MINUTES OF 262nd MEETING OF CENTRAL LICENSING BOARD HELD ON 23rd MAY, 2018

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262nd meeting of the Central Licensing Board (CLB) was held on 23rd May, 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. Muhammad Israr Additional Draftsman/Joint Secretary (Ex-officio), Ministry of Law and Justice, Islamabad.	Member
2.	Dr.Ikram-ul-Haque, Expert in QC/QA of drugs.	Member
3.	Syed Muied Ahmed, Expert in manufacturing of drugs	Member
4.	Prof. Dr. Abdullah Dayo, Dean, Faculty of Pharmacy, University of Sindh, Jamshoro	Member
5.	Prof. Dr. Mohammad Usman, Expert in manufacturing of drugs	Member
6.	Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar.	Member
7.	Dr. Abbas Khan, Chief Drug Inspector, Health Department, KPK.	Member
8.	Mr. Abdul Sattar Sohrani Representative Director (QA/LT), DRAP, Islamabad	Member
9.	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
10.	Mr. Nadeem Alamgir, Representative of Pharma Bureau	Observer
11.	Mr. Saboor Ahmed Sheikh and Mr. Arshad Mahmood, 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. Dr Hafsa Karam Ellahi, Addional Director (QA/LT) and Mr. Ayyaz Ahmed, Deputy Director (Lic), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 261st MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 261st meeting held on 2nd May, 2018. The Board also approved the typographical corrections in the minutes of the 261st meeting

for Miscellaneous items at Case No. 2, 3, 4 and 5 where words and phrases "basic manufacture" shall be read as "Formulation".

A. DRUG LICENSING DIVISION

Item-I: **GRANT OF NEW DRUG MANUFACTURING LICENCE.**

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s Hi-Med Pharmaceuticals, Plot No. 208-C, Sunder Industrial Estate, Lahore. **Sections 04** 1. Tablet (General) Section 2. Capsule (General) Section 3. Dry Powder for Suspension(General) Section. 4. Sachet (General) Section.	27-04-2018	**Good**	1. Dr. Ikram-ul-Haq, Member Central Licensing Board. 2. Mr. Munawar Hayyat, Chief Drug Controller, Govt. of the Punjab 3. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 4. Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - Keeping in view the facilities like building, HVAC system production machinery, equipment in Quality Control and Microbiology Laboratory, Water Treatment Plant, Testing Felicities, Technical Personnel, documentation, the panel of inspectors is of the opinion to recommend the grant of Drug Manufacturing License by way of formulation to M/s Hi-Med Pharmaceuticals, Plot No. 208-C, Sunder Industrial Estate, Lahore for above mentioned sections. **Decision by the Central Licensing Board in 262nd meeting** The Board considered and approved the grant of Drug Manufacturing Licence in the name of M/s Hi-Med Pharmaceuticals, Plot No. 208-C, Sunder Industrial Estate, Lahore for the following sections: 1. Tablet (General) Section 2. Capsule (General) Section 3. Dry Powder for Suspension (General) Section. **4.** Sachet (General) Section.			

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

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

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore DML No. 000052 (Formulation) **Section (02)** 1. Tablet (General) Section (revised). **2.** Capsule (General) Section (revised).	20-04-2018	----	1. Dr. Ikram-ul-Haq, Member Central Licensing Board. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Ms. Anam Saeed, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - Keeping in view the facilities like building, HVAC system, machinery and equipment, Instruments, personnel, documentation, Quality Control, the panel of inspectors is of the opinion to recommend the grant of above mentioned revised General sections to M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore. **Decision by the Central Licensing Board in 262nd meeting** The Board considered and approved the grant of following additional/ revised sections in the name of M/s CCL Pharmaceuticals (Pvt) Ltd, 62-Industrial Estate, Kot Lakhpat, Lahore on the recommendations of the panel of experts:- **Section (02)** 1. Tablet (General) Section (revised). 2. Capsule (General) Section (revised).			
2.	M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad. DML No.000496 (Formulation).	**20-04-2018**	**Good**	1. Prof. Dr. Gul Majid Khan, Chairman Department of Pharmacy, QAU, Islamabad. 2. Abdul Sattar Sohrani, Addl. Director (Lic),

	Section (01). i. Soft Gelatin Capsule (Section).			DRAP, Islamabad. 3. Mr. Arslan Tariq, Area FID-I, DRAP, Islamabad.
	Recommendations: "Keeping in view of the above facts on record, documents reviewed and people met during inspection the panel unanimously recommended the grant of additional Section i.e Soft Gelatin Capsule (Section) as well as the renewal of Drug Manufacturing License No. 000496 (by way of Formulation) of M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad except the tablet psychotropic section which was not operative at the time of inspection though built as per approved layout plan (453 sq. ft.) It was advised to regularize the layout plan for tablet psychotropic section as per Schedule B-I of the Drugs (L,R&A) Rules 1976. The firm has voluntarily stopped production, as per their undertaking, in tablet psychotropic section of all registered products granted in favour of this psychotropic section till rectification and verification of the observations pointed out during inspection. **Decision by the Central Licensing Board in 262nd meeting** The Board considered and approved the grant of following one additional sections in the name of M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts:- **Section (01)** 1. Soft Gelatin Capsule (Section).			
3.	M/s Tas Pharmaceuticals (Pvt) Ltd., Plot No. 209, Industrial Triangle, Kahuta Road, Islamabad. DML No.000375 (Formulation). **Section (04).** 1. Tablet Section (Psychotropic) – New. 2. Tablet (General) – Amended / Revised. 3. Packing Hall in place of Syrup Section. 4. Regularization of Cream / Ointment Section (General).	**04-04-2018**	**Good**	1. Dr. Masood ur Rehman, Additional Director (CD), DRAP, Islamabad. 2. Mr. Ahmed Din Ansari, DD, (QC), DRAP, Islamabad. 3. Mr. Babar Khan, DD, DRAP, Islamabad. 4. Mr. Arslan Tariq, Area FID-I, DRAP, Islamabad.
	Recommendations: "Keeping in view the said observations, people met on site; panel unanimously decided to recommended renewal of DML No. 000375 by way of Formulation with restoration of			

	production (which was held by the firm due to up gradation) and grant of additional / amended sections as mentioned above. **Decision by the Central Licensing Board in 262nd meeting** The Board considered and approved the grant of following additional/ amended/ new sections in the name of M/s Tas Pharmaceuticals (Pvt) Ltd., Plot No. 209, Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts:- **Section (04)** 1. Tablet Section (Psychotropic) – New. 2. Tablet (General) – Amended / Revised. 3. Packing Hall in place of Syrup Section. 4. Regularization of Cream / Ointment Section (General).			
4.	M/s Inshal Pharmaceuticals Industries, Plot No. 2, Street No. SS-2, National Industrial Zone, Rawat, Rawalpindi. DML No.000698 (Formulation). **Section (02).** 1. Amoxicillin / Penicillin Oral Powder Section (Veterinary). 2. Amoxicillin / Penicillin Liquid Vial Injectable Section (Veterinary).	**11-05-2018**	**Good**	1. Dr. Noor Muhammad Shah, Director, FDSL, DRAP, Islamabad. 2. Mr. Abdul Ghaffar, DD (Pricing), DRAP, Islamabad. 3. Dr. Hasan Afzaal, Area FID-III, DRAP, Islamabad. 4. Dr. Zunaira Faryal, AD (Lic), DRAP, Islamabad.
	Recommendations: The panel has recommended M/s Inshal Pharmaceuticals Industries, Plot No. 2, Street No. SS-2, National Industrial Zone, Rawat, Rawalpindi for the grant of additional sections mentioned above. **Decision by the Central Licensing Board in 262nd meeting** The Board considered and approved the grant of following two additional sections in the name of M/s Inshal Pharmaceuticals Industries, Plot No. 2, Street No. SS-2, National Industrial Zone, Rawat, Rawalpindi on the recommendations of the panel of experts:- **Section (02).** 1. Amoxicillin / Penicillin Oral Powder Section (Veterinary). 2. Amoxicillin / Penicillin Liquid Vial Injectable Section (Veterinary).			

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 Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad. DML No.000496 (Formulation). **Period:** Commencing on 29-03-2017 and ending on 28-03-2022	**20-04-2018**	**Good**	1.Prof. Dr. Gul Majid Khan, Chairman Department of Pharmacy, QAU, Islamabad. 2.Abdul Sattar Sohrani, Addl. Director (Lic), DRAP, Islamabad. 3.Mr. Arslan Tariq, Area FID-I, DRAP, Islamabad.
	Recommendations: "Keeping in view of the above facts on record, documents reviewed and people met during inspection the panel unanimously recommended the grant of additional Section i.e Soft Gelatin Capsule (Section) as well as the renewal of Drug Manufacturing License No. 000496 (by way of Formulation) of M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad except the tablet psychotropic section which was not operative at the time of inspection though built as per approved layout plan (453 sq. ft.) It was advised to regularize the layout plan for tablet psychotropic section as per Schedule B-I of the Drugs (L,R&A) Rules 1976. The firm has voluntarily stopped production, as per their undertaking, in tablet psychotropic section of all registered products granted in favour of this psychotropic section till rectification and verification of the observations pointed out during inspection. **Decision by the Central Licensing Board in 262nd meeting** The Board approved the renewal of Drug Manufacturing Licence No. 000496 (Formulation) in the name of M/s Valor Pharmaceuticals, Plot No. 124/A, Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the further period of five years commencing on 29-03-2017 and ending on 28-03-2022. The Board also suspended the production of the firm for Tablet Psychotropic sections till rectification of deficiencies as pointed out by the panel and subsequent approval by the Board.			

2	M/s Tas Pharmaceuticals (Pvt) Ltd., Plot No. 209, Industrial Triangle, Kahuta Road, Islamabad. DML No.000375 (Formulation) **Period:** **16-11-2015 to 15-11-2020.**	**04-04-2018**	**Good**	1.Dr. Masood ur Rehman, Additional Director (CD), DRAP, Islamabad. 2.Mr. Ahmed Din Ansari, DD, (QC), DRAP, Islamabad. 3.Mr. Babar Khan, DD, DRAP, Islamabad. 4.Mr. Arslan Tariq, Area FID-I, DRAP, Islamabad.
	Recommendations: "Keeping in view the said observations, people met on site; panel unanimously decided to recommended renewal of DML No. 000375 by way of Formulation with restoration of production (which was held by the firm due to up gradation). **Decision by the Central Licensing Board in 262nd meeting** The Board approved the renewal of Drug Manufacturing Licence No. 000375 (Formulation) in the name of M/s Tas Pharmaceuticals (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the further period of five years commencing on 16-11-2015 and ending on 15-11-2020 and also approved restoration / resumption of production of M/s Tas Pharmaceuticals (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad which was suspended by the Central Licensing Board.			
3.	M/s Inshal Pharmaceuticals Industries, Plot No. 2, Street No. SS-2, National Industrial Zone, Rawat, Rawalpindi. DML No.000698 (Formulation). Period: **08-12-2015 to 07-12-2020.**			1. Dr. Noor Muhammad Shah, Director, FDSL, DRAP, Islamabad. 2. Mr. Abdul Ghaffar, DD (Pricing), DRAP, Islamabad. 3. Dr. Hasan Afzaal, Area FID-III, DRAP, Islamabad. 4. Dr. Zunaira Faryad, AD (Lic), DRAP, Islamabad.
	Recommendations: The panel has unanimously recommended M/s Inshal Pharmaceuticals Industries, Plot No. 2, Street No. SS-2, National Industrial Zone, Rawat, Rawalpindi for the renewal of Drug Manufacturing License No. 000698 (Formulation) for further period. **Decision by the Central Licensing Board in 262nd meeting** The Board approved the renewal of Drug Manufacturing Licence No. 000698 (Formulation) in the name of M/s Inshal Pharmaceuticals Industries, Plot No. 2, Street No. SS-2, National Industrial Zone, Rawat, Rawalpindi on the recommendations of the panel of experts for the further period of five years commencing on 08-12-2015 and ending on 07-12-2020			

Item-IV: **MISCELLANEOUS CASES**

Case No. 1 **CHANGE OF TITLE OF M/S WELLNESS PHARMACEUTICALS (PVT) LTD, LAHORE.**

M/sWellness Pharmaceuticals (Pvt) Ltd, Plot No 33 Sunder Industrial Estate, Lahore under DML No. 000782 by way of formulation has submitted request for change of title of the firm as per Certificate of incorporation from S.E.C.P with prescribed Fee Challan of Rs.50,000/-. The detail is as under:

Current Title/legal status of firm as per Form-29	Proposed title of Firm as per Certificate of incorporation of S.E.C.P
M/s Wellness Pharmaceuticals (Pvt) Ltd.	M/s Horizon Healthcare (Private) Limited

Decision by the Central Licensing Board in 262nd meeting:

The Board considered and approved the change of title/ name of the firm /company from M/s Wellness Pharmaceuticals (Pvt) Ltd to M/s Horizon Healthcare (Private) Limited as per Form 29 and certificate issued by S.E.C.P as under;

Current Title/legal status of firm as per Form-29	Proposed title of Firm as per Certificate of incorporation of S.E.C.P
M/s Wellness Pharmaceuticals (Pvt) Ltd.	M/s Horizon Healthcare (Private) Limited

Case No. 2. **CHANGE OF MANAGEMENT OF M/S HORIZON HEALTHCARE (PRIVATE) LIMITED [FORMERLY M/S WELLNESS PHARMACEUTICALS (PVT) LTD], LAHORE.**

M/s Horizon Healthcare (Private) Limited [formerly M/s Wellness Pharmaceuticals (Pvt) Ltd], Plot No 33 Sunder Industrial Estate, Lahore under DML No. 000782 by way of formulation has submitted request for change in management of the firm as per Form 29 along with prescribed Fee Challan of 50,000/- as under:-

Previous management as per Form-29 of S.E.C.P	Retiring Management	Current management as per Form-A &Form-29 of S.E.C.P.
1. Mr. Haris Moin S/o Moinuddin Siddiqui CNIC No. 42101-8366563-9. 2. Mr. Hussain Murad S/o Murad CNIC No. 42101-0344151-7.	1.Mr. Haris Moin S/o Moinuddin Siddiqui CNIC No. 42101-8366563-9. 2.Mr. Hussain Murad S/o Murad CNIC No. 42101-0344151-7.	1. Mr. Khurram Sayani S/o Alauddin CNIC No. 42201-0493163-1. 2. Mr. Nazim Alauddin Sayani S/o Alauddin CNIC No. 42201-0493160-3. 3. Ms. Shaista Nazim W/o Nazim Alauddin Sayani CNIC No. 42000-0481851-8.

Decision by the Central Licensing Board in 262nd meeting:

The Board considered and approved the change of management of the company M/s Horizon Healthcare (Private) Limited [formerly M/s Wellness Pharmaceuticals (Pvt) Ltd] as per Form 29 and certificate issued by S.E.C.P as under;

Previous management as per Form-29 of S.E.C.P	Retiring Management	Current management as per Form-A &Form-29 of S.E.C.P.
1. Mr. Haris Moin S/o Moinuddin Siddiqui CNIC No. 42101-8366563-9. 2. Mr. Hussain Murad S/o Murad CNIC No. 42101-0344151-7.	1. Mr. Haris Moin S/o Moinuddin Siddiqui CNIC No. 42101-8366563-9. 2. Mr. Hussain Murad S/o Murad CNIC No. 42101-0344151-7.	1. Mr. Khurram Sayani S/o Alauddin CNIC No. 42201-0493163-1. 2. Mr. Nazim Alauddin Sayani S/o Alauddin CNIC No. 42201-0493160-3. 3. Ms. Shaista Nazim W/o Nazim Alauddin Sayani CNIC No. 42000-0481851-8.

Case No. 3 CHANGE OF TITLE OF M/S HIRRA PHARMACEUTICAL LABORATORIES, LAHORE.

M/s Hirra Pharmaceutical Laboratories, 1.3-Km, Asli Raiwind Road (Ladhaky Bhula) Lahore Cantt under DML No. 000449 by way of formulation has submitted request for change of title of the firm as per Form-29 S.E.C.P with prescribed Fee Challan of Rs.50,000/-. The detail is as under:

Current Title/name/Legal status of firm as per Form-1-A	Proposed title/Name/Legal Status of Firm as per Form-29& Form-A of S.E.C.P
M/s Hirra Pharmaceutical Laboratories , 1.3-KM, Asil Raiwind Road Lahore	M/s Hirra Pharmaceuticals, (Pvt) Ltd, 13-KM, Asil Raiwind Road, Lahore

Decision by the Central Licensing Board in 262nd meeting:

The Board considered and approved the change oftitle/ name of the companyM/sHirra Pharmaceutical Laboratories, 1.3-Km, Asli Raiwind Road (Ladhaky Bhula) Lahore Cantt as per Form-29 S.E.C.P

Current Title/name/Legal status of firm as per Form-1-A	Proposed title/Name/Legal Status of Firm as per Form-29& Form-A of S.E.C.P
M/s Hira Pharmaceutical Laboratories , 1.3-KM, Asil Raiwind Road Lahore	M/s Hira Pharmaceuticals, (Pvt) Ltd, 13-KM, Asil Raiwind Road, Lahore

Case No. 4. CHANGE OF MANAGEMENT OF M/S HIRRA PHARMACEUTICAL LABORATORIES (PVT) LTD., , LAHORE.

M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd., 1.3-Km, Asli Raiwind Road (Ladhaky Bhula) Lahore Cantt under DML No. 000449 by way of formulation has submitted request for change in management of the firm as per Form 29 along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-1A at the time of previous renewal	Added Management	Current Management as per Form-29& Form-A of SECP
1. Mr. Kamran Akhtar S/o Muhammad Akhtar Farooqi CNIC No. 54400-0918955-3. 2. Mr. Muhammad Farooq Shahzad S/o Shaikh Asmat Ullah CNIC No. 35202-2902531-9.	1. Mr. Bakhtiar Ahmed Ahmad S/o Sultan Ahmad CNIC No. 35202-8566682-1.	1. Mr. Kamran Akhtar S/o Muhammad Akhtar Farooqi CNIC No. 54400-0918955-3. 2. Mr. Muhammad Farooq Shahzad S/o Shaikh Asmat Ullah CNIC No. 35202-2902531-9. 3. Mr. Bakhtiar Ahmed Ahmad S/o Sultan Ahmad CNIC No. 35202-8566682-1.

Decision by the Central Licensing Board in 262nd meeting:

The Board considered and approved the change of management of the company M/s Hirra Pharmaceuticals, (Pvt) Ltd [formerly M/s Hirra Pharmaceutical Laboratories], 13-KM, Asil Raiwind Road, Lahore as per Form-29 S.E.C.P

Previous Management as per Form-1A at the time of previous renewal	Added Management	Current Management as per Form-29& Form-A of SECP
1. Mr. Kamran Akhtar S/o Muhammad Akhtar Farooqi CNIC No. 54400-0918955-3. 2. Mr. Muhammad Farooq Shahzad S/o Shaikh Asmat Ullah CNIC No. 35202-2902531-9.	1. Mr. Bakhtiar Ahmed Ahmad S/o Sultan Ahmad CNIC No. 35202-8566682-1.	1. Mr. Kamran Akhtar S/o Muhammad Akhtar Farooqi CNIC No. 54400-0918955-3. 2. Mr. Muhammad Farooq Shahzad S/o Shaikh Asmat Ullah CNIC No. 35202-2902531-9. 3. Mr. Bakhtiar Ahmed Ahmad S/o Sultan Ahmad CNIC No. 35202-8566682-1.

Case No. 5. CHANGE OF MANAGEMENT OF M/S S. FAZALILAHI & SONS (PVT) LTD, LAHORE.

M/s S. Fazalilahi & Sons (Pvt) Ltd,1.5-Km, Sunder Road, Raiwind Lahore under DML No. 000765by way of formulation has submitted request for change in management of the firm as per Form-A of SECP along with prescribed Fee Challan of 50,000/- as under:-

Pervious Management as per Form-1	Retiring Management	Current Management as per Form-A of SECP
1. Mr. Parvez Ihsan. 2.Mr. Ikram Ilahi S/o Ihsan Ilahi CNIC No 42301-0920920-5. 3.Mr. Nusrat Ihsan S/o Ihsan Ilahi CNIC No. 42301-4672486-9. 4. Mr. Masood Ihsan S/o Pervaiz Ihsan CNIC No. 42201-0598768-7.	1. Mr. Parvez Ihsan.	1. Mr. Fazal Ihsan S/o Ikram Ilahi CNIC No. 42301-3699622-5. 2. Mr. Ikram Ilahi S/o Ihsan Ilahi CNIC No 42301-0920920-5. 3. Mr. Nusrat Ihsan S/o Ihsan Ilahi CNIC No. 42301-4672486-9. 4. Mr. Masood Ihsan S/o Pervaiz Ihsan CNIC No. 42201-0598768-7.

Decision by the Central Licensing Board in 262nd meeting:

The Board considered and approved the change of management of the company M/s S. Fazalilahi & Sons (Pvt) Ltd,1.5-Km, Sunder Road, Raiwind Lahore as per Form-29 of S.E.C.P

Pervious Management as per Form-1	**Retiring Management**	**Current Management as per Form-A of SECP**
1. Mr. Parvez Ihsan. 2. Mr. Ikram Ilahi S/o Ihsan Ilahi CNIC No 42301-0920920-5. 3. Mr. Nusrat Ihsan S/o Ihsan Ilahi CNIC No. 42301-4672486-9. 4. 4. Mr. Masood Ihsan S/o Pervaiz Ihsan CNIC No. 42201-0598768-7.	1. Mr. Parvez Ihsan.	1. Mr. Fazal Ihsan S/o Ikram Ilahi CNIC No. 42301-3699622-5. 2. Mr. Ikram Ilahi S/o Ihsan Ilahi CNIC No 42301-0920920-5. 3. Mr. Nusrat Ihsan S/o Ihsan Ilahi CNIC No. 42301-4672486-9. 4. Mr. Masood Ihsan S/o Pervaiz Ihsan CNIC No. 42201-0598768-7.

Case No. 6. CHANGE OF MANAGEMENT OF M/S MEDISEARCH PHARMACAL (PVT) LTD, LAHORE.

M/s Medisearch Pharmacal (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore under DML No. 000549by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-1A	**Retiring Management**	**Proposed Management as per Form-29**
1. Mr. Zafar Iqbal Nagra 2. Ms. Munzza Adeeb W/o Zafar Iqbal Nagra CNIC No. 35200-4345926-8.	1. Mr. Zafar Iqbal Nagra	1. Mr. Uzair Nagra S/o Zafar Iqbal Nagra CNIC No. 35200-6402918-7. 2. Ms. Munzza Adeeb W/o Zafar Iqbal Nagra CNIC No. 35200-4345926-8.

Decision by the Central Licensing Board in 262nd meeting:

The Board considered and approved the change of management of the company M/s Medisearch Pharmacal (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore as per Form-29 of S.E.C.P

Previous Management as per Form-1A	Retiring Management	Proposed Management as per Form-29
1. Mr. Zafar Iqbal Nagra 2. Ms. Munzza Adeeb W/o Zafar Iqbal Nagra CNIC No. 35200-4345926-8.	1. Mr. Zafar Iqbal Nagra	1. Mr. Uzair Nagra S/o Zafar Iqbal Nagra CNIC No. 35200-6402918-7. 2. Ms. Munzza Adeeb W/o Zafar Iqbal Nagra CNIC No. 35200-4345926-8.

Case No. 7. CHANGE OF MANAGEMENT OF M/S TAGMA PHARMA (PVT) LTD, LAHORE.

M/s Tagma Pharma (Pvt) Ltd, 12.5-Km, Raiwind Road, Lahore under DML No. 000414by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Pervious Management as per Form-29	Retiring Management	Current Management as per Form-29 & Form-A
1. Mr. Abdul Aleem Shami S/o Abdul Ishfaq Shami CNIC No. 35202-1691245-9. 2. Mr. Naeem Shami S/o Abdul Ishfaq Shami CNIC No.35202-4717733-9. 3. Mr. Shahid Nadeem Shami S/o Abdul Ishfaq Shami CNIC No. 35202-8856537-1.	1. Mr. Abdul Aleem Shami S/o Abdul Ishfaq Shami CNIC No. 35202-1691245-9. 2. Mr. Naeem Shami S/o Abdul Ishfaq Shami CNIC No.35202-4717733-9.	1. Mr. Shahid Nadeem Shami S/o Abdul Ishfaq Shami CNIC No. 35202-8856537-1. 2. Ms. Saima Nadeem W/o Shahid Nadeem Shami CNIC No. 35202-2745329-2.

Decision by the Central Licensing Board in 262nd meeting:

The Board considered and approved the change of management of the company M/s Tagma Pharma (Pvt) Ltd, 12.5-Km, Raiwind Road, Lahore as per Form-29 of S.E.C.P

Pervious Management as per Form-29	Retiring Management	Current Management as per Form-29 & Form-A
1. Mr. Abdul Aleem Shami S/o Abdul Ishfaq Shami CNIC No. 35202-1691245-9. 2. Mr. Naeem Shami S/o Abdul Ishfaq Shami CNIC No.35202-4717733-9. 3. Mr. Shahid Nadeem Shami S/o Abdul Ishfaq Shami CNIC No. 35202-8856537-1.	1. Mr. Abdul Aleem Shami S/o Abdul Ishfaq Shami CNIC No. 35202-1691245-9. 2. Mr. Naeem Shami S/o Abdul Ishfaq Shami CNIC No.35202-4717733-9.	1. Mr. Shahid Nadeem Shami S/o Abdul Ishfaq Shami CNIC No. 35202-8856537-1. 2. Ms. Saima Nadeem W/o Shahid Nadeem Shami CNIC No. 35202-2745329-2.

Case No. 8. CHANGE OF MANAGEMENT OF M/S INTERVAC (PVT) LTD, SHEIKHUPURA.

M/s Intervac (Pvt) Ltd, Lahore, 18-Km, Lahore Sheikhupura Road, Sheikhupura under DML No. 000623 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-29	Retiring Management	Proposed Management as per Form-29
1. Mr. Ashfaq Ahmad Khan S/o Mumtaz Ahmad Khan CNIC No. 35200-1539217-3. 2. Ms. Shaheen AshfaqW/o Ashfaq Ahmad Khan. 3. Mr. Tanzeel Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35200-2431677-3. 4. Mr. Adeel Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35201-6134003-0.	1.Ms. Shaheen AshfaqW/o Ashfaq Ahmad Khan.	1. Mr. Ashfaq Ahmad Khan S/o Mumtaz Ahmad Khan CNIC No. 35200-1539217-3. 2. Mr. Nabeel Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35200-4211473-1. 3. Mr. Tanzeel Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35200-2431677-3. 4. Mr. Talha Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35200-2431772-3. 5. Mr. Adeel Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35201-6134003-0.

Decision by the Central Licensing Board in 262nd meeting:

The Board considered and approved the change of management of the company M/s Intervac (Pvt) Ltd, Lahore, 18-Km, Lahore Sheikhupura Road, Sheikhupura as per Form-29 of S.E.C.P

Previous Management as per Form-29	Retiring Management	Proposed Management as per Form-29
1. Mr. Ashfaq Ahmad Khan S/o Mumtaz Ahmad Khan CNIC No. 35200-1539217-3. 2. Ms. Shaheen AshfaqW/o Ashfaq Ahmad Khan. 3. Mr. Tanzeel Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35200-2431677-3. 4. Mr. Adeel Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35201-6134003-0.	1.Ms. Shaheen AshfaqW/o Ashfaq Ahmad Khan.	1. Mr. Ashfaq Ahmad Khan S/o Mumtaz Ahmad Khan CNIC No. 35200-1539217-3. 2. Mr. Nabeel Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35200-4211473-1. 3. Mr. Tanzeel Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35200-2431677-3. 4. Mr. Talha Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35200-2431772-3. 5. Mr. Adeel Ahmad Khan S/o Ashfaq Ahmad Khan CNIC No. 35201-6134003-0.

Case No. 9. CHANGE OF MANAGEMENT OF M/S INVENTOR PHARMA, KARACHI

M/s Inventor Pharma. Plot No. K/196, S.I.T.E (SHW) Phase-II, Karachi under DML No. 000866 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-1	Added Management	Proposed Management as per Partnership Deed
1. Mr. Imtiaz Ahmad S/o Haji Muhammad CNIC No. 44103-3035579-5.	1. Muhammad Jameel Jokhio S/o Muhammad Sharif CNIC No. 42501-2678780-5.	1. Mr. Imtiaz Ahmad S/o Haji Muhammad CNIC No. 44103-3035579-5. 2. Muhammad Jameel Jokhio S/o Muhammad Sharif CNIC No. 42501-2678780-5.

Decision by the Central Licensing Board in 262nd meeting:

The Board considered and approved the change of management of the firm M/s Inventor Pharma. Plot No. K/196, S.I.T.E (SHW) Phase-II, Karachi as per Partnership deed.

Previous Management as per Form-1	Added Management	Proposed Management as per Partnership Deed
1. Mr. Imtiaz Ahmad S/o Haji Muhammad CNIC No. 44103-3035579-5.	2. Muhammad Jameel Jokhio S/o Muhammad Sharif CNIC No. 42501-2678780-5.	3. Mr. Imtiaz Ahmad S/o Haji Muhammad CNIC No. 44103-3035579-5. 4. Muhammad Jameel Jokhio S/o Muhammad Sharif CNIC No. 42501-2678780-5.

Case No. 10 CHANGE OF TITLE / NAME OF M/S WALT DANZAY PHARMACEUTICALS, PLOT NO. 35-A, SMALL INDUSTRIAL ESTATE, TAXILA.

M/s Walt Danzay Pharmaceuticals, Plot No. 35-A, Small Industrial Estate, Taxila,, DML No. 000856 by way of (Formulation) has submitted request for change of title / name of the firm from partnership deed to Private Limited along with prescribed Fee Challan of 50,000/- as under:-

Previous Title/legal status of firm	Proposed title/ legal status of Firm as per Certificate of incorporation of S.E.C.P
M/s Walt Danzay Pharmaceuticals, 35-A, Punjab Small Industrial Estate, Taxila.	Horizon Healthcare (Pvt) Ltd., 35-A, Punjab Small Industrial Estate, Taxila.

Decision by the Central Licensing Board in 262nd meeting:

The Board considered and approved the change of title/ name of the firm /company from M/s Walt Danzay Pharmaceuticals, Plot No. 35-A, Small Industrial Estate, Taxila to M/s Horizon Healthcare (Private) Limited, Plot No. 35-A, Small Industrial Estate, Taxila as per Form 29 and certificate issued by S.E.C.P as under

Previous Title/legal status of firm	Proposed title/ legal status of Firm as per Certificate of incorporation of S.E.C.P
M/s Walt Danzay Pharmaceuticals, 35-A, Punjab Small Industrial Estate, Taxila.	Horizon Healthcare (Pvt) Ltd., 35-A, Punjab Small Industrial Estate, Taxila.

Case No. 11 **CHANGE OF MANAGEMENT OF M/S HORIZON HEALTHCARE (PRIVATE) LIMITED [FORMERLY M/S WALT DANZAY PHARMACEUTICALS], PLOT NO. 35-A, SMALL INDUSTRIAL ESTATE, TAXILA**

M/s Horizon Healthcare (Private) Limited [formerly M/s Walt Danzay Pharmaceuticals], Plot No. 35-A, Small Industrial Estate, Taxila,, DML No. 000856 by way of (Formulation) has submitted request for change in management of the firm as per Form 29 along with prescribed Fee Challan of 50,000/- as under:-

PREVIOUS MANAGEMENT AS PER PARTNERSHIP DEED.	RETIRING MANAGEMENT AS PER SALE DEED	CURRENT MANAGEMENT AS PER FORM 29
i. Arshad Mehmood S/o Khushi Muhammad, CNIC No. 61101-6927558-3. ii. Muhammad Shahid S/o Muhammad Yaqoob, CNIC # 34101-7007738-5.	i. Arshad Mehmood S/o Khushi Muhammad, CNIC No. 61101-6927558-3. ii. Muhammad Shahid S/o Muhammad Yaqoob, CNIC # 34101-7007738-5.	i. Mr. Khurum Sayani S/o Allauddin CNIC # 42201-0493163-1. ii. Mr. Nazim Allauddin Sayani S/o Allauddin, CNIC # 42201-0493160-3. iii. Mrs. Shaista Nazim W/o Nazim Allauddin Sayani, CNIC # 42000-0481851-8.

Decision by the Central Licensing Board in 262nd meeting:

The Board considered and approved the change of management of the company M/s Horizon Healthcare (Private) Limited [formerly M/s Walt Danzay Pharmaceuticals], Plot No. 35-A, Small Industrial Estate, Taxila,as per Form 29 and certificate issued by S.E.C.P as under;

PREVIOUS MANAGEMENT AS PER PARTNERSHIP DEED.	RETIRING MANAGEMENT AS PER SALE DEED	CURRENT MANAGEMENT AS PER FORM 29
1. Arshad Mehmood S/o Khushi Muhammad, CNIC No. 61101-6927558-3. 2. Muhammad Shahid S/o Muhammad Yaqoob, CNIC # 34101-7007738-5.	1. Arshad Mehmood S/o Khushi Muhammad, CNIC No. 61101-6927558-3. 2. Muhammad Shahid S/o Muhammad Yaqoob, CNIC # 34101-7007738-5.	1. Mr. Khurum Sayani S/o Allauddin CNIC # 42201-0493163-1. 2. Mr. Nazim Allauddin Sayani S/o Allauddin, CNIC # 42201-0493160-3. 3. Mrs. Shaista Nazim W/o Nazim Allauddin Sayani, CNIC # 42000-0481851-8.

Case No. 12 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S SYNTEX PHARMACEUTICALS, KAMRA ROAD ATTOCK CITY.**

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

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

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

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

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

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

Proceedings and Decision of Central Licensing Board in 262nd meeting

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

Case No.13 RENEWAL OF DRUG MANUFACTURING LICENSE NO. (000209) (FORMULATION) OF M/S CHIESI PHARMACEUTICALS (PVT) LTD [FORMERLY M/S JAMSON PHARMACEUTICALS LABS], MULTAN.

M/s Chiesi Pharmaceuticals (Pvt) Ltd [formerly M/s Jamson Pharmaceuticals Labs], 88-A, Industrial Estate, Multan was issued the License No. 000209 (Formulation) the application for renewal of DML is not received.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 27-06-2014 to 26-06-2019has not been received till date. Moreover, Federal Inspector of Drugs, Lahore has reported that he has visited the premises of the firm and no any person was available and gate was locked. He knocked the door many times but no any response was received. Moreover, no any corresponding record or any status of the firm is available in his office file regarding availability of its DML. Therefore, DML No. 000209 (Formulation) M/s Chiesi Pharmaceuticals (Pvt) Ltd [formerly M/s Jamson Pharmaceuticals Labs], 88-A, Industrial Estate, Multan may be declared as invalid hence cancelled.

Proceedings and Decision of Central Licensing Board in 262nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 6 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Chiesi Pharmaceuticals (Pvt) Ltd [formerly M/s Jamson

Pharmaceuticals Labs], 88-A, Industrial Estate, Multan under DML No. 000209 by way of formulation may not be declared cancelled by Central Licensing Board.

Case No. 14 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HANSEL PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Hansel Pharmaceuticals (Pvt) Ltd, Plot NO. 2, Pharma City, 30-Km, Multan Road, Lahore had applied for renewal of DML No. 000581 by way of Formulation for the period of 24-06-2015 to 23-06-2020 on 19-05-2015.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 9thNovember, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Details of premises including L.O.P.
2. Form – 29 from S.E.C.P along with attested copies of CNIC and affidavit regarding any change from previous renewal.
3. Approval letter of Q.C & Production manager or documents for approval.

The firm replied to this letter on 19th December 2016. Meanwhile, the firm had filed application for approval of Quality Control Incharge. Final Reminder letter was issued on 16th March, 2018 to the firm for submission of following documents.

1. Detail of management at the time of previous renewal and at present renewal, if any change, prescribed fee of Rs.50, 000/- for change in management.
2. Updated Form-29 duly attested from S.E.C.P.
3. Nothing due certificate regarding CRF from STO (updated).
4. Proof of all sections issued by Central Licensing Board.
5. Approval letter of Production Incharge, if and change then complete set of duly attested documents for Proposed Production Incharge (as per checklist).
6. Experience Certificate ofQuality Control Incharge from Hoover Pharmaceutical.
7. Copy of CNIC of proposed Quality Control Incharge.
8. **All documents should be duly attested.**

The firm submitted documents on 16th April, 2018 in reply to Final Reminder but following application for renewal of DML is still incomplete with following documents being deficient.

i. Submitted documents of Production Incharge are not duly attested.

ii. Resignation / retirement of earlier Production Incharge is not provided.

iii. Form-29 not attested from S.E.C.P.

Proceedings and Decision of Central Licensing Board in 262nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Hansel Pharmaceuticals (Pvt) Ltd, Plot NO. 2, Pharma City, 30-Km, Multan Road, Lahore under DML No. 000581 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 15 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S OVAL PHARMACEUTICALS , LAHORE.

M/s Oval Pharmaceuticals, 112/111, Quaid-e-Azam Industrial Estate, Town Ship, Lahore had applied for renewal of DML No. 000156 by way of Formulation for the period of 21-07-2014 to 20-07-2019 on 22-07-2014.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 17th October, 2014 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Your application for renewal of Drug Manufacturing License was received in this office on 25-07-2014 and copy of challan receipt of prescribed fee for renewal has been retained by STO, DRAP, Islamabad on 22-07-2014, hence date of receiving of your application in this Division is 22-07-2014. Therefore, under Rule 6 of Drugs (licensing, Registering & Advertising) Rules, 1976, you are required to deposit additional surcharge of Rs. 10,000/- for submitting renewal application delayed by two days from due date of renewal i.e. 20-07-2014.
2. To enlist the re-packing products and to deposit prescribed fee of Rs. 5,000/- for each product of re-packing for purpose of renewal.

3. Documents of production Incharge Mr. Ifthikhaar Hussain and Q.C Incharge Mr. Shoib Hussain as per checklist enclosed herewith. **All documents / information should be attested by gazette officer / notary public andalso signed and stamp by authorized Director / Owner of the firm.**

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

The firm replied to this letter on 26th November2014 but application was incomplete with following shortcomings and reminder letter was issued on 14th June, 2017 to the firm for completion of application:

1. Form C/D from registrar of firm for any change partnership / management of firm along with details of previous and new management along with requisite fee for change of management if any (attested).
2. N.O.C for CRF Attested.
3. Proof of all licensed/approved sections (Attested).

The firm submitted documents on 27th July, 2017 in reply to Reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Updated Nothing due certificate for CRF.
ii. Copy of approved master layout plan.
iii. Proof of CLB approved sections.
iv. Detail of management at the time of previous renewal and at present & if any change, prescribe fee of Rs. 50,000/- along with proper application for change of management.
v. Duly attested copy of Partnership deed along with CNIC copies of all partners.

Proceedings and Decision of Central Licensing Board in 262nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Oval Pharmaceuticals, 112/111, Quaid-e-Azam Industrial Estate, Town Ship, Lahore under DML No. 000156 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 16 **RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000469 AND GRANT OF ADDITIONAL SECTION OF M/S PERFECT PHARMA (PVT) LTD, LAHORE.**

M/s Perfect Pharma (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore had applied for renewal of DML No. 000469 by way of Formulation for the period of 01-03-2015 to 28-02-2020.

Proceedings and Decision of Central Licensing Board in 252nd meeting

The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 01-03-2015 to 28-02-2020 for the following sections

(i) External Preparation Section (Re-Packing) Ground Floor.
(ii) Cream/Ointment (General) First Floor.

The Board also allowed resumption of production on the recommendations of the panel for the above sections.

The Board however, deferred the renewal of Drug manufacturing Licence of following sections on the recommendations of the panel

- Tablet General
- Tablet (Psychotropic) (Ground Floor)
- Capsule (General) (Ground Floor)

The Board also authorized same panel for the purpose of verification of improvements and recommendations for resumption and renewal of deferred sections.

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

A letter was issued on 24th April, 2017 for inspection of the deferred sections of the firm.

Following Panel of Inspectors conducted the inspection on 09-02-2018.

1. Dr. Ikram-ul-Haq, Member Central Licensing Board.
2. Prof. Mubashir Butt, Gullab Davi Hospital, Lahore.
3. Mr. Abid Saeed Bag, Punjab Quality Control Board, Lahore (he could not join the panel due to his other official / professional commitment)
4. Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore.

Now inspection report is received and the conclusion is as under:

"Keeping in view the facilities like building, HVAC system, machinery and equipment, Instruments, personnel, documentation, Quality Control, testing facilities, the panel of

inspectors is of the opinion to recommend the renewal of Drug Manufacturing License of the following section to M/s Perfect Pharma (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore.

1. *Tablet (General) Section.*
2. *Capsule (General) Section.*

The panel also recommend the grant the following additional section to M/s Perfect Pharma (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore.

1. *Tablet (Psychotropic) Section".*

Proceedings and Decision of Central Licensing Board in 262nd meeting

The Board considering the facts on the record and recommendations of the panel of experts/ inspector decided renewal of Drug Manufacturing License of the following sections of M/s Perfect Pharma (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore.

3. Tablet (General) Section.
4. Capsule (General) Section.

2. The Board also granted approval of following additional section to M/s Perfect Pharma (Pvt) Ltd, 5-Km, Raiwind Manga Road, Lahore on the recommendations of the panel of experts/ inspector.

1. Tablet (Psychotropic) Section".

Case No.17. M/S POLYFINE CHEMPHARMA, 51-HAYATABAD INDUSTRIAL ESTATE, PESHAWAR – VIOLATION OF RULE 5(2A) & RULE 16 OF DRUGS (L,R&A) RULES, 1976.

M/s Polyfine Chempharma, Peshawar submitted the application for renewal of DML No. 000216 by way of formulation on 16-02-2016 for the period of 14-03-2016 to 13-03-2021, which was well on time as due date of renewal of said DML was 13-03-2016.

After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. To provide name of registered drugs.
ii. To provide details of premises including approved layout plan of the factory.
iii. Proof of approval of all licensed sections.
iv. No Objection Certificate for Central Research Fund (CRF) by Statistical Officer DRAP, Islamabad.

With reference to above letter, it is mentioned that as per available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. Licensing Division again issued reminder for completion of application of renewal of DML to the firm for information / documents as under;

i. To provide name of registered drugs.
ii. To provide details of premises including approved layout plan of the factory.
iii. Proof of approval of all licensed sections.
i. No Objection Certificate for Central Research Fund (CRF) by Statistical Officer DRAP, Islamabad

The firm submitted shortcoming documents as under;

i. List of names of registered drugs.
ii. Details of premises including approved layout plan of the factory.
iii. Proof of approval of all licensed sections.
iv. No Objection Certificate for Central Research Fund (CRF) by Statistical Officer DRAP, Islamabad.

Meanwhile, M/s Oakdale Pharmaceuticals, Peshawar submitted application for approval of Mr. Subhash Chandar as QC Incharge wherein they submitted experience letter purported to be issued by M/s Polyfine Chempharma, Peshawar mentioning that Mr. Subhash Chandar has resigned on 31st August, 2015 from M/s Polyfine Chempharma, Peshawar. But M/s Polyfine Chempharma, Peshawar in their DML renewal application dated 15-02-2016 claimed that they have not changed their QC Incharge since the previous renewal (14-03-2011 to 13-03-2016) and Mr. Subhash Chandar who was their approved QC Incharge at the time of previous renewal is still working with them.

A letter was issued to M/s Polyfine Chempharma, Peshawar to clarify their position regarding the resignation of their QC Incharge. Now the firm has declared that their QC Incharge Mr. Subhash Chandar resigned on 31-08-2015 and submitted documents of new QC Incharge in which following shortcoming has been observed;

i. The experience of proposed QC Incharge is less than prescribed experience of ten (10) years.

Decision of 252nd meeting of CLB.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of Drug Manufacturing Licence No. 000216 by way of formulation of M/s Polyfine Chempharma, Peshawar may not be rejected by Central Licensing Board.

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

A show cause notice dated 19th April, 2017 was issued to the firm.

Reply of the firm.

In this connection we explain our position as under:

1. that, we received a letter No. F.3-1/2006-Lic dated 07th April, 2016, asking us tosubmit the short documents required for the renewal of our Drugs ManufacturingLicense. The reply along with the requisite documents was submitted to thisAuthority on 13th April, 201G, vide our letter reference No. PC/TM/16 dated 13-04-016. (copy enclosed for ready reference).
2. That again we received a reminder vide letter No. F.3-1/97-Lic dated 28November 2016, asking us to submit information about approved layout plan,up to date CRF and list of products etc. The requisite information was providedto this Authority vide our letter No. PC/DRAP/LIC/16 date C7-12-2016. (copyenclosed for ready reference).
3. That we received a letter No. F.3-1/97-Lic. Dated 13th March 2017 asking us toclarity our position about the Quality Control Incharge and the reply to the saidletter was submitted to this authority vide letter No. PC/DRAP/LIC/17/03 Dated30-03-2017. (copy enclosed for ready reference)
4. That the proposed QC Incharge Mr. Shah Mehmood has been working in our QCDepartment since 16-05-2005, and presently he possesses an experience of 23Years in Quality Control. Copies of his experience certificates are enclosed forready reference). His name was present in the "List of Technical Staff" submitted with our previous renewal applications of 27th February 2006 and 25th February2011. As per record of the Ministry of Health, his last appointment was in JafsonPharmaceuticals Pvt Ltd. Peshawar on 14th May 2004, as Incharge QC. (copy ofthe MOH approval letter enclosed).
5. That in the meanwhile during the interim period our previous QC Incharge Mr.Subhash Chandar had been coordinating with us and was contractually supervising and observing our quality operations and documentation etc on regular basis.

We assure this authority and all concerned that we take particular care of the quality and standards of the products, manufactured and marketed by us, as that is the only way we can compete against the other players in the field.

Once again assuring you of our full obedience and compliance to the directions of theauthorities and strict adherence to GMP and cGMP requirements.

The firm has been called for personal hearing vide Licensing Division's letter dated 08-05-2017. Mr. Naeem Shahzad, Director and Mr. Shah Mahmood, Quality Control Manager. They contended that

Mr.Subhash Chandar , previously approved Quality Control Incharge left them in 2015 and Mr. Shah Mehmood has been signing the Quality Control reports.

Decision of Central Licensing Board in 253rd meeting

The Board after hearing the representative of the firm and perusal of facts on record noted that firm has been changing their statement and has been releasing medicines in the market without Quality checks. Therefore, the Board decided to:

i. Case may be referred to QA/LT Division for investigation regarding releasing of medicines without Quality checks.
ii. Suspend the licence of M/s Polyfine Chempharma, Peshawar Drug Manufacturing Licence No. 000216 by way of formulation for a period of three months from the date of issuance of letter.
iii. Documents submitted for completion of application for renewal of Drug manufacturing Licence shall be evaluated by the Division of Licensing and case would be brought before the Board in next the next meeting.

Before approval of the minutes of the meeting, the firm filed a Writ Petition challenging the Show Cause Notice issued to him. The Peshawar High Court, Peshawar disposed off the Writ Petition with the direction to the Appellate Board to consider the Writ Petition as an Appeal and decide the matter accordingly. The Appellate Board heard the case in 148th meeting and decided the case as under:

> *"The Board after hearing arguments and perusing record, observed that the firm did not take approval of the new Quality Control Incharge from the Licensing Division which is a mandatory requirement under Drugs (L,R&A) Rules, 1976 to ensure safety, efficacy and quality of drug. The Show Cause Notice dated 19.04.2017 was rightly issued by the Central Licensing Board in the prevailing facts and circumstances. The Board directed the firm to submit documents related to appointment and experience of proposed Quality Control Incharge to the Licensing Division which shall evaluate and decide the matter for compliances within thirty (30) days after giving personal hearing to the appellant."*
>
> *The matter of manufacturing and selling the medicine without provision of approved quality control incharge shall be strictly dealt by the licensing board or be referred to the QT/LT Division for investigation and to take legal action under drugs laws and rules.*

Proceedings of Licensing Division in compliance to the decision of Appellate Board

The firm has submitted all the required documents for approval of technical staff (quality control incharge)by licensing division which has been approved and application for renewal of DML No. 000216 (Formulation) is now complete.

Proceedings and Decision of Central Licensing Board in 262nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to constitute the following panel of inspectors / experts for renewal of Drug Manufacturing Licence.

1. Prof. Dr. Jamshaid Ali Khan, Professor of Pharmacy, University of Peshawar, Peshawar
2. Dr. Abbas Khan, Chief Drug Inspector, Department of Health, KPK
3. Additional Director (Licensing), DRAP, Islamabad
4. Area Federal Inspector of Drugs, DRAP, Peshawar.

The said panel shall also investigate matter of manufacturing and selling the medicine without provision of approved quality control incharge and shall submit report for the consideration of the Board.

Case No. 18 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ALINA COMBINE PHARAMCEUTICALS (PVT) LTD., KARACHI.

M/s Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi had applied for renewal of DML No. 000441 by way of formulation on 19-11-2014for the period of 30-10-2014 to 29-10-2019. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 22-12-2015under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. To deposit late fee surcharge of 08 days @ Rs.5,000/day.
2. To submit approval letter of QC Incharge.
3. To submit DML renewal application on prescribed Form-1A (enclosed).
4. List of total section of the firm and their letters for grant which were approved in meetings of Central Licensing Board.
5. To furnish updated Nothing Due Certificate issued by the Statistical Officer, DRAP, Islamabad regarding deposition of Central Research Fund.

The firm submitted documents on 23-09-2016 but following documents were still deficient /short and another letters were issued on 18-11-2016 to the firm with following shortcomings: -

1. Latest Form-29 duly attested alongwith attested CNIC copies of all Directors at present renewal and also at previous renewal.
2. NOC of latest CRF.
3. Approval letter of Production Incharge.
4. Attested Academic certificates of QC Incharge/Production Incharge.
5. Required Fee of Rs.5,000/- for change of QC Incharge.
6. Job acceptance letter of QC Incharge/Production Incharge.
7. Attested registration certificate of Pharmacy Council of Production Incharge.
8. Resignation letter of proposed QC Incharge/Production Incharge.
9. Resignation letter of previously approved Production Incharge.

The firm submitted documents on 27-12-2016 in reply to above mentioned letters. Upon Evaluation following shortcoming were present and a reminder was issued on 31-01-2017 with the following shortcomings;

1. Attested Academic certificates of QC Incharge/Production Incharge.
2. Attested registration certificate of Pharmacy Council of Production Incharge.
3. Attested CNIC copy of Production Incharge.
4. Attested resignation letter of previously appointed Production Incharge.
5. Attested resignation letter of Production Incharge from previous firm.
6. Attested job acceptance/appointment letter of proposed Production Incharge.
7. Attested experience certificates of Production Incharge.
8. Attested complete set of documents of QC Incharge (checklist enclosed) alongwith prescribed fee for change of QC Incharge.

No reply was received in response to above reminder and the firm was issued final reminder on 23-08-2017 with the following shortcomings;

1. Latest Form-29 duly attested alongwith attested CNIC copies of all Directors at present renewal and also at previous renewal.
2. NOC of latest CRF updated.
3. Approval letters of sections issued by CLB or submit master layout plan for regularization.
4. Complete set of attested documents of proposed QC Incharge alongwith prescribed fee.
5. Complete set of attested documents of proposed Production Incharge alongwith prescribed fee.

The firm has submitted documents in response to above final reminder. Upon evaluation following documents are still deficient;

1. NOC of latest CRF updated.
2. Complete set of attested documents of proposed Production Incharge and QC Incharge as per checklist.
3. Updated Form-29 & Form-A duly attested from S.E.C.P.
4. Attested copies of CNIC's of all directors
5. Approval/Grant of sections issued from CLB.
6.

Proceedings and Decision of Central Licensing Board in 260th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi DML No. 000441 by way of Formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

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

Before issuance of minutes of 260th meeting of CLB firm has submitted the required documents and application of renewal of DML is complete. Therefore, show cause notice was not issued to the firm.

Proceedings and Decision of Central Licensing Board in 262nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to revoke the Show Cause Notice with the warning to the firm to be careful in future for compliance of law.

QUALITY CONTROL CASES

Case No.1 **Request For lodging FIR 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.**

1. DRAP team conducted the raid on 06-03-2018 at the premises of M/s Everest Pharmaceuticals 124-industiral Triangle kahuta Road Islamabad. The firm was found in manufacturing of unregistered 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 FIR No. 05/2018 was registered in FIA/ACC Islamabad for contravention of the DRAP Act 2012/Drug Act 1976 and rules made thereunder against the following persons namely:

1. Ch. Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran izhar (owner of M/s Everest pharmaceuticals)
3. Noor Muhammad Mahar (owner of M/s Everest pharmaceuticals)
4. Mian Ishtiaq Ahmed (QC incharge), M/s Everest Pharmaceuticals

Accordingly, a letter No. F. 13-08/2018-QC dated 14-03-2018 was written to the Deputy Collector G-II MCC Appraisement (West) Karachi for providing complete import record of pharmaceuticals raw materials imported by the M/s Everest Pharmaceuticals during the last three years along with copies of Assistant Director (I&E) DRAP, stamped invoices submitted by the firm. The Customs Colectorate, 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 material imported by M/s Everest Pharmaceuticals 86-G, Model Town Lahore vide letter SI/Misc/15/2018 Group II dated 22-03-2018

2. The details of consignments is given below:-

SR.NO	NAME OF INDUSTRY/ SUPPLIER	INVOICE NO.	INVOICE DATE	RAW MATERIAL	QUANTITY	PERPORTEDLY RELEASED BY
1	M/S ARSHINE PHARMACEUTICAL CO,LIMITED	ZY201509037	17.09.2015	NAPROXEN SODIUM	500KG	SAIRA NAEEM
2	M/S HAZHOU CITY LINGHU XINWANG CHEMICALS, LTD. CHINA	XW150701	01.07.2015	MAGNESIUM STEARATE	1000KG	SAIRA NAEEM
3	M/S LA PALMA HOLLAND BV, HOLAND	4182-01	31.05.2015	LACTOSE MONOHYDRATE	2.60KG	SAIRA NAEEM

4	M/S AFINE CHEMICALS LIMITED, CHINA	HF15089	04.05.2015	TRIS (HYDROXYMETHYL) AMINO METHANE	300KG	SAIRA NAEEM
5	M/S MINGTAI CHEMICAL CO, LTD.TAIWAN	MT-1505115	07.05.2015	MICROCRYSTALLINE CELLULOSE	2000KG	SAIRA NAEEM
6	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15003	02.04.2015	XANTHAN GUM OHARMA GRADE 200MESH	25KG	SAIRA NAEEM
7	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15001	02.04.2015	XANTHAN GUM OHARMA GRADE 200MESH	25KG	SAIRA NAEEM
8	M/S NINGBO FREE TRADE ZONE MEDICIN PHARMACEUTICAL CO, LTD. CHINA	FS02E0118	04.03.2015	CLOTRIMAZOLE	100KG	SAIRA NAEEM
9	M/S IMPERIAL CHEM, INCORPORATION, INDIA	CJ/E/141	16.12.2014	IRON III HYDROXIDE POLYMALTOSE COMPLEX	500KG	SAIRA NAEEM
10	M/S DEPEW FINE CHEMICAL CO, LTD. CHINA	DE14W004	31.12.2014	CLOTRIMAZOLE	100KG	SAIRA NAEEM
11	M/S ZHEJIANG APELOA KANGYU PHARMACEUTICAL CO,LTD. CHINA	214835	09.03.2016	LEVOFLOXACIN	500KG	SAIRA NAEEM
12	M/S HAZHOU CITY LINGHU XINWANG CHEMICALS, LTD. CHINA	XW160121	21.01.2016	MICROCRYSTALLINE CELLULOSE	3000KG	SAIRA NAEEM
13	M/S 366 PHARMA (NANJING) CO, LTD. CHINA	366160217B2	17.02.2016	ASPARTAME	100KG	SAIRA NAEEM
14	M/S HANGZHOU	CMT160305	10.03.2016	PIROXICAMBCD	500KG	SAIRA NAEEM

	MAYTIME BIO-TECH CO,LTD. CHINA					
15	M/S BAKUL PHARMA PRIVATE LIMITED, INDIA	BPPL/EXP/42/15-16	31.08.2015	DOXOFYLLINE	200KG	SAIRA NAEEM
16	M/S INAVIR PHARMA TECH PVT LTD. INDIA	EXP/PPL/24/15-16	29.06.2015	GABAPANTIN	300KG	SAIRA NAEEM
17	M/S INFOARK CO,LTD. CHINA	2151010290	27.07.2015	GLUCOSAMINE SULFATE	500KG	SAIRA NAEEM
18	M/S SINOCHEM QINGDAO CO,LTD. CHINA	N15AD23387	15.06.2015	PHLOROGLUCINNOL DIHYDRATE, TRIMETHY	100KG, 100KG	SAIRA NAEEM
19	M/S INFOARK CO,LTD. CHINA	2151020300	03.08.2015	PIROXICAM BCD	510KG	SAIRA NAEEM
20	M/S NINGBO FREE TRADE ZONE MEDICIN PHARMACEUTICAL CO, LTD. CHINA	FS10E0503	15.06.2015	CLOTRIMAZOLE	100KG	SAIRA NAEEM
21	M/S BAKUL PHARMA PRIVATE LIMITED, INDIA	BPPL/EXP/32/16-17	10.08.2016	DOXOFYLLINE	200KG	SAIRA NAEEM
22	M/S JIANGXI TIANXIN PHARMACEUTICAL CO,LTD. CHINA	16JXTXI-0842	21.06.2016	VITAMIN B6 HCL	100KG	SAIRA NAEEM
23	M/S INFOARK CO,LTD. CHINA	2161010493	20.10.2016	PIROXICAM BCD	1005KG	SAIRA NAEEM
24	M/S ARSHINE PHARMACEUTICAL CO,LIMITED	ZY201605123	14.06.2016	PVP K-30	350KG	SAIRA NAEEM
25	M/S GLUFIC BIOSCIENCES LIMITED, INDIA	GBSL/109/16-17	25.08.2016	LIDOCAINE HCL	100KG	SAIRA NAEEM
26	M/S SHANDONG	16HD6103	14.06.2016	METHYL CELLULOSE	400KG	SAIRA NAEEM

	HEAD CO.LTD CHINA					
27	M/S SHANGHAI WELLTONE MATERIAL TECHNOLOGY CO,LTD. CHINA	16WT190613	13.06.2016	CROSPOVIDONE USP26	400KG	SAIRA NAEEM
28	**M/S LOHITHA LIFESCIENCES PVT, LTD. INDIA**	**11**	**24.02.2016**	**DOMPERIDONE BASE, DOMPERIDONE MALEATE**	**200KG, 25KG**	**ATIQ UL BARI**
29	M/S INFOARK CO,LTD. CHINA	2151010442	10.10.2015	CLOTRIMAZOLE	150KG	SAIRA NAEEM
30	M/S ARSHINE PHARMACEUTICAL CO,LIMITED	ZY201603134	08.04.2016	PVP K-30	300KG	SAIRA NAEEM
31	M/S ZHEJIANG TIANXIN PHARMACEUTICAL CO, LTD. CHINA	17TXI-996	01.04.2017	NAPROXEN SODIUM	1000KG	SAIRA NAEEM
32	M/S JAINGXI SYNERGY PHARMACEUTICAL, IMPORT AND EXPORT CO,LTD. CHINA	JXS170827	21.09.2017	ACECLOFENAC EP4	500KG	SAIRA NAEEM
33	M/S ZHEJIANG JIANFENG INTERNATIONAL TRADE CO ,LTD. CHINA	ZC17003	06.02.2017	CLOTRIMAZOLE	21KG	SAIRA NAEEM
34	M/S METROCHEM API PRIVATE LTD, INDIA	AE293	23.11.2016	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	300KG	SAIRA NAEEM
35	M/S JIANGXI TIANXIN PHARMACEUTICAL CO,LTD. CHINA	JXS170239	03.03.2017	GABAPANTIN	1000KG	SAIRA NAEEM
36	M/S MALLADI DRUGS & PHARMACEUTICALS LIMITED, INDIA	MS-EXP1651652582	28.02.2017	FEXOFENADINE HCL	500KG	SAIRA NAEEM

37	M/S METROCHEM API PRIVATE LTD, INDIA	AE303	29.11.2016	PANTOPERAZOLE SODIUM	300KG	SAIRA NAEEM
38	M/S SINOCHEM QINGDAO CO,LTD. CHINA	N16AD59521	27.10.2016	PHLOROGLUCINNOL DIHYDRATE	500KG	SAIRA NAEEM
39	M/S METROCHEM API PRIVATE LTD, INDIA	AE073	31.05.2016	OMEPRAZOLE	200KG	SAIRA NAEEM
40	M/S 366 PHARMA (NANJING) CO, LTD. CHINA	366161104B1	04.11.2016	ASPARTAME	200KG	SAIRA NAEEM

03. 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 pharmaceuticals raw materials stands illegal in violation of Drug (import &Export) Rules, 1976 framed under the Drug Act 1976.

04. As the records 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 pharmaceutical 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 Panel Code and Clause (I) (e) of the paragraph A of the Schedule-II of the DRAP Act 2012 read with Section 23 (1)(a)(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.

05. The permission to lodge FIR against the responsible accused persons was given vide letter No. F.13-8/18-QC dated 17-04-2018 of the DRAP Islamabad by Director QA/LT DRAP, Islamabad.

06. The FID Lahore has already requested to FIA for registration of FIR for illegally importing pharmaceutical raw material through forged import authorization and without any Drug Import license and take strict legal action 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. Mian Ishtiaq Ahmed(QC incharge), M/s Everest Pharmaceuticals

07. The case is submitted for consideration of the CLB for ratification/endorsement of the order issued by the Director QA/LT, DRAP Islamabad being authorized by the CLB to grant permission for registration of FIR against the accused persons. It is further submitted that there are 39 consignments of pharmaceuticals raw materials which were released by the Custom authorities on the submission of forged documents by M/s Everest Pharmaceuticasl without obtaining import license under the Drugs (Import & Export) rules 1976. This is also cognizable offence under the Drug Act 1976/DRAP Act 2012. It is therefore submitted that all the 39 permissions may be ratified

01. Decision of 262nd Meeting of CLB:-

The CLB considered the record, reports and invoices of the 39 consignments forwarded by Custom Authorities regarding Pharmaceuticasl Raw Materials imported by Everest Pharmaceuticals through forged documents, reply by Ms Saira Naeem ADC received through and response of Lahore office vide their letter No. 7014/2018-DRAP(AD-IV) dated 23rd May 2018. The CLB unanimously decided that as per official record available M/s Everest Pharmaceutical prepared forged documents and imported pharmaceutical raw materials without obtaining Drug Import license as required under the Drug Act 1976 and Drugs (Import & Export Rules) 1976. Already permission granted by the Director QA/LT being authorized by the CLB for granting permission registration of FIR against the accused persons mentioned in para 6 of this case was endorsed/ratified by CLB for the registration of 39 FIRs in the following consignments.

SR.NO	NAME OF INDUSTRY/ SUPPLIER	INVOICE NO.	INVOICE DATE	RAW MATERIAL	QUANTITY	PERPORTEDLY RELEASED BY
1	M/S ARSHINE PHARMACEUTICAL CO,LIMITED	ZY2015090037	17.09.2015	NAPROXEN SODIUM	500KG	SAIRA NAEEM
2	M/S HAZHOU CITY LINGHU XINWANG CHEMICALS, LTD. CHINA	XW150701	01.07.2015	MAGNESIUM STEARATE	1000KG	SAIRA NAEEM
3	M/S LA PALMA HOLLAND BV, HOLAND	4182-01	31.05.2015	LACTOSE MONOHYDRATE	2.60KG	SAIRA NAEEM
4	M/S AFINE CHEMICALS LIMITED, CHINA	HF15089	04.05.2015	TRIS (HYDROXYMETHYL) AMINO METHANE	300KG	SAIRA NAEEM
5	M/S MINGTAI CHEMICAL CO, LTD.TAIWAN	MT-1505115	07.05.2015	MICROCRYSTALLINE CELLULOSE	2000KG	SAIRA NAEEM
6	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15003	02.04.2015	XANTHAN GUM OHARMA GRADE 200MESH	25KG	SAIRA NAEEM
7	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15001	02.04.2015	XANTHAN GUM OHARMA GRADE 200MESH	25KG	SAIRA NAEEM

8	M/S NINGBO FREE TRADE ZONE MEDICIN PHARMACEUTICAL CO, LTD. CHINA	FS02E0118	04.03.2015	CLOTRIMAZOLE	100KG	SAIRA NAEEM
9	M/S IMPERIAL CHEM, INCORPORATION, INDIA	CJ/E/141	16.12.2014	IRON III HYDROXIDE POLYMALTOSE COMPLEX	500KG	SAIRA NAEEM
10	M/S DEPEW FINE CHEMICAL CO, LTD. CHINA	DE14W004	31.12.2014	CLOTRIMAZOLE	100KG	SAIRA NAEEM
11	M/S ZHEJIANG APELOA KANGYU PHARMACEUTICAL CO,LTD. CHINA	214835	09.03.2016	LEVOFLOXACIN	500KG	SAIRA NAEEM
12	M/S HAZHOU CITY LINGHU XINWANG CHEMICALS, LTD. CHINA	XW160121	21.01.2016	MICROCRYSTALLINE CELLULOSE	3000KG	SAIRA NAEEM
13	M/S 366 PHARMA (NANJING) CO, LTD. CHINA	366160217B2	17.02.2016	ASPARTAME	100KG	SAIRA NAEEM
14	M/S HANGZHOU MAYTIME BIO-TECH CO,LTD. CHINA	CMT160305	10.03.2016	PIROXICAMBCD	500KG	SAIRA NAEEM
15	M/S BAKUL PHARMA PRIVATE LIMITED, INDIA	BPPL/EXP/42/15-16	31.08.2015	DOXOFYLLINE	200KG	SAIRA NAEEM
16	M/S INAVIR PHARMA TECH PVT LTD. INDIA	EXP/PPL/24/15-16	29.06.2015	GABAPANTIN	300KG	SAIRA NAEEM
17	M/S INFOARK CO,LTD. CHINA	2151010290	27.07.2015	GLUCOSAMINE SULFATE	500KG	SAIRA NAEEM
18	M/S SINOCHEM QINGDAO CO,LTD. CHINA	N15AD23387	15.06.2015	PHLOROGLUCINNOL DIHYDRATE, TRIMETHY	100KG, 100KG	SAIRA NAEEM

19	M/S INFOARK CO,LTD. CHINA	2151020300	03.08.2015	PIROXICAM BCD	510KG	SAIRA NAEEM
20	M/S NINGBO FREE TRADE ZONE MEDICIN PHARMACEUTICAL CO, LTD. CHINA	FS10E0503	15.06.2015	CLOTRIMAZOLE	100KG	SAIRA NAEEM
21	M/S BAKUL PHARMA PRIVATE LIMITED, INDIA	BPPL/EXP/32/16-17	10.08.2016	DOXOFYLLINE	200KG	SAIRA NAEEM
22	M/S JIANGXI TIANXIN PHARMACEUTICAL CO,LTD. CHINA	16JXTXI-0842	21.06.2016	VITAMIN B6 HCL	100KG	SAIRA NAEEM
23	M/S INFOARK CO,LTD. CHINA	2161010493	20.10.2016	PIROXICAM BCD	1005KG	SAIRA NAEEM
24	M/S ARSHINE PHARMACEUTICAL CO,LIMITED	ZY201605123	14.06.2016	PVP K-30	350KG	SAIRA NAEEM
25	M/S GLUFIC BIOSCIENCES LIMITED, INDIA	GBSL/109/16-17	25.08.2016	LIDOCAINE HCL	100KG	SAIRA NAEEM
26	M/S SHANDONG HEAD CO.LTD CHINA	16HD6103	14.06.2016	METHYL CELLULOSE	400KG	SAIRA NAEEM
27	M/S SHANGHAI WELLTONE MATERIAL TECHNOLOGY CO,LTD. CHINA	16WT190613	13.06.2016	CROSPOVIDONE USP26	400KG	SAIRA NAEEM
28	M/S INFOARK CO,LTD. CHINA	2151010442	10.10.2015	CLOTRIMAZOLE	150KG	SAIRA NAEEM
29	M/S ARSHINE PHARMACEUTICAL CO,LIMITED	ZY201603134	08.04.2016	PVP K-30	300KG	SAIRA NAEEM
30	M/S ZHEJIANG TIANXIN PHARMACEUTICAL CO, LTD. CHINA	17TXI-996	01.04.2017	NAPROXEN SODIUM	1000KG	SAIRA NAEEM

31	M/S JAINGXI SYNERGY PHARMACEUTICAL, IMPORT AND EXPORT CO,LTD. CHINA	JXS170827	21.09.2017	ACECLOFENAC EP4	500KG	SAIRA NAEEM
32	M/S ZHEJIANG JIANFENG INTERNATIONAL TRADE CO ,LTD. CHINA	ZC17003	06.02.2017	CLOTRIMAZOLE	21KG	SAIRA NAEEM
33	M/S METROCHEM API PRIVATE LTD, INDIA	AE293	23.11.2016	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	300KG	SAIRA NAEEM
34	M/S JIANGXI TIANXIN PHARMACEUTICAL CO,LTD. CHINA	JXS170239	03.03.2017	GABAPANTIN	1000KG	SAIRA NAEEM
35	M/S MALLADI DRUGS & PHARMACEUTICALS LIMITED, INDIA	MS-EXP1651652258 2	28.02.2017	FEXOFENADINE HCL	500KG	SAIRA NAEEM
36	M/S METROCHEM API PRIVATE LTD, INDIA	AE303	29.11.2016	PANTOPERAZOLE SODIUM	300KG	SAIRA NAEEM
37	M/S SINOCHEM QINGDAO CO,LTD. CHINA	N16AD59521	27.10.2016	PHLOROGLUCINNOL DIHYDRATE	500KG	SAIRA NAEEM
38	M/S METROCHEM API PRIVATE LTD, INDIA	AE073	31.05.2016	OMEPRAZOLE	200KG	SAIRA NAEEM
39	M/S 366 PHARMA (NANJING) CO, LTD. CHINA	366161104B1	04.11.2016	ASPARTAME	200KG	SAIRA NAEEM

Case No.02 **Import of Raw Material issued to M/s Everest Pharmaceuticals**

DRAP team conducted the raid on 06-03-2018 at the premises of M/s Everest Pharmaceuticals 124-industiral Triangle kahuta Road Islamabad. The firm was found in manufacturing of unregistered 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 were sealed and FIR No. 05/2018 was registered in FIA/ACC Islamabad for contravention of the DRAP Act 2012/Drug Act 1976 and rules made there under against the following persons namely:

1. Ch. Muhammad Usman (Owner of M/s Everest Pharmaceuticals)
2. Dr. Kamran izhar (owner of M/s Everest pharmaceuticals)
3. Noor Muhammad Mahar (owner of M/s Everest pharmaceuticals)
4. Mian Ishtiaq Ahmed (QC incharge), M/s Everest Pharmaceuticals

2. Accordingly, a letter was written to the Deputy Collector G-II MCC Appraisement (West) Karachi for providing complete import record of pharmaceuticals raw materials imported by the M/s Everest Pharmaceuticals during the last three years along with 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, along with goods declaration-GD-I of the pharmaceutical raw material imported by M/s Everest Pharmaceuticals 86-G, Model Town Lahore vide letter SI/Misc/15/2018 Group II dated 22-03-2018

3. LIST OF ADC INVOICES FOR IMPORT OF RAW MATERIAL ISSUED TO M/S EVEREST PHARMA, ISB W.E.F 01.01.2015 TO 30.12.2017

SR.NO	NAME OF INDUSTRY/ SUPPLIER	INVOICE NO.	INVOICE DATE	RAW MATERIAL	QUANTITY	PERPORTEDLY RELEASED BY
1	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPRGC14007	09.09.2014	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	
2	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPRGC14008	09.09.2014	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	
3	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPRGC14009	09.09.2014	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	
4	M/S SHANDONG FUFENG FERMANTATIO	SYF15068	15.05.2015	XANTHAN GUM OHARMA GRADE	3000KG	SAIRA NAEEM

	N CO, LTD.			200MESH		
5	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15004	10.06.2015	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	SAIRA NAEEM
6	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15005	10.06.2015	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	SAIRA NAEEM
7	M/S MAHENDRA INDUSTRIAL ESTATE, INDIA	EXP/652/15-16	08.07.2015	NIMSULIDE	150KG	SAIRA NAEEM
8	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15008	10.06.2015	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	SAIRA NAEEM
9	M/S ROSS COTTON INTERNATIONAL , AUSTRALIA	3097	20.10.2015	OSSEIN MINERAL COMPLEX	1500KG	SAIRA NAEEM
10	M/S AARTI DRUGS LIMITED, INDIA	EXP/1969/15-16	22.01.2016	METFORMIN HYDROCHLORIDE	500KG	SAIRA NAEEM
11	M/S LA PALMA HOLLAND BV, HOLAND	4248-01	21.02.2016	LACTOSE MONOHYDRATE	3000KG	SAIRA NAEEM
12	M/S INDOCO REMEDIES LIMITED, INDIA	API/EXP/083/16-17	25.07.2016	DOMPERIDONE BP	500KG	SAIRA NAEEM
13	M/S HIKAL LIMITED, INDIA	HLBE/2016-17/115	27.07.2016	GABAPANTIN	500KG	SAIRA NAEEM
14	M/S IMPERIAL CHEM, INCORPORATION, INDIA	ICI/E/063	10.06.2016	IRON III HYDROXIDE POLYMALTOSE COMPLEX	1000KG	SAIRA NAEEM
15	M/S SREEKARA ORGANICS, INDIA	EXP/SO/018/16-17	24.10.2016	FEXOFENADINE HCL	500KGS	SAIRA NAEEM

16	M/S ROSS COTTON INTERNATIONAL , AUSTRALIA	3196	20.10.2016	OSSEIN MINERAL COMPLEX UST GRADE/ SUSPENSION GRADE	1500KG/ 500KG	SAIRA NAEEM
17	M/S SINOCHEM QINGDAO CO,LTD. CHINA	N116AD59586	22.11.2016	PHLOROGLUCINOL TRIMETHYL	500KG	SAIRA NAEEM
18	M/S BAKUL PHARMA PRIVATE LIMITED, INDIA	BPPL/EXP/84/16-17	15.02.2017	DOXOFYLLINE	200KG	SAIRA NAEEM
19	M/S HANGZHOU HYPER CHEMICALS LIMITED, CHINA	HP1706085	28.06.2017	TRIS (HYDROXYMETHYL) AMINO METHANE	500KG	SAIRA NAEEM
20	M/S LOHITHA LIFESCIENCES PVT, LTD. INDIA	7	26.08.2017	DOMPERIDONE BP	500KG	SAIRA NAEEM
21	M/S TAIZHOU SEAFRESH INTERNATIONAL TRADE CO, LTD	TZ171025	25.10.2017	GLUCOSAMINE SULFATE	1000KG	SAIRA NAEEM
22	M/S ZHEJIANG CHIRAL MEDICINE CHEMICALS CO, LTD. CHINA	CMC17D1202	20.01.2018	GABAPANTIN	1000KG	SAIRA NAEEM

04. 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 pharmaceuticals raw materials stands illegal in violation of Drug (import &Export) Rules, 1976 framed under the Drug Act 1976.

05. As the records 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 pharmaceutical 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 Panel Code and Clause (I) (e) of the paragraph A of the Schedule-II of the DRAP Act 2012 read with Section 23 (1)(a)(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.

06. The FID Lahore may be allowed for registration of FIR for the violations mentioned in para 5 due to illegal import of pharmaceutical raw material through forged import authorization and without

any Drug Import license and take strict legal action according to law as mentioned above against the following

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. Mian Ishtiaq Ahmed (QC incharge), M/s Everest Pharmaceuticals

01. Proceedings of 262nd Meeting of CLB:-

The CLB considered the reports and invoices of the 22 consignments forwarded by Custom Authorities regarding Pharmaceuticals Raw Materials imported by Everest Pharmaceuticals through forged documents. Uzma Barkat AD I&E, DRAP, Lahore received through whatsapp and response of Lahore office vide their letter dated 7014/2018-DRAP(AD VI) dated 23rd May, 2018.

She stated that the DRAP Lahore has checked the available record and after examining and verification of the documents, it is concluded that none of the invoices or Drug Import License (DIL) regarding clearance of said 22 consignments of pharmaceutical raw material,as detailed above, was ever attested/ issued during the specified period, i.e., Jan, 2015 to April 2018, by the DRAP office Lahore. Queries raised by QA/LT Division were responded as under

Sr. no.	Query from QA/LT Division	Reply from DRAP Lahore
1	whether applications and relevant documents for clearance were submitted to DRAP Lahore office?	**The said applications and relevant documents were never submitted to DRAP Lahore, as per available office record.**
2	Whether drug import licenses were issued to M/s Everest Pharmaceuticals, Islamabad regarding import of raw materials in question?	**No drug import license was issued to M/s Everest Pharmaceuticals, Islamabad regarding import of raw materials in question by DRAP, Lahore, as per available office record.**
3	Whether diary/ dispatch numbers on the invoices from the official record are genuine or otherwise?	**Diary/ dispatch numbers on the invoices are not genuine, as per official record of DRAP, Lahore.**
4	Whether clearance certificates were issued and invoices were attested by DRAP Lahore office?	**the said clearance certificates were neither issued nor invoices were attested by DRAP office, Lahore.**
5	Whether Ms. Saira Naeem was competent to issue clearance to the companies/ firms licensed at Islamabad?	**Ms. Saira Naeem is not competent clearance to the companies/ firms licensed at locations other than territorial jurisdiction of DRAP office, Lahore.**

M/s Saira Naeem explained that she remained on maternity leave and is on leave since 26th October 2015 for three months. It is also said that she is on leave w.e.f February 2017 till date. It is pertinent to mention that some of the invoices were signed and stamped during her leave period. She stated that she followed standard procedure in practice and record of every firm is available in the office.

Decision of 262nd meeting of CLB:-

The CLB unanimously decided that as per official record presented before CLB, M/s Everest Pharmaceutical prepared forged documents and imported pharmaceutical raw materials without obtaining Drug Import license as required under the Drug Act 1976 and Drugs (Import & Export Rules) 1976. CLB granted permission for registration of 22 FIRs in the following consignments.

SR.NO	NAME OF INDUSTRY/ SUPPLIER	INVOICE NO.	INVOICE DATE	RAW MATERIAL	QUANTITY	PERPORTEDLY RELEASED BY
1	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPRGC14007	09.09.2014	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	No one
2	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPRGC14008	09.09.2014	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	No one
3	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPRGC14009	09.09.2014	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	No one
4	M/S SHANDONG FUFENG FERMANTATION CO, LTD.	SYF15068	15.05.2015	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	SAIRA NAEEM
5	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15004	10.06.2015	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	SAIRA NAEEM
6	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15005	10.06.2015	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	SAIRA NAEEM

7	M/S MAHENDRA INDUSTRIAL ESTATE, INDIA	EXP/652/15-16	08.07.2015	NIMSULIDE	150KG	SAIRA NAEEM
8	M/S DEOSEN BIOCHEMICAL LTD, CHINA	SPKGC15008	10.06.2015	XANTHAN GUM OHARMA GRADE 200MESH	3000KG	SAIRA NAEEM
9	M/S ROSS COTTON INTERNATIONAL , AUSTRALIA	3097	20.10.2015	OSSEIN MINERAL COMPLEX	1500KG	SAIRA NAEEM
10	M/S AARTI DRUGS LIMITED, INDIA	EXP/1969/15-16	22.01.2016	METFORMIN HYDROCHLORIDE	500KG	SAIRA NAEEM
11	M/S LA PALMA HOLLAND BV, HOLAND	4248-01	21.02.2016	LACTOSE MONOHYDRATE	3000KG	SAIRA NAEEM
12	M/S INDOCO REMEDIES LIMITED, INDIA	API/EXP/083/16-17	25.07.2016	DOMPERIDONE BP	500KG	SAIRA NAEEM
13	M/S HIKAL LIMITED, INDIA	HLBE/2016-17/115	27.07.2016	GABAPANTIN	500KG	SAIRA NAEEM
14	M/S IMPERIAL CHEM, INCORPORATION, INDIA	ICI/E/063	10.06.2016	IRON III HYDROXIDE POLYMALTOSE COMPLEX	1000KG	SAIRA NAEEM
15	M/S SREEKARA ORGANICS, INDIA	EXP/SO/018/16-17	24.10.2016	FEXOFENADINE HCL	500KGS	SAIRA NAEEM
16	M/S ROSS COTTON INTERNATIONAL , AUSTRALIA	3196	20.10.2016	OSSEIN MINERAL COMPLEX UST GRADE/ SUSPENSION GRADE	1500KG/ 500KG	SAIRA NAEEM
17	M/S SINOCHEM QINGDAO CO,LTD. CHINA	N116AD59586	22.11.2016	PHLOROGLUCINOL TRIMETHYL	500KG	SAIRA NAEEM
18	M/S BAKUL PHARMA PRIVATE LIMITED, INDIA	BPPL/EXP/84/16-17	15.02.2017	DOXOFYLLINE	200KG	SAIRA NAEEM

19	M/S HANGZHOU HYPER CHEMICALS LIMITED, CHINA	HP1706085	28.06.2017	TRIS (HYDROXYMETHYL) AMINO METHANE	500KG	SAIRA NAEEM
20	M/S LOHITHA LIFESCIENCES PVT, LTD. INDIA	7	26.08.2017	DOMPERIDONE BP	500KG	SAIRA NAEEM
21	M/S TAIZHOU SEAFRESH INTERNATIONAL TRADE CO, LTD	TZ171025	25.10.2017	GLUCOSAMINE SULFATE	1000KG	SAIRA NAEEM
22	M/S ZHEJIANG CHIRAL MEDICINE CHEMICALS CO, LTD. CHINA	CMC17D1202	20.01.2018	GABAPANTIN	1000KG	SAIRA NAEEM

02. permission for lodging of FIRs in above mentioned 22 consignments through forged documents by M/s Everest Pharmaceuticals Islamabad without obtaining Drug Import License was granted against the following accused persons;-

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. Mian Ishtiaq Ahmed (QC incharge), M/s Everest Pharmaceuticals

Case No.03 **Seizure of illegally manufacture Stocks of M/s Everest Pharmaceuticals (Pvt) Ltd Islamabad through Raid on Shah Mansoor Medicose near Bacha Khan Medical Complex Shah Mansoor Swabi**

Mr. Atiq-ul-Bari, FID-II, Peshawar vide letter No. F. 12-1-38/2018-EverestPharma-DRAP/1253 dated 29th March, 2018 in compliance to letter No. F. 4-5/2018-QC, dated 06-03-2018 and 07-03-2018.

02. The FID informed that he alongwith Abdul Hafeez Marwat, Area Provincial Drug Inspector visited the premises of Shah Mansoor Medicose, Near Bacha Khan Medical Complex, Shah Mansoor, Swabi.

03. The FID-II, Peshawar also informed that as per directions stocks of various products claimed to manufacture by M/s. Everest Pharmaceuticals, Islamabad were recovered and seized on Form-2. Details of products seized are as following:

Sr. No.	Name of Drug	Reg. No.	Batch No.	Mfg. Date	Expiry Date	Claimed to be Manufactured	Quantity

						by	
01.	Everlong Tab	077718	130	05/17	05/19	Everest Pharma, Islamabad	01 Pack
02.	Evergaba Tab	072070	233	07/17	07/19	-do-	04 Packs
03.	Evertam Tab	072008	139	05/17	05/19	-do-	01 Pack
04.	Dolorest Plus Capsules	072199	285	08/17	08/19	-do-	06 Packs
05.	Dutam Tablet	072011	259	07/17	07/19	-do-	01 Pack
06.	Lax Capsule	068806	381	11/17	11/19	-do-	01 Pack

04. The FID further informed that Shah Mansoor Medicose, Swabi provided warranty of Fauji Medicine Company, Mardan for seized drugs. Fauji Medicine Company, Mardan provided warranty of Royal Enterprises, Gulberg, Peshawar. Royal Enterprises Gulberg, Peshawar provided warranty of Everest Pharma, Islamabad.

05. That the accused persons given below have violated the provisions of **Schedule-II, of DRAP** Act 2012 and hence, committed offences as under:-

a. A. (1)(a)(vii) i.e. export, import are 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;

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

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

d. (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.

06. The Prohibitions mentioned in para 5 are offences and punishable under schedule III of DRAP Act 2012

a. (1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.

b. (1)(c), Imports without license any therapeutic goods for the import of which a license is required.

c. (2)(b) gives to the purchaser a false warranty in respect of any therapeutic goods sold by him that the therapeutic goods does not is any way contravene the provisions of schedule II and is

not able to prove that, when gave the warranty , he had good and sufficient reason to believe the same to be true.

d. (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.

e. (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

06. Permission For Safe Custody of the Seized stock)

The FID has requested to necessary permission for safe custody of sized stock till the decision of the case.

07. Permission for Lodging of FIR

The FID has requested to grant the permission of lodging of FIR of the following accused persons:-

1. M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.
2. Ch. Muhammad Usman (Chief Executive officer), M/s Everest Pharmaceuticals Islamabad
3. Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad
4. Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad
5. Ch. Muhammad Usman, Production In charge, M/s Everest Pharmaceuticals Islamabad
6. Mian Ishtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad
7. Ch. Muhammad Usman warrantors for M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranties on behalf of M/s Everest Pharmaceuticasl Islamabad.
8. Iftikhar Ahmed Qureshi S/o Muhammad Siddique Qureshi of proprietor M/s Royal Enterprises Al Habib Street House No.02 Near Prime Apartment Peshawar.

Decision of 262nd meeting of CLB

The Central Licensing Board examined/evaluated the record and facts of the case in the light of investigations conducted by the FID Peshawar and Quality Assurance Division and decided as under:-

01. **The accused persons given below have violated following the provisions** of **Schedule-II, of DRAP Act 2012 which fall under prohibitions:-**

a. A. (1)(a)(vii) i.e. export, import are 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;

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

c. 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;

d. (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.

02. The Prohibitions mentioned in para 1 herein above are offences and punishable under the provisions of schedule III of DRAP Act 2012

f. (1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.

g. (1)(c), Imports without license any therapeutic goods for the import of which a license is required.

h. (2)(b) gives to the purchaser a false warranty in respect of any therapeutic goods sold by him that the therapeutic goods does not is any way contravene the provisions of schedule

II and is not able to prove that, when gave the warranty , he had good and sufficient reason to believe the same to be true.

i. **(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.**

j. **(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**

03. Permission For Safe Custody of the Seized stock)

The CLB allowed the permission for safe custody of the seized stocks to the FID Peshawar till the finalization of the case.

04. Permission for Lodging of FIR

The CLB allowed the permission for lodging the FIR to the FID Peshawar against the following accused persons:-

1. **M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.**
2. **Ch. Muhammad Usman (Chief Executive officer), M/s Everest Pharmaceuticals Islamabad**
3. **Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad**
4. **Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad**
5. **Ch. Muhammad Usman, Production In charge, M/s Everest Pharmaceuticals Islamabad**
6. **Mian Ishtiaq Ahmed QC Incharge, M/s Everest Pharmaceuticals Islamabad**
7. **Ch. Muhammad Usman warrantors for M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranties on behalf of M/s Everest Pharmaceuticasl Islamabad.**
8. **Iftikhar Ahmed Qureshi S/o Muhammad Siddique Qureshi of proprietor M/s Royal Enterprises Al Habib Street House No.02 Near Prime Apartment Peshawar.**

Case No.04 i. Manufacture & Sale of Sub-Standard Drugs by M/S Standard Drug Company, Hyderabad. –Recommendation of Cancellation of Drug Manufacturing License (DML) of 12 Samples of M/S Standard Drug Company, Hyderabad, "Under Section 41 of Drugs Act, 1976".

ii Non compliance to the conditions of license identified by the Appellate panel – Recommendation of Cancellation of Drug Manufacturing License (DML) under Section 41 of Drug Act 1976.

The case of the M/s Standard Drug Company Hyderabad presented before the 259th meeting of CLB held on 29-30March 2018 and the Board was decided as under

Decision of 259the meeting of CLB Case:-

"The CLB after deliberation and thread bare discussion decided to issue show cause notice to M/s Standard Drug Company Hyderabad on the basis of short comings/deficiencies identified and forwarded by Appellate Panel in their report

4. In light of decision of above the Show Cause notice was issued to the M/s Standard Drug Company Hyderabad, on 04th May 2018 the contents of the show cause notice issued to the firm are as under:-

INSPECTION REPORT OF STANDARD COMPANY BY INSPECTION PANEL CONSTITUTED BY THE APPELLATE BOARD

OBSERVATIONS

A: General:

1. *Manufacturing facility is in a very old building.*
2. *Layout of the facility approved by DRAP was not available.*
3. *No written document was available that shows the sections approved by DRAP.*
4. *No job descriptions were available for the staff.*
5. *There was no program for training or health check of the staff.*
6. *No document was available to show the HVAC design.*
7. *Factory inspection book was not avaialbe on the premises.*
8. *Technical persons available and met during the inspection had little knowledge of GMP and pharma operations and failed to satisfy the queries of panel.*
9. *There was no system for writing and control of SOPs. Few SOPs were avaialbe in the QC but did not cover the main operation. These were not adequate, uncontrolled and not signed.*
10. *There was no documentation control. There was no concept of self inspection, market complaints, product recall, deviation or change control.*
11. *Materials were purchased from open market. No concept of supplier approval.*

B: Warehouse/Stores:

1. *No air curtains were provided at the entrance.*
2. *No procedure was avaialbe for uniform change in change room.*
3. *No cabinet/place was available for placing clean/used uniforms.*
4. *No area available for material clean-down.*

5. *No balance was available for weighin/checking the received/incoming materials.*
6. *No status labeling for any of the storage areas.*
7. *No area for sampling of raw materials.*
8. *No monitoring and recording of temperature in raw material storage area.*
9. *No log of weighing balance in material dispensing area.*

C: Manufacturing areas:

1. *HVAC was found to be unsatisfactory and not working. No air pressure differentials in manufacturing areas. Manometers were not installed in most of the areas. Two gauges were installed at one place but were very old and not working.*
2. *Most of the machines and equipment were very old and rusted and were not qualified/validated.*
3. *There was no validation program. Cleaning validatino for production machinery was not performed.*
4. *Instruments, gauges were old and not calibrated.*
5. *Granulating solution room was very dirty.*
6. *Walls and ceiling were not smooth. Areas were dirty and unhygienic.*
7. *No coving in any manufacturing area. Ledges in the rooms.*
8. *Crevices and cracks in floors and ceilings.*
9. *Uneven tiles in liquid filling room.*
10. *Paint peeling off at many places.*
11. *Tablet solvent coating carried out in open pans. No exhaust availabe.*

D: QC Laboratory:

1. *Test method references not available.*
2. *No HVAC in micro laboratory.*
3. *There was no concept of out of specification and product quality review.*
4. *Environmental monitoring of manufacturing areas was not carrid out.*
5. *A second hand HPLC was recently purchased but not yet commissioned.*

E:- Conclusion & Recommendation by the panel

The panel observed a number of critical shortcomings in building, production machinery, HVAC system, documentation etc. Therefore, based on the areas inspected, the people met and documents reviewed, and considering the findings of inspection the panel recommends to continue with the cancellation of drug manufacturing license of Ms Standard Drug Company, Hyderabad."

5. Accordingly show cause notice was issued under Section 41 of Drug Act 1976 read with rule 12 of the Drugs (Licensing Registering and Advertising) rules 1976 that the premises does not comply with condition of license and violated the mandatory provisions of Drug Act 1976. On the basis of non compliance to the provisions of Drug Act 1976, why manufacturing license of your premises namely "M/s Standard Drug Company at E-6/A, SITE, Hyderabad" shall not be cancelled. It was further reminded that production of the manufacturing unit was suspended by the Appellate Board and any such activity will tantamount to the illegal activity and cognizable offence under the DRAP Act 2012 and rules frame there under.

6. The firm replied the show cause notice vide letter No. Nil dated 16-05-2018. The firm have called for personal hearing in the meeting

Proceedings of 262nd meeting of CLB:-

Mr. Imtiaz Ahmed MD, M/s Standard Drug Company Hyderabad appeared along with Mr. Almas before the CLB. They submitted their point of view as under:

1. **The firm submitted that their reply that they appeals against the decision of the RB cancelling registration of our 12 impugned samples are pending before the Appellate Board and therefore the CLB is not expected to deliberate on this issue further being subjudice at a higher forum**

2. **Preliminary position:-The Appellate panel referred to in the show cause notice was constituted by the Appellate Board in our Appeal (No.45/2017) against eh cancellation of our DML by the CLB in its 252nd meeting held on 15th March 2017 During personal hearing the Honorable Appellate Board was informed that eh CLB decision was violative of the principle of double jeopardy as provided under the constitution of Pakistan the Appellate Board observed that the CLB should act**

3. **Independently while deciding the matter placed before it the instant decision seems to have been taken under the grip of and reiterating CLB earlier decision.**

4. **Kindly note that the Appellate panel inspection was conducted on 12the December 2017 and now it is over six months during this period we have taken leap further and made considerable improvements and rectified the shortcomings noted by the Appellate Panel Which can be verified through a re inspection by the CLB.**

5. **Manufacturing facility is in a very old building:-**

It is true that the unit is located in a building constructed some four decades back wherein the DML was granted originally in 1977 However the conditions of license or the requirement of GMP is a purpose build and maintained building. Thus being old building is not a shortcoming per see.

6. **Extracts from panel inspection dated 12th November 2010**

Production Facilities:-

The firm is licensed to manufacture following dosage forms

1. **Tablets (General)**
2. **Liquid Syrups**
3. **Dry Powder Suspension**
4. **Ointments/Creams**
5. **External Preparations.**

7. Extracts from panel inspection dated 21st June 2012

Following section are available in the firm:-

1. **Tablets (General)**
2. **Liquid Syrups**
3. **Dry Powder Suspension**
4. **Ointments/Creams**
5. **External Preparations**

8.` Extracts from panel inspection report dated 12th November 2010

Storage and other facilities

The firm has sufficient facilities for the storage of raw materials packing materials and finished goods with proper identification of areas like receiving bays quantine, released rejected and finished goods areas. Goods were properly stored and dispensed for which firm has facility for dispensing booth installed with HEPA filters it was advised to

09. Extract from inspection report dated 21st June 2012

Storage Area:- Storage area observed neat and clean and maintain well. Material were stored and stocked as per their status. Management should also think for provision of more spacious were house in further as well to cope the storage requirements

Cool area also provided in the ware house and observed maintained well

10. Extracts From panel inspection report dated 11th October 2013

Racks has been provided in warehouse for placement of raw materials sampling booth and dispensing booths has been maintained and placed at their designated area

11. The MD of the firm stated that he has rectified the shortcomings and ready to fulfill all the observations of the panel and agreed to submit fresh layout plan for approval as per current requirements of the law.

Decision of 262nd meeting of CLB:-

The CLB examined and considered the Appellate panel inspections report, reply of the firm to the show cause notice and personal hearing of the MD of the M/s Standard Drug Company Hyderabad.

The Board considered the case at length. Mr. Syed Muid Ahmed who was also member of the Appellate panel briefed the members about the shortcomings and deficiencies. After detailed debate following was decided**:-**

1. **The firm shall submit fresh layout plan for approval by the licensing Division as per current requirements of law.**
2. **The firm will submit compliance report in the light of layout approval and shortcomings/deficiencies identified by the Appellate panel as conveyed in the show cause notice.**
3. **Following panel will inspect the premises and verify compliance report in the light of approved layout plan and observations of Appellate panel.**
    a. **Syed Muid Ahmed (member CLB)**
    b. **Professor Dr. Abdullah Dayo Dean Faculty of Pharmacy University of Sindh Jamshoro (member CLB)**
    c. **Additional Director Karachi**

d. Area FID.

4. **Meanwhile the production shall remain suspended as per decision of the Appellate Board. Any violation to this condition will be considered as non compliance and matter will be decided in the light of show cause notice.**
5. **The show cause notice will remain intact till matter is finalized by CLB which will decide the fate of the manufacturing license in the light of inspection report or any violation report whichever is received in this context.**

Case No05:- **M/s Marush International Karachi Inquiry No.21/2017 of FIA Corporate Crime Circle Karachi and permission for Lodging FIR Prosecution thereof**

Mr. Ghazanfar Abbas s/o Muhammad Nawaz filed compliant against M/s Marush Pvt Ltd Karachi importing unregistered products

02. That an enquiry No. 21/2017 was registered against Director/CEO of M/s Marush International Pvt Ltd 6-Noor Estate building Sharah-e-Faisal, Karachi & M/s Marush Internal Lahore in collaboration with FIA corporate Crime Circle Karachi alleging import of un registered therapeutic goods on fake DRAP NOCs. FIA authorities had provided following letters/NOCs suspected to be issued by this office in favor of M/s Marush International Karachi and intended to be verified by this office its genuineness they further had requested for submission of import record of the firm vide letter No. FIA/CCC/ENQ-21/2017/3990-91 dated 20-09-2017

i. The letter No.F.1287-16/2016-DCA (K) dated 07th March 2016 (for import of (M) CEVAC IBIRC vaccine in 2500DS ANG Pack size claimed to be issued by Dr. Fayaz Mughal (ADC)(DCA K)

ii. The letter No.2861-14/2014-DCA (K) dated 11th August 2014 of Import of VECTORMUNE FP MG with sterile Diluent and applicator 1000 DS vaccine claimed to be issued by Dr. Shoib Ahmed ADC Karachi

iii. The letter No. F.3-2/2010-DCA (K) dated 20th April 2010 for import of temporary import of unregistered products claimed to be issued by Mr. Abdul Rasool Shaikh ADC Karachi

03. The matter was immediately brought into knowledge of Director (QA/LT) DRAP Islamabad vide this office letter No. F.01-31/2014-DRAP K FIA dated 22nd September 2017 for necessary directions

DRAP Islamabad vide letter No.F.14-15/2017-QC dated 09th October 2017 accorded the permission to provide the import record/documents to FIA authorities. In this connection competent authority vide letter No. F.14-15/2017-QC dated 09th October 2017 had also constituted a committee to investigate the matter under the DRAP Act 2012/Drug Act 1976and rules frame thereunder Meanwhile this office has extended cooperation and provided the relevant import record/documents to FIA authorities

04. The constituted facts finding committee in tier thorough investigation report had confirmed that aforesaid letters/NOCs produced by M/s Marush Pvt Ltd Karachi were fake and not issued/endorsed by the DRAP Karachi office. The firm illegally formatted those NOCs and had used those for the clearance of unregistered drugs from the customs authorities.

05. Furthermore on the directions of DRAP Islamabad letter no. 14-15/2017-QC dated 19-01-2018 the Executive District officer/ District Health officer, health department Karachi was requested vide

the letter No. F-01-31/2017-DRAP (K) dated 12-02-2018 for cancellation/suspension of Drug Sale license No.0183 dated 06-09-2016 (by way of whole sale) issued to M/s Marush Pvt ltd Karachi

06. In response to the request made to Director health Services Karachi Division Karachi the DSL issued in favor of M/s Marush International Karachi was cancelled suspended vide letter No. DHS/License/1480/86 dated 26-12-2018.

07. Keeping in view o above submission it can clearly be established that M/s Marush Pvt Ltd Karachi is involved in importing and selling of unregistered Drugs/medicine on fake DRAP letters NOCs thus has violated the section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(c), 23(1)(d), 23(1)(f) of Drugs Act 1976 read with schedule II of DRAP Act 2012 that are punishable under section 27(1)(a) & 27(1)(c) of Drugs Act 1976 read with schedule III of DRAP Act 2012 and rules framed thereunder:

08. As the accused persons have prepared forged documents on behalf of ADC Karachi and obtained clearance from the custom authorities

1. The letter **No.F.1287-16/2016-DCA (K) dated 07th March 2016** (for import of **(M) CEVAC IBIRC vaccine in 2500DS ANG Pack** size claimed to be issued by Dr. Fayaz Mughal (ADC)(DCA K). the said letter was prepared and 54 hundred vials of the vaccines were cleared without registration
2. The letter **No.2861-14/2014-DCA (K) dated 11th August 2014** of Import of **VECTORMUNE FP MG with sterile Diluent and applicator 1000 DS vaccine** claimed to be issued by Dr. Shoib Ahmed ADC Karachi.
3. The letter No. **F.3-2/2010-DCA (K) dated 20th April 2010** for import of temporary import of unregistered products claimed to be issued by Mr. Abdul Rasool Shaikh ADC Karachi

09. The FID has requested that contents of the case may be placed before the upcoming meeting of CLB for grant of permission to lodging 03 FIRs on the above mentioned violations in addition to violations of PPC for preparing forged documents against the following accused persons:-

1. *M/s Marush International Pvt Ltd 6 Noor Estate Building Shah ra e Faisal Karachi thorough through owner Muzamil Hussain Shah.*
2. *Muzamil Hussain Shah owner of M/s Marush International Pvt Ltd 6 Noor Estate Building Shah ra e Faisal Karachi*
3. *Muhammad Usman S/o Muhammad Jamal Shah (proprietor M/s Marush International 6 Noor Estate Building Shah ra e faisal Karachi.*

Decision of 262nd meeting of CLB:-

The CLB examined request of the FID and considered the following documents, record and facts:-

i. **Report of Federal Inspector of Drug Karachi.**
ii. **Complaint filed by Mr. Malik Ghazanfar Abbas S/o Malik Muhammad Nawaz Resident in Lahore.**

iii. **Investigation Report on the import of unregistered therapeutics goods consignments by M/s Mahrush International Pvt Ltd 6-Noor State Building Karachi forwarded by Chairman of the committee on 31-10-2017**

iv. **Inquiry report conducted by committee of DRAP Islamabad and documents presented before the Committee.**

v. **Record of PE&R Division related to M/s Mahrush Pvt Ltd.**

vi. **Record of Biological Division related to M/s Mahrush Pvt ltd.**

vii. **Record of Legal Affairs Division related to M/s Mahrush Pvt ltd.**

viii. **Record of QA/LT, Division related to M/s Mahrush Pvt ltd.**

The CLB after examination of above mentioned record and facts of the case unanimously decided as under:-

1. Enquiry Report revealed that M/s Mahrush International Pvt Ltd Karachi prepared forged documents on behalf of three different ADCs at DRAP office Karachi and imported unregistered drugs 03 different consignments as under :-

I. The letter **No.F.1287-16/2016-DCA (K) dated 07th March 2016** (for import of **(M) CEVAC IBIRC vaccine in 2500DS ANG Pack** size claimed to be issued by Dr. Fayaz Mughal (ADC)(DCA K). the said letter was prepared and 54 hundred vials of the vaccines were cleared without registration. There was no ADC namely Dr. Fayaz Mughal (ADC)(DCA Karachi.

II. The letter **No.2861-14/2014-DCA (K) dated 11th August 2014** of Import of **VECTORMUNE FP MG with sterile Diluent and applicator 1000 DS vaccine** purportedly issued by Dr. Shoib Ahmed ADC Karachi. Dr Shoaib denied issuance of any clearance certificate issued in this neither behalf nor records are available.

III. The letter No. **F.3-2/2010-DCA (K) dated 20th April 2010** for import of temporary import of unregistered products claimed to be issued by Mr. Abdul Rasool Shaikh ADC Karachi. Abdul Rasool Shaikh also denied issuance of any clearance letter.

02.The above findings were concluded by the enquiry committee which was constituted by the Director QA/LT Division. It was concluded the accused persons prepared forged documents on behalf of Assistant Drug Controller and hence committed the offences under section 420,467,468,471&472 of Pakistan Panel Code.

03. That accused persons also imported unregistered drugs in violation to Clause (1)(a)(vii) of the paragraph A of the schedule-II of the DRAP Act 2012 read with section 23(1)(a)(vii) of the Drugs Act 1976.

04. That accused persons also violated clause (1) (x) of para A of schedule II of DRAP Act 2012.

05. That offences committed by accused persons are punishable under provisions of PPC mentioned in para 2 herein above. The violations mentioned in para 3 and para 4 herein above are punishable under para (1) (a) and para (4) of schedule III of the DRAP Act 2012 read with section 27(1)(a) and section 27(4) of the Drug Act 1976.

06. The Import of unregistered drugs is cognizable offence under Para (2)(a) of the Schedule-IV to the DRAP Act 2012 read with section 30 (2)(a) of the Drug Act 1976.

07. That registration of lodging of 03 FIRs against the following accused persons is allowed in 03 different cases as mentioned in para 1 herein above

I. M/s Marush International Pvt Ltd 6 Noor Estate Building Shah ra e Faisal Karachi thorough through owner Muzamil Hussain Shah.

II. Muzamil Hussain Shah owner of the M/s Mahrush International Pvt Ltd 6 Noor Estate Building Shah ra e Faisal Karachi t

III. Muhammad Usman Ali Shah S/o Muhammad Jamal Shah (proprietor M/s Marush International 6 Noor Estate Building Shah ra e faisal Karachi.(As mentioned in Drug Sale license No.0183 dated 06-09-2016)

08. The FID is directed to file the separate complaint for occurrence of each illegal activity for registration of FIR against the accused persons and forward complete case before this Board as investigations are completed.

Case No.06 **Corrections in the Agenda and minutes of 260th meeting of CLB regarding the case of Mano Traders Sargodha**

In correct subject i.e. Manufacture and sale of un registered drug product Ever long tablet 60mg B. No. 131 Mfg date 05-17, Exp date 05-19 Mfg by Everst Pharmaceutical Islamabad

Corrected subject:- Manufacture and sale of un registered drug product Ever long tablet 60mg B. No. 449 Mfg date 10-15, Exp date 10-17 Mfg by Everst Pharmaceutical Islamabad

Warrantor has been mentioned as under:-

Mr. Khuram Naeem and Ch. Muhammad Usman are warrantors for M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranties on behalf of M/s Everest Pharmaceuticasl Islamabad.

Corrected one

Dr. Kamran Izhar, Khuram Naeem and Ch. Muhammad Usman are warrantors for M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranties on behalf of M/s Everest Pharmaceuticasl Islamabad

Zaheer afzal nominated in the renewal application as production pharmacist has also been concerted as manufacturer through his petition and also been included in the list of accused persons.

FID Lahore

Mr. Asim Rauf, Abdul Rashid Shaikh along with Zeeshan Haider Kazmi provincial Inspector of drugs Sargodha, inspected M/s Mano Traders 521-A Satellite Town Lahore at Sargodha on 26-11-2015 and recovered Everlong 60mg Tablets B.NO.449 mfg by Everest Pharmaceuticals Islamabad.

2. A referred the case to the Chairman Licensing Board vide his letter No.18558/2015-DRAP (L-IV) dated 27-11-2015

3. M/s Mano Traders Sargodha submitted 03 invoices issued by M/s Everest pharmaceuticals Islamabad to them as under:-

i. Invoice No. EPO/205 dated 27-10-2015 indicating the sale of Everelong tablet B.No. 449 to M/s Mano traders Sargodha

ii. Invoice No. EPO/200 dated 19-09-2015 indicating the sale of following unregistered drugs by M/s Everest Pharmaceuticals to Mano Traders Sargodha mfg by M/s Everest Pharmaceuticals Islamabad.

- Ossolife Susp B.No. 091, mfg by M/s Everest Pharmaceuticals Islamabad.
- Zycin 250mg Tab, B.No.261, mfg by M/s Everest Pharmaceuticals Islamabad.
- Zycin 500mg Tab, B.No. 251, mfg by M/s Everest Pharmaceuticals Islamabad.
- Ossolife-D Tablet, B.No.1261, mfg by M/s Everest Pharmaceuticals Islamabad.
- Evertam 0.4mg Tab. B.No. 012, mfg by M/s Everest Pharmaceuticals Islamabad.

iii. Invoice No. EPSG/005 dated 21-11-2015 for the sale of unregistered tablets maintain B.no. 424 mfg by Everest Pharmaceuticals Islamabad to Mano traders

4. That Mano traders also submitted sale and stock report duly attested and signed by them indicating the sale and purchase of stocks mfg by M/s Everest Pharmaceuticals Islamabad.

05. That the accused persons given below have violated the provisions of Schedule-II, of DRAP Act 2012 and hence, committed offences as under:-

a. A. (1)(a)(vii) i.e. export, import are 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;
b. A. (1)(a)(x) i.e. export, import are manufacture for sale or sell any therapeutic good in contravention of any of the provision of this Act are rules made thereunder;
c. A. (1)(b), manufacture for sale any theraputice goods except under and in accordance with the condition of a license issued under this Act and;
d. (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.

05. The Prohibitions mentioned in para 5 are offences and punishable under schedule III of DRAP Act 2012

k. (1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.
l. (1)(c), Imports without license any therapeutic goods for the import of which a license is required.
m. (2)(b) gives to the purchaser a false warranty in respect of any therapeutic goods sold by him that the therapeutic goods does not is any way contravene the provisions of schedule II and is not able to prove that, when gave the warranty , he had good and sufficient reason to believe the same to be true.
n. (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.
o. (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

06. Permission For Safe Custody of the Seized stock)

The FID has requested to necessary permission for safe custody of sized stock till the decision of the case.

07. Permission for Lodging of FIR

The FID has requested to grant the permission of lodging of FIR of the following accused persons:-

1. *M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.*
2. *Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad*
3. *Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad*
4. *Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad*
5. *Muhammad Arshad, Production In charge, M/s Everest Pharmaceuticals Islamabad*
6. *Mian Ishtiaq Ahmed Assistant QC Incharge, M/s Everest Pharmaceuticals Islamabad*
7. *Mr. imtiaz Ahmed Quality Control manager of Everest Pharmaceuticasl*
8. Mr. Khuram Naeem and Ch. Muhammad Usman are warrantors for M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranties on behalf of M/s Everest Pharmaceuticasl Islamabad.

08. it is therefore requested that above subject mentioned corrections may be corrected in the minutes of the meeting to the extent of correction in batch No. 449, manufacturing date 10/15 and expiry date 10/17 of Everlong tablets along with amendments for addition of accused Dr. Kamran Izhar in the accused list as warrantor of M/s Everest Pharmaceuticals who issued false warranties of Everlong tablets B.No. 449 to M/s Mano traders pharmaceuticals distributors 521-A Satellite town Sargodha vide invoice No. EPO/205 dated 27-10-2015. Similarly Khuram Naeem issued invoice No. EPO/200 dated 19-09-2015 and Ch.Usman Issued invoice No. EPSG/005 dated 21-11-2015 to M/s Mano Traders Sargodha.

09. Zaheer Afzal nominated in the renewal application as Production Pharmacist has also been connected as manufacturer through his petition and also been included in the list of accused persons.

10. it is therefore requested that corrections as indicated in the subject and para 8 and 9 may be approved to be made part of the decision

Decision of 262nd meeting CLB:-

The CLB examined the record and facts of the case and decided as under:

1. The subject of the case, Batch No. manufacturing and Expiry date were corrected and it may be read with as under:-

"subject:- Manufacture and sale of un registered drug product Ever long tablet 60mg B. No. 449 Mfg date 10-15, Exp date 10-17 Mfg by Everst Pharmaceutical Islamabad."

2. That Mano traders also submitted sale and stock report duly attested and signed by them indicating the sale and purchase of stocks mfg by M/s Everest Pharmaceuticals Islamabad.

03. That the accused persons given below have violated the provisions of Schedule-II, of DRAP Act 2012 and hence, committed offences as under:-

a. A. (1)(a)(vii) i.e. export, import are 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;

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

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

d. (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.

04. The Prohibitions mentioned in para 3 herein above are offences and punishable under schedule III of DRAP Act 2012

p. (1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.

q. (1)(c), Imports without license any therapeutic goods for the import of which a license is required.

r. (2)(b) gives to the purchaser a false warranty in respect of any therapeutic goods sold by him that the therapeutic goods does not is any way contravene the provisions of schedule II and is not able to prove that, when gave the warranty , he had good and sufficient reason to believe the same to be true.

s. (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.

t. (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

05. <u>Permission For Safe Custody of the Seized stock)</u>

The CLB allowed the safe custody of the seized drugs till the finalization of the case

06. <u>Permission for Lodging of FIR</u>

The CLB granted the permission of lodging of FIR to the FID of the following accused persons:-

1. ***M/s Everest Pharmaceuticals Islamabad. Through owner, Ch. Muhammad Usman.***
2. ***Ch. Muhammad Usman (owner), M/s Everest Pharmaceuticals Islamabad***
3. ***Dr. Kamran Izhar (Partner), M/s Everest Pharmaceuticals Islamabad***
4. ***Noor Muhammad Mahar (Partner), M/s Everest Pharmaceuticals Islamabad***
5. ***Muhammad Arshad, Production In charge, M/s Everest Pharmaceuticals Islamabad***
6. ***Mian Ishtiaq Ahmed Assistant QC Incharge, M/s Everest Pharmaceuticals Islamabad***
7. ***Mr. imtiaz Ahmed Quality Control manager of Everest Pharmaceuticasl***
8. **Mr. Khuram Naeem and Ch. Muhammad Usman are warrantors for M/s Everest Pharmaceuticals Islamabad who signed and issued above mentioned false warranties on behalf of M/s Everest Pharmaceuticasl Islamabad. Khuram Naeem issued invoice No. EPO/200 dated 19-09-2015 and Ch.Usman Issued invoice No. EPSG/005 dated 21-11-2015 to M/s Mano Traders Sargodha.**
9. **Dr. Kamran izhar is also warrantor of M/s Everest Pharmaceuticals who issued false warranties of Everlong tablets B.No. 449 to M/s Mano traders pharmaceuticals distributors 521-A Satellite town Sargodha vide invoice No. EPO/205 dated 27-10-2015.**
10. **Zaheer Afzal is also nominated in the renewal application as Production Pharmacist and is connected as manufacturer verified through his petition and also been included in the list of accused persons.**

Case No.07 (i) <u>PERMISSION FOR SAFE CUSTODY OF STOCK (SUSPECTED SPURIOUS/ UNREGISTERED) SEIZED ON PRESCRIBED FORM- 2</u>

(ii) <u>EXTENSION IN THE PERIOD ORDER " MADE NOT TO DISPOSE OFF" FOR 28 DAYS INITIALLY FOR THE DRUG MENTIONED ON FORM-1, AT THE PREMISES SITUATED AT PLOT NO. 1730/31 AND 1730/12, BALDIA TOWN, 3, KARACHI.</u>

The Hakim Masood FID Karachi, DRAP informed that he along with the followings conducted raid:

i. Dr. Abdul Rasool Sheikh (team leader/ FID , DRAP, Karachi).
ii. Dr. Kirshan (AD/ FID, DRAP, Karachi.)
iii. Dr. shoaib (FID, DRAP, Karachi and Baluchistan).,
iv. Dr. Kashif (Assistant Director/ ADC, DRAP, Karachi)
v. Dr. Farman Bozdar (Assistant Director/ ADC, DRAP, Karachi.)
vi. Dr. Waqar Ahmed (AD, DRAP, Karachi/ Coordinator police ref no. f. 13-8/2018/QC dated 21-03-2018, DRAP, Isb.
vii. and Muhammad Aslam (S.H.O., Police Station Baldia town) with the team of police official inspected the premises situated at plot no. 1730/31 and 1730/12, Baldia town, 03, Karachi.

02. The FID further informed that he seized the suspected stocks of following drug (unregistered/ spurious) on Form-2 and samples also taken for test/ analysis purpose on prescribed Form-3 (form not given) under the DRAP Act, 2012. Details are as under:

Sr. No.	**Name of Drug (s)**	**Reg. no.**	**Batch no.**	**Manufacturing date & Expiry date**	**Name of Allopathic ingredient Identification and test report No.**	**Manufactured by:**
01.	Knight rider extra powder tester delay capsule	2005-2006-10236	Nil	12-2016 1202020	Sildenafil Citrate identifications vide test report No.KQSC.242/2018 and declared unregistered drug	Royal herbal ent. Co,.plot no. 1730, near office, baildia town. No. 3, Karachi, Pakistan.

					product	
2.	Unlabelled filled capsule	Nil	Nil	Nil	Sildenafil Citrate identifications vide test report No.KQSC .246/2018 and declared unregistered drug product	Nil
3.	Unlabelled off white powder	Nil	Nil	Nil	Sildenafil Citrate identifications vide test report No.KQSC .247/2018 and declared unregistered drug product	nil

Sr. No.	**Name of Drug (s)**	**Reg. no.**	**Batch no.**	**Manufacturing date & Expiry date**	**Name of Allopathic ingredient Identification and test report No.**	**Manufactured by:**
01.	Knight rider extra powder tester delay capsule	Nil	Nil	02-12-2016 01-12-2020	Sildenafil Citrate identifications vide test report No.KQSC .242/2018 and	Royal herbal ent. Co,.plot no. 1730, near office, baildia town. No. 3, Karachi, Pakistan.

					declared unregistered drug product	
02.	Knight rider extra tester delay tester	Nil	Nil	02-12-2016 01-12-2020	Lidocaine identificati identificati ons vide test report No.KQSC .243/2018 and declared unregistered drug product	Royal herbal ent. Co,.plot no. 1730, near office, baildia town. No. 3, Karachi, Pakistan.
03.	Knight rider Herbal Delay Cream	Nil	Nil	Nov-2014 October 2022	Lidocaine identificati ons vide test report No.KQSC .245/2018 and declared unregistered drug product	Royal herbal ent. Co,.plot no. 1730, near office, baildia town. No. 3, Karachi, Pakistan.
04.	Tiger Balm	Nil	Nil	01-11-2016 01-11-2021	Methyl Salicylate identified vide report No. KQ. SC.244/20 18 dated 30-04-2018 and declared unregistered drug product	

03. The FID further informed that at the time of inspection the suspected owner Mr,.Saddique Sheikh of Ms Royal herbal Ent. Co, was at large/ not available and Mr. Muhammad Rafique

(introduced himself brother of Siddique) was looking after the business along with the under age (13-17 years) old labor accompanied during the inspection.

04. The FID also informed that **the permission for safe custody of seized drug of above seized along with permission for prosecution in drug court may kindly be issued at the earliest.**

05. Similarly, the FID along with same members of team inspected the same premises (situated at plot no. 1730/31 and 1730/12, Baldia town no. 3, Karachi on 10th April, 2018).

06. The FID informed that during the inspection, the suspected stocks/ Equipments of following drug (unregistered/ spurious) were recovered and it was found that the firm Ms. Royal Herbal Ent,. Co. is operating without Drug Manufacturing License or Enlistment number, therefore "**order made not to dispose off**" for the available stock on prescribed form-1 under DRAP Act, 2012. The details are as under:

Sr. No	**Name of Drug (s)**	**Batch no.**	**quantity**	**Mfg date**	**Expiry date**	**Purported to be Manufactured by:**
01.	Knight rider/ capsule	Nil	Huge	02-12-2016	01-12-2020	Royal Herbal Ent. Co,. Karachi.
2.	Condomnsgovernment of Sindh	1706083	Huge	06-2017	02-2022	Suzhou Wing Enterprise Development Co,. China
3.	Manufacturing tanks	01	Nil	Nil	Nil	Nil
4.	Tester filling machine	01	Nil	Nil	Nil	Nil
5.	Sealing machine	01	Nil	Nil	Nil	Nil
6.	Misc. packing materials of US AID and Government of Sindh	Huge	Nil	Nil	Nil	Nil

07. The FID also informed that the extension in period for the order made "**not to dispose off**" may kindly be extended as per Drugs Act 1976 and DRAP Act 2012.

Decision of 262nd meeting of CLB:-

The CLB considered the record of the case and decided as under:-

1. **Allowed safe custody to the Federal Inspector of drugs till the finalization of the case.**
2. **The Board also extended the not to dispose off period/sealing for further 90 days.**

3. **FID shall seize all the stocks which have been identified containing allopathic ingredients vide CDL Test reports.**
4. **It was also decided that FID should complete the investigations as soon as possible and send complete case fixing the responsibility of the offence.**
5. **The matter may also be shared with HOTC Division that the manufacturing unit is involved in heinous crime of unlicensed manufacturing of Allopathic drugs without product registration created safety concerns for the users under the garb of Herbal medicines.**

Case No.08 Permission for lodging of FIR for manufacture and sale of spurious and substandard drug namely Magnett-DS suspension Batch No.6291D

During market inspection the Muhammad Arif Ch. FID Peshawar took samples of Magnett-DS Suspension Batch No. 6291D from the premises of M/s Malik Medical house on Form-3 on 19-03-2018 and sent to the FGA CDL Karachi on Form-4 for test analysis

02. The FGA CDL Karachi declared the dug as under:

S.No.	Name of Drug	Batch No.	Claimed to be Mfg By	Test Report No. & Date	Result/Remarks
1.	Magnett DS Suspension	6291D	M/s S.J&G Fazul Ellahi (Pvt) Ltd Karachi	IP-49/2018(04-05-2018)	Spurious and substandard

03. Manufacture portion was sent to claimed manufacturer S.J&G Fazul Ellahie Pvt Ltd Karachi dated 21-03-2018 in response S.J G Fazul Ellahie disowned the drugs hence the drug is spurious under section 3/z-b(2) of the drugs Act 1976

04. On 21-03-2018 and 26-04-2017 Asad Ali proprietor of Malik Medical House Peshawar was asked to provide valid Drug Sale License warranty and other relevant documents but the reply of these letter are still awaited

05. Asad Ali proprietor of Malik Medical House Peshawar was served with a show cause notice to explain his position for manufacture and sale of spurious and substandard drug but the same was returned with the remarks that (Banda Yaha si Chala Gia Hn)

06. Asad Ali S/o Javed Khan proprietor of Mali Medical House Peshawar has violated Drug Act 1976 by manufacturing and selling of spurious and substandard which is an offence under section 23 of the Drugs Act 1976 and punishable under section 27(1) of the Drug Act 1976.

Permission of Lodging the FIR

07. **Hence the FID Peshawar requested to allowed to lodge FIR against the accused person Asad Ali S/o Javed Khan proprietor of Malik Medical House Shop No. 26 Amin Mansion G.T. Road peshawr for manufacturing spurious/substandard drug.**

Decision of 262nd meeting of CLB:-

The CLB examined record of the case including test reports and granted the Permission of Lodging the FIR against the accused person namely "Asad Ali S/o Javed Khan proprietor of Malik Medical House Shop No. 26 Amin Mansion G.T. Road peshawr for manufacturing and selling spurious/substandard drug". The said accused is also involved in manufacturing and selling of spurious/substandard drugs without having manufacturing license and product registration as required under the law. The offences of the accused persons are cognizable under schedule IV of the DRAP Act 2012 read with Section 30 of the Drug Act 1976.

The FID is directed to file complain for registration of FIR against the accused person and forward complete case for consideration of the CLB.

Case No. 09. <u>Vitamin B12 Injection Reg No.011203 Batch NoJ-2817, J-1118, J-2817 manufacture by M /s Ahson Drug Company SITE Tando Adam</u>

Mr. Abdul Rasool Shaikh FID Karachi along with team of DRAP officers inspected M/s Faisal Medicose Shop No. 1115/B2 New Sabzi Mandi Super Highway Karachi and M/s Akhwan Medicine & Company Shop No. 81/2 Bismillah Market near New Sabzi Mandi Super highway Karachi on 25-04-2018 to eradicate spurious/unregistered drugs from the market. During course of inspection FID Karachi recovered suspected spurious & Substandard drugs which were taken for the purpose of test analysis on Form 3 and remiaing stokc were ordere not to dispose of on prescribed Form-I under section 18 of the Drugs Act 1976 the details of the drug as under:-

Name of Drug	**Batch No..**	**Quanitity**	**Mfg Date**	**Exp. Date**	**Purported to be manufacturedd by**
Vitamin B12 Injection (Reg No. 011203	J-2817	100ampx1x18 packs	08-17	08-19	M/s Ahson Drug Company SITE Tando Adam
do	J-1118	100ampx1x3 packs	01-18	01-20	Do
do	J-2817	100ampx1x71 packs	08-17	08-19	Do

02. The FID Karachi request to **extend the period for ordered Not to dispose** of as per Drugs Act 1976 and rules framed there under till the fate of the case

<u>Decision of 262nd meeting of CLB:-</u>

1. **Allowed safe custody to the Federal Inspector of drugs till the finalization of the case.**
2. **The Board also extended the not to dispose off period for further 90 days.**
3. **It was also decided that FID should complete the investigations as soon as possible.**