**MINUTES OF 267th MEETING OF CENTRAL LICENSING BOARD HELD ON 31st DECEMBER, 2018**

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267th meeting of the Central Licensing Board (CLB) was held on 31st December, 2018 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Mr. Ghulam Rasool Dutani, Director Drug Licensing, Drug Regulatory Authority of Pakistan, Islamabad.

Following members attended the meeting: -

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| **S. No.** | **Name & Designation** | **Status** |
|  | Prof. Dr. Mohammad Usman, Expert in manufacturing of drugs | Member |
|  | Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar. | Member |
|  | Mr. Muhammad Israr, Law Expert, Mininstry of Law & Justice Division. | Member |
|  | Syed Abdul Saleem, Chief Inspector of Drugs, Government of Baluchistan, Quetta | Member |
|  | Dr. Hafsa Karam EllahiRepresentative Director (QA/LT), DRAP, Islamabad | Member |
|  | Zakir Shah, Provincial Drug inspector, Nominee of of CDI Govt of Khyber Pakhutonkhuwa. | Member |
|  | Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad. | Secretary/Member |
|  | Mr. Khalid Munir & Mr. Farooq Bukhari, Representative of Representative of PPMA. | Observer |
|  | Mr.Nadeem Alamgir, Representative of Pharma Bureau. | Observer |

The meeting started with the recitation of verses from the Holy Qura’an. The Chairman Central Licensing Board welcomed the honorable members and participants of the meeting. He stated that all the legal and codal formalities would be taken into account for disposal of cases and respective Divisions shall be responsible for the contents, errors and omissions of agenda and minutes. Mr. Abdul Sattar Sohrani, Deputy Director (Quality Control) Mr. Ayyaz Ahmad, Deputy Director (Lic), Dr. Muhammad Yaqoob AD (Lic.), Dr. Muhammad Usman, AD (Lic) and Dr. Zunaira Farayad, Assistant Director (Lic), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

**Item-I CONFIRMATION OF THE MINUTES OF 266thMEETING**

 The Central Licensing Board (CLB) formally confirmed the minutes of its 266thmeeting of the Central Licensing Board (CLB) which was held on 24th October, 2018.

**A. DRUG LICENSING DIVISION**

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

Following cases have been forwarded by the respective panel of experts for grant of new Drug Manufacturing Licenses. Same are placed before the Board for its consideration/decision, please.

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| **S #** | **Name of the firm** | **Date of Inspection / Type of License** | Ranking/ Evaluation | **Inspection Panel Members** |
| 1 | M/s Zamko Pharmaceuticals (Pvt) Ltd, 641-A, Sunder Industrial Estate, Lahore.**Sections 03**1. Tablet (General) Section
2. Capsule (General) Section
3. Oral Powder Suspension (General) Section.
 | 17-07-2018 | **Good** | 1. Dr. Ikram-ul-Haq, Member Central Licensing Board.
2. Mr. Munawar Hayat, Chief Drugs Controller, Punjab.
3. Additional Director, (E&M) DRAP, Lahore (Not present)
4. Ms. Ufaq Tanveer, Area Federal Inspector of Drugs, Lahore.
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| **Recommendations of the panel: -**Keeping in the view the facilities like building, HVAC system, machinery and equipment, personnel, documentation and Quality Control Testing facilities the panel of inspectors is of the opinion to recommend the grant of Drug manufacturing License to M/s Zamko Pharmaceuticals (Pvt) Ltd, 641-A, Sunder Industrial Estate, Lahore for above mentioned three sections.**Decision of the Central Licensing Board in 267th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Zamko Pharmaceuticals (Pvt) Ltd, 641-A, Sunder Industrial Estate, Lahore with following sections:**Section (03)**1. Tablet (General) Section
2. Capsule (General) Section
3. Oral Powder Suspension (General) Section.
 |
| 2. | M/s Dynatis Pakistan (Pvt) Ltd, Plot No. 710, Sunder Industrial Estate, Lahore.**Sections 06**1. Tablet Section (General).
2. Capsule Section (General).
3. Sachet Section (General).
4. Cream / Ointment Section (General)
5. Cream / Ointment Section (Steroidal) Section
6. Lotion (General) Section.
 | 04-12-2018 | **Good** | 1. Dr. Farzana Chaudhary, Director, UVAS, Lahore
2. Mr. Asim Rauf, Additional Director, DRAP, Lahore
3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, Lahore.
 |
| **Recommendations of the panel: -**Keeping in view the facilities like building HVAC system, machinery and Equipment, instrument, personnel, documentation, Quality Control, Testing facilities, the panel of inspectors wasof the opinion to recommend the grant of Drug Manufacturing License to M/s Dynatis Pakistan (Pvt) Ltd, Plot No. 710, Sunder Industrial Estate, Lahore for the following sections:1. Tablet Section (General).
2. Capsule Section (General).
3. Sachet Section (General).
4. Cream / Ointment Section (General)
5. Cream / Ointment Section (Steroidal)
6. Lotion Section (General).

**Decision of the Central Licensing Board in 267th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Dynatis Pakistan (Pvt) Ltd, Plot No. 710, Sunder Industrial Estate, Lahore with following sections:**Section (06)**1. Tablet Section (General).
2. Capsule Section (General).
3. Sachet Section (General).
4. Cream / Ointment Section (General)
5. Cream / Ointment Section (Steroidal)
6. Lotion Section (General).
 |
| 3. | M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.**Sections 02**1. Tablet Section (General).
2. Capsule Section (General).
 | 13-11-2018&17-12-2018 | **Good** | 1. Prof. Dr. Muhammad Usman, Member, CLB, DRAP, Islamabad.
2. Additional Director (QA&LT-I), DRAP, Islamabad.
3. Mr. Khalid Mahmood, FID-II, DRAP, Islamabad.
 |
| **Recommendations of the panel: -**“Keeping in view the facts, detailed visit of facility and supporting documents provided by the company, the panel **recommends** M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI,NIZ, Rawat for the grant of Drug Manufacturing License (Formulations) for the following sections namely;1. Tablet Section (General).
2. Capsule Section (General).

**Decision of the Central Licensing Board in 267th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, Industrial Estate, Rawat.**Section (02)**1. Tablet (General) Section
2. Capsule (General) Section.
 |
| 4. | M/s Vetec Laboratory, Plot No. 20, S-5, RCCI, Rawat.**Sections 02**1. Oral Powder Section (Veterinary).
2. Oral Liquid Section (Veterinary).
 | 13-11-2018&17-12-2018 | **Good** | 1. Prof. Dr. Muhammad Usman, Member, CLB, DRAP, Islamabad.
2. Mr. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad.
3. Mr. Hasan Afzaal, FID-III, DRAP, Islamabad.
4. Hafiz Muhammad Umair, Assistant Director (I&E), DRAP, Islamabad.
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| **Recommendations of the panel: -**“GMP is a continual improvement process and keeping in view the observations during inspection, areas visited, documents reviewed it is concluded that M/s Vetec Laboratory, Plot No. 20, S-5,, RCCI has basic facilities for manufacturing and testing of pharmaceuticals (Veterinary); for future working, suggestions for improvement have been discussed with the representatives of the firm. Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **recommended** M/s Vetec Laboratory, Plot No. 20, S-5,, RCCI, Rawat. for the grant of Drug Manufacturing License for the following sections namely;1. Oral Powder Section (Veterinary).
2. Oral Liquid Section (Veterinary).

**Decision of the Central Licensing Board in 267th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Vetec Laboratory, Plot No. 20, S-5, RCCI, Rawat.**Sections Section (02)**1. Oral Powder Section (Veterinary).
2. Oral Liquid Section (Veterinary).
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| 5. | M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat.**Sections 05**1. Capsule Section (Cephalosporin).
2. Dry Powder for Suspension Section (Cephalosporin).
3. Tablet Section (General).
4. Capsule Section (General).
5. Sachet Section (General).
 | 08-11-2018&13-11-2018 | **Good** | 1. Prof. Dr. Muhammad Usman, Member, CLB, DRAP, Islamabad.
2. Mr. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad.
3. Mr. Khalid Mahmood, FID-II, DRAP, Islamabad.
 |
| **Recommendations of the panel: -**“Keeping in view the facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **recommended** M/s Benson Pharmaceuticals, Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat for the grant of Drug Manufacturing License (Formulation) for the following sections namely and shifting of DML please:-1. Capsule Section (Cephalosporin).
2. Dry Powder for Suspension Section (Cephalosporin).
3. Tablet Section (General).
4. Capsule Section (General).
5. Sachet Section (General).

Production shall be conducted of the approval of Transfer of DML by CLB.**Decision of the Central Licensing Board in 267th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name M/s Benson Pharmaceuticals, with same number at new premises Plot No. 3, Main Road, National Industrial Zone, RCCI, Rawat, with following sections:**Section (05)**1. Capsule Section (Cephalosporin).
2. Dry Powder for Suspension Section (Cephalosporin).
3. Tablet Section (General).
4. Capsule Section (General).
5. Sachet Section (General).

The firm shall manuafacture drugs after approval from the Drug Registration Board. |
| 6 | M/s Avensis Pharmaceuticals, Plot No.F-24/1, Eastern Industrial Zone, Port Qasim, Karachi.**Sections (09)**1. Capsule (General) Section
2. Sachet (General) Section
3. Liquid Ampoule & Vial (General) Section
4. SVP Infusion (General) Section
5. Tablet (Psychotropic) Section
6. Liquid Ampoule (Psychotropic) Section
7. Dry Powder Suspension (Cephalosporin) Section
8. Capsule (Cephalosporin) section
9. Dry Powder Injection (Cephalosporin) Section
 | 28-11-2018 | **Good** | 1. Dr. Abdullah Dayo, Member Central Licensing Board.
2. Director DTL, Karachi.
3. Area FID, DRAP, Karachi.
 |
| **Recommendations of the panel: -***M/s Avensis Pharmaceuticals Ltd,. Plot No. F-54/1, Eastern Industrial Zone, Port Muhammad Bin Qasim, Karachi was inspected on 28th November 2018 by the panel constituted as per DRAP letter No. F. 2-6/2017-Lic dated 5th November 2018 for the purpose of Grant of Drugs Manufacturing License (By way of Formulation) for following sections:*

|  |  |
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| ***Ground Floor*** | ***First Floor*** |
| *1.* | *Capsule (General) Section* | *7.* | *Tablet (Psychotropic) Section* |
| *2.* | *Sachet (General) Section* | *8.* | *Liquid Ampoule (Psychotropic) Section* |
| *3.* | *Liquid Ampoule & Vial (General) Section* | *9.* | *Dry Powder Suspension (Cephalosporin) Section* |
| *4.* | *SVP Infusion (General) Section* | *10.* | *Capsule (Cephalosporin) Section* |
| *5.* | *Quality Control & Microbiology Lab* | *11.* | *Dry Powder Injection (Cephalosporin) Section* |
| *6.* | *Raw Material Store*  | *12.* | *Packaging Material Store* |
|  | *\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\** | *13.* | *Finished Good Store* |

*The Firm has built as per approved layout plan and has necessary equipment for production and quality control lab. Technical persons were available at the time of inspection. Currently the functions of QC and QA were supervised by single person, firm has directed to hire QA head on priority. Dedicated 21AHUs has been provided for different sections and were observed functional (Annexure M).**The premises of above mentioned sections were visited and related documents were reviewed. Appointment letters of some technical persons were reviewed (Annexure N). Some SOPs were also reviewed. However, firm’s management is committed for continuous improvements and has assured prompt compliance.**Keeping in view the facility inspected, people met, documents reviewed and observations made,* ***the panel recommends the grant of DML by way of formulation for above mentioned sections.*****Decision of the Central Licensing Board in 267th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name *M/s Avensis Pharmaceuticals Ltd,. Plot No. F-54/1, Eastern Industrial Zone, Port Muhammad Bin Qasim, Karachi,*  with following sections:**Sections (09)**1. Capsule (General) Section
2. Sachet (General) Section
3. Liquid Ampoule & Vial (General) Section
4. SVP Infusion (General) Section
5. Tablet (Psychotropic) Section
6. Liquid Ampoule (Psychotropic) Section
7. Dry Powder Suspension (Cephalosporin) Section
8. Capsule (Cephalosporin) section
9. Dry Powder Injection (Cephalosporin) Section
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| 7 | M/s Norwich Pharmaceuticals, Plot No. 220, Kahuta Industrial Triangle, Kahuta Road, Islamabad**Sections 03**1. Capsule section (Cephalosporin )
2. Dry powder injection (Cephalosporin)
3. Dry powder suspension (Cephalosporin)
 | 19-12-2018 | **Good** | 1. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad.
2. Additional Director (Licensing), DRAP, Islamabad.
3. Babar Khan, Area Federal Inspector of Drugs, Islamabad.
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| **Recommendations of the panel: -**“Keeping in view the facts on record, the panel unanimously recommended the approval of Drug Manufacturing License by way of formulation to newly established Pharmaceutical Unit to M/s Norwich Pharmaceuticals, Plot No. 220, Kahuta Industrial Triangle, Kahuta Road, Islamabad.**Decision of the Central Licensing Board in 267th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name M/s Norwich Pharmaceuticals, Plot No. 220, Kahuta Industrial Triangle, Kahuta Road, Islamabad with following sections:**Sections (03)**1. Capsule section (cephalosporin )
2. Dry powder injection (cephalosporin)
3. Dry powder suspension (cephalosporin)
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**Item-III**: **GRANT OF ADDITIONAL SECTIONS/EXPANSION/AMENDMENTS ETC.**

Following cases have been forwarded by the respective panel of experts for grant of additional sections. The same are placed before the Board for its consideration/decision, please.

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| **S #** | **Name of the firm** | **Date of Inspection**  | Ranking/ Evaluation | **Inspection Panel Members** |
| 1. | M/s Novartana Pharmaceuticals (Pvt) Ltd, 87-B, Sunder Industrial Estate, Lahore.DML No. 000738 (Formulation)**Section (01)**Liquid Injectable Ampoule / Vial (General) Section | 29-06-2018&19-08-2018 | **Good** | 1. Dr. Farzana Chaudhary, Director, UVAS, Lahore
2. Mr. Munawar Hayat, Drug Controller, Health Department, Govt. of Punjab.
3. Dr, Mubashir Butt, Professor of Pharmacy, Gulab Davi Hospital, Lahore.
4. Ms Ufaq Tanveer, Federal Inspector of Drugs, Lahore.
 |
| **Recommendations of the panel: -**In view of the improvements, made by the firm and compliance with reference to previous observations, the panel of inspectors is of the opinion to recommend the grant of additional section i.e. Liquid Injectable Ampoule / Vial (General) Section to M/s Novartana Pharmaceuticals (Pvt) Ltd, 87-B, Sunder Industrial Estate, Lahore. However, the firm was advised to strictly monitor the pressure differentials and to avoid cross contamination during operation. **Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the grant of following one additional section in the name of M/s Novartana Pharmaceuticals (Pvt) Ltd, 87-B, Sunder Industrial Estate, Lahore. **Section (01)**1. Liquid Injectable Ampoule / Vial (General) Section
 |
| 2. | M/s Caliph Pharmaceuticals (Pvt) Ltd., Plot No.17, Special Industrial Zone (EPZ), Risalpur, KPK.**Sections 06**1. Cream/ointment / Lotion Section (General) (New).
2. Sachet Section, (General) (New).
3. Tablet Section (General)(Regularization)
4. Dry Powder Suspension Section (General) (Regularization)
5. Capsule Section (General)(Regularization)
6. Liquid Syrup Section (General)(Regularization)
 | 06-11-2018 | **Good** | 1. Dr. Muhammad Usman, Member CLB.
2. Additional Director (E&M), DRAP, Peshawar.
3. Area Federal Inspector of Drugs, DRAP, Peshawar.
 |
| **Recommendations of the panel: -**In compliance to DRAP Islamabad letter No.F.3-6/2005-Lic (Vol-I) dated 25-10-2018, 12th July, 2018 and 15th February, 2018, the constituted panel conducted detailed inspection of the firm for the grant of additional sections, renewal of DML No.000748 (Formulation) and regularization of layout plan.The firm has been established as per approved layout plan. All the production sections have been provided with basic requisite equipments/machinery, with HVAC facilities installed in each section. Equipments were found in working and calibrated. Log books have been properly maintained. Dispensing, manufacturing, quality control testing, water testing record was checked and found satisfactory. Manufacturing and quality control operations are carried out as per SOPs.Quality control has been equipped with the required instruments for the test/analysis of raw materials and finished products and have been calibrated. Log books found available and maintained. Written testing SOPs for the registered products is being followed. Recent editions of the official books were available.The newly established additional sections have been provided with all the required storage areas like the raw materials, packing materials and finished products equipped with racks, pallets, hygrometers, ACs etc.Sufficient qualified technical staff has been employed in production, quality control and quality assurance. Job descriptions for each person has been specified. Keeping in view the available manufacturing, quality control and environmental facilities, qualified staff employed, documentation reviewed and observations made, the panel unanimously recommend the renewal of DML No.000748, by way of formulation, granted to M/s Caliph Pharmaceuticals (Pvt) Ltd., Plot No.17, Special Industrial Zone (EPZ), Risalpur, Khyber Pakhtunkhawa Pakistan and regularization of the layout plan approved vide letter No. F.3-6/2005-Lic (Vol-I) dated 16th March, 2017 for the following sections;1. Tablet Section (General)
2. Dry Powder Suspension Section (General)
3. Capsule Section (General)
4. Liquid Syrup Section (General)

**The panel also unanimously recommends the grant of following two additional sections as well.**1. Cream/ointment/Lotion Section (General).
2. Sachet Section (General).

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the grant of following two additional sections and regularization of follwing four sections in the name of M/s Caliph Pharmaceuticals (Pvt) Ltd., Plot No.17, Special Industrial Zone (EPZ), Risalpur, Khyber Pakhtunkhwa. **Sections (06)**1. Tablet Section (General) **Regularization**
2. Dry Powder Suspension Section (General) **Regularization**
3. Capsule Section (General) **Regularization**
4. Liquid Syrup Section (General) **Regularization**
5. Cream/ointment/Lotion Section (General).**New**
6. Sachet Section (General).**New**
 |
| 3. | M/s Atco Laboratories Ltd., Plot No.B-18, S.I.T.E., Karachi.DML No. 000188 (Formulation)**Section / Facility (05)**1. Tablet (General) Section.
2. Capsule (General) Section.
3. Sachet (General) Section.
4. Dry Powder Suspension (General) Section.
5. Packaging Section.
 | 23-10-2018 | **Good**  | 1. Mr. Ghulam Sarwar, Member Drug Registration Board.
2. Director CDL, Karachi.
3. Area FID, DRAP, Karachi.
 |
| **Recommendations of the panel: -**Keeping in view the construction of new sections for solid forms (General Tablets, General Capsules, General Sachet, Dry Powder and Packaging Section) as per approved layout plan provided with suitable HVAC system, dedicated utilities and high-tech machines, **the panel recommended the grant of above additional sections to the firm**. It is further submitted that the firm has installed some of the equipment (list attached) in their respective sections for which they have proper DQ and IQ. Rest of the equipment will either be transferred from the old sections or bought through new purchases. *Firm is advised to add rest of the equipment as per there plan (copy enclosed) in the new sections and perform all the qualification / validation studies. The firm is also advised to perform risk assessment for potential cross assessment caused by the personnel on using common secondary change room for sachet filling, table blisting and dry powder filling sections and arrange for necessary controls.**It is further advised that firm will submit summary of study reports to DRAP including members of this panel to arrange for necessary controls for batter GMP compliance.***Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the grant of following Five New/ additional sections/facility in the name of M/s Atco Laboratories Ltd., Plot No.B-18, S.I.T.E., Karachi. **Section / Facility (05**1. Tablet (General) Section.
2. Capsule (General) Section.
3. Sachet (General) Section.
4. Dry Powder Suspension (General) Section.
5. Packaging Section.

Federal inspector of Drugs shall ensure and submit detailed report after installation of rest of machinery by the firm . |

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| 4. | M/s Abbott Laboratories (Pakistan) Ltd., Opposite Radio Pakistan Transmission Centre, Karachi.DML No. 000001 (Formulation)**Section/Facility (02)**1. Tablet (General) Section (Amendments).
2. Raw Material Store (Amendments).
 | **12-09-2018** | **Good**  | 1. Syed Muied Ahmad, Member Central Licensing Board.
2. Director DTL, Karachi.
3. Area FID, DRAP, Karachi.
 |
| **Recommendations of the panel: -**The premises of the above mentioned sections where amendments have made were visited and related documents were reviewed. The amendments were found as per layout plan approved by DRAP, Islamabad. Some SOPs required upgradation and necessary revision. However, firm’s management is committed for continuous improvement. In view of above, panel recommends the grant of amendments in following areas;1. Tablet (General) Section (**First Floor**).
2. Raw Material Store (**Ground Floor**).

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the grant of amendements in following sections/facility in the name of M/s Abbott Laboratories (Pakistan) Ltd., Opposite Radio Pakistan Transmission Centre, Karachi .**Section/Facility (02)**1. Tablet (General) Section (Amendments). (**First Floor**).
2. Raw Material Store (Amendments). (**Ground Floor**).
 |
| 5. | M/s Tabros Pharma (Pvt) Ltd., Plot No.L-20/B, Sector 22, F.B. Industrial Area, Karachi.DML No. 000106 (Formulation)**Section (02)**1. Liquid Syrup (General) Section, Shifted to First Floor.
2. Packing Material Store and Finished Goods Store on Ground Floor.
 | **13-12-2018** | **Good** | 1. Mr. Ghulam Sarwar, Member Drug Registration Board.
2. Dr. Najam-us-Saqib, Additional Director, DRAP, Karachi.
3. Mr. Sajjad Ahmed Abbasi, FID, DRAP, Karachi.
 |
| **Recommendations of the panel: -**M/s. Tabros Pharma (Pvt) Ltd, was inspected by the panel members in connection with the Grant of Amendment/Expansion in layout plan vide DRAP’s letter reference No.F.2-5/87-Lic(Vol-III) dated 26-11-2018. Following are the observations:M/s. Tabros Pharma (Pvt) Ltd, has made amendments and shifting of liquid syrup section (general), packaging material store and finished products store as per lay-out plan approved by DRAP, Islamabad. Liquid syrup section observed and equipped with necessary machines and equipments required for production of their registered products. HVAC system observed installed and operational in the section and differential pressures were also been displayed.Keeping in view, peoples met, documents reviewed and observations made during inspection, including the commitment of management towards exports, the panel recommended the grant of amendment/expansion in layout plan i.e.1. Liquid Syrup (General) Section, Shifted to First Floor.
2. Packing Material Store and Finished Goods Store on Ground Floor.

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the grant of amendements/Revised in following sections/facility in the name of M/s Tabros Pharma (Pvt) Ltd., Plot No.L-20/B, Sector 22, F.B. Industrial Area, Karachi . **Section/Facility (02)**1. Liquid Syrup (General) Section, Shifted to First Floor.
2. Packing Material Store and Finished Goods Store on Ground Floor.
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| 6 | M/s WnsFeild Pharmaceuticals, Plot No.122, Block A, Phase-V, Industrial Estate, Hattar.**Section (01)**1. Tablet (Steroidal Hormone) Section.
 | 05-01-2018 &05-12-2018 | **Good** | 1. Prof. Dr. Jamshed Ali Khan, Peshawar University, Peshawar.
2. Director DTL, Peshawar.
3. Area Federal Inspector of Drugs, DRAP, Peshawar.
 |
| **Recommendations of the panel: -**In compliance to DRAP Islamabad letter No.F.3-2/06-Lic (Vol-I) dated 12-12-2017, factory premises of M/s Wnsfeild Pharmaceuticals (Pvt) Ltd., Hattar was inspected by the constituted panel for the grant of additional tablet Hormones (Steroidal) section. The firm has established a dedicated tablet hormones (steroidal) section as per approved layout plan (approved vide Licensing Division, DRAP Islamabad letter No.F.3-2/2006-Lic (Vol-II) dated 05-09-2018), provided with basic machinery for manufacturing of tablet dosage form. Equipments were found in working condition. A dedicated HVAC unit has also been provided. A separate raw material store with laminar flow dispensing hood is also available. Keeping in view the manufacturing, quality control and environmental facilities provided, the technical and qualified staff employed, the constituted panel unanimously recommends the grant of additional tablet hormones (steroidal) section vide Drug Manufacturing License (DML) No.000610) by way of formulation to M/s Wnsfeild Pharmaceuticals Industrial Estate Hattar, Khyber Pakhtunkhawa as per revised layout plan approved via Licensing Division, DRAP, Islamabad letter No.F.3-2/2006-Lic (vol-II) dated 05-09-2018.**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the grant of One additional section in the name of M/s WnsFeild Pharmaceuticals, Plot No.122, Block A, Phase-V, Industrial Estate, Hattar. **Section (01)**1. Tablet (Steroidal Hormone) Section.
 |
| 7 | M/s Bryon Pharmaceuticals (Pvt) Ltd., 48-Industrial Estate, Hayatabad, Peshawar.**Sections(02)**1. Dry Suspension (Cephalosporin).
2. Capsule (Cephalosporin)
 | 03-10-2018 | **Good** | 1. Prof. Dr. Muhammad Saeed, Expert in Pharmacy.
2. Prof. Dr. Jamshed Ali Khan, Member CLB.
3. Area Federal Inspector of Drugs, DRAP, Peshawar.
4. Area Assistant Director, DRAP, Peshawar.
 |
| **Recommendations of the panel: -**As per facilities checked and technical people met the panel of experts unanimously **recommends** grant of the following additional sections to Bryon Pharmaceuticals (Pvt) Ltd., 48, Hayatabad Industrial Estate, Peshawar (DML No.000388);1. Dry Suspension (Cephalosporin).
2. Capsule (Cephalosporin)

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the grant of Two Additional sections in the name of M/s Bryon Pharmaceuticals (Pvt) Ltd., 48-Industrial Estate, Hayatabad, Peshawar. **Sections(02)**1. Dry Suspension (Cephalosporin).
2. Capsule (Cephalosporin)
 |
| 8 | M/s Z-Jans Pharmaceuticals (Pvt) Ltd, 148-A, Industrial Estate, Hayatabad, Peshawar.**Sections(04)**1. Capsule Section (General) (**Relocated**)
2. Dry Suspension Section (General) (**Relocated**)
3. Capsule Section (Cephalosporin) (**Relocated**)
4. Dry Suspension Section (Cephalosporin) (**Relocated**)
 | **26-10-2018&26-12-2018** | **Good** | 1. Prof. Dr. Jamshed Ali Khan, Faculty of Pharmacy, Peshawar University, Peshawar.
2. Director, Drug Testing Laboratory, Peshawar.
3. Area Federal Inspector of Drugs, DRAP,
 |
| **Recommendations of the panel: -**Keeping in view the above, **the panel unanimously recommends** the grant of renewal of DML by way of formulation to M/s Z-Jans Pharmaceuticals (Pvt) Ltd, 148-A, Industrial Estate, Hayatabad, Peshawar and **approval of amendments/relocated of revised layout plan of following sections as communicated vide letter No.F.3-1/2000-Lic (Vol-II) dated 18th December, 2018**,1. Capsule Section (General) (**Relocated**)
2. Dry Suspension Section (General) (**Relocated**)
3. Capsule Section (Cephalosporin) (**Relocated**)
4. Dry Suspension Section (Cephalosporin) (**Relocated**)

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the grant of Amendments/Relocation of following Four sections in the name of M/s Z-Jans Pharmaceuticals (Pvt) Ltd, 148-A, Industrial Estate, Hayatabad, Peshawar .**Sections(04)**1. Capsule Section (General) (**Relocated**)
2. Dry Suspension Section (General) (**Relocated**)
3. Capsule Section (Cephalosporin) (**Relocated**)
4. Dry Suspension Section (Cephalosporin) (**Relocated**)
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| 9. | M/s Avicenna Laboratories (Pvt) Ltd, 14-Km, Faisalabad Road, Bhikhi, Sheikhpura.DML No. 000328 (Formulation)**Section (04)**1. Oral Powder Section (Veterinary) (Ammended).2. Oral Liquid Section. (Veterinary) (Ammended).3. Viral Vaccine (Veterniary) (New).4. Liquid Injectable (General) Section (New). | 22-10-2018 | **---** | 1. Dr. Ikram-ul-Haq, Member Central Licensing Board.
2. Dr. Qurban Ali, Veterinary Expert.
3. Mr. Asim Rauf, Additional Director, DRAP, Lahore

4. Ms. Majida Mujahid, Federal Inspector of Drugs, Lahore. |
| **Conclusion of report:-**Panel observed that their vaccine section (already existing section and liquid injectable General (Additional Section) were not ready for inspection. Firm informed that they need two months for the up-gradation and renovation of the vaccine and injectable section.**Recommendations of the panel: -**Keeping in view the above improvements made by the firm, the members of the panel recommends the renewal of Drug Manufacturing License of Oral Liquid Section & General Powder Section only. **Decision by the Central Licensing Board in 267th meeting**The Board considered and **approveed** the grant of following ammended sections in the name of M/s Avicenna Laboratories (Pvt) Ltd, 14-Km, Faisalabad Road, Bhikhi, Sheikhpura on the recommendations of the panel of experts:-**Section (02)**1.Oral Powder Section (Veterinary) (Ammended).2.Oral Liquid Section. (Veterinary) (Ammended).The Board considered and **did not approve** the grant of following two additional sections in the name of M/s Avicenna Laboratories (Pvt) Ltd, 14-Km, Faisalabad Road, Bhikhi, Sheikhpura on the recommendations of the panel of experts:-**Section (02)**1. Viral Vaccine (Veterniary)
2. Liquid Injectable (General)
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| 10. | M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.DML No. 000340 (Formulation)**Section/Facility (01)**1. R&D Laboratory (New).
 | 14-12-2018 |  | 1. Dr. Muhammad Usman, Member CLB.
2. Additional Director (Licenisng), DRAP, Islamabad.
3. Area FID, DRAP, Islamabad.
 |
| **Recommendations of the panel: -**Panel verified the establishment of sections as per approved layout plan for the manufacturing, Keeping in view the above, the panel unanimously recommend for the Regularization / Amendment of revised layout plan as of today. **Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the grant of following one additional section/facility in the name of M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad. **Section/Facility (01)**1. R&D Laboratory (New). |
| 11. | M/s Pharmagen Ltd, 34-Km, Ferozepur Road, Lahore.DML No. 000325 (Semi Basic)**Additional Chemicals** Additional Chemical required for manufacturing of **Cephradine** is;1. Tetramethylguanidine (TMG)

Additional Chemical required for manufacturing of **Cefixime** are as follow :1. Butyl Acetate
2. Phenol
3. Sodium Bromide
4. Triphenyl Phosphine

Additional Chemical required for manufacturing of **Clarithromycin** are as follow :1. Erthromycin Thiocyanate.
2. Erthromycin Thiocyanate Oxime.
3. Hydroxyl Amine Hydrochloride
4. Dimethyl Amine.
5. Methyl Iodide
6. 2-Methoxy Propene.
 | 7-12-2018 | **Good** | 1. Dr. Farzana Chaudhary, Director, UVAS, Lahore
2. Mr. Asim Rauf, Additional Director, DRAP, Lahore.
3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, Lahore.
 |
| **Recommendations of the panel: -**Keeping in view the presentation given by the firm, facilities, technical personnel and infra structure available for manufacturing / synthesis of the product and long deliberation discussion, the panel was of the view to **recommend** to accede to the request of the firm for import of additional chemicals required by the M/s Pharmagen (Pvt) Ltd, Lahore as follows:Additional Chemical required for manufacturing of **Cephradine** is :1. Tetramethylguanidine (TMG)

Additional Chemical required for manufacturing of **Cefixime** are as follow :1. Butyl Acetate
2. Phenol
3. Sodium Bromide
4. Triphenyl Phosphine

Additional Chemical required for manufacturing of **Clarithromycin** are as follow :1. Erthromycin Thiocyanate.
2. Erthromycin Thiocyanate Oxime.
3. Hydroxyl Amine Hydrochloride
4. Dimethyl Amine.
5. Methyl Iodide
6. 2-Methoxy Propene.

The panel also recommended to perform validations studies as required under relevant regulations for the required flow / root of synthesis and final permission be granted subject to submission and approval of said validation study prior to commercial marketing of the API’s.**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the grant of following additional chemicals for manufacturing of API’s in the name of M/s Pharmagen Ltd, 34-Km, Ferozepur Road, Lahore. **Additional Chemicals**Additional Chemical required for manufacturing of **Cephradine** is :1. Tetramethylguanidine (TMG)

Additional Chemical required for manufacturing of **Cefixime** are as follow :1. Butyl Acetate
2. Phenol
3. Sodium Bromide
4. Triphenyl Phosphine

Additional Chemical required for manufacturing of **Clarithromycin** are as follow :1. Erthromycin Thiocyanate.
2. Erthromycin Thiocyanate Oxime.
3. Hydroxyl Amine Hydrochloride
4. Dimethyl Amine.
5. Methyl Iodide
6. 2-Methoxy Propene.

The Board considered the recommendations of panel of experts and decided that the firm shall perform validations studies as required under relevant regulations for the required flow / route of synthesis and final permission be granted subject to submission and approval of said validation study to be verified by panel of experts prior to commercial marketing of the API’s. |
| 12. | M/s Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad. **Section (01)****Second Floor**1. Liquid Vial SVP (X-ray Contrast Media) Section
 | **19-09-2018** |  **GOOD** | * 1. Dr. Obaid Ullah, Director (P,E&R).
	2. Additional Director (Lic), DRAP, Islamabad.
	3. Area FID, DRAP, Islamabad.
 |
| **Recommendations of the panel: -**Keeping in view of the above facts on record, the panel unanimously **recommends the approval of above (01) new section** to M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad. **Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the grant of following one additional section in the name of M/s Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad. Under DML No. 000651(Formulation) on the recommendations of the panel of experts: **Section (01)**1. **Second Floor**Liquid Vial SVP (X-ray Contrast Media) Section |

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

Following cases have been forwarded 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.

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| **S #** | **Name of the firm** | **Date of Inspection** | **Ranking/ Evaluation** | **Inspection Panel Members** |
| 1. | M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore.DML No. 000493 (Formulation)**Period**: Commencing on 27-02-2017 ending on 26-02-2022 | **26-11-2018** | Unsatisfactory | 1. Dr. Farzana Chaudhary, Director, UVAS, Lahore
2. Mr. Abid Saeed Baig, Secretary PQCB, Govt. of Punjab, Lahore.
3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, Lahore.
 |
| **Recommendations of the panel: -**The Panel of inspectors **Does Not Recommend** the renewal of DML bearing No. 000493 issued in favour of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore.**Decision by the Central Licensing Board in 267th meeting**The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.  |
| 2. | M/s Radiant Pharma (Pvt) Ltd, 43-E, Sunder Industrial Estate, Lahore.DML No. 000776 (Formulation)**Period**: Commencing on 13-03-2018 ending on 12-03-2023 | 12-10-2018 | **Good** | 1. Dr. Farzana Chaudhary, Director, UVAS, Lahore
2. Prof. Dr. Mahmood Ahmed, Ex Dean Bahawalpur University.
3. Mr. Asim Rauf, Additional Director, DRAP, Lahore
4. Ms. Ufaq Tanveer, Federal Inspector of Drugs, Lahore.
 |
| **Recommendations of the panel: -**Keeping in view the manufacturing facilities like building HVAC system, machinery and Equipment, instrument, personnel, documentation, Quality Control, Testing facilities, the panel of inspectors is of the opinion to recommend the renewal of Drug Manufacturing License to M/s Radiant Pharma (Pvt) Ltd, 43-E, Sunder Industrial Estate, Lahore for the following sections:1. Tablet Section (General).
2. Capsule Section (General).
3. Liquid Syrup Section.
4. Dry Powder Suspension (General).
5. Sachet Section.
6. Dry Powder Injectable Section.

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000776 (Formulation) in the name of M/s Radiant Pharma (Pvt) Ltd, 43-E, Sunder Industrial Estate, Lahore,on the recommendations of the panel of experts for the further period of five years commencing on 13-03-2018 and ending on 12-03-2023. |
| 3. | M/s Zafa Chemie, Raiwind Manga Bypass, Near Sunder Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore.DML No. 000589 (BasicManufacturer)**Period**: Commencing on 05-04-2016 ending on 04-04-2021 | 02-10-2018 | **Good** | 1. Dr. Farzana Chaudhary, Director, UVAS, Lahore
2. Prof. Dr. Mahmood Ahmed, Ex Dean Bahawalpur University.
3. Mr. Asim Rauf, Additional Director, DRAP, Lahore
4. Ms. Ufaq Tanveer, Federal Inspector of Drugs, Lahore.
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|  | **Recommendations of the panel: -**Keeping in view the approval of the site and building, layout plan by DRAP, Islamabad and the facilities like building HVAC system, machinery and Equipment, instrument, personnel, documentation, Quality Control and Microbiological Laboratories, water treatment and testing facilities, the panel of inspectors recommends the renewal of Drug Manufacturing License to M/s Zafa Chemie, Raiwind Manga Bypass, Near Sunder Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore.**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000589 (Basic Manufacturer) in the name of M/s Zafa Chemie, Raiwind Manga Bypass, Near Sunder Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore on the recommendations of the panel of experts for the further period of five years commencing on 05-04-2016 and ending on 04-04-2021. |
| 4. | M/s Avicenna Laboratories (Pvt) Ltd, 14-Km, Faisalabad Road, Bhikhi, Sheikhpura.DML No. 000328 (Formulation)**Period**: Commencing on 05-10-2017 ending on 04-10-2022 | 22-10-2018 | **Good** | 1. Dr. Ikram-ul-Haq, Member Central Licensing Board.
2. Dr. Qurban Ali, Veterinary Expert.
3. Mr. Asim Rauf, Additional Director, DRAP, Lahore

4. Ms. Majida Mujahid, Federal Inspector of Drugs, Lahore. |
| The panel inspected following section of the firm 1) Oral Powder Section 2) Oral Liquid Section. **Recommendations of the panel: -**Keeping in view the above improvements made by the firm, the members of the panel recommends the renewal of Drug Manufacturing License of Oral Liquid Section & General Powder Section only. **Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000328(Formulation) in the name of M/s Avicenna Laboratories (Pvt) Ltd, 14-Km, Faisalabad Road, Bhikhi, Sheikhpura on the recommendations of the panel of experts for following two sections for the further period of five years commencing on 05-10-2017 and ending on 04-10-2022;* 1. Oral Powder (Veterniry) Section
	2. Oral Liquid (Veterniry) Section.
 |
| 5. | M/s Medivet (Pvt) Ltd, 16-Km, Sheikhupura Road, Lahore. DML No. 000269 (Formulation) | 28-08-2018&25-10-2018 | **Good** | 1. Dr. Qurban Ali, DG, NVBL, Islamabad.
2. Mr. Anjum Pervaiz, Provincial Drugs Inspector, Lahore.
3. Ms. Majida Mujahid, Federal Inspector of Drugs, Lahore.
4. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, Lahore.
 |
| The Central Licensing Board, in its 252nd meeting held on 15th March, 2017 renewed the DML of the firm for all section except Liquid Injectable (Veterinary) Section.**Recommendations of the panel: -**Keeping in view the above improvements made by the firm, in Liquid Injectable Section the members of the panel recommends the renewal of Drug Manufacturing License of Liquid Injectable Section only.**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the resumption of production in the following section.1. Liquid Injectable (Veterinary) Section.
 |
| 6. | M/s Allmed (Pvt) Ltd, Plot No. 590, Sunder Industrial Estate, Lahore. DML No. 000645 (Formulation)**Period**: Commencing on 21-08-2018 ending on 20-08-2023 | 12-11-2018 | **Good** | 1. Dr. Zaka-ur-Rehman, Secretary, Punjab Pharmacy Council, Punjab.
2. Mr. Asim Rauf, Additional Director, DRA, Lahore.
3. Ms. Ufaq Tanveer, Asif, Federal Inspector of Drugs, Lahore.
 |
| **Recommendations of the panel: -**Keeping in view the facilities like building HVAC system, Equipment, instrument, personnel, documentation, SOP availability, Quality Control and Testing facilities Panel of inspectors recommends the renewal of Drug Manufacturing License No. 000645 of M/s Allmed (Pvt) Ltd, Plot No. 590, Sunder Industrial Estate, Lahore for the following sections:1. Tablet and Capsule Section (General).
2. Tablet and Capsule Section (Psychotropic).
3. Liquid Syrup and Suspension.
4. Liquid Injectable Section (Ampoules).
5. Liquid Vial Infusion Section

It is pertinent to mention here as per available record of Licensing Division the firm possess following section.1. Tablet and Capsule Section (General).
2. Tablet (Psychotropic).
3. Capsule Section (**General Antibiotic**).
4. Liquid Syrup (**General**).
5. Liquid Injectable Section (**General**) (Ampoules).
6. Liquid Vial Section (**General Antibiotic**).

**Decision by the Central Licensing Board in 267th meeting**The Board considered and deffered the case of renewal of Drug Manufacturing Licence No. 000645(Formulation) in the name of M/s Allmed (Pvt) Ltd, Plot No. 590, Sunder Industrial Estate, Lahore for clarification regarding sections from DRAP Lahore. |

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| 7. | M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd., 1.3-Km (Asli Raiwind Road, Ladhaky Bhular) Lahore.DML No. 000449 (Formulation)**Period**: Commencing on 01-08-2015 ending on 31-07-2020 | 23-10-2018 |  | 1. Dr. Farzana Chaudhary, Director, UVAS, Lahore
2. Dr. Qurban, Member, Drug Registration Board.
3. Mr. Asim Rauf, Additional Director, DRAP, Lahore.
4. Mr. Shoaib Ahmed, Federal Inspector of Drugs, Lahore.
 |
| The panel inspected following sections of the firm.1. Powder (General Veterinary) Section.
2. Oral Liquid (Veterinary) Section.
3. Vaccine (Veterinary) Section.

**Recommendations of the panel: -**The Panel of inspectors, therefore, **does not recommend** the renewal of Drug Manufacturing License bearing No. 000449 of M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd, 1.3-Km (Asil Raiwind Road, Lodhaky Bhular) Lahore in respect to all approved sections.**Decision by the Central Licensing Board in 267th meeting**The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.  |
| 8. | M/s Novartana Pharmaceuticals (Pvt) Ltd, 87-B, Sunder Industrial Estate, Lahore.DML No. 000738 (Formulation)**Period**: Commencing on 16-08-2017 ending on 15-08-2022 | 16-11-2018 | **Good** | 1. Dr. Farzana Chaudhary, Director, UVAS, Lahore
2. Mr. Anjum Pervaiz, Consultant, Registration and Licensing, PDCU, Govt. of Punjab.
3. Mr. Asim Rauf, Additional Director, DRAP, Lahore.
4. Ms Ufaq Tanveer, Federal Inspector of Drugs, Lahore.
 |
| **Recommendations of the panel: -**Keeping in view the facts, the Panel of inspector was of the opinion to recommendthe renewal of Drug Manufacturing License by way of formulationto M/s Novartana Pharmaceuticals (Pvt) Ltd, 87-B, Sunder Industrial Estate, Lahore. for the following sections.1. Tablet Section (General).
2. Capsule Section (General).
3. Liquid Syrup Section (General).

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000738(Formulation) in the name of M/s Novartana Pharmaceuticals (Pvt) Ltd, 87-B, Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for following three sections for the further period of five years commencing on 16-08-2017 ending on 15-08-2022.1. Tablet Section (General).
2. Capsule Section (General).
3. Liquid Syrup Section (General).
 |
| 9. | M/s Selmore Pharmaceuticals (Pvt) Ltd, 36-Km, Multan Road, Lahore.DML No. 000507 (Formulation)**Period**: Commencing on 16-11-2017 ending on 15-11-2022 | 05-03-2018;17-08-2018 &16-10-2018. | **Good** | 1. Dr. Ikram-ul-Haq, Member Central Licensing Board.
2. Mr. Asim Rauf, Additional Director, DRAP, Lahore
3. Ms. Majida Mujahid, Federal Inspector of Drugs, Lahore.
4. Ms. Zunaira Faryad, Assistant Director (Licensing), DRAP, Islamabad.
 |
| **Recommendations of the panel: -**In the light of the inspection conducted by the panel and based on the findings, the panel of inspectorsrecommended grant of renewal of Drug Manufacturing License by way of formulation ofM/s Selmore Pharmaceuticals (Pvt) Ltd, 36-Km, Multan Road, Lahore, for the following sections.1. Veterinary Bolus.
2. Veterinary Aerosol.
3. Veterinary Oral Liquid.
4. Veterinary Oral Powder.
5. Veterinary Liquid Injection.
6. Veterinary Penicillin Oral Powder.
7. Veterinary Penicillin Dry Powder for Injection.
8. Veterinary Penicillin Liquid Injection.
9. Veterinary Hormone Liquid Injection.
10. Human Penicillin Capsule.
11. Human Penicillin Dry Powder Suspension.
12. Human Penicillin Dry Powder Injection.

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000507(Formulation) in the name M/s Selmore Pharmaceuticals (Pvt) Ltd, 36-Km, Multan Road, Lahore. on the recommendations of the panel of experts for the further period of five years commencing on Commencing on 16-11-2017 ending on 15-11-2022 for following sections.1. Veterinary Bolus.
2. Veterinary Aerosol.
3. Veterinary Oral Liquid.
4. Veterinary Oral Powder.
5. Veterinary Liquid Injection.
6. Veterinary Penicillin Oral Powder.
7. Veterinary Penicillin Dry Powder for Injection.
8. Veterinary Penicillin Liquid Injection.
9. Veterinary Hormone Liquid Injection.
10. Human Penicillin Capsule.
11. Human Penicillin Dry Powder Suspension.
12. Human Penicillin Dry Powder Injection.
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| 10 | M/s Prix Pharmaceutica (Pvt) Ltd, Plot No. 05, Pharmacity, 30-Km, Multan Road, Lahore.DML No. 000587 (Formulation)**Period**: Commencing on 15-10-2015 ending on 14-10-2020 | 13-06-2018;10-10-2018&11-12-2018 | **Good** | 1. Dr. Ikram-ul-Haq, Member Central Licensing Board.
2. Mr. Anjum Pervaiz, Consultant, Registration and Licensing, PDCU, Govt. of Punjab.
3. Ms. Uzma Barkat, Federal Inspector of Drugs, Lahore.
4. Ms. Sara Mehreen, Assistant Director, DRAP, Lahore.
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| **Recommendations of the panel: -**In the light of the inspection conducted by the panel and based on the findings, the panel of inspectorsrecommended grant of renewal of Drug Manufacturing License by way of formulation ofM/s Prix Pharmaceutica (Pvt) Ltd, Plot No. 05, Pharmacity, 30-Km, Multan Road, Lahore, for the following veterinary sections:1. Bolus Section (Veterinary).
2. Oral General Powder Section (Veterinary).
3. Oral Powder Section (General Antibiotic)
4. Oral Liquid Section (Veterinary)
5. Liquid Injectable Section (General) (Veterinary)
6. Oral Powder Section Penicillin (Veterinary).

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000587(Formulation) in the name M/s Prix Pharmaceutica (Pvt) Ltd, Plot No. 05, Pharmacity, 30-Km, Multan Road, Lahore on the recommendations of the panel of experts for the further period of five years commencing on Commencing on 15-10-2015 ending on 14-10-2020 for following secions.1. Bolus Section (Veterinary).
2. Oral General Powder Section (Veterinary).
3. Oral Powder Section (General Antibiotic)
4. Oral Liquid Section (Veterinary)
5. Liquid Injectable Section (General) (Veterinary)
6. Oral Powder Section Penicillin (Veterinary).
 |
| 11 | M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar.DML No. 000583 (Formulation)**Period**: Commencing on 02-09-2015 ending on 01-09-2020. | **09-03-2018 &26-07-2018** | **Good** | 1. Prof. Dr. Jamshed Ali Khan, Faculty of Pharmacy, Peshawar University, Peshawar.
2. Director DTL, Peshawar.
3. Area Federal Inspector of Drugs, DRAP, Peshawar.
4. Dr. Muhammad Usman, Assistant Director (Licensing), DRAP, Islamabad.
 |
| **Recommendations of the panel: -**Keeping in view the above, the panel unanimously recommends the grant of renewal of DML by way of formulation to M/s Hicon Pharmaceuticals, Hayatabad, Peshawar for following sections only;1. Tablet Section (General)
2. Tablet Section (General Antibiotic)
3. Liquid Syrup Section (General)

However, the panel **did not recommend Capsule Section and Dry Powder Section** due to pending work for approval of revised layout plan for dedicated Cephalosporin Facility.**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000583(Formulation) in the name M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar.on the recommendations of the panel of experts for the further period of five years Commencing on 02-09-2015 ending on 01-09-2020 for following sections only.1. Tablet Section (General)
2. Tablet Section (General Antibiotic)
3. Liquid Syrup Section (General)

The Board considered and did not approve the renewal of Drug Manufacturing Licence No. 000583 of M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar for **Capsule Section (Cephalosporin) & Dry Powder Suspension (Cephalosporin)**. The Board further decided that the licensee shall rectify the shortcomings noted by the panel within a period not less than one month under Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 from the date of issuance of decision of the Board in the said sections. The licensee shall inform regarding rectifications made and accordingly panel would be constituted to verify the improvements made. Manufacturing in the said sections/premises shall remain suspended till decision by the Board. The Central Licening Board will take a decision on the recommendations of the panel either to grant renewal of licence or reject the application for the said sections and inform the licencee accordingy*.* |
| 12. | M/s Caliph Pharmaceuticals (Pvt) Ltd., Plot No.17, Special Industrial Zone (EPZ), Risalpur, Khyber Pakhtunkwa.DML No. 000748 (Formulation)**Period**: Commencing on 13-08-2017 ending on 12-08-2022. | **06-11-2018** | **Good** | 1. Dr. Muhammad Usman, Member CLB.
2. Additional Director (E&M), DRAP, Peshawar.
3. Area Federal Inspector of Drugs, DRAP, Peshawar.
 |
| **Recommendations of the panel: -**In compliance to DRAP Islamabad letter No.F.3-6/2005-Lic (Vol-I) dated 25-10-2018, 12th July, 2018 and 15th February, 2018, the constituted panel conducted detailed inspection of the firm for the grant of additional sections, renewal of DML No.000748 (Formulation) and regularization of layout plan.The firm has been established as per approved layout plan. All the production sections have been provided with basic requisite equipments/machinery, with HVAC facilities installed in each section. Equipments were found in working and calibrated. Log books have been properly maintained. Dispensing, manufacturing, quality control testing, water testing record was checked and found satisfactory. Manufacturing and quality control operations are carried out as per SOPs.Quality control has been equipped with the required instruments for the test/analysis of raw materials and finished products and have been calibrated. Log books found available and maintained. Written testing SOPs for the registered products is being followed. Recent editions of the official books were available.The newly established additional sections have been provided with all the required storage areas like the raw materials, packing materials and finished products equipped with racks, pallets, hygrometers, ACs etc.Sufficient qualified technical staff has been employed in production, quality control and quality assurance. Job descriptions for each person has been specified. Keeping in view the available manufacturing, quality control and environmental facilities, qualified staff employed, documentation reviewed and observations made, **the panel unanimously recommend the renewal of DML No.000748, by way of formulation, granted to M/s Caliph Pharmaceuticals (Pvt) Ltd., Plot No.17, Special Industrial Zone (EPZ), Risalpur, Khyber Pakhtunkhawa Pakistan** and regularization of the layout plan approved vide letter No. F.3-6/2005-Lic (Vol-I) dated 16th March, 2017 for the following sections;1. Tablet Section (General)
2. Dry Powder Suspension Section (General)
3. Capsule Section (General)
4. Liquid Syrup Section (General)

The panel also unanimously recommends the grant of following two additional sections as well.1. Cream/ointment/Lotion Section (General).
2. Sachet Section (General).

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000748(Formulation) in the name M/s Caliph Pharmaceuticals (Pvt) Ltd., Plot No.17, Special Industrial Zone (EPZ), Risalpur, KPK on the recommendations of the panel of experts for the further period of five years commencing on 13-08-2017 ending on 12-08-2022.. |
| 13. | M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachi.DML No. 000746 (Formulation)**Period**: 27-08-2017 to 26-08-2022 | **08-08-2018** | **N/A** | 1. Dr. Abdullah Dayo, Member CLB.
2. Dr. Saif-ur-Rehman, Director CDL, Karachi.
3. Mr. Abdul Rasool Sheikh, FID, DRAP, Karachi.
 |
| **Recommendations of the panel: -**The panel conducted inspection on 08-08-2018 and noted following observations;Observations: 1. During inspection the panel came to know that the firm had been granted DML No. 000746 (Formulation) in the year 2012 and in the subsequent years the firm got almost 16 registrations in all four approved sections that are Tablet (General), Capsule (General), Capsule (Cephalosporin) and Dry Powder Suspension (Cephalosporin).
2. The panel observed that firm had not manufactured a single batch of any of their registered products. The in complete documents were shown purporting the only trial batch of Cefixime manufacturing during past six years.
3. The panel observed the unit under inoperable conditions and management was of the view that due to high operational cost and limited number of registrations they were unable to start it for commercial purpose.
4. The panel observed that the firm had relocated some of their storage areas and provided HVAC aimlessly in those sections. The additional section of Cream/Ointment was noted incomplete during inspection.
5. It was very difficult for the panel to asses their current GMP compliance lever amid such inactive conditions although firm possesses sufficient number of registrations and could have started production to meet the national regulatory requirements.

**Conclusion.** Based on the above observations the panel decided to defer the grant of renewal of their DML, grant of additional section of Cream/Ointment and regularization of their existing LOP. Panel further requests the board concerned to see the current inactive status of their DML under DRAP Act, 2012/Drug Act, 1976.**Decision by the Central Licensing Board in 267th meeting**The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.  |
| 14. | M/s Spencer & Company (Pvt) Ltd, D-105, S.I.T.E, Karachi.DML No. 000272 (Formulation)**Period**: 19-07-2015 to 18-07-2020 | **13-09-2018 & 18-10-2018** | **Un-satisfactory** | 1. Mr. Syed Muied Ahmed, Member Central Licensing Borad.
2. Director DTL, Sindh Karachi. (**Not available**)
3. Director CDL, DRAP, Karachi
4. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -****Conclusion:-**1. Firm has some penicillin, veterinary and Topical products which needs to be de-registered forthwith as no dedicated sections exist for them.
2. The available arrangements with the firm for production and quality control of their registered products needs massive up gradation / improvements especially in areas mentioned under pint no. 4 of Observations, for compliance with cGMP regulations.

**Recommendations:-**1. Penicillin, Topical products and veterinary products registered in the name of the firm should be de-Registered forthwith as no dedicated sections exist for them.
2. Renewal of drugs manufacturing license (No. 000272 By way of Formulation) may be deferred till rectification of observations/ Improvements as identified by the panel. **Renewal not recommended**.

**Decision by the Central Licensing Board in 267th meeting**The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.  |
| 15. | M/s ICI Pakistan (Formerly M/s. Wyeth Pakistan Ltd), Plot No. S-33, Hawkes Bay Road, S.I.T.E, Karachi.DML No. 000006 (Formulation)**Period**: 31-03-2015 to 30-03-2020 | **28-08-2018** | **Good** | 1. Mr. Syed Muied Ahmed, Member Central Licensing Borad.
2. Dr. Najam-us-Saqib, Additional Director, DRAP, Karachi.
3. Dr. Muzaffar Ali Jaffri, Director DTL, Sindh Karachi.
4. Mr. Sajjad Ahmed Abbasi, Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -**M/s ICI Pakistan Limited was inspected by the panel as constituted vide DRAP letter No. F.2-8/2000-Lic (Vol-1) dated; 02-03-2018 in connection with renewal of DML No.000006 validity 30-03-2015, following are the observations;M/s ICI Pakistan (Formerly M/s Wyeth Pakistan Limited) is engaged in the manufacture of liquid syrup and tablet dosage forms, it is an old unit however well maintained and built as per layout plan as approved but the licensing authority.Production sections were observed equipped with necessary machines and equipment required for production of their registered products. HVAC system observed installed and seen operational.QC Laboratory also observed equipped with necessary equipments required for test/analysis of registered drugs. QC methods were observed validated and duly signed and approved by authorized technical personKeeping in view people met, documents reviewed, and observations made during inspection including management commitment towards the exports, t**he panel recommended the renewal of DML by way of formulation by way of formulation.****Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000006(Formulation) in the name M/s ICI Pakistan (Formerly M/s. Wyeth Pakistan Ltd), Plot No. S-33, Hawkes Bay Road, S.I.T.E, Karachi. for the further period of five years commencing on 31-03-2015 ending on 30-03-2020. |

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| --- | --- | --- | --- | --- |
| 16. | M/s Yusaf Ali Shah Chemical Industries (Pvt) Ltd., Plot No. 191/1, Street No.L-10, 131-Indutrial Estate, Gadoon Amazai District Swabi.DML No. 000371 (Formulation)**Period**: Commencing on 01-04-2016 ending on 31-03-2021. | **24-07-2018 &20-12-2018** | **Good** | 1. Prof. Dr. Jamshed Ali Khan, Faculty of Pharmacy, Peshawar University, Peshawar.
2. Director, Drug Testing Laboratory, Peshawar.
3. Area Federal Inspector of Drugs, DRAP, Peshawar.
4. Area Assistant Director, DRAP, Peshawar.
 |
| **Recommendations of the panel: -**“Keeping in view the above, the panel unanimously recommends the grant of renewal of DML by way of formulation to M/s Yusaf Ali Shah Chemical Industries (Pvt) Ltd., Plot No. 191/1, Street No.L-10, 131-Indutrial Estate, Gadoon Amazai District Swabi for following section only.1. **Liquid Infusion 100ml in Glass Bottles (General) Only.**

The firm shall resume production after producing valid registration letters of products in 100ml glass bottle for their registered products and shall also de-register their products having other volumes/packing.”**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000371(Formulation) in the name M/s Yusaf Ali Shah Chemical Industries (Pvt) Ltd., Plot No. 191/1, Street No.L-10, 131-Indutrial Estate, Gadoon Amazai District Swabi.on the recommendations of the panel of experts for the further period of five years Commencing on 01-04-2016 ending on 31-03-2021.The Board also decided to refer the case to Drug Registration Board for cancellaion of Drugs registered in the name of the firm (in Large Volume Parentrals). |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 17. | M/s Z-Jans Pharmaceuticals (Pvt) Ltd, 148-A, Industrial Estate, Hayatabad, Peshawar.DML No. 000485 (Formulation)**Period**: Commencing on 11-04-2016 ending on 10-04-2021. | **26-10-2018 &26-12-2018** | **Good** | 1. Prof. Dr. Jamshed Ali Khan, Faculty of Pharmacy, Peshawar University, Peshawar.
2. Director, Drug Testing Laboratory, Peshawar.
3. Area Federal Inspector of Drugs, DRAP, Peshawar.
 |
| **Recommendations of the panel: -**Keeping in view the above, **the panel unanimously recommends the grant of renewal of DML by way of formulation** to M/s Z-Jans Pharmaceuticals (Pvt) Ltd, 148-A, Industrial Estate, Hayatabad, Peshawar and approval of amendments/relocated of revised layout plan of following sections as communicated vide letter No.F.3-1/2000-Lic (Vol-II) dated 18th December, 2018,1. Capsule Section (General) (**Relocated**)
2. Dry Suspension Section (General) (**Relocated**)
3. Capsule Section (Cephalosporin) (**Relocated**)
4. Dry Suspension Section (Cephalosporin) (**Relocated**)

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000485(Formulation) in the name M/s Z-Jans Pharmaceuticals (Pvt) Ltd, 148-A, Industrial Estate, Hayatabad, Peshawar.on the recommendations of the panel of experts for the further period of five years Commencing on 11-04-2016 ending on 10-04-2021. |
| 18. | M/s Saibins Pharmaceutical, Plot No.316, Industrial Triangle, Kahuta Road, Islamabad.DML No. 000773 (Formulation)**Period**: Commencing on 12-02-2018 ending on 11-02-2023 | **26-07-2018 & 28-12-2018** | **Good** | 1. Dr. Gul Majeed, Prof. of Phamracy, Quaid-e-Azam University, Islamabad.
2. Dr. Muhammad Usman, Member CLB.
3. Area FID, DRAP, Islamabad.
4. Assistant Director (Licensing), DRAP, Islamabad.
 |
| **Recommendations of the panel: -**Keeping in view of the above facts on record, the panel unanimously recommended the renewal of Drug Manufacturing License by way of formulation to M/s Saibins Pharmaceuticals, Plot No.316, Industrial Triangle, Kahuta Road, Islamabad.**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000773 (Formulation) in the name of M/s Saibins Pharmaceutical, Plot No.316, Industrial Triangle, Kahuta Road, Islamabad.on the recommendations of the panel of experts for the further period of five years Commencing on 12-02-2018 ending on 11-02-2023. |

**ITEM – V MISC CASES**

**Case No.1. CHANGE OF MANAGEMENT OF M/S FRIENDS PHARMA (PVT) LTD, LAHORE.**

M/s Friends Pharma (Pvt) Ltd, 31-Km Ferozepur Road Lahore under DML No. 000513by way of formulationhas submitted request for change in management of the firm as per Form-1A along with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Retiring Management** | **New management**  |
| 1. Mr. Naveed Zafar.
2. Mr. Nadeem Zafar.
3. 3. Ms. Sajeela Sarwar.
 | 1. Mr. Nadeem Zafar. | 1. Mr. Naveed Zafar S/o Zafar Ali CNIC No. 35202-2903328-9.
2. Ms. Sajeela Sarwar W/o Nadeem Zafar CNIC No. 35202-2842681-8.
 |

**Decision by the Central Licensing Board in 267th meeting:**

The Board considered and endorsed the change of management of M/s Friends Pharma (Pvt) Ltd, 31-Km Ferozepur Road Lahore under DML No. 000513 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Retiring Management** | **New management**  |
| 1. Mr. Naveed Zafar.
2. Mr. Nadeem Zafar.
3. Ms. Sajeela Sarwar.
 | 1. Mr. Nadeem Zafar. | 1. Mr. Naveed Zafar S/o Zafar Ali CNIC No. 35202-2903328-9.
2. Ms. Sajeela Sarwar W/o Nadeem Zafar CNIC No. 35202-2842681-8.
 |

**Case No.2. CHANGE OF MANAGEMENT OF M/S ALFALAH PHARMA (PVT) LTD, LAHORE.**

 M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore under DML No. 000461by way of formulationhas submitted request for change in management of the firm as per Form-A along with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Retiring Management** | **New management**  |
| 1. Muhammad Waseem Chaudhry S/o Chaudhry Rafique.
2. 2. Muhammad Naeem Chaudhry S/o Chaudhry Rafique.
 | 1. Muhammad Waseem Chaudhry S/o Chaudhry Rafique.
2. Muhammad Naeem Chaudhry S/o Chaudhry Rafique.
 | 1. Mr. Abdul Rasheed S/o Haji Afzal Elahi CNIC No. 35401-2165829-1.
2. Mr. Zia-ullah S/o Abdul Rasheed CNIC No. 35401-7212373-3.
3. Ms. Nagina Begum W/o Abdul Rasheed CNIC No. 35401-3830761-6.
4. Ms. Shagufta ZiaW/o Zia-Ullah CNIC No. 35401-6491093-6.
 |

**Decision by the Central Licensing Board in 267th meeting:**

The Board considered and endorsed the change of management of M/s M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore under DML No. 000461by way of Formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Retiring Management** | **New management.** |
| 1. Muhammad Waseem Chaudhry S/o Chaudhry Rafique.
2. 2. Muhammad Naeem Chaudhry S/o Chaudhry Rafique.
 | 1. Muhammad Waseem Chaudhry S/o Chaudhry Rafique.
2. Muhammad Naeem Chaudhry S/o Chaudhry Rafique.
 | 1. Mr. Abdul Rasheed S/o Haji Afzal Elahi CNIC No. 35401-2165829-1.
2. Mr. Zia-ullah S/o Abdul Rasheed CNIC No. 35401-7212373-3.
3. Ms. Nagina Begum W/o Abdul Rasheed CNIC No. 35401-3830761-6.
4. Ms. Shagufta ZiaW/o Zia-Ullah CNIC No. 35401-6491093-6.
 |

**Case No.3. CHANGE OF MANAGEMENT OF M/S SURGE LABORATORIES (PVT) LTD, DISTRICT SHEIKHUPURA**

M/s Surge Laboratories (Pvt) Ltd, 10-Km Faisalabad Road, Bhikhi District Sheikhupura under DML No. 000649 by way of Semi Basic Manaufacture has submitted request for change in management of the firm as per Form-Aalong with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Retiring Management** | **New management**  |
| 1. Mr. Abdul Majid S/o Ch. Ghulam Nabi CNIC No. 42301-0969191-7.
2. Ms. Saleha Sultana W/o Dr. Abdul Majid CNIC No. 42301-0512065-8.
3. Mr. Muhammad Ali Majid S/o Dr. Abdul Majid CNIC No. 42301-5590648-9
4. Mr. Abdullah Majid S/o Dr. Abdul Majid CNIC No. 42301-1356206-7.
5. Ms. Humera Jawad W/o Jawad Saeed CNIC No. 42301-8539616-8
 | 1. Mr. Abdul Majid S/o Ch. Ghulam Nabi CNIC No. 42301-0969191-7.
 | 1. Ms. Saleha Sultana W/o Dr. Abdul Majid CNIC No. 42301-0512065-8.
2. Mr. Muhammad Ali Majid S/o Dr. Abdul Majid CNIC No. 42301-5590648-9
3. Mr. Abdullah Majid S/o Dr. Abdul Majid CNIC No. 42301-1356206-7.
4. Ms. Humera Jawad W/o Jawad Saeed CNIC No. 42301-8539616-8.
 |

**Decision by the Central Licensing Board in 267th meeting:**

The Board considered and endorsed the change of management of M/s Surge Laboratories (Pvt) Ltd, 10-Km Faisalabad Road, Bhikhi District Sheikhupura under DML No. 000649by way of Semi Basic Manaufacture as under ;

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Retiring Management** | **New management**  |
| 1. Mr. Abdul Majid S/o Ch. Ghulam Nabi CNIC No. 42301-0969191-7.
2. Ms. Saleha Sultana W/o Dr. Abdul Majid CNIC No. 42301-0512065-8.
3. Mr. Muhammad Ali Majid S/o Dr. Abdul Majid CNIC No. 42301-5590648-9
4. Mr. Abdullah Majid S/o Dr. Abdul Majid CNIC No. 42301-1356206-7.
5. Ms. Humera Jawad W/o Jawad Saeed CNIC No. 42301-8539616-8
 | 1. Mr. Abdul Majid S/o Ch. Ghulam Nabi CNIC No. 42301-0969191-7.
 | 1. Ms. Saleha Sultana W/o Dr. Abdul Majid CNIC No. 42301-0512065-8.
2. Mr. Muhammad Ali Majid S/o Dr. Abdul Majid CNIC No. 42301-5590648-9
3. Mr. Abdullah Majid S/o Dr. Abdul Majid CNIC No. 42301-1356206-7.
4. 4. Ms. Humera Jawad W/o Jawad Saeed CNIC No. 42301-8539616-8.
 |

**CASE NO. 4. CHANGE OF MANAGEMENT OF M/S SERAPH PHARMACEUTICAL, PLOT NO. 210, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD**

M/s Seraph Pharmaceutical, Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad, under DML No. 000860 by way of Formulation has submitted request for change in management of the firm as per partnership deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

|  |  |  |
| --- | --- | --- |
| **Existing Management** | **Incoming management.** | **New Management**  |
| * 1. Mr. Saeed Akbar S/o Muhammad Akbar CNIC No. 37405-5589573-1.
	2. Qazi Abdur Rashid S/o M. Afzal Ul Haq CNIC No. 13503-0648082-7.
 | 1. Mr. Safeer Ahmed S/o Muhammad Bashir CNIC No. 37105-2487441-7.
2. Syed Munir Ud Din S/o Syed Zain Ul Abideen CNIC No. 61101-1986111-9.
3. Mr. Muhammad Ashfaq S/o Gulistan CNIC No. 13101-0849056-9.
 | 1. Mr. Saeed Akbar S/o Muhammad Akbar CNIC No. 37405-5589573-1.
2. Qazi Abdur Rashid S/o M. Afzal Ul Haq CNIC No. 13503-0648082-7.
3. Mr. Safeer Ahmed S/o Muhammad Bashir CNIC No. 37105-2487441-7.
4. Syed Munir Ud Din s/o Syed Zain Ul Abideen CNIC No. 61101-1986111-9.
5. Mr. Muhammad Ashfaq S/o Gulistan CNIC No. 13101-0849056-9.
 |

**Decision by the Central Licensing Board in 267th meeting:**

The Board considered and endorsed the change of management M/s Seraph Pharmaceutical, Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad, under DML No. 000860 by way of Formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Existing Management** | **Incoming management.** | **New Management**  |
| 1. Mr. Saeed Akbar S/o Muhammad Akbar CNIC No. 37405-5589573-1.
2. Qazi Abdur Rashid S/o M. Afzal Ul Haq CNIC No. 13503-0648082-7.
 | 1. Mr. Safeer Ahmed S/o Muhammad Bashir CNIC No. 37105-2487441-7.
2. Syed Munir Ud Din S/o Syed Zain Ul Abideen CNIC No. 61101-1986111-9.
3. Mr. Muhammad Ashfaq S/o Gulistan CNIC No. 13101-0849056-9.
 | 1. Mr. Saeed Akbar S/o Muhammad Akbar CNIC No. 37405-5589573-1.
2. Qazi Abdur Rashid S/o M. Afzal Ul Haq CNIC No. 13503-0648082-7.
3. Mr. Safeer Ahmed S/o Muhammad Bashir CNIC No. 37105-2487441-7.
4. Syed Munir Ud Din s/o Syed Zain Ul Abideen CNIC No. 61101-1986111-9.
5. Mr. Muhammad Ashfaq S/o Gulistan CNIC No. 13101-0849056-9.
 |

**Case No.5. CHANGE OF MANAGEMENT OF M/S RASCO PHARMA, LAHORE**

M/s Rasco Pharma, 5.5-Km, Ali Raza Abad, Holiday Park, Raiwind Road, Plot No. 27, Lahore , DML No. 000530 by way of formulation has submitted request for change in management of the firm as per partnership deed along with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Retiring Management** | **New management**  |
| 1. Mr. Muhammad Rashid Sajjad S/o Muhammad Yaqoob, CNIC No. 35202-7716882-1.
2. Ms. Abida Tabassum W/o Muhammad Rashid Sajjad, CNIC No. 35202-7775892-8.
3. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1.
4. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7.
5. Ms. Amina Rashid D/o Muhammad Rashid Sajjad, CNIC No. 35202-9635683-6.
 | 1. Mr. Muhammad Rashid Sajjad S/o Muhammad Yaqoob, CNIC No. 35202-7716882-1.
2. Ms. Abida Tabassum W/o Muhammad Rashid Sajjad, CNIC No. 35202-7775892-8.
3. Ms. Amina Rashid D/o Muhammad Rashid Sajjad, CNIC No. 35202-9635683-6.
 | 1. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1.
2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7.
 |

**Decision by the Central Licensing Board in 267th meeting:**

The Board considered and endorsed the change of management of M/s Rasco Pharma, 5.5-Km, Ali Raza Abad, Holiday Park, Raiwind Road, Plot No. 27, Lahore , DML No. 000530 by way of Formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Existing Management** | **Retried Management** | **New Management**  |
| 1. Mr. Muhammad Rashid Sajjad S/o Muhammad Yaqoob, CNIC No. 35202-7716882-1.
2. Ms. Abida Tabassum W/o Muhammad Rashid Sajjad, CNIC No. 35202-7775892-8.
3. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1.
4. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7.
5. Ms. Amina Rashid D/o Muhammad Rashid Sajjad, CNIC No. 35202-9635683-6.
 | 1. Mr. Muhammad Rashid Sajjad S/o Muhammad Yaqoob, CNIC No. 35202-7716882-1.
2. Ms. Abida Tabassum W/o Muhammad Rashid Sajjad, CNIC No. 35202-7775892-8.
3. Ms. Amina Rashid D/o Muhammad Rashid Sajjad, CNIC No. 35202-9635683-6.
 | 1. Mr. Amir Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-6996190-1.
2. Mr. Adil Rashid S/o Muhammad Rashid Sajjad, CNIC No. 35202-0934106-7.
 |

**Case No.6. CHANGE OF MANAGEMENT OF M/S THE SEARLE COMPANY LTD, LAHORE.**

 M/s The Searle company Ltd, 32-Km, Multan Road, Lahore under DML No. 000647 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Retiring Management** | **New management**  |
| 1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3.
2. Mr. Rashid Abdulla S/o Abdulla A. Razzaq CNIC No. 42201-1132967-1.
3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.
4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803.
5. Mr. Ayaz Abdulla S/o Shahid Abdulla CNIC No. 42201-8726172-1.
6. Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9.
7. Mr. Munis Abdulla S/o Rashid Abdullah CNIC No. 42201-99825171.
 | 1. 1. Mr. Munis Abdulla S/o Rashid Abdullah CNIC No. 42201-99825171.
 | 1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3.
2. Mr. Rashid Abdulla S/o Abdulla A. Razzaq CNIC No. 42201-1132967-1.
3. Mr. Hussain lawai S/o Haji Moosa CNIC No. 914000-140464-5.
4. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.
5. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803.
6. Mr. Ayaz Abdulla S/o Shahid Abdulla CNIC No. 42201-8726172-1.
7. Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9.
 |

**Decision by the Central Licensing Board in 267th meeting:**

The Board considered and endorsed the change of management of M/s The Searle company Ltd, 32-Km, Multan Road, Lahore under DML No. 000647 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Existing Management**  | **Retiring Management** | **New Management**  |
| 1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3.
2. Mr. Rashid Abdulla S/o Abdulla A. Razzaq CNIC No. 42201-1132967-1.
3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.
4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803.
5. Mr. Ayaz Abdulla S/o Shahid Abdulla CNIC No. 42201-8726172-1.
6. Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9.
7. Mr. Munis Abdulla S/o Rashid Abdullah CNIC No. 42201-99825171.
 | 1. Mr. Munis Abdulla S/o Rashid Abdullah CNIC No. 42201-99825171.
 | 1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3.
2. Mr. Rashid Abdulla S/o Abdulla A. Razzaq CNIC No. 42201-1132967-1.
3. Mr. Hussain lawai S/o Haji Moosa CNIC No. 914000-140464-5.
4. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.
5. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803.
6. Mr. Ayaz Abdulla S/o Shahid Abdulla CNIC No. 42201-8726172-1.
7. Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9.
 |

**Case No. 7 CHANGE OF TITLE OF M/S VANTAGE PHARMACEUTICAL, DISTRICT FAISALABAD.**

M/sVantage Pharmaceutical,Plot No. 54-RB, Sarhali, 6-Km, Sangla Hills, Shahkot Road, District Faisalabad under DML No. 000836by way of formulation has submitted request for change of title of the firm as per Certificate of incorporation Form S.E.C.P with prescribed Fee Challan of Rs.50,000/-. The detail is as under:

|  |  |
| --- | --- |
| **Existing Name**  | **New Name**  |
| M/sVantage Pharmaceutical, District Faisalabad | M/sVantage Laboratories (Pvt) Ltd, District Faisalabad |

**Decision by the Central Licensing Board in 267th meeting:**

The Board considered and endorsed the change of title of M/sVantage Laboratories (Pvt) Ltd, [Formerly M/sVantage Pharmaceutical], Plot No. 54-RB, Sarhali, 6-Km, Sangla Hills, Shahkot Road, District Faisalabad under DML No. 000836 by way of formulation as under ;

|  |  |
| --- | --- |
| **Existing Name**  | **New Name**  |
| M/sVantage Pharmaceutical, District Faisalabad | M/sVantage Laboratories (Pvt) Ltd, District Faisalabad |

**Case No. 8. CHANGE OF MANAGEMENT OF M/S VANTAGE LABORATORIES (PVT)**

**LTD,[FORMERLY M/SVANTAGE PHARMACEUTICAL], DISTRICT FAISALABAD.**

M/sVantage Laboratories (Pvt) Ltd, [Formerly M/sVantage Pharmaceutical], Plot No. 54-RB, Sarhali, 6-Km, Sangla Hills, Shahkot Road, District Faisalabad under DML No. 000836 by way of formulationhas submitted request for change in management of the firm as per Form-D along with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **incoming Management** | **New management**  |
| 1. Mr. Muhammad Tehseen Alvi S/o Muhammad Aslam Alvi CNIC No. 35202-2609765-3.
 | 1. Ms. Huma Batool W/o Muhammad Tehseen Alvi CNIC No. 61101-0341433-0
 | 1. Mr. Muhammad Tehseen Alvi S/o Muhammad Aslam Alvi CNIC No. 35202-2609765-3.
2. Ms. Huma Batool W/o Muhammad Tehseen Alvi CNIC No. 61101-0341433-0
 |

**Decision by the Central Licensing Board in 267th meeting:**

The Board considered and endorsed the change of management of M/sVantage Laboratories (Pvt) Ltd, District Faisalabad [Formerly M/sVantage Pharmaceutical], Plot No. 54-RB, Sarhali, 6-Km, Sangla Hills, Shahkot Road, District Faisalabad under DML No. 000836 by way of formulationas under ;

|  |  |  |
| --- | --- | --- |
| **Existing Management**  | **Incoming Management**  | **New Management**  |
| 1. Mr. Muhammad Tehseen Alvi S/o Muhammad Aslam Alvi CNIC No. 35202-2609765-3.
 | 1. Ms. Huma Batool W/o Muhammad Tehseen Alvi CNIC No. 61101-0341433-0
 | 1. Mr. Muhammad Tehseen Alvi S/o Muhammad Aslam Alvi CNIC No. 35202-2609765-3.
2. Ms. Huma Batool W/o Muhammad Tehseen Alvi CNIC No. 61101-0341433-0
 |

**Case No. 9 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDELLA PHARMACEUTICALS (PVT) LTD, LAHORE**

M/s Medella Pharmaceuticals (Pvt) Ltd, Plot No. 569/570, Sunder Industrial Estate, Raiwind Road, Lahore had applied for renewal of DML No. 000749 by way of formulation for the period of
31-08-2017 to 30-08-2022 on 25-08-2017.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13thDecember, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Complete application on prescribed Form-1A for renewal of DML as per checklist.
2. Documents should be duly attested.

The firm submitted their reply on 10th January, 2018 After evaluation of the submitted documents, final reminder was issued on 22ndFebruary, 2018 to the firm with following shortcomings: -

1. Duly attested signed and stamped Form-1A.
2. Classes of Drugs.
3. Update Form-29 (Attested by S.E.C.P) if change of management, prescribed fee of Rs. 50,000/- for change of management.
4. CNIC Copies of all Directors.
5. Prescribed fee of Rs. 10,000/- for change of Production Incharge and Quality Control Incharge.
6. Registration Certificate from pharmacy council of Production Incharge.
7. Resignation letter of earlier Production Incharge and Quality Control Incharge.
8. Resignation letter of proposed Production Incharge from previous firm.
9. Undertaking as whole time employee on stamp paper of Production Incharge and Quality Control
10. Copy of CNIC of Production Incharge and Quality Control Incharge..
11. All documents should be duly attested.

The firm submitted documents on 15th May, 2018 in reply to Final Reminder. Upon Evaluation following shortcoming has been observed and application for renewal of DML is **still incomplete.**

1. Duly signed & stamped Form-1A.
2. Classes of Drugs.
3. Latest certified true copy of Form-29 (Attested by SECP), if any change in management, prescribe fee of Rs.50, 000/- for change of management.
4. Duly attested CNIC copies of all Directors.
5. Duly attested resignation/retirement of earlier proposed Production Incharge and Quality Control Incharge.

**Proceedings and Decision of Central Licensing Board in 263rdmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medella Pharmaceuticals (Pvt) Ltd, Plot No. 569/570, Sunder Industrial Estate, Raiwind Road, Lahore under DML No. 000749 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**

The Show Cause notice dated 8thAugust, 2018 was issued to the M/s Medella Pharmaceuticals (Pvt) Ltd, Plot No. 569/570, Sunder Industrial Estate, Raiwind Road, Lahore.

 The firm did not reply the show cause notice and the application for renewal of DML is incomplete till date.

A letter of Personal hearing has been issued on 18th October, 2018.

**Proceedings and Decision of Central Licensing Board in 266th meeting**

No person on the behalf of the firm appeared before the Board, therefore, the Central Licensing Board decided to serve the show cause notices to the firm through Additional Director (E&M) DRAP Lahore .

**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**

A letter of copy of show cause notice was issued on 12th December, 2018 to Additional Director (E&M) DRAP Lahore to ensure delivery and receiving of letter to the firm and submit compliance.

The firm replied the show cause notice but following documents are still deficient in the application.

1. Prescribe fee of Rs.50, 000/- for change of management.
2. Latest certified true copy of Form-29 (Attested by SECP).
3. Duly attested resignation/retirement of earlier Production Incharge.

Aletter of Personal hearing has been issued on 24thDecember, 2018.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

Mr. Imran Ahmed Khan appeared before the Board and contended that currently no prodcution activity is carried out at premsis. During his presence, following shortcomings were still not addressd in completion of application for renewal of DML.

1. Prescribe fee of Rs.50, 000/- for change of management.
2. Duly attested resignation/retirement of earlier Production Incharge.

The Board after hearing the representative of the firm and considering the facts on the record and after thread bare deliberation decided to suspend the Drug Manufacturing Licence No. 000749 by way of formulation issued in the name of M/s Medella Pharmaceuticals (Pvt) Ltd, Plot No. 569/570, Sunder Industrial Estate, Raiwind Road, Lahore till settelemnt of codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 , Rule 19, Rule, 5(6) and Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. If the firm completes the codal formalities, the Chairman Central Licensing Board shall pass an order for revocation of suspension. However, case would be brought before Central Licensing Board in forthcoming meeting for endorsement of decision taken by the Chairman.

**Case No. 10 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S BASEL PHARMACEUTICAL, MULTAN.**

M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, Multan had applied for renewal of DML No. 000726 by way of Formulation for the period of 21-06-2016 to 20-06-2021 on 06-06-2016.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 3rd October, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form 1-A
2. Classes of Drugs
3. Dosage form of Drugs
4. Name (s) of drugs Registered / approved
5. Chang (s) in name of proprietor / director / partner (If any)
6. Detail of premises including layout plan and proof of section form CLB
7. Nothing due certificate regarding CRF from STO.
8. Resignation of earlier Production Incharge & QC Incharge.
9. Resignation of appointee Production Incharge & QC Incharge from Pervious firm.
10. Experience of QC Incharge is less than 10 year.
11. Job Acceptance / joining letter from production Incharge.

No reply was receive from the firm. Final Reminder letter was issued on 10thJanuary, 2017 to the firm for submission of following documents.

1. Form1-A duly signed and stamped.
2. Classes of Drugs.
3. Dosage Forms of Drugs.
4. Name(s) of drugs registered/Approved.
5. Detail of premises including approved master layout plan.
6. Proof of sections approved by CLB.
7. CNIC copies of All Directors/Partners.
8. Nothing due certificate regarding CRF from STO (Updated).
9. Resignation of earlier Production Incharge & QC Incharge.
10. Resignation of appointee Production Incharge & QC Incharge from Pervious firm.
11. Experience certificates of Proposed Production Incharge & QC Incharge(Not less than 10 years in relevant field)
12. Job Acceptance / joining letter from production Incharge.
13. Undertaking as whole time employee on stamp paper of both Production Incharge & QC Incharge.
14. Registration Certificate from pharmacy council of Production Incharge.
15. CNIC copy of Production Incharge.

The firm did not reply to final reminder and application for renewal of DML is still incomplete.

**Proceedings and Decision of Central Licensing Board in 265thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, Multan, under Drug Manufacturing Licence No. 000726 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**

The Show Cause notice dated 5th September 2018 was issued to the M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, Multan.

The firm did not reply the show cause notice and the application for renewal of DML is incomplete till date.

A letter of Personal hearing has been issued on 18th October, 2018.

**Proceedings and Decision of Central Licensing Board in 266th meeting**

No person on the behalf of the firm appeared before the Board, therefore, the Central Licensing Board decided to serve the show cause notices to the firm through Additional Director (E&M) DRAP Lahore .

**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**

The firm replied to Show Cause Notice that Mr. Nadeem Khalid Proprietor of firm due to severe health issues is unable to attend personal hearing. He has further stated that the firm already closed due to maintenance work and also informed Area FID.

Furthermore, Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore, has informed that the undersigned visited the premises of M/s Basel Pharmaceuticals, Multan on 18-10-2018, to check the GMP compliance and production status of the firm. At the time of visit, Mr. Muhammad Ayoub, Security Guard was present, who opened the gate of the unit, and informed that owner of the factory, Mr. Nadeem was seriously ill, so the factory was closed since long. Mr. Nadeem was contacted in phone. He confirmed that he was seriously ill and got heart surgery. He also stated that he was not in the position to run the factory. Hence he was directed to inform to DRAP before taking any step and the production will remain stopped meanwhile.

Aletter of Personal hearing has been issued on 24thDecember, 2018.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

No Person appeared on the behalf of firm. The Board after hearing the representative of the firm and considering the facts on the record and after thread bare deliberation decided to suspend the Drug Manufacturing Licence No. 000749 by way of formulation issued in the name of M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, Multan till settelemnt of codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 and Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. If the firm completes the codal formalities, the Chairman Central Licensing Board shall pass an order for revocation of suspension. However, case would be brought before Central Licensing Board in forthcoming meeting for endorsement of decision taken by the Chairman.

**Case No.11. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S SYNTEX PHARMACEUTICALS, KAMRA ROAD ATTOCK CITY.**

M/s Syntex Pharmaceuticals, Kamra Road Attock City had applied for renewal of DML No. 000290 by way of formulation for the period of 06-01-2015 to 05-01-2020 on 06-01-2015.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 1st February, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Attested copies of CNIC of all Directors / legal status of firm / Form C if applicable, Affidavit in case of propartnership mentioning.
2. Approval letter of Quality Control Manager.
3. Approval letter of Production Manager.
4. Nothing due certificate regarding CRF from STO.
5. All documents attested as per check list (Attached).

The firm submitted their reply on 22nd December, 2017. After evaluation of the submitted documents, Final Reminder was issued on 28th November, 2017, to the firm with following shortcomings: -

1. Attested copies of CNIC of all Directors / legal status of firm / Form C if applicable, Affidavit in case of propartnership mentioning.
2. Approval letter of Quality Control Manager.
3. Approval letter of Production Manager.
4. Nothing due certificate regarding CRF from STO.
5. All documents attested as per check list (Attached).

Firm did not submit their reply to Final Reminder and following documents are still deficient /short and application for renewal of DML was incomplete.

1. Attested copies of CNIC of all Directors / legal status of firm / Form C if applicable, Affidavit in case of partnership mentioning.
2. Approval letter of Quality Control Manager.
3. Approval letter of Production Manager.
4. Nothing due certificate regarding CRF from STO.
5. All documents attested as per check list (Attached).

**Proceedings and Decision of Central Licensing Board in 262ndmeeting.**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Syntex Pharmaceuticals, Kamra Road Attock City under DML No. 000290 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

The Show Cause Notice dated 13th August, 2018 was issued to the M/s Syntex Pharmaceuticals, Kamra Road, Attock City.

In reply to the Show Cause notice firm has submitted the documents application for renewal of DML is still deficient with following documents:-

1. Attested copy of CNIC of Director of firm.
2. Approval letter of Quality Control Incharge.

Meanwhile, a letter received from Area Federal Inspector of Drugs-IV, DRAP, Islamabad wherein she has intimated following observations about M/s Syntex Pharmaceuticals, Kamra Road, Attock City:-

* + 1. The undersigned has been appointed as Federal Inspector of Drugs-IV in place of the then FID and area accordingly is assigned and the subject company now falls in my territorial jurisdiction. The subject letter was forwarded to firm as well the area FID as per provision of Rule 5(2A) of Drugs (Licensing, Registering & Advertising) Rules, 1976.
		2. It is intimated that the perusal of previous reports of the then Area Federal of Drugs also revealed that the firm now comes under residential area which is prohibited under schedule-B-II of the Drugs (Licensing Registering & Advertising) Rules, 1976, as per report forwarded by three member panel (copy enclosed).
		3. In view of above, since matter is of great importance regarding the violations of submission of incomplete application for renewal of Drug Manufacturing License as well as located in residential area which may pose great threat to public health as in past the incidences of blasts in boilers / tray dryers happened which amounted to loss of precious lives of public residing near the such entrepreneurs like (M/s Orient Laboratories, Lahore) on which the suo-moto action had also been taken by the Apex Court regarding the negligence of concerned authorities.

The firm has been called for personal hearing vide Licensing Division letter dated 24th December, 2018.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

Abdul Rahim Mirza CEO of the firm appeared before the board and contended that his existing facility is located in residential area. He furthur contended that he has submitted application for establishment of pharmaceutical unit at new site and he will submit shortcominsg documents in the application for new site within one week. He also contended he will submit the layout paln for the new site till the end of feburary 2019 and will submit application for grant of Drug manufacturing licence till November 2019. The Board after hearing the representative of the firm and considering the facts on the record and after thread bare deliberation decided to suspend the Drug Manufacturing Licence No. 000290 by way of formulation under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 issued in the name of M/s Syntex Pharmaceuticals, Kamra Road Attock City till shifting of the firm to new premises.

**Case No. 12. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S WISE PHARMACEUTICALS, PLOT NO. 3-A, STREET NO. S-1, RCCI, INDUSTRIAL ESTATE, RAWAT, RAWALPINDI.**

M/s Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi, had applied for renewal of DML 000625 by way of (Formulation) for the period of 25-09-2017 to 24-09-2022. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13th December, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

**Renewal.**

1. Form 1-A.
2. Classes of Drugs.
3. Dosage forms of drugs.
4. Name(s) of drugs registered / approved.
5. Change(s) in name of proprietor / directors / partners (if any).
6. Detail of premises including layout plan.
7. Section wise detail of machinery for manufacture.
8. Section wise detail of machinery for Quality Control Lab.
9. Name and Qualification of Production & Quality Incharge.
10. Nothing due certificate regarding CRF from STO.
11. Proof of Licensed Section from CLB.
12. All documents should be duly attested.

**Detail of management.**

1. Detail of Management at the time of previous renewal and present renewal.
2. Partnership Deed attested / Sole Proprietor.
3. All documents duly should be attested.

The firm submitted their reply on 18th January, 2018 After evaluation of the submitted documents, final reminder was issued on 10th April, 2018 to the firm with following shortcomings: -

**Renewal.**

1. Form 1-A.
2. Classes of Drugs.
3. Dosage forms of drugs.
4. Name(s) of drugs registered / approved.
5. Change(s) in name of proprietor / directors / partners (if any).
6. Detail of premises including layout plan.
7. Section wise detail of machinery for manufacture.
8. Section wise detail of machinery for Quality Control Lab.
9. Name and Qualification of Production & Quality Incharge.
10. Nothing due certificate regarding CRF from STO.
11. Proof of Licensed Section from CLB.
12. All documents should be duly attested.

**Detail of management.**

1. Detail of Management at the time of previous renewal and present renewal.
2. Partnership Deed attested / Sole Proprietor.
3. All documents duly should be attested.

Firm has submited their reply in response to this Division’s Final Reminder and following documents are still deficient /short and application for renewal of DML was incomplete:-

**Renewal.**

1. Attested copy of CNIC of Mr. Sajjad Ahmad, QC Incharge.
2. Resignation / retirement of earlier QC Incharge.
3. Undertaking as whole time employee on stamp paper of QC Incharge.
4. Nothing due certificate regarding CRF from STO.
5. All documents should be duly attested.

**Detail of management.**

1. There is change in management from previous management following documents are required:-

a). NOCs from retiring / outgoing management.

b). CNICs of all directors (Previous & New).

c). Prescribed fee for change of management.

1. All documents duly should be attested.

**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**

The Show Cause notice dated 4th December, 2018 was issued to the M/s Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi.

Reply of the show cause is received from the firm and documents were evaluated and following shortcoming has still been observed:-

**Renewal.**

1. Nothing due certificate regarding CRF from STO.
2. Appointment letter of newly appointed QC Incharge (Syed Mohsin Ali Shah).
3. Job acceptance letter of appointee.
4. Copy of CNIC of newly appointed Quality Control Incharge.
5. Registration Certificate from Pharmacy Council.
6. Experience Certificates of Quality Control Incharge are not readable (not less than 10 years).
7. Resignation letter of appointee from previous firm is not readable.

**Detail of management.**

a). Submitted NOC of Mr. Rajab Sultan Raja is not attested.

The firm has been called for personal hearing vide Licensing Division letter dated 24th December, 2018.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

Mr. Abdullah Managing Partner, M Rashid Abbasi Manager Accounts of the firm appeared before the board and submitted the required documents. The Board considering the facts on record decided to revoke the Showcause Notice issued to the firm and also issue warning to the firm to be careful in future for compliance of the law.

**CASE NO. 13. M/S MEDIWAYS INTERNATIONAL, LAHORE**

**Background:-**

M/s Mediways International, Multan Road, Lahore was inspected on 09.02.2015 by Mr. Ajmal Sohail Asif, FID Lahore to see/verify the GMP compliance. During inspection the FID pointed out a number of serious shortcomings and gross violations including the following:-

**Change Rooms:**

1. Air curtains were installed but were not functional at the time of inspection.
2. No Separate change room was provided for visitors or executives.
3. Change rooms were very small and need to be reorganized in respect of outside doors.
4. The firm was also advised to provide cabinets in the change rooms for keeping the workers belongings etc.
5. It was also noticed that at the time of inspection the change rooms were not maintained and were not neat and clean.

**Storage Areas:**

1. Quarantine area not properly demarcated and separated from the de-dusting area.
2. The firm has provided a dispensing hood which was placed in the raw material store for recipients. But it seemed not to be in use, since there were no accessories like balance, scoops etc inside the dispensing booth.
3. Balances and other accessories for dispensing were available on one of the racks of raw materials.
4. No separate facility for sampling of the materials was available; the firm was advised to provide proper sampling facility.
5. The firm was also advised to rearrange the placement of dispensing hood providing separate cabin and proper flow of pre and post dispensed materials
6. However packing material store was congested the firm was advised to expand the storage area for packing materials.

**Production Areas:**

1. HVAC was not functional at the time of inspection due to load shedding as informed by management of the firm.
2. The firm was advised to partition this room for separation of de-cartooning and bottle blowing functions.
3. It was also noticed that all the doors in production area were wooden and the firm was advised to replace all the wooden doors.

**Quality Control Laboratory:**

1. It was noticed that QC lab was accessed through the de-dusting/ quarantine area of raw material store; the firm was advised to provide some other entrance to QC laboratory in order to avoid unnecessary movements QC of staff in stores.

**Quality Assurance:**

1. During the last inspection the firm has presented a QA officer but at the time of this inspection no QA personnel was present.
2. From ware houses to production and quality control no prevalence/involvement of quality assurance was observed.
3. The management of the firm was also advised during previous inspection to strengthen the QA department but no improvement was seen in this department.
4. Due to lack of QA system, deviations from SOPs, GMP, GSP etc, were observed in stores, manufacturing areas and quality control.
5. Non existence of an independent check and balance system may result in compromises, by manufacturing and QC personnel, for routine deviations from practices and procedures. Such a situation may pose a great potential of compromises on overall quality of the products being manufactured.

**Sanitation and Hygiene:**

1. The equipments in QA laboratory and different gauges, matters and equipment in manufacturing areas were not calibrated.
2. There was no system for qualification and validation of machines, procedures and practices.
3. The firm has no procedures for cleaning validation and was advised to develop.

**Products Recalls:**

1. The firm was advised to assign a separate area for recall products and demark it well

**Self Inspection and Quality Audit:**

1. No record was available for any audit.

**Personnel:**

1. However, there was no technical person to look after the QA.
2. The firm was advised to establish proper QA department and to hire appropriate personnel to strengthen the QA

**Training:**

1. However, It was not being implemented as no record was available

**Equipment & Machinery:**

1. However, the firm was advised to upgrade the syrup filling machine.
2. The machines/equipments were not properly labeled regarding the status.
3. However, the firm was advised to purchase the FTIR on priority basis.

**Materials:**

1. The firm was advised to purchase the materials from manufacturers or authorized suppliers.
2. The firm was also advised to conduct vendor qualification.
3. The firm has not developed a proper material management system.
4. The materials were not properly labeled.
5. The firm was advised to affix the label on each and every container / bag of a lot of material.
6. The firm was also advised to develop and implement the procedures for safety and security of the workers/personnel handling the materials in stores and also to mark the racks and allocate locations of the materials.
7. In packing materials store the firm was advised for safe storage of printed materials and unit cartons under lock and key.

**Documentation:**

1. It was found that some of the SOPs and BMRs needed review, improvement and updating regarding the actual practices.
2. The log books for QC equipment were not maintained.
3. The firm was advised to prepare procedure for OOS, cleaning validation etc.

**Good Practices in Production:**

1. In general the practices were observed not to be in accordance with the prescribed procedures.
2. The firm was asked to present the BMR for the last batch of a product namely “Antizile Syrup” but the management failed to produce any documentation.

**Good Practices in Quality Control:**

1. There were procedures for QC analysis but they needed to be updated.
2. The log books for instruments and equipments were not maintained.
3. In general the practices were observed not to be in accordance with the prescribed procedures.

**Utilities**

**Water Purification System:**

1. The firm was advised to install transfer pipes for supply of purified water to manufacturing area to minimize the exposure to external environment during manual transfer.

**HVAC System:**

1. The firm was advised to repair the manometer so that the pressure gradients in buffer and manufacturing areas may be checked.

**The FID further concluded that:** The non compliant behavior of the firm towards advises made during previous panel inspection; the firm was considered to be operating at unsatisfactory level of the compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under.

**Action Taken by DRAP**: - Accordingly, a show cause notice and suspension of production order in all section was issued to the firm on 20.03.2015 with immediate effect.

**Reply of the firm**: - In response to show cause notice the firm vide letter No. Nil dated 15.06.2015 submitted their reply and requested to verify the shortcomings through area FID.

**Proceedings of 245th meeting of CLB held on 30.12.2015**

 Mr. Jamil Ahmad, CEO of the firm appears before the Board. He informed that the observations given by the FID were given attention and most of the observations have been rectified and compliance report was also submitted. The firm is ready for inspection.

**Decision of 245th meeting of CLB held on 30.12.2015**

The case was placed before the Central Licensing Board for consideration. The Board after thorough discussion, keeping in view the available record, compliance report and request from CEO of the firm, decided to conduct panel cGMP inspection of the firm, on approved Schedule B-II cGMP format and panel will also submit report in tabulated form identifying the previous observations and the current status, by the following members:-

1. Dr. Ikram ul Haq, Member, CLB
2. Dr. Zaka ur Rehman, Member, CLB
3. Mr. Ajmal Sohail Asif, Area FID.

Accordingly decision of 245th meeting of CLB was conveyed to the firm on 10.02.2016

**Letter of Secretary PQCB, Lahore:-**

 Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab informed that Deputy Drug Controller Allama Iqbal Town Lahore alongwith other members inspected the premises on 16.06.2016. The team observed that:-

1. Manufacturing of Drugs was being carried out under unhygienic conditions.
2. Improper storage of drugs (at 40 degree Centigrade).
3. Illegal or unauthorized import of raw materials without label (misbranded).

 The case was placed in 249th meeting of CLB held on 29.08.2016.

**Proceedings of the 249th meeting of CLB**

The Board was informed that Mr. Ajmal Sohail Asif, FID conducted inspection of the firm on 09.02.2015. The firm was issued order for suspension of production activities and issued showcause notice / Suspension of production order No.F.4-4/2001-QA on 20.03.2015. Accordingly, the case was discussed in 245th Meeting of CLB, wherein the CLB had constituted following panel of experts to verify the improvements:-

1. Dr. Ikram ul Haq
2. Dr. Zaka ur Rehman
3. Mr. Ajmal Sohail Asif

Inspection report of the firm is still awaited. The Board also discussed and evaluated the reports / cases forwarded by the Secretary, PQCB, Punjab, Lahore and Chief Drug Controller, Punjab for cancellation / suspension of DML of the firm M/s Mediways, Lahore. The Board also consider sub Rule 3 of Rule 5 of Punjab Drugs Rules, 2007 which categorically stated that *“The provincial and district Board shall examine a case referred to it by an inspector and shall , if an action is proposed to be taken against a person under the Act or the rule, issue a showcause notice to the personal and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority.”*

**Decision of the 249th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, the Board considered the recommendations of the Secretary, PQCB, Punjab and took a serious notice on illegal / unauthorized manufacturing and violation of the orders of the DRAP’s letter No. No.F.4-4/2001-QA dated 20.03.2015. The Board decided to issue a showcause notice to the firm M/s Mediways, Lahore on illegal / unauthorized production activities and disobeying the orders of DRAP.

Accordingly showcause notice was issued to the firm on 03.10.2016.

**Proceedings of the 250th Meeting of CLB**

Mr. Jamil Ahmed, Chief Executive of the firm M/s Mediways International, Lahore appeared before the Board for personal hearing. He informed that the production is suspended since March, 2015, as per direction of the Division of QA&LT. The provincial government during the raid sealed the premises, which was later on de-sealed on the order of the Drug Court, Lahore. He also informed that inspection book is also in the custody of provincial drug inspector, which has not been handed over to him till date, despite number of requests. Dr. Ikram ul Haq, Member CLB informed the Board that he along-with other members of the panel visited the firm, in compliance to decision of 245th Meeting of CLB, but the firm was found closed and the inspection could not be carried out.

**Decision of the 250th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, non serious and non-professional attitude of the firm, , the Board decided to:-

1. Suspend the Drug Manufacturing License of the firm M/s Mediways International, Lahore for a period of six months under Section 41 of the Drugs Act, 1976 read with Rule 12 (1) of the Drugs (LR&A) Rules, 1976.
2. Direct the area FID to visit the firm on alternate months to verify the suspension of production and submit report.
3. Resumption of production shall only be allowed after completion of suspension of DML period, verification by the panel of experts and subsequent approval from the Competent Authority.

**Updated status:-**

The panel constituted by the Director QA&LT conducted inspection of the firm on 26.12.2017 (received on 17.04.2018). The panel submitted detailed inspection report including previous observations and updated status on Schedule B-II format and recommended as under:-

 *“Based on the areas inspected, the people met and the documents reviewed, and considering the finding of the inspection in comparison with the observations of the previous inspection, the panel of inspectors does not consider the firm to be at a satisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under. The plot size is smaller than the prescribed requirement. However, CLB in its 241st meeting held on 15.5.2015 decide “to allow two years time for shifting of unit / enhancement of plot size according to rules”; and that two years period. Therefore, the panel of inspectors does not recommend M/s Mediways International, 16KM Multan Road, Lahore, for resumption of production. The report is forwarded herewith for further consideration and necessary action”.*

**Proceedings of the 261st meeting of the CLB**

The case was placed before the board for appraisal in the light of recommendations of the panel of experts in its report dated 26.12.2017.

**Decision of the 261st Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendation of the panel of experts in its report dated 26.12.2017, the Central Licensing Board decided to:-

1. Further extend Suspension of DML period for next six months from the date of issuance of decision of 261st meeting of CLB.
2. The Licensing Division Shall place the case in forthcoming meeting of CLB in the light of decision of 241st meeting of CLB.

**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**

 The Central Licensing Board in its 241st meeting held on 15th May, 2015 has considered the case of M/S Mediways International, Lahore and decided as under:

* *“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.”*

 The same decision was conveyed to the firm vide letter issued on 24th August, 2015 but till date no application is received from the firm for shifting of their existing facility and application for renewal of DML No. 000468 (Formulation) for period of 09-02-2015 to 08-02-2020 is incomplete with following documents being deficient:

1. Nothing due certificate regarding CRF (Updated).
2. Approval letters of Production Incharge and Quality Control Incharge, if not approved, complete set of duly attested documents (as per checklist) of qualified staff alongwith prescribed fee of Rs.10,000/-
3. Detail of management at the time of previous renewal and at present renewal, if any change, prescribed fee of Rs.50, 000/- for change in management.
4. CNIC copies of owner/partners.
5. Proof of CLB approved sections.
6. Legal status of the firm.

**Proceedings and Decision of Central Licensing Board in 265thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19,Schedule B-II and Rule 20 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/sMediways International, Multan Road, Lahore, under Drug Manufacturing Licence No. 000468 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**

The Show Cause notice dated 27thSeptember, 2018 was issued to the M/sMediways International, Multan Road, Lahore which was returned back. Then The Additional Director (E&M),DRAP, Lahore requested to ensure delivery and receiving of show cause notice to the firm.

 The firm repliedto the show cause notice and the application for renewal of DML is incomplete till date with following short comings.

1. Nothing due certificate regarding CRF (Updated).
2. Proof of CLB approved sections.
3. Undertaking as sole proprietor on stamp paper.

Furthermore, the firm requested to allow three year for shifting unit after earning some revenue as the production has remained suspended for two years.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to call the firm M/s Mediways International, Multan Road, Lahore for personal hearing in forthcoming meeting of the Central Licensing Board.

**Case No.14. M/s TRIGON PHARMACEUTICALS (PVT) LTD, LAHORE.**

 A copy of letter is received from Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab wherein he has informed that Provincial Quality Control Board has suspended the Drug Manufacturing License of M/s Trigon Pharmaceuticals (Pvt) Ltd, Lahore, for 15 days vide ordered dated 31st May, 2018 based on the inspection report (i.e. Inspection conducted on dated 23rdMay, 2018)submitted by Drug inspector Industries, Ferozepur Road & Raiwind Road, Lahore. The Board further decided to re-inspect the factory premises after 15 days by Chief Drug Controller to evaluate CAPA and remedial measures taken by the firm for further necessary action.

Orders of the Provincial Quality Control Board, Punjab marked as **Annex-I**.

**Decision of the Central Licensing Board in 265th meeting**

The Board considered and deliberated the case in the light of orders of the PQCB, Punjab and legal provisions. The Board decided to seek updated report from PQCB.

**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**

A letter was issued to Secretary PQCB on 17th September, 2018 in compliance of decision of the Board. A Copy of Order issued by the PQCB in its 191st meeting held on 16-08-2018 considered the case of M/s Trigon Pharmaceuticals (Pvt) Ltd, Lahore was received. The decision of the Board is as under:-

*“The Board after considering the inspection report, due deliberation and discussion decided to allow M/s Trigon Pharmaceuticals (Pvt) Ltd, Lahore to resume production operations in Cephalosporins Dry Powder Injections, Psychotropic injectable. Steroidal injectable and General Liquid Injections (Vials, Ampoules), strictly in accordance with law”.*

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board after perusal of the record discussed that no further action is warranted.

**Case No. 15 APPROVAL OF PRODUCTION INCHARGE & QUALITY CONTROL INCHARGE OF M/S DIVINE PHARMACEUTICALS, LAHORE.**

M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore had applied for approval of Production Incharge & Quality control Incharge on 27-07-2018. The application for the was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 31st August, 2108.

1. Prescribed fee of Rs. 10,000/- alongwith complete set of duly documents of technical staff (as per checklist).

 The firm submitted their reply on 25th September, 2018. After evaluation of the submitted documents, final reminder was issued on 6th November, 2018 to the firm with following shortcomings: -

1. Complete set of duly attested documents of technical staff (as per checklist).

The firm has not replied to Final reminder and application for approval of Production Incharge & Quality control Incharge is incomplete.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provisions of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000850 by way of Formulation in the name of M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore may not be suspended or cancelled by Central Licensing Board.

**Case No. 16 APPROVAL OF PRODUCTION INCHARGE OF M/S ORTA LABORATORIES (PVT) LTD, LAHORE.**

 M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohlanwal, Lahore had applied for approval of Production Incharge on 10th November, 2017. The application for the was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on
27th December, 2107.

1. CNIC Copy of appointee (Valid CNIC)
2. Registration certificate from Pharmacy Council (Valid Copy).
3. Resignation of earlier Production Incharge.
4. **All documents should be duly attested**

 The firm submitted their reply on 17thJanuary, 2018. After evaluation of the submitted documents, final reminder was issued on 5thMarch, 2018 to the firm with following shortcomings: -

1. Resignation / retirement of earlier Production Incharge.
2. Registration certificate from pharmacy council which is valid as of today.
3. All documents should be duly attested.

The firm has not replied to Final reminder and application for approval of Production Incharge is incomplete.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No.000075 by way of Formulation in the name of M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohlanwal, Lahore may not be suspended or cancelled by Central Licensing Board.

**Case No. 17 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FLOW PHARMACEUTICALS (PVT) LTD, LAHORE.**

M/s Flow Pharmaceuticals (Pvt) Ltd, 17-Km,Sheikhupura Road,, Lahore had applied for renewal of DML No. 000428 by way of formulation for the period of 26-03-2016 to 25-03-2021 on 28-03-2016.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 3rd October, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Change (s) in name of proprietor / director partner (if an change)
2. Detail of premises including layout plan and proof of section from CLB.
3. Latest Form 29 attested by S.E.C.P.
4. Approval letter of Production Incharge an QC Incharge.
5. Nothing due certificate regarding CRF from STO.

The firm did not submit their reply and again a letter dated 1st February, 2018 was issued to the firm with following shortcomings:

1. Due date of renewal application is 25-03-2016 and renewal application was received on 28-03-2016 which is 03 days late. According to Rule 6 of Drugs (L, R&A) rule 1976 the additional surcharge 5,000/- each day and total Rs. 15,000/- = (03X5000) should be deposited.
2. Form-29 at the time of previous renewal and latest Form-29 duly attested by S.E.C.P
3. Nothing due certificate regarding CRF from STO (R&D) DRAP, (Updated).
4. Approval letters of Production Incharge, and Quality Control Incharge if change, complete set of duly attested documents (As per checklist) alongwith prescribe fee of Rs-10,000/-
5. Detail of premises including copy of approved master layout plan.
6. Proof of sections approved by Central Licensing Board.
7. **All documents should be duly attested.**

The firm did not reply and final reminder dated 31st May, 2018 was issued to the firm with following shortcomings: -

1. Due date of renewal application is 25-03-2016 and renewal application was received on 28-03-2016 which is 03 days late. According to Rule 6 of Drugs (L, R&A) rule 1976 the additional surcharge 5,000/- each day and total Rs. 15,000/- = (03X5000) should be deposited.
2. Form-29 at the time of previous renewal and latest Form-29 duly attested by S.E.C.P
3. Nothing due certificate regarding CRF from STO (R&D) DRAP, (Updated).
4. Approval letters of Production Incharge, and Quality Control Incharge if change, complete set of duly attested documents (As per checklist) alongwith prescribe fee of Rs-10,000/-
5. Detail of premises including copy of approved master layout plan.
6. Proof of sections approved by Central Licensing Board.
7. **All documents should be duly attested.**

Reply of the firm is still awaited and application for renewal of DML is incomplete as of today.

Meanwhile, A copy of letter is received from Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab wherein he has informed that Provincial Quality Control Board has suspended the Drug Manufacturing License of M/s Flow Pharmaceuticals (Pvt) Ltd, Lahore, for 15 days w.e.f 17-9-2018 vide ordered dated 17th September, 2018 based on the inspection report (i.e. Inspection conducted on dated 5th July,2018)submitted by Drug inspector Industries, Lahore. The Board further decided to direct Drug Inspector industries to re-inspect the factory premises after 15 days to evaluate CAPA and remedial measures taken by the firm for further necessary action.

Orders of the Provincial Quality Control Board, Punjab marked as **Annex-I**.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A),Rule 5(6), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of DML No. 000428 by way of formulation of M/s Flow Pharmaceuticals (Pvt) Ltd, 17-Km,Sheikhupura Road,Lahore may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board. The Central Licensing Board also decided to seek updated report from PQCB on the matter pending before them.

**Case No. 18 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S BIO FINE PHARMACEUTICALS (PVT) LTD, MULTAN.**

M/s Bio Fine Pharmaceuticals (Pvt) Ltd, 74-Industrial Estate, Multan had applied for renewal of DML No. 000334 by way of formulation for the period of 19-07-2014 to 18-07-2019 on 09-07-2014.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 3rd November, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form – 29 from the S.E.C.P.
2. Details of Management / Directors / Partners of company.
3. Attested CNIC copies of all Management / Directors / Partners.
4. Approval letters of Quality Control / Production Incharge also mention (if any changes).
5. Any change in management / Directors / Partners also mention (if any changes) then documents for approval.
6. NOC for Central Research Fund.

The firm submitted their reply on 24th January, 2016 and final reminder dated 3rd May, 2018 was issued to the firm with following shortcomings: -

1. Nothing due certificate regarding CRF from STO (updated).
2. Updated Form-29 duly attested from S.E.C.P along with CNIC copies of all directors.
3. Prescribed fee of Rs.50,000/- for change ofthe management.
4. Proof of all sections issued by the Central Licensing Board.
5. All documents should be duly attested.

Reply of the firm is still awaited and application for renewal of DML is incomplete as of today.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000334 by way of formulation of M/s Bio Fine Pharmaceuticals (Pvt) Ltd,
74-Industrial Estate, Multan may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

**CASE NO. 19.RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S OBSONS PHARMACEUTICALS , LAHORE.**

**Case Background:**

The case was placed in 243rd meeting of CLB held on 9th September, 2015 as under: -

|  |  |  |  |
| --- | --- | --- | --- |
| **S No.** | **Name of the firm** | **Date of Inspection / Type of License** | **Decision of CLB** |
|  | M/s. Obsons Pharmaceuticals, 209-S, Industrial Estate, Kot Lakhpat, Lahore.DML No. 000416 (Formulation) | **04-06-2015**(Formulation) | **The Board was apprised of the back ground of the case and reply of the panel as under:****Background:** The case was previously considered in 242nd meeting of CLB held on 8th July, 2015.Previous recommendations of panel.As per current policy and the SRO No.470(1)/98, dated 15-05-1998 and schedule B to the Drug Act 1976, the firm does not full fill the requirement of area land i.e. of 2000 sq. yards so the panel of experts is not in a position to recommend the renewal of Drug Manufacturing License No. 000416 (by way of formulation) to M/s. Obsons Pharmaceuticals, 209-S, Industrial Estate, Kot Lakhpat, Lahore and suggests that the case may be referred to the Honorable Drug Licensing board for further decision in this regard the management may be directed to full fill the requirement of area as per SRO No.470(1)/98, dated 15-05-1998 within a shortest period of time. In the meantime, they may be allowed to carry on production at the present premises by maintaining the cGMP conditions. DML was granted to them before promulgation of SRO No.470(1)/98, dated 15-05-1998Decision of CLB of 242nd meeting held on Wednesday, 08th July, 2015Deferred the renewal of DML for want of following information from panel: 1. Rating of the firm with regard to inspection as same is not mentioned. 2- Deficient area/plot of the firm as same is not mentioned. 3- Compliance of GMP with regard to renewal of DML.The panel was conveyed above decision of CLB on 4th August, 2015. In reply the panel has furnished as under: -1. I have the honour to refer to DRAP, Islamabad letter No.F.1-84 (Vol-III), dated 04-08-2015 on the subject cited.
2. The panel inspection report of M/s Obsons Pharmaceutical (Pvt) Ltd, Lahore has already been sent to your good office vide this office letter No. 9319/2015-DRAP (Lic), dated 07-07-2015.
3. The detailed section wise evaluation proforma is attached herewith for ready reference, duly signed by the members of the panel.
4. So far as the plot size is concerned the firm has total land / area, 1295 sq. yards. However, as per SRO.470 (1)/98, dated 15-05-1998 Schedule B to the Drugs (Licensing, Registering & Advertising) Rules, 1976, the minimum area of 2,000 sq. yard is required. In this way, the firm is deficient of 705 sq. yards as per the requirement.
5. The firm fulfills the basic requirements for manufacturing of their registered products. As per GMP requirements, however, some points for further improvements were discussed with the management.

**Keeping in view the above situation, the Board decided and deferred the case for personal hearing of the firm. Board further directed that the firm shall be informed about the observations of inspection panel.** |

Accordingly, firm was called for personnel hearing before the Board, please.

Proceedings:

Mr. S.M. Naeemullah CEO M/s Obsons Pharmaceuticals appeared before the Board. He submitted that they were granted license in 1996 and subsequent renewals have been made from time to time. At present, firm have four sections having the prescribed area however the overall size of the plot is less than 2000 sq. yards as the license was granted before the promulgation of SRO 470(I)/98. Mr. Khurram Shahad Mughal representative of M/o Law, Justice and Human Rights, Islamabad informed the Board that it is mandatory to fulfill the conditions of SRO 470(I)/98 i.e. plot size should not be less than 2000 sq. yards. Mr. S.M. Naeemullah admitted the condition of 2000 sq. yards of plot size and submitted an undertaking to Board stating that they will arrange the required area as per SRO 470(I)/98 dated 15-05-1998 within the period of three years i.e. 30-12-2018.

Decision of CLB:

* In the light of undertaking by the firm that they will arrange the required area as per SRO 470(I) /98 dated 15-05-1998 with in the period of three years i.e. 13-12-2018, the Board approved the renewal of DML of the firm

Board further decided and directed the firm to develop new premises with plot size of not less than 2000 sq. yards as per given undertaking within 03 years.

M/s Obsons Pharmaceuticals209-S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore had applied for renewal of DML No. 000416 by way of formulation for the period of 17-08-2015 to 16-08-2020 on 05-08-2015.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 8th June, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Nothing due certificate regarding CRF
2. Detail of management / Partner / director and if any change
3. Copies of all directors CNIC (Attested)
4. Proof Sections From CLB
5. Approved layout plan of firm.

The firm did not reply to this letter.Meanwhile, the firm applied on 23rd May, 2016 for approval of Ms. Nadia Saeed Khan as Quality Control Incharge. Application was incomplete and a letter was issued on 30th November, 2016 for completion of application with following shortcomings.

1. Fee of 5000/- for proposed QC Incharge.
2. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
3. Undertaking as whole time employee.
4. All documents should be duly attested.

 The firm did not response to letter of shortcomings and filed a new application of Quality Control Incharge. Application of Mr. Muhammad Asim is received for approval as Production Incharge but application was incomplete and the firm was asked vide letter dated 28th December, 2017 for completion of application:

1. Prescribed fee of Rs. 5000/- retained from STO, DRAP, Islamabad.
2. Appointment letter and job acceptance letter.
3. Undertaking as whole time employee on stamp paper.
4. Resignation of appointee from previous firm.
5. All documents should be duly attested.

The firm, then, submitted documents of Proposed Production Incharge i.e. Mr. Muhammad Nadeem. Final Reminder dated 13th April, 2018 was issued with following shortcomings:

1. Updated Nothing due certificate regarding CRF from STO, DRAP, Islamabad.
2. Detail of management at the time of previous renewal and at present renewal, if any change, prescribed fee of Rs. 50,000/- for change of management.
3. Legal status of the applicant, if sole proprietor, Undertaking as sole proprietor on Stamp Paper. If Partnership firm, Copy of partnership deed and Form-C from Registrar of firms alongwith CNIC copies of owner/partners/Directors.
4. Copy of approved master layout plan.
5. Proof of CLB approved sections, if not available, apply for regularization of layout plan.
6. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of proposed Production Incharge (Not less than 10 years).
7. Resignation/retirement of earlier Production Incharge.
8. Prescribed fee of Rs.5000/- original challan retained from STO, DRAP, Islamabad (Quality Control Incharge).
9. Complete set of duly attested documents (as per checklist) for approval of proposed Quality Control Incharge.
10. All documents should be duly attested.

The firm submitted documents on 06-07-2018 in reply to reminder along with new application for approval of Production Incharge but following documents are still deficient in the application:

1. Prescribed fee of Rs. 50,000/- for change of management.
2. NOC from previous management.
3. Dissolution certificate of firm from registrar of firms.
4. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of proposed Quality Control Incharge (Not less than 10 years in relevant field).
5. Valid/ renewed Registration Certificate from Pharmacy Council (Quality Control Incharge& Production Incharge).
6. All documents should be duly attested.

Meanwhile, request for extension of time frame given to the firm for shifting of their existing unit in the light of SRO-470(1) /98.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) ,Rule 16, Rule 19 and Schedule B (Paragraph 1.3) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of DML No. 000416 by way of formulation of M/s Obsons Pharmaceuticals209-S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

**Case No. 20 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HARMANN PHARMACEUTICAL LABORATORIES (PVT) LTD, LAHORE**

M/s HarmannPharmaceutical Laboratories (Pvt) Ltd, Plot No. 569/570, Sunder Industrial Estate, Raiwind Road, Lahore had applied for renewal of DML No. 000145 by way of formulation for the period of 09-01-2016 to 08-01-2021 on 21-12-2015. The application for the renewal of DML of the firm was evaluated and a letter dated 27th December, 2017 for following shortcomings / deficiencies was issued to the firm under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Fee of Rs. 50,000/- for change of management as there seems to be change in management of the firm. The detail of which is as under:
2. Updated Form-29 and Form-A duly attested from S.E.C.P.
3. CNIC copies of all Directors of previous and current management.
4. Nothing due certificate regarding CRF from STO (Updated).
5. Prescribe fee of Rs.10, 000/- for proposed Production Incharge &Q.C Incharge.
6. Duly attested complete set of documents for approval of proposed Production Incharge.
7. Undertaking as whole time employee on stamp paper (Production Incharge and QC Incharge).
8. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976(Q.C Incharge).
9. Proof of sections approved by Central Licensing Board.

The firm submitted their reply on 22ndJanuary, 2018 After evaluation of the submitted documents, final reminder dated 25th May, 2018 was issued to the firm with following shortcomings: -

1. Fee of Rs. 50,000/- for change of management.
2. Updated Form-29 and Form-A duly attested from S.E.C.P.
3. CNIC copies of all Directors of previous and current management.
4. Nothing due certificate regarding CRF from STO (Updated).
5. Duly attested complete set of documents for approval of new Production Incharge& Quality Control Incharge (as per checklist) along with Prescribe fee of Rs.10, 000/-
6. All documents should be duly attested.

In the meanwhile, the firm applied for change of Production and Quality Control Incharge on 06-06-2018 and letter dated 06th June, 2018 of following shortcomings was issued to the firm:

1. Complete set of duly attested documents for Proposed Production Incharge and Quality Control Incharge as (per check list) along with prescribe fee of Rs. 10,000/-.

The firm submitted documents on 26th June, 2018 in reply to Final Reminder. Following documents are still deficient and application for renewal of DML is still incomplete.

1. Certified true copy of Latest Form-29& Form-A duly attested by SECP as the Forms submitted by the firm are not certified true copies.
2. Complete set of duly attested documents (as per checklist) of proposed Production Incharge along with prescribe fee of Rs.5000/-.
3. Duly attested appointment and job acceptance letter of proposed Q.C Incharge.
4. Duly attested Undertaking as whole time employee on Stamp paper of proposed Q.C Incharge.
5. Duly attested resignation / retirement of earlier Q.C Incharge.
6. Prescribe fee of Rs.5000/- for approval of proposed Q.C Incharge.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5(2A),Rule 5(6),Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of DML No. 000145 by way of formulation of M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, Plot No. 569/570, Sunder Industrial Estate, Raiwind Road, Lahore may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

**Case No. 21. CONVERSION OF UNIVERSITY OF SARGODHA PHARMACEUTICAL LABORATORIES INTO RESEARCH / TRAINING ENTITY ONLY.**

A Pharmaceutical industrial Unit (University of Sargodha Pharmaceutical Laboratories) was established by the University of Sargodha for commercial and research purpose and requisite license was attained from Drug Regulatory Authority of Pakistan, vide license No.000859, dated 21-06-2017 for the said purpose.

It is to inform you that the syndicate of the university of Sargodha in its 1/2018 meeting held on 12-05-2018 has declared Pharmaceutical Industrial Unit as Research entity only, in order to provide research opportunities to the student of university of Sargodha and to strengthen the research activities at UOS. Photocopy of notification is attached for reference.

Now, as per decision of the syndicate, the above Industrial Unit will be used only as “Research and Training Unit” for Pharmacy students and researchers, as well as other integrated disciplines. This Pharmaceutical Industrial Unit will not be run for commercial purpose.

1. This is for your kind information and subsequent necessary action in this regard please,
2. It is requested that kindly facilities in this regards according to the law and Licensing terms to run above unit as research and training only.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to call the firm for personal hearing in forthcoming meeting of the Central Licensing Board.

**CASE NO.22 REQUEST FOR ADDITIONAL SECTION OF M/S TAS PHARMACEUTICALS, ISLAMABAD.**

M/s TAS Pharmaceuticals, Islamabad, wherein the firm has informed that the panel recommends the Capsules General Section in his panel inspection dated 07-03-2011, but the section approval letter was not received till today. Now the firm has requested for issuance of section approval letter.

The Central Licensing Board in its 227th meeting held on 1st& 2nd June, 2011 approved the Capsule General Section of M/s. TAS Pharmaceuticals, Islamabad mentioned vide para 139/N. The issuance of letter was pending due to non availability of Nothing Due Certificate regarding deposition of CRF. Now the firm has submitted CRF upto 31-12-2017 and the above section is also present in inspection report conducted by panel dated 27-04-2018.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to issue the section approval letter for Capsule (General) Section in the name of M/s. TAS Pharmaceuticals, Islamabad under Drug Manufacturing License No. 000375 (Formulation).

**Case No. 23. GRANT OF DRUGS FOR RE-PACKING**

M/s Wellcare Pharmaceuticals, A-7 Punjab Small Industrial Estate, Sargodha, under Drug Manufacturing Licence No. 000465 by way of formulation has submitted Application for Grant of Re-packing drugs as per Schedule-D. Firm has submitted challan Fee of 5,000/ per product.

|  |  |  |
| --- | --- | --- |
| **Sr.No** | **Name of drugs for Repacking** | **Schedule-D** |
| 01 | Glycerin. | Yes |
| 02 | Liquid Paraffin | Yes |

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation approved the following repacking drugs in the name of M/s Wellcare Pharmaceuticals, A-7 Punjab Small Industrial Estate, Sargodha, under Drug Manufacturing Licence No. 000465 by way of formulation:

|  |  |
| --- | --- |
| **Sr.No** | **Name of drugs for Repacking** |
| 01 | Glycerin. |
| 02 | Liquid Paraffin |

**Case No. 24. NON DEPOSITION OF CRF SINCE 2010 BY M/S ZUMARS PHARMA, FTY. (PVT) LTD., KARACHI UNDER DML NO.000116 (FORMULATION)**

A letter was received from Director (B&A), DRAP, Islamabad wherein he had informed the Licensing Division that the CRF status of M/s Zumars Pharma, FTY, (Pvt) Ltd., Karachi is outstanding since
01-07-2010 till date in response, a letter dated 15-05-2018 was issued to the firm to submit no objection certificate (updated CRF) issued from Statistical Officer DRAP within fifteen days positively.

The firm has not submitted the no objection certificate (updated CRF) till date.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule12 and Rule 19(14) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the DML No. 000116 by way of formulation of M/s Zumars Pharma, FTY, (Pvt) Ltd., Karachi may not be suspended by Central Licensing Board.

**Case No. 25. APPROVAL OF MASTER LAYOUT PLAN / AUTHENTICATION /
REGULARIZATION OF EXISTING FACILITY, DRUG
MANUFACTURING LICENSE NO.000272 (FORMULATION) OF M/S SPENCER & COMPANY (PVT) LTD, D-105, S.I.T.E, KARACHI.**

M/s Spencer & Company (Pvt) Ltd, D-105, S.I.T.E, Karachi., DML No. 000272 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

|  |  |
| --- | --- |
| **Basement** | **Ground Floor** |
| 1. Raw Material Storage Area.
 | 1. Biological Products (rDNA Protein Products, Heparins, Monoclonal Antibodies) Section.
 |
| 1. Packing Material Store (Bio-Tech Products).
 | 1. Oral Liquid (Syrup/Suspension/Drop) (General / General Antibiotic) Section.
 |
| **Second Floor** | 1. Granulation / Pelletization / Taste Masking Area (General / General Antibiotic) Section.
 |
| 1. Liquid Injectable – SVP (General / General Antibiotic) Section.
 | 1. Liquid Injectable- LVP (General / General Antibiotic) Section.
 |
| 1. Quality Control Laboratory
 | 1. Packing Material Store.
 |
| 1. Tablets (Psychotropic) Section.
 | 1. R&D Laboratory.
 |
| 1. Capsules (Psychotropic) Section.
 | **First Floor** |
| 1. Liquid Injectable – SVP (Psychotropic) Section.
 | 1. Biological Products (Human Vaccines Killed / Concentrate & Antisera).
 |
| 1. Tablets (General / General Antibiotic) Section.
 | 1. Tablet (General / General Antibiotic) Section.
 |
| 1. Capsules (General / General Antibiotic) Section.
 | 1. Capsule (General / General Antibiotic) Section.
 |
| 1. Dry Powder Suspension (General / General Antibiotic) Section.
 | 1. Sachet (General / General Antibiotic) Section.
 |
| 1. Quality Control Laboratory (Biological Products).
 | 1. Liquid / Freeze Dried Injectable (General / General Antibiotic) Section.
 |
| **\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*** | 1. Quality Control Laboratory.
 |
| **\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*** | 1. Tablets (Hormone) Section.
 |
| **\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*** | 1. Gel / Cream / Ointment (General / General Antibiotic) Section.
 |

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

1. Mr. Syed Muied Ahmed, Member Central Licensing Borad.
2. Director DTL, Sindh Karachi. (**Not available**)
3. Director CDL, DRAP, Karachi
4. Area Federal Inspector of Drugs, DRAP, Karachi.

**Recommendations: -**

**Conclusion:-**

1. Firm has some penicillin, veterinary and Topical products which needs to be de-registered forthwith as no dedicated sections exist for them.
2. The available arrangements with the firm for production and quality control of their registered products needs massive up gradation / improvements especially in areas mentioned under pint no. 4 of Observations, for compliance with cGMP regulations.

**Recommendations:-**

1. Penicillin, Topical products and veterinary products registered in the name of the firm should be de-Registered forthwith as no dedicated sections exist for them.
2. Renewal of drugs manufacturing license (No. 000272 By way of Formulation) may be deferred till rectification of observations/ Improvements as identified by the panel. Renewal not recommended.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation did not approve the Regularization of the facility/sections of M/s Spencer & Company (Pvt) Ltd, D-105, S.I.T.E, Karachi., DML No. 000272 (Formulation) upon recommendations of the panel of experts.

**Case No. 26 REQUEST FOR CONVERSION OF SECTION FROM BIOTECH LYOPHILIZATION INTO GENERAL LYOPHILIZATION SECTION UNDER LICENSING NO. 000576 (FORMULATION).**

The Central licensing Board in its 225th meeting held on 22nd October, 2010 approved the Biotech Lyophilization section. Now M/s Neutro Pharma (Pvt) Ltd, 9.5-Km, Sheikhupura Road, Lahore had applied for conversion of Biotech Lyophilization into **General Lyophilization Section.**

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board deliberated that the Biotech Lyophilization section is more sophisticated facility than General section, it already inspected by the panel of experts and firm does not have any registered Biotech product. The Board after considering the facts and decided to grant the conversion of Biotech Lyophilization into **General Lyophilization Section**

**CASE NO.27 CORRECTION IN THE NAME OF PELLETS OF M/S VISION PHARMACEUTICALS (PVT) LTD., ISLAMABAD.**

Mr. Babar Khan, FID-I, DRAP, Islamabad wherein he has informed that M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad for manufacturing of following APIs inadvertently words “Taste Masked Pellets” have been missed in the table mentioned in the inspection report conducted on 9th& 19th July, 2018 as per detail below:-

|  |  |  |
| --- | --- | --- |
| **S. No.** | **Name of Pellets as appeared in the inspection report.** | **Correct name of Pellets in the inspection report.** |
| 1. | Linezolid | Linezolid Taste Masked Pellets |
| 2. | Paracetamol. | Paracetamol Taste Masked Pellets. |
| 3. | Famotidine. | Famotidine Taste Masked Pellets. |

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to approve the correction name of pallets of M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad of following pallets.

|  |  |  |
| --- | --- | --- |
| **S. No.** | **Name of Pellets as appeared in the inspection report.** | **Correct name of Pellets in the inspection report.** |
| 1. | Linezolid | Linezolid Taste Masked Pellets |
| 2. | Paracetamol. | Paracetamol Taste Masked Pellets. |
| 3. | Famotidine. | Famotidine Taste Masked Pellets. |

**CASE NO.28 REGULARIZATION / AMENDMENT OF REVISED LAYOUT PLAN OF M/S ICI PAKISTAN LTD, KARACHI .**

M/s ICI Pakistan Ltd, Karachi., DML No. 000006 (Formulation), has applied for regularization of layout plan of running facility for their existing sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory:

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

1. Mr. Syed Muied Ahmed, Member Central Licensing Board.
2. Director DTL, Sindh Karachi.
3. Mr. Najam-us-Saqib, Additional Director (E&M), DRAP, Karachi
4. Area Federal Inspector of Drugs, DRAP, Karachi.

Accordingly, Panel has inspected the premises and verified the below mentioned section.

**Recommendations: -**

Licensed Finished Goods Facility is located at plot no. C opposite gate no. 2 N., truck Stand, Hawksbay road, Karachi.

Keeping in view the layout of the firm as approved by the DRAP, Panel recommends the regularization of layout plan.

1. Tablet (General) Section.
2. Tazocin / Bulk Packaging Section.
3. Packaging Material Store (General).
4. Quality Control Lab.
5. Liquid Syrup (General) Section.
6. Raw Material Store (General).

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to approve the Regularization of following sections/facilities of M/s ICI Pakistan Ltd, Karachi., DML No. 000006 (Formulation) :

1. Tablet (General) Section.
2. Tazocin / Bulk Packaging Section.
3. Packaging Material Store (General).
4. Quality Control Lab.
5. Liquid Syrup (General) Section.
6. Raw Material Store (General).

The Board also decided to seek clarification from the firm regarding Licensed Finished Goods Facility located at plot no. C opposite gate no. 2 N., truck Stand, Hawksbay road, Karachi.

**Case No.29 APPROVAL OF MASTER LAYOUT PLAN / AUTHENTICATION /
REGULARIZATION OF EXISTING FACILITY, UNDER DRUG
MANUFACTURING LICENSE NO. 000746(FORMULATION) OF M/S APEX PHARMACEUTICALS (PVT) LTD Plot No.D-21-A/1, S.I.T.E., SUPER HIGHWAY,KARACHI.**

M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachi. DML No. 000746 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were licensed before the promulgation of S.R.O. 470/98 dated
15th May 1998 when approval of layout plan was not mandatory: -

* + - 1. Capsule Section (Cephalosporin)
			2. Dry Powder Suspension (Cephalosporin)
			3. Tablet Section (General)
			4. Capsule Section (General)
			5. Quality Control Laboratory
			6. Raw Material Store
			7. Packaging Material Store
			8. Raw Material Store

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

1. Dr. Abdullah Dayo, Member CLB.
2. Dr. Saif-ur-Rehman, Director CDL, Karachi.
3. Mr. Abdul Rasool Sheikh, FID, DRAP, Karachi.

Accordingly, Panel has inspected the premises and verified the above mentioned section.

**Recommendations: -**

The panel conducted inspection on 08-08-2018 and noted following observations;

**Observations**:

1. During inspection the panel came to know that the firm had been granted DML No. 000746 (Formulation) in the year 2012 and in the subsequent years the firm got almost 16 registrations in all four approved sections that are Tablet (General), Capsule (General), Capsule (Cephalosporin) and Dry Powder Suspension (Cephalosporin).
2. The panel observed that firm had not manufactured a single batch of any of their registered products. The in complete documents were shown purporting the only trial batch of Cefixime manufacturing during past six years.
3. The panel observed the unit under inoperable conditions and management was of the view that due to high operational cost and limited number of registrations they were unable to start it for commercial purpose.
4. The panel observed that the firm had relocated some of their storage areas and provided HVAC aimlessly in those sections. The additional section of Cream/Ointment was noted incomplete during inspection.
5. It was very difficult for the panel to asses their current GMP compliance lever amid such inactive conditions although firm possesses sufficient number of registrations and could have started production to meet the national regulatory requirements.

**Conclusion.**

Based on the above observations the panel decided to defer the grant of renewal of their DML, grant of additional section of Cream/Ointment and regularization of their existing LOP. Panel further requests the board concerned to see the current inactive status of their DML under DRAP Act, 2012/Drug Act, 1976.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation did not approve the Regularization of the facility/sections of M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachi. DML No. 000746 (Formulation) upon recommendations of the panel of experts.

**CASE NO.30 REGULARIZATION / AMENDMENT OF REVISED LAYOUT PLAN OF M/S WERRICK PHARMACEUTICALS.**

Miss Mahvash Ansari, FID-IV, DRAP, Islamabad wherein she has submitted inspection report for regularization / amendment of revised layout plan of M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad for following sections;

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

The conclusion of inspection report is as under:-

“Panel verified the establishment of sections as per approved layout plan for the manufacturing, Keeping in view the above, the panel unanimously recommend for the Regularization / Amendment of revised layout plan as of today”.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation approve the Regularization of following facility/sections M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad DML No. 000340 (Formulation) upon recommendations of the panel of experts.

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

**Case No. 31 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S T.G PHARMA, KARACHI**

M/s T.G Pharma, E-30, Sector 15, Korangi Industrial Area, Karachi had applied for renewal of DML No. 000547 by way of formulation for the period of 24-07-2014 to 23-07-2019 on 23-07-2014.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 23rd February, 2016 and 2nd March, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Proper application on Form-IA on firm’s letter head dully signed / stamp by CEO of firm.
2. No Objection Certificate for Central Research Fund (CRF) (updated) issued by Statistical Officer DRAP, Islamabad
3. Legal status of the firm along with details of ownership, attested copies of CNIC’s.
4. List of total section of the firm and their letters of approval which were issued by Central Licensing Board.
5. Approval letter of QC Incharge and Production Incharge if (not available) then provide complete documents of technical persons i.e QC Incharge and Production Incharge according to checklist (enclosed).

Firm did not submit the shortcoming documents and a Final Reminder letter was issued on 10th July, 2017 under Rule 5{2A} of Drugs (Licensing, Registering & Advertising) Rules, 1976 of following shortcomings.

1. Proper application on Form-IA on firm’s letter head dully signed / stamp by CEO of firm.
2. Nothing due certificate regarding CRF from STO (Updated).
3. Legal status of the firm along with details of ownership, attested copies of CNIC’s. .
4. Approval letters of sections issued by the Central Licensing Board
5. Approval letter of proposed Quality Control Incharge and Production Incharge, if any change then provide set of duly attested documents for Proposed Quality Control Incharge and Production Incharge (as per check list) along with prescribe fee.
6. Documents should be duly attested.

**Proceedings and Decision of Central Licensing Board in 256thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s T.G Pharma, E-30, Sector 15, Korangi Industrial Area, Karachi Drug Manufacturing Licence No. 000547 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**

The Show Cause notice dated 05th January, 2018 was issued to the M/s T.G Pharma, E-30, Sector 15, Korangi Industrial Area, Karachi.

No reply of the show cause notice is received from the firm.

**A letter of Personal hearing has been issued on 17th January, 2018**

**Proceedings and Decision of Central Licensing Board in 257thmeeting**

No person appeared on behalf of the firm. The Board decided to defer the case for giving one more opportunity and service of notice through Federal Inspector of Drugs.

**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**

Firm submitted documents on 2nd February, 2018 in reply to personal hearing letter dated 17th January, 2018 but following documents are still deficient /short and application for renewal of DML is still incomplete.

1. Nothing due certificate regarding CRF from STO (Updated).
2. Legal status of the firm either Sole proprietor / Partnership firm at this renewal and at time of previous renewal alongwith attested CNIC copies of all partners / owners.
3. Approval letter of all section issued by CLB or if not available then submitted layout plan for regularization.
4. Approval letter of proposed Quality Control Incharge and Production Incharge, if any change then provide complete set of duly attested documents for Proposed Quality Control Incharge and Production Incharge (as per check list) along with prescribe fee.

 A letter of Personal hearing has been issued

**Proceedings and Decision of Central Licensing Board in 259thmeeting**

Dr. Waseem Siddiqui appeared before the Board. He contested that documents regarding CRF is submitted with concerned Division. However, he could not satisfy the Board regarding the deficient documents. The Board after hearing the representative of the firm and considering the facts on the record and after thread bare deliberation decided to suspend the Drug Manufacturing Licence No. 000547 by way of formulation issued in the name of M/s T.G Pharma, E-30, Sector 15, Korangi Industrial Area, Karachi 000547 till settlement of codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16, Rule, 19 and Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. If the firm completes the codal formalities, the Chairman Central Licensing Board shall pass an order for revocation of suspension. However, case would be brought before Central Licensing Board in forthcoming meeting for endorsement of decision taken by the Chairman.

The firm submitted the required documents and application for renewal of DML was complete. Therefore, as the firm completed all the codal formalities, the Chairman Central Licensing Board passed an order for revocation of suspension orders on 20-12-2018 as authorize the Central Licensing Board .

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board ratified the decision taken by the Chairman Central Licensing Board.