DIVISION OF DRUG LICENSING
DRUG REGULATORY AUTHORITY OF PAKISTAN
ISLAMABAD
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MINUTES OF 239th MEETING OF CENTRAL LICENSING BOARD HELD ON THURSDAY, 22nd JANUARY, 2015.

239th meeting of the Central Licensing Board (CLB) was held on Thursday, 22nd January, 2015 in the Committee Room of Ministry of National Health Services, Regulations & Coordination at Local Government & Rural Development Complex, G-5/2, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Mr. A.Q Javed Iqbal, Director (QA/LT), as representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad.	Member
2.	Mr. Atta-ur-Rehman, Chief Drug Inspector, Department of Health, Govt. of Balochistan.	Member
3.	Mr. Afrasiyab, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa.	Member
4.	Mr. Khurram Shahzad Mughal, Assistant Consultant as representative of M/o Law, Justice and Human Rights, Islamabad.	Member
5.	Dr. Ikram-ul-Haq, QC/QA Expert	Member
6.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
7.	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
8.	Prof. Dr. Gul Majeed Khan, Professor of Pharmacy	Member
9.	Prof. Dr. Muhammad Saeed, Professor of Pharmacy	Member
10.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
11.	Mr. Tauqeer-ul-Haq, Representative of PPMA	Observer
12.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
13.	Mr. Muhammad Farooq Memon , representative of PCDA	Observer

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

The Chairman apprised the members of the Board that proceedings of CLB shall be conducted in an amicable and responsible way to deliver to the public and stake holders in a transparent and efficient manner. Quality shall be given priority and there shall be zero tolerance. He further added that all the legal and codal formalities regarding convening of the meeting have been fulfilled. Mr. Ahmed Din Ansari DDC (QC), Mr. Khalid Mehmood DDC (QC) & 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 238th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 238th meeting held on Wednesday, 19th November, 2014.

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 of the firm	Date of Inspection / Type of License	Decision of CLB
1.	**M/s. Winthrox Laboratories (Pvt) Ltd, K-219-A, S.I.T.E Super Highway Karachi.**	26-12-2014 **(By way of Formulation)**	**Approved the grant of DML with following sections:** **Sections (06)** 1. Tablet (General). 2. Capsule (General) 3. Oral Dry Powder Suspension (General) 4. Sachet (General) 5. Liquid Syrup (General) 6. Eye Drops (General).
2.	**M/s. Mission Pharmaceutical Laboratories (Pvt) Ltd, S.I.T.E Super Highway Karachi.**	14-01-2015 **(By way of Formulation)**	**Approved the grant of DML with following sections:** **Sections (10)** 1. Tablet (General). 2. Capsule (General) 3. Liquid syrup (General) 4. Liquid Injection Ampoule 5. Capsule (General Antibiotic) 6. Dry Powder Suspension (General Antibiotic) 7. Capsule Cephalosporin 8. Oral Dry Powder Suspension (cephalosporin) 9. Liquid Dialysis Solution (by inline sterilization filling) 10. Powder for Dialysis The Board rejected the Dry Powder Injectable (Cephalosporin) section as mentioned by the panel in the inspection report due to non-approval of layout plan for the said section.

3.	**M/s Amaan Pharma, 30-KM, Sheikhupura Road, Lahore**	14-01-2015 (By way of Formulation)	**Approved the grant of DML with following sections:** **<u>Sections (03)</u>** 1. Liquid Injection Ampoule (General) 2. Liquid Injection Ampoule (Hormone) 3. Liquid Injection Ampoule (Steroid)
4	**M/s Ice Berg Pharmaceuticals (Pvt) Ltd, Plot No. 144, Nowshehra Industrial Estate, Risalpur.** **<u>Section (06)</u>** 1. Tablet (General) 2. Capsule (General) 3. Oral Dry Suspension (General). 4. Capsule (Cephalosporin). 5. Oral Dry Suspension (Cephalosporin) 6. Warehouses (Cephalosporin).		The Board was apprised that following panel was constituted for the inspection of grant of DML of the firm: 1. Prof. Dr. Muhammad Saeed, Member CLB. 2. Chief Drug Inspector, Peshawar. 3. Area Federal Inspector of Drugs, DRAP, Peshawar. 4. Mr. Imranullah Khan, Provincial Drug Inspector, Peshawar. 5. Area ADC, DRAP, Peshawar. The panel except prof. Dr. Muhammad Saeed conducted the inspection and rated firm good. The Board asked from Prof. Dr. Muhammad Saeed that why he did not join the inspection. Prof. Dr. Muhammad Saeed expressed his reservation that he was informed about inspection in last moments before the date of CLB meeting creating emergency situation so he was unable to join. He further explained that sometimes it is extremely difficult rather impossible to spare time for panel inspections from already planned schedule of the University engagements / duties when the coordinating personnel inform at the eleventh hour. He also discouraged conducting inspections by creating emergency situation. **Keeping in view the above factual situation & significance of the inspection as being important act for grant of DML, and unanimous opinion of all members, the Board deferred the grant of DML for re-inspection of the premises by the same panel.**

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

Proceedings:

Before considering the cases of grant of additional sections/expansion/amendments etc Mr. A.Q.Javed Iqbal, Director QA/LT apprised the Board that new sections shall be considered after confirmation of previous record of GMP of the firm and the firms whose GMP track record is not good shall not be given more new sections:

Prof. Dr. Gul Majeed also added that if our objective is quality then we should consider the previous GMP record before approving new sections.

Dr. Ikram ul Haque opined that if conditions of new sections are satisfactory then it should be considered for approval. He further added that evaluation of inspectors for GMP differs from person to person.

Syed Jawed Yousuf Bukhari also added that panel shall be given mandate of GMP inspections when panel is going for the inspection of new sections.

Decision of CLB

Keeping in view the above discussion, the Board unanimously deliberated the matter and decided that in future QA and LT Division shall forward the non-compliant GMP report to Licensing Division immediately so that Licensing Division may update the GMP record of the relevant firm while preparing the agenda for the meeting of CLB; however, the Board considered the following cases as per previous practice.

After above discussion, 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 Sayyed Pharmaceutical Industry (Pvt) Ltd, Plot No. 67/2, Phase 3, Industrial Estate, Hattar.**	DML No.000697 (Formulation)	**The Board approved the grant of additional sections as under:-** **Sections (02)** 1. Capsule (Cephalosporin) 2. Oral Dry Powder Suspension (Cephalosporin)
2.	**M/s. Fynk Pharmaceuticals Industry (Pvt) Ltd, 19-KM, GT Road, Kaka Shah Kaku, District Sheikhupura**	DML No.000494 (Formulation)	**The Board approved the grant of additional sections as under:-** **Sections (02)** 1. Cream/Ointment (General) 2. Cream/Ointment (Steroids)

3.	**M/s. Ipram International,Plot No.26, Street No.SS-3, National Industrial Zone, Rawt, Rawalpindi.**	DML No.000551 (Formulation)	**The Board approved the grant of additional section as under:-** **<u>Section (01)</u>** Capsule (Cephalosporin)
4.	**M/s. International Pharma Labs,Raiwind Road, Bobhtian Chow, Defence Road, 1-KM, Toward Kahna, Lahore.**	DML No.000582 (Formulation)	**The Board approved the grant of additional sections as under:-** **<u>Sections (03)</u>** 1. Veterinary Penicillin Liquid Injectable 2. Veterinary Penicillin Powder Injectable 3. Veterinary Hormone Injectable
5.	**M/s. Envoy Pharmaceuticals (Pvt) Ltd, 27-KM, Multan Road, Lahore.**	DML No.000607 (Formulation)	**The Board approved the grant of amendments in layout plan for already existing sections as under:** **<u>Sections (02)</u>** 1. Capsule (Cephalosporin) 2. Oral Dry Powder Suspension (Cephalosporin)
6.	**M/s. Aventek pharmaceuticals (Pvt) Ltd, Plot No.44-C, Sunder Industrial Estate, Lahore**	DML No.000660 (Formulation)	**The Board approved the grant of additional sections as under:-** **<u>Sections (03)</u>** 1. Tablet (General) 2. Capsule (General) 3. Sachet (General)
7.	**M/s. Wellborne Pharmachem and Biologicals, Hattar.**	DML No.000657 (Formulation)	While considering the case of grant of additional section of the firm, the Board was apprised that the panel also inspected cephalosporin capsule, dry powder suspension, Injectable vial and general tablet, capsule and general ampoule injection areas (which were already licensed) and observed the following deficiencies:- i) In change room there was no insect killer. ii) In raw material store no de-dusting area was in quarantine area. iii) In sampling room no balances and dispensing table found. iv) No proper rejection room provided. v) In powder mixing room safety chain not provided.

			vi) Magnihelic gauges in some areas were not working. vii) In vial washing room HVAC duct sides found seepage of water from the roof. viii) Nitrogen gas cylinders kept outside the factory not covered and protected from heat. ix) In QC dissolution apparatus and stability chamber found out of order. **Keeping in view the recommendations of panel as good for grant of additional section, the Board approved the grant of additional section as under:-** **<u>Sections(01):</u>** **Dry Powder vials Injectable (General) (at place of already approved lyophilized Injectable vials General).** **The Board further decided that same panel as mentioned under shall inspect the firm to see GMP conditions and verify the compliance of shortcomings observed during the inspection in other areas of the licensed premises:** **1. Prof. Dr. Gul Majeed, Member CLB.** **2. Dr. Tariq Sidique, DDG, DRAP, Islamabad.** **3. Mr. Rehmantullah Baig, FID, DRAP, Peshawar.** 4. **Mr. Adnan Shahidullah, ADC DRAP, Lahore.**

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

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

S No.	Name of the firm	Type of license	Decision of CLB
1.	**M/s. Standpharm Pakistan (Pvt) Ltd. 20-KM, Ferozepur Road, Lahore.** **Renewal Period** **07-09-2014 to 06-09-2019**	**DML No.000051 (Formulation)**	**Approved the Grant of Renewal of DML** The Board was apprised that the firm possesses the following sections, however firm does not possess the formal letter from CLB of these sections: 1. Tablet (General) 2. Tablet (Antibiotics) 3. Tablet (Psychotropic) 4. Liquid Syrup & Suspension 5. Sachet 6. Injectable (Ampoules) 7. Injectable Infusion 8. Dry Powder Injectable (General) 9. Capsule (General) 10. Oral Dry Powder Suspension (Cephalosporin) 11. Capsule (Cephalosporin) **The Board decided that the firm be directed to regularize the master layout plan of these sections for obtaining formal letter of above sections.**
2.	**M/s. Bryon Pharmaceutical (Pvt) Ltd, Industrial Estate, Hayatabad, Peshawar.** **Renewal Period** **25-06-2014 to 24-06-2019**	**DML No.000388 (Formulation)**	**Approved the Grant of Renewal of DML** The Board was apprised that the firm possesses the following sections, however firm does not possess the formal letter from CLB of these sections: 1. Tablet (General) 2. Tablet (Psychotropic) 3. Dry Powder (General) 4. Capsule (General) 5. Liquid Syrup 6. Ointment / Cream (General) **The Board decided that the firm be directed to regularize the master layout plan of these sections for obtaining formal letter of above sections.**

3.	**M/s. Remington Pharmaceutical Industries (Pvt) Ltd, 18-KM, Multan Road, Lahore.** **Renewal Period** **18-06-2013 to 17-06-2018**	**DML No.000061 (Formulation)**	**Approved the Grant of Renewal of DML for following sections:** 1. Tablet (General) 2. Capsule (General) 3. Tablet, Capsule and Dry Powder (General Antibiotic/ Quinolones). 4. Sachet (General) 5. Capsule (Cephalosporin) 6. Dry Powder Suspension (Cephalosporin) 7. Eye, Ear & Nose (General) Solution/Suspension 8. Eye, Ear & Nose (Steroid) Solution/Suspension 9. Eye ointment (Steroid) 10. Eye ointment(General) 11. Ointment/Cream/Lotion (General) 12. Ointment/Cream/Lotion (Steroid) 13. Ear, Nose & Throat (General Solution/Suspension 14. Ear, Nose & Throat (Steroid) Solution/Suspension 15. Oral Liquid (General) Syrup/Suspension.
4.	**M/s. Noble Pharma, Plot No.B-1, Old Industrial Area, Mirpur Azad Kashmir** **Renewal Period** **30.01.2014 to 29.01.2019**	**DML No.000652 (Formulation)**	**The board was apprised that the panel has made following observations during the visit.** i. The raw material store and packing material store found overloaded. The management is advised to purchase new racks and pellets for the placement of materials. ii. Small volume weighing scale need to be provided in the oral dispensing area. iii. Some of the electric power plugs needs to be concealed. iv. Over printing area need to be segregated and exhaust system need to be provided in this area. v. Sitting chair in the packing hall need to be replaced with new chair, having back rest. vi. Buffering/Polishing of mixer need to be done in Oral Dry Powders (Vet). vii. In Oral Liquid (Vet) Section,

			transfer pipes of liquid needs to be replaced. viii. Weighing balance need to be provided in the dispensing hood of sterile Liquid Injection (Vet). ix. Installation qualification of some of the equipments in the sterile Liquid Injection (Vet) area needs to be done. x. Cracks wee found on the epoxy paint of sterile area, this need to be maintained. xi. Door of dispatch bay of packing hall of sterile Liquid Injection (Vet) need to be replaced. xii. Lights of the sterile Liquid Injection (Vet) need to be concealed. xiii. The management has purchased HPLC and atomic absorptions. However Installation Qualification and Performance Qualification of HPLC and atomic absorptions need to be done. xiv. Installation qualification and calibration of the equipments of Quality Control Lab was also not done. Installation qualification, performance qualification and Calibration of autoclaves and double Door sterilizers of inject able area needs to be done. **Keeping in view the above observations, the board considered and deferred the renewal of DML for show cause notice with personal hearing.**
5.	**M/s. English Pharmaceutical Industries, Link Katar Bund Road, Thokar Niaz Beg, Lahore.** **Renewal Period 19-08-2014 to 18-08-2019**	**DML No.000339 (Formulation)**	**Approved the Grant of Renewal of DML for following sections except Tablet-I (General) and Capsule (General):** 1. Tablet-II (General Antibiotic) 2. Liquid Syrup (General) 3. Oral Dry Powder Suspension (General) 4. Oral Dry Powder Suspension (Cephalosporin) 5. Capsule (Cephalosporin) 6. Dry Powder Injection (Cephalosporin) 7. Liquid Injection Ampoule (General) 8. Liquid Infusion SVP (General) 9. Capsule (Penicillin)

			10. Oral Dry Powder Suspension (Penicillin) 11. Sterile Dry Powder Injectable (Penicillin) 12. Dry Powder Injectable (General) The Board was apprised that the inspection was conducted by the panel on 17-08-2014 and 30-09-2014 in which panel made certain observations in QC Laboratory, Capsule (General), Tablet-I (General) sections. In response to above observations, the firm submitted revised layout plan along with compliance report, for shifting their Tablet (General), Capsule (General), Oral Dry Powder Suspension (General) Section from ground floor to second floor and expansion of Q.C Laboratory on ground floor at place of Tablet (General) Sections which were approved on 16-01-2015. **The Board constituted the same panel along with Dr. Ikram ul Haq for inspection and verification of observations made by the panel during their inspection for renewal of DML purpose. The composition of panel is as under:** **1. Dr. Ikram ul Haq, Member CLB.** **2. Mr. Jamil Anwar, Director Drug Testing Laboratory, Lahore.** **3. Mr. Ayaz Ali Khan, Chief Drug Controller, Punjab** **4. Mr. Asim Rauf, FID, DRAP, Lahore.** **5. Mrs. Aisha Irfan, FID, DRAP, Lahore.** **The Board further decided to refer the following observations of panel related to registrations of drugs to Registration Board for their information and further necessary action.** **i. It was observed that M/s English Pharma has been granted approximately 400 registrations, it is recommended that No new registration of Drugs be given to the firm till the extension of facility, in addition already given registrations be reduced rationally.** **ii. Panel recommended to suspend registration of lyophilized products till the clarification about the**

			procedural validations, verifying filling of lyophilized material maintain its effectiveness and physical parameters under the condition of filling as practiced by the firm. **The board was further apprised by the Licensing Division that the firm possesses the registrations of Carbepenems (Meropenem), Psychotropics (Clonazepam) and Steridal Injection (dexamethasone as sodium phosphate) but does not possess the dedicated /segregated facilities for these products as required under rules. The Board decided to refer these products to Registration Board also for their information and further necessary action.**
6.	**M/s. Envoy pharmaceuticals (Pvt) Ltd, 27-KM, Multan Road, Lahore.** **Renewal period 21-03-2012 to 20-03-2017**	**DML No.000607 (Formulation)**	**Approved the Grant of Renewal of DML for following sections:** 1. Tablet General 2. Tablet General Antibiotic 3. Capsule General 4. Oral Dry Powder Suspension (Cephalosporin) 5. Capsule (Cephalosporin)
7.	**M/s. Convell Laboratories, Saidu Sharif, Swat.** **Renewal period 26-02-2013 to 25-02-2018**	**DML No.000509 (Formulation)**	**Approved the Grant of Renewal of DML** The Board was apprised that the firm possesses the following sections, however firm does not possess the formal letter from CLB of these sections: 1. Tablet (General / Antibiotic) 2. Oral Dry Powder Suspension (General / Antibiotic) 3. Capsule (General) 4. Liquid Syrup (General) 5. Tablet (Psychotropic) 6. Capsule (Cephalosporin) 7. Oral Dry Powder Suspension (Cephalosporin) 8. Oral Dry Powder Suspension (Penicillin) 9. Capsule (Penicillin) **The Board decided that the firm be**

			directed to regularize the master layout plan of these sections for obtaining formal letter of above sections.
8.	**M/s. Vega Pharmaceuticals (Pvt) Ltd, 30-KM, Multan Road, Lahore.** **Renewal period** **17-07-2014 to 16-07-2019**	**DML No.000542 (Formulation)**	**Approved the Grant of Renewal of DML for 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)
9.	**M/s. Curatech Pharma (Pvt) Ltd, 35-KM, Multan Road, Lahore.** **Renewal period** **17-07-2012 to16-07-2017**	**DML No.000619 (Formulation)**	**Approved the Grant of Renewal of DML for following sections: -** 1. Capsule (General) 2. Tablet (General)
10.	**M/s. Standard Drug Company, E/6-A, SITE, Hyderabad.** **Renewal period** **11-07-2014to10-07-2019**	**DML No.000118 (Formulation)**	**Approved the Grant of Renewal of DML** **Director QA/LT apprised the Board that production of syrup section of the firm was suspended and later an inspection was conducted wherein panel has recommended the resumption of production in syrup section.** **The Board accordingly, allowed the production in syrup section.** 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. Capsule 2. Tablet 3. Syrup 4. Ointment 5. Dry Syrup **The Board decided that the firm be directed to regularize the master layout plan of these sections for obtaining formal letter of above sections.**

11.	**M/s. Caraway Pharmaceuticals, Plot No. 12, Street No.S-4, National Industrial Zone, Rawat Rawalpindi.** **Renewal period** **11-07-2014to10-07-2019**	**DML No.000629 (Formulation)**	**Approved the Grant of Renewal of DML for following sections: -** 1. Tablet (General) 2. Tablet (Antibiotic) 3. Capsule (General) 4. Cream/Ointment/Gel (General) 5. Cream / Ointment/Gel (Steroid) 6. Lotion/Shampoo Medicated (External preparation) 7. Capsule (Cephalosporin) 8. Oral Dry Powder Suspension (Cephalosporin) 9. Dry Powder Injection (Cephalosporin) 10. Liquid Ampoule (Injectable) 11. Liquid Vial (Infusion)
12.	**M/s. Fynk Pharmaceuticals Industry (Pvt) Ltd, 19-KM, GT Road, Kaka Shah Kaku, District Sheikhupura.** **Renewal period** **17-03-2012 to 16-03-2017**	**DML No.000494 (Formulation)**	**Approved the Grant of Renewal of DML for following sections:** 1. Capsule (Cephalosporin) 2. Tablet (Antibiotic) 3. Tablet (General) 4. Liquid Syrup and Suspension (General) 5. Liquid Injection Ampoule (Psychotropic) 6. Liquid Injection Ampoule (General) 7. Dry Powder Suspension (General) 8. Dry Powder Suspension (Cephalosporin) 9. Dry Powder Injection (Cephalosporin) 10. Capsule (General)

13.	**M/s. Macquins International, F-2/H, P.T.C. Industrial Complex, SITE, Karachi.** **Renewal Period 30-04-2012to 29-04-2017**	**DML No.000497 (Formulation)**	**Approved the Grant of Renewal of DML** **The Board further approved and regularized the previous renewal tenure from 30-04-2007 to 29-04-2012 as the firm had applied for renewal of DML within validity of time/date.** The Board was apprised that the firm possesses the following sections, however firm does not possess the formal letter from CLB of these sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup 4. Dry Powder Suspension (General) 5. Ophthalmic Drops 6. Sterile Liquid Injection (Ampoules & Vials) 7. Oral Dry Powder Suspension (Cephalosporin) 8. Dry Powder Sterile Injection (Cephalosporin) 9. Capsule (Cephalosporin) **The Board decided that the firm be directed to regularize the master layout plan of these sections for obtaining formal letter of above sections.**
14.	**M/s. Pharmawise Labs (Pvt) Ltd, 25-KM, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.** **Renewal period 21-12-2009 to 20-12-2014**	**DML No.000182 (Formulation)**	**The Board was apprised about the recommendations of the panel as under: -** • The panel of inspectors visited the above said premises with reference to DRAP letter No.F.1-7/85-Lic (V-Ii) dated 19-03-2014 for renewal of their DML No. 000182 by way of formulation and discussed the matter with the Chief Executive of M/s Pharmawise Labs (Pvt) Ltd, Lahore, Ch. Nadir Khan, as no further advices can be given to spend money more and more for converting the existing premises to meet the latest requirements of the building and HVAC, because the same building was constructed in year, 1988. The Chief

			Executive, Ch Nadir Khan also agreed with the observations of the panel, so the firm has given the following undertaking: • *We agreed with the observations of the learned panel that it will not be advisable to spend more and more for converting the existing premises to meet the latest requirements of building etc. we M/s Pharmawise labs. Purchased a one Acre plot at Sunder Industrial Estate in the year 2007. We therefore, undertake to build new manufacturing premises at 48 Sunder Industrial Estate, Lahore for which we shall submit the building plan to DRAP, Islamabad within one month and accordingly construct new factory within 18 months, in accordance with the latest DRAP advise and by laws.* • The panel agreed to recommend to grant of time for construction of their new plant. Till that their the firm may continue production in this premises by maintaining and trying their level best to meet the GMP conditions for manufacturing of their products as the quality, efficacy and safety of the products is the responsibility of the licensee. This also advised to the management to remain in touch and submit their progress from time to time to the DRAP Islamabad under intimation to this office. **Keeping in view the above situation, the Board after through discussion and deliberations decided for Personal Hearing of the firm on the basis of undertaking submitted to the panel during inspection.**

15.	**M/s. Pakistan Pharmaceutical Products (Pvt) Ltd, D-122, SITE, Karachi.** **Renewal period 05-07-2014 to 04-07-2019**	**DML No.000091 (Formulation)**	**Approved the Grant of Renewal of DML.** The Board was apprised that as per available record licensing division the master layout plan for the below mentioned sections has been regularized / authenticated vide letter dated 05th January, 2015 and following panel was constituted to verify the facility as per approved layout plan. However, report of said panel is awaited. 1. Syed Muied Ahmed, Member CLB. 2. Area, FID, DRAP, Karachi. 3. Area, ADC, DRAP, Karachi. 4. Mr. Farman Ali Bozdar, ADC, CDL, Karachi **Sections (16):** 1. Injectable Ampoule (General) 2. Tablet (General) 3. Capsule (General) 4. Cream /Ointment/ Gel (General) 5. Oral Liquid (General) 6. Ear/Eye Drops (General) 7. Warehouse (General) 8. Warehouse (Cephalosporin) 9. Capsule (Cephalosporin) 10. QC Lab 11. Oral Dry Powder Suspension (Cephalosporin) 12. Dry Powder Vials Injectable (Cephalosporin) 13. Warehouse (Penicillin) 14. Tablet (Penicillin) 15. Capsule (Penicillin). 16. Oral Dry Powder Suspension(Penicillin) **Keeping in view the above situation, the Board decided to regularize the above sections after consideration of awaited report.**

16.	**M/s Silver Surgical Complex (Pvt) Ltd, SITE, Super Highway, Karachi.** **Renewal Period** **19-11-2014 to 18-11-2019**	**DML No.000674 (Formulation)**	**Approved the Grant of Renewal of DML for following sections: -** 1. Disposable Syringes in blister packing 2. I.V Cannula
17.	**M/s. Ipram International, Plot No.26, Street No.SS-3, National Industrial Zone, Rawt, Rawalpindi.** **Renewal period** **28-08-2014 to 27-08-2019**	**DML No.000551 (Formulation)**	**Approved the Grant of Renewal of DML for following sections: -** 1. Sterile Dry Powder for Injection section (Cephalosporin) 2. Oral Dry Powder suspension section (Cephalosporin). 3. Liquid Ampoule (Injectable) General
18.	**M/s. N.B.S Pharma, 8-KM, Thokar Raiwind Road, Lahore.** **Renewal period** **24-01-2010 to 23-01-2015**	**DML No.000467 (Formulation)**	**Approved the Grant of Renewal of DML for following sections:** 1. External Preparations (General) 2. Repacking.
19.	**M/s. Florence Pharmaceuticals (Pvt) Ltd, Plot No.266, Industrial Triangle Kahuta Road, Islamabad.** **Renewal period** **18-06-2013 to 17-06-2018**	**DML No.000635 (Formulation)**	Prof. Dr. Gul Majeed Khan expressed his concern that he was also nominated as member of the panel for inspection vide letter dated 28th August, 2013 but he was not contacted for inspection for months. However, he reminded the Area FID for conducting the inspection of the firm from time to time. Licensing Division, DRAP, Islamabad apprised Board that area FID informed this division on 26-09-2014 that Prof. Dr. Gul Majeed Khan was not available for inspection because he is on vacation. Accordingly, a letter was issued from this office on 26-09-2014 wherein Prof. Dr. Azhar Hussain, Dean, Faculty of Pharmacy Hamdard University has been nominated to conduct pending inspection of firm at place of Prof. Dr. Gul Majeed Khan. This panel had then inspected the firm on 16-10-2014 and company requested for one month time. Second inspection was

			conducted on 14-01-2015 wherein Dr. Azhar Hussain was contacted and he informed that he is busy in office with his seniors and can't join the panel for inspection. The inspection was carried out/conducted on the instruction of Chairman Quality Control. **The Board observed that neither Prof. Dr. Gul Majeed Khan nor his alternate nominee Prof. Dr. Azhar Hussain, Dean, Faculty of Pharmacy Hamdard University was part of the said inspection.** **Keeping in view the above situation, the Board unanimously deliberated the case and deferred the renewal of DML for re-inspection by the panel constituted vide letter dated 28-08-2013 in which Prof. Dr. Gul Majeed khan was member of the panel. The report shall be presented in upcoming meeting of CLB.**
20.	**M/s. Alen Pharmaceuticals (Pvt) Ltd, Nowshera Industrial Estate, Risalpur.** **Renewal period 16-09-2014 to 15-09-2019**	**DML No.000435 (Formulation)**	**Approved the Grant of Renewal of DML for following sections: -** 1. Capsule (General/ Antibiotics) 2. Tablet (General/Antibiotics) **The Board further approved and regularized the previous renewal tenure from 16-09-2009 to 15-09-2014 as the firm had applied for renewal of DML within validity of time/date.**

21.	**M/s. Bosch Pharmaceutical (Pvt) Ltd, Plot No.221, Sector 23, Korangi Industrial Area, karachi.** **Renewal period** **16-02-2015 to 15-02-2020**	**DML No.000350 (Formulation)**	**Approved the Grant of Renewal of DML for following sections: -** 1. Liquid Injectable Ampoule – I 2. Liquid Injectable Ampoule – II 3. Injectable Liquid Ampoules (Psychotropic) 4. Lyophilized Powder Injectable Vials 5. Tablet (General)-I 6. Tablet (General) – II 7. Oral Dry Powder Suspension (Penicillin) 8. Capsule (Penicillin) 9. Tablet (Penicillin) 10. Dry Powder Injectable (Penicillin) 11. Capsule (General) 12. Dry Powder Injectable (Cephalosporin) 13. Oral Dry Powder Suspension (Cephalosporin) 14. Tablet (Cephalosporin) 15. Oral Dry Powder Suspension (Cephalosporin) 16. Capsule (Cephalosporin)
22.	**M/s. Scotmann Pharmaceuticals Plot No.5-D, Sector I-10/3, Industrial Area, Islamabad.** **Renewal period** **22-06-2012 to 21-06-2017**	**DML No.000498 (Formulation)**	The Board was apprised that CLB in its 238th meeting held on 19-11-2014 approved the Grant of Renewal of DML and Board further decided to re-inspect and verify the Bio-Tech antiviral & BioTech Interferon sections by following panel as per approved layout plan: • Director Biological, DRAP, Islamabad10 • Director NCL, Islamabad. • Area FID, DRAP, Islamabad. **Keeping in view the recommendations of panel, the Board considered and approved the renewal of DML for following section as verified according to approved layout plan :** 1. Bio-Tech Antiviral vaccine (Vials) 2. Bio-Tech Interferon **(**Vials/Ampoule/Pre-filled syringes)

23.	**M/s. Mega Pharmaceuticals Ltd, 27-KM, Raiwind Road, Lahore.** **Renewal period 17-04-2014 to 16-04-2017**	**DML No.000537 (Formulation) .**	**Approved the Grant of Renewal of DML for following sections: -** 1. Tablet (General) 2. Capsule (General) 3. Oral Dry Powder Suspension (Antibiotic) 4. Tablet (Antibiotics) 5. Oral Dry Powder Suspension (Cephalosporin) 6. Capsule (Cephalosporin)
24.	**M/s. Rotexmdica Pakistan (Pvt) Ltd, Industrial Triangle, Kahuta road,** **Renewal period 29-01-2014 to 28-01-2019**	**DML No.000651 (Formulation)**	**Approved the Grant of Renewal of DML for following sections: -** 1. Tablet (General) 2. Capsule (General)
25.	**M/s. Swiss Pharmaceutical (Pvt) Ltd, A-159, SITE, Super Highway Karachi.** **Renewal period 08-09-2014 to 07-09-2019**	**DML No.000438 (Formulation)**	**Approved the Grant of Renewal of DML except Capsule (Penicillin), Oral Dry Powder Suspension (Penicillin), Eye Drop (General) & Eye Ointment (General) due to observations made by the panel that these sections are non-operational since long and lack proper facilities for production. The Board further directed firm to not start production in above mentioned three sections, unless inspected and approved by Central Licensing Board.** **The Board authorized the same panel for re-inspection for Capsule (Penicillin), Oral Dry Powder Suspension (Penicillin), Eye Drop (General) & Eye Ointment (General) after submission of compliance report by the firm as under: -** 1. Dr. Muied Ahmed Member CLB. 2. Dr. Tanveer Alam DDG (E&M) DRAP, Karachi. 3. Dr. Najam-us-Saqib, FID, DRAP, Karachi. 4. Mrs. Ume Laila Area ADC, DRAP, Karachi. The Board was apprised that the firm possesses the following sections, however

			firm does not possess the formal letter from CLB of these sections: 1. Tablet (General) 2. Oral Liquid / syrup (general) 3. Ointment / Cream (General) 4. Capsule (cephalosporin) 5. Capsule (General) 6. Dry powder suspension (General) 7. Oral Dry Powder suspension 8. Capsule (cephalosporin) 9. Ampoule and vial injection (general) 10. Dry powder injection (cephalosporin) 11. Capsule (Penicillin) 12. Oral Dry Powder Suspension (Penicillin) 13. Eye Drop (General) 14. Eye Ointment (General) **The Board decided that the firm be directed to regularize the master layout plan of these sections for obtaining formal letter of above sections.**
26.	**M/s. Webros Pharmaceuticals Plot No.1, street No. 10, RCCI, National Industrial Zone, Rawat, Rawalpindi** **Renewal period** **10-04-2014 to 09-04-2019**	**DML No.000538 (Formulation)**	**Approved the Grant of Renewal of DML for following sections: -** 1. Tablet (Section) 2. Capsule (Section) 3. Dry powder suspension (General) 4. Semi solid section (general) 5. Semi solid section (steroidal) 6. Dry powder suspension (cephalosporin) 7. Capsule (cephalosporin)

ITEM NO. V MISCELLANEOUS CASES.

1. MANUFACTURING REQUIREMENTS FOR VARIOUS CLASSES OF DRUGS INCLUDING STEROIDS.

The case was placed before the Board as under: -

Brief Background of the Case

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

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

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

Accordingly, case was presented in 236th meeting of Central Licensing Board held on 27th June 2014, for consideration of the Board.

Decision of CLB in its 236th meeting held on 27th June 2014

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

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

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

- **For manufacturing requirements of anti-inflammatory steroids, the Board referred the case back to Registration Board for clear and candid recommendations from its committee so that CLB may decide accordingly. The said committee may be enlarged**

for better scientific discussion and recommendations keeping in view the domestic dynamics as well.

1. Registration Board in its 245th meeting considered reference sent by Central Licensing Board in 236th meeting for clear and candid recommendations regarding manufacturing requirement of steroidal drugs. Accordingly, the Board discussed the manufacturing requirement for steroid drugs and advised to members, PPMA & Pharma bureau to forward their scientific comments and relevant references on manufacturing requirements for various classes of drugs including steroid. These comments were considered in 246th meeting and decided as follows:-

   "***Registration Board discussed comments of its members, stake holder, and international practices and agreed that for all topical preparations viz eye/ear preparations, external preparation (Cream/Ointment/Gel/Lotion/Spray) and aerosols, steroid manufacturing areas for these dosage forms provided that manufacturer has segregated dispensing booths, validation and controls studies for processes and adequate system to minimize and potential risk of cross contamination. Registration Board decided to forward above recommendation to Licensing Division for ultimate decision by Central Licensing Board***"

Proceedings of CLB:

The Baord discussed the case thoroughly. All pros and cons were taken into consideration. The point of view of PPMA and Pharma Bureau was also taken during discussion. All members of the Board unanimously agreed to the decision of Registration Board; however, the CLB observed that the decision of Registration Board is merely for Steroidal Topical Preparation. The Board was also apprised of the background working of the Registration Board.

Decision of CLB:

After thorough deliberations and keeping in view the recommendations/decision of Registration Board and point of view of stake holders, the Board unanimously decided as under: -

1. **Steroidal topical preparations like Eye/Ear Drops, Sterile Eye Ointment, External Preparation i.e. Cream/Ointment/Gel, Lotions, Spray/aerosols, suppositories, vaginal preparation, intra oral preparations, Nasal drops etc shall be manufactured in General facility/area subject to following conditions that the: -**

   a. ***Manufacturers shall have segregated dispensing booths, cleaning validation and controls studies for processes and adequate system to minimize the potential risk of cross contamination,***
   b. ***Commercial marketing of above products shall be allowed by Registration Board after confirmation and verification of conditions as in (1.a.) above.***

2. **Segregated manufacturing facility shall be required for the manufacturing of Steroidal Injections, Syrup and Oral Solid dosage forms (Tablet, capsules, granules etc).**

2. CHANGE OF MANAGEMENT OF M/S ENVOY PHARMACEUTICALS (PVT.) LTD

The case was placed before the Board as under: -

M/s Envoy Pharmaceuticals (Pvt.) Ltd, 27-km Multan Road, Lahore DML NO. 000607 (Formulation) has submitted its application for change of management.

2. The firm has provided meetings of Board of Directors of M/s Envoy Pharmaceuticals (Pvt.) Ltd held on January 10, 2011 at 3:00pm at the registered office of the company. The meeting was chaired by **Mr. Ghawas Bashir (CEO of the company)** and attended by the following persons/Directors:-

1) Mr. Qulb-i-Hussain Naqvi (Director)
2) Mr. Zaffar Abbas Bhatti (Director)
3) Syed Ijaz Hussain Naqvi (Director)
4) Mr.Ejaz Malik (Director)
5) Mr. Imran Hameed (Director)
6) Mr. Nasir Khan S/O Mr. Muhammad Ishaq -**New**
7) Mr. Faiq Hussain Zaidi S/O Syed Shaiq Hussain Zaidi-**New**

3. During meeting, **the resignations of Mr. Qulb-i-Hussain Naqvi, Mr. Ejaz Malik, Mr. Imran Hameed, Mr. Zafar Abbas Bhatti and Syed Ijaz Hussain Naqvi** were discussed and it was unanimously resolved that resignations of said directors of the company were accepted with immediate effect.

4. **The resignation of Mr. Ghawas Bashir, CEO of the company** was also accepted with immediate effect. The matter regarding filling up causal vacancy created due to resignation of Mr. Ghawas basher, CEO of the company was discussed and it was unanimously resolved that **Mr. Nasir Khan** be and is hereby co-opted as Chief Executive Officer of the company.

Due to transfer of shares and resignations of existing management of the firm, it was considered by the company Board to formally record the current and final position of new management and current shareholding as follows:-

01	**(New CEO of the Company/Director)** **Mr. Nasir Khan S/O Mr. Muhammad Ishaq** **CNIC :** 35201-1634064-5 **Address:** Al Madina Building Store, Chungi Gujarpura, Lahore
02	**(New Director of the firm)** **Mr. Faiq Hussain Zaidi S/O Syed Shaiq Hussain Zaidi** **CNIC:** 35202-2041473-9 **Address:** 242- Sikandar Block, Allama Iqbal Town, Lahore

5. The firm has submitted Form 29, Form 21, Form A issued by Security Exchange Commission of Pakistan & Minutes of meeting of Board of Directors, CNIC photocopies. All the documents/information submitted by firm has been examined by Licensing Division, DRAP, Islamabad and found in order.

Decision of CLB:

The Board considered and approved the new management of M/s Envoy Pharmaceuticals (Pvt) Ltd, 27-KM, Multan Road, Lahore DML No.000607 (formulation) as under: -

Old Management	New Management
1. Mr. Ghawas Bashir **(CEO)** **Directors** 2. Mr. Qulb-i-Hussain Naqvi (resigned). 3. Mr. Ejaz Malik (resigned). 4. Mr. Imran Hameed (resigned). 5. Mr. Zafar Abbas Bhatti (resigned). 6. Syed Ijaz Hussain Naqvi (resigned).	**1.** Mr. Nasir Khan S/O Mr. Muhammad Ishaq **(CEO/ Director)** CNIC : 35201-1634064-5 Address: Al Madina Building Store, Chungi Gujarpura, Lahore **2.** Mr. Faiq Hussain Zaidi S/O Syed Shaiq Hussain Zaidi **(Director)** CNIC: 35202-2041473-9 Address: 242- Sikandar Block, Allama Iqbal Town, Lahore

3. DELEGATION OF FUNCTIONS OF THE CENTRAL LICENSING BOARD.

The case was placed on the agenda as under: -

The Board was apprised that the Central Licensing Board in its 237th meeting held on 1st October, 2014 had approved and delegated its powers retrospectively with certain modifications to its Chairman, Secretary and Director Quality Assurance and Laboratory Testing under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) rules, 1976 in order to facilitate timely disposal of routine and day to day business of Central Licensing Board.

The new proposal along with a brief history of delegation of functions/powers of the Board was presented before the Board as under:

S #	Powers	Relevant Provision of Act / Rule (s)	Power delegated in 232nd meeting	Power delegated in 234th meeting	Power delegated in 237th meeting	New Proposal
1.	Show Cause Notice regarding contravention of any of the provisions of the Drugs Act, 1976 and rules framed there under. For cancellation and suspension of DML for such period either wholly or in respect of some of the drugs to which it relates.	Section 41 and Rule 12 of Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB	Chairman CLB	Chairman CLB	Same as before to Chairman CLB
2.	Suspensions of Production	Section 41 and Rule 12 of Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB	Chairman Returned his function to CLB delegated in 232 meeting of CLB	Chairman CLB	Chairman CLB returned back his function to CLB delegated in 234th meeting of CLB.
3.	Lodging of FIR	Section 19(7) read with 30(b) of Drugs Act, 1976.	Chairman CLB	The function has already been delegated to Director QA/LT or all DDG(s) Provincial Head Quarter or Officer	Director Quality Assurance and Laboratory testing	**-same-** Director Quality Assurance and Laboratory testing

				Incharge of the representative province of DRAP so shall remain as above.		
4.	Approval of layout plan	Schedule "B" Section 1 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB through a committee comprising of DDG (Lic) DDC (Lic) DDC (Lic) ADC (Lic)	Chairman CLB through respective desk officer under Rule 8 (10) Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB (The committee shall be constituted for the purpose of evaluation / assessment and analysis of the layout plan and shall furnish its recommendations accordingly to the Chairman CLB for approval).	Director Drug Licensing / Chairman CLB (The committee shall be constituted for the purpose of evaluation / assessment and analysis of the layout plan and shall furnish its recommendations accordingly to the Chairman CLB for approval).
5.	i) Approval of change of legal status of firm for licensed units (i.e. name, management or any other legal change) ii) Approval of drugs (molecules) for basic and semi basic manufacturing. iii) Approval of Repacking items under Schedule D of drugs Act 1976 and Rules framed	Rule 5(6) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 read with Rule 8 (10) of aforementioned Rules.	Chairman CLB	Central Licensing Board shall consider such requests in future as Chairman CLB returned back the said delegated function to Board. For powers 5(i)(ii) the inspections are mandatory before grant of any items / drugs under respective Schedule etc.	Change of management was delegated to Chairman CLB	Central Licensing Board shall consider such requests in future as Chairman CLB returned back the said delegated function to Board. For powers 5(i)(ii) the inspections are mandatory before grant of any items / drugs under respective Schedule etc.

	there under.					
6.	Constitution / amendments in constitution of panel for inspection for grant/renewal of Drug Manufacturing License, grant of Additional Section and verification/ checking of conditions of License etc of firms.	Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 of aforementioned Rules.	Chairman CLB	Chairman CLB	Chairman CLB	Chairman Central Licensing Board / Director Drug Licensing.
7.	Extension in Sealing period of Licensed manufacturers where Contravention(s) is/are of Conditions of DMLs only.	Section 18(h) read with Section 19(7) of the Drugs Act, 1976 and Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB	Chairman CLB	Chairman CLB	Chairman Central Licensing Board.
8.	Correction of typographical error in recording minutes of the meeting of the CLB.	Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB	Chairman CLB	Chairman CLB	Chairman Central Licensing Board.
9.	Issuance of Inspection Book	Rule 8(10) read with Rule 19(4) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.	Secretary CLB	Secretary CLB	Secretary CLB	Secretary CLB
10	Approval of Technical Staff Communication / Issuance of Decisions of Central Licensing Board.	Rule 15 and 16 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 read with Rule 8 (10) of	Secretary CLB	Secretary CLB	Secretary CLB	Secretary CLB

		aforementioned Rules.				
11	Site approval.	Rule 8 (10) of aforementioned Rules.	Secretary CLB	Secretary CLB	Secretary CLB	Secretary CLB
12	Approval of change of legal status of unlicensed firm (name, management or any other legal change)	Rule 8 (10) of aforementioned Rules.	Secretary CLB	Secretary CLB	Secretary CLB	Chairman CLB
13	Functions performed by Officers of Division of licensing in context with disposal of day to day business of Central Licensing Board regarding communication of decisions as per provisions laid down under the Drugs Act, 1976 and Rules (Drugs (LR&A) Rules, 1976) framed there under for exercising the power in implementation of rules (Drugs (LR&A) Rules, 1976).	Rule 8 (10) of aforementioned Rules.	----------	----------	----------	Through respective desk officers of Division of Drug Licensing after getting approval from Chairman CLB.

Decision of CLB:

The Central Licensing Board approved and delegated its functions/powers related to Division of Drug Licensing to its Chairman and Secretary under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 in order to facilitate timely disposal of routine and day to day business of Central Licensing Board as under:

S No.	Functions / Powers	Function / Powder Delegated to
	Delegation of Functions / Powers related to Division of Drug Licensing	
1.	Show Cause Notice under Rule 8(16) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB
2.	Issuance of Inspection Book	Secretary CLB
3.	Approval of layout plan and constitution of committee for evaluation of layout plan. (The committee shall be constituted for the purpose of evaluation / assessment and analysis of the layout plan and shall furnish its recommendations accordingly to the Chairman CLB for approval).	Chairman CLB
4.	Approval of Technical Staff and communication / Issuance of decisions of Central Licensing Board.	Secretary CLB
5.	Approval of Site for establishment of pharmaceutical unit	Secretary CLB
6.	Approval of change of legal status of firm for un-licensed units (i.e. change of Name & Management / Director / Owner etc or any other legal change of the firm.)	Chairman CLB
7.	Implementation of decisions of Appellate Board related to Division of Drug Licensing	Chairman CLB
8.	Constitution / amendments in constitution of panel for inspection for grant/renewal of Drug Manufacturing License, Grant of Additional Sections and Verification / Checking of conditions of License etc of firms.	Chairman CLB
9.	Correction of typographical error in recording minutes of the CLB.	Chairman CLB

Following functions which were earlier delegated to Chairman CLB have been returned back to the Central Licensing Board.

S No.	Functions / Powers
1.	Approval of change of legal status of firm for licensed units (i.e. change of Name & Management / Director / Owner etc or any other legal change of the firm.)
2.	Approval of drugs / APIs (Molecules) for basic, and semi basic manufacturing. (The inspections shall be made mandatory before grant of any item(s) / drugs/ APIs under respective Schedule etc.)
3.	Approval of Repacking items under Schedule D of Drugs Act 1976 and Rules framed there under. (The inspections shall be made mandatory before grant of any item(s) / drugs/ APIs under respective Schedule etc.)
4.	Extension in Sealing period of Licensed manufacturers where Contraventions(s) is / are of Conditions of DMLs only.

B. Quality Control Cases

Case No. I **Manufacture & Sale of Substandard and De-Registered Drugs-Contravention of Provisions of the Drugs Act 1976 and Rules Framed there Under.**

Case Background.

1. The Federal Inspector of Drugs (FID), Karachi-III vide his letter dated 21-04-2014 informed that he alongwith Dr. Shahid Hussain, FID Karachi and others raided the premises of M/s Ankaz Pharmax (Pvt) Ltd., Karachi on 19-04-2014 at 07.45 AM. The raid was conducted on the source information of FIA Crime Circle Karachi. Deputy Director FIA Mr. Fakeer Muhammad headed the raid alongwith his team. Ten samples of different products were taken from the manufacturers premises for test/analysis on the prescribed Form-3.

2. The FID vide his investigation report of the case intimated that eight samples of the drugs taken have been declared to be substandard by the Federal Government Analyst, CDL Karachi. In the light of the same, the FID issued explanation letter regarding the matter of manufacture and sale of substandard drugs to the firm. As per documents provided by the FID, the firm challenged the test reports and requested to get the samples retested from the Appellate Laboratory, NIH Islamabad.

3. The FID vide his investigation report of the above case also reported that the firm was found manufacturing its one of de-registered product namely syrup Rumin mentioning the old manufacturing date on the label. It has been intimated that Syrup Rumin was found stored in bulk in big vessel placed in liquid manufacturing areas of the firm. A huge quantity of finished goods of same de-registered syrup was also seen placed in finished good wear house.

4. The FID concluded that the manufacturer is guilty of manufacturing substandard drugs and de-registered drug in violation to the provisions of Drugs Act 1976 and rules framed there under. He has requested for cancellation DML of the firm or permission to lodge the prosecution against the firm.

5. Following persons of the firm were held responsible for committing the offence by the FID.

i. Ali Abbass, Managing Director of the firm.

ii. Akbar Ali, Production Incharge.

iii. Safdar Alam, Quality Control Incharge.

6. As per record of Quality Control Section, registration of this product was cancelled by DRB in its 237th meeting held on 26-02-2013, which was communicated of the firm vide their officer letter bearing No.03-16/2012-QC, dated 22-03-2013.

7. The Appellate Laboratory declared 04 samples as Substandard and one of these as Misbranded whereas 03 samples were declared as of Standard quality by the Appellate Lab (NIH) Islamabad.

8. As per procedure Show cause notices were issued to the firm and other accused, in the light of the test reports of the Appellate Lab and report of the FID, offering them opportunity of personal hearing before the Drug Registration Board.

9. The case of manufacture and sale of substandard and de-registered drugs by M/s Ankaz Pharmex (Pvt.) Ltd, Karachi was considered by the Drug Registration Board in its 246th meeting held on 10th & 11th December 2014. Mr. Saleem Isharat Hussain, Technical Consultant of the firm, appeared before the Board on behalf of the firm on 11-12-2014. The Drug Registration Board after hearing the representative of the company, deliberations made, available record and facts of the case decided as under:-

I. "To cancel the registration of the following products of the firm:-

i. Rumin (Ibuprofen) 400mg Tablet, Reg. No. 007545.
ii. Rumin (Ibuprofen) 200mg Tablet, Reg. No. 007543.
iii. Tab. Biprim (Co-Trimoxazole) DS, Reg. No. 008409.

II. The Board further decided to recommend to the Central Licensing Board for cancellation of the Drug Manufacturing License of the firm on the violation of manufacturing of already De-registered product i.e. Rumin Suspension Reg. No. 008526."

10. The case was accordingly placed before the Center Licensing Board (CLB) for consideration of recommendation of the Drug Registration Board regarding cancellation of Drug Manufacturing License (DML) of M/s Ankaz Pharmex (Pvt.) Ltd, Karachi and request of the area Federal inspector of Drugs, Karachi for cancellation of DML of the firm or permission to lodge the prosecution against the firm as narrated above.

Decision of the CLB:-

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

"To Issue show cause notice to the firm for cancellation of Drug Manufacturing License (DML) of M/s Ankaz Pharmex (Pvt.) Ltd, Karachi as per Section 41 of the Drugs Act 1976 and also for prosecution of the above named firm and the accused persons in the Drug Court for Sindh, Karachi".

Supplementary Agenda of Licensing Division

The board deferred the following supplementary agenda for next meeting due to paucity of time.

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

Following cases have been recommended by the respective panel of experts for grant of additional sections/expansion/amendments etc of already licensed pharmaceutical manufacturers. The same are placed before the Board for its consideration/decision, please: -

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	**M/s Weather Folds Pharmaceutical 69/2,Phase-II, Industrial Estate, Hattar.** DML No.000644 (Formulation) **Section (03)** 3. Dry Powder Injection (General) 4. Liquid Injection (General) 5. Liquid Syrup (General) 6. Sachet (General)	20-01-2015	**Good**	1. Mr. Afrasayab Chief Drug Inspector Peshawar. 2. Dr. Khalid Khan Senior analyst DTL, KPK. 3. Mr. Rehmatullah, Baig Alvi, FID, DRAP, Peshawar. 4. Mr. Adnan Shahidullah, ADC, DRAP, Peshawar.

Recommendations by the Panel:-

In reference to DRAP letter No.F.3-8/2007-Lic dated 16th Jan, 2015. The constituted panel conducted detail inspection of M/s. Weather Folds Pharmaceutical 69/2,Phase-II, Industrial Estate, Hattar on 20-01-2015 regarding Additional Section

1. Dry Powder Injection (General)
2. Liquid Injection (General)
3. Liquid Syrup (General)
4. Sachet (General)

The firm has constructed the additional section as per approved layout plan. All separated from each other. They have provided HAVC system found in working condition. In dry powder injection they have provided dry powder filling and sealing machine under LGC. They provided sterile facility in dry powder vial and ampoule filling area. In ampoule section they have provided ampoule filling machine under laminar flow hood. They have provided 3 buffer change rooms with sterile HVAC facility. They have provided separate rooms for raw material and finished goods store. In liquid syrup they have all the manufacturing facility for filling, sealing. In sachet section they have provided sachet filling machine and cone mixer.

In QC they have provided all the required equipments in microbiology. They have appointed well qualified pharmacists, chemists and a microbiologist to test their registered products. Therefore, the panel recommends grant of additional sections dry powder injection (General), liquid injection (general), liquid syrup (General), Sachet (general) by way of formulation.

2.	**M/s Lotus Pharmaceutical plot No.18-A, Street No.8, Sector I-10/3, Islamabad.** DML No.000661 (Formulation) **Section (03)** 1. Dry Powder Injectable (Cephalosporin) 2. Oral Powder (Cephalosporin)	20-01-2015	**Good**	1. Dr. Ahmad Mahmood Mumtaz, DDG, DRAP, Islamabad. 2. Dr. Muhammad Fakhruddin Aamir, FID, DRAP, Islamabad. 3. Sardar Shabbir Ahmed, Drug Inspector, ICT, Islamabad.
	Recommendations by the Panel:- Cephalosporin section were not read and company has requested for some time, so these will be inspected later and a separate report will be submitted after re-inspecting the cephalosporin section.			

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

Following cases have been recommended by the respective panel of experts for grant of Renewal of Drug Manufacturing Licenses. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	**M/s. Rehman Rainbow (Pvt) Ltd. 82-KM, Industrial Estate, Kot Lakhpat, Lahore.** **DML No.000510 (Formulation)** **Renewal Period** **18-06-2013 to 17-06-2018**	17-12-2014	**Good**	1. Prof. Dr. Muhammad Jamshaid, Dean Faculty of Pharmacy, university of Central Punjab, Lahore. 2. Dr. Sheikh Akhter Hussain, DDG, DRAP, Lahore. 3. Abdul Rashid Shaikh, FID, DRAP, Lahore. 4. Dr. Akber Ali, ADC, DRAP, Lahore.
	Recommendations of the panel: - In the light of above the panel of inspectors is of the opinion to recommend the renewal of DML by way of formulation for the following sections to M/s Rehman Rainbow, 82-KM, Industrial Estate, Kot Lakhpat, Lahore. **Following sections are mentioned in inspection report for renewal.** 1. Gauze Section. 2. Bandage Section. 3. Medicated Dressing Section. 4. Cotton Section. 5. Disposable syringes. The above sections have been granted by Central Licensing Board and confirmed from the available record of Licensing Division.			

	M/s Lotus Pharmaceutical plot No.18-A, Street No.8, Sector I-10/3, Islamabad. DML No.000661 (Formulation) **Renewal period 16-06-2014 to 15-06-2019**	20-01-2015	**Good**	1. Dr. Ahmad Mahmood Mumtaz, DDG, DRAP, Islamabad. 2. Dr. Muhammad Fakhruddin Aamir, FID, DRAP, Islamabad. 3. Sardar Shabbir Ahmed, Drug Inspector, ICT, Islamabad.
	Recommendations by the Panel:- Viewing the facts and facilities present at the time of inspection, the panel unanimously recommends for the grant of renewal of DML by way of formulation. **Following sections are mentioned in inspection report for renewal.** 1. Tablet (General) 2. Capsule (General) 3. Dry Powder for Suspension (General) 4. Liquid Syrup The above sections have been granted by Central Licensing Board and confirmed from the available record of Licensing Division.			

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