

**MINUTES OF 248th MEETING OF CENTRAL LICENSING BOARD
HELD ON WEDNESDAY 13th JULY, 2016**

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248th meeting of the Central Licensing Board (CLB) was held on Wednesday 13th July, 2016 in the Division of Drug Licensing, Drug Regulatory Authority of Pakistan, 3rd Floor, TF Complex, G-9/4, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad. (Dr. Abdul Rasheed, CQC attended as representative of QA/LT Division)	Member
2.	Dr. Zaka-ur-Rehman, Chief Drug Controller, Department of Health, Govt. of Punjab.	Member
3.	Mr. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh.	Member
4.	Mr. Akbar Jan, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa.	Member
5.	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
6.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
7.	Prof. Dr. Muhammad Saeed, Professor of Pharmacy	Member
8.	Mr. Khurram Shahzad Mughal, Consultant M/o Law, Justice and Human Rights, as representative of M/o Law, Justice and Human Rights, Islamabad.	Member
9.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
10.	Mr. Khalid Munir, Chief Executive, Trigon Pharmaceuticals (Pvt) Ltd., as Representative of PPMA	Observer
11.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
12.	Mr. Kamran Anwar, Secretary General PCDA , representative of PCDA	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. Mr. Zeeshan Nazir Bajar DDC (QA), Mr. Adnan Faisal Saim DDC (QC) & Dr. Akbar Ali ADC (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

LICENSING DIVISION

Item-I CONFIRMATION OF THE MINUTES OF 246th MEETING

The Central Licensing Board (CLB) formally confirmed the minutes of its 247th meeting held on 29th April, 2016.

Item-II: GRANT OF NEW DRUG MANUFACTURING LICENSES.

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

S#	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s Hudson Pharma (Pvt) F-93, North Western Industrial Zone Port Qasim Authority, Karachi.	02-05-2016 Formulation	The Board approved the grant of DML by way of formulation with following one section: <u>Sections (01)</u> 1. Plastic Ampoules (BFS Technology)
2.	M/s Simaxx Chemical, Plot No. 188-A, Industrial Eastate, Hayatabad, Peshawar.	28-05-2016 Repacking	The Board approved the grant of DML by way of repacking with following two sections: <u>Sections (02)</u> 1. Liquid (Re-Packing) 2. Powder (Re-Packing)
3.	M/s Demont Research Laboratories (Pvt) Ltd, 20-Km, Sharikpur Road Sheikhupura.	25-05-2016 Formulation	The Board approved the grant of DML by way of formulation with following four sections: <u>Sections (04)</u> 1. Tablet Section (General) 2. Capsule Section (General) 3. Dry Suspension (General) 4. Sachet Section (General)
4.	M/s Genetics Pharmaceuticals (Pvt.) LTD. Plot No. 539-A Sunder Industrial Estate, Lahore.	15-06-2016 Formulation	The Board approved the grant of DML by way of formulation with following two sections: <u>Sections (02)</u> 1. Tablet(General) 2. Capsule (General)

Item-III: GRANT OF ADDITIONAL SECTIONS/EXPANSION/AMENDMENTS IN LOPs ETC.

The Board considered following cases of Grant of Additional Sections & Expansion/Amendments in Layout Plans (LOPs) 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 / DML No.	Date of Inspection	Decision of CLB
1.	M/s Bosch Pharmaceutical (Pvt) Ltd, Plot No. 209, Sector 23, Korangi Industrial Area Karachi. DML No. 000707 (Formulation)	19-05-2016	The Board approved the grant of amendment / expansion in already existing section as under:- <u>Section (01)</u> 1. Sterile Injectable Ampoule (General) (Amended)
2.	M/s Alen Pharmaceuticals (Pvt) Ltd, 138-Nowshera Industrial Estate, Raislpur DML No. 000435 (Formulation)	06-06-2016	The Board approved the grant of two additional sections as under:- <u>Sections (02):</u> 1. Capsule (Cephalosporin) 2. Dry Powder Suspension (Cephalosporin)
3.	M/s Le-Mendoza Pharmaceutical (Pvt) Ltd, Plot No. 7, Sector 23, Korangi Industrial Area Karachi. DML No. 000140 (Formulation)	31-08-2015	The Board approved the grant of amendments in layout plan / expansion in the area Quality Control Laboratory and quality Assurance.
4.	M/s Linear Pharma. Plot No. 18, Street No. S-4 National Industrial Zone. RCCI, Rawat DML No. 000670 (Formulation)	01-05-2016	The Board approved the grant of two additional sections as under:- <u>Sections (02)</u> 1. Liquid Ampoule Injectable (General) 2. Liquid Vial Injectable (General)
5.	M/s Synchro Pharmaceuticals, 77-Quai-e-Azam Industrial Estae, Kot Lakhpat, Lahore DML No.000575 (Formulation)	29-03-2016	The Board approved the grant of four additional sections as under:- <u>Sections (04)</u> 1. Liquid Injectable Ampoule (Psychotropic) 2. Liquid Vial Injectable (Dental Cartridge) 3. Liquid Ampoule Injectable (General / General Antibiotic) 4. Liquid Vials Injectable (General /General Antibiotic)

6.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km ,Shiekhupura, Road, Faisalabad. DML. No. 000616 (Formulation).	28-06-2016	The Board approved the grant of two additional sections as under:- <u>Sections (02)</u> 1. Cream/Ointment/Gel/Lotion (General/Non-Steroidal). 2. Cream/Ointment/Gel/Lotion (Steroidal).
7.	M/s Harrison Pharmaceuticals, 10 Km Lahore Road, Sargodha. DML. No. 000634 (Formulation).	31-03-2016	The Board approved the grant of three additional sections as under:- <u>Sections (03)</u> 1. Liquid Syrup(General) 2. Capsule (General) 3. Dry Powder Suspension (General)
8.	M/s PDH Laboratories (Pvt) Ltd, 9.5-KM Sheikhupura Road, Lahore. DML. No. 000039 (Formulation).	17-05-2016 & 13-06-2016	The Board approved the grant of one additional section as under:- <u>Section (01)</u> 1. Dry Powder Injection (Penicillin)
9.	M/s Moreno Iglisias Research Laboratories (Pvt) Ltd., Lahore.	17-06-2016	The Board approved the grant of two additional sections as under:- <u>Sections (02)</u> 1. Veterinary Dry Powder (General). 2. Veterinary Dry Powder (General Antibiotic).

Item-IV: GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE.

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	Date of Inspection	Decision of CLB
1.	M/s Bosch Pharmaceutical (Pvt) Ltd, Plot No. 209, Sector 23, Korangi Industrial Area Karachi. DML No. 000707 (Formulation)	19-05-2016	The Board approved the renewal of DML for following sections as per recommendations of panel: <u>Sections (06)</u> <ol style="list-style-type: none">1. Sterile Ophthalmic / Ear Drops and Nebulizer.2. Sterile Infusion (General)3. Sterile injection Ampoules (general)4. Cream / Ointment / Lotion5. Penicillin Injection6. Dry Powder Vial Injectable (Cephalosporin)
2.	M/s Highnoon Laboratories Limited, 17.5-Km Multan Road Lahore DML No. 000155 (Formulation)	24-03-2016	The Board approved the renewal of DML for following sections as per recommendations of panel: <u>Section (08)</u> <ol style="list-style-type: none">1. Tablet (General)2. Capsule (General)3. Sachet Dry Powder4. Dry Powder Suspension (General)5. Topical Cream / Ointment (General)6. Oral Liquid (General)7. Tablet (Hormone)8. Capsule (Hormone)
3.	M/s Merck (Pvt) Ltd, 7-Jail Road, Quetta. DML No. 000028 (Formulation)	13-05-2016 & 14-05-2016	The Board approved the renewal of DML for following sections as per recommendations of panel: <u>Sections (07)</u> <ol style="list-style-type: none">1. Tablet (General)2. Capsule (General)3. Dry Powder Syrup (General)4. Sachet (General)5. Liquid Syrup (General)6. Cream / Ointment Semi-Solids (General)7. Sterile Liquid Injection (General) <p>Board approved the amendments in layout plan for better level of GMP compliance.</p> <p>Board further allowed the resumption of production activities in sterile liquid injection section which was voluntarily halted by the firm for the up-gradation and revamping of the area.</p>

4.	M/s. Linear Pharma. Plot No. 18, Street No. S-4 National Industrial Zone. RCCI, Rawat DML No. 000670 (Formulation)	01-05-2016	The Board approved the renewal of DML for following sections as per recommendations of panel: <u>Sections (05)</u> 1. Tablet Section (General) 2. Capsule Section (General) 3. Dry Powder for Suspension (Cephalosporin) 4. Sterile Dry Powder for Injectable (Cephalosporin) 5. Capsule (Cephalosporin)
5.	M/s. Servier Research & Pharmaceuticals (Pakistan) (Pvt) Ltd, 9-Km Sheikhpura Road, Lahore. DML No. 000155 (Formulation)	05-05-2016	The Board approved the renewal of DML for following section as per recommendations of panel: <u>Section (01)</u> 1. Tablet (General) Section
6.	M/s. Karim Industries, ½-Km Lahore, Raiwind Road, Lahore DML No.000254 (Formulation)	14-04-2016	The Board approved the renewal of DML for following sections as per recommendations of panel: <u>Sections (05)</u> 1. Bandage open wove (Cotton Bandage BPC) Section. 2. Absorbent Cotton Wool. 3. Absorbent Guaze Roll BPC 4. Cotton Crepe Bandage (Medi Crepe Bandage 0BPC) 5. Surgical Gauze Swab BPC (Soft Gauze)
7.	M/s Shifa Laboratories (Pvt) Ltd, 39- industrial Estate, Gulberg III, Lahore. DML No.000473 (Formulation)	01-03-2016 & 04-05-2016	The Board approved the renewal of DML for following two sections as per recommendations of panel. <u>Sections (02)</u> 1. Oral Liquid Section (General) 2. Ear Drop Section. The Board deferred the renewal of Tablet (General) section due to following observations of panel: - <ul style="list-style-type: none"> The section was not properly maintained. HVAC was not provided in some rooms like drying room, some compression cubicles and coating room. Doors were wooden. False ceiling in compression cubicles was not proper and smooth. Flooring was epoxy coated but it was not smooth. Panel was of the opinion that this section was not suitable for manufacturing of tablets at the time of inspection.

			<p>The Board further directed the firm not to conduct the manufacturing operations till up-gradation, re-inspection and approval of renewal of above section by Central Licensing Board.</p> <p>Board also directed to ask the firm for confirmation of sections under operation and closed by the firm.</p>
8.	<p>M/s. SB Pharma, 5-E, Industrial Triangle, Kahuta Road, Islamabad</p> <p>DML No.426 (Formulation)</p>	24-05-2016	<p>The Board approved the renewal of DML for following sections as per recommendations of panel.</p> <p><u>Sections (02)</u></p> <ol style="list-style-type: none"> 1. Oral Liquid Section (General) 2. Ear Drop Section
9.	<p>M/s. Synchro Pharmaceuticals, 77- Quai-e-Azam Industrial Estate, Kot Lakhpat, Lahore.</p> <p>DML No. 575 (Formulation)</p>	29-03-2016	<p>The Board approved the renewal of DML for following sections as per recommendations of panel.</p> <p><u>Sections (07)</u></p> <ol style="list-style-type: none"> 1. Tablet (General). 2. Capsule (General). 3. Dry Powder for Suspension (General) 4. Oral Liquid General 5. Capsule Cephalosporin 6. Dry Powder for suspension Cephalosporin 7. Dry Powder for Injectable Cephalosporin
10.	<p>M/s CCL Pharmaceuticals (Pvt). Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.</p> <p>DML No.00052 (Formulation)</p>	21-03-2016	<p>The Board approved the renewal of DML for following sections as per recommendations of panel.</p> <p><u>Sections (10)</u></p> <ol style="list-style-type: none"> 1. Tablet General 2. Capsule General 3. Dry Powder for Suspension (General) 4. Oral Liquid General 5. Liquid Injectable General 6. Capsule. 7. Tablet Cephalosporin 8. Capsule Cephalosporin 9. Dry Powder for suspension Cephalosporin 10. Dry Powder for Injectable Cephalosporin
11.	<p>M/s. A'raf (Pvt) Ltd, 23-Km Raiwind Road, Lahore.</p>	26-05-2016	<p>The Board approved the renewal of DML for following sections as per recommendations of panel:</p> <p><u>Sections (03)</u></p> <ol style="list-style-type: none"> 1. Tablet (General) 2. Capsule (General) 3. External Preparation (General Liquid)

12.	M/s. Harrison Pharmaceuticals, 10 Km Lahore Road, Sargodha. DML No.000634 (Formulation)	31-03-2016	The Board approved the renewal of DML for following section as per recommendations of panel: <u>Section (01)</u> 1. Tablet (General)
13.	M/s PDH Laboratories (Pvt) Ltd, 9.5-KM Sheikhupura Road, Lahore. DML.No.000039 (Formulation)	17-05-2016 & 13-06-2016	The Board approved the renewal of DML for following section as per recommendations of panel. <u>Sections (01)</u> 1. Injectable (Penicillin) 2. Liquid Injectable (General) 3. Cream/Ointment (Steroidal) 4. Injectable (Veterinary) 5. Oral Liquid (Veterinary)
14.	M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd, Plot No. 50, Sector 28, Korangi Industrial Area Karachi DML No. 000144 (Formulation)	27-06-2016	The Board approved the renewal of DML for following section as per recommendations of panel. <u>Sections (09)</u> 1. Tablet (General) 2. Capsule (General) 3. Ointment / Cream / Gel (General) 4. Oral Liquid (General) 5. Capsule (Penicillin) 6. Tablet (Penicillin) 7. Oral Dry Powder Suspension (Penicillin) 8. Capsule (Cephalosporin) 9. Oral Dry Suspension (Cephalosporin)

Item No. V **Miscellaneous Cases**

Case No.1. **CODE OF ETHICS:**

The case was placed before the Board as under: -

- In view of the current scenario of National revolutions against eradication of corruption and to ensure the transparency of the licensing procedure a code of ethics may be devised. In this regard a formal statement of commitment is prepared for consideration of the Board.

“All the members of CLB shall strive hard for fulfillment of the responsibilities enshrined with full Zeal and Zest by utilizing their professional skills with honest and integrity for the betterment of public at large. It is also resolved that the establishments will be guided in terms of up-gradation in quality in the subject field so that safe and effective medical devices are provided to patients. Nomination as member of CLB is a great honor along with responsibility and the members assure that they will not be involved in any activity which comes under the definition of conflict of interest. The members further resolved that the decision of the CLB shall be kept confidential till finalization and approval of minutes of the meeting of CLB.”

Decision of CLB:

The Board considered and deferred the matter for rephrasing the above code of ethics in consultation with law expert.

Case No.2. M/S MEDI MARKER'S PHARMACEUTICALS (PVT) LTD, PLOT NO.A-104, SITE, HYDERABAD.

The case was placed before the Board as under: -

- A letter No. 17468-2015-DRAP (Lic) dated 04-11-2015 was received from Mr. Abdul Rasheed Sheikh, Federal Inspector of Drugs Lahore along with following orders of Honorable Drug Court Lahore passed on 03-11-2015 and Non-bail able warrants of accused for execution.

On the last date of hearing N.B.W were issued and the same be forwarded to Deputy Inspector General Hyderabad. The reply from the DIG is received, further marked to the Superintendent of Police Hyderabad, but no reply from the S.P Hyderabad is received as yet.

Let us issued N.B.W of arrest of the accused for 20-11-2015 and again forwarded to the DIG Hyderabad with the direction that the previous warrant were not returned back yet. In these circumstances the attitude of the Sindh Police is highly objection. The copy of the order be sent to the DIG and S.P Hyderabad along with warrants with the direction to get execute the warrant and produce the accused before the court, if he failed then a responsible officer not below the rank of Sub Inspector is directed to appear before.

The N.B.W of arrest of the accused forwarded to the Drug Regulatory Authority of Pakistan through Federal Drug Inspector Lahore with the direction to get execute the warrant of the accused and till the arrest of the accused their license may immediately be suspended and the factory premises of the accused shall be scaled under intimation to this Court.

Announced
03-11-2015

- In this regards Drug Regulatory Authority of Pakistan has taken following actions: -

Action Taken by Division of Quality Assurance/Laboratory Testing (QA/LT):

- i. Division of (QA/LT) has passed directions to Area Federal Inspector of Drugs Hyderabad, Mr. Hakim Masood to execute the N.B.W against the accused persons in pursuance of orders of Honorable Drug Court Lahore.

Action Taken by Division of Drug Licensing:

- i. Division of Drug Licensing requested the Deputy Director General (E&M) Lahore to get complete case record from the relevant provincial Drug Inspector and Honorable Drug Court Lahore so that the case may be processed further.
- ii. The orders of Honorable Drug Court Lahore dated 03-11-2015 were placed before the Central Licensing Board (CLB) in its 245th meeting held on 30th December, 2015 for its consideration. The Board considered and decided as under:

Decision of CLB:

Keeping in view the facts of the case, proceeding of the Board and opinion of law expert; the Board considered and decided as under: -

- The Board adopted and endorsed the actions taken by Licensing Division.
- The Board decided to issue a Show Cause notice with personal hearing to the M/s. Medi Marker's Pharmaceuticals (Pvt) Ltd that why their drug

manufacturing license may not be suspended in pursuance of the orders of Honorable Drug Court.

- Orders of Honorable Drug Court for sealing of factory premises shall be executed by QA/LT Division through concerned FID.
- The Board directed to send an interim report to the Honorable Drug Court Lahore.
- On 12-01-2016 ,FID appeared before the court and informed that the compliance of Courts Orders dated 03-11-2015 are in progress for the completion of codal formalities and the compliance report will be submitted to the court ,the Honorable Drug Court Lahore has passed further orders dated 12-01-2016 on the above mentioned case in which Drug Regulatory Authority of Pakistan is directed to get execute warrants when they appeared for reply of Show Cause Notice and completed the proceedings and submit report before the court on 28-01-2015.
- On 28-01-2016 again FID appeared before the Honorable Drug Court, Lahore and Submitted the Interim report On behalf of DRAP, and informed Honorable Court regarding progress being made in compliance of the Courts orders. He has further stated that the honorable Drug Court directed to complete the codal formalities and suspend the license of M/s Medi-Markers Hyderabad, till the appearance of accused before the Court under intimation to the court and if they failed, Dr. Muhammad Aslam, Chief Executive Officer, DRAP is directed to appear himself before the court on 17-02-2016. (Copy of order sheet at page 323/Corr).
- Accordingly the Show Cause Notice /Personal Hearing letter was served to the firm; **accordingly, firm was called for personal hearing.**

Proceedings of 247th meeting of CLB

Muhammad Fahim Regulatory Manager of the firm appeared before the Board and presented their point of view in a statement as under:-

“We hereby state that CEO of the company Dr. Abdul Shakoor Usman, Production Manager Mr. Munsif Ali Qureshi and QC Manager Raheela Saleem has appeared before Drug Court Lahore and an instruction to Drug Regulatory Authority for suspension of license was withdrawn by Drug Court Lahore on February 08, 2016. The same was also delivered by Abdul Rasheed Shaikh FID, Lahore through Drug Court.

For the personal hearing called up by licensing Board on February 22, 2016, we could not personally attend the hearing due to some unavoidable circumstances and feel very sorry for the same and assures the Board for personal presence every time whenever Board will call.

We hereby confirm that we are attending the Drug Court Lahore on each hearing and hopefully our case will be settled very soon from court and orders of the Drug Court Lahore will be provided to Central Licensing Board.

We are very thankful to the Licensing Board giving us a chance for clarification of our position”.

Decision of 247th meeting of CLB:

The Board considered and decided to inform the Honorable Drug Court, Lahore regarding the personal hearing and the person appeared before the Board.

Current Proceedings:-

- A letter No. 8174/2016-DRAP (Lic) dated 07-06-2016 was received from Mr. Abdul Rasheed Sheikh, Federal Inspector of Drugs Lahore along with following orders of Honorable Drug Court Lahore passed on 01-06-2016 and Non-bail able warrants of accused for execution.

The State etc Present: DDPP for the State Accused absent Sheikh Abdul Rasheed Federal Drug Inspector Present	Versus	Medimarker's
<p>Sheikh Abdul Rasheed Federal Inspector informed that warrants issued by this court were forwarded to Drug Regulatory Authority Islamabad for executions but despite all the efforts were made for execution of warrants, no reply or comply is received yet. From the perusal of record it transpires that this court passed the order for the cancellation of license of M/s Medimarkers Pharmaceutical and after that the accused appeared before the court and moved application through their council for withdrawal of warrants and restoration of license but accused again did not made appearance. Now, it is difficult to procure the attendance of the accused who play hide and seek towards court attended. Drug Regulatory Authority, Islamabad is directed to suspend the manufacturing license of M/s Medimarkar's Pharmaceutical, Situated at A-104 S.I.T.E area Hyderabad Pakistan under intimation to this court by or before 17-6-2016. Abdul Rasheed Sheikh Federal Inspector is directed to intimate the orders of this court to the Drug Regulatory Authority and also informed this court for the proceedings of suspension of license.</p> <p>Meanwhile repeat the N.B.W of the accused for 17-06-2016 date already fixed and notice to surety also be issued to show cause or to pay the penalty.</p> <p><u>Announced</u> 01-06-2016</p>		

Actions Taken by Division of Quality Assurance/Laboratory Testing (QA/LT):

1. The N.B.W of arrest of the accessed and sealing of the Firm, were processed by QA/LT division and issued letter No.F.No.2-4/2003/Licensing dated 26-05-2016 and forwarded to concerned F.I.D for execution and copied to Registrar Drug court Lahore for information.

Actions Taken by Division of Drug Licensing:

1. Report has been prepared to intimate the proceedings and decision of CLB to Drug Court Lahore.
2. The orders of suspension of the license of the firm were processed and with the approval of Chairman CLB were placed in agenda of upcoming meeting of CLB for consideration.

Latest Court Orders:

Another letter No.9157/2016-DRAP(L-I) dated 21-06-2016 has been received in Licensing Division on 24-06-2016 along with the orders of Drug Court Lahore, dated 17-06-2016.

On the last date of N.B.W of arrest against the accused issued and forwarded to the Federal Drugs Regulatory Authority, Islamabad, with the direction to suspend the license of M/s Medimarkers Pharmaceuticals. Today Abdul Rasheed Sheikh, Federal Inspector of Drugs present in the court informed that the proceedings of cancellation of license was initiated and still in process and the N.B.W of arrest are forwarded to concerned Federal Inspector, Karachi but no reply received yet.

Abdul Rasheed Sheikh is directed to expedite the process of cancellation of license and complete the proceedings immediately .Meanwhile, Federal Drug Inspector, Karachi is directed to seal the Medimarker's Pharmaceuticals, situated at A-104 S.I.T.E area Hyderabad, Karachi under intimation to this court.

Now to come up for 14-07-2016 further proceedings. Meanwhile, Notice to the surety to appear before the court on the next date of hearing.

ANNOUNCED

17-06-2016

As per the above latest orders of the Drug court following actions are taken:

Actions Taken by Division of Quality Assurance/Laboratory Testing (QA/LT):

- The N.B.W of arrest of the accessed and sealing of the Firm, were processed by QA/LT division and issued letter No. Dy.No.905/2016-QC dated 28th June, 2016 and forwarded to concern F.I.D for execution and copied to Registrar Drug court Lahore for information.

Actions Taken by Division of Drug Licensing:

- The orders of suspension of the license of the firm were processed and with the approval of Chairman CLB were placed in agenda of upcoming meeting of CLB for consideration.

Proceeding of 248th Meeting:

CQC apprised the Board that he has asked from Area FID about compliance of the Court Orders and Area FID has informed that he is in compliance of Court Orders and will seal the factory by today i.e. 13th July, 2016.

Decision of CLB of 248th Meeting:

Keeping in view the proceeding and facts of the case, the Board considered and decided as under: -

- **The Board adopted and endorsed the actions taken by Licensing Division and Quality Assurance/Laboratory Testing QA/LT Division.**
- **The Board decided to issue a Show Cause notice with personal hearing to the M/s. Medi Marker's Pharmaceuticals (Pvt) Ltd that why their drug manufacturing license may not be cancelled in pursuance of the orders of Honorable Drug Court.**
- **The Board directed to send an interim report to the Honorable Drug Court Lahore.**
- **The Board advised to communicate the decision of CLB thru Area FID, at factory premises and residential address of the owner.**

Case No. 3 GRANT OF DRUGS FOR RE-PACKING:

The case was placed before the Board as under: -

M/s Simaxx Chemicals Industrial Estate, Hayatabad, Jamrud Road, Peshawar has submitted Application for Grant of Re-packing drugs as per Schedule-D. Firm has submitted challan Fee of 5000/ per product.

Sr. No	Name of drugs for Repacking	Schedule-D
01	Glycerin	Yes
02	Liquid paraffin (Heavy)	Yes
03	Castor oil	Yes
04	Boric Acid	Yes
05	Calamine	Yes
06	Gentian Violet	Yes
07	Kaolin	Yes
08	Zinc Oxide	Yes
09	Iodine	Yes
10	Ichthammol	Yes

Decision of CLB:

The Board considered and approved the following drugs for re-packing as per Schedule-D under newly granted DML in the name of M/s Simaxx Chemicals Industrial Estate, Hayatabad, Jamrud Road, Peshawar: -

S. No.	Name of Drug for Repacking
01	Glycerin
02	Liquid paraffin (Heavy)
03	Castor oil
04	Boric Acid
05	Calamine
06	Gentian Violet
07	Kaolin
08	Zinc Oxide
09	Iodine
10	Ichthammol

Case No.4: CHANGE OF TITLE OF THE FIRM:

The case was placed before the Board as under: -

M/s Rasco Pharma, 5.5 Km, Near Ali Raza Abad, Holiday Park, Plot #27,Raiwind Road, Lahore has submitted request for change of firms title/Status as per Form-29 from S.E.C.P along with prescribed Fee Chalan of 50000/- as under: -

Present Name/Title /Status of Firm	New Name/Title/Status of Firm
Rasco Pharma, 5.5 Km, Near Ali Raza Abad, Holiday Park, Plot #27,Raiwind Road, Lahore	Rasco Pharma (Pvt.) Ltd., 5.5 Km, Near Ali Raza Abad, Holiday Park, Plot #27,Raiwind Road, Lahore

Decision of CLB:

The Board considered and acknowledged the change of management from old to new as per Form 29 issued by Security Exchange Commission of Pakistan as under: -

Old Name/Title /Status of Firm	New Name/Title/Status of Firm
Rasco Pharma, 5.5 Km, Near Ali Raza Abad, Holiday Park, Plot #27,Raiwind Road, Lahore	Rasco Pharma (Pvt.) Ltd., 5.5 Km, Near Ali Raza Abad, Holiday Park, Plot #27,Raiwind Road, Lahore

Case No.5: CHANGE IN MANAGEMENT OF THE FIRM:

The case was placed before the Board as under: -

M/s Himont Pharmaceuticals (Pvt.) Ltd, Lahore has submitted request for change in management of the firm as per Form-29 from S.E.C.P along with prescribed Fee Chalan of 50000/- as under;

Existing Management	Retiring Management	New Management As per Form-29
1. Mr. Intesar A. Siddiqui 2. Dr.Muhammad Umar	-----	1. Mr. Intesar A. Siddiqui 2. Dr.Muhammad Umar. 3. Saami A. Siddiqui.

Decision of CLB:

The Board considered and acknowledged the change of management from old to new as per Form 29 issued by Security Exchange Commission of Pakistan as under: -

Existing Management	Retiring Management	New Management As per Form-29
1. Mr. Intesar A. Siddiqui 2. Dr.Muhammad Umar	Nil	1. Mr. Intesar A. Siddiqui 2. Dr.Muhammad Umar. 3. Saami A. Siddiqui.

Case No.5 INCREASE OF TECHNICAL PERSON'S EXPERIENCE FROM 3 TO 10 YEARS.

The case was placed before the Board as under: -

Brief History:

It is submitted that the Drugs (Licensing, Registering & Advertising) Rules, 1976 were notified under S.R.O No. 145(1)/76, dated 12th February, 1976. It is further submitted that: -

- Rule 15 (c) & (e) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 provides for provisions for qualification and experience of technical staff (Production Incharge and Quality Control Incharge) for Grant or Renewal of a license to manufacturing drugs by way of basic or semi-basic manufacture. Previously these rules required two years' experience in basic or semi basic manufacturing.
- Rule 16 (c)(i)(ii)&(e) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 provides for provisions for qualification and experience of technical staff (Production Incharge and Quality Control Incharge) for Grant or Renewal of a license to manufacturing drugs by way of Formulation. Previously these rules required three years experience for Pharmacy Degree holders and Ten years for Chemistry Degree holders.

4th meeting of DRAP Authority held on 25th April, 2013

It is submitted that previously Authority in its 4th meeting held on 25th April, 2013 has considered the said matter and decided accordingly as under:

Decision of Authority: The Authority approved the following amendment under Rule 15(C) & (e) and Rule 16 (c) & (e) of the Drugs (Licensing, Registering & Advertising) Rules, 1976:-

1. The qualification and experience of Production Incharge for semi basic and basic manufacture under rule 15(C) may be increased from **two** years to **ten** years.
2. The qualification and experience of Quality Control Incharge for semi basic and basic manufacture under rule 15(e) may be increased from **two** years to **ten** years.
3. The qualification and experience of Production Incharge for manufacturing by way of formulation as laid down under Rule 16(c) may be increase as under:-
 - i. Under rule 16 (c) (i), the required experience may be increased form **three** years to **ten** years.
 - ii. Under Rule 16 (c) (ii) the required experience may be increased from **ten** to **fifteen** years.
 - iii. Under Rule 16 (c) (iii) the required experience may be increased from **three to ten** years.
 - iv. Under Rule 16(c)(iii) the required experience for section incharge may be increased from **sufficient experience** to **not less than three years** experience.
4. The qualification and experience of Quality Control Incharge for manufacture by way of formulation under rule 16(e) may be increased from **three** years to **ten** years and in the proviso of said rules from **sufficient experience** to **ten** years.
5. Provision for availability of alternative staff in the absence of qualified staff shall also be placed in rules.”

Accordingly, SRO No. 1134 (I) / dated 17th July, 2014 was notified in the light of decision of 4th DRAP Authority meeting which is in practice at present.

Request of PPMA

The above matter has been taken up by the Licensing Division on the request of PPMA and placed in 30th meeting of DRAP Authority held on 23rd December, 2015 for its consideration.

The complete case which was placed in Agenda is as under: -

Chairman, Pakistan Pharmaceutical Manufacturers Association (PPMA) in letter addressed to CEO DRAP has submitted as under: -

“We are obliged indeed for your patient hearing to the genuine grievances / hardships of the industry facing since long presented by our delegation which met you in your office on 6th November, 2015.

According to the Policy 10 years’ experience personnel’s are mandatory. We would like to draw your kind attention that there are more than 700 pharmaceutical units in Pakistan and industry cannot have persons with such vast experienced and it is hardly to find out.

Therefore, it is humbly requested to kindly reduce the experience from 10 years to 5 years.”

Decision of Authority taken in its 30th meeting:

“Division of Licensing was advised to prepare a working paper on the matter of experience required for appointment of technical person in the pharmaceutical industry; keeping in view of the reservations of the PPMA on the subject issue regarding difficulties for finding a pharmacist with ten years’ experience; which is leading to non-compliance and court cases and according to them that may ultimately cause shortages of drugs. The subject agenda items shall be placed before the Licensing Board for its evaluation and recommendation and thereafter shall be brought before the Authority, as required. The agenda item may be evaluated in line with practices followed in regional countries and WHO guidelines / recommendations, if available in the subject matter”.

The minutes of the 30th meeting of the Authority have been received in the Licensing Division on 30-12-2015 and the action has been initiated accordingly.

Recommendations of Senate Standing Committee on National Health Services Regulations and coordination: The said committee in its meeting held on 06th January, 2016 has given following recommendation:

“The Committee recommended that requirement of experience for appointment of technical persons in licensed pharmaceutical industries should be five to six years.”

A meeting of PPMA with Honorable Minister of State was held 10-02-2016 in which following instructions were passes on:

“The decrease in required experience for qualified person for license from 10 years to 5 years to be implemented as already decided.”

Decision of 246th meeting of CLB held on 22-02-2016:

Keeping in view the back ground of case, directions of DRAP Authority and recommendations of Senate Standing Committee on National Health Services Regulations and Coordination; the Board approved following recommendations for consideration of Authority and onward amendments in relevant rules accordingly: -

Existing Rules/Experiences	Recommendations of CLB
The experience of Production Incharge for semi basic and basic manufacture under rule 15(c) is ten years.	The experience of Production Incharge for semi basic and basic manufacture under rule 15(c) may be decreased from ten years to eight years.
The experience of Quality Control Incharge for semi basic and basic manufacture under rule 15(e) is ten years.	The experience of Quality Control Incharge for semi basic and basic manufacture under rule 15(e) may be decreased from ten years to eight years.
The experience of Production Incharge for manufacturing by way of formulation as laid down under Rule 16(c)(i) is ten years.	The experience of Production Incharge for manufacturing by way of formulation as laid down under Rule 16(c)(i) may be decreased from ten years to six years.
<u>Rule 16 (c)(ii):</u> a masters degree in science with chemistry or pharmaceutical chemistry as the principal subject who has not less than fifteen years practical experience in the manufacture of drugs intended to be manufactured, knowledge of pharmacy which, in the opinion of Central Licensing Board, is adequate for the purpose; or	Rule 16 (c)(ii) shall be omitted.
Under Rule 16 (c) (iii) the required experience is ten years.	Under Rule 16 (c) (iii) the required experience may be decreased from ten years to six years. In sub-clause (iii) of Rule 16 (c), for the word “medicine”, the words “pharmacy or microbiology or biotechnology” shall be substituted;
The experience of Quality Control Incharge for manufacture by way of formulation under rule 16(e) is ten years.	The experience of Quality Control Incharge for manufacture by way of formulation under rule 16(e) may be decreased from ten years to six years.
“Provided further that there shall be a separate incharge for the in process control of the drugs being manufactured who shall possess a degree in pharmacy or a masters degree in chemistry, with sufficient experience.”	“Provided further that there shall be a separate Quality Assurance Incharge for the in process control of the drugs being manufactured who shall possess a degree in pharmacy or a masters degree in chemistry, with eight years experience.”

Decision of 34th meeting of Drug Regulatory Authority of Pakistan:

The decision of 246th meeting of CLB was placed before the DRAP meeting and Authority decided as under:

“The Authority approved the recommendations of the central Licensing Board for the required experience of technical persons and advised the drugs licensing Division to proceed for amendments in the Drugs (Licensing, Registration & Advertising) Rules, 1976 in light of the decision of the central licensing Board. The Authority further advised the Concerned Division to look into the suggestions for Re-discussing in the Central Licensing Board, the required experience on the basis of other qualification.”

New proposal is submitted as under: -

Existing Rules/Experiences	Recommendations of CLB
Rule 16(c)(iii) reads as under: - (iii) any foreign qualification the quality and	After recommendations of CLB, Rule 16(c)(ii) has already been omitted, so it is recommended that the words “or sub-clause (ii)” shall also be

<p>content of the training of which are comparable with those described in sub-clause (i) or sub-clause (ii) and is approved for the purpose of this sub-rule by the Central Licensing Board.</p>	<p>omitted.</p>
<p>Rule 16(c)(iii) reads as under: -</p> <p>(e) The Quality Control Department shall be independent of the manufacturing unit and its incharge shall be a whole time employee of the manufacturer and shall possess a degree in pharmacy, or a degree [masters] in science with chemistry or a degree in medicine or pharmacology (for pharmacological testing) or a degree in microbiology (for microbiological testing) and has six years experience in testing of types of drugs intended to be manufactured:</p>	<p>Rule 16(c)(iii) shall be amended as under with the addition of proviso as under: -</p> <p>(e) The Quality Control Department shall be independent of the manufacturing unit and its incharge shall be a whole time employee of the manufacturer and shall possess a degree in pharmacy and has six years experience in testing of types of drugs intended to be manufactured:, or a degree [masters] in science with chemistry and has ten years experience in testing of types of drugs intended to be manufactured:</p> <p>Provided that for pharmacological testing there shall be a separate employee who shall possess a degree in pharmacy or a master degree in pharmacology and has six years experience in testing of types of drugs intended to be manufactured; and for microbiological testing there shall be a separate employee who shall possess a degree in pharmacy or a degree in microbiology and has six years experience in testing of types of drugs intended to be manufactured:</p>
<p>“Provided further that there shall be a separate incharge for the in process control of the drugs being manufactured who shall possess a degree in pharmacy or a masters degree in chemistry, with sufficient experience.”</p>	<p>The said proviso shall be amended as under:</p> <p>Provided further that there shall be a separate Head of Quality Assurance for the quality assurance of the drugs being manufactured who shall possess a degree in pharmacy with eight years experience.”</p>

Decision of CLB:

Keeping in view the background of the case and directions of DRAP Authority, the Board considered and furnished the following recommendations for consideration of Authority and onward amendments in the relevant rules accordingly: -

Existing Rules/Experiences	Recommendations of CLB
<p>Rule 16(c)(iii) reads as under: -</p> <p>(iii) any foreign qualification the quality and content of the training of which are comparable with those described in sub-clause (i) or sub-clause (ii) and is approved for the purpose of this sub-rule by the Central Licensing Board.</p>	<p>After recommendations of CLB in its 247th meeting held on 29th April, 2016, Rule 16(c)(ii) has already been omitted, so it is recommended that the words “or sub-clause (ii)” shall also be omitted.</p>
<p>Rule 16(e) reads as under: -</p> <p>(e) The Quality Control Department shall be independent of the manufacturing unit and its incharge shall be a whole time employee of the manufacturer and shall possess a degree in pharmacy, or a degree [masters] in science with chemistry or a degree in medicine or pharmacology (for pharmacological testing) or a degree in microbiology (for microbiological testing) and has six years experience in testing of types of drugs intended to be manufactured:</p>	<p>Rule 16(e) shall be amended as under with the addition of proviso as under: -</p> <p>(e) The Quality Control Department shall be independent of the manufacturing unit and its incharge shall be a whole time employee of the manufacturer and shall possess a degree in pharmacy and shall have minimum six years experience in testing of types of drugs intended to be manufactured; or a master degree in science with chemistry and shall have minimum ten years experience in testing of types of drugs intended to be manufactured:</p> <p>Provided that for pharmacological testing there shall be an additional employee who shall possess a degree in pharmacy or a master degree in pharmacology and shall have minimum six years experience in testing of types of drugs intended to be manufactured; and for microbiological testing there shall be an additional employee who shall possess a degree in pharmacy or a master degree in microbiology and shall have minimum six years experience in testing of types of drugs intended to be manufactured:</p>
<p>“Provided further that there shall be a separate incharge for the in process control of the drugs being manufactured who shall possess a degree in pharmacy or a masters degree in chemistry, with sufficient experience.”</p>	<p>The said proviso shall be amended as under:</p> <p>Provided further that there shall be an independent Head of Quality Assurance for the quality assurance of the drugs being manufactured who shall possess a degree in pharmacy with eight years experience.”</p>

Case No.6 PROVISION OF INFORMATION AND ENDORSEMENT OF MANUFACTURING PROCESS FLOW / PROTOCOL OF MANUFACTURING AND TESTING OF APIs/ BULK DRUGS.

The case was placed before the Board as under: -

Background of the Case.

The case was presented in 246th meeting of Central Licensing Board held on 22nd February, 2016 and decided as under: -

Decision of CLB:

Keeping in view the above situation, the Board considered, discussed and unanimously decided for panel inspection of the above firms by following panel: -

1. Prof. Dr. Saeed Sb. Member CLB
2. Dr. Ikram-ul-Haq, Member CLB
3. Syed Muid Ahmed, Member CLB
4. Syed Javed Yousuf Bukhari, Member CLB
5. Area FID, DRAP, Lahore

The Board further directed the panel: -

- to verify the complete process of manufacturing of every API as per requirement of Rule 10 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
- to sign / endorse the complete report and their manufacturing process flows of APIs.

The Board further decided that in future above procedure shall be followed for approval any new API.

Following cases have been recommended by the respective panel of experts for provision of information and endorsement of manufacturing process flow / protocol of manufacturing and testing of Apis/ Bulk Drugs.

S#	Name of the firm	Date of Inspection / Type of License	Inspection Panel Members	Remarks
1.	M/s Alpha chemical (Pvt) Ltd, 65-km Lahore-Multan National Highway, Industrial Zone, Chunian, Kasur. DML No. 000373 By way of Basic Manufacture	04-06-2016	1. Dr. Ikram ul Haq, Member CLB 2. Syed Muied Ahmed, Member CLB. 3. Syed Javed Yousaf Bukhari, Member CLB. 4. Mr. Abdul Rashid Shaikh, FID DRAP Lahore.	The individual process flow chart diagram of each API along with list of starting/raw materials duly endorsed by firm's representatives and panel members is annexed with the report.

2.	M/s Pharmagen Ltd, Kot Nabi Baksh Wala, Ferozpur Road, Lahore. DML No. 000325 by way of Semi Basic Manufacture	30&31-05-2016	1. Prof. Dr. Muhammad Saeed, Member CLB 2. Dr. Ikram ul Haq, Member CLB 3. Syed Muied Ahmed, Member CLB. 4. Syed Javed Yousaf Bukhari, Member CLB. 5. Mrs. Majida Mujahid, FID DRAP Lahore.	-do-
3.	M/s Zafa Chemie, Raiwind Manga Bypass, Mouza Bahikot, Distt: Lahore. DML No. 000589 by way of Basic Manufacturer	04-06-2016	1. Prof. Dr. Muhammad Saeed, Member CLB 2. Dr. Ikram ul Haq, Member CLB 3. Syed Muied Ahmed, Member CLB. 4. Syed Javed Yousaf Bukhari, Member CLB. 5. Mrs. Majida Mujahid, FID DRAP Lahore.	-do-
4.	M/s Zenith Chemical Industries (Pvt) Ltd., Lahore. DML No 000733 by way of Semi Basic Manufacture	03-06-2016	1. Prof. Dr. Muhammad Saeed, Member CLB 2. Dr. Ikram ul Haq, Member CLB 3. Syed Muied Ahmed, Member CLB. 4. Syed Javed Yousaf Bukhari, Member CLB. 5. Mr. Ajmal Sohail Asif, FID DRAP Lahore.	-do-
5.	M/s Citi Pharma (Pvt) Ltd, 3-KM Head Baloki Road, Phool Nagar Kasur. DML No. 000429 by way of Semi Basic Manufacture	01-06-2016	1. Prof. Dr. Muhammad Saeed, Member CLB 2. Dr. Ikram ul Haq, Member CLB 3. Syed Muied Ahmed, Member CLB. 4. Syed Javed Yousaf Bukhari, Member CLB. 5. Mr. Abdul Rashid Shaikh, FID DRAP Lahore.	-do-

Proceedings of the Board:

The Board appreciated the efforts done by panel. Prof. Dr. Muhammad Saeed further emphasized the efforts rendered by Dr. Ikram ul Haq member of the panel.

Decision of CLB:

The Board appraised the matter and deferred till next meeting for comprehensive presentation of the case.

Case No 7: CHANGE IN MANAGEMENT OF THE FIRM:

The case was placed before the Board as under: -

M/s SPL Pharmaceuticals (Pvt.) Ltd, Hattar has submitted request for change in management of the firm as per Form-29 from S.E.C.P along with prescribed Fee Chalan of 50000/- as under;

Existing Management	Retiring Management	New Management As per Form-29
1. Mrs. Zohra Ahmed, CEO 2. Ms Tayyaba Jafer 3. Syed Jafer Hassan	1. Mrs. Zohra Ahmed, CEO 2. Ms Tayyaba Jafer 3. Syed Jafer Hassan	1. Mr. Abdul Aziz, CEO 2. Mrs. Nida Aziz 3. Mr. Zakera Aziz.

Decision of CLB:

The Board considered and acknowledged the change of management from old to new as per Form 29 issued by Security Exchange Commission of Pakistan as under: -

Old Management	Retiring Management	New Management As per Form-29
1. Mrs. Zohra Ahmed, CEO 2. Ms Tayyaba Jafer 3. Syed Jafer Hassan	1. Mrs. Zohra Ahmed, CEO 2. Ms Tayyaba Jafer 3. Syed Jafer Hassan	1. Mr. Abdul Aziz, CEO 2. Mrs. Nida Aziz 3. Mr. Zakera Aziz.

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

Division of Quality Assurance / Laboratory Testing

Quality Assurance Cases (GMP Non-Compliance)

Index

S. No.	Name of firm
Item No. I GMP Non-compliance Cases (New)	
1.	M/s Al-Falah Pharma (Pvt) Ltd, Lahore
2.	M/s Medipak Limited, Lahore
3.	M/s Venus Pharma, Lahore
4.	M/s Jawa Pharmaceuticals (Pvt) Ltd, Lahore
5.	M/s A.Z. Pharmaceuticals Co., Ltd, Manga Road, Raiwind, Distict Kasur
Item No. II (Court Case)	
1.	M/s Marion Labs, Karachi
Item No. III (Supplementary Agenda)	
1.	M/s A.H Pharmaceuticals (Pvt) Ltd, Faisalabad
2.	M/s Zaynoon Pharmaceuticals (Pvt) Ltd, Peshawar
3.	M/s Medisave Pharmaceutical, Lahore
4.	M/s Ideal Pharmaceutical Industries, Lahore
5.	M/s Quaper Pharma, Sargodha

Item No. I (GMP Non-compliance Cases New)

Case No. i:- M/s Al-Falah Pharma (Pvt) Ltd, Lahore

Background of the case

Mrs. Aisha Irfan, area FID, Lahore conducted inspection of company on 12.11.2015 to verify the GMP compliance and production activities. The FID informed that the factory gate was locked and no security guard was present. Shopkeeper from nearby shop informed that the factory is closed for the last many months and the security guard has also left the premises 2-3 months ago. This is the second inspection of the firm for monitoring of the status. She further informed that in the previous inspection conducted on 13.03.2015; the owner Mr. Chowdhary Waseem informed that the production would be restarted within 02 months time period, however even after lapse of 08 months same situation prevails. Recently, the firm also got extension in the contract period from M/s Synchron Pharma, Lahore of ten drugs. Mr. Waseem CEO of the firm also did not submit any compliance.

Action Taken by DRAP:- Accordingly, a show cause notice was served to the firm for above mentioned violations on 28.04.2016.

Reply of the firm:- The firm vide letter No. Nil dated 31.05.2016 informed that the dispute has been arisen among the directors. Therefore, the management has decided to stop the manufacturing process till the final decision of the directors. The further requested to grant them six months so that, they shall be able to conduct smooth affairs of the company and also among the directors and they shall be able to fulfill shortcomings for maintaining GMP.

Proceedings of the 248th Meeting of CLB

Mr. Muhammad Saleem, Quality control Manager and Mr. Zia Ullah, Director of the firm M/s Al-Falah Pharma (Pvt) Ltd, Lahore appeared before the Board for personal hearing. Mr. Zia Ullah informed that Mr. Waseem Chaudhary was partner in the firm. There is a dispute between the partners and the factory was closed due to the dispute between the partners. Now they have purchased they shares from Mr. Saleem Chaudhary. In this regard Mr. Zia Ullah also provided copies of the bank drafts and copies of the agreement deed between the partners. He further informed that it will take about 03 months to ready for inspection.

Decision of the 248th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, reply of the firm and non serious attitude of director of the firm, the Board decided to suspend the Drug Manufacturing License of the firm M/s Al-Falah Pharma (Pvt) Ltd, 12-KM, Sheikhupura Road, Lahore for a period of six months under Section 41 of the Drugs Act, 1976 and Rule 12 of the Drugs (LR&A) Rules, 1976. The Board further directed to the management of the firm to submit form 29 from SECP indicating the new management and then get approval from Division of Licensing in this regard.

Case No. ii:- M/S MEDIPAK LIMITED, LAHORE

Background of the case

Mr. Abdul Rashid Shaikh, FID, Lahore conducted inspection of company on 13.04.2016 to verify the GMP compliance and production activities. The FID noticed number of observations, which needs urgent attention and rectification. The observations include:-

- Replace the wooden fixture and doors from the premises.
- Appoint qualified person in all sections as per the requirement of Drugs Act, 1976 and Rules framed there under.
- Ensure the availability of qualified person in their stores as well.
- Review SOPs for manufacturing and sterilization of the batch as per available capacity and maintain their proper BMR.
- Ensure the proper clean and lint free uniforms for all workers.
- Take the safety measures regarding the exposure of hazardous solvent used for the assembling of IV sets components.
- Ensure the airtight closed containers for the storage of their raw materials with proper identification to avoid any mixing.
- Ensure the separate dispensing hood for the steroidal materials to avoid any cross contamination.
- The buffer of the area needs repair maintain and paints.
- Ensure the emergency alarm system.
- Review and upgrade the SOPs for the maintenance of cold chain from manufacture till user end along-with documented evidence.
- Ensure the placement to data logger for the monitoring of storage from manufacture to user end.
- Improve the improvers' storage areas.
- Ensure the separate bags for different products to avoid to cross contamination of floor bed dryer.
- Ensure the filtration of the air which is being used for the dryer.
- Ensure the availability of proper dispensing booth.
- Ensure the closed trolleys for the transportation of dispensed material from dispensing area to the production floor.
- Review the SOPs for the storage of post dispensed material.
- Review the organogram of the organization by avoiding the conflict of interest.
- Make the GC functional as at the time of visited was out of order due to some technical reasons.
- Proper install the newly purchased liquid particle counter.
- Ensure the data backup system for the records.
- Get the calibration of major equipment and machinery and also advised to develop the separate log books for each and every main equipment and machinery for the traceability of their function and maintenance.
- Improve the storage condition of their finished foods stores by installation of AC and monitored their proper record without fail.

- Develop the proper and regular internal and external training program for workers and other technical staff and maintain their records.
- Get the medical certificate of all workers and maintain their record.
- Maintain the proper record of changing of all filters placed on different lines and maintain their record.
- Get the certificate from the concerned authorities boilers and get calibration of all the gauges and maintain their record.
- Buffers of solution preparations and filling areas need repair and maintenance.

Action Taken by DRAP:- Accordingly, show cause notice was served to the firm for above mentioned violations on 25.05.2016.

Reply of the firm: - The firm vide letter No. Nil dated 03.06.2016 submitted detailed reply of showcause notice including compliance status with 25 annexures.

Proceedings of the 248th Meeting of CLB

Mr. Nasir Chaudhary, Managing director and Mr. Tufail Ahmed, head of quality Assurance of the firm M/s Medipak Limited, Kot Lakhpat, Lahore appeared before the Board for personal hearing. Mr. Nasir Chaudhary informed to the Board that they are responsible company and always try to comply the cGMP requirements. He further informed that they are ISO 9000 and 14000 certified company and they are the only in Pakistan who are recommended for ISO 17025 accreditation. He further added that during inspection the FID noted 29 observations, out of which 25 have been rectified and the remaining shall be rectified shortly. The Chairman, CLB inquired about the time for which they would be ready for inspection. Mr. Nasir Chaudhary informed that they are ready for inspection.

Decision of the 248th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, compliance report of the firm, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members:-

- i. Dr. Abdur Rashid, Chairman, Quality Control
- ii. Dr. Zaka ur Rehman, CDC, Punjab
- iii. Mr. Abdul Rashid Shaikh, Area FID, Lahore

The Board also decided to direct the panel to submit brief report in tabulated form identifying the previous observations and the current status.

Background of the case

Mr. Ajmal Sohail Asif, area FID, Lahore conducted inspection of the company on 12.04.2016 to verify the GMP compliance and production activities. The FID noticed number of observations, which needs urgent attention and rectification. The observations include:-

Storage Area:-

- Arrange the racks at a proper distance from walls to improve the cleanliness of less accessible areas.
- Expand the finished good storage area.

Tablet Sections (General, antibiotic, psychotropic and steroid):-

- Improve the flooring of this section
- Provide HVAC in blistering room.
- Install manometers in each compression cubicle to monitor pressure gradients to avoid cross contamination.
- Improve the packing tables in steroidal tablet section.

Human injectable sections (Vial and Ampoule):-

- Repair flooring where required.
- Improve optical checking tables.
- Epoxy coating at some places was damaged the firm was advised to redo epoxy of floors where required.

Quality Assurance:-

- Hire more staff and strengthen the QA department.
- Re-organize the job descriptions specifying the responsibilities and reporting relationships of the various staff.

Qualification and Validation:-

- Validate the manufacturing and analytical procedures as per VMP.
- Perform cleaning validations.

Product Recalls:-

- Conduct mock recall to check effectiveness of the recall SOP and to update the SOP in this regard.

Self Inspection and Quality Audit:-

- Properly implement the SOP and maintain the records.

Personnel:-

- Immediately hire more pharmacists to supervise each manufacturing section.
- Strengthen the QA section by hiring more experienced technical personnel as QA manager.

Materials:-

- Affix the label on each and every container/bag of a lot of a material.
- Physically segregate different materials placed on one rack/pellet.

Documentation:-

- Review and update the SOPs where required.

- Improve BMRs by incorporating dispensing tags.

Good Practices in Quality Control:-

- The firm was using in house working standards for testing and was advised to purchase reference standards.

Water purification system

- Implement the procedure for the sanitization of the water supply system as per SOP.

HVAC System:-

- In some areas the pressure gradients in buffers need to be adjusted in cascade manner for proper control of classified areas.
- Install manometers in each compression cubicle.

Action Taken by DRAP:- Accordingly, a show cause notice was served to the firm for above mentioned violations on 08.06.2016.

Reply of the firm:- The firm vide letter No. Nil dated 13.06.2016 informed that the observations were non-critical as mentioned by FID. They requested for the withdrawal of showcause notice and informed that all observations have been rectified.

Proceedings of the 248th Meeting of CLB

Mr. Umair Parvaiz Siddiqui, Director, Mr. Umar Parwaiz Siddiqui, Director and Mr. Akbar Ali Malhi, Production Manager of the firm M/s Venus Pharma, Multan Road, Lahore appeared before the Board for personal hearing. Mr. Umair Parvaiz Siddiqui informed to the Board that the necessary improvements have been made, including replacements of broken tiles and packing tables. He further informed that a compliance report in this regard has already been submitted in the Division of QA< and now the same may be verified by the FID.

Decision of the 248th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, compliance report of the firm, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members:-

- i. Mr. Ajmal Sohail Asif, Area FID, Lahore
- ii. Mr. Munawar Hayat, Director, DTL, Lahore
- iii. Mr. Akbar Ali, ADC (Lic), Islamabad

The Board also decided to direct the panel to submit brief report in tabulated form identifying the previous observations and the current status.

Case No. iv:- M/s Jawa Pharmaceuticals (Pvt) Ltd, Lahore

Background of the case

Mr. Abdul Rashid Shaikh, area FID, Lahore conducted inspection of company on 31.03.2016 to verify the GMP compliance and production activities. The FID noticed number of observations, which needs urgent attention and rectification. The observations include:-

- The main door of worker's entrance needs to be replaced.
- To display the change over SOPs in the area.
- Washrooms of the area need to be upgrade, maintained etc.
- To install proper exhaust fans with covers and concealed the lights.

Store:-

- It is advised:
- To ensure availability of the vacuum cleaner in the receiving / de-dusting area.
- To properly concealed the doors.
- To improve the light in all areas of the store.
- Walls of the store area need repair / maintenance and paint work.
- To make the corners of walls smooth and round.
- Display the status of things like cleaned / to be cleaned etc in the area.
- To ensure proper labeling on each container like quarantine, sampled, released or rejected etc in their respective colors.
- To maintain the proper purchase / sale record of these drugs and to properly maintain testing and manufacturing record of drugs being controlled drugs.
- To improve the storage condition of the packing material store.
- To review and upgrade the proper SOPs for handling and dispensing of controlled drugs by maintaining their log book.
- Import and export their raw materials and finished drugs as per import and export rules of Drugs Act 1976.
- To ensure the availability of closed trolleys for the transportation of post-dispensed materials from the dispensing area to the production floor.
- To upgrade and review their SOPs and storage of primary packing materials.
- To make the functional the cargo lift for cephalosporin area and upgrade it.
- The area of cargo lift needs repair, paint and improvement of lights.
- To re-arrange the pellets in the raw material store for the proper placement of their active and inactive materials separately.

Packing Hall:-

- It is directed:
- To immediately install air conditioner in packing hall without fail to make its temperature and environment comfortable.
- To get the medical fitness certificate for each worker and maintain their proper record.
- To design the proper training program of the workers / operators and officers and also maintain their record of internal and external trainings.
- To validate the area as the drug were being exposed in that area for packing.
- The electric panel needs to be properly maintained.
- To maintain all records of purchase of new bottle.

Finished Goods Store:-

- It is directed:
- To revise the placement of racks in the area.

- To improve the lighting and paints in the area.
- The door of the finished goods store needs to be replaced.
- The cargo lift needs to be maintained.
- To ensure safety mechanism in this regard.
- To ensure availability of the SS closed containers for the storage of in-process drugs / materials.
- To improve the lightening and also validate HVAC of the areas, which was found closed.
- To validate the fluid-bed dryer for each and every machine/instrument for its proper record keeping regarding their maintenance and functionality for traceability of the system.
- To appoint certified engineer for maintenance of premises without fail.
- To appoint qualified person in each and every section as per requirement of the Drug Act, 1976 and rules framed there under without fail.
- To develop proper separate and independent quality assurance department under the senior technical personnel without fail.

Action Taken by DRAP:- Accordingly, a show cause notice was served to the firm for above mentioned violations on 03.05.2016.

Reply of the firm:- The firm vide letter No. JPPL/MD/619 dated 11.05.2016 informed that all observations have been rectified.

Proceedings of the 248th Meeting of CLB

Mr. Baqir Jawa, Managing Director and Mr. Shoukat Hayat, Quality Control Manager of the firm M/s Jawa Pharmaceuticals (Pvt) Ltd, Kot Lakhpat, Lahore appeared before the Board for personal hearing. Mr. Baqir Jawa informed to the Board that the compliance report on the observations noted by the FID has already been submitted in the Division of QA<. All observations were addressed.

Decision of the 248th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, compliance report of the firm, the Board decided to conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members:-

- i. Dr. Abdul Rashid, Chairman Quality Control, Islamabad
- ii. Dr. Sheikh Akhter Hussain, DDG (E&M), Lahore
- iii. Mr. Abdul Rashid Shaikh, Area FID, Lahore

The Board also decided to direct the panel to submit brief report in tabulated form identifying the previous observations and the current status.

Background of the case

Mr. Abdul Rashid Shaikh, FID, Lahore conducted inspection of company on 06.04.2016 to verify the GMP compliance and production activities. The FID noticed number of observations, which needs urgent attention and rectification. The observations include:-

Packing Hall:-

It is directed to:-

- i) Close the window and install air conditioner in the packing hall.
- ii) Provide the proper uniforms to all the workers.
- iii) Ensure the safety mechanism for sealing of poly bags over the bottles.
- iv) Improve the lights in the both autoclave and packing areas immediately.
- v) Ensure the properly leak test before the packing.
- vi) Review the SOPs for optical / psychical checking of the bottles.
- vii) Get the medical certificates of all the workers and maintain their record.
- viii) Improved the cleanliness of the areas immediately.
- ix) Close all other entrances except the main entrance and also ensure the air curtain.
- x) Review the SOPs, for release, dispatch and re-arrange the storage of the finish drugs like quarantine, released and rejected etc by covering the batches with the relevant colored ribbon for identification of their status.
- xi) Ensure the safety of the building / structure etc.
- xii) Install the temperature monitoring devices in the areas and also maintain their record.
- xiii) Improve the lights in the stores.
- xiv) Review and upgrade the SOPs for release of the finished drugs.
- xv) Get the certificates of boilers from the concerned department and also to ensure availability of the safety and fire fighting systems.

Quality Control Laboratory:-

It is directed to:-

- xvi) Proper installation of liquid particle counter as per its requirements.
- xvii) Make the TOC functional, as the management informed that the system is non-functional due to some technical reasons.
- xviii) Appoint the experienced microbiologist in the microbiological laboratory without fail.
- xix) Develop proper separate and independent quality assurance department under the supervision of the senior technical person and to review all the systems.

- xx) Ensure the proper storage of working standard and also directed to ensure availability of the reference standards for the quality control system.
- xxi) Upgrade the testing and manufacturing SOPs as per current pharmacopial requirements.
- xxii) Maintain the proper record for validation of the processes, areas maintenance, and change of HEPA filters of their HVAC system.

Action Taken by DRAP:- Accordingly, a show cause notice was served to the firm for above mentioned violations on 03.05.2016.

Reply of the firm:- The firm vide letter No. AZP/2016/Production/4481 dated 09.05.2016 submitted reply of showcause notice and informed that some of the observations have been rectified.

Proceedings of the 248th Meeting of CLB

Mr. Waseem Ikram, Quality Assurance Manager and Mr. Muhammad Javed Iqbal, Production Incharge of the firm M/s A..Z Pharmaceuticals Co. Ltd, 4-KM, Manga Raiwind Road Lahore appeared before the Board for personal hearing. Mr. Muhammad Javed Iqbal informed that he has joined the job on 18.06.2016. The reply of the observation has already been submitted. Mr. Jawed Bukhari and Mr. Syed Muid Ahmed, Member CLB inquired about the manufacturing procedures and technical staff. The representatives of firm fail to satisfy the Honorable Members. The representatives of the firm further added that they have appointed a new microbiologist.

Decision of the 248th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, reply of the firm, non serious attitude of director of the firm and on the poor knowledge of the technical staff of the firm, even the firm is involved in the manufacturing of sterile products, the Board decided to suspend the Drug Manufacturing License of the firm M/s A..Z Pharmaceuticals Co. Ltd, 4-KM, Manga Raiwind Road Lahore for a period of three months, under Section 41 of the Drugs Act, 1976 and Rule 12 of the Drugs (L,R&A) Rules, 1976.

Item No. II (Court Case)

Case No. i:- M/S MARION LABS, KARACHI V/S M/S ROYAL GROUP PHARMACEUTICALS, LAHORE

Background of the case

- The matter is related to a dispute between the manufacturer M/s Marion laboratory, Karachi and the exporter M/s Royal Group, Karachi. The subject case is subjudice between the companies, without any directions to the DRAP, from the August Court.
- The exporter M/s Royal Group, Karachi directly exported 10,260 vials of Marivell 500 ml manufactured by M/s Marion laboratory, Karachi, to Rwanda and Tanzania, by taking NOC from the Assistant Drugs Controller, Karachi.
- The consignment after reaching at the destination was reported substandard by the RBC (Rwanda Bio Medical Centre).
- The case was presented in 231st meeting of CLB held on 30.01.2013, wherein the Board directed both the firms to expedite the destruction of substandard batches "Injection Marivell-5 (Dextrose 5%) 500ml manufactured by M/s Marion Laboratories (Pvt) Ltd, Karachi which are lying at port Darussalam."
- To proceed further, the case was again presented in 232nd meeting held on 29-30th July, 2013. Both the firms (Royal Group and Marion Lab) were called before CLB wherein, the exporter M/s Royal Group gave presentation through its representative while M/s Marion Lab did not appear. The Board in the light of facts/details upheld its previous decision of destruction of substandard consignments of drugs "Injection Marivell-5 (Dextrose 5%) 500ml lying at Port Darussalam (Tanzania) and Rwanda in a manner as has been devised/agreed upon by both the parties in its previous meeting.
- Mr. Abdul Ghaffar, DDC (Pricing) was nominated as a representative from DRAP to accompany with M/s Marion Lab and Royal Group to proceed to Darussalam for destruction of substandard batches.
- The case was presented before CLB in its 235th Meeting alongwith the report of DRAP's nominee Mr. Abdul Ghaffar, DDC (Pricing).

The CLB in its 235th Meeting held on 15.05.2014 after thorough discussion and keeping the facts on records decided as follows:

" Committee/panel comprising of the following members have been constituted to investigate the matter (M/s Royal Group, Karachi Vs M/s Marion Laboratories (Pvt) Ltd, Karachi for subject matter medicines exported to Rwanda and Tanzania) in depth and submit a report to the Board in the next meeting of CLB for consideration:

- i) **A.Q. Javed Iqbal, Director (QA/LT), DRAP**
- ii) **Chief Drug Inspector, Sindh/ Member CLB**
- iii) **Syed Jawed Yousuf Bukhari, Member CLB**
- iv) **Area FID, Karachi**

Summary of the report on Visit to Rwanda & Tanzania by DRAP's Nominee

The DRAP nominee reported that during meeting with officials of Tanzania Revenue Authority (TRA), the TRA allowed to take the medicines under questions (lying at port of Tanzania destined to Rwanda) back to Pakistan for destruction. The exporter (M/s Royal Group, Karachi) informed the DRAP's nominee verbally as well as through email that officials of Rwanda Biochemical Centre, Government Rwanda did not allow them the destruction of rejected goods in Kigali (Rwanda) because they could not get permission from Rwanda Environmental Body for destruction of rejected goods. M/s Royal Group has been informed by the officials of Rwanda Biochemical Centre that once the issues of payment get settled then they will be allowed to take the rejected material back to Pakistan for final destruction.

The DRAP's nominee has summarized that the major issue is payment to the Shipping Company/Tanzania Revenue Authority/Tanzania Port Authority and Rwandan Government and being purely a commercial issue, it should be resolved by the M/s Royal Group, exporter and M/s Marion Laboratories, Karachi, manufacturer. DRAP has extended its maximum cooperation at all stages.

➤ In 241st Meeting of Central Licensing Board, The firm M/s Marion Lab, Karachi has brought the attention on the Rule-27 (b) of Drug Import & Export Rules, 1976 under Drugs Act, 1976. The CLB after through discussion and deliberation decided *“that the licensing authority under Drugs (Import & Export) Rules 1976 of Drugs Act, 1976 shall decide the case in the light of rule 27(b).”*

- The Rule 27(b) of the Drugs (Import & Export) Rules 1976 of Drugs Act, 1976 is reproduced as under:

“27. General provisions regarding export: *An exporter of drugs, except where such export is for personal use, shall comply with the following general provisions namely:--*

(b) The exporter shall, on being informed by the Registration Board or the Licensing authority or an officer authorized by it in this behalf or the Chairman of the Provincial Quality Control Board that any part of any batch of a drug has been found in contravention of any of the provisions of the Act or the rules made thereunder and on being directed so to do, withdraw the remainder of that batch from export and so far as practicable, recall the issues already made from that batch and dispose of it in such

manner as the Board, or, as the case may be, the licensing authority, may direct.”

- The decision of the Central Licensing Board for the implementation of the Rule 27(b) of Drugs (Import & Export) Rules, 1976, was conveyed to Deputy Director General (E&M), Karachi and Licensing Authority i.e. Mrs. Umme Laila, ADC for the implementation of the orders and submission of the compliance report.

Present Status

- On 23.09.2015 decision of the CLB made in its 241st meeting was conveyed to Mrs. Umme Laila, ADC (I&E), i.e. Licensing Authority and she was directed to implement decision of the CLB. Reminders were issued on 27.01.2016, 21.04.2016 and 25.05.2016.
- Mrs. Umme Laila, ADC (I&E) vide office letter No. 1-03/2013-ADC-I (K) dated 12.05.2016 submitted reply including detailed reply submitted by M/s Royal Group, Karachi on behalf of their counsel Mohsin Tayebaly & Co. She recommended that
 - *“Based on the proceedings and facts, initiation of any legal action against parties, legal consent / guidance should be sort from legal department of DRAP Islamabad as the case No. 1587/2012 dated 27.02.2015 filled by M/s Royal group Karachi and case No. 126/2015 dated 21.04.2015 filled by M/s Marion Labs, Karachi are under trial in Honorable High court of Sindh at Karachi.”*
- Decisions of the Honorable High Court of Sindh at Karachi in case No. 1587/2012 dated 27.02.2015 filled by M/s Royal group Karahci and case No. 126/2015 dated 21.04.2015 filled by M/s Marion Labs, Karachi are as under

Case No. 1587/2012 dated 27.02.2015	Case No. 126/2015 dated 21.04.2015
“The defendant (M/s Marion Labs, Karachi) is directed to full fill its commitment of destroying the drugs in question after bring them back / re-exporting them to Pakistan from wherever they are lying, at present at his cost for ultimate destruction of the same in Pakistan. This will include payment of demurrages charges and charges for obtaining the NOC from the Tanzininan Port Authorities and shipping charges. The plaintiff (M/s Royal Group, Karachi) shall also participate in obtaining the	“Through instant high court appeal, the appellant has impugned the order dated 27.02.2015 passed by the learned Single Judge of this Court in Suit No. 1587/2015, whereby the appellant has been directed to implement the terms of Settlement dated 29.04.2013 reached between the parties during pendency of the suit, on the grounds that while passing the impugned order, the learned Single Judge has not taken cognizance of the changed circumstances as well as non-

<p>required NOC from the port authorities of Tanzania as agreed by the Plaintiff in the settlement. The plaintiff the Royal Group is also directed to account for the money that it has paid to the shipping line as well as other accounts of entire expenditure required by the defendant and of the amount US dollars 7890/- paid by the defendant to the plaintiff for payment to freight Africa and, facilitate the defendant in obtaining the necessary NOC form the government concerned for the re-export of the aforesaid drugs. The defendant shall be entitled to lay of claim of such additional charges against the plaintiff, the payment / re-imburement of which shall be determinant in accordance with the law in separate proceeding / suit”</p>	<p>compliance of the terms of the Settlement by the respondent, due to which, the appellant could not as such implement the terms of settlement. Per learned counsel, the learned Single Judge through impugned order has even modified the terms of the Settlement reached between the parties, hence requests that the impugned order may be set-aside”.</p>
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- I. Accordingly on the recommendations of the Mrs. Umme Laila, ADC (I&E), the case was referred to Division of Legal Affairs for seeking the opinion that whether:-
 - i. The firm M/s Royal Group, Karachi may be called for personnel hearing in forthcoming meeting of CLB for not complying the orders of CLB made in its 241st meeting held on 15.05.2015 despite reminders.
 - ii. Any punitive action can be taken against M/s Royal Group, Karachi keeping in view the decision of the 1587/2012 and 126/2015.

- II. The Director Legal Affairs opined that *“In view of the records placed on this file. As no order baring the DRAP for action as proposed is available, the proposal seems workable.”*

Proceedings of the 248th Meeting of CLB

DDC (QA) informed to the Board that a letter of personnel hearing was issued to the firm M/s Royal Group, Karachi on 28.06.2016, Mrs. Umm-e-Laila, ADC (I&E), Karachi was informed telephonically regarding the case and copy of the letter was also sent to

ADC (I&E) through whatsapp. No representative of the firm M/s Royal group Karachi appeared before the Board. The Board go through decision of the Honorable High Court of Sindh at Karachi in its orders 1587/2012 dated 27.02.2015 and 126/2015 dated 21.04.2015. The Board also considers the opinion of the Division of the Legal Affairs regarding the case. Representative from Ministry of Law, Justice and Human Rights study the case in detail and gave his valuable input on the case.

Decision of the 248th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, decision of the Honorable High Court of Sindh at Karachi and valuable input of representative of Division of Law, Justice and Human Rights, the Board decided to:

1. uphold its previous decision made in 241st meeting of CLB held on 15.05.2015, in which it was decided that:-

“The licensing authority under Drugs (Import & Export) Rules 1976 of Drugs Act, 1976 shall decide the case in the light of rule 27(b).”

- The Rule 27(b) of the Drugs (Import & Export) Rules 1976 of Drugs Act, 1976 is reproduced as under:

“27. General provisions regarding export: *An exporter of drugs, except where such export is for personal use, shall comply with the following general provisions namely:--*

(b) The exporter shall, on being informed by the Registration Board or the Licensing authority or an officer authorized by it in this behalf or the Chairman of the Provincial Quality Control Board that any part of any batch of a drug has been found in contravention of any of the provisions of the Act or the rules made thereunder and on being directed so to do, withdraw the remainder of that batch from export and so far as practicable, recall the issues already made from that batch and dispose of it in such manner as the Board, or, as the case may be, the licensing authority, may direct.”

2. The Board further decided to Direct the Licensing Authority {ADC (I&E), Karachi} to:-
- a. Take further action in the light of Rule 24(iv) of Drugs (Import and Export) Rules, 1976, which states that:-

“Rule 24 (iv)

Conditions of License to export drugs: A license to export drugs other than finished drugs shall be subject to the following conditions:-

(iv) The licensee shall, on being informed by the licensing authority that any part of any batch of a drug has been found by the licensing authority not to conform to the required specification and on being directed so to do, withdraw the remainder of that batch from export and so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that batch. ”

- b. Direct the Licensing Authority to comply the directions of the CLB and dispose off the case under Rule 29 of the Drugs (Import & Export) Rules, 1976, which is reproduced as under:-

“Rule 29

Suspension and cancellation of license to export drugs: *If the manufacturer or licensee fails to comply with any of the conditions of license to export drugs or violates any of the provisions of the Act or the rules made thereunder, the licensing authority may, after giving the licensee an opportunity of being heard, by an order in writing stating the reasons therefore, suspend or cancel it for such period as it thinks fit or cancel for all times, either wholly or in respect of some of the drugs, to which it relates or, if the nature of offence is so serious that it is likely to endanger the public health, may prohibit the export of all other drugs of the said manufacturer:*

Provided that a person who is aggrieved by the suspension or cancellation of his license, may within sixty days of the receipt of such order, appeal to the Appellate Board. ”

Item No. III SUPPLEMENTARY AGENDA

CASE NO. I:- M/S A.H PHARMACEUTICALS (PVT) LTD, FAISALABAD

Background:-

Inspection of the company was conducted on 11.02.2016 by Mr. Ajmal Sohail Asif, FID, Lahore with reference to this Authority's letter of even number dated 08.09.2014 to verify the GMP compliance and production activities of the firm. The FID noticed a number of critical observations in the sterile manufacturing area.

Action taken by DRAP:-

A suspension of production order was served to the firm on 08.03.2015. The firm vide letter No. Nil dated 13.04.2016 submitted compliance report and informed that all the observations have been rectified. The Director QA< constituted following panel to conduct the inspection of the firm in order to check the improvements made by the firm:-

- i) Director, Drugs Testing Laboratory, Faisalabad.
- ii) Mr. Zia Husnain, FID, Lahore
- iii) Mr. Ajmal Sohail Asif, FID, Lahore

The panel including Mr. Ajmal Sohail Asif, FID and Mr. Zia Husnain, FID, Lahore conducted inspection of the firm on 06.06.2016. One member of the panel i.e. Mr. Shafiq Khan, Director DTL Faisalabad did not join the panel for inspection. Inspection was scheduled after proper coordination and mutual consent of all panel members, however, when panel reached the premises, Director DTL Faisalabad informed that he could not join the panel for inspection because he has been suspended by the Punjab Government and is no more Director as the day of inspection.

Updated status

The panel inspected the firm on 03.06.2016 & 06.06.2016 and submit report on approved Schedule (B-II) cGMP format and also submit report in tabulated form identifying the previous observations and the current status.

Recommendations of the panel

“ The management of the company expressed very firm commitment for earlier compliance to the suggestions and for further improvements as planned and committed.

Keeping in view the improvements made by the firm, earlier compliance and positive attitude of the management towards betterment, the firm may be allowed to resume the production in all sections.”

Recommendations of the panel was placed before the Director QA< for resumption of production, as the CLB in its 237th meeting has delegated the powers of “resumption of production – subject to the inspection and recommendation of the panel comprising at least 03 members” to Director (QA<). The Director QA< gave remarks on the note sheet of the related file that:-

“ Since CLB's meeting is schedule on 13.07.2016 hence its better to place the matter before Board for its appraisal / concurrence.”

Proceedings of the 248th Meeting of CLB

The case was discussed in detail. The Board critically evaluated panel inspection report conducted on 03.06.2016 & 06.06.2016 and considered recommendations of the panel, verification of the rectification of the shortcomings noted and detailed report on approved Schedule B-II proforma under Drugs (LR&A) Rules, 1976.

Decision of the 248th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and inspection report of the firm, on approved Schedule B-II proforma under Drugs (LR&A) Rules, 1976 and detailed report in tabulated form, conducted on 03.06.2016 & 06.06.2016, the Board decided to: -

- Resume production activities of the firm M/s A.H Pharmaceuticals (Pvt) Ltd, Faisalabad.
-

CASE NO. II:- M/S Zaynoon Pharmaceuticals (Pvt) Ltd, Peshawar

Background:-

Dr. Farnaz Malik, Chief, NIH, Islamabad submitted monthly activity report for the month of July, 2015. The report shows that, 01 Batch of Children NAFPOL (Paracetamol) Suspension 60ml, manufactured by M/s Zaynoon Pharmaceuticals, Peshawar has been declared substandard. This sample was sent by the Secretary, PQCB, Punjab, Lahore for appellate testing. The Chairman, QC and Director (QA/LT) took a serious notice on such violation. The Director (QA/LT) has constituted the following panel for thorough GMP inspection of the firm, on prescribed GMP proforma.

- a. Prof. Dr. Muhammad Saeed, Member, CLB
- b. Mr. Imranullah, Provincial Drugs Inspector, KPK
- c. Area FID, Peshawar

Action taken by DRAP:-

A showcause notice / suspension of production order was served to the firm on 11.11.2015. The firm vide letter No. ZPPL/16/002 dated 09.02.2016 submitted compliance report and informed that all the observations have been rectified. The case was placed before the CLB in its 245th meeting held on 30.12.2015 wherein the Board has decided as under:-

*After thorough discussion, keeping in view pros and cons of the case and the available record, the Board has decided to:- *

- i. Continue the suspension of production under rule 12 of the Drugs (LR&A) Rules, 1976 of the Drugs Act, 1976 till the purchase of HPLC and stability chamber.*
- ii. The panel which was constituted by the Director (QA/LT) for the purpose of cGMP inspection will verify the purchase of the above stated equipments.*
- iii. Conduct panel cGMP inspection of the firm, on approved Schedule B-II format under the Drugs (LR&A) Rules, 1976, the panel will submit report within fifteen days, in tabulated form identifying the previous observations and the current status, by the following members:-*
 - a) Prof. Dr. Muhammad Saeed, Member, CLB*
 - b) Mr. Imranullah, Provincial Drugs Inspector, KPK*
 - c) Area FID, Peshawar*

Updated status

The panel re-inspected the firm on 11.05.2016 and submitted report in tabulated form identifying the previous observations and the current status:-

Recommendations of the panel

“ Therefore the panel recommends to restore the production of the firm.”

Recommendations of the panel was placed before the Director QA< for resumption of production, as the CLB in its 237th meeting has delegated the powers of “resumption

of production – subject to the inspection and recommendation of the panel comprising at least 03 members” to Director (QA<). The Director QA< gave remarks on the note sheet of the related file that:-

“ Since CLB’s meeting is schedule on 13.07.2016 hence its better to place the matter before Board for its appraisal / concurrence.”

Proceedings of the 248th Meeting of CLB

The case was discussed in detail. The Board critically evaluated panel inspection report conducted on 11.05.2016 & 13.07.2016 and considered recommendations of the panel, verification of the rectification of the shortcomings noted and detailed report.

Decision of the 248th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and detailed inspection report of the firm in tabulated form, conducted on 11.05.2016 & 13.07.2016, the Board decided to: -

- Resume production activities of the firm M/s Zaynoon Pharmaceuticals (Pvt) Ltd, Peshawar.
-

CASE NO. III:- M/S MEDISAVE PHARMACEUTICAL, LAHORE

Background:-

Inspection of the company was conducted on 09.12.2015 by Dr. Sheikh Akhter Hussain, DDG (E&M) and Mr. Asim Rauf, area FID, Lahore to verify the GMP compliance and production activities of the firm. The panel noticed a number of critical observations in the sterile liquid for injection (Infusion) and Cephalosporin Injection Section.

Action taken by DRAP:-

A show cause notice / stop production order in Sterile Liquid Infusion Section (General) & Dry Powder for Injection Section (Cephalosporin) was served to the firm on 13.01.2016. The firm vide letter No. Nil dated 19.01.2016 submitted compliance report and informed that all the observations have been rectified. The case was discussed in the 246th meeting of CLB wherein the Board has decided to:-

Conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members.

- i. Dr. Ikram ul Haq, Member, CLB
- ii. Mr. Asim Rauf, FID, Lahore
- iii. Mrs. Aisha Irfan, FID, Lahore

The Board decided to direct the panel to also submit report in tabulated form identifying the previous observations and the current status. and

The production will remain stop till recommendation by the panel for resumption of production and accordingly approval from the Board.

Updated status

The panel inspected the firm on 09.05.2016 and submit report on approved Schedule (B-II) cGMP format and also submit report in tabulated form identifying the previous observations and the current status as under:-

Observations noted by FID on 09.12.2015	Improvements noted by the panel on 09.05.2016
The stock i.e., empty bottles were lying on floor in cooling zone without any status.	Management has removed the bottles. Area was satisfactory.
Flip off caps were found lying in sterile area without any status.	-do-
The doors for washing, filling etc were found open thus pressure was not maintained.	The doors were found properly closed. Different pressures were found maintained.
Drains were found open in infusions injectable section. Filling pipe was being passed though open door.	Drains were closed. No. Non-conformance was observed.

Dustbins were found open with different trash material.	The observation was attended.
Ceftriaxone empty containers were lying in the cephalosporin sterile area.	The containers were removed. Area was satisfactory.
Different articles i.e., brush screws etc were found lying in the hatch in the cephalosporin area.	Non-conformance was removed.
Epoxy needs re-coating in above areas as various patches without epoxy could be seen etc.	Area was found satisfactory.
The conditions were not GMP compliant. The humidity level in one room in Infusion section was 67%. In addition to the observations noted above the panel further directed the management of the firm to stop the manufacturing activities in Injectable General (Infusion) and Cephalosporin Dry Powder Injectable Section and attend to the above observations including improving GMP compliant. It was directed to provide compliance report at the earliest.	Area was found satisfactory.

Recommendations of the panel

The panel gave 206 in rating 'A' and 68 in rating 'B' on approved Schedule B-II cGMP format. Moreover the panel recommended as under:-

The firm M/s Medisave Pharmaceutical, 578-579, Sundar Industrial Estate, Lahore has attended to the non-conformance observed on 09.12.2015 along-with overall improvement as per their abilities. The firm was also planning to purchase liquid particle counter (LPC). The panel informed them this is essential to have for Quality control of injectable. Firm intended that a quotation process had already been initiated and documentation thereof was provided. The panel advised the firm to immediately finalize the purchase and install the instrument in order to up-grade quality control operations. The overall status of the firm was found to be satisfactory in terms of actions taken by the firm for improvements in the light of inspection dated 09.12.2015.

The CLB in its 237th meeting has delegated the powers of "resumption of production – subject to the inspection and recommendation of the panel comprising at least 03 members" to Director (QA<). The Director QA< gave remarks on the covering letter of the inspection report that:-

“ *Place the case before the CLB.* ”

Proceedings of the 248th Meeting of CLB

The case was discussed in detail. The Board critically evaluated panel inspection report conducted on 09.05.2016 and considered recommendations of the panel, verification of the rectification of the shortcomings noted and detailed report on approved Schedule B-II proforma under Drugs (LR&A) Rules, 1976.

Decision of the 248th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and inspection report of the firm, on approved Schedule B-II proforma under Drugs (LR&A) Rules, 1976 and detailed report in tabulated form, conducted on 09.05.2016, the Board decided to: -

- Resume production activities of the firm M/s Medisave Pharmaceuticals, Lahore.

CASE NO. IV:- M/S IDEAL PHARMACEUTICAL INDUSTRIES, LAHORE

Background:-

Inspection of the company was conducted on 11.12.2015 by Mr. Ajmal Sohail Asif, FID and Mrs. Majida Mujahid, FID, Lahore to verify the GMP compliance and production activities of the firm. The panel noticed a number of severe shortcomings and gross violations.

Action taken by DRAP:-

A show cause notice / stop production order in all sections was served to the firm on 21.01.2016. The firm vide letter No. Nil dated 27.01.2016 submitted compliance report and informed that all the observations have been rectified. The case was discussed in the 246th meeting of CLB wherein the Board has decided to:-

Conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976 by the following members.

- i. Dr. Ikram ul Haq, Member CLB
- ii. Mrs. Majida Mujahid, FID, Lahore
- iii. Mr. Ajmal Sohail Asif, FID, Lahore

The Board further decided to ask the panel to also submit the report in tabulated form identifying the previous observations and the current status of the observations noted by the panel in its inspection conducted on 11.12.2015. and

The production will remain stop till recommendation by the panel for resumption of production and accordingly approval from the Board.

Updated status

The panel inspected the firm on 23.05.2016 and submit report in tabulated form identifying the previous observations and the current status.

Recommendations of the panel

In the light of instant inspection and positive attitude of firm toward GMP compliance, the panel is of the view that firm may be allowed to resume production in following sections:-

- i. Oral Liquid Section (General)
- ii. Tablet Section (General)
- iii. Capsule Section (General)

The CLB in its 237th meeting has delegated the powers of “resumption of production – subject to the inspection and recommendation of the panel comprising at least 03 members” to Director (QA<). The Director QA< gave remarks on the covering letter of the inspection report that:-

“ *Please include in agenda of CLB meeting.* ”

Proceedings of the 248th Meeting of CLB

The case was discussed in detail. The Board critically evaluated panel inspection report conducted on 23.05.2016 and considered recommendations of the panel, verification of the rectification of the shortcomings noted and detailed report on approved Schedule B-II proforma under Drugs (LR&A) Rules, 1976.

Decision of the 248th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and inspection report of the firm, on approved Schedule B-II proforma under Drugs (LR&A) Rules, 1976 and detailed report in tabulated form, conducted on 23.05.2016, the Board decided to: -

- Resume production activities of the firm M/s Ideal Pharmaceutical Industries, Lahore in following sections, on the recommendation of the panel:-
 - i. Oral Liquid Section (General)
 - ii. Tablet Section (General)
 - iii. Capsule Section (General)
-

CASE NO. V:- M/S QUAPER (PVT) LTD, SARGODHA

Background:-

Inspection of the company was conducted on 22.02.2016 by Dr. Sheikh Akhter Hussain, DDG (E&M), Mr. Asim Rauf, FID, Abdul Rashid Sheikh, FID and Mr. Ajmal Sohail Asif, FID, Lahore to verify the GMP compliance and production activities of the firm. The panel noticed a number of severe shortcomings and gross violations.

Action taken by DRAP:-

A suspension of production order in all sections was served to the firm on 07.03.2016. The firm vide letter No. Nil dated 07.03.2016 submitted compliance report and informed that all the observations have been rectified. The Director (QA/LT) constituted following panel for thorough GMP inspection of the firm:-

- i) Director, Drugs Testing Laboratory, Faisalabad.
- ii) Mr. Zia Husnain, FID, Lahore.
- iii) Mr. Asim Rauf, Area FID, Lahore

Updated status

The panel inspected the firm on 30.05.2016 and submit report on approved Schedule (B-II) cGMP format and also submit report in tabulated form identifying the previous observations and the current status.

Recommendations of the panel

The panel gave 107 in rating 'A' and 78 in rating 'B' on approved Schedule B-II cGMP format. Moreover the panel recommended as under:-

Panel of inspectors recently inspecting the unit has gone through the up gradation steps taken by the firm as above. However the actual compliance to GMP operations could not be ascertained as the unit was closed. Panel of inspectors accordingly reached to the following recommendations:-

- i. Recommended for resumption of operations in the light of the up-gradations done by the management.
- ii. To re-evaluate the unit in production mode to assess the GMP compliance to various operations, in the next two months by the panel as the practical operations related to inspection pro-forma could not be evaluated due to non-operational mode.

The CLB in its 237th meeting has delegated the powers of "resumption of production – subject to the inspection and recommendation of the panel comprising at least 03 members" to Director (QA<). The Chairman QC gave remarks on the inspection report that:-

“ *Prepare supplementary agenda for Board meeting.* ”

Proceedings of the 248th Meeting of CLB

The case was discussed in detail. The Board critically evaluated panel inspection report conducted on 30.05.2016 and considered recommendations of the panel, verification of the rectification of the shortcomings noted and detailed report on approved Schedule B-II proforma under Drugs (LR&A) Rules, 1976.

Decision of the 248th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record and inspection report of the firm, on approved Schedule B-II proforma under Drugs (LR&A) Rules, 1976 and detailed report in tabulated form, conducted on 30.05.2016, the Board decided to: -

- Resume production activities of the firm M/s Quaper (Pvt) Ltd, Lahore.

Quality Control Cases
Old case

Case No.01

Subject: - **Manufacture & Sale of Spurious, Sub-Standard, Adulterated and Un-Registered Drugs etc. by Masil Khan and others at House No.3, Located at Sardar Colony, Charsadda Road, Peshawar.No. F.04-02/2014-CQC**

The case was presented before the Central licensing Board in its 248th meeting held on 13-07-2016 as agenda of the case with case background as follows:-

Brief of the case

The FID Peshawar, DDG (E&M) and ADC, DRAP, Peshawar along with team of FIA, raided a residential house No. 3, located at Sadar Colony, Charsadda Raod, Peshawar on 19-02-2014. Huge quantities of spurious medicines of multinational brands were being manufactured at the said premises at the time of raid/inspection. The FID made seizure of labels, cartons, vials, sealing machine and other materials vide Form-2 and samples of some drugs were also drawn for test/analysis vide Form-3. FID Peshawar in his final report of the case has submitted that aforesaid samples of some drugs have been declared Spurious, Substandard, Adulterated, Un-registered drug products and in violation of Section 23(1)(h) of the Drugs Act 1976 by the Federal Government Analyst, CDL, Karachi. The test reports of these samples have already been provided to the firm during the course of investigation of the case by the FID. The results of the Federal Government Analyst (FGA) regarding the samples drawn are summarized below:-

S.No.	Name of Drugs	Mfg by.	Batch No.	Expiry Date.	Remarks on test report with its No.
1.	Rociphin 1gm Inj. (Cefriaxone)	H.Hoffman Roche Switzerland (Repacked by Martin Dow Karachi)	B0050	02-2016	(Spurious & Substandard) RIP.49/2014 dated 27-03-2014 (page 23/corr)
2.	Tazocine EF 4.5gm Inj.	Wyeth Lederle Italy (Repacked by Wyeth Pakistan Karachi)	AGP8/11	12.2014	(Spurious & Substandard) RIP.50/2014 dated 25-04-2014 (page 88/corr)
3.	Fosfomycin 1.0 gm Inj.	M/s China Chongging, China.	110681	06-2014	(Substandard) RIP.52/2014 dated 25-04-2014 (page 26/corr)
4.	Fortun 1gm Inj	Glaxo Smithkline, Pakistan Ltd, Karachi	LBF6/3	Nil	(Spurious & Substandard) RIP.53/2014 dated 27-03-2014 (page 22/corr)
5.	Glucantone Inj.1.5g/5 ml	M/s HauptPharma Liveron, France.	0868	01/2019	(Adulterated, Substandard & Un-registered drug product) RIP.54/2014 dated 25-04-2014 (page 91/corr)
7.	Sulzone 2.0g Inj.	M/s Suzhou Dawnrays Pharma China (Marketed by BioCare Pharma Karachi)	120232001	09/2015	(Spurious & Substandard) RIP.55/2014 dated 25-03-2014 (page 24/corr)

8.	Decadron Inj.	M/s OBS Pakistan Pvt Ltd, Karachi	D697	02/2015	(Spurious & Substandard) RIP.83/2014 dated 10-04-2014 (page 38/corr)
9.	Heparin Leo Inj.	M/s Leo Pharma, Denmark	DE3171	10/2015	(Spurious & Substandard) RIP.56/2014 dated 25-04-2014 (page 25/corr)
10	Vial without labels having white powder	Nil	Nil	Nil	Contravention of Section 23(1)(h) of Drugs Act 1976 RIP.57/2014 dated 10-04-2014 (page 95/corr)
11	Red Coloured Capsule without any label	Nil	Nil	Nil	Contravention of Section 23(1)(h) of Drugs Act 1976 RIP.58/2014 dated 10-04-2014

The FID in his report had also mentioned that portions of samples were also sent to the claimed manufacturers for verification of their genuineness and in response M/s GSK, Karachi, M/s Wyeth Pakistan Ltd, Karachi, M/s Martin Dow, Karachi, M/s Biocare Pharma Lahore and M/s OBS, Pakistan Karachi, have disowned these drugs. Hence the products were declared as of Spurious quality are under Section 3(z-b)(ii) of the Drugs Act 1976. The explanation letters were also sent to the accused Masil Khan S/o Mir Wais Khan by the FID but no reply was received. The FIR No.12/2014 dated 19-02-2014 was lodged with FIA, ACC, Peshawar for violation of Section 23(1)(a)(i), 23(1)(a)(vii) & 23(1)(b) of the Drugs Act 1976. One of the accused namely Masil Khan S/o Mir Wais Khan is in jail since then. The FIA submitted the investigation challan of the subject case on 03-03-2015 in the office of FID Peshawar and held the following accused persons responsible for the aforesaid offences.

- i. Masil Khan S/o Mir Wais Khan, R/o Sardar Colony Cahrsadda Road, Peshawar
- ii. Shakeel S/o Mir Wais Khan, R/o Sardar Colony Cahrsadda Road, Peshawar.
- iii .AlamZaib S/o Aurangzaib R/o Muslimabad, Station Koroona, Mardan Road Charsadda.
- iv. Muhammad Amir S/o Aurangzaib R/o Muslimabad, Station Koroona, Mardan Road Charsadda.

The FID had also requested for permission to prosecute these accused persons in Drug Court Peshawar for violation of Section 23 punishable under Section 27 of the Drugs Act 1976.

The case was placed before Central Licensing Board in its 241st meeting held on 15th May 2015 where the Board had considered the matter and decided as under:-

The Board after thorough discussions and deliberations considered the above case and decided as under:-

- **The Board allowed prosecution after fulfillment of all legal and codal formalities under the Drugs Act 1976 and relevant rules framed there under.**

Current Status: Request for permission for Prosecution

“The permission given by the Board vide its 241st meeting was conveyed to FID Peshawar for taking further necessary action in the matter. Now the FID Peshawar has requested to grant the

permission for prosecution of another (03) three accused persons who were shown absconder in previous investigation and now the Federal Investigation. Agency has also held responsible following three accused:-

- i. Haji Abdul Karim S/o Mir Wais resident of Sardar Colony, Budany Pul Charsadda Road Peshawar.
- ii. Amir Ali resident of Bandar Road Sanda Stop Lahore
- iii. Chaudhry Arshad of Lahore Printing press Lahore.”

Accordingly show cause notice was served to above 03 nominated accused persons and were called for personal hearing before the Central Licensing Board in its 248th meeting held on 13/07/2016 by given them the chance to be heard.

Proceeding of the Board:

The Board waited for the accused persons to appear before it but till closing of the Meeting but none of the accused persons appeared before the Board for giving opportunity of Personal Hearing

The Honorable Members of the Board discussed the case in detail and were in view that it was better if the FID launch the prosecution as was allowed in 241st meeting held on 15th May 2015.

Decision of 248th meeting of Central Licensing Board

The Board after detailed discussion, deliberation and keeping in view the facts of the case, and all taking other relevant pros and cons and cases unanimously decided to prosecute the following persons for contravention of section 23 of the Drugs Act 1976 punishable under section 27 of the Drugs Act 1976 with the direction to the area Federal Inspector of Drugs (FID) to launch the prosecution within 15 days in the Drug Court Peshawar and report compliance to the DRAP accordingly.

- i. Haji Abdul Karim S/o Mir Wais resident of Sardar Colony, Budany Pul Charsadda Road Peshawar.
- ii. Amir Ali resident of Bandar Road Sanda Stop Lahore
- iii. Chaudhry Arshad of Lahore Printing press Lahore.”

New Cases

Case No.02

PERMISSION FOR PROSECUTION FOR THE OFFENCE U/S 23 PUNISHABLE U/S 27 OF THE DRUGS ACT 1976.

The case was presented before the Central licensing Board in its 248th meeting held on 13-07-2016 as agenda of the case with case background as follow:

Brief of the case

The FID Lahore Mrs Aisha Irfan inspected/raided on 02-12-2014 (As corrected vide FID letter No. 9158/2016-DRAP (L-III) dated 21-06-2016 which in her previous letter was 01-12-2014) along with Mr. Ajmal Sohail Asif, FID, Mr. Zia Husnain FID (V), Mr. Shaikh Rasheed FID, Mr. Akbar Ali ADC and FIA raiding party headed by Mr. Asif Ali Mian Assistant Director FIA, Mr. Ijaz Ahmad Inspector FIA and Mr. Muhammad Khan Niazi, ASI FIA, the premises of M/s Khalid Pharmacy, 6-S Lalik Chowk Phase 2 DHA Lahore . At the time of inspection/raid Mr. Muhammad Abdul Rehman S/o Sohail Akhtar Khan (purchaser) was present and Mr. Khalid Mehmood Butt S/o Yasin Butt (Proprietor) and (Qualified person) Mr. Zuhair Mehdi s/o Shaikh Zafar Mehdi were absent at the time of raid. The FID had mentioned that during inspection huge quantity of un-registered (smuggled/unwarranted) drugs including different brands of sexual drugs and many other branded drugs were available at the premises.

The FID seized un-registered drugs on prescribed form-2 and nominated following persons as suspected accused.

- i. Mr. Muhammad Abdul Rehman S/o Sohail Akhtar Khan resident of house no.773 street no.22 Muhalla Mustafaabad Lahore Cantt. (Purchaser/Present)
- ii. Mr. Khalid Mehmood But S/o Yasin Butt, Resident of H# 34 Krishna Gali Banswala Bazar Lahore Proprietor.
- iii. Zuhair Mehdi s/o Shaikh Zafar Mehdi house 38-B, gali No. 1 muhalla Pak Nagar Akram Road Lahore (Qualified person).

The permission on behalf of the Central licensing Board had been granted telephonically by Dr. AQ Javed Iqbal, Director QA/LT, DRAP Islamabad to the FID Lahore, Mrs Aisha Irfan for lodging FIR under the rules and subsequently in writing. The FID was allowed to proceed as per law against the nominated persons and to submit the report with recommendations.

The FID vide her letter dated 13-04-2015 informed that while the case was under investigation, accused were released on bail by the Chairman Drug Court Lahore, she forwarded the copy of incomplete challan, submitted to her by the FIA Lahore, along with her letter and informed that complete challan would be submitted when received.

In response to the FID's letter, she was asked to conduct her own inquiry vide Quality Control Section letter No. 04-13/2014-QC dated 05-05 2015.

The FID in her letter No. 9158/2016-DRAP (L-III) dated 21-06-2016 mentioned that the said case of M/S Khalid Pharmacy situated at 6-S Lalik Chowk Phase-II, DHA Lahore was presented before the Honorable Chairman Drug Court, Lahore on 20-06-2016. The Honorable Chairman Drug Court directed to submit the complaint/challan of M/s Khalid Pharmacy situated at 6-S Lalik Chowk Phase-II DHA Lahore with immediate effect, i.e. before 18-07-2016.

Accordingly the FID Lahore Aisha Irfan has requested to place the matter before the **Central Licensing Board for grant of permission for prosecution in the Drug Court Lahore before the 18-07-2016.**

Since the case submitted by the FID Mrs Aisha Irfan was not complete, hence she was asked to submit complete case with its all details consisting both the findings of FIA and herself supported by the necessary documents.

Accordingly the FID submitted complete case containing copy of the complete challan submitted by the FIA and her investigation alongwith recommendations wherein she has nominated the following accused persons:-

1. Mr. Muhammad Abdul Rehman S/o Sohail Akhtar Khan (purchaser/present) resident of house no.773 street no.22 MuhallaMustafaabad Lahore Cantt.	2. Mr. Khalid Mehmood Butt S/o Muhammad Younas Butt, Proprietorof M/s Khalid Pharmacy, 6-S Lalik Chowk Phase 2 DHA Lahore / absent. Resident of H# 34 street 02 Krishna GaliBansawala Bazar Lahore.
3. Zuhair Mehdi s/o Shaikh Zafar Mehdi (Qualified Person M/s Khalid Pharmacy, 6-S Lalik Chowk Phase 2 DHA Lahore) house 38-B, gali No. 1 muhalla Pak Nagar Akram Road Lahore	

Accordingly show cause notice dated 27-06-2016 was served to all above nominated accused persons giving them the opportunity of personal hearing before the Central Licensing Board.

The area FID was directed to ensure the delivery of show cause notices to the accused persons. The FID telephonically confirmed receiving of the show cause notice by the said accused persons.

The aforesaid accused persons were called for personal hearing before the CLB in its 248th meeting scheduled to be held on 13-07-2016.

Proceeding of the Board:

The Board waited for the accused persons to appear before it but till closing of the Meeting none of the accused persons appeared before the Board.

Decision of the Board

The Board after detailed discussion, deliberation and keeping in view the facts of the case and direction of the Honorable Drug Court Lahore, unanimously decided to prosecute the following persons for contravention of section 23 of the Drugs Act 1976 punishable under section 27 of the Drugs Act 1976 with the direction to the area Federal Inspector of Drugs (FID) to launch the prosecution forthwith and ensure submission before 18th July 2016 and report to the Central Licensing Board.

1. Mr. Muhammad Abdul Rehman S/o Sohail Akhtar Khan (purchaser/present) resident of house no.773 street no.22 MuhallaMustafaabad Lahore Cantt.	2. Mr. Khalid Mehmood Butt S/o Muhammad Younas Butt, Proprietorof M/s Khalid Pharmacy, 6-S Lalik Chowk Phase 2 DHA Lahore / absent. Resident of H# 34 street 02 Krishna GaliBansawala Bazar Lahore.
3. Zuhair Mehdi s/o Shaikh Zafar Mehdi (Qualified Person M/s Khalid Pharmacy, 6-S Lalik Chowk Phase 2 DHA Lahore) house 38-B, gali No. 1 muhalla Pak Nagar Akram Road Lahore	

Case No.3

Manufacturing and Sale of Unlawful Drugs recovered from M/s Cherwel Enterprises Gadoon Amazai, District Swabi.No. F.03-51/2014-QC

The case was presented before the Central licensing Board in its 248th meeting held on 13-07-2016 as agenda of the case with case background as follows:

Brief of the case

The FID Peshawar Mr. Rehmatullah Baig Alvi vide letter No.F.10.107-114/2014-Cherwel Ent-DRAP1290 dated 25th April 2016 informed that he and Syed Welayat Shah DDG (E&M) Peshawar along with FIA team comprising of Mr. Naseer Khan FIA Inspector Mr. Fazle Akbar FIA Inspector and Mr. Zafar Iqbal Sub-Inspector FIA on 18-10-2014 inspected the premises named Cherwel Enterprises situated at plot No.187/2 Lane-9 Gadoon Amazai Industrial Estate Swabi. During inspection huge quantity of drugs were recovered and seized. Raw Materials Labeling& packaging (printing Materials) were also recovered. Samples of the suspected drugs/materials were taken. The samples were sent to CDL Karachi for the purpose of test analysis on Form4. The FID stated that whole procedure of sampling under section 19 of the Drugs Act 1976 was adopted including portions to manufacturers and warranties manufacturers etc. The FID further stated that machines recovered during the raid were recorded on Form-I under Section 18(1) for not to dispose off. The premises was sealed and Ramzan Chowkidar was held responsible to keep a watch on the factory and its machinery till the decision of the case. The CDL Karachi declared the drugs by giving opinion mentioned against each.

Name of Drug	Manufactured by	Batch No.	Expiry Date	Remarks/Test Report No.
Viptowel tab. 1000mg	Cherwell Enterprises Gadoon	001	03.2016	Unregistered/ Substandard/ Spurious RIP.156/2014 dated 14-11-2014
Accutane Cap 20 mg	Aims Pharma Islamabad	Nil	Nil	Counterfeit Spurious RIP.157/2014 dated 12-11-2014
Gevolox Plus tab	Hilton Pharma Karachi	Nil	Nil	Substandard Spurious RIP 158/2014 dated 02-12-2014
Suspected to be Evolox 400mg tab Found without strip	Bayer schering Karachi	Nil	Nil	Substandard/spurious RIP.159/2014 dated 17-11-2014
White Powder suspected to be Xanax (Alprazolam)	Pfizer Karachi	Nil	Nil	Substandard/Spurious RM.180/2014 dated 13-11-2014
Lactos Monohydrate Powder (Suspected to be monohydrate Lactose)	Kerry ingredient	14010	Use within 03 years	Spurious/Unregistered RM.181/2014 dated 12-11-2014

Cap well-D tab	Cherwell Enterprise Gadoon	Nil	12.2016	Unregistered/spurious RIP.160/2014 dated 13- 11-2014
Evemol soft Gel Cap. 600mg	Cherwell Enterprises Gadoon	Nil	Nil	Unregistered/spurious RIP.161/2014 dated 13- 11-2014

2. In reference to manufacture's portion M/s Aim Pharmaceutical disowned tab Accutane M/s Hilton Pharma Karachi disowned Gevolox tab mg, M/s Bayer Schering Karachi disowned Evolox 400mg tablet M/ Pfizer Karachi disowned white powder and empty blister strips of Xanax Tab suspected to be Xanax (Alprazolam), hence the product is spurious under section 3 (z-b)(ii) of Drugs Act 1976.

3. The FID stated that Show cause served to the accused persons Mohammad Sajid S/o Inayat Kahn and Shahid Ali S/o Inayat Khan proprietors of Cherwel Enterprises Gadoon Amazai with the directions to explain their position and provide documents/invoices/names and persons/printing press from where they procured the raw materials, printing materials, excipients etc within 07 days of the receipt of the notice but the accused failed to comply with the instructions of the FID. The FID stated that both the accused during the raid recorded their statement that Ihsanullah of Bannu and Fayaz of Mardan were their business partners but could not produce any evidence of their alleged involvement in the said business.

4. The FID stated that the FIA Peshawar submitted complete challan of the case of Cherwell Enterprises Gadoon Amazai to the FID office. The FID further stated that FIA judicial file has enough proofs of the alleged involvement of both the persons in sale of unregistered/ counterfeit/spurious drugs.

5. The FID Peshawar has requested to allow the permission for prosecution against the following accused persons in Drug Court.

i. Mohammad Sajid S/o Inayat Kahn, owner of Cherwell Plot No.187/2 Lane 9 Gadoon Industrial Estate Swabi Resident of Tandail Abad, KhweshgiPayan, District Nowshera, Presently Gulbahar Colony, Risalpur Cant. District Nowshera.

ii. Shahid Ali S/o Inayat Khan Owner of Cherwel Enterprises Gadoon Plot No.187/2 Lane 9 Gadoon Industrial Estate Swabi Resident of Tandail Abad, KhweshgiPayan, District Nowshera, Presently Gulbahar Colony, Risalpur Cant. District Nowshera.

6. Accordingly show cause notice was served to above nominated accused and accused were called for personal hearing before the Central Licensing Board in its 248th meeting by giving them the opportunity to be heard in person.

Proceeding of the Board:

The Board waited for the accused persons to appear before it but till closing of the Meeting none of the accused persons appeared before the Board for giving opportunity of Personal Hearing.

Decision of the Board

The Board after detailed discussion, deliberation and keeping in view the facts of the case including the information provided by the FID telephonically that personal hearing letter could not be served to both of accused persons as they have shifted their premises. The FID further informed that he had requested to FIA for assistance for the delivery of show cause notice and personal hearing letters. Accordingly the Board decided to defer the case on the basis of majority of the vote.

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