MINUTES OF 249th MEETING OF CENTRAL LICENSING BOARD HELD ON MONDAY 29th AUGUST, 2016

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249th meeting of the Central Licensing Board (CLB) was held on Monday 29th August, 2016 in the Committee Room, Ministry of National Health Services Regulation and Coordination, G-5/1, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, Drug Regulatory Authority of Pakistan.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Dr.Ikram-ul-Haque ,QC/QA Expert.	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. Abbas Khan, Deputy Director, representative of Department of Health, Govt. of Khyber Pakhtunkhwa.	Member
5.	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
6.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
7.	Mr. Khurram Shahzad Mughal, Consultant M/o Law, Justice and Human Rights, as representative of M/o Law, Justice and Human Rights, Islamabad.	Member
8.	Representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad. (Dr. Abdul Rasheed, CQC attended as representative of QA/LT Division)	Member
9.	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary
10.	Mr. Khalid Munir, Chief Executive, Trigon Pharmaceuticals (Pvt) Ltd., as Representative of PPMA	Observer
11.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
12.	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.

He further added that all the legal and codal formalities would be taken into account for disposal of cases. Mr. Zeeshan Nazir Bajar DD (QA), Mr. Adnan Faisal Saim DD(QC) & Dr. Akbar Ali AD (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

LICENSING DIVISION

Item-I **CONFIRMATION OF THE MINUTES OF 248th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 248th meeting held on 13th July, 2016.

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

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

S#	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s Tayyab Laboratories (Pvt) Ltd, Plot No. 13-A Street No. N-5, RCCI Rawat, Rawalpindi.	**11-08-2016 Formulation**	The Board approved the grant of DML by way of formulation with following sections: **Sections (04)** 1. Tablet (General) Section. 2. Tablet (Psychotropic) Section. 3. Capsule (General) Section. 4. Oral Liquid (General) Section.
2.	M/s Next Pharmaceutical Product (Pvt.) Ltd., Plot No. 44, A-B, Sunder Industrial Estate, Lahore	**01-08-2016 Formulation**	The Board approved the grant of DML by way of formulation with following sections: **Sections (04)** 1. Capsule (General) Section. 2. Tablet (General) Section 3. Oral Liquid (General) Section. 4. Cream / Ointment / Gel Section. (General)

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 / DML No.	Date of Inspection	Decision of CLB
1.	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14-Km, Adyala Road, Rawalpindi. DML No. 000333 (Formulation)	**17-08-2016**	The Board approved the grant of following additional sections /amendment as under:- **Sections:** 1. Pelletization Section **(For in house use only)** 2. Cream/Ointment /Gel (Steroid) 3. Sterile Eye Drops (Steroid) 4. Tablet (Hormone) 5. Cream/Ointment/Gel (Hormone) 6. Lyophilized Injection ampoule (Hormone) 7. Liquid Injection ampoule (Hormone) 8. Oral Liquid Section **(Relocation**) 9. Topical Section (General) (Extension) **(Relocation).**
2.	M/s Alza Pharmaceuticals, Alshifa Trust Eye Hospital, Jhelum Road Rawalpindi. DML No. 000423 (Formulation)	**01-06-2016**	The Board approved the grant of following additional sections as under:- **Section (02)** 1. Steroidal Eye Drops Section. 2. Steroidal Semisolid Section (Skin Cream / Ointment)
3.	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. DML No. 000565 (Formulation)	**03-08-2016**	The Board approved the grant of following additional section as under:- **Section (01)** Dry Powder Suspension (General)
4.	M/s Indus Pharma (Pvt) Ltd, Plot No. 26,27,63,64,65,66 & 67, Sector 27, Korangi Industrial Area, Karachi DML No. 000124 (Formulation)	**19-07-2016**	The Board approved the grant of following additional sections as under:- **Sections:** 1. Oral Dry Powder Suspension (General) 2. Tablet (General) 3. Capsule (General) 4. Main Change Room

5.	M/s Sharex Laboratories (Pvt) Ltd, K.L.P Road, Sharex Colony, Sadiqabad Distt. Rahim Yar Khan. DML No. 000 (Formulation)	**11-05-2016**	The Board approved the grant of following additional sections as under:- **Section (03)** 1. Dry Powder Injection (Cephalosporin) 2. Dry Powder Suspension (Cephalosporin) 3. Capsule (Cephalosporin)
6.	M/s Bosch Pharmaceuticals (Pvt) Ltd, Plot No. 221, Sector 23, Korangi Industrial Area Karachi. DML No. 000350 (Formulation)	**19-08-2016**	The Board approved the grant of following additional sections as under:- **Section (01)** Capsule Pellets filling (General) Section-II

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

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

S. No	Name of the firm / Type of License	Date of Inspection	Decision of CLB
1.	M/s Aries Pharmaceutical (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. DML No. 000565 (Formulation)	**03-08-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 31-12-2014 to 30-12-2019.
2.	M/s NovaMed Pharmaceuticals, 28-Km, Ferozepur Road Lahore. DML No. 000590 (Formulation)	**26-07-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 08-04-2016 to 07-04-2021.
3.	M/s Ophth Pharma (Pvt) Ltd, Plot No.241, Sector 24, Korangi Industrial Area, Karachi DML No. 000488 (Formulation)	**04-08-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 05-05-2016 to 04-05-2021.

4.	M/s Sharex Laboratories (Pvt) Ltd, K.L.P Road, Sharex Colony, Sadiqabad Distt. Rahim Yar Khan. DML No. 000079(Formulation)	**11-05-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 30-09-2015 to 29-09-2020.
5.	M/s Pharmagen Limited, Kot Nabi Bukhsh wala,34-Km Ferozepur road Lahore, DML No. 000325 (Semi Basic Manufacturing)	**16-08-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 25-10-2015 to 24-10-2020.
6.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hattar. DML No. 000644 **(**Formulation)	**04-08-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period. w.e.f 27-09-2013 to 26-09-2018.
7.	M/s Pearl Pharmaceuticals, Plot No. 204, St No. 01, I-10/3, Industrial Area Islamabad. DML No. 000479	**02-08-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 01-09-2015 to 31-08-2020
8.	M/s Libra (Pvt) Ltd, 77-Peshawar Industrial Estate Hayatabad, Peshawar. DML No. 000369 (Formulation)	**24-08-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 17-10-2015 to 16-10-2020
9.	M/s Attabak Pharmaceutical Industries, 5-C, I-10/3, Industrial Area, Islamabad. DML No. 000552 (Formulation)	**19-08-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 30-10-2014 to 29-10-2019.

Item No. V Miscellaneous Cases

Case No.1. APPLICATION FOR RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000358– BY WAY OF FORMULATION OF M /S ZAYNOON PHARMACEUTICALS (Pvt) Ltd.PESHAWAR;

The Renewal of Drug Manufacturing License No. 000358 of M/s Zaynoon Pharmaceuticals (Pvt) Ltd. Peshawar was due on 07-09-2015. The firm did not submit DML renewal Application till to date .Under Rule 6 of the Drugs (Licensing Registering & Advertising), 1976 a license is valid for a period of five years and may be renewed for further period of five years, if application is made before expiry of validity or within sixty days after period of expiry with payment of additional surcharge of Rupees five thousand for each day.

2. As DML renewal application is not submitted till to date. Hence the said Drug Manufacturing License is not valid under the Drugs Act, 1976 and rules framed there under. However as per Rule 5 (3) "if the application for Renewal of License is made after the expiry of the validity of the License, it shall be treated as a fresh application.

3. Licensing Division has already conveyed the status of DML to area F.I.D; the same may be conveyed to firm also that there Drug Manufacturing License is no more valid however firm may submit application as per rule 5(3).

Decision of CLB:

The Board deliberated on the case and decided as under:

i. **Drug Manufacturing License No.000358(by way of formulation) of M/s Zynoon Pharmaceuticals (Pvt) Ltd 27-28 B, Industrial Estate Hayatabad, Peshawar, is not valid and same shall be conveyed to firm.**

ii. **The firm may makes Afresh application for grant of same Drug Manufacturing Licence number. Moreover site verification and lay out approval shall be waived subject to fulfillment of codal formalities.**

iii. **The Board authorized Chairman and Secretary of the Board to convey such decisions in future in such cases on case to case basis and cases would be placed before the Board for appraisal and concurrence.**

iv. **The above decisions will be conveyed to Drug Registration Board and QA/LT Division for their necessary actions at their end.**

Case No.2. **APPLICATION FOR RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000274 – BY WAY OF FORMULATION OF M/S SURGICAL TEXTILE 70 Km MULATAN ROAD NEAR PATOKI**

The Renewal of Drug Manufacturing License No. 000274 of M/s Surgical Textile, 70 Km Multan Road near Patoki, was due on 18-07-2015. The firm has submit ted DML renewal Application109 days late after due dated-e 18-07-2015 .Under Rule 6 of the Drugs (Licensing Registering & Advertising), 1976 a license is valid for a period of five years and may be renewed for further period of five years, if application is made before expiry of validity or within sixty days after period of expiry with payment of additional surcharge of Rupees five thousand for each day.

2. As the application for renewal of license was made three months and seventeen days after expiry of validity of license. Hence the said Drug Manufacturing License is not valid under the Drugs Act, 1976 and rules framed there under. However as per Rule 5 (3) "if the application for Renewal of License is made after the expiry of the validity of the License, it shall be treated as a fresh application.

3. Licensing Division has already conveyed the status of DML to area F.I.D; the same may be conveyed to firm also that there Drug Manufacturing License is no more valid however firm may submit application as per rule 5(3).

Decision of CLB:

The Board deliberated on the case and decided as under:

i. **Drug Manufacturing License No.000274 (by way of formulation)of M/s Surgical Textiles (Pvt.) Ltd. 70 Km,Multan Road ,near Patoki, District Kasor, is not valid and same shall be conveyed to firm.**

ii. **The firm may makes Afresh application for grant of same Drug Manufacturing Licence number. Moreover site verification and lay out approval shall be waived subject to fulfillment of codal formalities.**

iii. **The Board authorized Chairman and Secretary of the Board to convey such decisions in future in such cases on case to case basis and cases would be placed before the Board for appraisal and concurrence.**

iv. **The above decisions will be conveyed to Drug Registration Board and QA/LT Division for their necessary actions at their end.**

QUALITY ASSURANCE CASES (GMP NON COMPLIANCE)

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

Case No. i:- M/S BAJWA PHARMACEUTICALS (PVT) LTD, LAHORE GUJRANWALA ROAD, KOHRI DISTICT SHEIKHUPURA

Background of the case

Mrs. Aisha Irfan, FID, Lahore conducted inspection of company on 27.04.2016 to verify the GMP compliance and production activities. The FID noticed a number of observations, which need urgent attention and rectification. The FID has directed to:-

Premises
Entries

- The outside door of the female workers entry was wide opened and the room was full of flies. The air curtain was also not in operation.

Stores:
Raw Material Store

- It was observed that drums of benzyl alcohol, propylene glycol and formalin etc were stored in de-dusting area.
- Temperature / humidity was not being monitored and temperature logs were not available.
- Air conditioner was also required in quarantine area.
- Proper SOP for sampling required as it was being done by a metric pass worker without the presence of qualified person.
- Seepage on the roof above dispensing hood was seen.

Finished Goods Store

- It was observed that finished goods store was over loaded and in-process quarantine store was also full of its capacity and the firm had stored the remaining finished goods in a corridor in front of the packing hall and even demarcated another corridor in which the finished goods and in-process quarantine goods were stored.
- Temperature / humidity was not being maintained and monitored in finished goods store.

Packing Material Store

- In some unit cartons of different products the manufacturing/expiry dates were already printed of previous months for which the batch would be manufactured in future.

Production Areas:
General Liquid Injectable Section:
De-cartoning Area

- The double door inter lock system meant for transfer of ampoules, was not fully functional, which was linked to ampoule washing area.

Washing Area

- The firm was advised to final washing through distilled water.

Ampoule Filling Area

- Laminar flow hood trolley for transfer of ampoules from sterilizer to filling machine was available, however it was not functional.

- DOP test for filters were not being performed.

Autoclave Room

- As advised by the panel in previous inspection at the time of grant of DML, that large capacity autoclave should be installed or batch size should by such, that one batch could be sterilized at one time, however upon inspection it was observed that this practice was not being followed. Batch size of 50,000 and even 60,000 ampoules were manufactured and autoclaved in 02 or 03 parts while sterility of only one part was being performed.

In-Process Quarantine Store

- It was overloaded and some in-process batches were even placed in corridors without temperature maintenance. The firm was advised to curtail this practice immediately.

Water Treatment Plant

- The firm was asked to develop SOPs for the cleaning / validation of water treatment plant.

Safety Measures

- A door was provided for the purpose of emergency exit, however it was not proper and was being opened widely by workers frequently as observed during inspection that the door was meant for emergency exit was opened and the workers were going out and in through it outside the door, the waste such as broken ampoules / cartons were dumped. The door was directly opened in to the corridor in injectable area.
- The firm was directed to close it with lock and key and should only be used in case of emergency / fire incident only.
- Proper SOPs for waste disposal should also be developed and waste should be incinerated.

Quality Control Laboratory

- HPLC was not functioning and the calibration of Polarimeter was expired. Stability Chamber also had some electrical problem.
- The liquid particle counter required to be attached with printer and printed readings should be attached with BMR.
- It was advised to install Laminar Flow Hood and place liquid particle counter under it.
- Cold incubator required.
- The microbiologist was advised to purchase micro-organisms cultures for required tests.

Quality Assurance

- The firm was asked to implement quality assurance SOPs at each and every step.
- It was observed that almost four batches of Pivacine-SP Injection Batch No. 001, 002, 003 and 004 (Bupvicane) Registration No. 078950 were placed in an unauthorized area, on a stair case, when asked about the status, the Director Mr. Kashif Bajwa Informed that due to misprinting on outer cartons and ampoules i.e. intramuscular IM injection, where as it is for spinal block, the firm had to recall the batches from market.
- The firm however, failed to provide relevant documents such as number of products recalled, utilized, complained from hospitals/market if any etc. Moreover, the product was placed openly on staircase instead of rejection store under lock and key.

Action Taken by DRAP:- Accordingly, a show cause notice was served to the firm for above mentioned violations on 24.06.2016.

Reply of the firm: - The firm vide letter No. BPL/MOH/16/020 dated 02.07.2016 submitted detailed reply of showcause notice and informed that all observations noticed by FID have been rectified. The firm requested to give a chance for personnel hearing before the Board.

Proceedings of the 249th Meeting of CLB

Mr. Farrukh Bajwa, CEO of the firm M/s Bajwa Pharma (Pvt) Ltd, Lahore appeared before the Board for personal hearing. Mr. Farrukh Bajwa informed that the observations noted by the FID have been rectified. The Board during scrutiny of the case noticed that the FID during inspection observed that four batches of Pivacine-SP Injection Batch No. 001, 002, 003 and 004 (Bupvicane) Registration No. 078950 were placed in an unauthorized area, on a stair case. On query of the FID, the Director Mr. Kashif Bajwa informed that due to misprinting on outer cartons and ampoules i.e. intramuscular IM injection, where as it is for spinal block, the firm had to recall the batches from market. Mr. Farrukh Bajwa informed that the batch size is 60,000 and 95% products have been recalled. The recalled products have been destroyed, but he could not produce any evidence / destruction certificate for proper destruction of said batches. Mr. Farrukh Bajwa failed to explain about the status of remaining 5% quantity of the said batches. The Board took a very serious notice on such non-serious attitude and gross negligence of the QA, QC and Production department of the firm.

Decision of the 249th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, reply and non serious attitude of the firm, especially misprinting of labels and unit cartons of Pivacine-SP Injection Batch No. 001, 002, 003 and 004 (Bupvicane) Registration No. 078950 and marketing thereof i.e. IM instead of Spinal Block, the Board decided to:-

i. Suspend the Drug Manufacturing License of the firm M/s Bajwa Pharma (Pvt) Ltd, Lahore for a period of three months under Section 41 of the Drugs Act, 1976 and Rule 12 (1) of the Drugs (LR&A) Rules, 1976.

ii. Direct the firm to issue batch recall notice in the print media to recall Pivacine-SP Injection Batch No. 001, 002, 003 and 004 (Bupvicane) Registration No. 078950.

iii. Direct the area FID to get complete record from the firm and submit detailed report regarding the recall of the said product.

iv. Refer the case to DRB for cancellation of registration of product namely Pivacine-SP Injection (Bupvicane) Registration No. 078950.

Case No. ii:- M/S REKO PHARMACAL (PVT) LTD, MULTAN ROAD, LAHORE

Background of the case

On 30.03.2016 Dr. Zaka ur Rehman, Chief Drug Controller, Punjab, Mr. Asim Rauf, FID and Mr. Ajmal Sohail Asif, Area FID, DRAP, Lahore conducted inspection of company to verify the GMP compliance and production activities. The panel noticed number of observations, which needs urgent attention and rectification. The observations include:-

Change Rooms:

- The doors of the change rooms were found rusted and need repainting, cross over bench need to be improved.

Storage Areas:

The firm was advised to:-

- Improve the sanitation and general cleanliness of the area.
- Provide and exterior solvent storage area for volatile and inflammable materials, which were placed within the RM store.

Oral Liquid Section:

- The firm was advised to improve the flooring of the area and paint on the walls.
- This bottle blowing area was not properly maintained it was dirty, paint was peeled off from walls and ceiling and needs repair and maintenance.

Psychotropic Tablet & Capsule Section:

- Paint on walls at some places and of few doors was peeled off.

General Tablet and Capsule Section:

- The firm was advised to improve the general cleanliness and maintenance of the area.

Cephalosporin Area (Oral Dry Powder Suspension and Capsule)

- The firm was advised to completely close the staircase and cargo lift for proper dedication of the area.

Quality Assurance:

- QA department was advised to assure that findings of this inspection should be addressed effectively and on urgent basis.

Sanitation and Hygiene:

- The firm was advised to improve the sanitation and cleanliness of bottle blowing area of oral liquid section.

Qualification and Validation:

The firm was advised to:-

- Conduct cleaning validations.
- Develop procedures and conduct performance qualifications for installed machinery.
- Validate all the QC testing methods.

Personnel:

- The firm was advised to hire more pharmacist for production department at least one pharmacist for each manufacturing section.

Equipment and Machinery:

The firm was advised to:-

- Conduct performance qualification of installed machinery.
- Provide a dedicated blistering machine for cephalosporin capsule section.
- Provide a gradient of HPLC.
- Label the machines.
- Maintain the log books for use and repair maintenance of these instruments, equipment and machinery.
- Some of the machines/equipment were not properly labeled regarding the status.

Documentation:

- The firm was advised to update the SOPs where required.

Good Practices in Quality Control:

- The firm was using in-house working standards for testing and was advised to purchase official reference standards.
- The firm was also advised to conduct all the compendia tests for APIs.

Action Taken by DRAP:- Accordingly a show cause notice was served to the firm for above mentioned violations on 24.06.2016.

Reply of the firm: - The firm vide letter No. Nil dated 11.07.2016 and 26.07.2016 submitted detailed reply of showcause notice and requested for withdrawal of showcause notice.

Proceedings of the 249th Meeting of CLB

Mrs. Seema Khalid, Director, Mian Khalid, Director and Mr. Akram Khan, Procurement Head of the firm M/s Reko Pharma, Lahore appeared before the Board for personal hearing. Mrs. Seema Khalid informed to the Board that 95% of the observation noticed by the FID has been rectified and a complete report has already been submitted in the Directorate of QA&LT. She further informed that blister machine for capsule cephalosporin section has been purchased.

Decision of the 249th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, compliance report 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. Mr. Ajmal Sohail Asif, FID, Lahore
iii. Mrs. Aisha Irfan, FID, Lahore

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

Case no. III:- **M/S Pharmawise Labs (Pvt) Ltd, Kot Lakhpat Industrial Estate, Lahore**

Background of the case

Mr. Abdul Rashid Shaikh, FID, Lahore conducted inspection of the company on 20.05.2016 to verify the GMP compliance and production activities. The FID noticed number of observations, which needs urgent attention and rectification. The observations include:-

- Review and upgrade their organogram by avoiding the confect of interest.
- Develop separate and independent quality assurance department under the supervision of senior qualified / technical person without fail.
- Document No. SO#OPR005 dated 12.01.2013, Revision # 2 SOPs for product recall was observed and advise to review and upgrade it.
- SOPs for testing and release of finished product. Document No. SOP No.QC004 dated 13.12.2015, Revision # 2 SOPs for product recall was observed and advise to review and upgrade it.
- Develop the proper SOPs for the vendor qualification and evaluate their vendors and generate their vender qualification reports of their raw and packing materials and other supplier.
- Ensure the availability of reference standards of their products.
- Appoint more technical and trained staff for each section as per Drug Act, 1976 and rules framed there under.

Stores

- Upgrade and review their dispensing and sampling SOPs.
- Import and export their raw materials and finish drugs as per Import and Export Rules of Drug Act, 1976.
- Ensure the SS closed containers for the storage of their in process materials and drugs.
- Ensure the medical certificates of all workers.
- Develop proper and regular trainings program for workers and senior technical staff and maintained their records.
- Ensure the inkjet printer for the clear printing of their Batch number, date of manufacturing and date of expiry.

Quality Control Laboratory:

- Ensure the availability of FTIR.
- Upgrade their testing and manufacturing methods as per current pharmacopoeal requirements.
- Ensure further analytical balance for quality control.
- Ensure all the necessary accessories for HPLC, like others required columns and column oven etc.
- Ensure to double beam spectrophotometer.
- Upgrade their Polarimeter.

- Remove the wooden fixture and furniture from the premises.
- Ensure the availability of potentiometer.

Action Taken by DRAP:- Accordingly, a show cause notice was served to the firm for above mentioned violations on 24.06.2016.

Reply of the firm: - The firm vide letter No. Nil dated 20.07.2016 and 04.08.2016 submitted detailed reply of showcause notice and requested for personnel hearing before the CLB.

Proceedings of the 249th Meeting of CLB

Ch. Nadir, Chief Executive, Ch. Nouman Nadir, Director (QA) and Mrs. Saba Rehman, QCM of the firm M/s Pharmawise Labs (Pvt) Ltd, Lahore appeared before the Board for personal hearing. Ch. Nadir informed to the Board that potentiometer has been purchased and other equipments will be purchased shortly. The Board advised the representatives of the firm to upgrade quality control equipments with reference to testing methods, as per pharmacopoeial requirements.

Decision of the 249th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, compliance report 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. Syed Muid Ahmed, Member CLB.
ii. Dr. Abdur Rashid, CQC
iii. Mr. Akbar Jan, Chief Drug Inspector, KPK.
iv. Mr. Abdul Rashid Shaikh, FID, Lahore.

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

Case No. iv:- **M/S Hamaz Pharmaceuticals (Pvt) Ltd, Multan**

Background of the case

Syed Zia Husnain, FID, Lahore conducted inspection of company on 02.06.2016 to verify the GMP compliance and production activities. The FID noticed number of observations, which needs urgent attention and rectification. The observations include:-

- Store temperature is not satisfactory.
- Temperature of packaging material store is also not satisfactory.
- Segregated dispensing and storage not provided.
- De-dusting area not provided in R.M store.
- Color of quarantine strips is not yellow which should be rectified.

General / General Antibiotic Area

- Mixer is old and need to be re-placed.
- FB dryer is also rusted and need to be replaced.
- HVAC in packing room is required.
- Granulator and pour compression machines were also very old and required to be re-placed.

Cephalosporin Area

- Capsule filling machine needs to be changed.

Penicillin Area

- Sampling booth required to be installed.
- Dispensing also be done under HVAC system.
- Segregation of raw materials APIs and non-actives be done.
- Tablet penicillin area is not satisfactory.
- Only one single punch machine is place in same room where granulation was carried out.
- Revamp the tablet area before start of production in tablet Section.
- Double door hatch advised between bottle blowing area and production area.
- No working was going on.

Quality Assurance

- It needs further up-gradation.

Validation and Calibration

- Carry on the process validations and keep records.

Water Treatment

- Time to time check the quality of water and keep records in future as well.

The FID further concluded that:-

- Install air conditioners in raw material store and packing material store
- Develop de-dusting area for general raw material.
- Color of quarantine slips should be yellow rejected item area should be in lock and key.
- Install HVAC in paste preparation area of general tablet section.
- Change the old rusted granulators, compression machines and FB dryers.

- Change capsule filling and sealing machine in cephalosporin capsule section.
- Install digital polarimeter in QC laboratory.
- Make the FTIR operational on urgent basis.
- HVAC be installed in dispensing area of penicillin section.
- Re-vamp the tablet (penicillin) area immediately.
- Double door hatch be given in bottle blowing and production area of penicillin section.
- Give the supply of water in coating area of penicillin section.
- Production of steroidal must be stopped till segregated of dispensing / storage in line with current guidelines of DRAP.

Action Taken by DRAP:- Accordingly, a show cause notice was served to the firm for above mentioned violations on 24.06.2016.

Reply of the firm: - The firm vide letter No. Nil dated 09.07.2016 submitted detailed reply of showcause notice and requested for withdrawal of showcause notice.

Proceedings of the 249th Meeting of CLB

Mr. Adnan Zafar, Managing Director, Mr. Muhammad Ashraf, QCM and Mr. Shakeel Azhar, Director of the firm M/s Hamaz Pharmaceuticals (Pvt) Ltd, Multan appeared before the Board for personal hearing. Mr. Adnan Zafar informed to the Board that most of the observations has been rectified and purchase order for new equipments, as per direction, has been issued and will be installed within 2 weeks. Mr. Adnan Zafar further added that segregation for steriodal section has been completed, as per directions passed by the FID. Mr. Adnan Zafar informed to the Board that they are ready for inspection.

Decision of the 249th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, compliance report of the firm, the Board decided to:-

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

   a. Dr. Ikram ul Haq, Member CLB.
   b. Director DTL, Multan.
   c. Syed Zia Husnain, Area FID, Lahore

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

iii. Get approval of change in layout plan, as advised by the FID, by the Licensing Division.

Case No. v:- **M/S MEDICURE LABORATORIES, F-109, HUB RIVER ROAD, S.I.T.E., KARACHI**

Background of the case

Mrs. Muneeza Khan, Area FID and Mrs. Umm-e-Laila, ADC, DRAP, Karachi conducted inspection of company on 14.07.2016 to verify the GMP compliance and production activities. The panel noticed number of major and critical observations, which needs urgent attention and rectification. The observations include:-

i) In last GMP inspection the firm had undertaken to overcome most critical observations within next six months and till that their production activities would remain suspended. But instead of overcoming all that observations of last inspection there noticed active production in liquid syrup, tablet and in rests of the manufacturing areas during this inspection under same unsanitary and unhygienic conditions without the active supervision of senior in-charge pharmacist. Not only were this, lot of other critical non-compliances also observed.

ii) During the course of inspection a huge No. of major and minor non-GMP compliances and contraventions to the Drug Act, 1976 were observed in all areas from storage (Raw, Packing and Finished Store)

iii) Severe poor and dirty, unhygienic condition found in all areas.

iv) No HVAC, Air conditioning present in the factory.

v) Expired chemicals being used with no labeling.

vi) No validation, no calibration, no dispensing booth, no area monitoring, no SOPs found.

vii) No documentation present.

viii) 5 workers found in production in street clothes and shoes engaged in coating process.

ix) No qualified staff present in the factory.

x) The FID recommended to lock / seal M/s Medicure Laboratories, Hub River Road, S.I.T.E., Karachi under section 18 (1) (h) till further instructions by the DRAP, Islamabad.

Premises:

xi) All the areas were seen not in accordance with the GMP provisions as flow of materials and workers not identified and even not followed and ultimately creating risks for the final products and workers as well.

xii) The firm was keeping all the raw materials / packaging material in two rooms and in corridors in front of QC lab which is not the designated area as per their stores. No air conditioning was provided in sores to maintain the required temperature. All raw materials were found in open paper bags and containers without proper labeling and status tags. No documentation found in stores. All materials were mixed and no segregation was found. Area was found full of dust and unhygienic poor material handling observed. No dispensing booth present. GSP guidelines are not followed in spirit.

Production Areas:

xiii) During the inspection in the manufacturing areas some male workers were engaged in the tablet coating process in street clothes and street shoes. There was not concept of clean clothes and clean shoes for production area. No change room with amenities found. All the production was controlled by these workers under the supervision of only technical persons present during the inspection.

xiv) All of the production areas found extremely dirty and under unhygienic poor conditions with unclean dirty rusted broken equipments and machinery. Floors were found wet and very dirty.

xv) Rests of the critical non-compliances are as follows:-

a. There is no HVAC or air conditioning in the whole factory.
b. No validation or calibration performed.
c. No documentation, no SOPs in place or followed.
d. No QC testes or procedures performed.
e. No area monitoring or scientific risk management in place observed.
f. In short the firm has no proper QA system in place and none of technical person for QA was there.

Quality Control:

xvi) Base line equipments were not in place required for testing of their registered products and even calibration records of some equipment kept in lab, was not found.

xvii) No testing process was seen at the time of inspection. No log books, no documentation and record keeping were found.

xviii) All equipments were broken down and found non operation.

xix) Very unhygienic and poor house-keeping observed in QC.

xx) A well established and qualified lab at the premises is not provided.

xxi) A complete QC failure was noticed.

Sanitation and Hygiene:

xxii) Extremely poor sanitary conditions and house-keeping was observed in the whole factory. No proper change rooms, lack of the essential amenities and necessary buffer and air locks do not exist. HVAC facility installed in the whole factory. Workers were not provided any sort of training on GMP issues; cleanliness was not up to the mark. Overall facilities did not have efficiency to control contamination and cross contamination.

Personnel

xxiii) The personnel met during the visit showed very casual behavior to the GMP issues. They were not seemed to have aware of any GMP guidelines. Qualified and experienced staff and more training is requi red on risk based GMP issues so that system can be improved. Organization chart should be re-organized; persons should be given duties in writing. Overall they need professionally qualified and experienced persons for better GMP compliance.

Training

xxiv) Training of staff, records and documentation found insufficient. It was advised to conduct regular training of staff, maintain the training material and manuals available to the staff.

The FID further concluded that

xxv) Based on the areas inspected, the people met and the documents reviewed, and finding of the inspection that is a number of critical and major contraventions of GMP guidelines. Under the explained circumstances M/s Medicure Laboratories, Karachi may not be allowed to manufacture and based on the above critical observations the undersigned has left no option except to lock and seal the whole premises under section 18 (1) (h) of Drugs Act, 1976 because there was chance of manipulation and un-authorize manufacturing.

xxvi) The FID recommended for cancelation of DML of the firm in larger public interest based on the historic evidences.

Action Taken by DRAP:- Accordingly, a show cause notice & suspension of production order was served to the firm for above mentioned violations on 25.07.2016.

Reply of the firm:- The firm vide letter No. Nil dated 30.07.2016 informed that they may be given 03 months time to further upgrade. Moreover he requested to appear before the CLB for personnel hearing.

Proceedings of the 249th Meeting of CLB

Mr. Shah Meer Hussain, Managing Director and Mr. Haider Ali, Managing Partner of the firm M/s Medicure Labs, Karachi appeared before the Board for personal hearing. Mr. Shah Meer Hussain denied the observations noted by the FID. He added that HVAC is installed in the firm. The unit was closed due to the Eid holidays. At the time of the inspection, it was first working day after eid holidays and no production activities were in process. The workers were cleaning the equipments / premises before commencement of production. Mr. Shah Meer Hussain requested to grant him a suitable time for the renovation of the firm.

Decision of the 249th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, non-serious attitude of the firm, recommendations of the FID to cancel DML of the firm and request of Mr. Shahmeer Hussain to gave them a suitable time for renovation of the firm, the Board decided to suspend the Drug Manufacturing License of the firm M/s Medicure Labs, Karachi for a period of six months, under Section 41 of the Drugs Act, 1976 and Rule 12 (1) of the Drugs (L,R&A) Rules, 1976.

Item No. II (Misc. Cases)

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

Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab informed that teams of experts/Drug Inspectors conducted GMP inspections of various pharmaceutical manufacturing units and reported the violations found there by Provincial Quality Control Board, Punjab. He added that the Board after due deliberations recommended cancellation/suspension of Drug Manufacturing Licenses of the firms who were involved in violations of Good Manufacturing Practices (GMP), conditions of license and were involved in manufacturing / selling of substandard drugs. Mr. Abid Saeed Baig further requested to look into the matter and direct the concerned authority to take action in the best interest to curve the menace of spurious and substandard drugs. Detail of the cases is as below:-

Sr. No.	Name of Pharmaceutical Manufacturer M/s Lahore Chemical and Pharmaceuticals Works, Lahore **Violations reported**
1.	i. Stocking / manufacturing of drugs from expired active pharmaceutical ingredient. ii. Violation of conditions of DML. iii. GMP violations. iv. Water for injection as treated and stored in an open steel tank with surrounding air free non-sterile. **Decision of PQCB** i. Permission for prosecution. ii. Recommendations to DRAP Islamabad for cancellation / suspension of DML. **Updated status / Action taken by DRAP.** Syed Zia Husnain, FID conducted inspection of the firm on 04.06.2015 and informed that Some advises were given for further up-gradation. Management shows positive response fo **Proceedings of the 249th meeting of CLB** The Board discussed and evaluated the reports / cases forwarded by the Secretary, PQCB, Controller, Punjab for cancellation / suspension of DML of the firm M/s Lahore Chemica Lahore. The Board also consider sub Rule 3 of Rule 5 of Punjab Drugs Rules, 2007 which *provincial and district Board shall examine a case referred to it by an inspector and shall taken against a person under the Act or the rule, issue a showcause notice to the personal for hearing before taking the action about the prosecution of the person or recommending s license to the licensing authority."* **Decision of the 249th Meeting of CLB** After thorough discussion/deliberations, considering all the pros and cons of the case, keep the Board considered the recommendations of the Secretary, PQCB, Punjab and observe provided under the rule 5(3) of the Punjab Drugs Rule, 2007 has not been observed. There Board that following information / documents / record is required in order to proceed further: i. Copy of the notification of the Provincial Inspector of Drugs under Section 17 of the D ii. Copy of the inspection report of the firm iii. Copies of the test reports of the samples of the firm (if any) iv. Showcause notice issued to the firm. v. Reply of the firm. vi. Letter of personnel hearing issue to the firm under Section 41 of the Drugs Act, 1976 vii. Copy of the minutes of the meeting. viii. Copy of the permission for prosecution (if any). ix. Copy of the report of the appellate testing Under Section 22 (5) of the Drugs Act, 197 x. Enquiry report (if any). xi. Reason for imposing both penalties including prosecution and recommendation for c of the firm. Even the Rule 5(3) of the Punjab Drugs Rules, 2007 states that *"The pr examine a case referred to it by an inspector and shall, if an action is proposed to b the Act or the rule, issue a showcause notice to the personal and provide him an taking the action about the prosecution of the person or recommending suspension the licensing authority."* The Board further decided that the representative of the firm shall also be asked to submit the PQCB and may be given an opportunity of personnel hearing in the forthcoming meeting

2.	**Name of Pharmaceutical Manufacturer** M/s Drug Pharm, Lahore **Violations reported by PQCB, Punjab, Lahore** i. Storage of raw materials under un-controlled storage conditions. ii. No designated area for APIs active and inactive. iii. Records were not properly maintained. iv. Machines working under bad /un-hygienic conditions. v. Flooring of syrup section was not up to the mark. vi. Violation of cGMP. **Decision of PQCB** i. Permission for prosecution. ii. Recommendations to DRAP Islamabad for cancellation / suspension of DML. **Updated status / Action taken by DRAP.** Mrs. Aisha Irfan, FID conducted inspection of the firm on 18.03.2016 and noticed few ob follow up letter on 27.04.2016. The firm on 12.05.2016 submitted compliance report. **Proceedings of the 249th meeting of CLB** The Board discussed and evaluated the reports / cases forwarded by the Secretary, PQCB, Controller, Punjab for cancellation / suspension of DML of the firm M/s Drug Pharm, Lahor rule 3 of Rule 5 of Punjab Drugs Rules, 2007 which categorically stated that *"The pro examine a case referred to it by an inspector and shall , if an action is proposed to be taken or the rule, issue a showcause notice to the personal and provide him an opportunity for h about the prosecution of the person or recommending suspension or cancellation of his lice* **Decision of the 249th Meeting of CLB** After thorough discussion/deliberations, considering all the pros and cons of the case, keep the Board considered the recommendations of the Secretary, PQCB, Punjab and observe provided under the rule 5(3) of the Punjab Drugs Rule, 2007 has not been observed. There Board that following information / documents / record is required in order to proceed further: i. Copy of the notification of the Provincial Inspector of Drugs under Section 17 of the D ii. Copy of the inspection report of the firm iii. Copies of the test reports of the samples of the firm (if any) iv. Showcause notice issued to the firm. v. Reply of the firm. vi. Letter of personnel hearing issue to the firm under Section 41 of the Drugs Act, 1976 vii. Copy of the minutes of the meeting. viii. Copy of the permission for prosecution (if any). ix. Copy of the report of the appellate testing Under Section 22 (5) of the Drugs Act, 197 x. Enquiry report (if any). xi. Reason for imposing both penalties including prosecution and recommendation for c of the firm. Even the Rule 5(3) of the Punjab Drugs Rules, 2007 states that *"The pr examine a case referred to it by an inspector and shall, if an action is proposed to b the Act or the rule, issue a showcause notice to the personal and provide him an taking the action about the prosecution of the person or recommending suspension the licensing authority."* The Board further decided that the representative of the firm shall also be asked to submit the PQCB and may be given an opportunity of personnel hearing in the forthcoming meeting

3.	**Name of Pharmaceutical Manufacturer** M/s Aneeb Pharma, Lahore **Violations reported by PQCB, Punjab, Lahore** i. There were no overall, shoe cover, masks, gloves available at the entrance and mo wearing overall and gloves. ii. Raw material store was not maintained properly as active raw material were stor temperature was not controlled. iii. Temperature / humidity record was not maintained. iv. Air conditioning and HVAC system were not working properly. v. Equipments and instruments of QC was not labeled and calibrated. vi. Manufacturing of Drugs without supervision of qualified person vii. Manufacturing of Drugs without controlled temperature conditions. viii. Manufacturing of Drugs under dusty unhygienic conditions. ix. Without labeling / misbranded x. Gross violations of GMP. **Decision of PQCB** i. Recommendations to DRAP Islamabad for cancellation / suspension of DML. **Updated status / Action taken by DRAP.** Panel of inspectors conducted inspection of the firm on 19.01.2016. The firm was issue foll firm on 16.04.2016 submitted compliance report. FID was asked to verify the improvements **Proceedings of the 249th meeting of CLB** Mr. Khalid Munir, Representative of PPMA during the meeting provided the orders of Honor in Writ Petition No. 26761-16 dated 27.08.2016. The Honorable Judge, Lahore High Cour that ***"This request is tenable. The respondent No. 2 is directed to decide the review p pending before him through a speaking order after giving an opportunity of hearing t and strictly in accordance with law. Till the disposal of the said appeal or applicatio by the petitioner, communicated to the petitioner vide letter dated 08.08.2016, no adopted against the petitioner."*** Keeping in view the orders passed by the Honorable Judge, Lahore High Court, Lahore, case till decision in the said writ petition.
4.	**Name of Pharmaceutical Manufacturer** M/s Mediways, Lahore **Violations reported by PQCB, Punjab, Lahore** i. Manufacturing of Drugs under unhygienic conditions. ii. Improper storage of drugs (at 40 degree Centigrade). iii. Illegal or unauthorized import of raw materials without label (misbranded). **Decision of PQCB** i. Permission for prosecution. ii. Recommendations to DRAP Islamabad for cancellation / suspension of DML. **Updated status / Action taken by DRAP.** Mr. Ajmal Sohail Asif, FID conducted inspection of the firm on 09.02.2015. The firm Suspension of production order on 20.03.2015. The case was discussed in 245th Meetin constituted following panel of experts to verify the improvements:- a. Dr. Ikram ul Haq b. Dr. Zaka ur Rehman c. Mr. Ajmal Sohail Asif **Proceedings of the 249th meeting of CLB**

	The Board was informed that Mr. Ajmal Sohail Asif, FID conducted inspection of the firm issued order for suspension of production activities and issued showcause notice / Suspe No.F.4-4/2001-QA on 20.03.2015. Accordingly, the case was discussed in 245th Meeting constituted following panel of experts to verify the improvements:- a. Dr. Ikram ul Haq b. Dr. Zaka ur Rehman c. Mr. Ajmal Sohail Asif Inspection report of the firm is still awaited. The Board also discussed and evaluated the r Secretary, PQCB, Punjab, Lahore and Chief Drug Controller, Punjab for cancellation / sus Mediways, Lahore. The Board also consider sub Rule 3 of Rule 5 of Punjab Drugs Rules, that *"The provincial and district Board shall examine a case referred to it by an inspe proposed to be taken against a person under the Act or the rule, issue a showcause notice an opportunity for hearing before taking the action about the prosecution of the person o cancellation of his license to the licensing authority."* **Decision of the 249th Meeting of CLB** After thorough discussion/deliberations, considering all the pros and cons of the case, keep the Board considered the recommendations of the Secretary, PQCB, Punjab and too unauthorized manufacturing and violation of the orders of the DRAP's letter No. No.F.4-4/2(Board decided to issue a showcause notice to the firm M/s Mediways, Lahore on illegal / u and disobeying the orders of DRAP.
5.	**Name of Pharmaceutical Manufacture** M/s Orta Labs, Lahore **Violations reported by PQCB, Punjab, Lahore** i. Temperature / humidity record was not maintained. ii. Storage without label or without record. iii. Violation of condition of DML. iv. Violation of cGMP. **Decision of PQCB** i. Permission for prosecution. ii. Recommendations to DRAP Islamabad for cancellation / suspension of DML. **Updated status / Action taken by DRAP.** Mr. Asim Rauf, FID conducted inspection of the firm on 09.04.2014. The firm was issued s production order on 03.07.2014. The case was discussed in 245th Meeting of CLB wh following panel of experts to verify the improvements made by the firm:- a. Dr. Ikram ul Haq b. Dr. Zaka ur Rehman c. Mr. Asim Rauf d. Mr. Ajmal Sohail Asif **Proceedings of the 249th meeting of CLB** Mr. Khalid Munir, Representative of PPMA during the meeting provided the orders of Honor in Writ Petition No. 26762-16 dated 27.08.2016. The Honorable Judge, Lahore High Cour that ***"The provincial quality control board is directed to decide the petitioner revi preferably within period of 45 days from the date of receipt of certified copy of this or application of petitioner is decided, no coercive measures shall be taken agai***

	observation, this writ petitioner stands disposed off." Keeping in view the orders passed by the Honorable Judge, Lahore High Court, Lahore, case till decision by the PQCB, as per decision of Honorable Judge, Lahore High Court, Lah
6.	**Name of Pharmaceutical Manufacture** M/s Redex Pharma, Faisalabad **Violations reported by PQCB, Punjab, Lahore** i. Violation of condition of license. ii. Violation of GMP. iii. In the absence of qualified person. iv. Manufacturing and printing label of drugs with false manufacturing and expiry date. **Decision of PQCB** i. Permission for prosecution. ii. Recommendations to DRAP Islamabad for cancellation / suspension of DML. **Updated status / Action taken by DRAP.** Mr. Ajmal Sohail Asif, FID conducted inspection of the firm on 14.05.2015. The firm was is orders and showcause notice/suspension of production order No.F.4-30/90-QA (Vol-I) o case was discussed in 246th Meeting of CLB wherein the CLB had constituted following improvements made by the firm:- a. Prof. Dr. Saeed. b. Dr. Moid Ahmed. c. Mr. Ajmal Sohail Asif **Proceedings of the 249th meeting of CLB** The Board was informed that Mr. Ajmal Sohail Asif, FID conducted inspection of the firm issued showcause notice / Suspension of production order on 24.06.2015. The case was CLB, wherein the CLB had constituted following panel of experts to verify the improvements a. Prof. Dr. Saeed. b. Dr. Moid Ahmed. c. Mr. Ajmal Sohail Asif Inspection report of the firm is still awaited. The Board also discussed and evaluated the rep Madina Town, Faisalabad, which categorically stated that *"On 17.05.2016, during inspecti re-packingof the drugs were carrying out in non approved and un-hygienic rooms plant/manufacturing unit which was under maintenance and construction work was b inspection."* **Decision of the 249th Meeting of CLB** After thorough discussion/deliberations, considering all the pros and cons of the case, keep the Board considered the recommendations of the Secretary, PQCB, Punjab and took a ser orders of the DRAP letter dated 24.06.2015. The Board decided to issue a showcause notic Pharma, Faisalabad on illegal/unauthorized production activities and disobeying the orders
7.	**Name of Pharmaceutical Manufacture** M/s Sanna Labs, Faisalabad **Violations reported by PQCB, Punjab, Lahore** i. Manufacturing / stocking / selling substandard drugs (Sanamoxil-15) Batch No. SX-014 ii. Issuance of false warranty. **Decision of PQCB**

	i. Permission for prosecution. ii. Recommendations to DRAP Islamabad for cancellation / suspension of DML. **Updated status / Action taken by DRAP.** Inspection for the renewal of DML was conducted on11.03.2016 by a panel comprising of fo a. Dr. Ikram ul Haq b. Dr. Qurban Ali, NVL c. Mr. Ajmal Sohail Asif d. Rana Abdul Mateen, Secretary, PQCB The case was placed before the CLB in its 247th meeting of CLB and renewal was granted. **Proceedings of the 249th meeting of CLB** Mr. Sheikh Muhammad Nawaz, Advocate on behalf of the firm M/s Sanna Labs, Faisalaba of Honorable Judge, Lahore High Court, Lahore in Writ Petition No. 24578-16 dated 25 Honorable Judge, Lahore High Court, Lahore Bench on 25.07.2016 passed orders that ***meanwhile, no coercive measures shall be taken against the petitioner."*** The Honor Lahore Bench on 29.07.2016 passed orders that ***"Learned Law officer seeks further tir comments. Let him do so. To come up on 19.09.2016. Interim relief already granted sh*** Keeping in view the orders passed by the Honorable Judge, Lahore High Court, Lahore, case till decision in the said writ petition.
8.	**Name of Pharmaceutical Manufacture** M/s B.J Pharma, Lahore **Violations reported by PQCB, Punjab, Lahore** i. Manufacturing / stocking / selling of misbranded and substandard drugs. ii. Issuance of false warranty. **Decision of PQCB** i. Permission for prosecution. ii. Recommendations to DRAP Islamabad for cancellation / suspension of DML. **Updated status / Action taken by DRAP.** Mrs. Aisha Irfan, FID conducted inspection of the firm on 20.01.2016. The firm was 17.02.2016. The case was discussed in 247th Meeting of CLB wherein the CLB had const to verify the improvements made by the firm:- a. Dr. Ikram ul Haq. b. Ch. Zeeshan Nazir. c. Mrs. Aisha Irfan. **Proceedings of the 249th meeting of CLB** Mr. Khalid Munir, Representative of PPMA during the meeting verbally informed that the fi stay order form the Honorable Lahore High Court, Lahore in Writ Petition No. 26879-16 da Judge, Lahore High Court, Lahore Bench passed orders that ***"Till decision of the re coercive measures shall be adopeted against the petitioner."*** Keeping in view the orders passed by the Honorable Judge, Lahore High Court, Lahore, case till decision in the said writ petition.
9.	**Name of Pharmaceutical Manufacture** M/s Axis Pharma, Faisalabad **Violations reported by PQCB, Punjab, Lahore** i. Manufacturing / stocking / selling substandard drugs. ii. Issuance of false warranty. **Decision of PQCB**

	i. Permission for pro;secution. ii. Recommendations to DRAP Islamabad for cancellation / suspension of DML. **Updated status / Action taken by DRAP.** On receiving complaint regarding manufacturing of substandard drugs from Governr constituted by the competent authority to probe the matter. Inspection report is still awaited. **Proceedings of the 249th meeting of CLB** Mr. Khalid Munir, Representative of PPMA during the meeting provided the orders of Honor Lahore in Writ Petition No. 26741-16 dated 25.08.2016. The Honorable Judge, Lahore Hig ordered that ***"This request is tenable. The respondent No. 2 is directed to decid petitioner, if still pending before him through a speaking order after giving an o petitioner expeditiously and strictly in accordance with law. Till the disposal of the interim relief submitted by the petitioner, communicated to the petitioner vide letter measures shall be adopted against the petitioner."*** Keeping in view the orders passed by the Honorable Judge, Lahore High Court, Lahore decision in the said writ petition.
10.	**Name of Pharmaceutical Manufacture.** M/s Perfect Pharma, Lahore **Violations reported by PQCB, Punjab, Lahore** i. Manufacturing / stocking / selling of substandard drugs. ii. Issuance of false warranty. **Decision of PQCB** i. Permission for prosecution. ii. Recommendations to DRAP Islamabad for cancellation / suspension of DML. **Updated status / Action taken by DRAP** Mr. Asim Rauf, FID conducted inspection of the firm on 18.03.2013. The firm was issued s production order on 23.04.2014. Following panel of experts was constituted to verify the imp a. Dr. Sheikh Akhter Hussain. b. Mr. Moazzam Ali. c. Mr. Asim Rauf. d. Mrs. Quaratul Ain Jamil. The case was discussed in 232nd Meeting of CLB wherein the CLB has decided to allow and conduct GMP with larger panel. The following panel was constituted for re-inspection of the firm:- a. Mr. Ayaz Ali Khan. b. Mr. Ajmal Sohail Asif. c. Mrs. Aisha Irfan. d. Area ADC, Lahore **Proceedings of the 249th meeting of CLB** The Board discussed and evaluated the reports / cases forwarded by the Secretary, PQCB, Controller, Punjab for cancellation / suspension of DML of the firm M/s Perfect Pharma, L sub Rule 3 of Rule 5 of Punjab Drugs Rules, 2007 which categorically stated that *"The p examine a case referred to it by an inspector and shall , if an action is proposed to be taker or the rule, issue a showcause notice to the personal and provide him an opportunity for about the prosecution of the person or recommending suspension or cancellation of his lice* **Decision of the 249th Meeting of CLB** After thorough discussion/deliberations, considering all the pros and cons of the case, keep

	the Board considered the recommendations of the Secretary, PQCB, Punjab and observe provided under the rule 5(3) of the Punjab Drugs Rule, 2007 has not been observed. There Board that following information / documents / record is required in order to proceed further: i. Copy of the notification of the Provincial Inspector of Drugs under Section 17 of the D ii. Copy of the inspection report of the firm iii. Copies of the test reports of the samples of the firm (if any) iv. Showcause notice issued to the firm. v. Reply of the firm. vi. Letter of personnel hearing issue to the firm under Section 41 of the Drugs Act, 1976 vii. Copy of the minutes of the meeting. viii. Copy of the permission for prosecution (if any). ix. Copy of the report of the appellate testing Under Section 22 (5) of the Drugs Act, 197 x. Enquiry report (if any). xi. Reason for imposing both penalties including prosecution and recommendation for c of the firm. Even the Rule 5(3) of the Punjab Drugs Rules, 2007 states that *"The pr examine a case referred to it by an inspection and shall, if an action is proposed to b the Act or the rule, issue a showcause notice to the personal and provide him an taking the action about the prosecution of the person or recommending suspension the licensing authority."* The Board further decided that the representative of the firm shall also be asked to submit the PQCB and may be given an opportunity of personnel hearing in the forthcoming meetin

QUALITY ASSURANCE CASES

Case No.01

Deferred cases.

Subject: - **Manufacturing and Sale of Unlawful Drugs recovered from M/s Cherwel Enterprises Gadoon Amazai, District Swabi.No. F.03-51/2014-QC**

The case was presented before the Central licensing Board in its 248th meeting held on 13-07-2016 as agenda of the case with case background as follows:

Brief of the case

The FID Peshawar Mr. Rehmatullah Baig Alvi vide letter No.F.10.107-114/2014-Cherwel Ent-DRAP1290 dated 25th April 2016 informed that he and Syed Welayat Shah DDG (E&M) Peshawar along with FIA team comprising of Mr. Naseer Khan FIA Inspector Mr. Fazle Akbar FIA Inspector and Mr. Zafar Iqbal Sub-Inspector FIA on 18-10-2014 inspected the premises named Cherwel Enterprises situated at plot No.187/2 Lane-9 Gadoon Amazai Industrial Estate Swabi. During inspection huge quantity of drugs were recovered and seized. Raw Materials Labeling& packaging (printing Materials) were also recovered. Samples of the suspected drugs/materials were taken. The samples were sent to CDL Karachi for the purpose of test analysis on Form4. The FID stated that whole procedure of sampling under section 19 of the Drugs Act 1976 was adopted including portions to manufacturers and warranties manufacturers etc. The FID further stated that machines recovered during the raid were recorded on Form-I under Section 18(1) for not to dispose off. The premises was sealed and Ramzan Chowkidar was held responsible to keep a watch on the factory and its machinery till the decision of the case. The CDL Karachi declared the drugs by giving opinion mentioned against each.

Name of Drug	Manufactured by	Batch No.	Expiry Date	Remarks/Test Report No.
Viptowel tab. 1000mg	Cherwell Enterprises Gadoon	001	03.2016	Unregistered/ Substandard/ Spurious RIP.156/2014 dated 14-11-2014
Accutane Cap 20 mg	Aims Pharma Islamabad	Nil	Nil	Counterfeit Spurious RIP.157/2014 dated 12-11-2014
Gevolox Plus tab	Hilton Pharma Karachi	Nil	Nil	Substandard Spurious RIP 158/2014 dated 02-12-2014
Suspected to be Evolox 400mg tab Found without strip	Bayer schering Karachi	Nil	Nil	Substandard/spurious RIP.159/2014 dated 17-11-2014
White Powder suspected to be Xanix (Alprazolam)	Pfizer Karachi	Nil	Nil	Substandard/Spurious RM.180/2014 dated 13-11-2014
Lactos Monohydrate Powder (Suspected to be monohydrate	Kerry ingredient	14010	Use within 03 years	Spurious/Unregistered RM.181/2014 dated 12-11-2014

Lactose)				
Cap well-D tab	Cherwell Enterprise Gadoon	Nil	12.2016	Unregistered/spurious RIP.160/2014 dated 13-11-2014
Evemol soft Gel Cap. 600mg	Cherwell Enterprises Gadoon	Nil	Nil	Unregistered/spurious RIP.161/2014 dated 13-11-2014

2. In reference to manufacture's portion M/s Aim Pharmaceutical disowned tab Accutane M/s Hilton Pharma Karachi disowned Gevolox tab mg, M/s Bayer Schering Karachi disowned Evolox 400mg tablet M/ Pfizer Karachi disowned white powder and empty blister strips of Xanax Tab suspected to be Xanax (Alprazolam), hence the product is spurious under section 3 (z-b)(ii) of Drugs Act 1976.

3. The FID stated that Show cause served to the accused persons Mohammad Sajid S/o Inayat Kahn and Shahid Ali S/o Inayat Khan proprietors of Cherwel Enterprises Gadoon Amazai with the directions to explain their position and provide documents/invoices/names and persons/printing press from where they procured the raw materials, printing materials, exciepients etc within 07 days of the receipt of the notice but the accused failed to comply with the instructions of the FID. The FID stated that both the accused during the raid recorded their statement that Ihsanullah of Bannu and Fayaz of Mardan were their business partners but could not produce any evidence of their alleged involvement in the said business.

4. The FID stated that the FIA Peshawar submitted complete challan of the case of Cherwell Enterprises Gadoon Amazai to the FID office. The FID further stated that FIA judicial file has enough proofs of the alleged involvement of both the persons in sale of unregistered/ counterfeit/spurious drugs.

5. The FID Peshawar has requested to allow the permission for prosecution against the following accused persons in Drug Court.

i. ***Mohammad Sajid S/o Inayat Kahn, owner of Cherwell Plot No.187/2 Lane 9 Gadoon Industrial Estate Swabi Resident of Tandail Abad, KhweshgiPayan, District Nowshera, Presently Gulbahar Colony, Risalpur Cant. District Nowshera.***

ii. ***Shahid Ali S/o Inayat Khan Owner of Cherwel Enterprises Gadoon Plot No.187/2 Lane 9 Gadoon Industrial Estate Swabi Resident of Tandail Abad, KhweshgiPayan, District Nowshera, Presently Gulbahar Colony, Risalpur Cant. District Nowshera.***

6. Accordingly show cause notice was served to above nominated accused and accused were called for personal hearing before the Central Licensing Board in its 248th meeting by giving them the opportunity to be heard in person.

Proceeding of the Board:

The Board waited for the accused persons to appear before it but till closing of the Meeting none of the accused persons appeared before the Board for giving opportunity of Personal Hearing.

248th meeting of CLB Decision:-

The Board after detailed discussion, deliberation and keeping in view the facts of the case including the information provided by the FID telephonically that personal hearing letter could not be served to both of accused persons as they have shifted their premises. The FID further informed that he had requested to FIA for assistance for the delivery of show cause notice and personal hearing letters. Accordingly the Board decided to defer the case on the basis of majority of the vote.

Current Status

The FID has requested to Director FIA Phase-V Hayattabad Peshawar for the delivery of Show Cause notice to the concern accused persons. The FID has telephonically informed that he is making effort to ensure the personal appearance of the accused persons in the meeting of CLB on 29-08-2016. The accused persons again called for personal hearing before the Central Licensing Board in its 249th meeting by giving them the opportunity to be heard in person.

Proceedings of 249th meeting of CLB

Mohammad Sajid S/o Inayat Khan *(owner of Cherwell Plot No.187/2 Lane 9 Gadoon Industrial Estate Swabi Resident of Tandail Abad, KhweshgiPayan, District Nowshera, Presently Gulbahar Colony, Risalpur Cant. District Nowshera) and* ***Shahid Ali S/o Inayat Khan*** *Gadoon Plot No.187/2 Lane 9 Gadoon Industrial Estate Swabi Resident of Tandail Abad, KhweshgiPayan, District Nowshera, Presently Gulbahar Colony, Risalpur Cant. District Nowshera) were appeared before the Board Central Licensing Board and pleaded their case and informed the Board that they were not owner of the Cherwel Enterprises Gadoon Amazai. They informed the Board that Mr. Fayyaz and Mr. Ihsanullah are owner of the Cherwell Enterprises Gadoon Amazai. They further stated that Mr. Fayyaz and Ihsanullah through a fake stamp paper showed them as tenant wherein they had not signed. They claimed that they have not taken any salary from Cherwell Enterprises Gadoon Amazai as they had left the job from Cherwell Pharma Hattar in September 2014 while the current case was registered in October 2014.*

Mr. Shahid Ali stated that Mr. Ihsanullah has filed an application in the Drug Court for the recovery of the case property.

Mr. Sajid Ali S/o Inayat Ali claimed that all documents of FBR, NTN and firm registration certificate are with the name of Mr. Fayyaz Khan.

The Board directed the Quality Control Section of DRAP to advise both accused persons (Mr. Shahid Ali and Mr. Sajid Ali) telephonically to submit their written statement.

Decision:-

The Board after detailed discussion, deliberation and keeping in view the facts of the case including the information provided by the Mr. Shahid Ali S/o Inayat Ali, and Mr. Sajid Ali, S/o Inayat Ali decided as under:-

It appears that the version of accused primafacie carry weightage therefore the Board recommended keeping in view all the facts and involvement of other accused persons namely Mr. Fayyaz and Mr. Ihsanullah should also be investigated through FID.

New Cases

Case No.1

Subject: - **Manufacturing and Sale of Unregistered Drug Product-PregEase Tablets Batch No.15021 by M/s Zestech Sciences, Karachi for ICI Pakistan, Karachi**
F. No. 4-07/2015- (QC)

The FID-II, Karachi inspected the premises of M/s ICI Pakistan Limited 5- West Wharf Road Karachi on 19-03-2015 and took the sample of Tab Preg Ease Batch No.15021 manufactured by M/s Zestech Sciences Karachi. The sample was sent to the CDL Karachi for test analysis. However, the Federal Government Analyst, CDL, Karachi vide its test report No. KQ.102/2015 dated 13-05-2015 to Karachi, has been declared as Un-registered drug product under the Drug Act, 1976 by CDL, Karachi.

The result of CDL test Report

Remarks:- "***The label of the sample claims " Natural Nutritional Supplement to help calm nausea & vomiting of pregnancy (NVP) vitamin B6 and calcium have been identified as allopathic ingredients. Hence, the sample is declared as un Registered Drug product under the Drug Act 1976"***

The FID has issued letter to M/s. ICI Pakistan Ltd, Karachi for selling the subject cited Un-registered drug product.

2 The FID served the explanation letter on 26th May 2015 to the firm to explain their position. In reply to the FID explanation the M/s Zestech Sciences Karachi requested for retesting of drug in question under the provision of Drugs Act 1976 on 30th June 2015. The sample was sent to the Appellate Laboratory NIH Islamabad. The Appellate Laboratory has also declared the sample of substandard quality along with remarks mentioning the sample unregistered and unlicensed.

The result of Appellate Laboratory:-

Assay:-	**Stated**	**Found**	**Limit**	**Percentage**
Vitamin B6	2mg/tab	1.903mg/tab	90-110%	95.14%
Folic Acid	400mcg/tab	415.68mcg/tab	90-110%	103.92%
Calcium	124.1mg/tab	11.18mg/tab	90-110%	9.018%

Does not comply with manufacturer's specification.

The FID Karachi Peshawar furnished the responsible persons in his report are as under:-

I.	**Mr. Ahsan Feroz**	**Proprietor**
II.	**Mr. Mumtaz Ali Khan**	**Production Incharge**
III.	**Mr. Ejaz ahmad Paracha**	**QC Manager**

Recommendations of FID:-

"Based on the above submission and Lab reports it can easily be concluded that the drug Preg Ease is un registered un-licensed and Sub-Standard product hence sheer violation of Section 23

&27 of Drugs Act 1976 by the manufacturer M/s Zestech Sciences Plot No. 47/23, Korangi Industrial area Karachi based on the violations committed by the firm it is concluded that the contents of case may be kept on the agenda of upcoming meeting of CLB for permission of prosecution against the firm or the contents may be sent to Director OTC & Herbal for his comments in the light of the SRO 412".

The show cause notice were issued to the accused offering them opportunity of personal hearing before the Central Licensing Board. The Firm has submitted the reply of show cause notice.

Decision

The Board deferred the case due to paucity of time.

Case No.2

Subject:- Report of Inspection of Quality Operation Laboratory University of Veterinary Animal Sciences Lahore (UVAS). F. No. 13.03/2016-(QC)

The Inspection was conducted on 28-01-2015 of the University of Veterinary Animal Sceinces Lahore by a panel comprising of Dr. Sheikh Akhter Hussain, Deputy Director General (E&M) Asim Rauf Federal inspector of Drugs DRAP Lahore and Syed Zia Husnain Federal Inspector of Drugs DRAP Lahore . The panel thoroughly conducted the inspection of Bioequivalence Center UVAS on 28-01-2015. It was observed by the said panel that the manufacturing of veterinary vaccine namely UVAS HS-VAC (aqueous based) for veterinary use is being done without license at Quality operation laboratory UVAS Lahore. On the direction of panel, FID also took the sample of said vaccine for laboratory test and sent to National Control Laboratory (NCL) it was reported by the panel that the sample did not qualify the quality test requirements and forwarded the matter of manufacturing of drugs without license which is violation of the Drugs Act 1976.

Mr. Syed Zia Husnain FID Lahore submitted that University of Veterinary and Animal Sciences (UVAS) is a public Sector organization. Dr. Khushi Muhammad, Director Quality Operation Laboratory of UVAS was responsible person for manufacturing of UVAS-HS-VAC (aqueous based) Veterinary vaccine

The area FID has mentioned that manufacturing of unregistered drug and without license is violation of Section 23(1)(a) (vii) and section 23(1) (b) of Drugs Act 1976. It is also the violation of Section A(1) (a) (vii) and A(1) (b) of Schedule-II of Drug Regulatory Authority of Pakistan (DRAP) Act 2012.

The show cause notice was issued to the accused offering them opportunity of personal hearing before the Central Licensing Board.

Proceedings of 249th meeting of CLB

Mr. Masood Rabbani Dean of the UVAS Lahore appeared before the Board and pleaded their case. In the discussion Mr. Masood Rabbani stated that their university has signed a M.U with the Government of Punjab for manufacturing of the veterinary vaccine. He further stated that they supplied vaccine through the Punjab Government. He ensured that they are not manufacturing vaccine after the current incident. The Board asked him to not to manufacture the vaccines as committed till the approval of the Board and to submit the reply within 15 days along with relevant documents like:-

1. Chief Minister Punjab direction to manufacture of vaccine.
2. Sale record to whom Sale to Punjab Government.
3. MOU, signed by Secretary Government of Punjab.
4. No. of batches and quantity produced.
5. Labels indicating that price label is mentioned or not.
6. Labels indicating the name of manufacturer
7. To whom under supervision and qualification of the persons manufacturing was being done.
8. List of equipment and facility for production and quality control of vaccine.

9. The documents indicating how the quality was determined.
10. Manufacturing procedure
11. How the method of preparation was developed.
12. 500 million rupees given by Chief Minister Punjab for what purpose? Biological production and training center
13. Agreement between UVAS university and others regarding manufacturing and sale of vaccine.
14. Future planning?

Decision:-

The Board after detailed discussion, deliberation and keeping in view the facts of the case including the information provided by the Mr. Masood Rabbani Dean of the UVAS Lahore decided that the case will be discussed in the light of reply of UVAS Lahore and the production of vaccine remained stopped till the approval of the Board.