DIVISION OF DRUG LICENSING
DRUG REGULATORY AUTHORITY OF PAKISTAN
ISLAMABAD
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MINUTES OF 241st MEETING OF CENTRAL LICENSING BOARD HELD ON FRIDAY, 15th May, 2015.

241st meeting of the Central Licensing Board (CLB) was held on Friday, 15th May, 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.	Dr. Zaka-ur-Rehman, Chief Drug Controller, Department of Health, Govt. of Punjab.	Member
3.	Mr. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh.	Member
4.	Mr. Afrasiyab, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa.	Member
5.	Mr. Atta-ur-Rehman, Chief Drug Inspector, Department of Health, Govt. of Balochistan.	Member
6.	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
7.	Dr. Ikram-ul-Haq, QC/QA Expert	Member
8.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
9.	Prof. Dr. Gul Majeed Khan, Professor of Pharmacy	Member
10.	Prof. Dr. Muhammad Saeed, Professor of Pharmacy	Member
11.	Mr. Khurram Shahzad Mughal, Consultant M/o Law, Justice and Human Rights, as representative of M/o Law, Justice and Human Rights, Islamabad.	Member
12.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
13.	Mr. Khalid Munir CEO Trigon Pharmaceuticals as Representative of PPMA	Observer
14.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
15.	Mr. M. Asim Jamil Secretary General PCDA , representative of PCDA	Observer

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

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. Dr. Ahmed Mehmood Mumtaz CQC, Mr. Ahmed Din Ansari DDC (QC), Mr. Adnan Faisal Saim DDC (QA) & 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 240th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 240th meeting held on Friday, 06th March, 2015.

Item-II: **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 & Address of the firm	Date of Inspection / Type of License	Decision of CLB
1.	**M/s Vetz Pharmaceuticals (Pvt) Ltd., Plot No.Q-1, SITE, Kotri, Sindh.**	**11-04-2015** **(By way of Formulation)**	**Approved the grant of DML with following three sections:** **Sections (03): -** 1. Oral Powder (Veterinary). 2. Oral Liquid (Veterinary). 3. Sterile Liquid Vials Injection (Veterinary).
2.	**M/s Alza Pharmaceuticals (Formerly M/s Al-Shifa Pharmaceuticals, Rawalpindi) Alshifa Trust Eye Hospital, Jhelum Road, Rawalpindi.**	**10-04-2015** **(By way of Formulation)**	**Approved the re-grant / shifting of DML # 000482 (Formulation)** **From** their previous site/location on the first floor of commercial area of M/s AlShifa Trust Eye Hospital, Rawalpindi located inside their compound wall **to** their new site within same compound wall with following sections:- **Licensed Section(s) shifted (01)** 1. Ophthalmic Drops (General) **New Section(s) (01)** **1.** Cream / Ointment / Gel (General) The Board noticed that panel of inspectors/experts were given mandate to inspect the **(i)** Cream/Ointment/Gel (General) section and **(ii)** Eye Drop (General) section as per request of the firm; wherein the firm has informed that their premises is ready for inspection as per approved layout plan dated 16th June 2011 for the said two sections.. Whereas, panel of experts have mentioned two additional sections in the inspection

			report for which firm did not possess approval of layout plan and there is no record of these sections in the Secretariat of the Central Licensing Board, the name of these sections are as under:- 1. Cream/Ointment/Gel (Steroid) 2. Drops (Steroid) **Therefore, the Board after thorough discussion and deliberations decided to direct firm to get approval of layout plan for the Cream/Ointment/Gel (Steroid) and Drops (Steroid) Section and inform the Central Licensing Board for inspection of these sections as and when ready for inspection according to approved layout plan.**
3.	**M/s PCP Laboratories, 90-K.M. Akhtarabad, District Okara.**	**30-03-2015** **(By way of Formulation)**	Licensing Division apprised the Board regarding a court case filed in the Honorable Court of Senior Civil Judge Renala Khurd, District Okara regarding disputes between the owners of the firm and shareholders as under:- **Present**: Learned Counsel for the petitioner / plaintiff. Power of Attorney of Mr. Ch. Mohammad Arshad on behalf of defendant No.1. Argument heard and record perused. Let summons / notice be issued in the name of the defendants / respondents No. 2 to 8 subject to deposit of process fee along with registered envelop AD for 24-04-2015 AND submission of written statement and written reply on behalf of defendant No.1. 2. Along with suit, the petitioner / plaintiff has also moved an application for grant of temporary injunction which is duly supported by an affidavit. 3. The contention raised by the plaintiff / petitioner needs consideration therefore, replying upon the affidavit attached with the plaint, in the meanwhile respondents are restrained from doing any illegal act in contravention to the provisions of partnership deed till next date of hearing. However, this order shall have no effect upon any other judicial order or proceedings before any competent forum and shall stand vacated if not extended explicitly on next date of hearing. **Announced:** **Dt.09-04-2015** Ghulam Murtaza Virk Civil Judge 1st Class, Okara.

			The Board after perusal of court case and observing pros & cons of the case **Approved the grant of DML with following two sections:** **Sections (02)** 1. Oral Dry Powder Suspension (Cephalosporin). 2. Capsule (Cephalosporin). According to Rule 10(4-7) of the Drugs (Licensing, Registering & Advertising) Rules 1976, the Board rejected the grant of **Dry Powder Injection Vials (Cephalosporin)** on the basis of recommendations of the panel wherein it is mentioned that ***firm does not have appropriate facility for the manufacturing of Injectable products.***
4	**M/s GMP Pharmaceuticals, 28-KM. Sheikhupura Road, Lahore.**	**03-04-2015 (By way of Formulation)**	**Approved the grant of DML with following five sections.** **Sections (05): -** 1. Capsule (Cephalosporin). 2. Oral Dry Powder Suspension (Cephalosporin). 3. Dry Powder Injectable Vials (Cephalosporin) 4. Liquid Injectable Ampoule (General) & 5. Liquid injection Infusion/vials – Small Volume Parenterals (General) ***with direction to manufacture and filling of one dosage form i.e. Ampoule or vial at one time***.
5	**M/s Ice Berg Pharmaceuticals (Pvt) Ltd. Plot No. 144, Nowshehra Industrial Estate, Risalpur.**	**16-03-2015** **(By way of Formulation)**	The Licensing Division apprised the Board regarding an unsigned & unknown complaint against the firm in which owners of the firm were suspected for manufacturing fake medicines and business of illegal drugs in namak mandi, Peshawar and declaring that owners of the firm were caught prison more than 20 times due to manufacturing of fake medicines. Accordingly, Investigation was made by the Area Federal Inspector of Drugs upon the directions of the Director

			QA/LT, DRAP. Area Federal Inspector of Drugs submitted inspection report wherein he stated that the owners of the firm have no connection with the manufacturing of fake medicines. Prof. Dr. Muhammad Saeed, Member of the Board and who was also the member of the inspection panel, informed the Board that firm provided an undertaking to the panel during inspection that they have no connection with any illegal Drug Manufacturer. **Keeping in view the above position, inspection report of the panel, investigation report of area FID and additionally ascertaining that anonymous complaint has no legal binding for consideration, the Board after thorough discussions and deliberations, approved the grant of DML with following five sections:** **<u>Section (05)</u>** 1. Tablet (General) 2. Capsule (General) 3. Oral Dry Suspension (General). 4. Capsule (Cephalosporin). 5. Oral Dry Suspension (Cephalosporin)
6	**M/s Gallop Water Sciences,** **Plot No. 404, Sunder Industrial Estate, Lahore.**	**13-04-2015** **(By way of Formulation)**	**Approved the grant of DML with following one section** **Sections (01): -** IV Solutions (LVP) (By LDPE packing)
7	**M/s Soma Laboratories,** **43-D Sunder Industrial Estate, Raiwind Road Lahore.** **DML # 000225 (Formulation)** *Re-grant / shifting of licensed unit from residential area to*	**25-03-2015** **(By way of Formulation)**	**Approved the grant /shifting of DML No. 000225 (Formulation) from residential area (692-N, Samanabad Lahore) to industrial area (43-D Sunder Industrial Estate, Raiwind Road Lahore) with following sections and conditions:** **Sections shifted / re-granted (02): -** 1. Tablet (General) 2. Sachet (General)

	Industrial area.		**New Section (01)** 1. Capsule (General) **<u>Conditions</u>** • Cessation of manufacturing operations and surrendering of existing DML and inspection book. • The firm will not conduct its Formulation operations at their previous site at 692/N, Samanabad, Lahore.
8	**M/s Zeta Pharmaceuticals Plot No. 494-A, Sunder Industrial Estate, Raiwind Road Lahore.**	**29-04-2015** **(By way of Formulation)**	**Approved the grant of DML with following two sections.** **Sections (02): -** **1.** Tablet (General) **2.** Capsule (General)
9	**M/s Revive Pharmakon 10-KM, Raiwind Road, Lahore.**	**28-04-2015** **(By way of Formulation)**	**Approved the grant of DML with following one section:-** **Sections (01): -** 1. IV Solutions (LVP) by LDPE Packing.
10	**M/s Mafins Pharma Plot Nol. A/5, S.I.T.E., Super Highway, Karachi.**	**12-05-2015** **(By way of Formulation)**	**Approved the grant of DML with following three sections:-** **<u>Section (03)</u>** 1. Tablet (General) 2. Capsule (General) 3. Cream/Gel/Ointment (General).
11	**M/s Ras Pharmaceuticals (Pvt) Ltd 25-KM, Lahore Road, Multan.**	**10-03-2015** **(By way of formulation)**	**Approved the grant of DML with following three sections:-** **<u>Section (03)</u>** 1. Oral Liquid (Antibiotic) - Veterinary 2. Oral Powder (General) (Vitamin Premix Section) - Veterinary 3. Oral Powder (General Antibiotic) - Veterinary
12	**M/s. Mediflow Pharmaceuticals (Pvt) Ltd., Plot # ID-100, Sector 30, Korangi Industrial Area, Karachi.**	**14-05-2015** **(By way of Formulation)**	**Approved the grant of DML with following one section:-** **Section (01)** Large Volume Parenterals by LDPE Packing

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

The Board considered following cases of Grant of Additional Sections & Expansion/Amendments in Layout Plans (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 High-Q Pharmaceutical Plot No. 224, Sector 23, Korangi Industrial Area, Karachi.**	**DML No.000597 (Formulation)**	**The Board approved the grant of three additional sections as under:-** **New Sections (03)** 1. Capsule (Cephalosporin) 2. Oral Dry Powder Suspension (Cephalosporin) 3. Dry Powder Injection Vials (Cephalosporin) The Board noticed that the panel has mentioned in the inspection report that firm has seventeen cephalosporin products registered in form of dry powder injection, capsule and dry powder suspension, as per DRAP letter No.F.3-2/2013-Reg-II (M238) dated 19th September, 2013 without having approved manufacturing facility from CLB. Consequently, the Board directed to inform Drug Registration Board to look into the matter for further necessary action.
2.	**M/s Pharmagen Limited 34-KM, Ferozepur Road, Lahore.**	**DML No.000325 (Semi Basic Manufacture)**	**The Board approved the enlistment of additional Active Pharmaceutical Ingredient i.e. Sofosbuvir to be manufactured in approved general facility of the firm by way of semi basic manufacture.**
3.	**M/s Kohinoor Industries 159-160/B, Industrial Estate, Sahiwal .**	**DML No.000197 (Formulation)**	**The Board approved the grant of two additional sections as under:-** **New Sections (02)** 1. Cream / Ointment (General). 2. Sachet (General) Under Rule 10 of the Drugs (Licensing, Registering & Advertising) Rules 1976, the Board rejected the request of the firm for grant of **Sterile Guaze Section** on the basis of the

			observations of the panel as under:- i) .Necessary protocol in order to perform the sterilization process was not developed. ii) Installation qualification for the EO Chamber was not provided. iii) The residual testing facility was not available. iv)Class "A" environment in clean room was not maintained. v) The staff was not aware regarding precautionary measures for handling EO chamber for the sterilization process
4.	**M/s. Mass Pharma (Pvt) Ltd., 17-KM, Ferozepur Road, Lahore.**	**DML No.000444 (Formulation)**	**The Board approved the amendments made in the following seven licensed sections according to the approved layout plan:-** **<u>Amendments in licensed Sections (07)</u>** 1. Dry Injection (Cephalosporin) 2. Capsule (Cephalosporin) 3. Oral Dry Powder (suspension). 4. Liquid Injectable vials (small volume Parenterals) 5. Cream / Ointment / Gel (General) 6. Cream / Ointment / Gel (Steroid) 7. Warehouse (cephalosporin)
5.	**M/s. Saffron Pharmaceuticals (Pvt) Ltd., 19-KM, Shikhupura Road, Faisalabad.**	**DML No.000616 (Formulation)**	**The Board approved the amendments made in the following three licensed sections according to the approved layout plan:-** **<u>Amendments in licensed Sections (03)</u>** 1. Tablet (Hormone). 2. Finished Goods Store 3. Packing material store (General)
6.	**M/s Wilshire Labs (Pvt) Ltd., 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.**	**DML No.000232 (Formulation)**	**The Board approved the grant of one additional section as under:-** **<u>New Section (01)</u>** 1. Injectable Ampoule (Narcotic / Psychotropic)
7.	**M/s Bosch Pharmaceuticals (Pvt) Ltd., Plot No. 209, Sector 23, Korangi Industrial Area Karachi.**	**DML No.000707 (Formulation)**	**The Board approved the amendments made in the following one licensed section according to the approved layout plan:-** **<u>Amendment in licensed Section (01)</u>** Dry Powder Vial Injectable (Cephalosporin)

8.	**M/s Bosch Pharmaceuticals (Pvt) Ltd., Plot No. 221, Sector 23, Korangi Industrial Area Karachi.**	**DML No.000350 (Formulation)**	**The Board approved one new section and the amendments made in the following four licensed sections according to the approved layout plan:-** **New Section:** 1. Sachet (Cephalosporin) **Amendments in licensed Sections (04)** 1. Penicillin Packing Hall. 2. Tablet Section (Penicillin). 3. Capsule Section (Penicillin). 4. Dry Powder Suspension (Penicillin) Under Rule 10 of the Drugs (Licensing, Registering & Advertising) Rules 1976, the Board rejected **Sachet (General) Section** on the basis of the observations of the panel as under:- • Sachet Section (General) was in progress, for which the management of the M/s Bosch Pharmaceuticals (Pvt) Ltd, Plot No. 221, Sector 23, Korangi Industrial Area Karachi should approach (when the section is ready) to the DRAP authorities (Licensing section) for the inspection / approval accordingly.
9.	**M/s Citi Pharma (Pvt) Ltd., 3.5 KM Head Baloke Road, Phool Nagar, District Kasur.**	**DML No.000429 (Semi-Basic)**	**The Board approved the following one additional section** **Section: (01)** Penicillin by way of Semi-Basic Manufacture The Board further advised the members of the panel to sign the flow chart /diagram / process of the APIs intended to be manufactured at penicillin facility.
10.	**M/s Bio-Labs (Pvt) Ltd., Plot No.145, Industrial Triangle, Kahuta Road, Islamabad.**	**DML No.000296 (Formulation)**	**The Board approved the one additional section of the firm as under:** **Section (01)** Oral Powder (Penicillin)
11.	**M/s Global Pharmaceuticals (Pvt) Ltd., Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad.**	**DML No.000417 (Formulation)**	**The Board approved the grant of one additional section of the firm as under:-** **Section (01)** Soft Gel Capsule (General)
12.	**M/s Mallard Pharmaceuticals (Pvt) Ltd., 23-KM, Lahore Road, Qadirpur Rawan, Multan.**	**DML No.000622 (Formulation)**	**The Board approved the grant of one additional section of the firm as under:-** **Section (01)** Injectable Vials Veterinary (General / General Antibiotics)

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

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

S No.	Name of the firm	Type of license	Decision of CLB
1.	**M/s. Otsuka Pakistan Limited., F/49 Hub Industrial Estate, Lasbela, Balochistan.** **Renewal period: 22-05-2014 to 21-05-2019.**	**DML No. 000281 (Formulation)**	**Approved the Grant of Renewal of DML for the following four sections:** 1. Plabottle (plastic bottles) infusion section 500ml (Large Volume Parenterals). 2. Small Volume Parenteral - Plabottle 3. Large Volume Parenteral -Glass Vials. 4. Aseptically filled Injection Plabottle (Plastic Bottles)
2.	**M/s. Tabros Pharma (Pvt) Ltd., Plot No.L-20/B, Sector 22, F.B. Industrial Area, Karachi.** **Renewal period 08-01-2015 to 07-01-2020:-**	**DML No. 000106 (Formulation)**	**Approved the Grant of Renewal of DML for the following fifteen sections:** 1. Tablet (General/ General Antibiotic) 2. Liquid Syrup Section. 3. Sachet section (General) 4. Capsule (General/ General Antibiotic) 5. Cream/Ointments/Gel (General) 6. Lotion (General) 7. Dry Powder Suspension (General) 8. Sterile Liquid Injection Ampoule – General 9. Sterile Liquid Injection Glass Vials – General 10. Dry Powder Injection Glass Vials - General 11. Sterile Dry Powder Injection glass vials (Cephalosporin) 12. Capsule (Cephalosporin)\ 13. Tablet (Cephalosporin)\ 14. Oral Dry Powder Suspension (Cephalosporin) 15. Sachet (Cephalosporin).

3.	**M/s. OBS Pakistan Limited** **C-14, Manghopir Road, Karachi.** **Renewal period** **31-03-2015 to 30-03-2020:**	**DML No.000061 (Formulation)**	**Approved the Grant of Renewal of DML for following Six sections:** **Section (06)** 1. Soft Gel Capsule (General). 2. Soft Gel Capsule (Hormone). 3. Liquid Vials SVP (General). 4. Tablet (Hormone). 5. Tablet (General). 6. Warehouse & Quality Control Laboratory.
4.	**M/s. Jinnah Pharmaceuticals (Pvt) Ltd.,** **13th KM, Lahore Road, Multan.** **Renewal period** **12-05-2010 to 11-05-2015**	**DML No.000578 (Formulation)**	**Approved the Grant of Renewal of DML for the following three sections:** **Sections (03)** i) Tablet (General) ii) Capsule (General) iii) Sachet (General)
5.	**M/s. Leads Pharma (Pvt) Ltd.,** **Plot No.81-A, Street No.6, I-10/3, Islamabad.** **Renewal period** **26-06-2014 to 25-06-2019**	**DML No.000392 (Formulation)**	**Approved the grant of Renewal of DML for following twelve sections:** i) Oral Liquid - General **Veterinary** ii) Bolus – General **Veterinary** iii) Liquid Injection Vials – General **Veterinary** iv) Oral Powder – General **Veterinary** v) Oral Powder antibiotics **Veterinary** vi) Tablet – General- **Human** vii) Capsule (General)- **Human** viii) Sterile Dry Powder Injection Glass Vials (Cephalosporin)- **Human** ix) Oral Dry Powder Suspension (Cephalosporin)- **Human** x) Capsule (Cephalosporin)- **Human** xi) Tablet (Psychotropic) - **Human** xii) Capsule (Psychotropic)- **Human**
6.	**M/s. Life Pharmaceutical Company** **24-III, Industrial Estate, Multan.** **Renewal period** **29-12-2014 to 28-12-2019**	**DML No. 000194 (Formulation)**	**Approved the Grant of Renewal of DML for following eight sections:** **Sections (08)** 1. Liquid Syrup /. Suspension 2. External preparation 3. Tablet (General) 4. Capsule (General) 5. Oral Dry Powder Suspension (General) 6. Cream / Ointment (General) 7. Re-Packing (Liquid) 8. Re-Packing (Powder)

7.	**M/s. Mass Pharma (Pvt) Ltd.,** **17-KM, Ferozepur Road, Lahore.** **Renewal period** **24-11-2014 to 23-11-2019.**	**DML No.000444 (Formulation)**	**Approved the Grant of Renewal of DML for the following ten sections:** **Sections (10)** i) Tablet (General) ii) Liquid Injectable Ampoule (General) iii) Tablet (General Antibiotic) iv) Cream/Ointment/Gel (Steroidal) v) Cream/Ointment/Gel (General) vi) Capsule (Cephalosporin) vii) Oral Dry Powder Suspension (Cephalosporin) viii) Dry Powder Injectable vials (Cephalosporin) ix) Capsule (General) x) Injectable Vials (SVP) - General
8.	**M/s. Seagull Surgical Cotton Bandage Industry** **Tower Point, Beg Colony, Gojra Road, Jhang.**	**DML No.000482 (Formulation)**	The Board noticed that the composition of the panel that had conducted inspection is different from the composition of the panel constituted by Chairman CLB/ Director Licensing vide letter dated 27-10-2014. The panel constituted by the Chairman CLB on 24-10-2014, is as under:- 1. Chief Drug Controller (Punjab), Mmeber CLB 2. Director, Drug Testing Laboratory, Punjab, Lahore 3. Deputy Director General (E & M), DRAP, Lahore 4. Area Federal Inspector of Drugs, DRAP, Lahore While the panel inspected the premises is as under:- 1. Mr. Asim Rauf, FID /DDG , DRAP, Lahore 2. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore 3. Mr. Muhammad Anwar Arshad Junaid, DDC/Provincial Drug Inspector, Jhang The Board showed displeasure on such practices of the members of the panel who are nominating any other person at their own to conduct inspection on their behalf which is not allowed as the constitution of panel of experts is the domain of CLB

			which is delegated to its Chairman. **The Board unanimously decided to defer the case for re-inspection by the same panel with same composition as constituted by Chairman CLB / Director Licensing vide letter dated 27-10-2014.**
5.	**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)**	**Approved the Grant of Renewal of DML for following three sections:** **<u>Sections (03)</u>** i) Veterinary Oral Powder - General ii) Veterinary Oral Liquid - General iii) Veterinary Liquid Vials Injection - General
10.	**M/s. Lemendoza Pharmaceuticals (Pvt) Ltd., Plot No.7 Sector 23 Korangi Industrial Area, Karachi.** **Renewal period** **18-03-2015 to 17-03-2020**	**DML No.000140 (Formulation)**	**Approved the Grant of Renewal of DML for the following six sections:** **<u>Sections (06)</u>** 1. Tablet (General) 2. Capsule (General) 3. Syrup (Oral Liquid) 4. Oral Dry Powder Suspension (General Antibiotics) 5. Topical (Cream / Ointment/ Gel) 6. Injection (Ampoule).
11.	**M/s. Max Pharmaceuticals Plot No. 12, Street No. N-7 National industrial Zone, Rawat, Islamabad.** **Renewal period** **15-10-2014 to 14-10-2019.**	**DML No.000671 (Formulation)**	**Approved the Grant of Renewal of DML for the following six sections:** **<u>Sections (06)</u>** i). Tablet (General) ii). Capsule (General) iii). Cream / Ointment / Gel (General) iv). Liquid Syrup (General) v). Capsule (Cephalosporin) vi). Oral Dry Powder Suspension.

12.	**M/s. Lisko Pakistan (Pvt) Ltd.,** **L-10, Block No. 21, Shaheed Rashid Minhas Road, Federal B Industrial Area, Karachi.** **Renewal period 03-06-2014 to 02-06-2019.**	**DML No.000110 (Formulation)**	**Approved the Grant of Renewal of DML for following ten sections:** 1. Tablet (General) 2. Tablet (Cephalosporin) 3. Tablet (Penicillin) 4. Capsule (General) 5. Capsule (Penicillin) 6. Capsule (Cephalosporin) 7. Liquid Syrup (General) 8. Oral Dry Powder Suspension (Penicillin) 9. Oral Dry Powder Suspension (Cephalosporin) 10. Oral Dry Powder Suspension (General) **Board further allowed the resumption of production which was suspended in 238th meeting of Central Licensing Board due to observations of the panel made during inspection for renewal of DML.**
13.	**M/s. Siza International (Pvt) Ltd.,** **18-KM, Ferozepur Road, Lahore.** **Renewal period 27-10-2014 to 26-10-2019**	**DML No.000259 (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. Parenteral (Large Volume) 2. Parenteral vial 3. Parenteral Ampoule 4. Tablet (General) 5. Capsule (General) 6. Dry Powder Suspension (General) 7. Tablet (Cephalosporin) 8. Capsule (Cephalosporin) 9. Dry Powder Suspension (Cephalosporin) 10. Oral Liquid (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.**

14.	**M/s. Raazee Therapeutics (Pvt) Ltd., 48-KM, Lahore-Kasur Road, Kasur.** **Renewal period 07-09-2014 to 06-09-2019**	**DML No.000437 (Formulation)**	**Approved the renewal of DML for the following eleven sections:** **<u>Sections (11)</u>** 1. Oral Liquid (General). 2. Tablet (General). 3. Capsule (General). 4. Tablet (General Antibiotics) 5. Dry Powder Suspension (General Antibiotic). 6. Capsule (General Antibiotic) 7. Capsule (Cephalosporin) 8. Oral Dry Powder Suspension (Cephalosporin). 9. Dry Powder Injectable Vials (Cephalosporin). 10. Liquid Vials SVP (General) 11. Liquid Ampoule SVP (General Antibiotic)
15.	**M/s. A.Z. Pharmaceuticals Co. Ltd, 4-KM, Manga Road, Raiwind, District Kasur.**	**DML No.000338 (Formulation)**	**Approved the Grant of Renewal of DML for the following one section: -** **<u>Sections (01)</u>** 1. Large Volume Parenterals (Infusion)
16.	**M/s. Trison Research Laboratories (Pvt) Ltd., Plot No. 72-A, Punjab Industrial Estate, Sargodha.**	**DML No.000623 (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. **Recommendations of the panel:** i. In Quality Control, Manger of the firm had resigned for last six months. Mr. Zahid Imran, Quality Control Officer was officiating at the time of inspection. ii. The firm had ordered for dispensing booth to upgrade the sampling facility and it was yet to be installed. iii. The firm was also in the process of

			addition of stability chamber, FTIR in Quality Control laboratory. iv. Improvement of building of the unit was also planned by the management. v. Complete segregated area for Cephalosporin was required for good cGMP compliance, meanwhile firm needed to stop operations for Cephalosporin products till complete dedication.
17.	**M/s English Pharmaceuticals Industries, Link Katar Bund Road, Thokar Niaz Beg, Lahore.**	**DML No.000339 (Formulation)**	**Approved the Grant of Renewal of DML for Capsule (General) section which was subjected for re-inspection in 239th meeting of CLB.**
18.	**M/s Mallard Pharmaceuticals (Pvt) Ltd., 23-KM, Lahore Road, Qadirpur Rawan, Multan.**	**DML No.000622 (Formulation)**	**The Board was apprised that the case of firm was of grant of additional section but mistakenly placed under the cases of Renewals of DMLs.** **Now in minutes, it has been placed under the cases of grant of Additional Sections, please.**
19.	**M/s Trigon Pharmaceuticals (Pvt) Ltd.,** **8-KM, Raiwind Road, Lahore** **Renewal period 16-10-2014 to 15-10-2019**	**DML No.000342 (Formulation)**	**Approved the Grant of Renewal of DML for the following nine sections:** **<u>Sections (09)</u>** 1. Liquid Injection Ampoule (General) 2. Liquid Injection Ampoule (Antibiotic) 3. Liquid Injection Ampoule (Psychotropic) 4. Cephalosporin Dry Powder Injectable Vials. 5. Oral Dry Powder Suspension (General) 6. Liquid Syrup (General) 7. Tablet (General). 8. Ointment/Cream/Gel (General) 9. Lotion (General)

20.	**M/s Shawan Pharmaceuticals Plot No. 37 Street No.NS-1, National Industrial Zone, Rawat Rawalpindi.** **Renewal period** **19-06-2013 to 18-06-2018.**	**DML No.000627 (Formulation)**	**The Board approved the renewal of DML for the following five sections:** **Sections (05)** 1) Capsule (Cephalosporin) 2) Oral Dry Powder Suspension (Cephalosporin) 3) Sterile powder Injection Vials (Cephalosporin) 4) Tablet (General) 5) Capsule (General) **The Board also allowed resumption of production in all areas of the firm which was suspended in 240th meeting of CLB due to observations of the panel made during inspection for renewal of DML of the firm.**
21.	**M/s Shaheen Pharmaceuticals Saidu Sharif, Sawat.** **Renewal period** **31-12-2014 to 30-12-2019.**	**DML No.000562 (Formulation)**	**Approved the Grant of Renewal of DML for the following five sections:** **Sections (05)** 1) Tablet (Quinolone) 2) Oral Liquid (General) 3) Oral Dry Powder Suspension (General) 4) Capsule (General) 5) Tablet (General)
22.	**M/s Citi Pharma (Pvt) Ltd., 3.5 KM Head Baloke Road, Phool Nagar, District Kasur.** **Renewal period** **26-06-2013 to 25-06-2018.**	**DML No.000512 (Formulation)**	**Approved the Grant of Renewal of DML for the following six sections:** **Sections (06)** 1. Oral Liquid (General) 2. Tablet (General) 3. Tablet (Antibiotic) 4. Capsule (General) 5. Oral Dry Powder Suspension (Cephalosporin) 6. Capsule (Cephalosporin)

23.	**M/s Biogen Pharma 8-km, Chakbeli Khan Road, Rawat, Rawalpindi.** **Renewal period 19-06-2013 to 18-06-2018.**	**DML No. 000639 (Formulation)**	**The Board approved the renewal of DML for following five sections:** **<u>Sections (03)</u>** i) **Veterinary** Oral Liquid (General) ii) **Veterinary** Oral Powder (General) iii) **Veterinary** Liquid Injection Vials (General) iv) Tablet (General) – **Human** v) Cream/Ointment/Gel (General) - **Human**
24.	**M/s. Wilson's Pharmaceuticals. Plot No. 366, 387-388, Sector I-9, Industrial Area, Islamabad.** **Renewal period 30-09-2014 to 29-09-2019.**	**DML No. 000239 (Formulation)**	**The Board approved the renewal of DML for the following six sections only:** 1. Tablet (General) 2. Capsule (General) 3. Oral Dry Powder for Suspension (General) 4. Oral Liquid (General) 5. Sachet (General) 6. Ointment/Cream/Gel (General) The Board was apprised about the panel observations that as under: • During inspection it was noticed that the sections namely **tablet Psychotropic / Narcotic, cephalosporin dry powder for suspension, cephalosporin capsule, penicillin dry powder suspension** were not operative and the management informed that the production in these section have been stopped and the section will be made operative after their up gradation subsequent to the approval of layout plan which have been submitted to DRAP. • The non-operative sections will be re-inspected when the company inform about its readiness to the directorate of licensing. **The Board accordingly decided and not allowed manufacturing / production in above said sections due to above said observations of panel.**

25.	**M/s Bio-Labs (Private) Limited** **Plot No.145, Industrial Triangle, Kahuta Road, Islamabad.** **Renewal period 15-10-2014 to 14-10-2019.**	DML No.000296 (Formulation)	**The Board approved the grant of Renewal of DML for the following fifteen sections:** **<u>Human Sections (12)</u>** 1. Infusion (General) 2. Lyophilized vials (General) 3. Dry Suspension (General) 4. Cream / ointment (General) 5. Dry Vials Injection (Cephalosporin) 6. Liquid Syrup 7. Tablet (Psychotropic) 8. Capsule (Cephalosporin) 9. Ampoule Injection General) 10. Dry Suspension (Cephalosporin) 11. Capsule (General) 12. Tablet (General) **<u>Veterinary Sections (03)</u>** 13. Oral Powder –Veterinary 14. Oral Liquid –Veterinary 15. Vaccines –Veterinary
26.	**M/s Davis Pharmaceutical Laboratories** **Plot No.121, Industrial Triangle, Kahuta Road, Islamabad.** **Renewal period 15-06-2014 to 14-06-2019**	DML No.000432 (Formulation)	**Approved the grant of Renewal of DML for the following five sections:** **<u>Sections (05)</u>** 1. Liquid Syrup (General) 2. Tablet (General) 3. Capsule (General) 4. Sachet (General) 5. Cream / Ointment / Gel (General)

ITEM NO. V MISCELLANEOUS CASES.

Case No.1 <u>Regularizations of Layout Plans of M/s Wilshire Labs (Pvt) Ltd, 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore</u>

The case was placed the Board as under: -

M/s Wilshire Labs (Pvt) Ltd, 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore. DML NO. 000232 (Formulation), 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: -

S.#	Ground Floor
1.	Tablet (General)
2.	Capsule (General)
3.	Dry Powder Suspension (General)

Accordingly, master layout plan of firm was approved/regularized/authenticated for the above mentioned sections and a panel was constituted comprising of **(i).** Dr. Ikram – Ul – Haque , Member CLB **(ii).** Mr. Jamil Anwar, Director, Drug Testing Laboratory, Lahore **(iii).** Mr. Abdul Rashid Shaikh, Area FID, DRAP, Lahore and **(iv).** Rana Ahsan Ul Haque Ather, ADC, DRAP, Lahore and requested to verify the above sections of firm as per approved layout plan.

Accordingly, panel inspected the premises and verified all the above mentioned sections and recommended as under:-

Recommendations of the Panel
In the light of above, the panel of experts is of the opinion to recommend the grant of Injectable narcotic/ Psychotropic section as an additional section to the M/s Wilshire Labs (Pvt) Ltd, 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore ***and also recommend the regularization of the layout plan for the following sections:*** -

1) Tablet (General)
2) Capsule (General)
3) Dry Powder Suspension (General)

<u>Decision of CLB</u>

The Board after discussion / deliberations has approved the regularization/ authentication of existing sections of M/s Wilshire Labs (Private) Limited located at 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore under DML # 000232 (Formulation) according to approved layout plan as under:-

1) ***Tablet (General)***
2) ***Capsule (General)***
3) ***Dry Powder Suspension (General)***

Case No.2 Regularizations of Layout Plans of M/s. Tabros Pharma (Pvt) Ltd, Plot No.L-20/B, Sector 22, F.B. Industrial Area, Karachi.

The case was placed the Board as under: -

M/s. Tabros Pharma (Pvt) Ltd, Plot No.L-20/B, Sector 22, F.B. Industrial Area, Karachi DML NO. 000106 (Formulation), 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: -

S.#	Ground Floor
1.	Tablet (General/ General Antibiotic)
2.	Liquid Syrup (General).
3.	Sachet section (General)
4.	Capsule (General/ General Antibiotic)
5.	Cream/Ointments/Gel (General)
6.	Lotion (General)
7.	Oral Dry Powder Suspension (General)
8.	Sterile Liquid Injection Ampoule - General
9.	Sterile Liquid Injection Vials - General
10.	Dry Powder Vials Injection - General
11.	Sterile Dry Powder Injection Vials (Cephalosporin)
12.	Capsule (Cephalosporin).
13.	Tablet (Cephalosporin)
14.	Oral Dry Powder Suspension (Cephalosporin)
15.	Sachet (Cephalosporin)

Accordingly, layout plan of firm was approved/regularized/authenticated and a panel was constituted comprising of **(i).** Syed Jawed Yousaf Bukhari, Member CLB **(ii).** Dr. Saif-Ur-Rehman Khattak, CDL, Karachi **(iii).** Mr. Abdul Rasool Shaikh, Area FID, DRAP, Karachi **(iv).** Mr. Farman Ali Bozdar, ADC, CDL, Karachi and **(v).** Ms. Ume Laila, Area ADC, DRAP, Karachi and requested to verify the above sections of firm as per approved layout plan.

Accordingly, panel inspected the premises and verified all the above mentioned sections with recommendations as under:-

Recommendations of the Panel

The panel during inspection reviewed in detail critical documents relating to manufacturing, QC, QA and utilities and found a good level of compliance, the panel further noted that all the above sections are given as per approved layout plan and same are recommended to be regularized. Keeping in view the existing GMP conditions, capabilities of working personnel, stabilities of machineries / equipment and the attitude of the management towards better compliance the panel unanimously recommends the grant of renewal of their DML No.000106 by way of formulation for next five years.

Based on the above detailed observations the panel recommends the regularization of all above sections and it is also unanimously recommended that their DML No. 000106 by way of formulation may be revalidated for the next five years based on the level of the compliance and attitude of the higher management towards GMP.

Decision of CLB

The Board after discussion / deliberations has approved the regularization/ authentication of existing sections of M/s. Tabros Pharma (Private) Limited located at Plot No.L-20/B, Sector 22, F.B. Industrial Area, Karachi under DML # 000106 (Formulation) according to approved layout plan as under:

S.#	Ground Floor
1.	Tablet (General/ General Antibiotic)
2.	Liquid Syrup (General).
3.	Sachet section (General)
4.	Capsule (General/ General Antibiotic)
5.	Cream/Ointments/Gel (General)
6.	Lotion (General)
7.	Oral Dry Powder Suspension (General)
8.	Sterile Liquid Injection Ampoule - General
9.	Sterile Liquid Injection Vials - General
10.	Dry Powder Vials Injection - General
11.	Sterile Dry Powder Injection Vials (Cephalosporin)
12.	Capsule (Cephalosporin).
13.	Tablet (Cephalosporin)
14.	Oral Dry Powder Suspension (Cephalosporin)
15.	Sachet (Cephalosporin)

Case No.3 **Regularizations of Layout Plan of M/s OBS Pakistan Ltd, C-14, Manghopir Road, Karachi.**

The case was placed the Board as under: -

M/s OBS Pakistan Ltd, C-14, Manghopir Road, Karachi DML No. 000012 (Formulation), 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: -

S.#	Sections
1.	Soft Gel Capsule (General).
2.	Soft Gel Capsule (Hormone).
3.	Liquid Vials SVP (General).
4.	Tablet (Hormone).
5.	Tablet (General).
6.	Warehouse & QC Laboratory.

Accordingly, layout plan of firm was approved/regularized/authenticated and a panel comprising of following members was requested to verify the above sections of firm as per approved layout plan.

1. Syed Muied Ahmed, Member CLB.
2. Mr. Qaiser Muhammad, Chief Drug Inspector, Sindh.
3. Dr. Tanweer Alam, Director CDL, Karachi.
4. Muneeza Khan Area FID, DRAP Karachi.
5. Ms. Ume Laila, Area ADC, DRAP, Karachi

Accordingly, panel inspected the premises and verified all the above mentioned sections with recommendations as under:-

Recommendations of the Panel

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. 000012 having dedicated HVAC and a per approved Layout plan

Decision of CLB

The Board after discussion / deliberations has approved the regularization/ authentication of existing sections of M/s. OBS Pakistan Limited located at C-14, Manghopir Road, Karachi under DML # 000012 (Formulation) according to approved layout plan as under:

S.#	Sections
1.	Soft Gel Capsule (General).
2.	Soft Gel Capsule (Hormone).
3.	Liquid Vials SVP (General).
4.	Tablet (Hormone).
5.	Tablet (General).
6.	Warehouse & QC Laboratory.

Case No.4 **Regularizations of Layout Plan of M/s. Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.**

The case was placed the Board as under: -

M/s. Life Pharmaceutical Company, 24-III, Industrial Estate, Multan DML No. 000194 (Formulation), 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: -

i. Liquid syrup (General)
ii. External Liquid preparation (General)
iii. Re-packing Powder.

Accordingly, layout plan of firm was approved/regularized/authenticated and a panel was constituted comprising of following members who were requested to verify the above sections of firm as per approved layout plan.

1. Dr. Ikram-ul-Haq, Member CLB.
2. Jamil Anwar, Director DTL, Lahore.
3. Dr. Zaka-ur-Rehman, Chief Drug Controller, Lahore
4. Syed Zia Husnain, FID, DRAP, Lahore.
5. Rana Ahsan ul Haq Athar, ADC, DRAP, Lahore.

Accordingly, panel inspected the premises and verified all the above mentioned sections with recommendations as under:-

Recommendations of the Panel

Panel has physically inspected the unit and seen various documents. In view of the above facilities like building, equipments, production, quality control, documentation and quality assurance, at the time of inspection, the panel of inspectors recommends the following for M/s Life Pharmaceutical Company 24-III, Industrial area Multan for consideration by the Board concerned under Drugs Act, 1976.

i. Renewal of Drug Manufacturing License.
ii. Regularization / authentication of liquid syrup general section, external preparation section, re-packing powder section.
iii. Regularization / authentication of master layout plan.

Steroidal / Topical for Cream/Ointment/Gel/ Lotion preparation manufacturing in general facility according to the decision of the central Licensing Board in its 239th as referred by firm during inspection may also be considered by the board concerned under Drugs Act 1976.

Decision of CLB

The Board after discussion / deliberations has approved the regularization/ authentication of existing sections of M/s. Life Pharmaceutical Company located at 24-III, Industrial Estate, Multan under DML # 000194 (Formulation) according to approved layout plan as under:

i. Liquid Syrup (General)
ii. External Liquid Preparation (General)
iii. Re-Packing Liquid

Case No.5 **Change in Excipients (Inactive) Composition Of Microencapsulation Product "Clarithromycin Taste Masked Coated Granules 38% W/W" By Way Of Semi Basic Manufacture against DML No.000649 Dated 12-12-2013.**

The case was placed the Board as under: -

M/s Surge Laboratories (Pvt) Ltd has requested with a fee of Rs.5000/- on the subject cited above and submitted that for the improvement of the product quality they would like to change the inactive composition of Clarithromycin Taste Masked Granuales 38% (by way of semi basic manufacture) as under: -

Specification of existing composition which we submitted alongwith application for DML on 29-12-2008	Specification of proposed composition
Eatch Batch of 40 kgs contain: Active Ingredient: Clarithromycin Powder USP…..15.2kg Inactive Ingredients: Kollicoat MAE 30 DP…….71.883kg Castor Oil……3.235Kg Distilled Water……71.883kg	Eatch Batch of 40 kgs contain: Active Ingredient: Clarithromycin USP (5% overage included).. 19.000kg. Inactive Ingredient: Acrypol 934P (Carbomer USP)....12.000kg Ethanol BP (Commercial)……35.000Lit* Distilled Water BP……40.000Lit* Hydroxyproply Methyl Cellulose 606USP (HPMC-606)……..2.480kg. Isopropyl Alcohol BP……30.000Lit* Distilled Water BP……..10.000Lit* Methacrylic Acid Copolymer USP Type A (L-100)……...14.365kg Polyethylene Blycol-6000 BP (PEG 6000) 2.155kg. Isopropyl Alcohol BP…….84.000 Lit* Distilled Water BP……..21.000 Lit* *These materials are volatilized during drying and coating process thus not included in final product.

In support firm has submitted following documents: -

- Data for 06 months accelerated stability studies.
- Undertaking that real time stability studies will be continued upto the completion of shelf life.
- Copy of DML letter and renewal.
- Nothing Due Certificate regarding deposition of Central Research Fund.
- Master Formulas / BMR of existing and proposed excipients / composition.
- Documents confirming that proposed excipients / inactive is of pharmaceutical grade.

Decision of CLB

The Board after thorough discussion and deliberations deferred for complete scientific and technical data from the firm.

Case No. 6 M/S ELIXIR LABORATORIES (PVT) LTD., 26-S, INDUSTRIAL AREA, KOT LAKHPAT, LAHORE AREA SHORT.

The case was placed the Board as under: -

M/s Elixir Laboratories (Private) Limited located at 26-S, Industrial Area, Kot Lakhpat, Lahore submitted application for renewal of DML # 000288 (Formulation) of their firm for the period 07-09-2014 to 06-09-2019 which was received in this Secretariat of Licensing Division DRAP on 18-09-2014. The application of renewal of DML was 11 days delayed from its due date of renewal of DML.

Following shortcomings were noticed in application of renewal of DML of the firm which were conveyed to the firm vide letter dated 14th January 2015.

i. To deposit additional surcharge of Rs. 55000/- according to Rule 6 of Drugs (Licensing, Registering & Advertising) Rules 1976 for submitting application for renewal of Drug Manufacturing License of your firm on **18th September 2014,** which is delayed by 11 days from the due date i.e. **07th September 2014**.

ii. To furnish documents/ information of production and Q.C Incharge as per checklist enclosed herewith. The experience and qualification of proposed technical experts shall meet the requirement of Rule 16 of Drugs (Licensing, Registering & Advertising) Rules 1976. ***All documents/information should be attested by gazette officer or notary public and shall be signed by authorized person of the firm also.***

iii. In inspection report of firm dated 26-03-2011, the management of the firm reiterated that they are under the active process of shifting the unit to Sunder Industrial Estate and the construction of the basement has been completed. In this regard firm was directed to furnish Plot Allotment, Plot possession letter, plot demarcation, site verification report of area Federal Inspector of Drugs, Site approval letter from competent authority, layout plan approval from competent authority & necessary supported documents for the plot in Sundar Industrial Estate for the purpose of shifting of licensed unit

iv. It has been further noticed during scrutiny of application of renewal of DML that firm has included 03 more directors in management and one of the existing director i.e. Mrs. Ayesha Nadeem has resigned from directorship as reflected from Form 29 issued by SECP. Therefore firm was required to furnish application of change of management of the firm with following information/documents.
   a) To deposit prescribed fee of Rs. 50,000/- and submit the retained copy of challan in this division.
   b) To furnish the photocopies Form A, Form 29, Form 21, Certificate of Incorporation and Memorandum of Association issued and attested by Security Exchange Commission of Pakistan.
   c) To furnish copy of agreement/deed of 03 new directors with the existing directors.

Firm submitted the reply of the letter issued from this Division on 14th January 2015 wherein shortcomings in the application for renewal of DML of the firm were conveyed according to Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rules 1976.

It was advised to the firm in the letter of this Division according to Rule 6 of the Drugs (Licensing, Registering & Advertising) Rules 1976, to deposit additional surcharge of Rs.

55000/- for submission of application of renewal of DML, addressed to Secretary CLB on 18th September 2014 which was 11 days delayed from due date of renewal i.e. **07th September 2014.** But firm in their reply stated that renewal fee was deposited on 2nd September 2014 within the stipulated time and receipt deposit slip (DRAP) enclosed with renewal application was subsequently dispatched to DRAP (Licensing Board) through Courier (TCS) on 09th September 2014. Copy of Courier slip is enclosed and at (Page 249/Corr.).

It is pertinent to mention here that it is clear in Rule 5 of the Drugs (Licensing, Registering & Advertising) Rules 1976 that application for renewal of DML shall be made on prescribed For 1A to the Central Licensing Board through its Secretary.

In this regard, the application of renewal of DML of the firm on prescribed Form 1-A, was received in DRAP via Diary No. 94 R & I dated 18-09-2014 which is the actual date of receipt of application, delayed by 11 days from the due date.

Furthermore, in the letter issued from this Division, firm was also advised to deposit prescribed Fee of Rs. 50,000/- along with other documents, for change in management of the firm but firm has not deposited the prescribed fee and stated in their reply that firm has informed to Security Exchange Commission of Pakistan and accordingly Form A and Form 29 were initiated and forwarded to SECP with required fee as per law.

Firm was also advised to provide details of the documents for their new plot to fulfill the requirement of the rules because existing unit is of 01 kanal and 04 marlas area which is less than the minimum area i.e. 2000 square yards. In their reply, it is stated that for the time being it is not possible to shift the unit to their new plot due to change in management and handing over to the said property to relieving partner. Firm stated that they are working on various alternate options and soon apprise this office about the actual schedule.

It is to bring in notice that firm has committed for shifting of their unit since March 2011 and now more than 04 years have been passed but still firm is in strategy to delay it further.

Decision of CLB

The Board after thorough discussion and deliberations decided for Show Cause with Personal Hearing.

Case No. 7 UNSIGNED INSPECTION REPORT OF M/S WEATHER FOLDS PHARACEUTICALS, PLOT NO.62/2, PHASE-II INDUSTRIAL ESTATE HATTAR.

The case was placed the Board as under: -

The Board was apprised that the said case was considered in 238th meeting of CLB held on 19-11-2014 and Board decided as under: -

M/s Weather Folds Pharmaceuticals 69/2 Phase-2 Industrial Estate Hattar.	DML NO. 000644 (Formulation)	While discussing the case: - Prof. Dr. Muhammad Saeed, Member CLB apprised the Board that he was also the member of the panel but he was not the part of panel inspection of the firm for which this report has been submitted for consideration of CLB. He further added that previously an inspection for renewal of DML of the firm was conducted in the month of September 2014. Accordingly report was written and signed by some members in which renewal of DML was not recommended due to serious violation of GMP. The said inspection report has not been submitted to CLB as yet. Prof. Dr. Muhammad Saeed apprised the Board that Q.C Incharge of the firm was absent from last 06 months as informed by production Incharge. Q.C Lab was totally out of order. The material of another company was placed in the premises. The HVAC system was out of order in Oral Solid Dosage section. There was extreme violation of GMP practices. Prof. Dr. Muhammad Saeed excused for being the panel member of this firm. **Keeping in view the above serious observations1 of one of the panel member of inspection team (also member of CLB), the Board discussed and deliberated the case thoroughly and unanimously decided as under:** **"Deferred the for renewal of DML for re-inspection by the following panel:** **1. Prof. Dr. Gul Majeed Khan, Member CLB.** **2. Chief Drug Inspector, KPK** **3. Director DTL, Peshawar** **4. Mr. Muhammad Arif Chaudhary, DDC (Reg-I), DRAP, Islamabad.** **5. Area FID, DRAP, Peshawar** **6. Area ADC, DRAP, Peshawar.** **The Board has desired to seek that inspection report from area FID wherein Dr. Saeed has signed for**

		submission to CLB. **The Board expressed its displeasure about such practices of field offices.**

Accordingly, inspection report was sought from area FID wherein Dr. Saeed signed for submission to CLB. The area FID sent the said report in which following recommendations are made: -

Recommendations:

The constituted panel after the checking the equipment and technical staff in QC and Production directed the firm to stop production and improve the following short coming points mentioned as under:-

1. To bring HpLC, DT and UV into functional condition as they are out of order.
2. To purchase Stability Chamber, Air Sampler, Particle Counter.
3. They are directed to appoint Microbiologist as the firm do not have any Microbiologist for proper microbial testing.
4. The Quality Control Incharge Mr.Aftab Alam was absent from duty since 1st June 2014. The firm is directed to appoint new QC Incharge.
5. They have only one QC analyst Mr. Tanveer who was having two years experience and performs all tests in QC. The firm is directed to appoint two more QC Analyst and QA Inspector.
6. The opening between QC and Production Corridor should be closed by hatch system.
7. The management of the firm was directed to appoint two more pharmacists as the firm has 4 sections (1) Tablet General (2) Capsule General (3) Dry syrup Cephalosporin (4) Capsule Cephalosporin and Injectable Cephalosporin.
8. In IPQ store the firm has provided HVAC ducting but not functional nor A/C provided in this room. It was very hot and humid there at the time of inspection. They are directed to bring HVAC into functional or provide split AC facilities.
9. The entire flooring at ground floor cephalosporin area was having rough cemented floor except corridor, therefore the firm is directed to replace it with chips of marble flooring so that contamination of dust particle could be controlled.
10. The firm has provided HVAC ducting to the entire facilities but was not in working condition at the time of inspection. They are using split AC. The firm is directed to bring all the HVAC ducting into working condition.
11. Injectable Area: The firm are directed to bring the Hot air sterilization machine into working.
12. All the Hepa filters to be tested by DOP or by Poly Alpha Olefin method (PAO).
13. In Raw Material store: the firm are directed to improve the cemented broken rough floor into chips or marble flooring to avoid contamination.
14. All the raw material drums should be labeled properly.
15. The firm is directed to appoint pharmacist in raw material store.
16. In dispensing room the HVAC should be brought into functional on split AC to be provided alongwith dehumidifier.
17. They are directed to maintain he record of humidity and temperature before dispensing the raw material.

18. In Tablet Section the firm is directed to improve the exhaust duct of tray drier outside the room with proper safety system.
19. They are directed to provide cone mixer for dry mixing (Lubrication) of raw material.
20. All the HVAC ducting in tablet area should be brought into operational.
21. The grant of additional section cannot be recommended as it was under construction at the time of inspection.

All the above points discussed with the management / technical staff accompanied the panel members at the time of inspection. The firm was directed to stop production and improve all the deficiencies at their earliest.

-Sd/-

(Prof. Dr. Muhammad Saeed)
Member Central Licensing Board

(Dr. Khalid Khan)
Director DTL, Peshawar

(Rehmatullah Baig Alvi)
Federal Inspector of Drugs, Peshawar

(Adnan Shahidullah)
Assistant Drug Controller, Peshawar

(Imran Khan)
Provincial Drug Inspector, Peshawar

The case was placed for the appraisal of the Board. Accordingly, the Board was appraised.

Case No. 8 **M/S NOVINS INTERNATIONAL (PVT) LTD PLOT # E-37, 38, PORT QASIM AUTHORITY, KARACHI.**

The case was placed the Board as under: -

1. **M/s Novins International (Private) Limited** was initially granted DML No. # 000541 (Formulation) on 17th July 2004 for manufacturing of drugs at the premises located at **E 37 & 38, Port Qasim, Karachi** and according to Rule 6 of Drugs (Licensing, Registering & Advertising) Rules 1976 framed under the Drugs Act, 1976, ***a license issued under this chapter, unless earlier suspended or cancelled, be in force for a period of five years from the date of issue and may thereafter be renewed for period of five years.*** **(Annex - II).**

2. At present, the renewal of DML of the firm was due for the period i.e. **from 17-07-2014 to 16-07-2019.**

3. According to the Rule 5(1) & 6[1] of Drugs (Licensing, Registering & Advertising) Rules 1976 framed under the Dugs Act, 1976 which are reproduced as under:-

Rule 5 (1) of the Drugs (Licensing, Registering & Advertising) Rules 1976

"Application for grant or renewal of a license referred to in clauses (i) to (iv) of Rule 3 shall be made in Form 1 [or 1-A] to the Central Licensing Board addressed to its Secretary".

Rule 6[1] of the Drugs (Licensing, Registering & Advertising) Rules 1976

if application for renewal is made before the expiry of the period of validity of a license, the license shall continue in "force until" orders are passed on such application.

4. As per above mentioned rules, firm should have to apply for renewal of DML of the firm on prescribed Form 1-A and application of renewal of DML would have to be received in this Division before the expiry of the period of the validity of the license **i.e. 17-07-2014** but application of the renewal of DML of the firm was received in this Division on 16-09-2014 which was sixty two (62) days delayed [15 days of July, 31 days of August and 16 days of September = total 62 days] from the due date of renewal of DML. It is also pertinent to mention that according to Rule 6[2] of Drugs (Licensing, Registering & Advertising) Rules 1976 ***if an application for renewal is made after the expiry of the period of validity of a license but within sixty days of its expiry, the license shall continue in force on payment of additional surcharge of rupees five thousand for each***

day the application is delayed, and thereafter until order are passed on the such application. But in this case the application for renewal of DML was received even after sixty days of the expiry of the validity of the license.

5. Therefore, the firm was directed to apply afresh grant vide this Division's letter of even number dated 13-03-2015, according to Rule 5(3) of Drugs (Licensing, Registering & Advertising) Rules 1976 which states that ***"if the application for renewal of the license is made after the expiry of the period of the validity of the license, it shall be treated as a fresh application for the grant of license"***

6. Now the firm **M/s Novins International (Private) Limited** under DML # 000541 (Formulation) for the premises located at **E-37 & 38, Port Qasim, Karachi** filed a constitutional petition # D-1647 of 2015 in the Honorable High Court of Sindh, Karachi against this Division's letter of even number dated 13-03-2015 regarding expiration of the period of validity of their license and directions to apply afresh grant.

7. The Honorable Court in the said case, has passed the orders that ***Let notices be issued to the respondents as well as to DAG for 22nd April 2015, till then letter dated 13-03-2015 of the Drugs Regulatory Authority of Pakistan shall remain suspended.***

8. The parawise comments preparation is under process by Licensing Divisionn and next date of hearing of the case in Honorable Court is 22-05-2015.

9. The case was submitted for appraisal of the Board.

The case was placed for the appraisal of the Board. Accordingly, the Board was appraised.

Case No. 9 M/S KLIFTON PHARMA, PLOT NO. D-2, SITE, KOTRI, JAMSHORO.

The case was placed the Board as under: -

M/s. Klifton Pharma, Plot # D-2, S.I.T.E, Kotri, Jomshoro was granted license for manufacture of drugs for the period of five years w.e.f. 13-06-2009.

Accordingly, the renewal of DML # 000666 (Formulation) was due on 13-06-2014 for the next five years.

The application for renewal of DML of the firm was received in this Division on 18-11-2014 which is almost 05 months delayed from due date of renewal i.e. 13-06-2014.

Therefore, the license of the firm stands invalid because application shall be treated as fresh for grant of license according to Rule 5(3) of the Drugs (Licensing, Registering & Advertising) Rules 1976 which is reproduced as under:-
"if the application for renewal of the license is made after the expiry of the period of the validity of the license, it shall be treated as a fresh application for the grant of license"

Accordingly, firm was informed vide letter dated 13th March 2015, regarding expiration of validity of the license and advised to apply afresh grant on prescribed Form 1 along with all prerequisites as per rules. In the same letter, area Federal Inspector of drugs was requested to immediately visit the firm and take necessary action according to rules.

Syed Hakim Masood, area Federal Inspector of drugs Hyderabad at Karachi submitted inspection report in this regard wherein it was stated that he visited the premises of M/s Klifton Pharma Located at Plot No.D-2, SITE, Kotri Jamshoro on 11th April 2015 with reference to this office letter dated 13th March, 2015. The premises were found closed and none of the person was available at the premises to open the gate.

The case was submitted for appraisal of the Board.

The case was placed for the appraisal of the Board. Accordingly, the Board was appraised.

Case No. 10 M/S JAFSON PHARMACEUTICALS (PVT) LTD, 65 INDUSTRIAL ESTATE, JAMRUD ROAD PESHAWAR.

The case was placed the Board as under: -

M/s Jafson Pharmaceuticals (Private) Limited was granted Drug Manufacturing License (DML) # 000505 (Formulation) for the premises located at 65- Industrial Estate Hyatabad, Peshawar, on 07th October 2002 for the period of 05 years, for manufacturing of drugs in Tablet, Dry Syrup, Capsule and Liquid.

Afterwards, renewal of DML was due for the period 07-10-2012 to 06-10-2017 for which no application found in file and record of this division reflects that firm failed to applied renewal of DML of the firm before the period of expiry of validity of the license and according to Rule 5 (3) of Drugs (Licensing, Registering & Advertising) Rules 1976 firm requires to apply afresh grant.

Later on, a letter dated 13th April 2015 was received from Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore wherein he stated that Honorable Drug Court, Lahore, while hearing a case of manufacturing and sale of substandard drug namely **"Jaflex"** manufactured by **M/s Jafson Pharmaceuticals (Pvt.) Ltd, 65-Industrial Estate, Hayattabad, Peshawar,** filed by Provincial Drug Inspector noticed the continuous absence of accused namely Jaffar Hussain, Chief Executive of the above mentioned firm. He further stated that the Court called him and directed to hand over the NBW (non bail able warrant) of the accused for execution as the case is fixed for 30-04-2015. The Court directed the Licensing Authority to suspend the above said license of the accused immediately till further order.

In this regard, Licensing Division contacted area Federal Inspector of Drugs, Peshawar to provide GMP status of the firm.

Area Federal Inspector of Drugs submitted inspection report dated 22-12-2014 wherein he advised firm to stop production due to serious GMP violations and accordingly a show cause notice was served to the firm from Division of QA/LT, DRAP, Islamabad on 25th February 2015.

It is now submitted that license of the firm has been expired as explained above and accordingly firm has been informed vide letter dated 05-05-2015 according to Rule 5 (3) of Drugs (Licensing, Registering & Advertising) Rules 1976 to apply for afresh grant. The rule is reproduced as under:-

"if the application for renewal of the license is made after the expiry of the period of the validity of the license, it shall be treated as a fresh application for the grant of license"

The case was submitted appraisal of the Board.

The case was placed for the appraisal of the Board. Accordingly, the Board was appraised.

Case No. 11 M/S VEGA PHARMACEUTICALS (PVT) LTD, PLOT # 4 PHARMA CITY, 30 KM, MULTAN ROAD, LAHORE.

The case was placed the Board as under: -

The Renewal of the license of the firm was approved in 239th meeting of CLB with the following sections: -

1. Eye Drops (Steroid)
2. Cream/Ointment/Gel (General)
3. Cream/Ointment/Gel (Steroid)
4. Capsule (General)
5. Tablet (General)
6. Dry Powder Injectable (Cephalosporin)
7. Oral Dry Powder Suspension (Cephalosporin)
8. Capsule (Cephalosporin)

It is stated that firm possess total 09 sections for manufacturing of drugs, but in the agenda of the last meeting of the Board, eight sections were mentioned as stated above and **Eye Drops (General) section** was mistakenly not mentioned which was approved at the time of grant of license to the firm and also mentioned in the inspection report of renewal of DML of the firm.

It is therefore submitted that CLB may permit for issuance of letter for renewal of **Eye Drops (General) Section** which was missed in record of agenda and minutes of last meeting of the Board due to typographical mistake, please.

Decision of CLB

The Board allowed Eye Drops (General) Section along with all the above sections as mentioned in agenda and minutes of 240th meeting of CLB for renewal of DML of the firm.

Case No. 12 RENEWAL OF DML OF M/S KATRINA PHARMACEUTICAL INDUSTRIES (PVT.) LTD., SHEIKHUPURA.

The case was placed the Board as under: -

The renewal of DML # 000344 (Formulation) of M/s Katrina Pharmaceutical Industries (Private) Limited located at 10-km Sheikhupura Road, Sheikhupura was not recommended by the panel who conducted inspection on 14-12-2007 for renewal of DML for the period 14-12-2004 to 13-12-2009.

Firm was then issued a show cause notice on 23-05-2008 and directed to appear before the Board on 26-05-2008.

Firm appeared before the Board in its 212th meeting held on 26-05-2008, to avail opportunity of personal hearing wherein Chief Executive of the firm Mr. Afzal Hameed submitted undertaking for voluntary stoppage of production with immediate effect and stated that they will be ready for inspection after one month.

Firm was again inspected by the then area FID on 15-06-2009 and inspection report he stated that firm had not done any compliance with reference to previous inspection report and renewal of DML was also not recommended by the panel.

Firm was again served a show cause notice dated 29-07-2009 and advised to appear before the Board for personal hearing on 31st July 2009. However firm did not appear before the Board for personal hearing.

Afterwards, firm submitted application of renewal of DML for the period of next five years **i.e. 14-12-2009 to 13-12-2014** for which a panel was constituted on 25-02-2011 but no inspection report received from that panel yet.

Meanwhile, Area Federal Inspector of Drugs, DRAP, Lahore visited firm on 06-03-2013 for routine GMP inspection and reported that firm was closed for the past many years and firm has not done any improvements in their premises.

Firm was then again served show cause notices on 23rd December 2013, 24th February 2014 with advise to appear before CLB for personal hearing but firm failed to appear in any of the meetings of the Board for personal hearing.

The case was then again discussed in 234th meeting held on 27th February, 2014 wherein the Board decided as under; -

Decision of CLB in its 234th meeting

The Board after thorough discussion / deliberations and facts on grounds considered and decided as under:-

- Fresh status report by panel comprising of Dr. Ikram ul Haq, Member CLB, Ahmad Mehmood Mumtaz, CQC, DDG (E&M), Lahore and Area FID, Lahore.

- Opinion from Law Division that the firm has been called twice for personal hearing but did not attended for personal hearing so whether CLB can decide for suspension / cancellation of Drug Manufacturing License ex-parte under section 41 of Drugs Act, 1976.
- Last and final opportunity of personal hearing in the forthcoming meeting of CLB and letter shall be sent through Registered Post and receipt of same shall be retained

With respect to the decision of the Board in its meeting, the panel inspection report is still awaited.

Opinion from Division of Legal Affairs, DRAP, has been taken with respect to failure of the firm to appear before the Board for personal hearing. In this regard, the comments of Division of Legal Affairs, DRAP are as under:-

"***Section 41 of the Drugs Act, 1976 and Rule 12 of the Drugs (Licensing, Registering & Advertising) Rules 1976 are clear that an opportunity of being heard is to be provided to the licensee and obviously he cannot be forced physically for such appearance. Similarly the licensee cannot be allowed to defeat the law and the rules by his non appearance. Therefore, if all conditions given in the respective provisions of law and rules have been satisfied in a bonafide manner, the Board may go ahead in taking the decision***"

***Current status of the license of the firm*:-**

As per record of Licensing Division, DRAP, Islamabad, the both previous tenure of renewal of DML of the firm i.e. **14-12-2004 to 13-12-2009 and 14-12-2009 to 13-12-2014** has been expired. Firm has now submitted application for renewal of DML of the firm for the period of next five years **i.e. 14-12-2014 to 13-12-2019** which is well before the expiry of the period of validity of the license therefore license of the firm shall continue in force till any further orders passed on such application according to Rule 5 of the Drugs (Licensing, Registering & Advertising) Rules 1976.

The firm was called for availing last opportunity of personal hearing.

Proceedings of the case:-

Mr. Shoib Afzal S/O Mr. Afzal Hameed appeared before the Board as representative of the firm on behalf of his father (the owner of the firm). He stated that firm is closed since year 2008 because HVAC system installation is not completed due to financial constraint. He further added that their firm has made some modifications in the existing building by addition of more sections and accordingly got approval of layout plan from Central Licensing Board. Previously, firm possess very low number of registered products in tablet section due to which survival in the market was very difficult. The representative of the firm informed that they have submitted application for renewal of DML for the period 14-12-2014 to 13-12-2019 and their license is valid and further informed that their unit will be ready for inspection after 05 months.

Decision of CLB

The Board after hearing the representative of the firm and on the basis of the commitment decided to allow 05 month time to the firm for completing the installation of HVAC system according to the approved layout plan and also directed the firm to not start production unless inspected and granted permission by Central Licensing Board.

Case No. 13 RENEWAL OF DRUG MANUFACTURING LICENSE #M/S MEDIWAYS INTERNATIONAL, 16 KM MULTAN ROAD, LAHORE

The case was placed the Board as under: -

The case of firm for renewal of Drug manufacturing License No. 000468 (Formulation) for the period 09-02-2010 to 08-02-2015 is discussed in 233rd meeting of CLB and decided as under: -

"The Board did not allow the waiver of minimum plot size (i.e. total plot size 1 Kanal and 3 marlas) so deferred the renewal of DML and decided to strictly adhere to the provision of Schedule-B of Drugs (LR&A) Rules, 1976. The Board further decided to issue Show Cause Notice and Personal Hearing in the next meeting of CLB."

The above decision of CLB was conveyed to the firm on 26-02-2014 but firm did not reply the said letter yet. Meanwhile, firm has submitted application of renewal of DML for the further five years i.e. from 09-02-2015 to 08-02-2020 which is under scrutiny / evaluation process.

Firm appeared before the Board and proceedings of the case are as under:-

Proceedings of the case:-

Mr. Jamil Ahmed, Owner /CEO of the firm appeared before the Board as representative of the firm. He stated that their firm was initially granted license in year 2000 and afterwards they got renewal of DML for the period of next five years from 09-02-2005 to 08-02-2010. He requested the Board to allow him further 05 years for shifting of their unit to the new site according to the requirements of the rules.

The Secretary CLB apprised the Board that application of renewal of DML for the further five years i.e. from 09-02-2015 to 08-02-2020 has been received in Licensing Division which is well before the expiry of period of validity of the license and under scrutiny / evaluation process; so the Board may pass directions for the same, please.

Deputy Drugs Controller of Division of QA/LT, DRAP apprised the Board that the production of the firm is already stopped die to GMP non- compliance and in this regard, firm has been served Show Cause Notice.

Decision of the Board:

The Board after hearing the representative of the firm and on the basis of the commitment decided:

- ***To allow two years time for shifting of unit / enhancement of plot size according to the rules.***
- ***To scrutinize the application of the renewal of DML of the firm for the period 09-02-2015 to 09-02-2020 and inform the applicant the status of the application according to Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rules 1976 and conduct inspection of the firm after completion of application of renewal of DML.***

Case No. 14 M/S PHARMEDIC CHEMICALS, 24-KM MULTAN ROAD, LAHORE.

The case was placed the Board 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 by Licensing Division 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. Afterwards, 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).

Now the firm has submitted an undertaking and stated that the honorable authorities of Environmental Protection Agency, Government of Punjab, Lahore has advised the following;

i) A properly designed 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 provisions of Punjab environmental protection Act, 1997 (amended 2012).

The case was presented in 240th meeting of CLB held on 06-03-2015 for appraisal of the Board because complete inspection report of the panel was not received.

Now complete inspection report of the panel dated 12th March 2015, has been received in the Licensing Division wherein recommendations of the panel are as under:-
"In the light of the physical verification of the site and scrutiny of documents provided by the applicant, and considering the report of Environmental Protection Agency, Punjab the panel recommends that the site may be approved for establishment of a Pharmaceutical unit by way of semi basic manufacturing, as per requirements laid down under paragraph 1 of section 1 of the Schedule B (S.R.O 470(I)/98 dated 15-05-1998) of the Drugs (Licensing, Registering & Advertising) Rules 1976 "

Proceedings:

The Board observed that in the report of Environmental Protection Agency, it is clearly mentioned that ambient air quality may fluctuate and unit is located nearby a waste water drain.

Dr. Zaka- Ur-Rehman, Chief Drug Controller, Punjab / Member CLB (who was also the member of the panel) apprised the Board that since management of the firm has taken preventive measures by building a huge wall between water drain and premises but still obnoxious smell is all around the surroundings of the premises due to the open water drain.

The Board further enlightened the conditions for grant / renewal of a license to manufacture drugs by basic or semi basic manufacture under Rule 15 (a) of the Drugs (Licensing, Registering & Advertising) Rules 1976 wherein it is stated that "the applicant shall provide premises which shall be suitable for intended use, in size and construction and shall be located in an area free from offensive and obnoxious odors and other possible sources of contamination.

The Board showed serious concern with safety of the public health as it will be injustice with the mandate of hygienic conditions required for manufacturing of Active Pharmaceutical

ingredient(s) which shall be used in the different formulation for treatment of disease.

The Board is also of the point of view that evaluation of the surroundings of the proposed premises of the applicant shall be made on the scientific and technical basis related to the manufacturing of Active Pharmaceutical Ingredients. Air quality and surroundings of the premises shall be verified according to the requirements of the hygienic condition for APIs intended to be manufactured by the applicant in the future.

Decision of CLB

In the light of above proceedings, the Board after thorough discussion, deliberation and keeping in view the scientific importance of the matter and public health decided to re-inspect the premises under Rule 15(a) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 by the panel comprising of:-

(i) Dr. Ikram – Ul – Haq, Member CLB
(ii) Prof. Dr. Gul Majeed Khan, Member CLB
(iii)Prof. Dr. Muhammad Saeed, Member CLB
(iv) Syed Mueed Ahmed, Member CLB
(v) Area Federal Inspector of Drugs, DRAP, Lahore

Case No. 15 **ORDERS OF HONORABLE LAHORE HIGH COURT, LAHORE REGARDING WRIT PETITION NO. 10988/2007 FILED BY M/S MICKO INDUSTRIAL CHEMICALS CO. (PRIVATE) LIMITED, 28-KM FEROZEPUR ROAD, LAHORE.**

The case was placed the Board as under: -

The case was presented before the Board as under:-

M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore submitted application for renewal of DML # 000183 (Formulation) for the period 17-11-2005 to 16-11-2010 for which a panel was constituted on 23-09-2005 for inspection of the firm comprising of following experts / inspectors:-

1. Dr. Ijaz Ahmad, Associate Professor, University of Veterinary and Animal Sciences, Lahore.
2. Area Federal Inspector of Drugs, DCA, Lahore
3. Area Assistant Drugs Controller, DCA, Lahore

The above mentioned panel conducted inspection of the firm for renewal of DML and submitted report on 17-08-2006 wherein panel stated that overall condition of the firm was good. The firm had given undertaking that they would remove the shortcomings pointed out within 15 days. Therefore, the panel is of the opinion that firm may be granted renewal of their Drug Manufacturing License by way of formulation and re-packing.

After receipt of inspection report in this office, the then ADC (L & A) issued a letter to Federal Inspector of Drugs, DCA, Lahore, he stated that firm had submitted an under taking to the panel to rectify the shortcomings as pointed out by the panel, but the compliance report concerning the same had not been received so far therefore area FID was requested to verify the same and submit report within 07 days positively.

The area Federal Inspector of Drugs inspected the premises on 31-10-2007, along with Mr. Ghazanfar Ali Khan, ADC, Lahore to check the rectification of shortcomings pointed out during inspection dated 20-07-2006. The area FID submitted inspection report wherein a number of serious GMP non compliance were reported and she suggested that production of the firm be stopped and renewal of DML may not be considered in light of critical shortcomings and failure of commitment given by the firm to remove the deficiencies pointed out by the panel during previous inspection.
The area FID sealed the factory and on the form of sealing of the factory she stated that ***M/s Micko Industrial Chemicals , 28-km Ferozepur Road, Lahore is sealed due to the violation of Section 27(3) of the Drugs Act, 1976 and various other provisions of the Drugs Act, 1976 and rules framed there under . The owner Mr. Khursheed Alam snatched the samples of drugs taken for the purpose of test analysis from driver Ismail with Form 3. FIR was launched in police station, Kahana and the factory is sealed in the presence of Mr. Ghazanfar, ADC, Javed Iqbal, ASI and Tahir Iqbal, Head Constable .***

The firm was then served a Show Cause Notice on 19th November 2007 by the then Secretary CLB and directed to submit reply of the show cause within 15 days.

A letter dated 17-11-2007 was again received from Ms. Aisha Khalil, the then area FID wherein she informed that owner of the firm had challenged the legal process of panel and the accused Mr. Khurshid Alam Sheikh filed a writ petition No. 10988/2007 in Honorable Lahore High Court Lahore through his counsel requesting the Court to declare the sealing order illegal and for award of cost incurred on this petition. Mr. Justice Syed Hamid Ali Shah issued a one sided interin order dated 07-11-2007 hence suspended the sealing order of panel without hearing the panel, till next hearing and ordered for submission of reply and parawise comments in this regard.
In compliance of court order dated 07-11-2007 she along with Mr. Ghazanfar Ali Khan ADC visited the premises on 14-11-2007 to de-seal the factory and found that the seals were broken by the owner and production of drugs was in process. The position was also brought in to the kind notice of Honorable Court vide etter No. 9067/2007-DCA (L-II) dated 14-11-2007.
On 05th December 2007, a letter was issued to the firm from this office by the then Secretary CLB wherein it was stated that refer to the panel inspection report of the firm conducted by area FID Lahore on 14-11-2007 wherein it was reported that production was in-progress while the conditions of renewal of DML have not been fulfilled as reported by the panel during inspection conducted on 30-10-2007. As this is an offence under Rule 13 of the Drugs (Licensing, Registering & Advertising) Rules 1976, therefore, firm was directed to suspend the production with immediate effect till removal of the deficiencies and re-inspection by a panel and approval of Central Licensing & Registration Board.

Recently, On 23-04-2015, a letter was received from Assistant Registrar , wherein he forwarded the order sheet of Honorable Lahore High Court, Lahore for the Writ Petition # 10988/2007 & 11839/2007. The contents of the order sheets are as under:-

Mr. Bashir Ahmad Tariq, Advocate for the Petitioner.
Ms. Saadia Malik, learned Standing Counsel for Pakistan along with Ayesha Irfan, Federal Inspector Drugs.

Through this single order I intend to dispose of writ petition Nos. 10988 and 11889 of 2007 as both are based on common facts.

2. In W.P NO. 10988/2007 order dated 30-10-2007 is challenged whereby the factory of the petitioner was sealed for violation of Section 27 (3) and other provisions of the Drugs Act, 1976 and also for the reason that owner of the factory namely Khurshid Alam Sheikh had snatched samples taken from the factory premises by the Federal Drug Inspector.
In other writ petition No. 11889/2007 order for suspension of production is challenged.

3. Facts, which have surfaced after arguments from both sides, are that he inquiry report was being prepared by the Federal Drug Inspector when samples of some illegal drugs were allegedly snatched by the owner of the factory. Statedly, due to violation of the statutory provisions and the illegal act by the owner, the factory premises were sealed. As per learned Standing Counsel's assertions, the factory was de-sealed illegally and production was commenced by the petitioner, therefore, another order for suspension of production was passed.

4. Due to multiplicity of litigation, facts of the case are confused. It is asserted by the petitioner that its factory is sealed and production is suspended whereas learned Standing Counsel submits that the production is being carried out illegally at the

sealed premises.

5. Be that as it may, it is settled proposition that this Court cannot look into factual controversies in exercise of its constitutional jurisdiction. For resolution of dispute on facts as well as on legal side, this matter is referred to Central Licensing Board, before which report has already been filed by the Federal Drugs Inspector. The Board shall provide opportunity of being heard to the petitioner and shall pass a speaking order within 45 days positively under intimation to the Deputy Registrar (Judicial) of this Court.

Till decision no coercive measures shall be taken

RECORD AND STATUS OF FIRM IN LICENSING DIVISION

The five years tenure of renewal of DML of the firm for the period 17-11-2005 to 16-11-2010 has been expired without any further orders by Central Licensing Board.
Afterwards, firm submitted application for renewal of DML of the firm for the next five years i.e. **from 17-11-2010 to 16-11-2015** for which a panel of experts/inspectors was constituted on 10th March 2011 comprising of following members:-

1. Dr. Farzana Chaudhary, (Member DRB) Director IPS University ad Animal Sciences, Lahore
2. Dr. Noor Muhammad Shah, Deputy Director General (L & A), Islamabad.
3. Dr. Sheikh Akhtar Hussain, Deputy Director General (E & M), DCA, Lahore
4. Area Federal Inspector of Drugs, DCA, Lahore.

The report of the above mentioned panel is still awaited.

It is also submitted here that Ms. Aisha Irfan, Area Federal Inspector of Drugs also updated Licensing Division about the recent orders passed by Honorable Court and case background. she stated that all the action taken by her on the directions of the Central Licensing & Registration Board and as per the Drugs Act, 1976 and rules framed there under, hence, no malafide intentions were involved, and the actions were taken in **Good Faith** by her. **She also requested that she may also be provided with an opportunity to present this case in Central Licensing Board personally.**

Therefore, the case is placed before the Licensing Board as per orders of the High Court for further directions in the matter.
The firm, M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore and Ms. Aisha Irfan, FID, DRAP, Lahore were called for personal hearing.

Proceedings of the case:

Licensing Division, DRAP apprised the Board that the order sheet of the Honorable Court was received in the Secretariat of the Licensing Division in late hours at Friday on 08th May 2015.

After receipt of the orders of the Honorable Court, Licensing Division processed the case on 11th May 2015 and after approval from competent Authority, letter for personal hearing was issued through Courier to the firm on 13th May 2015.

Area Federal Inspector of Drugs, DRAP, Lahore was contacted telephonically to deliver the copy of the letter of personal hearing to the firm in person but she informed that she couldn't deliver letter because she was at hospital for treatment of illness of his father and her assistant may also not deliver the letter to the firm in person because she is a female. After that, Deputy Director General (E&M), DRAP, Lahore was requested on 14th May 2015 to depute a person from his office who shall deliver letter to the management of the firm by hand. Accordingly, Mr. Shahid Mehmood, LDC, DRAP, Lahore was sent to deliver the letter of personal hearing to the firm, by hand.

When he reached the location of the firm and contacted the person, Mr. Shoib (son of the owner of the firm) opened the gate and viewed the letter and requested him to be seated so that he may contact his father (Owner of the firm) before receiving the letter.

After half an hour, he came and refused to receive letter of personal hearing from him and stated that his father is not in the factory and currently outside the city. Mr. Shahid Mehmood also given in writing the conversation.

Decision of the Board:

The Board after thorough discussion and deliberation decided:-

1. ***To provide another opportunity of personal hearing to the firm.***
2. ***To deliver letter of personal hearing to the firm by registered post/UMS/ through courier.***
3. ***To submit an interim report for the appraisal of Honorable Court, regarding current status of the case in the Central Licensing Board.***

Case No. 16 RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S MARION LABORATORIES (PRIVATE) LIMITED, D-43, TEXTILE AVENUE, S.I.T.E, KARACHI.

The case was placed the Board as under: -

- M/s Marion Laboratories (Private) Limited was initially granted Drug Manufacturing License (DML) for the manufacturing of Drugs in **LVPs (Infusion)** at premises located at D-43, Textile Avenue, S.I.T.E, Karachi, in 199th meeting of Central Licensing Board held on 23rd – 24th August 2006.

- Accordingly, Firm was issued DML # 000599 (Formulation) for the period of five years w.e.f. 16th September 2006.

- Afterwards, firm submitted application for renewal of DML for the period 16-09-2011 to 15-09-2016 which was well before the period of expiry of validity period of the license. Therefore, license of the firm is continue in force till further orders passed by Central Licensing Board according to Rule 6 of the Drugs (Licensing, Registering & Advertising) Rules 1976 which reproduced as under:-

  "Provided that if application for renewal is made before the expiry of the period of the validity of a license, the license shall continue in "force until" orders are passed on such application"
- The application of renewal of the license dated 08th September 2011 was not entertained at the time of submission, due to devolution of the then Ministry of Health.

- After the establishment of the Drug Regulatory Authority of Pakistan in November 2012, the application of renewal of the firm was scrutinized by Licensing Division and shortcomings in the application of renewal of DML were conveyed to the firm on 05th March 2015 according to Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rule 1976 which reproduced as under:-

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

- The shortcomings in the application of renewal of DML conveyed to the firm vide letter dated 05th March 2015, are as under:-
-

  (i) Differential fee of Rs. 32,500/- for renewal of Drug Manufacturing License, as fee revised for renewal of DML is 50,000/-
  (ii) Names / List of total licensed sections of the firm and proof of grant/approval of sections from Central Licensing Board.
  (iii) Details of premises including copy of approved layout plan by competent Authority.
  (iv) Details of proposed production and Q.C Incharge as per checklist enclosed herewith. The technical experts shall possess minimum 10 years experience in the

relevant fields after academic qualification according to Rule 16 of Drugs (Licensing, Registering & Advertising) Rules 1976 after promulgation of S.R.O 470 (I)/98 dated 15-05-1998.

(v) Copy of latest form 29 issued and attested by Security Exchange commission of Pakistan along with CNIC photocopies of all directors.

(vi) An undertaking on letter head of the firm signed by all directors of the firm stating that all information/ documents provided with application of renewal of Drug Manufacturing License is complete and correct and management of firm shall be responsible for hiding or providing wrong information.

(vii) Nothing Due certificate issued by Statistical Officer , DRAP, Islamabad, regarding deposition of Central Research fund up to 31-12-2015.

- On 01-04-2015, firm has submitted reply with respect to the letter issued from this Division regarding shortcomings in their application for renewal of DML.

- In the reply, firm stated that all liable requirements were submitted to Licensing Division in liable period and only liable inspection was supposed to be conducted.

- According to record of Licensing Division DRAP, Islamabad, the application of renewal of DML of the firm is still incomplete and firm fails to rectify or complete the application within the specified period of 30 days under Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rules 1976. Therefore the application of the firm is liable to be rejected.

The case was presented in 241st meeting of the Board wherein the Board decided as under:-

Decision of the Board:

The Board decided to issue a Show Cause Notice with personal hearing to the firm.

Case No. 17 **USAGE OF OLD COMPANY NAME PACKAGING /LABELING COMPONENTS BY M/S THE SEARLE COMPANY SITUATED AT PLOT NO.F-319, SITE, KARACHI DML NO.000016 (FORMULATION).**

The case was placed the Board as under: -

The Central Licensing Board in its 233rd meeting held on 30-31 December, 2014 has considered the subject matter and decided as under: -

"The Board in the light of panel inspection report of M/s. Searle Company, Plot No.F-319, SITE, Karachi (DML No.000016-Formulation) decided to destroy the available packaging /labeling components bearing old company name (The Searle Pakistan Ltd.,) under Schedule-B(II)6.3.4 in the presence of panel. A show cause notice and personal hearing on violation of conditions of Drug Manufacturing License shall be issued to the firm and case shall be presented before CLB in its next meeting".

Accordingly, a panel was constituted for the destruction of available packaging /labeling components bearing old company name (The Searle Pakistan Ltd.,) and the same has been conveyed to DDG (E&M), and area FID, Karachi.
As per above decision of CLB a Show Cause Notice has been issued and further firm has been called for personal hearing, please.

In 234th meeting of CLB held on 27-02-2014, the case was again discussed on the bais of inspection report of the panel and the Board decided as under:-

Decision of CLB

The Board after thorough discussion / deliberations and facts on grounds decided for panel inspection for confirmation of using packing / labeling components bearing old company name. The Board further decided to refer the complete case to Registration Board for its consideration / decision to recall the products of the said firm bearing old company name (The Searle Pakistan Ltd.,).

The company then filed a Writ in the High Court of Sindh, Karachi C.P. No.D-1256 of 2014 against the decision of the Central Licensing Board.

The Honorable High Court of Sindh has passed the order dated on 21-04-2015 as under: -

"Counsel for the petitioner has filed a statement asserting therein that packaging material presently used by the petitioner contains the petitioner's present as well as previous name which could be used for one year and thereafter such packing material would only contain the present name of the petitioner i.e. The Searle Company Limited. DAG say that on the basis of this statement petition may be disposed of. Order accordingly.

Counsel for the petitioner says that in view of above, impugned show-cause notices as well as decision thereon dated 24-02-2014 may be quashed. DAG on the instruction from Federal Inspector of drugs C\concedes, therefore, the impugned show-cause notice as well as the decision thereon is hereby quashed".

S/d-
Judge.

The case was placed for the appraisal of the Board. Accordingly, the Board was appraised.

CASE NO. 18. **M/S SAMI PHARMACEUTICALS (PRIVATE) LIMITED LOCATED AT F-95&145, OFF, HUB RIVER ROAD, S.I.T.E, KARACHI DML # 000072 (FORMULATION)**

The case was placed the Board as under: -

M/s Sami Pharmaceuticals (Private) Limited located at F 95 & 145, Off Hub River Road, S.I.T.E, Karachi under DML # 000072 (Formulation) were granted following additional sections in 238th meeting of CLB held on 19th November 2014.

Biotech Sections (02)

i) rDNA Facility
ii) Vaccine Section (Anti- Sera Only)

Firm now submitted a letter dated 03-01-2015 wherein they have requested to change the nomenclature of approved sections as under:-

From approved name	To proposed name
"Vaccine Section (anti-sera only)	"Human Vaccines & Antisera"

Firm stated that by mistake, they informed at time of issuance of the letter of grant that they will produce only antisera for which dossiers have already been submitted.

On scrutiny of record of Licensing Division, DRAP, Islamabad it has been noticed that firm got approval of layout plan on 21-07-2009 (Page 37/Corr.) for **Vaccine section**.

Firm has provided reference of a comparison of Production requirements for Vaccines and Anti-sera in the same area as per WHO Technical Report Series that Vaccine and Antisera as per WHO TRS both can be produced in the same area with validated cleaning protocols They further added that the Panel of Experts inclusive of the then Director Biologicals, which conducted the inspection of our facility on 17th October 2014, has observed that *From the available expertise, data and infrastructure presented before the present inspection panel it is concluded that the Firm has the capability of manufacture and perform quality control the Biological Drugs mentioned in their request letter i.e., Interferon, Pegylated Interferon, Filgrastim, Pegylated Filgrastim, Erythropoietin, Antisera products and human vaccine. The animal testing is to be performed in collaboration with Dow University of Health Sciences, Karachi.* The Panel further concluded that *"……The Firm has the capability to manufacture and perform the quality control of the Biological Drugs mentioned in their request letter i.e., Interferons, Pegylated Interferons, Filgrastim, Pegylated Filgrastim, Erythropoietin, Antisera products and human vaccines……"*

Firm has submitted Process Flows of Vaccines and Antisera which show that both are on the same pattern , Cleaning Validation Protocol for Vaccines and Antisera Sectionare also provided.

Firm has requested to amend the nomenclature of the approved section as under:

1. rDNA Facility
2. Human Vaccines and Antisera

Decision of CLB:

The case was presented in 241st meeting of CLB wherein the Board decided for inspection of the premises for checking facility for manufacturing of Human Vaccines by following panel who conducted inspection for grant of rDNA facility and Vaccine Section (Anti- Sera Only)

i) Syed. Javed Yousaf Bukhari, Member CLB.
ii) Mr. Abdul Samad, Director NCLB, DRAP, Islamabad
iii) Mr. Qaiser Muhammad, CDL, Health Department, Sindh
iv) Ms. Muneeza Khan, Area FID-II, DRAP, Karachi
v) Ms. Ume Laila, Area ADC, DRAP, Karachi.

CASE NO. 19. **M/S CIBA PHARMACEUTICALS (PRIVATE) LIMITED A-371, SITE, NOORIABAD, MAIN SUPER HIGHWAY, KARACHI.**

The case was placed the Board as under: -

The case of M/s Ciba Pharmaceuticals (Pvt) Ltd for grant of Drug Manufacturing License was presented in 240th meeting of Central Licensing Board and Board decided as under: -

"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".***

Accordingly, decision of Board was conveyed to the firm, and firm replied on 13th April, 2015 with undertaking as under: -

"We M/s Ciba Pharmaceuticals (Private) Limited A-371, SITE, Nooriabad, main Super Highway, Karachi, give undertaking to DRAP that if any objection will be raised internationally regarding the name of M/s Ciba Pharmaceutical (Pvt) Ltd, such as under company is operating / manufacturing internationally under the name of M/s Ciba Pharmaceutical (Pvt) Ltd and if such information is received to us from DRAP with enough worthy evidence then we will be ready to act upon DRAP's directions".

After that a letter was also issued to Securities and Exchange Commission of Pakistan for confirmation whether name "M/s Ciba Pharmaceuticals (Pvt) Ltd, Karachi resembles with other registered company or otherwise.

In reply of Securities and Exchange Commission of Pakistan has stated that "No other company with names M/s Ciba Pharmaceuticals (Pvt) Ltd is registered with this office".

The case was submitted for solicited orders of Board for issuance of Drug Manufacturing of License.

Decision of CLB

The Board after thorough deliberation decided ***not to approve*** *the nomenclature in the name & style of* ***M/s Ciba Pharmaceuticals (Private) Limited*** *as there is very possible likelihood that the common citizens will be deceived by this name as it belonged to a very reputable company in the Pharmaceutical Industry i.e. Ciba-Giegy which had a long history of marketing their pharmaceutical products in Pakistan.*

Therefore allowing such name which is in resemblance with the well reputed company doing business in Pakistan in past, will mislead and confuse people of Pakistan who might think the revival of the company which is in fact no more in the Pakistan.

The Board further advised to the company to choose a name which shall not resemble with any other existing Pharma company or Pharma traders or existing in past and to also ensure that the name selected for their company should portray true inculcate of their business and have difference with any other name on the register.

CASE NO. 20. **APPROVAL OF DRAFT MINUTES THROUGH EMAIL FROM MEMBERS OF CENTRAL LICENSING BOARD.**

The case was placed the Board as under: -

It is submitted as per practice in vogue the minutes of CLB meeting are approved as per following procedure: -

- Preparation of draft minutes by Secretary CLB.
- Approval of draft minutes by Chairman CLB.
- Circulation of draft minutes to all members via email for their perusal / approval.
- Preparation and approval of fair minutes for signature of all members on hard copy.
- Circulation of fair minutes to concerned quarters for implementation.

Since, above procedure usually takes two-three weeks, so to minimize the said procedure, it is proposed that draft minutes be approved within three days and in case of no reply within 3 days, the draft minutes shall be deemed to have been approved.

Decision of CLB:

The Board unanimously approved the proposal with the advice that agenda of the meeting shall be sent to the members of the Board at least three days before the date of the meeting of the Board.

CASE NO. 20. **CHANGE OF STATUS OF M/S MACTER INTERNATIONAL (PVT) LTD TO M/S MACTER INTERNATIONAL LIMITED FOR THEIR LICENSE PREMISES UNDER DML NOs. 000141 (FORMULATION), 000111 (BASIC MANUFACTURE) & 000641 (FORMULATION).**

M/s Macter International (Pvt) Ltd, for their premises at F-216, SITE, Karachi, holding DML No.000141 (Formulation), DML No. 000111 (Semi Basic Manufacture) and DML No. 000641 (Formulation).

M/s Macter International (Pvt) Ltd, E-40/A, SITE, Karachi DML No.000641 (Formulation), applied for change of name/ title as under:-

From	To
M/s Macter International (Pvt) Limited,	M/s Macter International Limited,

The firm has submitted following documents / information to the Licensing Division along with the applications as under:-

Fee of Rs.50,000/- for each of three licenses = total 150,000/-
GMP Certificate
Certificate from Securities and Exchange Commission of Pakistan for change of title
Nothing Due Certificate (31-12-2015)
List of Directors (**same as before)**
Forms-29
CNIC copies of directors
Memorandum and Article of Association

All documents/ information have been evaluated by Licensing Division, DRAP and after fulfilling all legal and codal formalities, the case is submitted for consideration of the Board please.

Proceedings:

The Board was apprised that the firm has applied for the change of name/title for its three units having DML No.000141 (Formulation), DML No. 000111 (Semi Basic Manufacture) and DML No. 000641 (Formulation). The firm has submitted Rs.50,000/- for each (Total Rs.150,000/-) as fee for change of name/title.

Decision of CLB:

Keeping in view the submitted documents and proceedings, the Board after thorough discussions and deliberations approved the change of name/title of firm from M/s. Macter International (Pvt) Limited, to M/s. Macter International Limited, for three Drug Manufacturing Licenses i.e. DML No.000141 (Formulation), DML No. 000111 (Semi Basic Manufacture) and DML No. 000641 (Formulation).

QUALITY CONTROL CASES

Case No. I **Manufacture & Sale of Spurious, Sub-Standard, Adulterated and Un-Registered Drugs etc. by Masil Khan and others at House No.3, Located at Sardar Colony, Charsadda Road, Peshawar**.

Case Background

The FID Peshawar, DDG (E&M) and ADC, DRAP, Peshawar along with team of FIA, raided a residential House No. 3, located at Sadar Colony, Charsadda Raod, Peshawar on 19-02-2014. Large quantities of spurious medicines of multinational brands were being manufactured at the said premises at the time of raid/inspection. The FID made seizure of labels, cartons, vials, sealing machine and other materials vide Form-2 and samples of some drugs were also drawn for test/analysis vide Form-3. The FID Peshawar in his final report of the case has submitted that samples of some drugs have been declared Spurious, Substandard, Adulterated, Un-registered drug products and in violation of Section 23(1)(h) of the Drugs Act 1976 by the Federal Government Analyst, CDL, Karachi. The results of the FGA regarding the samples drawn are summarized as follows:-

S.No	Name of Drugs	Mfg by.	Batch No.	Expiry Date.	Remarks on test report with its No.
1.	Rocephin 1gm Inj. (Cefriaxone)	H.Hoffman Roche Switzerland (Repacked by Martin Dow Karachi	B0050	02-2016	(Spurious & Substandard) RIP.49/2014 dated 27-03-2014.
2.	Tazocine EF 4.5gm Inj.	Wyeth Lederle Italy (Repacked by Wyeth Pakistan Karachi	AGP8/11	12.2014	(Spurious & Substandard) RIP.50/2014 dated 25-04-2014.
3.	Fosfomycin 1.0 gm Inj.	M/s China Chongging, China.	110681	06-2014	(Substandard) RIP.52/2014 dated 25-04-2014.
4.	Fortun 1gm Inj	Glaxo Smithkline, Pakistan Ltd, Karachi	LBF6/3	Nil	(Spurious & Substandard) RIP.53/2014 dated 27-03-2014.
5.	Glucantine Inj.1.5g/5ml	M/s Haupt Pharma Liveron, France.	0868	01/2019	(Adulterated, Substandard & Un-registered drug product) RIP.54/2014 dated 25-04-2014.
6.	Sulzone 2.0g Inj.	M/s Suzhou Dawnrays Pharma	120232001	09/2015	(Spurious & Substandard

		China (Marketed by BioCare Pharma Karachi			RIP.55/2014 dated 25-03-2014.
7.	Decadron Inj.	M/s OBS Pakistan Pvt Ltd, Karachi	D697	02/2015	(Spurious & Substandard) RIP.83/2014 dated 10-04-2014.
8.	Heparin Leo Inj.	M/s Leo Pharma, Denmark	DE3171	10/2015	(Spurious & Substandard) RIP.56/2014 dated 25-04-2014.
9	Vial without labels having white powder.	Nil	Nil	Nil	Contravention of Section 23(1)(h) of Drugs Act 1976 RIP.57/2014 dated 10-04-2014.
10	Red Coloured Capsule without any label.	Nil	Nil	Nil	Contravention of Section 23(1)(h) of Drugs Act 1976 RIP.58/2014 dated 10-04-2014.

2. The FID in his report has also mentioned that portions of samples were also sent to the claimed manufacturers for verification of their genuineness and in response M/s GSK, Karachi, M/s Wyeth Pakistan Ltd, Karachi, M/sMartin Dow, Karachi, M/s Biocare Pharma Lahore and M/s OBS, Pakistan Karachi, have disowned these drugs. Hence the products were declared as of Spurious quality are under Section 3(z-b)(ii) of the Drugs Act 1976. The explanation letters were also sent to the accused Masil Khan S/o Mir Wais Khan by the FID but no reply was received.

3. FIR No.12/2014 dated 19-02-2014 was lodged with FIA, ACC, Peshawar for violation of Section 23(1)(a)(i), 23(1)(a)(vii) & 23(1)(b) of the Drugs Act 1976. One of the accused namely Masil Khan S/o Mir Wais Khan is in jail since then. The FIA has submitted investigation challan of the subject case on 03-03-2015 in the office of FID Peshawar and has held the following accused persons responsible for the aforesaid offences.

i. Masil Khan S/o Mir Wais Khan, R/o Sardar Colony Cahrsaddar Road, Peshawar
ii. Shakeel S/o Mir Wais Khan, R/o Sardar Colony Cahrsaddar Road, Peshawar.
iii. Alam Zaib S/o Aurangzaib R/o Muslimabad, Station Koroona, Mardan Road Charsadda.
iv. Muhammad Amir S/o Aurangzaib R/o Muslimabad, Station Koroona, Mardan Road Charsadda.

The FID has also requested for permission to prosecute these accused persons in Drug Court Peshawar for violation of Section 23 punishable under Section 27 of the Drugs Act 1976:-

4. As per procedure, a show cause notice was preparer for approval of Chairman CLB against the afore named accused persons but the Chairman, Central Licensing Board do not have the delegation of the power in this regard. DRA for approval accordingly but was not acceded to for want of delegation of power in this regard.

5. One of the accused namely Masil Khan S/o Mir Wais Khan is in jail and the show cause notice in the case has not been issued so far the case is placed before the CLB for approval and issuance of show cause notice, delegation of power if desired and grant permission to the FID to launch prosecution in the Drug Court, Peshawar against the accused persons for violation of provisions of Section 23 punishable under Section 27 of the Drugs Act 1976.

F. No.04-02/2014-CQC

Government of Pakistan

Drug Regulatory Authority of Pakistan

Ministry of National Health Services, Regulation & Coordination

****

Islamabad, the May, 2015.

Masil Khan S/o Mir Wais Khan, House No. 3, Gali No.3B, Sardar Colony Charsadda Road **Peshawar.**	Shakeel S/o Mir Wais Khan, House No. 3, Gali No.3B, Sardar Colony Charsadda Road **Peshawar**
Alam Zaib S/o Aurangzaib R/o Muslimabad, Station Koroona, Mardan Road**, Charsadda**.	Muhammad Amir S/o Aurangzaib R/o Muslimabad, Station Koroona, Mardan Road**, Charsadda**.

(Show Cause Notice)

Subject: - **Manufacture & Sale of Spurious, Sub-Standard, Adulterated and Un-Registered Drugs etc. by Masil Khan and others at House No.3, Located at Sardar Colony, Charsadda Road, Peshawar**.

I am directed to refer to the subject cited above and to say that the FID Peshawar, DDG (E&M) and ADC, DRAP, Peshawar along with team of FIA, raided a residential house No. 3, located at Sadar Colony, Charsadda Raod, Peshawar on 19-02-2014. Huge quantities of spurious medicines of multinational brands were being manufactured at the said premises at the time of raid/inspection. The FID made seizure of labels, cartons, vials, sealing machine and other materials vide Form-2 and samples of some drugs were also drawn for test/analysis vide Form-3. FID Peshawar in his final report of the case has submitted that samples of some drugs have been declared Spurious, Substandard, Adulterated, Un-registered drug products and in violation of Section 23(1)(h) of the Drugs Act 1976 by the Federal Government Analyst, CDL, Karachi. The test reports of these samples have already been provided to you during the course of investigation of the case by the FID. The results of the FGA regarding the samples drawn are summarized below:-

S.No.	Name of Drugs	Mfg by.	Batch No.	Expiry Date.	Remarks on test report with its No.
1.	Rocephin 1gm Inj. (Cefriaxone)	H.Hoffman Roche Switzerland (Repacked by Martin Dow Karachi	B0050	02-2016	(Spurious & Substandard) RIP.49/2014 dated 27-03-2014.
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		Karachi			
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2. The FID in his report has also mentioned that portions of samples were also sent to the claimed manufacturers for verification of their genuineness and in response M/s GSK, Karachi, M/s Wyeth Pakistan Ltd, Karachi, M/sMartin Dow, Karachi, M/s Biocare Pharma Lahore and M/s OBS, Pakistan Karachi, have disowned these drugs. Hence the products were declared as of Spurious quality are under Section 3(z-b)(ii) of the Drugs Act 1976. The explanation letters were also sent to the accused Masil Khan S/o Mir Wais Khan by the FID but no reply was received.

3. FIR No.12/2014 dated 19-02-2014 was lodged with FIA, ACC, Peshawar for violation of Section 23(1)(a)(i), 23(1)(a)(vii) & 23(1)(b) of the Drugs Act 1976. The FIA has submitted investigation report challan of the subject case on 03-03-2015 in the office of FID Peshawar and has held all of you responsible for the aforesaid offences. The FID has also requested for permission for your prosecution in Drug Court Peshawar due to contravention of provisions of Section 23 punishable under Section 27 of the Drugs Act 1976.

4. You are hereby required to show cause in writing, within 07 days of receipt of this letter, as to why the following action(s) should not be initiated against you:

i. Prosecution in the Drug Court.
ii. Any other action the Board may deem fit.

5. In case you desire to be heard in person, please intimate the same, otherwise ex-parte decision shall be taken.

Ahmed Din Ansari
Deputy Drugs Controller (QC-I)
For Secretary, Central Licensing Board

Copy to: -
FID Peshawar, with the request to ensure delivery of this letter to all the above named accused persons under intimation to this Directorate.

Ahmed Din Ansari
Deputy Drugs Controller (QC-I)
For Secretary, Central Licensing Board

<u>Decision of CLB</u>

The Board after thorough discussions and deliberations considered the above case and decided as under:-

- ***The Board allowed prosecution after fulfillment of all legal and codal formalities under the Drugs Act 1976 and relevant rules framed there under.***

- ***The Board also delegated its function of issuing Show Cause Notice for unlicensed firm to Director QA/LT, DRAP.***

Case No. II Any other Item with permission of Chair

Director QA/LT, with the permission of Chair, presented the following agenda for consideration of Board.

PERMISSION FOR PROSECUTION IN THE DRUG COURT REGARDING UNLAWFUL MANUFACTURING OF TABLET EVERLONG BY M/S EVEREST PHARMACEUTICALS, 124, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD.

1. Kindly refer to this office previous letter even no. dated 27-02-2015 addressed to Director QA/LT.

2. Inspection of M/s Everest Pharmaceuticals, Islamabad was conducted on 27-02-2015 at about 12:25 noon by the team comprising the undersigned, Mr. Muhammad Ansar, ADC, DRAP Islamabad, Rana Naveed Anwar, Assistant Director FIA, Mr. Kashif Riaz Awan, Sub Inspector FIA, Mr. Ghulam Rasool, Sub Inspector FIA, Mr. Munir Ahmad ASI, FIA, along with local police on the directions of Director QA/LT, DRAP Islamabad. At the time of inspection, the outer gate of the factory was found closed with the board that the factory will remain closed for three days w.e.f. 26-02-2015 due to the death of father of the Admin Officer, Zaher Afzal. The team asked the Security Guard, on duty, to open the gate; however, he did not complied even after repeated requests. One of the members of the team from FIA entered the premieses and opened the main door of the factory. The main entrance of the factory was also found locked, however, the team entered into the premises from the side door. It was found that the Director Operations of M/s Everest Pharmaceuticals, Islamabad Ms. Uzma Younas along with and Mr. Imtiaz Ahmad, QC Manager and Mr. Arshad Khan Production Incharge Pharmacist of M/s Everest Pharmaceuticals, Islamabad were present in the premises.

3. Upon search / inspection of the premises, it was noticed that the tablet **Everlong 60mg** (**4 batches**) with different packing designs was stocked in the premises despite the fact that the registration letter of the said product and been withheld by the DRAP vide letter No.F.3-1/2010-Reg-III (M224) dated 22-01-2014. Mr. Usman, CEO was informed about the said letter by the undersigned and he admitted at that time that his firm is not producing the said product. Accordingly, the stock, being manufactured in violation of the Drug Act, 1976 were seized on Form-2 and the tablet section of the firm was sealed in accordance with the provisions of section 18(1)(h) of the Drug Act, 1976 in presence of Miss Uzma Younas, Director Operations / General Manager and Mr. Imtiaz Ahmad, QC Manager and Mr. Arshad Khan, Production Pharmacist of M/s Everest Pharmaceuticals, Islamabad. The said activity was witnessed by Mr. Muhammad Ansar, ADC, DRAP Islamabad, Rana Naveed Anwar, Assistant Director FIA, Mr. Kashif Riaz Awan, Sub Inspector FIA, Mr. Ghulam Rasool, Sub Inspector FIA, Mr. Munir Ahmad ASI, FIA.

4. It was also informed by the Director Operations of M/s Everest Pharmaceuticals, Islamabad during said inspection that they have also manufactured three (3) batches of tablet **Sovir (Sofosbuvir) 400mg** for the purpose of stability studies / clinical trials. The said product has never been registered in the name of the said firm. Statement of Miss Uzma Younus in their connection is also enclosed herewith.

5. In compliance with the provisions of Drug Act, 1976, the matter was reported to the Director QA/LT vide letter of even No. dated 27-02-2015 for seeking permission for registration of FIR against the concerned accused for commission of cognizable offence of manufacturing

un-registered/de-registered drugs under section 23 of the Drugs Act, 1976. The said permission was granted by the Director QA/LT vide letter No. F.04-15/2015-QC dated 27-02-2015 and the undersigned was allowed to lodge the FIR against the following accused for unlawful manufacturing of aforementioned drugs at the premises of M/s Everest Pharmaceuticals, Plot No. 124 Kahuta Triangle, Islamabad: -

i. Muhammad Usman S/o Zaheer Ahmed, CEO of Everest Pharma.
ii. Dr. Kamran Izhar S/o Izhar Ahmed, Director of M/s Everest Pharma.
iii. Ms. Uzma Yonous D/o Muhammad Yonous, General Manager of Everest Pharma.
iv. Mr. Imtiaz Ahmed S/o Muhammad Hanif, QC Manager, Everest Pharma.
v. Mr. Arshad Khan S/o Chaman Gul, Production Pharmacist, Everest Pharma.

6. The undersigned requested the Assistant Director FIA (ACC), Iqbal Town, Expressway, Islamabad to lodge the FIR against the nominated accused under Section 23 of the Drugs Act, 1976, which is punishable under section 27(1) of the Drugs Act, 1976. Accordingly, FIR No. 12/2015 was registered on 27-02-2015 at 5:00 pm against the nominated accused.

7. In compliance with the Section 19(5) (b) of the Drug Act, 1976, the undersigned requested the Board for grant of permission to keep the seized drugs in safe custody till decision of the case vide office letter of even No. dated 02-03-2015. The said permission was subsequently conveyed vide letter No.F.041-15/2015-QC dated 09-03-2015.

8. The undersigned vide office letter of even no. dated 02-03-2015 and subsequent reminder directed the firm i.e. M/s Everest Pharmaceuticals, Islamabad and its head office situated at Lahore, to furnish the manufacturing record, testing data, sale record, record of purchase of raw materials and packing material of tablet Everlong 60mg, batch No.721, 707, 983 and 159 and tablet Sovir 60 mg. M/s Everest Pharmaceuticals, Islamabad did not provide the said documents / information.

9. The Assistant Director, FIA submitted interim report u/s 173 Cr.PC mentioning that all four accused persons are involved in the commission of crime u/s 109 PPC, 23/77 of the Drugs Act, 1976 whereas accused Dr. Kamran Izhar is absconder.

10. Aforementioned in view, the case is being referred to the CLB for granting permission, after fulfillment of all legal/ codal formalities, for prosecution and submission of interim complaint against the following accused in the court of law for commission of offences u/s 23(1)(a,vii) punishable u/s 27(1) of the Drug Act, 1976 and any other action as permissible under the law.

i. M/s Everest Pharmaceuticals, Kahuta Triangle, Islamabad through its Chief Executive Muhammad Usman S/o Zaheer Ahmed, CEO of Everest Pharma.
ii. Dr. Kamran Izhar S/o Izhar Ahmed, Director of M/s Everest Pharma.
iii. Ms. Uzma Yonous D/o Muhammad Yonous, General Manager of Everest Pharma.
iv. Mr. Imtiaz Ahmed S/o Muhammad Hanif, QC Manager, Everest Pharma.
v. Mr. Arshad Khan S/o Chaman Gul, Production Pharmacist, Everest Pharma.

(Dr. Muhammad Fakhruddin Aamir)
Federal Inspector of Drugs-I
Islamabad

Proceedings of Board

The representative of the Division of QA/LT briefed about the unauthorized manufacturing of Everlong Tablet and by M/s. Everest Pharmaceuticals, Islamabad. The registration of Everlong Tablet has been withheld by the DRAP and firm is manufacturing un-registered drug.

Accordingly, the Board discussed that whether this case is related to Central Licensing Board or Registration Board because some members were of the view that under Section 7(11) of the Drugs Act,1976 such cases fall under the domain of Registration Board, while some other members pointed out that illegal manufacturing was carried within the licensed premises.

The members opined the various pros and cons of the case then the representative of Law Division (Member of CLB) was asked to furnish the opinion. After perusal of the case, the representative of Law Division opined that "This case falls under the domain of Central Licensing Board and this may be taken as opinion of Law Ministry".

Decision of CLB:

Keeping in view the proceedings of the Board and the legal opinion; the Board after thorough discussions and deliberations decided as under:-

- ***The Board allowed prosecution after fulfillment of all legal and codal formalities under the Drugs Act, 1976 and relevant rules framed there under.***

QUALITY ASSURANCE CASES (GMP)

Index

Case No. 1: **M/s Royal Group & Marion Laboratories, Karachi.**

Background of the case:

Mr. Saif ur Rehman Khattak. FID-IV Karachi inspected M/S Marrion Laboratories, Karachi on 02.11.2011 and reported a large number of severe shortcomings and provisions of the Drugs Act 1976 and rules framed there under. The firm voluntarily undertook to stop the production activities for rectification of the shortcomings and also submitted an action plan for improvements.

The FID reported that the firm was asked several times for submission of compliance report but they replied that improvements are underway. He further reported that he was informed by some QC personnel of the firm that despite the voluntary closure of the production the firm is continuously involved in the manufacturing of the large & small volume parental without any technical staff. Re-labeling of expired and sub-standard drugs (returned from market) was also underway. He further informed that these illegally manufactured products are not only being sold in Pakistan but also exported to Afghanistan and some African countries.

On 19.03.2012, Ms Ume Laila, ADC inspected the firm for supplying export of firm's products to South Africa of the stocks and for test and analysis she also confirmed the manufacturing activities were being undertaken under very unhygienic conditions without the supervision of any technical / qualified person. She further reported that these illegally manufacturing products are being released without any QC test. The sample sent to CDL, Karachi also declared the samples as of Sub-standard quality as detailed below:-

- Two samples of 5% Dextrose were declared substandard on the basis of non-compliance to Bacterial Endotoxin test.

- Two samples of Normal Saline were declared substandard on the basis of non-compliance to assay.

A joint inspection of the firm with the provincial inspectors was made on 30th March, 2012. The stocks available in the factory warehouse and some record were seized by the provincial inspector.

The firm exported 5% dextrose to Government of Rwanda through M/s Royal Group Pakistan and Rwanda Biomedical Centre reported that the consignment to be of sub-standard quality.

Keeping in view this grave situation of GMP and violation of provisions of the Drug Act 1976 the firm was served with a show cause notice on June 2012 in respect of following:

a. Severe non compliance of the GMP in contravention of rule 2 of the Drugs Licensing, Registration and Advertising) Rules 1976.
b. Manufacturing of sterile drugs in unhygienic condition in contravention of Rule 19(1) & 20(a) of the Drug (Licensing Registering and Advertising) Rules 1978.
c. Manufacturing without the direct supervision of the qualified/technical staff in contravention of Rule 16© & 19 (1) of the Drugs (Licensing Registering and Advertising) Rules 1978.
d. Non compliance to remove the defects or irregularities as identified by the FID in contravention of Rule 19(5) of the Drugs (Licensing Registering and Advertising) Rules 1978.

e. Manufacture, sale & export of sub-standard, adulterated and expired drugs in contravention of section 23(1)(a)(iv,v,vi & x) of the drugs Act 1976.

The firm was directed to recall the substandard products exported to other countries and in local market and destroy the same in the presence of representatives of Ministry of Health.

In response to show cause notice, the firm has replied that allegations framed against them are baseless and if any it was due to negligence of qualified persons who have been fired due to their unethical practices. The firm requested to conduct a panel inspection to evaluate the GMP compliance and to resume the production.

The CLB 229th Meeting

Dr. Ismael Malik consultant of the firm represented before CLB on behalf of the firm and informed that they have rectified all the shortcomings pointed out by the FID. He requested to inspect the firm and allow them resumption of production.

Decision 229th CLB Meeting : The Board after through deliberations and discussion decided as under:

- To conduct the inspection of the firm by a panel comprising Mr. Aman Ullah, Director Drug Testing Laboratory, Quetta, Dr. Khalid Khan, Director Drug Testing Laboratory, Peshawar and area FID. Scope of the inspection will be to verify the rectification of shortcomings and GMP compliance by the firm. The resumption of the production will be allowed after the verification of the GMP compliance by the panel.

- To recall sub-standard batches exported countries at the earliest and intimate this agency.

The above panel inspected the firm on 12.09.2012, the panel recommended resumption of production. Hence the firm was allowed to resume the production with the approval of Chairman, CLB (Member Licensing and CEO, DRAP).

The firm was failed to recall the substandard batches to exported countries as mentioned in above CLB decision due to conflict between manufacturer (M/s Marion Lab) and exporter (M/s Royal Group, Karachi).

CLB 231st Meeting

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

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

- Settlement between Exporter (M/s Royal Group) and Manufacturer (M/s Marion Lab, Karachi)

Both the firms were gone on settlement agreement dated 29.04.2013 (recorded in terms of order dated 30.04.2013 as the exporter has filed suit No. 1587/2012 in the Honorable Sindh High Court, Karachi

CLB 232nd Meeting

To proceed further, the case was presented in 232nd meeting held on 29-30th July, 2013. Both the firms (Royal Group and Marion Lab) were called before CLB wherein, the exporter M/s Royal Group gave presentation through its representative while M/s Marion Lab did not appear. The Board in the light of facts/details, decided the case as under:-

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

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

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

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

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

CLB 235th Meeting

The Licensing Section has submitted a reference to QA Directorate regarding resumption of production of the firm for which GMP inspection is required. The case was presented before CLB in its 235th Meeting alongwith the report of DRAP's nominee Mr. Abdul Ghaffar, DDC (Pricing).

a) Summary of the report on Visit to Rwanda & Tanzania by DRAP's Nominee

The DRAP nominee reported that during meeting with officials of Tanzania Revenue Authority (TRA), the TRA allowed to take the medicines under questions (lying at port of Tanzania destined to Rwanda) back to Pakistan for destruction. The exporter (M/s Royal Group, Karachi) informed the DRAP's nominee verbally as well as through email that officials of Rwanda Biochemical Centre, Government Rwanda did not allow them the destruction of rejected goods in Kigali (Rwanda) because they could not get permission from Rwanda Environmental Body for destruction of rejected goods. M/s Royal Group has been informed by the officials of Rwanda Biochemical Centre that once the issues of payment get settled then they will be allowed to take the rejected material back to Pakistan for final destruction.

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

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

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

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

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

Decision of CLB:

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

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

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

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

Present Status

REPORT BY MEMBERS OF THE PANEL

i) REPORT OF MEMBER OF THE PANEL (DR. OBAID ALI, AREA FID)

Dr. Obaid Ali, area FID and also the member of the panel sent a signed report which was not signed by the other member of the panel. (Flag-A)

iii) REPORT OF MEMBER OF THE PANEL (SYED JAWED YOUSUF BUKHARI, MEMBER, CLB)

The other member of the panel Syed Jawed Yousuf Bukhari forwarded his signed comments separately in response to the interim report submitted by Dr. Obaid Ali (Flag B)

iii) REPORT OF MEMBER OF THE PANEL (CHIEF DRUG INSPECTOR, MEMBER, CLB)

Chief Drug Inspector, Sindh was in Islamabad and could not accompany the panel.

iv) REPORT OF MEMBER OF THE PANEL (MR. A.Q. JAVED, DIRECTOR QA/LT))

a. Findings

The company when visited on 23.12.2015, which was in no shape to be inspected, checked and verified for GMP compliance. Since the company is already been closed and there was no staff seen in the premises, only Mr. Imran Saboor accompanied the three membered panel. One of the members of the panel i.e. Chief Drug Inspector, Sindh was in Islamabad and could not accompany the panel.

When Mr. Imran Saboor was asked that in how much time he could resume the production if given permission by the CLB, the answer was one month. However after some reconsideration he said it might take three months. The representative of M/s Royal Group was contacted by the FID and as informed by him the CEO of the company was traveling abroad to Canada in those days. They were asked if any body could represent their company (Royal Group) on that day, the answer was "no". Subsequently the representative met the FID later on some other day and informed that he was not in a position to answer any queries because he was not well aware of the facts and only CEO of the company could give response.

b. Conclusion

1. Since it is a commercial dispute between two parties, it was extremely difficult for the panel to play an investigational role and pass any judgment.
2. Due to non availability of all the stake holders and the witnesses involved in the whole transaction it was not possible for the panel to fix any responsibility on any party.
3. To do the proper GMP inspection it is important that the company may be given a time line to come into proper shape and get ready for the inspection.
4. Both the parties have already gone into litigation against each other on different occasions and the present status of the case is subjudice.

5. Due to non consensus of all the panel members and absence of one of the members, the matter is submitted to the Honorable Central Licensing Board alongwith duly signed report by the FID and comments of the other panel members accordingly.

LITIGATIONS

1. Suit No. 1587/2012 filed by M/s Royal Group, Karachi in Sindh High Court, Karachi
In above suit /case, DRAP and Federal of Pakistan is not a party.

2. Summary Suit No. 65/2012 filed by M/s Marion Lab, Karachi in the Court of Additional District Judge, South, Karachi for recovery of Rs.55,88,416/-.
In above suit /case, DRAP and Federal of Pakistan is not a party.
3. Suit No. 805/2014 filed by M/s Marion Lab, Karachi in Sindh High Court, Karachi against Federation of Pakistan, DRAP, Collector of Customs and M/s Royal Group, Karachi.

4. C.P No. 347-D of 2015 filed by M/s Marion Lab, Karachi in Sindh High Court, Karachi against Federation of Pakistan and DRAP.
The case is placed before the CLB for consideration please.

Decision of CLB:

The Board after thorough discussion and deliberations considered and decided as under:

- **Allowed three months time to the M/s Marion Laboratories (Pvt) Ltd, Karachi for GMP Improvements. After three months and submission of compliance report, the panel inspection shall be carried out before giving the permission for resumption of production.**

The Board also considered under the issue of export of substandard medicine and conflict between manufacturer (M/s. Marion Lab) and exporter (M/s. Royal Group, Karachi) and decided as under:

- **The Licensing Authority of Drugs (Import & Export) Rules, 1976 under Drugs Act, 1976 shall decide the case in the light of Rule-27 (b) of the said Rules, and the action shall be initiated accordingly.**

Case No. 2:- **M/s Meridoa Company, Karachi: (In The Light of the Decision of the Central Licensing Board)**

Background of the Case

M/s Meridoa Company, Karachi was inspected on 08.03.2013 by Dr. Shahid Hussain, FID Karachi with reference to see/verify the GMP compliance of the firm. During inspection, the FID had pointed out number of shortcomings in all sections.

2. Conclusion/Recommendations of FID: - The FID concluded and directed the firm to stop production immediately and also recommended to cancel the drug manufacturing license of the firm in larger public interest.
3. 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.

CLB 232nd Meeting

The firm was called for personal hearing in CLB in 232nd meeting held on 29-30th July, 2013 and case was placed before the Board.

Personal Hearing & Stance of representative/Owner of firm:- The owner of the firm informed that he is intending to perform Aitiqaf from the same evening due to which he is unable to travel and appear personally before the Board on 30.07.201, and requested that his case may be deferred for next meeting.

Decision:- The Board decided to defer the case till next meeting of Central Licensing Board. The production will remain stopped till the final approval by Central Licensing Board and upheld the decision of stoppage of production. The firm is directed to relevant provisions of Rule 12, 16, 19, 20 of Drug (Licensing, Registering & Advertising) Rules, 1976 shall be strictly adhered to.

CLB 233rd Meeting

The case was placed before Central Licensing Board (CLB) in its 233rd meeting held on 31-31st December, 2013 wherein the representative of the firm, Mr. Amin Motiwala, Owner, appeared before the Board and submitted his point of view. The CLB after hearing the representative, considering the legal formalities and detailed discussion/deliberation decided as under:

Decision of CLB

" The Board acceded to the request of the company and decided to get the firm re-inspected by a panel of experts. The panel has to send a compliance report in this regard to the Chairman, Central Licensing Board. "

Panel Inspection

In compliance to the decision of the CLB, the following panel was constituted to conduct the inspection of firm in order to check/verify the improvements made by the firm:

1. Mr. Jawed Yousuf Bukhari, Member CLB
2. Area FID, Karachi
3. Area ADC, Karachi

On further enquiry by Director QA/LT

Syed Jawed Yousuf Bukhari, member CLB inspected the firm on 01.04.2015 and physically checked the installation and commission of chilling unit with AHU in oral liquid department (which was not done in the last panel inspection dated 24.10.2014). The member CLB asked to start the HVAC system for proper operation and performance and found that the system was operating satisfactory at the time of his physically inspection.

Present Status:

The above mentioned panel inspected the firm on 24.10.2014 and concluded as under:

" In the light of the improvement carried out by firm which was observed during panel inspection and commitment of the management for compliance of cGMP and their positive attitude to Quality and GMP, the panel has recommended for resumption of their production activities. "

The case is placed before the CLB for consideration please.

Decision of CLB:

The Board was of the view that powers functions "Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members" has already been delegated to Director Quality Assurance and Laboratory Testing, by CLB. The Board asked to clarify the matter as to whether the case is for consideration for decision by CLB or just for its appraisal. In response, Director QA/LT clarified that this case is brought for the appraisal of the Honorable Board. The Board was appraised accordingly.

Case No. 3:- **M/s. Espoir Pharma, Karachi**

Background of the case:

The area FID Mr. Abdul Rasool Sheikh found that the firm was involved in the manufacturing of herbal products. He took some samples from the premises for test analysis by CDL, Karachi. The Government Analyst remarked that

" Since the samples were not labeled therefore, the information regarding composition, registration number, batch number, date of manufacturing and expiry and the manufacturer are not available, hence, the Federal Inspector of Drugs concerned may determine guidance of the Directorate of Registration. "

On the basis of clarification given by the firm, the FID informed that herbal products were being manufactured in the premises. Hence a showcause notice was issued on 18.02.2014 by QC section.

The case was presented in Central Licensing Board (CLB) for discussion in its 234th meeting held on 27.02.2014. Mr. Imran Shoaib and Mr. GH Akbar Channa, Managing Director appeared before the Board and explained their position. In view of available record, facts of the case and submission of the firm's representatives, the CLB decided as under:

i. Suspension of DML of M/s Espoir Pharma, Karachi, for three months.

ii. GMP inspection by following panel:

1. Mr. Jawed Yousuf Bukhari, member CLB
2. Dr. Saif ur Rehman Khattak, Director, CDL, Karachi
3. Mr. Abdul Rasool Sheikh

iii) Destruction of the stocks of unregistered products & submission of report thereof.

Current Status

In compliance to the above direction, the company was stopped manufacturing for 03 months. 145 kg of unregistered nutraceutical had been destroyed at D-Tech Waste Solutions (Annex-I) in the presence of FID, Karachi.

The above panel inspected the firm on 12.02.2015. The team of 03 experts recommended the resumption of production activities and advise the firm to adhere strict GMP compliance and the level of compliance may be monitored during active production.

The case is place before CLB for consideration please.

Decision of CLB:

The Board was of the view that powers functions "Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members" has already been delegated to Director Quality Assurance and Laboratory Testing, by CLB. The Board asked to clarify the matter as to whether the case is for consideration for decision by CLB or just for its appraisal. In response, Director QA/LT clarified that this case is brought for the appraisal of the Honorable Board. The Board was appraised accordingly.

Case No. 4 **M/s Eros Pharma (Pvt) Ltd, Karachi**

Background of the Case

The area FID Dr. Shahid Hussain inspected the firm on 09.03.2012 and made various advises to the firm for improvement by observing shortcomings. The firm assured the FID for improvements and voluntarily stoppage of production. The area FID Dr. Shahid Hussain alongwith area ADC Dr. Shoaib Ahmed in a visit on 06.03.2013 of the firm observed that besides renovation and upgradation, the firm was doing manufacturing. On the report of FID the firm was ordered to stop/suspend production till the approval by DRAP vide letter dated 26.04.2013. On the request of the firm for re-inspection after completion of improvements/renovations, the Chairman CLB / CEO, DRAP constituted a panel comprising of DDG (E&M), CDI, Sindh and area FID, Karachi to re-inspect the firm to check the GMP condition of the firm. The above panel inspected the firm on 08.07.2013 and recommended the resumption of production activities. The case was placed before CLB in its 232nd Meeting held on 29-30th July, 2013 where the Mr. Khalid Akhter, Director of the firm appeared before the CLB. The CLB after hearing the firm's representative decided as under:

i) The Board on the recommendations of the panel allowed the provisional resumption of production.

ii) The firm shall be re-inspected in working condition by a larger panel within 30 days time period after the resumption of production as per provision of Schedule B-II of Drugs (Licensing, Registering and Advertising) Rules, 1976 framed under Drugs Act, 1976 specially containing provision for GMP compliance.

In compliance to CLB decision the Chairman CLB made a panel comprising of CDI, Sindh, Director CDL, Karachi, area FID and area ADC to conduct the inspection of the firm in working condition. The above panel inspected the firm on 03.02.2014 and concluded that the firm was voluntarily closing their production activities in their all section except liquid manufacturing area for upgradation. The panel also concluded that the same panel will re-inspect the firm after completion of their renovation work.

Letter to firm

In the light of above panel inspection report the firm was directed not to resume the production activities till the completion of upgradation as suggested by the panel vide letter dated 31.03.2014.

Re-inspection of the firm

On the request of the firm for re-inspection after completion of upgradation the same above panel (dated 03.02.2014) was advised to conduct the re-inspection vide letter dated 11.06.2014. The panel inspected the firm on 16.02.2015 wherein, the panel recommended to the firm as under:

" Keeping in view static GMP conditions the panel recommended the resumption of production activities in production sections except cephalosporins (capsules and dry syrup) and eye drop section, both under redesigning and qualification therefore production in these two sections will be decided after successful completion of the work by the firm and inspection of the same for GMP compliance. "

The case is placed before CLB for consideration and resumption of production please

Decision of CLB:

The Board was of the view that powers functions "Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members" has already been delegated to Director Quality Assurance and Laboratory Testing, by CLB. The Board asked to clarify the matter as to whether the case is for consideration for decision by CLB or just for its appraisal. In response, Director QA/LT clarified that this case is brought for the appraisal of the Honorable Board. The Board was appraised accordingly.

Case No.5: **M/s Pharmadic Laboratories (Pvt) Ltd, Lahore**

Background of the Case

In October 2012, the company, M/s Pharmadic Laboratories (Pvt) Ltd, Lahore was issued cGMP certificate and renewal. In December, 2013 an incident of supply of substandard interferon injection at KPK was referred to the Quality Assurance Section for further processes. The Quality Control Section had constituted following team for inspection of the company:

1. Sheikh Ansar Ahmed, Director, DRAP
2. Mr. Abdul Samad Khan, Director, NCL
3. Dr. Uzair ul Ghani Irfan (Expert Member Biological Committee)
4. Dr. Obaid Ali, DDC, Biological (Coordinator)
5. Area FID, Lahore

The said team had not inspected the firm for more than 10 months.

Meeting of CLB 236th

The case was placed before CLB in its 236th Meeting held on 27th June, 2014. The CLB after thorough discussion had decided as under:-

"Following panel will conduct the GMP inspection of the Biological Section of the firm and will submit conclusive report with clear and candid recommendations on the subject matter for the consideration of CLB before resumption of production."

1. Dr. Ikram Ullah
2. Mr. Ayaz Ali Khan
3. Sheikh Ansar Ahmed
4. Mr. Abdul Samad Khan
5. Mr. Ajmal Sohail Asif
6. Mr. Zafar Minhas

The team inspected the firm on 25.11.2014 and recommended as under:-

i. The firm was advised to hire experienced, trained and conscientious technical personnel to run and supervise the biological section and quality control

ii. The firm was advised to shift the microbiology laboratory from within the injectable manufacturing area and to establish an appropriate microbiology laboratory equipped with proper equipment and instruments.

iii. The firm was advised to upgrade optical checking apparatus as per WHO guidelines and preferably purchase some digital particle detector/counter

iv. The firm was advised to upgrade the bioactivity laboratory regarding provision of growing and de-growing facility and biosafety cabinet

v. The firm was advised to establish a functional, independent and effective Quality Assurance department

vi. The firm was advised to validate the manufacturing and quality control procedures for interferon and also validate the HVAC system.

vii. The firm was advised to approach directorates of registration and Licensing of DRAP for regularization of any change of made in master formula of interferon injection and layout of biological section.

Action taken by DRAP

In the light of observations made by the above panel an explanation letter was issued to the firm on 17.02.2015 alongwith the directions to area FID to follow up the case.

Reply of Firm

The firm replied vide their letter dated 23.02.2015 that they have rectified all the guidance of the panel for further improvements and requested to resume their production in biological section.

Follow Up of the case

As a follow up the case the Federal Inspector of Drugs, Lahore Mr. Ajmal Sohail Asif, inspected the firm's Biological Section on 03.03.2015 and reported the improvements made by the company as under:

i. The firm has hired two new technical persons following

   i. Mr. Muhammad Asif M.Sc, Chemistry as Quality Assurance Manager
   ii. Ms. Kiran Baka, Pharm.D. s assistant quality control manager

The persons were present at the time of inspection and their appointment letters were seen

ii. The firm has shifted the microbiology laboratory from injectable area. A new microbiology laboratory has been established in quality control laboratory. It comprises of a room for media preparation, a room for instrumentation and incubation and a sterility testing room accessed through two buffers with gowning and de-gowning facility. Sterility testing room and buffers were equipped with HVAC and floors were coated with epoxy.

iii. The firm has provided a new optical checking apparatus as per specifications of BP.

iv. The firm has upgraded the bioactivity laboratory by providing buffers and gowning/de-gowning facility. Biosafety cabinet was maintained and functional at the time of visit.

v. The firm has hired a QA manager, having 13 years experience. The firm intimated that they have established an independent QA department. The organizational chart was seen.

vi. The firm has validated its HVAC system through external source in December, 2014, Validation reports were seen. The firm informed that they have developed validation master protocol and validation of manufacturing process will be conducted when production will be allowed.

vii. The firm intimated that they have informed the directorate of registration regarding change in master formula of interferon injection, copy of letter was seen.

Request of the company

The Chief Executive of the company, M/s. Pharmadic, Lahore has submitted that their company has never been asked to stop production, the supply of Interferon Injection to government of KPK and storage condition available at various places at KPK is totally a different issue. The Chief Executive further pleaded that the Honorable Drug Court and High Court had ordered in favour of their product. Accordingly they have attached the copies of the honorable court's orders (Annex A).

M/s. Pharmadic, Lahore has further informed that they had sent a letter in May, 2014 wherein, they informed about starting of production but instead of understanding our point of view, a committee of six experts from various disciplines has inspected our company and made minor observations. These observations were immediately rectified, which was confirmed by the FID, Lahore, Mr. Ajmal Sohail Asif, on 03-03-2015. The company has attached a letter received from provincial coordinator, Government of KPK for further supply of the same product because patients already on this medicines are suffering because of non availability of the products (Annex-B)

Present Status

The company was conveyed the decision of CLB meeting (235^{th}) vide letter dated 27.08.2014 that a panel will conduct the inspection of Biological Section of the firm and will submit conclusive report for consideration of CLB before resumption of production. The panel inspected the firm and gave the advices/recommendations to the firm which has been verified by the area FID vide his inspection dated 03.03.2015.

The case is placed before the CLB for consideration and the representative of the company has also been called for any question by the Honorable CLB.

Proceedings of the case:-

Mr. Ijaz, General Manager of the firm & Mr. Appeared before the Board as representative of the firm. They requested the Board to grant permission for manufacturing of drugs in interferon section as all the improvements in the section have been done as per instruction of the panel and same has been verified by area FID.

The Chairman CLB asked the firm that for shifting of the microbiological laboratory outside from the interferon section, did firm get approval of layout plan from Licensing Division ? In response, Mr. Ijaz, General Manager of the firm replied that their firm had not yet applied for approval layout plan for such purpose.

The Board took serious notice of such attitude of the firm that they don't have knowledge about legal procedures and bindings. The Board directed the firm to get approval of layout plan according to the changes made in the section.

Decision of CLB

Keeping in view the proceeding of the case, the Board after thorough discussion and deliberation decided that:

- **Firm shall rectify the observations made by the panel on 25-11-2014.**
- **Firm shall get approval of layout plan from competent Authority, for the changes made in the design of interferon sections and shifting of Microbiology Laboratory of Interferon.**
- **The firm shall be re-inspected by the same panel after submission of compliance report with respect to observations made by the panel on 25-11-2014.**

CASE NO. 6: - **M/s Spadix Pharmaceuticals Rawat**

An inspection of the company was conducted on 30.05.2014 by Ch. Zeeshan Nazir, FID, Islamabad with reference to see/verify the GMP compliance. The FID has pointed out number serious and critical shortcomings in all sections. A show cause notice was issued on 21.07.2014 by the Authority to the firm. In response to show cause notice, the firm submitted the compliance report.

Action Taken by DRAP

A panel comprising of the following experts re-inspected the firm to verify the improvements made by the firm:

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

The inspection of the panel was not conducted but in the meanwhile the area FID Mr. Zeeshan Nazir Bajar informed the licensing section vide his letter dated 30.03.2015 about the temporary closing of the factory and production by the firm due to financial crises and NAB cases.

Reply of the firm:

The firm is still close, till the NAB cases finalizes. The case is placed before the CLB for information please.

Decision of CLB:

The Board was of the view that powers functions "Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members" has already been delegated to Director Quality Assurance and Laboratory Testing, by CLB. The Board asked to clarify the matter as to whether the case is for consideration for decision by CLB or just for its appraisal. In response, Director QA/LT clarified that this case is brought for the appraisal of the Honorable Board. The Board was appraised accordingly.

Case No. 7. M/S JFRIN PHARMCEUTAL LABORATORY, HUB, BALOCHISTAN

The inspection of company was conducted on 30.12.2014 by Mr. Abdul Rasool Sheikh, FID, DRAP, Quetta for cGMP compliance. During inspection, the FID had pointed out number of shortcomings in all sections and recommended to suspend the DML till the compliance of specified conditions of the license.

Action Taken by DRAP:

A showcause notice was served to the firm on 02.02.2015 with the direction to immediate remove the shortcomings.

Reply of the Firm

The firm replied to the show cause notice informing that they have removed all the shortcomings and ready for inspection. A panel comprising of DDG(E&M), Karachi, area FID and area ADC, DRAP, Quetta to conduct the inspection of the firm in order to check the status of the firm during working condition. The panel inspected the firm on 02.04.2015 and recommended as under:

" Keeping in view the above stated conditions and attitude of the higher management towards better compliance of the management the panel recommends as follows:

1. The firm may be allowed to resume their production activities with formal approval of Chairman Drug Licensing Division DRAP Islamabad

2. The firm may continuously be re-inspected at defined interval to monitor their compliance level."

The case is placed before CLB for consideration and resumption of production.

Decision of CLB

The Board was of the view that powers functions "Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members" has already been delegated to Director Quality Assurance and Laboratory Testing, by CLB. The Board asked to clarify the matter as to whether the case is for consideration for decision by CLB or just for its appraisal. In response, Director QA/LT clarified that this case is brought for the appraisal of the Honorable Board. The Board was appraised accordingly.

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

The inspection of company was conducted by Mrs. Majida Mujahid, FID Lahore on 10.01.2014 she observed various shortcomings and advise the firm to submit compliance report of rectification immediately to her for re-inspection.

Letter to the firm The firm was asked vide letter dated 10.02.2014 to rectify the observations and submit the comprehensive report.

Reply of the firm The firm vide their letter received on 26.02.2014 informed that they will be able to finish all the rectifications by the end of March 2014.

Action Taken by DRAP A panel comprising of following was made on 06.03.2014 to conduct the inspection of the firm to check the GMP and improvements made by the firm.

i. Dr. Ikram Ullah, Member, CLB
ii. DDG (E&M), Lahore
iii. Area FID, Lahore

The above panel inspection could not be conducted since one year while the Area FID, Lahore inspected the firm on 02.02.2015 with reference to see/verify the GMP compliance of the company. The FID has noticed that the firm has failed to improve the observation made during last inspection conducted by her on 10.01.2014.

Explanation letter :- An explanation letter was issued on 03.04.2015 to the firm

Reply of the firm: The firm claimed that they had spent over rupees 80 lac on rectifying the observations of FID. The visit of FID on 02.02.2015 was just a filler as she did not mention a single word about HEPA Filters, HVAC system, Buying of LFC, hiring of technical staff like quality assurance, microbiologists and store pharmacist and epoxy painting of all three injectable sections.

The firm stated, "Last but not the least, validation of all the equipments and machinery has been carried out by third party. So the facts mentioned vaguely against our factory are incorrect and grossly malicious. It is requested that the inspection of our factory may kindly be carried out on priority please."
The representative of the company has been called for explaining their position before the Board please.

Decision of CLB

The Board was of the view that powers functions "Resumption of Production – Subject to re-inspection and recommendation of a panel comprising at least 3 members" has already been delegated to Director Quality Assurance and Laboratory Testing, by CLB. The Board asked to clarify the matter as to whether the case is for consideration for decision by CLB or just for its appraisal. In response, Director QA/LT clarified that this case is brought for the appraisal of the Honorable Board. The Board was appraised accordingly.

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