MINUTES OF 263rd MEETING OF CENTRAL LICENSING BOARD HELD ON 11th JUNE, 2018

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263rd meeting of the Central Licensing Board (CLB) was held on 11th June, 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 inQC/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.	Mr. Adnan Rizvi, Sr. Drug Inspector, Health Department, Sindh.	Member
8.	Mr. Abid Saeed Baig, Secretary, PQCB, /Chief Drug Controller Primary and Secondary Health Care Department, Punjab	Member
9.	Mr. Abdul Sattar Sohrani Representative Director (QA/LT), DRAP, Islamabad	Member
10.	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
11.	Mr. Nadeem Alamgir, Representative of Pharma Bureau	Observer
12.	Mr Kamaran Anwar, Representative of PC&DA	Observer

The meeting started with the recitation of verses from the Holy Qura'an. The Chairman Central Licensing Board welcomed the honorable members and participants of the meeting. He stated that all the legal and codal formalities would be taken into account for disposal of cases and respective Divisions shall be responsible for the contents, errors and omissions of agenda and minutes. Mr. Ayyaz Ahmed, Deputy Director (Lic), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 262nd MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 262nd meeting held on 23rd May, 2018.

A. DRUG LICENSING DIVISION

Item-I: **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 Pakhiem International Pharma (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore. DML No. 000492 (Formulation) **Section (02)** **1.** Cream & Ointment (General) Section. **2.** Liquid Syrup (General) Section.	06-03-2018	**Good**	1. Dr. Ikram-ul-Haq, Member Central Licensing Board. 2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 3. Mr. Hafiz Muhammad Jawad Ali, Federal Inspector of Drugs, DRAP, Lahore. 4. Mr. Rana Ihsan ul Haq, Assistant Director (I&E), DRAP, Lahore
	Recommendations of the panel: - Panel has thoroughly inspected the unit and also discussed various technical aspects at length with technical staff. As the quality assurance is a continuous process, the firm shows commitment towards the development of quality culture to ensure the GMP guideline. Keeping in view of the above all, the panel recommended M/s Pakhiem International Pharma (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore for approval of aforesaid sections. **Decision by the Central Licensing Board in 263rd meeting** The Board considered and approved the grant of following two additional sections in the name of M/s Pakhiem International Pharma (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore.on the recommendations of the panel of experts:- **Section (02)** **1.** Cream & Ointment (General) Section. **2.** Liquid Syrup (General) Section.			

2.	M/s Zeta Pharmaceutical (Pvt) Ltd, Plot No. 494-A, Sunder Industrial Estate, Raiwind Road, Lahore DML No. 000818 (Formulation) **<u>Section (01)</u>** 1. Sachet (General) Section.	**28-05-2018**	**Good**	1. Dr. Mehmood Ahmed, Ex Dean, University of Bahawalpur. 2. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs. DRAP, Lahore.

Recommendations of the panel: -

Keeping in view the facilities like building, HVAC system, machinery& equipment, instruments, personnel, documentation, and Quality Control and testing facilities, panel of inspectors recommends the Grant of aforesaid additional section to M/s Zeta Pharmaceutical (Pvt) Ltd, 494/A, Sunder Industrial Estate, Raiwind Road, Lahore.

Decision by the Central Licensing Board in 263rd meeting

The Board considered and approved the grant of following one additional sections in the name of M/s Zeta Pharmaceutical (Pvt) Ltd, Plot No. 494-A, Sunder Industrial Estate, Raiwind Road, Lahore on the recommendations of the panel of experts:-

<u>Section (01)</u>

1. Sachet (General) Section.

3.	M/s Citi Pharma (Pvt) Ltd, 3.5-Km, Head Balloki Road, District Kasur DML No. 000429 (Semi Basic) **API's (03)** 1. Cephradine. 2. Cephalexin. 3. Cefixime.	**24-04-2018**	**Good**	1. Mr.Syed Mueed Ahmad, Member, Production Expert. 2. Mr. Shahid Nasir. Member Quality Control Expert. 3. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 4. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs. DRAP, Lahore.
	Recommendations of the panel: - The Panel observed that the firm has rectified most of the shortcomings pointed out during previous inspection. Therefore, based on the areas inspected, the people met and documents reviewed and considering the findings of inspection the panel was of the opinion that firm possessed the facility for manufacturing of aforesaid API's. The Panel of inspectors recommends the grant of additional section under DML No. 000429 in favour of M/s Citi Pharma (Pvt) Ltd to manufacture Active Pharmaceutical Ingredients (API's) by way of semi-basic manufacturing as per above mentioned list **subject to manufacturing of pilot scale batches of each API and submission of manufacturing and QC data to CLB prior to commencing commercial manufacturing and marketing the APIs.** **Decision by the Central Licensing Board in 263rd meeting** The Board considered and approved the grant of following additional APIs in the name of M/s Citi Pharma (Pvt) Ltd, 3.5-Km, Head Balloki Road, District Kasur on the recommendations of the panel of experts:- **API's (03)** 1. Cephradine. 2. Cephalexin. **3.** Cefixime. However, the firm shall conduct stability studies on first three batches.			
4.	M/s Moringa Pharmaceuticals (Pvt) Ltd, 35-A, Sunder Industrial Estate, Lahore. DML No. 000769 (Formulation) **Amendments (11)** 1. Provision of additional buffer in both male and female cloak	**06-06-2018**	**Good**	1. Dr. Ikram-ul-Haq, Member CLB. 2. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 3. Mr. Anjum Pervaiz, Consultant Registration &

	rooms. 2. Provision of post dispensing room in place of overprinting room. 3. Provision of transfer window between Solid Dispensing room and post dispensing room. 4. Existing door between solid dispensing room and Corridor is removed. 5. Provision of Volatile liquid store in place of existing room for return and recalls which is shifted in some portion of Finished Goods Store. 6. Provision of Non Volatile liquid store in place of existing Buffer area in Finished Goods Store which is shifted to office area of Finished Goods Store. 7. Provision of liquid pre-dispensing area and dispensing area. 8. Provision of over printing room in place of stacking area in Syrup section. 9. R&D Laboratory in place of Keeping Sample Store. 10. eeping Sample Store. 11. Visitor's waiting room alongwith ladies change room.			Licensing, PDCU. 4. Ms. Ufaq Tanveer, Federal Inspector of Drugs. DRAP, Lahore.
	Recommendations of the panel: - Keeping in view the facilities like building, HVAC system, machinery& equipment, instruments, personnel, documentation, and Quality Control microbiology lab, water treatment and testing facilities and the up gradation done in the light of amended layout plan, panel of inspectors recommends the renewal of Drug Manufacturing License to M/s Moringa Pharmaceuticals (Pvt) Ltd, Plot No. 35-A, Sunder Industrial Estate, Lahore for the following sections. The amendments in the layout have been carried out Satisfactory and as per approved			

	by DRAP. 1. Tablet (General and Antibiotics) Section. 2. Capsule (General and Antibiotics) Section. 3. Dry Suspension (General) Section. 4. Liquid Syrup (General) Section. **Decision by the Central Licensing Board in 263rd meeting** The Board considered and approved the improvements in the existing building as made as per approved Lay out plan on the recommendations of the panel of experts. The Board also allowed resumption of production which was previously stopped for the purpose of improvements to be made as per lay out plan.

Item-II: **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 News Pharma, 42-Sunder Industrial Estate, Lahore DML No. 000775 (Formulation) **Period**: 18-02-2018 to 17-02-2023	**26-04-2018**	**Nil**	1. Dr. Ikram-ul-Haq, Member CLB. 2. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs.
	Recommendations of the panel: - Keeping in view the facilities like building, HVAC system, machinery, equipment, personnel, documentation, and Quality Control microbiology lab, water treatment and testing facilities, panel of inspectors recommends the renewal of Drug Manufacturing License of the following sections to M/s News Pharma, 42-Sunder Industrial Estate, Lahore i. Liquid Injection (General). ii. Dry Powder Injection (Cephalosporin).			

	Meanwhile a letter is received from Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab wherein he has informed that Provincial Quality Control Board has suspended the Drug Manufacturing License of M/s News Pharma, for 15 days vide ordered dated 31st May, 2018 based on the inspection report (i.e. Inspection conducted on dated 24th May, 2018)submitted by Provincial Inspector of Drugs, Sunder Industrial Estate, & Multan Road, Lahore. Orders of the Provincial Quality Control Board, Punjab marked as **Annex-I**. **Decision by the Central Licensing Board in 263rd meeting** The Board considered and deliberated the case in the light of orders of the PQCB, Punjab and legal provisions. The Board decided to defer the renewal of the firm subject to submission of CAPA and further orders of the PQCB, Punjab on the matter.

2.	M/s Moringa Pharmaceuticals (Pvt) Ltd, 35-A, Sunder Industrial Estate, Lahore. DML No. 000769 (Formulation) **Period**: 07-03-2018 to 06-03-2023	**06-06-2018**	**Good**	1. Dr. Ikram-ul-Haq, Member CLB. 2. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 3. Mr. Anjum Pervaiz, Consultant Registration & Licensing, PDCU. 4. Ms. Ufaq Tanveer, Federal Inspector of Drugs. DRAP, Lahore.
	Recommendations of the panel: - Keeping in view the facilities like building, HVAC system, machinery& equipment, instruments, personnel, documentation, and Quality Control microbiology lab, water treatment and testing facilities and the up gradation done in the light of amended layout plan, panel of inspectors recommends the renewal of Drug Manufacturing License to M/s Moringa Pharmaceuticals (Pvt) Ltd, Plot No. 35-A, Sunder Industrial Estate, Lahore for the following sections. The amendments in the layout have been carried out Satisfactory and as per approved by DRAP. 1. Tablet (General and Antibiotics) Section. 2. Capsule (General and Antibiotics) Section. 3. Dry Suspension (General) Section. 4. Liquid Syrup (General) Section.			

	Decision by the Central Licensing Board in 263rd meeting The Board approved the renewal of Drug Manufacturing Licence No. 000769 (Formulation) in the name of M/s Moringa Pharmaceuticals (Pvt) Ltd, Plot No. 35-A, Sunder Industrial Estate, Lahore, on the recommendations of the panel of experts for the further period of five years Commencing on 07-03-2018 ending on 06-03-2023.			
3.	M/s Pharma Health Pakistan (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore. DML No. 000761 (Formulation) **Period**: 28-11-2017 to 27-11-2022	**21-05-2018**	**V. Good**	1. Dr. Ikram-ul-Haq, Member CLB. 2. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 3. Mr. Anjum Pervaiz, Health Department Government of Punjab, Lahore. 4. Mr. Shoaib Ahmed, Federal Inspector of Drugs. DRAP, Lahore.
	Recommendations of the panel: - Keeping in view the facilities like building, HVAC system, machinery& equipment, instruments, personnel, documentation, and Quality Control microbiology lab, water treatment and testing facilities and the up gradation done in the light of amended layout plan, panel of inspectors recommends the renewal of Drug Manufacturing License for the following sectionsto M/s Pharma Health Pakistan (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore. 1. Tablet (Hormone) Section. 2. Capsule (Hormone) Section. 3. Liquid Syrup (Hormone) Section. **Decision by the Central Licensing Board in 263rd meeting** The Board approved the renewal of Drug Manufacturing Licence No. 000761 (Formulation) in the name of M/s Pharma Health Pakistan (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore, on the recommendations of the panel of experts for the further period of five years Commencing on 28-11-2017 ending on 27-11-2022.			
4.	M/s Sami Pharmaceuticals (Pvt) Ltd, Plot No. F-95, Off Hub River Road, S.I.T.E, Karachi	**26-04-2018**	**V. Good**	1. Dr. Ghulam Sarwar, Member DRB, DRAP. 2. Dr. Noor Us Saba, Director Biological, DRAP,

	DML No. 000072 (Formulation) **Period**: 21-08-2015 to 20-08-2020			Islamabad 3. Dr. Najam Us Saqib, Additional Director, DRAP, Karachi. 4. Mr. Syed Hakim Masood, Federal Inspector of Drugs. DRAP, Karachi.
	Recommendations of the panel: - Keeping in view the Management commitment for continuous improvement, existing technical staff, facilities, The panel recommends the renewal of Drug Manufacturing License No. 000072 (Formulation) of M/s Sami Pharmaceuticals (Pvt) Ltd, Plot No. F-95, Off Hub River Road, S.I.T.E, Karachi. **Decision by the Central Licensing Board in 263rd meeting** The Board approved the renewal of Drug Manufacturing Licence No. 000072 (Formulation) in the name of M/s Sami Pharmaceuticals (Pvt) Ltd, Plot No. F-95, Off Hub River Road, S.I.T.E, Karachi, on the recommendations of the panel of experts for the further period of five years Commencing on 21-08-2015 ending on 20-08-2020.			
5.	M/s Marvi Pharmaceuticals, Plot No. 70, Sector-24, Korangi Industrial Area, Karachi. DML No. 000148 (Formulation) **Period**: 10-07-2015 to 09-07-2020	**14-04-2018**	**Good**	1. Dr. Ghulam Sarwar, Member DRB, DRAP. 2. Dr. Kalbe Hasan Rizvi, Chief Drug Inspector, Sindh. 3. Dr. Najam-Us-Saqib, Additional Director, DRAP, Karachi. 4. Dr. Najam-Us-Saqib, Federal Inspector of Drugs. DRAP, Karachi.

	Recommendations of the panel: - Panel recommends the renewal of grant of renewal of Drug Manufacturing License (Formulation)below mentioned sections. 1. Tablet (General) Section. 2. Liquid Syrup (General) Section. 3. Capsule (General) Section. 4. Ointment (General) Section. 5. Capsule (Penicillin) Section. 6. Dry Powder Suspension (Penicillin) Section. **Decision by the Central Licensing Board in 263rd meeting** The Board approved the renewal of Drug Manufacturing Licence No. 000148 (Formulation) in the name of M/s Marvi Pharmaceuticals, Plot No. 70, Sector-24, Korangi Industrial Area, Karachi., on the recommendations of the panel of experts for the further period of five years Commencing on 10-07-2015 ending on 09-07-2020.

6	M/s Maple Pharmaceuticals, Plot No.147, Sector-23, Korangi Industrial Area, Karachi. DML No. 000620 (Formulation) **Period**: Commencing on 17-07-2017 ending on 16-07-2022.	**29-11-2017**	**Good**	1. Syed Muid Ahmed, Member CLB. 2. Chief Drug Inspector, Karachi. 3. Director CDL, Karachi. 4. Area FID, DRAP, Karachi.

Recommendations of the panel: -

During the inspection panel observed that the firm is well equipped with necessary production and QC facilities in Tablet, Capsule and Dry Powder Suspension Sections. However, Oral Liquid Section, Ointment and Sachet Sections required to be up-graded with focus on equipment and machinery etc. Based on the areas inspected, people met and the documents reviewed panel recommends the grant of renewal of DML No.000620 (Formulation) **for following sections only**;

i. Tablet (General).
ii. Capsule (General).
iii. Dry Powder Suspension (General).

Decision by the Central Licensing Board in 263rd meeting

The Board approved the renewal of Drug Manufacturing Licence No. 000620 (Formulation) in the name of M/s Maple Pharmaceuticals, Plot No.147, Sector-23, Korangi Industrial Area, Karachi, on the recommendations of the panel of experts for the further period of five years Commencing on 17-07-2017ending on 16-07-2022 for the following sections namely;

i. Tablet (General).
ii. Capsule (General).
iii. Dry Powder Suspension (General).

*However, the Board considered and did not approve the renewal of Drug Manufacturing Licence for***Oral Liquid Section, Ointment and Sachet Sections**. *The Board further decided that the licensee shall rectify the shortcomings noted by the panel within a period not less than one month under Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 from the date of issuance of decision of the Board in the said sections. The licensee shall inform regarding rectifications made and accordingly panel would be constituted to verify the improvements made. Manufacturing in the premises shall remain suspended till decision by the Board. The Central Licening Board will take a decision on the recommendations of the panel either to grant renewal of licence or reject the application for the said sections and inform the licencee accordingly*

CASE No. 7. **GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE.**

Case Background

The Case for grant of renewal of DML of M/s Aims Pharmaceuticals, Plot No. 291, Industrial Triangle Kahuta Road, Islamabad for the period of 21-03-2017 to 20-03-2020 was placed in 256th meeting of Central Licensing Board held on 9th and 10th November, 2017 and board decided as under:-

> "The Board approved the renewal of Drug Manufacturing License for the further period w.e.f **21-03-2017 to 20-03-2022.**

It is submitted that the recommendations of the panel were as under:-

> *"Keeping in view the above said observations, people met on site, documents reviewed; the panel unanimously* ***recommended not to grant*** *renewal of DML to M/s Aims Pharmaceuticals till the rectification of the shortcomings pointed out by the panel and verification of compliance of these by the same panel."*

Due to typographical mistake the words **board approved the renewal** were inadvertently mentioned in minutes.

Proceedings and Decision of Central Licensing Board in 257th meeting

The Board approved the correction in decision of the 256th meeting of the Central Licensing Board and decision may be read as under:

"*The Board considered the case and did not approve the renewal of Drug Manufacturing Licence. The Board further decided that the licensee shall rectify the shortcomings noted by the panel within a period not less than one month under Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 from the date of issuance of decision of the Board. The licensee shall inform regarding rectifications made and accordingly panel would be constituted to verify the improvements made. Manufacturing in the premises shall remain suspended till decision by the Board. The Central Licening Board will take a decision on the recommendations of the panel either to grant renewal of licence or reject the application and inform the licencee accordingly*."

The following panel members re-inspected the Firm after rectification of shortcoming pointed out by the previous panel members. The following case has 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 Aims Pharmaceuticals, Plot No. 291, Industrial Triangle Kahuta Road, Islamabad. DML No. 000608 (Formulation) **Period**: **21-03-2017 to 20-03-2022.**	**31-05-2018**	**Good**	1. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad. 2. Dr. Gul Majeed, Prof. of Pharmacy, Quaid-i-Azam University, Islamabad. 3. Babar Khan, Area FID, Islamabad. 4. Assistant Director (Licensing-III), DRAP, Islamabad.
	Recommendations of the panel: - Keeping in view the above said observation summarized in last column, people met on site, documents reviewed; the panel unanimously recommended to grant renewal of DML to M/s Aims Pharmaceuticals. **Decision by the Central Licensing Board in 263rd meeting** The Board approved the renewal of Drug Manufacturing Licence No. 000608 (Formulation) in the name of M/s Aims Pharmaceuticals, Plot No. 291, Industrial Triangle Kahuta Road, Islamabad, on the recommendations of the panel of experts for the further period of five years Commencing on **21-03-2017** ending on **20-03-2022.** The Board also revoked the suspension of production of the firm for further period and allowed resumption of the production with immediate effect.			

Case No. 8 <u>INSPECTION REPORT OF M/S HIMONT PHARMACEUTUCALS, LAHORE.</u>

A panel inspection report pertaining to M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore forwarded vide letter No. F. No. 1-59/2017-FID IV dated 21st June, 2017, on the subject cited above. The panel observed that in Cephalosporin Section approved change room was not being used and it has been converted into washing area. The firm was using another room for entrance which was not provided with proper change over facility for workers. It was observed that the workers in the section were just wearing a coat over their street cloths. The panel was of the opinion that in this sensitive area of manufacturing the workers should wear proper uniform to avoid any chance of cross contamination, additionally it may pose a greater risk on workers and others safety due to exposure to the Cephalosporin powders sticking on the cloths. The panel advised the firm to provide proper change over facility for the workers. In the Capsule (General) Section, the firm has provided only manual Capsule filling machines, which seems not to be appropriate to meet the latest GMP

requirements. The Panel recommended the renewal Drug Manufacturing License to all approved sections except Capsule (General) and Cephalosporin (injectable, oral dry powder suspension &capsule) section.**The case was accordingly placed before the Central Licensing Board in its 255th meeting held on 16-17th August, 2017.**

The Central Licensing Board considered the facts of the case, legal provisions and decided as under;

> *"The Board decided to issue Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for suspension or cancellation for Capsule (General) and Cephalosporin (injectable, oral dry powder suspension & capsule) section on the recommendations of the panel of experts".*

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

The Show Cause notice dated 12th January, 2018 was issued to the M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore.

Reply of the show cause is received from the firm which is as under:-

Sr. No	Observations	Status
1	**General Capsule Area** • It was noted that in the general capsule section the firm has provided only manual capsule filling machine which seemed not to be appropriate to meet • The latest GMP requirement Capsule polisher and metal detector to be installed.	• **Complied** semi-automatic machine installed • **Complied.** Capsule polisher and metal detector installed.
2	**Capsule Area (Cephalosporin)** Capsule was neat and clean provided with the required machine and equipment. HVAC system was installed and functional. It was note provided with proper change over just wearing a coat over their street cloths addition to cross contamination may also pose a greater risk on workers own and others safety due to exposure to the Cephalosporin powders sticking on the cloths. The firm was also advised to provide capsule polisher and metal detector in the section.	• **Complied.** Change over facility provided • **Complied,** Capsule polisher and metal detector installed.
3	**Oral Dry Powder Suspension(Cephalosporin)** Metal was neat and clean provide with the require machine and equipment. HVAC system was installed and functional. It was not provided with proper change over facility for workers. The workers in the section were just wearing a coat over their street cloths which in addition to cross contamination may also pose a greater risk on workers and others safety due to exposure Cephalosporin powders sticking on the cloths.	• **Complied,** Change over facility provided
4	**Dry Powder Injectable (Cephalosporin)** Section was neat and clean provided with the require machine and equipment. HVAC system was installed and functional. It was noted that entrance to this section was not provided with	• **Complied,** Change over facility provided

	proper change over facility for workers. The workers in section were just wearing a coat over their street cloths which in addition to cross contamination may also pose a greater risk on workers own and others safety due to exposure to the Cephalosporin powders sticking on the cloths.	
5	**Quality Control** In quality department the firm possesses necessary equipment to carry out the testing / analysis for the products being manufactured quality control equipment were installed and calibrated. Among the major instruments the firm possesses the HPLC, UV spectrophotometer. Karl Fisher, TOC, and liquid particle analyzer etc. The microbiology lab was also equipped. However, it was noted that FTIR was out of order; the firm was advised to make it functional at earliest.	• FTIRhas been sent for diagnosis and rectification of problem to Perkin Elmer Company**.**

The firm has been called for personal hearing vide Licensing Division letter dated 17th January, 2018.

Proceedings and Decision of Central Licensing Board in 257th meeting.

Dr. Maqsood Ahmed, Head Quality Operations appeared before the Board and contended that all rectifications have been made as per advice of the panel of experts. He further requested that panel of experts may be constituted for verification of the improvements made **in Capsule (General) and Cephalosporin (injectable, oral dry powder suspension & capsule) section.** The Board after hearing the representative of the firm decided to constitute same panel for verification of improvements made. The Board also authorized that Chief Drug Controller may be replaced with Mr. Anjum Pervaiz in the panel.

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

The letter of panel inspection dated 27thFebruary, 2018 was issued to the M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore.

Inspection report received from Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. The conclusion of inspection report is as under:

S #	Name of the firm	Date of Inspection	Ranking / Evaluation	Inspection Panel Members
1	M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore DML No. 000231 (Formulation)	**22-05-2018**	**Good**	1.Dr. Ikram Ul Haq, Member of CLB / Expert in QC of Drugs. 2.Dr. Shafiq Ur Rehman, Director, Drug Testing Laboratory, Lahore. 3.Mr. Ajmal Sohail Asif, FID,

				DRAP, Lahore. 4.Mr. Shoaib Ahmed, FID, Lahore.

"Keeping in view ratification done by the firm & observation made by the panel on various parameters. The Panel of inspectors recommends the renewal of DML bearing No. 000231 in respect of **Capsule (general) and Cephalosporin (Injectable / Oral Dry Powder Suspension and Capsule) section** with held during last inspection for want of improvement".

Decision by the Central Licensing Board in 263rd meeting

The Board approved the renewal of Drug Manufacturing Licence No. 000231 (Formulation) in the name of M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore, on the recommendations of the panel of experts for the further period of five years Commencing on **21-03-2017** ending on **20-03-2022**for the following sections.

1. Capsule (general)
2. Injectable Section (Cephalosporin)
3. Oral Dry Powder Suspension Section (Cephalosporin)
4. Capsule Section (Cephalosporin)

The Board also revoked the suspension of production of the firm in above sections for further period and allowed resumption of the production with immediate effect.

Item-IV: **MISCELLANEOUS CASES**

CASE NO. 1 CHANGE OF MANAGEMENT OF M/S CITI PARMA (PVT) LTD, DISTRICT KASUR

M/s Citi Parma (Pvt) Ltd. 3.5 km, Head Baloki Road, Bhai Bheru Distt. Kasur under DML No. 000429 by way of Semi Basichas submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Existing Management as per Form-A	Retiring Management	Proposed Management as per Form-A
1. Mr. Ateeq-ur-Rehman CNIC No. 35202-2896835-1. 2. Mr. Nadeem Amjad CNIC No. 35202-5060989-7.	1. Mr. Ateeq-ur-Rehman CNIC No. 35202-2896835-1.	1. Mr. Nadeem Amjad S/o Shar Muhammad CNIC No. 35202-5060989-7. 2. Mr. Rizwan Ahmad S/p Shar Muhammad CNIC No. 35202-6462958-5.

Decision by the Central Licensing Board in 263rd meeting:

The Board considered and endorsed the change of management from old to new management of M/s Citi Parma (Pvt) Ltd. 3.5 km, Head Baloki Road, Bhai Bheru Distt. Kasur, under DML No. 000429by way of basic manufacture as per Form-A as under;

Existing Management as per Form-A	Retiring Management	New Management as per Form-A
1. Mr. Ateeq-ur-Rehman CNIC No. 35202-2896835-1. 2. Mr. Nadeem Amjad CNIC No. 35202-5060989-7.	1. Mr. Ateeq-ur-Rehman CNIC No. 35202-2896835-1.	1. Mr. Nadeem Amjad S/o Shar Muhammad CNIC No. 35202-5060989-7. 2. Mr. Rizwan Ahmad S/o Shar Muhammad CNIC No. 35202-6462958-5.

Case No.2. **CHANGE OF LEGAL STATUS / NAME OF M/S VISION PHARMACEUTICALS, PLOT NO. 22-23, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

M/s Vision Pharmaceuticals, Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000517 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
Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle , Kahuta Road , Islamabad .	Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle , Kahuta Road , Islamabad .

Decision by the Central Licensing Board in 263rd meeting:

The Board considered and approved the change of title/ name of M/s Vision Pharmaceuticals, Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad, under DML No. 000517by way of Formulation as under;

Previous Title/legal status of firm	Proposed title / legal status of Firm as per Certificate of incorporation of S.E.C.P
Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle , Kahuta Road , Islamabad .	Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle , Kahuta Road , Islamabad .

Case No.3. **CHANGE OF LEGAL STATUS / NAME OF M/S VISION PHARMACEUTICALS, PLOT NO. 22-23, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000806 by way of Semi Basic 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
Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle , Kahuta Road , Islamabad .	Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle , Kahuta Road , Islamabad .

Decision by the Central Licensing Board in 263rd meeting:

The Board considered and approved the change of title/ name of M/s Vision Pharmaceuticals, Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad, under DML No. 000806by way of Semi Basic Manufacture as under;

Previous Title/legal status of firm	Proposed title / legal status of Firm as per Certificate of incorporation of S.E.C.P
Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle , Kahuta Road , Islamabad .	Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle , Kahuta Road , Islamabad .

Case No. 4 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDELLA PHARMACEUTICALS (PVT) LTD, LAHORE

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

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

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

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

11. All documents should be duly attested.

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

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

Proceedings and Decision of Central Licensing Board in 263rd 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 Medella Pharmaceuticals (Pvt) Ltd, Plot No. 569/570, Sunder Industrial Estate, Raiwind Road, Lahore under DML No. 000749 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 5 GRANT OF DRUGS FOR RE-PACKING:

M/s Risma Laboratories, A-2B, S.I.T.E, Karachi under Drug Manufacturing License No. 000053 by way of formulation has submitted Application for Grant of Re-packing drug as per Schedule-D. Firm has deposited fee of Rs. 5,000/- per product.

Sr.No	Name of drugs for Repacking	Schedule-D
01	Castor Oil	Yes
02	Liquid Paraffin	Yes
03	Glycerine	Yes

Proceedings and Decision of Central Licensing Board in 263rd meeting

The Board considering the case and decided to grant permission for above mentioned repacking items.

Case No. 6 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. (000684) (FORMULATION) OF M/S BRAND PHARMA INTERNATIONAL, K-105, PHASE-II, S.I.T.E, SUPER HIGHWAY, KARACHI**

M/s Brand Pharma International, K-105, Phase-II, S.I.T.E, Super Highway, Karachi was issued the License No. 000684 (Formulation) on 10-05-2010 and due date of renewal of License was 09-05-2015. 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 10-05-2015 to 09-05-2020 has not been received till date. Therefore, DML No. 000684 (Formulation) M/s Brand Pharma International, K-105, Phase-II, S.I.T.E, Super Highway, Karachi is no more valid.

Proceedings and Decision of Central Licensing Board in 257th meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000684 by way of formulation of M/s Brand Pharma International, K-105, Phase-II, S.I.T.E, Super Highway, Karachi may not be declared cancelled.

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

The Show Cause notice dated 27th February, 2018 was issued to the M/s Brand Pharma International, K-105, Phase-II, S.I.T.E, Super Highway, Karachi.

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

A letter of Personal hearing has been issued on 20th March, 2018.

Proceedings and Decision of Central Licensing Board in 259thmeeting

No person appeared on behalf of the firm. The Board deferred the case for want of report from Federal Inspector of Drugs and service of showcause notice to the firm through Federal Inspector of drugs.

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

Report of Federal Inspector of Drugs, Karachi is received wherein it is stated that Area Federal Inspector of Drugs Mr. Abdul Rasool Sheikh visited the firm on 25th May, 2018. The firm was found closed and no one was available to receive the showcause notice. It is learnt that firm is purchased is other management and there contact details / whereabouts are not available.

Proceedings and Decision of Central Licensing Board in 263rd meeting

The Board considered the case on the facts mentioned above and decided to declare the Drug Manufacturing Licence No. 000684 of M/s Brand Pharma International, K-105, Phase-II, S.I.T.E, Super Highway, Karachi invalid/ cancelled under Section 41 of the Drugs Act, 1976 read with Rule 5 (2A) and Rule 6 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as applicant fail to file an application for renewal of Drug Manufacturing Licence with effect from 10-05-2015.

Case No. 7 **APPROVAL OF MASTER LAYOUT PLAN / AUTHENTICATION / REGULARIZATION OF EXISTING FACILITY, DRUG MANUFACTURING LICENSE NO.000072 (FORMULATION) OF M/S SAMI PHARMACEUTICALS (PVT) LTD, PLOT NO. F-95, OFF HUB RIVER ROAD, S.I.T.E, KARACHI**

M/S Sami Pharmaceuticals (Pvt) Ltd, Plot No. F-95, Off Hub River Road, S.I.T.E, Karachi,DML No. 000072 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

Basement	Ground Floor
i). Raw Material Storage Area.	i). Biological Products (rDNA Protein Products, Heparins, Monoclonal Antibodies) Section.
ii). Packing Material Store (Bio-Tech Products).	ii). Oral Liquid (Syrup/Suspension/Drop) (General / General Antibiotic) Section.
Second Floor	iii). Granulation / Pelletization / Taste Masking Area (General / General Antibiotic) Section.
i). Liquid Injectable – SVP (General / General Antibiotic) Section.	iv). Liquid Injectable- LVP (General / General Antibiotic) Section.
ii). Quality Control Laboratory	v). Packing Material Store.
iii). Tablets (Psychotropic) Section.	vi). R&D Laboratory.

iv). Capsules (Psychotropic) Section.	**First Floor**
v). Liquid Injectable – SVP (Psychotropic) Section.	i). Biological Products (Human Vaccines Killed / Concentrate & Antisera).
vi). Tablets (General / General Antibiotic) Section.	ii). Tablet (General / General Antibiotic) Section.
vii). Capsules (General / General Antibiotic) Section.	iii). Capsule (General / General Antibiotic) Section.
viii). Dry Powder Suspension (General / General Antibiotic) Section.	iv). Sachet (General / General Antibiotic) Section.
ix). Quality Control Laboratory (Biological Products).	v). Liquid / Freeze Dried Injectable (General / General Antibiotic) Section.
**********	vi). Quality Control Laboratory.
**********	vii). Tablets (Hormone) Section.
**********	viii). Gel / Cream / Ointment (General / General Antibiotic) Section.

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

1. Dr. Ghulam Sarwar, Member DRB, DRAP.
2. Dr. Noor Us Saba, Director Biological, DRAP, Islamabad
3. Dr. Najam Us Saqib, Additional Director, DRAP, Karachi.
4. Mr. Syed Hakim Masood, Federal Inspector of Drugs. DRAP, Karachi.

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

Recommendations: -

The Panel of inspectors endorsed the regularization of the above mentioned section to M/sSami Pharmaceuticals (Pvt) Ltd, Plot No. F-95, Off Hub River Road, S.I.T.E, Karachi

Decision of Central Licensing Board in 263rd meeting

The Board considered the case and approved the regularization of the existing facility as per approved Lay out plan on the recommendations of the panel of experts.

Quality Control Cases)

CASE NO. 1 MANUFACTURE OF UN-REGISTERED DRUGS

Mr. Syed Hakim Masood, FID-III & IV, Karachi vide No. F. SHM-NTF-35-40/2018-DRAP(K) dated 18.05.2018 has informed with reference to his visit alognwith officers and officials of DRP, Karachi on 10.04.2018, where in FID-III&IV, Karachi took following samples for the purpose of test/analysis on prescribed Form-3 also seized on prescribed Form-2 and order "Made not to dispose off" on prescribed Form-I under the Drugs Act 1976/DRAP Act 2012.

Serial No.	Name of Drug	Reg. No.	Batch No.	Manfg. Date	Expiry Date	Manufactured By
1	Knight Rider Extra Powder Tester Delay Capsule	Nil	Nil	12-2016	12-2020	M/s Royal Herbal Ent.. Co., Plot No. 1730, Near Office, Baldia Town No. 3, Karachi-Pakistan
2	Knight Rider Tester Delay Tester	Nil	Nil	02-12-2016	01-12-2020	-do-
3	Tiger Balm	Nil	Nil	01-11-2016	01-11-2021	-do-
4	Knight Rider Herbal Delay Cream	Nil	Nil	Nov. 2014	Oct. 2017	-do-
5	Unlabelled Filled Capsule	Nil	Nil	Nil	Nil	Nil
6	Unlabelled Off White Powder	Nil	Nil	Nil	Nil	Nil

2. FID submitted that the above samples were sent to the Federal Government Analyst, Central Drugs Laboratory, Karachi, for the purpose of test/analysis on prescribed Fomr-4. The sealed portion of the products was also send to the Chairman CLB vide this office letter of even no. dated 10th April, 2018.

3. The Federal Government Analyst, CDL, Karachi, has declared the following **06 samplesas "Un-registered". Details are as under**

Serial No.	Name of Drug	Name of Allopathic ingredient identified	Batch No.	Manfg. Date	Expiry Date	Manufactured By	Result
1	Knight Rider Extra Powder Tester	**as Salfinadil Citrate**	Nil	12-2016	12-2020	M/s Royal Herbal Ent.. Co., Plot No. 1730, Near Office, Baldia Town No. 3, Karachi-Pakistan	**Un-Registered Drug Product** vide test report No. KQ.SC. 242/2018 Dated 30.04.2018
2	Knight Rider Tester Delay Tester	**As lidocain identified**	Nil	02-12-2016	01-12-2020	-do-	**Un-Registered Drug Product** vide test report No. KQ.SC. 243/2018 Dated 30.04.2018
3	Tiger Balm	**As Methyl Salicylate**	Nil	01-11-2016	01-11-2021	-do-	**Un-Registered Drug Product** vide test report No. KQ.SC. 244/2018 Dated 30.04.2018
4	Knight Rider Herbal Delay Cream	**As lidocain identified**	Nil	Nov. 2014	Oct. 2017	-do-	**Un-Registered Drug Product** vide test report No. KQ.SC. 245/2018 Dated 30.04.2018
5	Unlabelled Filled Capsule	**as Salfinadil Citrate**	Nil	Nil	Nil	Nil	**Un-Registered Drug Product** vide test report No. KQ.SC. 246/2018 Dated 30.04.2018
6	Unlabelled	**as**	Nil	Nil	Nil	Nil	**Un-**

	Off White Powder	**Salfinadil Citrate**					**Registered Drug Product** vide test report No. KQ.SC. 247/2018 Dated 30.04.2018

4. FID-III&IV, Karachi informed that he has directed the firm to explain their position that why action may not be taken against them under the Drugs Act 1976 & DRAP Act 2012

5. The reply of the firm was un-satisfactory as reported by the FID-III&IV, Karachi which he has received vide Dy. No. 1432 dated 14.05.2018 alongwith enclosures

6. Findings of FID-III&IV, Karachi is as under:

"as per above said Federal Government Analyst, CDL, Karachi test reports M/s Royal Herbal Ent. Co. situated at Plot No. 1730/121, Near Office, Baldia Town No. 3, Karachi is involved in manufacturing and selling of Un-registered Drugs which is in violation of Section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b) and 23(1)(e) of the Drug Act 1976 enacted with DRAP Act 2012.

7. 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 therapeutic goods except under and in accordance with the condition of a license issued under this Act and;
d. A (1)(e), Import or export any therapeutic goods drugs for the import or export of which a license is required except under , and in accordance with the conditions of such license.
e. A (1)(i) sell any therapeutic good without having warranty in the prescribed form bearing the name and batch number of the therapeutic good issued

08. The Prohibitions mentioned in para 2 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)(b) Manufactures for sale any therapeutic good without a license.
c. (1)(c), Imports without license any therapeutic goods for the import of which a license is required.
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

9. FID III&IV, Karachi has requested that permission of "lodging of FIR may be grant against the following accused persons

"in the light of above, permission for FIR against the following accused persons may kindly granted at the earliest:

1. M/s Royal Herbal Enterprises company (Pvt) (Ltd), 1730/121 Gujrat Colony Baldia Town Karachi.
2. Muhammad Rafiq s/o Muhammad Mustafa CNIC No. 42401-1720339-1
3. Muhammad Siddiq s/o Muhammad Mustafa CNIC No. 424013-961859-1

Decision:

The Central Licensing Board considered the report of Federal Inspector of Drugs Karachi, test reports and relevant record of the case and decided as under:

1. That the accused persons 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 therapeutic goods except under and in accordance with the condition of a license issued under this Act and;

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

e. A (1)(i) sell any therapeutic good without having warranty in the prescribed form bearing the name and batch number of the therapeutic good issued

2. The Prohibitions mentioned in para 2 are offences and punishable under 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)(b) Manufactures for sale any therapeutic good without a license.

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

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

3. FID, Karachi is allowed to "lodge FIR against the following accused persons for violations mentioned in para 1& 2 herein above.

i. **M/s Royal Herbal Enterprises company (Pvt) (Ltd), 1730/121 Gujrat Colony Baldia Town Karachi.**
ii. **Muhammad Rafiq s/o Muhammad Mustafa CNIC No. 42401-1720339-1**
iii. **Muhammad Siddiq s/o Muhammad Mustafa CNIC No. 424013-961859-1**

Case No.02 **M/s Marush International Pvt Ltd Lahore**

Mr. Ghazanfar Abbas filed complained against Mahrush International Pvt Ltd that the company is importing following products and doses without any registration and without any lawful authority on the basis of fake and factitious letters allegedly issued by DRAP

i. **Clon H/120,2500 DS**
ii. **SHS,1000 DS.**
iii. **Hipra Pox, 1000DS**
iv. **Hipra Viar ILT, 1000DS**
v. **Toxi Pra, 57, 250ml**
vi. **Sevac New K, 1000 doses**
vii. **Vectormune Fp-MG**
viii. **Hipra Viar BPL/2**
ix. **Hipra ND Broiler, BPL/2**
x. **H Pravac ND Broiler**
xi. **Diluents, 400MI**
xii. **Solvent, Hipra 1000DS**

2. Accordingly Additional Director Lahore was asked to investigate the matter. Following officers investigated the matter at length

1. **Mr. Ajmal Sohail Asif**
2. **Area FID**
3. **Rana Ihsan ul Haq ADC Lahore**

3. The said committee completed their investigations and it was revealed that M/s Mahrush International has imported illegally a number of drugs the list was verified from the record of PE &R Division and Biological Division. After correspondence with the Directorate of Custom and investigation FBR Lahore it was stated by them that Directorate of Intelligence and investigation have detected mega scam of fiscal fraud and money laundering committed by M/s Mahrush International 123 K Model Town Lahore raid were conducted on the business premises and ware house on 11-02-

2017 which lead to the recovery of overwhelming evidence against the said importer and FIR No.5/2017 dated 11-02-2017 has been registered during the raid on the ware house on the importer a large quantity of offending goods was also recovered and seized under section 168 of the Custom Act 1969 they also requested that registration status of the drug mentioned may be confirmed to this office to complete the process of auction further a comprehensive list of registered drugs may also be provided. The custom authorities as mentioned following offences in the Challan

a. **Massive mis-declaration of value by suppressing the actual transactional value of the imported goods by way of submission of fake import invoices and other documents before Customs for clandestine clearance.**
b. **illegal import of poultry medicines/vaccines by presenting fake/irrelevant provisional authorizations of the Drug Regulatory Authority of Pakistan.**
c. **Transfer of foreign exchange of the suppressed values to the suppliers abroad through illegal means.**

4. The investigation of the case was conducted by the officer in association with co investigating officer Mr. Muhammad Mube intelligence officer. The investigation conducted so far emerged the following

a. Accused persons namely Shahzad Aslam and Mubashir Nawaz Al Incharge and Accountant respectively of M.s Marush International were arrested on 11-02-2017 However they were discharged frc vide order dated 13-02-2017 passed by this learned court Therefore the above tow accused persons have not been mentioned in lour their interim challan
b. Accused Muhammad Zia uddin is the import Manger of international Lahore who was arrested on 11-02-2017 at Karachi shifted to Lahore through process of the court of law At presser accused person is in judicial custody and confined to District Lahore the post arrest bail of the above accused persons has dismissed vide order dated 02-03-2017 passed by this learned court
c. Accused Ansar Mahmood is the General manger of M/s Marush Lahore He was arrested on 25-02-2017 for his involvement in p0resent the above accused persons is in judicial custody and confine camp Jail Lahore His post arrest bail has also been dismiss dated 13-03-2017 passed by this learned court. His post arrest bail also been dismissed by the Lahore High Court Lahore dated 28-04-2017 passed in Criminal Miscellaneous No.4437-B
d. Accused Muzammil Hussain Shah is the Director of m/s Marush 123 K model Town Lahore He is also privy to fiscal fraud company case. The poultry/animal drugs/vaccines/antibiotics etc subject instant case are registered in the name of M/s marush

Pvt Ltd As per modus operandi M/s Marush Pvt Limited used to issued name of its sister concern firm M/s marush international Lahore for import of the above poultry drugs honorable Lahore High Court which was also dismissed vide dated 28-04-2017 passed by the Special Appellate Court at Lahore High Court in Criminal miscellaneous No.4743-B/2017later was admitted to ad interim pre arrest bail allowed by a Division bench Lahore High Court in WP No25659/2017 which subjudice.

e. Accused Syed Usman Ali Shah is the sole proprietor of M/s marush Lahre he is one of the two accused persons in the case All the poultry/animal drugs vaccines etc subject matter of the instant case have been imported by M/s marush Lahore on the basis of indents issued by the company father i.e. M/s marush Pvt Ltd Lahore accused person obtained pre arrest interim bail in the instant case w.p dismissed vide order dated 16-04-2017 passed by this learned court he could not be arrested due to his non availability in the court late arrest bail petition No.20276-B/2017 was also dismissed vide order 2 passed by the special Appellate Court at Lahore At present the above accuse persons has been admit interim pre arrest bail allowed by a Division bench of High Court Lahore in SP No.25657/2017 which is still subjudice.

5. Accordingly FID Lahore directed Marush International Lahore to explain their position about the import of 13 unregistered drugs which were verified by the PE&R and Biological Divisions as unregistered. FID also asked for provision of attested copies of drug sale license CNIC and other documents. M/s Marush Pvt Lahore informed that following offences are incorporated in the FIR No.05/2017

1. Section 16 power to prohibit or restrict importation and exportation of goods
2. Section 32A. Fiscal fraud.

6. but as per FIR nature of offences as under:-

a. **Fiscal fraud/mis-declaration of actual transactional value of the imported goods submission of fake documents before customs and fraudulent evasion of duty/taxes in import of poultry vaccines, medicines etc.**

7. The FID Lahore mentioned that as some of the seized products of M/s Marush International Lahore declare as un registered by your good self vide DRAP Islamabad letter No. F.No.14-15/2017-QC dated 18-05-2018 and stock/sale of unregistered drugs is prohibited under the drugs Act 1976/DRAP Act 2012 and is offence under Schedule II of the DRAP Act 2012 which is punishable under schedule III of DRAP Act 2012 so the case may be proceeded under the law.

8. As per Drug Act 1976, section 2 stipulate as under:-

Application of other laws not barred: The provisions of this Act shall be in addition to and not in derogation of the Dangerous Drugs Act 1930 (II of 1930) and any other law for the time being in force.

Request for permission of FIR

09. As the importer has committed offence by importing unregistered products without authorization from the DRAP as required under the law. **It is therefore requested that permission for lodging the FIR** may be allowed against the following accused persons:-

1. **Syed Muzamil Hussain Shah S/of Muhammad Jamal Shah**
2. **Syed Usman Ali Shah s/o Muzamil Husain Shah**
3. **Muhammad Zia uddin S/o Muhammad yousaf uddin**
4. **Ansar Mahmood son of Muhammad Siddique**

Proceeding of 263rd meeting:

The Central Licensing Board examined and considered the following documents:

i. **Report of Federal Inspector of Drug Lahore.**
ii. **Complaint filed by Mr. Malik Ghazanfar Abbas S/o Malik Muhammad Nawaz Resident in Lahore.**
iii. **Investigation Report by the DRAP Lahore about the import of unregistered therapeutics goods consignments by M/s Mahrush International Pvt Ltd 123 Model Town, Lahore.**
iv. **Inquiry proceedings of the 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.**
ix. **Record of FIR no. 5/2017 against M/s Mahrush International pvt limited Lahore under the Customs Act.**
x. **Challan of the case in FIR no. 5/2017 under Customs Act.**

Decision:

A. The Central Licensing Board considered the request of Federal Inspector of Drugs, Lahore and unanimously decided to permit the FID Lahore for registration of FIR against the following accused persons.

1. **Syed Muzamil Hussain Shah S/of Muhammad Jamal Shah, Caste Syed, R/o House no. 318-W, phase-III, Defense Housing Authority Lahore cantt: [director of M/s Marush Limited Lahore.**

2. **Syed Usman Ali Shah S/o Muzamil Husain Shah, Caste Syed, R/o House `no. 318-W, phase-III, Defense Housing Authority, Lahore Cantt [sole proprietor of M/s Marush International Lahore.**
3. **Muhammad Zia uddin S/o Muhammad yousaf uddin, Caste Uddin, R/o B-6, Railway Housing society, Project no. 3, Model Colony, District Malir, Karachi.**
4. **Ansar Mahmood son of Muhammad Siddique, Caste khokhar, R/o House no. 1457/16, Street no. 103, Sarfraz Rafiqui Road, Lahore Cantt.**

B. That the above said accused persons imported un-registered drugs without valid authorization from DRAP. They have violated the following provisions of DRAP Act 2012/ the Drugs Act, 1976 and rules framed there under including Drugs (Import & Export) Rules, 1976.

C. That the accused persons 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;

D. The Prohibitions mentioned in para 2 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. (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.

c. (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

The meeting ended with the vote of thanks to and by the Chair.