	Medisave, Lahore
viii.	Surgitex Rehman Rainbow, Lahore
ix.	Rehmat Pharma, Lahore

Case No. i:- M/s Avicenna Laboratories (Pvt) Ltd, District Sheikhupura

The case was presented before the Central Licensing Board as under:

Background of the case

Inspection of company was conducted on 08.01.2016 by Mrs. Aisha Irfan, area FID, Lahore to verify the GMP compliance and production activities of the firm. The FID noticed a number of major and critical observations, which needs urgent attention and rectification. The observations include:-

Staff

i) Mr. Muhammad Shafeeq, production In-charge left the factory for the last 06 months, as informed by QC In-charge.
ii) QA In-charge was also present.

Changing Area:

iii) Dirty coats hanging openly without cupboard.
iv) The area was not maintained.
v) Stinking smell from washrooms was observed.

Stores:-

Raw material store:

vi) No labels of quarantine were pasted on cartons.
vii) Sampling hood was not provided and the sampling rod was not working hence the workers started taking samples from cartons with scoops without wearing gloves.
viii) No proper pharmacist appointed in store.
ix) Dispensing hood installed but was not proper as weighing balance.

Finished goods store:

x) The door of finished goods store directly opened outside without buffer or dispatch area.

Packaging material store:

xi) Proper cleaning required.

Production Area:-

Oral Powder Section:

xii) Bottle blowing area not available.
xiii) Bottle cleaning area as mentioned in layout was not available.
xiv) The location of change rooms were also changed from layout.
xv) Cone mixer of 50 kg capacity was installed in mixing room without safety barrier.
xvi) HVAC system installed but was not functional.

Oral Liquid Section:

xvii) The machinery was dismantled in the manufacturing area.
xviii) No status label pasted on machinery.

xix) The pipes were dismantled.
xx) Flooring is very dirty with black stains everywhere.

Quarantine Room:

xxi) The quarantine room had been converted to label printing room.
xxii) No IP&QC developed.

Quality Control:

xxiii) The calibrations of equipments were expired.
xxiv) Stability chamber, FTIR not available.
xxv) KARL Fischer, polarimeter was not provided.
xxvi) Proper fume hood required.
xxvii) The BMRs were checked and found incomplete.

Quality Assurance:

xxviii) No proper QA department developed.

The FID further concluded that:-

xxix) In view of above observations the firm is directed to immediately stop production as without production In-charge the production cannot be conducted.
xxx) The firm also has registration of inject-able products while inject-able section in not approved.
xxxi) Some products also contain penicillin, hence de-registration of products is recommended.

Action Taken by DRAP:- After receiving inspection report, a show cause notice / stop production order in all sections was issued to the firm on 21.01.2016.

Reply of the firm:- Reply of the firm is still awaited.

Proceedings of the 246th Meeting of CLB

Mr. Rafaqat Ali, Quality Control Manager and newly appointed Production Manager Mr. Aamir Hussain (But not yet approved by the Licensing Division) appeared before the Board for personnel hearing. They informed that ex-production manager was not feeling well, that's why he was not present in the facility at the time of inspection of FID on 08.01.2016. It was misunderstanding to FID that production manager left the factory for the last 06 months. They further informed to the Board that Karl fischer and digital polarimeter have been purchased, however FTIR could not be purchased yet due to financial constraints. They also informed that most of the observations identified by FID during his inspection on 08.01.2016 have been rectified and they are ready for inspection for verification of the improvements.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case and keeping in view the available record, the Board decided to conduct panel cGMP inspection of the firm M/s Aviceena Labs, Sheikhupura on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976, by the following members:-

i. Dr. Ikram ul Haq, Member CLB
ii. Mr. Ajmal Sohail Asif, FID, Lahore
iii. Mrs. Aisha Irfan, FID, Lahore

Production of the firm will remain stop till recommendation by the panel for resumption of production and accordingly approval from the Board.

Case No. ii:- M/s Ideal Pharmaceutical Industries, Lahore

The case was presented before the Central Licensing Board as under:

Background:-

M/s Ideal Pharmaceutical Industries (Pvt) Ltd, Lahore was inspected on 13.02.2015 by Mrs. Majida Mujahid, FID, Lahore to see/verify the GMP compliance. During the inspection the FID pointed out a number of severe shortcomings and gross violations.

Current Position:-

Mr. Ajmal Sohail Asif, FID and Mrs. Majida Mujahid, FID conducted inspection of the firm M/s Ideal Pharmaceutical Industries (Pvt) Ltd, Lahore on 11.12.2015 and pointed out number of serious and critical shortcomings in all section.

Inspection conducted on 13.02.2015	Inspection conducted on 11.12.2015
Executive/workers entries Separate executive / workers entries were provided. They directed to improve area regarding to civic work / sanitation / hygienic as per cGMP requirements	Same
Ware House Raw material, packing and Finished goods Store Following observations were made during inspection:-	
• Firm has provided dispensing booth (fitted with HEPA Filter) in dispensing area. They were advised to seamless scoops and with required accessories should be provided.	GMP compliant scoops not yet provided
• Dispensing booth as advised in last GMP inspection should be provided	Done.
• Temperature / humidity record should be maintained and signature by authorized personnel.	Done.
• Firm has segregated penicillin store from general store with partition. They were advised to shift store in penicillin section.	Firm has not provided dedicated store for penicillin materials within the penicillin section.
• Wooden racks should be replaced with S.S. racks and reset of other S.S. racks required paint.	Partially improved.
• Identification label should be cleared and fixed on each container.	Done.

• Packing material store should be re-arranged in order to avoid mixing of labels.	Partially improved.
• Gaps between doors / floors should be concealed to stop entry of Rodent / inspects.	Not done.
• Firm has provided dispensing area for storage of liquids immediate attention was needed regarding to maintain of ware house. They were further advised to GSP is requires its true letter / spirit.	Partially improved
Syrup Section This section was consist of bottle blowing area, manufacturing area and filling / packing area. They were advised to:-	
• Improve bottle blowing area, regarding to removal all drainage and concealed them properly	Partially improved
• All naked wire should be concealed properly	Partially improved
• Area should be brighter with not proper GMP standard lights.	Not done.
• Working of air handling system should be improved	Not done.
• Civic worker is needed in above said area	Partially done.
Manufacturing / filling / packing Area:-	
• HVAC system was installed but needed validation at time of inspection.	HVAC did not seem to be working effectively.
• All drainage hole should be concealed / properly.	Partially done.
• Log books of machineries/ equipments were available but they were advised to maintain log book properly.	Done.
• All required machineries / equipments required maintenance / buffing / polishing.	Not properly done.
• All naked wire should be concealed properly.	Not done.
General Tablet / General Antibiotic Section.	

	Partially improved
• They were advised to maintain all production area regarding to civic work (do paint where required).	Not done.
• Improved floor of production area.	Not done.
• Remove old compression and other machines with GMP model machinery / equipment.	HVAC seemed not to be working effectively.
• Improve working of HVAC system and validation by third party.	Not satisfactory.
• Maintain all machineries / equipment in production area.	Proper tray dryer not provided.
• Remove manual made dryer in drying room.	
• However, they were provided fluid bed dryer in above said area.	Manometer was not installed in compression cubicles.
• Install manometer outside of each compression area to monitor differential pressure between production area / corridor.	Not done.
• Install HVAC / Air handling system in coating area.	Provided one balance in compression lobby. Advised to provide proper IPQC.
• In process testing equipments balance should be provided at station of each compression machine.	Partially improved.
• Improve area regarding to general maintenance.	
General Capsule Section	
• Manual capsule filling machine should be replace with semi automatic machine.	Done.
• HVAC system should be validate.	HVAC seemed not to be working effectively.
Penicillin Section (Dry Powder / Suspension / Capsule):-	
• HVAC system should be validate.	HVAC seemed not to be working effectively.
• All doors of section should be fixed	Not done

properly. • Flooring need improvements. • Manual capsule filling machine should be replaced with semi automatic machine. • No activity was going on at time of inspection.	Not done. Not done Not done.
Water Treatment:- • Single RO system should be replaced with double RO system. • Each column should be labeled and SOPs for water treatment should be developed.	Same. Same.
Quality Control / Quality Assurance Department:- • They were advised to purchase FTIR, automatic polarimeter on priority basis and shifted their method of testing on HPLC.	Not done.
Quality Assurance They were advised to develop an independent quality assurance department with trained technical staff	Hired one pharmacist to look after QA, but it needs to be independent and more strengthen.
Documentation • They were directed to review / improve SOPs, testing method regarding to quality control and production.	Partially improved

Action Taken by DRAP:- Accordingly, a show cause notice / stop production order in all sections was issued to the firm on 21.01.2016.

Reply of the firm:- The firm vide letter No. Nil dated 27.01.2016 has informed that most of the observations have been rectified. They further requested for re-inspection.

Proceedings of the 246th Meeting of CLB

Mian Muhammad Nazir, CEO of the firm M/s Ideal Pharmaceutical Industries (Pvt) Ltd, Lahore appeared before the Board for personnel hearing. He informed to the Board that most of the observations noticed in the previous inspection conducted by the FID on 13.02.2015 were found rectified by the panel in its inspection conducted on 11.12.2015. He further informed that the raw material store of the penicillins has been shifted in the penicillin section as per recommendation of the panel. Validation of HVAC has been done by Apex Air (Expert firm in HVAC technology), on query raised by Dr. Ikram, Member, CLB, CEO of the firm informed that Polarimeter has been purchased however;

they will purchase FTIR very soon. He further informed that all the observations identified by panel have been rectified and they are ready for verification of the improvements.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and request of CEO of the firm Ideal Pharmaceuticals, Lahore, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members.

i. Dr. Ikram ul Haq, Member CLB
ii. Mrs. Majida Mujahid, FID, Lahore
iii. Mr. Ajmal Sohail Asif, FID, Lahore

The Board further decided to ask the panel to also submit the report in tabulated form identifying the previous observations and the current status of the observations noted by the panel in its inspection conducted on 11.12.2015. and

The production will remain stop till recommendation by the panel for resumption of production and accordingly approval from the Board.

Case No. iii: - **M/s Albro Pharmaceutical, Lahore**

The case was presented before the Central Licensing Board as under:

Background of the case

Mr. Abdul Rashid Shaikh, FID and Mrs. Saira Naeem, area ADC, Lahore conducted inspection of the firm M/s Albro Pharmaceutical, Lahore on 12.06.2015, to verify the GMP compliance and production activities. Following critical observations were noticed by the panel during their visit:-

General Information

- Land of the firm does not fulfill the requirements of SRO. 470 (1)/98 dated 15.05.1998 Schedule-B to the Drugs (Licensing, Registration & Advertisement) Rules, 1976. It is advised to shift the manufacturing facility to appropriate area to fulfill the requirement of above said SRO till then; the management is directed to strictly maintain the cGMP requirements for the manufacturing of registered drugs.

Workers Entrance:

- It is advised to improve the workers entrance.

Oral Liquid Section:

- The firm was advised to replace the drains with GMP drains in the section.
- The firm was advised to replace the cooking vessel for the syrup manufacturing.
- The firm was advised to conceal the lights of areas.

Raw Material Store:

- The firm was advised to ensure the availability of closed trolleys for the transportation of dispensed materials from store to production floor.
- The firm was advised to affix the proper labeling with relevant colours on the quarantine materials released or rejected
- The firm was advised to improve the storage condition of liquid materials by keeping in view the safety measures.
- The firm was advised to review and upgrade the dispensing SOPs.

Tablet Section:

- The firm was directed to ensure availability of the Double Cone Mixer.
- The firm was directed to ensure the availability of separate bags for each product for Fluid-bed dryer.
- The firm was directed to review the manufacturing SOPs as far as batch size is concerned.
- The firm was directed to ensure the batch size as per available manufacturing capacity.

Quality Control Laboratory:

- The firm was advised to ensure the FTIR, KARL Fischer and Automatic Polarimeter.
- The firm was advised to upgrade the SOPs for testing methods as per current pharmacopoeia requirements.

- The firm was advised to develop separate and independent Quality Assurance Department under the supervision of senior technical person without fail.
- The firm was advised to get internal and external audit and then its CAPA, and the report be submitted to the office of FID.
- The firm was advised to ensure to make the stability chamber functional, conduct stability of the products and maintain their record as per guidance of stability study.

The FID further directed the management to:-

- Remove the shortcomings at the earliest. The re-inspection will be conducted accordingly.

Action Taken by DRAP:- After receiving inspection report, a show cause notice was issued to the firm on 10.11.2015.

Reply of the firm:- In response of the show cause notice, the firm vide letter No. Nil dated 23.11.2015 informed that many of the observations has been resolved and improved.

Proceedings of the 246th Meeting of CLB

Mr. Waseem Ahmad Bari, Director and Mr. Sibtul Hassan Abaas, Production Manager of the firm M/s Albro Pharma, Lahore appeared before the Board for personnel hearing. Mr. Waseem Ahmad Bari informed to the Board that the existing plot is about 2.5 Kanal and assured that he will purchase the new plot of 4 kanal (size) in next six months. He has submitted an undertaking stating that the facility will be developed in four years. He further informed that all the observations identified by FID have been rectified and are ready for inspection for verification of the rectification.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and request of Director of the firm M/s Albro Pharma, Lahore, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members.

i. Dr. Zaka ur Rehman, Member, CLB
ii. Mr. Abdul Rashid Sheikh, FID, Lahore
iii. Mr. Zia Husnain, FID, Lahore

The Board further decided to ask the panel to also submit the report in tabulated form identifying the previous observations and the current status of the observations noted by the panel in its inspection conducted on 12.06.2015. and

To purchase the plot of 4 kanals in 06 months and complete the facility within a period of 2 years

Case No. iv:- **M/s Ali Industries (Pvt) Ltd, Lahore**

The case was presented before the Central Licensing Board as under:

Background of the case

Dr. Sheikh Akhter Hussain, Mr. Asim Rauf and Mrs. Sara Mehreen, ADC, DRAP, Lahore conducted inspection of the firm M/s Ali Industries (Pvt) Ltd,, Lahore on 10.03.2015, to verify the GMP compliance and production activities. Following critical observations were noticed by the panel:-

a. Male / Female change rooms were found unsatisfactory sanitation and hygienic condition. However the washrooms were in pathetic condition and located outside of the production building.

b. The panel while inspecting the washrooms in a separate building also noted various locked rooms. The panel asked the firm to open those rooms for evaluation. In one of the room different articles like raw materials etc were found in very untidy manners. One of the raw material “lethanmol” were found expired. In addition unlabelled bottles of “Calamine Lotion” and “Dewase Drops” under filling were placed instead of the fact production of the unit was stopped.

c. The management was asked to clarify about the stuff placed in very untidy and unorganized manner without proper storage condition. Upon not receiving satisfactory reply the stock was seized and sealed in a room for further investigation. The FID sealed the stock on prescribed form 2.

d. The firm was advised to upgrade their quality control laboratory through provision of FTIR, Karl Fisher, Digital Polarimeter and also go for improvements in layout of the building in future as the syrup filling area etc which was very congested.

e. The panel of inspectors recommended re-inspecting the facility after firm provides GMP compliant washroom facility and strengthening the quality control laboratory as above.

f. The panel recommended to clarify from the firm the stuffing of different articles containing raw materials (both expired and valid) etc, under unhealthy atmospheric and improper storage conditions.

Action Taken by DRAP:- After receiving inspection report, a show cause notice was issued to the firm on 22.12.2015 and corrigendum was issued on 06.01.2016.

Reply of the firm:- Reply of the firm is still awaited.

Proceedings of the 246th Meeting of CLB

Mr. Asif Siddiqui, CEO, Mr. Shams Ali Hashmi, Consultant and Mr. Khalid Umer, Manager Regulatory Affairs of the firm M/s Ali Industries, Lahore appeared before the Board for personnel hearing. They informed to the Board that the management of the firm M/s Ali Industries, Lahore was changed in December, 2014 and now the things are

moving in better way. Mr. Asif Siddiqui informed the Board that FTIR, Karl fischer and Digital Polaritmeter have been purchased. Mr. Asif Siddiqui further informed that all the observations identified by the panel in its inspection conducted on 10.03.2015 have been rectified and they are ready for inspection for verification of the improvements made by them.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and request of the CEO of the firm, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members.

i. Dr. Ikram ul Haq, Member, CLB
ii. Dr. Zaka ur Rehman, Member, CLB
iii. Mr. Asim Rauf, FID, Lahore

The Board further decided to ask the panel to also submit the report in tabulated form identifying the previous observations and the current status of the observations noted by the panel in its inspection conducted on 10.03.2015.

Case No. v:- M/S INSHAL PHARMACEUTICAL INDUSTRIES, RAWAT

The case was presented before the Central Licensing Board as under:

Background of the case

Mr. Khalid Mehmood, Area FID conducted inspection of the firm M/s Inshal Pharmaceutical Industries, Rawat on 04.12.2015, to verify the GMP compliance and production activities. Following observations were noticed by the panel:-

Observations:-

i) The firm was advised to appoint two more pharmacists in the production area.
ii) Entry doors needs to be properly concealed to avoid the entry of dust into the production area.
iii) The management was directed to prepare and submit the quarterly production record to the Directorate of Registration, which were not submitted since 2011.
iv) The dispensing hood of the dispensing area need proper fitting.
v) Door of packing material store needs to be properly concealed to avoid the entry of dust.
vi) Hygrometers and manometers installed in the production area which was found not working at the time of visit.
vii) The management was directed to replace the hygrometers and manometers.
viii) The technical staff was directed to maintain the record of temperature and humidity in the production areas.
ix) The floor of the areas needs polishing and cleaning.
x) New paint need to be done in all production areas.
xi) Lights of the all production areas need to be replaced.
xii) Cap of cube mixer needs buffing.
xiii) Epoxy paint applied on the floor of the sterile liquid area, which need urgent attention at the time of inspection.
xiv) The management was advised to provide the calibration certificates from the third party.
xv) The management was advised to appoint quality assurance manager to implement QA system in its true letter and spirit.
xvi) Till to date no internal audit has been done.
xvii) The calibration certificates of the third party were found un-signed and not been reviewed by the technical staff of the company.
xviii) The management was directed to schedule training of pharmacists and workers on cGMP, Health and Safety, GLP, GSP, Hygiene and on implementation of SOPs.
xix) The technical staff was directed to design SOPs for product recall ad complaint and implement it.

Oral Liquid Section (Veterinary):-

xx) The management was advised to provide filtration assembly in the manufacturing area.

Quality Control Laboratory:-

xxi) The management was advised to provide updated additions of official books like B.P and U.S.P log books of equipment.

The FID further concluded that:-

xxii) Shortcomings were noticed during the visit. The management was advised to rectify the observations noticed during the visit and submit the compliance report in this regard.

Action Taken by DRAP:- After receiving inspection report, a show cause notice was issued to the firm on 22.12.2015.

Reply of the firm:- In response of the show cause notice, the firm vide letter No. Nil dated 01.01.2016 informed that all the observations have been rectified and they are ready for inspection.

Proceedings of the 246th Meeting of CLB

Syed Ijaz Hussain Shah, Director and Mr. Qayum Nawaz, Production Manager of the firm M/s Inshal Pharmaceutical Industries, Rawat appeared before the Board. Syed Ijaz Hussain Shah, they informed that all the observations identified by FID during his inspection conducted on 04.12.2015 have been rectified and they are ready for inspection for verification of improvements.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and request of the Director of the firm, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members.

i. Dr. Gul Majeed Khan, Member, CLB
ii. Ch. Zeeshan Nazir, DDC (QA)
iii. Mr. Khalid Mehmood, FID-II, Islamabad

The Board further decided to ask the panel to also submit the report in tabulated form identifying the previous observations and the current status of the observations noted by the FID in his inspection conducted on 04.12.2015.

Case No. vi: - **M/S MY LABS (PVT) LTD, BAHAWALPUR**

The case was presented before the Central Licensing Board as under:

Background of the case

Syed Zia Husnain, area FID, Lahore has conducted inspection of the company on 08.10.2015 to verify GMP compliance and production activities. Following observations were noticed:-

Executive and Worker entry

i) Automatic shoe cover machine is required e.g. gown, scarf, gloves, mask, caps, provide etc.

ii) The management has been advised for further improvements.

Raw Material & Packaging Material Store:

iii) It is advised that proper color demarcation be done for quarantine, approved and rejected area. Safety helmets advised.

iv) It is advised to focus to avoid cross contamination during dispensing.

v) It is advised to install air conditioners in packaging material store and also temperature and humidity monitoring devices also be installed.

Liquid Injectable Section (Veterinary General):

vi) It is advised to improve washing process.

vii) It is advised for more improvements pertaining to validation of systems and also keeps on focusing to avoid the cross contaminations.

Water Treatment Plant:

viii) It is advised that TDS and conductivity of the water be tested frequently and all other necessary tests be performed and documented for production of safe and effective drugs.

Calibration and Validation:

ix) It is advised to timely calibrate the equipments/machinery as per scheduled time as required.

x) It is advised that the process of validation be continued time to time as per requirements of the respective process and in this regard master validation plan be established.

The FID further concluded that:

xi) Develop segregated area for manufacturing of penicillin containing drugs as per law and take necessary approvals from the concerned board under DRAP Act 2012. Till the development of segregated penicillin area, production of penicillin containing drugs is stopped.

xii) Safety helmets required to be arranged in stores.

xiii) Air conditioners required to be installed in packaging material store. Temperature and humidity also be monitored.

xiv) Shoe dispenser required to be installed.

xv) Safety bar be provided in the operational area of Q-Mixer.

xvi) Process validations and calibrations of equipments required to done time to time and document the same. Develop the master validation plan.

xvii) Conduct the annual review of products.

xviii) Develop SOP for change control.

xix) Recall and compliant system required to be improved.

xx) Self inspection system required to be developed and document the same.

Action Taken by DRAP:- After receiving inspection report, a show cause notice / stop production order of penicillin products was issued to the firm on 26.11.2015. The matter of grant of penicillin products without approved section was also referred to Secretary, DRB for taking action.

Reply of the firm:- In response of the show cause notice, the firm vide letter No. Nil dated 04.12.2015 informed that all the observations have been rectified and they are ready for inspection.

Proceedings of the 246th Meeting of CLB

Mr. Ghlam Bari, Director Technical of the firm M/s My Labs. Bahawalpur appeared before the Board for personnel hearing. He informed that on the direction of FID, they have stoped manufacturing of Penicillin products, as they had not approved facility for manufacturing of Penicillin products. Now they have got approval of layout plan of penicillin section from Licensing Division and they are developing a new section of penicillin. He further informed that the observations identified by FID have been rectified and they are ready for inspection for verification of the improvements.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and request of the Director of the firm, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members.

i. Mr. Muawar Hayat, Director, DTL, Bahawalpur
ii. Dr. Zaka ur Rehman, Member, CLB
iii. Syed Zia Husnain, FID, Lahore

The Board further decided to direct the panel to also submit report in tabulated form identifying the previous observations and the current status. and

The production of penicillin products will remain stop till development of facility/approval from the Licensing Division and recommendation by the panel for resumption of production.

Case No. vii: - **M/S MEDISAVE PHARMACEUTICAL, LAHORE**

The case was presented before the Central Licensing Board as under:

Background of the case

Dr. Sheikh Akhter Hussain, DDG (E&M) and Mr. Asim Rauf, area FID, Lahore has conducted inspection of the company on 09.12.2015 to verify GMP compliance and production activities. The panel noticed a number of observations/ violations in sterile liquid for injection (Infusion) and Cephalosporin Injection Section, which includes:-

i) The stock i.e., empty bottles were lying on floor in cooling zone without any status.

ii) Flip off caps were found lying in sterile area without any status.

iii) The doors for washing, filling etc were found open thus pressure was not maintained.

iv) Drains were found open in infusions injectable section. Filling pipe was being passed though open door.

v) Dustbins were found open with different trash material.

vi) Ceftriaxone empty containers were lying in the cephalosporin sterile area.

vii) Different articles i.e., brush screws etc were found lying in the hatch in the cephalosporin area.

viii) Epoxy needs re-coating in above areas as various patches without epoxy could be seen etc.

ix) The conditions were not GMP compliant.

x) The humidity level in one room in Infusion section was 67%.

xi) It was directed to provide compliance report at the earliest.

xii) In addition to the observations noted above the panel further directed the management of the firm to stop the manufacturing activities in Injectable General (Infusion) and Cephalosporin Dry Powder Injectable Section and attend to the above observations including improving GMP compliant.

Action Taken by DRAP:- After receiving inspection report, a show cause notice / stop production order in Sterile Liquid Infusion Section (General) & Dry Powder for Injection Section (Cephalosporin) was issued to the firm on 13.01.2016.

Reply of the firm:- In response of the show cause notice, the firm vide letter No. Nil dated 19.01.2016 informed that all the observations have been rectified and they are ready for inspection.

Proceedings of the 246th Meeting of CLB

Ch. Imtiaz Ahmad, CEO and Mr. Rashid Nazir, QCM of the firm M/s Medisave Pharma, Lahore appeared before the Board for personnel hearing. Ch. Imtiaz Ahmad, CEO informed that the improvements have already been done and accordingly compliance report was also submitted in QA Section. He added that recently a team from Uganda has visited the facility and qualified the firm. He further added that the observations identified by FID have been rectified and they are ready for inspection.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and request of the Director of the firm M/s Medisave Pharma, Lahore, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members.

i. Dr. Ikram ul Haq, Member, CLB
ii. Mr. Asim Rauf, FID, Lahore
iii. Mrs. Aisha Irfan, FID, Lahore

The Board decided to direct the panel to also submit report in tabulated form identifying the previous observations and the current status. and

The production will remain stop till recommendation by the panel for resumption of production and accordingly approval from the Board.

Case No. viii:- **M/s Rehman Rainbow (Pvt) Ltd Lahore**

The case was presented before the Central Licensing Board as under:

Background of the case

i. A fire incident had taken place at M/s Rehman Rainbow, Lahore which claims life of 03 persons in which two male workers and a female pharmacist.
ii. The FID advised the firm to submit comprehensive report covering the reasons for incidence and measure taken to avoid such incidences in future.
iii. The firm was advised to stop their production till the finalization of investigation and permission from DRAP.
iv. A panel comprising of Mr. Asim Rauf, FID, Mr. Ajmal Sohail, FID and Mr. Abdul Rasheed Sheikh, FID, Lahore inspected the firm on 27.03.2015 and directed the firm to stop their production.
v. The panel also enclosed the FIR in reported in Kot Lakhpat Police station filled by victim's relative.
vi. Stop production order was served by this Directorate on 05.05.2015 with the direction to explain the reasons for such incident.
vii. On 23.05.2015, Firm submitted compliance report alongwith the necessary documents such as withdrawal of FIR filled by victim's relative and requested to allow them to resume the manufacturing as they are suffering alot due to said orders.
viii. The Director (QA/LT) constituted a panel comprising of following members to check the GMP compliance:-
    i. Mr. Asim Rauf, FID,
    ii. Mr. Ajmal Sohail, FID
    iii. Mr. Abdul Rasheed Sheikh, FID, Lahore

ix. The panel inspected the firm on 01.09.2015 & 09.10.2015 and informed as under:-

Sr. No	Inspection dated 27.03.2015	Inspection dated 01.09.2015 & 09.10.2015
i.	The firm may be directed to stop all the manufacturing operations firm till the facility is revamped and investigated for reason of failure of controls that took the lives of workers, and actions taken by the firm to prevent its reoccurrence and to plug in the corrective actions.	The manufacturing unit was not operational at the time of inspection. The firm, however provided documents regarding investigation regarding the incidence which caused the loss of three lives. The investigation was done by M/s Premier Technologies Hameed House No. 4098, West End Street Gulzar-e-Quaid, Rawalpindi. The said firm pointed out gapes in the safety for possible reasons of the incident. Furthermore the recommendations for prevention of such like incident were also given. The same agency prepared a compliance report of the gap analysis on the basis of inspection done on 21.03.2015
ii.	Perform the gap analysis	As per recommendations the firm M/s Rehman

	of the manufacturing premises through specialized external agencies for electric safety, fire fighting safety and the building strength etc.	Rainbow, Lahore got the following safety certificates. M/s Silicon Engineers (Pvt) Ltd, has issued a test certificate in the light of inspection conducted on 15.09.2015, indicating that the defects pointed out have been removed by the manufacturing firm. Architect, Jawaid Iqbal issued building structural stability report that the overall building complex of Surgitex Rehman Rainbow, Lahore was in a good condition and needed not structural maintenance at that time (dated 04.09.2015) A firefighting system check certificate was obtained by Hussain Habib Corporation (Pvt) Ltd, Lahore stating that the system was in normally working condition.
iii.	Keep apprised DRAP Islamabad about the investigations carried out by the Police against registered FIR.	The panel has attached the proceedings regarding investigation against FIR which is showing that the relatives of the deceased persons have withdraw their complaint against the company owners.

The panel recommended the resumption of production activities in order to access GMP compliance specifically related to storage of volatile liquids.

Proceedings of the 246th Meeting of CLB

The case was discussed in detail. Keeping in view the panel inspections of the firm conducted on 27.03.2015, 01.09.2015 and 09.10.2015. The investigation conducted by M/s Premier Technologies, Rawalpindi, test report of M/s Silicon Engineers, Lahore, Structure stability report issued by Architect Mr. Javed Iqbal and fire fighting check certificate issued by Hussain Habib Corporation Lahore (all steps performed by the firm by itself) was also discussed in detail. Dr. Ikram ul Haq, Member CLB inquired about the fait of the FIR lodged by the victim's family, he was informed that the FIR has been withdrawn by victim's family as per record provided by the concerned FID and Panel.

Decision of the 246th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and recommendations of the panel in its inspection conducted on 27.03.2015, 01.09.2015 and 09.10.2015, the Board decided to allow resumption of production activities of the firm M/s Rehman Rainbow (Pvt) Ltd, Lahore in order to access GMP compliance specifically related to storage of volatile liquids. The Board further decided to direct the Area FID to conduct the follow up inspection within 03 months of resumption of production and submit report.

Case No.ix:- M/S REHMAT PHARMA, LAHORE

The case was presented before the Central Licensing Board as under:

Background of the case

Mrs. Aisha Khalil, FID, Lahore had conducted the inspection of the firm M/s Rehmat Pharma, Lahore on 29.05.2014 to check the GMP compliance, wherein she noticed a number of critical observations.

Action Taken by DRAP:-
The firm was served showcause notice on 04.08.2014
Reply of the firm:-
The firm vide letter No. Nil dated 13.08.2014 had submitted the reply of the showcause notice.
Action Taken by DRAP:-
The Director (QA/LT) on 29.09.2014 had constituted the following panel to conduct the GMP inspection of the firm:-

i. DDG (E&M) Lahore
ii. Area FID, Lahore
iii. Area ADC, Lahore

The above panel inspected the firm on 17.11.2015 and informed that management of the firm showed positive response for compliance to further upgrade the plant to manufacture safe and effective drugs.

Proceedings of the CLB in its 245th Meeting

In 245th meeting of CLB, it was informed to the Board by the QA/LT Division that the matter of withdrawal of showcause notices was referred to the Director (Legal Affairs) for seeking legal opinion. The Director (LA) had opined that " No authority has been delegated to decide upon the allegations in the show cause notice or withdraw it; understanding there by that after issuance of the show cause notice the matter should be brought before the Board itself for a decision in the matter."

In the light of opinion of the Legal Affairs Division and decision of the Central Licensing Board in its 245th Meeting, case was placed before the Board for consideration.

Decision

The Board endorsed the opinion of Director (Legal Affairs) and decided to withdraw the showcause notice issued to M/s Rehmat Pharma, Lahore, keeping in the panel inspection of the firm M/s Rehmat Pharma, Lahore conducted on 17.11.2015, in which the panel informed that management of the firm showed positive response for compliance to further upgrade the plant to manufacture safe and effective drugs.

Draft Minutes of 246th Meeting of the CLB Held on 22nd February 2016

Case No. 01

Subject: - **Manufacture & Sale of Spurious / Un-Registered) Herbal Spring Capsule Batch No. Nil By Wajid Ali Khan Of M/S Wajid Traders, Al-Karim Medicine Market, Namakmandi Peshawar. F. No. 4- 07/2013-QC**

The case was placed before the Board in its 246th meeting held on 22nd February 2016 as under:-

Brief of the case

The FID Peshawar, during a search raid along with Inspector FIA Mr. Naeem Khan and other FIA officials of Crime Circle Peshawar, against spurious drugs on 11.02.2013, drew samples of different herbal products including Spring Capsule Batch No. Nil manufacturing and Expiry dated Nil claimed to be manufactured by Mhafiz Dawakhana Lahore from M/s Wajid Traders, Al-Karim Medicine Market. Namakmandi, Peshawar vide Form-3. The samples were sent to CDL Karachi for the test analysis and the results of the FGA, CDL, Karachi regarding the sample under reference are as follows:-

Identification:- **Diclofenac Sodium identified,** however Steroids not identified as suspected by the inspector of Drugs.

Remarks:- The label claims herbal product and therefore, should not contain any allopathic ingredient Since, Diclofenac Sodium is an allopathic drug, therefore, the sample is declared as an **Un-Registered Drug Product**" under Drugs Act 1976

The FID served an explanation letter to Wajid Ali Khan of M/s Wajid Traders Al-Karim Medicine Market, Namakmandi, Peshawar along with the CDL test report, to explain his position in the matter of sale of un-registered drug product and furnish invoice warranty, if any, but not reply was received.

The FIR bearing No.141/2013 dated 11-02-2013 was lodged with FIA, ACC, Peshawar by the FID after having permission from the competent authority at that time against the accused person for violation of Section 23 punishable under Section 27 of the Drugs Act 1976. Wajid Ali Khan was arrested by the FIA and during investigation, it was disclosed that he has purchased the drug from Muhammad Asif, Proprietor of M/s Akbar DawaKhana, Mardan. He was also arrested for interrogation by FIA authorities but he flatly denied the supply of unregistered Spring Capsule to of M/s Wajid Traders, Peshawar. M/s Muhafiz DawaKhana also disowned the drug and categorically asserted that the sample under reference has not been manufactured by them and hence the product is Spurious under Section 3(z-b)(ii) of the Drugs Act 1976. It was further stated that after the availability of spurious/counterfeit Spring Capsule in the market they stopped manufacturing of this herbal drug in 2009.

FIA submitted investigation challan of the subject case on 19-03-2015 in the office of FID Peshawar and has held following two persons responsible for manufacturing and sale of spurious/unregistered drug. The FID has also requested for permission to prosecute both in Drug Court Peshawar for violation of Section 23 punishable under Section 27 of the Drugs Act 1976:-

Wajid Ali Khan S/o Muhammad Akbar Proprietor M/s Wajid Traders, Al-Karim Medicine Market. Namakmandi, Peshawar, R/o Ring Road Garhi Qamar Din Peshawar. Permanent address:- Maskin Abad, Jalala, Tehsil Takht Bhai, District Mardan	Muhammad Asif Khan S/o Bahadar Khan, Proprietor of M/s Akbar DawaKhana, Imran Market, Charsadda Road, New Adda, Mardan. R/o Muhallah Shaheen, Mazdoorabad, Tehsil Takht Bhai, Mardan

A show cause notice was issued to the accused offering them opportunity of personal hearing before Central Licensing Board. The accused persons were called before the CLB in its 246th meeting held on 22-02-2016 for defending their case respectively

Proceedings:-

Mr. Wajid Ali Khan s/o Muhammad Akbar CNIC No.1610208955837 of M/s Wajid Traders Al-Karim Medicine Market, Namakmandi, Peshawar was appeared before the Central Licensing Board on account of personal hearing and informed that he is on bail and he purchased some medicines from M/s Akbar Dawakhana Mardan by considering as unani and without noticing that batch number was not mentioned on them.

Muhammad Asif s/o Bhadur Khan M/s Akbar DawaKhana appeared before the Board on account of personal hearing and stated that he was not a manufacturer rather merely a shop keeper and that he had purchased spring Capsules from M/s Muhafiz Dawa Khana against proper purchase bill with warranty. He further added that he always purchase stock of medicines on bills with warranties and while selling to purchasers he always issues warranties accordingly. He further stated that drug under reference (i.e those spring Capsules, which were recovered from Wajid Herbal Traders) was not supplied by him to Mr. Wajid Ali as these were without batch No.

Decision of CLB

The Board after detailed discussions, deliberations, considering point of view of persons appeared before the Board, taking in account the legal/codal provisions and keeping in view the facts of the case, and as per available record decided to allow for the prosecution of the following accused persons in the Drug Court, Peshawar in contravention of section 23 of the Drugs Act 1976 which is punishable under section 27 of the Drugs Act 1976, as per request of FID Peshawar.

1. Wajid Ali Khan S/o Muhammad Akbar Proprietor M/s Wajid Traders, Al-Karim Medicine Market. Namakmandi, Peshawar, R/o Ring Road Garhi Qamar Din Peshawar. Permanent address:- Maskin Abad, Jalala, Tehsil Takht Bhai, District Mardan	2.Muhammad Asif Khan S/o Bahadar Khan, Proprietor of M/s Akbar DawaKhana, Imran Market, Charsadda Road, New Adda, Mardan. R/o Muhallah Shaheen, Mazdoorabad, Tehsil Takht Bhai, Mardan

Case No.02

Subject: - **Manufacture and sale or (Counterfeit/ un-registered) Drugs by M/s Qudratullah Herbal Traders, Namakmandi, Namakmandi, Peshawar. F. No.04-06/2013-QC**

The case was placed before the Board in its 246th meeting held on 22nd February 2016 as under:-

Brief of the case

The FID Peshawar, along with Inspector of FIA Mr. Naeem Khan and other FIA, official inspected the M/s Qudratullah Herbal Traders Namakmandi Peshawar, on 11-02-2013, during the search raid various un- registered herbal and Homeo/Unani drugs were drawn from the M/s Qudratullah Herabl Traders Namakmandi Peshawar. The FID Peshawar send the samples to Federal Government Analyst (FGA), CDL, Karachi, for test analysis. However the FGA, CDL, Karachi, identified allopathic ingredients in the following herbal drugs, the Federal Government Analyst, CDL, Karachi has been declared the sample as "**Un-Registered**

S.No.	Name of Drug	Mfg by	Batch No.	Expiry Date	Remarks/Test report No.
1.	Easy Life Capsule	Gold Life Homeo & Herbal Pharma Lahore	EL-001	01/2014	**Un Registered** R.247/2013 dated 24-04-2013
2.	Arthoseen Capsule	M/s Al Nasar Lab Karachi	12/7	07/2014	**Un Registered** R.249/2013 dated 24-04-2013
3.	Vicks Balm	M/s Herbal Unani Pharma Lahore	0002	09/2015	**Un Registered** R.244/2013 dated 25-04-2013
4.	Sherbet Faulad	Top Treatment Lahore	29010246	10/2014	**Un Registered** R.253/2013 dated 24-04-2013

02. The FIA had lodged the FIR against the Suleman Khan and Javed Khan owner of M/s Qudratullah Herbal Traders Peshawar for violation of Section (23) punishable under Section (27) of the Drugs Act 1976. The FID Peshawar has informed that the FIA has submitted investigation Challan in the subject case on 07-03-2015 to the office of FID Peshawar. The FID reported that the FIA investigation has proved and charged Suleman Khan and Javed Khan owner of M/s Qudraullah Herbal Traders Namakmandi Peshawar, for manufacture and sale of Counterfeit and un-registered drugs which is violation of Section 23 punishable under Section 27 of the Drugs Act 1976, the FID Peshawar, requested to allow for prosecution under Section 30 the following accused persons in the Drugs Court Peshawar, for violation of Section 23 punishable under Section 27 of Drugs Act 1976. Following persons of the firm have been held responsible for committing the offence by the FID.

1. Suleman Khan S/o Muhammad Akbar, of M/s Qudratullah Herbal Traders, Namakmandi, Namakmandi, Peshawar Resident of Maskeen Abad Jalala Takhat Bhai District Mardan	2. Javed Khan S/o Hanifullah owner of M/s Qudratullah Herbal Traders, Namakmandi, Namakmandi, Peshawar, Resident of House No.854, Umar Farooq Sheikh abad No.4, P.O Gulbahar Peshawar

A show cause notice was issued to the accused offering them opportunity of personal hearing before Central Licensing Board. The accused persons were called before the CLB in its 246th meeting held on 22-02-2016 for defending their case respectively.

The letters of personal hearing were returned back with the remarks that address is incomplete

Proceedings:-

Suleman Khan, Owner of the firm did not appear before the Board for personal hearing, however Mr. Javed Khan S/o Hanifullah CNIC No.17301-1394456-5 was appeared before the CLB meeting and stated that the show cause notice was not received to him. He further stated that on 22-2-2016 he was informed from FID Peshawar office about the Board's meeting so he reached Islamabad. He said that his address was Sajid General Store Shaikhabad No.4 Muhallah Umar Farooq beron ganj gate Peshawar. He stated that he was the sale man and not the owner of the firm and he is on bail. He further stated that Mr. Suleman Khan was also on bail. He informed that he had done phone to Mr. Suleman Khan about the Board meeting.

The FID Peshawar during the meeting telephonically confirmed that copies of show cause notice and personal hearing letters were handed over to the accused persons.

Decision of CLB

The Board after detailed discussions, deliberations, considering point of view of persons appeared before the Board, taking in account the legal/codal provisions and keeping in view the facts of the case, and as per available record decided to allow for the prosecution of the following accused persons in the Drug Court, Peshawar in contravention of section 23 of the Drugs Act 1976 which is punishable under section 27 of the Drugs Act 1976, as per request of FID Peshawar.

1. Suleman Khan S/o Muhammad Akbar, of M/s Qudratullah Herbal Traders, Namakmandi, Namakmandi, Peshawar Resident of Maskeen Abad Jalala Takhat Bhai District Mardan	2. Javed Khan S/o Hanifullah owner of M/s Qudratullah Herbal Traders, Namakmandi, Namakmandi, Peshawar, Resident of House No.854, Umar Farooq Sheikh abad No.4, P.O Gulbahar Peshawar

Case No.3

Subject: **Manufacture & Sale of Un-Registered drug Super Skoon Tablets Batch No. SS001 by M/S Royal Herbal Homoeo Pharmacy Redg, Faisalabad. F. No. 04-10/2015-QC**

The case was placed before the Board in its 246th meeting held on 22nd February 2016 as under:-

Brief of the case

The FID Peshawar along with FIA Inspector (Crime Circle) Peshawar Mr. Gul Rehman visited M/s Wajid Herbal Medicine (Ware House) Shah Qabool Colony Namakmandi Peshawar on 01-06-2015 and took samples of Super Sakoon tablet Batch No. SS -001 and Afex-M Capsule Batch No. Nil and sent to the Federal Federal Government Analyst, CDL Karachi for test analysis, the CDL Karachi declared the sample as un-registered drug product and the result/remarks as under:-

S.No.	Name of Drug	Mfg by	Batch No.	Expiry Date	Remarks/Test report No.
1.	Super Skoon Tablets	M/s Royal Herbal Homeo Pharmacy Regd. Faisalabad	SS-001	December 2016	Report No. RIP 58/2015 dated 07th August 2015 Remarks:- Label claim " Herbal Homoeo medicine for the Treatment of rheumatism & Arthritis" The HPLC result reveals that tablet contains 17.122mg Fluoxetine pr tablet Since, Fluoxetine HCL is an allopathic drug and the sample (super Skoon tablets is not registered with DRAP (Directorate of Registration) Government of Pakistan Hence the sample is declare un registered Drug product under the Drugs act 1976
2.	Afex-M Capsules	M/s Huma Herbal Products Regd Karachi	Nil	January 2018	Report No. R.IP.59/2015 dated 30th July 2015 Remarks:- Label claim Herbal product for complete sexual

					disease for men having erectile dysfunction Since Sildenafil Citrate is an allopathic durg and the sample (Afex M Capsules) is not registered with DRAP (Directorate of Registration) Islamabad government of Pakistan Hence the sample is decalred un registered Drug product under the Drugs Act 1976

The Federal Government Analyst CDL Karachi has declared both the above mentioned medicines as un-Registered vide Test Reports No. RIP 58/2015 dated 07.08.2015 and RIP 59/2015 dated 30.07.2015 Show cause notice served to M/s Wajid Herbal medicine Peshawar vide letter No. F. 10-46-48/2015-Wajid-DRAP 3205 on 19.08.2015 for manufacture and sale of unregistered drugs In reply M/s Wajid Herbal Peshawar provided purchase invoices/warranties of Toyal Herbal & Homeo Pharmacy Faisalabad and Huma Herbal Pharma North Industrial area Karachi

The FID served the show cause notice vide letter No. F. 10-46-48/2015-Wajid-DRAP 3205 on 05.10.2015 were served to Muhammad Khalid S/o Muhammad Yaqoob of M/s Royal Herbal & Homeo Pharmacy Faisalabad and Mushtaq Khan S/O Fazal Dad Khan Abbasi of M/s Huma Herbal Pharma North Industrial Area Karachi for manufacture and sale of Un-Registered Super Skoon Tablet Batch No. SS-002 and Afex-M Capsules Nil respectively.

In response Mushtaq khan S/o Fazal Dad Khan flatly denied the supply/provision of Afex-M Capsules Batch No. Nil to Wajid Herbal Medicine Shah Qabool Colony Peshawar He further asserted that he has no concern with M/s Huma Herbal Product Karachi

The FID Peshawar served the show case notice to the Muhammad Khalid S/o Muhammad Yaqoob of M/s Royal Herbal and Homeo Pharmacy Faisalabad whcih was returned back to his office with the Urdu remarks on envelop (Lainy say Inkari Hn).

The FID Peshawar requested for permission to lodged the FIR with the FIA crime circle Peshawar against the following persons:-

1. **Muhammad Khalid S/o Muhammad Yaqoob, Satyana Road, House No.15 Mohallah Umar Housing Colony, Faisalabad City, Faisalabad of M/s Royal Herbal & Homeo Pharmacy Faisalabad.**
2. **Mushtaq Khan S/o Fazal Dad Khan Abbasi, Chirala P.O Khas, Tehsil Dheer Kot District Bagh, M/s Huma Herbal Pharma North Industrial area.**
3. **Wajid Herbal medicine (Ware House) Shah Qabool Colony Namak Mandi Peshawar.**

The Show cause notice issued to the accused persons and called for personal hearing

Proceedings:-

Mr.Taimoor Zafar Advocate appeared before the CLB on 22-02-2016 on behalf of Mushtaq Khan S/o Fazal Dad Khan, from M/s Huma Herbal Pharma North Industrial area, Karachi and

Mr. Wajid Ali Khan s/o Muhammad Akbar CNIC No.1610208955837 from Wajid Herbal medicine (Ware House) Shah Qabool Colony Namakmandi Peshawar was appeared before the Central Licensing Board.

Muhammad Khalid S/o Muhammad Yaqoob, Satyana Road, House No.15 Mohallah Umar Housing Colony, Faisalabad City, Faisalabad of M/s Royal Herbal & Homeo Pharmacy Faisalabad did not appear before the Board (the personal hearing letters was returned back without any reason mentioning on the letters).

Mr. Taimoor Zafar Advocate informed the Board that his client Mr. Mushtaq Khan is a sales man of new Imtiaz DawaKhana Faisalabad for the last 15 years and during this period his client has neither joined any other company nor supplied any product of any other company to any retailer or distributor. He claimed that his client had no concern with M/s Huma Herbal Products Karachi and Royal Herbal and Homeo Pharmacy. He denied the supply of Afex-M Capsules by his client to any retailer/ Medical Store including Wajid Herbal medicines. He requested for the termination of proceeding against his client.

Mr. Wajid Ali Khan s/o Muhammad Akbar informed the Board that he had purchased the subject medicines super skoon from Royal Herbal and Homeo Pharmacy Faisalabad whose owner is Mr. Muhammad Khalid. He said that he purchased Afex Capsules from M/s Huma Herbal Karachi whose owner is Mr. Mushtaq Khan. He stated that he did the payment to the Mushtaq Khan from M/s Huma Herbal Karachi through Easy Pesa. He informed the Board that he had warranties of said medicines which he has submitted to the FID.

Decision of CLB

The Board after detailed discussion, deliberations, considering point of view of persons appeared before the Board, taking in account the legal/codal provisions and keeping in view the facts of the case, and as per available record decided to allow the FID Peshawar for the lodging the FIR of the following accused persons as per his request.

1. **Muhammad Khalid S/o Muhammad Yaqoob, Satyana Road, House No.15 Mohallah Umar Housing Colony, Faisalabad City, Faisalabad of M/s Royal Herbal & Homeo Pharmacy Faisalabad.**
2. **Mushtaq Khan S/o Fazal Dad Khan Abbasi, Chirala P.O Khas, Tehsil Dheer Kot District Bagh, M/s Huma Herbal Pharma North Industrial area.**
3. **Wajid Herbal medicine (Ware House) Shah Qabool Colony Namak Mandi Peshawar.**

Case No.04

Subject:- **Manufacturing and Sale of Unlawful Drugs at the Residential House of Noorul Bashar located at palangzai Matta Mughal Khel District Charsadda**

The case was placed before the Board in its 246th meeting held on 22nd February 2016 as under:-

Brief of the case

The FID Peshawar submitted that Noor ul Bashar S/o Shah Khail resident of Palangzai Matta Mughal Khel Tehsil Shabqadar District Charsadda and his business partner Hajji Abdul Karim S/o Mir Wais Khan resident of Sardar Colony Badany Pul Peshawar were involved in manufacturing and selling of spurious drugs A team comprising the FID Mr. Adnan Shahidullah Assistan Drugs Controller Peshawar Mr. Naseer Khan and Fazle Akbar Inspectors FIA Mr. Zafar Iqbal Sub Inspector FIA and other FIA contingents raided the residential house of Noorul Bashar on 01.04.2014 A considerable stock of spurious/substandard Adulterated drugs alongwith stickers labels and unit carton of different spurious drugs of different pharmaceutical firms were recovered and seized. All samples were sent to the Central Drugs Laboratory Karachi for test/analysis. The result of Federal Government Analyst is given below.

S.No.	Name of Drugs	Mfg by.	Batch No.	Expiry Date.	Remarks on test report with its No.
1.	Tienam-500 Inj.	Merck & Co. Inc USA.	2072650	08.2014	**(Spurious Substandard, Adulterated)** RIP.113/2014 dated 06-06-2014
2.	Vancomycin Injection	Abbot Karachi	18232XV	06.2014	**(Spurious & Substandard)** RIP.114/2014 dated 06-06-2014.
3.	Heparinol-5000 Injection	Ain Medicare Malysia	V2200099	03-2016	**(Spurious Substandard)** RIP.116/2014 dated 06.06.2014.
4.	Mersilk Black Braided Silk Structure Sterile	Jhonson & Jhonson Karachi	Nil	Nil	**Substandard** RIP.118/2014 dated 13.05.2014.
5.	Fosfomycin 1.0g Injection	China chongging China	110681	06.2014	**Substandard** RIP.115/2014 dated 08-05-2014
6.	Glucantine Injection .	Haupt Pharma Livron France	0866	03.2016	**Substandard, Adulterated.** RIP.112/2014 dated 08.05-2014
7.	Sterile Water for injection.	Wunan Grand Pharma China	20121022	10.2015	**Misbranded** RIP.120/2014 dated 19-05-2014
8.	Claforan 1.0g Injection	Snofi Aventis Karachi	WA015	04/2015	**(Spurious & Substandard)** RIP.121/2014 dated 02.06-2014.
9	Vial Filled with white Liquid	Nil	Nil	Nil	**Contravention of Section 23(1)(h) of Drugs Act 1976** RIP.57/2014 dated 10-04-2014 (page 95/corr)

Portions of the samples were also sent to the relevant manufacturer for verification and comments. M/s Abbot Laboratories Karachi disowned vancomycine Injection (500ml/vila) batch No.18232XV, M/s Johnsons & Johnsons disowned Mersilk Suture Batch No.Nil , M/s B rooks Pharma Ltd Karachi Disowned the sample Acuron Injection Batch No.009Gl , M/s Sanofi-Aventis Pakistan Ltd Disowned sample Claforan 1.0G Injection Batch No.WA015, M/s Elixir Laboratories Lahore could not analyze its product Aqua Pro water for injection die to inadequate quantity of one ampoule however they said that they had never supplied Aqua Pro Water for injection the accused Persons. Therefore the products recovered from the said premises are spurious as per section 3(z-b)(ii)

The FID Peshawar served the Show cause notice vide letter No. F.80.92/2014-Noorul Bashar-DRAP 1188 dated 30-06-2014 to the Noorul Bashar S/o Shah Khail for manufacture and sale of spurious Substandard and adulterated drugs but no comments/reply was furnished by the accused persons to this office until now.

After seeking permission from competent authority FIR was lodged against Noorul Bashar and his business partner Haji Abdul Karim for violation of section 23(1)(a)(i), (b) punishable under section 27(1) of the Drugs Act 1976. Noorul Bashar got his BBA from Drugs Court Peshawar and Haji Abdul Kaim is absconder. During investigation by FIA Noorul Bashar stated that he is taxi driver and before this he was working in Saudi Arabia from 1996 to 2003 as a laborer he stated that Haji Abdul Karim S/o Mir Wais Khan is his brother in law and that he has not business terms with Haji Abdul Karim regarding un-lawful drugs He further stated that the recovered drugs from his house are kept by Haji Abdul Karim fro some days.

The FIA submitted investigation Challan in the subject case on 27.03.2015 to the office of FID. And the FIA investigation has charged Noorul Bashar and Haji Abdul Karim for manufacture and sale of Spurious Substandard Adulterated drugs which is violation of Section 23(1)(a)(i), (b) punishable under section 27(1) of the Drugs Act 1976. The printing of label and packages for spurious/ un-registered drugs is also an offence under Section 26 of the Drugs Act 1976

The FID has also requested for permission to prosecute both in Drug Court Peshawar for violation of Section 23 (1)(a)(i),(b) punishable under Section 27 of the Drugs Act 1976:-

Noorul Bashar S/o Shah Khail, R/o Palangzai Matta Mughal Khel Tehsil Shabqadar District Charsadda	Haji Abdul Karim S/o Mir Wais Khan Resident of House No.02 Street No. 4 Razaq Town Chakra Road Rawalpindi, Permanent Adress House No.3-B Badani Pul, Sardar Colony Charsadda Road Peshawar

As per procedure a show cause notice was issued to the accused offering them opportunity of personal hearing before Central Licensing Board. Accordingly the letter of personal hearing has also been issued to the firm and both of aforesaid the accused persons.

Proceedings:-

Mr. Noor ul Bashar S/o Shah Khail CNIC No.17101-2240609-9 was appeared before the Board and informed that Mr. Abdul Karim was his relative and now he is abroad. Furthermore he told that Mr. Abdul Karim telephonically requested to keep some of his goods for some days. He said that after some days FIA arrested Mr. Shakeel (Brother of Mr. Abdul Karim) who informed FIA that his (Abdul Karim) some material/goods were lying in the house of Noor ul Bashar. He (Noorul Bashar) said that then the FIA recovered the goods from his house then he came to know about the FIR and now he was on bail. He said that he was driver and no link with the business of medicines.

The letter to Haji Abdul Karim for personal hearing was returned back with the. Remarks:- "has left the house hence returned back"

Decision of CLB

The Board after detailed discussion, deliberations, considering point of view of persons appeared before the Board, taking in account the legal/codal provisions and keeping in view the facts of the case and as per available record decided to allow for the prosecution of the following accused persons in the Drug Court, Peshawar in contravention of section 23 of the Drugs Act 1976 which is punishable under section 27 of the Drugs Act 1976, as per request of FID Peshawar.

Noorul Bashar S/o Shah Khail, R/o Palangzai Matta Mughal Khel Tehsil Shabqadar District Charsadda	Haji Abdul Karim S/o Mir Wais Khan Resident of House No.02 Street No. 4 Razaq Town Chakra Road Rawalpindi, Permanent Adress

	House No.3-B Badani Pul, Sardar Colony Charsadda Road Peshawar

Case No.05

Subject: - **Manufacture/Sale of De-Registered Drug – Rumin Suspension - Contravention of Provisions of the Drugs Act 1976 and rules framed there under. F. No. 3-17/2014-QC**

The case was placed before the Board in its 246th meeting held on 22nd February 2016 as under:-

Brief of the case

The Federal Inspector of Drugs (FID), Karachi-III vide his letter dated 21-04-2014 informed that he alongwith Dr. Shahid Hussain, FID Karachi and others raided the premises of M/s Ankaz Pharmax (Pvt) Ltd., Karachi on 19-04-2014 at 07.45 AM. The raid was conducted on the source information of FIA Crime Circle Karachi. Deputy Director FIA Mr. Fakeer Muhammad headed the raid alongwith his team. Ten samples of different products were taken from the manufacturers premises for test/analysis on the prescribed Form-3.

- The FID vide his investigation report of the case intimated that eight samples of the drugs taken have been declared to be substandard by the Federal Government Analyst, CDL Karachi. In the light of the same, the FID issued explanation letter regarding the matter of manufacture and sale of substandard drugs to the firm. As per documents provided by the FID, the firm challenged the test reports and requested to get the samples retested from the Appellate Laboratory, NIH Islamabad.

- The FID vide his investigation report of the above case also reported that the firm was found manufacturing its one of de-registered product namely syrup Rumin mentioning the old manufacturing date on the label. It has been intimated that Syrup Rumin was found stored in bulk in big vessel placed in liquid manufacturing areas of the firm. A huge quantity of finished goods of same de-registered syrup was also seen placed in finished good wear house.

- The FID concluded that the manufacturer is guilty of manufacturing substandard drugs and de-registered drug in violation to the provisions of Drugs Act 1976 and rules framed there under. He has requested for cancellation DML of the firm or permission to lodge the prosecution against the firm.

- Following persons of the firm were held responsible for committing the offence by the FID.

  i. Ali Abbass, Managing Director of the firm.
  ii. Akbar Ali, Production Incharge.
  iii. Safdar Alam, Quality Control Incharge.

- As per record of Quality Control Section, registration of this product was cancelled by DRB in its 237th meeting held on 26-02-2013, which was communicated of the firm vide their officer letter bearing No.03-16/2012-QC, dated 22-03-2013.

- The Appellate Laboratory declared 04 samples as Substandard and one of these as Misbranded whereas 03 samples were declared as of Standard quality by the Appellate Lab (NIH) Islamabad.

- As per procedure Show cause notices were issued to the firm and other accused, in the light of the test reports of the Appellate Lab and report of the FID, offering them opportunity of personal hearing before the Drug Registration Board.

246th meeting of Registration Board:-

- The case of manufacture and sale of substandard and de-registered drugs by M/s Ankaz Pharmex (Pvt.) Ltd, Karachi was considered by the Drug Registration Board in its 246th meeting held on 10th & 11th December 2014. Mr. Saleem Isharat Hussain, Technical Consultant of the firm, appeared before the Board on behalf of the firm on 11-12-2014. The Drug Registration Board after hearing the representative of the company, deliberations made, available record and facts of the case decided as under:-

I. "To cancel the registration of the following products of the firm:-

i. Rumin (Ibuprofen) 400mg Tablet, Reg. No. 007545.
ii. Rumin (Ibuprofen) 200mg Tablet, Reg. No. 007543.
iii. Tab. Biprim (Co-Trimoxazole) DS, Reg. No. 008409.

II. The Board further decided to recommend to the Central Licensing Board for cancellation of the Drug Manufacturing License of the firm on the violation of manufacturing of already De-registered product i.e. Rumin Suspension Reg. No. 008526."

239th meeting of Central Licensing Board:-

. The case was accordingly placed before the Central Licensing Board (CLB) in its 239th meeting held on 22nd January 2015, for consideration of recommendation of the Drug Registration Board regarding cancellation of Drug Manufacturing License (DML) of M/s Ankaz Pharmex (Pvt.) Ltd, Karachi and request of the area Federal inspector of Drugs, Karachi for cancellation of DML of the firm or permission to lodge the prosecution against the firm as narrated above.

Decision of 239th meeting of the CLB:-

The Board was apprised about the case. The Board after deliberations, taking into consideration all the facts of the case and available record decided as under:-

"To Issue show cause notice to the firm for cancellation of Drug Manufacturing License (DML) of M/s Ankaz Pharmex (Pvt.) Ltd, Karachi as per Section 41 of the Drugs Act 1976 and also for prosecution of the above named firm and the accused persons in the Drug Court for Sindh, Karachi".

Accordingly a show cause notice along with giving the opportunity of personal hearing, was issued to the following accused persons as nominated by the FID Karachi.

i. Ali Abbass, Managing Director of the firm.
ii. Akbar Ali Production Incharge.
iii. Safdar Alam, Quality Control Incharge.

246th meeting of Central Licensing Board:-

Proceedings:-

The firm and its nominated persons were called for personal hearing before the CLB in its 246th meeting held on 22-02-2016. Mr. Ali Abass S/o S.M Abass (MD of the firm) was appeared before the CLB and informed that there is writ petition in the Sindh High Court wherein the firm has challenged the decision of the Registration Board for cancellation of the registration of the Rumin suspension and he further informed that there is also stay order in the favor of the firm vide Sindh High Court order dated 18-12-2014. The order of the Court dated 18-12-2014 was read out before the Board. On the question regarding availability/presence of any other order of the Court relevant to this case after 18-12-2014, he negated and further informed that next date of hearing of the case in Honorable Sindh High Court was not yet fixed.

Decision:-

The Board after detailed discussions, deliberations, considering point of view of person appeared before the Board, taking in account the legal/codal provisions and keeping in view the facts of the case and as per available record decided **defer the case for clarity of the case and to take the opinion from legal affairs Division of DRAP, that whether the CLB may proceed or not in the case in the light of order of the Honorable Sindh High Court dated 18-12-2014 which is reproduce as under:-**

"Till the next date of hearing, respondents are directed to conduct themselves strictly in accordance with law and not to take any action against the petitioner without due process of law".

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