MINUTES OF 258th MEETING OF CENTRAL LICENSING BOARD HELD ON 8TH MARCH , 2018

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258th meeting of the Central Licensing Board (CLB) was held on 8th March, 2018 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Mr. Ghulam Rasool Dutani, Director Drug Licensing, Drug Regulatory Authority of Pakistan, Islamabad.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Mr. Abdul Sattar Sohrani Representative Director (QA/LT), DRAP, Islamabad	Member
2.	Mr. Farooq Bashir Butt, Drug Controller, Primary and Secondary Health Care Department, Govt. of Punjab, Lahore	Member
3.	Mr. Imranullah Khan, Senior Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa, Peshawar	Member
4.	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
5.	Dr.Ikram-ul-Haque , Expert inQC/QA of drugs.	Member
6.	Prof. Dr. Abdullah Dayo, Dean, Faculty of Pharmacy, University of Sindh, Jamshoro	Member
7.	Prof. Dr. Mohammad Usman, Expert in manufacturing of drugs	Member
8.	Prof Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar	Member
9.	Mr. KhurramShahzad Mughal, Consultant M/o Law, Justice and Human Rights, as representative of M/o Law and Justice, Islamabad.	Member
10.	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
11.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
12.	Mr. Shahzad Hussain Ch Anwar, Representative of PCDA.	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. Mst. Hafsa Karam Ellahi, Deputy Director/ Additional Director (QA/LT-I), Mr. Abdul Sattar Sohrani, Deputy Director (QC) Dr. Muhammad Yaqoob AD (Lic.), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 257thMEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 257thmeeting held on January 24-25, 2018.

LICENSING DIVISION

ITEM-II. M/S EVEREST PHARMACEUTICALS, PLOT NO.124, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

1. M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad has submitted the application for renewal of DML No. 000535 by way of formulation on 28-03-2014 on time as due date of renewal of DML was 31-03-2014.After evaluation of the renewal application of the firm a letter for completion of application for renewal of DML was issued on 7th May, 2014. With reference to above letter the firm has submitted one page reply on 3rd June, 2014 and stated that requisite documents / information have already been provided vide their earlier request letter.

2. It is mentioned that in available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. On 25th February, 2015 Licensing Division issued another letter for completion of application of renewal of DML to the firm in which mentioned that no correspondence from your side had been received in this Division regarding receipt of documents / information deficient in your application for renewal of DML and advised to the firm to furnish the required information / documents to this office within 20 days of issuance of this letter in case of failure to rectify the application within the specified period, the application for renewal of DML may be rejected by the Central Licensing Board.

3. On 17th March, 2015 the firm has submitted their one page reply and stated that an FIR in FIA is lodged on misunderstanding of DRAP and their production Manager and Q.C manger were arrested. They will be able to reply the letter of Licensing Division after resolution of the case. They requested to hold any proceeding / any further order till resolution of the case.

Proceedings of CLB

4. Case was submitted for consideration and orders of the Board. Chairman Quality Control (CQC) informed the Board that recently there were two FIRs which have been now quashed by Islamabad High Court.

Decision of Central Licensing Board in 247th meeting:

5. The Board in the light of information provided by CQC that the said FIRs have been quashed, so Board decided to direct the firm to provide the requisite information / documents for the purpose of renewal of Drug Manufacturing License.

Action by Licensing Division

6. Licensing Division communicated the above decision of the Central Licensing Board to M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad 15th June, 2016 but envelope returned with the following remarks:

The same letter were communicated to the firm through Federal Inspector of Drugs, Islamabad on 22nd November, 2016 and 29th November, 2016 but those letters were also returned back with following remarks:

7. Now, final reminder has been issued to the firm and copy of the same was send to area Federal Inspector of Drugs to deliver the letter by hand and report. The report by the area Federal Inspector of Drugs is as under:

> "***It is hereby report that I, Hasan Afzaal (FID-III, Islamabad) was informed by Dr. Fakharuddin Aamir (additional Director-QA&LT-II) on direction of Dr. Sheikh Akhtar Hussain (Director- QA/LT) on Friday 2nd june, 2017 at 4:00 pm to report to the Licensing Division for delivery of a letter to Everst Pharmaceuticals. The letter was handed over by Mr. Manzoor Bozdar (Additional director- Licensing) at 5:00 pm. I was accompanied by Mr. Sarfarz (driver-Admin) to the firm. We reached the firm at 6.00PM, where Mr. Waqar (Employee everest Pharmaceuticals) refused to receive the letter. We pasted a copy of the letter alongwith that day's newspaper and video graphed the proceedings. A short summary of this report was conveyed via Whats App alongwith the video was forwarded to the Director (QA/LT), Director (Licensing), Additional Director (QA/LT-II) and Additional Director (Licensing).***"

8. Following shortcomings have been communicated to the firm under Rule 5(2A) in the above said letter:

i. Complete document / information of your proposed Quality Control Incharge Mr. Imtiaz Ahmed & Production Incharge Mr. Muhammad Arshad as per checklist enclosed herewith for your guidance. All documents should be attested by gazette officer or Notary Public and also signed by CEO / Director / Authorized person with seal / stamp of the firm.

ii. Updated copy of Nothing Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of Central Research Fund up to 31-12-2014.

iii. Attested photocopy of latest Partnership deed within CNICs of all the Directors as per partnership deed and certificate of Registration with Registrar of the firm.

iv. Details of the premises i.e. approval letter of sections issued by Secretary Central Licensing Board & to also furnish copy f approval layout plan of the building.

v. Details of equipment / machinery for Quality Control Laboratory.

vi. Name of the drugs registered / approved.

Decision of Central Licensing Board in 254th meeting.

9. 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 their application for renewal of M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad DML No. 000535 by way of formulation may not be rejected by Central Licensing Board or License may not be suspended or cancelled by Central Licensing Board.

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

10. The Show Cause notice dated 22nd June, 2017 was issued to the M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad. The said Show Cause Notice is returned un-delivered. Consequently, Show Cause Notice was published in Print Media dated 22nd July, 2017.

11. Now a letter is received from M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad through legal Counsel M/s Farooq Law Associates, Advocates and Attorneys, Islamabad. They had stated that his client M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road, Islamabad owned by Ch. Muhammad Usman have shown him the show cause notice published on 22.07.2017 in the daily "Dunya", Islamabad calling upon them to answer the show cause notices issued to them regarding their application for renewal of their Drug Manufacturing License. He has further stated that he has instruction to state at the outset that no notice purportedly sent by Secretary Central Licensing Board to his client was received. The notice of 15-06-2016, 22-11-2015 and 02-06-2017 were never received by his client. However, the notice of 25-02-2015 was duly replied and necessary information provided to Secretary Central Licensing Board. His client has the apprehension that the Central Licensing Board is working against his interest on which Chief Executive Officer of DRAP was removed by the Hon'rable Islamabad High Court. The publication of notice and other proceedings are based on malafide intension of DRAP. His client has never neglected or refused to comply with the necessary information required by DRAP for renewal of his license. He has, therefore, requested to desist from taking any illegal

action against his client without providing him right of hearing. He has requested for providing him copies of the notices said to have been issued to his client on 15-06-2016, 22-11-2015 and 02-06-2017 as same did not reach his client. He has further, requested to provide a copy of Minutes of 253rd meeting of Central Licensing Board held on 15-16th May, 2017 so as to enable his client to meet the objection, if any, to the renewal of his license. He also further stated that please note that any adverse action taken against his client without providing rights of hearing will be illegal. A copy of this notice has been retained in his office for further action.

Proceedings by Licensing Division

12. It is submitted that M/s Farooq Law Associates, Advocates and Attorneys, Islamabad has been provided all copies of correspondence made with M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad and he has been assured that Central Licensing Board is a statutory body working independently and not takes influence from any quarter. More over, letter of **personal hearing** has been served to M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad on his company address and through legal counsel M/s Farooq Law Associates, Advocates and Attorneys, 201, Dosal archade, 47-W, Blue Area, Islamabad. No reply from the firm is received yet.

13. Meanwhile, a copy of the Orders of the Islamabad High Court, Islamabad in Writ Petition No. 2836 of 2017 are received which are reproduced as under:

> "*The learned counsel, inter-alia, contends that the petitioner had earlier filed a constitutional petition in this Court whereby appointment of the Chairman, Drug Regulatory Authority (hereinafter referred to as the "Authority") had been challenged. The learned counsel further contends that for malafide reasons the impunged proceedings have been initiated. The learned counsel has stressed that the Drug Regulatory Authority is aware of the address of the petitioner yet a show cause notice has been published in a daily newspaper. The learned counsel has further argued that application for renewal of the license is pending before the Authority since 28-03-2014, which has not been processed. The leaned counsel has stated that there is no reason, whatsoever, in the facts and circumstances of the case for publication of the show cause notice in the daily newspaper.*
>
> *Let notice be issued to the respondents for filing of report and parawise comments within a fortnight.*
>
> *Relist after a fortnight.*

C.M. No.01 of 2017

Notice. Final order shall not be passed till the next date fixed. However, the petitioner shall appear before the competent authority. The latter shall afford an opportunity of hearing to the petitioner.

C.M. No. 02-E of 2017.

Exception sought for is allowed, subject to all just and legal exceptions."

Proceedings and Decision of Central Licensing Board in 255th meeting

14. Right of hearing was provided to M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad as per direction of the Honourable Islamabad High Court, Islamabad. The letter of personal hearing has also been served to M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad on his company address and through legal counsel M/s Farooq Law Associates, Advocates and Attorneys, 201, Dosal Archade, 47-W, Blue Area, Islamabad. However, petitioner failed to appear before the Board himself or through legal counsel on the date and time of hearing without any intimation. The Board did not pass any orders as per Orders of the Honourable Islamabad High Court, Islamabad. The Board however, decided that facts/ proceedings would be made part of the parawise comments to be submitted before the Honourable Islamabad High Court, Islamabad.

Proceedings by Licensing Division.

A panel of following experts / inspectors was constituted for renewal of Drug Manufacturing License:-

1. Maj. Gen. Tahir Mukhtar Syed, Member Drug Registration Board.
2. Syed Muied Ahmed, Member Central Licensing Board.
3. Additional Director (QA/LT), DRAP, Islamabad.
4. Area Federal Inspector of Drugs, DRAP, Islamabad.

Panel of inspectors inspected the premises of M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad on 31-01-2018 and concluded as under:-

1. "Keeping in view of above stated facts, firm is operating in un-satisfactory GMP conditions and is not fulfilling the requirements of conditions of license as required under the Drugs (Licensing, Registering & Advertising) Rules, 1976. Moreover, premises is not built in light of requirements under the Drugs (Licensing, Registering & Advertising) Rules, 1976. In light of critical observations noted during inspection

including but not limited to carrying out of manufacturing without approved qualified staff, without approved layout plan, manufacturing without having valid registration letters, the panel unanimously decided not to recommend the renewal of Drug Manufacturing License by way of formulation of the M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road, Islamabad (DML No.000535).

Keeping in view, the fact that firm don't have approved qualified staff as well as no record of import of raw material, therefore, it is recommended that production activities shall be stopped with the immediate effect".

Moreover, on the directions of the Honourable Supreme Court of Pakistan, following officers of the Drug Regulatory Authority of Pakistan seized the stock of M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad and locked and sealed the premises with the following observations and recommendations:-

1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT-I), DRAP, Islamabad.
2. Dr. Obaid Ullah, Director (PE&R), DRAP, Islamabad.
3. Dr. Muhammamd Fakhruddin Aamir, Additional Director (QA/LT-II), DRAP, Islamabad.
4. Mr. Abdul Sattar Sohrani, Deputy Director (QC), DRAP, Islamabad.
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, DRAP, Islamabad.
9. Dr. Arslan, FID, DRAP, Islamabad.
10. Mr. Hassan Afzaal, FID, DRAP, Islamabad.

Observations:

Detailed inspection of the manufacturing unit was conducted. A large number of drugs were seized on Form-2 and some of the samples were also taken on Form-3 for test / analysis . 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 is involved in:-

i. Manufacturing and sale of unregistered drugs.
ii. Manufacturing of Drugs with raw material smuggled / imported without approval of DRAP and without having import license.

iii. Violation of GMP as prescribed under the rules.
iv. Manufacturing of government property drugs without valid purchase orders.
v. The firm was manufacturing drugs in unhygienic conditions violating the conditions of license.
vi. Manufacturing / storage of drugs without identifiable labels.
vii. Keeping Unidentifiable raw materials.
viii. Keeping Expired raw materials
ix. Without master production record / batch manufacturing record.
x. Manufacturing of Drugs without approved technical persons responsible for manufacturing and testing of drugs.
xi. Without Quality Control record and release certificates.

3. All the recovered un-registered drugs, labels of unregistered and government property drugs, therapeutic goods and available records were listed and inventory was prepared and all these recoveries were witnessed by the :-

i. DRAP Officers mentioned above.

4. Token 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.

i. Qualified technical personnel involvement in the manufacturing, selling and testing was not visible.
ii. Shelf life of the manufactured products were awarded without support of stability data.
iii. Master production record and batch manufacturing record were not available for the products being manufactured.
iv. Marketing authorization of most of the products were not obtained from the authority as prescribed under the law.
v. Release certificates were not available for the active pharmaceutical ingredients and finished products.
vi. Sanitization and cleanliness conditions of the process areas were poor.
vii. Unhygienic conditions were prevailing in the manufacturing unit.
viii. 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.
ix. Packing material store was established outside the licensed premises in the open areas covered by ordinary roof.
x. Most of the raw materials and semi finished tablets and capsules were packed into shopping bags without identification labels.
xi. Syrup manufacturing areas and ointment cream sections were used as ware house for semi finished products and raw materials.
xii. Expired raw materials available in the working areas of ware house.

Recommendations:

The firm was running in poor GMP conditions and continuation of manufacturing will be risk for public health. Moreover the owner Ch. Muhammad Usman and other persons mentioned have committed offence under Schedule II of DRAP Act, 2012 which is punishable under schedule III of the DRAP, Act, 2012. Manufacturing and selling of unregistered drugs and import of drugs without valid drug import license are cognizable offences under schedule IV of DRAP, Act, 2012. Permission for registration of FIR against the accused persons is recommended. The premises was locked and sealed on the basis of above violations in the presence of following persons. It is also recommended that the license of the premises shall be withdrawn to save the public health.

Decision of the Central Licensing Board in 258th meeting

Central Licensing Board considered the following:-

1. Application for renewal filed by M/s. Everest Pharmaceutical, Islamabad.
2. Correspondence of Licensing Division with the M/s. Everest Pharmaceutical
3. Minutes of the previous Meetings of the Central Licensing Board.
4. Inspection Report of M/s. Everest Pharmaceutical by panel on 31.01.2018
5. Inspection Report of M/s. Everest Pharmaceutical by DRAP on the direction of Supreme Court on 06.03.2018.
6. The directions of the Supreme Court of Pakistan dated 06.03.2018 in HRC No.5845-G of 2018.

After the examination of the above record, the Central Licensing Board unanimously decided to reject the renewal application of the M/s Everest Pharmaceutical and cancel the Drug Manufacturing License No. 000535 by way of formulation issued in the name of M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for violation of Rule, 16, 19 of the 20 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Decision is based on the following grounds:-

1. Renewal application of M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad was incomplete. After evaluation of the renewal application of the firm a letter for completion of application for renewal of DML was issued on 7th May, 2014, but applicant failed to complete the renewal application.

2. On 17th March, 2015 the firm has submitted their one page reply and stated that FIR in FIA has been lodged in FIA on misunderstanding of DRAP and their production Manager and Q.C Manger were arrested. They will be able to reply the letter of Licensing Division after adjudication of the case. They requested to hold any proceeding / any further order till resolution of the case.

3. Licensing Division communicated the above decision of the Central Licensing Board to M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad 15th June, 2016 but envelope returned with the following remarks:

The same letter were communicated to the firm through Federal Inspector of Drugs, Islamabad on 22nd November, 2016 and 29th November, 2016 but those letters were also returned back with following remarks:

4. Final reminder was issued to the firm and copy of the same was send to area Federal Inspector of Drugs to deliver the letter by hand and report. The report by the area Federal Inspector of Drugs is as under:

> "***It is hereby report that I, Hasan Afzaal (FID-III, Islamabad) was informed by Dr. Fakharuddin Aamir (additional Director-QA&LT-II) on direction of Dr. Sheikh Akhtar Hussain (Director- QA/LT) on Friday 2nd june, 2017 at 4:00 pm to report to the Licensing Division for delivery of a letter to Everst Pharmaceuticals. The letter was handed over by Mr. Manzoor Bozdar (Additional director- Licensing) at 5:00 pm. I was accompanied by Mr. Sarfarz (driver-Admin) to the firm. We reached the firm at 6.00PM, where Mr. Waqar (Employee everest Pharmaceuticals) refused to receive the letter. We pasted a copy of the letter alongwith that day's newspaper and video graphed the proceedings. A short summary of this report was conveyed via Whats App alongwith the video was forwarded to the Director (QA/LT), Director (Licensing), Additional Director (QA/LT-II) and Additional Director (Licensing).***"

Following shortcomings were communicated to the firm under Rule 5(2A) in the above said letter:

i. Complete document / information of your proposed Quality Control Incharge Mr. Imtiaz Ahmed & Production Incharge Mr. Muhammad Arshad as per checklist enclosed herewith for your guidance. All documents should be attested by gazetted officer or

Notary Public and also signed by CEO / Director / Authorized person with seal / stamp of the firm.

ii. Updated copy of Nothing Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of Central Research Fund up to 31-12-2014.

iii. Attested photocopy of latest Partnership deed within CNICs of all the Directors as per partnership deed and certificate of Registration with Registrar of the firm.

iv. Details of the premises i.e. approval letter of sections issued by Secretary Central Licensing Board & to also furnish copy of approval layout plan of the building.

v. Details of equipment / machinery for Quality Control Laboratory.

vi. Name of the drugs registered / approved.

5. 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 their application for renewal of M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad DML No. 000535 by way of formulation may not be rejected by Central Licensing Board or License may not be suspended or cancelled by Central Licensing Board.

6. The Show Cause notice dated 22nd June, 2017 was issued to the M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad. The said Show Cause Notice is returned un-delivered. Consequently, Show Cause Notice was published in Print Media dated 22nd July, 2017.

7. A letter was received from M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad through legal Counsel M/s Farooq Law Associates, Advocates and Attorneys, Islamabad. They stated that his client M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road, Islamabad owned by Ch. Muhammad Usman have shown him the Show Cause Notice published on 22.07.2017 in the daily "Dunya" Newspaper, Islamabad calling upon them to answer the Show Cause Notices issued to them regarding their application for renewal of their Drug Manufacturing License. He further stated that he has instruction to state at the outset that no notice purportedly sent by Secretary Central Licensing Board to his client was received. The notice of 15-06-2016, 22-11-2015 and 02-06-2017 were never received by his client. However, the notice of 25-02-2015 was duly replied and necessary information provided to Secretary Central Licensing Board. His client has the apprehension that the Central Licensing Board is working

against his interest on which Chief Executive Officer of DRAP was removed by the Hon'rable Islamabad High Court. The publication of notice and other proceedings are based on malafide intention of DRAP. His client has never neglected or refused to comply with the necessary information required by DRAP for renewal of his license. He, therefore, requested to desist from taking any illegal action against his client without providing him right of hearing. He has requested for providing him copies of the notices said to have been issued to his client on 15-06-2016, 22-11-2015 and 02-06-2017 as same did not reach his client. He further, requested to provide a copy of Minutes of 253rd meeting of Central Licensing Board held on 15-16th May, 2017 so as to enable his client to meet the objection, if any, to the renewal of his license. He further stated that any adverse action taken against his client without providing right of hearing will be illegal. A copy of this notice has been retained in his office for further action.

8. M/s Farooq Law Associates, Advocates and Attorneys, Islamabad were provided all copies of correspondence made with M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad. Moreover, letter of **personal hearing** was served upon M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad on his company address and through legal counsel M/s Farooq Law Associates, Advocates and Attorneys, 201, Dosal archade, 47-W, Blue Area, Islamabad. No reply from the firm was ever received.

9. Proceedings were stopped due to restraining orders of the Islamabad High Court, Islamabad in Writ Petition No. 2836 of 2017.

10. Right of hearing was provided to M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad as per direction of the Honourable Islamabad High Court, Islamabad. The letter of personal hearing has also been served to M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad on his company address and through legal counsel M/s Farooq Law Associates, Advocates and Attorneys, 201, Dosal Archade, 47-W, Blue Area, Islamabad, which was not returned. However, petitioner failed to appear before the Board in person or through his legal counsel on the date and time of hearing without any intimation. The Board did not pass any orders as per Orders of the Honourable Islamabad High Court, Islamabad.

11. A panel of following experts / inspectors was constituted for renewal of Drug Manufacturing License:-

1. Maj. Gen. Tahir Mukhtar Syed, Member Drug Registration Board.
2. Syed Muied Ahmed, Member Central Licensing Board.
3. Additional Director (QA/LT), DRAP, Islamabad.
4. Additional Director (Lic), DRAP, Islamabad.
5. Area Federal Inspector of Drugs, DRAP, Islamabad.

Panel of inspectors inspected the premises of M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad on 31-01-2018 and concluded as under:-

1. "Keeping in view of above stated facts, firm is operating in un-satisfactory GMP conditions and is not fulfilling the requirements of conditions of license as required under the Drugs (Licensing, Registering & Advertising) Rules, 1976. Moreover, premises is not built in light of requirements under the Drugs (Licensing, Registering & Advertising) Rules, 1976. In light of critical observations noted during inspection including but not limited to carrying out of manufacturing without approved qualified staff, without approved layout plan, manufacturing without having valid registration letters, the panel unanimously decided not to recommend the renewal of Drug Manufacturing License by way of formulation of the M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road, Islamabad (DML No.000535).

12. DRAP Inspection panel of following officers on the direction of Honourable Supreme Court of Pakistan, inspected M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad and locked and sealed the premises with the following observations and recommendations:-

1. Dr. Hafsa Karam Elahi, Additional Director (QA&LT-I), DRAP, Islamabad.
2. Dr. Obaid Ullah, Director (PE&R), DRAP, Islamabad.
3. Dr. Muhammamd Fakhruddin Aamir, Additional Director (QA/LT-II), DRAP, Islamabad.
4. Mr. Abdul Sattar Sohrani, Deputy Director (QC), DRAP, Islamabad.
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, DRAP, Islamabad.
9. Dr. Arslan, FID, DRAP, Islamabad.
10. Mr. Hassan Afzaal, FID, DRAP, Islamabad.

Observations:

Detailed inspection of the manufacturing unit was conducted. A large number of drugs were seized on Form-2 and some of the samples were also taken on Form-3 for test / analysis . 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 is involved in:-

i. Manufacturing and sale of unregistered drugs.
ii. Manufacturing of Drugs with raw material smuggled / imported without approval of DRAP and without having import license.
iii. Violation of GMP as prescribed under the rules.
iv. Manufacturing of government property drugs without valid purchase orders.
v. The firm was manufacturing drugs in unhygienic conditions violating the conditions of license.
vi. Manufacturing / storage of drugs without identifiable labels.
vii. Keeping Unidentifiable raw materials.
viii. Keeping Expired raw materials
ix. Without master production record / batch manufacturing record.
x. Manufacturing of Drugs without approved technical persons responsible for manufacturing and testing of drugs.
xi. Without Quality Control record and release certificates.

13. All the recovered un-registered drugs, labels of unregistered and government property drugs, therapeutic goods and available records were listed and inventory was prepared and all these recoveries were witnessed by the :-

i. DRAP Officers mentioned above.

14. Token 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.

i. Qualified technical personnel involvement in the manufacturing, selling and testing was not visible.
ii. Shelf life of the manufactured products were awarded without support of stability data.
iii. Master production record and batch manufacturing record were not available for the products being manufactured.
iv. Marketing authorization of most of the products were not obtained from the authority as prescribed under the law.
v. Release certificates were not available for the active pharmaceutical ingredients and finished products.
vi. Sanitization and cleanliness conditions of the process areas were poor.
vii. Unhygienic conditions were prevailing in the manufacturing unit.

viii. 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.
ix. Packing material store was established outside the licensed premises in the open areas covered by ordinary roof.
x. Most of the raw materials and semi finished tablets and capsules were packed into shopping bags without identification labels.
xi. Syrup manufacturing areas and ointment cream sections were used as ware house for semi finished products and raw materials.
xii. Expired raw materials available in the working areas of ware house.

15. Recommendations:

The firm was running in poor GMP conditions and continuation of manufacturing will be risk for public health. Moreover the owner Ch. Muhammad Usman and other persons mentioned have committed offence under Schedule II of DRAP Act, 2012 which is punishable under schedule III of the DRAP, Act, 2012. Manufacturing and selling of unregistered drugs and import of drugs without valid drug import license are cognizable offences under schedule IV of DRAP, Act, 2012. Permission for registration of FIR against the accused persons is recommended. The premises was locked and sealed on the basis of above violations in the presence of above mentioned officers. It is also recommended that the license of the premises shall be withdrawn to save the public health.

QUALITY ASSUARANCE AND LAB. TESTING DIVISION

Item No. 1 **INSPECTION REPORT OF M/S EVEREST PHARMACEUTICALS, PLOT NO. 124, KAHUTA ROAD, INDUSTRIAL TRIANGLE, ISLAMABAD**

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

i. Dr. Hafsa Karam Elahi, Additional Director QA&LT-I, Islamabad
ii. Dr. Obaid Ullah, Director PE&R, DRAP, Islamabad
iii. Dr. Muhammad Fakhruddin Aaamir, Additional Director QA/LT-II, Islamabad
iv. Mr. Abdul Sattar Sohrani, Deputy Director QC
v. Ch. Zeeshan Nazir, Deputy Director, DRAP, Islamabad
vi. Dr. Ghazanfar Ali, Deputy Director DRAP, Islamabad
vii. Mr. Abdullah, Deputy Director DRAP, Islamabad
viii. Mr. Akhtar Abbas Khan, Deputy Director, Islamabad
ix. Dr. Arslan, FID, Islamabad
x. Mr. Hassan Afzaal, FID, Islamabad

2. Accused Ch. Muhammad Usman asked someone to bring keys. Unknown person brought keys and opened the doors at 11:40 am. Detailed inspection of the manufacturing unit was conducted. A large number of drugs were seized on Form-2 **(copy attached)** and some of the samples were also taken on Form-3 for test / analysis **(copy attached)**. 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 is involved in:-

i. Manufacturing and sale of unregistered drugs.
ii. Manufacturing of Drugs with raw material smuggled / imported without approval of DRAP and without having import license.
iii. Violation of GMP as prescribed under the rules.
iv. Manufacturing of government property drugs without valid purchase orders.
v. The firm was manufacturing drugs in unhygienic conditions violating the conditions of license.
vi. Manufacturing / storage of drugs without identifiable labels.
vii. Keeping Unidentifiable raw materials.
viii. Keeping Expired raw materials
ix. Without master production record / batch manufacturing record.
x. Manufacturing of Drugs without approved technical persons responsible for manufacturing and testing of drugs.
xi. Without Quality Control record and release certificates.

3. All the recovered un-registered drugs, labels of unregistered and government property drugs, therapeutic goods and available records were listed and inventory was prepared and all these recoveries were witnessed by the followings:-

i. DRAP Officers mentioned above.

4. Token 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.

i. Qualified technical personnel involvement in the manufacturing, selling and testing was not visible.
ii. Shelf life of the manufactured products were awarded without support of stability data.
iii. Master production record and batch manufacturing record were not available for the products being manufactured.
iv. Marketing authorization of most of the products were not obtained from the authority as prescribed under the law.
v. Release certificates were not available for the active pharmaceutical ingredients and finished products.
vi. Sanitization and cleanliness conditions of the process areas were poor.
vii. Unhygienic conditions were prevailing in the manufacturing unit.
viii. 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.
ix. Packing material store was established outside the licensed premises in the open areas covered by ordinary roof.
x. Most of the raw materials and semi finished tablets and capsules were packed into shopping bags without identification labels.
xi. Syrup manufacturing areas and ointment cream sections were used as ware house for semi finished products and raw materials.
xii. Expired raw materials available in the working areas of ware house.

Conclusion of Inspection:-

The firm was running in poor GMP conditions and continuation of manufacturing will be risk for public health. Moreover the owner Ch. Muhammad Usman and other persons mentioned above have committed offence under Schedule II of DRAP Act, 2012 which is punishable under schedule III of the DRAP, Act, 2012. Manufacturing and selling of unregistered drugs and import of drugs without valid drug import license are cognizable offences under schedule IV of DRAP, Act, 2012. Permission for registration of FIR against the accused persons is recommended. The premises was locked and sealed on the basis of above violations in the presence of following persons. It is also recommended that the license of the premises shall be withdrawn to save the public health.

The report was signed by the following DRAP officers

Ser #	Name of experts
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

05. The Additional Director QA&LT requested for the grant of permission for FIR vide reference letter No.No.F.1-1/2018-Addl. Dir QA&LT-I as under:-

> **"Permission for Registration of FIR against Ch. Muhammad Usman, Dr. Kamran Izhaar, Noor Muhammad Mehr, 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.**

This is with reference to the subject cited above and to say that the undersigned alongwith FIA and NAB teams reached in front of M/s Everest Pharma, Plot No. 124, Industrial Triangle, Kahuta Road, Islamabad at 11:00 am on the direction of Supreme Court of Pakistan in HRC case No. 5845-G/2018, but the factory was found closed and main door was locked. DRAP team comprising of following officers:-

i. Dr. Hafsa Karam Elahi, Additional Director QA&LT-I, Islamabad
ii. Dr. Obaid Ullah, Director PE&R, DRAP, Islamabad
iii. Dr. Muhammad Fakhruddin Aaamir, Additional Director QA/LT-II, Islamabad
iv. Mr. Abdul Sattar Sohrani, Deputy Director QC
v. Dr. Ghazanfar Ali, Deputy Director DRAP, Islamabad
vi. Mr. Abdullah, Deputy Director DRAP, Islamabad
vii. Mr. Akhtar Abbas Khan, Deputy Director, Islamabad
viii. Dr. Arslan, FID, Islamabad
ix. Mr. Hassan Afzaal, FID, Islamabad

During inspection following contraventions were identified and recorded on prescribed form and owner Ch. Muhammad Usman accused person involved in:-

i. Manufacturing and selling of unregistered drugs.
ii. Manufacturing of Drugs with raw material smuggled / imported without approval of DRAP and without having import license.
iii. Violation of GMP as prescribed under the rules.

iv. Manufacturing of government property drugs without approval of labels from the DRAP.
v. The firm was manufacturing drugs in unhygienic conditions violating the conditions of license.
vi. Manufacturing / storage of drugs without identifiable labels.
vii. Unidentifiable raw materials
viii. Expired raw materials
ix. Without master production record / batch manufacturing record.
x. Manufacturing of Drugs without approved technical persons responsible for manufacturing and testing of drugs.
xi. Without Quality Control record and release certificates.

06. It is therefore requested that permission to register FIR against the persons mentioned in the subject of M/s Everest Pharmaceuticals, Islamabad who are involved in manufacturing and selling of unregistered drugs / therapeutic drugs and import / smuggling of drugs and active pharmaceutical ingredients without obtaining import license from the DRAP as required under DRAP Act, 2012 and rules framed thereunder may be granted immediately".

07. That Director QA/LT, DRAP, Islamabad granted permission for registration of FIR as under:-

This is with reference to your letter dated 06.03.2018 wherein it was informed that a team of DRAP alongwith FIA and NAB teams inspected M/s Everest Pharma, Plot No. 124, Industrial Triangle, Kahuta Road, Islamabad on the direction of Supreme Court of Pakistan in HRC case No.5845-G/2018 and recommended for registration of FIR against the subject mentioned accused persons. The case was placed before the competent authority wherein the Director QA&LT is pleased to grant permission to launch FIR against the subject mentioned accused persons and forward the report after complete investigation by FIA authorities.

08. As the matter was urgent and accused Ch.Mohammad Usman was already in police custody, it was immediately required to file application for registration of FIR by the Additional Director QA/LT, DRAP Islamabad. Accordingly the permission for registration of FIR was granted by the Director QA&LT, DRAP, Islamabad under powers delegated by Central Licensing Board against the following accused persons of M/s Everest Pharma, Plot No. 124, Kahuta Road, Industrial Triangle, Islamabad responsible for manufacturing and selling of unregistered drugs and import / smuggling of active pharmaceutical ingredients without import license and clearance from DRAP

"1. **Ch. Muhammad Usman, owner**

2. Dr. Kamran Izhaar Partner

3. Noor Muhammad Mehr Partner (as per writ petition filed by him)

4. **CH. Muhammad Usman, Production In-charge**

5. **Muhammad Ishtiaq, QC Incharge**

09. The matter is submitted for consideration of the Central Licensing Board for ratification/endorsement of the permission for grant of registration of FIR against the above mentioned accused persons.

Proceedings and decision of the Central Licensing Board

The Central Licensing Board considered the facts decided to endorse the permission granted by Director Quality Assurance and Laboratory Testing.

Item No. II **REQUEST FOR PERMISSION TO KEEP THE SEIZED STOCK UNDER SAFE CUSTODY TILL DECISION OF THE CASE AS REQUIRED UNDER DRAP ACT, 2012 AND EXTENSION IN SEALING PERIOD OF M/S. EVEREST PHARMA, PLOT NO. 124, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

DRAP inspection team alongwith FIA and NAB teams reached in front of M/s. Everest Pharma, Plot No.124, Industrial Triangle, Kahuta Road, Islamabad at 11.00am on the direction of Supreme Court of Pakistan in H.R.C case No.5845-G/2018, but the factory was found closed and main door was locked. DRAP team was comprised of following DRAP officers:-

i. Dr. Hafsa Karam Elahi, Additional Director QA&LT-I, Islamabad
ii. Dr. Obaid Ullah, Director PE&R, DRAP, Islamabad
iii. Dr. Muhammad Fakhruddin Aaamir, Additional Director QA/LT-II, Islamabad
iv. Mr. Abdul Sattar Sohrani, Deputy Director QC, Islamabad
v. Ch. Zeeshan Nazir, Deputy Director, QA, Islamabad
vi. Dr. Ghazanfar Ali, Deputy Director DRAP, Islamabad
vii. Mr. Abdullah, Deputy Director DRAP, Islamabad
viii. Mr. Akhtar Abbas Khan, Deputy Director, Islamabad
ix. Dr. Arslan, FID, Islamabad
x. Mr. Hassan Afzaal, FID, Islamabad

2. It has been informed by the Additional Director QA & LT/as Federal Inspector of Drugs, Islamabad locked and sealed the premises under the DRAP Act, 2012. It has been requested that necessary permission for keeping the seized stocks/articles/records safe custody till the finalization of case may be allowed.

3. The case is being submitted to the Central Licensing Board for seeking permission to keep the seized stock under safe custody till decision of the case required under schedule V(5)(b) of DRAP Act, 2012 read with Section 19(5)(b) of Drug Act, 1976 and Rules framed thereunder. The details showing the seized materials/record/labels/registered/drugs on form-2 (copies attached). It has been also requested by the Additional Director QA & LT that extension in sealing period may also be granted for further period as required in the law.

4. It is pertinent to mentioned that the owner and production Incharge Ch. Muhammad Usman refused to sign the seizer form-2, form-3 and keys sealed by the undersigned in a packet. It has been requested by the Additional Director (QA&LT-I) that said matter may also be placed before the Central Licensing Board for further direction, please.

Proceedings and decision by the Central Licensing Board in 258th meeting

The Central Licensing Board considered the case and decided to:

i. allowed custody of seized stock/ articles.
ii. Period of sealing extended for 90 days from the date of sealing.
iii. The Board directed area Federal Inspector of Drugs to approach the concerned FIA Police Station and handover the keys to concerned zonal Director FIA.

Meeting ended with the vote of thanks to and by the chair.