DIVISION OF DRUG LICENSING
DRUG REGULATORY AUTHORITY OF PAKISTAN
ISLAMABAD
*****

MINUTES OF 236th MEETING OF CENTRAL LICENSING BOARD HELD ON FRIDAY, 27th JUNE, 2014.

236th meeting of the Central Licensing Board (CLB) was held Friday, 27th JUNE, 2014 in the office of Director Drug Licensing, Room N0. 225, 2nd Floor, Block – C, Pakistan Secretariat, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP, Islamabad/Chairman CLB.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	A.Q Javed Iqbal, Director (QA), as representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad.	Member
2.	Mr. Atta-ur-Rehman, Chief Drug Inspector, Department of Health, Govt. of Balochistan.	Member
3.	Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa (K.P.K). (Mr. Imranullah Khan, Drug Inspector, Peshawar attended meeting on behalf of Chief Drug Inspector, KPK.)	Member
4.	Mr. Ayaz Ali Khan, Chief Drug Controller, Department of Health, Govt. of Punjab.	Member
5.	Dr. Ikram-ul-Haq, QC/QA Expert	Member
6.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
7.	Syed Muid Ahmed, Expert in manufacturing of drugs.	
8.	Prof. Dr. Gul Majeed Khan, Professor of Pharmacy	Member
9.	Prof. Dr. Muhammad Saeed, Professor of Pharmacy	Member
10.	Mr. Ejaz Asad Rasool, J.S, M/O Law ,Justice & Human Rights as Law Expert nominated by Secretary, Ministry of Law and Justice, Government of Pakistan, Islamabad.	Member
11.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
12.	Mr. Usman Shoukat, Representative of PPMA	Observer
13.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer

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

The Chairman apprised the members of the Board that proceedings of CLB shall be conducted in an amicable and responsible way to deliver to the public and stake holders in a transparent and efficient manner. He further added that all the legal and codal formalities regarding convening of the meeting have been fulfilled.Mr. Ahmed Din Ansari DDC (QC), Mr. Adnan Faisal Saim, DDC (Q.A.) and Mr. Salateen Waseem Philip ADC/DDC (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

A. LICENSING DIVISION

Item-I **CONFIRMATION OF THE MINUTES OF 235th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 235th meeting held on 15th May, 2014.

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

The Board considered the following cases of Grant of New Drug Manufacturing Licenses(DML) in the light of recommendations by respective panel of experts/inspectors and decided as under: -

S No.	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s IPP (Pvt) Ltd, Swat, Valley Road, Gulkada No. III Saidu Sharif Swat. **(DML No. 000244)**	21-06-2014 (Formulation)	Approved the grant of shifting and renewal of DML of M/s IPP (Pvt) Ltd, Swat to their new location at Valley Road, Gulkada No. III Saidu Sharif, Swat with same DML No. 000244 and with following sections & conditions: - **Sections (02):** 1. Tablet (General / Antibiotic) 2. Capsule (General / Antibiotic) **Conditions** • Cessation of manufacturing operations at old premises and surrendering of existing DML. • The firm shall not conduct its formulation operations at their previous site after grant of renewal and shifting of DML at new site.
2.	M/s. Izfaar Pharmaceutical Industries, 542/A-B, Sunder Industrial Estate, Lahore.	26-05-2014 Formulation (Veterinary)	**Approved the grant of DML with following sections:-** **Sections (02):** 1. Veterinary Liquid Injection (General). 2. Veterinary Liquid Injection (General Antibiotic).

3.	M/s MTI Medical (Pvt) Ltd, Plot No. 586-587, Sunder Industrial Estate, Raiwind Road, Raiwind Lahore.	10-06-2014 Formulation	**Approved the grant of DML with following sections:-** **<u>Sections (4):</u>** 1. Oral Liquid (General). 2. Tablet (General). 3. Capsule (General) 4. Oral Dry Powder Suspension (General) **The Board rejected the Lyophilized Vial Injectable (General) Section due to following shortcomings observed by the panel of experts: -** • The water treatment plant needed I.Q and P.Q to make sure the quality of water as per laid down criteria. • The microbiology lab needed up-gradation in terms of facilities with provision of laminar flow hood, Triple head assembly, area qualification and hiring of microbiologist with required qualification & experience. • I.Q and P.Q data needed to be generated for lyophilizer. • The area validation data required for classified areas.
4.	M/s. Aurik Pharmaceuticals, Plot No. 6 & 7, Street No. S-9, National Industrial Zone, (RCCI) Rawat, Rawalpindi.	19-06-2014 Formulation	**Approved the grant of DML with following sections:-** **<u>Sections (02):</u>** 1. Tablet (General). 2. Capsule (General).

5.	M/s Sigma Pharma International (Pvt) Ltd, Plot No. E-50, NWIZ Port Qasim Karachi. **<u>Sections (05):</u>** 1. Capsule (General). 2. Dry Powder Suspension (General). 3. Cream / Ointment (General). 4. Tablet (General) 5. Sachet (General).	23-06-2014 Formulation	**Deferred the grant of DML due to in-appropriate panel inspection report. Board discouraged such reporting and directed for re-inspection once the firm fulfills the shortcomings by following panel: -** **1. Dr. Jawed Yousaf Bukhari, Member CLB.** **2. Dr. Saif-ur-Rehman Khattak, Director, Central Drug Laboratory.** **3. Mr. Qaiser Muhammad, CDI Sindh, Members CLB (in place of Secretary PQCB, Sindh).** **4. Dr. Obaid Ali, Area FID, DRAP, Karachi.** **5. Mrs. Ume Laila, ADC, DRAP, Islamabad.** **The Board desired that area FID shall furnish clear, candid & speaking report after panel inspection on the prescribed format for the said purpose instead of separate reporting.**
6.	M/s. Al-Fazal Pharma Industries (Pvt) Ltd, 16-KM, Sheikhupura Road, Lahore.	23-06-2014 Formulation	**Approved the grant of DML with following sections:-** **<u>Sections (03):</u>** 1. Oral Liquid (General). 2. Capsule (General). 3. Cream/Ointment/Gel (General)

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

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

<table>
<tr><th>S #</th><th>Name of the firm</th><th>Type of License</th><th colspan="2">Decision of CLB</th></tr>
<tr><td>1</td><td>M/s Pharmagen Limited, Kot Nabi Bukhsh Wala, 34-Km, Ferozepur Road, Lahore.</td><td>DML No.000325 (Semi Basic Manufacture)</td><td colspan="2">The Board approved the grant of following additional section with APIs as under:-

<u>Section(01):</u>
1. Active Pharmaceutical Ingredients Manufacturing (General & Steroidal APIs)</td></tr>
<tr><td></td><td></td><td></td><td colspan="2">General Section APIs</td></tr>
<tr><td></td><td></td><td></td><td>1.</td><td>Ciprofloxacin Hydrochloride</td></tr>
<tr><td></td><td></td><td></td><td>2.</td><td>Moxifloxacin Hydrochloride</td></tr>
<tr><td></td><td></td><td></td><td>3.</td><td>Pefloxacin Mesilate</td></tr>
<tr><td></td><td></td><td></td><td>4.</td><td>Levofloxacin</td></tr>
<tr><td></td><td></td><td></td><td>5.</td><td>Norfloxacin</td></tr>
<tr><td></td><td></td><td></td><td>6.</td><td>Azithromycin</td></tr>
<tr><td></td><td></td><td></td><td>7.</td><td>Clarithromycin</td></tr>
<tr><td></td><td></td><td></td><td>8.</td><td>Sulfamethoxazole</td></tr>
<tr><td></td><td></td><td></td><td>9.</td><td>Omeprazole</td></tr>
<tr><td></td><td></td><td></td><td>10.</td><td>Esomeprazole Magnesium Trihydrate</td></tr>
<tr><td></td><td></td><td></td><td>11.</td><td>Paracetamol</td></tr>
<tr><td></td><td></td><td></td><td>12.</td><td>Pyrazinamide</td></tr>
<tr><td></td><td></td><td></td><td>13.</td><td>Naproxen Sodium</td></tr>
<tr><td></td><td></td><td></td><td>14.</td><td>Ibuprofen</td></tr>
<tr><td></td><td></td><td></td><td>15.</td><td>Simvastatin</td></tr>
<tr><td></td><td></td><td></td><td>16.</td><td>Atorvastatin Calcium Trihydrate</td></tr>
<tr><td></td><td></td><td></td><td>17.</td><td>Amlodipine Besylate</td></tr>
<tr><td></td><td></td><td></td><td>18.</td><td>Montelukast Sodium</td></tr>
<tr><td></td><td></td><td></td><td>19.</td><td>Mefenamic Acid</td></tr>
<tr><td></td><td></td><td></td><td colspan="2">Steroidal Section APIs</td></tr>
<tr><td></td><td></td><td></td><td>20.</td><td>Dexamethasone Sodium Phosphate</td></tr>
<tr><td></td><td></td><td></td><td>21.</td><td>Dexamethasone Acetate</td></tr>
<tr><td></td><td></td><td></td><td>22.</td><td>Betamethasone Sodium Phosphate</td></tr>
<tr><td></td><td></td><td></td><td>23.</td><td>Betamethasone Valerate</td></tr>
</table>

			24. Betamethasone dipropionate
2.	**M/s Rasco Pharma, 5.5-Km, Raiwind Road, Holiday Park Plot No. 27, Lahore.** **Sections (02)** 1. Ampoule and Vial (low volume infusion) General 2. General antibiotic Injection	**DML No.000530 (Formulation)**	The Board was apprised that Licensing Division has approved the Liquid Injection (General) as per approved layout plan dated 30-11-2010 but the panel at its own has recommended the following two sections namely (1) Ampoule and Vial (low volume infusion) General (2) General antibiotic Injection. **The Board after through discussion approved the grant of following additional section as per approved layout plan:-** **<u>Section (01):</u>** 1. Liquid Injection General (Small Volume Vial)
3.	**M/s. Bosch Pharmaceutical (Pvt) Ltd, Plot No. 221, Sector 23 Korangi Industrial Area Karachi.**	**DML No.000350 (Formulation)**	**Board approved the grant of one additional section and amendments in layout plan for already granted sections as under: -** **<u>Section(01):</u>** 1. Oral Dry Powder Suspension (General) **<u>Amendments in layout plan for already approved sections</u>** 2. Capsule (General) Section Amended / Expanded. 3. Ampoule (General) Section Amended / Expanded. 4. Tablet (General) Section Amended / Expanded. 5. In Process Quarantine of Injectable Section Including Optical Check Room & Packing Hall.
4.	**M/s Arsons Pharmaceuticals (Pvt) Ltd, 22-Km, Multan Road, Lahore.**	**DML No.000514 (Formulation)**	**The Board approved the grant of following one additional section in the light of decision taken in 233rd meeting of CLB for segregated sections for psychotropic drugs:-** **<u>Section (01)</u>** 1. Tablet Psychotropic

5.	**M/s International Pharma Lab, Raiwind Road, Bobhatian Chow, Defence Road, 1 KM, Toward Kahna, Lahore.** **Formulation Sections (3):** 1. Vet Penicillin Injectable Section. 2. Vet Dry Powder Suspension Section. 3. Vet Hormone Liquid Injectable Section.	**DML No. Formulation**	**The Board observed that the panel has rated the firm as Satisfactory/Average whereas for approval the firm shall have rating of good or very good; so Board deferred the grant of additional sections till compliance of following observations made by the panel during inspection: -** • Appoint Quality Assurance Manager to strengthen and operationalize the Quality Assurance System effectively, which at present was not operational. • Quality Control Laboratory needed comprehensive improvement in terms of space and documentation. At present the access is from the outside of the building which needs to be redesigned. • Microbiological Laboratory needed to be upgraded in terms of validation of the classified areas, provision of triple head filtration assembly, improvement of epoxy coating of the sterile area, smooth surfaces, development and strict maintenance of temperature and humidity control. • The edges in the sterile manufacturing area of Penicillin, Hormone and micro laboratory should be coved / smoothened. • Improve overall SOPs and documentations in Production and Quality Control. • Washing machine for ampoules and vial needs to be replaced with GMP compliant washing machine. • The access of the receiving and dispatch of raw material and finished goods is devoid of receiving bay, which needs to be provided. • Although the firm has got the layout plan re-approved vide letter No.F.1-14/2002-lic (Pt) dated 31-03-2014 which was previously approved earlier but still require storage area for raw material and finished goods to be enhanced. • Air condition / HVAC System needs to be strengthened in the raw material and finished goods store. • Procurement of FTIR. • The Raw Material store of newly established hormonal section requires 2-8^{0}C storage for oxytocin, which needs to be provided.

			The firm shall be re-inspected once it fulfills the above observations / shortcomings.
6.	**M/s. Sami Pharmaceuticals (Pvt) Ltd, F-95, SITE, Karachi.**	**DML No. Formulation**	**The Board approved the grant of following additional sections as under:-** **<u>Sections (12)</u>** 1. Oral Liquid (General)**.** 2. Tablet (General)**.** 3. Capsule (General)**.** 4. Sachet (General)**.** 5. Freeze Dried Products (General)**.** 6. Tablet (Psychotropic) 7. Capsule (Psychotropic) 8. Liquid Injection (Psychotropic). 9. QC Lab. 10. Tablet (General Antibiotics) 11. Capsule (General Antibiotics). 12. Oral Dry Suspension (General Antibiotics) **The Board deferred following biotech sections for re-inspection as the Director Biologicals DRAP (member of inspection panel) could not accompany the panel inspection. Board further decided that in new panel for inspection of biotech sections; members from Division of Biological Evaluation & Research or ECBD shall be included:** **1. rDNA Facility.** **2. Vaccine Section (Anti-Sera Only)**

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 #	Name of the firm	Type of License	Decision of CLB
1.	M/s. Farm Aid Group Pakistan, Plot No. 3/2, Phase I & II, Hattar Industrial Estate, Hattar Haripur.	DML No.000298 (Formulation-Veterinary)	The Board was apprised that as per inspection report, firm is doing some improvements and white washing of walls and ceiling in human tablet section, therefore the panel recommended the grant of Renewal of DML of only veterinary sections. **The Board after thorough discussion approved the grant of renewal of DML of veterinary section only except human tablet section.**
2.	M/s. Linz Pharmaceuticals (Pvt) Ltd, Plot No. 31-4/H, Sector 15, Korangi Industrial Area, Karachi.	DML No.000540 (Formulation)	**Approved the Grant of Renewal of DML**
3.	M/s. Wellborne Pharmachem and Biological. Plot No.51/1,52/2, Phase-II, Industrial Estate, Hattar.	DML No.000657 (Formulation)	The Board was apprised that the panel recommended the grant of Renewal of DML by way of Formulation of Tablet, Capsule, Dry Syp and Injectable section of General and Cephalosporin except Biological section as the firm is installing new latest equipment and upgrading the system of biological section. **The Board after thorough discussion approved the grant of renewal of DML except Biological section.** **Board further decided that in new panel for inspection of Biological section; members from Division of Biological Evaluation & Research or ECBD shall be included.**

<table>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>4.</td><td>M/s Rasco Pharma, 5.5-Km, Raiwind Road, Holiday Park Plot No. 27, Lahore.</td><td>DML No.000530 (Formulation)</td><td>Approved the Grant of Renewal of DML</td></tr>
<tr><td>5.</td><td>M/s Arsons Pharmaceuticals (Pvt) Ltd, 22-Km, Multan Road, Lahore</td><td>DML No.000514 (Formulation)</td><td>Approved the Grant of Renewal of DML</td></tr>
<tr><td>6.</td><td>M/s Regent Laboratories, C-20, SITE, Super, Highway, Karachi.</td><td>DML No.000506 (Formulation)</td><td>As per recommendations of panel of inspectors, the Board approved the grant of renewal of DML for following sections:-

<table>
<tr><td>1.</td><td>Veterinary powder (General)</td></tr>
<tr><td>2.</td><td>Veterinary Liquid (General)</td></tr>
<tr><td>3.</td><td>Capsule (Penicillin)</td></tr>
<tr><td>4.</td><td>Dry Powder Suspension (Penicillin)</td></tr>
<tr><td>5.</td><td>Tablet (Hormone)</td></tr>
<tr><td>6.</td><td>Tablet (General)</td></tr>
<tr><td>7.</td><td>Liquid Syrup (General)</td></tr>
<tr><td>8.</td><td>Cream / Ointment (General)</td></tr>
<tr><td>9.</td><td>QC Laboratory</td></tr>
<tr><td>10.</td><td>Stores</td></tr>
<tr><td>11.</td><td>Dry Suspension Antibiotic</td></tr>
</table>

The Board further directed the firm to apply as per rules for approval of following sections after fulfillment of legal / codal formalities as per recommendations of the panel: -

<table>
<tr><td>1.</td><td>Veterinary Vitamin (General)</td></tr>
<tr><td>2.</td><td>Tablet (Psychotropic)</td></tr>
<tr><td>3.</td><td>Capsule (Psychotropic)</td></tr>
<tr><td>4.</td><td>Dry powder Suspension (cephalosporin)</td></tr>
<tr><td>5.</td><td>Tablet (Antibiotic)</td></tr>
<tr><td>6.</td><td>Capsule (Antibiotic)</td></tr>
<tr><td>7.</td><td>Capsule (General)</td></tr>
<tr><td>8.</td><td>Sachet</td></tr>
<tr><td>9.</td><td>Cream / ointment (Steroidal)</td></tr>
<tr><td>10.</td><td>Cream Ointment (General Antibiotic)</td></tr>
<tr><td>11.</td><td>Liquid External preparation</td></tr>
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Item No. V **Miscellaneous Cases**

Case No. 1. Steroidal Preparation

Registration board in its various meetings deferred cases for registration for steroidal preparations and constituted a committee comprising of Dr. Tariq Siddique and Dr. Obaid Ali for determination of the requirement. Views of PPMA and Pharma Bureau were also taken by the committee. Recommendations of committee are as follows: -

> "Although in the state of compliance of GMP regulation and current expectation of science, handling of anti-inflammatory steroids / hormones in common manufacturing area of non-sensitive drugs with appropriate controls is acceptable, but domestic dynamics does not give reasonable space to allow across the board for handling of sensitive materials in common manufacturing facilities of different drugs. However, depending upon the level of facility compliance, material sensitivity, product dosage and demonstration of sustainable effectiveness of stringent controls to prevent cross contamination, case decision may be considered"

Decision of Registration Board: Registration Board decided to forward recommendations of the committee to Licensing Division for decision, as Schedule B-II is catered by that Division.

Proceedings / Decision of CLB

The Board was apprised that Registration Board has referred the case for soliciting recommendations from Central Licensing Board in light of recommendation of the committee constituted by the Registration Board for manufacturing requirements of anti-inflammatory steroids / hormones.

After thorough deliberations and discussions, the Board decided as under: -

- **Schedule-B (5.2) of Drugs (Licensing, Registering & Advertising) Rules, 1976 already specifies dedicated facilities for production of hormones.**

- **For manufacturing requirements of anti-inflammatory steroids, the Board referred the case back to Registration Board for clear and candid recommendations from its committee so that CLB may decide accordingly. The said committee may be enlarged for better scientific discussion and recommendations keeping in view the domestic dynamics as well.**

Case No. 2 Discontinuation of Local Production for Ethicon Sutures by M/s Johnson & Johnson Pakistan (Pvt) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi.

1. **M/s Johnson & Johnson Pakistan (Pvt) Ltd** informed the Licensing Division regarding discontinuation of local production of their Ethicon sutures as the part of Johnson & Johnson's ongoing business review process in Pakistan and working towards identifying alternative solutions that will hopefully avoid an out of stock situation or disruptions to the supply of Ethicon sutures. They have further provided the plan which includes details concerning the dismantling procedures of associated equipment and a Raw Material Destruction Plan.

2. Johnson & Johnson Pakistan further stated that they will of course continue to follow all local regulatory requirements throughout the plant closure process and if any question arises then to contract Dr. Choudary Muhammad Aslam, Director Plant Operations.

3. Submitted for the consideration and decision by the Board

Proceedings of the Board

During discussion, Director QA/LT informed that the firm is going to close down its sutures facility due to pricing issue. He is receiving complaints regarding shortage of sutures.

Decision of the Board:

The Board after thorough deliberations and discussion decided:

- **To call the firm for personal hearing.**
- **To refer the case to Registration Board for priority consideration with regard to registration of alternate products, in case firm discontinues its local production of sutures.**

Case No. 3. Renewal of Drug Manufacturing Licenses of M/s. Macter International (Pvt) Ltd, Karachi. (i) DML No.000141 (Formulation) & (ii) DML No. 000111 (Basic Manufacture).

Brief Background

- Application for renewal of DML No. 000141 (Formulation) was received on Form-IA on 10th October, 2009 for the further period 24-11-2009 to 23-11-2014
- Application for renewal of DML No. 000111 (Basic Manufacturer) was received on Form 1A on 15-09-2009.
- The panel inspection for renewal of DML No. 000111 (Basic Manufacture) was conducted on 22-07-2010 by following Members:
  i. Mr. M. Moti-Ur-Rab, Member CLB
  ii. Mr. Salim Isharat Hussain Secretary PQCB, Karachi.
  iii. Mr. Ahmad Din Ansari, FID, Karachi.

- The panel recommend the renewal of DML No. 000111 (Basic Manufacturer) and rated the firm **Good**

- A panel constituted for renewal of DML No. 000141 (Formulation) on 22-04-2010 which is as under; -
  - Mr. M. Moti-Ur-Rab, Member CLB.
  - Area FID, Karachi.
  - Mr. Saif-ur-Rehman Khattak, FID, Karachi.

- Inspection conducted by the panel for renewal of DML No. 000141 (Formulation) on 29-07-2010 with "**Good"** rating with following remarks:

  "Firm has been provided with good facilities for manufacturing and QC of drugs registered in the name of firm and being produced at the site, sufficient technical personnel have been engaged to supervise the activities being carried out keeping in view the good facilities made available and well maintenance of plant, ***the panel recommended the renewal of firm's Drugs Manufacturing License No.000141 (formulation). It is appreciated that that at the pointation of panel, the firm under took to develop dedicated area for manufacturing of solid dosage psychotropic drugs within six month time".***

- The case was placed on agenda of 225th meeting of Central Licensing Board held on 22nd October, 2010 as under:

Name of the firm	**Type of License/ Date of Inspection**	**Panel Includes**
M/s Macter International (Pvt) Ltd., Karachi	Formulation/ Basic 29.07.2010 **Extract at page. 14**	Mr. M. Moti-ur-Rab, Member CLB Mr. Ahmed Din Ansari FID Karachi Dr. Saif-ur-Rehman Khattak, FID Karachi The panel has advised the firm to develop dedicated area for Psychotropic section within six months time.

Decision of the Board taken in 225th meeting (reproduced as per approved minutes)

The Board approved renewal of drugs manufacturing licenses of the following firms on the recommendations of the panels of experts.

S #	Name of the firm	Type of License	Duration
1.	*M/s Macter International (Pvt) Ltd., Karachi.	Formulation	24.11.2009 to 23.11.2014

*N.B: The firms shall be directed to immediately attend to the shortfalls pointed out by the panels within a period of 1-3 months. Follow up inspections shall also be conducted preferably by the same panels which shall be constituted as per existing procedures / instructions.

- The decision of the Board was conveyed to the firm on 30-11-2010.
- On 23-09-2011 a panel inspection was made for the grant of additional section for manufacturing of rDNA (Bio Technology Products) under DML No. 000141 – Formulation by following members:
    1. Mr. Sheikh Ansar Ahmed Drugs Controller QA
    2. Mr. Hyder Bux Buzdar, DDG (E&M) Karachi.
    3. Dr. Saqlain Gillani Member Biological Committee
    4. Mr. Ahmad Din Ansari FID Karachi

    - The panel in its report inspected Biotech, Tablet Psychotropic and Sachet Manufacturing areas and given following remarks in recommendations:
        - The panel recommended the approval of new section for the manufacturing of recombinant DNA (Biotech) protein sterile products both in Liquid Injectable and Lyophilized Injectable forms.
        - As per good facilities made available for manufacturing of Tablets (Psychotropic) and Sachets (General), the panel recommended the approval of areas of both of these too.
    - The firm had applied for the approval of revised layout plan for Segregated / Dedicated area for manufacturing of Table Psychotropic.
    - The layout plan for Segregated / Dedicated area for manufacturing of Table Psychotropic was approved on 01-04-2014.

2. Agenda of 225th meeting reflects as both the inspection reports were placed but minutes does not reflect the recording of both reports for renewal of DMLs. The available signed copy of minutes reflects only renewal of DML No. 000141 (Formulation).

3. Now the case is submitted for consideration of the Board.

Decision of CLB:

The Board after thorough deliberations and discussion decided to re-inspect the firm before granting the renewal of DML of both licenses i.e DML No.000141 -Formulation & DMLNo.000111-BasicManufacture.

Case No. 4 CHANGE OF NAME OF FIRM

The Following un-licensed firm has applied for the change of its company name and submitted the requisite documents and prescribed fee and justification there-of which is as under:-

Justification:-

We are pleased to state that we are giving brief identification to our product with most modern rDNA facility as well as other specific international standards to other products therefore we have changed our unlicensed unit name.

S. No	From	To
1	M/s Pharmedic Laboratories (Pvt) Ltd Address: 17-Km, Multan Road, Lahore Un-licensed unit	M/s Pharmedic Pharmaceutical Industries (Pvt) Ltd Address: 17-Km, Multan Road, Lahore Un-licensed unit

Decision: The Board approved the change of name of un-licensed firm as above.

Item-VI ANY OTHER ITEM WITH PERMISSION OF CHAIR

Shortage of Tab. Xanax of M/s. Pfizer Labs. Karachi.

After discussing regular Agenda, the Director (QA/LT) appraised the Board as any other item regarding the severe shortage of Tab. Xanax of M/s. Pfizer Labs Karachi, due to rejection of firm's psychotropic manufacturing section by the Central Licensing Board in its 235th meeting on the recommendation of two separate reports each of which were not signed by all the members of panel.

Majority of the Board's members were of the opinion that since the Central Licensing Board in its 235th meeting had already decided and rejected the approval of firm's psychotropic section in accordance with the recommendation of panel under Rule 10 of Drugs (Licensing, Registering & Advertising) Rules 1976; hence panel inspection of their facility to verify removal of deficiencies/ short comings pointed out during the last inspection shall be conducted accordingly.

It was further informed by Syed Muid Ahmed, Member CLB who was also member of the Fact Finding Committee constituted by Division of QA/LT that the firm has addressed most of the observations made by the panel.

===== The End =====

QUALITY ASSURANCE CASES (GMP)

Item No. I

(Old Cases of Quality Assurance)

Case No. 1:- Lahore Pharma, Lahore

M/s Lahore Pharma, Lahore was inspected on 14.03.2013 by a panel comprising of Mr. Nadeem Iqbal, Member Central Licensing Board, Mrs. Aisha Khalil, FID Lahore and Mr. Akbar Ali, ADC Lahore with reference to see/verify the GMP compliance. During the inspection, the panel has pointed out number of serious shortcomings in all sections. The panel concluded and directed the firm to stop production immediately.

Action Taken by DRAP: - A show cause notice was issued to the firm on 29.04.2013 along with the direction to stop production in all sections with immediate effect.

Proceedings in 232nd Meeting: The case was placed before the Central Licensing Board in its 232nd meeting held on 29-30th July, 2013 wherein Mr. Muhammad Saeed, Owner of the firm appeared before the Board. He submitted the reply of the show cause notice to the Board informing that they have made improvements as suggested by the FID. They are ready for inspection and also requested to withdraw the show cause notice. The Board after thorough deliberations on the instant case took the decision accordingly on case to case basis.

Decision of CLB in 232nd meeting Held on 29-30th July, 2013

i) The Board decided that the production will remain stopped till the final decision by Central Licensing Board.

ii) The Board also decided to get the firm re-inspected by a panel to verify the improvements made by the firm in the light of shortcomings identified by the area FID.

iii) *The panel inspection report will be presented in next meeting of CLB as and when received for further consideration and decision by the Board.*

In compliance to the decision of the Central Licensing Board, the Chairman, Central Licensing Board/Director (QA/Lab Testing & Lic) has constituted a larger panel comprising the following to conduct the inspection of the firm in the light of the decision of the Central Licensing Board to check/verify the GMP compliance in all sections:

i) Mr. Ayaz Ali Khan, Member, Central Licensing Board,
ii) Mr. Zia Husnain, FID Lahore,
iii) Area FID Lahore and
iv) Mr. Akbar Ali ADC Lahore

Surprise Inspection by FID: The FID inspected the firm before the panel inspection to check the production status and improvements made by the firm and reported that no production and QC staff was present, same situation prevails, no progress in installation of HVAC. Some production activities in cream/ointment and external liquid area were observed. Upon query, Mr. Saeed's (Owner) son showed very in appropriate behaviors with the FID. He criticized the concerned authorities for

imposing the conditions/requirements of HVAC system, GMP compliance on audit proforma Schedule B-II.

Another show cause notice has been served to the firm on 20.02.2014 along with the direction to stop production, immediately.

Proceedings in 234th Meeting of CLB:-

The representative of the company was called for personal hearing in its 234th meeting of CLB held on 27.02.2014 and the case was placed before the Central Licensing Board for consideration. Mr. Muhammad Saeed, Managing Partner appeared before the Board wherein, it was informed that he was not involved in any production activities, at the time of FID visit the technical staff were not present on 22-01-2014. The representative plea that his son (who was present during the inspection) was not a technical person and does not know anything related to Pharma industry. He requested the Board for favorable action and for re-inspection of the firm so that progress in removal of previous objections can be proved.

Decision of CLB of 234th Meeting of CLB Held on 27th Feb 2014:

The case was placed before Central Licensing Board for consideration. The Board after through deliberation, keeping in views the facts on record and hearing the views of firm's representatives decided the following:

1. *Upholds the Board's previous decision of suspension of production activities till the inspection by panel and final approval by Central Licensing Board.*
2. *Inspection by panel for verifying the improvements in the GMP compliance.*
3. *The company be warned on the manufacturing of products, in violation of CLB's earlier decision.*

Present Status:

A panel comprising of six members inspected the firm on 29-04-2014 and concluded that keeping in view the nature of the products (Topical preparation only) manufactured at this premises and the improvement made like installation AHU. Hiring of the pharmacist, provision of receiving bay/de-dusting areas, renovation of stores and installation of dispensing hood as directed, the panel recommended resumption of the production activities in the repacking section only (Topical/ external preparation only. Panel also recommends re-inspect the unit, once the firm installs HVAC as per their commitment in other sections within a time period of three months/ once the firm intimates to DRAP, Islamabad. M/s Lahore Pharma, Lahore has filed a Writ Petition No.24518-2013 against Federal Inspector of Drugs, Lahore & Deputy Drugs Controller for Secretary Licensing Board, Islamabad, in the Honorable Lahore High Court, Lahore. The parawise are under process for which Lahore at Lahore Office.

The Case is subjudice and placed before the Central Licensing Board for information, please.

Decision of CLB.

The Board observed that since the case was subjudice, and firm has lodged the case before court for relief. The Board after considering the recommendations of panel for resumption of production activities in the re-packing section only vide its inspection report dated 29-04-2014 decided the following:

1. ***The Board allowed the resumption of production in re-packing section only.***

Case No.2 M/s Pharmedic Laboratories (Pvt) Ltd, Lahore.

Resumption of production in: Interferon manufacturing Section (Biological Section)

The Federal Drug Inspector Lahore Mr. Ajmal Sohail Asif (Vide his letter dated 25-04-2014) has forwarded the letter of the firm M/s Pharmadic Laboratories, Lahore wherein the firm has requested to allow them resumption of production and consumption of raw material in the large interest of patients. The FID submitted that a panel comprising officials of NAB, DR. OBAID ALI DDC and the FID (AJMAL SOHAIL) visited the firm on 05-12-2013 with reference to inquiry of supply of sub-standard HEpaferon injection to Govt. of KPK. During visit the panel observed that the firm has closed its Biological section and up-gradation / renovation work was going on. There was no production at that time and management of the firm informed that they have stopped production due to up-gradation of manufacturing facility. The FID keeping in view the sensitivity of the matter (the case is still subjudice and under inquiry by NAB and anti-corruption department) requested to Director (QA/LT) that a panel of experts may be constituted to evaluate the GMP and Licensing requirements of the Biological Section Prior to allowing resumption of production to the firm.

The Federal Drug Inspector Lahore Mr. Ajmal Sohail Asif vide his letter dated 13-05-2014 forwarded the letter of the firm M/s Pharmadic Laboratories, Lahore and informed that they are going to re-start production in Biological area on 12-05-2014 as they have completed their up gradation and renovation work. The FID requested the director QA to expedite the matter and constitute a panel of experts to evaluate the GMP and licensing requirements of the Biological section prior to allowing resumption of production to the firm.

Brief of the Case:

The matter of M/s Pharmadic Laboratories, Lahore is that the firm has intimated to federal drug inspected Lahore that they are resuming their production in Biological area on 12 May, 2014 as they have stopped production in their Biological on Voluntarily basis due to annual maintenance and up-gradation of HVAC system and renovation on 26th November 2013.

The firm has informed to FID that they have completed the following up-gradation according to GMP requirements.

- Replaced all the terminal HEPA filters of 0.2 um with new ones and validated for the quality of purified, sterile and particle free air as per GMP requirement (validation certificates attached). Installed new air handling unit having sufficient capacity to keep sterile are under positive pressure.
- All the ducts and fabrication work of HVAC system have been replaced / upgraded.
- All areas have been repainted with Epoxy paint for GMP compliance.
- All the walls, roof and other areas have been painted with polyurethane paint for smooth surface to avoid microbial growth.
- All the equipment and machines are re-calibrated.

The firm has also informed to FID that the changed against them regarding substandard interferon injections have been dropped and they have been declared not guilty by the Chairman Drug Court KPK Peshawar after facing trial and the complaints have been dismissed being devoid of merits (Copy enclosed).

The firm informed to FID that after the afore-mentioned up-gradation and renovation they were going to restart production in Biological Area on 12th May, 2014.

Comments of Directorate of Quality Assurance and Lab Testing of DRAP.

As per record of the quality control section the brief of the case is "Supply of Substandard hepaferon injection to the Government of KPK. Honorable High Court of Peshawar took suomoto action; in addition the case is being under investigation by NAB and Anticorruption department. As per report of FID (Mr. Ajmal Sohail) health department KPK apparently did not intend to receive stock, so it was difficult for firm to keep this stock in the cold storage or unknown/infinite period. The FID further informed that now firm intend to discard this stock that is why stock has been placed without observing storage condition.

By procuring from the firm and seeing the orders of the Honorable High Court Peshawar dated 22-10-2013 and the orders of Honorable Drug Court Peshawar dated 15-04-2014. The directorate of Quality Assurance was on a view that the DRAP was not the party in the said case therefore certified copy could not be obtained.

The directorate of QA has also view that the company had not been stopped from production by the QA directorate. Hence a panel of experts may be constituted including the persons having fair knowledge of Biological. So directorate of biological should be approached in the matter.

The directorate of QA has view that the implementation of drug registration board be done by the concerned directorate (Biological).

The directorate of QA is on the view that unfortunately stills no panel inspection as been done due to one or the other reason. Company has requested for GMP inspection.

The directorate of QA has proposed following panel to do the needful.

1. Sheikh Ansar Ahmed — Director Biological
2. Abdul Sammad Khan — Director NCLB
3. Mr. Zafar Minhas — Deputy Director NCLB
4. Area FID

Comments of Directorate of Biological of DRAP:

The directorate of Biological has view that in 241st meeting held on 23-12-2013 the director NCLB (Abdul Sammad Khan) brought the issue before registration board on 23-12-2013. Following was decision "Board deferred the case till report of NAB and decision by Peshawar High Court. Moreover registration board ratified the above action taken by NCLB". The directorate of Biological has the view that there is nothing on record that registration board had ratified what action? And if it is about stoppage of production and about Quality Assurance failure where is report? And what is outcome? All operations needed to be clarified. Director QA is requested to stream line things before panel inspection. Further new panel be given clear

mandated to act upon. The directorate of Biological has proposed that Mr. Zafar Minhas (Micro Biologist-Vaccine Standardization Expert) be included in panel.

The directorate of biological has view that quality Lapse resulted due to poor storage arrangement at the end of receiver viz.e.viz, quality of supply, transportation, cold chain management etc, and nothing is related to ECBD, which is responsible for pre-registration evaluation about safety of product. Hence decision of registration board in 241st meeting is uncalled for.

The directorate of Biological as a view that noting about finding by the NAB is available to act upon. The director QA may proceed for company inspection if he considers that any GMP lapse is there.

Comments of CEO of DRAP

A meeting is suggested along with Director Biological and Director QA.

Decision of Above Meeting

In the meeting of Director QA and Director Biological with CEO DRAP it was decided that the case should be discussed in the forthcoming meeting of CLB for further decision

Decision of CLB

The Board after through deliberation, keeping in views the facts on record decided that:

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

  a. **Dr. Ikram-Ul-Haq, Member CLB**
  b. **Mr. Ayaz Ali Khan, Chief Drug Controller, Punjab.**
  c. **Shaikh Ansar Ahmed Director Biologicals.**
  d. **Mr. Abdul Samad Khan, Director NCLB.**
  e. **Mr. Zafar Minhas, Deputy Director NCLB**
  f. **Mr. Ajmal Sohail Asif Area FID, Lahore.**

i) **The FID Peshawar and area FID Lahore will provide the attested copies of Orders of Drug Court and High Court, Peshawar and the present status of NAB Inquiry for the appraisal of CLB.**

Item No. II: ANY OTHER ITEM WITH THE PERMISSION OF CHAIR

QUALITY CONTROL CASES

Item-I: (New case)

Case No.1: MANUFACTURE AND SALE OF SPURIOUS AND SUB-STANDARD BRONCOMARS POWDER (FOR VET USE ONLY) BY M/S A-ONE POULTRY SERVICES, MADINA MARKET, NEW ADDA, MARADAN. (F. NO. 04-03/2014-QC)

The FID Peshawar along with ADC Peshawar and Provincial drug Inspector inspected a premise at Madina Market, New Adda Mardan on 24-07-2014 on a complaint from M/s D-Maarson Pharma, Islamabad. Samples of various drugs including Broncomars Powder, Batch No. Nil purported to be manufactured by M/s D-Maarson Pharmaceutical, Islamabad were taken for test/analysis. The seizure were also made and FIR was lodge with FIA Crime Circle Peshawar against Abdul Wali, the Proprietor of M/s A-one Poultry Services. New Adda, Mardan. The Federal Government Analyst declared Broncomrs Powder batch No. Nil as spurious and substandard vide Test Report R.LIP. 643/2013 dated 23rd September 2013.

2. The Claimed manufacturer M/s D-Maarson Pharmaceutical Islamabad also disowned the drug and the FIA in its Challan has also found Abdul Wali of M/s A-One Poultry Servicers, New Addda, Mardan as guilty in the case. The FID has requested permission for prosecutions of above mentioned accused in Drug Court Peshawar for manufacturing and selling of spurious and substandard drugs.

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

4. The Board considered the case and decided as under.

Decision: -

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

"The case was deferred on the ground that one more opportunity of personal hearing be provided to the accused ensuring the delivery of letter of personal hearing through the area FID".

Old/Deferred Case

Case No. 2: INCORRECT LABELING OF PHENERGAN ELIXIR BY M/S SANOFI-AVENTIS KARACHI-(F. No. 3-08/2014-QC)

The case of Incorrect Labeling of Phenergan Elixer Batch No. WL 111 manufacturing by M/s Sanofi-Aventis Karachi Board was considered by the CLB in its 234th meeting held on 27-02-2014. The Board, after detailed deliberation in the light of the report of the DRAP's inquire Committee and the actions taken by the firm to avoid such mix-up in future, took the following decision: -

i. The firm should carryout candid and detail investigation of the incidence of mislabeling of Phenergan Elixir on top priority basis and submit a comprehensive repot along with their finding, conclusion and the steps taken for avoiding recurrence of such incidence in future.
ii. In view of the rectifications measures taken, the firm is allowed to resume production operations in the Oral Liquid Section.
iii. The inadequacies pointed out by the investigation Committee in its report should be addressed on top priority and the firm should also submit a compliance report for CLB in this regard for its consideration.
iv. Warning be issued to the firm in order to refrain from such mishaps in future.

2. The firm submitted detailed compliance report regarding the decision mentioned above at Para 1 (i) & (iii). The firm further claimed that inadequacies pointed out by the investigation committee of DRAP in its report have also been addressed and appropriate actions have been taken. The firm also requested to allow for disposal of incorrect labeled recalled stock i.e. 57156 packs of Phenergan Elixir, Batch No. WL-111.

3. In view of above he Board again considered the case in its 235th meeting held on 15-05-2014. The Board after considering the submissions of the firm and thorough discussions and deliberation on the matter decided as under: -

i. Verification by the same DRAP's inquiry committee for the measures taken by the firm itself and actions taken on the recommendation of the aforesaid committee.
ii. Deferred the disposal of incorrect labeled recalled stock i.e. 57156 packs of Phenergan Elixir, Batch No. WL-111 till next meeting of the Board for

consideration / decision in the light of submission of the report by the above said DRAP committee.

4. Accordingly letter for inspection of the unit for the purpose of verification of measures taken by the firm itself and actions taken on the recommendations of the aforesaid committee was issued on the date of the receipt of minutes of the 235th meeting of CLB i.e 19-06-2014. The DDG (E&M) DRAP Karachi was also requested to furnish the inspection report in the matter within 07 days. The same is awaited.

5. The case was considered by the Board and decided as under.

Decision: -

The board was apprised about the latest position of the case and it was decided to defer the case till next meeting of CLB as the report of DRAP's Inquiry Committee has not been received so far.

ITEM-II ANY OTHER ITEM WITH PERMISSION OF CHAIR

===== The End =====