DIVISION OF DRUG LICENSING
DRUG REGULATORY AUTHORITY OF PAKISTAN
ISLAMABAD

MINUTES OF 237th MEETING OF CENTRAL LICENSING BOARD HELD ON WEDNESDAY THE 1st OCTOBER, 2014.

237th meeting of the Central Licensing Board (CLB) was held on Wednesday the 01st October, 2014 in the Committee Room of Ministry of National Health Services, Regulations & Coordination at Local Government & Rural Development Complex, G-5/2, Islamabad under the Chairmanship of A. Q. Javed Iqbal, Director Drug Licensing / Director Quality Assurance & Laboratory Testing, DRAP, Islamabad/Chairman CLB.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Mr. Ahmad Mehmood Mumtaz, Chairman Quality Control, as representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad.	Member
2.	Mr. Atta-ur-Rehman, Chief Drug Inspector, Department of Health, Govt. of Balochistan.	Member
3.	Mr. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh	Member
4.	Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa (K.P.K). (Mr. Imranullah Khan, Drug Inspector, Peshawar attended meeting on behalf of Chief Drug Inspector, KPK.)	Member
5.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
6.	Syed Muid Ahmed, Expert in manufacturing of drugs.	
7.	Prof. Dr. Muhammad Saeed, Professor of Pharmacy	Member
8.	Mr. Ejaz Asad Rasul, J.S, M/O Law ,Justice & Human Rights as Law Expert nominated by Secretary, Ministry of Law and Justice, Government of Pakistan, Islamabad.	Member
9.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
10.	Mr. Shakeel Irfan, Representative of PPMA	Observer
11.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
12.	Muhammad Farooq Memon, Representative of PCDA	Observer

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

The Chairman apprised the members of the Board that proceedings of CLB shall be conducted in a transparent and efficient manner. Quality shall be given priority and there shall be zero tolerance by the Authority as far as the quality of medicines. He further added that all the legal and codal formalities regarding convening of the meeting have been fulfilled. Chairman showed his concern on the absence of the representation of PPMA as observer at the start of meeting, however on telephonic reminder the representative joined the meeting after 01:00 p.m. Mr. Ahmed Din Ansari DDC (QC), Mr. Adnan Faisal Saim, DDC (Q.A.) and Mr. Salateen Waseem Philip ADC/DDC (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

A. LICENSING DIVISION

Item-I **CONFIRMATION OF THE MINUTES OF 236th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 236th meeting held on 27th June, 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 made by respective panel of experts/inspectors and decided as under: -

S No.	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s Bajwa Pharmaceuticals (Pvt) Ltd, 33-KM, Main GT Road, Khori District Sheikhupura.	23-06-2014 Formulation	**Deferred for re-inspection by the same panel as under: -** 1. Dr. Ikram-ul-Haq, Member CLB. 2. Mrs. Aisha Khalil, FID, DRAP, Lahoe. 3. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore. 4. Rana Ahsan-ul-Haq Athar, ADC DRAP, Lahore.
2.	M/s Sigma Pharma International (Pvt) Ltd, Plot No. E-50, NWIZ Port Qasim Karachi. 1.	12-09-2014 Formulation	**Approved the grant of DML with following sections:-** **Sections (05):** 1. Capsule (General). 2. Oral Dry Powder Suspension (General). 3. Cream / Ointment/Gel (General). 4. Tablet (General) 5. Sachet (General).
3.	M/s Shazal's Pharmaceuticals (Pvt) Ltd, Industrial Estate, Hattar. DML No.000592 (Formulation) (valid upto 26-04-2016)	27-09-2014 Formulation **(Re-Grant)**	**Approved the grant of DML with same DML number (000592 Formulation) and following sections:-** **Sections (04):** 1. Tablet (General). 2. Capsule (General). 3. Oral Dry Powder Suspension (Cephalosporin). 4. Capsule (Cephalosporin).

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

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

S No.	Name of the firm	Date of Inspection	Decision of CLB
1.	M/s Pharmatec Pakistan (Pvt) Ltd, D-86-A, SITE, Karachi. DML No.000024 (Formulation)	24-07-2014	**The Board approved the grant of additional section & area as under:-** **Section (01)** 1. Cream/Ointment (General) **Areas** 1. Ware Houses and Utilities area
2.	M/s Sanofi Aventis Paksitan Limited, Plot No.23, Sector 22, Korangi Industrial Area Karachi. DML No.000007 (Formulation)	11-08-2014	**The Board approved the grant of area as under:-** **Area** 1. Trolly Storage Area for Haemaccel.
3.	M/s Pfizer Pakistan Limited, B-2, SITE, Karachi, DML No.000025 (Formulation)	09-09-2014	**The Board approved the grant of additional section as under:-** **Section (01)** Tablet (Psychotropic)
4.	M/s Ahad International Pharmaceutical Ltd, 13-Km Gomal University Multan Road Dera Ismail Khan. DML No. 000433 (Formulation)	06-09-2014	**The Board approved the grant of additional section as under:-** **Section (01):** Ampoule Injection (General)
5.	M/s ARP (Pvt) Ltd, Plot No. 12&12A, Street No.W-3, National Industrial Zone, Rawat, Rawalpindi. DML No. 000682 (Formulation)	19-09-2014	**The Board approved the grant of additional sections as under:-** **Sections (05):** 1. Tablet (General). 2. Capsule (General) 3. Sachet (General) 4. Oral Dry Powder Suspension (General). 5. Semi solids Cream / Ointment/ Gel (General).

6.	M/s Nortech Pharmaceuticals (Pvt) Ltd, Plot No. 203, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000792 (Formulation)	11-08-2014	**The Board approved the grant of additional sections as under:-** **Section (01):** 1. Ampoule / Vial SVP (General)
7.	M/s. Semos Pharmaceuticals (Pvt) Ltd, 11-B, Sector 12-A, North Karachi. DML No.000335 (Formulation)	24-07-2014	**The Board approved the grant of additional sections as under:-** **Sections (03):** 1. Capsule (Cephalosporin). 2. Oral Dry Powder Suspension (Cephalosporin). 3. Sterile Dry Powder Vial Injection (Cephalosporin).

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

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

S No.	Name of the firm	Date of Inspection	Decision of CLB
1.	M/s. Pliva Pakistan (Pvt) Ltd, Balochistan Plot No. B-77, Hub Industrial Area, Hub Balochistan. DML No.000280 (Formulation)	21-07-2014	**Approved the Grant of Renewal of DML**
2.	M/s. Fynk Pharmaceuticals, 19-KM, GT Roda, Kala Shah Kaku, Lahore. DML No.000494 (Formulation)	22-05-2014	The Board observed that the panel cannot decide itself for re-inspection and cannot take on their own any other expert / inspector who is not member of panel for inspection. However, if panel seems that there is need to co-opt any other expert then the permission shall be taken accordingly. **Board discussed thoroughly and deferred for re-inspection by following panel: -** 1. Chairman Quality Control, DRAP, Islamabad. 2. DDG (E&M), DRAP, Lahore. 3. Area FID, DRAP, Lahore. 4. Mr. Asim Rauf, FID, DRAP, Lahore.
3.	M/s. Unexo Lab (Pvt) Ltd, 9.5 K.M. Sheikhupura Road, Lahore. DML No.000065 (Formulation)	02-06-2014	**Approved the Grant of Renewal of DML**
4.	M/s. Asian Fibre, Plot No.41-42, Sector 25, Korangi Industrial Area Karachi. DML No.000668 (Formulation)	02-07-2014	**Approved the Grant of Renewal of DML** Board further advised that the firm shall take such measures to reduce environmental pollution and protection of personnel.

5.	M/s. Indus Pharma (Pvt) Ltd, 65/27, Korangi Industrial Area, Karachi. DML No.000124 (Formulation)	13-08-2014	**Approved the Grant of Renewal of DML**
6.	M/s. Noa Hemis Pharmaceutical, plot No. 154, Sector 23, Korangi Industrial Area, Karachi. DML No.000525` (Formulation)	15-07-2014	Deferred for three months and re-inspection shall be carried out after compliance of observations by the same panel as under: - 1. Syed Mueed Ahmed, Member CLB. 2. Dr. Saif-ur-Rehman Khattak, Director CDL, DRAP, Karachi. 3. Dr. Shahid Hussain, Area FID, DRAP, Karachi. 4. Dr. Shoaib Ahmed, Area, Assistant Drug Controller, DRAP, Karachi.
7.	M/s. Gelcap (Pakistan) Limited, plot No.B-43, HITE, Hub Hub Lasbella, Balochistan. DML No.000282` (Semi Basic)	03-09-2014	**Approved the Grant of Renewal of DML**
8.	M/s Ahad International Pharmaceutical Ltd, 13-Km Gomal University Multan Road Dera Ismail Khan. DML No. 000433 (Formulation)	06-09-2014	**Approved the Grant of Renewal of DML**
9.	M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore. DML No. 000660 (Formulation)	21-08-2014	**Approved the Grant of Renewal of DML**
10.	M/s Searle Company Limited, 32-KM, Multan Road, Lahore. DML No. 000647 (Formulation)	20-08-2014	**Approved the Grant of Renewal of DML**

11.	M/s. Otsuka Pakistan Limited, F/4-9, Hub Industrial Trading Estate, Hub Lasbella, Balochistan. DML No.000281` (Formulation)	3&4-09-2014	The Board decided to issue show cause notice and deferred the renewal for three months due to the following observations / deficiencies made by the panel:

Observations / Deficiencies

Quality Management

During the inspection the panel noted that the QC, QA, Production and Management team is well familiar with the concepts of TQM but in some areas stringent and serious steps are not taken to avoid or prevent the defects/non-compliances merely defects are detected and noted not well prevented. Details of each defect would be given in respective heads/chapters. The policy adopted by the management seams in contravention of the DRAP cGMP Rules especially a self-declared organogram is forcefully implemented which may directly compromise the quality of the product. Warehouse is supervised by a mathematician who directly reports to Senior Manager of Material Management who doesn't come under the umbrella of TQM hence required QA checks in stores were found compromised ultimately affecting the quality of the finished products.

Raw and Active materials are not well sampled and analyzed as per approved SOPs. Only a single container from each batch is opened in un-controlled environment and after drawing required quantity this is sealed un-scientifically. This was proved from the unavailability of LOG books.

The same critical risks were also identified in dispensing areas where returned raw materials have been found messed and stored irrationally even the wrong labels were pasted which resulted in confusing the existing status of the messed materials. These materials were also found un-attended.

Released Materials were found placed under quarantine that is considered as the violation of GSP. No QA involvement was noted in stores as this section comes under the direct authority of CEO of the firm.

Hence a serious violation of corporate's quality policy was observed in stores and even no corrective action in this regard is proposed from Director QA.

A serious anomaly was also found while reviewing product release documents as all the batch documents are reviewed by QA Manager but final release is granted by QC Manager. The Management had no scientific and regulatory justification behind that logic.

Less serious QA checks were also noted during microbial testing.

More serious non-compliance which firm practices while knowing all the risks behind it, is the non-simulated availability of technical staff in second and third shift and even the less trained staff is placed in late shifts with no defined authority. This may be a high risk area if any mishap occurs during the late shifts and the Management did not show any emergency plan to deal with un-expected risks.

Concealment of facts were also observed during documents review like a person in QA holds a BSc Degree but his JD declares him B. Pharmacy.

Internal Audit documents revealed that the Major Risks identified in last report are not yet planned to address. Thus follow-up inspection would be conducted with neglecting the compliance of previous major observations. Therefore a compromised QMS would prevail which ultimately affects the quality of final product.

	Working SOPs found devoid of some essential information for the authority hence critical steps and instructions while performing a particular activity are not followed resultantly creating risks. Vendors are qualified and only approved sources are used for all critical raw and packing materials like PP, PE, dextrose and for other electrolytes and amino acids. Trainings are periodically conducted. Complaints and recalls are observed well treated. Almost all critical processes are qualified and validated. Master Plan found existed and followed accordingly. **BASED ON THE ABOVE DESCRIBED FACTS THERE OVERALL QMS IS RATED SATISFACTORY AND NEEDS URGENT ACTIVE IMPROVEMENTS.** **Personnel:** The firm has sufficient technical person in each section and they have the required experienced as well. But same strength of qualified personnel is followed in rest of the shifts. Therefore Panel strongly recommended hiring of more officers in all the sections to meet the same conditions in all the shifts so that inherent risks may be minimized. **Premises:** QC and Management block are together but well separated and provided with authorized entry. QC was found less spacious and not so properly defined and segregated. Production is carried out separately and is divided into three manufacturing areas according to the size of the containers used. Only sterile products are manufactured. The activities were found halted due to some machine problems therefore active production was not underway at the time of inspection. Raw Materials and Finished Products are separately stored. Stores were found irregularly arranged, found less organized and under the supremacy of a non-technical person with the irrelevant qualification. De-dusting and receiving bays are not scientifically designed. Movement of the material to the dispensing, sampling and production areas were noticed un-scientific and without determining the hazardous effects upon environmental exposure. Retrieval of documents was noticed un-satisfactory. **Equipment:** The firm has required machines and equipment in production areas and in QC Lab. But it was strongly recommended to obtain more advance equipment for the identification of the raw materials. **Documents:** Several documents were checked during inspection and leaving a few documents the rests were found satisfactory. Scientific approach hardly reflects from the documents. Retrieval was found very lazy as the management seemed reluctant to show some critical documents besides several requests. **Production:** Production activities are carried out as per approved working SOPs but unfortunately authority starts after the dispensing of the materials. Status of machines was clearly

	pasted. Overall practices in all the production areas were found good at the time of inspection. **Sanitation & Hygiene:** During the inspection the panel observed a good degree of cleanliness in sterile production areas. Personnel working in the 100 Class are given autoclaved clothes and other necessary protective. Change rooms for workers were seen cleaned at the time of the visit but lacked of proper air handling system thus burdened air and a little raised temperature was felt inside the change rooms. Rest of the auxiliary production areas were found maintained at desired temperatures. QC Lab has fewer spaces and due to the absence of proper HVAC System hazardous chemical vapors may be felt and the constant exposure of that may be a safety hazard for the working personnel. Cabinets and other shelves are of wooden which may aggravate the emergency situations. Acids and other lethal chemical are stored in these wooden cabinets and no separate spaces are allocated for such purposes. Micro Lab was observed in very worst conditions as proper air handling is not provided and almost all critical tests are carried out under un-controlled environmental conditions thus the reliability becomes under question. No proper designing qualification of micro lab has been carried out a merely monitoring via exposing the plates was found only means to monitor the inside burdened air. Overall conditions in lab were found un-satisfactory at the time of inspection. Raw material stores represented almost the same scenario. No proper air handling system is installed here hence the elevated temperature and humidity ratios were observed. Storage conditions are monitored and recorded but with casual attitude of the working personnel. Mops and other cleaning utensils are placed just outside of the so-called cool room. No proper area has been designated for de-dusting. Floors were un-smooth and un-cleaned. QA is not authorized to cross-check the conditions and take notice against the GSP violations. Rejected materials are placed in a designated areas but beside the quarantined materials and no schedules are given to when and how to destroy and discard the said materials. Cleaning Schedules were not in place thus the monitoring was less stringent. Overall conditions in stores were rated as below satisfactory. **Quality Control:** In QC lab the firm has provided necessary and baseline equipment list is annexed. In-house calibration is periodically carried out. SOPs and necessary documents were also available.		
12.	M/s. Stanley Pharmaceuticals (Pvt) Ltd, Industrial estate, Hayatabad, Peshawar. DML No.000434 (Formulation)	17-09-2014	**Approved the Grant of Renewal of DML**
13.	M/s. Cherwel Pharmaceuticals (Pvt) Ltd, Industrial Estate, Hattar, DML No.000606 (Formulation)	27-09-2014	**Approved the Grant of Renewal of DML**

14.	M/s. Semos Pharmaceuticals (Pvt) Ltd, 11-B, Sector 12-A, North Karachi. DML No.000335 (Formulation)	27-09-2014	**Approved the Grant of Renewal of DML**
15.	M/s Unison Chemical Works, Post Office Araian, 15-km Raiwind Road, Lahore DML NO. 000174 (Formulation)	29-09-2014	**Approved the Grant of Renewal of DML**
16.	M/s AGP Healthcare (Pvt.) Ltd, Karachi	22-09-2014	**Approved the Grant of Renewal of DML** The Board directed that the area FID be asked to propose revised/new Evaluation Form which may be used during inspections, for the consideration of the Board.

Item-V **Misc Cases**

1) Delegation of Functions / Powers.

Decision of CLB.

The Central Licensing Board approved and delegated its powers retrospectively with certain modifications to its Chairman, Secretary and Director Quality Assurance and Laboratory Testing under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) rules, 1976 in order to facilitate timely disposal of routine and day to day business of Central Licensing Board.

S No.	Functions / Powers	Function / Powder Delegated to
	Delegation of Functions / Powers related to Division of Drug Licensing	
1.	Show Cause Notice regarding contravention of any of the provision of the Drugs Act, 1976 and rules framed there under.	Chairman CLB
2.	Suspensions of Production	Chairman CLB
3.	Issuance of Inspection Book	Secretary CLB
4.	Approval of layout plan and constitution of committee for evaluation of layout plan. (The committee shall be constituted for the purpose of evaluation / assessment and analysis of the layout plan and shall furnish its recommendations accordingly to the Chairman CLB for approval).	Chairman CLB
5.	Approval of Technical Staff and communication / Issuance of decisions of Central Licensing Board.	Secretary CLB
6.	Site approval	Secretary CLB
7.	Approval of change of name of an unlicensed firm / unit (before the approval of site).	Secretary CLB
8.	Approval of change of name of a firm for licensed units/unlicensed units (after the site approval).	Chairman CLB
9.	Enlistment of drugs / APIs (Molecules) for basic, and semi basic manufacturing. (The inspections shall be made mandatory before grant of any item(s) / drugs/ APIs under respective Schedule etc.)	Chairman CLB
10.	Implementation of decisions of Appellate Board related to Division of Drug Licensing	Chairman CLB
11.	Approval of Repacking items under Schedule D of Drugs Act 1976 and Rules framed there under. (The inspections shall be made mandatory before grant of any item(s) / drugs/ APIs under respective Schedule etc.)	Chairman CLB
12.	Constitution / amendments in constitution of panel for inspection for grant/renewal of Drug Manufacturing License, Grant of Additional Sections and Verification / Checking of conditions of License etc of firms.	Chairman CLB

13.	Extension in Sealing period of Licensed manufacturers where Contraventions(s) is / are of Conditions of DMLs only.	Chairman CLB
14.	Correction of typographical error in recording minutes of the CLB.	Chairman CLB
15.	Approval of the change of management / Director / Owner etc of licensed firm after verification of relevant legal documents.	Chairman CLB
	Delegation of Functions / Powers related to the Division of Quality Assurance & Laboratory Testing	
16.	Show Cause Notice regarding contravention of any of the provision of Drugs Act, 1976 and rules framed there under (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
17.	Suspensions of Production (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing
18.	Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members	Director Quality Assurance and Laboratory Testing
19.	Permission to Lodge FIR	Director Quality Assurance and Laboratory Testing
20.	Panel Constitution (GMP Inspections and related issues etc)	Director Quality Assurance and Laboratory Testing
21.	Constitution/ amendments in constitution of panel for inspection for GMP compliance and quality control matters.	Director Quality Assurance and Laboratory Testing
22.	To continue the period of "not to dispose-of stocks orders passed by FID" for three months.	Director Quality Assurance and Laboratory Testing
23.	To continue custody of the seized stocks by the FID till decision of the case.	Director Quality Assurance and Laboratory Testing
24.	To grant approval for sending Board's portion of drug samples to the Appellate Laboratory	Director Quality Assurance and Laboratory Testing
25.	Grant of extension in the time of testing to Federal Government Analyst.	Director Quality Assurance and Laboratory Testing
26.	Issue of Show Cause Notices/Circulars/Communication of Minutes/Decisions/Directions of the Board to the Concerned quarters regarding GMP and Quality Control matters on behalf of Secretary Board.	Deputy Drugs Controller (QA)/ Deputy Drugs Controller (QC)

2) M/S HYGEIA PHARMACEUTICALS, PLOT NO. 295, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD.

The case was placed in agenda as under: -

Central Licensing Board in its 233rd meeting held on 30-31st December 2013 has approved/granted new section **i.e. Cream / ointment (General)**. The firm has now requested to issue the grant letter for said section titled as **Cream/Ointment/Gel (General)** because most of the firms have the combined section and are manufacturing the gel in the same.

DECISION OF CLB

The Board considered and approved the section name from Cream / Ointment (General) to Cream / Ointment / Gel (General).

3) ESTABLISHMENT OF PHARMACEUTICAL UNIT M/S QAMAR COTTON INDUSTRIES DIPALPUR CHOWK OKARA.

The case was placed in agenda as under: -

M/s Qamar Cotton Industries was inspected by area Federal Inspector of Drugs for site verification for purpose of establishment of a Pharmaceutical Unit. The area FID during the inspection of the site noticed that approximately 03 kanal area of the site was covered with already constructed godawan. Moreover it was also noticed that on the back side along the distance of approximately 1000 ft. there was running a brick kiln; another brick kiln was seen on the last the front side approximately 800 feet from the site. Both the kilns were in running condition and black smoke was coming out.

Recommendations of area FID

In the light of the above, the location and surrounding of the proposed site is not suitable for Pharmaceutical unit as of today as per requirement laid down under paragraph 1 of schedule "B" (SRO. 470(i)/98 dated 15-05-1998 under Rule 16(a) of the Drugs (Licensing, Registering & Advertising) Rules 1976.

DECISION OF CLB

In the light of recommendations of inspection report of site verification by Area Federal Inspector of Drugs that the site is not suitable for Pharmaceutical unit as of today as per requirement laid down under paragraph 1 of schedule "B" (SRO. 470(i)/98 dated 15-05-1998 under Rule 16(a) of the Drugs (Licensing, Registering & Advertising) Rules 1976; the Board considered and rejected the site for establishment of Pharmaceutical Unit of M/s Qamar Cotton Industries, Okara located at Dipalpur Chowk, Okara.

4) DISCONTINUATION OF LOCAL PRODUCTION FOR ETHICON SUTURES BY M/S JOHNSON & JOHNSON PAKISTAN (PVT) LTD, PLOT NO. 10 & 25, SECTOR 20, KORANGI INDUSTRIAL AREA, KARACHI.

The case was placed in agenda as under: -

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

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

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

Decision of the Central Licensing Board in 236th meeting held on 27-06-2014:

The Board after thorough deliberations and discussion decided:

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

Proceedings

Muhammad Arif Tahir Country Manager and Aasma Zuberi Regulatory Manger of M/s Johnson & Johnson appeared before the Board and stated their point of view that: -

- There will be no impact on patients due to discontinuation of local production as they will import sutures to meet the demand and ensure availability.
- They have already applied for the registration of alternate codes for these sutures so that there may not to be any shortages in the market.

- They informed that they have stock of sutures up to September, 2104.

Chairman and the members of the Board urged the company and emphasized that preferably the company should reconsider the decision of closing down their manufacturing operations in Pakistan. They were also told to take up the issue at the level of their Headquarter.

The company should not have stopped their local production. However, they have informed due to different reasons including financial viability that they are closing down some of their production plants in countries like France and Pakistan.

Decision of CLB

The Board discussed the issue thoroughly and deferred the case for the following:-

- **The company is directed to ensure the availability of alternate codes of sutures after getting their products registered.**
- **The Board requested to the Division of PE&R for the registration of their alternate products on fast track basis.**
- **The company is advised also to contact their Headquarter for transfer of technology to Pakistan in the larger interest of the public.**

5) M/s Cresent Cotton, Chowk Depalpur, Okara.

The case was placed in agenda as under: -

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.

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).

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.

1. The FID in her report concluded that the firm was located in commercial area.

2. Tehseel Officer (P&C), TMA Okara was also requested vide letter No. F. 1-7/84-Lic (Vol-I) dated 20-05-2013 for verification of a separate Industrial Area in Tehsil Okara but the reply is still awaited.

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 in 235th meeting held on 15-05-2014

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.

Proceedings

Mr. Ch. Shahid Hameed on behalf of Ch. Abdul Hameed managing partner / director appear before the Board and stated his point of view that they may be given 10-15 years period to shift their industry to an industrial area, however, realizing that his request was impracticable, he himself offered that they should be given 03 years period for shifting.

Decision of CLB

The Board considered and deferred for the case with following decisions: -

- **The company shall be directed to submit an undertaking on judicial paper that they will shift their unit to an industrial area within a period of two years.**

- **Environmental Protection Agency shall be requested for inspection of the area surroundings of the firm with regard to the environmental pollution and air particle count.**

6) Case for Change of Management of M/s Ambrosia Pharmaceuticals, Rawat DML No.000561 (Formulation).

The case was placed in agenda as under: -

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.

3. 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 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".

Decision of CLB in 235th meeting of CLB held on 15-05-2014

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:-

i) 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.

ii) 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.

iii) The same DML No. shall be granted as and when approved by the CLB.

4. The decision could not be conveyed to the firm due to typographical mistake that the application was change of management but in minutes it was recorded that application was of renewal, therefore the said decision was not communicated to the firm. Meanwhile, firm has applied alongwith fee for the change of management of firm, which is mentioned in proceeding paras.

5. The application for change of management of the firm has been examined by Licensing Division once again. It has been noticed that many of the firms were entertained previously by CLB for change of management of the firm which were without surrendering of the DML issued previously and inspection book. Some of the names of the firms approved for change of management are as under:-

S No.	Name of the firms for change of management	Date of Approval
1.	M/s Swiss Pharmaceuticals (Pvt.) Ltd, Karachi	221st meeting of CLB held on 30-12-2009
2.	M/s Genome Pharmaceuticals (Pvt.) Ltd., Hattar.	212th meeting of CLB held on 26-05-2008
3.	M/s OBS Healthcare (Pvt) Ltd., Karachi.	212th meeting of CLB held on 26-05-2008
4.	M/s Crown Pharmaceutical Islamabad.	212th meeting of CLB held on 26-05-2008
5.	M/s Nexus Pharma (Pvt) Ltd., Plot No 4/19, Sector 21, Korangi Karachi.	214th meeting of CLB 08-10-2008
6.	M/s CSH Pharmaceuticals - North (Pvt) Ltd., Peshawar	206th meeting of CLB held on 08-09th June 2008

6. As License of immovable property/premises is a mere grant of right by licensor to the licensee to enjoy the licensed property and is not transferable, heritable and assignable. Therefore it is practice / SOP of this Licensing Division to charge the new management a fee of Rs. 50,000/- equivalent to the fee for renewal of DML of the firm.

7. The Drugs Act, 1976 and rules framed there under are silent about change of management of the firm, however during the renewal of DML of the firm, the applicant is required to mention on prescribed Form 1-A regarding names of the proprietor/partners of the firm.

Decision of CLB

The Board considered and approved the change of management of M/s Ambrosia Pharmaceuticals, Rawat DML No. 000561 (Formulation).

7) Regularizations of Layout Plans

The case was placed in agenda as under: -

M/s Mediceena Pharma (Pvt) Ltd, Raiwind Road, Lahore has applied for regularization of their following existing sections: -

1. Tablet Section (General)
2. Tablet (Antibiotic General)
3. Capsule (Cephalosporin)
4. Oral Dry Powder Suspension (Cephalosporin)
5. Dry Powder Vials Injectable (Penicillin)
6. Tablet (Penicillin)
7. Capsule (Penicillin)
8. Capsule (General)
9. Oral Dry Powder Suspension (Penicillin)
10. Oral Dry Powder Suspension (General Antibiotics)
11. Dry Powder Vials Injection (General)
12. Liquid Ampoule SVP (General)
13. Liquid Infusion Injectable (General Antibiotics)
14. Semisolid – ointment (General)
15. Liquid Syrup / Suspension (General)
16. Liquid Ampoules SVP-2 (General)
17. Dry Powder Injectable (Cephalosporin)
18. Tablet (Cephalosporin)
19. Eye Drop Section (General).
20. Capsule (General Antibiotic)

Accordingly, layout plan of firm was approved and Area FID was requested to verify the above sections of firm as per approved layout plan.

Recommendations of Area FID are as under: -

S.No	Name of Firm	Date of inspection	Recommendations of FID
1	M/s Mediceena Pharma (Pvt) Ltd, Raiwind Road, Lahore. DML No.000475` (Formulation)	14-07-2014	The Area FID has verified the all above sections and submitted details on evaluation form. He has further added following comments:- The facilities, personals, equipments, building, HVAC, QC and Quality Assurance operations provided by the firm were supporting GMP compliance at the premises. Overall manufacturing / quality control conditions were GMP compliant at the time of inspection.

Decision of CLB

The Board considered and deferred for the verification of sections through a panel.

8) Change of Name of Firm & Change of Management

The case was placed in agenda as under: -

The Following firm has applied for the change of management and its company name which has been registered under Companies Ordinance 1984 by Security Exchange Commission of Pakistan and submitted the requisite documents which has been examined and found in order by Licensing Division, DRAP. The change of the name of the firm is as under:-

S. No	From	To
1	M/s Pharma King Industrial Company, Plot No. C-7/1, North Western Industrial Zone of Port Qasim, Karachi. DML No.000588 (Semi Basic Manufacturer)	M/s Saakh Pharma (Pvt) Ltd, Plot No. C-7/1, North Western Industrial Zone of Port Qasim, Karachi. DML No.000588 (Semi Basic Manufacturer)

Decision of CLB

The Board considered and approved the change of management and company name as under: -

From	To
M/s Pharma King Industrial Company, Plot No. C-7/1, North Western Industrial Zone of Port Qasim, Karachi. **DML No.000588 (Semi Basic Manufacturer)**	**M/s Saakh Pharma (Pvt) Ltd, Plot No. C-7/1, North Western Industrial Zone of Port Qasim, Karachi.** **DML No.000588 (Semi Basic Manufacturer)**

9. Regularizations of Layout Plans

The case was placed in agenda as under: -

M/s CKD Pharmaceuticals (Pvt) Ltd, DML NO. 000144 (Formulation), 50/28, KIA, Karachi has applied for regularization of layout plan of running facility for their following existing sections which were being licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

1. Tablet (General) Section
2. Cream / Ointment / Gel (General) Section
3. Oral Liquid (General) Section
4. Capsule (General) Section
5. Capsule (Cephalosporin) Section
6. Oral Dry Suspension (Cephalosporin)
7. Capsule (Penicillin) Section
8. Tablet (Penicillin) Section
9. Oral Dry Powder Suspension (Penicillin) Section

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

Accordingly, area FID has inspected the premises and verified all the above mentioned sections

Decision of CLB

The Board considered and deferred for the verification of sections through a panel.

B. QUALITY CONTROL CASES

(Deferred Cases).

Case No 1 : Manufacture and Sale of Spurious and Sub-Standard Broncomars Powder (For Vet. Use only) By-M/s A-One Poultry Services, Madina Market, New Adda, Maradan. (F.No.04-03/2014-QC)

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

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

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

4. The case was placed before Central Licensing Board in its 236th meeting held on 27-06-2014. The Board after taken into consideration also facts of the case and available record decided as under:-

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

5. Accordingly letters of personal hearing to the firm and the accused person in the case was issued in the light of the above decision of the Board.

6. The case was considered by the Board in its 237th meeting held on 01-10-2014

Decision:-

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

"To grant permission to the Federal Inspector of Drugs, Peshawar for prosecution of the above name firm and the accused person in the Drug Court Khyber PakhtunKhwa, Peshawar".

Old/Deferred Case

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

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 labelled recalled stock i.e. 57156 packs of Phenergan Elixir, Batch No. WL-111.

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

i. Verification by the same DRAP's inquiry committee for the measures taken by the firm itself and actions taken on the recommendation of the aforesaid committee.

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

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

5. The case was considered by the Board in its 236th CLB meeting held on 27-06-2014. The Board was apprised about the latest position of the case and it was decided to

deferred the case till next meeting of the CLB as the report of DRAPs inquiry committee has not been received so far

6. DRAPs Inquiry Committee report has been received which on perusal reflect that firm's compliance to many of the observations have been made at good level. However compliance towards some points has been rated by the panel as satisfactory and poor as well.

7. The case was considered by the Board in its 237th meeting held on 01-10-2014.

Decision:-

The Board was apprised about the case. The Board after taking into consideration firm's compliance in the light of the verification by the panel, all the facts of the case and available record decided as under:-

> ***"The same panel will witness the destruction of the recalled stocks of the drug under reference i.e Phenergan Elixer Batch No.WL111 manufactured by Sanofi-Aventis Karachi. A report to this effect shall be submitted to the Directorate of Quality Assurance for its record".***

C. QUALITY ASSURANCE CASES (GMP)

Item No. I: Cases of Quality Assurance

Case No. 1:- M/s Dr. Sethi Pharma Industries, Chichawatni

Background:
On repeatedly anonymous complaints received in DRAP against M/s Dr. Sethi Pharma, Chichawatni, wherein, number of allegations was leveled against the company. It was decided to conduct inspection of the company.

Action taken by DRAP:

The inspection of the company was conducted was conducted by Mrs. Aisha Irfan, FID Lahore and Mr. Ajmal Sohail Asif, FID Lahore on 07.07.2014. The FID Lahore was asked to inspect the company at an odd hour without informing the company. The team of inspectors during inspection noticed that the firm was involved in the manufacturing of cosmetic products in the rooms located near to the main road. One of the rooms was approved as finished goods store of the firm. The inspectors sealed 07 rooms in the presence of the Chief Executive of the firm. The FID had seized some items on Form-2, under section 18 (1) (f) of the Drugs Act, 1976.

Previously, the FID Lahore Mr. Arif Ch had carried out inspection of the company on 23.05.2012, the FID in his inspection report wrote the following directions:

> *"No production activity is going on, general vocal was took with the management and certain suggestions were given. The detailed inspection for GMP will be conducted as and when the management resumes the production after completing the renovation".*

During this period i.e. from 23.05.2012 to 07.07.2014, no inspection report of the company has been found in the file.

Reply of the Company:

i) The Chief Executive of the company M/s Dr. Sethi Pharma, Chichawatni, submitted that the Central Licensing Board had not issued any show cause notice since May 2012 to date and no personal hearing was granted. The office of FID Lahore was visited few times and a letter was written to the FID for re-inspection but the inspection was not carried out till 07.07.2014. This inspection was made only on the compliant of their competitor i.e. M/s Arson Pharma, Lahore, the compliant M/s Arson, Lahore was found wrong. The CEO of M/s Dr. Sethi Pharma pleaded that the order of stop production are not in consonance of Drugs Act, 1976 and are not issued by the CLB.

ii) The Chief Executive of the firm has further submitted that they were not aware about the law position regarding the whole land of 10 kanal is considered to the pharmaceutical firm. They claim that they were not aware the tenant was using the rooms for keeping the cosmetic products. The Chief Executive of the firm assured that they will be careful in

future and requested for de-sealing of the room so the renovation and up-gradation could be possible.

i) M/s Dr. Sethi Pharma, Chichawatni further stated that the panel of inspectors has reported that the complaint of M/s Arson, Lahore was not in order and no product resembling to their company was present in their premises and manufactured by them.

ii) The inspection team visited all the room on 07.07.2014, they have not noticed contravention of cGMP in the production blocks.

The case is placed before CLB for its consideration and decision, and the representative of the firm has been called for personal hearing, please.

Proceedings:

The firm was called for personal hearing on 01.10.2014 and the case was placed before CLB in its 237th meeting. Mr. Dur Muhammad, General Manager of the firm and Hafiz Anwar ul Haq, Manager, Regulatory Affairs were appeared before the Board wherein they admitted that the manufacturing of registered products and other products were being done in the premises surrounded by the same wall. They submitted their apology to the Board and requested to de-seal the area with the assurance that in future such practices will not be repeated.

The opinion of all three stakeholders i.e. PPMA, Pharma Bureau and PCDA were taken and they were unanimously in the view that this violation is very serious and appropriate action has to be taken.

Decision of CLB:

The Board after through deliberation, keeping in views the facts on record and hearing the views of firm's representatives decided as follows:

1. ***The Drug Manufacturing License (DML) of the firm is suspended for three months with immediate effect.***
2. ***The same panel shall visit along with Chairman, Quality Control, Islamabad to make the inventory of the seized goods and will report within one month. The report will be presented before the next meeting of Central Licensing Board.***

Case No. 2: 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 in 235th meeting of Central Licensing Board held on 15.05.2014 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.***

The case was again placed before CLB for its consideration and decision, and the representative of the firm was called for personal hearing, please.

Proceedings:

The firm was called for personal hearing on 01.10.2014 and the case was placed before CLB in its 237th meeting. Mr. Naushad Akhai, Director of the company sent an email in which he informed that he is under treatment in USA. His treatment of Cholecystitis is under process. He cannot reach Pakistan to appear before the Board. He requested for grace period for re-inspection of his factory as he is not in position to travel.

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 the email of firm's representative decided as follows:

1. ***The License of the firm is suspended for three months as the firm has been served show cause notice which was not replied.***
2. ***Taking into consideration the report of the panel and also information provided by the Chief Drugs Inspector, Sindh (Member CLB) that the company when it was visited always gave a deserted look and only a family of Chowkidar was living there. However, the Owner/CEO of the company Mr. Naushad Akhai has given the one or other reasons at two different times through email with the excuse of illness for not appearing before the Board for personal hearing.***
3. ***Final notice be sent to the Owner that in case if personal appearance will not be made by CEO/Owner or through legal representative before the CLB in the next meeting, the Board may cancel the License.***

Case No. 3:- **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.

Reply of the firm:

The representative of the firm had informed that they are ready for inspection. Subsequently, the case was again placed before the Central Licensing Board in its 235th meeting held on 15.05.2014.

Decision of CLB in its 235th meeting held on 15.05.2014:

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.

Current Position:

The inspection of the firm was conducted on 23.07.2014 by above mentioned panel wherein the panel concluded as under:

> *"The panel has observed that the firm has done improvements and rectified most of the deficiencies pointed out in previous GMP inspection, however, overall GMP will be checked when the operation of the firm starts, during active production by the Federal Inspector of Drugs. Meanwhile, the panel recommends to resume the production activities of 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 resumption of production of M/s British Pharma, Lahore is allowed.***

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

Case No. 4:- **M/s Epharm Laboratories, Karachi**

A panel comprising DDG (E&M), Karachi, Mr. Tanveer Alam, FID Karachi, Dr. Najam-us-Saquib, and ADC Karachi, Mrs. Ume-Laila inspected M/s Epharm Lab, Karachi on **30.01.2014** with reference to a complaint regarding manufacturing of injection products. The panel had stopped production on witnessing that the firm was involved manufacturing of substandard Injection "D-Dron (Dexamethasone) 1m/IV Batch No. DF137, DF 134, DF 138, DF 139. M/s Epharm Lab, Karachi was directed to recall all the substandard batches from the market/institutions. The team has so far not informed the out of their own order of recall to DRAP.

A follow up inspection of the firm was conducted after approx one and half month on **19.03.2014** by the same panel. The panel in their report informed that the order of stop production is withdrawn automatically, because the firm has made improvements since its previous inspection. This was an interim upgradation report and the panel was of the opinion that the management can resume the pilot trial batches production in the liquid injectable section that were ordered to shut down during the previous visit, that is now automatically void under the rules.

A third inspection of the firm was also reported by the panel after two months on **08.05.2014** in continuation of previous inspection conducted on 19.03.2014 wherein the panel concluded that they believe that firm's management has upgraded the liquid injectable area and replaced the manufacturing facility with new one and strengthened the QA & QC system. **The panel recommended for resumption of production in liquid injectable section that was ordered in previous visit.** The panel claimed that stoppage of production has already become void under the rules and the firm may be officially allowed to resume the production.

The case was placed before CLB for its consideration and decision.

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 case has been deferred by the Board and directed the QC Section to process the case of substandard batches of D-Dron (Dexamethasone) for placing in upcoming meeting of Drug Registration Board (DRB).***

2. ***The panel should not have permitted to resume the production at their own, however, such practices should be avoided in future..***

Case No. 5:- **M/s Pfizer Pakistan Ltd, Karachi**

Background of the Case: The inspection of M/s Pfizer Pakistan, Karachi was advised for new psychotropic section by CLB through a large team of experts. The inspection was conducted on 20.01.2014 As an outcome of inspection, two inspection reports were generated, one by the area FID, Mrs. Muneeza Khan and other by Dr. Saif-ur-Rehman Khattak, Director CDL Karachi, whereas, Mrs. Ume Laila had signed on both the reports. One of the CLB members, Syed Muid Ahmad abstained and did not sign on either of the report. The report written by Dr. Saif-ur-Rehman Khattak, Director CDL, Karachi and Mr. Abdul Rasool Shaikh, FID Karachi had also made number of accusation against Mrs. Muneeza Khan.

Action Taken by DRAP: A Fact Finding Committee (FFC) of the following officers was constituted by the CEO, DRAP:

i) Mr. Asif Ruaf, Federal Inspector of Drugs, Lahore
ii) Syed Muid Ahmad, Member, Central Licensing Board

Conclusion/Recommendation of FFC: The FFC recommends to adopt a homogenized, non discriminatory and uniform criteria to follow for the inspections. For this purpose the specific proformas for each manufacturing sections is highlighting the provision, facility and availability of prerequisite and critical parameter/minimum compliance level for licensing etc. be devised to minimize the personal discretion and accordingly eliminate misuse of authority by any one. The proforma should be scored base and objectively devised.

- SOPs be developed and circulate for report writing after panel inspection any difference of opinion if any should be a part of the panel report.
- The DRAP office Karachi should be fully operational in terms of proper chain of command. As the issue under question should be a part of the panel report.
- TNA (train needs assessment) should be a regular and permanent feature of DRAP in order to assess and address the interpersonal relationships and behavioral aspect of officers as per latest management guidelines.
- Continuous education and regular monitoring may be made part of QA system for all officers.
- Station Incharge be effectively operationlized and made part of respective Board's meetings to discuss monitoring/performance evaluation of office under his jurisdiction.

The case was placed before CLB for information and further necessary action, 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. ***The Board advised that in future TORs of such committees should be well defined.***

Agenda Item-III (Additional Agenda)

Case No. 6: 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.

Decision of CLB:

The case was placed before the Central Licensing Board in its 235th meeting held on 15.05.2014 for consideration, the Board after thorough discussion and keeping the facts on records had 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.*

Present Position:

M/s Safina Pharmaceutical (Pvt) Ltd, Lahore conducted on 19.09.2014 by Mrs. Aisha Irfan in her inspection with reference to witness the destruction of 1300 bottles of S-xime suspension 100 mg/ 5ml (cefexime) by the firm and to verify the improvements made by the firm in cream/ointment and Cephalosporin section. The FID confirmed the destruction of above 1300 bottles bearing B. No. SX0495 and concluded as under**:**

> *"Keeping in view the observations and improvements done by the firm, it is **recommended that cream/ointment and cephalosporin sections** may be allowed".*

	Panel inspection dated 16.04.2014	**FID Inspection dated 19-09-2014**
Purpose	To verify improvements	Routine and witness of destruction
Cephalosporin Section	The cephalosporin section was not checked as on the day of inspection due to short circuiting of wires of split air conditioner caught fire. However, the firm immediately took safety measure and extinguished the fire. However, due to smoke the whole section turned black and some places false ceiling was also melted. No casualty was reported. The firm was asked to improve the condition of fluidized bed dryer.	➢ The Cephalosporin Section is situated in a separate building. Executive/workers entries provided. Air supply has been given in the entry. Changing facility was provided. ➢ In the Cephalosporin dry powder suspension/capsule areas, necessary machinery was installed. HVAC system was installed firm was however asked to validate the system in future. Overall the firm has maintained the area
Cream Ointment Section	In cream/ointment section necessary machineries such as steam jacket mixer was installed and functional. HVAC system was also functional. The R.O water treatment plant was out of order and needed upgradation. Installation of supply line of R.O water is also required in the section.	In Cream/ointment section necessary machinery was installed such as steam jacketed vessel. R.O water treatment supply has been provided as directed by the panel in previous inspection. HVAC system was functional and the area was maintained.
Conclusion	Keeping in view, findings of inspection, the panel recommends that the firm may be allowed to resume the production in general tablets and general antibiotic tablets sections only. The reinspection of the firm will be conducted after the firm submits compliance of the deficiencies pointed out in cream/ointment and cephalosporin sections.	*Keeping in view the observations and improvements done by the firm, it is* ***recommended that cream/ointment and cephalosporin sections*** *may be allowed.*

The case was placed before CLB for its consideration and decision.

<u>Decision of CLB</u>:

The CLB decided that the resumption will be considered after the panel inspection.

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