MINUTES OF 275th MEETING OF CENTRAL LICENSING BOARD HELD ON 25thJUNE, 2020

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275thmeeting of the Central Licensing Board (CLB) was held on 25thJune, 2020 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.	Dr. Muhammad Usman, Expert member Manufacturing of Drugs	Member
2.	Mr. Zahid Khan, Chief Drug Inspector, Peshaawar, Department of Health, Govt of Khyber Pakhtunkhwa.	Member
3.	Mr. Azhar Jamal Saleemi, Chief Drug Controller, Primary and Secondary Health Department, Government of Punjab, Lahore	Member
4.	Mr.Abid Ali, Deputy Draftsman, , Ministry of Law & Justice Division, Islamabad	Member
5.	Mr. Zeeshan Nazir , Deputy Director Representative Director (QA/LT), DRAP, Islamabad	Member
6.	Mr. Manzoor Ali Bozdar, Addl Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/Member
7.	Mr. Saleem Iqbal, Representative of PPMA.	Observer
8.	Mr.Nadeem Alamgir Representative of Pharma Bureau.	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 especially Mr. Azhar Jamal Saleemi, Chief Drug Controller, Primary and Secondary Health Department, Government of Punjab, Lahore and Mr. Zahid Khan, Chief Drug Inspector, Peshaawar, Department of Health, Govt of Khyber Pakhtunkhwa who were attended meeting for the first tim. 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. The Central Licensing Board discussed and decided that initial draft minutes of the meeting would be prepared by concerned sections of Divisions and counter verified by the Secretary, Central Licensing Board before submitting to the members of the Board. Ms. Mahvash Ansari, Deputy Director (QC), Mr. Ayyaz Ahmed, Deputy Director (Licensing), Mr. Muhammad Usman, AD (Lic), Mr. Abdullah Bangash, AD (Lic), Ms. Zunaira Faryad, AD (Lic) and Mr. Sanaullah Babar, AD (QC), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 274th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 274th meeting of the Central Licensing Board (CLB) which was held on 7th April, 2020**.**

Item-II: **GRANT OF NEW DRUG MANUFACTURING LICENSES.**

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s Health Capsule Pakistan (Pvt) Ltd, Plot No, 25, Phase 1A, M3 Industrial City, Sahianwala, Faisalabad. **Section:** Hard Gelatin Empty Capsule Shells.	09-06-2020	**Good**	1. Dr Munawar Hayat, Chief Drugs Controller, Punjab 2. Dr. Farzana Chaudhary, Expert Member. 3. Mr Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore

Recommendations of the panel: -

"Based on the areas inspected. The technical personnel met and the documents reviewed and considering the finds of the inspection the panel verifies that the firm possesses the facility for the manufacturing of products as per following sections:

a. Hard Gelatin Empty Capsule Shells

The Panel of Inspectors **recommends** the grant of Drug Manufacturing License by way of Formulationin respect of above-mentioned section to M/s Health Capsule Pakistan (Pvt) Ltd, Plot No, 25, Phase 1A, M3 Industrial City, Sahianwala, Faisalabad".

Decision of the Central Licensing Board in 275th meeting

The Board considered the facts that the firm has applied for grant of Drug Manufacturing Licence by way of Basic manufacture and panel was given mandate for semi basic manufacture, therefore, Board approved the grant of Drug Manufacturing License by way of Semi Basic Manufacture in the name of M/s Health Capsule Pakistan (Pvt) Ltd, Plot No, 25, Phase 1A, M3 Industrial City, Sahianwala, Faisalabadwith following section:

Section:
Empty Hard Gelatin Capsule Shells

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

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

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi. DML No. 000351 (Formulation) **Sections/facilities (05)** i. Packaging Material Store (unlicensed)- Amendments- **Basement** ii. Finished Goods Store- Amendments **-Ground Floor** iii. Raw Material Store (unlicensed)– Amendments- **First Floor** iv. Quality Control Laboratory- **Third Floor** v. Research & Development Laboratory- **New**	**26-03-2020**	**Good**	1. Chief Drug Inspector Sindh, Karachi. 2. Additional Director/Area FID, DRAP, Karachi.

***Recommendations of the panel**:*

Based on the people met, documents reviewed and areas inspected, and amendments/construction and maintenance made by the panel, as per layout plan approved by the DRAP authorities as per letter No. F. 2-12/93-Lic (Vol-IV) dated 3rd September, 2019, panel recommends the grant of amendments and new facilities for.

i. Packaging Material Store (unlicensed)- Amendments- **Basement**
ii. Finished Goods Store- Amendments **-Ground Floor**
iii. Raw Material Store (unlicensed)– Amendments- **First Floor**
iv. Quality Control Laboratory- **Third Floor**
v. Research & Development Laboratory- **New**

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of Additional sections/ facilities/ amendments in the name of M/s Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi:

Sections/facilities (05)

i. Packaging Material Store (unlicensed)- Amendments- **Basement**

	ii. Finished Goods Store- Amendments -**Ground Floor** iii. Raw Material Store (unlicensed)– Amendments- **First Floor** iv. Quality Control Laboratory- **Third Floor** v. Research & Development Laboratory- **New**			
2.	M/s Safe Pharmaceuticals (Pvt) Ltd, Plot No. C-1-20, Sector 6-B, North Karachi Industrial Area, Karachi DML No. 000349 (Formulation) **Section (01)** Dry Powder suspension (General)-New	**13-03-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi.

***Recommendations of the panel**: -*

Based on the above stated facts the panel unanimously recommends the grant of renewal of DML No. 000349 for the next five years for following sections and also recommends the grant of additional section of Dry Powder Suspension (G).

Sr. No	**Name of Sections**	**Sr. No**	**Name of Sections**
i.	Tablet (General)	ii.	Liquid Syrup (General)
iii.	Capsule (General)	iv.	Tablet (Psychotropic)
v.	Liquid Injection (General)	vi.	Oral Dry Powder Suspension (Cephalosporin)
vii.	Dry Powder Injectable (Cephalosporin)	viii.	Capsule (Cephalosporin)
ix.	Dry Powder Injectable (Lyophilized)	x.	Liquid Injection (Psychotropic)
xi.	**Dry Powder suspension (General)-Additional Section**		

The firm was further advised to shift immediately their sachet and cream/Ointment section at appropriate place after formal approval of Drug Licensing Division and also suggest the regularization of current layout plan.

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of Additional sections/ facilities/ amendments in the name of M/s Safe Pharmaceuticals (Pvt) Ltd, Plot No. C-1-20, Sector 6-B, North Karachi Industrial Area, Karachi

Section (01)

Dry Powder suspension (General)-New

<table>
<tr>
<td>3.</td>
<td>M/s Saakh Pharma (Pvt) Ltd, Plot No.C-7/1, N.W.I.Z. Port Qasim Authority, Karachi
DML No. 000588 (Semi-Basic)
<u>New APIs (16)</u>
<u>Pellets& Taste Masking</u>
<u>(06)</u>
Cephalosporin facility (Revised), Warehouse (Revised),
Quality Control shifted from ground floor to first floor
Microbiology Laboratory – expansion</td>
<td>18.06.2020</td>
<td>Good</td>
<td>1. Director DTL, Karachi
2. Additional Director E&M), DRAP, Karachi.
3. Area FID, DRAP, Karachi.</td>
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<td colspan="5">
During the inspection, it was observed that company has well equipped production facilities required for the manufacturing of the APIs.Quality Control Laboratory also seen equipped for performing test/analysis the API in question. HVAC system seen installed and observed operational in the GMP areas of Production section.
Based on area inspected, the people met & documents reviewed & findings of the inspection, panel recommends the approval for grant of:
A; Amendments of Cephalosporin facility, Warehouse, Quality Control shifted from ground floor to first floor & Microbiology Labortory expansion as per approved master plan.
B: Manufacturing of following APIs.
<table>
<tr><th>S.No</th><th>Product Name (API)</th><th>S.No</th><th>Pellets</th></tr>
<tr><td>1.</td><td>Atorvasatin Calcium (USP/BP</td><td>1.</td><td>Aspirin USP/BP</td></tr>
<tr><td>2.</td><td>Diclofenac Potassium (USP/BP)</td><td>2.</td><td>Diclofenac Potassium (USP/BP)</td></tr>
<tr><td>3.</td><td>Diclofenac Sodium USP</td><td>3.</td><td>Diclofenac Sodium USP</td></tr>
<tr><td>4.</td><td>Divalproex Sodium Ph. Eur/BP</td><td>4.</td><td>Duloxetine HCl USP/BP</td></tr>
<tr><td>5.</td><td>Ibuprofen USP</td><td>5.</td><td>Flurbiprofen USP/BP</td></tr>
<tr><td>6.</td><td>Moxifloxacin Hcl USP</td><td>6.</td><td>Itraconazole USP/BP</td></tr>
<tr><td>7.</td><td>Pyrazinamide USP</td><td>7.</td><td>Mebeverine HCl (In-house)</td></tr>
<tr><td>8.</td><td>Simvastatin USP/BP</td><td>8.</td><td>Pantoprazole Sodium USP/BP</td></tr>
<tr><td>9.</td><td>Valproic Acid Ph.Eur/BP</td><td></td><td></td></tr>
<tr><td>10.</td><td>Tramadol Hcl USP</td><td></td><td></td></tr>
<tr><td>11.</td><td>Metronidazole USP</td><td></td><td></td></tr>
</table>
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</table>

12.	*Metronidazole Benzote USP*		
13.	*Glimeprdide in-hosue*		
14.	*Iron Soucrose USP*		
15.	*Remdisvir (In house)*		
16.	*Favipiravir (In-house)*		

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the amendments in lay Out Plan and grant of Additional API in the name of M/s Saakh Pharma (Pvt) Ltd, Plot No.C-7/1, N.W.I.Z. Port Qasim Authority, Karachi in the light of recommendations of Committee at (Item IV case 4):

A. Amendments of Cephalosporin facility, Warehouse, Quality Control shifted from ground floor to first floor & Microbiology Labortory expansion as per approved master plan.

B: Manufacturing of following APIs.

S.No	*Product Name (API)*	*S.No*	*Pellets*
1.	*Atorvastatin Calcium (USP/BP*	*17.*	*Aspirin USP/BP*
18.	*Diclofenac Potassium (USP/BP)*	*9.*	*Diclofenac Potassium (USP/BP)*
19.	*Diclofenac Sodium USP*	*10.*	*Diclofenac Sodium USP*
20.	*Divalproex Sodium Ph. Eur/BP*	*11.*	*Duloxetine HCl USP/BP*
21.	*Ibuprofen USP*	*12.*	*Flurbiprofen USP/BP*
22.	*Moxifloxacin Hcl USP*	*13.*	*Itraconazole USP/BP*
23.	*Pyrazinamide USP*	*14.*	*Mebeverine HCl (In-house)*
24.	*Simvastatin USP/BP*	*15.*	*Pantoprazole Sodium USP/BP*
25.	*Valproic Acid Ph.Eur/BP*		
26.	*Tramadol HCl USP*		
27.	*Metronidazole USP*		
28.	*Metronidazole Benzoate USP*		
29.	*Glimepiride in-house*		
30.	*Iron Sucrose USP*		
31.	*Remedesivir (In house)*		
32.	*Favipiravir (In-house)*		

<table>
<tr><td rowspan="2">4.</td><td>M/s Saffron Pharmaceuticals (Pvt) Ltd, 19-KM, Sheikhpura Road, Faisalabad.

DML No. 000616 (Formulation)
<u>Name of Sections (03)</u>
1. Capsule (Cephalosporin).
2. Oral Dry Powder Suspension (Cephalosporin).
3. Dry Powder Injectable (Cephalosporin).</td><td>12-02-2020</td><td>Good</td><td>1. Dr. Munawar Hayat, Chief Drugs Controller, Lahore.
2. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore.
3. Dr. Akbar Ali, AD, DRAP, Lahore.</td></tr>
<tr><td colspan="4">Recommendations of the panel: -
“Based on the areas inspected the technical people met and the documents reviewed and considering the findings of the inspection the panel verified that the firm has developed the following facilities as per amended layout plan;

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

The panel of inspectors <u>Recommends</u>the approval / grant of above mentioned sections / facilities in favour of M/s Saffron Pharmaceuticals (Pvt) Ltd, 19-KM, Sheikhpura Road, Faisalabad under DML bearing No. 000616

<u>Decision of the Central Licensing Board in 275th meeting</u>
The Board considered and approved the grant of Additional sections/ facilities/ amendments in the name of M/s Saffron Pharmaceuticals (Pvt) Ltd, 19-KM, Sheikhpura Road, Faisalabad
<u>Section (03)</u>
1. Capsule (Cephalosporin).
2. Oral Dry Powder Suspension (Cephalosporin).
3. Dry Powder Injectable (Cephalosporin).</td></tr>
<tr><td rowspan="2">5.</td><td>M/s Surge Laboratories (Pvt) Ltd, 10-KM, Faisalabad Road, Bikhi, District Sheikhupura.

DML No. 000484 (Formulation)
<u>Name of Sections (01)</u>
1. Sterile Dry Powder Injectable (General).</td><td>20-02-2020</td><td>Good</td><td>1. Dr. Farzana Chowdhary, Member, CLB, DRAP, Islamabad.
2. Dr. Munawar Hayat, Chief Drugs Controller, Lahore.
3. Majida Mujahid, Area FID, DRAP, Lahore.</td></tr>
<tr><td colspan="4">Recommendations of the panel: -
“Keeping in view the above observations during the panel inspection of M/s Surge Laboratories (Pvt) Ltd, 10-KM, Faisalabad Road, Bikhi, District Sheikhupura, panel recommends.

The grant of Sterile Dry Powder Injectable (General) as “Additional Section: under Drug</td></tr>
</table>

	Manufacturing License No. 000484 by way of Formulation to M/s Surge Laboratories (Pvt) Ltd, 10-KM, Faisalabad Road, Bikhi, District Sheikhupura. **Decision of the Central Licensing Board in 275th meeting** The Board considered and approved the grant of Additional sections/ facilities/ amendments in the name of M/s Surge Laboratories (Pvt) Ltd, 10-KM, Faisalabad Road, Bikhi, District Sheikhupura **Name of Sections (01)** 1. Sterile Dry Powder Injectable (General) new			
6.	M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad DML No. 000600 (Formulation). **Name of Sections (02)** 1. Capsule (Ceph). 2. Dry Powder for Suspension (Ceph).	21-01-2020 & 21-02-2020	**Satisfactory / Average**	1. Prof. Dr. Muhammad Usman, Member, CLB, DRAP, Islamabad. 2. Dr. Masood ur Rehman, Addl. Director (Pharmacy Services), DRAP, Islamabad. 3. Mr. Hasan Afzaal, Area FID-III, DRAP, Islamabad.
	Recommendations of the panel: - "Keeping in view the above facts, detailed visit of facility as of today and review of documents the panel unanimously **Recommended** M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad for the Renewal of Drug Manufacturing License No. 000600 (Formulation) for the following sections namely; 1. Tablet Section (General). 2. Capsule-I Section (General). 3. Capsule-II Section (General). 4. Tablet Section (Psychotropic). 5. Cream / Ointment Section (General). 6. Dry Suspension Section (General). 7. Sachet Section (General). 8. Sterile Ophthalmic (General). The panel has also verified the amendments in the Layout of the following sections; 1. Capsule (Cephalosporin). 2. Dry Powder for Suspension (Cephalosporin). **Decision of the Central Licensing Board in 275th meeting** The Board considered and deferred the grant of Additional sections/ facilities/ amendments in the name of M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad as panel of inspectors has rated it as satisfactory / average while Board has clear recommendations time and again that firms of at least good or very good rating may be			

	rcommended. The Board, therefore, decided to get the facility re-inspected by the following panel: 1. Mr. Manzoor Ali Bozdar, Secretary, Central Licensing Board 2. MsMahvash Ansari, Deputy Director (QC) 3. Area Federal Inspector of Drugs, DRAP, Islamabad			
7.	M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad. DML No. 000667(Formulation). **Name of Sections (01)** 1. Topical Semisolid (Cream / Ointment / Gel) Section (New section).	09-06-2020	**Good**	1. Dr Munawar Hayat, Chief Drugs Controller, Punjab 2. Dr. Farzana Chaudhary, Expert Member. 3. Mr Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore
	Recommendations of the panel: - " Based on the areas inspected, the technical people met and the documents reviewed and considering the findings of the inspection the panel verified a satisfactorily maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirement of DML as per Drug (Licensing , Registering and Advertising) Rules, 1976 and capacity & capability of the firm in respect of manufacturing and quality control of all registered products and approved sections and newly applied section as per following list. 1. Tablet Section (General). 2. Capsule Section (General). 3. Dry Powder Sachet Section (General). 4. Oral Liquid Section (General). 5. Topical Semisolid (Cream / Ointment / Gel) Section (New section). The Panel of Inspectors **recommends** the renewal of Drug Manufacturing License No. 000667and grant of new manufacturing section in favour of M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad" **Decision of the Central Licensing Board in 275th meeting** The Board considered and approved the grant of Additional sections/ facilities/ amendments in the name of M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad **Name of Sections (01)**			

	Topical Semisolid (Cream / Ointment / Gel) Section (New section).			
8.	M/s Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad. DML No. 000806 (Semi Basic manufacture) **Name of APIs (01).** 1) Remedesivir INN	**22-06-2020**	**Good**	1. Dr. Muhammad Usman, Member CLB. 2. Dr. Hafsa Karam Elahi, Additional Director (QA&LT Division), DRAP, Islamabad (**Not Present**). 3. Mr. Babar Khan, Area FID, Islamabad.
	Recommendations of the panel: - Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended the grant of following additional API by the way of Semi Basic (000806)** of M/s Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan. 1. Remdesivir INN **Decision of the Central Licensing Board in 275th meeting** The Board considered and approved the grant of Additional API in the name of M/s Vision Pharmaceuticals (Pvt) Ltd., Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistanin the light of recommendations of Committee at (Item IV case 4): 1. Remdesivir INN			
9	M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore DML No. 000325 (Semi-Basic Manufacture). **Name of API's (03)** 1. Empagliflozin (In House Specs). 2. Dapagliflozin (In House Specs). 3. Remedesivir (In House Specs).	**22-06-2020**	**Good**	1. Dr. Farzana Chaudrhary, Expert Member. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore. 4. Miss Maham Misbah, Assistant Director, DRAP, Lahore.

	***Recommendations of the panel**: -* *The panel of inspectors recommends M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore having DML No. 000325 the grant of new additional APIs as under:* *1. Empagliflozin* *2. Dapagliflozine.* *3. Remedesivir.* **Decision of the Central Licensing Board in 275th meeting** The Board considered and approved the grant of Additional API in the name of M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore on the recommendations of the panel of experts in the light of recommendations of Committee on API at (Item IV case 4): **Name of API's (03)** 1. Empagliflozin (In House Specs). 2. Dapagliflozine (In House Specs). 3. Remedesivir (In House Specs).			
10	M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore DML No. 000325 (Semi-Basic Manufacture). **Name of API's (02)** 1. Moxifloxacin (USP/BP/EP). 2. Ciprofloxacin (USP/DP/EP).	**22-06-2020**	**Good**	1. Dr. Farzana Chaudrhary, Expert Member. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore. 4. Miss Maham Misbah, Assistant Director, DRAP, Lahore.
	***Recommendations of the panel**: -* *The panel of inspectors recommends M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore having DML No. 000325 the grant of the additional APIs base (Ciprofloxacin base) and Moxifloxacin HCI from Moxifloxacin Q-Ester raw material.* **Decision of the Central Licensing Board in 275th meeting** The Board considered and approved the grant of Additional API in the name of M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore on the recommendations of the panel of experts: **Name of API's (01)** 1. Moxifloxacin (USP/BP/EP).			

	The Board also decided to call the representative of the firm in the next meeting of the Board for seeking clarification for manufacturing of Ciprofloxacin base instead of Ciprofloxacin HCL			
11	M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore DML No. 000325 (Semi-Basic Manufacture). **Name of API's (03)** 1. Esomeprazole Magnesium Trihydrate Pellets (Manufacturer Specs). 2. Dexlansoperazole Pellets (Manufacturer Specs). 3. Omeprazole Pellets (Manufacturer Specs).	**22-06-2020**	**Good**	1. Dr. Farzana Chaudrhary, Expert Member. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore. 4. Miss Maham Misbah, Assistant Director, DRAP, Lahore.
	***Recommendations of the panel**: -* *The panel of inspectors recommends M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore having DML No. 000325 the grant of approval of using starting raw material powder (Omeprazole, Esomeprazole Magnesium Trihydrate and Dexlansoprazole powder) for the manufacturing of Omeprazole, Esomeprazole Magnesium Trihydrate and Dexlansoprazole Pellets subject to the condition that the import of such raw material powder will only be used for production of Pellets to make it commercially viable.* **Decision of the Central Licensing Board in 275th meeting** The Board considered and approved the grant of Additional API in the name of M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore on the recommendations of the panel of experts in the light of recommendations of Committee on API at (Item IV case 4): **Name of API's (01)** 1. Dexlansoprazole Pellets (Manufacturer Specs). The Board considered the case and decide to seek clarification from the panel of experts for not making recommendations as requested and mentioned in letter for inspection for Esomeprazole Magnesium Trihydrate Pellets (Manufacturer Specs) and Omeprazole Pellets (Manufacturer Specs).			

<table>
<tr><td>12</td><td>M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore

DML No. 000325 (Semi-Basic Manufacture).

<u>Name of API's (03)</u>
1. Hydroxy Chloroquine Sulphate (USP/BP/EP).
2. Chloroquine Phosphate (USP/BP/EP).
3. Favipiravir (In House Specs).</td><td>22-06-2020</td><td>Good</td><td>1. Dr. Farzana Chaudrhary, Expert Member.
2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore.
4. Miss Maham Misbah, Assistant Director, DRAP, Lahore.</td></tr>
<tr><td></td><td colspan="3">Recommendations of the panel: -
The panel of inspectors recommends M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore having DML No. 000325 the grant of new additional APIs as under:
1. Hydroxy Chloroquine Sulphate (USP/BP/EP).
2. Chloroquine Phosphate (USP/BP/EP).
3. Favipiravir (In House Specs).

<u>Decision of the Central Licensing Board in 275th meeting</u>
The Board considered and approved the grant of Additional API in the name of M/s Pharmagen Ltd., 34-Km, Ferozepur Road, Lahore on the recommendations of the panel of experts in the light of recommendations of Committee on API at (Item IV case 4):

<u>Name of API's (03)</u>
1. Hydroxy Chloroquine Sulphate (USP/BP/EP).
2. Chloroquine Phosphate (USP/BP/EP).
3. Favipiravir (In House Specs).</td></tr>
</table>

Item-IV: **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 Tabros Pharma (Pvt) Ltd, Plot No. L-20/B, Sector 22, F. B Industrial Area, Karachi DML No. 000106 (Formulation) **Period**: 07-01-2020 to 06-01-2025.	**28-02-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi.
	Recommendations of the panel: - Based on the above stated observations, The panel recommends the renewal of DML NO. 000106(Formulation) of following sections i. Tablet (General/General Antibiotic). ii. Sterile liquid Injection vial SVP General iii. Liquid Syrup iv. Dry Powder Injection glass vial General v. Sachet (General) vi. Dry Powder Injection glass vial Cephalosporin vii. Capsule (Cephalosporin) viii. Capsule (General/General Antibiotic) ix. Cream/Ointment/Gel General x. Tablet Cephalosporin xi. Lotion General xii. Sachet Cephalosporin xiii. Dry Powder Suspension General xiv. Dry Powder Suspension Cephalosporin xv. Sterile liquid injection ampoule xvi. Tablet Steroid **Decision of the Central Licensing Board in 275th meeting**			

	The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Tabros Pharma (Pvt) Ltd, Plot No. L-20/B, Sector 22, F. B Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 07-01-2020 and ending on 06-01-2025 for the following sections: i. Tablet (General/General Antibiotic). ii. Sterile liquid Injection vialSVP General iii. Liquid Syrup iv. Dry Powder Injection glass vial General v. Sachet (General) vi. Dry Powder Injection glass vial Cephalosporin vii. Capsule (Cephalosporin) viii. Capsule (General/General Antibiotic) ix. Cream/Ointment/Gel General x. Tablet Cephalosporin xi. Lotion General xii. Sachet Cephalosporin xiii. Dry Powder Suspension General xiv. Dry Powder Suspension Cephalosporin xv. Sterile liquid injection ampoule xvi. Tablet Steroid			
2	M/s Hilton Pharma (Pvt) Ltd, Plot No. 13-14 & 43, Sector 15, Korangi Industrial Area, Karachi DML No. 000136 (Formulation) **Period**: 23-10-2019 to 22-10-2024.	**24-01-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Chief Drug Inspector Sindh, Karachi. 3. Area FID, DRAP, Karachi .
	Recommendations of the panel: - *Based on the stated facts and observations the panel unanimously recommended as follows:*			

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Biotech Facility (rDNA technology)	ii.	Oral dry powder suspension (General)
iii.	Sachet (General)	iv.	Tablet (General)
v.	Capsule (General)	vi.	Sterile Liquid Injection (SVP)
vii.	Capsule (Cephalosporin)	viii.	Dry Powder Suspension (Cephalosporin)
ix.	Sterile Dry Powder Injectable	x.	Liquid Syrup (Veterinary)

	(Ceph)		
xi.	Dry Powder (Veterinary)	xii.	Tablet (Psychotropic)
xiii.	Sachet (Pro biotic)	xiv.	QA Lab, QA PD Facilities (New)
xv.	Dedicated facility for Blistering & Packaging	xvi.	Oral Liquid (General)

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Hilton Pharma (Pvt) Ltd, Plot No. 13-14 & 43, Sector 15, Korangi Industrial Area, Karachion the recommendations of the panel of experts for the period commencing on 23-10-2019 and ending on 22-10-2024 for the following sections:

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Biotech Facility (rDNA technology)	ii.	Oral dry powder suspension (General)
iii.	Sachet (General)	iv.	Tablet (General)
v.	Capsule (General)	vi.	Sterile Liquid Injection (SVP)
vii.	Capsule (Cephalosporin)	viii.	Dry Powder Suspension (Cephalosporin)
ix.	Sterile Dry Powder Injectable (Ceph)	x.	Liquid Syrup (Veterinary)
xi.	Dry Powder (Veterinary)	xii.	Tablet (Psychotropic)
xiii.	Sachet (Pro biotic)	xiv.	QA Lab, QA PD Facilities (New)
xv.	Dedicated facility for Blistering & Packaging	xvi.	Oral Liquid (General)

3	M/s Reign Pharmaceuticals PCSIR, KLC Pvt, Ltd, TBIC Building-I PCSIR Laboratories Complex, Shahrah-e-Dr. Salim-uz-zaman Siddiqui, Off University Road, Karachi. DML No. 000757 (Formulation) **Period**: 28-11-2017 to 27-11-2022	**24-12-2019**	**Good**	3. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 4. Chief Drug Inspector Sindh, Karachi. 5. Area FID, DRAP, Karachi. 6. Dr. Krishan, Asst. Director, DRAP, Karchi.

***Recommendations of the panel**: -*

The panel reviewed their overall documentation, SOPs, inspected Manufacturing Facility, Quality Control Lab & Stores and met with their technical persons. Following are the observations:

1. The panel observed that the premises of M/s. Reign Pharmaceuticals PCSIR-Klc (Pvt) Ltd. Constructed as per DRAP's approved layout plan.

	2. An appropriate level of sanitation, cleanliness & workers hygiene was noted. 3. Personnel met during inspection were observed having prescribed qualification and experience and were well conversant regarding cGMP compliance. 4. The HVAC system was found installed and observed in working condition during inspection. 5. Basic equipment required for tests/analysis of the registered products seen in place and in operational condition. 6. The management of the firm has informed that they have the intention to shift the manufacturing facility from existing rented premises to the new site. Based on the stated observations, The panel recommends the grant of renewal of their DML NO. 000757 By Way of Formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid (General) 4. Sachet (General) 5. Dry Powder Suspension (General) **Decision of the Central Licensing Board in 275th meeting** The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Reign Pharmaceuticals PCSIR, KLC Pvt, Ltd, TBIC Building-I PCSIR Laboratories Complex, Shahrah-e-Dr. Salim-uz-zaman Siddiqui, Off University Road, Karachi on the recommendations of the panel of experts for the period commencing on 28-11-2017 and ending on 27-11-2022 for the following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid (General) 4. Sachet (General) 5. Dry Powder Suspension (General)			
4	M/s Bosch Pharmaceuticals Pvt. Ltd, Plot No. 221-223, Sector-23, Korangi Industrial Area, Karachi DML No. 000350 (Formulation) **Period**: 16-02-2020 to 15-02-2025	**27-02-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director E&M), DRAP, Karachi./Area FID, DRAP, Karachi.

***Recommendations of the panel**: -*

Based on the people met, documents reviewed and observation made during inspection, panel recommends the renewal of DML for the sections as mentioned in the aforementioned DRAP letter. It is further submit that section mentioned on the serial No. XVI and XVII are same, however on physical verification it is to confirm that section mentioned XVII may be reads as Oral Dry Powder Suspension (General).

firm was granted additional section namely : Dry Powder Suspension(General) by the Central Licensing Bord in its 236th meeting and accordingly letter for grant of the section was issued to the firm However, at the time of application for renewal of DML NO. 000350 (Formulation) for the tenure 16-02-2020 to 15-02-2025 firm didn't provide the approval letter of the said section along with Form-1A and therefore same was not included in the list of sections mentioned on the panel inspection letter for renewal of DML No. 000350 (Formulation) and panel was constituted for renewal of DML for following sections including two separate sections namely Oral Dry Powder Suspension (Cephalosporin) of which the approval letters were provided by the firm along with Form-1A.

Sr. No	**Name of Sections**	**Sr. No**	**Name of Sections**
i.	Dry Powder Injectable (Carbapenem) with warehouse	ii.	Sachet (General)
iii.	Sachet (Cephalosporin)	iv.	Liquid Injectable Ampoule-I
v.	Tablet (Penicillin)	vi.	Liquid Injectable Ampoule-II
vii.	Dry Powder Injectable (Penicillin)	viii.	Liquid Injectable Ampoule (Psychotropic)
ix.	Capsule (General)	x.	Lyophilized Powder Injectable Vials
xi.	Dry Powder (Injectable (Cephalosporin)	xii.	Tablet (General)-I
xiii.	Tablet (Cephalosporin)	xiv.	Oral Dry Powder Suspension (Penicillin)
xv.	Tablet (General)-II	xvi.	Oral Dry Powder Suspension (Cephalosporin)
xvii.	Oral Dry Powder Suspension (Cephalosporin)	xviii.	Capsule (Penicillin)
xix.	Capsule (Cephalosporin)		*******

Now the panel in its inspection report has recommended the renewal of DML for above mentioned sections and has also mentioned that firm posses Dry Powder Suspension(General) section on ground and the sections mentioned on the serial No. XVI and XVII (Oral Dry Powder

Suspension (Cephalosporin)) are same, however on physical verification it is to confirm that section mentioned XVII may be reads as Oral Dry Powder Suspension (General).

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Bosch Pharmaceuticals Pvt. Ltd, Plot No. 221-223, Sector-23, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 16-02-2020 and ending on 15-02-2025 for the following sections:

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Dry Powder Injectable (Carbapenem) with warehouse	ii.	Sachet (General)
iii.	Sachet (Cephalosporin)	iv.	Liquid Injectable Ampoule-I
v.	Tablet (Penicillin)	vi.	Liquid Injectable Ampoule-II
vii.	Dry Powder Injectable (Penicillin)	viii.	Liquid Injectable Ampoule (Psychotropic)
ix.	Capsule (General)	x.	Lyophilized Powder Injectable Vials
xi.	Dry Powder (Injectable (Cephalosporin)	xii.	Tablet (General)-I
xiii.	Tablet (Cephalosporin)	xiv.	Oral Dry Powder Suspension (Penicillin)
xv.	Tablet (General)-II	xvi.	Oral Dry Powder Suspension (Cephalosporin)
xvii.	Capsule (Cephalosporin)	xviii.	Capsule (Penicillin)

The Boaard decided to defer the case of renewal of Oral Dry Powder Suspension (Cephalosporin) till next meeting for seeking clarification regarding ambiguity of Oral Dry Powder Suspension (Cephalosporin) and Oral Dry Powder Suspension (General)

<table>
<tr><td>5</td><td>M/s. AGP Limited, B-23-C, S.I.T.E, Karachi.
DML No. 000348 (Formulation)
Period: 06-02-2020 to 05-02-2025</td><td>10-03-2020</td><td>Good</td><td>1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Additional Director E&M), DRAP, Karachi.
3. Area FID, DRAP, Karachi.</td></tr>
<tr><td></td><td colspan="4">Recommendations of the panel: -
Keeping in view overall GMP compliance and positive intention towards improvement, panel unanimously recommends the renewal of DML No. 000348 of M/s. AGP Limited, B-23-C, S.I.T.E, Karachi.
<table>
<tr><th>Sr. No</th><th>Name of Sections</th><th>Sr. No</th><th>Name of Sections</th></tr>
<tr><td>i.</td><td>Tablet (General)</td><td>ii.</td><td>Capsule (General)</td></tr>
<tr><td>iii.</td><td>Sachet (General)</td><td>iv.</td><td>Oral Liquid (General)</td></tr>
<tr><td>v.</td><td>Semi-Solid (Cream/Ointment)</td><td>vi.</td><td>Liquid Parental (General)</td></tr>
</table>
<u>Decision of the Central Licensing Board in 275th meeting</u>
The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s. AGP Limited, B-23-C, S.I.T.E, Karachi on the recommendations of the panel of experts for the period commencing on 06-02-2020 and ending on 05-02-2025 for the following sections. The Board also corrected the nomenclature of Liquid Parental (General) as fact on record reveals that firm has Liquid Ampoule (General).
<table>
<tr><th>Sr. No</th><th>Name of Sections</th><th>Sr. No</th><th>Name of Sections</th></tr>
<tr><td>i.</td><td>Tablet (General)</td><td>ii.</td><td>Capsule (General)</td></tr>
<tr><td>iii.</td><td>Sachet (General)</td><td>iv.</td><td>Oral Liquid (General)</td></tr>
<tr><td>v.</td><td>Semi-Solid (Cream/Ointment)</td><td>vi.</td><td>Liquid Ampoule (General)</td></tr>
</table></td></tr>
<tr><td>6</td><td>M/s Safe Pharmaceuticals (Pvt) Ltd, Plot No. C-1-20, Sector 6-B, North Karachi Industrial Area, Karachi
DML No. 000349 (Formulation)
Period: 06-02-2020 to 05-02-2025</td><td>13-03-2020</td><td>Good</td><td>2. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
7. Additional Director E&M), DRAP, Karachi.
8. Area FID, DRAP, Karachi.</td></tr>
</table>

***Recommendations of the panel**: -*

Based on the above stated facts the panel unanimously recommends the grant of renewal of DML No. 000349 for the next five years for following sections and also recommends the grant of additional section of Dry Powder Suspension (G).

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Liquid Syrup (General)
iii.	Capsule (General)	iv.	Tablet (Psychotropic)
v.	Liquid Injection (General)	vi.	Oral Dry Powder Suspension (Cephalosporin)
vii.	Dry Powder Injectable (Cephalosporin)	viii.	Capsule (Cephalosporin)
ix.	Dry Powder Injectable (Lyophilized)	x.	Liquid Injection (Psychotropic)
xi.	Dry Powder suspension (General)-Additional Section		

The firm was further advised to shift immediately their sachet and cream/Ointment section at appropriate place after formal approval of Drug Licensing Division and also suggest the regularization of current layout plan.

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Safe Pharmaceuticals (Pvt) Ltd, Plot No. C-1-20, Sector 6-B, North Karachi Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 06-02-2020 and ending on 05-02-2025 for the following sections with corrections in nomenclature of some sections:

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Liquid Syrup (General)
iii.	Capsule (General)	iv.	Tablet (Psychotropic)
v.	Liquid Injection Ampoule (General)	vi.	Oral Dry Powder Suspension (Cephalosporin)
vii.	Dry Powder Injectable (Cephalosporin)	viii.	Capsule (Cephalosporin)
ix.	Dry Powder Injectable (Lyophilized)	x.	Liquid Injection Ampoule (Psychotropic)

The Board also decided to serve showcause notice to the firm for shifting of sachet and cream/Ointment section as recommended by the panel. The Board also decided to advise the

	firm to submit the Lay Out Plan for regularization as recommended by the panel.			
	M/s. Manhattan Pharma., Plot No.209/3-B, Sector 5, Korangi Industrial Area, Karachi DML No. 000327 (Formulation) **Period**: 14-01-2017 to 13-01-2022	**23-04-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Chief Drug Inspector Sindh, Karachi. 3. Area FID, DRAP, Karachi.

***Recommendations of the panel**: -*

Based on the above stated facts the panel unanimously recommends the grant of renewal of DML No.000327 for the next five years for the following sections and also recommends the grant of additional section of sterile preparation liquid injectable (G) Section. The panel further recommends the regularization of their existing Lay out Plan.

1.	Oral liquid veterinary (General) section--- Regularization
2.	Oral Jar Powder veterinary (General) section--- Regularization
3.	Sterile Preparation Liquid Injectable (General) relocation at empty space
4.	Ware House (General) Shifted from Ground Floor
5.	Sterile Injectable Vial SVP Veterinary (General) Section New
6.	Quality Control Laboratory Regularization.
7.	Angara Autogenous Vaccine (Veterinary Section- Regularization.

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing License in the name of M/s. Manhattan Pharma., Plot No.209/3-B, Sector 5, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 14-01-2017 and ending on 13-01-2022for the following sections:

1.	Oral liquid veterinary (General) section--- Regularization
2.	Oral Jar Powder veterinary (General) section--- Regularization
3.	Sterile Liquid Injectable (General) relocation at empty space
4.	Ware House (General) Shifted from Ground Floor
5.	Sterile Liquid Injectable Veterinary (General) Section New
6.	Quality Control Laboratory Regularization.
7.	Angara Autogenous Vaccine (Veterinary Section- Regularization.

<table>
<tr>
<td>7</td>
<td>M/s Indus Phama Pvt. Ltd, Plot No. 26-27, 63-67, Sector-27, Korangi Industrial Area, KarachiDML No. 000124 (Formulation)
Period: 12-07-2019 to 11-07-2024</td>
<td>09-06-2020</td>
<td>Good</td>
<td>1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Additional Director E&M/Area FIDDRAP, Karachi.</td>
</tr>
<tr>
<td colspan="5">
Recommendations of the panel: -
Based on the people met, documents reviewed and observation made during inspection, panel recommends the renewal of DML No. 000124 and regularization of layout plan for the following sections:-
<table>
<tr><th>S. No.</th><th>Sections</th><th>S. No.</th><th>Sections</th></tr>
<tr><td>1.</td><td>Sterile Liquid (eye Drops) Section (General)</td><td>2.</td><td>Sterile Liquid (Injection and Infusion) Section.</td></tr>
<tr><td>3.</td><td>Oral Solids (Tablet) Section (General).</td><td>4.</td><td>Oral Solids (Capsule) Section (General).</td></tr>
<tr><td>5.</td><td>Oral Solids (Sachets) Section (General)</td><td>6.</td><td>Oral Liquid Section (General).</td></tr>
<tr><td>7.</td><td>Oral Solids (Dry Powder Suspension) Section (General)</td><td>8.</td><td>Parenteral Cephalosporin Section</td></tr>
<tr><td>9.</td><td>Capsule Cephalosporin Section</td><td>10.</td><td>Warehouse and Inventory Control Section</td></tr>
<tr><td>11.</td><td>Quality Control and Microbiology Laboratory</td><td>12.</td><td>Cold Chain Unit.</td></tr>
<tr><td>13.</td><td>Dry powder suspension (Cephalosporin).</td><td>14.</td><td>Warehouse (Cephalosporin)</td></tr>
</table>
<u>Decision of the Central Licensing Board in 275th meeting</u>
The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Indus Pharma Pvt. Ltd, Plot No. 26-27, 63-67, Sector-27, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 12-07-2019 and ending on 11-07-2024.
</td>
</tr>
</table>

8	M/s Lahore Chemical & Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulan Jalal-Ud-Din Roomi, Lahore DML No. 000064(Formulation). **Period**: 31-12-2016 to 30-12-2021	19-09-2019	**Good**	1. Dr. Ikram ul Haq, Member Central Licensing Board. 2. Ms. Shaheen Iqbal, Director Drug Testing Laboratories, Lahore. 3. Mr. Mubashir Ahmed Butt, Institute of Pharmacy, Gulab Devi Hospital, Lahore. 4. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, DRAP, Lahore.

Recommendations of the panel: -

"Keeping in view the facilities like building, HVAC System, machinery, equipments, personnel documentation and Quality Control, the panel of inspectors is of the opinion to **recommend** the renewal of Drug Manufacturing License No. 000064 by way of formulation toM/s Lahore Chemical & Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulan Jalal-Ud-Din Roomi, Lahore for the following section only:

1. Tablet Section (General).
2. Oral Liquid Section (General).
3. Liquid Infusion Section (General) (SVP).
4. Liquid Injectable Section (Ampoule).
5. Eye / Ear Drops Section.
6. External Preparation Section (Ointment / Cream General).
7. Capsule Section (General).
8. Dry Suspension (General)".

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Lahore Chemical & Pharmaceuticals Works (Pvt) Ltd,137-Shahrah-e-Moulan Jalal-Ud-Din Roomi, Lahoreon the recommendations of the panel of experts for the period commencing on 31-12-2016 and ending on 30-12-2021 for the following sections:

1. Tablet Section (General).
2. Oral Liquid Section (General).
3. Liquid Infusion Section (General) (SVP).
4. Liquid Injectable Section (Ampoule).
5. Eye / Ear Drops Section.
6. External Preparation Section (Ointment / Cream General).
7. Capsule Section (General).
8. Dry Suspension (General)".

9.	M/s Ameer Pharma (Pvt) Ltd, 23-Km, Sheikhupura Road, Lahore DML No. 000604 (Formulation). **Period**: 30-12-2016 to 29-12-2021	09-12-2019 and 26-01-2020	-	1. Dr. Ikram ul Haq, Member Central Licensing Board. 2. Mr. Munawar Hayat, Chief Drug Controller, Punjab. 3. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 4. Ms. Anam Saeed, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: - "Keeping in view the improvement made by the firm, implementation of the GMP and commitment for future improvement, the member of the panel are of opinion to **recommend** the grant of renewal of Drug Manufacturing License No. 000604 toM/s Ameer Pharma (Pvt) Ltd, 23-Km, Sheikhupura Road, Lahore for the following section:- 1. Liquid Injectable (General, General Antibiotic, Steroid, Narcotics). 2. Cephalosphirine Injectable Section. 3. General Tablet Section. 4. Oral Liquid Section. **<u>Decision of the Central Licensing Board in 275th meeting</u>** The Board considered case and decided to refer back the case to panel of experts for clear recommendations and rating of the firm.			
10.	M/s Don Valley Pharmaceuticals (Pvt) Ltd, 31-Km Main Ferozepur road, Lahore. DML No. 000395 (Formulation) **Period:**30-01-2019 to 29-01-2024	18-02-2020	**Good**	1. Dr. Zaka ur Rehman, Drug Controller Govt. of Punjab. 2. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - The panel of inspector **recommends** the renewal of M/s Don Valley Pharmaceuticals (Pvt) Ltd, 31-Km Main Ferozepur road, Lahore bearing DML No. 000395 (Formulation)of following approved sections:- 1. Tablet-I (General) 2. Tablet-II (General).			

3. Tablet (Psychotropic).
4. Tablet (Anti-Cancer).
5. Tablet Hormone (Bulk Import and Local repacking).
6. Dry Powder Suspension (General).
7. Capsule (General).
8. Sachet (General).
9. Oral Liquid (General).
10. Tablet (Penicillin).
11. Dry Powder Suspension (Penicillin).
12. Capsule (Penicillin).
13. Ointment Cream (General).
14. Dry Powder Oral Suspension (Cephalosporin).
15. Capsule (Cephalosporin).
16. Dry Powder Vial Injection (Cephalosporin).

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Don Valley Pharmaceuticals (Pvt) Ltd, 31-Km Main Ferozepur road, Lahore on the recommendations of the panel of experts for the period commencing on 30-01-2019 and ending on 29-01-2024 for the following sections:

1. Tablet-I (General)
2. Tablet-II (General).
3. Tablet (Psychotropic).
4. Tablet (Anti-Cancer).
5. Tablet Hormone (Bulk Import and Local repacking).
6. Dry Powder Suspension (General).
7. Capsule (General).
8. Sachet (General).
9. Oral Liquid (General).
10. Tablet (Penicillin).
11. Dry Powder Suspension (Penicillin).
12. Capsule (Penicillin).
13. Ointment Cream (General).
14. Dry Powder Oral Suspension (Cephalosporin).
15. Capsule (Cephalosporin).
16. Dry Powder Vial Injection (Cephalosporin).

11.	M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad DML No. 000600 (Formulation). **Period**: 15-09-2016 to 14-09-2021	21-01-2020 & 21-02-2020	**Satisfactory / Average**	1. Prof. Dr. Muhammad Usman, Member, CLB, DRAP, Islamabad. 2. Dr. Masood ur Rehman, Addl. Director (Pharmacy Services), DRAP, Islamabad. 3. Mr. Hasan Afzaal, Area FID-III, DRAP, Islamabad.

Recommendations of the panel: -

"Keeping in view the above facts, detailed visit of facility as of today and review of documents the panel unanimously **Recommended** M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad for the Renewal of Drug Manufacturing License No. 000600 (Formulation) for the following sectio0ns namely;

1. Tablet Section (General).
2. Capsule-I Section (General).
3. Capsule-II Section (General).
4. Tablet Section (Psychotropic).
5. Cream / Ointment Section (General).
6. Dry Suspension Section (General).
7. Sachet Section (General).
8. Sterile Ophthalmic (General).

The panel has also verified the amendments in the Layout of the following sections;

1. Capsule (Cephalosporin).
2. Dry Powder for Suspension (Cephalosporin).

Decision of the Central Licensing Board in 275th meeting

The Board considered and deferred the grant of renewal in the name of M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad as panel of inspectors has rated it as satisfactory / average while Board has clear recommendations time and again that firms of at least good or very good rating may be rcommended. The Board, therefore, decided to get the facility re-inspected by the following panel:

1. Mr. Manzoor Ali Bozdar, Secretary, Central Licensing Board
2. MsMahvash Ansari, Deputy Director (QC)
3. Area Federal Inspector of Drugs, DRAP, Islamabad

12.	M/s Spectrum Laboratories (Pvt) Ltd, 8-KM, Raiwind Road, Lahore DML No. 000364 (Formulation). **Period**: 16-09-2015 to 15-09-2020	06-02-2020	**Good**	1. Dr. Ikram Ul Haq, Member, CLB, DRAP, Islamabad. 2. Mr. Asim Rauf, Addl. Director, DRAP, Lahore. 3. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore. 4. Ms. Nusrat Rahman, Provincial Drug Inspector for Industries, Govt. of Punjab, Lahore.

Recommendations of the panel: -

"The panel of inspectors **Recommends**the renewal of DML bearing No. 000364 issued in favour of M/s Spectrum Laboratories (Pvt) Ltd, 8-KM, Raiwind Road, Lahorein respect of Tablet and Oral Liquid sections".

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Spectrum Laboratories (Pvt) Ltd, 8-KM, Raiwind Road, Lahore on the recommendations of the panel of experts for the period commencing on 16-09-2015 and ending on 15-09-2020for the following sections:

1. Tablet Section (General)
2. Oral Liquid Sections (General)

13.	M/s Unison Chemical Works, Post Office Araian 15-KM, Raiwind Road, Lahore. DML No.000174 (Formulation). **Period**: 31-05-2019 to 30-05-2024	19-11-2019	**Good**	1. Dr. Ikram Ul Haq, Member, CLB, DRAP, Islamabad. 2. Dr. Munawar Hayat, Chief Drugs Controller, Lahore. 3. Mr. Shoaib Ahmed, FID, DRAP, Lahore.

Recommendations of the panel: -

"Based on the areas inspected, technical people met and the documents reviewed, and considering the findings of inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per Drug (Licensing, Registering and Advertising) Rules, 1976; capacity and capability of the firm in respect of manufacturing and quality control of registered products and approved sections, the panel of inspectors **recommends** the Renewal of Drug Manufacturing License No. 000174 of M/s Unison Chemical Works, Post Office Araian 15-KM, Raiwind Road, Lahore, in respect to all approved sections".

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing Licence inthe

	name of M/s Unison Chemical Works, Post Office Araian 15-KM, Raiwind Road, Lahore on the recommendations of the panel of experts for the period commencing on 31-05-2019 and ending on 30-05-2024 for the following sections: 1. Liquid Injection Ampoule (General) 2. Liquid Injection Vial (General) 3. Capsule Section (General) 4. Tablet Section (General) 5. Tablet Section (Psychotropic) 6. Liquid Syrup (General)			
14.	M/s Pharmix Laboratories (Pvt) Ltd, 21-KM, Ferozepur Road, Lahore. DML No.000397 (Formulation). **Period**: 24-10-2018 to 23-10-2023	13-09-2019 07-10-2019 & 12-12-2019	**Good**	1. Dr. Farzana Chowdhary, Member, CLB, DRAP, Islamabad. 2. Dr. Mahmood Ahmed, Ex-Dean, University of Bahawalpur. 3. Mr. Shoaib Ahmed, FID, DRAP, Lahore.
	Recommendations of the panel: - "The panel of inspector recommends the renewal of M/s Pharmix Laboratories (Pvt) Ltd, 21-KM, Ferozepur Road, Lahore bearing DML No. 000397 subject to verification of all approved sections by the Licensing Division, DRAP, Islamabad". **<u>Decision of the Central Licensing Board in 275th meeting</u>** The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Pharmix Laboratories (Pvt) Ltd, 21-KM, Ferozepur Road, Lahoreon the recommendations of the panel of experts for the period commencing on 24-10-2018 and ending on 23-10-2023 for the following sections: 1. Liquid Syrup (General) 2. Dry Suspension (General Antibiotic) 3. Capsule Section (General Antibiotic) 4. Tablet Section (Hormone) 5. Capsule Section (General) 6. Tablet Section (General)			

15.	M/s Standpharm Pakistan (Pvt) Ltd, 20-KM, Ferozepur Road, Lahore DML No.000051 (Formulation). **Period**: 08-09-2019 to 07-09-2024	18-02-2020	**Good**	1. Dr. Farzana Chowdhary, Expert Member. 2. Dr. Munawar Hayat, Chief Drug Controller, Punjab, Lahore. 3. Mr. Shoaib Ahmed, FID, DRAP, Lahore.

Recommendations of the panel: -

"The panel of inspector **recommends** the renewal of M/s Standpharm Pakistan (Pvt) Ltd, located at 20-KM, Ferozepur Road, Lahore bearing DML No. 000051(Formulation) of following approved sections:-

1. Tablet (General).
2. Tablet General (Antibiotics).
3. Tablet Psychotropic.
4. Liquid Syrup General.
5. Sachet (General).
6. Oral Dry Powder Suspension Antibiotics.
7. Injectable Liquid Ampoule (General).
8. Injectable Liquid Infusion (General).
9. Capsule General.
10. Dry Powder Injection Cephalosporin.
11. Oral Dry Powder Suspension Cephalosporin.
12. Capsule Cephalosporin.
13. Tablets (Cephalosporin).

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Standpharm Pakistan (Pvt) Ltd, located at 20-KM, Ferozepur Road, Lahore on the recommendations of the panel of experts for the period commencing on 08-09-2019 and ending on 07-09-2024 for the following sections:

1. Tablet (General).
2. Tablet General (Antibiotics).
3. Tablet Psychotropic.
4. Liquid Syrup General.
5. Sachet (General).
6. QC Laboratories.
7. Oral Dry Powder Suspension Antibiotics.
8. Injectable Liquid Ampoule (General).
9. Injectable Liquid Infusion (General).
10. Capsule General.
11. Dry Powder Injection Cephalosporin.
12. Oral Dry Powder Suspension Cephalosporin.
13. Capsule Cephalosporin.
14. Tablets (Cephalosporin)

16.	M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad. DML No. 000667(Formulation). **Period**: 10-06-2019 to 09-06-2024	09-06-2020	**Good**	1. Dr Munawar Hayat, Chief Drugs Controller, Punjab 2. Dr. Farzana Chaudhary, Expert Member. 3. Mr Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore

Recommendations of the panel: -

"Based on the areas inspected, the technical people met and the documents reviewed and considering the findings of the inspection the panel verified a satisfactorily maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirement of DML as per Drug (Licensing , Registering and Advertising) Rules, 1976 and capacity & capability of the firm in respect of manufacturing and quality control of all registered products and approved sections and newly applied section as per following list.

1. Tablet Section (General).
2. Capsule Section (General).
3. Dry Powder Sachet Section (General).
4. Oral Liquid Section (General).
5. Topical Semisolid (Cream / Ointment / Gel) Section (New section).

The Panel of Inspectors **recommends** the renewal of Drug Manufacturing License No. 000667and grant of new manufacturing section in favour of M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad"

Decision of the Central Licensing Board in 275th meeting

The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabadon the recommendations of the panel of experts for the period commencing on 10-06-2019 and ending on 09-06-2024 for the following sections:

1. Tablet Section (General).
2. Capsule Section (General).
3. Dry Powder Sachet Section (General).
4. Oral Liquid Section (General).

17.	M/s Wenovo Pharmaceuticals,	13-01-2020	**-Good-**	1. Dr. Jamshaid Ali Khan,

	Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. DML No.000790 (Formulation). **Period**: 03-02-2019 to 02-02-2024			Member, Central Licensing Board, DRAP. 2. Mr. Abdul Sattar Sohrani, Additional Director (KPK), DRAP. 3. Ms. Mahvash Ansari, Area FID-IV, DRAP.
	"On the basis of facility visited, people met and documents reviewed, panel unanimously **recommends** the renewal of Drug Manufacturing License of M/s Wenovo Pharmaceuticals, with need of some improvements which have been discussed and agreed with the management". **Decision of the Central Licensing Board in 275th meeting** The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Wenovo Pharmaceuticals, Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi on the recommendations of the panel of experts for the period commencing on 03-02-2019 and ending on 02-02-2024.			
18	M/s Amson Vaccine & Pharma (Pvt) Ltd., Plot No.154, Kahuta Triagnle, Islamabad DML No. 000393(Formulation) **Period**: 21-06-2019 to20-06-2024	**04-02-2020**	**Very Good**	1. Dr. Muhammad Usman, Member CLB. 2. Dr. Noor Us Saba, Director (Biological Division), DRAP, Islamabad. 3. Mr. Babar Khan, Area FID, Islamabad.
	Recommendations of the panel: - Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended the renewal of Drug Manufacturing License** and regularization of following sections of Amson Vaccines & Pharma (Pvt) Ltd., Plot No.154, Industrial Triangle, Kahuta Road, Islamabad. i. Tablet Section (General) ii. Capsule Section (General) iii. Orals Liquid Section (General) iv. Dry Powder Injection Section (Steroid) v. Liquid Ampoule Injection (Vaccine) vi. Liquid Vial Injection (Vaccine/Sera) **Decision of the Central Licensing Board in 275th meeting**			

	The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Amson Vaccine & Pharma (Pvt) Ltd., Plot No.154, Kahuta Triagnle, Islamabad on the recommendations of the panel of experts for the period commencing on 10-06-2019 and ending on 09-06-2024 for the following sections: 1. Tablet Section (General) 2. Capsule Section (General) 3. Orals Liquid Section (General) 4. Dry Powder Injection Section (Steroid) 5. Liquid Ampoule Injection (Vaccine) 6. Liquid Vial Injection (Vaccine/Sera)			
19	M/s Pak Risen Pharmaceuticals, Plot No.3, Block B, Phase I&II, Industrial Estate Hattar, Haripur. DML No. 000573 (Formulation) **Period**: Commencing on 16-05-2015 to 15-05-2020.	**13-03-2020**	**Good**	1. Prof. Dr. Jamshed Ali Khan, Member CLB. 2. Dr. Muhammad Abbas, Chief Drug Inspector Khyber Pakhtunkhwa. 3. Mr. Zia Ullah, AD/FID-III, DRAP, Peshawar
	Recommendations of the panel: - Keeping in view the panel observations regarding, production, quality control and environmental facilities provided by the firm, the documents pertaining to production, quality control and quality assurance reviewed, SOPs implemented, the technical staff employed, the improvements and rectifications made by the firm in light of the last routine GMP inseption and commitment of the firm's management to remain strictly adhere to the cGMP guidelines, the panel unanimously **recommends the renewal of DML No.000573 (Formulation) w.e.f. 16-05-2015** of M/s Pak Risen Pharmaceuticals, Plot No.3, Block B, Phase I-II, Industrial Estate, Haripur. **<u>Decision of the Central Licensing Board in 275th meeting</u>** The Board perused the inspection report of the firm conducted for the purpose of renewal of Licence as the tenure of renewal is already completed.			
20.	M/s Leads Pharma (Pvt) Ltd., Plot No.81, Street No.6, I-10/3, Industrial Area, Islamabad. DML No. 000392 (Formulation) **Period**:	**25-02-2020**	**Good**	1. Dr. Muhammad Usman, Member CLB. 2. Dr. Hafsa Karam Elahi, Additional Director (QA&LT Division), DRAP, Islamabad.

	Commencing on 26-06-2019 to 25-06-2024.			3. Mst. Mahvash Ansari, FID, DRAP, Islamabad.
	Recommendations of the panel: - Based on the facility visited, people met and documents reviewed, panel unanimously recommend the renewal of M/s Leads Pharma (Pvt) Ltd., Plot No.81, Street No.6, I-10/3, Industrial Area, Islamabad. **Decision of the Central Licensing Board in 275th meeting** The Board considered and approved the grant of renewal of Drug Manufacturing Licence in the name of M/s Leads Pharma (Pvt) Ltd., Plot No.81, Street No.6, I-10/3, Industrial Area, Islamabadon the recommendations of the panel of experts for the period commencing on 26-06-2019 and ending on 25-06-2024.			

ITEM – V MISC CASES

Case No. 01. CHANGE OF MANAGEMENT OF M/S SEARLE COMPANY LIMITED, F-319, SITE, KARACHI.

M/S Searle Company Limited, Karachi under DML No. 000016 (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	New Management
1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3. 2. Mr. Rashid Abdulla S/o Abdulla A. Razzaq CNIC No. 42201-1132967-1. 3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9. 4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803. 5. Mr. Ayaz Abdulla S/o Shahid Abdulla CNIC No. 42201-8726172-1. 6. Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9. 7. Mr. Munis Abdulla S/o Rashid Abdullah CNIC No. 42201-99825171.	1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3. 2. Mr. Rashid Abdulla S/o Abdulla A. Razzaq CNIC No. 42201-1132967-1. 3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9. 4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803. 5. Mr. Ayaz Abdulla S/o Shahid Abdulla CNIC No. 42201-8726172-1. 6. Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9. 7. Mrs. Shaista Khaliq Rehman W/o Syed Khaliq Abdur Rehman CNIC No. 43201-8797867-2

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management of M/S Searle Company Limited, F-319, SITE, Karachi, under DML No. 000016 (By way of formulation) as under ;

Previous Management	New Management
1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3. 2. Mr. Rashid Abdulla S/o Abdulla A. Razzaq CNIC No. 42201-1132967-1. 3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9. 4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803. 5. Mr. Ayaz Abdulla S/o Shahid Abdulla CNIC No. 42201-8726172-1. 6. Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9. 7. Mr. Munis Abdulla S/o Rashid Abdullah CNIC No. 42201-99825171.	1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3. 2. Mr. Rashid Abdulla S/o Abdulla A. Razzaq CNIC No. 42201-1132967-1. 3. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9. 4. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803. 5. Mr. Ayaz Abdulla S/o Shahid Abdulla CNIC No. 42201-8726172-1. 6. Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9. 7. Mrs. Shaista Khaliq Rehman W/o Syed Khaliq Abdur Rehman CNIC No. 43201-8797867-2

Case No. 02. **CHANGE OF MANAGEMENT OF M/S SAFE PHARMACEUTICALS (PVT) LTD, PLOT NO. C-1-20, SECTOR 6-B, NORTH KARACHI INDUSTRIAL AREA, KARACHI.**

M/sSafe Pharmaceuticals (Pvt) Ltd, Plot no. c-1-20, sector 6-b, north Karachi industrial area, Karachi under DML No. 000349 (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:-

Sr. No	Current Management	Sr. No	New Management
1.	Mr. Muhammad Farooq Memon CNIC No. 42201-0622163-1	1	Mr. Muhammad Farooq Memon CNIC No. 42201-0622163-1
2.	Mr. Muhammad Saleem Memon CNIC No. 42000-0524844-3	2	Mr. Muhammad Saleem Memon CNIC No. 42000-0524844-3
3.	Mr. Muhammad Asif Sheikhani CNIC No. 42201-7801083-9		******
4.	Mr. Muhammad Ahmed Sheikhani		******

	CNIC No. 42201-6404551-3		

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Safe Pharmaceuticals (Pvt) Ltd, Plot no. c-1-20, sector 6-b, north Karachi industrial area, Karachi under DML No. 000349 (By way of Formulation) as under;

Sr. No	Current Management	Sr. No	New Management
1.	Mr. Muhammad Farooq Memon CNIC No. 42201-0622163-1	1	Mr. Muhammad Farooq Memon CNIC No. 42201-0622163-1
2.	Mr. Muhammad Saleem Memon CNIC No. 42000-0524844-3	2	Mr. Muhammad Saleem Memon CNIC No. 42000-0524844-3
3.	Mr. Muhammad Asif Sheikhani CNIC No. 42201-7801083-9		******
4.	Mr. Muhammad Ahmed Sheikhani CNIC No. 42201-6404551-3		******

Case No. 03. CHANGE OF MANAGEMENT OF M/S PAKISTAN PHARMACEUTICALS PRODUCT (PVT) LTD, PLOT NO. D-122, SITE, KARACHI.

M/S Pakistan Pharmaceuticals Product (Pvt) Ltd, Plot No. D-122, SITE, Karachi.underDML No. 000091 (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:-

Current Management	New Management
1. Mr. Owais A. Allahwala S/o. Nasir Ahmed Allahwala CNIC No. 42201-9237873-7. 2. Mr. Nasir Ahmed Allahwala S/o Noor Ahmed Allahwala CNIC No. 42201-6814153-3. 3. Mr. Muhammad Ilyas CNIC No. 42201-7330451-7	1. Mr. Owais A. Allahwala S/o. Nasir Ahmed Allahwala CNIC No. 42201-9237873-7. 2. Mr. Nasir Ahmed Allahwala S/o Noor Ahmed Allahwala CNIC No. 42201-6814153-3.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/S Pakistan Pharmaceuticals Product (Pvt) Ltd, Plot No. D-122, SITE, Karachi under DML No. 000091 (By way of formulation) as under ;

Current Management	New Management
1. Mr. Owais A. Allahwala S/o. Nasir Ahmed Allahwala CNIC No. 42201-9237873-7. 2. Mr. Nasir Ahmed Allahwala S/o Noor Ahmed Allahwala CNIC No. 42201-6814153-3. 3. Mr. Muhammad Ilyas CNIC No. 42201-7330451-7	1. Mr. Owais A. Allahwala S/o. Nasir Ahmed Allahwala CNIC No. 42201-9237873-7. 2. Mr. Nasir Ahmed Allahwala S/o Noor Ahmed Allahwala CNIC No. 42201-6814153-3.

Case No. 04. CHANGE OF MANAGEMENT OFM/S EPLA LABORATORIES (PVT) LTD, PLOT NO. D-12, ESTATE AVENUE, SITE, KARACHI

M/s Epla Laboratories (Pvt) Ltd, Plot No. D-12, Estate Avenue, SITE, Karachi under DML No. 000071 (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	New Management
1. Dr. Muhammad Tariq Siddiqui S/o Dr. (late) Ehtisham Ali Siddiqui CNIC No.42301-0170196-5. 2. Miss Mahvash Tariq Siddiqui D/o Dr. Muhammad Tariq Siddiqui CNIC No.42301-0997066-4. 3. Dr. Muhammad Haroon Siddiqui S/o Dr. (late) Ehtisham Ali Siddiqui CNIC No.42301-8277304-9.	1. Mr. Zaki Ahmed Khan S/o Muhammad Naseem Khan CNIC No.42301-0876596-9. 2. Dr. Muhammad Tariq Siddiqui S/o Dr. (late) Ehtisham Ali Siddiqui CNIC No.42301-0170196-5. 3. Miss Mahvash Tariq Siddiqui D/o Dr. Muhammad Tariq Siddiqui CNIC No.42301-0997066-4

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Epla Laboratories (Pvt) Ltd, Plot No. D-12, Estate Avenue, SITE, Karachi.underDML No. 000071 (By way of formulation)as under ;

Previous Management	New Management
1. Dr. Muhammad Tariq Siddiqui S/o Dr. (late) Ehtisham Ali Siddiqui CNIC No.42301-0170196-5. 2. Miss Mahvash Tariq Siddiqui D/o Dr. Muhammad Tariq Siddiqui CNIC No.42301-0997066-4. 3. Dr. Muhammad Haroon Siddiqui S/o Dr. (late) Ehtisham Ali Siddiqui CNIC No.42301-8277304-9.	1. Mr. Zaki Ahmed Khan S/o Muhammad Naseem Khan CNIC No.42301-0876596-9. 2. Dr. Muhammad Tariq Siddiqui S/o Dr. (late) Ehtisham Ali Siddiqui CNIC No.42301-0170196-5. 3. Miss Mahvash Tariq Siddiqui D/o Dr. Muhammad Tariq Siddiqui CNIC No.42301-0997066-4

CASE NO.05CHANGE OF MANAGEMENT OF M/S INSHAL PHARMACEUTICAL INDUSTRIES, RAWAT, RAWALPINDI.

M/s Inshal Pharmaceutical Industries, Plot No. 02, Street No. SS-2, National Industrial Zone, Rawat, Rawalpindiunder DML No. 000698 by way of formulation has submitted request for change in management of the firm as per Partnership deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	New Management
1. Syed Ijaz Hussain S/o Syed Intizar Hussain CNIC No. 35202-2629779-5. 2. Ms. Alliya Ijaz W/o Syed Ijaz Hussain CNIC No. 35202-2495140-4.	1. Syed Ijaz Hussain S/o Syed Intizar Hussain CNIC No. 35202-2629779-5. 2. Syed Arbab Hussain S/o Syed Intizar Hussain CNIC No. 61101-3829417-7.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Inshal Pharmaceutical Industries, Plot No. 02, Street No. SS-2, National Industrial Zone, Rawat, Rawalpindi under DML No. 000698 by way of formulationas under ;

Previous Management	New Management
1. Syed Ijaz Hussain S/o Syed Intizar Hussain CNIC No. 35202-2629779-5. 2. Ms. AlliyaIjaz W/o Syed Ijaz Hussain CNIC No. 35202-2495140-4.	1. Syed Ijaz Hussain S/o Syed Intizar Hussain CNIC No. 35202-2629779-5. 2. Syed Arbab Hussain S/o Syed Intizar Hussain CNIC No. 61101-3829417-7.

CASE NO.06CHANGE OF MANAGEMENT OF M/S GULF PHARMACEUTICALS ISLAMABAD.

M/s Gulf Pharmaceuticals, Plot No. 49, Street No. S-5, Rawalpindi Industrial Zone (RIZ), Islamabadunder DML No. 000750 by way of formulation has submitted request for change in management of the firm as per Partnership deed with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	New Management
1. Mr. Mohammad Wassi Shan S/o Mohammad Inayat Ullah CNIC No. 37405-2288811-1. 2. Mr. Mohammad Munawar Khan S/o Mohammad Ashfaq CNIC No. 37405-5834516-9.	1. Mr. Muhammad Wassi Shan S/o Muhammad Inayat Ullah CNIC No. 37405-2288811-1. 2. Mr. Muhammad Khurshid S/o Allah Dad CNIC No. 37405-1670752-7.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Gulf Pharmaceuticals, Plot No. 49, Street No. S-5, Rawalpindi Industrial Zone (RIZ), Islamabad under DML No. 000750 by way of formulationas under ;

Previous Management	New Management
1. Mr. Mohammad Wassi Shan S/o Mohammad Inayat Ullah CNIC No. 37405-2288811-1. 2. Mr. Mohammad Munawar Khan S/o Mohammad Ashfaq CNIC No. 37405-5834516-9.	1. Mr. Muhammad Wassi Shan S/o Muhammad Inayat Ullah CNIC No. 37405-2288811-1. 2. Mr. Muhammad Khurshid S/o Allah Dad CNIC No. 37405-1670752-7.

CASE NO.07CHANGE OF MANAGEMENT OF M/S MIRACLE PHARMACEUTICALS (PVT) LTD, RAWAT, ISLAMABAD.

M/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 08, Street No. 5, National Industrial Zone, Rawat, Islamabadunder DML No. 000593 by way of formulation has submitted request for change in management of the firm as per form-29with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	New Management
1. Mr. Altaf Hussain S/o Janhanzaib Khan CNIC No. 17301-3845742-7. 2. Mr. Janhanzaib Khan S/o Wazir Khan CNIC No. 17301-2731742-1. 3. Mr. Israr Hussain S/o Janhanzaib Khan CNIC No. 17301-5865534-1.	1. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-2468331-5 2. Mr. Altaf Hussain S/o Janhanzaib Khan CNIC No. 17301-3845742-7. 3. Mr. Muhammad Masood S/o Muhammad Dawood CNIC No. 54401-3218968-3.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Miracle Pharmaceuticals (Pvt) Ltd, Plot No. 08, Street No. 5, National Industrial Zone, Rawat, Islamabad under DML No. 000593 by way of formulationas under ;

Previous Management	New Management
1. Mr. Altaf Hussain S/o Janhanzaib Khan CNIC No. 17301-3845742-7. 2. Mr. Janhanzaib Khan S/o Wazir Khan CNIC No. 17301-2731742-1. 3. Mr. Israr Hussain S/o Janhanzaib Khan CNIC No. 17301-5865534-1.	1. Mr. Muhammad Dawood S/o Haji Momin CNIC No. 54201-2468331-5 2. Mr. Altaf Hussain S/o Janhanzaib Khan CNIC No. 17301-3845742-7. 3. Mr. Muhammad Masood S/o Muhammad Dawood CNIC No. 54401-3218968-3.

CASE NO.8CHANGE OF MANAGEMENT OF M/S MEGA PHARMACEUTICALS LTD, LAHORE.

M/s Mega PharmaceuticalsLtd, 27-Km, Raiwind Road, Lahore under DML No. 000537 by way of formulation has submitted request for change in management of the firm as per Form-A with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	New Management
1. Mr. Muhammad Tahir Azam CNIC No. 35202-9287376-5. 2. Mr. Intzar Hussain CNIC No. 35202-7717141-3. 3. Mr. Ahmad Khan CNIC No. 35202-2691064-5. 4. Mr. Abdul Samad CNIC No. 17301-1353215-9. 5. Dr. Misbha ul Aziz CNIC No. 42101-6795948-1. 6. Dr. Abdul Rehman CNIC No. 15602-8934746-3. 7. Mr. Shafqat Javed CNIC No. 33100-2399324-7.	1. Mr. Muhammad Tahir Azam S/o Turab Ali CNIC No. 35202-9287376-5. 2. Mr. Intzar Hussain S/o Muhammad Sain CNIC No. 35202-7717141-3. 3. Mr. Ahmad Khan S/o Mohammad Sharif Khan CNIC No. 35202-2691064-5. 4. Mr. Abdul Samad S/o Taj Muhammad CNIC No. 17301-1353215-9. 5. Mr. Habib Ur Rehman S/o Matee Ur Rehman CNIC No. 15602-9849631-9.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore under DML No. 000537 by way of formulationas under ;

Previous Management	New Management
1. Mr. Muhammad Tahir Azam CNIC No. 35202-9287376-5. 2. Mr. Intzar Hussain CNIC No. 35202-7717141-3. 3. Mr. Ahmad Khan CNIC No. 35202-2691064-5. 4. Mr. Abdul Samad CNIC No. 17301-1353215-9. 5. Dr. Misbha ul Aziz CNIC No. 42101-6795948-1. 6. Dr. Abdul Rehman CNIC No. 15602-8934746-3. 7. Mr. Shafqat Javed CNIC No. 33100-2399324-7.	1. Mr. Muhammad Tahir Azam S/o Turab Ali CNIC No. 35202-9287376-5. 2. Mr. Intzar Hussain S/o Muhammad Sain CNIC No. 35202-7717141-3. 3. Mr. Ahmad Khan S/o Mohammad Sharif Khan CNIC No. 35202-2691064-5. 4. Mr. Abdul Samad S/o Taj Muhammad CNIC No. 17301-1353215-9. 5. Mr. Habib Ur Rehman S/o Matee Ur Rehman CNIC No. 15602-9849631-9.

CASE NO.9 CHANGE OF MANAGEMENT OF M/S HARMANN PHARMACEUTICAL LABORATORIES (PVT) LTD, LAHORE.

M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, P.O Chung, 16-Km, Multan Road, Lahore under DML No. 000145 by way of formulation has submitted request for change in management of the firm as per Form-A with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	New Management
1. Mr. Muhammad Haseeb Khan. 2. Mst. Roshi Asif. 3. Mst. Abida Begum. 4. Mst. Uzma Mamon.	1. Mr. Muhammad Haseeb Khan S/o Mian Karm Elahi CNIC No. 35202-9014907-5. 2. Mr. Muhammad Hafeez Khan S/o Mian Karm Elahi CNIC No. 35202-8478971-5. 3. Mr. Muhammad Tahir Khan S/o Muhammad Hafeeb Khan CNIC No. 35202-4615722-5. 4. Mrs. Abida Begum W/o Dr. Muhammad Hafeez Khan CNIC No. 35202-4047487-0.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore under DML No. 000537 by way of formulationas under ;

Previous Management	New Management
5. Mr. Muhammad Haseeb Khan. 6. Mst. Roshi Asif. 7. Mst. Abida Begum. 8. Mst. Uzma Mamon.	5. Mr. Muhammad Haseeb Khan S/o Mian Karm Elahi CNIC No. 35202-9014907-5. 6. Mr. Muhammad Hafeez Khan S/o Mian Karm Elahi CNIC No. 35202-8478971-5. 7. Mr. Muhammad Tahir Khan S/o Muhammad Hafeeb Khan CNIC No. 35202-4615722-5. 8. Mrs. Abida Begum W/o Dr. Muhammad Hafeez Khan CNIC No. 35202-4047487-0.

CASE NO.10CHANGE OF MANAGEMENT OF M/S AVENTEK PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore under DML No. 000660 by way of formulation has submitted request for change in management of the firm as per Form-A and Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	New Management
1. Mr. Tahir Latif S/o Abdul Latif CNIC No. 35202-25606267-1. 2. Mst. Komal Tahir W/o Tahir Latif CNIC No. 35202-5941935-2.	1. Mr. Tahir Latif S/o Abdul Latif CNIC No. 35202-25606267-1. 2. Mst. Komal Tahir W/o Tahir Latif CNIC No. 35202-5941935-2. 3. Mr. Ahsan Tahir S/o Tahir Latif CNIC No. 35202-6944059-7.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore under DML No. 000660 by way of formulationas under ;

Previous Management	New Management
1. Mr. Tahir Latif S/o Abdul Latif CNIC No. 35202-25606267-1. 2. Mst. Komal Tahir W/o Tahir Latif CNIC No. 35202-5941935-2.	1. Mr. Tahir Latif S/o Abdul Latif CNIC No. 35202-25606267-1. 2. Mst. Komal Tahir W/o Tahir Latif CNIC No. 35202-5941935-2. 3. Mr. Ahsan Tahir S/o Tahir Latif CNIC No. 35202-6944059-7.

CASE NO.11 CHANGE OF MANAGEMENT OF M/S DYSON RESEARCH LABORATORIES (PVT) LTD LAHORE.

M/s Dyson Research Laboratories (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore under DML No. 000559 by way of formulation has submitted request for change in management of the firm as per Form-A and Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	New Management

1. Mr. Zafar Mustafa S/o Ghulam Mustafa Jajjah CNIC No.35202-1546650-7. 2. Mr. Tahir Sharif S/o Muhammad Sharif CNIC No. 35202-8557574-1. 3. Mrs. Tahira Khatoon W/o Muhammad Shahrif CNIC No. 35202-2574072-0. 4. Mr. Jehanzeb Rauf Kahlon S/o Ajmal Rauf Kahlon CNIC No. 35201-7891435-7. 5. Mr. Mahmood Ahmad Virk S/o Muhammad Younas CNIC No. 90403-0110978-7. 6. Mr. Faisal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3. 7. Mr. Iqbal Ahmad Choudhry S/o Shah Muhammad Shahi CNIC No. 35200-6814242-9. 8. Mr. Aftab Ahmad Virk S/o Muhammad Younas CNIC No. 35201-8499026-7. 9. Mr. MubasharJaved S/o Muhammad Tufail CNIC No. 35201-1514183-3.	1. Mr. Mahmood Ahmad Virk S/o Muhammad Younas CNIC No. 90403-0110978-7. 2. Mr. Faisal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3. 3. Mr. Aftab Ahmad Virk S/o Muhammad Younas CNIC No. 352010-499026-7. 4. Mr. Tahir Sharif S/o Muhammad Sharif CNIC No. 35202-8557574-1. 5. Mr. Zafar Mustafa S/o Ghulam Mustafa Jajjah CNIC No.35202-1546650-7. 6. Mr. Jehanzeb Rauf Kahlon S/o Ajmal Rauf Kahlon CNIC No. 35201-7891435-7. 7. Mr. MubasharJaved S/o Muhammad Tufail CNIC No. 35201-1514183-3. 8. Mr. Iqbal Ahmad Choudhry S/o Shah Muhammad Shahi CNIC No. 352006-814242-9. 9. Mrs. Tahira Khatoon W/o Muhammad Shahrif CNIC No. 35202-2574072-0. 10. Mr. Shahzad Shafique S/o Shafique Ahmed CNIC No. 35202-3030292-5.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Dyson Research Laboratories (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore under DML No. 000559 by way of formulationas under ;

Previous Management	New Management
1. Mr. Zafar Mustafa S/o Ghulam Mustafa Jajjah CNIC No.35202-1546650-7. 2. Mr. Tahir Sharif S/o Muhammad Sharif CNIC No. 35202-8557574-1. 3. Mrs. Tahira Khatoon W/o Muhammad Shahrif CNIC No. 35202-2574072-0. 4. Mr. Jehanzeb Rauf Kahlon S/o Ajmal Rauf Kahlon CNIC No. 35201-7891435-7. 5. Mr. Mahmood Ahmad Virk S/o	1. Mr. Mahmood Ahmad Virk S/o Muhammad Younas CNIC No. 90403-0110978-7. 2. Mr. Faisal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3. 3. Mr. Aftab Ahmad Virk S/o Muhammad Younas CNIC No. 352010-499026-7. 4. Mr. Tahir Sharif S/o Muhammad Sharif CNIC No. 35202-8557574-1.

Muhammad Younas CNIC No. 90403-0110978-7. 6. Mr. Faisal Mustafa Jajjah S/o Ghulam Mustafa Jajjah CNIC No. 34101-2601502-3. 7. Mr. Iqbal Ahmad Choudhry S/o Shah Muhammad Shahi CNIC No. 35200-6814242-9. 8. Mr. Aftab Ahmad Virk S/o Muhammad Younas CNIC No. 35201-8499026-7. 9. Mr. MubasharJaved S/o Muhammad Tufail CNIC No. 35201-1514183-3.	5. Mr. Zafar Mustafa S/o Ghulam Mustafa Jajjah CNIC No.35202-1546650-7. 6. Mr. Jehanzeb Rauf Kahlon S/o Ajmal Rauf Kahlon CNIC No. 35201-7891435-7. 7. Mr. MubasharJaved S/o Muhammad Tufail CNIC No. 35201-1514183-3. 8. Mr. Iqbal Ahmad Choudhry S/o Shah Muhammad Shahi CNIC No. 352006-814242-9. 9. Mrs. Tahira Khatoon W/o Muhammad Shahrif CNIC No. 35202-2574072-0. 10. Mr. Shahzad Shafique S/o Shafique Ahmed CNIC No. 35202-3030292-5.

CASE NO.12<u>CHANGE OF MANAGEMENT OF M/S GRAND PHARMA (PVT) LTD, RAWAT, ISLAMABAD.</u>

M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A, Road N-5, National Industrial Zone (RCCI), Rawat, Islamabadunder DML No. 000680 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	New Management
1. Mr. Abid Naeem S/o Abufazal Naeem Khawaja CNIC No.61101-9490168-3. 2. Mst. Taiba Naeem W/o Khild Naeem CNIC No. 61101-1753644-2. 3. Mr. Imtiaz ul Islam S/o Talib Din CNIC No. 61101-9830806-3.	1. Mr. Abid Naeem S/o Abufazal Naeem Khawaja CNIC No.61101-9490168-3. 2. Mst. Taiba Naeem W/o Khild Naeem CNIC No. 61101-1753644-2.

<u>Decision of the Central Licensing Board in 275th meeting:</u>

The Board considered and endorsed the change of management M/s Grand Pharma (Pvt) Ltd, Plot No. 5-A, Road N-5, National Industrial Zone (RCCI), Rawat, IslamabadunderDML No. 000680 by way of formulationas under ;

Previous Management	New Management

1. Mr. Abid Naeem S/o Abufazal Naeem Khawaja CNIC No.61101-9490168-3. 2. Mst. Taiba Naeem W/o Khild Naeem CNIC No. 61101-1753644-2. 3. Mr. Imtiaz ul Islam S/o Talib Din CNIC No. 61101-9830806-3.	1. Mr. Abid Naeem S/o Abufazal Naeem Khawaja CNIC No.61101-9490168-3. 2. Mst. Taiba Naeem W/o Khild Naeem CNIC No. 61101-1753644-2.

CASE NO.13 CHANGE OF MANAGEMENT OF M/S AMEER & ADNAN PHARMACEUTICALS (PVT) LTD, LAHORE

M/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd, Plot No. 47, Sunder Industrial Estate, Raiwind Road, Lahoreunder DML No. 000787 by way of formulation has submitted request for change in management of the firm as per Form-A& Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	New Management
1. Mr. Adnan Ghani S/o Abbas Ghani CNIC No. 35202-2930269-1. 2. Mr. Aamir Saleem Butt S/o Muhammad Saleem Butt CNIC No. 34101-2729552-1. 3. Mr. Abbas Ghani S/o Abdul Ghani CNIC No. 34101-2663147-9. 4. Mr. Yasir Butt S/o M. Saleem Butt CNIC No. 35202-2930275-9.	1. Mr. Adnan Ghani S/o Abbas Ghani CNIC No. 35202-2930269-1. 2. Mr. Aamir Saleem Butt S/o Muhammad Saleem Butt CNIC No. 34101-2729552-1.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd, Plot No. 47, Sunder Industrial Estate, Raiwind Road, Lahoreunder DML No. 000787 by way of formulationas under ;

Previous Management	New Management
1. Mr. Adnan Ghani S/o Abbas Ghani CNIC No. 35202-2930269-1. 2. Mr. Aamir Saleem Butt S/o Muhammad Saleem Butt CNIC No. 34101-2729552-1. 3. Mr. Abbas Ghani S/o Abdul Ghani CNIC No. 34101-2663147-9. 4. Mr. Yasir Butt S/o M. Saleem Butt CNIC No. 35202-2930275-9.	1. Mr. Adnan Ghani S/o Abbas Ghani CNIC No. 35202-2930269-1. 2. Mr. Aamir Saleem Butt S/o Muhammad Saleem Butt CNIC No. 34101-2729552-1.

CASE NO.14 CHANGE OF MANAGEMENT OF M/S MASS PHARMA (PVT) LTD, LAHORE

M/s Mass Pharma (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore under DML No. 000787 by way of formulation has submitted request for change in management of the firm as per Form-A & Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous Management	New Management
1. Mr. Ashfaq Ahmed S/o Mehar Muhammad Nawaz CNIC No. 35202-3705859-1. 2. Mr. Khawaja Muhammad Aslam S/o Khawaja Muhammad Ali CNIC No. 35202-9964519-3. 3. Mr. Khawaja Muhammad Akram S/o Khawaja Muhammad Ali CNIC No. 35202-3662275-5. 4. Mr. Shahzeb Akram S/o Khawaja Muhammad Akram CNIC No. 35200-1509201-1. 5. Mr. Iftikhar Javed S/o Muhammad Sharif Sheikh CNIC No. 42000-0576240-7.	1. Mr. Ashfaq Ahmed S/o Mehar Muhammad Nawaz CNIC No. 35202-3705859-1. 2. Mr. Khawaja Muhammad Akram S/o Khawaja Muhammad Ali CNIC No. 35202-3662275-5. 3. Mr. Shahzeb Akram S/o Khawaja Muhammad Akram CNIC No. 35200-1509201-1. 4. Mr. Iftikhar Javed S/o Muhammad Sharif Sheikh CNIC No. 42000-0576240-7.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Mass Pharma (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore under DML No. 000787 by way of formulationas under ;

Previous Management	New Management
1. Mr. Ashfaq Ahmed S/o Mehar Muhammad Nawaz CNIC No. 35202-3705859-1. 2. Mr. Khawaja Muhammad Aslam S/o Khawaja Muhammad Ali CNIC No. 35202-9964519-3. 3. Mr. Khawaja Muhammad Akram S/o Khawaja Muhammad Ali CNIC No. 35202-3662275-5. 4. Mr. Shahzeb Akram S/o Khawaja Muhammad Akram CNIC No. 35200-1509201-1. 5. Mr. Iftikhar Javed S/o Muhammad Sharif Sheikh CNIC No. 42000-0576240-7.	1. Mr. Ashfaq Ahmed S/o Mehar Muhammad Nawaz CNIC No. 35202-3705859-1. 2. Mr. Khawaja Muhammad Akram S/o Khawaja Muhammad Ali CNIC No. 35202-3662275-5. 3. Mr. Shahzeb Akram S/o Khawaja Muhammad Akram CNIC No. 35200-1509201-1. 4. Mr. Iftikhar Javed S/o Muhammad Sharif Sheikh CNIC No. 42000-0576240-7.

CaseNo.15 CHANGE OF MANAGEMENT OF M/S WILSHIRE LABORATORIES (PVT) LTD, 124/1, INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE.

M/s Wilshire Laboratories (Pvt) Ltd, 124/1, Industrial Estate, Kot Lakhpat, Lahore under DML No. 000232 (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	**New Management**
1. Mr. Amjad Ali Jawa S/o Sh. Zaheer Ali Jawa CNIC No. 35202-2722635-7. 2. Mrs. Tahseen Tahira W/o Amjad Ali Jawa CNIC No. 35202-2576262-2. 3. Mr. Asad Ali Jawa, S/o Amjad Ali Jawa CNIC No. 35202-2722600-3. 4. Ghazanfar Ali Jawa S/o Amjad Ali Jawa CNIC No. 35202-7157858-5.	1. Ghazanfar Ali Jawa S/o Amjad Ali Jawa CNIC No. 35202-7157858-5. 2. Mr. Asad Ali Jawa, S/o Amjad Ali Jawa CNIC No. 35202-2722600-3.

Decision of the Central Licensing Board in 275th meeting:

The Board considered and endorsed the change of management M/s Wilshire Laboratories (Pvt) Ltd, 124/1, Industrial Estate, Kot Lakhpat, Lahore under DML No. 000232 (By way of formulation) as under ;

Previous Management	**New Management**
1. Mr. Amjad Ali Jawa S/o Sh. Zaheer Ali Jawa CNIC No. 35202-2722635-7. 2. Mrs. Tahseen Tahira W/o Amjad Ali Jawa CNIC No. 35202-2576262-2. 3. Mr. Asad Ali Jawa, S/o Amjad Ali Jawa CNIC No. 35202-2722600-3. 4. Ghazanfar Ali Jawa S/o Amjad Ali Jawa CNIC No. 35202-7157858-5.	1. Ghazanfar Ali Jawa S/o Amjad Ali Jawa CNIC No. 35202-7157858-5. 2. Mr. Asad Ali Jawa, S/o Amjad Ali Jawa CNIC No. 35202-2722600-3.

Case No. 16 GRANT OF DRUGS FOR RE-PACKING:

M/s Sami Pharmaceuticals, (Pvt) Ltd, Plot No. F-129, S.I.T.E, Karachi, under Drug Manufacturing License No. 000731 (By way of Re-packing) has submitted application for Grant of Re-packing drugs (Powder) as per Schedule-D. Firm has submitted challan Fee of 5,000/ per product.

Sr. No.	Drug	Schedule-D
01	Boric Acid	Yes
02	Borax	Yes

Decision of the Central Licensing Board in 275th meeting:

The Board considered and approved following repacking drugs in the name of M/s Sami Pharmaceuticals, (Pvt) Ltd, Plot No. F-129, S.I.T.E, Karachi, under Drug Manufacturing License No. 000731 (By way of Re-packing)

Sr. No.	Drug
01	Boric Acid
02	Borax

Case No. 17. APPROVAL OF LAYOUT PLAN FOR REGULARIZATIONOF PENDING DRY POWDER INHALER (GENERAL) SECTION UNDER DRUG MANUFACTURING LICENSE NO.000141 (FORMULATION) OF M/S MACTER INTERNATIONAL LTD, PLOT NO. F-216, S.I.T.E, KARACHI.

The Central Licensing Board in its 272nd meeting approved the regularization of master layout plan of M/s Macter International Ltd, Plot No. F-216, S.I.T.E, Karachi, under DML No. 000141 (Formulation), and decided as under :

The Board considered and approved regularization of Lay out plan in the name of M/s. Macter International Ltd, Situated at Plot No.. F-216, S.I.T.E, Karachi on the recommendation of the panel of experts for the following sections:-

Ground floor:

1. Tablet (General),
2. Tablet (Psychotropic),
3. Oral Liquid, (syrup/suspension/ solutions),
4. Warehouse (RMS/PMS/FGS).

First Floor:

1. Ointment/Cream/Gel-I (General),
2. Ointment/Cream/Gel-II (General,
3. Aerosol Section,
4. Liquid Parental (SVP),
5. Liquid Parental (LVP),
6. Dry Powder Suspension (general),
7. Encapsulation (General) Including DPI Capsule,
8. Biotech (Lypholization/Liquid Section),

Second floor (A and B):

1. Dry Powder Suspension (Ceph),
2. Capsule (Ceph),
3. Injectable Section (Ceph),
4. Raw Material Store (Ceph),
5. Encapsulation (Steroid) Including DPI Capsule,
6. Raw Material Store (Steroid),
7. Quality Control Laboratory

The Board also decided to confirm availability of required equipments and machinery for General Dry Powder Inhaler manufacturing by the area Federal Inspector of Drugs in the light of the decision of the Drug Registraation Board as the same is confirmed by the panel in respect of DPI steroidal section and mentioned in the report.

The decision of the CLB was communicated to the firm.

Now the area FIDMr. Hakim Masood has submitted report regarding availability of required equipments and machinery for General Dry Powder Inhaler. The recommendations of the area FID are mentioned below:

Recommendations:-

In conclusion it is confirmed that the firm has requisite facilities for the manufacturing & testing of the DPI Capsule (General) & accordingly recommended for the grant of additional section

namely Encapsulation (General) including Dry Powder Inhaler as per recommendations of renewal of DML panel inspection dated 10-10-2019.

Decision of the Central Licensing Board in 275th meeting:

The Board considered the case and decided to call the company in the next meeting of the Board regarding seeking clarification for manufacturing of General as well as DPI in one and same Section.

Case No. 18. APPROVAL OF LAYOUT PLAN FOR REGULARIZATION UNDER DRUG MANUFACTURING LICENSE NO. 000124 (FORMULATION) OF M/S INDUS PHAMA PVT. LTD, PLOT NO. 26-27, 63-67, SECTOR-27, KORANGI INDUSTRIAL AREA, KARACHI.

M/s Indus Phama Pvt. Ltd, Plot No. 26-27, 63-67, Sector-27, Korangi Industrial Area, Karachi, DML No. 000124 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections: -

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

1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi
2. Additional Director E&M/Area FID DRAP, Karachi.

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

Recommendations:-

Based on the people met, documents reviewed and observation made during inspection, panel recommends the renewal of DML No. 000124 and regularization of layout plan for the following sections:-

S. No.	Sections	S. No.	Sections
1.	Sterile Liquid (eye Drops) Section (General)	2.	Sterile Liquid (Injection and Infusion) Section.
3.	Oral Solids (Tablet) Section (General).	4.	Oral Solids (Capsule) Section (General).
5.	Oral Solids (Sachets) Section (General)	6.	Oral Liquid Section (General).
7.	Oral Solids (Dry Powder Suspension) Section (General)	8.	Parenteral Cephalosporin Section

9.	Capsule Cephalosporin Section	10.	Warehouse and Inventory Control Section
11.	Quality Control and Microbiology Laboratory	12.	Cold Chain Unit.
13.	Dry powder suspension (Cephalosporin).	14.	Warehouse (Cephalosporin)

Decision of the Central Licensing Board in 275th meeting:

The Board considered the case and approved the regularization of the Lay Out plan for the manufacturing facility as under:

S. No.	Sections	S. No.	Sections
1.	Sterile Liquid (eye Drops) Section (General)	2.	Sterile Liquid (Injection and Infusion) Section.
3.	Oral Solids (Tablet) Section (General).	4.	Oral Solids (Capsule) Section (General).
5.	Oral Solids (Sachets) Section (General)	6.	Oral Liquid Section (General).
7.	Oral Solids (Dry Powder Suspension) Section (General)	8.	Parenteral Cephalosporin Section
9.	Capsule Cephalosporin Section	10.	Warehouse and Inventory Control Section
11.	Quality Control and Microbiology Laboratory	12.	Cold Chain Unit.
13.	Dry powder suspension (Cephalosporin).	14.	Warehouse (Cephalosporin)

CASE NO.19 CHANGE OF STATUS OF SITE FROM PHARMACEUTICALS TO NUTRACEUTICALS

Site of M/s Havo Pharmaceuticals, Faisalabad for establishment of Pharmaceutical unit was approved at Plot No. P-28(A), Phase-1A, M-3 Industrial Estate, Faisalabad dated 04-03-2014and later on layout plan was approved dated 14-05-2014. Now, the firm has requested for withdrawal of their site as they decided to change the status from Pharmaceuticals to Nutraceuticals. Mr. Ajmal Sohail Asif, Federal Inspector of Drug, DRAP, Lahore has also forwarded a copy of inspection report. He conducted inspection to check the site suitable for establishment a Nutraceuticals unit / herbal manufacturing unit.

Decision of the Central Licensing Board in 275th meeting:

The Board considered the case and decided to accept the request of the firm for withdrawal of approval of site and Lay out plan accorded from Division of Licensing under delegated powers of the Central Licensing Board for manufacturing of pharmaceutical products / drugs.

CASE NO.20. CORRECTION IN ADDRESS ON DRUG MANUFACTURING LICENSE M/S JENNER RESEARCH LABORATORIES, SHEIKHUPURA.

M/s Jenner Research Laboratories, Sheikhupura had applied for site verification at site located at M-2, Pharmazone, 26th Km Lahore Sharikpur Road, Dhamkey, District Sheikhupura then site was approved at 26th Km Lahore Sharikpur Road, Dhamkey, District Sheikhupura and layout plan of the firm was also approved at the same address. Late on, the firm filed application for grant of Drug Manufacturing License and in Form-1 address of the firm was Plot No. 2, M-2, Pharmazone, 28th Km Lahore Sharqpur Road, District Sheikhupura and Form-2 was issued to the firm with the address Plot No. 2, M-2, Pharmazone, 28th Km Lahore Sharqpur Road, District Sheikhupura.

Now the firm has requested to correct the address on Drug Manufacturing License as Plot No. 3, M-2, Pharmazone, 26th Km Lahore Sharqpur Road, District Sheikhupura.

Decision of the Central Licensing Board in 275th meeting:

The Board considered the case and decided to call the firm in the next meeting of the Board to apprise the Board with all documentary evidence in support of the claim. Moreover, information may also be sought from Industrial Estate.

Case No. 21 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S JAWA PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore had applied for renewal of DML No. 000150 by way of Formulation for the period of 24-12-2019 to 23-12-2024 on 17-10-2019.

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 04thFebruary, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed and stamped Form-1A (as per format)
ii. Duly attested CNIC copies of all Directors.
iii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management.
iv. Latest certified true copy of Form-29 (duly attested by SECP).

The firm replied to this letter on 24thFebruary 2019 but application was incomplete with following shortcomings and reminder letter was issued on 29thApril, 2020 to the firm for completion of application:

i. Latest certified true copy of Form-29 mentioning names of all Directors duly attested by SECP.

The firm submitted documents on 06thMay, 2020 in reply toReminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest certified true copy of Form-29 mentioning names of all Directors duly attested by SECP.

Proceedings and Decision by the Central Licensing Board in 275th 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 Jawa Pharmaceuticals (Pvt) Ltd, 112/10-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, Drug Manufacturing Licence No 000150 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 22 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S DRUGPHARM (PVT) LTD, LAHORE**

M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore had applied for renewal of DML No. 000366 by way of formulation for the period of 24-04-2016 to 23-04-2021 on 15-04-2016.

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 23th August, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Classes of Drugs.
2. Dosage forms of drugs.
3. Change (s) in name of proprietor / directors / partners.
4. Detail of premises including approved layout plan of the factory / proof of section from CLB.
5. Copy of approval production and QC Incharge
6. Noting due certificate regarding CRF from STO.
7. Form-29 from S.E.C.P and CNIC of partners

The firm submitted their reply on 8th September, 2016 After evaluation of the submitted documents, a letter was issued on 30th January, 2017 to the firm with following shortcomings: -

1. Attested Form-29 from S.E.C.P along with copies of CNIC of all directors.
2. Any change in directors from last renewal along with Form-29 at previous renewal.
3. N.O.C for C.R.F (attested up to 2015).
4. Approved copy of Layout Plan.
5. Approved of technical staff or application / documents.
6. All documents should be duly attested.

The firm submitted their reply on 23th February, 2017 After evaluation of the submitted documents, Final Reminder was issued on 19th June, 2017 to the firm with following shortcomings: -

1. Attested Form-29 from S.E.C.P along with copies of CNIC of all directors.
2. Any change in directors from last renewal along with Form-29 at previous renewal.
3. N.O.C for C.R.F (attested up to 2016).
4. Approved copy of Layout Plan.
5. Approved of technical staff or application / documents.
6. All documents should be duly attested.

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

1. Attested Form-29 from S.E.C.P along with copies of CNIC of all directors.
2. Any change in directors from last renewal along with Form-29 at previous renewal.
3. N.O.C for C.R.F (attested up to 2016).
4. Approved copy of Layout Plan.
5. Approved of technical staff or application / documents.
6. All documents should be duly attested.

Moreover, The Hon'ble Chairman, Drug Court, Balochistan Quetta has passed an order whereby it is stated that a case No. 37/17 is filed before Hon'ble Drug Court, Quetta in respect of M/s DrugPharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore. Accused are not appearing before the Court despite issuance of Non bailable warrants repeatedly. Therefore, Chairman Drug Court, Balochistan, Quetta has ordered to cancel the Drug Manufacturing Licence of said firm and report in this regard may be forwarded to Chairman Drug Court, Balochistan, Quetta.

Proceedings and Decision of Central Licensing Board in 256th 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 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore Drug Manufacturing License No. 000366 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.

The Show Cause notice dated 05th January, 2018 was issued to the M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore

A letter of Personal hearing has been issued on 17th January,2018.

Proceedings and Decision of Central Licensing Board in 257th meeting

No representative of the of the firm appeared before the Board. The Board considering the facts on the record and after thread bare deliberation decided to cancelDrug Manufacturing License No. 000366 by way of formulation issued in the name of M/s Drugpharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahoreon the orders of the Court under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

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

The Central Licensing Board in its 257th meeting held on 24-25th January, 2018 cancelled the Drug Manufacturing Licence No. 000366 (Formulation)M/s Drugpharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore and the same decision was conveyed to the firm vide letter dated 20th March, 2018.

The firm filed appeal in Appellate Board against the decision of CLB. Appellate Board in its 151st sitting held on 16th January, 2019" considered the appeal of the firm and decided as under:-

> *"The Board, after hearing arguments and perusing record if the case, decided to remand the case back to the Central Licensing Board with direction to decide a fresh the application for renewal of DML No. 000336 submitted by M/s DrugPharm (Pvt) Ltd, Lahore in forthcoming meeting.*
>
> *The Licensing Division shall constitute panel for inspection of the firm to be carried out after two months of the communication of this decision. Dr. Farzana Chaudhary and Mr. Shahid Nasir (Member, Appellate Board) are to be included in the Panel. The panel so constituted may allow production if the firm is complying with Good Manufacturing Practices (GMP) guidelines".*

Licensing Division then afresh evaluate the application of the firm and following shortcoming in the application were conveyed to the firm vide letter dated 3rdJuly 2019.

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of 50,000/-.
iii. Latest certified true copy of Form-29 (duly attested by S.E.C.P).
iv. Duly attested CNIC copies of all directors.
v. Section approval letters of all sections issued by Central Licensing Board, if not available, apply for regularization of layout plan.
vi. Complete set of duly attested documents of proposed Production Incharge and Quality Control Incharge (as per checklist) along with prescribed fee of Rs. 10,000/-.

Firm did not submit their reply till date and application for renewal of DML is still incomplete. File forwarded to Legal Affairs Division, DRAP for legal opinion whether the Drug Manufacturing Licence of the firm is valid or the decision of Central Licensing Board is intact.

Reply of the Legal Affair Division

Appellate Board in its 151st meeting held on 16th January, 2019 decided to remand back the case to Central Licensing Board with direction to decide afresh the application of renewal of DML No. 000336 submitted by M/s Drugpharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore in its forthcoming meeting. The Licensing division the afresh evaluate the renewal application of the firm and shortcoming were conveyed to firm but the firm did not reply yet. In the light of above available facts, Legal Affairs Division is opined that the decision of the Appellate Board is still intact and Central Licensing Board may finally decide the renewal application of the firm according to its procedure.

Proceedings and Decision by the Central Licensing Board in 275th 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), 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Drug Pharm (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore Drug Manufacturing License No. 000366 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

Case No. 23 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S BAYER PAKISTAN (PVT) LTD [FORMERLY M/S MEDIPHARM (PVT) LTD], LAHORE.

The Central Licensing Board in 257th meeting held on 24-25 January, 2018 approved the renewal of DML of M/s Bayer Pakistan (Pvt) Ltd, [Formerly M/s Medipharm (Pvt) Ltd], Lahore. The decision of the Board as under:-

M/s Medipharm (Pvt) Ltd., 108, Kot Lakhpat, Industrial Estate, Lahore. **DML No. 000243 (Formulation).**	**07-12-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f. **18-11-2014 to 17-11-2019** The Board considered the case and **did not**

		approve the renewal of **Psychotropic section**. 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 Psychotropic section shall remain suspended till decision by the Board. The Central Licensing Board will take a decision on the recommendations of the panel either to grant renewal of Psychotropic section or reject the application and inform the licencee accordingly.

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

The renewal of DML letter dated 19thMarch, 2018 was issued to the M/s Medipharm (Pvt) Ltd., 108, Kot Lakhpat, Industrial Estate, Lahore.

The firm then requested for panel constitution for inspection of the firm for the purpose of renewal of Tablet Psychotropic section and panel was constituted vide letter dated 29th April, 2020.

The panel of expert inspected the firm dated 18-06-2020 and the recommendation of the panel is as under:-

> "In view of above proceedings, based as the areas inspected, the panel **recommends** the renewal and resumption of production of Psychotropic Tablet section of M/s Bayer Pakistan (Pvt) Ltd, Lahore".

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Board considered the case and decided to cease the suspension of Tablet Section (Psychotropic) of M/s Bayer Pakistan (Pvt) Ltd, Lahore and allowed the renewal and resumption of production in Tablet Section (Psychotropic).

Case No. 24 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FILIX PHARMACEUTICALS (PVT) LTD, RAWAT, ISLAMABAD.**

M/s Filix Pharmaceuticals (Pvt) Ltd, Plot No. 4-A, Main Road, R.C.C.I, Rawat, Islamabad had applied for renewal of DML No. 000779 by way of Formulation for the period of 30-08-2018 to 29-08-2023 on 10-08-2018.

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 7thSeptember, 2018 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Form 1A alongwith enclosure / annexure / flags.
ii. Classes of Drugs.
iii. Dosage form of drugs.
iv. Detail of management at the time of previous renewal and present renewal.
v. In case if firm is Private Limited then Certificate of incorporation with SECP, Memorandum and Article of Association, Form-A and Form-29 may also be furnished.
vi. Declaration of firm on stamp paper in case of sole proprietorship company alongwith CNIC.
vii. Partnership deed attested in case of partnership deed alongwith CNICs.
viii. Detail of premises including layout plan
ix. Proof of licensed sections from CLB.
x. Approval letter of Production / Quality Control Incharge in case of change than submit required documents as per check list.
xi. All documents duly should be attested.

The firm replied to this letter on 19thNovember, 2018 but application was incomplete with following shortcomings and reminder letter was issued on 21st May, 2019 to the firm for completion of application:

For Renewal of DML.

i. Detail of management at the time of previous renewal and present renewal.
ii. In case if firm is Private Limited then Certificate of incorporation with SECP, Memorandum and Article of Association, Form-A and Form-29 may also be furnished.

For Production Incharge (Amjad Ikram).

i. Experience Certificate as under Drug (Licensing, Registering and Advertising) Rules, 1976 not less than 10 years.

All documents duly should be attested.

The firm submitted documents on 16th July, 2019 in reply toReminder but application was incomplete with following shortcomings and final reminder letter was issued on 26th February, 2020 to the firm for completion of application:

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 (duly attested by SECP).
iii. Updated Nothing Due Certificate regarding CRF from STO (R&D),DRAP.

The firm submitted documents on 02nd April, 2020 in reply tofinal reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 (duly attested by SECP).
iii. Updated Nothing Due Certificate regarding CRF from STO (R&D),DRAP.

Proceedings and Decision by the Central Licensing Board in 275th 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), 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Filix Pharmaceuticals (Pvt) Ltd, Plot No. 4-A, Main Road, R.C.C.I, Rawat, Islamabad Drug Manufacturing License No. 000779 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

Case No. 25 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AGROR PHARMA (PVT) LTD, RAWAT, ISLAMABAD.

M/s Agror Pharma(Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat, Islamabad had applied for renewal of DML No. 000791 by way of Formulation for the period of 03-02-2019 to 02-02-2024 on 23-01-2019.

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 29thMay, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

1. Detail of management at the time of previous renewal and present renewal.
2. Attested Form 29 from SECP alongwith CNICs of all Directors.
3. Proof of sections approved by the Central Licensing Board.
4. Nothing due certificate regarding CRF from STO DRAP updated.

For Production Incharge (Mr. Abid Maqsood).

i. Appointment letter and job acceptance letter
ii. Resignation of the earlier production Incharge.
iii. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

For Quality Control Incharge (Mr. Salah ud Din).

i. Appointment letter and job acceptance letter
ii. Resignation of the earlier Quality Control Incharge
iii. Resignation / retirement of earlier approved QC Incharge.
iv. All documents should be duly attested.

The firm replied to this letter on 23rd May, 2019 but application was incomplete with following shortcomings and reminder letter was issued on 8th November, 2019 to the firm for completion of application:

For Renewal of DML.

1. Detail of management at the time of previous renewal and present renewal.
2. Attested Form 29 from SECP along with CNICs of all Directors.
3. Proof of sections approved by the Central Licensing Board.

For Quality Control Incharge (Mr. Salah ud Din).

1. Appointment letter and job acceptance letter of appointee.
2. Resignation / retirement of earlier approved QC Incharge.
3. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
4. All documents should be duly attested.

For Production Incharge (Khalid Rehman Khattak).

1. Appointment letter.
2. Job acceptance letter by the appointee.
3. Copy of CNIC of appointee.

4. Resignation / retirement of earlier approved Production Incharge.
5. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
6. All documents should be duly attested.

The firm submitted documents on 18th December, 2019 in reply to final reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Prescribed fee of Rs. 50,000/- for change of management as there is change in management of the firm.
ii. Latest certified true copy of Form-29 duly attested by SECP mentioning detail / name of all Directors / CEO.
iii. Duly attested CNIC copies of all Directors.
iv. Duly attested CNIC copy of proposed Production Incharge.

Proceedings and Decision by the Central Licensing Board in 275th 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), 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Agror Pharma(Pvt) Ltd, Plot No. 4, Street No. SS-4, National Industrial Zone, Rawat Drug Manufacturing License No. 000791 by way of formulation may not be rejected or Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

Case No. 26 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S BAJWA PHARMACEUTICALS (PVT) LTD, DISTRICT SHEIKHUPURA.

M/s Bajwa Pharmaceuticals (Pvt) Ltd, 36-Km, Lahore-Gujranwala Road, Khori, District Sheikhupura had applied for renewal of DML No. 000805 by way of Formulation for the period of 02-12-2019 to 01-12-2024 on 20-09-2019.

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 25thFebruary, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 (duly attested by SECP).
iii. Duly attested CNIC copies of all Directors.
iv. Detail of management at the time of grant of DML & at present, if any change, apply for change of management.
v. Proof of licensed Sections / section approval letters of all sections approved by CLB, if not available, apply for regularization of Layout Plan.
vi. Approval letter of Production Incharge and Quality Control Incharge, if not approved, apply for approval of technical staff.

The firm replied to this letter on 10th March, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 8th April, 2020 to the firm for completion of application:

i. Complete set of duly attested documents (except appointment and job acceptance letters) of proposed Production Incharge and quality Control Incharge alongwith prescribed fee of Rs. 10,000/-.

The firm submitted documents on 22nd April, 220 in reply to final reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Registration certificate from Pharmacy Council of Quality Control Incharge and Production (valid / renewed).
ii. Resignation / retirement of earlier Production Incharge.
iii. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Production Incharge).

Moreover, It is pertinent to mention here that proposed Quality Control Incharge Mr. Ammar Yasir Bhutta Joined the firm w.e.f. 26-05-2016 and proposed Production Incharge Mr. Abdul Khaliq Joined the firm w.e.f. 26-06-2015 and the firm filled their application on 21-04-2020. Upon inquiring the firm regarding carrying out production activities without approved technical staff the firm has stated that they have intimated DRAP Lahore regarding appointment of technical staff.

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License No. 000805by way of formulation in the name of M/s Bajwa Pharmaceuticals (Pvt) Ltd, 36-Km, Lahore-Gujranwala Road, Khori, District Sheikhupura may not be suspended or cancelled.

Case No.27. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The detail of the firm is as under:-

1.	000871	M/s AAA Health Pharmaceutical Laboratories	Never

Decision by the Central Licensing Board in 269th meeting:

The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund.

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

The Show Cause notice dated 16thMay, 2019was issued to the M/sAAA Health Pharmaceutical Laboratories, Rawat, Islamabad. The firm replied to the show cause notice dated 23rd July, 2019. The firm submitted audit report but did not submitted Nothing Due Certificate.

A letter has been issued to Budget & Account Division, DRAP, Islamabad to provide updated status regarding CRF contribution by M/s AAA Health Pharmaceutical Laboratories, Rawat, Islamabad vide letter dated 19th February, 2020.

Budget & Account Division, DRAP, Islamabad replied this letter on 20th February, 2020 and issued "Nothing Due Certificate" valid upto 31-12-2019 against DML No. 000871 of M/s AAA Health Pharmaceutical Laboratories, Rawat, Islamabad.

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Board considered the case and decided to cease the operation of Show Casue Notice with immediate effect.

Case No. 28 RENEWAL OF DML OF M/S KATRINA PHARMACEUTICAL INDUSTRIES (PVT.) LTD., SHEIKHUPURA.

The case was placed the Board as under: -

The renewal of DML # 000344 (Formulation) of M/s Katrina Pharmaceutical Industries (Private) Limited located at 10-km Sheikhupura Road, Sheikhupura was not recommended by the panel who conducted inspection on 14-12-2007 for renewal of DML for the period 14-12-2004 to 13-12-2009.

Firm was then issued a show cause notice on 23-05-2008 and directed to appear before the Board on 26-05-2008.

Firm appeared before the Board in its 212th meeting held on 26-05-2008, to avail opportunity of personal hearing wherein Chief Executive of the firm Mr. Afzal Hameed submitted undertaking for voluntary stoppage of production with immediate effect and stated that they will be ready for inspection after one month.

Firm was again inspected by the then area FID on 15-06-2009 and inspection report he stated that firm had not done any compliance with reference to previous inspection report and renewal of DML was also not recommended by the panel.

Firm was again served a show cause notice dated 29-07-2009 and advised to appear before the Board for personal hearing on 31st July 2009. However firm did not appear before the Board for personal hearing.

Afterwards, firm submitted application of renewal of DML for the period of next five years **i.e. 14-12-2009 to 13-12-2014** for which a panel was constituted on 25-02-2011 but no inspection report received from that panel yet.

Meanwhile, Area Federal Inspector of Drugs, DRAP, Lahore visited firm on 06-03-2013 for routine GMP inspection and reported that firm was closed for the past many years and firm has not done any improvements in their premises.

Firm was then again served show cause notices on 23rd December 2013, 24th February 2014 with advise to appear before CLB for personal hearing but firm failed to appear in any of the meetings of the Board for personal hearing.

The case was then again discussed in 234th meeting held on 27th February, 2014 wherein the Board decided as under; -

Decision of CLB in its 234th meeting

The Board after thorough discussion / deliberations and facts on grounds considered and decided as under:-

- Fresh status report by panel comprising of Dr. Ikram ul Haq, Member CLB, Ahmad Mehmood Mumtaz, CQC, DDG (E&M), Lahore and Area FID, Lahore.
- Opinion from Law Division that the firm has been called twice for personal hearing but did not attended for personal hearing so whether CLB can decide for suspension / cancellation of Drug Manufacturing License ex-parte under section 41 of Drugs Act, 1976.
- Last and final opportunity of personal hearing in the forthcoming meeting of CLB and letter shall be sent through Registered Post and receipt of same shall be retained

With respect to the decision of the Board in its meeting, the panel inspection report is still awaited.

Opinion from Division of Legal Affairs, DRAP, has been taken with respect to failure of the firm to appear before the Board for personal hearing. In this regard, the comments of Division of Legal Affairs, DRAP are as under:-

"***Section 41 of the Drugs Act, 1976 and Rule 12 of the Drugs (Licensing, Registering & Advertising) Rules 1976 are clear that an opportunity of being heard is to be provided to the licensee and obviously he cannot be forced physically for such appearance. Similarly the licensee cannot be allowed to defeat the law and the rules by his non appearance. Therefore, if all conditions given in the respective provisions of law and rules have been satisfied in a bonafide manner, the Board may go ahead in taking the decision***"

***Current status of the license of the firm*:-**

As per record of Licensing Division, DRAP, Islamabad, the both previous tenure of renewal of DML of the firm i.e. **14-12-2004 to 13-12-2009 and 14-12-2009 to 13-12-2014** has been expired. Firm has now submitted application for renewal of DML of the firm for the period of next five years **i.e. 14-12-2014 to 13-12-2019** which is well before the expiry of the period of validity of the license therefore license of the firm shall continue in force till any further orders passed on such application according to Rule 5 of the Drugs (Licensing, Registering & Advertising) Rules 1976.

The firm was called for availing last opportunity of personal hearing.

Proceedings of the case:-

Mr. Shoib Afzal S/O Mr. Afzal Hameed appeared before the Board as representative of the firm on behalf of his father (the owner of the firm). He stated that firm is closed since year 2008 because HVAC system installation is not completed due to financial constraint. He further added that their firm has made some modifications in the existing building by addition of more sections and accordingly got approval of layout plan from Central Licensing Board. Previously, firm possess very low number of registered products in tablet section due to which survival in the market was very difficult. The representative of the firm informed that they have submitted application for renewal of DML for the period 14-12-2014 to 13-12-2019 and their license is valid and further informed that their unit will be ready for inspection after 05 months.

Decision by the Central Licensing Board in 241st meeting:

The Board after hearing the representative of the firm and on the basis of the commitment decided to allow 05 month time to the firm for completing the installation of HVAC system according to the approved layout plan and also directed the firm to not start production unless inspected and granted permission by Central Licensing Board.

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

The letter was issued vide letter dated 20th August, 2015 to M/s Katrina Pharmaceutical Industries (Pvt) Ltd, Sheikhupura.

The Firm has filled new application on 06-12-2019 for renewal of DML for period of 14-12-2019 to 13-12-2024. The application for the renewal of DML of the firm was evaluated. Following documents being shortcoming / deficient.

i. Properly filled, signed & stamped Form-1A (as per format).
ii. Updated NDC regarding CRF from STO, DRAP.
iii. Latest certified true copy of Form-29 duly attested by SECP (original).
iv. Duly attested CNIC copies of all Directors.
v. Section approval letters of all sections approved by CLB, if not available, apply for regularization of layout plan.
vi. Name and qualification of qualified staff.
vii. Approval letters of Production Incharge and Quality Control Incharge.
viii. Classes of Drugs.
ix. Section wise detail of machinery in Production and Quality Control.

A letter has been issued to QA & LT Division, DRAP, Islamabad to provide the current GMP status of the firm vide letter dated 06th March, 2020.

QA & LT Division, DRAP, Islamabad replied this letter on 16th March, 2020 and stated as under:

> As per the available record. It is submitted that Ms. Aisha Irfan the than FID conducted inspection of the firm M/s Katrina Pharmaceutical Industries (Pvt) Ltd, 10-Km, Sheikhupura Faisalabad Road, Sheikhupura on 09-05-2016. The FID informed that *"The Central Licensing Board in its 241st meeting held on 15-05-2015, have decided to allow 05 months time period of the firm for completing the installation of HVAC system. However, even after lapse of one year, the firm failed to submit any progress and compliance in this regard. The factory is not in working condition for the last many years. The undersigned have visited the factory almost thrice and all the time it was found closed and non-functional. Apparently it seemed that no renovation work / installation of HVAC has been done. The unit is not functional for the last seven years approximately and renewal of Drug Manufacturing License has not been granted. Hence, under these circumstances it is proposed that DML of the firm M/s Katrina Pharmaceutical Industries (Pvt) Ltd, 10-Km, Sheikhupura Faisalabad Road, Sheikhupura*

may be cancelled under Rule 12 of (Licensing, Registering and Advertising) Rules 1976 in order to avoid any illegal activities in the firm. "

Proceedings and Decision by the Central Licensing Board in 275th 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), 16, and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Katrina Pharmaceutical Industries (Private) Limited located at 10-km Sheikhupura Road, Sheikhupura Drug Manufacturing Licence No. 000344 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board

Case No. 29 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S GULF PHARMACEUTICALS, ISLAMABAD.

M/s Gulf Pharmaceuticals, Plot No. 49, Street No. S-5, National Industrial Zone, Rawat. DML No. 000750 (Formulation) **Period**: **16-08-2017 to 15-08-2022**	**02-02-2018 & 07-02-2018**	**Good**	1. Dr. Abdur Rashid, Additional Director (H&OTC), DRAP, Islamabad. 2. Dr. Zunaira Faryad, AD (Lic), DRAP, Islamabad. 3. Dr. Hassan Afzaal, FID-III, DRAP, Islamabad.

Recommendations of the panel: -

"Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **recommended** M/s Gulf Pharmaceuticals, Plot No. 49, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi for the renewal of Drug Manufacturing License No. 000750 (Formulation).

Decision by the Central Licensing Board in 259th meeting

The Board approved the renewal of Drug Manufacturing Licence No. 000750 (Formulation)in the name of M/s Gulf Pharmaceuticals, Plot No. 49, Street No. S-5, National Industrial Zone, Rawat,

Rawalpindi on the recommendations of the panel of experts for the further period of five years commencing on**16-08-2017** and ending on **15-08-2022.**

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

The renewal of DML letter dated07thMay, 2018was issued to the M/s Gulf Pharmaceuticals, Plot No. 49, Street No. S-5, Rawalpindi Industrial Zone (RIZ), Islamabad.

M/s Gulf Pharmaceuticals, Islamabad, has stated that their premises had been inspected on dated 02-02-2018 and 07-02-2018 by panel inspection for renewal of DML in which panel has recommended for renewal of DML No. 000750 for the following sections namely along with additional sections as under:

1. Tablet Section (General).
2. Capsule Section (General).
3. Cream / Ointment Section (General).
4. Oral Liquid Section (General).
5. Dry suspension Section.

The firm has requested to issue the approval letter of aforesaid sections.

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Board considered and decided to issue letter of Sections as per approved Lay Out Plan and mentioned by the panel in tis inspection report.

Case No. 30 APPROVAL OF QUALITY CONTROL INCHARGE OF M/S CURE LABORATORIES (PVT) LTD, RAWAT, RAWALPINDI.

Mr. Ameer Hussain, approved Quality Control Incharge of M/s Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi, under Drug Manufacturing Licence No. 000897 by way of formulation had resigned w.e.f, 06-03-2019. The firm filed application for approval of new Quality Control Incharge on 13-11-2019.The application was evaluated and letter for following shortcomings / deficiencies was issued to the firmon 22nd January, 2020.

i. It has been noticed that there is duplication in dates of experience certificates of proposed Quality Control Incharge i.e Ambrosia Pharmaceutical, Islamabad 16th August, 2004 to 9th January, 2007 and Goodman Laboratories, Islamabad 1st December, 2006 to 12th February, 2014, the said person was working at two different organizations at the same time. Moreover, the previous Quality Control Incharge resigned on 6th March, 2019 from your firm and Quality Control testing has been continued without the supervision of approved Quality Control Incharge.

ii. You are therefore required to justify your position in writing regarding said experience and for violating the Rule 16 and 19 of Drugs (Licensing, Registering & Advertising) Rules 1976.

The firm submitted their reply on 6thFebruary, 2020. The application was complete and propose Quality Control Incharge was approved.

The firm carried production activity without approved Quality Control Incharge which is violation of Rule 16 of the Drugs (Licensing, Registering and Advertising) Rule, 1976.

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing Licence No. 000897by way of formulation in the name of M/s Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2, National Industrial Zone, Rawat may not be suspended or cancelled.

Case No. 31. <u>RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S PHARMACARE LABORATORES (PVT) LTD, LAHORE.</u>

M/s Pharmacare Laboratories (Pvt) Ltd, Lahore, had applied for renewal of DML 000255 by way of (Formulation) for the period of 13-06-2019 to 12-06-2024. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 18th July, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Nothing due certificate regarding CRF from STO (updated).
ii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee.
iii. CNIC copies of all Directors.
iv. Latest certified true copy of Form-29 (attestation by SECP).
v. Section approval letter of all sections approved by Central Licensing Board.
vi. List of technical staff working in Production & Quality Control department.
vii. All documents should be duly attested.

2. The firm submitted their reply on 6th August. 2019 After evaluation of the submitted documents, final reminder was issued on 14th October, 2019 to the firm with following shortcomings: -

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

3. Firm has submitted their reply in response to this Division's Final Reminder and following documents are still deficient /short and application for renewal of DML was incomplete:-

i. Nothing-due certificate regarding CRF from STO (updated).

ii. Latest certified true copy of Form-29 (Attestation by SECP Without the phrase of (SECP) to not take responsibility of contents of form.

iii. Section approval letter of all sections approved by Central Licensing Board, if not available, apply for regularization of layout plan.

4. Meanwhile inspection report by the panel constituted 2017 for the term 13-06-2014 to 12-06-2019 is received which was conducted on 16-1-2020 as blow:

	M/s Pharmacare Laboratories (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore. DML No.000255 (Formulation). **Period**: 13-06-2014 to 12-06-2019	16-01-2020	Good	1. Dr. Farzana Chowdhary, Member, CLB, DRAP, Islamabad. 2. Syed Shahid Nasir, Expert, Member. 3. Aisha Irfan, FID, DRAP, Lahore.
	Recommendations of the panel: - "The panel of inspectors **do not recommends**the renewal of Drug Manufacturing License to M/s Pharmacare Labs (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore".			

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Central Licensing Board considered the case and noted with serious observations for delays in coordinating and conducting of panel Inspections by the Federal Inspector of Drugs. The Board perused the inspection report of the panel on record where serious observations are recorded in terms of GMP non Compliance. The Board, therefore, decided to stop production of the firm with immediate effect in public interest.

The Board considering the facts on the record in respect of renewal application for the period 13-06-2019 to 12-06-2024and 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 Pharmacare Labs (Pvt) Ltd, 129/1, Industrial Estate, Kot Lakhpat, Lahore Drug Manufacturing Licence No. 000255 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board

Case No. 32. <u>RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MTI MEDICAL (PVT) LTD, LAHORE.</u>

M/s MTI Medical (Pvt) Ltd, Plot No. 586, Sunder Industrial Estate, Lahore had applied for renewal of DML 000801 by way of (Formulation) for the period of 19-09-2019 to 18-09-2024. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 30th September, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed and stamped Form-1A (as per format)
ii. Updated Nothing Due Certificate regarding CRF from STO (R&D) DRAP, Islamabad.
iii. Detail of management at the time of grant of DML and at present, if any change, apply for change of management.
iv. Latest Certified true copy of Form-29. (Attestation by SECP).
v. Duly attested CNIC Copy of all Directors / CEO.
vi. Approval letters of Production Incharge and Quality Control Incharge, if not approved, submit application with prescribed fee to Licensing Division.

The firm submitted their reply on 6th November. 2019 After evaluation of the submitted documents, final reminder was issued on 12thFebruary, 2020to the firm with following shortcomings: -

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 attested by SECP.
iii. Duly attested copies of experience certificates of Quality Control Incharge.
iv. Duly attested copies of resignation of earlier Production Incharge and Quality Control Incharge.
v. Duly attested copies of resignation /retirement of proposed Production Incharge and Quality Control Incharge from previous firms.

Firm has submitted their reply in response to this Division's Final Reminder on 09th March, 2020 and following documents are still deficient /short and application for renewal of DML was incomplete:-

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Latest certified true copy of Form-29 attested by SECP.

Proceedings and Decision by the Central Licensing Board in 275th 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 MTI Medical (Pvt) Ltd, Plot No. 586, Sunder Industrial Estate, Lahore Drug Manufacturing Licence No. 000801 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board

Case No. 33 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HOOVER PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Hoover Pharmaceuticals (Pvt) Ltd, Plot No. 16, Zain Park Industrial Area, Saggain Bypass Road, Lahorehad applied for renewal of DML No. 000676 by way of Formulation for the period of 09-12-2019 to 08-12-2024 on 15-10-2019.

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 10thFebruary, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Properly filled, signed and stamped Form-1A (as per format).
ii. Proof of sections approved by CLB, if not available, apply for regularization of layout plan.
iii. Latest certified true copy of Form-29 (duly attested by SECP).
iv. Duly attested CNIC copies of all Directors.

v. Prescribed fee of Rs. 50,000/- for change of management as there is change in management of the firm.

The firm replied to this letter on 27th February, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 29th April, 2020 to the firm for completion of application:

i. Prescribed fee of Rs. 50,000/- for change in management of the firm.
ii. Latest certified true copy of Form-29 duly attested by SECP (original)
iii. Proof of sections approved by Central Licensing Board / Section approval letters, if not available then apply for regularization of layout plan.

The firm submitted documents on 20th May, 220 in reply to final reminder but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest certified true copy of Form-29 duly attested by SECP (original).

Proceedings and Decision by the Central Licensing Board in 275th 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 Hoover Pharmaceuticals (Pvt) Ltd, Plot No. 16, Zain Park Industrial Area, Saggain Bypass Road, Lahore Drug Manufacturing Licence No. 000676 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board

CASENO.34 WITHDRAWAL/VOLUNTARY SURRENDER OFDRUG MANUFACTURING LICENSE NO. 000054 (BASIC MANUFACTURE) OF M/S ASPIN PHARMA (PVT) LIMITED, KARACHI.

M/s Aspin Pharma (Pvt) Ltd, Karachi submitted request for renewal of DML No. 000054(Basic manufacture|) which was evaluated and letter regarding following shortcoming/deficient documents was issued to the firm.

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

(ii) Detail/names of all licensed sections/facilities for Basic manufacture on firm's letter head along with approval letters of all API's issued from CLB.
(iii) Section wise detail of machinery for manufacture and Quality control for Basic Manufacture.
(iv) Names and approval letters of both production incharge and QC incharge.

In response to the said letter, firm has stated that it intends to voluntary withdraw application for the DML No. 000054(Basic Manufacture) since currently Basic manufacturing is not part of our business plan and we plan to start in the near future.

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Board considering the case and decided to accept the request of the firm. Hence, DML No. 000054(Basic Manufacture) M/s Aspin Pharma (Pvt) Ltd, Karachi stands cancelled with immediate effect being withdrawn.

CASE NO.35. REGULARIZATION OF LAYOUT PLAN OF M/S AMSON VACCINE & PHARMA (PVT) LTD., PLOT NO.154, KAHUTA TRIAGNLE, ISLAMABAD.

M/s Amson Vaccine & Pharma (Pvt) Ltd., Plot No.154, Kahuta Triagnle, Islamabad, DML No. 000393 (Formulation), has applied for regularization of layout plan of running facility for their existing following sections;

Existing Sections/New Facility.			
1.	Tablet (General)	2.	Capsule Section (General)
3.	Orals Liquid Section (General)	4.	Dry Powder Injection Section (Steroid)
5.	Liquid Ampoule Injection (Vaccine)	6.	Liquid Vial Injection (Vaccine/Sera)
7.	Quality Control Laboratory	8.	Warehouse

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.

i. Dr. Muhammad Usman, Member CLB.
ii. Dr. Noor Us Saba, Director (Biological Division), DRAP, Islamabad.
iii. Mr. Babar Khan, Area FID, Islamabad.

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

Recommendations of the panel: -

Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** the renewal of Drug Manufacturing License and **regularization** of following sections of Amson Vaccines & Pharma (Pvt) Ltd., Plot No.154, Industrial Triangle, Kahuta Road, Islamabad.

i. Tablet Section (General)
ii. Capsule Section (General)
iii. Orals Liquid Section (General)
iv. Dry Powder Injection Section (Steroid)
v. Liquid Ampoule Injection (Vaccine)
vi. Liquid Vial Injection (Vaccine/Sera)
vii. Quality Control Laboratory
viii. Warehouse

Proceedings and Decision by the Central Licensing Board in 275th meeting:

The Board considered the case and decided to approve the regularization of following sections as per approved Lay Out Plan on the recommendation of the panel of expert.

1. Tablet Section (General)
2. Capsule Section (General)
3. Orals Liquid Section (General)
4. Dry Powder Injection Section (Steroid)
5. Liquid Ampoule Injection (Vaccine)
6. Liquid Vial Injection (Vaccine/Sera)

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