**MINUTES OF 279th MEETING OF CENTRAL LICENSING BOARD HELD ON FEBRUARY 18, 2021**

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279thmeeting of the Central Licensing Board (CLB) was held on 18th February,2021 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad. Mr.Akhtar Abbas, Representative Division of Quality Assurance and Laboratory Testing Division/Member Central Licensing Board, Drug Regulatory Authority of Pakistan, Islamabad presided the meeting in the absence of Chairman as provided under Rule 8(8) of the Drugs (Licensing, Registering & Advertising) Rules, 1976. Following members attended the meeting:-

| S.No | Name & Designation | Status |
|---|---|---|
| 1. | Mr. Abid Ali, Law Expert, Ministry of Law & Justice Division, Islamabad | Member |
| 2. | Mr. Azhar Jamal Saleemi, Chief Drug Controller, Primary and Secondary Health Department, Government of Punjab, Lahore | Member |
| 3. | Mr. Muhammad Shoaib Ansari, Chief Inspector of Drugs, Government of Sindh, Karachi | Member |
| 4. | Mr. Zahid Khan, Chief Drug Inspector Peshawar, Govt of KPK, Peshawar. | Member |
| 5. | Mr. Manzoor Ali Bozdar, Addl Director, Drug Regulatory Authority of Pakistan, Islamabad | Secretary/ Member |
| 6. | Mr. Saboor Ahmad, Representative of PPMA. | Observer |
| 7. | Mr. Uzair Nagra, Representative of PPMA. | Observer |
| 8. | Ms. Atif Iqbal, Representative, PCDA | Observer |
| 9. | Mr.Nadeem Alamgir Representative of Pharma Bureau. | Observer |

The meeting started with the recitation of Holy verses. The Chairperson 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 thereof. The Central Licensing Board discussed and decided that initial draft minutes of the meeting would be prepared by concerned sections of Divisions and counter verified by the Secretary, Central Licensing Board before submitting to the members of the Board for perusal and concurrence. Secretary Licensing Board presented the agenda before the Board. Mr. Muhammad Asad Malik, Deputy Director (Licensing), Mr. Muhammad Usman, AD (Lic), Mr. Abdullah Bangash, AD (Lic), Ms. Zunaira Faryad, AD (Lic), Ms. Haleema Shareef AD (Lic), Mr. Sanaullah Babar, AD (QC) assisted the Secretary Central Licensing Board in presenting the agenda.

## DRUG LICENSING DIVISION

**Item-I** **CONFIRMATION OF THE MINUTES OF 278th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 278th meeting of the Central Licensing Board (CLB) which was held on 10-11th December, 2020.

## 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.

| S # | Name of the firm | Date of Inspection / Type of License | Ranking/ Evaluation | Inspection Panel Members |
|---|---|---|---|---|
| 1. | M/s Lakhani Pharma (Pvt) Ltd, Sheikh Zayed Road, Rahim Yar Khan.<br><br>**Section (01):**<br>i. IV Infusion Section | **03-02-2021** | **Good** | 1) Mr. Zakaur Rehman, Govt. of Punjab.<br>2) Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.<br>3) Mr. Shahrukh Ali, Assistant Director, DRAP, Lahore. |
| | **Recommendations of the panel:**<br>*"Keeping in the view the manufacturing facilities present in the unit, the members of the panel* ***recommends*** *the grant of New Drug Manufacturing Licensing to M/s. Lakhani Pharma (Pvt.) Ltd. Situated at Sheikh Zayed Road, Rahim Yar Khan for the following section only":-*<br>*i. IV Infusion Section."*<br>**Decision of the Central Licensing Board in 279th meeting**<br>The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Lakhani Pharma (Pvt) Ltd, Sheikh Zayed Road, Rahim Yar Khan. (By way of Formulation) on the recommendations of the panel of experts for the following section:<br>**Section (01):**<br>i. IV Infusion Section | | | |

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

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

| S # | Name of the firm | Date of Inspection / Type of License | Ranking/ Evaluation | Inspection Panel Members |
|---|---|---|---|---|
| 1. | M/s Citi Pharma (Pvt) Ltd,<br>3-Km, Head Balloki Road, Bhai Pheru, District Kasur.<br><br>DML No. 000512 (Formulation)<br><br>**Section (01)**<br>i. Tablet (Psychotropic) Section. | **16-12-2020** | **Good** | 1) Dr. Farzana Chaudhary, Expert Member.<br>2) Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.<br>3) Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore. |
| | **Recommendations of the panel:**<br>"Panel has thoroughly inspected the unit, evaluated the documents shown by the firm and discussed various technical aspects in detail. Details of equipments of Production and Quality Control departments and list of technical staff duly signed by the firm members are attached with this report for perusal of Central Licensing Board.<br>On the basis of depiction mentioned above, documentations revealed and submitted by the firm, physical panel inspection of the unit, panel has unanimously **recommended** the facility added by M/s Citi Pharma (Pvt) Ltd,3-Km, Head Balloki Road, Bhai Pheru, Kasur for grant of Tablet (Psychotropic) Section under Drug Manufacturing License No. 000512 (Formulation)."<br>**Decision of the Central Licensing Board in 279th meeting**<br>The Board considered and approved the grant of following new section in the name of M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, Bhai Pheru, District Kasur. under DML No. 000512 (Formulation) on the recommendations of the panel of experts;<br>**Sections/Facility (01)**<br>i. Tablet (Psychotropic) Section- New | | | |
| 2. | M/s. Mafins Pharma, Plot No. A-5, S.I.T.E. Super Highway Industrial Area, Karachi.<br><br>DML No. 000820 (Formulation)<br><br>**Section (01):**<br>i. Dry Powder Syrup (General) - New | **29-01-2021** | **Good** | 1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi<br>2) Additional Director (E&M), DRAP, Karachi.<br>3) Area FID, DRAP, Karachi. |

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| | ***Recommendation of panel :***<br>*"Keeping in view the above stated facts, documents reviewed personnel met and attitude of the management towards constant improvements the panel unanimously* ***recommends*** *the grant of renewal of their DML No. 000820 (Formulation) for the next five years from and panel also recommends the grant of additional section of Dry Powder Syrup (General)."*<br>**Decision of the Central Licensing Board in 279th meeting**<br>The Board considered and approved the grant of following new section in the name of M/s Mafins Pharma,Plot No. A-5, S.I.T.E. Super Highway Industrial Area,Karachi.under DML No. 000820 (Formulation) on the recommendations of the panel of experts;<br>i. Dry Powder Syrup (General) - New | | | |
| 3. | M/s Aspin Pharma (Pvt) Ltd,Plot No. 10 & 25, Sector 20, Korangi Industrial Area,Karachi.<br><br>DML No. 000045 (Formulation)<br><br>**Sections/Facility (04)**<br>i. Ointment/Cream/Gel (General) – Revised.<br>ii. Research & Development Laboratory – Revised.<br>iii. Ware House – Revised.<br>iv. Quality Control Laboratory- Revised Regularization | **26-01-2021** | **Good** | 1) Additional Director (E&M)/Area FID, DRAP, Karachi.<br>2) Area FID, DRAP, Karachi.<br>3) Affan Ali, Assistant Director CDL, Karachi. |
| | **Recommendation of panel:**<br>"Keeping in view the above stated facts, people met and documents reviewed during detail inspection of the facility, the panel unanimously **recommends** the grant of renewal of their DML No. 000045 for the next five years commencing from31-03- 2020 and also recommends the approval of changes made in the facilities as per approved layout."<br>**Decision of the Central Licensing Board in 279th meeting**<br>The Board considered and approved the grant of following sections/facilities in the name of M/s Aspin Pharma (Pvt) Ltd**,** Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi. under DML No. 000045 (Formulation) on the recommendations of the panel of experts;<br>i. Ointment/Cream/Gel (General) – Revised.<br>ii. Research & Development Laboratory – Revised.<br>iii. Ware House – Revised.<br>iv. Quality Control Laboratory- Revised Regularization | | | |
| 4. | M/s Atco Laboratories Limited, Plot No. B-18, S.I.T.E, Karachi.<br><br>DML No. 000188(Formulation).<br><br>**Sections(04):** | **05-01-2021** | **Good** | 1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi<br>2) Mr. Awais Ahmed, Area FID, Karachi.<br>3) Ms. Mahrukh Mughal, AD, CDL, Karachi. |

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| | i. Cream/Ointment (General) Section- **Revised**. Ground Floor.<br>ii. Gel(General) Section- **Relocated from 2nd floor to ground floor.**<br>iii. Lotion(General) Section- **Revised**. Second Floor<br>iv. Cream/Ointment (General) Section- **Second Floor- Revised**. | | | |
| | **Recommendations of the panel: -**<br>"The firm has provided all required equipments, machinery, utilities, staff etc. At the time of the inspection all relevant documents, SOP were available. The utilities, HVAC, water treatment were found well maintained. Keeping in view above mentioned facts, the panel unanimously **recommends** the grant the approval of additional sections of M/s Atco Laboratoreis, Plot No. B-18, SITE Karachi of following sections:-<br>1. Cream/Ointment Section (General)-Revised-Ground Floor<br>2. Gel Section (General) - Relocated from 2nd to ground Floor<br>3. Cream/Ointment Section (General)-Second Floor. Revised<br>4. Lotion section (General)-Second Floor. Revised<br>Furthermore, panel is advised to perform the risk assessment for Technology transfer from old building to new area. Firm is also advised to enhance training program for QC analyst and warehouse staff regarding their routine activities."<br>**Decision of the Central Licensing Board in 279th meeting**<br>The Board considered and approved the grant of following sections in the name of M/s Atco Laboratories Limited, Plot No. B-18, S.I.T.E, Karachi under DML No. 000188 (Formulation) on the recommendations of the panel of experts for following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;<br>i. Cream/Ointment (General) Section- **Revised**. Ground Floor.<br>ii.Gel(General) Section- **Relocated from 2nd floor to ground floor.**<br>iii.Lotion(General) Section- **Revised**. Second Floor<br>iv. Cream/Ointment (General) Section- **Second Floor- Revised**. | | | |
| 5. | M/s. Medicaids Pakistan (Pvt) Ltd, Plot No. 10, Sector 27, Korangi Industrial Area, Karachi<br><br>DML No. 000139 (Formulation)<br>**Sections for inspection:**<br>1. Dry Powder Injection (Cephalosporin)- **New.** | **14-01-2021** | **Good** | 1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi<br>2) Chief Drug Inspector, Sindh.<br>3) Area FID, Karachi. |
| | **Recommendations of the panel:**<br>"Panel inspected the firm in detail and observed that the manufacturing sections, Q.C Lab, | | | |

Water Treatment Plant, Quality Assurance System etc and critical documents Processes, SOPs and BMRs followed the written procedures, in general. The firm is built as per layout plan approved by the DRAP authorities Islamabad (Annex-Q). HVAC System seen installed and observed operational in all the production sections. The firm is exporting products to Afghanistan and Philippines and registration for the purpose of export is in process in various countries as well.

Based on the people met, documents reviewed and observation made during the inspection, panel recommends the renewal of DML and regularization for the sections as mentioned in the aforementioned DRAP letter. The sections are summarized below."

| Sr.# | Name of Sections | Sr.# | Name of Sections |
|---|---|---|---|
| i. | Capsule (General) | ii. | Sterile Ophthalmic Drops (General) |
| iii. | Liquid Syrup (General) | iv. | Dry Powder Suspension (Cephalosporin_) |
| v. | Dry Powder Suspension (General) | vi. | Tablet (Cephalosporin) |
| vii. | Liquid Injectable (General) | viii. | Capsule (Cephalosporin) |
| ix. | Dry Powder Injection (General) – SVP | x. | Sterile Dry Powder Injection (Cephalosporin) - **New** |
| xi. | Tablet (General) | xii. | ********** |

**Decision of the Central Licensing Board in 279th meeting**

The Board considered and approved the grant of following new section in the name of M/s Medicaids Pakistan (Pvt) Ltd, Plot No. 10, Sector 27, Korangi Industrial Area, Karachi under DML No. 000139 (Formulation) on the recommendations of the panel of experts;

i. Dry Powder Injection (Cephalosporin)- **New.**

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| 6. | M/s. Ciba Pharmaceuticals (Pvt) Ltd, A-371, Nooriabad, SITE, District Jamshoro<br><br>DML No. 000825 (Formulation)<br>**Sections/Facility (04)**<br><br>**i.** Ointment/Cream/Gel (General)-**Revised**<br>**ii.** Capsule Section-**Revised**<br>**iii.** Quality Control Laboratory-**Revised**<br>**iv.** Raw Material Store-**Revised** | **13-01-2021** | **Good** | 1) Muhammad Shoaib Ansari, Chief Drug Inspector Sindh<br>2) Syed Hakim Masood, Area, FID, DRAP, Karachi<br>3) Mahrukh Mughal, AD, CDL, Karachi |

**Recommendations of the panel:**

"M/s CIBA Pharmaceuticals (Pvt) Ltd, A-371, SITE Nooriabad District Jamshoro was inspected by the panel on 13-01-2021 as per directions contained in DRAP reference letter No. F.2-10/2006-Lic(Vol-I) for the purpose of renewal of DML No. 000825 (formulation). Following are the observations and recommendation of the panel members:

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<td colspan="4">
The firm is build/constructed as per approved layout plan/amendments vide DRAP Islamabad letter No. F. 2-10/2006-Lic (Vol-I), dated 21st December, 2020. The facility is provided with necessary amenities and other required services/utilities. The firm has installed necessary equipments and machinery in each section required for manufacturing and testing of registered products. The relevant documents of qualification and validation were reviewed and found satisfactorily maintained. Methods are validated/verified as per SOP. Certain documentation regarding analysis of raw materials and finished products were also reviewed and found acceptable. SOPs for market complaint, recalls trainings, OOS, change control management, market returns self-inspection. HVAC System is provided in each section was observed operational.<br><br>
Based on the above observations, documents reviewed personal met and commitment of the management for continuous up-gradation and intention for export of products to various countries, the panel recommends the grant of renewal of their DML No. 000825 (by way of formulation) and amendments in for following sections:
<table>
<tr><td>S.No.</td><td>Name of Sections</td><td>S.No.</td><td>Name of Sections</td></tr>
<tr><td>i.</td><td>Tablet (General)</td><td>ii.</td><td>Sachet(General)</td></tr>
<tr><td>iii.</td><td>Capsule (General)</td><td>iv.</td><td>Ointment/Cream/Gel(Steroid)</td></tr>
<tr><td>v.</td><td>Ointment/Cream/Gel(General)</td><td>vi.</td><td>Dry Powder Suspension (General)</td></tr>
<tr><td>vii.</td><td>Ointment/Cream/Gel (General)-Revised</td><td>viii.</td><td>Quality Control Laboratory-Revised</td></tr>
<tr><td>ix.</td><td>Capsule Section-Revised</td><td>x.</td><td>Raw Material Store-Revised</td></tr>
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<br>
<u>Decision of the Central Licensing Board in 279th meeting</u><br><br>
The Board considered and approved the grant of following revised sections /facility in the name M/s Ciba Pharmaceuticals (Pvt) Ltd, A-371, Nooriabad, SITE, District Jamshoro. under DML No. 000825 (Formulation) on the recommendations of the panel of experts;<br>
i. Ointment/Cream/Gel (General)-Revised<br>
ii. Capsule Section-Revised<br>
iii. Quality Control Laboratory-Revised<br>
iv. Raw Material Store-Revised
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<td>7.</td>
<td>M/s Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.<br><br>DML No. 000651 (Formulation)<br><br><u>Sections/Facility (06).</u><br>i. Conversion from Cream/Ointment to Ceram/Oitnment/Lotion (Preparation & Filling)<br>ii. Gel (Preparation & Filling)<br>iii. R&D Facility.<br>iv. Relocation/extension of Stores</td>
<td>16-01-2021</td>
<td>Good</td>
<td>1) Deputy Director QA/LT, DRAP, Islamabad.<br>2) Area Federal Inspector of Drugs, DRAP, Islamabad.</td>
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| | (Raw/Packaging/Finished)<br>v. Relocation of Male/Female Change Rooms<br>vi. Relocation/Extension of Blister/Packing Halls | | | |

**Recommendations of the panel: -**

Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended the approval**of additional (new)/amended sections of Rotex Pharma (Pvt) Ltd., Plot #206-207, Industrial Triangle, Kahuta Road, Islamabad as per approved layout plan;

| Additional sections | Amended Sections |
|---|---|
| i. Conversion from Cream/Ointment to Ceram/Oitnment/Lotion (Preparation & Filling)<br>ii. Gel (Preparation & Filling)<br>iii. R&D Facility. | iv. Relocation/extension of Stores (Raw/Packaging/Finished)<br>v. Relocation of Male/Female Change Rooms<br>vi. Relocation/Extension of Blister/Packing Halls |

**Decision of the Central Licensing Board in 279th meeting**

The Board considered and approved the grant of following sections /facility in the name 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;

| Additional sections | Amended Sections |
|---|---|
| i. Conversion from Cream/Ointment to Ceram/Ointment/Lotion (Preparation & Filling)<br>ii. Gel (Preparation & Filling)<br>iii. R&D Facility. | i. Relocation/extension of Stores (Raw/Packaging/Finished)<br>ii. Relocation of Male/Female Change Rooms<br>iii. Relocation/Extension of Blister/Packing Halls |

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| 8. | M/s Jaskan Pharmaceuticals (Pvt) Ltd, Plot No. 50, Sunder Industrial Estate, Lahore.<br><br>DML No. 000796 (Formulation)<br><br>**Section/Facility (07)**<br>i. Warehouse (Revised)<br>ii. Change Rooms (Amendments).<br>iii. Packing Hall (Cephalosporin Section) (Revised).<br>iv. Injectable (Ampoule) | **26-10-2020** | **Good** | 1) Dr. Farzana Chaudhary, Expert Member.<br>2) Mr. Zakaur Rehman, Govt. of Punjab.<br>3) Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore. |

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| | (General) Section (New) (Amendments)<br>v. Injectable (Vial) (General) Section (New) (Amendments).<br>vi. Dry Powder for Injection (Cephalosporin) (New).<br>vii. Dry Powder for Suspension (Cephalosporin) (New). | | | |

**Recommendations of the panel:**

"Keeping in view the facilities like building, HVAC System, Purified water, other utilities, production machinery & equipments, personnel, documentation, quality control instruments and testing facilities, the panel of inspectors was of the opinion to **recommend** the renewal of Drug Manufacturing License and grant of additional and amended section to M/s. Jaskan Pharmaceutical (Pvt) Ltd, Plot No. 50 Sunder Industrial estate, Lahore for the following sections: -

i. Tablet Section (General)
ii. Capsule Section (General)
iii. Sachet Section (General)
iv. Oral Dry Powder Suspension Section (General) Revised

**Additional / Amended / Revised Section**

i. Warehouse (Revised)
ii. Change Rooms (Amendments).
iii. Packing Hall (Cephalosporin Section) (Revised).
iv. Injectable (Ampoule) (General) Section (New) (Amendments)
v. Injectable (Vial) (General) Section (New) (Amendments).
vi. Dry Powder for Injection (Cephalosporin) (New).
vii. Dry Powder for Suspension (Cephalosporin) (New)."

**Decision of the Central Licensing Board in 279th meeting**

The Board considered and approved the grant of following sections /facility in the name M/s Jaskan Pharmaceuticals (Pvt) Ltd, Plot No. 50, Sunder Industrial Estate, Lahoreunder DML No. 000796 (Formulation) on the recommendations of the panel of experts;

i. Warehouse (Revised)
ii. Change Rooms (Amendments).
iii. Packing Hall (Cephalosporin Section) (Revised).
iv. Injectable (Ampoule) (General) Section (New) (Amendments)
v. Injectable (Vial) (General) Section (New) (Amendments).

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| | vi. Dry Powder for Injection (Cephalosporin) (New).<br>vii. Dry Powder for Suspension (Cephalosporin) (New). | | | |
| 9. | M/s Attabak Pharmaceuticals Industries, 5C, I-10/3, Industrial Area, Islamabad.<br>DML No.000552 (Formulation)<br>**Name of Sections (06).**<br>1. Veterinary Bolus Section (General) **New.**<br>2. Veterinary Warehouses (Penicillin) **New.**<br>3. Veterinary Liquid Vials Inject-able (Penicillin) **New.**<br>4. Veterinary Dry Powder Injectable (Penicillin) **New.**<br>5. Oral Powder (Penicillin) **New.**<br>6. Q.C Laboratory **New.** | **08-02-2021** | **Good** | i. Prof. Dr. Gul Majeed, Member CLB.<br>ii. Mr. Abdullah, Additional Director (PE&R), DRAP, Islamabad.<br>iii. Area Federal Inspector of Drugs, DRAP, Islamabad. |
| | **Recommendations of the panel:**<br>"Keeping in view the improvement made by the firm w.r.t. their previous inspection majority of major shortcomings were addressed; the firm further assured the panelof Inspectors that they will addressed to the above mentioned week points in near future. The panel is of the view to **recommend** the grant of renewal and **additional sections (as per approved layout plan)**."<br>**Decision of the Central Licensing Board in 279th meeting**<br>The Board considered and approved the grant of following additional sections /facility in the name M/s Attabak Pharmaceuticals Industries, 5C, I-10/3, Industrial Area, Islamabadunder DML No. 000552 (Formulation) on the recommendations of the panel of experts;<br>i. Veterinary Bolus Section (General) **New.**<br>ii. Veterinary Warehouses (Penicillin) **New.**<br>iii. Veterinary Liquid Vials Inject-able (Penicillin) **New.**<br>iv. Veterinary Dry Powder Injectable (Penicillin) **New.**<br>v. Oral Powder (Penicillin) **New.**<br>vi. Q.C Laboratory **New.** | | | |
| 10. | M/s Agror Pharma (Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat.<br>DML No. 000791 (Formulation)<br>**Section (04)**<br>i. Tablet Section (General).<br>ii. Capsule Section (General).<br>iii. Cream / Ointment / Gel (General).<br>iv. Sachet Section (General). | **03-01-2021 & 04-01-2021** | **Good** | 1) Dr. Hafsa Karam Elahi, Additional Director (QA& Lt-1), DRAP, Islamabad.<br>2) Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad.<br>3) Ms. Mehwish Tanveer, AD (QC),DRAP, Islamabad. |

**Recommendations of the panel:**

"Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the approval of the following 04 new additional & renewal (for the exiting 03 sections) of DML No. 000791 of M/s. Agror Pharma (Pvt) Ltd, Plot No. 04, Street No. SS-4, National Industrial Zone, Rawat, (the detailed report is attached herewith):-

**Existing Sections:**

1. Capsule Section (Cephalosporin).
2. Dry Powder Injection Section (Cephalosporin).
3. Dry Powder Suspension Section (Cephalosporin).

**New Sections:**

1. Tablet Section (General).
2. Capsule Section (General).
3. Cream / Ointment / Gel (General).
4. Sachet Section (General).

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and approved the grant of following additional sections /facility in the name of M/s Agror Pharma (Pvt) Ltd, Plot No. 04, Street No. SS-4, National Industrial Zone, Rawat under DML No. 000791 (Formulation) on the recommendations of the panel of experts;

i. Tablet Section (General)-**New**
ii. Capsule Section (General)-**New**
iii. Cream / Ointment / Gel (General)- **New**
iv. Sachet Section (General)-**New**

**Item-IV**: **GRANT OF RENEWAL OF DML.**

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.

| S # | Name of the firm | **Date of Inspection / Type of License** | **Ranking/ Evaluation** | Inspection Panel Members |
|---|---|---|---|---|
| 1. | M/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd, Plot No. 47, Sunder Industrial Estate, Raiwind Road, Lahore.<br><br>DML No.000787 (Formulation)<br><br>Tenure: Commencing on03-02-2019 &ending on02-02-2024 | **28-10-2020** | **Good** | 1) Dr. Farzana Chaudhary, Expert Member.<br>2) Mr. Zaka ur Rehman, Govt. of Punjab.<br>3) Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore. |
| | **Recommendations of the panel:**<br>"Keeping in view the areas inspected, meeting with technical professionals, evaluation of documents, the panel of Inspectors was of the opinion to **recommend** the renewal of Drug Manufacturing License toM/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd, Plot No. 47, Sunder Industrial Estate, Raiwind Road, Lahore for the following sections.<br>1) Tablet (General) Section.<br>2) Capsule (General) Section.<br>3) Liquid Injectable (SVP) (General) Section.<br>a) Ampoule.<br>b) Vial/Infusion."<br><br>**Decision of the Central Licensing Board in 279th meeting**<br><br>The Board considered and approved the grant of renewal of DML No. 000787 by way of formulation in the name of M/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd, Plot No. 47, Sunder Industrial Estate, Raiwind Road, Lahoreon the recommendations of the panel of experts for the period Commencing on03-02-2019 &ending on02-02-2024 for the following sections: -<br>1) Tablet (General) Section.<br>2) Capsule (General) Section.<br>3) Liquid Injectable (SVP) (General) Section.<br>c) Ampoule.<br>d) Vial/Infusion." | | | |
| 2. | M/s Nexus Pharma (Pvt) Ltd, Plot No. 4/19-4/36, Sector 21, Korangi Industrial Area, Karachi.<br><br>DML No. 000421 (Formulation)<br><br>Tenure: Commencing on 20-11-2020 &ending on 19-11-2025.<br>**Sections (09) :** | **29-01-2021** | **Good** | 1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi<br>2) Additional Director (E&M), DRAP, Karachi.<br>3) Area FID, DRAP, Karachi. |

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| | i.Tablet (General)<br>ii.Capsule (Cephalosporin)<br>iii.Liquid (General)<br>iv.Dry Powder suspension (Cephalosporin)<br>v.Ointment(General)<br>vi.Dry Powder Injection (Cephalosporin)<br>vii.Capsule (General)<br>viii.Eye Drops (sterile)<br>ix.Injection Liquid (General)<br>x.Sachet (General)<br>xi.Dry Powder Suspension (General) | | | |

**Recommendations of the panel: -**

"The firm is build/constructed as per approved layout plan by DRAP Islamabad, the facility is provided with necessary amenities and other required services/utilities. The firm has installed necessary equipments and machinery in each section required for manufacturing and testing of registered products. The relevant documents of qualification and validation were reviewed and found satisfactorily maintained. Methods are validated/verified as per SOP. Certain documentation regarding analysis of raw materials and finished products were also reviewed and found acceptable. SOPs for market complaint, recalls, trainings, OOS, change control management, market returns self-inspection were seen in place. Appropriate sanitation & hygienic conditions were noted during inspection. HVAC System is provided in each section was observed operational.

Based on the above observations documents reviewed, personnel met and commitment of the management for continuous up-gradation and intention for export of products to various countries, the panel **recommends** the grant of renewal of their DML No. 000421 (by way of formulation) for the next five years due form 11-2020."

**Decision of the Central Licensing Board in 279th meeting**

The Board considered and approved the grant of renewal of (DML No. 000421) by way of formulation in the name of M/s Nexus Pharma (Pvt) Ltd, Plot No. 4/19-4/36, Sector 21, Korangi Industrial Area, Karachi. On the recommendations of the panel of experts for the period commencing on 20-11-2020 & ending on 19-11-2025 for the following sections:-

i. Tablet (General)
ii. Capsule (Cephalosporin)
iii. Liquid (General)
iv. Dry Powder suspension (Cephalosporin)
v. Ointment (General)
vi. Dry Powder Injection (Cephalosporin)

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|---|---|---|---|---|
| | vii. Capsule (General)<br>viii. Eye Drops (sterile)<br>ix. Injection Liquid (General)<br>x. Sachet (General)<br>xi. Dry Powder Suspension (General) | | | |
| 3. | M/s. Mafins Pharma, Plot No. A-5, S.I.T.E. Super Highway Industrial Area, Karachi.<br><br>DML No. 000820 (Formulation)<br><br>Tenure**:**Commencing on 22-06-2020 & ending on 21-06-2025.<br>**Sections (03) :**<br><br>1. Tablet (General)<br>2. Capsule (General)<br>3. Cream/Ointment/Gel (General) | **27-01-2021** | **Good** | 1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi.<br>2) Additional Director (E&M), DRAP, Karachi.<br>3) Area FID, DRAP, Karachi. |
| | **Recommendation of panel :**<br>"Keeping in view the above stated facts,documents reviewed personnel met and attitude of the management towards constant improvements the panel unanimously **recommends** the grant of renewal of their DML No. 000820 (Formulation) for the next five years from 22-06-2020 and panel also recommends the grant of additional section of Dry Powder Syrup (General)."<br><br>**Decision of the Central Licensing Board in 279th meeting**<br><br>The Board considered and approved the grant of renewal of (DML No. 000820) by way of formulation in the name of M/s Mafins Pharma, Plot No. A-5, S.I.T.E. Super Highway Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 22-06-2020 & ending on 21-06-2025for the following sections: -<br><br>i. Tablet (General)<br>ii. Capsule (General)<br>iii. Cream/Ointment/Gel (General). | | | |
| 4. | M/s Aspin Pharma (Pvt) Ltd**,** Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi.<br><br>DML No. 000045 (Formulation)<br><br>**Tenure**. Commencing on 31-03-2020 & ending on 30-03-2025.<br>**Sections (03) :**<br><br>1. Tablet (General)<br>2. Capsule (General) | **26-01-2021** | **Good** | 1) Additional Director (E&M)/Area FID, DRAP, Karachi.<br>2) Area FID, DRAP, Karachi.<br>3) Affan Ali, Assistant Director CDL, Karachi. |

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|---|---|---|---|---|
| | 3. Cream/Ointment/Gel (General)<br>4. Liquid (Syrup) | | | |

**Recommendation of panel :**

"Keeping in view the above stated facts, people met and documents reviewed during detail inspection of the facility, the panel unanimously **recommends** the grant of renewal of their DML No. 000045 for the next five years commencing form 31-03-2020 and also **recommends** the approval of changes made in the facilities as per approved layout."

**Decision of the Central Licensing Board in 279th meeting**

The Board considered and approved the grant of renewal of (DML No. 000045) by way of formulation in the name of M/s Aspin Pharma (Pvt) Ltd**,** Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachion the recommendations of the panel of experts for the period Commencing on 31-03-2020 & ending on 30-03-2025.for the following sections:-

1. Tablet (General)
2. Capsule (General)
3. Cream/Ointment/Gel (General)
4. Liquid (Syrup)

| | | | | |
|---|---|---|---|---|
| 5. | M/s Zephyr Pharmatec (Pvt) Ltd, Plot No. A-39, S.I.T.E. II, Super Highway, Karachi.<br><br>DML No. 000403 (Formulation)<br><br>**Tenure**. Commencing on 02-04-2020& ending on 01-04-2025. | **20-11-2020** | **Good** | 1) Prof. Dr. Abdullah Dayo, Member, CLB Karachi<br>2) Chief Drug Inspector, Sindh.<br>3) Area FID, DRAP, Karachi. |

**Recommendations of the panel:**

"Keeping in view the stated facts, documents reviewed, personnel met and attitude of the firm management towards constant improvements the panel **recommends** the grant of renewal o their DML No. 000403 (Formulation) for the next five years due from 02-04-2020 for Tablet (G), Capsule(G), Ointment/Cream/Gel(G), Warehouse(G), Capsule (Cephalosporin), Warehouse (Cephalosporin), Dry Powder Suspension (Cephalosporin), Warehouse (Penicillin), Dry Powder Suspension (Penicillin), Capsule (Penicillin), Syrup(G), Sachet (G), Quality Control and Microbiology Laboratory and Dry Powder Suspension (G) section."

The panel has also **recommended** the regularization of existing layout plan vide addendum letter and reproduced as below:

"In addition to recommendations in the inspection report, the panel also **recommends** the regularization of the existing layout plan of M/s Zephyr Pharmatec (Pvt) Ltd, Karachi''

**Decision of the Central Licensing Board in 279th meeting**

The Board considered and approved the grant of renewal of (DML No. 000403) by way of formulation in the name of M/s Zephyr Pharmatec (Pvt) Ltd, Plot No. A-39, S.I.T.E. II, Super Highway, Karachi on the recommendations of the panel of experts for the period Commencing on 02-04-2020& ending on 01-04-2025.for the following sections:-

| S. No. | Sections | S. No. | Sections |
|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| 1. | Tablet Section (General) | 2. | Capsule (General) Section. |
| 3. | Ointment/Cream/Gel (General). | 4. | Ware House (General). |
| 5. | Capsule (Cephalosporin) | 6. | Ware House (Cephalosporin) |
| 7. | Dry Powder Suspension Section (Cephalosporin) | 8. | Ware House (Penicillin) |
| 9. | Dry Powder Suspension Section (Penicillin) | 10. | Capsule (Penicillin) |
| 11. | Syrup (General) | 12. | Sachet (General) |
| 13. | Quality Control and Microbiology Laboratory | 14. | Dry Powder Suspension (General) |

| | | | | |
|---|---|---|---|---|
| **6.** | M/s. Ciba Pharmaceuticals (Pvt) Ltd, A-371, Nooriabad, SITE, District Jamshoro<br><br>DML No. 000825 (Formulation)<br><br>**Tenure**. Commencing on 30-07-2020 & ending on 29-07-2025. | **13-01-2021** | **Good** | 1) Muhammad Shoaib Ansari, Chief Drug Inspector Sindh<br>2) Syed Hakim Masood, Area, FID, DRAP, Karachi<br>3) Mahrukh Mughal, AD, CDL, Karachi |

**Recommendations of the panel:**

*"*M/s CIBA Pharmaceuticals (Pvt) Ltd, A-371, SITE Nooriabad District Jamshoro was inspected by the panel on 13-01-2021 as per directions contained in DRAP reference letter No. F.2-10/2006-Lic(Vol-I) for the purpose of renewal of DML No. 000825 (formulation). Following are the observations and recommendation of the panel members:

The firm is build/constructed as per approved layout plan/amendments vide DRAP Islamabad letter No. F. 2-10/2006-Lic (Vol-I), dated 21st December, 2020. The facility is provided with necessary amenities and other required services/utilities. The firm has installed necessary equipments and machinery in each section required for manufacturing and testing of registered products. The relevant documents of qualification and validation were reviewed and found satisfactorily maintained. Methods are validated/verified as per SOP. Certain documentation regarding analysis of raw materials and finished products were also reviewed and found acceptable. SOPs for market complaint, recalls trainings, OOS, change control management, market returns self-inspection. HVAC System is provided in each section was observed operational.

Based on the above observations, documents reviewed personal met and commitment of the management for continuous up-gradation and intention for export of products to various countries, the panel recommends the grant of renewal of their DML No. 000825 (by way of formulation) and amendments in for following sections:

| S.No. | Name of Sections | S.No. | Name of Sections |
|---|---|---|---|
| i. | Tablet (General) | ii. | Sachet(General) |
| iii. | Capsule (General) | iv. | Ointment/Cream/Gel(Steroid) |
| v. | Ointment/Cream/Gel(General) | vi. | Dry Powder Suspension (General) |
| vii. | Ointment/Cream/Gel (General)-**Revised** | viii. | Quality Control Laboratory-**Revised** |
| ix. | Capsule Section-**Revised** | x. | Raw Material Store-**Revised** |

**Decision of the Central Licensing Board in 279th meeting**

The Board considered and approved the grant of renewal of (DML No. 000825) by way of formulation in the name of M/s Ciba Pharmaceuticals (Pvt) Ltd, A-371, Nooriabad, SITE, District Jamshoro on the recommendations of the panel of experts for the period Commencing on 30-07-2020 & ending on 29-07-2025for the following sections:-

| S.No. | Name of Sections | S.No. | Name of Sections |
|---|---|---|---|
| i. | Tablet (General) | ii. | Sachet(General) |
| iii. | Capsule (General) | iv. | Ointment/Cream/Gel(Steroid) |
| v. | Ointment/Cream/Gel(General) | vi. | Dry Powder Suspension (General) |

| | | | | |
|---|---|---|---|---|
| **7.** | M/s. Medicaids Pakistan (Pvt) Ltd, Plot No. 10, Sector 27, Korangi Industrial Area, Karachi<br><br>DML No. 000139 (Formulation)<br><br>Tenure. Commencing on 25-11-2019 & ending on 24-11-2024. | **14-01-2021** | **Good** | 1) Dr. Abdullah Dayo Member CLB, Karachi<br>2) Mr. Shoaib Ahmed Ansari, Chief Drug Inspector, Sindh<br>3) Dr. Najam-us-Saquib, FID, Karachi |

**Recommendations of the panel:**

"Panel inspected the firm in detail and observed that the manufacturing sections, Q.C Lab, Water Treatment Plant, Quality Assurance System etc and critical documents Processes, SOPs and BMRs followed the written procedures, in general. The firm is built as per layout plan approved by the DRAP authorities Islamabad (Annex-Q). HVAC System seen installed and observed operational in all the production sections. The firm is exporting products to Afghanistan and Philippines and registration for the purpose of export is in process in various countries as well.
Based on the people met, documents reviewed and observation made during the inspection, panel **recommends** the renewal of DML and regularization for the sections as mentioned in the aforementioned DRAP letter. The sections are summarized below."

| **Sr.#** | **Name of Sections** | **Sr.#** | **Name of Sections** |
|---|---|---|---|
| i. | Capsule (General) | ii. | Sterile Ophthalmic Drops (General) |
| iii. | Liquid Syrup (General) | iv. | Dry Powder Suspension (Cephalosporin_) |
| v. | Dry Powder Suspension (General) | vi. | Tablet (Cephalosporin) |
| vii. | Liquid Injectable (General) | viii. | Capsule (Cephalosporin) |
| ix. | Dry Powder Injection (General) – SVP | x. | Sterile Dry Powder Injection (Cephalosporin) - **New** |
| xi. | Tablet (General) | xii. | ********** |

**Decision of the Central Licensing Board in 279th meeting**

The Board considered and approved the grant of renewal of (DML No. 000139) by way of formulation in the name M/s. Medicaids Pakistan (Pvt) Ltd, Plot No. 10, Sector 27, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 25-11-2019 & ending on 24-11-2024for the following sections:-

| Sr.# | Name of Sections | Sr.# | Name of Sections |
|---|---|---|---|
| i. | Capsule (General) | ii. | Sterile Ophthalmic Drops (General) |
| iii. | Liquid Syrup (General) | iv. | Dry Powder Suspension (Cephalosporin_) |
| v. | Dry Powder Suspension (General) | vi. | Tablet (Cephalosporin) |
| vii. | Liquid Injectable (General) | viii. | Capsule (Cephalosporin) |
| ix. | Dry Powder Injection (General) – SVP | x. | Sterile Dry Powder Injection (Cephalosporin) - **New** |
| xi. | Tablet (General) | xii. | ********** |

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|---|---|---|---|---|
| 8. | M/s Jaskan Pharmaceuticals (Pvt) Ltd, Plot No. 50, Sunder Industrial Estate, Lahore.<br><br>DML No. 000796 (Formulation)<br><br>Tenure: Commencing on 26-03-2019 & ending on 25-03-2024 | **26-10-2020** | **Good** | 1) Dr. Farzana Chaudhary, Expert Member.<br>2) Mr. Zakaur Rehman, Govt. of Punjab.<br>3) Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore. |

**Recommendations of the panel:**

"Keeping in view the facilities like building, HVAC System, Purified water, other utilities, production machinery & equipments, personnel, documentation, quality control instruments and testing facilities, the panel of inspectors was of the opinion to **recommend** the renewal of Drug Manufacturing License and grant of additional and amended section to M/s. Jaskan Pharmaceutical (Pvt) Ltd, Plot No. 50 Sunder Industrial estate, Lahore for the following sections: -

i. Tablet Section (General)
ii. Capsule Section (General)
iii. Sachet Section (General)
iv. Oral Dry Powder Suspension Section (General) Revised

**Additional / Amended / Revised Section**

i. Warehouse (Revised)
ii. Change Rooms (Amendments).
iii. Packing Hall (Cephalosporin Section) (Revised).
iv. Injectable (Ampoule) (General) Section (New) (Amendments)
v. Injectable (Vial) (General) Section (New) (Amendments).
vi. Dry Powder for Injection (Cephalosporin) (New).
vii. Dry Powder for Suspension (Cephalosporin) (New)."

**Decision of the Central Licensing Board in 279th meeting**

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|---|---|---|---|---|
| | The Board considered and approved the grant of renewal of DML No. 000796 by way of Formulation in the name of M/s Jaskan Pharmaceuticals (Pvt) Ltd, Plot No. 50, Sunder Industrial Estate, Lahoreon the recommendations of the panel of experts for the period Commencing on 26-03-2019 & ending on 25-03-2024for the following sections:-<br><br>i. Tablet Section (General)<br>ii. Capsule Section (General)<br>iii. Sachet Section (General)<br>iv. Oral Dry Powder Suspension Section (General) Revised | | | |
| 9. | M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, Bhai Pheru, District Kasur.<br><br>DML No. 000429 (Semi Basic Manufacture)<br><br>Tenure: Commencing on27-02-2018 & ending on 26-02-2023. | **17-12-2020** | **Good** | 1) Dr. Farzana Chaudhary, Expert Member.<br>2) Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.<br>3) Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore. |
| | **Recommendations of the panel:**<br>"Panel has thoroughly inspected the unit, evaluated the documents provided by the management and discussed various technical aspects at length. Details of equipments of Production and Quality Control departments and copies of flow chart and list of technical staff duly signed by the firm are attached with this report for perusal of the Central Licensing Board.<br>Based on the details mentioned above, documentations revealed and submitted by the management, physical panel inspection of the unit, panel has **recommended** the facility M/s Citi Pharma (Pvt) Ltd,3-Km, Head Balloki Road, Bhai Pheru, Kasur for renewal of DML No. 000429 by way of Semi Basic Manufacturing."<br>**Decision of the Central Licensing Board in 279th meeting**<br>The Board considered and approved the grant of renewal of DML No. 000429 by way of Semi Basic Manufacturein the name of M/s Citi Pharma (Pvt) Ltd,3-Km, Head Balloki Road, Bhai Pheru, District Kasuron the recommendations of the panel of experts for the period Commencing on27-02-2018 & ending on 26-02-2023. | | | |
| 10. | M/s Jawa Pharmaceuticals (Pvt.) Ltd, 112/10, Quaid-e-Azam Industrial Area Kot Lakhpat Lahore.<br><br>DML No. 000150 (Formulation)<br><br>Tenure: 24-12-2019 to 23-12-2024. | **15-12-2020 & 16-12-2020 & 26-12-2021** | **Good** | 1) Dr. Ikram ul Haq, Member CLB.<br>2) Mr. Azhar Jamal Saleemi, CDC, Punjab.<br>3) Ms. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore. |

**Recommendations of the panel:**

"In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery / equipment, material, management, air handling, water treatment system, personnel and documentation etc. the panel **recommends** the renewal of Drug Manufacturing Licenseto M/s. Jawa Pharmaceuticals (Pvt.) Ltd., 112/10-Industrial Estate Kot Lakhapt, Lahore by way of formulation for the following section only:

1. Tablet Section (General).
2. Capsule Section (General).
3. Oral Liquid (General).
4. Dry Powder Suspension Section General Antibiotic.
5. Capsule Section General Antibiotic.
6. Cream / Ointment (Dermatology Section).
7. Liquid Injectable (Ampoule / Vail) Section (General).
8. External Preparation Section.
9. Capsule Section (Cephalosporin).
10. Dry Powder Suspension Section (Cephalosporin).
11. Dry Powder Injection Section (Cephalosporin).
12. Sachet Section (General).
13. Tablets Section (Psychotropic).
14. Capsule Section (Psychotropic).
15. Ophthalmic Section (General)."

**Decision of the Central Licensing Board in 279th meeting**

The Board considered and approved the grant of renewal of DML No. 000150 by way of Formulation in the name of M/s Jawa Pharmaceuticals (Pvt.) Ltd, 112/10, Quaid-e-Azam Industrial Area Kot Lakhpat Lahore on the recommendations of the panel of experts for the period Commencing on 24-12-2019 to 23-12-2024 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020:-

1. Tablet Section (General).
2. Capsule Section (General).
3. Oral Liquid (General).
4. Dry Powder Suspension Section General Antibiotic.
5. Capsule Section General Antibiotic.
6. Cream / Ointment (Dermatology Section).
7. Liquid Injectable (Ampoule / Vail) Section (General).
8. External Preparation Section.
9. Capsule Section (Cephalosporin).
10. Dry Powder Suspension Section (Cephalosporin).
11. Dry Powder Injection Section (Cephalosporin).
12. Sachet Section (General).
13. Tablets Section (Psychotropic).

| | | | | |
|---|---|---|---|---|
| | 14. Capsule Section (Psychotropic).<br>15. Ophthalmic Section (General). | | | |

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|---|---|---|---|---|
| 11. | M/s Attabak Pharmaceuticals Industries, 5C, I-10/3, Industrial Area, Islamabad.<br><br>DML No.000552 (Formulation)<br><br>Tenure:Commencing on 30-10-2019 & ending on 29-10-2024<br><br>**Section (01)**<br>1. Oral Powder Section | **08-02-2021** | **Good** | 1) Prof. Dr. Gul Majeed, Member CLB.<br>2) Mr. Abdullah, Additional Director (PE&R), DRAP, Islamabad.<br>3) Area Federal Inspector of Drugs, DRAP, Islamabad. |
| | **Recommendations of the panel:**<br>"Keeping in view the improvement made by the firm w.r.t. their previous inspection majority of major shortcomings were addressed; the firm further assured the panel of Inspectors that they will addressed to the above mentioned week points in near future. The panel is of the view to **recommend the grant of renewal** and additional sections (as per approved layout plan)."<br><br>**Decision of the Central Licensing Board in 279th meeting**<br><br>The Board considered and approved the grant of renewal of DML No. 000552 by way of Formulation in the name of M/s Attabak Pharmaceuticals Industries, 5C, I-10/3, Industrial Area, Islamabadon the recommendations of the panel of experts for the period Commencing on 30-10-2019 &ending on 29-10-2024 for the following sections: -<br>i. Liquid Injectable General Veterinary<br>ii. Oral Liquid General Veterinary<br>iii. Oral Powder Veterinary. | | | |
| 12. | M/s Zanctok Pharmaceutical Laboratories, Plot No . F/5, S.I.T.E., Hyderabad.<br>DML No. 000251 (Formulation)<br>**Period**.<br>Commencing on 29-11-2020 & ending on 28-11-2025. | **28-01-2021** | **Good** | 1) Prof. Dr. Abdullah Dayo, Expert Member, Karachi<br>2) Chief Drug Inspector, Sindh.<br>3) Area FID, DRAP, Karachi. |
| | **Recommendations of the panel: -**<br>"Based on the people met, areas visited and commitment of the Firm's management for continuous improvement, the panel is of the view of recommend<br>• Renewal of Drug Manufacturing License (By the way of Formulation) No. 000251 to the firm M/s Zanctok Pharmaceutical Laboratories, situated at Plot No. F/5, S.I.T.E, Hyderabad with following sections: | | | |

| | | | |
|---|---|---|---|
| Tablet General | Tablet General Antibiotic | Syrup General |
| Capsule General Antibiotic | Ointment/Cream/Gel (General) | Sachet (General) |
| External Preparation (Mouth Wash) | Tablet Psychotropic | Capsule General |
| Dry Powder Suspension (Cephalosporin) | | Capsule (Cephalosporin) |

**Decision of the Central Licensing Board in 279th meeting**

The Board considered and approved the grant of renewal of (DML No. 000251) by way of formulation in the name M/s Zanctok Pharmaceutical Laboratories, Plot No. F/5, S.I.T.E., Hyderabadon the recommendations of the panel of experts for the period Commencing on 29-11-2020 & ending on 28-11-2025 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020: -

| | | |
|---|---|---|
| Tablet General | Tablet General Antibiotic | Syrup General |
| Capsule General Antibiotic | Ointment/Cream/Gel (General) | Sachet (General) |
| External Preparation (Mouth Wash) | Tablet Psychotropic | Capsule General |
| Dry Powder Suspension (Cephalosporin) | | Capsule (Cephalosporin) |

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|---|---|---|---|---|
| 13. | M/s Amarant Pharmaceuticals (Pvt) Ltd , 158-D.,Toro Gadap Road, Super Highway Karachi.<br><br>DML No. 000584 (Formulation)<br><br>**Tenure**.Commencing on 07-10-2020 & ending on 06-10-2025. | **15-02-2021** | **Good** | 1) Chief Drug Inspector, Sindh.<br>2) Additional Director (E&M), DRTAP, Karachi.<br>3) Area FID, DRAP, Karachi. |

**Recommendations of the panel: -**

"As per instructions contained in DRAP Islamabad letter No. F.2-4/99-Lic(Vol-II), dated: 29th January, 2021, a detailed and comprehensive panel inspection of Ms. Amarant Pharmaceutical situated at Plot No. 158-D, Tore Gadap Road, Super highway Karachi was carried out, wherein their QA System, QC Lab, Production, Stores, utilities and respective documents were reviewed in details

Training records, with schedules and SOPs were noted at an appropriate level of compliance. During inspection various other documents like Validation Master Plan, change control and controlling the deviation, OOS, failures, treating marketing complaint and recalls were also reviewed and noted a satisfactory level of compliance.

The firm has sufficient equipment in QC lab, calibration records, log books and respective

retrieved data were reviewed during inspection and noted a satisfactory level of compliance.

The firm has facilities to manufacture Tablets (G), Capsule (G), Liquid (Syrup & Suspension) (G), Topical (Cream/Ointment/Gel) (G), Sachet (General), Capsule (Ceph.), Dry Powder Suspension (Ceph.), Tablet (Veterinary), Liquid (Veterinary) & Powder (Veterinary). The manufacturing facilities are kept at ground floor of the main building along with suitably connected stores. QC and PD lab facilities are given at first floor as per approved design. Dedicated areas of Cephalosporin and Veterinary Sections are provided with separate change rooms, separate AHUs and separate machineries for production. Overall a satisfactory level of compliance was not in manufacturing.

Keeping in view the above stated facts, people met and documents reviewed during detail inspection of the facility, the panel unanimously recommends the grant of renewal of their DML No. 000584 for the next five years."

**Decision of the Central Licensing Board in 279th meeting**

The Board considered and approved the grant of renewal of DML No. 000584 by way of formulation in the name M/s Amarant Pharmaceuticals (Pvt) Ltd , 158-D.,Toro Gadap Road, Super Highway Karachi. on the recommendations of the panel of experts for the period Commencing on 07-10-2020 & ending on 06-10-2025.for the following sections:-

| Sr. No | Name of Sections | Sr. No | Name of Sections |
|---|---|---|---|
| 1. | Tablet (General) | 2. | Capsule (Cephalosporin) |
| 3. | Ointment/Cream/Gel (General) | 4. | Tablet Section- Veterinary |
| 5. | Capsule (Non-Antibiotic) | 6. | Liquid Section- Veterinary |
| 7. | Dry Powder /Sachet (General) | 8. | Powder Section – Veterinary |
| 9. | Liquid (Syrup & Suspension)-General | 10. | Dry Powder Suspension (Cephalosporin) |

| | | | | |
|---|---|---|---|---|
| 14. | M/s Agror Pharma (Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat.<br><br>DML No. 000791 (Formulation)<br><br>**Tenure:** Commencing on 03-02-2019 & ending on 02-02-2024. | **03-01-2021 & 04-01-2021** | **Good** | 1) Dr. Hafsa Karam Elahi, Additional Director (QA& Lt-1), DRAP, Islamabad.<br>2) Mr. Babar Khan, Federal Inspector of Drugs, DRAP, Islamabad.<br>3) Ms. Mehwish Tanveer, AD (QC), DRAP, Islamabad. |

**Recommendations of the panel:**

"Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the approval of the following 04 new additional & renewal (for the exiting 03 sections) of DML No. 000791 of M/s. Agror Pharma (Pvt) Ltd, Plot No. 04, Street No. SS-4, National Industrial Zone, Rawat(the detailed report is attached herewith):-

**Existing Sections:**

1. Capsule Section (Cephalosporin).
2. Dry Powder Injection Section (Cephalosporin).
3. Dry Powder Suspension Section (Cephalosporin).

**New Sections:**

1. Tablet Section (General).

| | |
|---|---|
| | 2. Capsule Section (General).<br>3. Cream / Ointment / Gel (General).<br>4. Sachet Section (General)"<br>**Decision of the Central Licensing Board in 279th meeting**<br>The Board considered and approved the grant of renewal of DML No. 000791 by way of Formulation in the name ofM/s. Agror Pharma (Pvt) Ltd, Plot No. 04, Street No. SS-4, National Industrial Zone, Rawaton the recommendations of the panel of experts for the period commencing on 03-02-2019 & ending on 02-02-2024for the following sections: -<br>1. Capsule Section (Cephalosporin).<br>2. Dry Powder Injection Section (Cephalosporin).<br>3. Dry Powder Suspension Section (Cephalosporin). |

**ITEM – V MISC CASES**

**Case No. 1 CHANGE OF MANAGEMENT OF M/S CANDID PHARMACEUTICALS PASRUR.**

M/s Candid Pharmaceuticals, Opp Pasrur Sugar Mills, Sialkot Road, Pasrurunder DML No. 000450 by way of Formulation has submitted request for change in management of the firm as per Partnership Deedwith prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

| Previous Management | New Management as per Partnership Deed |
|---|---|
| 1. Dr. Muhammad Asif Khan S/o Alam Khan.<br>2. Mr. Liaqat Khan S/o Alam Khan.<br>3. Ms. Shabana Sherwani W/o Muhammad Asif Khan | 1. Mr. Muhammad Asif Khan S/o Alam Khan CNIC No. 35201-0782368-7.<br>2. Mr. Liaqat Khan S/o Alam Khan CNIC No. 35201-3634998-3. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management of M/s Candid Pharmaceuticals, Opp. Pasrur Sugar Mills, Sialkot Road, Pasrurunder DML No. 000450by way of Formulation as under;

| Previous Management | New Management as per Partnership Deed |
|---|---|
| 1. Dr. Muhammad Asif Khan S/o Alam Khan.<br>2. Mr. Liaqat Khan S/o Alam Khan.<br>3. Ms. Shabana Sherwani W/o Muhammad Asif Khan | 1. Mr. Muhammad Asif Khan S/o Alam Khan CNIC No. 35201-0782368-7.<br>2. Mr. Liaqat Khan S/o Alam Khan CNIC No. 35201-3634998-3. |

**Case No. 2 CHANGE OF MANAGEMENT OF M/S LINTA PHARMACEUTICALS (PVT) LTD, RAWAT.**

M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No. 03, Street No. S-5, National Industrial Zone, Rawat under DML No. 000810 by way of Formulation has submitted request for change in management of the firm as per Form-Awith prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

| Previous Management | New Management as per Form-A |
|---|---|
| 1. Mr. Muhammad Faheem Qureshi S/o Muhammad Bashir Qureshi CNIC No. 37405-7728519-5.<br>2. Mr. Inam Ullah Khan S/o Ikram | 1. Mr. Muhammad Aslam S/o Muhammad Shafi CNIC No. 35201-9116072-1.<br>2. Mr. Muhammad Faheem Qureshi S/o Muhammad Bashir Qureshi CNIC No. 37405- |

| | |
|---|---|
| Ullah Khan CNIC No. 37405-0364832-3.<br>3. Mr. Sheraz Ahmed S/o Gulzar Ahmed CNIC No. 37405-3274129-3. | 7728519-5.<br>3. Ms. Mayra Fahim W/o Muhammad Faheem Qureshi CNIC No. 37405-7150567-8. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No. 03, Street No. S-5, National Industrial Zone, Rawat under DML No. 000810 by way of Formulation as under ;

| Previous Management | New Management as per Form-A |
|---|---|
| 1. Mr. Muhammad Faheem Qureshi S/o Muhammad Bashir Qureshi CNIC No. 37405-7728519-5.<br>2. Mr. Inam Ullah Khan S/o Ikram Ullah Khan CNIC No. 37405-0364832-3.<br>3. Mr. Sheraz Ahmed S/o Gulzar Ahmed CNIC No. 37405-3274129-3. | 1. Mr. Muhammad Aslam S/o Muhammad ShafiCNIC No. 35201-9116072-1.<br>2. Mr. Muhammad Faheem Qureshi S/o Muhammad Bashir Qureshi CNIC No. 37405-7728519-5.<br>3. Ms. Mayra Fahim W/o Muhammad Faheem Qureshi CNIC No. 37405-7150567-8. |

**Case No.3CHANGE OF MANAGEMENT OF M/S GREATER PHARMA, RAWAT.**

M/s Greater Pharma, Plot No. 35, Street No. SS-3, National Industrial Zone, RCCI, Rawat under DML No. 000896 by way of Formulation has submitted request for change in management of the firm as per Affidavit with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

| Previous Management | New Management as per Affidavit |
|---|---|
| 1. Mr. Abdul Wadood Khan S/o Masood Khan CNIC No. 17301-0355625-1. | 1. Mr. Muhammad Dawood S/o Haji Momeen CNIC No. 54201-2468331-5. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management of M/s Greater Pharma, Plot No. 35, Street No. SS-3, National Industrial Zone, RCCI, Rawat under DML No. 000896by way of Formulation as under ;

| Previous Management | New Management as per Affidavit |
|---|---|
| 1. Mr. Abdul Wadood Khan S/o Masood Khan CNIC No. 17301-0355625-1. | 1. Mr. Muhammad Dawood S/o Haji Momeen CNIC No. 54201-2468331-5. |

**Case No.4 <u>CHANGE OF MANAGEMENT OF M/S AGROR PHARMA (PVT) LTD, RAWAT.</u>**

M/s Agror Pharma (Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat under DML No. 000791 by way of Formulation has submitted request for change in management of the firm as per Form-29with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

| Previous Management | New Management as per Form-29 |
|---|---|
| 1. Mrs. Fauzia Wali Khan W/o Nadeem Aleem Afridi CNIC No. 71501-3175288-6.<br>2. Ms. Aisha Ehsan W/o Tajammul Ehsan CNIC No. 42101-5410473-8.<br>3. Ms. Afifa Asad W/o Syed Asadullah CNIC No. 61101-6144333-0. | 1. Mr. Syed Asadullah S/o Syed Saleem Ullah CNIC No. 61101-6471672-3.<br>2. Mrs. Fauzia Wali Khan W/o Nadeem Aleem Afridi CNIC No. 71501-3175288-6.<br>3. Ms. Aisha Ehsan W/o Tajammul Ehsan CNIC No. 42101-5410473-8.<br>4. Ms. Afifa Asad W/o Syed Asadullah CNIC No. 61101-6144333-0. |

**<u>Decision of the Central Licensing Board in 279th meeting:</u>**

The Board considered and endorsed the change of management M/s Agror Pharma (Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat under DML No. 000791by way of Formulationas under ;

| Previous Management | New Management as per Form-29 |
|---|---|
| 1. Mrs. Fauzia Wali Khan W/o Nadeem Aleem Afridi CNIC No. 71501-3175288-6.<br>2. Ms. Aisha Ehsan W/o Tajammul Ehsan CNIC No. 42101-5410473-8.<br>3. Ms. AfifaAsad W/o Syed Asadullah CNIC No. 61101-6144333-0. | 1. Mr. Syed Asadullah S/o Syed Saleem Ullah CNIC No. 61101-6471672-3.<br>2. Mrs. Fauzia Wali Khan W/o Nadeem Aleem Afridi CNIC No. 71501-3175288-6.<br>3. Ms. Aisha Ehsan W/o Tajammul Ehsan CNIC No. 42101-5410473-8.<br>4. Ms. AfifaAsad W/o Syed Asadullah CNIC No. 61101-6144333-0. |

**Case No.5 CHANGE OF MANAGEMENT OF M/S IRZA PHARMA (PVT) LTD, DISTRCT SHEIKHUPURA.**

M/s Irza Pharma (Pvt) Ltd, 10/2-Km, Lahore Sheikhupura Road, P.O Kot Abdul Malik, District Sheikhupura under DML No. 000108 by way of Formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

| Previous Management | New Management as per Form-29 |
|---|---|
| 1. Mr. Abid Ali Jawa.<br>2. Mr. Sultan Ali Jawa. | 1. Mr. Muhammad Imran Jawa S/o Abid Ali JawaCNIC No. 35202-1908235-7.<br>2. Mst. Savaira Mariam W/o Sultan Ali Jawa CNIC No. 35202-2296623-2. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management M/s Irza Pharma (Pvt) Ltd, 10/2-Km, Lahore Sheikhupura Road, P.O Kot Abdul Malik, District Sheikhupura under DML No. 000108 (By way of formulation) as undersubject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;

| Previous Management | New Management as per Form-29 |
|---|---|
| 1. Mr. Abid Ali Jawa.<br>2. Mr. Sultan Ali Jawa. | 1. Mr. Muhammad Imran Jawa S/o Abid Ali JawaCNIC No. 35202-1908235-7.<br>2. Mst. Savaira Mariam W/o Sultan Ali Jawa CNIC No. 35202-2296623-2. |

**Case No. 6 CHANGE OF MANAGEMENT OF M/S. SCILIFE PHARMA (PVT) LTD, KARACHI.**

M/s Scilife Pharma (Pvt) Ltd, FD 57/58-A2, Korangi Creek Industrial Area,Karachi, under DML No. 000837 (By way of formulation) has submitted request for change in management of the firm as per

Form 29 and Form A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

| Previous management Form-1 Year 2016 | Newmanagement as per Form-29 & Form-A Year 2021 of S.E.C.P. |
|---|---|
| 1. Mr. Shahid Ghoury S/o Amanullah Khan Ghoury CNIC No. 42201-0119739-9 | 1. Mr. Inamur Rehman S/o Atique-ur-Rahman CNIC No.42201-0286874-3.<br>2. Mr. Viqar Hasan Siddiqui S/o Jamil Yousuf Siddiqui CNIC No.42201-6620728-3.<br>3. Mr. Asim Hussain Siddiqui S/o Izhar Hussain Siddiqui CNIC No. 42101-1610408-<br>4. Mr. Shahid Ghoury S/o Amanullah Khan Ghoury CNIC No. 42201-0119739-9. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management M/s Scilife Pharma (Pvt) Ltd, FD 57/58-A2, Korangi Creek Industrial Area, Karachi, under DML No. 000837 (By way of formulation) as under ;

| Previous management | New Management as per Form-29 & Form-A of S.E.C.P. |
|---|---|
| 1. Mr. Shahid Ghoury S/o Amanullah Khan Ghoury CNIC No. 42201-0119739-9 | 1. Mr. Inamur Rehman S/o Atique-ur-Rahman CNIC No.42201-0286874-3.<br>2. Mr. Viqar Hasan Siddiqui S/o Jamil Yousuf Siddiqui CNIC No.42201-6620728-3.<br>3. Mr. Asim Hussain Siddiqui S/o Izhar Hussain Siddiqui CNIC No. 42101-1610408-<br>4. Mr. Shahid Ghoury S/o Amanullah Khan Ghoury CNIC No. 42201-0119739-9. |

**Case No. 07. <u>CHANGE OF MANAGEMENT OF M/S. RECKITT BENCKISERPAKISTAN LTD, KARACHI.</u>**

M/s Reckitt Benckiser Pakistan Ltd, **F-18, S.I.T.E, Karachi**underDML No. 000022by way of formulation has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

| **Previous Management as per Form 1-A[year 2015)** | **NewManagement as per Form 29 (year 2020)** |
|---|---|
| 1. Mr. Aslam Khaliq<br>2. Mr. Paolo Borghesi<br>3. Mr. Naqi Hasnain Sheriff<br>4. Mr. Roopak Taneja<br>5. Mr. Sheikh Humayun<br>6. Mr. Shahzeb Malik | 1. Mr. Syed Kashan Hasan S/o Syed Anwar Saghir CNIC NO. 42301-0816739-3.<br>2. Mr. Akbar Ali Shah S/o Mazhar Hussain Shah CNIC NO. 42000-5264192-9.<br>3. Mr. Atif Hashmi S/o Hameed Akhtar Hashmi S/o CNIC No. 42101-1403487-3.<br>4. Mr. Adil Saeed Khan S/o Saeed Ahmed Khan CNIC No. 42201-0426657-7<br>5. Mr. Shahzeb Mahmood S/o Mateen Mahmood Mohajir CNIC No. 42301-0844790-7<br>6. Mr. Aslam Khaliq S/o Abdul Khaliq CNIC No. 61101-2180699-9 |

**<u>Decision of the Central Licensing Board in 279th meeting:</u>**

The Board considered and endorsed the change of management of M/s Reckitt Benckiser Pakistan Ltd, F-18, S.I.T.E, KarachiunderDML No. 000022by way of Formulation as under ;

| **Previous Management as per Form 1-A[year 2015)** | **New Management as per Form 29 (year 2020)** |
|---|---|
| 1. Mr. Aslam Khaliq<br>2. Mr. Paolo Borghesi<br>3. Mr. Naqi Hasnain Sheriff<br>4. Mr. Roopak Taneja<br>5. Mr. Sheikh Humayun<br>6. Mr. Shahzeb Malik | 1. Mr. Syed Kashan Hasan S/o Syed Anwar Saghir CNIC NO. 42301-0816739-3.<br>2. Mr. Akbar Ali Shah S/o Mazhar Hussain Shah CNIC NO. 42000-5264192-9.<br>3. Mr. Atif Hashmi S/o Hameed Akhtar Hashmi S/o CNIC No. 42101-1403487-3.<br>4. Mr. Adil Saeed Khan S/o Saeed Ahmed Khan CNIC No. 42201-0426657-7<br>5. Mr. Shahzeb Mahmood S/o Mateen Mahmood Mohajir CNIC No. 42301-0844790-7<br>6. Mr. Aslam Khaliq S/o Abdul Khaliq CNIC No. 61101-2180699-9 |

**Case No. 08. <u>CHANGE OF MANAGEMENT OF M/S. MEDIFLOW PHARMACEUTICALS (PVT) LTD,KARACHI.</u>**

M/s Mediflow Pharmaceuticals (Pvt) Ltd, Plot No. ID-100, Sector, 30, Korangi Industrial Area, KarachiunderDML No. 000822 (By way of formulation) has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

| **Previous Management (Year 2015 )** | **New Management as per Form 29 (year 2020)** |
|---|---|
| 1. Mr. Syed Ammar Bukhari S/o Syed tasaddaq BukhariCNIC No. 42000-0453773-5<br>2. Mr. Syed Farooq Bukhari S/o Syed Ammar BukhariCNIC No. 42301-0848866-5<br>3. Mr. Syed Khurram Bukhari S/o Syed Ammar BukhariCNIC No. 42201-5109935-1 | 1. Mr. Syed Ammar Bukhari S/o Syed tasaddaq BukhariCNIC No. 42000-0453773-5<br>2. Mr. Syed Farooq Bukhari S/o Syed Ammar BukhariCNIC No. 42301-0848866-5 |

**<u>Decision of the Central Licensing Board in 279th meeting:</u>**

The Board considered and endorsed the change of management of M/s Mediflow Pharmaceuticals (Pvt) Ltd, Plot No. ID-100, Sector, 30, Korangi Industrial Area, Karachi underDML No. 000822 (By way of formulation) as under ;

| **Previous Management (Year 2015 )** | **New Management as per Form 29 (year 2020)** |
|---|---|
| 1. Mr. Syed Ammar Bukhari S/o Syed tasaddaqBukhariCNIC No. 42000-0453773-5<br>2. Mr. Syed Farooq Bukhari S/o Syed Ammar BukhariCNIC No. 42301-0848866-5<br>3. Mr. Syed Khurram Bukhari S/o Syed Ammar BukhariCNIC No. 42201-5109935-1 | 1. Mr. Syed Ammar Bukhari S/o Syed tasaddaqBukhariCNIC No. 42000-0453773-5<br>2. Mr. Syed Farooq Bukhari S/o Syed Ammar BukhariCNIC No. 42301-0848866-5 |

**Case No.9 CHANGE OF MANAGEMENT OF M/S. SANOFI-AVENTIS PAKISTAN LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000007(FORMULATION)**

M/s Sanofi-Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, KarachiunderDML No. 000007 (By way of formulation) has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

| Previous Management as per Form-1A (Year 2015) | New Management as per Form-29 of SECP (Year 2020) |
|---|---|
| 1. Mr. Syed Babar Ali.<br>2. Mr. Arshad Ali Gohar<br>3. Mr. Syed Hyder Ali<br>4. Mr. Ayub Ahmed Siddiqui.<br>5. Mr. Mohammad Ibadullah.<br>6. Mr. Javed Iqbal.<br>7. Mr. Dr. Pius Stephan Hornstein.<br>8. Mr. Georges Jean, Marc- Henri.<br>9. Mr. Francois Jean LoiusBriens. | 1. Mr. Hermes Martet S/o. Mr. Daniel Martet Passport No. 13BF46775<br>2. Mr. Marc Antoine Lucchini S/o. Mr. Antoine Simon Lucchini Passport No. 13FV00005.<br>3. Mr. Rehmatullah Khan Wazir S/o Mr. Bangay Khan CNIC No. 42301-6301459-3.<br>4. Mr. Shahid Zaki S/o Sheikh Muhammad Zaki CNIC No. 42301-0952120-9.<br>5. Mr. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9.<br>6. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No. 42301-5510501-3.<br>7. Mr. Imtiaz Ahmed Husain Laliwala S/o Ahmed Husain Laliwala CNIC No. 42201-5114451-3<br>8. Mr. YaseerPirMuhamamd S/o Pir Muhammad Suleman CNIC No. 42201-9620109-1<br>9. Ms. Naira Adamyan W/o VilenAdamyan Passport No. 759183818.<br>10. Mr. Syed Hyder Ali S/o Syed Babar Ali CNICN No. 35201-1655225-1.<br>11. Mr. Asim Kamal S/o Sharafat Ali CNIC No. 42301-9423760-7. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management of M/s Sanofi-Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, KarachiunderDML No. 000007 (By way of Formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of

Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020: -

| Previous Management as per Form-1A (Year 2015) | New Management as per Form-29 of SECP (Year 2020) |
|---|---|
| 1. Mr. Syed Babar Ali.<br>2. Mr. Arshad Ali Gohar<br>3. Mr. Syed Hyder Ali<br>4. Mr. Ayub Ahmed Siddiqui.<br>5. Mr. Mohammad Ibadullah.<br>6. Mr. Javed Iqbal.<br>7. Mr. Dr. Pius Stephan Hornstein.<br>8. Mr. Georges Jean, Marc- Henri.<br>9. Mr. Francois Jean LoiusBriens. | 1. Mr. Hermes Martet S/o. Mr. Daniel Martet Passport No. 13BF46775<br>2. Mr. Marc Antoine Lucchini S/o. Mr. Antoine Simon Lucchini Passport No. 13FV00005.<br>3. Mr. Rehmatullah Khan Wazir S/o Mr. BangayKhan CNIC No. 42301-6301459-3.<br>4. Mr. Shahid Zaki S/o Sheikh Muhammad Zaki CNIC No. 42301-0952120-9.<br>5. Mr. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9.<br>6. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No. 42301-5510501-3.<br>7. Mr. Imtiaz Ahmed Husain Laliwala S/o Ahmed Husain Laliwala CNIC No. 42201-5114451-3<br>8. Mr. YaseerPirMuhamamd S/o Pir Muhammad Suleman CNIC No. 42201-9620109-1<br>9. Ms. Naira Adamyan W/o VilenAdamyan Passport No. 759183818.<br>10. Mr. Syed Hyder Ali S/o Syed Babar Ali CNICN No. 35201-1655225-1.<br>11. Mr. Asim Kamal S/o Sharafat Ali CNIC No. 42301-9423760-7. |

**Case No.10** **CHANGE OF MANAGEMENT OF M/S. GLAXOSMITHKLINE PAKISTAN LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000233 (FORMULATION)**

M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E. Karachiunder DML No. 000233 (By way of Formulation) has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

| Previous Management as per Form-1A Year 2015 | New Management as per Form-29 Year 2020 |
|---|---|
| 1. Mr. Salman Burney<br>2. Mr. Yahya Zakaria | 1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3. |

| | |
|---|---|
| 3. Mr. Mehmood Mandviwalla<br>4. Mr. Hussain Lawai<br>5. Mr. Renaud Savary | 2. Mr. Dmytro Olinyk , Passport No. PU 125808.<br>3. Mr. Mark Robert Dawson, Passport No. 761323952.<br>4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1.<br>5. Ms. ErumShakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0.<br>6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6.<br>7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management of M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E. Karachiunder DML No. 000233 (By way of Formulation) as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020:-

| Previous Management as per Form-1A Year 2015 | New Management as per Form-29 Year 2020 |
|---|---|
| 1. Mr. Salman Burney<br>2. Mr. Yahya Zakaria<br>3. Mr. Mehmood Mandviwalla<br>4. Mr. Hussain Lawai<br>5. Mr. Renaud Savary | 1. Mr. Abdul Samad S/o Haroon CNIC No. 42301-5079532-3.<br>2. Mr. Dmytro Olinyk , Passport No. PU 125808.<br>3. Mr. Mark Robert Dawson, Passport No. 761323952.<br>4. Mr. Mehmood Yousaf Mandviwala S/o Yousaf JeeMandviwala CNIC No. 42301-2010228-1.<br>5. Ms. ErumShakir D/o Muhammad Shakir Rahim CNIC No. 42101-7411745-0.<br>6. Mrs. Maheen Rahman W/o Abid Butt CNIC No. 42301-3079259-6.<br>7. Mr. Muneer Kamal S/o Ghulam Umar CNIC No. 42301-9417475-7. |

**Case No.11. CHANGE OF MANAGEMENT OF M/S. SANOFI-AVENTIS PAKISTAN LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000368 (BASIC MANUFACTURE)**

M/s Sanofi-Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, KarachiunderDML No. 000368 (By way of Basic manufacture) has submitted request for change in

management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 15,000/-. The detail of management is as under:-

| Previous Management as per Form-1A (Year 2015) | New Management as per Form-29 of SECP (Year 2020) |
|---|---|
| 1. Mr. Syed Babar Ali.<br>2. Mr. Arshad Ali Gohar<br>3. Mr. Syed Hyder Ali<br>4. Mr. Ayub Ahmed Siddiqui.<br>5. Mr. Mohammad Ibadullah.<br>6. Mr. Javed Iqbal.<br>7. Mr. Dr. Pius Stephan Hornstein.<br>8. Mr. Georges Jean, Marc- Henri.<br>9. Mr. Francois Jean LoiusBriens. | 1. Mr. Hermes Martet S/o. Mr. Daniel Martet Passport No. 13BF46775<br>2. Mr. Marc Antoine Lucchini S/o. Mr. Antoine Simon Lucchini Passport No. 13FV00005.<br>3. Mr. Rehmatullah Khan Wazir S/o Mr. Bangay Khan CNIC No. 42301-6301459-3.<br>4. Mr. Shahid Zaki S/o Sheikh Muhammad Zaki CNIC No. 42301-0952120-9.<br>5. Mr. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9.<br>6. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No. 42301-5510501-3.<br>7. Mr. Imtiaz Ahmed Husain Laliwala S/o Ahmed Husain Laliwala CNIC No. 42201-5114451-3<br>8. Mr. YaseerPirMuhamamd S/o Pir Muhammad Suleman CNIC No. 42201-9620109-1<br>9. Ms. Naira Adamyan W/o VilenAdamyan Passport No. 759183818.<br>10. Mr. Syed Hyder Ali S/o Syed Babar Ali CNICN No. 35201-1655225-1.<br>11. Mr. Asim Kamal S/o Sharafat Ali CNIC No. 42301-9423760-7. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management of M/s Sanofi-Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, KarachiunderDML No. 000368 (By way of Basic manufacture) as under ;

| Previous Management as per Form-1A (Year 2015) | New Management as per Form-29 of SECP (Year 2020) |
|---|---|
| 1. Mr. Syed Babar Ali.<br>2. Mr. Arshad Ali Gohar<br>3. Mr. Syed Hyder Ali | 1. Mr. Hermes Martet S/o. Mr. Daniel Martet Passport No. 13BF46775<br>2. Mr. Marc Antoine Lucchini S/o. Mr. Antoine Simon Lucchini Passport No. 13FV00005. |

| | |
|---|---|
| 4. Mr. Ayub Ahmed Siddiqui.<br>5. Mr. Mohammad Ibadullah.<br>6. Mr. Javed Iqbal.<br>7. Mr. Dr. Pius Stephan Hornstein.<br>8. Mr. Georges Jean, Marc- Henri.<br>9. Mr. Francois Jean LoiusBriens. | 3. Mr. Rehmatullah Khan Wazir S/o Mr. Bangay Khan CNIC No. 42301-6301459-3.<br>4. Mr. Shahid Zaki S/o Sheikh Muhammad Zaki CNIC No. 42301-0952120-9.<br>5. Mr. Syed Babar Ali S/o Late Syed Maratib Ali CNIC No. 35202-2455552-9.<br>6. Mr. Arshad Ali Gohar S/o Pir Ali Gohar CNIC No. 42301-5510501-3.<br>7. Mr. Imtiaz Ahmed Husain Laliwala S/o Ahmed Husain Laliwala CNIC No. 42201-5114451-3<br>8. Mr. YaseerPirMuhamamd S/o Pir Muhammad Suleman CNIC No. 42201-9620109-1<br>9. Ms. Naira Adamyan W/o VilenAdamyan Passport No. 759183818.<br>10. Mr. Syed Hyder Ali S/o Syed Babar Ali CNICN No. 35201-1655225-1.<br>11. Mr. Asim Kamal S/o Sharafat Ali CNIC No. 42301-9423760-7. |

**Case No.12 <u>CHANGE OF MANAGEMENT OF M/S MARTIN DOW LTD, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000267 (FORMULATION)</u>**

M/s Martin Dow Ltd, Karachi under Drug Manufacturing License No. 000267 by way of formulation has submitted request for change in management of the firm as per Form -29 with prescribed Fee Challan of 50,000/-. The detail is as under;

| Previous Management | New Management |
|---|---|
| 1. Mr. Muhammad Jawed Akhai S/o A. Sattar Akhai CNIC No.42000-1658201-1.<br>2. Mr. Muqtadir M.A Jawad S/o Shafiq Ahmed CNIC No.42201-5392112-5,<br>3. Syed Dawood S/o Syed Fasih Uddin Ahmed, LB-0060600 | 1. Mr. Ali Akhai S/o Muhammad Jawed Akhai CNIC No.42000-3326827-5.<br>2. Mr. Muqtadir M.A Jawad S/o Shafiq Ahmed CNIC No.42201-5392112-5.<br>3. Mr. Syed Dawood S/o Syed Fasih Uddin Ahmed, LB-0060600.<br>4. Mr. Javed Ghulam Mohammad S/o Ghulam Mohammad CNIC No. 42201-0556944-9. |

**<u>Decision of the Central Licensing Board in 279th meeting:</u>**

The Board considered and endorsed the change of management of M/s Martin Dow Ltd, Karachi under Drug Manufacturing LicenseNo. 000267 by way of formulationas under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-

8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;

| Previous Management | New Management |
|---|---|
| 1. Mr. Muhammad Jawed Akhai S/o A. Sattar Akhai CNIC No.42000-1658201-1.<br>2. Mr. Muqtadir M.A Jawad S/o Shafiq Ahmed CNIC No.42201-5392112-5,<br>3. Syed Dawood S/o Syed Fasih Uddin Ahmed, LB-0060600 | 1. Mr. Ali Akhai S/o Muhammad Jawed Akhai CNIC No.42000-3326827-5.<br>2. Mr. Muqtadir M.A Jawad S/o Shafiq Ahmed CNIC No.42201-5392112-5.<br>3. Mr. Syed Dawood S/o SyedFasih Uddin Ahmed, LB-0060600.<br>4. Mr. Javed Ghulam Mohammad S/o Ghulam Mohammad CNIC No. 42201-0556944-9. |

**Case No.13** **CHANGE OF MANAGEMENT OF M/S ZANCTOK PHARMACEUTICAL LABORATORIES, HYDERABAD, UNDER DRUG MANUFACTURING LICENSE NO. 000251 (FORMULATION)**

M/s Zanctok Pharmaceutical Laboratories, Hyderabad, under DML No. 000251 (Formulation) wherein the firm has submitted the request for change of management. The firm has deposited fee of Rs. 50,000/- The detail of documents is as under:

| Previous Management as per Form-1A Year 2013 | New Management as per Partnership deed Year 2020 |
|---|---|
| 1. Mr. Noor Ali s/o Sabaz Ali<br>2. Mr. Qaim Ali s/o Sabaz Ali<br>3. Mr. Muhammad Saleem s/o Abdul Karim<br>4. Mr. Wazir Ali Lasi s/o Qamruddin Lasi<br>5. Mr. Feroz Ali Pirwani s/o Ashique Ali Pirwani | 1. Mr. Muhammad Saleem S/O Abdul Kareem CNIC NO. 42201-4740769-7.<br>2. Mr. Feroz Ali Pirwani S/O Ashiq Ali Pirwani CNIC NO. 42201-0488047-5.<br>3. Mr. Fida Ali S/O Sabz Ali CNIC NO. 42201-9124195-7. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management of M/s Zanctok Pharmaceutical Laboratories, Hyderabad, under DML No. 000251 (Formulation)as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020: -

| Previous Management as per Form-1A Year 2013 | New Management as per Partnership deed Year 2020 |
|---|---|

| | |
|---|---|
| 1. Mr. Noor Ali s/o Sabaz Ali<br>2. Mr. Qaim Ali s/o Sabaz Ali<br>3. Mr. Muhammad Saleem s/o Abdul Karim<br>4. Mr. Wazir Ali Lasi s/o QamruddinLasi<br>5. Mr. Feroz Ali Pirwani s/o Ashique Ali Pirwani | 1. Mr. Muhammad Saleem S/O Abdul Kareem CNIC NO. 42201-4740769-7.<br>2. Mr. Feroz Ali Pirwani S/O Ashiq Ali Pirwani CNIC NO. 42201-0488047-5.<br>3. Mr. Fida Ali S/O Sabz Ali CNIC NO. 42201-9124195-7. |

**Case No.14** **CHANGE OF MANAGEMENT OF M/S SEARLE IV SOLUTIONS (PVT) LTD, 1.5-KM, MANGA RAIWIND ROAD, MANGA MANDI, DISTT, LAHORE.**

M/s Searle IV Solutions (Pvt) Ltd, 1.5-KM, Manga Raiwind Road, Manga Mandi, Distt, Lahore DML No. 000586 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 as per Form-A | New management as per Form-29 |
|---|---|
| 1. Mr. Muhammad Mansoor Dilawar.<br>2. Khawaja Mushtaq Ahmed.<br>3. Hafiz Abdul Rauf. | 1. Mr. Muhammad Mansoor Dilawar S/o Muhammad Maqsood, CNIC 35202-6194911-3.<br>2. Khawaja Mushtaq Ahmed S/o Khawaja Noor Elahi, CNIC No. 38403-5384555-5.<br>3. Ms. Abida Mansoor W/o Muhammad Mansoor Dilawar, CNIC No. 35202-7276319-6. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management M/s Searle IV Solutions (Pvt) Ltd, 1.5-KM, Manga Raiwind Road, Manga Mandi, Distt, Lahoreunder DML No. 000586, as under ;

| Existing management as per Form-A | New management as per Form-29 |
|---|---|
| 1. Mr. Muhammad Mansoor Dilawar.<br>2. Khawaja Mushtaq Ahmed.<br>3. Hafiz Abdul Rauf. | 1. Mr. Muhammad Mansoor Dilawar S/o Muhammad Maqsood, CNIC 35202-6194911-3.<br>2. Khawaja Mushtaq Ahmed S/o Khawaja Noor Elahi, CNIC No. 38403-5384555-5.<br>3. Ms. Abida Mansoor W/o Muhammad Mansoor Dilawar, CNIC No. 35202-7276319-6. |

**Case No. 15 CHANGE OF MANAGEMENT OF M/S RAS PHARMACEUTICALS (PVT) LTD, 25-KM, LAHORE ROAD, MULTAN.**

M/s Ras Pharmaceuticals (Pvt) Ltd, 25-KM, Lahore Road, Multan, under DML No. 000821 by wayof (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:-

| Previous management as per Form-29. | New management as per Form-29. |
|---|---|
| 1. Mr. Muhammad Ayub Anjum S/o Abdul Sattar CNIC No. 36302-7746736-7.<br>2. Imdad Hussain Siddiqui S/o Khadim Hussain Siddiqui CNIC No.36302-4210963-9. | 1. Mr. Muhammad Ayub Anjum S/o Abdul Sattar CNIC No. 36302-7746736-7.<br>2. Mrs. Farhat W/o Muhammad Ayub CNIC No. 3630233464928. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management M/s Ras Pharmaceuticals (Pvt) Ltd, 25-KM, Lahore Road, Multanunder DML No. 000821, as under ;

| Previous management as per Form-29. | New management as per Form-29. |
|---|---|
| 1. Mr. Muhammad Ayub Anjum S/o Abdul Sattar CNIC No. 36302-7746736-7.<br>2. Imdad Hussain Siddiqui S/o Khadim Hussain Siddiqui CNIC No.36302-4210963-9. | 1. Mr. Muhammad Ayub Anjum S/o Abdul Sattar CNIC No. 36302-7746736-7.<br>2. Mrs. Farhat W/o Muhammad Ayub CNIC No. 3630233464928. |

**Case No.16 CHANGE OF TITLE OF M/S TITLIS PHARMA, 628-A, SUNDAR INDUSTRIAL ESTATE, RAIWIND ROAD, LAHORE.**

M/s Titlis Pharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore under DML No. 000799, has requested for change of title of the company. The detail of status of firm is as under:-

| Previous Title of the firm. | New Title of the firm. |
|---|---|
| Titlis Pharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore. | Titlis Pharma (Private) Limited, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of title of M/s Titlis Pharma, 528-A, Sundar Industrial Estate, Raiwind Road, Lahore under DML No. 000799as under ;

| Previous Title of the firm. | New Title of the firm. |
|---|---|
| Titlis Pharma, Lahore. | Titlis Pharma (Private) Limited, Lahore. |

**Case No.17 CHANGE OF MANAGEMENT OF M/S. FEROZSONS LABORATORIES LTD., AMANGARH, NOWSHERA.**

M/s. Ferozsons Laboratories Ltd., Amangarh, Nowshera, under DML No. 000038 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

| Previous management as per Form-A &Form-29 | New management as per Form-A |
|---|---|
| 1. Mrs. Akhter Khalid Waheed W/o Late Mr. Khalid Waheed, CNIC. No. 37405-0348706-0<br>2. Mr. Osman Khalid Waheed S/o Mr. Khalid Waheed, CNIC. No. 37405-0384955-7<br>3. Mrs. Amna Paracha Khan W/o Mr. Saleem Zulfiqar Khan, CNIC. No. 61101-7905821-6<br>4. Mrs. Munize Azhar Pirahca W/o Mr. Azhar Mahmood Piracha CNIC No. 35202-2778956-0<br>5. Mr. Nihal Cassim S/o Firozuddin Cassim, CNIC. No.42301-8289704-9<br>6. Mr. Shahid Anwar S/o Mr. Abdul Rehman Farooqui CNIC No. 42201-0442011-5<br>7. Mr. Arshad Saeed Husain S/o Mian Shahid Husain, CNIC No. 42000-0504011-9 | 1. Mrs. Akhter Khalid Waheed W/o Late Mr. Khalid Waheed, CNIC. No. 37405-0348706-0<br>2. Mr. Osman Khalid Waheed S/o Mr. Khalid Waheed, CNIC. No. 37405-0384955-7<br>3. Mrs. Amna Paracha Khan W/o Mr. Saleem Zulfiqar Khan, CNIC. No. 61101-7905821-6<br>4. Mrs. Munize Azhar Pirahca W/o Mr. Azhar Mahmood Piracha CNIC No. 35202-2778956-0<br>5. Mr. Suleman Ghani S/o Malik Amjad Hussain, CNIC No.35202-9342267-9<br>6. Mr. Shahid Anwar S/o Mr. Abdul Rehman Farooqui CNIC No. 42201-0442011-5<br>7. Mr. Arshad Saeed Husain S/o Mian Shahid Husain, CNIC No. 42000-0504011-9 |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management M/s. Ferozsons Laboratories Ltd., Amangarh, Nowshera, under DML No. 000038, as under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;

| Previous management as per Form-A &Form-29 | New management as per Form-A |
|---|---|
| 1. Mrs. Akhter Khalid Waheed W/o Late Mr. Khalid Waheed, CNIC. No. 37405-0348706-0<br>2. Mr. Osman Khalid Waheed S/o Mr. Khalid Waheed, CNIC. No. 37405-0384955-7<br>3. Mrs. Amna Paracha Khan W/o Mr. Saleem Zulfiqar Khan, CNIC. No. 61101-7905821-6<br>4. Mrs. MunizeAzharPirahca W/o Mr. Azhar Mahmood Piracha CNIC No. 35202-2778956-0<br>5. Mr. Nihal Cassim S/o FirozuddinCassim, CNIC. No.42301-8289704-9<br>6. Mr. Shahid Anwar S/o Mr. Abdul Rehman | 1. Mrs. Akhter Khalid Waheed W/o Late Mr. Khalid Waheed, CNIC. No. 37405-0348706-0<br>2. Mr. Osman Khalid Waheed S/o Mr. Khalid Waheed, CNIC. No. 37405-0384955-7<br>3. Mrs. Amna Paracha Khan W/o Mr. Saleem Zulfiqar Khan, CNIC. No. 61101-7905821-6<br>4. Mrs. MunizeAzharPirahca W/o Mr. Azhar Mahmood Piracha CNIC No. 35202-2778956-0<br>5. Mr. Suleman Ghani S/o Malik Amjad Hussain, CNIC No.35202-9342267-9<br>6. Mr. Shahid Anwar S/o Mr. Abdul Rehman Farooqui CNIC No. 42201-0442011-5 |

| | |
|---|---|
| Farooqui CNIC No. 42201-0442011-5<br>7. Mr. Arshad Saeed Husain S/o Mian Shahid Husain, CNIC No. 42000-0504011-9 | 7. Mr. Arshad Saeed Husain S/o Mian Shahid Husain, CNIC No. 42000-0504011-9 |

**Case No.18** **M/S ROTEX PHARMA (PVT) LTD, PLOT NO. 206 & 207, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

M/s Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad, under DML No. 000651 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

| Previous management as per Form-29 | New management as per Form-A |
|---|---|
| 1. Mr. Khawaja Muhammad Umar Farooq S/o Khawaja Asghar Saeed, CNIC. No.61101-1855502-5.<br>2. Mr. Khawaja Asghar Saeed S/o Muhammad Yasin, CNIC. No. 61101-9793027-7.<br>3. Mrs. Afifa Asghar Saeed W/o Khawaja Asghar Saeed, CNIC. No. 61101-4272310-4. | 1. Mr. Khawaja Asghar Saeed S/o Muhammad Yasin, CNIC. No. 61101-9793027-7.<br>2. Mrs. Afifa Asghar Saeed W/o Khawaja Asghar Saeed, CNIC. No. 61101-4272310-4. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management of M/s Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000651 (Formulation), as under ;

| Previous management as per Form-29 | New management as per Form-A |
|---|---|
| 1. Mr. Khawaja Muhammad Umar Farooq S/o Khawaja Asghar Saeed, CNIC. No.61101-1855502-5.<br>2. Mr. Khawaja Asghar Saeed S/o Muhammad Yasin, CNIC. No. 61101-9793027-7.<br>3. Mrs. Afifa Asghar Saeed W/o Khawaja Asghar Saeed, CNIC. No. 61101-4272310-4. | 1. Mr. Khawaja Asghar Saeed S/o Muhammad Yasin, CNIC. No. 61101-9793027-7.<br>2. Mrs. Afifa Asghar Saeed W/o Khawaja Asghar Saeed, CNIC. No. 61101-4272310-4. |

**CASE NO.19** **CHANGE OF MANAGEMENT OF M/S PEARL PHARMACEUTICALS, PLOT NO.204, SECTOR 1, I-10/3, INDUSTRIAL AREA, ISLAMABAD.**

M/s Pearl Pharmaceuticals, Plot No.204, Sector 1, I-10/3, Industrial Area, Islamabad, under DML No. 000479 by way of formulation has submitted request for change in management of the firm as per

Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

| Previous management as per Form-1A | New management as per Partnership deed |
|---|---|
| 1. Sheikh Muhammad Latif<br>2. Muhammad Humayun Latif<br>3. Khalil -ur-Rehman | 1. Sheikh Muhammad Latif S/o Sheikh Noor-Ud-Din CNIC #37405-4315492-1<br>2. Muhammad Humayun Latif S/o Sheikh Muhammad Latif CNIC # 37405-4411347-1<br>3. Asad-ur-Rehman Khalil S/o Khalil Rehman CNIC # 37405-0694771-7. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management of M/s Pearl Pharmaceuticals, Plot No.204, Sector 1, I-10/3, Industrial Area, Islamabad, under DML No. 000479 by way of formulation, as under ;

| Previous management as per Form-1A | New management as per Partnership deed |
|---|---|
| 1. Sheikh Muhammad Latif<br>2. Muhammad Humayun Latif<br>3. Khalil -ur-Rehman | 1. Sheikh Muhammad Latif S/o Sheikh Noor-Ud-Din CNIC #37405-4315492-1<br>2. Muhammad Humayun Latif S/o Sheikh Muhammad Latif CNIC # 37405-4411347-1<br>3. Asad-ur-Rehman Khalil S/o Khalil Rehman CNIC # 37405-0694771-7. |

**CASE NO.20 CHANGE OF MANAGEMENT OF M/S SWAN PHARMACEUTICALS (PVT) LTD., 11-E, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

M/s Swan Pharmaceuticals (Pvt) Ltd., 11-E, Industrial Triangle, Kahuta Road, Islamabad, under DML No. 000699 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

| Previous management as per Form-A & Form-29 | New management as per Form-A |
|---|---|
| 1. Muhammad Waqar Wasih Chaudry S/O Muhammad Wasi Zafar CNIC# 35202-4549100-9<br>2. Muhammad Wasi Zafar S/O MuhamamdShaifi Zafar CNIC # 35202- | 1. Muhammad Waqar Wasih Chaudry S/O MuhammadWasi Zafar CNIC #. 35202-4549100-9<br>2. Muhammad Wasi Zafar S/O MuhamamdShaifi Zafar CNIC # |

| | |
|---|---|
| 9401936-9<br>3. Umair Wasi Chaudry S/O Muhammad Wasi Zafar CNIC# 35202-6182967-5<br>4. Ghulam Mujtaba S/o Ghulam Abbas CNIC # 35302-2010463-3<br>5. Ghulam Mustafa S/o Ghulam Abbas CNIC # 35302-1085637-5<br>6. GulnazWasi S/O Muhammad Wasi Zafar CNIC# 35202-1966152-0<br>7. Sumera Mushtaq S/o Ghulam Mujtaba Kharal CNIC # 33102-9081999-4<br>8. Fareeha Amir S/o Rao Amir Sultan CNIC # 35202-2439992-0 | 35202-9401936-9<br>3. Umair Wasi Chaudry S/O Muhammad Wasi Zafar CNIC# 35202-6182967-5<br>4. Ghulam Mujtaba Kharal S/o Ghlam Abbas CNIC # 35302-2010463-3<br>5. Sumera Mushtaq S/o Ghulam Mujtaba Kharal CNIC # 33102-9081999-4<br>6. GulnazWasi S/O Muhammad Wasi Zafar CNIC# 35202-1966152-0<br>7. Fareeha Amir S/o Rao Amir Sultan CNIC # 35202-2439992-0 |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management of M/s Swan Pharmaceuticals (Pvt) Ltd., 11-E, Industrial Triangle, Kahuta Road, Islamabad, under DML No. 000699 by way of formulationas under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;

| Previous management as per Form-A & Form-29 | New management as per Form-A |
|---|---|
| 1. Muhammad Waqar Wasih Chaudry S/O Muhammad Wasi Zafar CNIC# 35202-4549100-9<br>2. Muhammad Wasi Zafar S/O MuhamamdShaifi Zafar CNIC # 35202-9401936-9<br>3. Umair Wasi Chaudry S/O Muhammad Wasi Zafar CNIC# 35202-6182967-5<br>4. Ghulam Mujtaba S/o Ghulam Abbas CNIC # 35302-2010463-3<br>5. Ghulam Mustafa S/o Ghulam Abbas CNIC # 35302-1085637-5<br>6. GulnazWasi S/O Muhammad Wasi Zafar CNIC# 35202-1966152-0<br>7. Sumera Mushtaq S/o Ghulam Mujtaba Kharal CNIC # 33102-9081999-4<br>8. Fareeha Amir S/o Rao Amir Sultan CNIC # 35202-2439992-0 | 1. Muhammad Waqar Wasih Chaudry S/O MuhammadWasi Zafar CNIC #. 35202-4549100-9<br>2. Muhammad Wasi Zafar S/O MuhamamdShaifi Zafar CNIC # 35202-9401936-9<br>3. Umair Wasi Chaudry S/O Muhammad Wasi Zafar CNIC# 35202-6182967-5<br>4. Ghulam Mujtaba Kharal S/o Ghlam Abbas CNIC # 35302-2010463-3<br>5. Sumera Mushtaq S/o Ghulam Mujtaba Kharal CNIC # 33102-9081999-4<br>6. GulnazWasi S/O Muhammad Wasi Zafar CNIC# 35202-1966152-0<br>7. Fareeha Amir S/o Rao Amir Sultan CNIC # 35202-2439992-0 |

**Case No. 21 CHANGE OF TITLE OF M/S BIOGEN PHARMACEUTICALS, 8-KM, CHAKBELI ROAD, RAWAT.**

M/s Biogen Pharmaceuticals, 8-Km, Chakbeli Road, Rawat, under DML No. 000911 (Formulation) has requested for change of title of the company as per Form-D along with prescribed Fee Challan of 50,000/- as under:-.

| Previous Title as per Form-D | New Title as per Form-D |
|---|---|
| M/s Biogen Pharmaceuticals, 8-Km, Chakbeli Road, Rawat. | M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of title of /s Biogen Pharmaceuticals, 8-Km, Chakbeli Road, Rawat, under DML No. 000911 (Formulation) as under;

| Previous Title as per Form-D | New Title as per Form-D |
|---|---|
| M/s Biogen Pharmaceuticals, 8-Km, Chakbeli Road, Rawat. | M/s Biogen Life Sciences, 8-Km, Chakbeli Road, Rawat. |

**Case No.22 CHANGE OF MANAGEMENT OF M/S. THE SEARLE COMPANY LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000016(FORMULATION)**

M/s The Searle Company Limited, Plot No. F-319, S.I.T.E KarachiunderDML No. 000016 (By way of formulation) has submitted request for change in management of the firm as per Form 29 and Form A along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

| Current Management (Year 2020) | New Management as per Form-29 of SECP (Year 2020) |
|---|---|
| 1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3.<br>2. Mr. Rashid Abdulla S/o Abdulla A. Razzaq CNIC No. 42201-1132967-1.<br>3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.<br>4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803.<br>5. Mr. Ayaz Abdulla S/o Shahid Abdulla CNIC No. 42201-8726172-1.<br>6. Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9.<br>7. Mrs. Shaista Khaliq Rehman W/o | 1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3.<br>2. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.<br>3. Mrs. Shaista Khaliq Rehman W/o Syed Khaliq Abdur Rehman CNIC No. 43201-8797867-2<br>4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803.<br>5. Dr. Atta ur Rehman S/o Jamil ur Rehman CNIC No. 42000-3123678-7 |

| | |
|---|---|
| Syed Khaliq Abdur Rehman CNIC No. 43201-8797867-2 | |

**Decision of the Central Licensing Board in 279th meeting:**

The Board considered and endorsed the change of management M/s The Searle Company Limited, Plot No. F-319, S.I.T.E KarachiunderDML No. 000016 (By way of formulation)subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020: -

| Previous Management (Year 2020) | New Management as per Form-29 of SECP (Year 2020) |
|---|---|
| 1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3.<br>2. Mr. Rashid Abdulla S/o Abdulla A. Razzaq CNIC No. 42201-1132967-1.<br>3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.<br>4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803.<br>5. Mr. Ayaz Abdulla S/o Shahid | 1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3.<br>2. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.<br>3. Mrs. Shaista Khaliq Rehman W/o Syed Khaliq Abdur Rehman CNIC No. 43201-8797867-2<br>4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803. |

| | |
|---|---|
| Abdulla CNIC No. 42201-8726172-1.<br>6. Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9.<br>7. Mrs. Shaista Khaliq Rehman W/o Syed Khaliq Abdur Rehman CNIC No. 43201-8797867-2 | 5. Dr. Atta ur Rehman S/o Jamil ur Rehman CNIC No. 42000-3123678-7. |

**Case NO.21 SUSPENSION OF LICENSE OF M/S ONYX PHARMACEUTICALS, 30-A, SMALL INDUSTRIAL ESTATE, MANSEHRA, PAKISTAN.**

A letter No. 269 dated 10th May, 2019 is received from Hon'ble Mr. Mehta Rajesh Nath Kohli, Chairman, Drug Court Quetta, Balochistan wherein he has stated that a case No. 49/2017 is pending against Hafiz Muhammad Arif and Maaz Mehmood owners of M/s Onyx Pharmaceuticals, 30-A, Small Industrial Estate, Mansehra, Pakistan in which accused namely Mr. Maaz Mehmood being the owner has been charged with the commission of the offence and he is intentionally and deliberately avoiding to appear before this Court. It is therefore directed to suspend the license of the above mentioned company after fulfilling the requisite requirement as per law and intimate the same to this Court at your earliest.

**Decision by the Central Licensing Board in 270th meeting:**

*The Board in compliance to orders of Hon'ble Chairman, Drug Court Quetta, Balochistan 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 suspension of Drug Manufacturing License.*

Proceeding of Licensing Division in compliance to the decision of Central Licensing Board.

The firm was issued show cause notice as per decision of Central Licensing Board on 03rd July, 2019.

**Reply of the firm.**

The firm has replied vide their letter dated 19-07-2019, wherein the firm has forwarded copy of court orders of High Court of Balochistan, Quetta. The detail of Court order is as under;

*"In the meanwhile, the implementation of the impugned order dated 18th June, 2019 and the impugned Murasla dated 10th May, 2019, passed by the Chairman Drug Court, Balochistan, Quetta are hereby suspended till the next date of hearing."*

**Proceedings and Decision of the Central Licensing Board in 271st meeting**

The Board after perusal of facts on record decided to seek further confirmation of stay order as mentioned in the Order of the Hnourable High Court dated 18th June, 2019 from the firm as well as area Federal Inspector of Drugs and deferred the case till next date of meeting.

Another Order was received from the High Court of Balochistan, Quetta, which is re-produced as under;

*"Mr. Manzoor Ali Bozdar, Additional Director, DRAP/Secretary Central Licensing Board Islamabad entered appearance and state that details have already been*

*submitted before the Court and though the Federal Inspector of Drugs ('FID') are being posted by the Chief Executive Officer (CEO). However, powers with regard to registration of criminal cases, raids, sealing and seizure cannot be delegated without requisite notification by the Federal Government. He also submitted the copies of correspondence between DRAP and the Ministry of National Health Services, Islamabad.*

*2. In the instant case, the order passed by the Drug Court could not be implemented initially due to non-issuance of requisite notification and subsequently the ati-interim suspension order passed by this Court. However, we are dismayed to observe that the present Federal Inspector of Drugs was posted in January, 2020, but the Ministry has not taken any serious notice with regard to issuance of notification, while earlier charge was assigned to FID of Karachi Region, and we are unable to comprehend that for inspection of Pharmaceutical factories in Balochistan the charge was given to an FID of Karachi, which is a serious violation of Constitution of Pakistan and against the Provincial Autonomy.*

*Be that as it may, office to issue notice to CEO Drugs and Federal Secretary Ministry of Health Services Government of Pakistan, which shall accompany the copy of this order with direction either to ensure the issuance of requisite notification for the Province of Balochistan, and, in case of failure, to appear in person and submit a report in a personal capacity.*

*3. As far as the case of Onyx Pharma is concerned, since it relates to Provincial Quality Control Board. Therefore, the Secretary Provincial Quality Control Board is directed to proceed strictly in accordance with law and submit a report in this behalf. The officials present in court are directed to furnish the requisite details before the court on next date hearing.*

*To come up on 07.12.2020.*

*s/d MUHAMMAD KAMRAN KHAN MULAKHAIL*
*JUDGE*
*s/d ROZI KHAN BARRECH*
*JUDGE"*

Proceeding of Licensing Division in compliance to the decision of Central Licensing Board.

Accordingly, a letter for personal hearing was issued to the firm vide letter No.F.3-4/90-Lic (Vol-I) dated 01-12-2020.

**Decision of the Central Licensing Board in 278th meeting**

*Mr. Zahid Shafique, Director and Mr. Kamran Makhdoom General Manager Admin appeared on behalf of the firm . They contended that they were new management while drug was manufactured during the period of previous management. The Board after hearing the representatives of the firm and considering the Order of the High Court of Baluchistan, Quetta decided to suspend the Drug Manufacturing License No. 000440(by way of Formulation) of M/s Onyx Pharmaceuticals, 30-A, Small Industrial Estate, Mansehra, in the light of the Orders of the Drug Court of Baluchistan, Quetta dated 10th May, 2019 till further orders.*

Proceeding of Licensing Division in compliance to the decision of Central Licensing Board.

Accordingly, decision of CLB in its 278th meeting was conveyed to the firm vide letter NO. 3-4/90-Lic (Vol-I) dated 22/12/2020

**Now the firm,** M/S Onyx Pharmaceuticals, 30-A, Small Industrial Estate, Mansehra, Pakistan vide letter No Ref o/D/RL/IS/02 dated 25/01/2021 submitted application along with order of the Honorable High Courte of Balochisan, Quetta (Criminal Revision No. 19/2019) which is reproduced as under:

***Rozi Khan Barrech, J;-****This Criminal Revision Petition No. 19 of 2019 filed under section 435, 439 Cr.P.C., by the petitioner against the order/murasala dated 10.05.2019 passed by the Chairman Drug Court, Balochistan, Quetta, whereby the order has been made for suspension of the license of Ws Onyx Pharmaceuticals, 30-A Small Industrial Estate Mansehra.*

*2. Brief facts of the case are that on 05.07.2013 at 12:30 p.m., the complainant inspected M/s Nims Traders Saleem Medical Complex, M.A. Jinnah Road, Quetta, where Abdul Ghaffar son of Abdul Ghani proprietor of said drugs sales exhibit was present. The complainant took a sample of Paracetamol Syrup Suspension Batch No.L-071 manufactured by M/s Onyx Pharmaceuticals 30-A Small Industrial Estate Mansehra, Pakistan, into possession and sent the sample to the Government Analyst Provincial Drug Testing Laboratory, Government of Balochistan, Quetta on form 6 vide Memorandum DI Quetta Zone-D 118 dated 06.07.2013 for test analyst. The test report vide report dated 17.07.2013 was received, which was declared as a substandard.*

*3. After completion of the investigation, the Drug Inspector submitted a complaint No.49 of 2017 through Drug Inspector Quetta zone before the Drug court against the accused Hafiz Muhammad Arif and Maaz Mehmood. After framing charge and recording evidence of parties and statement of the accused, when the case was fixed for argument, meanwhile, the accused Maaz Mehmood jumped from the bail, non- bailable warrants of the accused were issued by the trial court. On 10.05.2019 the trial court sent a Marasala to Chief Executive Officer Drug Regulatory Authority, Islamabad, with the direction to suspend the license of the Ws Onyx Pharmaceuticals, 30-A Small Industrial Estate Mansehra, Pakistan.*

*Being aggrieved from the said Order, the petitioner filed the Instant petition.*

*4. We have learned counsel for the parties and have gone through the available record with their able assistance.*

*5. The learned trial court instead of obtaining proper procedure, i.e. issuing a notice of the surety under section 514-A Cr.P.C., proceeding under section 87 and 88 Cr.P.C., and attachment of the property of the absconding accused, the learned trial court ordered for suspension of the license of M/s Onyx Pharmaceuticals, 30-A Small industrial Estate Mansehra, without hearing the owner of the company which is a violation of the fundamental rights guaranteed under Article IO-A o the Constitution of Islamic Republic of Pakistan, 1973,* ***("the Constitution").***

6. *There is no any law mentioned by the learned trial court about the suspension of the license of the company, it was the duty of the trail court to first issue show cause notice under section 514-A Cr.P.C to the surety of the absconding accused and thereafter initiating an action under section 87 and 88 Cr.P.C.*

*In view of the above circumstances, the order/marasal dated 10.05.2019 passed by the Chairman Drug Court, Balochistan, Quetta, is not sustainable in the eyes of the law, as such, the same is hereby set aside and the petition is accepted.*

*SD/-ROZI KHAN BARRECH*
*JUDGE*
*SD/- MUHAMMAD KAMRAN KHAN MULAKHAIL*
*JUIDGE"*

**Case is submitted for consideration and orders of the Board please.**

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considered the order of the Honorable High Court Baluchistan Quetta whereby marasala of the Chairman Drug Court Balochistandated 10th May 2019 has been set aside . The Board therefore decided to cease the suspension of Drug Manufacturing License No. 000440(Formulation) of M/S Onyx Pharmaceuticals, 30-A, Small Industrial Estate, Mansehra for further period.

**Case No.22 WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTION BY M/S JAWA PHARMACEUTICALS (PVT) LTD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. 000150 (FORMULATION).**

M/s Jawa Pharmaceuticals (Pvt.) Ltd, 112/10, Quaid-e-Azam Industrial Area Kot Lakhpat Lahore under DML No. 000150 by way of Formulationhas submitted request for withdrawal of following licensed section namely:

i. Liquid Injectable (Ampoule) (Steroid) Section.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considered and acceded the request of the firm for withdrawal of following licensed sections of the firm :

i. Liquid Injectable (Ampoule) (Steroid) Section.

The Board also decided to inform the Drug Registration Board for necessary action at their end.

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

M/s Cortex Pharmaceuticals, Plot No. 16-A, SS-4, National Industrial Zone, Rawat under Drug Manufacturing License No. 000826 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 | Castor Oil | Yes |
| 03 | Liquid Paraffin (Heavy) | Yes |
| 04 | Icthammol | Yes |
| 05 | Gentian Violet | Yes |

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considered and approved the grant of following repacking products Rawat under Drug Manufacturing License No. 000826 by way of Formulation of M/s Cortex Pharmaceuticals, Plot No. 16-A, SS-4, National Industrial Zone,

| Sr.No | Name of drugs for Repacking | Schedule-D |
|---|---|---|
| 01 | Glycerin | Yes |
| 02 | Castor Oil | Yes |
| 03 | Liquid Paraffin (Heavy) | Yes |
| 04 | Ichthammol | Yes |
| 05 | Gentian Violet | Yes |

**Case No.24** **WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTION BY M/SLINTA PHARMACEUTICALS (PVT) LTD, RAWAT UNDER DRUG MANUFACTURING LICENSE NO. 000810 (FORMULATION).**

M/s Linta Pharmaceuticals (Pvt) Ltd, Plot No. 03, Street No. S-5, National Industrial Zone, Rawat under DML No 000810by way of Formulationhas submitted request for withdrawal of following licensed section namely:

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considered and acceded the request of the firm for withdrawal of following licensed sections of the firm :

i. Sachet (General) Section.

The Board also decided to inform the Drug Registration Board for necessary action at their end.

**Case No.25** **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/s HONIG PHARMACEUTICAL LABORATORIES, RAWALPINDI.**

M/s Honig Pharmaceutical Laboratories, 14-Km, Adyala Road, Rawalpindi had applied for renewal of DML No. 000550 by way of Formulation for the period of 28-08-2019 to 27-08-2024on 19-07-2019.

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 6th January, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Partnership deed along with CNIC copies of all Directors.
ii. Proof of licensed section from CLB.
iii. All documents should be duly attested.

The firm replied to this letter on 17th January,2020 and reminder letter was issued on 26th February, 2020 to the firm for completion of application:

i. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

The firm dd not reply to reminder and application for renewal of DML is still incomplete with following documents being deficient.

i. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.

**Proceedings and Decision by the Central Licensing Board in 278th meeting:**

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 and Rule 16of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000550 (by way of formulation) of M/s Honig Pharmaceutical Laboratories, 14-Km, Adyala Road, Rawalpindi may not be suspended or cancelled by Central

Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Show Cause notice dated 05th January, 2021 was issued to M/s Honig Pharmaceutical Laboratories, 14-Km, Adyala Road, Rawalpindi.

The firm has replied and submitted all deficient documents. Now, the application for renewal of DML is complete.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to cease the show cause notice in respect of Drug Manufacturing License No.000550 (By way of Formulation) of M/s Honig Pharmaceutical Laboratories, 14-Km, Adyala Road, Rawalpindi for further period.

**Case No.26 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/s ADVANCED PHARMACEUTICALS, RAWAT.**

M/s Advanced Pharmaceuticals, Plot No. 38, Street S-4, National Industrial Zone, RCCI, Rawat had applied for renewal of DML No. 000686 by way of Formulation for the period of 24-06-2020 to 23-06-2025on 03-06-2020.

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 13thAugust, 2020under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed and stamped Form-1A (as per format)
ii. Duly attested CNIC copies of owner / partners.
iii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management.
iv. Proof of sections/section approved by CLB, if not available, apply for regularization of layout plan.
v. Update NDC regarding CRF from STO (R&D) DRAP, Islamabad.
**vi. Documents should be duly attested.**

The firm replied to this letter on 29th September, 2020 and reminder letter was issued on 2nd November, 2020 to the firm for completion of application:

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Properly filled, signed and stamped Form-1A (as per prescribed format).

The firm replied to reminder on 12th November, 2020but the application for renewal of DML is still incomplete with following documents being deficient.

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.

:

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000686(by way of formulation) of M/s Advanced Pharmaceuticals, Plot No. 38, Street S-4, National Industrial Zone, RCCI, Rawat may not be suspended or cancelled by the Central Licensing Board.

**Case No.27** **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/s IPRAM INTERNATIONAL RAWAT.**

M/s Ipram International, Plot No. 26, Street SS-3, National Industrial Zone, Rawat had applied for renewal of DML No. 000551 by way of Formulation for the period of 27-08-2019to 26-08-2024on 26-08-2019.

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 9thOctober, 2020under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

**For Renewal of DML.**

i. Form 1A duly signed and stamped by CEO of the firm along with annexure.
ii. Detail of management at the time previous renewal and present renewal.
iii. Proof of Licensed Section from CLB.
iv. Nothing due certificate regarding CRF from STO upto 2019.

**For Change of Management.**

i. Request for change of management on letter head of the firm.
ii. Fee Challan Rs. 50,000/- retained by STO, DRAP, Islamabad.
iii. Revised / New partnership deed along with CNIC (s) copies of all directors.
iv. Form-C from registrar of firm.

The firm did not reply and Final reminder letter was issued on 26th October, 2020 to the firm for completion of application:

**For Renewal of DML.**

i. Form 1A duly signed and stamped by CEO of the firm along with annexure.
ii. Detail of management at the time previous renewal and present renewal.
iii. Proof of Licensed Section from CLB.
iv. Nothing due certificate regarding CRF from STO upto 2019.

**For Change of Management.**

i. Request for change of management on letter head of the firm.
ii. Fee Challan Rs. 50,000/- retained by STO, DRAP, Islamabad.
iii. Revised / New partnership deed along with CNIC (s) copies of all directors.

iv. Form-C from Registrar of firms.

The firm replied to reminder on 10th November, 2020but the application for renewal of DML is still incomplete with following documents being deficient.

i. Nothing due certificate regarding CRF from STO.
ii. Proof of Licensed Section from CLB.
iii. Detail of management at the time previous renewal and present renewal.
iv. Request for change of management on letter head of the firm.
v. Prescribed fee of Rs. 50,000/- for change of management.
vi. Duly attested Form-C from Registrar of firms, revised partnership deed and CNIC copies of all partners.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000551(by way of formulation) of M/s Ipram International, Plot No. 26, Street SS-3, National Industrial Zone, Rawat may not be suspended or cancelled by the Central Licensing Board.

**Case No.28 CORRECTION IN MINUTES OF M/S GRAND PHARMA (PVT) LTD, RAWAT**

| | | | |
|---|---|---|---|
| M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat.<br><br>DML No. 000680 (Formulation)<br>**Sections /Facility (02)**<br>1. Liquid Injection Vial (Steroid) Veterinary.<br>2. Liquid Injection Vial (General) Veterinary (Revised). | 08-10-2020 | Good | 1. Prof. Dr. Gul Majeed, Head & Dean faculty of Pharmacy, Quaid-e-Azam University Islamabad.<br>2. Dr. Hafsa Karam Elahi, Additional Director (QA &LT), DRAP, Islamabad.<br>3. Mr. Khalid Mahmood, Federal Inspector of Drugs-II, DRAP, Islamabad. |
| **Recommendations of the panel:**<br>Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommends** M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat for the grant of additional sections under Drug Manufacturing License No. 000680 (Formulation) as of today as per mandate given vide letter No. F.1-36/2006-Lic (Vol-II) dated14th September, 2020 for following sections as per approved layout plan.<br>1. Liquid Injection Vial (Steroid) Veterinary. | | | |

2. Liquid Injection Vial (General) Veterinary (Revised).

**Decision of the Central Licensing Board in 278th meeting**

The Board considered and approved the grant of additional & revised sections in the name M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat under DML No. 000680 (Formulation)on the recommendations of the panel of experts;

**Sections (02)**

1. Liquid Injection Vial (Steroid) Veterinary- New
2. Liquid Injection Vial (General) Veterinary (Revised).

Layout plan was approved for two additional sections i.eLiquid Injection Vial (Steroid) Veterinary & Liquid Injection Vial (General) Veterinary but in the inspection report Liquid Injection Vial (General) Veterinary section was mentioned as "Revised" section and the same was approved by CLB. Now, Case is submitted for consideration and correction, please.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to approve correction in name/title of Liquid Injection Vial (General) Veterinary section – New instead of Liquid Injection Vial (General) Veterinary section – Revised of M/sGrand Pharma (Pvt) Ltd, Plot No. 5-A Street No. N-5, National Industrial Zone, Rawat under DML No. 000680 (Formulation).

**Case No.29 REGULARIZATION OF LAYOUT PLAN OF M/S MEDICAIDS PAKISTAN (PVT) LIMITED., PLOT NO. 10, SECTOR 27, KORANGI INDUSTRIAL AREA,KARACHI.**

M/s Medicaid's Pakistan (Pvt) Ltd, Plot No. 10, Sector 27, Korangi Industrial Area, Karachiunder DML No. 000139(Formulation), had applied for regularization of layout plan of running facility for their existing sections;

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. Prof. Dr. Abdullah Dayo, Member CLB,Karachi.
2. Chief Drug Inspector, Sindh.
3. Area FID, DRAP, Karachi

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

-

**Recommendations of the panel:**

*"Panel inspected the firm in detail and observed that the manufacturing sections, Q.C Lab, Water Treatment Plant, Quality Assurance System etc and critical documents Processes, SOPs and BMRs followed the written procedures, in general. The firm is built as per layout plan approved by the DRAP authorities Islamabad (Annex-Q). HVAC System seen installed and*

*observed operational in all the production sections. The firm is exporting products to Afghanistan and Philippines and registration for the purpose of export is in process in various countries as well.*

*Based on the people met, documents reviewed and observation made during the inspection, panel recommends the renewal of DML and regularization for the sections as mentioned in the aforementioned DRAP letter. The sections are summarized below."*

| Sr.# | Name of Sections | Sr.# | Name of Sections |
|---|---|---|---|
| **1.** | Capsule (General) | 2. | Sterile Ophthalmic Drops (General) |
| **3.** | Liquid Syrup (General) | 4. | Dry Powder Suspension (Cephalosporin_) |
| **5.** | Dry Powder Suspension (General) | 6. | Tablet (Cephalosporin) |
| **7.** | Liquid Injectable (General) | 8. | Capsule (Cephalosporin) |
| **9.** | Dry Powder Injection (General) – SVP | 10. | Sterile Dry Powder Injection (Cephalosporin) - New |
| **11.** | Tablet (General) | 12. | ********** |

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the case and approved the regularization of lay out plan in the name of M/s Medicaid's Pakistan (Pvt) Ltd, Plot No. 10, Sector 27, Korangi Industrial Area, Karachi under DML No. 000139 (Formulation) on the recommendation of panel of experts for the following sections:-

**SECTIONS / FACILITIES :**

| Sr.# | Name of Sections | Sr.# | Name of Sections |
|---|---|---|---|
| 1. | Capsule (General) | 2. | Sterile Ophthalmic Drops (General) |
| 3. | Liquid Syrup (General) | 4. | Dry Powder Suspension (Cephalosporin_) |
| 5. | Dry Powder Suspension (General) | 6. | Tablet (Cephalosporin) |
| 7. | Liquid Injectable (General) | 8. | Capsule (Cephalosporin) |
| 9. | Dry Powder Injection (General) – SVP | 10. | Sterile Dry Powder Injection (Cephalosporin) - **New** |
| 11. | Tablet (General) | 12. | ********** |

**Case No.30 REGULARIZATION OF LAYOUT PLAN OF M/S ELITE PHARMA (PVT) LTD,9.5-KM, SHEIKHUPURA ROAD, LAHORE.**

M/s Elite pharma (Pvt) Ltd, 9.5-Km Sheikhupura Road, Lahore under DML No. 000455 (Formulation), had applied for regularization of layout plan of running facility for their existing following sections/facility:

| Revised/Regularized Sections/ Facility | | | |
|---|---|---|---|
| 1 | Liquid Injection (General) (Revised & Regularized). | 5 | Warehouse for Liquid Injectable Infusion (General) section (New). |
| 2 | Oral Dry Powder Suspension (Penicillin) Section (Revised). | 6 | Capsule (Penicillin) Section (Revised). |
| 3 | Warehouse for Cream/Ointment Sections (New). | 7 | Cream/Ointment/Gel (General) Section (Revised) |
| 4 | Warehouse for Cephalosporin (New). | 8 | Quality Control Laboratory (Revised) |

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. Area FID, DRAP, Lahore.
2. Area AD, DRAP, Lahore.

Accordingly, Panel has inspected the premises and recommendations of panel are as under:

**Recommendations of the panel:**

"Based on the findings of the inspection, the panel of inspectors **recommends** the regularization of the layout plan of the areas inspected subject to the minor amendments advised to the company"

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the case and approved the regularization of lay out plan in the name of M/s Elite pharma (Pvt) Ltd, 9.5-Km Sheikhupura Road, Lahore under DML No. 000455 (Formulation) on the recommendation of panel of experts for the following sectionssubject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020:-

| Revised/Regularized Sections/ Facility | | | |
|---|---|---|---|
| 1 | Liquid Injection (General) (Revised & Regularized). | 5 | Warehouse for Liquid Injectable Infusion (General) section (New). |
| 2 | Oral Dry Powder Suspension (Penicillin) Section (Revised). | 6 | Capsule (Penicillin) Section (Revised). |
| 3 | Warehouse for Cream/Ointment Sections (New). | 7 | Cream/Ointment/Gel (General) Section (Revised) |
| 4 | Warehouse for Cephalosporin (New). | 8 | Quality Control Laboratory (Revised) |

**Case No.31 REGULARIZATION OF LAYOUT PLAN OF M/S A'RAF (PVT) LTD,23-KM, RAIWIND ROAD, LAHORE.**

M/s A'raf (Pvt) Ltd, 23-Km Raiwind Road, Lahore under DML No. 000685 (Formulation), had applied for regularization of layout plan of running facility for their existing following sections/facility:

| Sr. No | Name of Section/Facility | Sr. No | Name of Section/Facility |
|---|---|---|---|
| 1 | Capsule (General) (regularized). | 4 | Warehouse (regularized). |
| 2 | Tablet (General) (regularized). | 5 | Quality Control Laboratory (regularized). |
| 3 | External Preparation (regularized). | 6 | Microbiology Laboratory (regularized). |

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. Area FID, DRAP, Lahore.
2. Area ADC, DRAP, Lahore.

Accordingly, Panel has inspected the premises and recommendations of panel are as under:

**Recommendations of the panel:**

"Keeping in view the inspection proceedings, the panel **verify** the regularization of above-mentioned sections/facility as per approved layout plan"

**Case is submitted for consideration and orders of the Board please.**

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the case and approved the regularization of lay out plan in the name of M/s A'raf (Pvt) Ltd, 23-Km Raiwind Road, Lahore under DML No. 000685 (Formulation) on the recommendation of panel of experts for the following sections:-

**SECTIONS / FACILITIES :**

| Sr. No | Name of Section/Facility | Sr. No | Name of Section/Facility |
|---|---|---|---|
| 1 | Capsule (General) (regularized). | 4 | Warehouse (regularized). |
| 2 | Tablet (General) (regularized). | 5 | Quality Control Laboratory (regularized). |
| 3 | External Preparation (regularized). | 6 | Microbiology Laboratory (regularized). |

**Case No. 32 REGULARIZATION OF LAYOUT PLAN OF M/S ZEPHYR PHARMATEC (PVT) LTD, PLOT NO. A-39, S.I.T.E. II, SUPER HIGHWAY, KARACHI**

M/s Zephyr Pharmatec (Pvt) Ltd, Plot No. A-39, S.I.T.E. II, Super Highway, Karachi under DML No. 000403 (Formulation), had applied for regularization of layout plan of facility for their existing following sections;

| S. No. | Sections | S. No. | Sections |
|---|---|---|---|
| 1. | Tablet Section (General) | 2. | Capsule (General) Section. |
| 3. | Ointment/Cream/Gel (General). | 4. | Ware House (General). |
| 5. | Capsule (Cephalosporin) | 6. | Ware House (Cephalosporin) |
| 7. | Dry Powder Suspension Section (Cephalosporin) | 8. | Ware House (Penicillin) |
| 9. | Dry Powder Suspension Section (Penicillin) | 10. | Capsule (Penicillin) |
| 11. | Syrup(General) | 12. | Sachet (General) |
| 13. | Quality Control Laboratory | 14. | Dry Powder Suspension (General) |

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. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Chief Drug Inspector, Sindh.
3. Area FID, DRAP, Karachi

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

**Recommendations of the panel:**

*"Keeping in view the stated facts, documents reviewed, personnel met and attitude of the firm management towards constant improvements the panel recommends the grant of renewal o their DML No. 000403 (Formulation) for the next five years due from 02-04-2020 for Tablet (G), Capsule(G), Ointment/Cream/Gel(G), Warehouse(G), Capsule (Cephalosporin), Warehouse (Cephalosporin), Dry Powder Suspension (Cephalosporin), Warehouse (Penicillin), Dry Powder Suspension (Penicillin), Capsule (Penicillin), Syrup(G), Sachet (G), Quality Control and Microbiology Laboratory and Dry Powder Suspension (G) section."*

*The panel has also recommended the regularization of existing layout plan vide addendum letter and reproduced as below:*

*"In addition to recommendations in the inspection report, the panel also recommends the regularization of the existing layout plan of M/s Zephyr Pharmatec (Pvt) Ltd, Karachi''*

**Case is submitted for consideration and orders of the Board please.**

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the case and approved the regularization of lay out plan in the name of M/s Zephyr Pharmatec (Pvt) Ltd, Plot No. A-39, S.I.T.E. II, Super Highway, Karachiunder DML No. 000403 (Formulation) on the recommendation of panel of experts for the following sections:-

**SECTIONS / FACILITIES :**

| S. No. | Sections | S. No. | Sections |
|---|---|---|---|
| 1. | Tablet Section (General) | 2. | Capsule (General) Section. |
| 3. | Ointment/Cream/Gel (General). | 4. | Ware House (General). |
| 5. | Capsule (Cephalosporin) | 6. | Ware House (Cephalosporin) |

| | | | |
|---|---|---|---|
| 7. | Dry Powder Suspension Section (Cephalosporin) | 8. | Ware House (Penicillin) |
| 9. | Dry Powder Suspension Section (Penicillin) | 10. | Capsule (Penicillin) |
| 11. | Syrup(General) | 12. | Sachet (General) |
| 13. | Quality Control Laboratory | 14. | Dry Powder Suspension (General) |

**Case No.33** **RENEWAL OF DML NO. 000119 (FORMULATION) OF M/S PAKISTAN PHARMACEUTICAL & CHEMICAL LABORAOTRIES (PVT) LTD, HYDERABAD**

The Firm has filled application for renewal of DML No. 000119 (Formulation) for the period commencing on 12-07-2019 and ending on 11-07-2024. The application was received on 23-07-2019 2019. The application for the renewal of DML of the firm was evaluated. Following documents were found deficient.

i. Application on Prescribed Form-1A signed by current management of the firm along with dully attested annexure/enclosure.
ii. Updated NOC regarding CRF from STO, DRAP.
iii. Updatedoriginalcertified true copy of Form-29 & Form-A issued by SECP (original).
iv. Duly attested CNIC copies of all Directors.
v. Section approval letters of all sections approved by CLB, if not available, apply for regularization of layout plan.
vi. Prescribed fee challan for renewal of DML retained by STO DRAP, Islamabad along with additional surcharge fee of Rs. 60,000 as the application is received 12 days late from due date of renewal of DML
vii. Names and Approval letters of Production In charge and Quality Control In charge.

A letter dated 03rd January 2020 was issued to the firm to submit the above mentioned shortcoming/deficient documents.

No reply was received from the firm and a Reminder dated 30th November 2020 was issued to the firm to submit the said documents but no reply/response is received from the firm and the application for renewal of DML is still deficient of above mentioned documents.

**Case is submitted for consideration and orders of the Board please.**

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 , Rule 16 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000119(by way of formulation) of **M/s Pakistan Pharmaceutical and**

**Chemical Laboratories (Pvt) Ltd, Hyderabad**may not be suspended or cancelled by the Central Licensing Board.

**Case No.34** **RENEWAL OF DML NO. 000234 (FORMULATION) OF M/S AJ MIRZA PHARMA (PVT) LTD, PLOT No. 44, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI.**

M/s A.J. Mirza Pharma (Pvt) Ltd, Karachi has submitted application for renewal of DML No. 000234(Formulation) for the tenure 10-07-2020 till 09-07-2025 which is received on 09-12-2020 while the due date was 09-07-2020.

The application for renewal of DML is received after more than sixty (60) days from due date for renewal of DML no. 000234 (Formulation) therefore, the DML of the firm was not valid .

In response a letter dated 12th January 2021 was issued to the firm to submit a fresh application for grant of DML (formulation) under Rule 5(3) of the Drugs (L,R&A) Rules, 1976.

Meanwhile firm has also afresh application for grant of Drug manufacturing License (Formulation).

**Case is submitted for consideration and orders of the Board please.**

**Proceedings and Decision by the Central Licensing Board in 279th meeting**

The Board considering the facts on the record and after thread bare deliberation decided that as the application for renewal of DML No. 000234 (Formulation) of M/s A.J. Mirza Pharma (Pvt) Ltd, Karachi is made after the expiry of the period of validity of License, therefore, Drug Manufacturing License DML No. **000234** (Formulation) is no more valid and stands cancelled.

**Case No.35** **RENEWAL OF DML NO. 000449 (FORMULATION) OF M/S HIRRA PHARMACEUTICALS (PVT) LTD, 1.3-KM, ASIL RAIWIND ROAD, LAHORE.**

Drug Manufacturing License No. 000449 (Formulation) was issued to M/s Hirra Pharmaceuticals (Pvt) Ltd, 1.3-Km, Asil Raiwind Road, Lahore. It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *"if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application"*. But, in this case the application for renewal of DML for the period 01-08-2020 to 31-07-2025 has not been received till date. Therefore, DML No. 000449 (Formulation) M/s Hirra Pharmaceuticals (Pvt) Ltd, 1.3-Km, Asil Raiwind Road, Lahore is no more valid.

However, the firm has filed new application for re-grant of DML on 11-11-2020 and shortcomings in the application has been conveyed to the firm vide letter No. F.1- 10/94-Lic (Vol-II) dated 01-01-2021.

**Proceedings and Decision by the Central Licensing Board in 279th meeting**

The Board considering the facts on the record and after thread bare deliberation decided that as the application for renewal of DML No. 000449 (Formulation) of M/s Hirra Pharmaceuticals (Pvt) Ltd, 1.3-Km, Asil Raiwind Road, Lahoreis made after the expiry of the period of validity of License, therefore, Drug Manufacturing License DML No. **000449** (Formulation) is no more valid and stands cancelled.

**Case No.36** **M/S MAKSON PHARMACEUTICALS, INDUSTRIAL AREA, I-10/3, ISLAMABAD – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.**

**Case background:**

M/s Makson Pharmaceuticals, Industrial Area, I-10/3, Islamabad submitted the application for renewal of DML No. 000560 by way of formulation on 12-01-2015 for the period of 08-12-2014 to 07-12-2019.

The Central Licensing Board in its 255th meeting held on 16th& 17th August, 2017 has considered the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to M/s Makson Pharmaceuticals, 80-B, Street # 06, I-10/3, Industrial Area, Islamabad and decided as under:-

**Decision of Central Licensing Board.**

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 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000560 by way of formulation of M/s Makson Pharmaceuticals, Industrial Area, I-10/3, Islamabad may not be rejected by Central Licensing Board or the Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

2. Accordingly a Show Cause Notice issued to firm on 21st September, 2017. In response to show cause notice the firm has submitted documents. Upon evaluation of submitted documents following shortcoming have still been observed in the DML renewal application:-

**Renewal of DML application.**

1. Name of total sections of licensed facility and their letters of grant issued after approval in meeting of Central Licensing Board.
2. Nothing due certificate regarding deposition of Central Research Fund updated.
3. Detail of management at the time of previous renewal and present renewal.

**Production Incharge.**

1. Appointment letter.
2. Job acceptance letter.
3. Registration Certificate from Pharmacy Council.
4. Resignation / retirement of earlier Production Manager.
5. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

**Quality Control Incharge.**

1. Appointment letter.

2. Job acceptance letter.
3. Resignation / retirement of earlier Production Manager.
4. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

The firm has also been called for personal hearing.

**Proceedings and Decision of Central Licensing Board in 256th meeting.**

Mr. Kifayat Malik Chairman, M/s Makson Pharmaceuticals, Industrial Area, I-10/3, Islamabad alongwith Mr. Sajjad Munir, Regulatory Affairs Manager appeared before the Board. He contended that there is no change of Management but at the same time he also contended that his firm is registered with SECP. He also contended that rubber stump affixed on the letters is with Private Limited. The Board also enquired that letter head of the firm does not bear title with Private Limited. He also informed the Board that company has also been outsourced. He could not satisfy the Board regarding change in title of the firm as well. The Board also observed that firm has been manufacturing and selling drugs without **approved** qualified staff since years. The Board after perusal of record and facts mentioned above and deliberations made by representative of the firm decided to reject the application of renewal of the Drug manufacturing Licence No. 000560 by way of formulation of M/s Makson Pharmaceuticals, Industrial Area, I-10/3, Islamabad with immediate effect 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.

**Decision of Appellate Board.**

Mr. Aamar Latif, Deputy Director (Appellate Board), DRAP, Islamabad wherein he has conveyed the decision of 151st meeting of appellate Board held on 16th January, 2019 in respect of M/s Makson Pharmaceuticals, Islamabad. The decision of Appellate Board is as under:-

> "The Board, after hearing arguments and perusing record of the case, decided to remand the case back to the Central Licensing Board with direction to decide a fresh the application for renewal of Drug Manufacturing License No. 000560 submitted by M/s Makson Pharmaceuticals, Islamabad in forthcoming meeting.
> The Licensing Division shall ensure that inspection of the firm be carried out within 15 days of the communication of this decision. The panel so constituted may allow production if the firm is complying with Good Manufacturing Practices (GMP) guidelines".

**Decision by the Central Licensing Board in 270th meeting:**

The Board in compliance to orders of Appelate Board decided that the firm will first get the application complete for renewal of Drug Manufacturing License and then process will be done accordingly.

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

In light of Decision of CLB in its 270thmeeting, letter NO. 1-24/2001-L-c dated 27/09/2019 was issue, accordingly.

The firm M/s. Makson Pharmaceuticals, Islamabad submitted vide letter NO. Nil dated Nil, which is reproduced as under;

1. *With reference to your letter # F-1-3/2018-AB(M-151), dated 4th February 2019 and letter # F-1-24/2001-Lic, regarding the subject cited above.*

2. *The whole world was jolted by a sudden spread of pandemic which affected all communities around the universe and Pakistan has not been exception. Unfortunately, working members of M/S Makson Pharmaceuticals were directly caught into it so administrative unit was totally closed. Though the danger of losing lives still exists nevertheless the Government of Pakistan has decided to open few offices, organization, schools etc.*

3. *The administrative members of M/S Makson Pharmaceuticals have been called back after a lapse of about one year and it has revealed that our time for submitting fee for renewal of licenses has overgone.*

4. *Even the strongest economies of the world have extended all possible facilities to the public organizations, departments and factories to resume without any penalty or extra charges rather have extended extra help from the government exchequer. We are not looking for any extra help but require your kindness to condone ten (10) months time period for the renewal of DML.*

5. *As per our understanding, the matter is sub-judice. We were in the process of completing documents when the Covid-19 broke-out so the same could not be submitted. Vide your letter No. F-1-3/2018-AD(M-151) dated 4th February 2019 wherein our DML was cancelled in 256th meeting of Central Licensing Board for the same we submitted an appeal against the cancellation order of our DML # 000560, before the Appellate Board in its 151st sitting held on 16th January 2019, it was ordered on our Appeal No. 03/2018 "The Board after hearing arguments and perusing record of the case, decided to remand the case back to the Central Licensing Board with direction to decide a fresh the application for renewal of Drugs Manufacturing License No.000560 submitted by M/s Makson Pharmaceuticals Islamabad in forthcoming meeting"*

6. *We were in process to get the inspection of company and Corona (COVID-19) started and all proceedings were stopped worldwide, now once activities have resumed, we are ready for inspection of plant, please consider your above mentioned decision and constitute a panel to inspect the company.*

It pertinent to mention that as per Rule 5 (6) of Drug (L, R & A) Rule, 1976 *"if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application". Furthermore,* Rule 5(3) states that *"If the application for renewal of the licence is made after the expiry of the period of the validity of the licence, it shall be treated as a fresh application for the grant of a licence.".* Application for renewal of DML for the period **08/12-2019 to 07-12-2024** of M/s Makson

Pharmaceuticals, Islamabad has not been received in Licensing Division. Therefore, DML No. **0000560** (Formulation) of M/s Makson Pharmaceuticals Islamabad is no more valid.

**Proceedings and Decision by the Central Licensing Board in 279th meeting**

The Board considering the facts on the record and after thread bare deliberation decided that as the application for renewal of DML No. 000560 (Formulation) of M/s Makson Pharmaceuticals Islamabad is made after the expiry of the period of validity of License, therefore, Drug Manufacturing License DML No. **0000560** (Formulation) is no more valid and stands cancelled.

**Case No.37 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000154 (FORMULATION) OF M/S ARDIN PHARMACEUTICALS, PLOT No. 56, SECTOR 27, KORANGI INDUSTRIAL AREA,KARACHI**

M/s Ardin Pharmaceuticals, Karachihas filled application for renewal of DML No. 000154 (Formulation) for the period commencing on 08-04-2020 and ending on 07-04-2025. The application was received on 25-03-2020. The application for the renewal of DML of the firm was evaluated and a letter dated 16-06-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Application on Prescribed Form-1A signed by current management of the firm along with dully attested annexure/enclosure.

The reply of the firm was received on 07-08-2020 and the documents submitted by the firm were evaluated and a Reminder dated 11-11-2020 was issued to the firm to submit following documents :

I. Application on Prescribed Form-1A signed by current management of the firm along with dully attested annexure/enclosure.

In response to this Division's Reminder dated 11th November 2020 the firm has submitted the documents for completion of application for renewal of DML No. 000154 (Formulation) which are evaluated and the application is still found deficient of following documents:

i. All enclosures/annexures of Form-1A are unattested.

ii. The production in charge **Mr. Tariq Yameen Waseem** & quality control in charge **Mr. Ain-ul-Haq**are not approved and firm has also not submitted the documents for approval of both technical staff**.**

**i.** Updated NOC of CRF.

ii. Attested Partnership deed (existing & amended) along with attested CNIC copies of all partners/directors.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 , Rule 16 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000154(by way of formulation) of M/s Ardin Pharmaceuticals, Plot No. 56, Sector 27, Korangi Industrial Area, Karachimay not be suspended or cancelled by the Central Licensing Board.

**Case No.38 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000415 (FORMULATION) OF M/S PLATINUM PHARMACEUTICALS (PVT) LTD, PLOT No. A-20, NORTH WESTERN INDUSTRIAL ZONE,PORT QASIM KARACHI**

M/s Platinum Pharmaceuticals (Pvt) Ltd, Karachihas filled application for renewal of DML No. 000415 (Formulation) for the period commencing on 07-08-2020 and ending on 06-08-2025. The application was received on 06-04-2020. The application for the renewal of DML of the firm was evaluated and a letter dated 22-06-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. All attested annexure/enclosures of Prescribed Form-1A .
ii. Detail of all licensed sections on firm's letter head.
iii. Updated original certified true copy of Form-29 & Form-A issued by SECP (original).

The reply of the firm was received on 27-7-2020 and the documents submitted by the firm were evaluated and a Reminder dated 06-10-2020 was issued to the firm to submit following documents :

i. Updated original certified true copy of Form-29 & Form-A issued by SECP.

In response to this Division's Reminder dated 06thOctober 2020 the firm has not submitted the required documents and instead has stated that firm has applied to SECP for issuance of updated Form-29 & Form-A and will submit the same as soon as received and the application is still found deficient of following documents:

i. Updated original certified true copy of Form-29 & Form-A issued by SECP.

**Case is submitted for consideration and orders of the Board please.**

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000415 (by way of formulation) of M/s Platinum Pharmaceuticals (Pvt) Ltd, Plot No. A-20, North Western Industrial Zone, Port Qasim Karachi may not be suspended or cancelled by the Central Licensing Board.

**Case No.39** **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000470 (FORMULATION) OF M/S ZAFA PHARMACEUTICAL LABORAOTIRES (PVT) LTD, PLOT No. C-208, C-217, H.I.T.E. DISTRICT LASBELLA, BALOCHISTAN**

M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, Baluchistan has filled application for renewal of DML No. 000470 (Formulation) for the period commencing on 02-03-2020 and ending on 01-03-2025. The application was received on 27-08-2019. The application for the renewal of DML of the firm was evaluated and a letter dated 28-01-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

(i) Original certified true copy of Form-29 & From-A for year 2019 issued from SECP along with attested CNIC copies of all directors.
(ii) Detail/names of all licensed sections on firm's letter head along with approval letters of all sections issued from CLB. Or if not available then submit layout plan for regularization of manufacturing facility.
(iii) Attested copy of Classes of Drugs
(iv) Attested copy of Dosage forms of drug
(v) Attested copy of Name(s) of drugs registered / approved
(vi) Attested copy of Section wise detail of machinery for manufacture
(vii) Attested copy of Section wise detail of machinery for Quality Control Lab
(viii) Attested copy of Name and Qualification of Production In charge.
(ix) Attested copy of Name and Qualification of QC In charge.

The reply of the firm was received on 12-02-2020 and the documents submitted by the firm were evaluated and a Reminder dated 21-05-2020 was issued to the firm to submit following documents:

i) Original certified true copy of Form-29 & From-A for year 2020 issued from SECP along with attested CNIC copies of all directors.

ii) Detail/names of all licensed sections on firm's letter head along with approval letters of all sections issued from CLB. Or if not available then submit layout plan for regularization of manufacturing facility.

In response to this Division's Reminder dated 21-05-2020the firm has not submitted the required documents and instead has stated that firm has already submitted the required documents andthe application is still found deficient of following documents:

i. Original certified true copy of Form-29 & From-A for year 2020 issued from SECP along with attested CNIC copies of all directors.

ii. Detail/names of all licensed sections on firm's letter head along with approval letters of all sections issued from CLB. Or if not available then submit layout plan for regularization of manufacturing facility

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000470(by way of formulation) of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, Plot No. C-208, C-217, H.I.T.E, District Lasbella, Baluchistan, may not be suspended or cancelled by the Central Licensing Board.

**Case No.40 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000148 (FORMULATION) OF M/S MARVI PHARMACEUTICALS, PLOT No. 70, SECTOR 24, KORANGI INDUSTRIAL AREA, KARACHI**

M/s Marvi Pharmaceuticals, Karachi has filled/submitted application for renewal of DML No. 000148 (Formulation) for the period commencing on 10-07-2020 and ending on 09-07-2025. The application for the renewal of DML of the firm was evaluated and a letter dated 08-10-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Application on Prescribed From-1A.

ii. Status of sections whether ready for inspection or otherwise in the light of approved layout plan for regularization vide letter Dated : 16-03-2018.

iii. Detail/names of directors of firm on firm's letter headattested CNIC copies of all directors.

iv. Notarized Updated Partnership deed.

v. Prescribed fee for change of management (if the management is changed from the last renewal of DML).

vi. Updated NOC of CRF issued from statistical officer DRAP.

No reply was received from the firm and a Reminder dated 05th January 2021 was issued to the firm to submit the said documents but no reply/response is received from the firm and the application for renewal of DML is still deficient of above mentioned documents.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 Rule 12 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000148(by way of formulation) of M/s Marvi Pharmaceuticals , Karachi, Plot no. 70, Sector 24, Korangi Industrial Area,Karachimay not be suspended or cancelled by the Central Licensing Board.

**Case No.41 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000438 (FORMULATION) OF M/S SWISS PHARMACEUTICALS (PVT) LTD, PLOT No. A-159, S.I.T.E. II, SUPER HIGHWAY, KARACHI**

M/s Swiss Pharmaceuticals (Pvt) Ltd, Karachihas filled application for renewal of DML No. 000438 (Formulation) for the period commencing on 08-09-201907-08-2020 and ending on 07-09-2024.. The application for the renewal of DML of the firm was evaluated and a letter dated 03-01-2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Submit layout plan for regularization of manufacturing facility along with prescribed fee.

ii. Detail of current management/directors on firm's letter head along with attested CNIC copies of all directors.

iii. Updated original certified true copy of Form-29 & Form-A issued by SECP.

The reply of the firm was received on 13-10-2020 and the documents submitted by the firm were evaluated and a Reminder dated 04-12-2020 was issued to the firm to submit following documents :

i. Updated original certified true copy of Form-29 & Form-A issued by SECP.

ii. Prescribed fee for change of management.
iii. Detail of all licensed sections on firm's letter head along with prescribed fee and two copies of layout plan for the purpose of regularization.

In response to this Division's Reminder , the firm has not submitted the required documents and instead has submitted letter dated 05-01-2021 and has stated that firm has applied to SECP for issuance of updated Form-29 & Form-A and has requested to give one month time to submit the document of Form-29 along with prescribed fee for change of management and the application is still found deficient of following documents:

i. Updated original certified true copy of Form-29 & Form-A issued by SECP.
ii. Prescribed fee for change of management.
iii. Detail of all licensed sections on firm's letter head along with prescribed fee and two copies of layout plan for the purpose of regularization.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 &Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000438(by way of formulation) of M/s Swiss Pharmaceuticals (Pvt) Ltd, Plot no. A-159, S.I.T.E. II, Super Highway,Karachimay not be suspended or cancelled by the Central Licensing Board.

**Case No.42 SURRENDERING OF ALREADY APPROVED/LICENSED SECTIONSOF M/S AMARANT PHARMACEUTICALS (PVT) LTD, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000584 (FROMULATION)**

M/s Amarant Pharmaceuticals (Pvt) Ltd, Karachi has submitted request for surrendering of following licensed sections at the time of submitting application for renewal of DML.

| S.No. | Section | Human/Veterinary |
|---|---|---|
| 1. | Tablet(Antibiotic General)(Quinolones) | Human |
| 2. | Dry Powder Suspension (Penicillin) | Human |
| 3. | Capsule (Penicillin) | Human |
| 4. | Powder Section (Penicillin) | Veterinary |

**Proceedings and Decision by the Central Licensing Board in 278th meeting:**

The Board considered and acceded the request of the firm for withdrawal of following licensed sections of the firm :

| S.No. | Section | Human/Veterinary |
|---|---|---|
| 1. | Tablet(Antibiotic General)(Quinolones) | Human |
| 2. | Dry Powder Suspension (Penicillin) | Human |
| 3. | Capsule (Penicillin) | Human |
| 4. | Powder Section (Penicillin) | Veterinary |

The Board also decided to conveyto Drug Registration Board for necessary action at their end.

**Case No. 43** **CHANGE OF TECHNICAL STAFF M/S ROGEN PHARMACEUTICAL, RAWAT.**

It is mentioned that a final reminder was issued to the M/s Rogen Pharmaceuticals, Rawat DML No. 000692 by way of (Formulation) on 21st May, 2019 for completion of change of Production Incharge application with following observation:-

**For Production Incharge (Mr. Muhammad Farooq).**

i. Copy of CNIC of appointee.
ii. Copy of Academic Degrees.
iii. Registration certificate from Pharmacy Council.
iv. Experience certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 not less than 6 years.
v. Resignation/retirement of earlier approved Production Incharge.
vi. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
vii. Undertaking as whole time employee on stamp paper as per check list.
viii. All documents should be duly attested.

The firm has submitted their reply in response to this Division's final reminder and submitted another application for approval of Production Incharge **Mr. Muhammad Asif Awan S/o Khushal Khan (B-Pharm), CNIC No. 54400-5978734-3 instead of Mr. Muhammad Farooq,**which are short of following documents**:-**

**For Production Incharge (Mr. Muhammad Asif).**

i. Copy of CNIC of appointee **(Not Attested).**
ii. Copy of Academic Degrees **(Not Attested).**
iii. Registration certificate from Pharmacy Council **(Not Attested).**
iv. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 not less than 6 years **(Not Attested).**
v. Resignation / retirement of earlier approved Production Incharge **(Not provided).**
vi. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm **(Not Attested).**
vii. Undertaking as whole time employee on stamp paper as per check list **(Not on proper format).**

Another application is received from the firm, wherein the firm has submitted documents for approval of Production Incharge **Syed Mudassir Abbas S/o Syed Ghulam Abbas** instead of **Mr. Muhammad Asif** which are also deficient of following documents:-

i. Copy of CNIC of appointee **(Not Attested).**

ii. Resignation / retirement of earlier approved Production Incharge **(Not provided).**

iii. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm **(Not provided).**

Meanwhile, another application is received from M/s Rogen Pharmaceuticals, Rawat, wherein the firm has submitted the documents for approval of Production Incharge **Mr. Shahzada Abdul Salam S/o Sher Afzal Khan (B-Pharm), CNIC No. 54400-3401992-5 instead of Syed Mudassir Abbas.**The application is deficient for following documents:-

i. Copy of CNIC of appointee **(Not Attested).**
ii. Copy of Academic Degrees **(Not Attested).**
iii. Registration certificate from Pharmacy Council **(Not Attested and also not renewed from 1996).**
iv. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 not less than 6 years **(Not Attested).**
v. Resignation / retirement of earlier approved Production Incharge **(Not provided).**
vi. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm **(Not provided).**

M/s Rogen Pharmaceuticals, Rawat has not completed their change of Production Incharge application. The firm carried out their production activities without approved Production Incharge since 2018. Manufacturing of Drugs without approved technical staff is violation of Rule 16 of the Drugs (Licensing, Registering & Advertising) Rules 1976.
The case may be placed in up-coming meeting of CLB for issuance of Show Cause Notice upon the violation of Rule 16 of Drug (LR&A) Rules, 1976 as a final reminder dated 21st May, 2019 has already been served to the firm regarding approval of Production Incharge.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000692(by way of formulation) of M/s Rogen Pharmaceuticals, Rawat may not be suspended or cancelled by Central Licensing Board.

**Case No.44 M/S MEDICON PHARMACEUTICAL INDUSTRIES (PVT) LTD., B-1/11, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR**

The firm, M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar submitted the application for renewal of DML No. 000215 by way of formulation on 26-05-2016 for the period of 14-06-2016 to 13-06-2021, which was well on time. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. To submit renewal of Drug Manufacturing License application on prescribed Form-1A (copy enclosed).
ii. To submit detail of management / owners with attested copies of CNIC's and Form-29 (previous and current).

a. With reference to above letter, it is mentioned that as per available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. Licensing Division issued final reminder on for completion of application of renewal of DML to the firm for information / documents as under;
   i. To submit renewal of Drug Manufacturing License application on prescribed Form-1A (copy enclosed).
   ii. To submit detail of management / owners with attested copies of CNIC's and Form-29 (previous and current).

b. No response of the firm was received with reference to above mentioned letter and final reminder and case was considered in 253rd meeting of the Central Licensing Board.

**c. <u>Decision of CLB in its 253rd meeting.</u>**

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 Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar DML No. 000440 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

(The Drug Manufacturing Number of the firm was erroneously written as "**000440**" instead of the correct Drug Manufacturing License Number i.e. "**000215**" which was corrected **in 255th meeting)**

d. Reply of Firm to Show Cause Notice

We may refer show cause notice dated 21-09-2017, which is received on 25-09-2017, we are sending following documents for consideration

i. Application for renewal of DML on prescribed Form-1A
ii. Detail of management /owners with attested CNICs and Form-29, previous and current alongwith Challan for Rs. 50,000/- being fee of Change of management.

e. The firm has fulfilled rest of the codal formalities for renewal of Drug Manufacturing Licensee excluding proof of approved sections.

f. Proceedings and Decision of Central Licensing Board in 256th meeting.

*Dr. Maqbool Ahmed, Chief Executive of the firm appeared before the Board and contended that all codal formalities has been completed and showcause notice may be withdrawn. The Board after hearing representative of the firm advised him to comply the legal requirements in time in future and also decided to cease the operation of the show cause notice issued to the firm.*

*g.* In light of the decision of Central Licensing Board letter was issued to the firm.

h. The firm has submitted LOP for regularization of the following sections;

i. Tablet Section (General)
ii. Capsule Section (General)
iii. Syrup Section (General)
iv. Sachet Section (General)
v. Tablet Section (Psychotropic)
vi. Capsule Section (Penicillin)
vii. Dry Powder Suspension Section (Penicillin)
viii. Capsule Section (Cephalosporin)
ix. Dry Powder Suspension Section (Cephalosporin)
x. Quality Control Lab
xi. Warehouse

i. . The above submitted LOP for regularization was discussed in LOP committee and following shortcomings have been observed;

i. The firm has deposited fee of Rs. 50000/- only whereas there are eleven sections in LOP under discussion and remaining fee of Rs. 5000/- needs to be deposited.
ii. Door for entry from male change room to general production corridor has not been given.
iii. The area for storage of non active material in raw material store (general) needs to be segregated.
iv. Sachet Section (General) needs to be divided into mixing and filling areas.
v. Man and material flow in Syrup Section (General) is not in order i.e. the entry is through packing hall and manufacturing area is away from filling area.
vi. Granulation and drying area has not been provided in Tablet Section (Psychotropic).
vii. Solution preparation area has not been provided with coating area in Tablet Section (Psychotropic).
viii. Door for entering to change room of penicillin area has not been given.
ix. Step over bench has not been shown in change room of penicillin area.
x. Transfer window needs to be installed between bottle blowing and Dry Powder Suspension filling area of Dry Powder Suspension Section (Penicillin).
xi. Sampling and dispensing areas has not been provided with raw material store of penicillin area.
xii. Entry of raw and packing material to the cephalosporin area is not in order.
xiii. Transfer window needs to be installed between bottle blowing and Dry Powder Suspension filling area of Dry Powder Suspension Section (Cephalosporin).

j. The firm was advised to submit revised LOP vide letter NO. 3-7/91-Lic (Vol-III) dated 19/02/2018 and 18/05/2019. However, LOP for regularization was not approved so for because the firm has not submitted Revised LOP for approval.

Now QA/LT Division, DRAP's has informed vide file No. 4-43/89-QA that Area FID, DRAP, Peshawar has conducted routine cGMP of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar on 14-12-2020. In the inspection report the Area FID has given following recommendation;

i. To follow up their application for renewal of DML and remove deficiencies if any pending on the part of firm.
ii. To shift their penicillin sections to separate block.
iii. To regularize their layout plan with consultation of Licensing Divi ion of DRAP Islamabad.
iv. To improve their Microbiology Lab.
v. To purchase primary reference standards initially for three top selling products and then gradually for remaining products.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar DML No. 000215 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

Case No.45 **CHANGE OF MANAGEMENT OF M/S SWAT PHARMACEUTICALS, VALLEY ROAD, SHERARI GULKADA NO. 3, SAIDU SHARIF SWAT KHYBER PAKHTOONKHWA.**

The Drug Manufacturing License No. 0000035 of M/s Swat Pharmaceuticals, was granted/transfer from old premises situated at Saidu Sharif Road, Amankot Mingora, Swat to new premise situated at Valley Road, Sherarai Gulkada No.3, Saidu Sharif Swat by CLB in its 277th meeting held on 15-16th October, 2020, accordingly with following detail.

| **Name, DML #, address and Sections** | **Sections** | **Type of Firm** | **Management** | **Rent agreement (Page/17** |
|---|---|---|---|---|
| M/s Swat Pharmaceuticals, Valley Road, Sherari Gulkada No. 3, Saidu Sharif Swat Khyber Pakhtoonkhwa. | 1. Tablet (General),<br>2. Tablet (Psychotropic),<br>3. Capsule (General),<br>4. Syrup (General),<br>5. Cream/ointment (General),<br>6. Sachet (General). | Soleproprietorship | Mr. Mubarak Ali S/o Alamgir CNIC No. 15602-0482661-1<br>**(Sole Proprietor)** | Rent agreement between Mr. Shahid Fazal S/O Fazal Rabi (owner of the land) and Mr. Mubarak Ali S/o Alamgir for 25 year |

Mr. Javed Waseem vide letter No. SP/Lic/008/20 dated 23-11-2020has submitted that management of the firm M/s Swat Pharmaceuticals, Valley Road, Sherarai Gulkada No.3, Saidu Sharif Swat has been changed and requested for change of management. The applicant also submitted following document with application;

i. Notarized copy of sale agreement (100/100) between Mr. Shahid Fazal Rabi , Mr Javeed Waseem and Mangnaish Kumar,
ii. Notarized copy of sale of share agreement (18/100) between Mr. Mubarak Ali S/o Alamgir and Mr. Shaid Fazal Rabi and Mr Javeed Waseem,
iii. Photocopy of NTN of the firm M/s Swat Pharmaceuticals, Valley Road, Sherarai Gulkada No.3, Saidu Sharif Swat,
iv. fee of Rs.50,000/- for change of management.

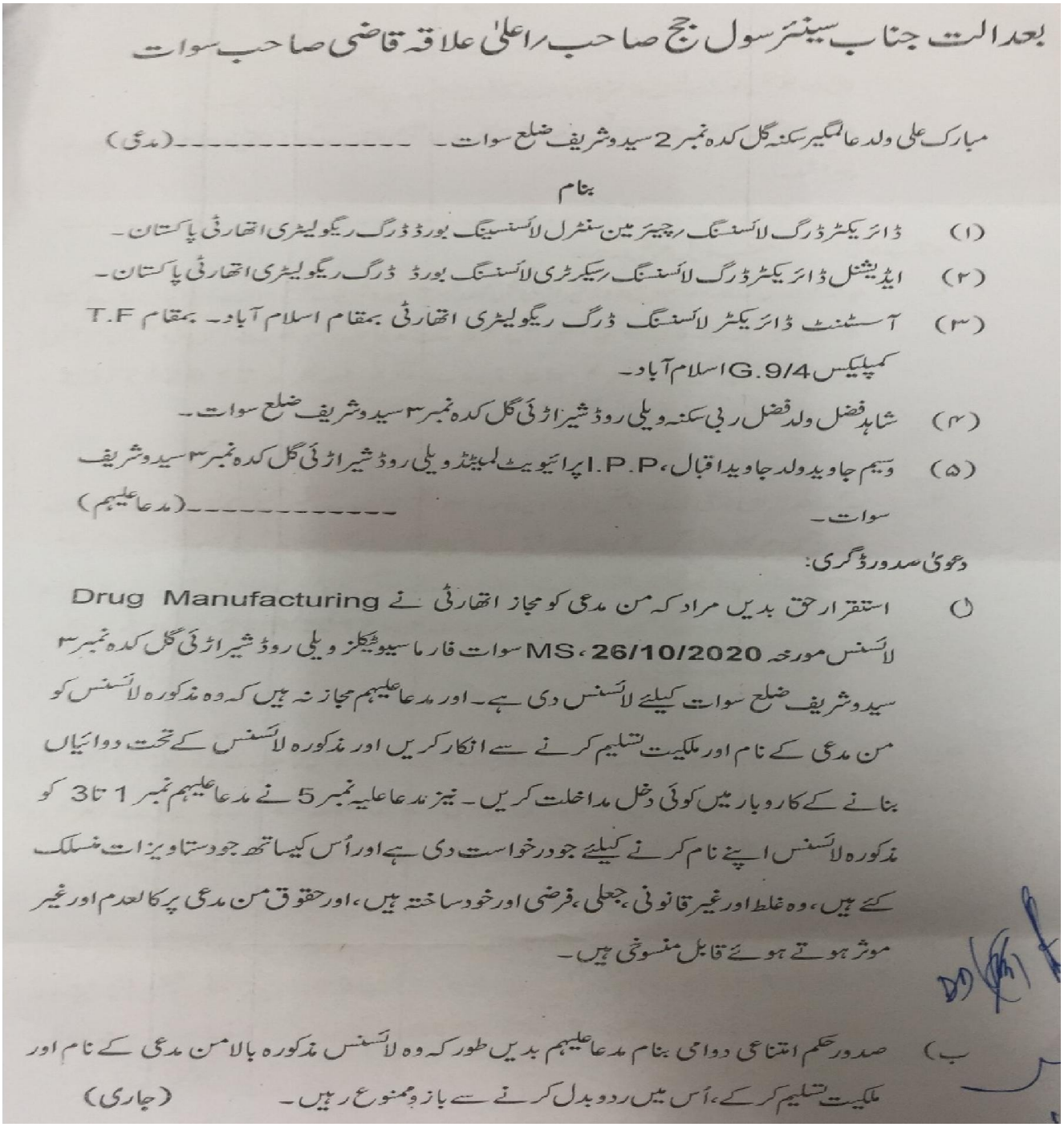
Detail of management is as under;

| **Previous Management Sole Proprietor Page 59/Corr** | **Current Management** |
|---|---|
| 1. Mr. Mubarak Ali S/o Alamgir CNIC No. 15602-0482661-1 | 1. Mr. Mangnaish Kumar S/o Mr. Ram Saroop CNIC No. 15602-3006910-9 |

Mr. Mubarak Ali CEO/Sole Proprietor of M/s Swat Pharmaceuticals, Valley Road, Sherarai Gulkada No.3, Saidu Sharif Swat vide letter No. Nil dated Nilhas informedthe Licensing Division, DRAP that the information submitted by Mr. Jawed Wasim are **totally wrong**. Mr. Mubarak

Ali has further submitted that the application submitted by Mr. Waseem Javid for change of management **may not be processed.**

Mr. Mubarak Ali CEO/Sole Proprietor of M/s Swat Pharmaceuticals, Valley Road, Sherarai Gulkada No.3, Saidu Sharif Swat filed an application in the Court of Senior Civil Judge, Swat. The application is in Urdu language and reproduced as under;



بعدالت جناب سینئر سول جج صاحب/اعلیٰ علاقہ قاضی صاحب سوات

مبارک علی ولد عالمگیر سکنہ گل کدہ نمبر 2 سیدو شریف ضلع سوات۔ ----------(مدعی)

بنام

(۱) ڈائریکٹر ڈرگ لائسنسنگ رجیسٹریشن سنٹرل لائسنسنگ بورڈ ڈرگ ریگولیٹری اتھارٹی پاکستان۔

(۲) ایڈیشنل ڈائریکٹر ڈرگ لائسنسنگ رسیکرٹری لائسنسنگ بورڈ ڈرگ ریگولیٹری اتھارٹی پاکستان۔

(۳) آسسٹنٹ ڈائریکٹر لائسنسنگ ڈرگ ریگولیٹری اتھارٹی بمقام اسلام آباد۔ بمقام T.F کمپلیکس G.9/4 اسلام آباد۔

(۴) شاہد فضل ولد فضل ربی سکنہ ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف ضلع سوات۔

(۵) وسیم جاوید ولد جاوید اقبال، I.P.P پرائیویٹ لمیٹڈ ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف سوات۔ ----------(مدعا علیہم)

دعویٰ صدور ڈگری:

(ا) استقرار حق بدیں مراد کہ من مدعی کو مجاز اتھارٹی نے Drug Manufacturing لائسنس مورخہ 26/10/2020، MS سوات فارماسیوٹیکلز ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف ضلع سوات کیلئے لائسنس دی ہے۔ اور مدعا علیہم مجاز نہ ہیں کہ وہ مذکورہ لائسنس کو من مدعی کے نام اور ملکیت تسلیم کرنے سے انکار کریں اور مذکورہ لائسنس کے تحت دوائیاں بنانے کے کاروبار میں کوئی دخل مداخلت کریں۔ نیز مدعا علیہ نمبر 5 نے مدعا علیہم نمبر 1 تا 3 کو مذکورہ لائسنس اپنے نام کرنے کیلئے جو درخواست دی ہے اور اُس کیساتھ جو دستاویزات منسلک کیے ہیں، وہ غلط اور غیر قانونی، جعلی، فرضی اور خود ساختہ ہیں، اور حقوق من مدعی پر کالعدم اور غیر موثر ہوتے ہوئے قابل منسوخی ہیں۔

(ب) صدور حکم امتناعی دوامی بنام مدعا علیہم بدیں طور کہ وہ لائسنس مذکورہ بالا من مدعی کے نام اور ملکیت تسلیم کر کے، اُس میں ردوبدل کرنے سے باز و ممنوع رہیں۔ (جاری)

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مالیت بغرض کورٹ فیس واختیار سماعت مبلغ 200 روپے مقرر کی جاتی ہے۔

بنائے دعویٰ عرصہ چند یوم قبل بعد از انکار مدعاعلیہم اندر حدود و اختیار سماعت عدالت ہذا پیدا شد۔

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جناب عالی! حسب ذیل عرض ہے۔

۱۔ یہ کہ من مدعی نے بمقام ویلی روڈ شیراڑئی گل کدہ نمبر ۳ سیدو شریف ضلع سوات، دوائیاں بنانے کیلئے کارخانہ تعمیر کرنے کا ارادہ کیا، اور اس سلسلے میں مدعاعلیہ نمبر 4 سے اُس کی ملکیتی اراضی بمقام شیراڑئی گل کدہ نمبر ۳ سوات، بروئے اقرار نامہ محررہ **22/7/2017**، 25 سال کیلئے لیز پر لے لیا۔ (نقل اقرار نامہ لف ہے)۔

۲۔ یہ کہ بعد ازاں مدعی نے اراضی مذکورہ پر فارماسیوٹیکلز یونٹ کے تعمیر کیلئے مجاز حکام کو درخواست دی، جس پر کاروائی کرتے ہوئے، فیڈرل انسپکٹر آف ڈرگ پشاور نے آسسٹنٹ ڈائریکٹر لائسنسنگ ڈرگ ریگولیٹری اتھارٹی کے احکامات کے روشنی میں موقع ملاحظہ کیا اور جائے مذکورہ فارماسیوٹیکلز یونٹ کے تعمیر کیلئے بروئے رپورٹ محررہ **26/8/2017**، موزوں قرار دی۔ (نقل رپورٹ لف ہے)۔

۳۔ یہ کہ جس کے بعد من مدعی نے دوسرے کوائف کو پورا کرنے کیلئے جائے مذکورہ بالا کا نقشہ بنایا اور مبلغ **-/30,000** روپے مطلوبہ فیس جمع کی، جو کہ متعلقہ حکام نے بروئے لیٹر محررہ **29/11/2017** منظور کیا ہے۔ (نقولات درخواست و منظوری لیٹر لف ہیں)۔

۴۔ یہ کہ بعد ازاں یونٹ میں ایزادگی کرنے کیلئے دوسرا نقشہ بنایا اور اس کے منظوری کیلئے مورخہ **01/01/2019**، مجاز حکام کو درخواست دی اور مبلغ **5000** روپے مطلوبہ فیس جمع کیا، اور جس کی منظوری بروئے لیٹر محررہ **04/02/2019** دی گئی۔ (نقولات درخواست، بینک رسید اور لیٹر، نقشہ لف ہیں)۔

(جاری)

۵۔ یہ کہ اس دوران من مدعی نے مجاز حکام کے ہدایت کی روشنی میں پہلے بمورخہ 31/01/2018 اور پھر بمورخہ 23/07/2018 ، پراگریس رپورٹس دے دی۔ (نقولات رپورٹس لف ہیں)۔

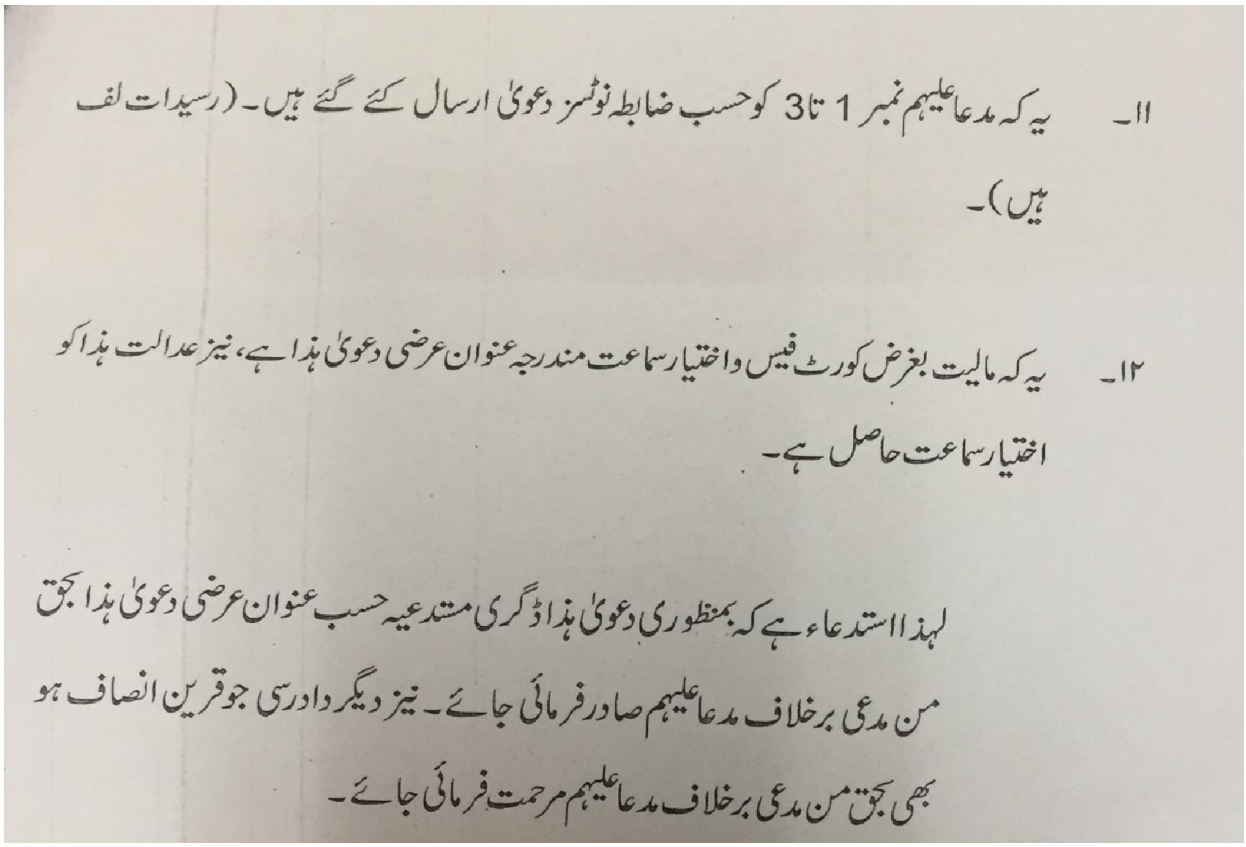
۶۔ یہ کہ بعدازاں مدعاعلیہ نمبر 3 کو لائسنس کے حصول کیلئے مروجہ فارم (الف) بھر کر درخواست دے دی، اور جس کیلئے بھی مطلوبہ فیس مبلغ ایک لاکھ روپے جمع کئے۔ (نقولات لف ہیں)۔

۷۔ یہ کہ جس کے بعد ڈرگ ریگولیٹری اتھارٹی آف پاکستان کے مقرر کردہ Panel نے ستمبر 2020 میں سائٹ کا آخری انسپکشن کیا اور جن کے رپورٹ کے بنیاد پر من مدعی کو لائسنس مذکورہ بالا دی گئی۔ (نقل لائسنس لف ہے)۔

۸۔ یہ کہ بعدازاں مدعاعلیہ نمبر 4 کے نیت میں فتور آکر من مدعی کو فارماسیوٹیکلز یونٹ مذکورہ بالا سے محروم کرنے کے درپے ہوا، اور اس دوران مدعاعلیہ نمبر 5 نے جعلی اور فرضی دستاویزات تیار کر کے جن کے بنیاد پر مدعاعلیہم نمبر 1 تا 3 کو لائسنس مذکورہ میں تبدیلی کیلئے درخواست دی ہے، جس کی وہ ہرگز مجاز نہ ہے۔

۹۔ یہ کہ مدعاعلیہ نمبر 5 کے درخواست پر ہر قسم کے کاروائی غلط، غیر قانونی، جعلی، فرضی اور مبنی بر بد نیتی اور بلا جواز ہے۔

۱۰۔ یہ کہ مدعاعلیہم کو کہا گیا کہ وہ مدعاعلیہ نمبر 5 کے درخواست پر من مدعی کے لائسنس مذکورہ بالا کی نسبت ہر قسم کی کاروائی سے باز و ممنوع رہیں، پہلے تو مدعاعلیہم ٹال مٹول کرتے رہیں اور اب چند یوم قبل صاف انکاری ہوئے، لہذا دعویٰ ہذا کی ضرورت لاحق ہوئی۔



۱۱۔ یہ کہ مدعا علیہم نمبر 1 تا 3 کو حسب ضابطہ نوٹسز دعویٰ ارسال کئے گئے ہیں۔ (رسیدات لف ہیں)۔

۱۲۔ یہ کہ مالیت بغرض کورٹ فیس واختیار سماعت مندرجہ عنوان عرضی دعویٰ ہذا ہے، نیز عدالت ہذا کو اختیار سماعت حاصل ہے۔

لہذا استدعاء ہے کہ بمنظوری دعویٰ ہذا ڈگری مستدعیہ حسب عنوان عرضی دعویٰ ہذا بحق من مدعی برخلاف مدعا علیہم صادر فرمائی جائے۔ نیز دیگر دادرسی جو قرین انصاف ہو بھی بحق من مدعی برخلاف مدعا علیہم مرحمت فرمائی جائے۔

Three summons dated 09/12/2020 were received in Licensing Division, DRAP from Honorable Civil Judge-IV, Mrs. Sidra Aslam, Swat. In these summons, Director Drug Licensing Division/Chairman CLB, Additional Director, Drugs Licensing Division/Secretary CLB, DRAP and Assistant Director Drugs Licensing Division, DRAP were directed to appear before the Honorable Civil Judge, Swat on 04th January, 2021.

Now the firm M/s Swat Pharmaceuticals, Valley Road, Sherarai Gulkada No.3, Saidu Sharif Swat vide letter NO. SPS/Lic/0001/21, dated 21/02/2021 submitted application for change of management. The firm **has not** deposited fee of Rs.50,000/- for change of management. The detail of management is as under;

| **Previous Management Sole Proprietor Page 59/Corr** | **Current (Proposed) Management** |
|---|---|
| 2. Mr. Mubarak Ali S/o Alamgir CNIC No. 15602-0482661-1 | 2. Mr. Mangnaish Kumar S/o Mr. Ram Saroop CNIC No. 15602-3006910-9 |

The firm has also submitted following documents namely;

i. NOC from Sole proprietor Mr. Mubarak Ali S/o Alamgir wherein he has stated that he has no objection on the transfer of ownership Of DML No. 000035 to the name of Mr. Nlangnesh Kumar, NIC No 15602—3006910-9
ii. Swat Civil Court Order 05 dated 06/01/2021 where request for withdrawal of plaintiff is dismissed as withdrawn
iii. Agreement between following
    a. Mr. Mubarak Ali S/o Alamgir,
    b. Mr. Shaid Fazal Rabi S/o Fazal Rabi,
    c. Mr. Waseem Javed S/o Javed Iqbal.

In light of above, documents submitted by Mr. Mubarak Ali S/o Alamgir for site verification and application of FORM-I as per Drugs(Licensing Registering & advertining) Rules 1976, for grant of DML and now application of change of management, it is revealed that the Sole Proprietor of the firm, Mr. Mubarak Ali S/o Alamgir has welling/intentionally concealed ownership/management of the firm.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000035 by way of formulation in the name of M/s Swat Pharmaceuticals, Valley Road, SheraraiGulkada No.3, Saidu Sharif Swatmay not be suspended or cancelled by Central Licensing Board.

**Case No.46 RENEWAL OF DRUG MANUFACTURING LICENCE M/S TREAT PHARMACEUTICAL INDUSTRY (PVT) LTD, A-37, SMALL INDUSTRIAL ESTATE, TOWNSHIP, KOHAT ROAD, BANNU**

The firm M/s Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township, Kohat Road, Bannu has submitted application for renewal of DML No.000352 by way of Formulation. The application was received on 14-02-2020 which was Nine (09) days late as the validity of License is 05-02-2020. The firm has not submitted Form-1A and supported documents and only deposited fee of Rs.50,000/ for renewal of DML.

A shortcoming letter was issued to the firm to rectify following **shortcoming** vide letter No.F.3-4/93-Lic (Vol-II) dated 01-09-2020 as per Drug (LR&A) Rules 1976;

i. Form-1A on prescribed format duly singed and stamped by CEO/Owner of the firm alongwith late fee of Rs.40,000/- @5000/day as the application is 08 days late and complete set of documents/annexures.

In response to s**hortcoming** letter the firm did not submitted their reply and **subsequently** a reminder vide letter No.F.3-4/93-Lic (Vol-II) dated 14-10-2020 was issued to the **firm** to **rectif**y above mentioned shortcoming.

In response to final reminder the firm has submitted their reply. The firm also **submitteddocument**s for change of **management**. The reply was evaluated as per Drugs (L,R&A) Rules 1976 and did not **rectified** following **shortcomings**;

i. Nothing due certificate (Central Research Fund) from STO, DRAP up to 31-12-2020 is not provided,
ii. Updated Form-29 issued and certified as "True Copy" by SECP is not provided.

**Proceedings and Decision by the Central Licensing Board in 278th meeting:**

*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, Rule 12 and Rule 19of the Drugs (Licensing, Registering and Advertising)*

*Rules, 1976 as to why Drug Manufacturing License No 000352 (by way of formulation) of M/s Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township, Kohat Road, Bannumay not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.*

Proceeding of Licensing Division in compliance to the decision of Central Licensing Board.

In light of Decision of The Central Licensing Board held on 10th& 11th December, 2020 was issued to the firm vide letter No.F.3-4/93-Lic (Vol-II) dated 11-01-2021

The firm M/s Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township, Kohat Road, Bannu has rectified above mentioned shortcomings.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000352 (By way of Formulation)ofM/s Treat Pharmaceutical Industry (Pvt) Ltd, A-37, Small Industrial Estate, Township, Kohat Road, Bannu, for further period.

**Case No.47 RENEWAL OF M/S LOWITT PHARMA (PVT) LTD., PLOT NO.24, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR**

The firm M/s Lowitt Pharma (Pvt) Ltd., Plot No.24, Industrial Estate, Hayatabad, Peshawar, wherein the firm has submitted the application for renewal of Drug Manufacturing No. 000568 (Formulation). The application was received on 12-05-2020 which is well on time as due date of License is 12-05-2020. The firm has submitted a fee of Rs. 50,000 . The application was evaluated as per Drugs (Licesning, Registering and advertising) Rules 1976 and found following shortcoming for which shortcoming letter No.03-3/2002-Lic (Vol-I) dated 01/09/2020 was issued to the firm;

i. Detail of management at the time of previous and current renewal.
ii. Updated copy of Form-29 issued and certified true copy by S.E.C.P.
iii. Proof of section(s) approval from Central Licensing Board and copy of approved layout plan.
iv. Up-to-date nothing due certificate (Central Research Fund) from STO, DRAP, Islamabad upto 31-12-2020.

In response to above quoted letter the firm has submitted their reply but did not rectified following shortcoming. Subsequently final reminder vide letter No.3-3/2002-Lic (Vol-I) dated 04/11/2020 was issued to rectify following shortcomings

i. Updated copy of Form-29 issued and certified true copy by S.E.C.P.
ii. Proof of section(s) approval from Central Licensing Board and copy of approved layout plan.

In response to above final reminder the firm has submitted their reply but as of today the firm did not rectified following shortcoming;

i. Updated copy of Form-29 issued and certified true copy by S.E.C.P.
ii. Proof of section(s) approval from Central Licensing Board and copy of approved layout plan.

**Proceedings and Decision by the Central Licensing Board in 278th meeting:**

*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 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000568 (by way of formulation) of M/s Lowitt Pharma (Pvt) Ltd., Plot No.24, Industrial Estate, Hayatabad, Peshawar may not be suspended or cancelled by Central Licensing Board or application for renewal of DML under Rule 5(2A) may not be rejected.*

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

In light of Decision of The Central Licensing Board held on 10th& 11th December, 2020 a show cause notice was issued to the firm vide letter No. F. 3-3/2002-Lic (Vol-I) dated08-01-2021.

The firmM/s Lowitt Pharma (Pvt) Ltd., Plot No.24, Industrial Estate, Hayatabad, Peshawar has rectified above mentioned shortcomings.

**Case is submitted for consideration and orders of the Board please.**

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000568 (By way of Formulation)ofM/s Lowitt Pharma (Pvt) Ltd., Plot No.24, Industrial Estate, Hayatabad, Peshawar for further period.

**Case No.48 RENEWAL OF DRUG MANUFACTURING LICENCE OF VETCON PHARMACEUTICALS (PVT) LTD., PLOT NO.7-10B, INDUSTRIAL ESTATE, BHIMBER, AZAD KASHMIR.**

M/s Vetcon Pharmaceuticals (Pvt) Ltd., Plot No.7-10B, Industrial Estate, Bhimber, Azad Kashmir had applied for renewal of DML No. 000307 by way of formulation for the period of 29-06-2020 on 28-06-2024.

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 17th March, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

**For Renewal of DML.**

i. Detail of management at the time of previous renewal and Present renewal.
ii. Latest original certified true copy of Form-29 & Form-21 issued by S.E.C.P. alongwith CNIC copies of all directors.
iii. Update Nothing due certificate regarding CRF from STO, DRAP, Islamabad.

**For Quality Control Incharge.**

i. Appointment letter and job acceptance letter.
ii. Copy of CNIC of appointee.
iii. Copies academic degrees.
iv. Experience certificate(s).
v. Resignation earlier Quality Control Incharge.
vi. Resignation of appointee from previous firm.
vii. Undertaking as whole time employee on stamp paper as per format of checklist (attached).

The firm submitted their reply on 21st April, 2020. After evaluation of the submitted documents, a final reminder was issued on 24th August, 2020 to the firm with following shortcomings: -

**For Renewal of DML.**

i. Proof of sections approved from Central Licensing Board (Approval letters).
ii. Detail and approval letter of Production Incharge
iii. Update Nothing due certificate regarding CRF from STO, DRAP, Islamabad.

**For Quality Control Incharge.**

i. Relevant experience certificate(s) (As per prescribed rules).
ii. Registration certificate from Pharmacy Council.
iii. Academic degrees where date of result is clearly mentioned.
iv. Submitted documents are not attested/notarized.

The firm submitted their reply to Final Reminder on 15th July, 2019 and following documents are still deficient /short and application for renewal of DML is still incomplete.

1. Form-1A dully signed and attested by the management of firm alongwith all enclosures.
2. Form-29 and Form-A for year 2019 (certified true copy) issued by S.E.C.P. alongwith prescribed fee for change of management (if management is changed).
3. Approval letter(s) of all sections issued from CLB.

**Proceedings and Decision by the Central Licensing Board in 278th meeting:**

*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, Rule 16 and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000307 (by way of formulation) of M/s Vetcon Pharmaceuticals (Pvt) Ltd., Plot No.7-10B, Industrial Estate, Bhimber, Azad Kashmir may not be suspended or cancelled by Central Licensing Board under Rule 5(2A)of the Drugs (Licensing, Registering and Advertising) Rules, 1976 or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976..*

Proceeding of Licensing Division in compliance to the decision of Central Licensing Board.

In light of Decision of The Central Licensing Board held on 10th& 11th December, 2020 was issued to the firm vide letter No. F. 5-1/90-Lic (Vol-II) dated.08-01-2021

The firm M/s Vetcon Pharmaceuticals (Pvt) Ltd., Plot No.7-10B, Industrial Estate, Bhimber, Azad Kashmir has rectified above mentioned shortcomings.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to cease the show cause notice in respect of Drug Manufacturing License No. 000307 (By way of Formulation)of M/s Vetcon Pharmaceuticals (Pvt) Ltd., Plot No.7-10B, Industrial Estate, Bhimber, Azad Kashmir, for further period.

**Case No.49 RENEWAL OF DRUG MANUFACTURING LICENCE OFM/S NOBLE PHARMA, PLOT NO. B-1, OLD INDUSTRIAL AREA, MIRPUR, AJK**

The firm, M/s Noble Pharma, Plot No. B-1, Old Industrial Area, Mirpur, AJK, has submitted application for renewal of Drug Manufacturing License No. 000652 (by way Formulation). The application was received on 08-01-2019 and due date of renewal of DML 30-01-2019. The firm has submitted a fee of Rs. 50,000. The application was evaluated as per Drugs (Licensing, Registering & Advertising) Rules 1976 and found following shortcomings;

i. Detail of management at the time of previous renewal and present renewal.
ii. Declaration of firm on stamp paper in case of sole proprietorship alongwith CNIC of Director.
iii. Proof of licensed section from CLB.
iv. Nothing Due Certificate regarding CRF from STO, DRAP up-to-date.

Accordingly, shortcoming letter vide letter No.F.5-2/2007-Lic dated 08-05-2019was issued to the firm to rectify above mentioned shortcomings.
In response to this office shortcoming letter, the firm submitted their reply and same was evaluated but the firm has not rectified following shortcoming. Subsequently a final reminder vide letter No. F.5-2/2007-Lic dated 18-08-2020 was issued to the firm to rectify following shortcoming;

i. Up to date nothing due certificate from STO, DRAP, Islamabad.

Till date the firm has not rectified above mentioned shortcoming.

**Proceedings and Decision by the Central Licensing Board in 278th meeting:**

*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 and Rule 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000652(by way of formulation) of M/s Noble Pharma, Plot No. B-1, Old Industrial Area, Mirpur, AJK,may not be suspended or cancelled by Central Licensing Board or application for renewal of DML under Rule 5(2A) may not be rejected.*

Proceeding of Licensing Division in compliance to the decision of Central Licensing Board.

In light of Decision of The Central Licensing Board held on 10th& 11th December, 2020 a show cause notice was issued to the firm vide letter No. F. 5-2/2007-Licdated. 11-01-2021

The firmM/s Noble Pharma, Plot No. B-1, Old Industrial Area, Mirpur, AJK, has rectified above mentioned shortcomings.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No. 000652 (By way of Formulation)ofM/s Noble Pharma, Plot No. B-1, Old Industrial Area, Mirpur, AJK, for further period.

**Case No. 50** **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S S.N.B. PHARMACEUTICALS (PVT) LTD., PESHAWAR**

The firm, M/s S.N.B. Pharmaceuticals (Pvt) Ltd., Peshawar wherein the firm has submitted the application for renewal of DML No. 000759 (Formulation) for the period of **20-09-2017** to **19-09-2022**. The application was received on **19-09-2017** which is well on time as validity of License is **19-09-2017**. The firm has submitted a fee of **Rs. 50,000** . The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Attested copy of up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad, has not been attached.
ii. Copy of approved layout plan, has not been attached.
iii. Approval letter(s) of CLB for all approved section(s), has not been attached.
iv. Fee Challan of Rs.50,000/- for change of management has not been attached.
v. Attested copy of Form-29 and Form-A of SECP showing current management has not been attached.
vi. The title of the firm mentioned on Form-29 is M/s S.N.B. Pharmaceuticals (Pvt) Ltd., whereas the title mentioned on Form-1A and letter head is M/s S.N.B. Pharma (Pvt) Ltd.

**Proposed Production Incharge (Mr. SahibzadaWali Ullah Khan).**

vii. Fee challan of Rs.5,000/- for change of Production Incharge has not been attached.
viii. Attested copy of registration certificate from Pharmacy Council, has not been attached.
ix. Attested copies resignation letter of proposed Production Incharge as well as previous Production Incharge, have not been attached.
x. Undertaking on stamp paper as whole time employee, has not been attached.

**Proposed QC Incharge (Mr. Muhammad Saleem).**

xi. Fee challan of Rs.5,000/- for change of QC Incharge has not been attached.
xii. Attested copies resignation letter of proposed QC Incharge as well as previous QC Incharge, have not been attached.
xiii. Undertaking on stamp paper as whole time employee, has not been attached.

Accordingly, shortcoming letter No. 3-1/2005-Lic dated10/10/2017was issued to rectify above mentioned shortcomings.

In response to above quoted letter the firm has submitted their response however, the firm has not rectified following shortcoming; subsequently final reminder vide letter No. 3-1/2005-Lic dated 06/11/2018 was issued to the firm;

i. Attested copy of up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.
ii. Copy of approved layout plan.
iii. Approval letter(s) of CLB for all approved section(s).
iv. Fee Challan of Rs.50,000/- for change of management.
v. Attested copy of Form-29 and Form-A of SECP showing current management.
vi. The title of the firm mentioned on Form-29 is M/s S.N.B. Pharmaceuticals (Pvt) Ltd., whereas the title mentioned on Form-1A and letter head is M/s S.N.B. Pharma (Pvt) Ltd.

**Proposed Production Incharge (Mr. SahibzadaWali Ullah Khan).**

i. Job acceptance letter of proposed Production Incharge.

ii. Undertaking as whole time employee of Production Incharge does not hold the signature of management.

**Proposed QC Incharge (Mr. Muhammad Saleem).**

i. Job acceptance letter of proposed QC Incharge.
ii. Copies of academic degrees of proposed QC Incharge.
iii. Undertaking as whole time employee of QC Incharge does not hold the signature of management.

Despite issuance of shortcoming letter and final reminder, the firm has not rectified following shortcomings;

i. Attested copy of up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad, has not been attached.
ii. Copy of approved layout plan, has not been attached.
iii. Approval letter(s) of CLB for all approved section(s), has not been attached.
iv. Fee Challan of Rs.50,000/- for change of management has not been attached.
v. Attested copy of Form-29 and Form-A of SECP showing current management has not been attached.

**Proposed Production Incharge (Mr. SahibzadaWali Ullah Khan).**

i. Fee challan of Rs.5,000/- for change of Production Incharge has not been attached.
ii. Attested copy of registration certificate from Pharmacy Council, has not been attached.
iii. Attested copies resignation letter of proposed Production Incharge as well as previous Production Incharge, have not been attached.
iv. Undertaking on stamp paper as whole time employee, has not been attached.

**Proposed QC Incharge (Mr. Muhammad Saleem).**

i. Fee challan of Rs.5,000/- for change of QC Incharge has not been attached.
ii. Attested copies resignation letter of proposed QC Incharge as well as previous QC Incharge, have not been attached.
iii. Undertaking on stamp paper as whole time employee, has not been attached.

**Proceedings and Decision by the Central Licensing Board in 278th meeting:**

*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 , Rule 16 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000759(by way of formulation) of M/s S.N.B. Pharmaceuticals (Pvt) Ltd., Peshawarmay not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.*

Proceeding of Licensing Division in compliance to the decision of Central Licensing Board.

In light of Decision of The Central Licensing Board held on 10th& 11th December, 2020 a show cause notice was issued to the firm vide letter No. F. 3-1/2005-Lic dated. 08-01-2021

The fim M/s S.N.B. Pharmaceuticals (Pvt) Ltd., Peshawar, has rectified above mentioned shortcomings.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000759 (By way of Formulation)ofM/s S.N.B. Pharmaceuticals (Pvt) Ltd., Peshawar for further period.

**Case No.51 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S PEARL PHARMACEUTICALS, PLOT NO.204, SECTOR 1, I-10/3, INDUSTRIAL AREA, ISLAMABAD**

The firm, M/s Pearl Pharmaceuticals, Plot No.204, Sector 1, I-10/3, Industrial Area, Islamabad submitted the application for renewal of Drug Manufacturing No. **000479 (Formulation).** The application was received on **27-08-2020** which is well on time as validity of License is **01-09-2020** (Page-54/Corr)**.** The firm has submitted a fee of **Rs. 50,000**. The application was evaluated as per Drugs (Licesning, Registering and advertising) Rules 1976 and found following shortcoming for which shortcoming letter No. F. 1-18/90-Lic Vol-III dated 30/09/2020 was issued to the firm;

i. Classes of drugs.
ii. Dosage form of drugs.
iii. Proof of licensed sections from Central Licensing Board.
iv. Updated NOC regarding CRF from STO, DRAP, Islamabad.
v. All documents should be signed and stamped by owner of the firm.

In response to above quoted letter the firm has submitted their response however, the firm has not rectified following shortcoming; subsequently final reminder vide letter No. F. 1-18/90-Lic Vol-III dated 13/01/2021 was issued to the firm;

i. Proof of section(s) approval by Central Licensing Board.

Despite issuance of shortcoming letter and final reminder, the firm has not rectified following shortcomings;

i. Proof of section(s) approval by Central Licensing Board.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000479 (by way of formulation) , M/s Pearl Pharmaceuticals, Plot No.204, Sector 1, I-10/3, Industrial Area, Islamabad may not be suspended or cancelled by Central Licensing Board or application for renewal of DML under Rule 5(2A) may not be rejected.

**Case No.52 CORRECTION IN THE LETTER.**

The Central Licensing Board in its 276th meeting held on 3rd September, 2020 considered and approved the grant of following four sections of M/s Quaper (Pvt) Ltd, 26-A, Small Industrial Estate Lahore Road, Sargodha under DML No. 000609 (Formulation).

i. Tablet (General) Section (Revised).
ii. Capsule (General) Section (New).
iii. R&D Laboratory (New).
iv. Sachet (General). (New).

It is submitted that due to typographical mistake words & phrases "Tablet (General) Section Revised" has been inadvertently mentioned instead of "Tablet (General) Section (New)" The same was conveyed to the firm vide letter dated 29th September, 2020.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to approve correction in name/title of "Tablet (General) Section (New)" instead of "Tablet (General) Section Revised" of M/s Quaper (Pvt) Ltd, 26-A, Small Industrial Estate Lahore Road, Sargodha under DML No. 000609 (Formulation).

**Case No.53** **INSPECTION REPORT FOR RESUMSION / SUSPENSION OF DRUG MANUFACTURING LICENCE OF M/S PHARMACARE LABORATORIES (PVT) LTD, 129/1, INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE.**

**Case background.** The Central Licensing Board in its 276th meeting held on 3rd September, 2020 has considered the facts on the record and decided to suspend the Drug Manufacturing Licensing No. 000255 (Formulation) for three months 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 of M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore.

The Board also observed that application for renewal of Drug Manufacturing License for the period commencing on 13-06-2019 and ending 12-06-2024 was short of the following documents despite of letter dated 18th July, 2019 and reminder dated 14th October, 2019 were issued to the company for completing the application for renewal of Drug Manufacturing License:-

i. Nothing Due Certificate regarding CRF from STO (updated).
ii. Latest certified true copy of Form-29 (Attestation by SECP without the phrase of (SECP) to not take responsibility of contents of form.
iii. Section approval letter of all sections approved by Central Licensing Board, if not available, apply for regularization of layout plan.

M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore has submitted their reply in response to this Division's letter dated 15th July, 2020 with following submissions:-

| S. #. | Points raised by Panel. | Reply of the firm. |
|---|---|---|
| 1. | i. The Building was not as per approved layout Plan. Several changes were made without approval.<br>ii. Proper emergency exits required.<br>iii. Smoke detectors / fire alarm were not installed.<br>iv. The firm had registration of cephalosporin Dry Powder suspension / capsule however dedicated section for cephalosporin products was not provided.<br>v. The flooring of the facility required improvements, cracks were as open dirty lights were seen.<br>vi. Certificate from building control Authority was also required. | i. Layout plan was approved.<br>ii. Key box and hammer has installed with emergency exit door.<br>iii. Smoke detector / Fire Alarm has been installed.<br>iv. Section was dedicated and segregated but separate entrance is under planning.<br>v. The flooring of facility has improved as per requirement of GMP.<br>vi. Structure certificate for building is available but new is inprocess. |
| 2. | i. In change area wash basins were installed before executive entry. It was advised to remove wash basins to avoid spillage of water. Coats were placed haphazardly cabinet. Factory slippers were placed on floor. It was advised to provide proper cabinet for factory shoes.<br>ii. The workers entries required improvements with respect to cleanliness and | i. In changing area of executive entry wash basin has removed.<br>ii. The worker entries have improved with respect to cleanness and implementation of changing sop's for worker. |

| | | |
|---|---|---|
| | implementation of changing SOPs for workers. | |
| 3. | i. In the raw material store, de-dusting was not provided. The quarantine area was also not proper.<br><br>ii. The flooring of the store required improvements, as cracks on the floors were accumulating dust particles.<br><br>iii. Segregated dispensing area for psychotropic / narcotics drugs was not available.<br>iv. Labeling on raw material was not proper, as quarantine and sampled slips were not posted on materials.<br>v. Temperature mapping of store was not being conducted. The firm was advised to computerize data of store. | i. In process.<br>ii. The flooring of store has repaired.<br>iii. Segregated dispensing hood order has been generated and come within few days.<br>iv. Quarantine and sampled slips has pasted on material.<br>v. Complied. |
| 4. | The Inactive materials were purchased from local market. It was advised to conduct vender qualification for all the raw materials. No separate area under lock and key was provided for rejected materials. | Complied. |
| 5. | Narcotic material was stored in a cabinet under lock and key the temperature humidity of which was not monitored. | The temperature / humidity record of narcotic material is being monitored. |
| 6. | The finished goods store was located out the main building No proper dispatch area provided. Cleanliness in the store was not satisfactory. | Complied. |
| 7. | In tablet section, the silverson mixer for wet granulation and fluidized bed dryer were installed in the same congested room, hence chances of cross contamination increased, if both were being used at the same time. | Silver mixer does not exist in factory and machinery of section is installed in segregated areas hence there are no chances for cross contamination. Single product is being processed in granulation section. |
| 8. | The machinery was not properly cleaned, powder from previous batch was seen in the fluidized bed dryer, no filter was installed in the dryer. The edges of dry granulator were very sharp, hence the worker safely could be compromised. | a-Pre-filters were installed at the time of inspection in fluid bed dryer.<br><br>b-Dry granulator has modified with smooth edges from safety point of view. |
| 9. | i. In the granulation room a partition of glass and aluminum was provided which was not smooth and clean. Firm was advised to remove that partition and provide smooth | i. Complied.<br>ii. Calibration is due.<br>iii. 2 compression machines were GMP complied but 2 compression machine is under planning for GMP complied. |

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| | partition if required.<br><br>ii. HVAC system was not functioned as no negative pressure was observed.<br><br>iii. Three rooms for compression of tablets were provided. The compression machines were not GMP compliant.<br>iv. The return ducts of HVAC system was not provided, Dust collectors were installed above the compression machines, which were full of powder of previous batches. The firm was advised to remove all dust collectors. Install proper HVAC return ducts in the area, and maintained negative pressure. | iv. The return ducts of HVAC system has installed in compression section. |
| 10. | It was observed that tablet cores Pharmic Tablet date of manufacturing 05/19 batch No. 0603 and MYZA Tablet Batch No. 0597 Date of Manufacturing 07/03/2019 were placed in the in-process quarantine area for the last 10-11 months, without blistering. No temperature / humidity was maintained in the area. The management was unable to explain such delays in packing. There was no concept of in-process delay time testing before packing. | In process delay time testing SOP has developed.<br><br>Temperature / humidity was maintained in the area at the time of inspection. |
| 11. | i. In Psychotropic / Narcotics Tablet Section The tray dryer did not have thermal probes for temperature monitoring. Thermanal mapping of dryer required. The granulator had dangerous edges, cone mixer was without safety rod.<br>ii. In the compression room, double door transfer hatch was required instead of single door hatch.<br>iii. The HVAC system did not have pre bag fitters at the return air vents, only grills were installed without filters, the system was not installed properly hence was not functional. | i. Safety rod has installed with Cone mixer.<br>ii. Under planning.<br>iii. The pre-filters has installed at the return air vents. |
| 12. | Cephalosporin Capsule and Dry Powder Suspension Section. Dedicated area with separate entries in the section were not provided. Separate raw material store / dispensing area for cephalosporin was also not available. | Under planning. |
| 13. | It was advised to deregister cephalosporin products, as proper area for the manufacturing | Area was dedicated but separate entrance is required which is in-process. |

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| | of cephalosporin products was not available. | |
| 14. | i. In Quality Control Laboratory. It was observed that HPLC was not working properly.<br>ii. Very old dissolution apparatus was installed.<br>ii. No sampler was available. The quality control Incharge was not aware, how to perform dissolution test as the procedure of testing sample from dissolution apparatus was not explained when asked by the panel.<br>v. Reference standards were not available. Raw materials were used as working standards which were not even placed in any dessicator.<br>v. Only one stability chamber was installed without any data logger and backup supply.<br>vi. The firm was advised to upgrade quality control equipment, purchase reference standards and perform tests as per pharmacopeial requirements. Microbiology Laboratory was also not developed. | i. Complied.<br>ii. Sampler has purchased.<br>iii. Apparatus was old but working properly as per pharmacopial specs.<br>iv. Working standards were available but USP/BP standards are in planning. Working standards has placed in desicator. Purchase of second Stability Chamber is in process. Data logger is required for stability chamber. Backup supply was available at the time of inspection. Tests are performed as per pharmacopeial methods or by validated methods. |
| 15. | The Documentation and record with respect to manufacturing SOP, BMRs and testing procedures required improvement. No annual product quality review, deviation in processes etc were being preformed, and recorded. | i. Manufacturing procedure SOP and BMR has revised and updated.<br>ii. All testing procedures are as per pharmacopoeia. |
| 16. | No self-inspection / audit was being conducted. The quality assurance department was not fully developed. | Previous inspection |
| 17. | No personal training of technical staff was being conducted, on GMP, HVAC system etc. | Training of technical staff has been conducted and record is available. |
| 18. | The water treatment plant was not functional at the time of inspection. The washing of equipment and paste making was being done through a tap water. | Complied. |
| 19. | The HVAC system was not properly functioning. Number of air changes, pressure difference and other controls were not as per requirement. In compression area of general tablet section return ducts were not installed. Ducts were without filters. Hence HVAC system required proper installation and validation. | a. In compression area of general tablet section return ducts has installed with prefilters.<br>b. HVAC previous validation has been available and new validation is in planning. |

M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, KotLakhpat, Lahore has submitted the CAPA report and deficient documents in the application for the renewal of DML for the period commencing on 13-06-2019 and ending 12-06-2024.

**Proceedings and Decision by the Central Licensing Board in 278th meeting:**

"The Board considering the facts on the record and after thread bare deliberation decided for re-inspection of the firm for resumption of production of M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, KotLakhpat, Lahore under DML No. 000255 (Formulation) by the same panel".

The panel has re-inspected the firm on 19-01-2021 and submitted their report for grant of Renewal of Drug Manufacturing License. The same is placed before the Board for its consideration/decision, please.

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| M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, KotLakhpat, Lahore .<br>DML No. 000255 (Formulation)<br>**Tenure**: Commencing on 13-06-2019 & ending on 12-06-2024 | **19-01-2021** | **Good** | 1) Dr. Farzana Chowdhary, Member, CLB, DRAP.<br>2) Syed Shahid Nasir, Expert Member.<br>3) Aisha Irfan, FID, DRAP, Lahore. |
| **Recommendations of the panel:**<br><br>"*The panel thoroughly inspected the firm and checked the rectifications of the deficiencies point out in previous inspection conducted for renewal of DML dated 16-01-2020. The inspection covered areas such as building and facility, production and in-process controls, material management, laboratory controls, documentation e.tc. Hence in view of above inspection, proceedings the panel observed that the firm had rectified most of the shortcomings, pointed out in previous inspection and has given undertaking for the development of microbiology laboratory as the firm do not have registration of sterile products. Therefore the panel recommends the renewal of DML by way of formulation to M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, KotLakhpat, Lahore for the following two sections;*<br><br>1. *Tablet Section (General).*<br>2. *Tablet Section (Psychotropic).* | | | |

**The case is hereby submitted for consideration and orders of the Board, please.**

**Decision of the Central Licensing Board in 279th meeting**

The Board considered the facts on record and decided to allow the resumption of production activities of M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, KotLakhpat, Lahore under DML No. 000255 (Formulation)subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020. The Board decided that as the application for renewal of DML of the firm is under process and firm has also submitted layout plan for regularization of manufacturing facility which is under process in the Division of drug licensing, therefore, firm may first complete the codalformalities for completion of application of renewal of DML and inform when it is ready for inspection in the light of approved layout plan.

**Case No.54** **RENEWAL OF PENDING LICENSED SECTION OF CAPSULE (GENERAL) UNDER DRUG MANUFACTURING LICENSE NO. 000012 (FORMULATION) OF M/S OBS PAKISTAN (PVT) LTD, KARACHI**

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| 4. | M/s OBS Pakistan (Pvt) Ltd, Plot No. C-14, Manghopir Road, S.I.T.E, Karachi.<br>DML No. 000012 (Formulation)<br>**Period**.<br>31-03-2020 till 30-03-2025 | **07-10-2020** | **Good** | 1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi<br>2. Chief Drugs Inspector, Govt of Sindh, Karachi.<br>3. Area FID, DRAP, Karachi. |

**Recommendations of the panel: -**

Keeping in view overall GMP compliance and positive intention towards improvements, Panel unanimously recommends the renewal of (DML No. 000012) by way of Formulation and Grant of Amendments in Sections (i) Tablet (General) Section (ii) Liquid Vial SVP (General) Section and (iii) Change Room (General) to the firm M/s. OBS Pakistan (Private) Limited, C-14, Manghopir Road Karachi. It is pertinent to mention the Firm has approved section as Capsule (General), however in panel Inspection letter issued vide letter No. F.2-1/2004-Lic (Vol-II), dated 20th May 2020, it was mistakenly typed as Soft Gelatin Capsule (General), which may be corrected in Grant of DML letter.

**Decision of the Central Licensing Board in 277th meeting**

The Board considered and approved the grant of renewal of (DML No. 000012) by way of formulation in the name of M/s OBS Pakistan (Pvt) Ltd, Plot No. C-14, Manghopir Road, S.I.T.E, Karachion the recommendations of the panel of experts for the period commencing on 31-03-2020 and ending on 30-03-2025 for the fowling sections:

**SECTIONS (5)**

1. Tablet (General)
2. Tablet (Hormone)
3. Liquid Vial SVP (General)
4. Soft Gelatin Capsule (Hormone)
5. Sachet (Hormone/ Soft Gel)

It was apprised to the Board that the lay out plan of the firm was regularized on 16th July, 2014 with the title Soft Gelatin Capsule (General) and panel for renewal of License was constituted on 30th March, 2015 which also mention the section as Soft Gelatin Capsule (General). The inspection report of the panel dated 8-4-2015 also mention Soft Gelatin Capsule (General). The Board, therefore, decided to defer the section for further clarification the matter.

Now firm has submitted documents regarding approval of Capsule (General) Section, therefore, **case of firm for renewal of pending licensed section namely Capsule (General) Section is placed before the CLB for consideration .**

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Central Licensing Board considered the facts on record approved the renewal of pending licensed section namely Capsule (General).

**Case No.55** **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000116 (FORMULATION) OF M/S ZUMARS PHARMA FTY (PVT) LTD, 02-MALIR INDUSTRIAL AREA, KARACHI**

M/s. Zumars Pharma FTY. (Pvt) Ltd,, Karachi submitted application for renewal of DML No. 000116 (Formulation) for the tenure commencing on 24-08-2020 and ending on 23-08-2025. The application was evaluated and a letter dated 05-10-2020 was issued to the firm to submit following documents for completion of application for renewal of DML.

i. Detail of licensed sections on firm's letter head along with approval lettersissued from the CLB or if not available then submit layout plan for regularization of manufacturing facility.
ii. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
iii. Prescribed fee for change of management (if the management is changed from the last renewal of DML).
iv. Name & approval letters of production Incharge Mr. Altaf Ali Sahito& Quality Control InchargeMr. Mukhtiar Ali or if not available then submit complete set of attested documents (as per checklist).
v. Updated NOC of CRF issued from statistical officer DRAP.

The firm submitted reply/documents on 09-12-2020 which were evaluated and after evaluation Reminder **dated 04-01-2021** was issued to the firm to submit following documents:

i. Detail / names of licensed sections as per dosage forms on firm's letter head.
ii. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
iii. Prescribed fee for change of management (if the management is changed from the last renewal of DML).
iv. Submit complete set of attested documents (as per checklist) for approval of production in charge and QC In charge.
v. Updated NOC of CRF issued from statistical officer DRAP.

In reply to reminder firm has only submitted documents of QC Incharge which are evaluated and following documents are found still found deficient and application for renewal of DML is still deficient of following documents:

i. Detail / names of licensed sections as per dosage forms on firm's letter head.
ii. Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
iii. Prescribed fee for change of management (if the management is changed from the last renewal of DML).
iv. Submit complete set of attested documents (as per checklist) for approval of production in charge.
v. Updated NOC of CRF issued from statistical officer DRAP.
vi. Relevant experience certificates of proposed QC Incharge.

vii. Resignation / retirement/Deathof earlier QC Incharge.
viii. Job acceptance letter by the proposed QC Incharge.
ix. Resignation or termination letter of QC Incahrge from the previous firm / promotion letter / transfer letter from the same firm.
x. Undertaking as whole time employee of proposed QC Incharge.

**Submitted for consideration of the Board, please.**

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

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 19of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000116 (by way of formulation) of M/s. Zumars Pharma FTY. (Pvt) Ltd, Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML under Rule 5(2A) may not be rejected.

## QUALITY ASSURANCE CASES

**Item No. I** **Panel Constitution**

**Case No. II** **M/S Wahabsons Pharma (Pvt) Ltd, Swat**

Mr. Zia Ullah, FID, Peshawar on 25.10.2018 conducted inspection of the firm M/s. Wahabsons Pharma (Pvt) Ltd, Plot No.402, 4 Km, Bunir Road, Bairkot Swat.

2. The FID noticed number of critical observations.

**Action taken by DRAP:**

3. The firm M/s Wahabsons Pharma (Pvt) Ltd, Swat was served Show Cause Notice and suspension of production orders in Dry Powder for Suspension Section (Cephalosporin) on 13.12.2018.

4. The Case was placed before the 267th meeting of CLB. Wherein the Board decided as under: -

**Decision of the 267thMeeting of CLB**

After thorough discussion/deliberations, the Central Licensing Board decided to suspend the Drug Manufacturing License of the firm M/s. Wahabsons Pharma (Pvt) Ltd, Swat under section 41 of the Drug Act, 1976 read with Rule 12 of the Drugs (LRA) Rules, 1976 till rectification of the observations noted by the FID in its report dated 25.10.2018.

5. The firm M/s. Wahabsons Pharma (Pvt) Ltd, Swat vide letter dated 25.10.2018 submitted compliance report and requested for verification of the observations. Compliance report is reproduced as under: -

**Updated Status:**

5. The firm vide letter dated 22.10.2020 submitted compliance report and requested for verifications of GMP compliance and rectification status.

***The case is placed before the Board for orders please***

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considered the case and decided to inspect the premises for verification of improvements made by the firm by following panel :

1. Dr. Jamshed Ali khan, Expert Member.
2. Federal Inspector of Drugs, Peshawar.
3. Mr. Adnan Shahid Ullah, AD, DRAP, Peshawar.

**Item No. II** **RESUMPTION OF PRODUCTION**

**Case No. I:** **M/S. HEALER LABORATORIES (PVT) LTD, PESHAWAR.**

**Background:**

Inspection of the firm M/s. Healer Laboratories (Pvt) Ltd., Plot No. 96/102, Small Industrial Estate, Kohat Road, Peshawar was conducted by Mr. Atiq-Ul-Bari, FID-II, DRAP, Peshawar on 04.09.2018 to verify the GMP compliance and production activities.

**Action taken by DRAP:**

2. The firm M/s. Healer Laboratories (Pvt) Ltd., Peshawar was served Show Cause Notice Order No.F.4-22/92-QA on 23.10.2018.

3. The case was placed before 267th meeting of Central Licensing Board. Wherein the Board decided as under: -

**Decision of the 267th Meeting of CLB**

After thorough discussion/deliberations, the Central Licensing Board decided to: -

i. Constitution of following panel of experts for detailed GMP inspection of the firm: -

   a) Prof. Dr. Jamshaid Ali Khan, Member, CLB
   b) The Area Federal Inspector of Drugs, Peshawar

ii. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 04.09.2018, with clear and candid recommendations.

4. The decision was conveyed to the quarter concerned vide letter dated 22.01.2019.

5. The panel conducted inspection of the firm M/s. Healer Laboratories (Pvt) Ltd, Peshawar on 26.03.2019 and concluded as under: -

*"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance."*

The panel further recommended the firm to: -

i. Provide an Air conditioner in Raw Material Quarantine area.
ii. Calibrate balances from external sources and provide digital balances in process QC and Capsule filling Section.
iii. Provide room for retention samples.

**Proceedings of 271st Meeting: -**

Quality Assurance Division presented the case before the Board, keeping in view the recommendations of panel in its report dated 26.03.2019. The Board raised query regarding the further recommendations made by the firm.

**Decision of the 271st Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to: -

i. Re-Inspect the firm by same panel of experts, constituted in 267th meeting of CLB, to verify the following improvements suggested by the panel in its report dated 26.03.2019:-

   a) Provide an Air conditioner in Raw Material Quarantine area.
   b) Calibrate balances from external sources and provide digital balances in process QC and Capsule filling Section.
   c) Provide room for retention samples.

ii. The panel shall submit detailed inspection report including rectification status of the observations with clear and candid recommendations.

iii. Production of the firm M/s. Healer Laboratories (Pvt) Ltd, Peshawar shall remain suspended till recommendation by panel and subsequent approval by the CLB.

6. The decision was conveyed to the quarter concerned vide letter dated 01.10.2019 and reminder on 16.09.2020.

**Panel Inspection**

7. Panel comprising of Prof. Dr. Jamshaid Ali Khan, Member CLB and the Area FID, DRAP, Peshawar in compliance to the decision of 271st meeting of CLB conducted inspection of the firm M/s. Healer Laboratories (Pvt) Ltd, Peshawar on 16.12.2020 and concluded as under:-

*"Based on the area inspected, the people met and documentations reviewed and considering the findings of inspection, the panel unanimously decided to recommend the resumption of production of M/s. Healer Laboratories (Pvt) Ltd. Peshawar.*

***It is pertinent to bring on record that, at present, the total size of the plot of the firm is less than 2000sq. yard, as described in Drug (Licensing, Registration and Advertising) Rules, 1976. The management of the firm informed that due to this reason they are in process of shifting the manufacturing facility and had already submitted lay-out of their new site to Licensing Division."***

*The case is placed before the CLB in compliance to the decision of 267th & 271st meeting of CLB and keeping view the recommendation of panel of experts in its report dated 16.12.2020 forresumption of production of M/s.Healer Laboratories (Pvt) Ltd, Peshawar.*

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considered the case and decided to defer the resumption of production. The Board further decided that Licensing Division may issue show cause notice under section 41 of the Drugs Act, 1976 read with Rule 12 for non compliance of Rule 16 of the Drugs (L,R&A) Rules,1976 for the matter referred by the panel of inspectors in its concluding remarks in its inspection report dated 16-12-2020.

# QUALITY CONTROL CASES (PRODUCT RELATED ISSUES)

Case No. 01: **MANUFACTURE/SALE OF UNREGISTERED DRUGS BY M/S. MEDICARE HOMEO STORE & CLINIC, KARACHI.**

Mr. Abdul Rasool Shaikh, FID-VI, DRAP, Karachi along with the DRAP team inspected M/s. Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi on 21-11-2019 and samples of following drugs/creams were taken for purpose of test/analysis on Prescribed Form-3;

| S. No. | Name of Drug | Batch No. | Mfg. Date | Exp. Date | Purported to be manufactured by |
|---|---|---|---|---|---|
| 1. | Midnight Cream | Nil | Nil | Nil | M/s. UM Homeopathic Pharma, Karachi. |
| 2. | 100 Minutes Cream | Nil | Nil | Nil | M/s. Medicare Homeopathic Pharma, Karachi. |

2. The sealed samples of above drugs/creams were sent by FID to Federal Government Analyst, CDL, Karachi for purpose of test/analysis vide memorandum No. ARS-253/2019-FID-VI(K) dated 22-11-2019.

3. M/s. Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi was directed by FID to provide bill warranties/invoices of above drugs/creams vide letters dated 22-11-2019 & 24-12-2019 but no reply was received.

4. The Government Analyst, CDL, Karachi vide test report No. NTF.KQ.572/2019 & No. NTF.KQ.573/2019 dated 20th January, 2020, declared the above-mentioned samples as **Unregistered Drug Products** as Lidocaine, an allopathic ingredient, was identified in both the creams.

5. In the light of above test reports of Federal Government Analyst, explanation letters date 31-01-2020 & 14-02-2020 were issued by FID to M/s. Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi for explaining their position. FID further submitted that the letter No. F. 254-257/2019-FID (K)-VI (NTF) dated 14-02-2020 issued to Medicare Homeo Store & Clinic, Karachi, returned back with the remarks that shop is closed.

6. Keeping in view the above facts, Area FID, stated that M/s. Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi, has violated Section 23(1)(a)(vii), 23(1)(a)(i) & 23(1)(h) of the Drugs Act, 1976 which is punishable under Section 27 of the Drugs Act, 1976 and therefore recommended as under;

i. That the permission for prosecution of below mentioned person, in Drug Court, may kindly be granted for manufacturing and selling of unregistered drug products and non-submission of bill warranty/invoice.
   a. M/s. Medicare Homeo Store & Clinic, Shop No. 02, 5/C, Near Board of Secondary Education, Nazimabad, Karachi.
   b. Muhammad Younas S/o Muhammad Ahmed (CNIC No. 42301-0878778-7)- Proprietor.
ii. That the Sindh Health Care Commission may be approached for cancellation/suspension of registration certificate No. SHCC/P-KHI/0593 dated 04-06-2018.

**Submitted for consideration of the Board.**

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Central Licensing Board considered the case and decided to allow the permission for prosecution of the accused mentioned in Para 6 as recommended by the federal inspector of drugs. The Board also allowed the request of Federal Inspector of Drugs to approach Sindh Health care commission for suspension cancellation of registration certificate No. SHCC/P-KHI/0593 dated 04-06-2018.

Case No. 02 : **SUBSTANDARD TABS. PARACETAMOL (BATCH NO. 1595) MANUFACTURED BY M/S. PAKISTAN PHARMACEUTICAL AND CHEMICAL LABORATORIES, A-34 SITE, HYDERABAD.**

The following case was discussed in the 297th meeting of Registration Board. Brief facts of the case are given as under:

2. The Case was initially decided by Registration Board in its **234th Meeting held on 23.07.2012** as under:

i. Suspension of registration of Paracetamol 500mg Tablet (Reg. No. 004251) for 2 months,
ii. Panel inspection of the firm for qualitative investigation of case.
iii. Resumption of production will be after satisfactory inspection report of panel and approval of chairman, Registration Board.
iv. Sampling of drug after resumption of production.

3. In its **291st Meeting held on 02-04th September, 2019,** The Registration Board decided as under:

- Area FID be directed to communicate the implementation of aforesaid Board's decision of the case.
- The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report:
  i. The area Additional Director, field office DRAP
  ii. The area FID
  iii. The area Assistant Director (I&E)

That the area FID shall submit a complete report including implantation status along with supporting documents/evidences/ annexures/inspection reports within 15 days positively. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.

4. Response of FID vide letter no.F.SAA-001/2019-FID-V(K)(INV) was received on 30th September, 2019 which is given as under:

> *"In compliance to decision of the Drug Registration Board undersigned along with Dr. Kirshan, Assistant Director, DRAP, Karachi visited the premises of M/s Pakistan Pharmaceuticals and chemicals, A-34, SITE, Hyderabad on dated 30th September, 2019 to ensure the implementation of the decision of the 234th Meeting of Drug Registration Board. During the course of the visit Mr. Sultan-ul-Haq Qureshi and Miss MaqsoodaBegam (QC In-charge) were present at the premises, the manufacturing section of the firm was closed and it was observed that there was no any manufacturing activity being carried out for some time period, in addition there was no any record of said batch of paracetamol available at the premises of*

*the firm and no any fresh stock of tablet paracetamol was available for re-sampling. The owner of the firm informed that they had never produced the said batch number (B.No. 10) of product paracetamol tablet and never received any letter pertaining to the said batch number from the DRAP, Islamabad / any concerned quarter."*

Additional Director, DRAP, Karachi was telephonically once again requested to send the implementation status before the meeting.

5. In its **293rd meeting held on 6-8th January, 2020,** the Registration Board decided as under:

- That area FID be directed to again visit the firm and communicate the implementation of Board's decision of the case.
- The Board once again directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report:
    1. The area Additional Director, field office DRAP
    2. The area FID
    3. The area Assistant Director (I&E)

That the area FID shall submit a complete report including implementation status along with supporting documents/evidences/ annexures/inspection reports within 15 days positively. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.

6. No report was submitted by the area FID DRAP Karachi, therefore, in its **295th meeting held on 08th – 11th June, 2020,** the Registration Board decided as under:

- Last/final chance shall be given to the FID/Investigation officer for compliance of the already communicated decision in the instant matter and submit complete report including implementation status along with supporting documents/evidences/ annexures/inspection reports within 15 days positively.
- QA&LT Division, DRAP, Islamabad is advised to direct Federal Inspector of Drugs/Investigation officers for compliance of decision of Registration Board within stipulated time.

7. In response to the communicated decision of 293rd meeting of Registration Board, FID-V, DRAP, Karachi submitted reply vide No.F.SAA.001/2019-FID-V (K) (INV) dated 12th June, 2020 and is given as under;

*"I have the honor to refer to the DRAP's letter no. F.03-65/2019-QC (293-RB) and this office earlier letter of even number dated 30 September, 2019 for the subject captioned above. In compliance of the directions passed by the Drugs Registration Board in its meeting no. 293, held on 06th - 08th January, 2020, the undersigned again visited the premises of M/s. Pakistan Pharmaceutical and Chemical Hyderabad on dated 04th June, 2020, the firm M/s. Pakistan Pharmaceutical and Chemical Hyderabad was found closed. Upon telephonic contact with the owner of the firm Mr. Sultan ul Haque Qureshi, he informed that currently he is on dialysis and the factory is closed these days and regarding telephonic discussion about the batch in question, he again informed that they had never produced the batch no. 10 of Paracetamol tablets and didn't receive any letter pertaining to the said batch number from DRAP, Islamabad or concerned quarter (the written response already submitted by the firm vide their letter of dated 30th September,2019 and the copy is enclosed herewith)."*

8. Moreover, in response to the communicated decision of 295th meeting of Registration Board, communicated to the quarter concerned vide letter No.F.03-28/2020-QC (295th RB) dated 19-08-2020, FID-VIII DRAP Karachi submitted reply vide No.F.SY.004/2020-FID-VIII (K) dated 31st August, 2020 and is given as under;

> "*In compliance to the directions passed by the Drug Registration Board in its meeting No. 295th, held on 08-11th June, 2020 the undersigned visited the premises of M/s Pakistan Pharmaceutical and Chemical Hyderabad on dated 28th August, 2020.*
>
> *The firm was found closed due to sudden death of the owner of the firm Mr. Sultan Ul Haque Qureshi. Owner's son Asad Ul Haque Qureshi assured to comply with the decision of RB communicated vide letter No.F.SY.001/2020-FID-VIII (K) dated 26th August, 2020.*
>
> *Furthermore, Factory was not operational and production was temporarily closed till 21st September, 2020 due to owner death. The written response of the firm is enclosed herewith.*
>
> *Keeping in view of the facts stated above, the case may be placed and discussed in the Central Licensing Board under section 19(7) of Drug Act 1976 for further directions."*

9. In its **296th meeting held on 08th – 10th December, 2020,** Registration Board after thorough deliberations constituted the following panel to conduct Panel inspection of the firmafter 21st September for qualitative investigation of case (Manufacture & sale of substandard Paracetamol tablets, Batch No.1595) and submit a complete report including implementation status of 234th meeting of Registration Board's decision along with supporting documents/evidences/ annexures/inspection reports without waiting for the minutes of the meeting and for further consideration of the Board;

- Dr. RafeeqAlam Khan, Member Registration Board.
- Additional Director, DRAP, Karachi.
- Area Federal Inspector of Drugs, DRAP, Karachi.

10. In response to the above said letter the panel forwarded their report vide reference No.F.05-01/2020-FID-VIII (K) dated 26-11-2020 regarding the subject of "Manufacture & sale of substandard Paracetamol Tablets, Batch No. 1595, Manufactured by M/s Pakistan Pharmaceutical and Chemical Hyderabad" wherein the panel have submitted the proceeding of inspection conducted by the panel on 15-10-2020 and is reproduced as under;

> *"That, despite of prior information to Mr. Asad ul Haque Qureshi, son of the owner, the main gate of the firm was observed closed till around 11:00 AM and panel members were waiting for opening of gate. A watchman was available inside the main gate of factory, who informed that he will not open the gate without prior approval of Mr. Asad ul Haque. The watchman opened the gate upon arrival of Mr. Asad ul Haque at around 11:00 AM.*
>
> *That, Mr. Asad ul Haque informed that keys of the production building was not available with him today and panel cannot visit the production and quality control premises today, and keys could be arranged after some days. Moreover, he also informed that he has no idea regarding the substandard paracetamol tablets as everything was in custody of his late father.*

*That, the present management of the firm didn't cooperate with the panel and neither produced the documents of the subject cited drug nor allowed the panel to visit the production, quality control and storage facilities."*

11. Keeping in view of the above cited facts and compliance of the management, the panel opined that management of the firm failed to comply the condition of registration and Drug Manufacturing License. Panel recommends the initiation of action under the Section 41 and 42 of the Drugs Act, 1976 and DRAP Act, 2012 in larger public interest.

12. The complete case along with the recommendations of the panel was placed before the Board in its 297th meeting. The Board showed grave concern that the firm did not allowthe panel to enter and inspect the premises and decided to refer the case to the Central Licensing Board with recommendations to cancel/suspend the Drug Manufacturing License of the firm.

**Proceedings and Decision by the Central Licensing Board in 279th meeting:**

The Board considered the case and decided to issue show cause notice to the firm under the law.