DIVISION OF DRUG LICENSING
DRUG REGULATORY AUTHORITY OF PAKISTAN
ISLAMABAD
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MINUTES OF 240th MEETING OF CENTRAL LICENSING BOARD HELD ON FRIDAY, 6th MARCH, 2015

240th meeting of the Central Licensing Board (CLB) was held on Friday, 6th March, 2015 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 Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Mr. A.Q Javed Iqbal, Director (QA/LT), 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. Afrasiyab Khan, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa.	Member
4.	Mr. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh.	Member
5.	Mr. Zaka-ur-Rehman, Chief Drug Controller, Department of Health, Govt. of Punjab.	Member
6.	Mr. Khurram Shahzad Mughal, Assistant Consultant as representative of M/o Law, Justice and Human Rights, Islamabad.	Member
7.	Dr. Ikram-ul-Haq, QC/QA Expert	Member
8.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
9.	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
10.	Prof. Dr. Gul Majeed Khan, Professor of Pharmacy	Member
11.	Prof. Dr. Muhammad Saeed, Professor of Pharmacy	Member
12.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
13.	Mr. Ehsan Awan & Mr. Khalid Munir, Representatives of PPMA	Observer
14.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
15.	Mr. Shahzad H Chowdhary , representative of PCDA	Observer

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

The Chairman apprised the members of the Board that proceedings of CLB shall be conducted in an amicable and responsible way to deliver to the public and stake holders in a transparent and efficient manner. Quality shall be given priority and there shall be zero tolerance. He further added that all the legal and codal formalities regarding convening of the meeting have been fulfilled. Mr. Ahmed Mehmood Mumtaz (CQC), Mr. Adnan Faisal Saim DDC (QA) & Mr. Salateen Waseem Philip ADC/DDC (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

During the proceedings of the meeting, newly appointed CEO DRAP, Dr. Muhammad Aslam Afghani jointed the meeting for introduction with members of the Board. The Chairman CLB and all members welcomed him. The CEO DRAP appreciated the services/technical inputs of all members rendering during CLB meetings for ultimate benefit of the patients. At the end he thanked all members for sparing time for public health cause. The Chairman and members also thanked him.

A. LICENSING DIVISION

Item-I **CONFIRMATION OF THE MINUTES OF 239th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of 239th meeting held on 22nd January, 2015.

Item-II: **(DEFERRED CASES OF 239TH MEETING OF CLB)**

Central Licensing Board in its 239th meeting held on 22nd January 2015 deferred the following cases for discussion in next meeting of CLB due to paucity of time. The Board considered the said cases and decided as under: -

A. GRANT OF ADDITIONAL SECTIONS/EXPANSION/AMENDMENTS ETC.

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 Weather Folds Pharmaceutical 69/2, Phase-II, Industrial Estate, Hattar.**	DML No.000644 (Formulation)	**The Board approved the grant of additional sections as under:-** **Section (04)** 1. Dry Powder Injection (General) 2. Liquid Injection Ampoule (General) 3. Liquid Syrup (General) 4. Sachet (General)
2.	**M/s Lotus Pharmaceuticals (Pvt.) Ltd. Plot No.118-A, Street No.8, Sector I-10/3, Industrial Area, Islamabad.** **Section (02)** 1. Dry Powder Injectable (Cephalosporin) 2. Oral Powder (Cephalosporin)	DML No.000661 (Formulation)	**Board deferred the grant of additional sections and decided for re-inspection when firm is ready and applies in writing accordingly.** **The Board expressed its displeasure that firm despite formally applying, was not ready for inspection as reported by the panel in its report.**

3.	**M/s Ardin Pharmaceuticals. Plot # 56, Sector 27, Korangi Industrial Area, Karachi**	DML No. 000154 (Formulation)	**The Board approved the grant of additional sections as under:-** **Sections (02)** 1. Capsule (General) 2. Cream /Ointment /Gel (General)
4.	**M/s. Medicaids Pakistan (Pvt.) Ltd, Plot # 10, Sector 27, Korangi Industrial Area, Karachi**	DML NO. 000139 (Formulation)	**The Board approved the amendment / re-shuffling of following existing sections as under:-** **Sections (06)** 1. Capsule (General) 2. Liquid Syrup (General) 3. Capsule (Cephalosporin) 4. Oral Dry Powder Cephalosporin) 5. Dry Powder Injectable (Cephalosporin) 6. Tablet (Cephalosporin)

B. GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE

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

S #	Name of the firm	Type of License	Decision of CLB
1.	**M/s. Rehman Rainbow (Pvt) Ltd. 82-KM, Industrial Estate, Kot Lakhpat, Lahore.** **Renewal Period** **18-06-2013 to 17-06-2018**	**DML No.000510 (Formulation)**	**Approved the Grant of Renewal of DML for following sections:** 1. Gauze Section. 2. Bandage Section. 3. Medicated Dressing Section. 4. Cotton Section. 5. Disposable syringes.
2.	**M/s Lotus Pharmaceutical plot No.18-A, Street No.8, Sector I-10/3, Islamabad.** **Renewal period** **17-06-2014 to 16-06-2019**	DML No.000661 (Formulation)	**Approved the Grant of Renewal of DML for following sections:** 1. Tablet (General) 2. Capsule (General) 3. Dry Powder for Suspension (General) 4. Liquid Syrup

3.	**M/s Medicaids Pakistan (Pvt.) Ltd, Plot # 10, Sector 27, Korangi Industrial Area, Karachi.** **Renewal Period** **25-11-2014 to 24-11-2019**	**DML NO. 000139 (Formulation)**	**Approved the Grant of Renewal of DML for following sections:** 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup 4. Capsule (Cephalosporin) 5. Tablet (Cephalosporin) 6. Oral Dry Powder Suspension (Cephalosporin) 7. Dry Powder Injection (Cephalosporin) 8. Sterile Ophthalmic Eye Drops (General) 9. Sterile Liquid Ampoule Injection (General)
4.	**M/s Ardin Pharmaceuticals, Plot # 56, Sector 27, Korangi Industrial Area, Karachi.** **Renewal Period** **08-04-2015 to 07-04-2019**	**DML NO. 000154 (Formulation)**	**Approved the Grant of Renewal of DML for following sections:** **1.** Tablet (General) **2.** Liquid Syrup **Board also allowed the resumption of production of the firm on recommendations of panel of experts as the manufacturing operations were voluntarily stopped by the firm itself for improvement of GMP compliance.**

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

The Board considered the following cases of grant of new drug manufacturing licenses in the light of recommendations of 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 Linta Pharmaceuticals (Pvt.) Ltd, Plot No. 3, Street No. S-5, RCCI, Rawat, Rawalpindi.	**30-01-2015 (Formulation)**	**Approved the grant of DML with following six sections:** **Sections (06):** 1. Tablet (General) 2. Capsule (General) 3. Sachet (General) 4. Cream / Ointment / Gel (General). 5. Oral Dry Powder Suspension (Cephalosporin) 6. Capsule (Cephalosporin)
2.	M/s. Ciba Pharmaceuticals (Pvt.) Ltd, A-371, S.I.T.E, Nooriabad, Main Super Highway, Karachi.	**03-04-2015 (Formulation)**	**Approved the grant of DML subject to change of name of firm with following six sections:** **Sections (06):** 1. Tablet (General) 2. Capsule (General) 3. Oral Dry Powder Suspension (General) 4. Sachet Section (General) 5. Cream / Ointment/ Gel (General) 6. Cream / Ointment / Gel (Steroidal) **The firm shall be asked to change its name as it resembles with some existing international pharmaceutical companies.** **The Board authorized the Chairman to dispose-off the case accordingly.** **The Board did not approve ear / eye drops as same was not ready.**
3.	M/s ICI Pakistan Limited, Life Sciences, 45-km, Off Multan Road, Lahore.	**03-03-2015 (Formulation)**	**Approved the grant of DML with following two sections:** **Sections (02):** 1. Veterinary Oral Dry Powder (General) 2. Veterinary Oral Liquid (General)

4.	M/s Bio-Oxime Pharmaceuticals. Plot # 31,32, Millat Garment City, Dry Port Road, Faisalabad.	**03-03-2015 (Formulation)**	**Approved the grant of DML with following two sections:** **Sections (02):** 1. Veterinary Oral Liquid (General) 2. Veterinary Oral Powder (General)

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

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

S #	Name of the firm	Type of License	Decision of CLB
1.	**M/s Genome Pharmaceuticals (Pvt) Ltd, 16/1, Phase-IV, Industrial Estate, Hattar.**	**DML No.000454 (Formulation)**	**The Board approved the grant of additional section and amendment in layout plan as under:-** **New Section (01)** 1. Sachet (General) **(Amendments in layout plan of existing section)** 1. Quality Control Laboratory
2.	**M/s. Fizi Pharmaceutical & Chemical Laboratories, 8-KM Raiwind Road, Lahore.** **Sections (03):** 1. General Veterinary vials Injectable section (being developed in place of existing haemodialysis section). 2. General Veterinary Powder (being developed in place of existing haemodialysis section). 3. Veterinary Liquid section (expansion)	DML No.000732 (Formulation)	**Board deferred the grant of additional sections and decided for re-inspection as and when firm will be ready and applies in writing accordingly.** **The Board expressed its displeasure that firm despite formally applying, was not ready for inspection as reported by the panel in its report.**

3.	**M/s Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road, Islamabad.**	DML No. 000439 (Formulation)	**The Board approved the grant of additional sections and amendment of layout plan of existing sections as under:-** **<u>New Sections (02):</u>** 1. Oral Dry Powder Suspension (General) 2. Tablet Cephalosporin **<u>Amendments in layout plans of Existing sections (04)</u>** 1. Capsule (General) 2. Oral Liquid (General) 3. Capsule (Cephalosporin) 4. Oral Dry Powder Suspension (Cephalosporin)
4.	**M/s Rasco Pharma 5.5 km, Near Ali Raza Abad, Holiday Park, Plot # 27, Raiwind Road, Lahore.**	DML No. 000530 (Formulation)	**The Board approved the grant of additional section as under:-** **<u>Section (01):</u>** 1. Liquid Injection Ampoule (General) [Filling of one dosage form i.e. ampoule or vials at one time]
5.	**M/s Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.**	DML No. 000517 (Formulation)	**The Board approved the grant of additional sections as under:-** **<u>Sections (06):</u>** 1. Tablet (General) 2. Capsule (General) 3. Small Volume Parenterals (Blow Fill Seal Technology) 4. Oral Dry Powder Suspension (General) 5. Sterile Dry Powder Injectable Vials (General) 6. Sachet (General) **The Board also approved the change of name of Large Volume & Small Volume Parenterals Section to Large Volume Parenterals Section**
6.	**M/s Ferozesons Laboratories Ltd, Amargarh, Nowshera.**	DML No. 000038 (Formulation)	**The Board approved the grant of additional section as under:-** **<u>Section (01):</u>** 1. Tablet (General)

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

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

S #	Name of the firm	Type of License	Decision of CLB
1.	**M/s Astellas Pharmaceutical (Pvt) Ltd, 15-C, Industrial Estate, Hayatabad, Peshawar.** DML No.000677 (Formulation)	DML No.000677 (Formulation)	**Approved the Grant of Renewal of DML for following sections:** 1. Dry Powder injection (Cephalosporin) 2. Capsule (Cephalosporin) 3. Dry Powder for Suspension (Cephalosporin)
2.	**M/s Noa Hemis Pharmaceutical, Plot No.154, Sector 23, Korangi Industrial Area, Karachi.**	DML No.000525 (Formulation)	**Approved the Grant of Renewal of DML** The Board was apprised that the firm possesses the following sections, however firm does not possess the formal letter from CLB of these sections: 1. Tablet (General) 2. Capsule (General) 3. Tablet (Antibiotics) 4. Capsule (Antibiotics) 5. Powder & Granules (Sachet) 6. Cream/Ointment - General 7. Cream/Ointment (Steroidal) 8. Oral Liquid (Syrup/Suspension) 9. Veterinary (Dry Powder General) 10. Veterinary (Dry Powder Antibiotic) 11. Veterinary (oral/syrup liquid) **The Board decided that the firm be directed to get regularized the master layout plan of these sections for obtaining formal letter of above sections.**

3.	**M/s Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road, Islamabad.**	DML No. 000439 (Formulation)	**Approved the Grant of Renewal of DML for following sections:** 1. Capsule General 2. Oral Liquid General 3. Oral Dry Powder Suspension (Cephalosporin) 4. Capsule (Cephalosporin) The Board was apprised that the firm possesses the following sections, however firm does not possess the formal letter from CLB of these sections: 1. Tablet (General) 2. Cream/Ointment - General **The Board decided that the firm be directed to get regularized the master layout plan of these sections for obtaining formal letter of above sections.**
4.	M/s Florence Farmaceuticals (Pvt.) Ltd, Plot # 266, Industrial Triangle, Kahuta Road, Islamabad **Renewal period 18-06-2013 to 17-06-2018**	DML No.000635 (Formulation)	**Approved the Grant of Renewal of DML for following sections:** 1. Capsule (Cephalosporin) 2. Oral Dry Powder Suspension (Cephalosporin) 3. Dry Powder Injectable (Cephalosporin)
5.	**M/s Shawan Pharmaceutcials Plot # 37, Road NS-1, National Industrial Zone, Rawat, Rawalpindi.** **Renewal period : 19-06-2013 to 18-06-2018**	**DML No. 000627 (Formulation)**	**In the light of following observations made during the inspection by the panel, the Board suspended the manufacturing operations in all areas of the premises for a period of three months under Rule 13 of Drugs (Licensing, Registering and Advertising) Rules, 1976 and directed the firm to rectify the observations made during inspection by the panel.**
	Details of observations are as under:- **General Area:-** i. Proper facility need to be developed for the Production of photosensitive products like mecobalamine. ii. Area needs up-gradation with prosper validation of production area, QC and HVAC system.		

iii. Sitting chair in the packing hall need to be replaced with new chair, having back rest.
iv. Energy savors installed in the ware houses, which must be replaced with concealed lights.
v. The technical staff is advised to pre-qualify at least three vendors, for each active and excipients, for the smooth and reliable supply of raw materials.

Sterile area:

i. Stay placed found in the vial filing and sealing area, which need to be removed.
ii. Manual double pass window is installed in the vial washing area, which needs to be replaced with automatic pass window.
iii. Covering need to be done in the corners of sterile area.
iv. Walls, floor and roof top of the sterile area need to be smooth.
v. Facility of double distilled water need to be provided in the vial washing.
vi. Final finishing of vials need to be done with double distilled water.
vii. SOPs of vial washing need to be revised.
viii. Distillation assembly need to be installed with double pass RO water treatment plant and supply of water in the vial washing area shall be through loops system.
ix. During visit, humidity of cephalosporin manufacturing area and ware houses found on higher side.
x. Validation of HVAC needs to be done in the cephalosporin area, which are moisture sensitive products.
xi. SOP for optical checking need to be revised and it must be implemented in its true spirit.
xii. Validation of official parameters.

QC Lab: -

i. Testing methods and SOPs of all the products need to be revised as per specifications.
ii. Validation of testing methods needs to be done, as per specification.
iii. Microbiologist was newly appointed and has no idea about the working of microbiology lab. Job specific training of microbiologist is necessary to run the microbiology lab.
iv. Microbiologist is advised to switch over to chromogenic method for endotoxin testing for the accuracy of results.
v. Microbiological testing SOPs need to be revised.
vi. Polarimeter is not available in the lab, which needs to be purchased.
vii. Energy savors installed in the microbiology which should be replaced with concealed lights.
viii. Stability chamber was out of order at the time of inspection. This needs to be repaired on urgent basis.
ix. The technical staff was advised to perform long term stability studies and accelerated stability studies on their registered products.
x. Lab need to be upgraded.
xi. Existing fume hood is not as per requirement, new fume hood need to be provided.
xii. Proper area need to be provided for the placement of acids and other hazardous liquids.
xiii. It was also advised that working standards for testing shall not be developed from the active ingredients being supplied by the suppliers of bulk materials.

QA Self Inspection & Training.

i. The management was advised to develop QA Department which shall be independent of the QC to counter verify the activities of both the production and quality control.
ii. Proper self-inspection / audit mechanism should be developed.
iii. There is lack of training / capacity building programs for both professional / working staff. The technical staff was advised to arrange training programs for the professionals and workers.

6.	**M/s. Renacon Pharma (Pvt) Ltd. 18-KM, Ferozepur Road, Opp. Nishter Colony, , Lahore.** **<u>Renewal Period</u>** **21-09-2010 to 20-09-2015**	DML No.000458 (Formulation)	The Board was apprised about the panel observations that the conditions of production at the present premises does not meet the requirement of GMP. The management of the firm be directed to shift their unit to a proper area and plant to be designed to fulfill the requirement of cGMP with the reference to S.R.O. 470(I)/98, dated 15-05-1998 and (Schedule-B) because the firm cannot maintain the cGMP standards at the present premises. The panel does not recommend the renewal of DML by way of formulation at the present premises. **The Board observed that the report of the panel was not clear and comprehensive and made it difficult to decide the case, so Board deferred for re-inspection by the following panel for clear and candid report:** **1. Dr. Ikram-ul-Haq Member, CLB** **2. Chief Drug Inspector, Member CLB** **3. Area FID, DRAP, Lahore.** **4. Ms. Aisha Irfan FID, DRAP, Lahore.** **The Board showed its displeasure on incomplete reporting by the panel of experts.**
7.	**M/s Murfy Pharmaceuticals, 8-KM, Raiwind Road, Lahore** **<u>Renewal Period</u>** **26-07-2014 to 25-07-2019**	DML No.000543 (Formulation)	**Approved the Grant of Renewal of DML for following sections:** 1. Tablet (General/Antibiotic) 2. Cream/Ointment/Gel (General/Antibiotic) 3. Capsule (General/Antibiotic) 4. Liquid Injectable Ampoule (General/Antibiotic)

ITEM NO. VI **MISCELLANEOUS CASES.**

1. **CHANGE OF MANAGEMENT OF M/S ARDIN PHARMACEUTICALS PLOT NO. 56, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI.**

The case was placed before the Board as under:

M/s Ardin Pharmaceuticals Plot No. 56, Sector 27, Korangi Industrial Area, Karachi DML NO. 000154 (Formulation) has submitted its application for change of management. The details of the directors of the firm are as under: -

Old Partners	Retiring Partner	New Partners
1. Mr. Muhammad Saeed Taqi S/O Muhammad Taqi Shaikh CNIC : 42301-6367050-3 Address: House No.58/2, 18th Lane Khayaban e badban, Phase-VII, Defense Housing Authority, Karachi. 2. Mr. Sheikh Shafiuddin CNIC : 42201-8957352-7 Address: House No. 95, Banlore Town, Karachi.	1. Mr. Sheikh Shafiuddin CNIC : 42201-8957352-7 Address: House No. 95, Banlore Town, Karachi. **(Retired)**	1. Mr. Muhammad Saeed Taqi S/O Muhammad Taqi Shaikh CNIC : 42301-6367050-3 Address: House No.58/2, 18th Lane Khayaban e badban, Phase-VII, Defense Housing Authority, Karachi. **(Same Partner)** 2. Mrs. Najma Saeed Taqi W/O Muhammad Saeed Taqi CNIC : 42201-8957352-7 Address: House No.58/2, 18th Lane Khayaban e Badban, Phase-VII, Defense Housing Authority, Karachi. **(New Partner)** 3. Ms. Noor Ul Huda D/o Muhammad Saeed Taqi CNIC : 42301-7761040-0 Address: House No.58/2, 18th Lane Khayaban e badban, Phase-VII, Defense Housing Authority, Karachi. CNIC: 35202-2041473-9 Address: 242- Sikandar Block, Allama Iqbal Town, Lahore.**(New Partner)**

The firm has submitted a prescribed fee of Rs.50,000/-, Sale deed, partnership deed, CNIC photocopies and certificate of registration with registrar of the firms. All the documents/information submitted by firm has been examined by Licensing Division, DRAP, Islamabad and found in order.

Decision of CLB

Keeping in view the facts on ground, the Board considered and approved the change of management of the firm from old partners to new partners as under:

Old Partners	New Partners
1. Mr. Muhammad Saeed Taqi S/O Muhammad Taqi Shaikh CNIC : 42301-6367050-3 Address: House No.58/2, 18th Lane Khayaban e badban, Phase-VII, Defense Housing Authority, Karachi. 2. Mr. Sheikh Shafiuddin CNIC : 42201-8957352-7 Address: House No. 95, Banlore Town, Karachi.	1. Mr. Muhammad Saeed Taqi S/O Muhammad Taqi Shaikh CNIC : 42301-6367050-3 Address: House No.58/2, 18th Lane Khayaban e badban, Phase-VII, Defense Housing Authority, Karachi. **(Same Partner)** 2. Mrs. Najma Saeed Taqi W/O Muhammad Saeed Taqi CNIC : 42201-8957352-7 Address: House No.58/2, 18th Lane Khayaban e Badban, Phase-VII, Defense Housing Authority, Karachi. **(New Partner)** 3. Ms. Noor Ul Huda D/o Muhammad Saeed Taqi CNIC : 42301-7761040-0 Address: House No.58/2, 18th Lane Khayaban e badban, Phase-VII, Defense Housing Authority, Karachi. CNIC: 35202-2041473-9 Address: 242- Sikandar Block, Allama Iqbal Town, Lahore.**(New Partner)**

2. **CHANGE OF MANAGEMENT OF M/s. BLOOM PHARMACEUTICALS (PVT) LTD, PLOT NO.30, PHASE-I&II, INDUSTRIAL ESTATE, HATTAR.**

The case was placed before the Board as under:

M/s. Bloom Pharmaceuticals (Pvt.) Ltd located at Plot # 30, Phase I & II, Industrial Estate, Hattar has requested for change of management.

The details of directors as per form 29 issued by Security Exchange Commission of Pakistan, are as under:-

Old Management as per Form 29 issued by SECP on 31-10-2013	**Retiring Directors**	**New Management as per Form 29 issued by SECP on 16-09-2014**
i) Mrs. Parveen Amjad Qureshi ii) Mrs. Zaib Un Nisa iii) Omer Khalid iv)Mrs. Sahiba Assad v) Faisal Saad vi)Mrs. Anjum Khalid i) Junaid Amjad ii) Rashid Asad vii) Saad Aziz	i) Omer Khalid – **Retired** ii) Mrs. Sahiba Assad – **Retired** iii) Faisal Saad – **Retired** iv)Mrs. Anjum Khalid -**Retired** iii) Junaid Amjad - **Retired** iv)Rashid Asad- **Retired** v) Saad Aziz - **Retired**	i) Mrs. Parveen Amjad Qureshi - **Same** ii) Mrs. Zaib Un Nisa - **Same** iii) Mr. Ahmad Raza - **NEW** iv)Sajid Zahoor – **New**

The firm has informed that one of the existing director/ chief executive officer i.e. Mr. Saad Aziz has been retired and new director Mr. Ahmad Raza, CNIC: 35202-8599970-7 residential address: Second floor, H#236, Mohalla Rewaz Garden, Lahore is chief Executive officer of firm

2. The firm has submitted documents/information as under:-

S #	**Documents**
01	Prescribed Fee of Rs 50,000/-
02	Minutes of meeting of Board of Directors
03	Form 29 Issued on 18-09-2014
04	Form A
05	Form 29 issued on 31-10-2013
06	Form A issued on 31-10-2013

3. Application for change in management of the firm is complete with all legal and codal formalities.

Decision of CLB

Keeping in view the facts on ground, the Board considered and approved the change of management of the firm from old management to new management as under:

Old Management	New Management
1. Mrs. Parveen Amjad Qureshi 2. Mrs. Zaib Un Nisa 3. Omer Khalid 4. Mrs. Sahiba Assad 5. Faisal Saad 6. Mrs. Anjum Khalid 7. Junaid Amjad 8. Rashid Asad 9. Saad Aziz	1. Mrs. Parveen Amjad Qureshi (CNIC No.32102-4340790-3) - **Same** 2. Mrs. Zaib Un Nisa (CNIC No.37405-9974325-8)- **Same** 3. Mr. Ahmad Raza (CNIC No. 35202-8599970-7)- **NEW** 4. Sajid Zahoor (CNIC No.37202-8075941-7)– **New**

3. **Case No.10 Application of M/s Abbott Laboratories Pakistan Ltd, Karachi for Cancellation of their DML (No. 000005 Basic Manufacture).**

The case was placed before the Board as under:

Brief Background:

The Central Licensing Board in its 232nd meeting discussed the case of M/s Abbott Laboratories Pakistan Ltd, Karachi for cancellation of their DML (000005) Basic Manufacture. After hearing the firm's representative Mr. Anis Shah, Director Plant Operation, and thorough discussion and deliberation among the members of the Board on the issue, the Central Licensing Board did not accede to the request of the firm for cancellation of their DML No. 000005 (Basic Manufacture) being indigenous API manufacturing unit. The following clarification from the firm and the Directorate of PE&R is awaited:

1. Documentary evidence supported by relevant documents / information mentioning that why this license has not been feasible to operate.
2. The drugs registration directorate shall be asked for clarification regarding approval of change of source of their Aluminum Hydroxide Gel for use in their registered products (i.e. Antacids like Dijex MP and Dijex).
3. The firm shall be asked to clarify that how the import of Aluminum Hydroxide Gels had been feasible in spite of enhanced duty structure where said API is approved for local production under the rules?
4. The firm shall also be asked how their Formulation Products are being manufactured if they have changed their source after closure of their facility?
5. Since, the representative of firm stated that they had been enhancing the capacity of this plant from 500 kg to 1000 kg in the past and now how this plant is suddenly unfeasible to run at once?
6. The Drug policy has given different incentives to basic / semi basic manufacture so the firm's request for cancellation of DML No. 000005 (basic manufacture) is absolutely illogical / irrational that tantamount to deprive this country from an API, being manufactured indigenously.

No clarification from the firm as well as from registration directorate received.

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

Board deferred the case till clarification/information by firm and Division of Pharmaceutical Evaluation & Research of DRAP.

Reply of M/s Abbott Laboratories Pakistan Ltd, Karachi

1. Basic manufacture of Aluminium Hydroxide Gel (AHG) was started by Boots Pakistan about 40 years ago. Initial installed capacity was 500 kg/day on two shift basis. Subsequently the capacity was enhanced to 1,000 kg/day in 1988. We started to face capacity constraint in 2005 which could not be overcome since the manufacturing process requires excessive quantity of water i.e. 23,000 liters to produce 1,000 kg of the material whereas water supply from the city government (Karachi Water & Sewerage Board) was significantly curtailed. Water quality from alternate source i.e. through private tankers was of inconsistent quality both from chemical and

microbiological purity perspective. This forced us to explore other sources of API supply as follows.

- Material from a local source had 6% lower potency, very short shelf life i.e. 10 days and very long lead time.
- Indian suppliers (Pharchem and Pradash) were qualified based on good quality, long shelf life (chemical 5 years; Microbiological 6 months) and competitive price.

Annual requirement of the API is 460,000 kg, going up to 650,000 kg by 2017. To meet this increasing demand, major capital investment to the tune of approx. Rs 400 million i.e. $3.7 million is required to build additional capacity. Detailed cost estimate for the project is enclosed. Annual import value for the material is just $300,000. Hence it is unviable to invest more than ten times the annual import cost of the API and while the depreciation expense of the upgrade will be $370,000 (i.e. 10% of the total investment per annum) which is even greater than the total annual cost of the API. Material, labour and other overheads will be in addition to this cost. Besides there is shortage of water supply to our plant and additional sanction of industrial natural gas load is nearly impossible to get.

2. We have valid Licenses to Import the API (copies enclosed).

3. There is no enhanced duty structure on the import of AHG. Its import is subject to 0% Import duty.

4. New sources have been qualified and the API is being imported under valid licenses for import.

5. It is unfeasible to run basic manufacturing due to scarcity of water, lack of additional sanction of natural gas load for heating requirements for the chemical reaction and $3.7 million to upgrade and enhance capacity.

6. We have neither been given nor availed any incentives under the Drug Policy for Basic Manufacture.

We would like to add that Aluminium Hydroxide Gel is used for the manufacture of OTC products whereas earlier several institutions/companies have discontinued basic manufacture of life saving APIs both in Public and Private sector e.g.

- Antibiotics Private Limited (prestigious penicillin fermentation plant)
- Kurram Chemicals
- Marker Alkaloids
- Glaxo (cephalosporins, steroids, antifungals, ranitidine etc.)
- Askari Pharmaceuticals and Himont discontinued basic manufacture

Hence we are not the only ones to request such cancellation rather several other examples of APIs of even lifesaving drugs, as mentioned above do exist.

Abbott Pakistan has major stakes in Pakistan and has made significant investment of more than $20.5 million in various projects during last four years and more than $10.2 million is approved

for investment in 2014. The investment has been made in cGMP improvements, capacity enhancement, energy, EHS etc.

In the light of above facts, figures and previous precedence, as specified above, we would again request the honorable board to approve cancellation of DML No. 000005 which covers manufacture of an OTC medicine (Aluminum hydroxide). Meanwhile we will continue to manufacture and supply all the SKUs of Dijex / Dijex MP, manufactured with the imported API and make them freely available in the market at the affordable price for the benefit of the patients.

Reply of Division of Pharmaceutical Evaluation & Registration

As per copies of registration letter available in record of registration section Dijex MP Syrup were registered for M/s. Boots, Karachi and letter does not contain any source of Aluminum Hydroxide Gel.

Decision of CLB:

Keeping in view the aforesaid submission and request of firm and information provided by Division of Pharmaceutical Evaluation & Registration and facts on ground; the Board discussed the case thoroughly and unanimously decided and canceled the Drug Manufacturing License No. 000005 by way of Basic Manufacture.

4. **CHANGE OF NAME / STATUS OF M/S ROTEXMEDICA PAKISTAN PVT LTD, PLOT NO. 206-207, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

The case was placed before the Board as under:

M/s. Rotexmedica Pakistan Pvt Ltd., plot NO. 206-207, Industrial Triangle, Kahuta Road, Islamabad have requested for change of name and status of their firm from:

M/s Rotexmedica Pakistan (Pvt.) Ltd

to

M/s Rotex Pharma (Pvt.) Ltd.

The firm has submitted following documents / information issued by Security Exchange Commission of Pakistan for change of name of the firm as under:-

S #	Documents
01	Certificate of Incorporation
02	Form A
03	Form 29
04	Memorandum of Association

02. There is no change in the management and the directors of the firm are same as at time of grant of DML.

Decision of CLB:

The Board considered and approved the change of name and status of the firm from M/s. Rotexmedica Pakistan (Pvt.) Ltd to M/s. Rotex Pharma (Pvt.) Ltd.

5. **Change of name and management of M/s. Johnson & Johnson Pakistan Pvt Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi DML NO. 000054 (Basic Manufacture) & DML NO. 000045 (Formulation)**

The case was placed before the Board as under:

M/s. Aspin Pharma (Pvt) Ltd., Karachi have submitted an application in Licensing Division and informed that they have purchased licensed pharmaceutical units of M/s Johnson & Johnson Pakistan Pvt Ltd located at Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi (DML NO. 000054 - Basic Manufacture) & (DML No. 000045 - Formulation) and requested for change of name and management of the firm as under:-

From (existing name)	To (proposed name)
M/s Johnson & Johnson Pakistan (Pvt.) Ltd	M/s Aspin Pharma (Pvt.) Ltd

The details of the directors of previous and new management of the licensed premises are as under:-

Previous management of M/s Johnsons & Johnson Pakistan (Pvt.) Ltd	New management of M/s Aspin Pharma (Pvt.) Ltd
i) Farrukh Fayyaz ii) Michael Del Prado iii) John T Crisan iv) Qamar Hussain Khan (Alternate to John T Crisan)	i) Mr. Tariq Moinuddin Khan S/o Mr. Khawaja Moinuddin Khan **(CEO)** CNIC :423010-725070-1 Present Address: 715 Mitchell Avenue Town of Montroyal Montreal, H4 P1 C9, Quebec , Canada Permanent Address: 16 Khayaban E Amir Khusro DHA Phase 6, Karachi, The & Distt Karachi South Pakistan. ii) Mrs. Adeela Tarek W/o Tareq Moinuddin Khan CNIC: 423010-683642-2 Present Address: 715 Mitchell Avenue Town of Montroyal Montreal, H4 P1 C9, Quebec , Canada Permanent Address: 16 Khayaban E Amir Khusro DHA Phase 6, Karachi, The & Distt Karachi South Pakistan iii) Mr. Syed Zeeshan Mohsin S/o Mr Syed Mobin Shaukat CNIC: 42301-6467474-3 Permanent address: House No. 64/1, Lane 12, Phase 7, DHA, Karachi

It is further submitted that M/s Aspin Pharma (Pvt.) Ltd., and M/s OBS Pakistan (Pvt.) Ltd are sister concern companies and they have jointly purchased the licensed pharmaceutical units including all assets/liabilities of the premises including equipment / machinery etc.

The management of M/s Aspin Pharma (Pvt.) Ltd., and M/s OBS Pakistan (Pvt.) Ltd is same as mentioned under: -

1. Mr. Tariq Moinuddin Khan S/o Mr. Khawaja Moinuddin Khan **(CEO)**
   CNIC :423010-725070-1
   Present Address: 715 Mitchell Avenue Town of Montroyal Montreal, H4 P1 C9, Quebec , Canada
   Permanent Address: 16 Khayaban E Amir Khusro DHA Phase 6, Karachi, The & Distt Karachi South Pakistan

2. Mrs. Adeela Tarek W/o Tareq Moinuddin Khan
   CNIC: 423010-683642-2
   Present Address: 715 Mitchell Avenue Town of Montroyal Montreal, H4 P1 C9, Quebec , Canada
   Permanent Address: 16 Khayaban E Amir Khusro DHA Phase 6, Karachi, The & Distt Karachi South Pakistan

3. Mr. Syed Zeeshan Mohsin S/o Mr Syed Mobin Shaukat
   CNIC: 42301-6467474-3
   Permanent address: House No. 64/1, Lane 12, Phase 7, DHA, Karachi.

M/s. OBS Pakistan (Pvt) Ltd have authorized to M/s Aspin Pharma (Pvt) Ltd to get the name and management change in their name. M/s. OBS Pakistan (Private) Limited have issued its NOC in favor of M/s Aspin Pharma (Pvt) Ltd accordingly.

The Chief Executive Officer and principal office of M/s Aspin Pharma (Pvt) Ltd and M/s OBS Pakistan (Private) Limited is same and as under:-

Office at 91 Shahrah-e-Iran, Block 5, Clifton , Karachi

The documents / information submitted are as under:-

i) Prescribed fee of Rs. 1,00,000/-
ii) Memorandum of Association, Form 29, Form A, Form 21 and Certificate of Incorporation, issued by Security Exchange Commission of Pakistan
iii) Sale agreement / asset purchase agreement between the two parties.

M/s Johnson & Johnson Pakistan Pvt Ltd, Karachi have also issued NOC in favor of M/s. Aspin (Pvt) Ltd., for the change of management and name as mentioned above.

Decision of CLB:

Keeping in view the available record and facts on ground, the Board considered and approved the change of name of firm from M/s Johnson & Johnson Pakistan (Pvt.) Ltd to M/s Aspin Pharma (Pvt.) Ltd for both Drug Manufacturing Licenses i.e. (DML No. 000054 - Basic Manufacture) & (DML No. 000045 - Formulation) located at Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi.

The Board also approved the change of management of the above both licensed units / firms from old management to new management as under: -

Previous management of M/s Johnsons & Johnson Pakistan (Pvt.) Ltd for (DML No.000054 - Basic Manufacture) & (DML No. 000045 - Formulation)	**New management of M/s Aspin Pharma (Pvt.) Ltd for (DML No. 000054 - Basic Manufacture) & (DML No. 000045 - Formulation)**
1. Farrukh Fayyaz 2. Michael Del Prado 3. John T Crisan 4. Qamar Hussain Khan (Alternate to John T Crisan)	1. Mr. Tariq Moinuddin Khan S/o Mr. Khawaja Moinuddin Khan **(CEO)** CNIC :423010-725070-1 Present Address: 715 Mitchell Avenue Town of Montroyal Montreal, H4 P1 C9, Quebec , Canada Permanent Address: 16 Khayaban E Amir Khusro DHA Phase 6, Karachi, The & Distt Karachi South Pakistan 2. Mrs. Adeela Tarek W/o Tareq Moinuddin Khan CNIC: 423010-683642-2 Present Address: 715 Mitchell Avenue Town of Montroyal Montreal, H4 P1 C9, Quebec , Canada Permanent Address: 16 Khayaban E Amir Khusro DHA Phase 6, Karachi, The & Distt Karachi South Pakistan 3. Mr. Syed Zeeshan Mohsin S/o Mr Syed Mobin Shaukat CNIC: 42301-6467474-3 Permanent address: House No. 64/1, Lane 12, Phase 7, DHA, Karachi

6. **Discontinuation of Local Production Of Sutures Of M/S Johnson & Johnson Pakistan (Pvt) Ltd, Plot No.10 & 25, Sector 20, Korangi Industrial Area, Karachi DML NO. 000045 (FORMULATION)**

The case was placed before the Board as under: -

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

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

3. Accordingly, case was submitted for consideration of the Board in its 236th meeting held on 27th June 2014.

Proceedings of the Board

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

Decision of the Board in its 236th meeting held on 27th June 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.**

4. Firm was then called for personal hearing in 237th meeting of CLB held on 01st October 2014 and case was discussed as under:-

Proceedings

Muhammad Arif Tahir Country Manager and Aasma Zuberi Regulatory Manger of M/s Johnson & Johnson appear 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 demand and keep available.
- They have already applied for registration for sutures so that there may be no shortage.
- They informed that they have stock of sutures upto October.

Chairman and members of the Board urged and emphasized not to close local unit in Pakistan and discuss the issue with their management.

Decision of CLB in its 237th meeting held on 01st October 2014

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

- (i) The company is directed to ensure the availability of alternative codes of sutures after registration and pricing.
- (ii) The Board unanimously requested to Division of PE&R for the registration of their alternative products on fast track basis.
- (iii) The company is advised to contact their Headquarter for transfer of technology in the larger public interest if possible.

5. In the reply of the firm with respect to para 4(i), they stated that they are fully committed to ensure uninterrupted supplies of ***"alternate codes of sutures"*** in the context and the spirit conveyed to them by the Honorable Board as soon as registration procedures are completed and Drug Registrations are formally granted to them for the alternate codes of sutures.

6. In the reply of the firm w.r.t para 4(ii), they stated that it would not be possible for their parent company to change the decision for discontinuation of local production for Ethicon sutures to the extent of Pakistan. They further stated that transfer of technology at this stage may not be feasible, commercially viable and compatible with the scope of current business model to ensure supply of same high quality products worldwide including Pakistan.

Decision of CLB:

After thorough discussion and keeping in view the submission of firm and facts on ground, the Board considered and approved the discontinuation of local production of sutures by M/S Johnson & Johnson Pakistan Pvt Ltd, Plot No.10 & 25, Sector 20, Korangi Industrial Area, Karachi (DML No. 000045-Formulation).

The Board further directed that firm shall ensure continuous availability of alternate sutures after registration.

The Board also emphasized that the Registration Board may process the applications of firm for registration of alternate sutures expeditiously to avoid the shortages.

7. **Regularizations of Layout Plan Of M/S Pakistan Pharmaceutical Products (Pvt) Ltd, Located At D-122, Site, Karachi Under DML NO. 000091 (Formulation)**

The case was placed before the Board as under:

M/s Pakistan Pharmaceutical Products (Pvt) Ltd, D-122, SITE, Karachi DML NO. 000091 (Formulation), has regularized layout plan on 05th January 2015, for their running facility of 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: -

<table>
<tr><th>S.#</th><th>Ground Floor</th><th>S.#</th><th>First Floor</th><th>S.#</th><th>Second Floor</th></tr>
<tr><td>1.</td><td>Injectable Ampoule (General)</td><td>8</td><td>Warehouse (Cephalosporin)</td><td>13</td><td>Warehouse (Penicillin)</td></tr>
<tr><td>2.</td><td>Tablet (General)</td><td>9</td><td>Capsule (Cephalosporin)</td><td>14</td><td>Tablet (Penicillin)</td></tr>
<tr><td>3.</td><td>Capsule (General)</td><td>10</td><td>QC Laboratory</td><td>15</td><td>Capsule (Penicillin)</td></tr>
<tr><td>4.</td><td>Cream/Ointment/Gel (General)</td><td>11</td><td>Oral Dry Powder Suspension (Cephalosporin)</td><td rowspan="4">16</td><td rowspan="4">Oral Dry Powder Suspension (Penicillin)</td></tr>
<tr><td>5.</td><td>Oral Liquid (General)</td><td rowspan="3">12</td><td rowspan="3">Dry Powder Vials Injectable (Cephalosporin)</td></tr>
<tr><td>6.</td><td>Ear / Eye Drops (General)</td></tr>
<tr><td>7.</td><td>Warehouse (General)</td></tr>
</table>

2. In this regard, a panel comprising of (i) Syed Muied Ahmed, Member CLB (ii) Area Federal Inspector of Drugs, DRAP, Karachi (iii). Area Assistant Drugs Controller, DRAP, Karachi (iv) Mr. Farman Ali Bozdar, ADC, CDL, Karachi, was requested to verify the above sections of firm as per approved/ regularized layout plan.

3. Accordingly, panel has inspected the premises on 21-01-2015 and verified all the above mentioned sections

Recommendations of the Panel

Keeping in view the good facilities made available and over all well-constructed plant in accordance with the approved layout plan, the panel verifies and recommends the approval of master layout plan / authentication / regularization of existing facility of the firm bearing Drug Manufacturing License by way of Formulation No.000091 having dedicated HVAC and as per approved layout plan.

Decision of CLB:

The Board considered and approved the authentication/regularization of following sections of firm:

S.#	Ground Floor	S.#	First Floor	S.#	Second Floor
1.	Injectable Ampoule (General)	8	Warehouse (Cephalosporin)	13	Warehouse (Penicillin)
2.	Tablet (General)	9	Capsule (Cephalosporin)	14	Tablet (Penicillin)
3.	Capsule (General)	10	QC Laboratory	15	Capsule (Penicillin)
4.	Cream/Ointment/Gel (General)	11	Oral Dry Powder Suspension (Cephalosporin)	16	Oral Dry Powder Suspension (Penicillin)
5.	Oral Liquid (General)	12	Dry Powder Vials Injectable (Cephalosporin)		
6.	Ear / Eye Drops (General)				
7.	Warehouse (General)				

8. **REGULARIZATIONS OF LAYOUT PLAN OF M/S BARRETT HODGSON PAKISTAN (PVT) LTD, LOCATED AT F-432, SITE, KARACHI UNDER DML NO. 000457 (FORMULATION)**

The case was placed before the Board as under:

M/s Barrett Hodgson Pakistan (Pvt) Ltd, F-432, SITE, Karachi DML No. 000457 (Formulation), has regularized Master layout plan of their running facility on 23rd July 2014, 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: -

Main Building Ground Floor			**Third Floor**
i.	Tablet (General) Section	xvi.	Oral Liquid (General) Section.
ii.	Capsule (General) Section.	xvii.	R & D Laboratory.
iii.	Sachet (General) Section.		**Fourth Floor**
iv.	Oral Dry Powder Suspension (General)	xviii.	Optical Checking and Packing Hall for Injectable (General)
v.	Oral Liquid (General) Section.		**Cephalosporin Building Ground Floor**
vi.	Raw material & Packing Material Stores (General) Section.	xix.	Raw Material & Packing Material Stores & Change Rooms
	First Floor		**First Floor**
vii.	Change Rooms	xx.	Capsule (Cephalosporin) Section.
viii.	Technical Area	xxi.	Oral Dry Powder Suspension (Cephalosporin) Section
	Second Floor	xxii.	Dry Powder Vial Injectable (Cephalosporin) Section.
ix.	Sterile Eye ointment (General) Section.		**Penicillin Building Ground Floor**
x.	Ear/Eye Drops (General) Section.	xxiii.	Raw Material Store
xi.	Liquid Vials SVP (General) Section.	xxiv.	Tablet (Penicillin) Section.
xii.	Liquid Ampoule SVP (General) Section.		**Finished Goods Store**
xiii.	Liquid Infusion Injectable (General)		
xiv.	Packing Hall for Oral Solid Dosage Form.		
xv.	Quality Control Laboratory.		

In this regard, a panel comprising of **(i) Syed Muied Ahmed, Member CLB (ii) Area Federal Inspector of Drugs, DRAP, Karachi (iii). Area Assistant Drugs Controller, DRAP, Karachi** was requested to verify the above sections of firm as per approved/ regularized layout plan.

3. Accordingly, panel has inspected the premises on 18-02-2015 and verified all the above mentioned sections

Report by the Panel

Panel constituted by referred Islamabad's letter visited the company for about 5 hours. Personnel from Quality & Manufacturing including Engineering represented and accompanied throughout the time spent. Panel compared the available approved map duly signed and stamped by ADCs of Islamabad (Lic) and Karachi (DCA) with the actual existing facility as per desired of CLB. Panel was also asked to verify installation of HVAC system as per approved layout plan. All are verified and no significant difference was observed by the panel.

Straightforwardly, the desired exercise does not give assurance of GMP unless it is not assessed for compliance.

FOR APPRAISAL OF BOARD: The panel was advised vide letter of even number dated 11th December 2014 to furnish inspection report with clear, candid and definite recommendations on the evaluation form, along with documents for installation of HVAC system, but panel has not attached a single document / information regarding evaluation form, installation of HVAC system as per approved layout plan.

Proceedings of the Board:

The Board was apprised that the area FID has shown somehow discomfort of the activity to verify the map by the CLB, whereas summary of approval of the map is not available to understand the facilitation of GMP compliance within manufacturing facility. He has also requested to allow one hour presentation before the Board so analysis of prevailing practice could be shown before the Board and further stated that current practice does not add significant value in mission of protection of public health and possess potential to provide legitimate support otherwise.

Licensing Division also apprised the Board that the above exercise of regularization / authentication of master layout plans of the firm(s) has been initiated for those existing manufacturing facilities for which firms don't possess letter(s) of grant/approval from CLB and were licensed before promulgation of S.R.O 470 (I)/98 dated 15-05-1998 when approval of layout plan of the buildings was not mandatory. The current exercise of regularization of existing licensed faculties is also based upon the recent / last inspection reports by the FIDs / panel wherein GMP conditions of the sections have been mentioned and stated good/satisfactory etc. In

fact, this exercise has been initiated in mission of protection of public health by avoiding the registration of those drugs of the firm(s) for which they don't possess a licensed section. The area FID has full rights to guide industry on technical matters to improve GMP conditions according to latest practices and procedures with a view to improve the standard of industry and quality control of drugs.

Decision of CLB:

The Board considered and approved the authentication/regularization of following sections of firm:

Main Building Ground Floor			**Third Floor**
i.	Tablet (General)	xvi.	Oral Liquid (General)
ii.	Capsule (General)	xvii.	R & D Laboratory.
iii.	Sachet (General)		**Fourth Floor**
iv.	Oral Dry Powder Suspension (General)	xviii.	Optical Checking and Packing Hall for Injectable (General)
v.	Oral Liquid (General)		**Cephalosporin Building Ground Floor**
vi.	Raw material & Packing Material Stores (General)	xix.	Raw Material & Packing Material Stores & Change Rooms
	First Floor		**First Floor**
vii.	Change Rooms	xx.	Capsule (Cephalosporin)
viii.	Technical Area	xxi.	Oral Dry Powder Suspension (Cephalosporin)
	Second Floor	xxii.	Dry Powder Vial Injectable (Cephalosporin)
ix.	Sterile Eye ointment (General)		**Penicillin Building Ground Floor**
x.	Ear/Eye Drops (General)	xxiii.	Raw Material Store
xi.	Liquid Vials SVP (General)	xxiv.	Tablet (Penicillin)
xii.	Liquid Ampoule SVP (General)	xxv.	Finished Goods Store
xiii.	Liquid Infusion Injectable (General)		
xiv.	Packing Hall for Oral Solid Dosage Form.		
xv.	Quality Control Laboratory.		

The Board considered and advised to follow current procedures and practices until new guidelines are developed and implemented. Instructions of Board shall be followed accordingly.

The Board further advised that Dr. Obaid Ali may send his presentation with recommendations through Director QA/LT, which; the Board will consider whether there is need of presentation before Board or otherwise.

The Board also asked the members of the Board i.e. Syed Jawed Yousaf Bukhari, Syed Muid Ahmed and Dr. Ikram ul Haque, Secretary CLB and Mr. Salateen Waseem Philip to develop the guidelines of layout plans for better GMP compliance.

9. RENEWAL OF DRUG MANUFCATURING LICENSE No. 000182 (FORMULATION) OF M/S PHARMAWISE LABS (PVT.) LTD LOCATED AT 25 – M, QUAID E AZAM INDUSTRIAL ESTATE, KOT LAKHPAT LAHORE

The case was placed before the Board as under:

Brief Background:

M/s Pharmawise Labs (Pvt.) Ltd, located at 25-M, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore had submitted application for renewal of DML NO. 000182 (Formulation) for the period 21-12-2009 to 20-12-2014. Accordingly, a panel comprising of following experts was constituted on 19th March 2014 to conduct inspection of the firm for renewal of DML.

i) Dr. Ikram Ul Haque , Member CLB
ii) Deputy Director General (E & M), DRAP, Lahore
iii) Area Federal Inspector of Drugs, DRAP, Lahore
iv) Area Assistant Drugs Controller, DRAP, Lahore

2. The panel conducted the inspection on 16-12-2014 and submitted its report for consideration of the Board.

3. Accordingly, case was discussed in 239th meeting of CLB held on 22nd January 2015. The Board was apprised about the recommendations of the panel as under: -

- The panel of inspectors visited the above said premises with reference to DRAP letter No.F.1-7/85-Lic (V-Ii) dated 19-03-2014 for renewal of their DML No. 000182 by way of formulation and discussed the matter with the Chief Executive of M/s Pharmawise Labs (Pvt) Ltd, Lahore, Ch. Nadir Khan, as no further advices can be given to spend money more and more for converting the existing premises to meet the latest requirements of the building and HVAC, because the same building was constructed in year, 1988. The Chief Executive, Ch Nadir Khan also agreed with the observations of the panel, so the firm has given the following undertaking:

- *We agreed with the observations of the learned panel that it will not be advisable to spend more and more for converting the existing premises to meet the latest requirements of building etc. we M/s Pharmawise labs. Purchased a one Acre plot at Sunder Industrial Estate in the year 2007. We therefore, undertake to build new manufacturing premises at 48 Sunder Industrial Estate, Lahore for which we shall submit the building plan to DRAP, Islamabad within one month and accordingly construct new factory within 18 months, in accordance with the latest DRAP advise and by laws.*

- The panel agreed to recommend to grant of time for construction of their new plant. Till that their the firm may continue production in this premises by maintaining and trying their level best to meet the GMP conditions for manufacturing of their products as the quality, efficacy and safety of the products is the responsibility of the licensee. This also advised to the management to remain in touch and submit their progress from time to time to the DRAP Islamabad under intimation to this office.

Decision of the Board in its 239th meeting held on 22-01-2015

Keeping in view the above situation, the Board after thorough discussion and deliberations decided for Personal Hearing of the firm on the basis of undertaking submitted to the panel during inspection.

Later, the firm has submitted a letter on 22-01-2015 and requested that they withdraw their undertaking dated 11-09-2014 and further requested to carry out the renewal inspection.

The firm has been called for personal hearing as per decision of CLB.

Proceedings:

Ch. Nadir Ali Khan, the CEo/Owner of the firm along with Mr. Noman Nadir represented the firm and appeared before the Board for personal hearing. He submitted that the panel has visited the factory premises but has not highlighted the deficiencies with respect to GMP and asked for signing the undertaking for shifting of the factory to other industrial area as this one is congested and not having space for further improvements even. He urged the whole Board to inspect the premises.

Prof. Dr. Gul Majeed emphasized that in future any such undertaken shall be taken in presence of witnesses. Other members also supported the said proposal / suggestion.

The Board was also apprised that the renewal tenure of the current case of renewal of DML has been expired on 20-12-2014 and firm has submitted its next renewal application for the period from 19-12-2014 to 20-12-2019.

Decision of CLB:

The Board after personal hearing of the firm and thorough discussion and deliberations considered and decided for the inspection of the firm for both renewal tenures (i.e. 21-12-2009 to 20-12-2014 and 21-12-2014 to 20-12-2019) by the following panel as under:

1. **Prof. Dr. Gul Majeed Khan, Member CLB**
2. **Prof. Dr. Muhammad Saeed, Member CLB**
3. **Syed Jawed Yousaf Bukhari, Member CLB**
4. **Syed Muied Ahmed, Member CLB**
5. **Area FID, DRAP, Lahore**

10. RENEWAL OF DRUG MANUFCATURING LICENSE NO. 000652 (FORMULATION) OF M/S M/S. NOBLE PHARMA, PLOT NO.B-1, OLD INDUSTRIAL AREA, MIRPUR AZAD KASHMIR.

The case was placed before the Board as under:

The case was considered and decided in 239th meeting of CLB as under: -

S No.	Name of the firm	Type of license	Decision of CLB
1.	**M/s. Noble Pharma, Plot No.B-1, Old Industrial Area, Mirpur Azad Kashmir** **Renewal Period 30.01.2014 to 29.01.2019**	**DML No.000652 (Formulation)**	**The board was apprised that the panel has made following observations during the visit.** i. The raw material store and packing material store found overloaded. The management is advised to purchase new racks and pellets for the placement of materials. ii. Small volume weighing scale need to be provided in the oral dispensing area. iii. Some of the electric power plugs needs to be concealed. iv. Over printing area need to be segregated and exhaust system need to be provided in this area. v. Sitting chair in the packing hall need to be replaced with new chair, having back rest. vi. Buffering/Polishing of mixer need to be done in Oral Dry Powders (Vet). vii. In Oral Liquid (Vet) Section, transfer pipes of liquid needs to be replaced. viii. Weighing balance need to be provided in the dispensing hood of sterile Liquid Injection (Vet). ix. Installation qualification of some of the equipments in the sterile Liquid Injection (Vet) area needs to be done. x. Cracks wee found on the epoxy paint of sterile area, this need to be maintained. xi. Door of dispatch bay of packing hall of sterile Liquid Injection (Vet) need to be replaced. xii. Lights of the sterile Liquid

			Injection (Vet) need to be concealed. xiii. The management has purchased HPLC and atomic absorptions. However Installation Qualification and Performance Qualification of HPLC and atomic absorptions need to be done. xiv. Installation qualification and calibration of the equipments of Quality Control Lab was also not done. Installation qualification, performance qualification and Calibration of autoclaves and double Door sterilizers of inject able area needs to be done. **Keeping in view the above observations, the board considered and deferred the renewal of DML for show cause notice with personal hearing.**

The firm has been called for personal hearing in the light of above decision of CLB.

Proceedings:

Mr. Faisal owner of the firm represented before the Board. He submitted that he is agree with the observations of panel members made during the inspection. He said that he has rectified the all shortcomings and now ready for inspection. The firm has not started its manufacturing in liquid injection since its grant due to some water problems. Now firm has rectified the water problem and ready for inspection and start of manufacturing.

Decision of CLB:

After hearing the firm's representative, the Board discussed the case thoroughly and decided for re-inspection by the same previous panel as under:

1. **Prof. Dr. Gul Majeed Khan, Member CLB**
2. **Mr. Muhammad Arif Chaudhary, DDC (Reg), DRAP, Islamabad**
3. **Ch. Zeeshan Nazir Bajar, FID-II, DRAP, Islamabad**
4. **Mr. Sayyad Hussain, DDC (LA), DRAP, Islamabad**

11. Establishment of a Pharmaceutical Unit - M/S Pharmedic Chemical, 24-KM, Multan Road, Lahore.

The case was placed before the Board for its appraisal as under:

i. Central Licensing Board in its 233rd meeting held on 30th &31st December 2013, considered the site verification report of M/s Pharmadic Chemicals, 24-km, Multan Road, Lahore for establishment of a pharmaceutical unit by way of basic manufacture.

The Board after thorough deliberations and keeping in view the rule position rejected the application of Site under Schedule-B (1.2) & (2) of Drugs (Licensing, Registering and Advertising) Rules, 1976.

ii. Firm had filed an appeal before Appellate Board against decision of CLB. Appellate Board in its 142nd meeting held on 24-06-2014 discussed the appeal of the appellant and decided as under:-

"In light of above discussion the Board decided to remand the case to Central Licensing Board for conduction of an inspection by a panel of experts keeping in view the environmental assessment and the rules made under the Drugs Act, 1976 and to decide the case accordingly. "

iii. Accordingly, a panel was constituted on 17th December 2014 for re-inspection of the site upon the direction of Appellate Board. The composition of panel is as under:-

a. Secretary Punjab Environmental Protection Council or his nominee being the member of the council with qualification & expertise in Environmental Impact Assessment with particular reference to environmental impact of subject case on the safety, efficacy, quality & purity of drugs / medicines planned to be product of the applicant.

b. Chief Drug Controller, Punjab

c. Area Federal Inspector of Drugs, DRAP, Lahore.

iv. Now a letter was received from Environmental Protection Agency Government of Punjab on 5th March, 2015 regarding site verification for establishment of pharmaceutical unit and submitted following recommendations: -

The undersigned alongwith Director (Monitoring, Laboratories & Implementation), EPA, Punjab, Lahore, visited the site of subject unit on 02-02-2015, Mr. Ajmal Sohail Asif, Area FID, DRAP, Lahore and Dr. Zaka Ur Rehman, Chief Drugs Controller, Punjab, were also present at site. Mr. Ijaz Hussain, General Manager, conducted inspection of the unit. It was informed that the proponent intends to start semi basic manufacturing of Paracetamol from para amino phenol and acetic acid which will be imported.

2. a waste water drain is passing nearby the unit. The production room of the unit is situated at a distance of 331 feet from the drain. Mr. Ijaz provided a copy of report of ambient air quality monitoring within premises of the unit in front of production hall conducted by M/s SGS Lab (a certified lab under certification of environmental labs. Regulations, 2000) (SGS Ref: ENV-LHR-764/2012). The ambient air quality may

fluctuate. Therefore , the authority has approved following conditions for the subject matters

Recommendations: -

i. A properly designed centralized air handling unit with infiltration facility for providing clean air entry into production room should be installed in the unit.

ii. The proponent shall ensure compliance of National Environmental quality Standards (NEQS) and relevant provision of Punjab environmental Protection act, 1997 (Amended 2012)

The Board was appraised about the case.

QUALITY ASSURANCES CASES

Case No.1:- **M/s Ahson Drug Company, Tandoadam**

The inspection of M/s Ahson Drug Company, Tandoadam conducted on 25.09.2013 by Dr. Najam-us-Saquib, FID Hyderabad at Karachi with reference to see/verify the GMP compliance of the firm. During inspection, the FID has pointed out number of serious shortcomings/deficiencies in all sections. The FID concluded that the firm was not operational at an acceptable level of compliance with GMP guidelines. He has recommended that it is quite dangerous and health hazardous for the public, that is why the firm was directed to stop production in all sections immediately.

Action taken by the DRAP: A show cause notice was served on 01.11.2013 by this Authority with the **direction to stop manufacturing** of drugs immediately.

Reply of the firm: The firm has submitted a reply in response of show cause notice stated that they have made improvements as suggested by the FID and requested for re-inspection.

The case was placed before the Central Licensing Board in its 233rd meeting held on 30-31st December, 2013 where after considering all aspects of the case, the Board had decided including the following:-

> ***"The company, M/s Ahson Drug Company, Tandoadam be re-inspected by a panel of experts within one month. The production of the company will remain suspended and the report will be submitted to CLB for approval".***

Accordingly in compliance to the decision of the Board, the Chairman, Central Licensing Board has constituted a panel comprising the following to conduct the inspection of in the light of the decision of the Central Licensing Board:

i) Syed Jawed Yousaf Bukhari, Member Central Licensing Board,
ii) Mr. Abdul Rasool Shaikh, FID Karachi,
iii) Area FID Karachi
iv) Area ADC Karachi

The above panel has inspected the firm on 16.01.2015 the panel has recommended the resumption of production with the remarks as:

" Based on the observations made during the visit, it revealed that M/S Ahson Drug Company situated at T/1, SITE, Tandoadam has taken serious steps to address almost all the shortcomings/discrepancies as noticed and pointed out during the previous visit.

Keeping in view the steps taken by the management towards strengthening of production and quality control facilities and positive intention towards compliance of cGMP, panel recommended the re-commencement of production activities after approval from the Central licensing Board, DRAP, Islamabad " .

Proceedings:

The case was placed before the Central Licensing Board for consideration. Mr. Qaiser Muhammad, CDI, Sindh (Member CLB) added his remarks for future consideration and record of CLB and informed that several samples of drugs have been declared substandard by CDL and DTL Sindh. He further informed that the Registration Board have de-registered their Paracetamol Tab. and Ampimox Cap.250 mg. He said that the firm has filed appeals in the Appellate Board but the Appellate Board in its 142nd meeting held on 24th June 2014 discussed the said appeals and unanimously dismissed both the appeals. He also informed that one case of manufacturing Sub-Standard Tab. Sumitran DS [co-trimaxazole] declared sub-standard by the DTL Sindh was still under trial in the Drug Court Sindh @ 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. ***The Board after considering the inspection report of the panel of experts and on the recommendation of the panel decided to allow the resumption of production to the firm.***

2. ***After 02 months, the firm will be inspected by a panel during working condition to check the overall GMP compliance***

Case No.2:- **M/s Hirra Pharmaceutical Labs, Lahore**

The inspection of M/s Hirra Pharmaceutical Labs, Lahore conducted on 27.05.2013 by Mrs. Majida Mujahid, FID Lahore with reference to see/verify the GMP compliance of the firm. During inspection, the FID has pointed out number of serious shortcomings/deficiencies in all sections. The FID had concluded and directed the firm to stop production in vaccine section.

Action taken by the DRAP: A show cause notice was served on 23.09.2013 with the **direction to stop manufacturing** in vaccine section immediately. The firm had not replied the show cause notice. A reminder has been sent to the firm on 12.11.2013.

Reply of the firm: The firm has submitted a reply of reminder of show cause notice in their letter dated 20.11.2013 stating that they are in process of upgradation, renovation in different sections as pointed out by the area FID during inspection. They will be ready within one month for re-inspection. They have also submitted that they will inform in writing to the Central Licensing Board for panel inspection.

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

Decision of CLB (in the meeting to 233rd):

The Board after thorough discussion and keeping the facts on records has decided as follows:-

The order of suspension of production in vaccine section will continue. A reminder be served to the company as the company has not yet informed the CLB for improvements

Current Status:

The decision of the CLB was conveyed to the firm. In response, the firm informed vide there letter dated 06.05.2014 that the renovation work is going on, will inform to the FID after completion of renovation / improvements.

The FID inspected the firm on 12.11.2013 and reported that the production in vaccine section was already stopped due to non GMP Compliance and the firm did not improved there general syrup section and general powder section regarding to all previous observations/ shortcomings. The report of the FID was incomplete so she was requested to submit the complete case for the appraisal of CLB.

The FID inspected again on 23.09.2014 and reported that the firm did not made any improvements regarding to all previous GMP inspections. She reported that the firm did not improve in all sections (copy enclosed).

The FID has categorically informed that the firm is running in pathetic condition.

The representative of the company is called for personal hearing for explaining the position

<u>Decision of CLB</u>:

Mr. Farooq Shahzad (Managing Director) appeared before the Board and informed that they have developed QC section and have approved layout plan from Licensing Board. He further stated that the delay from them was due to installation of HVAC which is now has been completed and the firm is ready for inspection.
The Board after hearing the views of the firm, concluded the following decisions:

i) The Board decided to conduct panel inspection of the firm in all sections to check GMP compliance of the firm.

ii) Following panel have been constituted to conduct inspection and report within one month:

1. ***Dr. Ikram Ullah, Member CLB.***
2. ***Dr. Muhammad Arshad, Member DRB / Vet. Vaccine Expert***
3. ***Area FID, DRAP, Lahore***

Case No.3- **M/s Grand Pharma, Rawat, Rawalpindi**
Case of De-sealing of 02 Rooms

A surprise panel inspection was conducted by Dr. Ahmad Mahmood Mumtaz, Chairman, QC/DDG(E&M), Mr. Chaudhary Zeeshan Nazir, FID and Mr. Muhammad Ansar, ADC, DRAP, Islamabad on 30.12.2014. The team noticed that the company was involved in the manufacturing of raw material by harvesting / incubating for 09 days in the specialized place developed underground. The FID through his letter No.F.3-4/2009-FID-II(Isd) dated 31.12.2014 informed that the panel also sealed two rooms of the Form 2 under clause F of Section 19 of Drugs Act, 1976 and seeked the permission for extension to keep the premises sealed under section 18 (1) (i) of the Drugs Act, 1976. The FID informed that the sealed keys were handed over to Mr. Abid Khawaja, Director of the firm and the inventory of the sealed room was as under:

Sr. No	Description
1.	**Two Connected Room:** **Room No. 1** 1. Centrifuge Machine (01) 2. Refrigerator (02) **Room No. 2** **1**. Fridge (01) **2.** Mixer/Shaker (01) **3.** Water Bath (01) 4. Fume Hood (01)
2.	**Room No. 2:** Chiller (01) **Note**: Sealed key Handed over to the management.

The directorate of Quality Assurance and Lab Testing by observing the violation of GMP guidelines Schedule B-II and the Drugs Act, 1976 issued an explanation letter on the following points to the firm:

- The team noticed that the company was involved in manufacturing of raw material by harvesting / incubating for 9 days in the specialized place developed under ground without permission.

- A lady and about 8 male boys worker manipulating the eggs by checking the developed embryo in the eggs. The eggs were incubator for 9 days in the special 03 incubators placed underground without permission.

- The extracted/segregated liver is being done in the main approved building then shifted in the under ground area.

- The panel was of the view that the management of the company had been hiding the process from the FID in the past.

- The company's management claimed that they were un-aware that approval of manufacturing of basic raw material could not be carried out without permission.

- In view of the above situation two rooms had been sealed in the presence of management which included Mr. Abid Khawaja, Director and Mr. Muhammad Ayaz, Incharge, Quality Control.

Action taken by the DRAP: An explanation letter served to the company on 10.02.2015 by this Authority with the direction to explain their position immediately.

Reply of the firm: In response to explanation the firm submitted the reply including the following points:

"The Grand Pharma (Pvt) Ltd., (GP) has been involved in manufacturing veterinary drugs (oral liquid) and biologics since May 2010 at the MOH approved facility. All of the biologics production activities at GP are carried out in bio-safe and environmentally controlled facilities, due to the nature of biologics manufacturing protocols, following standard GMP.

1. On 24th December 2014, few rooms in vaccine raw martial storage in the approved premises were found to develop dampness in the walls, which required to temporarily vacating the premises on emergency basis. For this purpose an office note was subsequently raised by the Project Director-GP intimating the concerned staff officer to inform the concerned section in the FID/DRA for moving out some equipment to the basement of the GP. This letter was reportedly sent to DRA on 29th December, 2014 to inform them regarding emergency shifting of equipment (copy attached).

2. During the panel visit of DRA on 30th December, 2014, due to the above mentioned problems at the approved material storage area, the embrocated eggs earlier shifted from the approved premises were being sorted out in the GP basement for selecting only the hatching eggs for shifting over to the approved production area. It is further clarified that these eggs were not being "harvested" as pointed out in your explanation letter. As the egg harvesting activity cannot be undertaken without bio-safety level-2 environment, which is only available in the approved area at GP. Technically, these eggs would only be considered as "Raw Material" component when the hatch able eggs are segregated from un-hatch able eggs and presented for further usage in vaccine production. The approved production protocol requires the use of 9-day embrocated eggs for this purpose. So in case of the above described emergency situation there was no way out to save these eggs, except to shift these partially incubated eggs to the basement temporarily and move them back for further usage to the approved facility.

3. As regard the separated embryo livers, it is stated that the embryo liver harvesting was also done for cell culture preparation in the approved facility but due to above described storage issue, its storage also had to be shifted temporarily down stairs. On the visit day, this stored material was being shifted back to the production area, without carrying out any manipulation in the premises in the basement. This material in its existing form would not be considered as "Raw Material" component till it was segregated to select the embryo livers capable to grow in cell culture flasks, which can only be achieved under bio-safety level-2 facility, only available in the approved area.

The above description indicates that only "storage activity" of the material used for preparing the actual Raw-material (called antigen), prior to even its clearance by QC was carried out in case of emergency situation described above. However, no production activity was ever carried out in the basement in this regard. Furthermore, the given list of the equipment found in the basement clearly indicates that no production related activity or raw material production activity was ever carried out in the basement.

4. This is further submitted that as the required repairs in the storage facility in main premises at GP have now been completed, the equipment placed in the sealed rooms may please be allowed for its shifting back to its original storage place in the approved premises.

5. The above narration precisely describes the actual position of the situation to the best of our knowledge and it is hoped that keeping in view our excellent past record of following GMP practices and ISO-9001 requirements at GP for the past 5 years, a lenient view of the situation is taken in the light of the emergency situation encountered by us. However, we further ensure to continuously undertaking all required procedures to abide by the requirements of GMP in this production unit in future as well ".

The representative of the company was called for personal hearing for explaining the position

Decision of CLB:

Mr. Abid Khawaja, Managing Director of the firm, appeared before the Central Licensing Board and informed that the firm has approval of the CLB for manufacturing vaccines (Biologicals) in the premises of Grand Pharma and Drug Registration Board has given registrations of vaccines. The materials which were sealed in unapproved area, was due to emergency arrangements because of dampness in the approved premises. He informed in reply of a question that the sealed materials were not used in routine as it were purchased for future expansion. He further informed that though they have sent the letter of information of emergency arrangements but there may be some communication error. He requested the CLB to take the lenient view as they have shifted the materials from approved area to unapproved area in emergency with good faith. He requested the CLB to take lenient view in this regard.

The Board after thorough discussion and keeping the facts on records has decided as follows:-

1. ***The Board after considering the reply of the firm decided to de-seal the premises already sealed by FID, Islamabad.***

2. ***To issue warning to the firm to be careful in future and they should take prior permission if they want to change in the manufacturing process.***

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