DIVISION OF DRUG LICENSING
DRUG REGULATORY AUTHORITY OF PAKISTAN
ISLAMABAD
****

MINUTES OF 242nd MEETING OF CENTRAL LICENSING BOARD HELD ON WEDNESDAY, 08th JULY, 2015.

242nd meeting of the Central Licensing Board (CLB) was held on Wednesday, 08th July, 2015 in the Office of Director Drug Licensing at 2nd Floor, Block-C, Pakistan Secretariat, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Dr. Zaka-ur-Rehman, Chief Drug Controller, Department of Health, Govt. of Punjab.	Member
2.	Mr. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh.	Member
3.	Mr. Afrasiyab Khan, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa.	Member
4.	Mr. Atta-ur-Rehman, Chief Drug Inspector, Department of Health, Govt. of Balochistan.	Member
5.	Prof. Dr. Gul Majeed Khan, Professor of Pharmacy	Member
6.	Prof. Dr. Muhammad Saeed, Professor of Pharmacy	Member
7.	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
8.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
9.	Mr. Khurram Shahzad Mughal, Consultant M/o Law, Justice and Human Rights, as representative of M/o Law, Justice and Human Rights, Islamabad.	Member
10.	Mr. Adnan Faisal Saim, DDC (QA) as representative of Division of Quality Assurance/Laboratory Testing	Member
11.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
12.	Mr. Tauqeer ul Haq and Mr. Saleem Iqbal as Representative of PPMA	Observer
13.	Mr. Nadeem Alamgir, as Representative of Pharma Bureau.	Observer

The Chairman CLB welcomed the honorable members of this Apex Forum & participants of the meeting. The meeting started with the recitation of verses from the Holy Quran.

The Chairman apprised the members of the Board that proceedings of CLB shall be conducted in an amicable and responsible way to deliver to the public and stake holders in a transparent and efficient manner. Quality shall be given priority and there shall be zero tolerance. He further added that all the legal and codal formalities regarding convening of the meeting have been fulfilled. Dr. Akbar Ali ADC (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

A. LICENSING DIVISION

Item-I **CONFIRMATION OF THE MINUTES OF 241st MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 241st meeting held on Friday, 15th May, 2015.

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

The Board considered the following cases of grant of new drug manufacturing licenses in the light of recommendations of respective panel of experts/inspectors and decided as under:

S No.	Name & Address of the firm	Date of Inspection / Type of License	Decision of CLB
1.	**M/s. Rakaposhi Pharmaceuticals (Pvt) Ltd, 97-E, Industrial Estate, Jamrud Road, Peshawar.**	**06-06-2015 (By way of Formulation)**	**Approved the re-grant of Drug Manufacturing License with same DML No. 000386 by way of Formulation with following seven sections:** **Sections (07)** 1. Tablet (General & Antibiotics) 2. Tablet (Psychotropic/ Narcotics) 3. Capsule (General/ Antibiotics) 4. Dry Powder Suspension (General & Antibiotics) 5. Capsule (cephalosporin) 6. Dry Powder Suspension (Cephalosporin) 7. Liquid (General)
2.	**M/s Jenner Pharmaceuticals (Pvt) Ltd, 28-KM Lahore Sharaqpur Road, District Sheikhupura.**	**19-05-2015 (By way of Formulation)**	**Approved the grant of DML by way of Formulation with following four sections:** **Sections (04)** 1. Tablet (General). 2. Capsule (General). 3. Dry Powder Suspension (General). 4. Sachet (General)
3.	**M/s Himedic Pharmaceuticals (Pvt) Ltd, 19-KM Link Multan Road, Lahore.**	**27-05-2015 (By way of Formulation)**	**Approved the grant of DML by way of Formulation with following three sections:** **Sections (03)** 1. Dry Powder for oral suspension (Cephalosporin) 2. Capsule (Cephalosporin) 3. Dry Powder for Injectable (Cephalosporin)

4	**M/s. Cortex Pharmaceuticals Plot No. 16-A, Street No. SS-4, National Industrial Zone RCCI Rawat, Rawalpindi.**	**30-06-2015 01-07-2015 (By way of Formulation)**	**The Board observed the following disclaimer which was part of panel inspection report and asked for its clarification:** **"Disclaimer**: - the assessment for strength of building does not fall under the ambit/mandate and scope of the inspection for which the firm has been advised to get certification from relevant building control authorities (BCA) as per prevailing laws and ensure proper emergency exits along with firefighting equipments in the premises". Prof. Dr. Gul Majeed Khan who was also member of inspection panel clarified that such disclaimer was not part of report it has been mentioned in error so needs to be ignored accordingly. **The Board after such clarification considered and approved the grant of DML by way of Formulation with following two sections:** **<u>Sections (02)</u>** 1. Liquid External Preparation (General) 2. Liquid Repacking (for drugs as per Schedule-D of the Drugs Act, 1976)

Item-III: <u>GRANT OF ADDITIONAL SECTIONS & EXPANSION/AMENDMENTS IN LOPs ETC.</u>

The Board considered following cases of Grant of Additional Sections & Expansion/Amendments in Layout Plans (LOP) etc of already licensed units in the light of recommendations by respective panel of experts/inspectors and decided as under: -

S #	Name of the Firm	Type of License	Decision of CLB
1.	**M/s Hamaz Pharmaceuticals (Pvt) Ltd, 13-KM, Bosan Road Lutfabad, Multan.**	**DML No. 000427 (Formulation)**	**The Board approved the grant of three additional sections as under:-** **<u>New Sections (03)</u>** 1. Liquid Injectable (Ampoule/Vial) (General and General Antibiotics) 2. Dry Powder Injectable (Cephalosporin) 3. Cream/Ointment/ Gel (General)

2.	**M/s Jawa Pharmaceuticals (Pvt) Ltd, 112/10, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.**	**DML No.000150 (Formulation)**	**The Board approved the grant of three additional sections as under:-** **Sections (03)** 1. Dry Powder Injectables (Cephalosporin) 2. Liquid Injectable (General Ampoules only) 3. External Preparations (General)
3.	**M/s Medicon Pharmaceutical Industry, 1/11-B, Industrial Estate, Hayatabad, Peshawar.**	**DML No.000215 (Formulation)**	**The Board approved the grant of one additional section as under:-** **Section (01)** 1. Tablet (Psychotropic)
4	**M/s OBS Pakistan Ltd, C-14, Manghupir Road, SITE, Karachi.**	**DML No.000012 (Formulation)**	**The Board approved the grant of one additional section as under:-** **Section (01)** 1. Sachet (Hormones) Soft Gel.
5	**M/s. Decent Pharma, Plot No.26 Street No. SS-3, National Industrial Estate, Rawat, Rawalpindi.**	**DML No.000766 (Formulation)**	**The Board approved the grant of three additional sections as under:-** **Sections (03)** 1. Powder (General) Veterinary 2. Liquid (General) Veterinary 3. Penicillin (Powder) Veterinary

Item-IV **GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSES.**

The Board considered the following cases of Grant of Renewal of Drug Manufacturing Licenses in the light of recommendations by panel of experts/inspectors subject to confirmation of deposition of CRF as admissible under the rules and decided as under: -

S No.	Name of the firm	Type of license	Decision of CLB
1.	**M/s. Lahore Pharma, 9-KM, Sheikhupura Road, Lahore.** **Renewal period:** 26-03-2011 to 25-03-2016	**DML No.000084 (Formulation)**	**Approved the Grant of Renewal of DML**
2.	**M/s. Ottoman Pharma, 10-KM, Raiwind Road, Lahore.** **Renewal period:** 05-08-2012 to 04-08-2017	**DML No.000502 (Formulation)**	**Approved the Grant of Renewal of DML**
3.	**M/s. Surgical Textile (Pvt) Ltd, 70 Km Multan Road, Near Patoki District Kasur.** **Renewal period:** 18-07-2015 to 17-07-2020	**DML No.000274 (Formulation)**	**Approved the Grant of Renewal of DML**

4.	**M/s. Medipak Ltd, 132-Industrial Estate, Kot Lakhpat , Lahore.** **Renewal period:** 25-07-2014 to 24-07-2019	**DML No.000257 (Formulation)**	**Approved the Grant of Renewal of DML for the following sections:** 1. Large Volume I.V. Infusion. 2. Tablet (General) 3. Capsule (General) 4. Irrigation Solution 5. Hemo Dialysis Solution 6. Eye drops (General) 7. Medical Devices (I.V. Sets only)
5.	**M/s. Amson Vaccine & Pharma (Pvt) Ltd, Plot No.154, Industrial Triangle Kahuta Road, Islamabad.** **Renewal period:** 20-06-2014 to 19-06-2019	**DML No.000393 (Formulation)**	**Approved the Grant of Renewal of DML.**
6.	**M/s. Ferozsons Laboratories Limited, Amangarh, Nowshera.** **Renewal period:** 02-05-2015 to 01-05-2020	**DML No.000038 (Formulation)**	**Approved the Grant of Renewal of DML.**
7.	**M/s. Lowitt Pharma (Pvt) Ltd, Plot No.24, Industrial Estate, Hayatabad, Peshawar.** **Renewal period:** 12-05-2015 to 11-05-2020	**DML No.000568 (Formulation)**	**Approved the Grant of Renewal of DML.** The Board observed that Dr. Khalid Khan Director DTL Peshawar was taken in panel inspection and signed the report also; whereas he was not member of the inspection panel. The Board took serious notice of such practices and directed to ask from area FID for its clarification.
8.	**M/s. Obsons Pharmaceuticals, 209-S, Industrial Estate, Kot Lakhpat, Lahore.** **Renewal period:** 06-08-2010 to 05-08-2015	**DML No.000416 (Formulation)**	**Deferred the renewal of DML for want of following information from panel:** 1. Rating of the firm with regard to inspection as same is not mentioned. 2- Deficient area/plot of the firm as same is not mentioned. 3- Compliance of GMP with regard to renewal of DML.

ITEM NO. V MISCELLANEOUS CASES.

Case No.1 CHANGE OF THE MANAGEMENT OF M/S UDL PHARMACEUTICALS (A DIVISION OF FIRST UDL MODARBA), E-44-45, NORTH WESTERIN INDUSTRIAL ZONE, PORT QASIM AUTHORITY, KARACHI, DML NO.000693 (FORMULATION).

The case was placed before the Board as under:

M/s. UDL Pharmaceuticals (a Division of first UDL Modarba), E-44-45 North Western Industrial Zone, Port Qasim Authority, Karachi, DML No.000693 (Formulation) has applied for change of management.

The management of the firm has been changed partially due to the unfortunate death of their Director / Chief Executive Officer **Mr. A W Rahi,** who passed away after a brief illness. The management of the firm has been partially changed as per Form 29 issued by Security Exchange Commission of Pakistan where this company is registered under:-

Pervious Management as per Form 29 issued on 12-01-2012	**Current Management as per Form 29 issued on 12-01-2015**
1. A W Rahi S/O Allah Dino Khan **CNIC:** 32301-1962382-9 Chief Executive & Director – **Retired/Died** 2. Rashid Abdullah S/O Abdullah Razzak **CNIC:** 42201-1132967-1 Director of the firm - **Retired** 3. Asad Abdullah S/O Shahid Abdullah **CNIC:** 42201-8964822-9 **(Share Holder)** Director of the firm 4. Syed Nasir Raza Rizvi S/O Syed Farzand Raza Rizvi **CNIC:** 42101-1739755-1 Director of the firm 5. Shuja Malik S/O Khalid Malik **CNIC:** 42301-1600531-9 Director of the firm 6. Muhammad Khubaib S/O Ghulam Nabi **CNIC:** 42301-5462662-3 Director of the firm **(Share Holder)**	1. Ather Naqvi S/O Muhammed Din **CNIC:** 42000-4488387-3 Chief Executive & Director – **Appointed-New** 2. Shuja Malik S/O Khalid Malik **CNIC:** 42301-1600531-9 Director of the firm – **Re-elected** 3. Syed Nasir Raza Rizvi S/O Syed Farzand Raza Rizvi **CNIC:** 42101-1739755-1 Director of the firm – **Re-elected** 4. Majid Hasan S/O Mahmood Hasan **CNIC:** 42201-0172348-5 Director of the firm - **New** 5. Abdul Rahim Suriya S/O Muhammed Siddiq **CNIC :** 42201-0757537-5 Director of the firm - **New**

The firm has submitted following information / documents along with the application of change in management.

S.No	Documents received
1.	A prescribed fee of Rs.50,000/-
2.	Extracts from the resolution of the Board of Directors
3.	Copy of Form-29 issued by SEC on 06-11-2014
4.	CNIC photocopies of all directors

Decision of CLB

Keeping in view the facts on ground, the Board considered and approved the change of management of the firm from old management to new management as under:

Old Management (as per Form-29)	New Management (as per Form-29)
1. A W Rahi S/O Allah Dino Khan **CNIC:** 32301-1962382-9 Chief Executive & Director – 2. Rashid Abdullah S/O Abdullah Razzak **CNIC:** 42201-1132967-1 Director of the firm - 3. Asad Abdullah S/O Shahid Abdullah **CNIC:** 42201-8964822-9 Director of the firm 4. Syed Nasir Raza Rizvi S/O Syed Farzand Raza Rizvi **CNIC:** 42101-1739755-1 Director of the firm 5. Shuja Malik S/O Khalid Malik **CNIC:** 42301-1600531-9 Director of the firm 6. Muhammad Khubaib S/O Ghulam Nabi **CNIC:** 42301-5462662-3 Director of the firm	1. Ather Naqvi S/O Muhammed Din **CNIC:** 42000-4488387-3 Chief Executive & Director – 2. Shuja Malik S/O Khalid Malik **CNIC:** 42301-1600531-9 Director of the firm – 3. Syed Nasir Raza Rizvi S/O Syed Farzand Raza Rizvi **CNIC:** 42101-1739755-1 Director of the firm – 4. Majid Hasan S/O Mahmood Hasan **CNIC:** 42201-0172348-5 Director of the firm - 5. Abdul Rahim Suriya S/O Muhammed Siddiq **CNIC :** 42201-0757537-5 Director of the firm -

Case No.2 **CHANGE OF THE MANAGEMENT OF M/S HARRISON PHARMACEUTICALS, 10-KM, LAHORE ROAD SARGODHA, DML NO.000634 (FORMULATION).**

The case was placed before the Board as under:

M/s Harrison Pharmaceuticals, 10-km, Lahore Road Sargodha, DML No.000634 (Formulation) has applied for change of management as under;-

Pervious Management	Current Management
1. Mr. Tahir Munir S./o Ch. Muhammad Munir Akbar. 2. Malik Saeed Akhtar S/o Malik Fazal ur Rehman.	1. Mr. Abdul Ghafir S/O Abdul Qayyum **CNIC:** 35202-5304270-1 2. Mr. Irfan Gulzar Anjum S/O Gulzar Muhammad **CNIC:** 38403-2956767-5 3. Mr. Muhammad Irshad Uppal S/O Muhammad Nawab ud Din Uppal **CNIC:** 35200-7366578-3 4. Mr. Usman Ali S/O Muhammad Gulazr Khan **CNIC:** 35202-2193693-3 5. Mr. Sajjad Hussain S/O Muhammad Gulzar Khan **CNIC :** 35202-7516210-1 6. Dr. Muhammad Saleem S/O Muhammad Siddiqui **CNIC :** 37405-0355334-1. 7. Dr. Muhammad Zubair Faisal S/O Muhammad Hafeez **CNIC :** 35202-6439427-3 8. Mr. Rashid Iqbal S/O Muhammad Iqbal **CNIC :** 35202-3203509-1

The firm has submitted following information / documents along with the application of change in management.

S.No	Documents received
1.	A prescribed fee of Rs.50,000/-
2.	Certificate of registration with registrar of firm
3.	Partnership deed of the new partners.
4.	CNIC photocopies of all directors
5.	Sale deed

Decision of CLB

Keeping in view the facts on ground, the Board considered and approved the change of management of the firm from old management to new management as under:

Old Management (as per Form-29)	New Management (as per Form-29)
1. Mr. Tahir Munir S./o Ch. Muhammad Munir Akbar. 2. Malik Saeed Akhtar S/o Malik Fazal ur Rehman.	1. Mr. Abdul Ghafir S/O Abdul Qayyum **CNIC:** 35202-5304270-1 2. Mr. Irfan Gulzar Anjum S/O Gulzar Muhammad **CNIC:** 38403-2956767-5 3. Mr. Muhammad Irshad Uppal S/O Muhammad Nawab ud Din Uppal **CNIC:** 35200-7366578-3 4. Mr. Usman Ali S/O Muhammad Gulazr Khan **CNIC:** 35202-2193693-3 5. Mr. Sajjad Hussain S/O Muhammad Gulzar Khan **CNIC :** 35202-7516210-1 6. Dr. Muhammad Saleem S/O Muhammad Siddiqui **CNIC :** 37405-0355334-1. 7. Dr. Muhammad Zubair Faisal S/O Muhammad Hafeez **CNIC :** 35202-6439427-3 8. Mr. Rashid Iqbal S/O Muhammad Iqbal **CNIC :** 35202-3203509-1

Case No.3 **CHANGE OF THE MANAGEMENT OF M/S PERFECT PHARMA (PVT) LTD, 5-KM, MANGA ROAD, RAIWIND LAHORE. DML NO.000469 (FORMULATION).**

The case was placed before the Board as under:

M/s Perfect Pharma (Pvt) Ltd, 5-kM, Manga Road, Raiwind Lahore, DML No.000469 (Formulation) has applied for change of management as under;-

Pervious Management As per From-29	Current Management As per From-29
Mr. Abdul Razzaq Khan, Chief Executive & Director. Rubana Razzaq, Director. .	Mr. Aijaz Ahmed, Chief Executive & Director. Mr. Asad Aijaz Malik, Director. Mr. Azhar Aijaz, Secretary.

The firm has submitted following information / documents along with the application of change in management.

S.No	A fee of Rs.50,000/-.
1.	Agreement of sale and transfer of shares.
2.	Transfer deeds.
3.	Form 29, duly attested From SECP.
4.	NOC from previous owners.
5.	Copy of CRF NOC.
6.	A fee of Rs.50,000/-.
7.	Copies of CNIC's

Decision of CLB

Keeping in view the facts on ground, the Board considered and approved the change of management of the firm from old management to new management as under:

Old Management (as per Form-29)	New Management (as per Form-29)
1. Mr. Abdul Razzaq Khan, Chief Executive & Director. 2. Rubana Razzaq, Director. .	1. Mr. Aijaz Ahmed, Chief Executive & Director. 2. Mr. Asad Aijaz Malik, Director. 3. Mr. Azhar Aijaz, Secretary.

CASE NO. 4. **M/S CIBA PHARMACEUTICALS (PRIVATE) LIMITED A-371, SITE, NOORIABAD, MAIN SUPER HIGHWAY, KARACHI.**

The case was placed before the Board as under:

Brief History

The case of M/s Ciba Pharmaceuticals (Pvt) Ltd for grant of Drug Manufacturing License was presented in 240th meeting of Central Licensing Board and Board decided as under: -

"Approved the grant of DML subject to change of name of firm with following six sections:
Sections (06):

1. ***Tablet (General)***
2. ***Capsule (General)***
3. ***Oral Dry Powder Suspension (General)***
4. ***Sachet Section (General)***
5. ***Cream / Ointment/ Gel (General)***
6. ***Cream / Ointment / Gel (Steroidal)***

- ***The firm shall be asked to change its name as it resembles with some existing international pharmaceutical companies.***
- ***The Board authorized the Chairman to dispose-off the case accordingly.***
- ***The Board did not approve ear / eye drops as same was not ready".***

Accordingly, decision of Board was conveyed to the firm, and firm replied on 13th April, 2015 with undertaking as under: -

"We M/s Ciba Pharmaceuticals (Private) Limited A-371, SITE, Nooriabad, main Super Highway, Karachi, give undertaking to DRAP that if any objection will be raised internationally regarding the name of M/s Ciba Pharmaceutical (Pvt) Ltd, such as under company is operating / manufacturing internationally under the name of M/s Ciba Pharmaceutical (Pvt) Ltd and if such information is received to us from DRAP with enough worthy evidence then we will be ready to act upon DRAP's directions".

After that a letter was also issued to Securities and Exchange Commission of Pakistan for confirmation whether name "M/s Ciba Pharmaceuticals (Pvt) Ltd, Karachi resembles with other registered company or otherwise.

In reply of Securities and Exchange Commission of Pakistan has stated that "No other company with names M/s Ciba Pharmaceuticals (Pvt) Ltd is registered with this office".

The case was submitted for solicited orders of Board for issuance of Drug Manufacturing of License.

Decision of CLB

The Board after thorough deliberation decided ***not to approve*** *the nomenclature in the name & style of* ***M/s Ciba Pharmaceuticals (Private) Limited*** *as there is very possible likelihood that the common citizens will be deceived by this name as it belonged to a very reputable company in the Pharmaceutical Industry i.e. Ciba-Giegy which had a long history of marketing their pharmaceutical products in Pakistan.*

Therefore allowing such name which is in resemblance with the well reputed company doing business in Pakistan in past, will mislead and confuse people of Pakistan who might think the revival of the company which is in fact no more in the Pakistan.

The Board further advised to the company to choose a name which shall not resemble with any other existing Pharma company or Pharma traders or existing in past and to also ensure that the name selected for their company should portray true inculcate of their business and have difference with any other name on the register.

Decision of 241st meeting of Central Licensing Board was conveyed to the firm on 25th June, 2015 accordingly.

Current Situation.

Firm has submitted their reply in response to above letter on 26-06-2015 and requested to issue the Drug Manufacturing License on the following grounds; -

In this respect you have also confirmed from the Securities & Exchange Commission of Pakistan (SECP) and SECP has replied you that there is no other company registered with this name of Ciba Pharmaceuticals (Pvt) Ltd except us. Therefore, legally you are bond to issue us Drug Manufacturing license in the name of Ciba Pharmaceuticals (Pvt) Ltd as per Cooperate Law of Pakistan.

As far as Common citizens are concerned they purchase medicine / drugs by the as brand name, our name is concern your observation belongs that it is very resemble with CIBA GIEGY which is not true because we are not using name of CIBA-GAEGY.

As per your record the DRAP/Ex-MOH has issued so many licenses to very resemble name companies for example such as: -

i) Schazoo Pharmaceutical Laboratories (Pvt) Ltd, DML No.000019 and Schazoo Zaka (Pvt) Ltd, DML No.000636. their Directors and Management of both the companies are differ from each other.

ii) The Searle Company Limited DML No.000647 and Searle IV Solution (Pvt) Ltd, DML No. 000585, their Directors and management of both the companies are differ from each other.

iii) The Mission Pharmacal (USA) has registered their product in Pakistan by DRAP/Ex-MOH, but DRAP has issued DML No.000809 to Mission Pharmaceutical Laboratories (Pvt) Ltd SITE Highway, Karachi. Without obtaining NOC from Mission Pharmacal USA. Mission Pharmaceutical Laboratories (Pvt) Ltd, SITE, Highway director was importing drugs same from Mission Pharmacal USA.

iv) Ex-MOH (DRAP) has registered product of Schering Plough (Pakistan) Pvt Ltd and on other hand imported product of Bayer Scharing (Pakistan) Pvt Ltd was also registered by Ex-MOH (DRAP) both the company name are resemble very much but Ex-MOH (DRAP) as given registration of drugs to both the companies.

v) One of well know company of Pakistan that is Qurshi International (Pvt) Ltd Lahore was operating in Pakistan but on the other hand Aftab Qurshi Dawakhana (Pvt) Ltd, also working in the same field of Qurshi Dawakhan. and Qurshi has no objection on the Aftab Qurshi name as it was listed at FBR list as per cooperate law of Pakistan.

vi) There were so many examples of registered drugs which resemble with the name of many Multinational Companies but the same name was registered in the name of local companies of Pakistan by Ex MoH (DRAP)

vii) Similarly DRAP issued DML No.000811 to ICI Pakistan Limited Life Sciences Whereas ICI Pakistan Ltd Life Sciences name was not exist in list of SECP, even ICI Pakistan Limited Life Science Not submitted their NTN number to the DRAP. Hence this name is very resemble with ICI Pakistan Ltd.

viii) We draw your kind attention to words the mater that we Ciba Pharmaceuticals (Pvt) Ltd are submitting our income tax return and other relative documents to FBR and SECP since the last Nine years and no objection raised by any authority / companies up till to date.

ix) You good office issued license to above said resemble name companies but here we feel that on our name objection are making un-necessary as registration of company name is preview of SEC not DRAP. In Pakistan and internationally Ciba Pharmaceuticals (Pvt) Ltd / CIBA GIEGY don't involve in Pharmaceutical manufacturing and pharmaceutical marketing process till today.

We humbly request your honor to issue us DML within 15 days as we are bearing irreparable monetary loss which is already late. Further we solicit you kindly let us know in writing if you need any documents or there is any other objection, or else we will refer this matter to our legal counsel for legal recourse which we would not like to.

Proceedings:

The members were apprised about the complete background of the case. The Board was also apprised about the reply of firm in which firm has justified for its name resemblance matter with the support of resembling names of already existing firms. The Law Expert (Member CLB) opined that the justification of firm is satisfactory with regard to name of the firm and all members also agreed upon the same.

Decision of CLB

Keeping in view the proceedings and facts on ground, the Board after through deliberations considered the matter and decided:

- **That the firm shall be issued Drug Manufacturing License with the name of M/s Ciba Pharmaceuticals (Private) Limited A-371, SITE, Nooriabad, Main Super Highway, Karachi (already approved in 240th meeting of CLB) with the condition that Ciba name shall not be misused in any way.**

Item VII **Regularizations of Layout Plan of M/s Medipak Ltd, Lahore.**

The case was placed before the Board as under:

M/s Medipak Ltd, 132 Industrial Estate, Kot Lakhpat, Lahore DML No. 000257 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections which were being licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

S.#	Sections
1.	Large Volume I.V. Infusion.
2.	Tablet and Capsule Section (General)
3.	Irrigation Solution.
4.	Hamo Dialysis Solution.
5.	Eye drops (General)
6.	Medical Devices (I.V. Sets only)

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

1. Dr. Ikram ul Haq, Member CLB.
2. Dr. Zaka ur Rehman, Chief Drug Controller, Punjab.
3. Abdul Rashid Shaikh, FID, DRAP, Lahore.
4. Ajmal Sohail Asif, FID, DRAP, Lahore.
5. Rana Ahsan ul Haq Athar, ADC, DRAP, Lahore.

Accordingly, panel has inspected the premises and verified all the above mentioned sections.

Recommendations of the Panel

In the light of above, the panel experts is of the opinion to recommend the Regularization of master layout plan and renewal of Drug Manufacturing License No. 000257 by way of Formulation in favour of M/s Medipak Ltd, 132-Industrial Estate, Kot Lakhpat, Lahore for the above sections.

Decision of CLB

The Board after discussion / deliberations has approved the regularization/ authentication of existing sections of M/s Medipak Ltd, 132 Industrial Estate, Kot Lakhpat, Lahore DML No. 000257 (Formulation) according to approved layout plan as under:-

S.#	Sections
1.	**Large Volume I.V. Infusion**
2.	**Tablet (General)**
3.	**Capsule (General)**
4.	**Irrigation Solution**
5.	**Hemo Dialysis Solution**
6.	**Eye drops (General)**
7.	**Medical Devices (I.V. Sets only)**

Item VIII **APPROVAL OF DRAFT MINUTES THROUGH EMAIL FROM MEMBERS OF CENTRAL LICENSING BOARD.**

The case was placed before the Board as under:

The Central Licensing Board in its 241st meeting held on 15th May, 2015 had considered and approved the subject item as under: -

It is submitted as per practice in vogue the minutes of CLB meeting are approved as per following procedure: -

- Preparation of draft minutes by Secretary CLB.
- Approval of draft minutes by Chairman CLB.
- Circulation of draft minutes to all members via email for their perusal / approval.
- Preparation and approval of fair minutes for signature of all members on hard copy.
- Circulation of fair minutes to concerned quarters for implementation.

Since, above procedure usually takes two-three weeks, so to minimize the said procedure, it is proposed that draft minutes be approved within three days and in case of no reply within 3 days, the draft minutes shall be deemed to have been approved.

Decision of CLB taken in 241st meeting :

The Board unanimously approved the proposal with the advice that agenda of the meeting shall be sent to the members of the Board at least three days before the date of the meeting of the Board.

Now case has been placed again for consideration of Board for following proposals:-

i) That the minutes of each and every meeting may be released for implementation / action after signature of 50% of members on hard copy and rest of members may sign on their availability. This will facilitate quick action on released minutes.

ii) That the decisions of CLB related to Division of Quality Assurance and Laboratory Testing may be issued by concerned officers mentioning their name and designation instead of just signing FOR SECRETARY CENTRAL LICENSING BOARD.

Decision of CLB

The Board approved the proposal as under:

- **The minutes can be released for implementation/action after signature of 50 percent members (out of the total attendance) on hard copy of the minutes.**
- **The officers of Division of Quality Assurance and Laboratory Testing while signing any correspondence on behalf of Secretary Central Licensing Board shall write their name and designation accordingly.**

= = = = =End of Licensing Division = = = = =

AGENDA/WORKING PAPER FOR 242nd MEETING OF THE CENTRAL LICENSING BOARD

Quality Assurance Cases (GMP)

INDEX

242nd MEETING FOR CENTRAL LICENSING BOARD (GMP CASES)

Case No. 1:- **M/S ORTA LABORATORIES (PVT) LTD, LAHORE**

Background of the case:

The inspection of subject company was conducted on 09.04.2014 by Mr. Asim Rauf, FID Lahore with reference to routine inspection your company. The FID has pointed out number of shortcomings in all sections including the following:-

1. The corridor leading to the quarantine area was very dirty/dusty, the mosquitoes and webs were seen.
2. Different types of stocks were lying on the floor without proper storage conditions.
3. Water for injection, toll manufactured were lying on the floor. The corridor was found being used for personal/workers moment from warehouse area to outside.
4. Empty vials of 10ml for dry powder injectable filling were lying in the corridor.
5. Mopping material liquid containers along with broom and mopping cloth was also lying in the corridor.
6. Quarantine area was flooded with different kinds of stocks without label. Ortaxime (Ceftoxime Sodium) 500 mg was without any label and status.
7. The sanitation level was poor.
8. The rejected material store was full of stocks & was not accessible.
9. The rejected stock was also found mixed in quarantine area.
10. The storage practices were poorly observed in packing material store.
11. The stock was lying in unorganized manner with poor sanitation conditions.
12. The aluminum foils was found mixed with raw material stores with poor temperature maintenance.
13. The overall condition of atmosphere and sanitation was found poor in packing material store.
14. The dispensing area was un-cleaned, filled with dust/powder files were placed in dispensing room.
15. The controlled area was without any air conditioner and atmospheric control.

16. The dry powder injectable area had been closed for renovation/upgradation by you.
17. No working was observed in injectable area and the dry powder injection was closed for renovation/ upgradation (permission o competent authority was required before renovation & closure of production).
18. Liquid injectable in the resting face was not impressive at all.
19. Re-fixation & recalibration/validation of the whole HVAC system, areas was directed with submission of report.
20. The epoxy needed to be re-done in the filling room.
21. The manometers in the filling room were not properly indicating the pressure differential.
22. The paint near sterilizer, filling area, washing area was needed to re-done as some patches were found worn off.
23. Stability chamber was out of order. FTIR was still not provided.
24. The retaining samples were found stocked in the wet chemistry laboratory which should be moved out and should a dedicated area for this purpose.
25. The reporting officer recommended immediate improvements and to keep halt the operations.

Action Taken by DRAP: - A show cause notice was issued to the firm on 03.07.2014 along with the direction to suspend their production activities till rectification of observations.
Reply of the firm: - Firm failed to submit any compliance report till to date.

The case is placed before the CLB for consideration please and the firm has been called for personnel hearing before the CLB.

Item No. II (Any other case with permission to the Chair)

Misc agenda Item No. II

As the Post of Director QA/LT post is lying vacant and Division of QA/LT in order to facilitate timely disposal of routine/day to day business of Central Licensing Board relating to contravention of various provisions of the Drugs Act, 1976 and DRAP Act, 2012, the QA/LT Division requires the following delegation of powers/functions to Chairman, QC on stop gap arrangement with immediate effect under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

DELEGATION OF FUNCTION

Sr #	Powers	Current Position Delegated in 237th Meeting of CLB	Revised Powers
1.	Suspensions of Production (in case of GMP and Quality Control matters)	Director Quality Assurance and Laboratory Testing	Chairman, Quality Control
2.	Resumption of Production (subject to re-inspection and recommendation of a panel comprising of atleast 03 members)	Director Quality Assurance and Laboratory Testing	Chairman, Quality Control
3.	Permission to Lodge FIR	Director Quality Assurance and Laboratory Testing	DDG (E&M) of field offices of DRAP and / or Chairman, QC
4.	Panel Constitution (GMP Inspections and related issues etc)	Director Quality Assurance and Laboratory Testing	Chairman, Quality Control
5.	Constitution / amendments in constitution of panel for inspection for GMP compliance and quality control matters.	Director Quality Assurance and Laboratory Testing	Chairman, Quality Control
6.	To continue the period of "not to dispose off stocks orders passed by FID" for three months.	Director Quality Assurance and Laboratory Testing	Chairman, Quality Control
7.	To continue custody of the seized stocks by the FID till decision of the case.	Director Quality Assurance and Laboratory Testing	Chairman, Quality Control
8.	To grant approval for sending Board's portion of drug samples to the Appellate Laboratory	Director Quality Assurance and Laboratory Testing	Chairman, Quality Control
9.	Grant of extension in the time of testing to Federal Government Analyst.	Director Quality Assurance and Laboratory Testing	Chairman, Quality Control

Decision of CLB

Mr. Adnan Faisal Saim, DDC (QA) attended the meeting as representative of Division of Quality Assurance/Laboratory Testing. He said that he would also present the agenda of QA cases but Board did not consider the agenda as it was not received / available in the office of Chairman CLB or Secretary CLB duly approved by Director/CQC QA/LT Division on the day and time of meeting. The Board further discouraged such careless attitude of QA/LT Division.

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