**MINUTES OF 268th MEETING OF CENTRAL LICENSING BOARD HELD ON 10th**

**JANURAY, 2019**

\*=\*=\*=\*=\*

268th meeting of the Central Licensing Board (CLB) was held on 10th January, 2019 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Mr. Ghulam Rasool Dutani, Director Drug Licensing, Drug Regulatory Authority of Pakistan, and Islamabad.

Following members attended the meeting: -

|  |  |  |
| --- | --- | --- |
| **S. No.** | **Name & Designation** | **Status** |
|  | Prof. Dr. Mohammad Usman, Expert in manufacturing of drugs | Member |
|  | Prof . Dr.Abdullah Dayo, Faculity of Pharmacy, University of Sindh, Jamshoro. | Member |
|  | Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar. | Member |
|  | Mr. Muhammad Israr, Law Expert, Mininstry of Law & Justice Division. | Member |
|  | Dr. Hafsa Karam Ellahi  Representative Director (QA/LT), DRAP, Islamabad | Member |
|  | Mr. Syed Saleem Shah Chief Drug Inspector, Government of Baluchistan. | Member |
|  | Mr. Syed Adnan Rizvi, Chief Drug Inspector, Government of Sindh. | Member |
|  | Mr. Abbas khan Chief Drug Inspector, Govt of Khyber Pakhutonkhuwa. | Member |
|  | Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad. | Secretary/Member |
|  | Mr. Khalid Munir, Representative of Representative of PPMA. | Observer |

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

**Item-I CONFIRMATION OF THE MINUTES OF 267thMEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 267th meeting of the Central Licensing Board (CLB) which was held on 31st December, , 2018 with the following corrections:

The expression “M/s Syntex Pharmacuticals Kamra Road Attock City till shifting of the firm to new premises” shall be read as “M/s Syntex Pharmacuticals Kamra Road Attock City till completion of codal formalities. However, the firm shall shift to new premises in given time as mentioned above”.

**A. DRUG LICENSING DIVISION**

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S #** | **Name of the firm** | **Date of Inspection** | Ranking/ Evaluation | **Inspection Panel Members** |
| 1. | M/s AGP Limited, B-23, S.I.T.E, Karachi.  DML No. 000348 (Formulation)  Facility:   1. R&D Lab **(New).** 2. QC Lab. **(Amendment).** | 20-11-2018 | **Good** | 1. Syed Mueed Ahmed, Member, CLB, Islamabad. 2. Dr. Najam-us-Saquib, FID / Additional Director, Karachi. 3. Area, FID, DRAP, Karachi. |
| “M/s AGP Limited, situated at B-23, S.I.T.E, Karachi, was inspected on 28th November 2018, by the panel constituted as per DRAP letter No.F.2-3/92-Lic (Vol-III) dated 6th November 2018 for the purpose of inspection in connection with amendments made in the existing QC Laboratory and establishment of a new Research and Development (R&D) Laboratory. Following are the observation:  During the inspection, panel observed that the firm has made amendments in the Quality Control Laboratory as per approved Layout plan, wherein offices are provided for the QC Manager, Deputy QC Manager and Regulatory Staff. A new R&D Laboratory has been provided by the management which was observed as per approved layout plan by the DRAP authorities. A dedicated QC Laboratory also has been established alongwith production areas of R&D, which was observed well equipped with necessary production and testing equipment including stability chambers for the research and developmental and new product developmental purposes. Adequate qualified personnel were also observed available with necessary experience. HVAC system seen installed and operational in R&D Laboratory.  Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection and vision of the management for international certifications, **panel recommends the grant of approval for new Research and Development Laboratory and Amendments in Quality Control Laboratory**”.  **Decision by the Central Licensing Board in 268th meeting**  The Board considered and approved the grant of following facility in the name of M/s AGP Limited, B-23, S.I.T.E, Karachi.(Formulation)  Facility:   1. R&D Lab **(New).** 2. QC Lab. **(Amendment).** | | | |
| **S #** | **Name of the firm** | **Date of Inspection** | Ranking/ Evaluation | **Inspection Panel Members** |
| 2. | M/s. Hansel Pharmaceutical (Pvt.) Ltd., Plot No. 02, Pharma City, 30-K.M. Multan Road, Lahore.  DML No. 000581 (Formulation)  **Section (03)**   1. Liquid Injectable (Hormone) Section (Re-located) 2. Tablet (Hormone) Section (Revised) 3. Tablet (General) Section (Revised) | **27-11-2018 &**  **11-12-2018 & 24-12-2018** | **-** | 1. Dr. Farzana Chowdhary, Director IPS, UVAS, Lahore. 2. Mr. Asim Rauf, Additional Director (E&M), Lahore. 3. Ms. Uzma Barkat, Federal Inspector of Drugs, Lahore. |
| **OBSERVATIONS**  **Raw Material Store (Main)**   1. Firm was storing raw material and Alu-PVC rolls in the same store. To overcome this shortcoming, firm converted the room for released inactive material storage in to room for storage of Aluminum foil and PVC rolls. 2. **Firm had shifted the bulk inactive material and some packing material which was previously placed in main RM store, to the basement. Firm had not taken approval from DRAP for use of this storage area in the basement. It was also seen that there was no temp/humidity maintenance and monitoring system in that area. Separate dispensing room HVAC yet to be provided.** 3. Civil work of new dispensing area was in process. Area was yet to be painted and HVAC system was yet to be installed   **General Capsule Section**   1. Manometer of mixing room was not functional.   **General Tablet Section**   1. Differential pressure in drying room was positive. 2. Differential pressure in compression cubicles was positive. 3. Air conditioners were installed in all three blistering rooms. Firm was advised to remove AC and provide HVAC system. **26.2˚C/47% RH** seen in Blistering 3 at the time of inspection. **24.1˚C/58% RH** seen in Blistering 1 at the time of inspection.   **General Tablet Section (Amended)**   1. Differential pressure was found to be positive in granulation room. 2. Manometer of coating room 2 was not functional. 3. Humidity of granulation area was not maintained.   **Temp/ humidity observed on 27/11/2018 = 21.2˚C/73% RH**  **Temp/ humidity observed on 11/12/2018 = 17.8˚C/70% RH**  **Temp/humidity observed on 24-12-2018= 15.8˚C/72% RH**   1. Firm had provided an emergency exit in the granulation area which was not present in the approved layout. This emergency exit was not safe and appropriate in the given location.   **Eye Drop Section**   1. RM store was very congested. Firm was using some analytical grade raw materials. The firm was advised to use pharmaceutical grade raw materials in manufacturing. 2. A window had been provided in the Solution preparation area for transfer of material to autoclave room which was opening in main corridor. Advised to provide proper pass through hatch. 3. The filling machine was installed directly under the HVAC diffuser blocking the HVAC supply. Moreover filling nozzles were directly under dead patch of LFC.   **Cream/Ointment Section**   1. Section was not operational 2. HVAC system of the area was under maintenance as informed by the firm’s management.   **Liquid Injectable Section (General)**   1. Firm had provided two solution preparation rooms and two filling areas. 2. The firm was advised to provide HVAC system in the buffer of ampoule washing area. 3. Firm was advised to provide flushed lights and windows in solution preparation and filling areas. 4. In material transfer room I, there was no HVAC return duct. Manometer was not installed. 5. In material transfer room II, there was neither HVAC supply nor return. Manometer was not installed. 6. The firm was advised to remove AC from Autoclave room and provide HVAC system. 7. The firm was advised to provide HVAC system in the whole corridor providing access to sterile areas. 8. De-cartoning area was just a closed room. There was no air treatment mechanism in de-cartoning area. The firm was advised to provide HVAC system in this area.   **Dry Powder Injection Section (Cephalosporin)**   1. Firm was advised to replace rusted hooks in vial washing area, provide GMP compliant drains throughout the unit and provide flushed lights and windows. Open tube lights and dead spaces were present in LFC. 2. Firm was advised to provide continuous LFC on filling machine without any dead patch.   **Dry Powder Suspension and Capsule Section (Cephalosporin)**   1. Firm was advised to provide physical partitioning between bottle filling and sealing operations. 2. Differential pressure was positive inside mixing and filling room. 3. Firm was advised to provide pressure gauges and suction in bottle blowing machine. 4. Dispensing hood room opens in to main corridor. There is a risk of cross contamination.   **Hormone Tablet Section**   1. No ventilation or temp/humidity maintenance and monitoring system was provided in quarantine area. 2. In the dispensing room and raw material released area, HVAC system was not functional. 3. Firm was advised to provide proper transfer hatch in dispensing area. 4. Humidity in granulation area : **23.3˚C/ 60% RH (area at rest)** 5. Humidity in mixing room area : **17.5˚C/ 66% RH (area at rest)** 6. Humidity in drying room area : **17.7˚C/ 64% RH (area at rest)** 7. Humidity in blistering area: **19.9˚C/ 69% RH (area at rest)** 8. **Packing hall had been provided an access to the basement where the finished goods will be stored as informed by the firm’s management. Firm had not obtained approval for this FG store from DRAP. It was also seen that there was no temp/humidity maintenance and monitoring system in that area.**   **Hormone Injection Section**   1. Dispensing hood was provided. However, firm was advised to provide proper enclosed dispensing room. 2. Sampling booth/area was not provided. 3. Calibration of gauges/equipment/machine parts in this section was yet to be completed. 4. Open tube lights had been installed in LFCs of both solution preparation areas and filling machines. The firm was advised to provide flushed lights. 5. The firm was advised to provide magnehelic gauge for pressure monitoring in buffers for material transfer. 6. Physical partitioning required between vial filling and sealing operation. 7. Water, compressed air, nitrogen gas filters were yet to be installed. 8. No LFC trolley for ampoule cooling/transfer was not provided.   **Quality Control Laboratory:**   1. Firm was advised to provide TOC analyzer.   The firm has submitted plan vide letter No. 271218/HP/DRAP/18 dated 27-12-2018 wherein they have given a timeline for rectification/compliance of the observations made during the inspections.  **Decision by the Central Licensing Board in 268th meeting**  The Board considered and deferred the case of M/s. Hansel Pharmaceutical (Pvt.) Ltd., Plot No. 02, Pharma City, 30-K.M. Multan Road, Lahore for rectification and subsequent panel inspection of the firm for following sections:  **Section (03)**   1. Liquid Injectable (Hormone) Section (Re-located) 2. Tablet (Hormone) Section (Revised) 3. Tablet (General) Section (Revised) | | | |

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S #** | **Name of the firm** | **Date of Inspection** | **Ranking/ Evaluation** | **Inspection Panel Members** |
| 1. | M/s Scotmann Pharmaceutical, Plot No. 5-D, I-10/3, Islamabad.  DML No. 000498 (Formulation)  **Period**: Commencing on 22-06-2017 ending on 21-06-2022 | **17-10-2018**  **&**  **22-11-2018** | - | 1. Director Biological, DRAP, Islamabad. 2. Additional Director (Lic), DRAP, Islamabad. 3. Additional Director (QA&LT), DRAP, Islamabad 4. Area Federal Inspector of Drugs, Islamabad. |
| “Panel verified the establishment of sections as per approved layout plan as well as the required facilities for manufacturing, quality control testing and storage of finished pharmaceutical product and raw material. Keeping in view the above, the panel unanimously recommends for the regularization of revised layout and grant of renewal of license”.  **Decision by the Central Licensing Board in 268th meeting**  The Board considered and approved the renewal of Drug Manufacturing Licence No. 000498 (Formulation) in the name of M/s Scotmann Pharmaceutical, Plot No. 5-D, I-10/3, Islamabad for the further period of five years Commencing on 22-06-2017 ending on 21-06-2022. | | | |
| 2. | M/s. Hansel Pharmaceutical (Pvt.) Ltd., Plot No. 02, Pharma City, 30-K.M. Multan Road, Lahore.  DML No. 000581 (Formulation)  **Period**: Commencing on  24-06-2015 ending on 23-06-2020 | **27-11-2018 &**  **11-12-2018 &  24-12-2018** | **-** | 1. Dr. Farzana Chowdhary, Director IPS, UVAS, Lahore. 2. Mr. Asim Rauf, Additional Director (E&M), Lahore. 3. Ms. Uzma Barkat, Federal Inspector of Drugs, Lahore. |
| **OBSERVATIONS**  **Raw Material Store (Main)**   1. Firm was storing raw material and Alu-PVC rolls in the same store. To overcome this shortcoming, firm converted the room for released inactive material storage in to room for storage of Aluminum foil and PVC rolls. 2. **Firm had shifted the bulk inactive material and some packing material which was previously placed in main RM store, to the basement. Firm had not taken approval from DRAP for use of this storage area in the basement. It was also seen that there was no temp/humidity maintenance and monitoring system in that area. Separate dispensing room HVAC yet to be provided.** 3. Civil work of new dispensing area was in process. Area was yet to be painted and HVAC system was yet to be installed   **General Capsule Section**   1. Manometer of mixing room was not functional.   **General Tablet Section**   1. Differential pressure in drying room was positive. 2. Differential pressure in compression cubicles was positive. 3. Air conditioners were installed in all three blistering rooms. Firm was advised to remove AC and provide HVAC system. **26.2˚C/47% RH** seen in Blistering 3 at the time of inspection. **24.1˚C/58% RH** seen in Blistering 1 at the time of inspection.   **General Tablet Section (Amended)**   1. Differential pressure was found to be positive in granulation room. 2. Manometer of coating room 2 was not functional. 3. Humidity of granulation area was not maintained.   **Temp/ humidity observed on 27/11/2018 = 21.2˚C/73% RH**  **Temp/ humidity observed on 11/12/2018 = 17.8˚C/70% RH**  **Temp/humidity observed on 24-12-2018= 15.8˚C/72% RH**   1. Firm had provided an emergency exit in the granulation area which was not present in the approved layout. This emergency exit was not safe and appropriate in the given location.   **Eye Drop Section**   1. RM store was very congested. Firm was using some analytical grade raw materials. The firm was advised to use pharmaceutical grade raw materials in manufacturing. 2. A window had been provided in the Solution preparation area for transfer of material to autoclave room which was opening in main corridor. Advised to provide proper pass through hatch. 3. The filling machine was installed directly under the HVAC diffuser blocking the HVAC supply. Moreover filling nozzles were directly under dead patch of LFC.   **Cream/Ointment Section**   1. Section was not operational 2. HVAC system of the area was under maintenance as informed by the firm’s management.   **Liquid Injectable Section (General)**   1. Firm had provided two solution preparation rooms and two filling areas. 2. The firm was advised to provide HVAC system in the buffer of ampoule washing area. 3. Firm was advised to provide flushed lights and windows in solution preparation and filling areas. 4. In material transfer room I, there was no HVAC return duct. Manometer was not installed. 5. In material transfer room II, there was neither HVAC supply nor return. Manometer was not installed. 6. The firm was advised to remove AC from Autoclave room and provide HVAC system. 7. The firm was advised to provide HVAC system in the whole corridor providing access to sterile areas. 8. De-cartoning area was just a closed room. There was no air treatment mechanism in de-cartoning area. The firm was advised to provide HVAC system in this area.   **Dry Powder Injection Section (Cephalosporin)**   1. Firm was advised to replace rusted hooks in vial washing area, provide GMP compliant drains throughout the unit and provide flushed lights and windows. Open tube lights and dead spaces were present in LFC. 2. Firm was advised to provide continuous LFC on filling machine without any dead patch.   **Dry Powder Suspension and Capsule Section (Cephalosporin)**   1. Firm was advised to provide physical partitioning between bottle filling and sealing operations. 2. Differential pressure was positive inside mixing and filling room. 3. Firm was advised to provide pressure gauges and suction in bottle blowing machine. 4. Dispensing hood room opens in to main corridor. There is a risk of cross contamination.   **Hormone Tablet Section**   1. No ventilation or temp/humidity maintenance and monitoring system was provided in quarantine area. 2. In the dispensing room and raw material released area, HVAC system was not functional. 3. Firm was advised to provide proper transfer hatch in dispensing area. 4. Humidity in granulation area : **23.3˚C/ 60% RH (area at rest)** 5. Humidity in mixing room area : **17.5˚C/ 66% RH (area at rest)** 6. Humidity in drying room area : **17.7˚C/ 64% RH (area at rest)** 7. Humidity in blistering area: **19.9˚C/ 69% RH (area at rest)** 8. **Packing hall had been provided an access to the basement where the finished goods will be stored as informed by the firm’s management. Firm had not obtained approval for this FG store from DRAP. It was also seen that there was no temp/humidity maintenance and monitoring system in that area.**   **Hormone Injection Section**   1. Dispensing hood was provided. However, firm was advised to provide proper enclosed dispensing room. 2. Sampling booth/area was not provided. 3. Calibration of gauges/equipment/machine parts in this section was yet to be completed. 4. Open tube lights had been installed in LFCs of both solution preparation areas and filling machines. The firm was advised to provide flushed lights. 5. The firm was advised to provide magnehelic gauge for pressure monitoring in buffers for material transfer. 6. Physical partitioning required between vial filling and sealing operation. 7. Water, compressed air, nitrogen gas filters were yet to be installed. 8. No LFC trolley for ampoule cooling/transfer was not provided.   **Quality Control Laboratory:**   1. Firm was advised to provide TOC analyzer.   The firm has submitted plan vide letter No. 271218/HP/DRAP/18 dated 27-12-2018 wherein they have given a timeline for rectification/compliance of the observations made during the inspections.  **Decision by the Central Licensing Board in 268th meeting**  The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License (No. 000581(Formulation) ) may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. | | | |

**Item-IV**: **MISC. CASES.**

**CASE NO.1. REGULARIZATION / AMENDMENT OF REVISED LAYOUT PLAN OF M/S SCOTMANN PHARMACEUTICAL, PLOT NO. 5-D, I-10/3, ISLAMABAD.**

Area FID-IV, DRAP, Islamabad wherein she has submitted inspection report for regularization / amendment of revised layout plan of M/s Scotmann Pharmaceutical, Plot No. 5-D, I-10/3, Islamabad for following sections;

**Top Floor.**

* + 1. Upgraded Microbiology Laboratory shifted within QC.

**Basement.**

1. Dry Suspension General Section **(Reallocated).**
2. Tablet Section General **(Reallocated).**
3. Liquid Section General **(Reallocated).**
4. Capsule Section General **(Reallocated).**

The conclusion of inspection report is as under:-

“Panel verified the establishment of sections as per approved layout plan as well as the required facilities for manufacturing, quality control testing and storage of finished pharmaceutical product and raw material. Keeping in view the above, the panel unanimously recommends for the regularization of revised layout and grant of renewal of license”.

**Proceedings and Decision of Central Licensing Board in 268thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to approve the Regularization of following sections/facilities of M/s Scotmann Pharmaceutical, Plot No. 5-D, I-10/3, Islamabad.

: **Top Floor.**

1. Upgraded Microbiology Laboratory shifted within QC.

**Basement.**

1. Dry Suspension General Section **(Reallocated).**
2. Tablet Section General **(Reallocated).**
3. Liquid Section General **(Reallocated).**
4. Capsule Section General **(Reallocated).**

**CASE NO.2.** **M/S KAKASIAN PHARMACEUTICALS (PVT) LTD,29th KM FEROZEPUR ROAD, LAHORE.**

Drug Manufacturing License No. 000353 (Formulation) was issued to M/s Kakasian Pharmaceuticals (Pvt) Ltd,29th Km Ferozepur 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 02-03-2015 to 01-03-2020 has not been received till date. Therefore, DML No. 000353 (Formulation) M/s Kakasian Pharmaceuticals (Pvt) Ltd, Lahore is no more valid.

**Proceedings and Decision of Central Licensing Board in 268th 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 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000353 by way of formulation M/s Kakasian Pharmaceuticals (Pvt) Ltd,29th Km Ferozepur Road, Lahore may not be declared cancelled.

**CASE NO.3.** **M/S ASTLE MEDICAL DEVICES PAKISTAN (PVT) LTD, PLOT NO. 545-B, SUNDER INDUSTRIAL ESTATE, LAHORE.**

Drug Manufacturing License No. 000743 (Formulation) was issued to M/s Astle Medical Devices Pakistan (Pvt) Ltd, Plot No. 545-B, Sunder Industrial Estate, 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 11-10-2017 to 10-10-2022 has not been received till date. Therefore, DML No. 000743 (Formulation) M/s Astle Medical Devices Pakistan (Pvt) Ltd, Lahore is no more valid.

**Proceedings and Decision of Central Licensing Board in 268th 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 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000353 by way of formulation M/s Astle Medical Devices Pakistan (Pvt) Ltd, Plot No. 545-B, Sunder Industrial Estate, Lahore may not be declared cancelled.

**CASE NO. 4. CHANGE OF MANAGEMENT OF M/S EPOCH PHARMACEUTICALS, PLOT NO. 83-85, SECTOR NO. 15, KORANGI INDUSTRIAL AREA, KARACHI .**

M/S Epoch Pharmaceuticals, Plot No. 83-85, Sector No. 15, Korangi Industrial Area, Karachi, under DML No. 000425 by way of Formulation has submitted request for change in management of the firm as per partnership deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under:-

|  |  |  |
| --- | --- | --- |
| **Existing Management** | **Retiring management.** | **New Management** |
| * 1. Mr. Muhammad Saleem S/o Abu Baker CNIC No. 42000-0448495-7.   2. Mrs. Amber W/o Muhammad Saleem CNIC No. 42000-0413358-6. | 1. Mrs. Amber W/o Muhammad Saleem CNIC No. 42000-0413358-6. | * 1. Mr. Muhammad Saleem S/o Abu Baker CNIC No. 42000-0448495-7.   2. Mr. Muhammad Samir S/o Muhammad Saleem CNIC No. 42000-6519127-5. |

**Decision by the Central Licensing Board in 268th meeting:**

The Board considered and endorsed the change of management M/S Epoch Pharmaceuticals, Plot No. 83-85, Sector No. 15, Korangi Industrial Area, Karachi under DML No. 000425 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Existing Management** | **Retiring management.** | **New Management** |
| 1. Mr. Muhammad Saleem S/o Abu Baker CNIC No. 42000-0448495-7. 2. Mrs. Amber W/o Muhammad Saleem CNIC No. 42000-0413358-6. | 1. Mrs. Amber W/o Muhammad Saleem CNIC No. 42000-0413358-6. | * 1. Mr. Muhammad Saleem S/o Abu Baker CNIC No. 42000-0448495-7.   2. Mr. Muhammad Samir S/o Muhammad Saleem CNIC No. 42000-6519127-5. |

**QUALITY CONTROL CASES**

**Case No. 01:-**

Subject: **FIR NO. 05/2018 IN FIA ACC, ISLAMABAD REGARDING MANUFACTURING AND SALE OF UN-REGISTERED DRUGS, SPURIOUS DRUGS, SUB-STANDARD DRUGS, MANUFACTURING OF DRUGS FROM RAW MATERIALS WITHOUT HAVING VALID IMPORT LICENSE & IMPORT AUTHORIZATION AND MANUFACTURE FOR SALE OF THERAPEUTIC GOODS EXCEPT UNDER AND IN ACCORDANCE WITH THE CONDITION OF A LICENSE ISSUED UNDER THIS ACT.**

The then area FID alongwith DRAP inspection team, FIA, Assistant Commissioner, Islamabad and NAB conducted a joint raid on 6th March, 2018 at M/s Everest Pharmaceuticals, Plot No. 124, Industrial Triangle, Kahuta Road, Islamabad at 11:00 am on the direction of Honourable Supreme Court of Pakistan in HRC case No. 5845-G/2018. DRAP team comprising of following DRAP officers:-

1. Dr. Hafsa Karam Elahi, Additional Director QA&LT-I, Islamabad
2. Dr. Obaid Ullah, Director PE&R, DRAP, Islamabad
3. Dr. Muhammad Fakhruddin Aamir, Additional Director QA/LT-II, Islamabad
4. Mr. Abdul Sattar Sohrani, Deputy Director QC, Islamabad
5. Ch. Zeeshan Nazir, Deputy Director, QA, Islamabad
6. Dr. Ghazanfar Ali, Deputy Director, DRAP, Islamabad
7. Mr. Abdullah, Deputy Director, DRAP, Islamabad
8. Mr. Akhtar Abbas Khan, Deputy Director, Islamabad
9. Dr. Arslan, FID, Islamabad
10. Mr. Hassan Afzaal, FID, Islamabad

2. Accused Ch. Muhammad Usman asked someone to bring keys. An unknown person brought keys and opened the doors at 11:40 am. Detailed inspection of the manufacturing unit was conducted. During inspection following contraventions were identified and recorded on prescribed form and accused persons found involved in:-

1. Manufacturing and selling of unregistered drugs.
2. Manufacturing of drugs with raw materials smuggled/imported without approval of DRAP and without having import license.
3. Violation of GMP as prescribed under the rules.
4. Manufacturing of government property drugs without valid purchase orders.
5. The firm was manufacturing drugs in unhygienic conditions violating the conditions of license.
6. Manufacturing/storage of drugs without identifiable labels.
7. Unidentifiable raw materials.
8. Expired raw materials
9. Without master production record/batch manufacturing record.
10. Manufacturing of drugs without approved technical persons responsible for manufacturing and testing of drugs.
11. Without Quality Control record and release certificates.

. All the recovered un-registered drugs, labels of unregistered and government supply/property drugs, therapeutic goods and available records were listed and inventory was prepared and all these recoveries were witnessed by above persons mentioned in para/1.

3. A large number of drugs were seized on Form-2 in the presence of witnesses. The owner namely Ch. Muhammad Usman refused to sign and receive the copies of Form-2 and keys in the presence of the witnesses by disobeying the lawful authority of the Inspector by committing an offence under section 27(3) of Drugs Act, 1976.

4. Nine (9) samples of different suspected unregistered, spurious and substandard drugs were also taken on Form-3 in the presence of witnesses for purpose of test/analysis under section 18(1)(c) of Drugs Act, 1976.

5. Accordingly, the Additional Director (QA&LT)/FID wrote a letter to the competent Authority for getting approval for lodging of FIR against the firm and accused persons**.** Accordingly, the competent authority granted approval for lodging of FIR against the firm and the accused persons. The Additional Director (QA&LT)/FID requested to FIA for lodging FIR against the firm and accused persons. Accordingly, FIA/ACC Islamabad registered an FIR No. 05/18.

6. The PE&R Division was requested to clarify the status of registration of 31 seized drugs on Form-2 and 9 drugs which taken for test/analysis on form-3 on 06.03.2018. Accordingly, the PE&R Division of DRAP replied that all 9 drugs which were taken on Form-3 are unregistered vide letter No.7-1/2018 dated 22nd March, 2018. The 29 drugs which were seized on Form-2 are declared unregistered out of 31 drugs vide letter No.7-1/2018 dated 22nd March, 2018.

7. A portion of each sealed samples of the said suspected drugs was sent to Federal Government Analyst, Central Drugs Laboratory, Karachi for purpose of test & analysis on Form-4 dated 7th March, 2018 under section 19(3)(i) of the Drugs Act, 1976 and other portion(s) of the each said samples were dispatched as per ibid Act excluding the sealed portion of samples of said drugs of the firm which were refused to receive and signed by the owner namely Ch. Muhammad Usman on 6th March, 2018 in the presence of the witnesses by disobeying the lawful authority of the Inspector by committing an offence under section 27(3) of Drugs Act, 1976. That the Federal Government Analyst (FGA), CDL, Karachi declared one of nine samples i.e. Cardol Tablets (Batch No. 054) as Un-Registered & **Spurious** vide test report no. R.IP.34/2018 dated 21.03.2018 and the other sample among nine i.e. Everchol tablets (Batch No. 062), manufactured by M/s Everest Pharmaceuticals, Islamabad as Un-Registered & **Sub-Standard** vide test report no. R.IP.37/2018 dated 21.03.2018. The FGA further declared rest of the seven (07) samples among nine as un-registered drugs in addition to 29 un-registered drugs seized during raid as mentioned in para 6 above as declared by PE&R Division of DRAP. That copies of the 09 test reports of the products were forwarded to the Owner of M/s Everest Pharmaceuticals, Islamabad through Superintendent Jail, Adyala Jail, Rawalpindi vide letter no. F.3-8/2003-FID-I(pt) dated 28.03.2018 and acknowledgment receipt were also obtained.

8. The case was under investigation by the FIA. Mr. Muhammad Riaz, Inspector FIA, ACC Islamabad who submitted interim challan dated 16th April, 2018 alongwith copy of the following documents against Ch. Muhammad Usman:-

1. Copy of FIR,
2. Letter for permission for registration of FIR
3. Permission of FIR
4. List of witnesses
5. Statement of witnesses
6. Seizure memo dated 06.03.2018,
7. Form-2
8. Form-3
9. Form1-A
10. Inspection report dated 31.01.2018
11. Letter dated 28.03.2018 for communication of test reports of samples
12. Remand applications
13. Conviction slips

9. Accordingly, the matter was placed before Central Licensing Board. The Board in its 261st meeting held on 02.05.2018 granted permission for prosecution against the firm and accused persons.

10. Accordingly, an interim complaint alongwith interim challan was filed in Drug Court, Islamabad by Additional Director (QA&LT)/FID on 29.06.2018 on which the Hon’ble court has taken cognizance.

11. Subsequently, the FIA has submitted 2nd interim challan (Supplementary Challan) dated 05th July, 2018 alongwith copy of the following documents against Dr. Kamran Izhar Qureshi:-

1. Copy of FIR,
2. Statement of witnesses
3. Seizure memo dated 17.05.2018,
4. Minutes of 256th meeting of DRB alongwith attendance
5. SECP Letter No. ARL1630 dated 25.04.2018,
6. Remand applications
7. Directorate of Industries & Labour (ICT) Letter dated 10.05.2018
8. CDA Estate Dir. Letter dated 09.05.2018
9. Conviction slips

12. Accordingly, the matter was placed before Central Licensing Board. The Board in its 265th meeting held on 09-10 August clarified that the permission for prosecution against the firm and all the accused persons has already been granted. Accordingly, this supplementary challan was filed in Drug court, Islamabad.

13. The Investigation Officer of FIA has now submitted another interim Challan dated 31.12.2018 against all the accused persons in which the accused persons namely Noor Muhammad Mahar and Ishtiaq Ahmad were mentioned in column No. 2 as Proclaimed Offender. The accused namely Dr. Kamran Izhar Qureshi has also been mentioned in column No. 2 as not challaned whereas accused namely Ch. Muhammad Usman has only been challaned.

14. During investigation of the case, Form-1A was obtained from record of Licensing Division which appears that Mr. Ch. Muhammad Usman, Dr. Kamran Izhar Qureshi and Mrs. Uzma Younus are the directors/partners/proprietors of the M/s Everest Pharmaceuticals, Islamabad. Further, the minutes of 256th of Drugs Registration Board alongwith attendance sheet in which Ch. Muhammad Usman was appeared before DRB as CEO of the M/s Everest Pharmaceuticals and Dr. Kamran Izhar Qureshi as Director of the firm. Furthermore, an agreement to sell was obtained from the record of Licensing Division in which Dr. Kamran Izhar Qureshi entered into an agreement to purchase the land on which M/s Everest Pharmaceuticals Islamabad is situated. An inspection report dated 14.03.2016 of the firm was also obtained from the record of the QA&LT Division in which during the inspection, Dr. Kamran Izhar Qureshi showed his presence in the firm as a partner of the firm before the penal of inspectors. Accused namely Noor Muhammad Mahar has filed a writ petition No. 517/18 titled Noor Muhammad Mahar Vs Federation of Pakistan etc in which at para No. 2, the said accused has mentioned himself as a manufacturer that is M/s Everest Pharmaceuticals, Islamabad. Dr. Kamran Izhar Qureshi has filed a suit titled Maark Pharma Vs Everest Pharmaceuticals etc in Civil court, Lahore in which the said accused has annexed an agreement with M/s Everest Pharma for distribution of Unregistered and sex inducing drugs. Further the Saint & Sailor Pharma has filed suit in civil court, Lahore against Everest pharma and others in which the same agreement regarding the unregistered and sex inducing drugs were annexed. It is pertinent to mention here that the Drugs Sale License of Saint & Sailor Pharma is on the name of Ch. Muhammad Usman. The Investigation officer has annexed an SECP letter in interim Challan of Dr. Kamran Izhar Qureshi in which SECP has conveyed to IO that M/s Maark Pharmaceuticals and M/s Saint & Sailor Pharma are both registered on the name of Dr. Kamran Izhar Qureshi. It is pertinent to mention here that the sex inducing unregistered drug about which the agreement of distribution filed with above said two civil suits has been declared unregistered by the Hon’ble Supreme Court of Pakistan vides judgment dated 10.10.2018.

15. In the light of above facts explained in foregoing para, the findings of the IO in the report u/s 173 Cr.P.C in above said FIR are not fair and just. He has placed Dr. Kamran Izhar Qurshi in column 2 of 173 Cr.P.C report which pertains to the “name and address of person who have not been challaned/proclaimed offenders”

The findings of the IO, FIA are based on

1. Old certificate of registration of the firm in 2005, and
2. SECP incorporation certificate of which was issued on 31-3-2009.
3. The company applied for being struck off u/s 439 of the Companies Act, 1984 and was struck off on 9-10-2013.
4. As per information provided by the Deputy Director-II of Estate Management Directorate-II, CDA, Islamabad vide letter No.CDA/EM-40(262)/IM/93/1290 dated 09.05.2018 wherein he has informed that *“as per record, Raja Muhammad Zahoor, Lessee of Plot No.124, Industrial Triangle Kahuta Road, Islamabad requested for issuance of NOC for transfter of lease-hold right in favor of Ch. Muhammad Usman s/o Zaheer Ahmed CNIC No.61101-7023927-7 issued on 17.07.2014*subject to provision of documents, but no documents received in this office up till now for change of title”.

The facts of the case already deliberated and finalized by the CLB has been overlooked/ignored by the IO, FIA. The record of the firm available with DRAP confirmed that he is Director/partner of the firm on the basis of following grounds which are as under:

1. The facts narrated by the IO in 173 Cr.P.C. report are old and are not relevant with the instant case registered on 06th March, 2018 vide FIR No. 05/2018. Both firm registration and company incorporation with SECP have been expired and not valid.
2. **He has been nominated as Director/partner in the renewal application for the grant of license filed by M/s Everest pharmaceuticals Islamabad on prescribed Form-IA.**
3. **Dr. Kamran Izhar Qureshi along with Ch. Usman principal accused appeared before the Registration Board in its 256th Meeting held on 09-10 Aug, 2016 as Director of M/s Everest Pharmaceuticals, Islamabad regarding the registration of Sovir (Sofosbuvir 400mg) Tablet and Ledisovir (Sofosbuvir 400mg and Ledisovir 90mg) Tablet. As a Director he responded the observations of panel of Inspectors who conducted inspection on 09th December 2015 to verify to genuineness of stability data for Product registration.**
4. **Agreement to sell for purchase of land submitted to the DRAP by M/s Everest Pharmaceuticals Islamabad with the land lord of the property also confirms the partnership of the Dr. Kamran Izhar Qureshi as its partner/ Director.**
5. An inspection report dated 14.03.2016 of the firm was also obtained from the record of the QA&LT Division in which during the inspection, Dr. Kamran Izhar Qureshi showed his presence in the firm as a partner of the firm before the penal of inspectors.
6. Dr. Kamran Izhar Qureshi has filed a suit titled Maark Pharma Vs Everest Pharmaceuticals etc in Civil court, Lahore in which the said accused has annexed an agreement with M/s Everest Pharma for distribution of Unregistered and sex inducing drugs.
7. The Investigation officer has annexed an SECP letter in interim Challan of Dr. Kamran Izhar Qureshi in which SECP has conveyed to IO that M/s Maark Pharmaceuticals registered on the name of Dr. Kamran Izhar Qureshi.
8. The Saint & Sailor Pharma has filed suit in civil court, Lahore against Everest pharma and others in which the same agreement regarding the unregistered and sex inducing drugs were annexed. It is pertinent to mention here that the Drugs Sale License of Saint & Sailor Pharma is on the name of Ch. Muhammad Usman.
9. Accused namely Noor Muhammad Mahar has filed a writ petition No. 517/18 titled Noor Muhammad Mahar Vs Federation of Pakistan etc in which at para No. 2, the said accused has mentioned himself as a manufacturer that is M/s Everest Pharmaceuticals, Islamabad.

16. Keeping in view the above mentioned facts/evidence available so far, the firm M/s Everest Pharmaceuticals, Islamabad through its owner Ch. Muhammad Usman and accused persons namely Ch. Muhammad Usman owner/Director of M/s Everest Pharmaceuticals, Islamabad, Dr. Kamran Izhar Qureshi, owner/Director of M/s Everest Pharmaceuticals, Islamabad, Noor Muhammad Mahar Owner of M/s Everest Pharmaceuticals, Islamabad, Ch. Muhammad Usman, Production Incharge and Muhammad Ishtiaq, QC Incharge of M/s Everest Pharmaceuticals, Islamabad have been found guilty of offences under section 109 PPC, Section 23, 27 of Drugs Act, 1976 r/w Schedule II & III of DRAP Act, 2012.

17. The IO (Investigation Officer), FIA has mentioned in his instant incomplete challan dated 31.12.2018 that the matter of further probe into the bank accounts belonging to the accused persons has been taken up and Islamabad High Court vide letters No. FIA/ACC/C-05/2018/1603 dated 28.11.2018 and 10.12.2018 has been requested for necessary permission and to issue directives to all scheduled bank in Pakistan for provision of bank records of accused persons and was followed up on 17.12.2018 from Registrar Office, Islamabad High Court, Islamabad which is still awaited. Upon receipt of necessary bank records and completion of proceedings u/s 87 Cr.P.C complete challan will be forwarded to trial court. The investigation is in progress.

18. The area FID, Islamabad requested that the case may please be placed in forthcoming meeting of Central Licensing Board and permission for prosecution against the firm M/s Everest Pharmaceuticals, Islamabad through its owner Ch. Muhammad Usman and accused persons namely Ch. Muhammad Usman, Dr. Kamran Izhar Qureshi, Noor Muhammad Mahar Owners/Partners/Directors of M/s Everest Pharmaceuticals, Islamabad, Ch. Muhammad Usman, Production incharge and Muhammad Ishtiaq, QC Incharge of M/s Everest Pharmaceuticals, Islamabad may kindly be granted after fulfillment of codal formalities, who committed offence under Schedule II A(1)(a)(i), A(1)(a)(v), A(1)(a)(vii), A(1) (a)(x), A(1)(b) & A(1)(e) of DRAP Act, 2012 read with section 23 of Drugs Act, 1976 and section 109 of Pakistan penal code, which is punishable under Schedule III 1(a), 1(c), 3, 4 & 6 of the DRAP, Act, 2012 read with section 27 of Drugs Act, 1976 and section 109 of Pakistan Penal Code. If approved, the complete complaint alongwith the Interim challan/report u/s 173 Cr.PC and all other relevant documents may be lodged in Drug Court by complainant/Federal Inspector of Drugs, Islamabad through Public Prosecutor to start prosecution of the instant case.

**18. It is submitted that Show Cause Notices for prosecution was issued to the following accused persons through routine procedure as well as through are FID, Islamabad** vide letter no. 03-01/2019-QC (2 68-CLB) dated 07.12.2018 as under:

1. **M/s Everest Pharmaceuticals, Plot No. 124, Industrial Triangle, Kahuta Road, Islamabad through its CEO/Managing Partner Ch. Muhammad Usman S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore – Through Dispatch Rider to Superintendent Adiyala Jail, Rawalpindi**
2. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals) S/o Zaheer Ahmed Ch. R/o 86-G, Model Town, Lahore – Through Dispatch Rider to Superintendent Adiyala Jail, Rawalpindi**
3. **Dr. Kamram Izhar (owner of M/s Everest Pharmaceuticals) R/o Address: House 397-D, Phase V, Defense Housing Authority, Lahore (CNIC: 35202-2713085-5)**
4. **Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)  
   CNIC: 54400-0553619-3;   
   Cell No.: 03009673869, 03224453577, 03224453578**
5. **Basti Khair Muhammad Meher, Near Aar C.A. Factory, Sadiqabad, Wahid Bakash Meher, Rahim Yar Khan.**
6. **Block No. 2, Sector C-1, Township, Lahore.**
7. **Flat No. 17, 2nd Floor, Abrar Centre, Wahdat Road, Lahore.**
8. **Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.**

**R/o Manki Mohalla-A, Tehsil Lahore, District Sawabi**

*“It is to inform you*

* 1. *That DRAP inspection team alongwith FIA and NAB teams reached in front of M/s Everest Pharma, Plot No. 124, Industrial Triangle, Kahuta Road, Islamabad on 06-03-2018 at 11:00 am on the direction of Supreme Court of Pakistan in HRC case No. 5845-G/2018. DRAP team was comprised of following DRAP officers:-*

1. *Dr. Hafsa Karam Elahi, Additional Director QA&LT-I, Islamabad*
2. *Dr. Obaid Ullah, Director PE&R, DRAP, Islamabad*
3. *Dr. Muhammad Fakhruddin Aaamir, Additional Director QA/LT-II, Islamabad*
4. *Mr. Abdul Sattar Sohrani, Deputy Director QC*
5. *Ch. Zeeshan Nazir, Deputy Director, DRAP, Islamabad*
6. *Dr. Ghazanfar Ali, Deputy Director DRAP, Islamabad*
7. *Mr. Abdullah, Deputy Director DRAP, Islamabad*
8. *Mr. Akhtar Abbas Khan, Deputy Director, Islamabad*
9. *Dr. Arslan, FID, Islamabad*
10. *Mr. Hassan Afzaal, FID, Islamabad*

*2. That detailed inspection of the manufacturing unit was conducted. A large number of drugs were seized on Form-2 & nine 09 samples were taken on prescribed Form-3 in presence of witnesses. Copies of Form 2 & Form 3 were given to the owner/CEO of the firm namely Ch. Muhammad Usman, however, he refused to receive the forms in presence of witnesses which is disobeying the lawful authority of the inspector under the Drugs Act, 1976 & DRAP Act, 2012.*

*3. During inspection following contraventions were identified and recorded on prescribed form and owner Ch. Muhammad Usman, Dr. Kamran Izhaar, Noor Muhammad Mahar, Ch. Muhammad Usman, Production In-charge and Muhammad Ishtiaq, QC Incharge of M/s Everest Pharma, Plot No. 124, Kahuta Road, Industrial Triangle, Islamabad and others responsible for manufacturing and selling of unregistered drugs and import / smuggling of active pharmaceutical ingredients without import license and clearance from DRAP. Accused person were involved in:-*

1. *Manufacturing and sale of unregistered drugs.*
2. *Manufacturing of Drugs with raw material smuggled / imported without approval of DRAP and without having import license.*
3. *Violation of GMP as prescribed under the rules.*
4. *Manufacturing of government property drugs without valid purchase orders.*
5. *The firm was manufacturing drugs in unhygienic conditions violating the conditions of license.*
6. *Manufacturing / storage of drugs without identifiable labels.*
7. *Keeping Unidentifiable raw materials.*
8. *Keeping Expired raw materials*
9. *Without master production record / batch manufacturing record.*
10. *Manufacturing of Drugs without approved technical persons responsible for manufacturing and testing of drugs.*
11. *Without Quality Control record and release certificates.*

*4. That all the recovered un-registered drugs, labels of unregistered and government property drugs, therapeutic goods and available records were listed and inventory was prepared in presence of the witnesses mentioned in paragraph 1 above.*

*5. That taken samples were seized on Form-2 and rest of the stocks were stored within the premises of the factory and factory was locked and sealed. Huge quantity of sealed unregistered drugs were also recovered. The firm was manufacturing and selling drugs from the active pharmaceutical ingredients and excipient without necessary clearance from the DRAP. The firm did not obtain the import license for most of the raw materials. Critical and major non-conformities of GMP compliance were identified by the inspection team especially in the following areas.*

1. *Qualified technical personnel involvement in the manufacturing, selling and testing was not visible.*
2. *Shelf life of the manufactured products were awarded without support of stability data.*
3. *Master production record and batch manufacturing record were not available for the products being manufactured.*
4. *Marketing authorization of most of the products were not obtained from the authority as prescribed under the law.*
5. *Release certificates were not available for the active pharmaceutical ingredients and finished products.*
6. *Sanitization and cleanliness conditions of the process areas were poor.*
7. *Unhygienic conditions were prevailing in the manufacturing unit.*
8. *There were mixups of raw materials, semi finished and finished products in all areas like process areas, ware houses, packing areas and raw material stores.*
9. *Packing material store was established outside the licensed premises in the open areas covered by ordinary roof.*
10. *Most of the raw materials and semi finished tablets and capsules were packed into shopping bags without identification labels.*
11. *Syrup manufacturing areas and ointment cream sections were used as ware house for semi finished products and raw materials.*
12. *Expired raw materials available in the working areas of ware house.*

*6. That FIR was registered at Police Station FIA ACC, Islamabad vide FIR No.05/2018 against accused persons involved heinous crimes. IO, FIA has submitted the in-complete challan U/s 173 Cr.P.C. on 01-01-2019. The FID, Islamabad forwarded challan and requested permission for prosecution in the court of law.*

*7. That the Assistant Director (I&E) vide letter 3-6/2017-I&E dated 21.11.2017 verified that you didn’t imported APIs in 2014, 2015 & 2017. Only 6 APIs were imported in 2016 but a huge quantity of APIs was found at premises of M/s Everest Pharmaceuticals, Islamabad during afore-said raid.*

*8. That the Federal Government Analyst, CDL, Karachi declared the sample of Cardol Tablets (Batch No. 054), Un-Registered & Spurious vide test report no. R.IP.34/2018 dated 21.03.2018.*

*9. That the Federal Government Analyst, CDL, Karachi declared the sample of Everchol tablets (Batch No. 062), manufactured by M/s Everest Pharmaceuticals, Islamabad as Un-Registered & Sub-Standard vide test report no. R.IP.37/2018 dated 21.03.2018. The seven (07) products taken by FID, Islamabad were also declared un-registered by the Federal Government Analyst, CDL, Karachi in addition to the seized drugs.*

*10. That copies of the 09 test reports of the products were forwarded to the Owner of M/s Everest Pharmaceuticals, Islamabad through Superintendent Jail, Adyala Jail, Rawalpindi vide letter no. F.3-8/2003-FID-I(pt) dated 28.03.2018 and acknowledgment receipt were also obtained.*

***11. That you all accused persons have violated the provisions of Schedule-II, of DRAP Act 2012 r/w relevant provisions of Section 23 of the Drugs Act, 1976 as under:-***

***a. A. (1)(a)(i) i.e. export, import or manufacture for sale or sell any spurious therapeutic good;***

***b. A. (1)(a)(v) i.e. export, import or manufacture for sale or sell any sub-standard therapeutic good;***

***c. A. (1)(a)(vii) i.e. export, import or manufacture for sale or sell any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceuticals evaluation;***

***d. A. (1)(a)(x) i.e. export, import or manufacture for sale or sell any therapeutic good in contravention of any of the provision of this Act are rules made thereunder;***

***e. A. (1)(b) manufacture for sale any therapeutic goods except under and in accordance with the condition of a license issued under this Act and;***

***f. A. (1)(e) Import or export any therapeutic goods drugs for the import or export of which a license is required except under , and in accordance with the conditions of such license.***

1. ***That Prohibitions mentioned above are offences and punishable under schedule III of DRAP Act 2012 r/w relevant provisions of Section 27 of the Drugs Act, 1976:-***
2. ***(1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.***
3. ***(1)(c), Imports without license any therapeutic goods for the import of which a license is required.***
4. ***(3) Obstruction of Inspector: Whoever obstructs and Inspector in the exercise of any power conferred upon him by or under this Act, or disobeys the lawful authority of any Inspector, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one lakh rupees, or with both.***
5. ***(4) i.e. contravention of rules:- subject to the provisions of clause (1) (2) and (3) whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or any rule shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one lakh rupees or with both.***
6. ***(6), Penalty for violating the prohibitions: whoever himself or by any other person on his behalf violates any prohibitions specified in schedule-II shall be punished with imprisonment for a term upto five years and with fine up to five hundred thousand rupees***

*12. That you are hereby asked to explain your position about the above said violations which are offences and crimes against the state & general public and why you should not be prosecuted in the Court of competent jurisdiction to award you punishment under the law.”*

19. The same Show Cause Notice was also published in the Urdu & English Daily Newspapers “Daily News, Express News, The News and Nawai Waqat” on 04-01-2019.

20. But no reply of show cause has been received till today.

21. Personal Hearing letters were issued to the accused persons vide letter no. 03-01/2019-QC (268-CLB) dated 02.01.2019.

**22. Decision of the Case:-**

* + 1. **Dr. Kamran Izhar Qureshi appeared before the Board and submitted his statement which is annexed as Annexure-A.**
    2. **Advocate Abubakar Gondal appeared before the Board on behalf of Noor Muhammad Mahar and documents consisting of application for stop proceeding alongwith order dated 09.01.2019 of Lahore High Court Lahore (W.P. No. 960/2019) reproduce as under:**

***“[…]***

***3. Learned Law Officer has objected to the maintainability of this petition and states that all the Respondents cited in this petition relate to Islamabad and fall within the territorial jurisdiction of Islamabad High Court and this Court has no jurisdiction to take cognizance of this petition in view of law laid down by this Court in case titled “Ch. Karamatullah Kahn vs Chairman Special Selection Board etc. (2018 PLC(CS) 555) and Shahrukh Aamir Ubaid vs National Highway and Motorway Police Islamabad (2017 PLC (CS) 368). She further staes that entire record of the Everest Pharmaceutical is with the Respondent No. 4 i.e. Registrar of Frims, Capital Territory, Islamabad and that the Petitioner has not filed any reply with the objection to the concerned authority which is also in Islamabad.***

***4. Faced with this situation, the counsel for the Petitioner states that he does not press this petition and feels contented if direction is issued to the Respondent No. 2 to hear and examine the record from Respondent No. 4 and 5 and then decide the matter within a period specified by this Court.***

***5. Learned Law Officer has no objection to this prayer.***

***6. In view of the above, this petition is disposed of with a direction to the Respondent No.2 to hear and examine the record from Respondent No. 4 and 5 and then decide the matter within a period of ten days.***

***7. Copy Dasti on payment of usual charges.”***

* + 1. **The Central Licensing Board after hearing the above mentioned accused and after examining the following documents on records and facts presented by the secretariat**

1. **Complaint filed before the CLB by the Additional Director/FIDs Islamabad region along with supporting documents.**
2. **FIR and interim challan submitted by the IO FIA along with relevant documents.**
3. **Request of the FID for the grant of permission for prosecution against the accused persons and Show Cause Notice issued to the accused persons.**
4. **Records of the Licensing Division in the files of Everest Pharmaceuticals Islamabad.**
5. **Record of QA/LT Division related to M/s Everest Pharmaceuticals Islamabad.**
6. **Record of PER Division related to M/s Everest Pharmaceuticals Islamabad**
7. **Record of Legal Affair Division related to M/s Everest Pharmaceuticals Islamabad**
8. **Inspection reports and writ petitions filed by M/s Everest pharmaceuticals and its owners/partners/ warrantors**
9. **Personal hearing of Dr. Kamran Izhar and documents presented by him.**
10. **Personal hearing of Advocate Abubakar Gondal on behalf of Noor Muhammad Mahar and documents presented by him including order dated 09.01.2019 of Lahore High Court Lahore (W.P. No. 960/2019).**
11. **Only accused Dr. Kamran Izhar Qureshi submitted reply of Show Cause Notice dated 10 January 2019.**
12. **Ch. Usman, owner/production Incharge and Mian Ishtiaq Ahmed Quality Control Incharge of M/s Everest Pharmaceuticals Islamabad neither appeared personally nor through any authorized counsel.**
13. **Dr. Kamran Izhar has been nominated as Director/partner in the renewal application for the grant of license filed by M/s Everest pharmaceuticals Islamabad on prescribed Form-IA.**
14. **Dr. Kamran Izhar Qureshi along with Ch. Usman principal accused appeared before the Registration Board in its 256th Meeting held on 09-10 Aug, 2016 as Director of M/s Everest Pharmaceuticals, Islamabad regarding the registration of Sovir (Sofosbuvir 400mg) Tablet and Ledisovir (Sofosbuvir 400mg and Ledisovir 90mg) Tablet. As a Director he responded the observations of panel of Inspectors who conducted inspection on 09th December 2015 to verify to genuineness of stability data for Product registration.**
15. **Agreement to sell for purchase of land submitted to the DRAP by M/s Everest Pharmaceuticals Islamabad with the land lord of the property also confirms the partnership of the Dr. Kamran Izhar Qureshi as its partner/ Director.**
16. **An inspection report dated 14.03.2016 of the firm was also obtained from the record of the QA&LT Division in which during the inspection, Dr. Kamran Izhar Qureshi showed his presence in the firm as a partner of the firm before the panel of inspectors.**
17. **Dr. Kamran Izhar Qureshi has filed a suit titled Maark Pharma Vs Everest Pharmaceuticals etc in Civil court, Lahore in which the said accused has annexed an agreement with M/s Everest Pharma for distribution of Unregistered and sex inducing drugs.**
18. **The Investigation officer has annexed an SECP letter in interim Challan of Dr. Kamran Izhar Qureshi in which SECP has conveyed to IO that M/s Maark Pharmaceuticals registered on the name of Dr. Kamran Izhar Qureshi.**
19. **The Saint & Sailor Pharma has filed suit in civil court, Lahore against Everest pharma and others in which the same agreement regarding the unregistered and sex inducing drugs were annexed. It is pertinent to mention here that the Drugs Sale License of Saint & Sailor Pharma is on the name of Ch. Muhammad Usman.**
20. **Accused namely Noor Muhammad Mahar has filed a writ petition No. 517/18 titled Noor Muhammad Mahar Vs Federation of Pakistan etc in which at para No. 2, the said accused has mentioned himself as a manufacturer that is M/s Everest Pharmaceuticals, Islamabad.**
    * 1. **The Board after thorough deliberations and examination of the above mentioned records concluded as under:-**
    1. **The record of the firm available with DRAP confirms that Dr. Kamran Izhar Qureshi is Director/partner and his Nexus with M/s Everest pharmaceuticals, Islamabad on the basis of following grounds:-**
21. **Dr. Kamran Izhar has been nominated as Director/partner in the renewal application for the grant of license filed by M/s Everest pharmaceuticals Islamabad on prescribed Form-IA.**
22. **Dr. Kamran Izhar Qureshi along with Ch. Usman principal accused appeared before the Registration Board in its 256th Meeting held on 09-10 Aug, 2016 as Director of M/s Everest Pharmaceuticals, Islamabad regarding the registration of Sovir (Sofosbuvir 400mg) Tablet and Ledisovir (Sofosbuvir 400mg and Ledisovir 90mg) Tablet. As a Director he responded the observations of panel of Inspectors who conducted inspection on 09th December 2015 to verify to genuineness of stability data for Product registration.**
23. **Agreement to sell for purchase of land submitted to the DRAP by M/s Everest Pharmaceuticals Islamabad with the land lord of the property also confirms the partnership of the Dr. Kamran Izhar Qureshi as its partner/ Director.**
24. **An inspection report dated 14.03.2016 of the firm was also obtained from the record of the QA&LT Division in which during the inspection, Dr. Kamran Izhar Qureshi showed his presence in the firm as a partner of the firm before the panel of inspectors.**
25. **Dr. Kamran Izhar Qureshi has filed a suit titled Maark Pharma Vs Everest Pharmaceuticals etc in Civil court, Lahore in which the said accused has annexed an agreement with M/s Everest Pharma for distribution of Unregistered and sex inducing drugs.**
26. **The Investigation officer has annexed an SECP letter in interim Challan of Dr. Kamran Izhar Qureshi in which SECP has conveyed to IO that M/s Maark Pharmaceuticals registered on the name of Dr. Kamran Izhar Qureshi.**
27. **The Saint & Sailor Pharma has filed suit in civil court, Lahore against Everest pharma and others in which the same agreement regarding the unregistered and sex inducing drugs were annexed. It is pertinent to mention here that the Drugs Sale License of Saint & Sailor Pharma is on the name of Ch. Muhammad Usman.**
    1. **The request filed by the counsel of Noor Muhammad Mahar was rejected on the grounds that it seems malafide on the part of the accused to delay the case for his vested interest. He has failed to defend the allegations conveyed to him through show cause notice. It is also confirmed on oath that Noor Muhammad Mahar vide W.P. 517/18 in Lahore High Court, Lahore submitted in the court that he is owner of M/s Everest Pharmaceuticals Islamabad. The Board has thoroughly examined order of the Lahore High Court Lahore in W.P.960/19 dated and is of the view that the Respondent No. 2 being Drug Regulatory Authority of Pakistan, through its Chief Executive Officer, T.F. Plaza, G-9, Islamabad shall examine record of respondents No 4 (Registrar of Firms, Capital Territory, Islamabad) and 5 (Everest Pharmaceutical through its CEO, 124-Industrial Triangle, Kohota Road, Islamabad) and decide therefore it is for Respondent No. 2 to implement this order in its letter and spirit.**
    2. **The investigations conducted by Additional Director QA/LT/ FID Islamabad/IO of FIA in FIR No. 05/2018 have collected sufficient evidence on the face of record to prove that the following persons are guilty of offences/penalties mentioned in para 4 & 5 herein below:**
28. **M/s Everest Pharma Plot No. 124 Industrial Triangle Kahutta Road Islamabad through Ch. Muhammad Usman;**
29. **Ch. Muhammad Usman S/o Zaheer Ahmed Choudhary Owner/ production incharge of M/s Everest Pharma Plot No. 124 Industrial Triangle Kahutta Road Islamabad. He was operating as owner as well as Production Incharge responsible for manufacturing of illegal and unlawful drugs;**
30. **Dr. Kamran Izhar Qureshi S/o Izhar Ul Haq Qureshi, R/o 201/2 R. Phase -2 Lahore & House No.397-D Phase 5 Defense Housing Society Lahore is M/s Everest Pharmaceuticals Islamabad;**
31. **Noor Muhammad Mehr Flat No. 17, second floor Abrar Center Wahdat Road Lahore owner of M/s Everest Pharma Plot No. 124 Industrial Triangle Kahutta Road Islamabad, Permanent address of the accused Basti Khair Muhammad Mehar near A ar C and factor Sadiqabad Wahid Bakhsh Mehar, District Rahim Yar Khan. He is also owner /partner of M/s Everest Pharmaceuticals Islamabad;**
32. **Mian Ishtiaq Ahmed QC Incharge of M/s Everest Pharma Plot No M/s Everest Pharmaceuticals Plot No. 124 Industrial Triangle Kahutta Road Islamabad. He is responsible for the quality control affairs of the M/s Everest Pharmaceuticals Islamabad.**
    1. **That you all accused persons have violated the provisions of Schedule-II, of DRAP Act 2012 r/w relevant provisions of Section 23 of the Drugs Act, 1976 as under:-**

***a. A. (1)(a)(i) i.e. export, import or manufacture for sale or sell any spurious therapeutic good;***

***b. A. (1)(a)(v) i.e. export, import or manufacture for sale or sell any sub-standard therapeutic good;***

***c. A. (1)(a)(vii) i.e. export, import or manufacture for sale or sell any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceuticals evaluation;***

***d. A. (1)(a)(x) i.e. export, import or manufacture for sale or sell any therapeutic good in contravention of any of the provision of this Act are rules made thereunder;***

***e. A. (1)(b) manufacture for sale any therapeutic goods except under and in accordance with the condition of a license issued under this Act and;***

***f. A. (1)(e) Import or export any therapeutic goods drugs for the import or export of which a license is required except under , and in accordance with the conditions of such license.***

* 1. **That Prohibitions mentioned above are offences and punishable under schedule III of DRAP Act 2012 r/w relevant provisions of Section 27 of the Drugs Act, 1976:-**

1. ***(1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.***
2. ***(1)(c), Imports without license any therapeutic goods for the import of which a license is required.***
3. ***(3) Obstruction of Inspector: Whoever obstructs and Inspector in the exercise of any power conferred upon him by or under this Act, or disobeys the lawful authority of any Inspector, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one lakh rupees, or with both.***
4. ***(4) i.e. contravention of rules:- subject to the provisions of clause (1) (2) and (3) whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or any rule shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one lakh rupees or with both.***
5. ***(6), Penalty for violating the prohibitions: whoever himself or by any other person on his behalf violates any prohibitions specified in schedule-II shall be punished with imprisonment for a term upto five years and with fine up to five hundred thousand rupees*** 
   * 1. **Federal Inspector of Drugs Islamabad is allowed to make the instant evidences as integral part of the original complaint for the prosecution before the Drug Court Islamabad against the accused persons mentioned in para 03 who have been proved guilty of offences mentioned in para 4 and which are punishable under the provisions of schedule III of DRAP Act 2012 mentioned in para 5, accordance with law.**

**Case No. 02:-**

Subject: **PERMISSION FOR PROSECUTION AGAINST THE MANAGEMENT OF M/S EVEREST PHARMACEUTICALS FOR THE ILLEGAL IMPORT OF PHARMACEUTICAL RAW MATERIAL THROUGH FORGED IMPORT CLEARANCE CERTIFICATE WITHOUT ANY DRUG IMPORT LICENSE W.R.T INCOMPLETE CHALLAN FOR FIR NO. C-79/2018 DATED 17.05.2018 - MAGNESIUM STEARATE.**

Brief facts of the case

*“lstighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6242/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.1.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons namely:- Ch. Muhammad Usman (Owner of M/s. Everest Pharmaceuticals) Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals) Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals) Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals 2. Accordingly a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (west), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (I&E), DRAP, stamped invoices submitted by the firm. The customs collectorate, amongst other, has provided the invoice, detailed below, purportedly signed and stamped by the Assistant Director (I&E), DRAP, Lahore alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-II), imported by M/s. Everest Pharmaceuticals, 86-G, Model Town, Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-III).*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Name of importer* | *Invoice No.* | *Dated* | *Name of raw material* | *Quantity* |
| *M/s. Everst Pharmaceuticals, 86-G, Model town, Lahore* | *XW150701* | *01.07.2015* | *Manesium Stereate* | *1000kg* |

*3. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation of Drug (Import & Export) rules, 1976, framed under the Drugs Act, 1976. 4. As the record show that the import authorizations is forged, bearing the fake Diary and Issue Nos. of DRAP Office, Lahore, and used for the illegal import of pharmaceuticals raw material, without any requisite Drug Import License, hence, the management of M/s. Everest Pharmaceuticals, has committed offence under section 420,467,468,471, & 472 of Pakistan Penal Code and Clause (1) (e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23 (1) (e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2) (a) of the Drugs Act, 1976, and is punishable under Clause (1) (c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. 5. The direction to lodge FIR against the responsible accused persons has been received vide letter No.F.13-8/18-QC, dated 17.04.2018 of the DRAP, Islamabad (Annex-IV). 6. It is, therefore, requested to register FIR for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the officer of DRAP, Lahore, in her official capacity:- 1. M/s Everest Pharmaceuticals, 86-G, Model town, Lahore, through its Managing Partner. 2. Ch. Muhammad Usman (Owner of M/s Everest Pharmaceuticals). 3. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals). 4. Noor Muhammad Mahar (Owner of M/s Everest Pharmaceuticals). 5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.”*

Furthermore, the Urdu part of the incomplete challan states that the IO FIA declared the mentioned accused person namely, Ch. Muhammad Usman S/O Zaheer Ahamd Chauhdary R/O 86-G Model Town, Lahore (Owner, Everest Pharmaceuticals, Islamabad) was found guilty in the light of statements witnesses and documentary evidences. It is therefore, the IO FIA submitted the incomplete challan to the extent of Ch. Muhammad Usman S/O Zaheer Ahamd Chauhdary and has requested to start the legal proceedings in the Court of competent jurisdiction.

**Decision: The Central Licensing Board considered the facts on record and decided as under:**

**1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:**

1. **M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman**
2. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)**
3. **Dr. Kamram Izhar (owner of M/s Everest Pharmaceuticals)**
4. **Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)**
5. **Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.**

**2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.**

**3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.**

**Case No. 03:-**

Subject: **PERMISSION FOR PROSECUTION AGAINST THE MANAGEMENT OF M/S EVEREST PHARMACEUTICALS FOR THE ILLEGAL IMPORT OF PHARMACEUTICAL RAW MATERIAL THROUGH FORGED IMPORT CLEARANCE CERTIFICATE WITHOUT ANY DRUG IMPORT LICENSE W.R.T INCOMPLETE CHALLAN FOR FIR NO. C-79/2018 DATED 17.05.2018 -GABAPANTIN.**

Brief facts of the case

*“lstighasa received from Ajmal Sohail Asif Federal Inspector of Drugs DRAP Lahore vide letter No. 6252/2018-DRAP-AD (l&E) which is being reproduced as under: The Director, Federal Investigation Agency, Lahore Sub: Request For Lodging FIR Against the Management of M/s. Everest Pharmaceuticals For the Illegal Import of Pharmaceutical Raw Materials Through Forged Import Clearance Certificate Without Any Drug Import License. I am directed to refer the subject cited above and to say that in pursuance of directions of the hon'able Supreme Court of Pakistan in HRC No. 5845-G/2018, a raid was conducted on premises of M/s. Everest Pharmaceuticals, 124-lndustrial Triangle, Kahuta Road, Islamabad. The firm was found in manufacturing of un-registered, spurious and sex inducing drugs on large scale. A large quantity of raw materials, which were being used in manufacturing of these drugs, was also recovered. Accordingly the premises was sealed and F.1.R No. 05/2018 was registered in F.I.A/ACC, Islamabad, for contravention of the DRAP Act, 2012/Drugs Act, 1976 and rules made thereunder against the following persons namely:- Ch. Muhammad Usman (Owner of M/s. Everest Pharmaceuticals) Dr. Kamran Izhar (Owner of M/s. Everest Pharmaceuticals) Noor Muhammad Mahar (Owner of M/s. Everest Pharmaceuticals) Muhammad Ishtiaq (QC Incharge), M/s. Everest Pharmaceuticals 2. Accordingly a letter No. F. 13-8/2018/QC, dated 14-03-2018, was written to the Deputy Collector G-II, MCC Appraisement (west), Karachi, (Annex-I) for providing complete import record of pharmaceutical raw materials imported by M/s. Everest Pharmaceuticals during the last three years alongwith copies of Assistant Director (I&E), DRAP, stamped invoices submitted by the firm. The customs collectorate, amongst other, has provided the invoice, detailed below, purportedly signed and stamped by the Assistant Director (I&E), DRAP, Lahore alongwith Goods Declaration-GD-I, of the pharmaceutical raw materials (Annex-II), imported by M/s. Everest Pharmaceuticals, 86-G, Model Town, Lahore, vide letter SI/Misc/15/2018 Group II, dated 22-03-2018 (Annex-III).*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Name of importer* | *Invoice No.* | *Dated* | *Name of raw material* | *Quantity* |
| *M/s. Everst Pharmaceuticals, 86-G, Model town, Lahore* | *EXP/PPL/24/15-16* | *29.06.2015* | *Gabapantin* | *300kg* |

*3. On the scrutiny of the record from DRAP, it transpired that above referred import authorization was never issued from DRAP office, Lahore, under the Drug (Import & Export) Rules, 1976. The import authorizations is forged, hence, the import of such pharmaceutical raw material stands illegal in violation of Drug (Import & Export) rules, 1976, framed under the Drugs Act, 1976. 4. As the record show that the import authorizations is forged, bearing the fake Diary and Issue Nos. of DRAP Office, Lahore, and used for the illegal import of pharmaceuticals raw material, without any requisite Drug Import License, hence, the management of M/s. Everest Pharmaceuticals, has committed offence under section 420,467,468,471, & 472 of Pakistan Penal Code and Clause (1)( e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23 (1) (e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2) (a) of the Drugs Act, 1976, and is punishable under Clause (1) (c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976. 5. The direction to lodge FIR against the responsible accused persons has been received vide letter No.F.13-8/18-QC, dated 17.04.2018 of the DRAP, Islamabad (Annex-IV). 6. It is, therefore, requested to register FIR for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import License, and take strict legal actions according to law, as mentioned above, against the following persons for committing forgery and using forged documents purportedly issued by the officer of DRAP, Lahore, in her official capacity:- 1. M/s Everest Pharmaceuticals, 86-G, Model town, Lahore, through its Managing Partner. 2. Ch. Muhammad Usman (Owner of M/s Everest Pharmaceuticals). 3. Dr. Kamran Izhar (Owner of M/s Everest Pharmaceuticals). 4. Noor Muhammad Mahar (Owner of M/s Everest Pharmaceuticals). 5. Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.”*

Furthermore, the Urdu part of the incomplete challan states that the IO FIA declared the mentioned accused person namely, Ch. Muhammad Usman S/O Zaheer Ahamd Chauhdary R/O 86-G Model Town, Lahore (Owner, Everest Pharmaceuticals, Islamabad) was found guilty in the light of statements witnesses and documentary evidences. It is therefore, the IO FIA submitted the incomplete challan to the extent of Ch. Muhammad Usman S/O Zaheer Ahamd Chauhdary and has requested to start the legal proceedings in the Court of competent jurisdiction.

**Decision: The Central Licensing Board considered the facts on record and decided as under:**

**1. To issue Show Cause Notices to the following accused persons for prosecution in the Drug Court of competent jurisdiction for the offences committed by them as stated herein below in para 2:**

* 1. **M/s Everest Pharmaceuticals, Islamabad through its CEO Ch. Muhammad Usman**
  2. **Ch. Muhammad Usman (owner of M/s Everest Pharmaceuticals)**
  3. **Dr. Kamram Izhar (owner of M/s Everest Pharmaceuticals)**
  4. **Noor Muhammad Mahar (owner of M/s Everest Pharmaceuticals)**
  5. **Muhammad Ishtiaq (QC Incharge), M/s Everest Pharmaceuticals.**

**2. The aforesaid accused persons have been found guilty under section 420,467,468,471 & 472 of Pakistan Penal Code and Clause (1)(e) of the paragraph A of the Schedule-II of the DRAP Act, 2012, read with Section 23(1)(e) of the Drugs Act, 1976, which is cognizable offence under Para (2) (a) of the Schedule-IV to the DRAP Act, 2012 read with Section 30(2)(a) of the Drugs Act, 1976, and is punishable under Clause (1)(c) of the Schedule-III of the DRAP Act, 2012, read with Section 27(1)(c) of the Drugs Act, 1976.**

**3. Personal Hearing may be given to the accused persons the forthcoming meeting of the CLB.**