**DIVISION OF DRUG LICENSING**
**DRUG REGULATORY AUTHORITY OF PAKISTAN**
**ISLAMABAD**
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## MINUTES OF 235th MEETING OF CENTRAL LICENSING BOARD HELD ON 15th MAY, 2014.

235th meeting of the Central Licensing Board (CLB) was held on 15th May, 2014 in the committee room of Ministry of National Health Services, Regulations & Coordination, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP, Islamabad.

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. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh. | Member |
| 3. | Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa (K.P.K), Peshawar. (Mr. Imranullah Khan, Drug Inspector, Peshawar attended meeting on behalf of Chief Drug Inspector, K.P.) | Member |
| 4. | Mr. Ayaz Ali Khan, Chief Drug Controller, Department of Health, Govt. of Punjab, Lahore. | Member |
| 5. | Dr. Ikram-ul-Haq, QC/QA Expert | Member |
| 6. | Syed Jawed Yousaf Bukhari, QC/QA Expert | Member |
| 7. | Prof. Dr. Gul Majeed Khan, Professor of Pharmacy | Member |
| 8. | Prof. Dr. Muhammad Saeed, Professor of Pharmacy | Member |
| 9. | Mr. Abdul Malik Ghauri, J.S-I as Law Expert nominated by Secretary, Ministry of Law and Justice, Government of Pakistan, Islamabad. | Member |
| 10. | Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad. | Secretary |
| 11. | 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.

Dr. Ahmed Mehmood Mumtaz, CQC/DDG (E&M), Mr. Ahmed Din Ansari DDC (QC), Mr. Khalid Mahmood, 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.

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

## A. LICENSING DIVISION

**Item-I** **CONFIRMATION OF THE MINUTES OF 234th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of 234th meeting held on 27th February, 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 # | Name of the firm | Date of Inspection / Type of License | Decision of CLB |
|---|---|---|---|
| 1 | M/s Oakdale Pharmaceuticals, Plot No. 114 Industrial Estate, Hayatabad, Peshawar. | 10-05-2014 (Formulation) | **Approved the Grant of DML with following Sections: -**<br><br>**Sections (06)**<br>1. Tablet (General).<br>2. Tablet (Antibiotic).<br>3. Capsule (General/ Antibiotic).<br>4. Sachet (General).<br>5. Oral Dry Powder Suspension (General / Antibiotic)<br>6. Oral Liquid Syrup (General / Antibiotic) |
| 2 | M/s Hawk Bio Pharma (Pvt) Ltd, Plot No. 10, St. No.S-6, National Industrial Zone, Rawat, Rawalpindi. | 06-05-2014 (Formulation)<br><br>**Veterinary** | **Approved the grant of DML with following sections:-**<br><br>**Sections (04)**<br>1. Veterinary Oral Powder General)<br>2. Veterinary Oral Powder (Antibiotic)<br>3. Veterinary Oral Liquid (General)<br>4. Veterinary Oral Liquid (Antibiotic) |
| 3 | M/s Titlis Pharma 528-A, Sundar Industrial Estate, Raiwind Road, Lahore. | 17-04-2014 (Formulation) | **Approved the grant of DML with following Sections:-**<br><br>**Sections (03)**<br>1. Tablet (General).<br>2. Capsule (General).<br>3. Liquid Syrup (General) |

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

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

| S # | Name of the firm | Type of License | Decision of CLB |
|---|---|---|---|
| 1 | M/s Linz Pharmaceuticals (Pvt) Ltd, Plot No. 31-G/H Sector-15, KIA, Karachi. | Formulation **DML No.000540** | **Board approved the amendments in layout plan for already granted sections as under: -**<br><br>1. Oral Dry Powder Suspension (Cephalosporin)<br>2. Dispensing Area (Cephalosporin)<br>3. Dispensing (General)<br>4. Raw Material Warehouse (Cephalosporin)<br>5. Raw Material Warehouse (General)<br>6. Amendment in Microbiology Laboratory. |
| 2 | M/s Pfizer Pakistan Limited,<br>B/02, SITE, Karachi.<br><br>Tablet (Psychotropic) Section | **Formulation DML No. 000058** | The Board after considering the gravity of observations/shortcomings mentioned in both the inspection reports generated separately by the members of same panel where the members of the panel unanimously did not recommend the approval of grant of additional section i.e. Tablet (Psychotropic) Section and after making thorough discussion and deliberations **decided and rejected the grant of Tablet (Psychotropic) Section under Rule 10 of Drugs (Licensing , Registering & Advertising) Rules 1976 due to following observations made by the panel of inspectors: -** |

**Observations of the panel: -**

i. Change rooms for the Psychotropic drugs were found devoid of some essential amenities including cross over benches, double shoe-cover, closets to keep gowns, caps and masks were not available at the time of inspection. There was no air handling system installed in the secondary change rooms.
ii. The Storage of API was defined in common raw material stores. The storage area for raw materials to be used in the manufacturing of Psychotropic product was not properly segregated as per rules. No segregation of quarantine, under test, released products was defined with proper partitioning. Mostly material were placed on the same floor and under the same roof.
iii. No sampling procedure as per USP guidelines and as under the Drugs Act, 1976 was followed.
iv. It was noted that a safety cabinet for the purpose of sampling and dispensing of only active Psychotropic drug was kept in the blending area of manufacturing section. No separate dedicated area for sampling and dispensing of active material was found, whereas excipients dispensing and sampling are being carried out in general sampling and dispensing both which are used for common purpose of sampling, dispending and staging on as and when needed basis.
v. Separate caging for individual dispensed batch keeping system was also found not up to the mark.
vi. No utility log books and cleaning log books were found in the manufacturing area and storage area (for dispensing and sampling record). As per WHO guidelines for inventory control of APIs for want of stock card, tally card, bin card nor at least following the quality management system for the planning and controls of psychotropic substances.
vii. All manufacturing operational procedures including sampling and dispensing of active materials in safety box, blending milling were carried out in a single same room. Two V-shaped blending vessels were also kept in the same room which is in the violation of the GMP requirements of safety, hygiene and hazards.

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|---|---|---|---|
| | viii. The installation and qualification seemed under question as sufficient documents were not shown and even available. Panel further noted that area qualification has not been carried out till to date and even noted not programmed in near future.<br>ix. A dedicated IPQC lab has not been provided in this segregated area.<br>x. The area/ corridor leading to the focused manufacturing premises was found dirty with normal open drains.<br>xi. Furthermore, the management has not demonstrated the efficiency of air handling system in the subject areas, pressure differential was seen not well maintained, air balancing has not been carried out, area monitoring efficiency was not exhibited. Overall HVAC system was partially existed with poor maintenance level.<br>xii. The primary change rooms are kept common but secondary changes are also given which were found devoid of some essential amenities.<br>xiii. Panel further noted that area qualification has not been carried out till to date and even noted not programmed in near future. Other necessary installations were seen in appropriate orders however milling activity has been accommodated in blending area instead of defined & designed one. In blending room two V-shaped vessels are kept with separate capacity, the installation of these vessels was seemed under question as sufficient supportive documents were not available.<br><br>**The Board was apprised that the panel has also observed that the firm possesses the registration of <u>Dry Powder Suspension (Azithromycin)</u> but practically the firm has not legally approved section to manufacture such types of products even no appropriate and defined places are allocated for its manufacturing. In this regard, the Board however, was apprised by Licensing Division that firm was granted Dry Powder Oral Section in 231st meeting of CLB held on 30-01-2013. The approval was conveyed to the firm by Secretary CLB on 12-02-2013 accordingly. The Board advised to refer case to Drug Registration Board to look into the matter for necessary action at their end.**<br><br>**The Board further discussed the procedure of conducting panel inspections and advised to develop a Standard Operating Procedure (SOP) for uniform reporting by Division of Drug Licensing & Division of Quality Assurance & Laboratory Testing jointly.** | | |
| 3. | M/s Wenovo Pharmaceuticals, Plot No. 31 & 32, Punjab Small Industrial Estate, Taxila | Formulation **DML No. 000791** | **The Board approved the grant of following additional sections as under:-**<br><br>**Sections(05):-**<br>1. Dry Powder Injection (Cephalosporin)<br>2. Oral Dry Powder Suspension (Cephalosporin)<br>3. Dry Powder Sachet (Cephalosporin)<br>4. Dry Powder Vial Injectable (General)<br>**5.** Liquid Ampoule SVP (General) |

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

The Board considered the following cases of Grant of Renewal of Drug Manufacturing License in the light of recommendations by panel of experts/inspectors subject to confirmation of 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 Farmigea Pakistan (Pvt). Ltd, 4.5, Km., Raiwind Manga Road, Raiwind, Lahore. | DML No.000471 (Formulation) | **Approved the Grant of Renewal of DML except for Steroidal Section.**<br><br>The firm has submitted an undertaking that they will not manufacture steroidal eye drops products till final approval of additional / segregated section. |
| 2. | M/s. Getz Pharma (Pvt) Limited, Plot No. 29-30, Sector -27, Korangi Industrial Area, Karachi. | DML No.000284 (Formulation) | **Approved the Grant of Renewal of DML** |
| 3. | M/s. Zinta Pharmaceutical, 168-Industrial Estate, Hayatabad, Peshawar. | DML No.000570 ( Formulation) | **Approved the Grant of Renewal of DML** |
| 4. | M/s BF Biosciences, Limited, 5KM, Sunder Raiwind Road, Lahore. | DML No.000655 (Formulation) | **Approved the Grant of Renewal of DML**<br>The Board was further apprised by Licensing Division that the firm in its renewal application has mentioned that they have registration of Omeprazole at Biotech facility where as panel in the inspection report has mentioned that the firm has dedicated biotech manufacturing facility only.<br>The Board in this regard advised to refer the case of registration of Omera Injection (Omeprazole) with Reg. No. 067967 to Drug Registration Board for its consideration and further necessary action accordingly. |
| 5 | M/s Allmed (Pvt) Ltd, Plot No.590, Sunder Industrial Estate, Lahore | DML No.000645 (Formulation) | **Approved the Grant of Renewal of DML** |

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|---|---|---|---|
| 6. | M/s Alliance Pharmaceutical Pvt. Ltd<br>112-A, Industrial Estate, Hayatabad Peshawar. | DML NO. 000594 (Formulation) | **Approved the Grant of Renewal of DML** |
| 7 | M/s Shafi Textile Faisalabad. | DML NO. 000436 (Formulation) | **Approved the Grant of Renewal of DML**<br>The Board further decided to get an affidavit / undertaking from the management of the firm that they will either purchase land / plot very much adjacent to the existing site (if possible) so as to amalgamate with existing premises to fulfill requirement of Plot size of 2000 square yards as required under Schedule B of Drugs (L,R& A) Rules 1976 framed under the Drugs Act, 1976, or they will shift their present facility at some other place in Industrial Area with required land of minimum 2000 Sq yards as per requirement of Schedule B of Drugs (L, R & A) Rules 1976. The process should be completed within next two years and detail of proposed project should be described in the undertaking by the Firm. |
| 8 | M/s Manhattan Pharma,<br>Plot No. 209/3-B, Sector-5, Korangi Industrial Area, Karachi. | **DML No. 000327 (Formulation)** | **Approved the Grant of Renewal of DML** |

**Item No.V. MISCELLANEOUS CASES.**

**Case No. 1.** **Renewal of DML of M/s Shazal's Pharmaceuticals, Hattar.**

The case was presented before the Board as under:-

**The brief background of the case is as under: -**

M/s Shazal's Pharmaceuticals, Hattar applied for renewal of their DML No 000592 (Formulation) on 05-05-2011.

2. On scrutiny it was noticed / observed that the application for renewal of DML 000592 (Formulation) of the firm was not submitted on prescribed Form 1-A, hence it was not tenable and was liable to be rejected as provided under rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. The firm was repeatedly asked to submit their application on prescribed Form 1-A along with all its pre-requisites within thirty days as admissible under above mentioned Rule but the firm did not respond to DRAP's correspondence to submit complete application for renewal of their DML.

3. Mr. Muhammad Afzal- CEO / Sole proprietor of the firm informed that he leased out his factory for a period of 05 years to Mr. Malik Mehrban w.e.f 1st August 2011 and had stated that from then onwards all the responsibility of production in the factory laid on the new party for any dispute with Govt. Department or court if arises due to any fault in products or in any other case during period of agreement. Later on he informed on 27-12-2011that agreement of lease had been cancelled. Accordingly, a letter was issued on 05-01-2012 from Licensing Section to the owner of the firm Mr. Muhammad Afzal stating therein that a Drug Manufacturing License is neither transferable nor assignable and Mr. Muhammad Afzal will be responsible for compliance of conditions of license and cGMP being the licensee under the provision of Drugs Act, 1976 and Rules framed there under.

4. An other letter was issued on 23-07-2013 from Licensing Division, DRAP wherein the firm was asked to complete / rectify the shortcomings observed in the application of renewal of DML along with all the documents / information within 30 days as required under Rule 5[2A] of Drugs (Licensing, Registering & Advertising) Rules 1976 which is reproduced as under:-

> **"*On receipt of an application for renewal of a license any objection or shortcoming in the application observed by the Central Licensing Board may be notified to the applicant and he shall be given a time period of thirty days for rectification or completion of the application. In case he fails to rectify or complete the application within the specified period, the application may be rejected*"**

5. It is pertinent to mention that the case had been brought before CLB in its 232nd meeting held on 30th & 31st July 2013 while considering their case for non compliance of cGMP, wherein during proceeding of personal hearing, the owner Mr. Muhammad Afzal had committed to fulfill the requirement of renewal application on prescribed Form-IA but he failed to comply with the said commitment till date.

6. Instead of responding to DRAP's correspondence for completion of their renewal application it was informed by the owner of the firm i.e. Muhammad Afzal that he had sold his company / firm M/s Shazal's Pharmaceuticals, Hattar to Mr. Rafi-ul-Mulk on 01-10-2013.

7. The required period of thirty days already expired on 22-08-2013 but the management of the firm failed to submit the complete application within said period thus application of renewal of DML of the firm was liable to be rejected after approval of CLB and thereby the DML would cease to exist. Furthermore, owner of the firm had already been informed vide letter dated 05-01-2012 that the license is neither heritable nor assignable but he did not pay any heed to the said instructions and he again sold the licensed/ unit M/s Shazal's Pharmaceuticals, Hattar, DML No. 000592 (Formulation) to Mr. Rafi-ul-Mulk on 01-10-2013.

8. In view of forgoing stated position, the application of renewal of DML is liable to be rejected as per Rule 5[2A] of Drugs (Licensing, Registering & Advertising) Rules 1976 and it is also a case of

change of management, hence the new management of the firm is subjected to apply afresh for grant of DML in the light of Law Division's opinion solicited while considering the case of M/s Qamar Cotton Industries, Okara, wherein the Law Division had opined that the Drug Manufacturing License cannot be transferred even to the legal heirs of the company established under the sole proprietorship. The Law Division further opined that the license is a permissive right of an individual and could not be transferable.

9. Hence in view of Law Division referred to opinion the license is neither transferable, assignable nor heritable from Mr. Muhammad Afzal, the present owner of M/s Shazal's Pharmaceuticals, Hattar as per available record of Licensing Division of DRAP to Mr. Rafi Ul Mulk (purchaser) as requested. It is proposed that both the persons may be informed about the situation / status accordingly. The case was placed before the Board in its 234th meeting held on 27-02-2014 for its consideration/decision

10. Decision taken in 234th meeting of CLB.

The Board after thorough discussion / deliberations and facts on ground decided and rejected the application for renewal of DML. The Board further decided for issuance of show cause notice to the firm and personal hearing in forthcoming meeting of CLB before suspension / cancellation of DML.

**11.** Accordingly the decision of the Board was communicated to the firm through Show Cause Notice and firm has now been called for personal hearing in 235th meeting of CLB.

**Proceedings**

Mr. Khyber Khan S/O Rafi ul Mulk claimed to be the new M.D / new owner of M/s Shazal's Pharmaceuticals appeared before the Board and briefed his point of view stating that at the time of purchasing unit, he was not aware about the relevant rules and regulations for carrying out pharmaceutical manufacturing business otherwise he would had complied with the said rules / legal provisions. He further informed that previous owner of the firm (Muhammad Afzal) also did not inform him to complete application of renewal of DML as per relevant rules.

**Decision of CLB**

**The Board after personal hearing, thorough discussion / deliberations, and also looking into facts on ground and taking in consideration the legal opinion of the Law Division in previous cases of the same nature decided as under:-**

- **The firm shall apply afresh for grant of DML after surrendering License and Inspection Book to Central Licensing Board and immediately stop production till re-grant of the DML as previous DML stands invalid due to rejection of application for renewal of DML.**
- **The Board waived off the condition of site verification and directed for fresh panel inspection on receipt of application on prescribed Form-1 along with all its pre requisites thereof.**
- **The same DML No. shall be granted as and when approved by the CLB.**

**Case No. 2 RENEWAL OF DML OF M/S WESTMONT PHARMACEUTICAL, GT ROAD GUJAR KHAN, RAWALPINDI.**

The case was presented before the Board as under:-

**The brief background of the case is as under: -**

The Drug Manufacturing License No. 000631 (Formulation) was issued to the firm on 19-06-2008 subject to certain conditions. Accordingly, renewal was due for the next five years w.e.f. 18-06-2013. On receipt of application for renewal for the period 18-06-2013 to 17-06-2018, certain shortcomings were observed in the application. These shortcomings were communicated to the firm vide DRAP's letter issued on 09th October, 2013 with the direction to furnish complete application as per Form-1A but firm did not provide the deficient information/documents for completion of renewal application. A reminder was issued on 12th February 2014 to submit complete application on prescribed Form 1-A but the firm again failed to complete their application. The Drugs (L, R &A) Rules, 1976 under rule 5(2A) states as under: -

> **"On receipt of an application for renewal of a license any objection or shortcoming of the application observed by CLB may be notified to the applicant and shall be given a time period of 30 days for rectification or completion of the application. In case he fails to rectify to complete the application within the specified period, the application may be rejected".**

2. Since, period of 30 days had been lapsed on 08th November 2013 however, a reminder was also issued on 12th February, 2014 to complete the application within seven days but no response was received.

3. Keeping in view of above it was proposed that the application of the firm may be rejected if the CLB deem appropriate, further this power may be given to the Chairman CLB so that in such cases the applications for renewal of DML which have not been completed by the licensee may be rejected after lapse of period of 30 days so as to strictly adhere to the provisions of the Rules. Accordingly the case was placed before the CLB for its consideration/decision in its 234th meeting held on 27-02-2014.

<u>Decision of CLB in its 234th meeting.</u>

The Board after thorough discussion / deliberations and facts on ground decided and rejected the application for renewal of DML. The Board further decided for issuance of show cause notice to the firm and personal hearing in forthcoming meeting of CLB before suspension / cancellation of DML.

3. Accordingly the decision of the Board was communicated to the firm through Show Cause Notice and firm has now been called for personal hearing in 235th meeting of CLB.

**Proceedings**

Dr. Ashfaq, Director of the firm; appeared before the Board and explained that since it was first renewal of DML of their firm and he was not aware of provision of rules & regulations particularly to submit shortcomings in the application of renewal within 30 days of communication from CLB as per Rule 5[2A] of Drugs (L,R&A)Rules 1976. He apologized before the Board for not submitting within prescribed time as per rules due to aforesaid reasons. However, he further informed that short supplied documents / information has recently been submitted to Licensing Division for completion of application of renewal.

**Decision of CLB**

**The Board, after thorough discussion / deliberation and taking in account the submission of Director of the firm during personal hearing, decided to direct the firm to submit complete application along with fresh fee for renewal of DML as per rules.**

**Case No.3** **Cancellation of Drug Manufacturing License No. (000663) (Formulation) of M/s Al-Aju Cotton Industries Mir Pur Khas Sindh.**

The case was presented before the Board as under:-

**The brief background of the case is as under: -**

Federal Inspector of Drugs Dr. Najam-us-Saquib visited M/s Al-Aju Cotton Industries on 28th June 2013 wherein the FID had reported that there was no production activity underway and premises were found closed. He had further informed that letters and reminders to the firms were issued but no reply from the firm was received. The neighboring person informed that there was no production activity since long and said premises alongwith other surrounding land had been purchased by another person namely Mr. Amjad Memon. On contact to Mr. Amjad Memon he had confirmed that he had purchased the whole land and he did not know about running a pharmaceutical unit, nor he was interested in the same. The FID had recommended for cancellation of Drug Manufacturing License of M/s Al-Aju Cotton Industries, Mirpur Khas, Sindh. Accordingly the case was placed in 233rd meeting of CLB held on 30th & 31st December 2013.

**Decision of CLB taken in 233rd meeting held on 30-31 December, 2013.**

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

Accordingly, Show Cause notice was issued to the firm and the firm was also called for personal hearing in the 234th meeting of CLB. The firm did not respond to the show cause notice. The case was again placed before the Board in its 234th meeting held on 27-02-2014 however firm also failed to appear for personal hearing despite of issuance of letter for the same.

Decision of CLB taken in 234th meeting of CLB held on 27-02-2014

The Board after thorough discussion / deliberations and facts on grounds considered and deferred the case for final opportunity of personal hearing and collection of DML and inspection book through Area FID before suspension / cancellation of DML.

3. Accordingly, the decision was conveyed to the firm for final opportunity of personal hearing and a letter was also issued to area FID to collect the DML and inspection book. But no response received from area FID and firm. Accordingly the case was once again presented in 235th meeting of CLB held on 15th May 2014 for consideration/decision.

**Decision of CLB**

**The Board after thorough discussion/deliberation and facts on ground decided to defer the case for report of area FID.**

**Case No. 4** **Change of Name(s) of Firm(s).**

The following cases were presented before the Board for consideration/decision for change of name(s) of the firm(s) after fulfilling all the relevant documents/information.

| S.NO | FROM | TO |
|---|---|---|
| 1. | M/s Martin Dow Pharmaceuticals Limited<br><br>Address: Plot No. 37, Sector 19, Korangi Industrial Area, KARACHI<br><br>DML No. 000267 (Formulation) | M/s Martin Dow Limited<br><br>Address: Plot No. 37, Sector 19, Korangi Industrial Area, KARACHI<br><br>DML No. 000267 (Formulation) |
| 2. | M/s Medimarker's Pharmaceuticals<br><br>Address: Plot #A-104, S.I.T.E Area Hyderabad.<br><br>DML No. 000615 (Formulation) | M/s Medimarker's Laboratories (Pvt.) Ltd<br><br>Address: Plot A-104, S.I.T.E Area, Hyderabad.<br><br>DML No. 000615(Formulation) |
| 3. | M/s Nortech Pharmaceuticals<br><br>Address: Plot No. 203, Sihala Industrial Triangle, Kahuta Road, Islamabad<br><br>DML No. 000792 (Formulation) | M/s Nortech Pharmaceuticals (Pvt.) Ltd<br><br>Address: Plot No. 203, Sihala Industrial Triangle, Kahuta Road, Islamabad<br><br>DML No. 000792 (Formulation) |
| 4. | M/s Jinnah Pharmaceuticals<br><br>Address: 13 km Lahore Road, Multan<br><br>DML No. 000578 (Formulation) | M/s Jinnah Pharmaceuticals (Pvt.) Ltd<br><br>Address: 13 km Lahore Road, Multan<br><br>DML No. 000578 (Formulation) |
| 5. | M/s Medera Pharmaceuticals<br>Address: Plot # 02, Street No. 04, National Industrial Zone, Rawat<br>DML No. 000714 (Formulation) | M/s Medera Pharmaceuticals (Pvt.) Ltd.<br>Address: Plot # 02, Street No. 04, National Industrial Zone, Rawat<br>DML No. 000714 (Formulation) |

**DECISION OF CLB.**

**The Board approved the cases for change of names of the above mentioned firms on the basis of documents submitted by firms under Rule 5(6) of Drugs (Licensing, Registering and Advertising) Rules, 1976 and also advised to direct these firms to consume/dispose of printed packaging material with previous name within 03 months of name change positively.**

**The Board advised that in future, justification for name change should be taken from firms.**

**Case No. 5** **Policy Regarding Establishment of Pharmaceutical Units Located in Residential Areas.**

The case was presented before the Board for consideration/decision/information as under:-

**Brief Back Ground**

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

The cases of the individual firms in detail are as under: -

| S.# | Name of Company / Case background |
|---|---|
| 1. | **M/s Bliss Industries Ltd, 225/2, J.M. Sadhu Naval Rai Road, Karachi.**<br>In response to show cause notice bearing No. F. 2-15/95-Lic (Vol-I) dated July 2012. M/s Bliss Pharmaceuticals had informed that they had started construction of their facility at new site in Korangi as per approved layout plan. But because of law and order situation in Korangi Karachi they could not completed their construction timely.<br><br>In compliance to the decision of CLB taken in its 231st meeting a panel comprising Syed Jawed Yousaf Bukhari, Member CLB, Area FID and Area ADC was constituted to conduct the inspection of the firm. Due to delay, a reminder was also issued for timely conduction of inspection of the firm to verify progress made by the firm at the new site so far. In compliance to the decision of CLB taken in its 231st meeting show cause notice/letter for personal hearing dated 25thJuly 2013, was issued and the firm's representative was called before the Board. None of the accused/ representative of the firm appeared before the Board for personal hearing.<br>**Decision of 232nd Meeting**<br>The Board in its 232nd meeting discussed the case in the light of decision taken in 231st meeting of the Board in detail. Syed Jawed Yousaf Bukhari member CLB furnished a panel report which was asked to inspect the new site of the firm in Korangi Industrial area.<br><br>The Board was apprised by him that Panel tried to contact Mr. Ashraf, representative / spokesman of the firm so that the new site may be inspected to check the progress but the management was not serious and that he did not coordinate and respond for the needful. It was also disclosed by the worthy member that the panel also tried to trace out the location of the new site in Korangi Industrial area, but failed to find out the same.<br><br>The Board in the light of above said report of the panel and decision taken in 231st meeting of the CLB decided that<br>**(i) To defer the case of firm located in the congested residential area of Karachi.**<br>(ii) **One more but the last opportunity of personal hearing be given to the owner / management of the firm.**<br>(iii) Failing to appear before the CLB, the license of the firm shall be suspended/ cancelled and case shall be forwarded to Registration Board for cancellation / suspension |

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| | of products registered in the name of firm.<br>IV**) Accordingly firm was called for personal hearing before cancelling/suspending DML**<br>**<u>Decision of 233 meeting.</u>**<br><br>The representative of M/s Bliss Industries Limited, Karachi appeared before the Board. The Board decided to suspend the DML of M/s Bliss Industries Ltd, 225/2, J.M. Sadhu Naval Rai Road, Karachi till the firm shifts its premises to an industrial area.<br><br>**Present Status: - The firm has filed a civil suit in the Court of II - Senior Civil Judge (East) at Karachi. The parawise comments have been prepared and are in process of vetting from Law Division.**<br><br>The case was presented before the Board in its 235th meeting held on 15-05-2014 for its appraisal.<br><br>**<u>Decision of CLB</u>**<br><br>**The Board decided to direct DDG (E&M) Karachi to follow up the matter and appear in the Court of II - Senior Civil Judge (East) at Karachi till fate of the case.** |
| **2.** | **M/s Cresent Cotton, Chowk Depalpur, Okara.**<br><br>A show cause notice was issued to M/s Cresent Cotton, Okara regarding their unit located in residential area. In response to Show Cause notice the firm had informed that it was located in commercial / industrial area instead of residential area and got NOC from TMA, Okara.<br><br>2. The Board in its 230th meeting decided to direct the area FID to inspect the premises again and take the necessary documents as the firm was claiming for verification. The Board also directed the area FID to take and verify the NOC obtained from TMA, Okara and approval from concerned provincial Building Control Authorities (BCA).<br><br>3. Subsequently the Area FID reported that the facility was located on Main Adda Road. In front of the factory there was a shop of Fazal Broast, TV repairing shop, a clinic, on left there are furniture making shops, Qamar Cotton Industries was also on same road, and beside the industry one house had been built above the shops. The firm had also produced an attested copy (verified) of a letter of Tehseel Officer TMA Okara certifying that Cresent Cotton Industry situated at Chowk Depalpur Road is a commercial / industrial area.<br><br>1. The FID in her report concluded that the firm was located in commercial area.<br><br>2. Tehseel Officer (P&C), TMA Okara was also requested vide letter No. F. 1-7/84-Lic (Vol-I) dated 20-05-2013 for verification of a separate Industrial Area in Tehsil Okara but the reply is still awaited.<br><br>The case was placed before the Board in its 232nd meeting held on 29th & 30th July 2013 for its consideration/ decision, keeping in view along with legal provision of Schedule "B" of Drugs (Licensing, Registering & Advertising) Rules, 1976, also of various industrial incidents/disasters which costed loss of precious human lives as in case of unfortunate incident of M/s Orient Labs, Lahore. |

**Decision of 232nd meeting**

The Board after thorough discussion / deliberation, considering the report of the FID and keeping in view the legal provisions decided as under: -
i). The case should be processed and actions shall be taken as per provisions of Schedule B of Drugs (L, R & A) Rules 1976.

ii). Management of the firm be asked to shift to some Industrial area as there is no provision of Law &Rules that allows Pharma unit in industrial/ commercial area, as per current status of the firm.

iii). Renewal of DML of the firm would be decided in the light of commitment of firm for shifting of their unit to some industrial area as per requirement of Law & Rules.

The decision of the Board was accordingly communicated to the firm and area FID for compliance.

The case was again placed before Board in its 233rd meeting for consideration/decision as under:-

The firm was issued DML in 1978, now, the TMA Okara as requested vide letter No. F. 1-7/84-Lic (Vol-I) dated 20-05-2013 for verification of a separate Industrial Area in Tehseel Okara. The TMA, Okara has provided a letter issued by office of TMA, Okara in which the TMA, Okara has informed that the firm is located in commercial/ industrial area as there was no declared industrial area in Okara.

**Decision of 233rd meeting of CLB.**

The Board decided to verify the letter issued from Tehsil Officer, TMA Okara through Federal Inspector of Drugs. The report shall be submitted before the Board.

The decision of the Board was accordingly communicated to area FID for compliance.

**Report of FID in the light of CLB Decision**

FID had verified the above said letter from Tehsil Municipal Officer TMA, Okara who had submitted as under: -

> ***"It is clarified that Tehsil Municipal Officer, Okara has no separate industrial area in Tehsil Okara. The office letter No. 302/TO (P&C) dated 05-09-2013 is issued by Tehsil Municipal Administration, Okara".***

Accordingly, the case along with its complete background was presented before the Board in its 235th meeting held on 15th May 2014 for consideration/decision.

**Decision of CLB**

**The Board after thorough discussion/deliberations and in view of facts on ground as narrated above decided to defer the case and provided opportunity of personal hearing to the firm in next meeting of CLB.**

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| **3.** | **M/s Soma Laboratories 692-N, Samanabad, Lahore.**<br><br>A show cause notice was issued to M/s Soma Laboratories, Lahore regarding their unit located in residential area. In response to Show Cause Notice the firm stated that they were not contravening the section 41 of Drugs Act, 1976 because they got license in 1981 while the rules for condition of location of manufacturing was added in the year 1998. The firm was called for personal hearing in 230th meeting of CLB but they did not appear before the Central Licensing Board. The Board took serious notice regarding manufacturing of drugs in residential area and decided to defer the case till next meeting and one more opportunity for personal hearing was granted.<br>Mr. Mian Ghulam Jelani appeared for personal hearing meeting of the Central Licensing Board in its 231st held on 30-01-2013 and committed that they will shift their unit within one year and had voluntarily stopped the production. The Board decided to suspend the production for a period of three months and verification from Area FID was also advised**.**<br><br>The area FID had submitted report dated 03-06-2013 stating that the firm was closed and no production activities was observed.<br><br>The case was placed before the Board for its consideration/ decision, keeping in view various industrial incidents / disasters which coasted loss of precious human lives as in case of unfortunate incident of M/s Orient Labs, Lahore.<br><br>**Decision of 232nd Meeting of CLB**<br><br>The Board after thorough discussion / deliberations, taking into account commitment of the firm before the CLB in its previous meeting and keeping in view the legal provisions decided as under: -<br>**(i). Suspension of DML of the firm with immediate effect for a period of six months** so as to avoid any industrial incident / disaster which may cost loss of precious human lives as occurred in case of M/s Orient Labs Lahore as the firm is located in congested residential area of Samanabad Lahore. The area FID should ensure the closure of unit / stoppage of production and report in this regard be submitted to CLB on monthly basis without fail.<br><br>ii).The Drug Registration Board was informed about the suspension of DML of the firm for further necessary action.<br><br>iii). The management be directed to shift their unit in industrial area and to furnish the progress report regarding the shifting of unit as per their commitment made before the CLB in its 231st meeting held on 30-01-2013.<br><br>iv). Area FID be directed to inspect the new site and submit its progress report. The report of Area FID is awaited.<br><br>Decision of 233rd Meeting of CLB.<br><br>Area FID be directed to inspect the new site and submit its progress report which is long awaited.<br>The case is deferred till next meeting of the Board. The Board directed to issue a letter to Area FID and provincial Govt.s to verify the availability of stocks and its report be furnished to CLB.<br><br>The decision was conveyed to the firm, but the letter has been received back undelivered.<br>The case was presented before the Board in its 235th meeting held on 15th May 2014 for consideration/decision.<br><br>**Decision of CLB**<br><br>**The Board decided and directed to deliver letter to the firm through area FID to ascertain the delivery of the letter, and one copy of said letter to be directly issued to the firm through registered mail.** |

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| **4.** | **M/s Shamsi Pharmacy, Samanabad, Lahore.**<br><br>A show cause notice was issued to M/s Shamsi Pharmacy, Lahore regarding their unit located in residential area. In response to show cause notice the firm had replied that they were not working in old unit since 2010. Area FID as reported that the firm had suspended its production and it was not operational. They also wanted to postpone the matter because of their father death and some family issues.<br><br>2 The firm was called for personal hearing in 230th meeting of CLB but they did not appear before the Central Licensing Board. The Board took serious notice regarding manufacturing of drugs in residential area and decided to defer the case till next meeting and one more opportunity for personal hearing was granted.<br><br>3. Mr. Faisal Maqbool the Son of deceased owner appeared before the Board in 231st meeting of CLB who committed that they are ready for inspection at new place. The Board in 231st meeting decided to get the inspection of the premises where firm intended to shift their unit and decided to suspend the production at the congested area of Samanabad. Lahore. The board further decided to get an inspection conducted by Area FID so as to verify the production activity at existing site.<br><br>4. The Area FID in response to DRAP letter dated 17-05-2013 had reported inspection of the facility to check the production status of the firm 20-06-2013 in the presence of Mr. Faisal Maqbool Son of deceased owner of the firm. It had been further reported that no production activity was going on at the time of inspection. However, finished goods were stored in large quantities in two rooms without any temperature control. Bundles of fresh units cottons of different products were also store bearing manufacturing date 2009 & 2010 etc. The FID also took samples of two products i.e. Mag. Sulphate B.P. Batch No. 43 Manufacturing date 06-2011 and Kaolin Light Batch No. 30 Mfg. date 06-2010 for test / analysis purpose. The FID had also stated that as per availability of sample of Mag. Sulphate bearing Manufacturing date 06-2011 and expiry date use within 04 years clearly show that the firm has manufacturing the products after 2010 which is contrary to the reply of firm about the closure of the unit since 2010. FID had also mentioned that the products of M/s Shamsi Pharmacy were also available in the Market bearing manufacturing dates 2009, 2010 and 2011 etc.<br><br>Accordingly, case was presented in 232nd meeting of CLB held on 29th & 30th July 2013 for consideration / decision of the Board after above mentioned inspection report.<br><br>Decision of 232nd Meeting of CLB<br><br>The Board after thorough discussion / deliberation, considering the report of the FID, taking into account commitment of the firm before the CLB in its previous meeting and keeping in view the legal provisions decided as under: -<br><br><u>(i). Suspension of DML of the firm with immediate effect for a period of six months</u> so as to avoid any Industrial incident / disaster which may cost loss of precious human lives as occurred in case of M/s Orient Labs Lahore as the firm is located in congested residential area of Samanabad Lahore.<br><br>ii). The Drug Registration Board be informed about the suspension of DML of the firm for further necessary action.<br>iii). The management be directed to shift their unit in industrial area and to furnish the progress report regarding the shifting of unit as per their commitment made before the |

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| | CLB in its 231st meeting held on 30-01-2013.<br>iv). Area FID be asked about the action taken on availability of products manufactured in the period of closure of firm available in the market. The report of FID is awaited.<br><br>After communication of above mentioned decision taken in 232nd meeting of CLB, case was again presented in 233rd meeting of CLB held on 30th & 31st December 2014.<br><br><u>Decision of 233rd Meeting of CLB.</u><br><br>The Board decided that Area FID be directed to inspect the site and submit its progress report which is long awaited.<br>The CLB uphold its previous decision. The Board directed to issue a letter to Area FID and provincial Govts to verify the availability of stocks and its report be furnished to CLB. The case is deferred till next meeting of the Board.<br><br>The above mentioned decision of CLB had been conveyed accordingly for compliance but no reply from field office received and also not from the firm. Reports were still awaited.<br><br>The case was again presented before the Board in its 235th meeting of CLB held on 15th May 2014 for consideration/decision:-<br><br>**<u>Decision of CLB</u>**<br><br>**The Board after thorough discussion /deliberation and keeping in view the facts on ground decided to defer the case and to direct firm for personal hearing in next meeting of CLB. The Board further directed to obtain progress report from Area FID & Provincial Govts for its decision taken in 233rd meeting.** |

**Case No. 6 <u>CASE FOR CHANGE OF MANAGEMENT OF M/S AMBROSIA PHARMACEUTICALS, RAWAT DML NO.000561 (FORMULATION).</u>**

M/s Ambrosia Pharmaceuticals, Rawat was granted DML No.000561 (Formulation) on 09-12-2004 in which two proprietors namely Mr.Anjum Ahmed Chief Executive and Mr. Nadeem Zia Managing partner. The firm while submitting the application for renewal of DML on 07-12-2009 submitted the two new names of partners namely Mr. Moeez Naved and Mr. Iftikhar Ahmed. The firm was intimated that the DML is neither transferable nor heritable. The firm submitted application for renewal of DML for the period 09-12-2009 to 08-12-2014 and case was discussed and approved before 223rd meeting of CLB held on 17th May, 2010.

2. The firm has again been sold by Mr. Moeez Naved and Mr. Iftikhar Ahmed to Mr.Abdul Aziz Lakhani and amr. Arif Lakhani.

Keeping in view of above following is submitted: -

a. Under Rule 5(1) wherein Form 1-A for renewal of DML has a proviso that the management is bound to disclose any change in respect of name of proprietors / directors / partners. In instant case the application was processed after change of ownership earlier.
b. Now the Drug Manufacturing License No.000561 (Formulation) has been issued DML w.e.f. 09-12-2009 which is valid up till 08-12-2014.
c. The Law Division while giving its opinion solicited with reference to defunct MoH reference No.F.2-2/99-AB, dated 23-05-2000 (page-203-204/Corr) while considering the case of M/s Qamar Cotton Industries, Okara opined as under: -

***'Mr. Qamar Uddin was sole proprietor of the firm as is evident from profroma 'A' on the record signed by Qamar Uddin himself. On his death the firm stood automatically dissolved. The DML was issued to Mr. Qamar Uddin with the death of the licensee the said license ceased to exist. The license to a sole proprietorship was a personal and permissive right which was neither assignable nor heritable".***

**<u>Decision of CLB</u>**

**The Board after personal hearing, thorough discussion / deliberations, and also looking into facts on ground and taking in consideration the legal opinion of the Law Division in previous cases of the same nature decided as under:-**

- **The firm shall apply afresh for grant of DML after surrendering License and Inspection Book to Central Licensing Board and immediately stop production till re-grant of the DML as previous DML stands invalid due to rejection of application for renewal of DML.**
- **The Board waived off the condition of site verification and directed for fresh panel inspection on receipt of application on prescribed Form-1 along with all its pre requisites thereof.**
- **The same DML No. shall be granted as and when approved by the CLB.**

**Case No. 7.** **Approval of Site of M/s Centurious Pharma (Pvt) Limited, Plot No.B-25, SITE, Karachi.**

**The brief background of the case is as under: -**

i). The site of the applicant located at Plot # B-25, S.I.T.E Karachi was inspected by area Federal Inspector of Drugs on 11-01-2013 for size, location and surrounding for establishment of a Pharmaceutical unit as mentioned in Section 1 of Schedule B of Drugs (Licensing, Registering & Advertising) Rules 1976. The recommendation of area Federal Inspector of Drugs for the site of the applicant was as under:-

***"the plot is located in developed Industrial Area not surrounded by any hazardous smoke producing or other incompatible industries, hence the plot under reference is recommended for establishment of a Pharmaceutical unit subject to vacation of the ground Floor of the said premises which is currently use for garments manufacturing within 03 months"***

ii). Area Federal Inspector of Drugs was again requested on 25-04-2013 to give clear recommendation and to ascertain whether garments factory has been shifted as pointed out in previous inspection report and also advised to give clear and candid recommendations as per requirement laid down in Schedule B para 1.1 of Drugs (Licensing, Registering & Advertising) Rules 1976.

iii). On 25-02-2014, area Federal Inspector of Drugs Ms Muneeza Khan telephonically informed that she has not recommended the site of the applicant for establishment of Pharmaceutical Unit in her report dated 24-05-2013 which was not received in this office. On the request of this office on 25-02-2014, area FID had sent the said report via fax wherein recommendations were as under:-

***"Undersigned observed cotton waving facility existed and operated in full swing. Therefore keeping in view the current explained situation the proposed site cannot be justified and recommended for establishment of a Pharmaceutical Unit"***

iv). A letter dated 26-02-2014 was then again issued to area Federal Inspector of Drugs to give clear recommendation and to verify again site verification status at present, so that accordingly action for cancellation/withdrawn of the site verification may be taken which was issued on 29-01-2014 on the basis of recommendation in first inspection report dated 11-03-2013 mentioned in para (i) of this case.

v). Accordingly area Federal Inspector of Drugs submitted inspection report on 20-03-2014 wherein recommendations are as under:-
***"Undersigned observed cotton weaving facility existed and operated in full swing therefore proposed site can not be justified for establishment of Pharmaceutical unit and in the light of the above proposed site is not recommended for establishment of a Pharmaceutical unit"***

vi). Hence now as per inspection report dated 20-03-2014 it is clear that site of the applicant is not suitable for establishment of a Pharmaceutical unit because firm did not fulfill the requirement to vacant the ground floor of the building which is still used for garment manufacturing

**Decision of CLB**

**The Board in light of latest inspection report of area FID dated 20-03-2014 decided and rejected the Site Approved previously for establishment of Pharmaceutical unit of M/s Centurious Pharmaceuticals (Pvt.) Ltd., Karachi due to non compliance of direction made in inspection report of area FID to vacate the ground floor of building which is still used for Cotton weaving facility as verified by Area FID in her recent inspection report which is a major violation of Para 1.1, Section I, Schedule B of Drugs (Licensing, Registering & Advertising) Rules, 1976.**

**Case No. 08** **CASE OF RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000210 (FORMULATION) OF M/S SACRED PHARMA (PVT.) LTD, SHEIKHUPURA**

**The brief background of the case is as under: -**

i). M/s Sacred Pharma (Pvt.) Ltd applied for renewal of Drug Manufacturing License No. 000210 (Formulation) for the period **(22-08-2010 to 21-08-2015).** The application was received in this office on 29-12-2010 which was 04 month and 08 days late from the due date i.e. 21-08-2010, thus it clearly shows that firm had submitted application for renewal after the period of validity of license i.e. 60 days as per Rule 6 of Drugs (Licensing, Registering & Advertising) Rules 1976. Therefore application for renewal of DML of the firm was liable to be rejected under Rule 5(3) of Drugs (Licensing, Registering & Advertising) Rules 1976 which reproduced as under:-
***"if the application for renewal of the license is made after the expiry of the period of the validity of the license, it shall be treated as a fresh application for the grant of license"***

ii). Accordingly firm was informed to apply for afresh grant of DML on 30-05-2011.but firm did not submit its reply with respect to the letter issued.

iii). Meanwhile area Federal Inspector of Drugs inspected the said unit and requested the Licensing section on 04-04-2013to provide latest status of DML of the firm.

iv). A letter was then issued from this office to area FID on 24-04-2013 that firm was required to apply afresh grant of DML because their license had been expired and also advised area FID to inspect the premises and ensure that there should no production activity under way of invalid license. But no report received from area FID

v). Meanwhile a letter was again received on 26-08-2013 from firm to issue renewal certificate. A letter was then again issued to firm to apply afresh grant of DML because the license had been expired and a letter was also issued to Deputy Director General (E&M), DRAP Lahore with request to direct area FID to ensure that no production activity is going on in the firm.

vi). Firm then again requested this office through their letter dated 29-10-2013 for issuance of renewal certificate.

vii). Area FID had submitted her report on 13-11-2013 that there was no production activity in the premises.

viii). The case background is representing the behavior of the licensee that he is showing his attitude as unaware of letter issued to him from this office regarding expiration of his current license and they are now bound to apply afresh license as per rules and law.

The case was presented with brief background before the Board in its 235th meeting held on 15th May 2014 for consideration/decision:-

**Decision of CLB**

**The Board after thorough discussion and deliberation and keeping in view facts on ground decided as under that:-**

1) **The firm shall be conveyed that their DML is no more valid under Rule 5(3) of Drugs (Licensing, Registering & Advertising) Rules 1976.**
2) **The firm shall be given final opportunity of personal hearing in next meeting of CLB.**
3) **The decision of CLB shall be conveyed through registered post and also through area FID.**

**Case No. 9 Renewal of DML of M/s BSN Medical (Pvt) Ltd, plot No, A/69, S.I.T.E Karachi**.

Brief background of the case is as under:-

i. The case of grant of renewal of Drug Manufacturing License No. 000085 (Formulation) of M/s BSN Medical (Pvt.) Ltd, Karachi for the period **08-01-2011 to 07-01-2016** was deferred by the Central Licensing Board in its 232nd meeting held on 29th & 30th July 2013 on the basis of inspection report of the panel and Board decided to get the unit re-inspected by a new panel.

ii. Afterwards, on the request of the firm, after rectification of shortcomings pointed out by the previous panel, a panel was re-constituted on 03-10-2013 for purpose of inspection of the firm for renewal of DML of the firm after rectification of shortcomings.

iii. This panel also observed some critical shortcomings and points to be rectified for better GMP Compliance. The inspection report of the panel was again presented in the 233rd meeting of Central Licensing Board held on 30th & 31st December 2013 wherein Board considered the case of the firm on the basis of inspection report of new panel and decided to suspend the Drug Manufacturing License No. 000085 (Formulation) in all areas for a period of three months under Rule 13 of Drugs (Licensing, Registering & Advertising) Rules 1976 which reproduced as under "***4[provided that if directed by the Central Licensing Board, the license shall rectify the observations made during the inspection within a period which shall not be less than one month and more than three months from the date of receipt of orders in this regard and during this period the manufacturing in that particular area or the premises, as the case may be, shall remain suspended and, until after re-inspection the Board grants renewal of license, or otherwise rejects the application and inform the license accordingly]***"

iv. Firm after receiving the letter of suspension of Drug Manufacturing License dated 14-02-2014, had placed a petition in the Honorable High Court of Sindh, Karachi C.P No. D-836 of 2014 Versus Federation of Pakistan & others.

v. An inspection was again conducted by a panel on the orders of Honorable Chief Justice of Sindh High Court Karachi vide C.P No. D-836 of 2014 by the panel re-constituted by Honorable High Court of Sindh for grant of renewal of DML of the firm.

vi. The panel re-constituted who inspected the unit also highlighted / indicated some shortcomings in the inspection report. Firm then submitted an undertaking on 24-03-2014 that they would comply with the orders dated 18-03-2014 passed by Honorable Court on 18-03-2014 in its true and proper letter and spirit and shall also cooperate with DRAP in this respect being their regulator.

vii. In compliance with the order of Honorable Chief Justice, High Court of Sindh at Karachi (C.P No. D-836/2014). The previously constituted panel comprising of three members and one from the Drug Regulatory Authority of Pakistan has re-inspected M/s BSN

Medical (Pvt.) Ltd, Karachi on dated 03-04-2014 to confirm that petitioner has removed the aforesaid non-conformances related to current Good Manufacturing Practices (cGMP) and the Drugs Act 1976 of DRAP. The panel was of the opinion that the company has shown visible efforts for the implementation of GMP guidelines in a very short period of time and removed the non-conformances that were indicated by the previous and current inspection teams. However Continuous improvement as per the Drugs Act, 1976 and DRAP Act 2012 has been required from M/s BSN Medical (Pvt.) Ltd, Karachi and for this they may be asked for providing an undertaking for that purpose.

viii. On the basis of above mentioned inspection report dated 03-04-2014, The Honorable Court heard the subject case on 16-04-2014, Mr. Muhammad Zahid Khan Deputy Attorney General-I after gone through the report dated 07-04-2014 submitted an statement in the Court that the report dated 07-04-2014, which shall be consider before the Central Licensing Board under Section 5 of the Drugs Act, 1976 **(Page 518/Corr.)**. However an order sheet **(Page 521/Corr.)** was passed by the Honorable Chief Justice in the High Court of Sindh, Karachi C.P No. D-836 of 2014 which are as under: -

***"We would, therefore, direct the Concerned Authority to revive the license of the petitioner instantly and preferably by tomorrow i.e. 17-04-2014. Since as per the above report the petitioner is now in conformity with the various relevant requirements they may resume production in accordance with law"***

ix. The case was referred for the opinion of Law Division which has conclude and opined as under: -

***It has also been submitted by the Assistant Drug Controller to the Court that there remains no impediment for revival of petitioner's manufacturing license. The Court has, therefore accordingly ordered the concerned authority to revive the license of the petitioner forthwith and preferably by the 17th April 2014, In view of the order of the High Court of Sindh dated the 16th April, 2014 there is no option but to revive the license of manufacturing as directed by the High Court of Sindh. The referring Ministry are advised that after fulfilling the requisite requirements to ensure implementation of the Order of the High Court of Sindh without undue loss of time.***

The case with brief background was presented before the Board in its 235th meeting of CLB held on 15th May 2015 for consideration/decision:-

**Decision of CLB**

**In the light of orders of High Court of Sindh, Board approved the grant of renewal of Drug Manufacturing License of the firm M/s BSN Medical (Pvt.) Ltd, Karachi.**

**Case No. 10. Request for approval to produce Pseudoephedrine Hcl from semi basic process i.e. by using Intermediate (+)-(IS, 2S)-2-Methylamino-1-Phenylpropan-1-OL Base by M/s Alpha Chemicals (Pvt.) Ltd, Lahore. (DML NO. 000373 -Basic Manufacturing)**

**The case was placed before the Board as under:-**

M/s. Alpha Chemicals (Pvt.) Ltd, DML NO. 000373 (Basic Manufacturing) has requested to grant approval to produce **Pseudoephedrine Hcl** from semi basic process i.e. by using Intermediate (+)-(IS, 2S)-2-Methylamino-1-Phenylpropan-1-OL Base.

Firm has already approval for manufacturing Pseudoephedrine Hcl by Basic Manufacturing as verified vide record of Licensing Division DRAP, Islamabad vide in recent renewal of DML of the firm for the period **08-01-2011 to 07-01-2016.**

Firm has explained their reasons for adopting semi basic manufacturing method for Pseudoephedrine Hcl from Intermediate i.e. (+)-(IS,2S)-2-Methylamino-1-Phenylpropan-1-OL Base, due to unavailability / shortage and import of **Acetic anhydride** and procuring Pharma grade molasses during 2005 onwards

The firm has license to manufacture drugs by way of Basic Manufacture, so under proviso of Rule 15(g)(iv), the firm may manufacture drugs by way of Semi Basic Manufacture. The said rule is reproduced as under: -

***"[provided that where a person possesses or applies for a license to manufacture by way of basic and he also intends to conduct semi basic manufacture of drugs, he may conduct such manufacture under the same license, subject to the approval of, and under such conditions as, Central Licensing Board may specify.]"***

**<u>Decision of CLB</u>**

**The Board after thorough discussion and deliberation decided to ask the firm to submit:-**

- **Five years track record of production, sale and purchase of Pseudoephedrine HCl.**
- **Justification for change of manufacturing process in detail with documentary evidence of the said drug substance.**

**The Board constituted following panel for inspection of the firm in this context: -**

**i). Dr. Ikram-Ul-Haque, Member CLB (will head the panel)**
**ii). Prof. Dr. Muhammad Saeed, Member CLB**
**iii). Area Federal Inspector of Drugs**
**iv). Salateen Waseem Philip, ADC / DDC (Lic)**

**The Board authorized the Chairman CLB to dispose of the case accordingly.**

**Case No. 11 REFORMS IN DIVISION OF DRUG LICENSING.**

The above case was placed on agenda for consideration of Board as under: -

Division of Drug Licensing is responsible for the licensing of the drug manufacturing facilities and to perform other functions connected therewith under the Drugs Act, 1976 and Drug Regulatory Authority of Pakistan Act, 2012. It discharges its functions through Central Licensing Board, a statutory body for considering and deciding the matters of licensing of the drug manufacturing facilities.

2. After inception of DRAP, this Division has convened three meetings of Central Licensing Board to dispose-off various applications of grant of new drug manufacturing licenses, renewal of drug manufacturing licenses and miscellaneous matters.

3. Promulgation of DRAP Act 2012 urges for improvements and keeping the pace with modern world and developing countries. Such steps can be taken after availability of enough resources. At present, acute problem of office accommodation, equipments, staff and IT technology is being faced which may be addressed to achieve the goals of the authority.

4. In order to update the data / information and to improve working efficiency of Licensing Division, it is proposed that following information may be obtained from all manufacturers as under: -

i. Copy of DML granted at initial stage along with proof of sections approved.
ii. Names of Owners/Directors etc. at initial stage and if changed later, the proof of approval of same.
iii. Subsequent proof of renewal of DML.
iv. Proof of approvals of additional section(s) obtained from time to time.
v. Sections running or existing without approval.
vi. Names of presently working approved technical persons along with qualification. In case of no such approval, the proof of application submitted to DRAP for approval of Technical staff.
vii. Present status of License / Renewal.

5. Above information may be collected through field offices by area FIDs on given pro-forma as under. The information so collected will be uploaded on website of DRAP and it will be helpful for future improvements.

LICENSING PROFILE OF FIRM

| S No. | Title | Information | Remarks if any |
|---|---|---|---|
| 1. | Name of firm | | |
| 2. | Type of License | | |
| 3. | Date of License Grant | | |
| 4. | Date of validity of License | | |
| 5. | Human / Veterinary | | |
| 6. | Sections Approved at initial grant of DML | | |
| 7. | Names of Owners/Directors/Partners/ Proprietors at initial stage and if changed later, the proof of approval of same. | | |
| 8. | Proof of Renewals | | |
| 9. | Proof of approvals of additional sections obtained from time to time | | |
| 10. | Sections running or existing without approval, if any | | |
| 11. | Names of presently working approved technical persons along with qualification. In case of no approval, the proof of application submitted to this Ministry for approval of Technical staff. | | |
| 12. | Present status of License / Renewal | | |
| 13. | Other information, if any | | |

Decision of CLB taken in 234th meeting.

The Board after thorough discussion and deliberation, considered and approved the proposal of reforms in Division of Drug Licensing through obtaining data / information as per above given proforma.

Further Progress

The above decision of CLB was conveyed to all field offices. It has been noticed that Licensing Division is receiving requests from already licensed firms for the regularization of layout plans, and granting of nomenclature to already established sections. The firms are also requesting for issuance of approval letter which may contain the names of their sections. Since these firms are old and some of these are having approvals of layout plans and some are not having approval of layout plan. Now these firms are requesting of regularization

The case is placed before Board for its consideration, please.

**Decision of CLB**

**The Board appreciated the initiative taken and further decided as under:-**

- **The Director (QA/LT) shall direct all field offices again to provide the information as per circulated Performa.**
- **The Board advised to add two other fields at Sr. No. 13 and 14 in already circulated form as under:-**
    a. **Inspection records**
    b. **Number of registered products**
- **All such application(s) for regularization of layout plan / sections shall be processed accordingly; and on its completion, the same shall be placed before the Board for its consideration.**

**Case No. 12 Inspections of M/s. Cibex (Pvt) Ltd, F-405, SITE, Karachi, M/s Healthtek (Pvt) Ltd, Plot No. 14, Sector 19, Korangi Industrial Area, Karachi, M/s Uniferoz (Pvt), Karachi and grievances of Mrs. Roohi Obaid DDC (Policy, Training & Pharmacy Services) one of member of inspection panels.**

The Central Licensing Board in its 233rd meeting held on 30-31 December, 2013 considered panel inspection reports of M/s. Cibex (Pvt) Ltd, F-405, SITE, Karachi for Grant of New DML **(S No. 6 of Item No. 2)**, M/s Healthtek (Pvt) Ltd, Plot No. 14, Sector 19, Korangi Industrial Area, Karachi for Grant of Additional Section & renewal of DML **(S No.9 of Item No. 3 & S No.16 of Item No.4)** and M/s Uniferoz (Pvt), Karachi for Renewal of DML **(S No.15 of Item No.4)** and made necessary decisions accordingly.

Mrs. Roohi Obaid DDC (Policy, Training & Pharmacy Services) & one of the member of referred to panels had shown her serious grievances in writing through three letters (Copies were annexed in agenda) on the relevant decisions of CLB including the personal remarks reflected in the minutes of said meeting. She requested for recall of said decisions of the CLB.

Accordingly, the case was placed before the Board for its consideration.

**Decision of CLB**

**The Board approved to expunge the following personal remarks as recorded in the minutes of 233rd meeting of CLB held on 30th & 31st December 2013 as under:-**

***"Mr. Javed Yousuf Bukhari (Memebr CLB) and also member of the inspection panel apprised the Board about unprofessional attitude of Mrs. Roohi Obaid (one of the members of said panel) during inspection proceedings".***

**Case No. 13. Renewal of DML of M/s. Marvi Pharmaceuticals, Plot No.70, Sector-24, Korangi Industrial Area, Karachi. (DML No.000148-Formulation)**

The case was placed before the Board as under: -

The case of renewal of DML No. 000148 (Formulation) for the period 10-07-2010 to 09-07-2015 was approved in 227th meeting of Central Licensing Board held on 01st & 2nd June 2011 subjected to installation of HVAC System and deposition of Central Research Fund. Afterwards production of the firm was stopped on 08-03-2013 due to GMP violation and case was taken up by QA Division, DRAP Islamabad. In 234th meeting of CLB held on 27-02-2014 the board after considering the inspection report of the panel of experts constituted by the DRAP, Islamabad allowed the resumption of production in all sections of M/s Marvi Pharmaceuticals.

2. The DML renewal certificate on Form 2 was not issued to the firm for the period 10-07-2010 to 09-07-2015 due to devolution of defunct Ministry of Health and later due to GMP Violations. Now the installation of HAVC System has been confirmed as reflected in latest GMP inspection report and firm has also submitted proof of deposition of Central Research Fund for which Nothing Due Certificate is awaited from Statistical Officer Drug Regulatory Authority of Pakistan.

3. The case is submitted for consideration the Board for issuance of renewal of DML, pl.

**Decision of CLB**

**Keeping in view the background of the case, the Board allowed the issuance of renewal of DML which was approved in 227th meeting of CLB held on 01st & 2nd June 2011.**

**Case No. 14 Establishment of Pharmaceutical Unit – M/s. Mediflow Pharmaceuticals (Pvt) Ltd., Plot No. ID-100, Sector-30, Korangi Industrial Area, Karachi.**

The case was placed before the Board as under: -

M/s Mediflow Pharmaceutical (Pvt.) Ltd. had previously applied for site verification and Central Licensing Board in its 232nd meeting held on 29th & 30th July 2013 rejected the site of the applicant located at ID-15 & 33, Sector 30 Korangi Industrial Area, Karachi on the basis that area of the plot acquired (1955 square yards) was not meeting the requirement of 2000 square yards as laid down under Section 1 of para 1.3 of Schedule B of Drugs (L, R & A) Rules 1976. The Board desired that the provision of rules shall be strictly adhered to and no relaxation could be granted on the request of the firm.

The details of the size of the plot at the time of rejection of the site were as under:

| Plot No. | Size in Square Yards |
|---|---|
| ID- 15 | 977.77 |
| ID-33 | 977.77 |
| **Total** | 1955.54 Square Yards |

M/s. Mediflow Pharmaceuticals (Pvt) Ltd., Plot No. ID-100, Sector-30, Korangi Industrial Area, Karachi has now applied afresh for site verification with required fee after purchasing and amalgamation of another plot of 1000 Sq. Yards along with relevant documents.

The total size of the final plot i.e ID-100 is 2995.54 Square Yards after amalgamation of Plot ID-15, ID-33 & ID-100. The detail of plot size is as under: -

| Plot No. | Size in Sq. Yards |
|---|---|
| ID-15 | 977.77 |
| ID-33 | 977.77 |
| ID-100 | 1000 |
| **Total** | **2995.54 Sq. Yards** |

Accordingly, Area Federal Inspector of Drugs was requested to inspect and verify the site of the applicant under name and style of M/s. Mediflow Pharmaceuticals (Pvt.) Ltd located at Plot # 100, Sector 30, Korangi Industrial Area, Karachi to check size of the plot is either 2995.54 sq. yard within the location and surrounding of the plot suitable for establishment of a Pharmaceutical unit.

Area FID has inspected the site and given following recommendations: -

| S No. | Item | Description |
|---|---|---|
| 1. | **Location** | INDUSTRIAL<br>Physical Address: Plot No. ID-100, Sector-30, Korangi Industrial area Karachi. |
| 2. | **Surroundings** | The subject Plot is surrounded as follows:<br>From North it is surrounded by Plot No.145<br>From South a 40 feet wide road.<br>From East the Plot is surrounded by Plot No.31<br>From West located a 300 feet wide road. |
| 3. | **Size** | The subject Plot after amalgamation of all three Plot Nos. 1-D/15, 1-D/33 & 1-D/100 measure around 2955.54 Square Yards and now the final Plot is designated, as Plot No 1-D/100 vide SBCA Letter No. Korangi/C-2/2014/27/L, dated: 28-03-2014. (Copy of SBCA Letter annexed). |
| 4. | **Recommendations** | During the visit it was observed that a boundary wall surrounds the subject Plot. The above Plot is located in a well-developed Korangi industrial area with all utilities available and complies the provision of Section 1 of Schedule B (SRO 470 (1) /98 dated 15-05-1998) under rule 16(a) of the drugs licensing, Registering and advertising) Rules of Drug Act 1976. Some well-known MNCs and well reputable National Pharmaceutical units are also located near the Plot. Therefore keeping in view the location/surrounding and their international collaboration the subject site is **recommended for established of a pharmaceutical unit.** |

**Decision of CLB**

**Keeping in view the background of the case that the firm has purchased additional plot (ID-100 of 1000 sq. yards) adjacent to the existing Plots No. ID-15 & ID-33 and amalgamation of all three plot as final Plot No. ID-100 by KDA with total area of 2995.54 sq. yards., the Board allowed the issuance of Site approval letter to the firm for Establishment of a Pharmaceutical unit.**

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# MINUTES OF 235th MEETING OF THE CENTRAL LICENSING BOARD HELD ON 15-05-2014

## QUALITY CONTROL CASES

**ITEM-I: Deferred/Follow-up Cases**

**Case No. 1: MANUFACTURE AND SALE OF ADULTERATED AND SUBSTANDARD SUSP. STANDARDMOL 60ML BATCH NO. S-120 BY M/S STANDARD DRUG COMPANY, HYDERABAD. (F. No. 3-39/2013-QC)**

The case of Adulterated and substandard samples of Standardmol 60ml Suspension Batch No. S-120 manufactured by M/s Standard Drug Company, Hyderabad was considered by the Drug Registration Board in its 241st meeting held on 23-12-2013. The Board, in view of the personal hearing and detail scrutiny of the case record, took following decisions:-

i. Cancel registration of Standardmol Suspension.
ii. Recommendation to the Central Licensing Board for suspension/ cancellation of Syrup/ Liquid Section of Standard Drug Company, Hyderabad.

2. The case was accordingly placed before the Central Licensing Board in its 234th meeting held on 27-02-2014 and considered the recommendations of the Drug Registration Board regarding suspension/cancellation of Syrup/ Liquid Section of Standard Drug Company, Hyderabad. The Board decided to issue show cause notice to the firm.

3. As per decision of the Board in its 234th meeting show cause notices were issued to M/s Standard Drug Company, Hyderabad. The firm replied the show cause notice vide their letter dated 04-04-2014 and desired to be heard in person regarding the matter. Accordingly the firm and the accused persons were called for personal hearing by the Board.

**Decision of the Board:-**

**The Board again considered the case providing personal hearing to the firm. Keeping in view the available record/facts of the case and detailed discussion/deliberations decided as under:-**

- **Suspended Oral Syrup/Liquid Section of the firm for three months.**

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

The case of Incorrect Labeling Of Phenergan Elixer Batch No.WL111 manufactured 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 inquiry Committee and the actions taken by the firm to avoid such mix-up in future, took the following decisions:-

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 report 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.

4. In view of above the Board again considered the case and after thorough discussion/deliberation decided as under:-

**<u>Decision of the Board:-</u>**

**The Board after considering the submissions of the firm and thorough discussions & deliberations on the matter decided as under: -**

- **Verification by same DRAP Inquiry Committee for the measures taken by firm itself and actions taken on the recommendations of afore said Committee.**

- **Deferred the disposal of incorrect labeled recalled stock i.e. 57156 packs of Phenergan Elixir, Batch No. WL-111till next meeting of the Board for consideration/decision in the light of submission of report by the above said DRAP Committee.**

## Minutes for 235th Meeting of the Central Licensing Board

## Quality Assurance Cases (GMP)

# Item No. I

## (Quality Assurance Cases)

**Case No. 1:-** **M/s Standard Drug Company, Hyderabad**

The inspection of M/s Standard Drug Company, Hyderabad was conducted on 22.07.2013 by Dr. Najam-us-Saquib, FID Karachi with reference to see/verify the GMP compliance. During the inspection, the FID has pointed out number of serious GMP violations and recommended that **the production and QC operations should be stopped to avoid** any possible public health hazard. The DRAP served show cause notice with the approval of the Chairman, CLB on 02.09.2013 to the company with the direction to stop manufacturing in all sections immediately.

The firm in reply submitted the compliance report and informed that they have made improvements as advised by the FID. The company further informed that they are ready for re-inspection. In response, the Chairman, Central Licensing Board has constituted a panel comprising of Syed Jawed Yousaf Bukhari, Member CLB, Mr. Abdul Rasool Shaikh, FID Karachi, area FID Karachi and ADC CDL to re-inspect the firm to check the GMP condition of the firm.

The panel reported that the firm has taken serious steps towards improving, renovation of the areas and addressed almost all the deficiencies and shortcomings pointed out by the FID during previous inspection and recommended that the resumption of the production may be allowed.

The case was placed before the Central Licensing Board in its 234th meeting held on 27th February, 2014. The Central Licensing Board after thorough discussion has decided as under:

> ***The Board after making detailed discussion in the light of other issues related to the firm deferred the case for the next meeting of Central Licensing Board.***

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

**Decision of CLB**:

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 as under: -

*i) To allow resumption of production in the all sections except syrup section.*

*ii) The Board decided to keep suspended the production in Syrup Section of M/s Standard Drugs Company, Hyderabad till the product specific report of the panel conducted within 03 months for verifying the improvements of facilities.*

*iii) The product specific inspection be conduct by a panel constituted by the Directorate of Quality Assurance.*

**Case No. 2:** **M/s Ameer Pharma (Pvt) Ltd, Lahore**

M/s Ameer Pharma (Pvt) Ltd, Lahore was inspected on 13.01.2014 and 15.01.2014 by a panel comprises by Mr. Asim Rauf DDG (E&M) Lahore, Mrs. Aisha Khalil, FID Lahore and Rana Ihsan-ul-Haq Athar, ADC Lahore to check the GMP compliance. The panel has pointed out number of shortcomings in all sections. The Panel reported that the procedures of manufacturing were not being followed, quality control staff was not strengthen, proper production schedule had not been followed; keeping in view the capacity and work load in the areas. The panel further reported major critical deviations from the procedures and the firm was directed to rectify the shortcomings. The observations of the panel and quantification of the cGMP performa directed the firm to **immediately stop operational activities in the liquid Injectable section**. The GMP of the firm is rated with the scoring as poor compliance (c) 123 and even non-compliance (D) 04, fair compliance (B) 144. The scoring of GMP indicates alarming and pathetic/poor condition of GMP by the firm.

**Action Taken by DRAP**: -

Show cause notice was issued to the firm on 03.02.2014 along with the direction to suspend manufacturing of drugs **in the liquid Injectable section** till the decision of the Central Licensing Board.

The case was placed before the Central Licensing Board in its 233rd meeting held on 27.02.2014 where after considering all aspects of the case, the Board had decided including the following:-

1. *Upholds the Board's previous decision of suspension of production in **Liquid Injectable Section** till re-inspection by the panel and final approval by Central Licensing Board.*
2. *Re-inspection of the firm be carried out by the following panel of experts:*
   - *a) Dr. Ikram Ullah, Member Central Licensing Board*
   - *b) Chairman, Quality Control*
   - *c) DDG (E&M), Lahore*
   - *d) Area FID, Lahore*

**The panel conducted the inspection on 10.04.2014** and concluded that the firm has done improvements in the liquid Injectable section since the previous inspection. The firm was closed; the FID will continue to monitor the production activities as per routine inspections. Keeping in view the improvements done by the firm, evaluation of knowledge of the technical staff, the precautions being observed in the section and the validation of the areas, **the panel recommended to resume the production in the Liquid Injectable section.**

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

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided as follows: -

1. *On considering the inspection report of the panel of experts allowed resumption of production in Liquid Injectable Section of M/s Ameer Pharma (Pvt) Ltd, Lahore.*
2. *The firm would be re-inspected within 03 months by a panel at the time of active production.*

**Case No. 3: M/s Shafi Textile Faisalabad**

M/s Shafi Textile, Faisalabad was inspected on 20.03.2013 by Mr. Ajmal Sohail Asif, FID Lahore with reference to see/verify the GMP compliance of the firm. During the inspection, the FID has reported that at the time of inspection the firm was closed. Only the gate keeper was present, who informed that production activities are stopped for the last many days. There was no technical person and owner was present. The production areas were locked and could not be inspected. The FID contacted the owner of the firm on mobile; he informed that they are only supplying the cotton bandage and non-sterile gauze to armed forced hospital. At present, they have no order to supply thus there was no manufacturing for few months. The FID further submitted that renewal of DML of the firm was due w.e.f.08.09.2009. A panel was constituted on 28.09.2009 by DRAP comprising Dr. Farzana Ch. Member CLB, Area FID and area ADC to inspect the firm for grant of renewal of DML. The FID has further reported that an action on the recommendation of the panel regarding the cancellation of the DML of the firm is still pending with Licensing Section and nothing has been communicated to the FID Lahore regarding the status of DML of the firm in response to above mentioned reports.

**Action Taken by DRAP**: Accordingly, a show cause notice was issued to the firm on 23.04.2013 along with the direction to stop production in all sections with immediate effect. In response of the show cause notice, the firm had submitted that they have started searching of a bigger plot for construction of new manufacturing unit in suitable area. Now a days, they have procure supply order from Pakistan Defense Forces and do not afford to stop manufacturing and requested that the show cause notice may be withdraw and allow them to continue their production in same premises and they are ready for re-inspection at any time.

The case was placed before the Central Licensing Board in its 232nd meeting held on 29-30th July, 2013, wherein the Board after hearing the views of the firm and keeping in view the relevant legal provisions/codal formalities and thorough deliberations of the honorable members decided as under:-

***i) After hearing the views and request of the firm, the Board decided that the Licensing Section may be asked to expedite the inspection for renewal of DML immediately and this case will be considered in the light of report of panel inspection for renewal of DML.***

***ii) The production will remain stopped till the final decision by Central Licensing Board and in the light of report for renewal of Drugs Manufacturing License by Licensing Section.***

Following panel was constituted on 13.04.2014 for conducting the inspection of the firm.

a) Mr. Ikram Ul Haq, Member, Central Licensing Board
b) Mr. Ajmal Sohail Asif, FID Lahore
c) Mrs. Aisha Khali, FID Lahore
d) Dr. Akbar Ali, ADC Lahore

The panel recommended for resumption of production and grant of renewal of DML by way of formulation.

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided including as follows:

1. *On considering the inspection report of the panel of experts constituted by DRAP, Islamabad allowed resumption of production in all sections of M/s Shafi Textile Corporation, Faisalabad.*

2. *The firm would be re-inspected within 03 months by a panel at the time of active production.*

**Case No. 4:** **M/s Alco Chemical (Pvt) Ltd, Lahore**

M/s Alco Chemical (Pvt) Ltd, Lahore was inspected on 18.03.2013 by Mrs. Majida Mujahid, FID Lahore with reference to see/verify the GMP compliance of the firm. During the inspection the FID has pointed out some shortcomings and also reported that the production of the firm was stopped due to up-gradation and major contraventions/shortcomings

**Action Taken by DRAP**:- The firm was directed to stop production in all sections with immediate effect on 14.05.2013 and also directed to submit compliance report after completion of renovation and up-gradation work.

The case was placed before the Central Licensing Board in its 232nd meeting held on 29-30th July, 2013, wherein the Board after hearing the views of the firm and keeping in view the relevant legal provisions/codal formalities and thorough deliberations of the honorable members decided as under:-

***i) The CLB after hearing the views of the firm, decided to constitute a panel to inspect the firm to check/verify the improvements made by the firm and also check the GMP compliance of the firm in the light of the shortcomings pointed out by the FID.***

***ii) The Board upheld the decision of stoppage of production till the final approval by Central Licensing Board.***

Following panel was constituted on 12.03.2014 for conducting the inspection of the firm.

e) Mr. Ayaz Ali Khan, Chief Drug Controller, Punjab
f) Mrs. Majida Mujahid, FID Lahore
g) Mrs. Aisha Khalil, FID Lahore
h) Dr. Akbar Ali, ADC Lahore

The panel recommended for resumption of production to the firm and to conduct follow-up inspection by the FID to check the validation of testing and manufacturing operations during the active production.

**Decision of CLB**:
The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided including as follows:

1. *On considering the inspection report of the panel of experts constituted by DRAP, Islamabad allowed resumption of production M/s Alco Chemical (Pvt) Ltd, Lahore.*

2. *The firm would be re-inspected within 03 months by a panel at the time of active production.*

**Case No. 5: M/s Ferroza International Pharmaceuticals (Pvt) Ltd, Lahore**

M/s Ferroza International Pharmaceuticals (Pvt) Ltd, Lahore was inspected 07.03.2013 by Mrs. Majida Mujahid, FID Lahore with reference to check the GMP compliance. During the inspection, the FID has pointed out a number of gross violations and critical shortcomings in all sections particularly in dry powder suspension/capsule section, Cephalosporin Section Oral (Dry Powder/Capsule).

**Action Taken by DRAP**:- The firm was directed to stop production in Cephalosporin Section with immediate effect and also directed to remove the shortcomings pointed out by the FID.

The case was placed before the Central Licensing Board in its 232nd meeting held on 29-30th July, 2013, wherein the Board after hearing the views of the firm and keeping in view the relevant legal provisions/codal formalities and thorough deliberations of the honorable members decided as under:-

***i) The Board after hearing the views of the firm decided to constitute a larger panel to inspect the firm on audit performa schedule B-II in all sections in order to check/verify the GMP compliance.***

***ii) The production in cephalosporin section will remain stopped till the final decision by Central Licensing Board.***

Following panel was constituted on 12.03.2014 for conducting the inspection of the firm.

a) Mr. Ayaz Ali Khan, Chief Drug Controller, Punjab
b) Mrs. Majida Mujahid, FID Lahore
c) Mrs. Aisha Khali, FID Lahore
d) Rana Ahsan-ul-Haq Athar, ADC Lahore

The panel recommended for resumption of production in Cephalosporin Section.

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided including as follows:

1. *On considering the inspection report of the panel of experts constituted by DRAP, Islamabad allowed resumption of production in Cephalosporin Section of M/s Ferroza International Pharmaceutical (Pvt) Ltd, Lahore.*

2. *The firm would be re-inspected within 03 months by a panel at the time of active production.*

**Case No. 6: M/s Xenon Pharmaceutical (Pvt) Ltd, Lahore**

M/s Xenon Pharmaceutical (Pvt) Ltd, Lahore conducted on 11.03.2013 by Mrs. Aisha Khalil, FID Lahore with reference to see/verify the GMP compliance of the firm. During the inspection the FID has pointed out a number of severe and critical shortcomings in all sections.

**Action Taken by DRAP**:- Accordingly, a show cause notice was issued to the firm on 23.04.2013 along with the direction to stop production in all sections with immediate effect.
The case was placed before the Central Licensing Board in its 232nd meeting held on 29-30th July, 2013, wherein the Board after hearing the views of the firm and keeping in view the relevant legal provisions/codal formalities and thorough deliberations of the honorable members decided as under:-

***i) The Board allowed the firm to resume production provisionally in all their sections except in steroidal sections as recommended by the panel.***

***ii) The production of steroidal sections will remain stopped till the provision/approval of dedicated facilities and subsequent approval by the Central Licensing Board.***

***iii) The Board also decided to conduct the inspection of the firm by a larger panel on audit perform as laid down under Schedule B-II in order to check/verify the GMP compliance of the firm in working condition within 30 days after resumption of production.***

Following panel was constituted on 12.03.2014 for conducting the inspection of the firm.

a) Mr. Ayaz Ali Khan, Chief Drug Controller, Punjab
b) Mr. Asim Rauf, DDG (E&M), Lahore
c) Mr. Ajmal Sohail Asif, FID Lahore
d) Mrs. Aisha Khali, FID Lahore
e) Mrs. Saira Naeem, ADC Lahore

The panel recommended for resumption of production in Oral Liquid Steroidal products as the firm has segregated mixing/filling areas.

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided as follows:

1. *On considering the inspection report of the panel of experts constituted by DRAP, Islamabad allowed resumption of production of Oral Liquid Steroidal products of M/s Xenon Pharmaceutical (Pvt) Ltd, Lahore.*

3. *The firm would be re-inspected within 03 months by a panel at the time of active production.*

**Case No. 7:** **M/s Euro Pharma International, Karachi**

M/s Euro Pharma International, Karachi was inspected on 05.03.2013 by a panel comprising Mr. Abdul Rasool Shaikh, FID Karachi and Mrs. Ume Laila, ADC Karachi with reference to verify the investigation matter pertaining to illegal import of raw material and also to verify the GMP compliance. During the inspection, the panel has pointed out a number of serious and critical 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 23.04.2013 along with the direction to stop production in all sections with immediate effect.

The case was placed before the Central Licensing Board in its 232nd meeting held on 29-30th July, 2013, wherein the Board after hearing the views of the firm and keeping in view the relevant legal provisions/codal formalities and thorough deliberations of the honorable members decided as under:-

***i) The production of firm will remain stopped till the rectification of the shortcomings as identified by the panel on 05.03.2013and final decision by the Central Licensing Board.***

***ii) The Board decided to constitute a panel to re-inspect the unit in the light of intimation by the firm regarding improvements made and get the firm re-inspected accordingly.***

***iii) The Board also directed the firm to provide the status of the matter decided by the Custom Authorities to QA Section immediately.***

***iv) DDG (E&M), Karachi will be directed to coordinate and pursue with Custom Authorities to have update of the matter and inform to QA Section accordingly.***

Following panel was constituted on 11.12.2013 for conducting the inspection of the firm.

a) Chief Drug Inspector, Sindh
b) DDG (E&M) Karachi
c) Director CDL, Karachi
d) Area FID, Karachi
e) Area ADC Karachi

The aforesaid panel inspected the firm on 08.04.2014 and the panel unanimously decided to recommend **the cancellation of DML No.000172** by way of formulation in larger public interest.

**Proceedings:** The firm was called for personal hearing to appear before the Board. Mr. Naushad, Director of the firm had sent an email and informed that he is abroad and due to which he cannot attend the meeting in this short notice.

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided as follows:

1. *The Board after making detailed discussion on the case and in the light of the request of the firm, decided to defer the case for the next meeting of Central Licensing Board.*
2. *The Licensing section be requested to verify and confirm that Mr. Naushad Ali is the CEO/Managing Director/Director of the company***.**

**Case No. 8:- M/s Farmegia Pakistan (Pvt) Ltd, Lahore**

M/s Farmigea Pakistan (Pvt) Ltd, Lahore was inspected on 16.01.2008. The firm was closed for the last five years since 16.01.2008 by the FID Lahore due to critical shortcomings pointed out in eye drop section and stop production order was issued by the defunct Ministry of Health on 27.02.2008.

The firm submitted that due to financial problems, they did not develop facilities as per GMP requirements during 5 years but in 2013 they have made improvements and ready for inspection.

A panel inspection of the firm was conducted on 06.05.2013 comprising the following with reference to Licensing letter No.F.1-1/93-Lic (Vol-Vi) dated 19.03.2013:

a) Dr. Sheikh Akther Hussain, Director (Pharmacy Service),
b) Mr. Nadeem Iqbal, Member CLB,
c) Mr. Asim Rauf, FID Lahore
d) Mr. Ahsan-ul-Haq Athar, ADC Lahore

The case was placed before the Central Licensing Board in its 232nd meeting by the Licensing Section wherein after thorough discussion, the Board had decided as under:-

*"The CLB deferred the case of grant of two additional sections to the firm. The Board decided to get clarification from QA/QC regarding stoppage of production since 2008 and non-compliance of cGMP of the firm. A surprise re-inspection of the facility by a panel of experts was desired by the Board to check overall GMP compliance level of the firm. The Board also decided that Provincial Governments may be asked to check availability of products of M/s Farmigea Pakistan, Lahore in the market/institutions as production has been stopped since 2008".*

Later on, another panel comprising the following was constituted by the Chairman, Central Licensing Board wherein the panel was directed to conduct the inspection of the firm in order to check/verify the GMP compliance as well as renewal of DML of the firm:

a) Mr. Ayaz Ali Khan, Chief Drug Controller, Punjab
b) Mr. Asim Rauf, FID Lahore
c) Mrs. Aisha Khalil, FID Lahore
d) Ms. Quratul-Ain, ADC Lahore

The aforesaid panel inspected the firm on 04.03.2014 and recommended for the renewal of DML and resumption of production to the firm.

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided as follows:

1. *On considering the inspection report of the panel of experts constituted by DRAP, Islamabad allowed resumption of production of M/s Farmegia Pakistan (Pvt) Ltd, Lahore in all sections except steroid products till availability of segregated facility.*
2. *The production in the steroidal section will remain suspended till the approval of the section by the Central Licensing Board.*
3. *The above decision would be conveyed to the Drug Registration Board.*
4. *The firm would be re-inspected within 03 months by a panel at the time of active production.*

**Case No. 9:- M/s British Pharma, Lahore**

The case was placed before the Central Licensing Board in its 233rd meeting held on 30-31st December, 2013. The production of the firm was stopped since 23.04.2013 on GMP violations. The representative of the firm Mr. Muhammad Akram, Production In charge appeared before the Board and submitted his point of view before the Board. The Central Licensing Board after hearing the representatives, considering the legal formalities and detailed discussion/deliberation decided as under:

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

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

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

**Latest Position**:

The representative of the firm has informed that they are ready for inspection.

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided as follows:

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 the following panel for verifying the improvements in the GMP compliance:*
    - *a) Mr. Ayaz Ali Khan, Chief Drug Controller/Member Central Licensing Board*
    - *b) Area FID, Lahore*
    - *c) ADC Lahore.*
3. *Resumption of Production shall be allowed after verification of the improvements made by the firm by the panel and final approval by the Central Licensing Board.*

**Case No. 10:-** **M/s Epoch Pharmaceuticals, Karachi**

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

**Action taken by the DRAP**:

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

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

f) Syed Jawed Yousaf Bukhari, Member Central Licenisng Board.
g) Dr. Muhammad Tanweer Alam, DDG (E&M) Karachi.
h) Mr. Abdul Rasool Shaikh, Area FID, Karachi.
i) Dr. Shoaib Ahmad, ADC Karachi

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

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

Sterile cephalosporin
Oral cephalosporin,
Oral penicillin and
Ophthalmic sections

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

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

**Proceedings**:

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

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

**Decision of CLB**:-

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

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

The inspection of the firm was conducted on 14.02.2014, 25.02.2014 and 17.04.2014 by Mr. Abdul Rasool Shaikh, FID Karachi to verify the production activities and progress made by the firm. The FID reported that during the course of periodic inspection, it was found that no active production was underway in all those areas in which the firm was directed to stop production. The risks and GAPs identified in earlier panel inspections were found sufficiently addressed. The panel comprising of the following conducted the inspection of the firm on 14.05.2014 and recommended the resumption of production:

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

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided as follows:

1. *On considering the inspection report of the panel of experts constituted by DRAP, Islamabad allowed resumption of production of M/s Epoch Pharmaceuticals, Karachi.*
2. *The firm would be re-inspected within 03 months by the same panel at the time of active production.*

**Case No. 11:-** **M/s Mass Pharmaceuticals (Pvt) Ltd, Lahore**

M/s Mass Pharmaceuticals (Pvt) Ltd, Lahore informed the Federal Inspector of Drugs on 16.09.2013 regarding their intention to upgrade and renovate few of the production areas as per plan approved on 20.03.2013. The FID, Mrs. Majida Mujahid inspected the firm on 08.11.2013 and reported that the production activities were stopped for the purpose of up-gradation and renovation work in the plant.

On receiving the inspection report of the FID, the firm was directed by this Authority on 21.12.2013 not to resume the production activities till the completion of up-gradation and renovation work.

Later on, the firm had informed that they are ready for inspection. A panel comprising of the following inspectors conducted the inspection of the firm on 19.03.2014 to check the improvements claimed by the firm:

i) Chairman, Quality Control
ii) DDG (E&M), Lahore
iii) Area FID, Lahore

The panel reported that the firm has made improvements in GMP by renovation and recommended resumption of production. Accordingly, the firm was advised by this Authority on 19.04.2014 to continue the production as usual.

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided as follows:

> *The Board endorsed the decision of continuation of production of M/s Mass Pharmaceuticals (Pvt.) Ltd, Lahore after making up-gradation, improvements and verification by the panel of inspectors.*

- **Case No. 12:- M/s Surgical Textile Kasur**

M/s Surgical Textile Kasur, was inspected on 29.05.2012 and 18.10.2012 by Mr. Abdul Rashid Sheikh, FID Lahore with reference to see/verify the GMP compliance of the firm. The FID pointed out some shortcomings in the section.

The FID directed the firm during his inspection on 29.05.2012 to make improvements and establish microbiological lab and intimate him before starting the production. The FID again inspected the firm on 18.10.2012 for verifications and found that the firm had discontinued the production for improvements.

Later on, the firm informed the FID and DRAP that they have completed the renovation/upgradation work and ready for inspection. On their request, a panel was constituted by this Authority on 24.02.2014 of the following officers to conduct the inspection.

i) Chairman, Quality Control
ii) Area FID, Lahore
iii) ADC Lahore

The panel inspected the firm on 17.03.2014 and reported that the firm has made improvements in GMP by renovation and recommended resumption of production.

Accordingly, the firm was advised by this Authority on 06.05.2014 to continue the production as usual.

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided as follows:

*The Board endorsed the decision of continuation of production of resumption of production of M/s Surgical Textile Kasur after making up-gradation, improvements and verification by the panel of inspectors.*

**Case No. 13:-** **M/s Aptcure (Pvt) Ltd, Lahore**

The case was placed before the Central Licensing Board its 233rd meeting of CLB held on 31.12.2013 wherein the Board after hearing the views of the firm and keeping in view the relevant legal provisions/codal formalities and thorough deliberations of the honorable members decided as under:-

*i) The Board after considering the inspection report of the panel of experts constituted by competent authority agreed to the recommendations of the panel and allowed the resumption of production in all sections.*

*ii) The Board directed to issue a strong warning to firm for producing limited batches of their different products for fulfilling the supply orders of hospitals during suspension period of their DML as reported by area FID and confessed by the firm also.*

*iii) The Board further directed that area FID will collect the details of production of batches and firm is directed to recall the stocks for destruction manufactured during suspension period from market and hospital.*

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

The FID informed that the firm has no stock of products manufactured by them during suspension period.

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided as follows:

*The Board decided to conduct case specific inspection regarding and recall the stocks for destruction by a following panel:*

*a) Mr. Ayaz Ali Khan, Chief Drug Controller, Punjab/Member CLB.*

*b) Area FID, Lahore*

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

M/s Safina Pharmaceuticals (Pvt), Lahore, conducted on 10.10.2013 by Mrs. Aisha Khalil, FID Lahore, with reference to see/verify the GMP compliance of the firm. The FID had pointed out number of serious shortcomings and gross GMP violations in all sections.

**Action Taken by DRAP:** A show cause notice was issued by this Authority on 19.11.2013 with the direction to stop production in all section.

**Reply of the firm**: The firm has submitted compliance report and requested for re-inspection of their unit.

The Chairman, Central Licensing Board/Director (QA/Lab Testing & Lic) had constituted the following panel on 23.12.2014 to conduct the re-inspection of the firm in order to check the improvements made by the firm:

i) DDG (E&M), Lahore.
ii) Mr. Ajmal Sohail Asif, FID Lahore
iii) Area FID, Lahore

The aforesaid panel inspected the firm on 16.04.2014 and **recommended that the firm may be allowed to resume the production in General Tablet and General Antibiotic Tablet sections only**. The re-inspection of the firm will be conducted after the firm submits compliance of the deficiencies pointed out in Cream/Ointment and Cephalosporin Sections.

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

**Decision of CLB**:
The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided as follows:

1. *On considering the inspection report of the panel of experts constituted by DRAP, Islamabad allowed resumption of production in General Tablet and General Antibiotic Tablet Sections only of M/s Safina Pharmaceuticals, Lahore.*

2. *The firm would be re-inspected within 03 months by a panel at the time of active production.*

**Case No. 15:-** **M/s Royal Group & Marion Laboratories, Karachi.**

The case of M/s Royal Group, Karachi and M/s Marion Laboratories (Pvt) Ltd, Karachi was presented in 231st meeting of CLB meeting held on 31.01.2013 wherein following decisions was taken:-

> *"The case was placed before the Board in its 231st meeting, wherein M/s Royal Group and M/s Marion Laboratories (Pvt) were called for personnel hearing. After hearing deliberated views of both the firms, the Board directed to both firms to expedite the destruction of substandard batches "Injection Marivell-5 (Dextrose 5%) 500ml manufactured by M/s Marion Laboratories (Pvt) Ltd, Karachi which are lying at port Darussalam and M/s Marion Laboratories (Pvt) Ltd, Karachi had committed to the Board for bearing the expenditures. M/s Marion Laboratories (Pvt) Ltd, Karachi has submitted an undertaking to the Board in this regard".*

Later on the case was presented before the Central Licensing Board in its 232nd meeting held on 29-30th July, 2013 wherein the Board in the light of fore going facts/details, decided the case as under:-

i) ***The Board upheld its previous decision of destruction of substandard consignments of drugs*** *"Injection Marivell-5 (Dextrose 5%) 500ml lying* ***at Port Darussalam( Tanzania) and Rwanda in a manner as has been devised/agreed upon by both the parties in 231st meeting of CLB.***

ii) ***The Board took serious note as why M/s Marion Laboratories (Pvt) Ltd, Karachi did not comply with the previous order of the Board for destruction of substandard medicines exported from Pakistan. The Board was of the view that sanctity of Pakistan is at risk and strict action under the Drugs Act, 1976 and rules framed there under should be initiated immediately against M/s Marion Laboratories (Pvt) Ltd Karachi for supply of substandard Injection Marivell-5 (Dextrose 5%) 500ml to M/s Royal Group for export purpose to Rwanda.***

iii) ***The Board decided to suspend the Drug Manufacturing License of M/s Marion Laboratories (Pvt) Ltd, Karachi for period of six months for which intimation to Drug Registration Board shall be conveyed accordingly.***

iv) ***The Board also decided to send recommendation to the Registration Board for cancellation/suspension of registration of Injection Marivell-5 (Dextrose 5%) 500ml under section 42 of Drugs Act, 1976 and rules framed there under for manufacturing and supply of substandard drug in the importing country.***

v) ***Resumption of production in the facility will only be allowed by CLB after comprehensive inspection of firm with regard to compliance/ conformity to the conditions of DML and compliance towards the GMP as required under the law/rules.***

The Licensing Section has submitted a reference to QA Directorate regarding resumption of production of the firm for which GMP inspection is required. The case is submitted to seek the permission of panel inspection if the Central Licensing Board allow the QA Directorate to constitute the panel.

## Report on Visit to Rwanda & Tanzania by DRAP's Nominee

A team comprising of representatives of M/s Royal Group Karachi, M/s Marion Laboratories (Pvt) Ltd, and Drug Regulatory Authority of Pakistan (DRAP) visited Tanzania and Rwanda to expedite the destructions. The DRAP nominee submitted the report which is also under consideration of Honorable High Court Sindh, Karachi. The DRAP nominee reported that during with officials of Tanzania Revenue Authority (TRA), the TRA allowed to take the medicines under questions (lying at port of Tanzania destined to Rwanda) back to Pakistan for destruction. He also reported that on 11th September, 2013, Royal Group attended the meeting themselves and informed him that it was not mandatory to DRAP to attend the said meeting because it was purely concerned with taking up the issues of payments etc. However, they informed the DRAP's nominee verbally as well as through email that officials of Rwanda Biochemical Centre, Government Rwanda did not allow them the destruction of rejected goods in Kigali (Rwanda) because they could not get permission from Rwanda Environmental Body for destruction of rejected goods. M/s Royal Group has been informed by the officials of Rwanda Biochemical Centre that one the issues of payment get settled then they will be allowed to take the rejected material back to Pakistan for final destruction.

**Summary:**

The DRAP's nominee has summarized that the major issue is payment to the Shipping Company/Tanzania Revenue Authority/Tanzania Port Authority and Rwandan Government and being purely a commercial issue, it should be resolved by the M/s Royal Group, exporter and M/s Marion Laboratories, Karachi, manufacturer. DRAP has extended its maximum cooperation at all stages.

**M/s Marion Laboratories (Pvt) Ltd, Karachi Submission:**

M/s Marion Lab, Karachi has brought the attention of Central Licensing Board/Drug Registration Board and DRAP on the Rule-27 (b) of Drug Import & Export Rules, 1976 under Drugs Act, 1976 which states as under:

> *"The exporter shall, on being informed by the Registration Board or the Licensing Authority or an officer authorized by it in this behalf or the Chairman of the Provincial Quality Control Board that any part of any batch of a drug has been found in contravention of any of the provisions of the Act or the rules made thereunder and on being directed so to do, withdraw the remainder of the batch from export and so far as practicable, recall the issues already made from that batch and dispose of it in such manner as the Board, or, as the case may be the Licensing Authority, may direct".*

The firm (M/s Marion Lab, Karachi) through their various letters to DRAP seeked the action against exporter (M/s Royal Group, Karachi) with the information that all actions of DRAP were focused on them (M/s Marion Lab being manufacturer of subject matter medicines).

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

**Decision of CLB**:

The case was placed before the Central Licensing Board for consideration, the Board after thorough discussion and keeping the facts on records has decided as follows:

i) *A Committee/panel comprising the following members have been constituted to investigate the matter (M/s Royal Group, Karachi Vs M/s Marion Laboratories (Pvt) Ltd, Karachi for subject matter medicines exported to Rwanda and Tanzania) in depth and submit a report to the Board in the next meeting of CLB for consideration:*

   *i) Dr. A.Q. Javed Iqbal, Director (QA/LT), DRAP, Islamabad*
   *ii) Chief Drug Inspector, Sindh*
   *iii) Mr. Jawed Bukhari, Member CLB*
   *iv) Area FID, Karachi*

ii) *The same panel will also inspect M/s Marion Laboratories (Pvt) Ltd, Karachi in order to check/verify the GMP compliance before resumption of production.*

# Item No.II:

## Case No.16:

## Voluntary Stoppage of Production

a) The company who voluntarily stop production for renovation and up-gradation of their manufacturing facility or other area.

b) The company, which was advised by the FID for improvement and to intimate after renovation, up-gradation and making changes in the pharmaceutical manufacturing facilities.

In both the above cases a panel re-inspects the pharmaceutical manufacturing facilities. On the recommendation of the panel, the company may start the production as usual after the approval of Director QA which has been the practice in the past also. The case was placed before the Central Licensing Board for consideration.

**Decision:**

**The Board took following policy decisions: -**

- **The Board authorized the Director (QA/LT) who is member of CLB to resume production after verification by area FID or panel:**
    - **If a firm makes voluntary stoppage of production for general maintenance and there is no change in layout / process /machine.**
- **The Board fixed the duration period for 2-4 weeks for general maintenance.**

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