MINUTES OF 255th MEETING OF CENTRAL LICENSING BOARDHELD ON AUGUST 16-17, 2017

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255th meeting of the Central Licensing Board (CLB) was held on June 16-17, 2017 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Mr. Shaikh Faqeer Muhammad, Director Drug Licensing, Drug Regulatory Authority of Pakistan.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1	Dr Fakharuddin Aamir, Addl. Director (QA/LT), Representative Quality Assurance and Laboratory Testing, Islamabad	Member
2	Mr. Akbar Jan, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa, Peshawar	Member
3	Syed Saleem Shah, Chief Drug Inspector, Department of Health, Govt. of Balochistan, Quetta	Member
4	Syed Kalbe-e-Hasan Rizvi, Chief Drug Inspector, Department of Health, Govt. of sindh, Karachi	Member
6	Dr. Muhammad Saleem Butt, Representative Drug Controller Primary and Secondary Health Care Department, Govt. of Punjab, Lahore	Member
5	Mr. KhurramShahzad Mughal, Consultant M/o Law, Justice and Human Rights, as representative of M/o Law and Justice, Islamabad.	Member
6	Dr.Ikram-ul-Haque , Expert inQC/QA of drugs.	Observer
7	Syed Muied Ahmed, Expert in manufacturing of drugs.	Observer
8	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
9	Mr Sabooor Ahmed Sheikh, Chief Executive Officer , Karachi Chemical Industries (Pvt) Ltd., and Mr. Arshad Mehmood, Managing Partner, Welwrd Pharmaceuticals as Representatives of PPMA	Observer
10	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
11	Mr. Kamran Anwar , representative of PCDA	Observer

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

Item-I CONFIRMATION OF THE MINUTES OF 253rdMEETING

The Central Licensing Board (CLB) formally confirmed the minutes of its 254th meeting held on 15th June, 2017.

LICENSING DIVISION

Item-II: GRANT OF NEW DRUG MANUFACTURING LICENSES.

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

S#	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1	M/s N.S Pharma, Plot No. 576-577, Sunder Industrial Estate, Lahore.	**08-06-2017 (Formulation)**	The Board approved the grant of Drug Manufacturing Licence by way of formulation with following sections **Sections (04)** 1. Tablet (General) 2. Capsule (General) 3. Sachet (General) 4. Liquid Injectable Ampoule / Vial (General).
2	M/s Newton Health Care (Pvt) Ltd, Plot No. N-8 & 9, HITE, Hub, Balochistan	**19-07-2017 (Formulation)**	The Board approved the grant of Drug Manufacturing Licence by way of formulation with following sections **Sections (04)** 1. Tablet (General) 2. Capsule (General) 3. Oral Dry Powder Suspension (General) 4. Oral Liquid Syrup Section.
3	M/s AAA Health Pharmaceutical Laboratories, Plot No. 9-A, Street No. 9-5, RCCI , Rawat	**13-06-2017 (Formulation)**	The Board approved the grant of Drug Manufacturing Licence by way of formulation with following sections **Sections (05)** **1.** Tablet (General) **2.** Capsule (General) **3.** Dry Suspension (General) **4.** Capsule (Ceph) **5.** Dry Suspension (Ceph) The Board also recommended that applicant may be advised for similarity of name at site approval stage.

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

The Board considered following cases of Grant of Additional Sections & Expansion/Amendments 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 Reckitt Benckiser (Pvt) Ltd, Plot No. F-18, S.I.T.E. Karachi DML No. 000022 (Formulation)	**01-06-2017**	The Board approved the grant of following additional sections /amendment as under:- **Areas of Section (02)** 1. Microbiology Laboratory 2. Sampling Booth in Quarantine
2	M/s Baariq Pharmaceuticals, Plot No. 600, Sunder Industrial Estate, Sunder Raiwind Road, Lahore DML No. 000715 (Formulation)	**22-06-2017**	The Board approved the grant of following additional sections /amendment as under:- **Section (04)** 1. Liquid Injection (General)Veterinary. 2. Oral Powder-IIVeterinary 3. Liquid Injection (Penicillin)Veterinary 4. Oral Powder (Penicillin)Veterinary
3	M/s Neomedix, Plot No 5, Street No. N-5, NIZ, Rawat DML No. 000539 (Formulation)	**18-07-2017**	The Board approved the grant of following additional sections /amendment as under:- **Section (02)** **1.** Oral Dry Powder for suspension (General) Section The Board did not approved the following Section on the recommendations of the panel of Inspectors: **1.** Cream / Ointment Section (General)
4	M/s Paktex Industries, 2.5-Km, Tatly Road, Sroyabad, Kamoke DML No. 000376 (Formulation)	**30-06-2017**	The Board approved the grant of following additional sections /amendment as under:- **Sections (1)** Quality Control Laboratoryincluding new Microbiology Laboratory.

5	M/s Weather Folds Pharmaceutical, Plot No.69/2, Phase-II, Industrial Area, Hattar. DML No. 0000644 (Formulation)	**17-06-2017**	The Board approved the grant of following additional sections /amendment as under:- **Section (01)** i. Tablet Section (Hormone)

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 M/s Paktex Industries, 2.5-Km, Tatly Road, Sroyabad, Kamoke DML No. 000376 (Formulation)	**30-06-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **06-02-2016 to 05-02-2021**
2.	M/s Sunrise Pharma (Pvt) Ltd, Plot No. 594-A, Sunder Industrial Estate, Raiwind Road, Lahore DML No. 000712 (Formulation)	**19-06-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **20-06-2016 to 19-06-2021**
3.	M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahore DML No. 000231 (Formulation)	**11-05-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **27-09-2015 to 26-09-2020** except ***Capsule (General) and Cephalosporin (injectable, oral dry powder suspension & capsule)*** *sections.* The Board also decided to issue Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for suspension or cancellation of above section on the recommendations of the panel of experts. The Board while considering the case

			observed that inspection report is submitted without the signature of the representative of the firm. The Board, therefore, directed that in future inspection report shall also be submitted on inspection Book with the signature of the firm.
4.	M/s Baariq Pharmaceuticals, Plot No. 600 Sunder Industrial Estate, Sunder Raiwind Road, Lahore DML No. 000715 (Formulation)	**22-06-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f**15-06-2016 to 14-06-2021**
5.	M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area North Karachi. DML No. 000598 (Formulation)	**15-07-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f**12-07-2016 to 11-07-2021**
6.	M/s Neomedix, Plot No 5, Street No. N-5, NIZ, Rawat DML No. 000539 (Formulation)	**18-07-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f**02-04-2014 to 01-04-2019**
7.	M/S Pakistan Institute of Nuclear Science & Technology (PINSTECH), Islamabad DML No. 000730 (Formulation)	**17-05-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f25-06-2016 to 24-06-2021
8.	M/s Akson Pharmaceuticals (Pvt)Ltd. , Plot No 9-B/1&2, Street No.D-1,Old Industrial Estate Mirpur, Azad Kashmir. DML No. 000486 (Formulation)	**25-07-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f**12-04-2016 to 11-04-2021**

9.	M/s BSN Medical (Pvt) Ltd, Plot No. A/69, S.I.T.E, Manghopir Road, Karachi DML No. 000085 (Formulation)	**05-08-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f 08-01-2016 to 07-01-2021
10.	M/s Kaizen Pharmaceuticals (Pvt) Ltd, Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi DML No. 000755 (Formulation)	**05-08-2017**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f24-09-2017 to 23-09-2022

Item No. V Miscellaneous Cases.

Case No. 1 <u>CHANGE OF MANAGEMENT OF M/S XENON PHARMACEUTICALS (PVT) LTD,9.5-KM, SHEIKHUPURA ROAD, LAHORE.</u>

M/sXenon Pharmaceuticals (Pvt) Ltd,9.5-Km, Sheikhupura Road, Lahore, DML No. 000077 by way of formulation has submitted request for change in management of the firm as per Form-29 from S.E.C.P along with prescribed Fee Challan of 50,000/- as under:-

Existing Management	Retired Management	New Management as per Form 29
1. Mr. Zulfiqar A Malik S/o Malik Bashir Ahmad CNIC No. 35201-3453399-5. 2. Mrs. Raheela ZulfiqarMalik CNIC No. 35201-8628248-6.	1. Mrs.Raheela Zulfiqar Malik CNIC No. 35201-8628248-6	1. Mr. Zulfiqar A Malik S/o Malik Bashir Ahmad CNIC No. 35201-3453399-5. 2. Mr. Hashim Zulfiqar Malik S/o Zulfiqar A Malik CNIC No. 35201-5866896-3. 3. Mr. Qasim Zulfiqar Malik S/o Zulfiqar A Malik CNIC No. 35201-9110727-3.

<u>Decision of CLB:</u>

The Board considered and endorsed the change of management from old to new management ofM/sXenon Pharmaceuticals (Pvt) Ltd,9.5-Km, Sheikhupura Road, Lahore, DML No. 000077 by way of formulation as per Form-29 issued by SECP as under;

Existing Management	Retired Management	New Management as per Form 29
1. Mr. Zulfiqar A Malik S/o Malik Bashir Ahmad CNIC No. 35201-3453399-5. 2. Mrs. Raheela ZulfiqarMalik CNIC No. 35201-8628248-6.	1. Mrs.Raheela Zulfiqar Malik CNIC No. 35201-8628248-6	1. Mr. Zulfiqar A Malik S/o Malik Bashir Ahmad CNIC No. 35201-3453399-5. 2. Mr. Hashim Zulfiqar Malik S/o Zulfiqar A Malik CNIC No. 35201-5866896-3. 3. Mr. Qasim Zulfiqar Malik S/o Zulfiqar A Malik CNIC No. 35201-9110727-3.

Case No. 2 **CHANGE OF MANAGEMENT OF M /S WELLNESS PHARMACEUTICAL (Pvt) LTD, PLOT No. 33, SUNDAR INDUSTRIAL ESTATE, LAHORE.**

M/s Wellness Pharmaceutical (Pvt) Ltd, Plot No. 33, Sundar Industrial Estate, Lahore, DML No. 000782 by way of formulation has submitted request for change in management of the firm as per Form-29 from S.E.C.P along with prescribed Fee Challan of 50,000/- as under:-

Existing Management as per Form-29 from S.E.C.P	**Retired Managementas per Form 29**	**New Management as per** Form-29 from S.E.C.P
1. Mr. Maqsood Ahmad S/o Abdul Ghafoor CNIC No.35202-2471782-3. 2. Mr. Syed Qulb-i-Hussain S/o Syed Nawazish Ali CNIC No. 35401-1589094-3. 3. Mr. Ashfaq Anwar S/o Muhammad Anwar CNIC No. 35200-1433968-7. 4. Mr. Muhammad Arshad S/o Ameer Din S/o 35202-9682565-9.	1. Mr. Maqsood Ahmad S/o Abdul Ghafoor CNIC No. 35202-2471782-3. 2. Mr. Syed Qulb-i-Hussain S/o Syed Nawazish Ali CNIC No. 35401-1589094-3. 3. Mr. Ashfaq Anwar S/o Muhammad Anwar CNIC No. 35200-1433968-7. 4. Mr. Muhammad Arshad S/o Ameer Din S/o 35202-9682565-9.	1. Mr. HarisMoin S/o Moinuddin Siddiqui CNIC No. 42101-8366563-9. 2. Mr. Hussain Murad S/o Murad CNIC No. 42101-0344151-7.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Wellness Pharmaceutical (Pvt) Ltd, Plot No. 33, Sundar Industrial Estate, Lahore, DML No. 000782 by way of formulation as per Form-29 issued by SECP as under;

Existing Management as per Form-29 from S.E.C.P	**Retired Managementas per Form 29**	**New Management as per** Form-29 from S.E.C.P
1. Mr. Maqsood Ahmad S/o Abdul Ghafoor CNIC No.35202-2471782-3. 2. Mr. Syed Qulb-i-Hussain S/o Syed Nawazish Ali CNIC No. 35401-1589094-3. 3. Mr. Ashfaq Anwar S/o Muhammad Anwar CNIC No. 35200-1433968-7. 4. Mr. Muhammad Arshad S/o Ameer Din S/o 35202-9682565-9.	1. Mr. Maqsood Ahmad S/o Abdul Ghafoor CNIC No. 35202-2471782-3. 2. Mr. Syed Qulb-i-Hussain S/o Syed Nawazish Ali CNIC No. 35401-1589094-3. 3. Mr. Ashfaq Anwar S/o Muhammad Anwar CNIC No. 35200-1433968-7. 4. Mr. Muhammad Arshad S/o Ameer Din S/o 35202-9682565-9.	1.Mr. HarisMoin S/o Moinuddin Siddiqui CNIC No. 42101-8366563-9. 2.Mr. Hussain Murad S/o Murad CNIC No. 42101-0344151-7.

Case No. 3 **CHANGE OF MANAGEMENT OF M/S WELL CARE PHARMACEUTICALS, A/7, PUNJAB SMALL INDUSTRIAL ESTATE, SARGODHA.**

M/s Well Care Pharmaceuticals, A/7, Punjab Small Industrial Estate, Sargodha, DML No. 000465 by way of formulation has submitted request for change in management of the along with prescribed Fee Challan of Rs.50,000/- as under:-

Existing Management (As per Partnership Deed)	**Retiring Management**	**NewManagement (As per Transfer deed & NOC)**
1.Mr. Tahir Farooq S/o Ch. Akber Ali CNIC No. 38403-5610345-5. 2.Mr. Muhammad Amjad Mehmood S/o Abdul Majeed CNIC No. 38403-0689764-9. 3.Mr. Malik Saeed Akhtar S/o Malik Fazal-Ur-Rehman Aslam CNIC No. 38403-4294132-1.	1.Mr. Tahir Farooq S/o Ch. Akber Ali CNIC No. 38403-5610345-5. **2.**Mr. Muhammad Amjad Mehmood S/o Abdul Majeed CNIC No. 38403-0689764-9.	1. Mr. Malik Saeed Akhtar S/o Malik Fazal-Ur-Rehman Aslam CNIC No. 38403-4294132-1.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Well Care Pharmaceuticals, A/7, Punjab Small Industrial Estate, Sargodha, DML No. 000465 by way of formulation as under;

Existing Management (As per Partnership Deed)	**Retiring Management**	**NewManagement (As per Transfer deed & NOC)**
1. Mr. Tahir Farooq S/o Ch. Akber Ali CNIC No. 38403-5610345-5. 2. Mr. Muhammad Amjad Mehmood S/o Abdul Majeed CNIC No. 38403-0689764-9. 3. Mr. Malik Saeed Akhtar S/o Malik Fazal-Ur-Rehman Aslam CNIC No. 38403-4294132-1.	1.Mr. Tahir Farooq S/o Ch. Akber Ali CNIC No. 38403-5610345-5. **2.**Mr. Muhammad Amjad Mehmood S/o Abdul Majeed CNIC No. 38403-0689764-9.	1. Mr. Malik Saeed Akhtar S/o Malik Fazal-Ur-Rehman Aslam CNIC No. 38403-4294132-1.

Case No.4. **CHANGE OF THE TITLE /NAME AND MANAGEMENT OF M/S BIOCEF (PVT)_ LTD,SUNDER INDUSTRIAL ESTATE LAHORE,DML NO.000864 (BY WAY OF FORMULATION).**

M/s Biocef (Pvt) Ltd, Plot No. 517, Sunder Industrial Estate Lahore, DML No.000864 (by way of Formulation)has applied for change of management with a prescribed fee of Rs.50,000/- and its challan in original duly retained by Statistical Officer DRAP Islamabad. Detail is as under: -

Existing Name (As per SECP)	Interm Name (As per SECP)	New Name (As per SECP)
M/s. Biocef (Pvt) Ltd, Plot No. 517, Sunder Industrial Estate, Lahore	M/s. Procef Laboratories Private Ltd, Plot No. 517, Sunder Industrial Estate, Lahore	M/s. CUREXA HEALTH (PRIVATE) LIMITED Plot No. 517, Sunder Industrial Estate, Lahore

Decision of CLB:

The Board considered and approved the change of title of M/s Biocef (Pvt) Ltd, Plot No. 517, Sunder Industrial Estate Lahore, DML No.000864 by way of formulation as per Form-29 issued by SECP as under;

Existing Name (As per SECP)	Interm Name (As per SECP)	New Name (As per SECP)
M/s. Biocef (Pvt) Ltd, Plot No. 517, Sunder Industrial Estate, Lahore	M/s. Procef Laboratories Private Ltd, Plot No. 517, Sunder Industrial Estate, Lahore	M/s. CUREXA HEALTH (PRIVATE) LIMITED Plot No. 517, Sunder Industrial Estate, Lahore

Case No. 5 **CHANGE OF THE TITLE /NAME AND IZFAAR PHARMACEUTICALS INDUSTRRIES, 542/A SUNDER INDUSTRIAL ESTATE LAHORE,DML NO.000800 (BY WAY OF FORMULATION).**

M/s Izfaar Pharmaceuticals Industries ,542/A Sunder Industrial Estate Lahore,DML No.000800 (By way of Formulation) has applied for change of Name/ title of Firm with a prescribed fee of Rs.50,000/- and its challan in original duly retained by Statistical Officer DRAP Islamabad. Detail is as under: -

Existing Name (As per Partnership Deed)	New Name (As per SECP)
M/s Izfaar Pharmaceuticals Industries,542/A Sunder Industrial Estate Lahore	M/s Izfaar Pharmaceuticals (Pvt.)Ltd. ,542/A Sunder Industrial Estate, Lahore

Decision of CLB:

The Board considered and approved the change of title M/s Izfaar Pharmaceuticals Industries ,542/A Sunder Industrial Estate Lahore,DML No.000800by way of formulation as per Form-29 issued by SECP as under;

Existing Name (As per Partnership Deed)	New Name (As per SECP)
M/s Izfaar Pharmaceuticals Industries,542/A Sunder Industrial Estate Lahore	M/s Izfaar Pharmaceuticals (Pvt.)Ltd. ,542/A Sunder Industrial Estate, Lahore

Case No.6. CHANGE OF THE MANAGEMENT OF M/S BRITISH PHARMACEUTICALS, 23-KM, SHEIKHUPURA ROAD, LAHORE,DML NO.000729 (FORMULATION)

M/s British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore wherein the firm has submitted following details in respect of detail of management, with a prescribed fee of Rs.50,000/- and its challan in original duly retained by Statistical Officer DRAP Islamabad. Detail is as under: -

Management at the time of Grant of DM / Existing Management	Retiring Management	New Management as per Partnership deed
1.Muhammad Aslam S/o Abdl Karim, CNIC No. 42101-44644806-9. 2.Mian Tahir Mahmood S/o Muhammad Tufail, CNIC No. 35202-3061128-7. 3.Muhammad Imtiaz Bajwa S/o Muhammad Rafique Bajwa CNIC No. 36302-4490048-3	1. Muhammad Aslam S/o Abdl Karim,CNIC No. 42101-44644806-9. 2. Mian Tahir Mahmood S/o Muhammad Tufail, CNIC No. 35202-3061128-7. 3. Muhammad Imtiaz Bajwa S/o Muhammad Rafique Bajwa CNIC No. 36302-4490048-3	1. Mr. Amir Siddique S/o Muhammad Hanif, CNIC No. 35201-5524144-3. 2. Mr. Shahzad Ahmed S/o Khawaja Muhammad Hanif, CNIC No. 35201-4525763-1. 3. Mst. Tania Aamir W/o Aamir Siddique CNIC No. 38403-2047790-8

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s British Pharmaceuticals, 23-KM, Sheikhupura Road, Lahore by way of formulation as per Partnership Deed as under;

Management at the time of Grant of DM / Existing Management	Retiring Management	New Management as per Partnership deed
3.Muhammad Aslam S/o Abdl Karim, CNIC No. 42101-44644806-9. 4.Mian Tahir Mahmood S/o Muhammad Tufail, CNIC No. 35202-3061128-7. 3.Muhammad Imtiaz Bajwa S/o Muhammad Rafique Bajwa CNIC No. 36302-4490048-3	4. Muhammad Aslam S/o Abdl Karim,CNIC No. 42101-44644806-9. 5. Mian Tahir Mahmood S/o Muhammad Tufail, CNIC No. 35202-3061128-7. 6. Muhammad Imtiaz Bajwa S/o Muhammad Rafique Bajwa CNIC No. 36302-4490048-3	4. Mr. Amir Siddique S/o Muhammad Hanif, CNIC No. 35201-5524144-3. 5. Mr. Shahzad Ahmed S/o Khawaja Muhammad Hanif, CNIC No. 35201-4525763-1. 6. Mst. Tania Aamir W/o Aamir Siddique CNIC No. 38403-2047790-8

Case No. 7 **CHANGE OF MANAGEMENT OF M/S AIMS PHARMACEUTICALS, PLOT NO. 291, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

M/s Aims Pharmaceuticals, Plot No. 291, Industrial Triangle, Kahuta Road, Islamabad has submitted request for change in management of the firm as per partnership deed along with prescribed Fee Challan of Rs.50,000/- as under:-

Existing Management as per Partnership Deed	Retiring Management as per Partnership Deed	New Management as per Partnership Deed
1. Nadeem Iqbal Butt S/o Ghulam Mohammad Butt CNIC 37405-9318677-1. 2. Sheikh Khalid Mehmood S/o Ghulam Khuwaja CNIC # 61101-2763783-7. 3. Mr. Muhammad Daud S/o Tariq Mehmood CNIC # 61101-7697360-5. **4.** Mr. Muhammad Yahya S/o Tariq Mehmood CNIC # 61101-8313875-7.	1. Sheikh Khalid Mehmood S/o Ghulam Khuwaja CNIC # 61101-2763783-7. 2. Mr. Muhammad Daud S/o Tariq Mehmood CNIC # 61101-7697360-5.	1.Nadeem Iqbal Butt S/o Ghulam Mohammad Butt CNIC 37405-9318677-1. 2.Mr. Muhammad Yahya S/o Tariq Mehmood CNIC # 61101-8313875-7. 3.Malik Nadeem Younas S/o Malik Muhammad Younas CNIC # 37405-0639686-9.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Aims Pharmaceuticals, Plot No. 291, Industrial Triangle, Kahuta Road, Islamabadby way of formulation as per Partnership Deed as under;

Existing Management as per Partnership Deed	Retiring Management as per Partnership Deed	New Management as per Partnership Deed
1. Nadeem Iqbal Butt S/o Ghulam Mohammad Butt CNIC 37405-9318677-1. 2. Sheikh Khalid Mehmood S/o Ghulam Khuwaja CNIC # 61101-2763783-7. 3. Mr. Muhammad Daud S/o Tariq Mehmood CNIC # 61101-7697360-5. **4.** Mr. Muhammad Yahya S/o Tariq Mehmood CNIC # 61101-8313875-7.	1.Sheikh Khalid Mehmood S/o Ghulam Khuwaja CNIC # 61101-2763783-7. 2.Mr. Muhammad Daud S/o Tariq Mehmood CNIC # 61101-7697360-5.	1. Nadeem Iqbal Butt S/o Ghulam Mohammad Butt CNIC 37405-9318677-1. 2. Mr. Muhammad Yahya S/o Tariq Mehmood CNIC # 61101-8313875-7. 3. Malik Nadeem Younas S/o Malik Muhammad Younas CNIC # 37405-0639686-9.

Case No. 8. CHANGE OF MANAGEMENT OF M/S RELIANCE PHARMA, ISLAMABAD.

M/s Reliance Pharma, Plot No. 8, Street No. S-8, RCCI, Industrial Estate, Islamabad DML No. 000724, has submitted request for change in management of the firm as per partnership deed along with prescribed Fee Challan of Rs. 50,000/- as under:-

Existing Management as per partnership deed	Retiring Management as per partnership deed	New Management as per Partnership Deed
1. Syed Naeem Yaqoob S/o Syed Masdar Ali Shah Gillani. CNIC No. 61101-4776582-3 2. Ahsan Hafeez S/o Muhammad Hafeez Ahmed. CNIC No. 37405-1038132-3 3. Mr. Ali Asad S/o Muhammad Asad. CNIC No. 37405-8538837-5 4. Umair Afzal S/o Najam Rehan. CNIC No. 37405-7864334-9	1. Syed Naeem Yaqoob S/o Syed Masdar Ali Shah Gillani. CNIC No. 61101-4776582-3 2. Mr. Ali Asad S/o Muhammad Asad. CNIC No. 37405-8538837-5	1. Ahsan Hafeez S/o Muhammad Hafeez Ahmed. CNIC No. 37405-1038132-3 2. Umair Afzal S/o Najam Rehan. CNIC No. 37405-7864334-9 3. Mr. Muhammad Ahmad Yaqoob S/o Muhammad Arshad Khawaja. CNIC No. 37405-8083411-7 4. Mr. Shehzad Ahmed S/o Mr. Taj Muhammad. CNIC No. 34202-0780764-7

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Reliance Pharma, Plot No. 8, Street No. S-8, RCCI, Industrial Estate, Islamabadby way of formulation as per Partnership Deed as under;

Existing Management as per partnership deed	Retiring / Outgoing Management as per partnership deed	New Management as per Partnership Deed
1. Syed Naeem Yaqoob S/o Syed Masdar Ali Shah Gillani. CNIC No. 61101-4776582-3 2. Ahsan Hafeez S/o Muhammad Hafeez Ahmed. CNIC No. 37405-1038132-3 3. Mr. Ali Asad S/o Muhammad Asad. CNIC No. 37405-8538837-5 4. Umair Afzal S/o Najam Rehan. CNIC No. 37405-7864334-9	1. Syed Naeem Yaqoob S/o Syed Masdar Ali Shah Gillani. CNIC No. 61101-4776582-3 2. Mr. Ali Asad S/o Muhammad Asad. CNIC No. 37405-8538837-5	1. Ahsan Hafeez S/o Muhammad Hafeez Ahmed. CNIC No. 37405-1038132-3 2. Umair Afzal S/o Najam Rehan. CNIC No. 37405-7864334-9 3. Mr. Muhammad Ahmad Yaqoob S/o Muhammad Arshad Khawaja. CNIC No. 37405-8083411-7 4. Mr. Shehzad Ahmed S/o Mr. Taj Muhammad. CNIC No. 34202-0780764-7

Case No. 9. CHANGE OF MANAGEMENT OF M/S MEDISYNTH PHARMACEUTICALS, ISLAMABAD.

M/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-5, National Industrial Zone, Rawat DML No. 000718 has submitted request for change in management of the firm as per partnership deed along with prescribed Fee Challan of Rs. 50,000/- as under:-

Existing Management as per Partnership Deed	Retiring	New Management as Partnership Deed
1. Mr. Ali Waqas S/o Hazrat Ali CNIC # 61101-3255492-1. 2. Mr. Arif Jan S/o Muhammad Jan Khan CNIC # 17301-7652042-3. 3. Mr. Arshad Hussain S/o Abdul Quddus CNIC # 16101-0489653-9. 4. Mr. Riaz Ahmed S/o Sher Mohammad CNIC # 16102-1023615-1.	1. Mr. Arshad Hussain S/o Abdul Quddus CNIC # 16101-0489653-9. 2. Mr. Riaz Ahmed S/o Sher Mohammad CNIC # 16102-1023615-1.	1. Mr. Ali Waqas S/o Hazrat Ali CNIC # 61101-3255492-1. 2. Mr. Arif Jan S/o Muhammad Jan Khan CNIC # 17301-7652042-3.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Medisynth Pharmaceuticals, Plot No. 55, Street No. S-5, National Industrial Zone, Rawat by way of formulation as per Partnership Deed as under;

Existing Management as per Partnership Deed	Retiring	New Management as Partnership Deed
1.Mr. Ali Waqas S/o Hazrat Ali CNIC # 61101-3255492-1. 2.Mr. Arif Jan S/o Muhammad Jan Khan CNIC # 17301-7652042-3. 3.Mr. Arshad Hussain S/o Abdul Quddus CNIC # 16101-0489653-9. 4.Mr. Riaz Ahmed S/o Sher Mohammad CNIC # 16102-1023615-1.	1. Mr. Arshad Hussain S/o Abdul Quddus CNIC # 16101-0489653-9. 2. Mr. Riaz Ahmed S/o Sher Mohammad CNIC # 16102-1023615-1.	1. Mr. Ali Waqas S/o Hazrat Ali CNIC # 61101-3255492-1. 2.Mr. Arif Jan S/o Muhammad Jan Khan CNIC # 17301-7652042-3.

Case No. 10. CHANGE OF MANAGEMENT OF M/S AMSON VACCINES & PHARMA (PVT) LTD., INDUSTRIAL TRIANGLE, KAHUTTA ROAD, ISLAMABAD.

M/s Amson Vaccines & Pharma (Pvt) Ltd., Industrial Triangle, Kahutta Road, Islamabad **(DML No.000638)**has submitted request for change in management of the firm as per Form 29 of SECP along with prescribed Fee Challan of Rs. 50,000/- as under:-

Existing Management (as per Form 29)	Retiring	New Management (as per Form 29)
1. Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan CNIC No. 37405-9227345-7. 2. Syed Saleem Asghar S/o Asghar Ali Sagheer (CNIC No. 37405-0386356-5). 3. Mr. Nauman Shamim S/o Shamim Ahmed Khan (CNIC No. 37405-0508257-1)	1.Mr. Nauman Shamim S/o Shamim Ahmed Khan (CNIC No. 37405-05082571).	1. Mr. Dilawar Khan S/0 Roshan Khan (CNIC No. 16101-9288045-5). 2. Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan (CNIC No. 37405-9227345-7. 3. Syed Saleem Asghar S/o Asghar Ali Sagheer (CNIC No. 37405-0386356-5).

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Amson Vaccines & Pharma (Pvt) Ltd., Industrial Triangle, Kahutta Road, Islamabad **(DML No.000638)**by way of formulation as per Form 29 of SECPas under;

Existing Management (as per Form 29)	Retiring	New Management (as per Form 29)
1. Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan CNIC No. 37405-9227345-7. 2. Syed Saleem Asghar S/o Asghar Ali Sagheer (CNIC No. 37405-0386356-5). 3. Mr. Nauman Shamim S/o Shamim Ahmed Khan (CNIC No. 37405-0508257-1)	1.Mr. Nauman Shamim S/o Shamim Ahmed Khan (CNIC No. 37405-05082571).	1. Mr. Dilawar Khan S/0 Roshan Khan (CNIC No. 16101-9288045-5). 2. Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan (CNIC No. 37405-9227345-7. 3. Syed Saleem Asghar S/o Asghar Ali Sagheer (CNIC No. 37405-0386356-5).

Case No. 11. CHANGE OF MANAGEMENT OF M/S NEOMEDIX, PLOT NO. 5, N/5, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD.

M/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad has submitted request for change in management of the firm as per partnership deed along with prescribed Fee Challan of Rs. 50,000/- as under:-

Existing Management as per partnership deed	Retiring	New Management as per partnership deed
1.Mr. Muhammad Saleem Qureshi S/o S. Muhammad Iqbal CNIC # 37405-0513987-3. 2.Mr. Muhammad Usman Qureshi S/o Muhammad Saleem Qureshi CNIC # 37405-0505114-3. 3.Mrs. Itrat Batool Qureshi W/o Muhammad Saleem Qureshi CNIC # 37405-0466371-4	1.Mrs. Itrat Batool Qureshi W/o Muhammad Saleem Qureshi CNIC # 37405-0466371-4	1.Mr. Muhammad Saleem Qureshi S/o S. Muhammad Iqbal CNIC # 37405-0513987-3. 2.Mr. Muhammad Usman Qureshi S/o Muhammad Saleem Qureshi CNIC # 37405-0505114-3.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Neomedix, Plot No. 5, N/5, National Industrial Zone, Rawat, Islamabad by way of formulation as per Partnership Deed as under;

Existing Management as per partnership deed	Retiring / Outgoing Management	New Management as per partnership deed
1. Mr. Muhammad Saleem Qureshi S/o S. Muhammad Iqbal CNIC # 37405-0513987-3. 2. Mr. Muhammad Usman Qureshi S/o Muhammad Saleem Qureshi CNIC # 37405-0505114-3. 3. Mrs. Itrat Batool Qureshi W/o Muhammad Saleem Qureshi CNIC # 37405-0466371-4	1. Mrs. Itrat Batool Qureshi W/o Muhammad Saleem Qureshi CNIC # 37405-0466371-4	1. Mr. Muhammad Saleem Qureshi S/o S. Muhammad Iqbal CNIC # 37405-0513987-3. 2. Mr. Muhammad Usman Qureshi S/o Muhammad Saleem Qureshi CNIC # 37405-0505114-3.

Case No. 12. CHANGE OF MANAGEMENT OF M/S SIAM PHARMACEUTICAL, PLOT NO. 217, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

M/s Siam Pharmaceutical, Plot No. 217, Industrial Triangle, Kahuta Road, Islamabad, DML NO. 000711has submitted request for change in management of the firm as per partnership deed along with prescribed Fee Challan of Rs. 50,000/- as under:-

Previous Management (As per Partnership Deed)	Retiring	New Management (As per Partnership Deed)
1.Mr. Faisal Muzamil S/o Muzammil Hussain CNIC # 37405-4805522-3. 2.Mr. Rashid Muzamil S/o Muzammil Hussain CNIC # 61101-5136210-3. 3.Mr. Asim Muzamil S/o Muzammil Hussain CNIC # 37405-6158148-7. 4.Mr. Kamran Sajid S/o Mohammad Aslam Johar CNIC # 37406-3391491-7.	1. Mr. Kamran Sajid S/o Mohammad Aslam Johar CNIC # 37406-3391491-7.	1.Mr. Faisal Muzamil S/o Muzammil Hussain CNIC # 37405-4805522-3. 2.Mr. Rashid Muzamil S/o Muzammil Hussain CNIC # 61101-5136210-3. 3.Mr. Asim Muzamil S/o Muzammil Hussain CNIC # 37405-6158148-7. 4.Mr. Qasim Farooq S/o Ansar Farooq CNIC # 37405-5587025-9. 5.Mr. Mehrban Ali S/o Sheikh Sultan CNIC # 61101-4842050-7.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Siam Pharmaceutical, Plot No. 217, Industrial Triangle, Kahuta Road, Islamabad,DML NO. 000711by way of formulation as per Partnership Deed as under;

Previous Management (As per Partnership Deed)	Retiring Management	New Management (As per Partnership Deed)
1. Mr. Faisal Muzamil S/o Muzammil Hussain CNIC # 37405-4805522-3. 2. Mr. Rashid Muzamil S/o Muzammil Hussain CNIC # 61101-5136210-3. 3. Mr. Asim Muzamil S/o Muzammil Hussain CNIC # 37405-6158148-7. 4. Mr. Kamran Sajid S/o Mohammad Aslam Johar CNIC # 37406-3391491-7.	1.Mr. Kamran Sajid S/o Mohammad Aslam Johar CNIC # 37406-3391491-7.	1. Mr. Faisal Muzamil S/o Muzammil Hussain CNIC # 37405-4805522-3. 2. Mr. Rashid Muzamil S/o Muzammil Hussain CNIC # 61101-5136210-3. 3. Mr. Asim Muzamil S/o Muzammil Hussain CNIC # 37405-6158148-7. 4. Mr. Qasim Farooq S/o Ansar Farooq CNIC # 37405-5587025-9. 5. Mr. Mehrban Ali S/o Sheikh Sultan CNIC # 61101-4842050-7.

Case No. 13 CHANGE OF MANAGEMENT OF M/S ROCK PHARMACEUTICAL LABORATORIES (PVT) LTD., PLOT NO.134&135-B, NOWSHERA INDUSTRIAL ESTATE, RISALPUR.

M/s Rock Pharmaceutical Laboratories (Pvt) Ltd, Plot No.134&135-B, Nowshera Industrial Estate,Risalpur License No. 000691 by way of formulation has submitted request for change in management of the firm as per Form -29 with prescribed Fee Challan of Rs.50,000/- as under;

Existing Management as per Form-29 and Form-A of SECP	Newly appointed management as per Form-29 and Form-A of SECP	Proposed management as per Form-29 and Form-A of SECP
1. Mr. Aamir Saleem S/o Muhammad Saleem CNIC No.17301-9419987-7 2. Mr. Tahir Saleem S/o Muhammad Saleem CNIC No.17301-1669380-7	1. Mr. Mazhar Saleem S/o Muhammad Saleem CNIC No.17301-4702545-3 2. Mr. Qaiser Saleem S/o Muhammad Saleem CNIC No. 17301-1669379-9	1. Mr. Aamir Saleem S/o Muhammad Saleem CNIC No.17301-9419987-7 2. Mr. Tahir Saleem S/o Muhammad Saleem CNIC No.17301-1669380-7 3. Mr. Mazhar Saleem S/o Muhammad Saleem CNIC No.17301-4702545-3 4. Mr. Qaiser Saleem S/o Muhammad Saleem CNIC No.17301-1669379-9

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Rock Pharmaceutical Laboratories (Pvt) Ltd, Plot No.134&135-B, Nowshera Industrial Estate,Risalpur License No. 000691 by way of formulation as per Form 29 of SECPas under;

Existing Management as per Form-29 and Form-A of SECP	Newly appointed management as per Form-29 and Form-A of SECP	New management as per Form-29 and Form-A of SECP
1. Mr. Aamir Saleem S/o Muhammad Saleem CNIC No.17301-9419987-7 2. Mr. Tahir Saleem S/o Muhammad Saleem CNIC No.17301-1669380-7	1. Mr. Mazhar Saleem S/o Muhammad Saleem CNIC No.17301-4702545-3 2. Mr. Qaiser Saleem S/o Muhammad Saleem CNIC No. 17301-1669379-9	1. Mr. Aamir Saleem S/o Muhammad Saleem CNIC No.17301-9419987-7 2. Mr. Tahir Saleem S/o Muhammad Saleem CNIC No.17301-1669380-7 3. Mr. Mazhar Saleem S/o Muhammad Saleem CNIC No.17301-4702545-3 4. Mr. Qaiser Saleem S/o Muhammad Saleem CNIC No.17301-1669379-9

Case No. 14 CHANGE OF MANAGEMENT OF M/S HASSAN PHARMACEUTICAL(PVT) LTD, 99A, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR.

M/s Hassan Pharmaceutical (Pvt) Ltd, 99A, Industrial Estate, Hayatabad, Peshawar License No. 000357 by way of formulation has submitted request for change in management of the firm as per Partnership Deed with prescribed Fee Challan of Rs.50,000/- as under;

Previous Management as per Form-A of SECP	Newly appointed management as per Form-H and Partnership deed	Proposed management as per Form-H and Partnership deed
1. Mr. Muhammad Nawaz S/o Mr. Muhammad Hayat CNIC No.17301-2891116-7 2. Mrs. Azra Bibi W/o Muhammad Nawaz CNIC No.17301-1086887-0	1. Mr. Hassan Nawaz S/o Muhammad NawazCNIC No.17301-5182703-5 2. Mr. Qamar Abbas S/o Muhammad Nawaz CNIC No. 17301-1434318-7 3. Mr. Ali Hamza S/o Muhammad NawazCNIC No.17301-612522-9	1. Mr. Muhammad Nawaz S/o Mr. Muhammad Hayat CNIC No.17301-2891116-7 2. Mrs. Azra Bibi W/o Muhammad Nawaz CNIC No.17301-1086887-0 3. Mr. Hassan Nawaz S/o Muhammad NawazCNIC No.17301-5182703-5 4. Mr. Qamar Abbas S/o Muhammad Nawaz CNIC No.17301-1434318-7 5. Mr. Ali Hamza S/o Muhammad NawazCNIC No.17301-6125229-9

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Hassan Pharmaceutical (Pvt) Ltd, 99A, Industrial Estate, Hayatabad, Peshawar License No. 000357 by way of formulation as per Partnership Deed as under;

Previous Management as per Form-A of SECP	Newly appointed management as per Form-H and Partnership deed	Proposed management as per Form-H and Partnership deed
1. Mr. Muhammad Nawaz S/o Mr. Muhammad Hayat CNIC No.17301-2891116-7 2. Mrs. Azra Bibi W/o Muhammad Nawaz CNIC No.17301-1086887-0	1.Mr. Hassan Nawaz S/o Muhammad NawazCNIC No.17301-5182703-5 2.Mr. Qamar Abbas S/o Muhammad Nawaz CNIC No. 17301-1434318-7 3.Mr. Ali Hamza S/o Muhammad NawazCNIC No.17301-612522-9	1. Mr. Muhammad Nawaz S/o Mr. Muhammad Hayat CNIC No.17301-2891116-7 2. Mrs. Azra Bibi W/o Muhammad Nawaz CNIC No.17301-1086887-0 3. Mr. Hassan Nawaz S/o Muhammad NawazCNIC No.17301-5182703-5 4. Mr. Qamar Abbas S/o Muhammad Nawaz CNIC No.17301-1434318-7 5. Mr. Ali Hamza S/o Muhammad NawazCNIC No.17301-6125229-9

Case No.15. CHANGE OF TITLE OF M/S HASSAN PHARMACEUTICAL (PVT) LTD, 99A, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR.

M/s Hassan Pharmaceutical (Pvt) Ltd, 99A, Industrial Estate, Hayatabad, Peshawar License No. 000357 by way of formulation has submitted request for change of title of the firm as per Form -H with prescribed Fee Challan of Rs.50,000/- as under;

Existing Title of the firm as per Form-29 and Form-A of SECP	New Title of the firm as per Farm-H and Partnership deed
M/s Hassan Pharmaceutical (Pvt) Ltd.	M/s Hassan Pharmaceutical

Decision of CLB:

The Board considered and approved the change of title M/s Hassan Pharmaceutical (Pvt) Ltd, 99A, Industrial Estate, Hayatabad, Peshawar License No. 000357 by way of formulation as per Partnership Deed as under;

Previous Title of the firm as per Form-29 and Form-A of SECP	Current Title of the firm as per Farm-H and Partnership deed
M/s Hassan Pharmaceutical (Pvt) Ltd.	M/s Hassan Pharmaceutical

Case No. 16. CHANGE OF TITLE OF M/S HIZAT PHARMACEUTICAL INDUSTRIES (PVT) LTD, 170-IDUSTRIAL ESTATE, HAYATABAD, PESHAWAR.

M/s Hizat Pharmaceutical Industries (Pvt) Ltd, 170-Idustrial Estate, Hayatabad, Peshawar, Drug Manufacturing License No. 000315(by way of formulation) has submitted request for change of title of the firm as per Form -H with prescribed Fee Challan of Rs.50,000/- as under;

Previous Title as per Notice under Section 439(3) of Companies Ordinance 1984	New Title as per Form-H
M/s M/s Hizat Pharmaceutical Industries (Pvt) Ltd. 170-Idustrial Estate, Hayatabad, Peshawar	M/s Pharmaceutical Industry, 170-Idustrial Estate, Hayatabad, Peshawar

Decision of CLB in its 253rd meeting:

The considered request of M/s Hizat Pharmaceutical Industries (Pvt) Ltd. 170-Idustrial Estate, Hayatabad, Peshawar and accorded approval for change of title/ name of firms/ company as under:-

Present Name/Title of Firm/Company	New Name/Title of Firm/ Company (as per Form-H)
M/s Hizat Pharmaceutical Industries (Pvt) Ltd. 170-Idustrial Estate, Hayatabad, Peshawar	M/s Pharmaceutical Industry, 170-Idustrial Estate, Hayatabad, Peshawar

New title was mistakenly writtenas “M/s Pharmaceutical Industry” in the minutes whereas the correct title is “M/s Hizat Pharmaceutical Industry”.

Present Name/Title of Firm/Company	New Name/Title of Firm/ Company (as per Form-H)
M/s Hizat Pharmaceutical Industries (Pvt) Ltd. 170-Idustrial Estate, Hayatabad, Peshawar	M/s Hizat Pharmaceutical Industry, 170-Idustrial Estate, Hayatabad, Peshawar

Decision of CLB

The Board approved the correction in the name as M/s Hizat Pharmaceutical Industry, 170-Idustrial Estate, Hayatabad, Peshawar

Case No. 17 <u>CHANGE OF MANAGEMENT OF M/S CKD PHARMACEUTICALS PAKISTAN (PVT) LTD, 50/28, KORANGI INDUSTRIAL AREA, KARACHI.</u>

M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd, 50/28, Korangi Industrial Area, Karachi, DML No. 000144 by way of formulation has submitted request for change in management of the firm as per Form-29 from S.E.C.P along with prescribed Fee Challan of 50,000/- as under:-

Existing Management as per sale deed and Form-29	Retiring Management	Proposed Management as per Form-29
1. Mr. Ahsan Sultan Ahmed S/o Sultan Ahmed CNIC No. 42201-3110080-9. 2. Mr. Shahab Ahmed S/o Muhammad Ahmed CNIC No. 42301-0887778-3. 3. Mr. Anas Sultan Ahmed S/o Sultan Ahmed CNIC No. 42201-0775491-9.	1. Mr. Ahsan Sultan Ahmed S/o Sultan Ahmed CNIC No. 42201-3110080-9. 2. Mr. Shahab Ahmed S/o Muhammad Ahmed CNIC No. 42301-0887778-3. 3. Mr. Anas Sultan Ahmed S/o Sultan Ahmed CNIC No. 42201-0775491-9.	1. Mr. Syed Mustafa Hussain Kazmi S/o Syed Abrar Hussain Kazmi CNIC No. 42201-0716021-7.

<u>Decision of CLB:</u>

The Board considered and endorsed the change of management from old to new management ofM/s CKD Pharmaceuticals Pakistan (Pvt) Ltd, 50/28, Korangi Industrial Area, Karachi, DML No. 000144 by way of formulation as per Form 29 of SECPas under;

Existing Management as per sale deed and Form-29	Retiring Management	Proposed Management as per Form-29
1. Mr. Ahsan Sultan Ahmed S/o Sultan Ahmed CNIC No. 42201-3110080-9. 2. Mr. Shahab Ahmed S/o Muhammad Ahmed CNIC No. 42301-0887778-3. 3. Mr. Anas Sultan Ahmed S/o Sultan Ahmed CNIC No. 42201-0775491-9.	1.Mr. Ahsan Sultan Ahmed S/o Sultan Ahmed CNIC No. 42201-3110080-9. 2.Mr. Shahab Ahmed S/o Muhammad Ahmed CNIC No. 42301-0887778-3. 3.Mr. Anas Sultan Ahmed S/o Sultan Ahmed CNIC No. 42201-0775491-9.	1. Mr. Syed Mustafa Hussain Kazmi S/o Syed Abrar Hussain Kazmi CNIC No. 42201-0716021-7.

Case No. 18 CHANGE OF MANAGEMENT OF M/S RISMA LABORATORIES, A-2B, SITE, KARACHI.

M/sRisma Laboratories, A-2B, SITE, Karachi, DML No. 000053 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-1A	Retiring Management	Current Management as per Partnership deed
1. Mr. Raiz Ahmed Sheikh S/oSheikh Muhammad Din CNIC No. 42201-9838609-5.	1. Mr. Raiz Ahmed Sheikh S/o Sheikh Muhammad Din CNIC No. 42201-9838609-5.	1. Mr. SohailRaiz S/o Raiz Ahmed Sheikh CNIC No. 42201-4157252-3. 2. Mr. Salman Raiz S/o Raiz Ahmed Sheikh CNIC No. 42201-4252157-3.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/sRisma Laboratories, A-2B, SITE, Karachi, DML No. 000053by way of formulation as per Partnership Deed as under;

Previous Management as per Form-1A	Retiring Management	Current Management as per Partnership deed
1.Mr. Raiz Ahmed Sheikh S/oSheikh Muhammad Din CNIC No. 42201-9838609-5.	1. Mr. Raiz Ahmed Sheikh S/o Sheikh Muhammad Din CNIC No. 42201-9838609-5.	1. Mr. SohailRaiz S/o Raiz Ahmed Sheikh CNIC No. 42201-4157252-3. 2. Mr. Salman Raiz S/o Raiz Ahmed Sheikh CNIC No. 42201-4252157-3.

Case No.19 CHANGE OF MANAGEMENT OF M/S MERCK (PVT) LTD., JAIL ROAD QUETTA.

M/s Merck (Pvt) Ltd., Jail Road, Quetta License No. 000028 by way of formulation has submitted request for change in management of the firm as per Form -29 with prescribed Fee Challan of 50,000/- as under;

Previous Management as per Form-29 of SECP	Retiring Management as per Form-29 of SECP	Current Management as per Form-29 of SECP
1. Abdul Baqy Khan S/o Abdul Shakoor Khan CNIC No.42101-8330800-5 2. Dr. Peter-Ul Rich Mannheimer Passport No. 4075097570 3. Minocher K. Marker S/o KhursheedK. Marker CNIC No.42301-1002346-7 4. Tanveer Sultan Moledina S/o Sultan Abdullah Moledina CNIC No.42201-8540685-7	1. Abdul Baqy Khan S/o Abdul Shakoor Khan CNIC No.42101-8330800-5 2. Dr. Peter-Ul Rich Mannheimer Passport No. 4075097570 3. Minocher K. Marker S/o KhursheedK. Marker CNIC No.42301-1002346-7 4. Tanveer Sultan Moledina S/o Sultan Abdullah Moledina CNIC No.42201-8540685-7	1. Syed Anis Ahmed Shah S/o Syed Fazal Hussain ShahCNIC No.42301-4602118-1 2. Syed Dawood S/o Syed Fasih Uddin Ahmed Passport No.LB0060600 3. Mr. Ali Aamir S/o Abid Ali CNIC No.42301-0740467-9

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Merck (Pvt) Ltd., Jail Road, Quetta License No. 000028by way of formulation as per Form 29 of SECPas under;

Previous Management as per Form-29 of SECP	Retiring Management as per Form-29 of SECP	Current Management as per Form-29 of SECP
1. Abdul Baqy Khan S/o Abdul Shakoor Khan CNIC No.42101-8330800-5 2. Dr. Peter-Ul Rich Mannheimer Passport No. 4075097570 3. Minocher K. Marker S/o KhursheedK. Marker CNIC No.42301-1002346-7 4. Tanveer Sultan Moledina S/o Sultan Abdullah Moledina CNIC No.42201-8540685-7	1. Abdul Baqy Khan S/o Abdul Shakoor Khan CNIC No.42101-8330800-5 2. Dr. Peter-Ul Rich Mannheimer Passport No. 4075097570 3. Minocher K. Marker S/o KhursheedK. Marker CNIC No.42301-1002346-7 4. Tanveer Sultan Moledina S/o Sultan Abdullah Moledina CNIC No.42201-8540685-7	1.Syed Anis Ahmed Shah S/o Syed Fazal Hussain ShahCNIC No.42301-4602118-1 2.Syed Dawood S/o Syed Fasih Uddin Ahmed Passport No.LB0060600 3.Mr. Ali Aamir S/o Abid Ali CNIC No.42301-0740467-9

Case No. 20. CHANGE OF MANAGEMENT OF M/S KARACHI CHEMICAL INDUSTRIES (PVT) LTD.KARACHI.

M/s Karachi Chemical industries (Pvt) Ltd, DML License No. 000048 by way of formulation has submitted request for change in management of the firm as per Form -29 with prescribed Fee Challan of 50,000/- as under;

Previous Management as per Form-29 of SECP	Retiring Management	Proposed Management as per Form-29 of SECP
1.Mr. Saboor Ahmed S/o Haji Muhammad Rafiq CNIC No. 42201-7842077-5. 2.Mrs. Ishrat Tabbasum W/o Saboor Ahmed CNIC No. 42201-8127992-0. 3.Mrs. FouziaTayyabW/o Muhammad Tayyab CNIC No. 42201-1455726-2. 4.Mr. Muhammad Athar Tayyab S/o Muhammad Tayyab CNIC No. 42201-7671107-1.	1. Mrs. FouziaTayyabW/o Muhammad Tayyab CNIC No. 42201-1455726-2. 2. Mr. Muhammad Athar Tayyab S/o Muhammad Tayyab CNIC No. 42201-7671107-1.	1.Mr. Saboor Ahmed S/o Haji Muhammad Rafiq CNIC No. 42201-7842077-5. 2.Mrs. Ishrat Tabbasum W/o Saboor Ahmed CNIC No. 42201-8127992-0. 3.Mrs. Zafar Amin W/o Muhammad Amin Khan CNIC No. 42301-9562803-6. 4.Mrs. Maria Jawad Khan W/o Jawad Amin Khan CNIC No. 42301-9571353-6.

Decision of CLB:

The Board considered and endorsed the change of management from old to new management ofM/s Karachi Chemical industries (Pvt) Ltd, DML License No. 000048by way of formulation as per Form 29 of SECPas under;

Previous Management as per Form-29 of SECP	Retiring Management	New Management as per Form-29 of SECP
1. Mr. Saboor Ahmed S/o Haji Muhammad Rafiq CNIC No. 42201-7842077-5. 2. Mrs. Ishrat Tabbasum W/o Saboor Ahmed CNIC No. 42201-8127992-0. 3. Mrs. FouziaTayyabW/o Muhammad Tayyab CNIC No. 42201-1455726-2. 4. Mr. Muhammad Athar Tayyab S/o Muhammad Tayyab CNIC No. 42201-7671107-1.	1. Mrs. Fouzia Tayyab W/o Muhammad Tayyab CNIC No. 42201-1455726-2. 2. Mr. Muhammad Athar Tayyab S/o Muhammad Tayyab CNIC No. 42201-7671107-1.	1. Mr. Saboor Ahmed S/o Haji Muhammad Rafiq CNIC No. 42201-7842077-5. 2. Mrs. Ishrat Tabbasum W/o Saboor Ahmed CNIC No. 42201-8127992-0. 3. Mrs. Zafar Amin W/o Muhammad Amin Khan CNIC No. 42301-9562803-6. 4. Mrs. Maria Jawad Khan W/o Jawad Amin Khan CNIC No. 42301-9571353-6.

Case No.21. RENWAL OF M/S SWAT PHARAMCEUTICALS, SAIDU SHARIF ROAD, AMANKOT, SWAT.

M/s Swat Pharmaceuticals, Saidu Sharif Raod, Amankot, Swat submitted the application for renewal of DML No. 000035 by way of formulation on 03-02-2015 for the period of 30-04-2015 to 29-04-2020, which was well on time. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. Deposited fee challan of Rs.50,000/- for change of management alongwith requisite documents is not attached.
ii. Up-to-date nothing due certificate (CRF) from STO is not attached.

Proposed Production Incharge

iii. Experience of proposed Production Incharge is less than prescribed period of ten (10) years.
iv. Deposited fee challan of Rs.5,000/- for change of Production Incharge is not attached.
v. Resignation letter of already approved Production Incharge is not attached.

Proposed QC Incharge

vi. Experience of proposed QC Incharge is less than prescribed period of ten (10) years.
vii. Deposited fee challan of Rs.5,000/- for change of QC Incharge is not attached.
viii. Resignation letter of already approved QC Incharge is not attached.
ix. Resignation letter of proposed QC Incharge from previous firm is not attached.

2. With reference to above letter, the firm submitted shortcoming documents. Upon evaluation letter with following observation was issued to the firm;

i. Upon evaluation it was transpired that the management of M/s Swat Pharmaceuticals, Swat has been changed as under;

Previous Management as per Form-1A	**Current Management as per Affidavit**
i) Mr. Habib-Ur-Rehman. ii) Mr. Inayat-Ur-Rehman.	i) Mr. Mubarak Ali

ii. The agreement submitted by you regarding change in management of M/s Swat Pharmaceuticals, Swat states that you purchased share of Mr. Inayat-ur-Rehman i.e. 21.376% of the total capital. You are hereby again advised to clarify the status regarding ownership of remaining 78.624% share of the said firm.

3. With reference to above letter, a final reminder was issued to the firm with the same observations. With reference to final reminder, the firm submitted some documents regarding the management of the firm the detail of which is as under;

i. Existence/Exemption Certificate from Assistant Commissioner Babuzai.
ii. National Tax certificate.
iii. Affidavit from Mr. Habib-Ur-Rehman.
iv. Account Certificate from Bank of Khyber.
v. Affidavit from Mr. Mubarak Ali.

4. **Facts mentioned at para 3 above exists as such which are placed before the Board for consideration, please.**

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000035by way of formulation ofM/s Swat Pharmaceuticals, Saidu Sharif Raod, Amankot, Swatmay not be rejected by Central Licensing Board.

Case No.22. <u>M/S YOUSAF ALI SHAH CHEMICAL INDUSTRIES (PVT) LTD., PLOT NO.191/1, STREET L-10, GADOON AMAZAI, SWABI-NON COMPLETION OF APPLICATION FOR RENEWAL OF DRUG MANUFACTURING LICENCE.</u>

M/s Yousaf Ali Shah (Pvt) Ltd, Plot No.191/1, Street L-10, Gadoon Amazai, Swabi submitted the application for renewal of DML No. 000371 by way of formulation on 25-05-2016 for the period of 01-04-2016 to 31-03-2021, which was 55 days late. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. To submit renewal of Drug Manufacturing License application on prescribed Form-1A (copy enclosed).
ii. Renewal application is 55 days late as you deposited a late fee for 54 days, deposit more late fee i.e. Rs.5000/- for one day.

2. With reference to above letter, the firm has submitted DML renewal application on Form-1A with some attachments. Upon evaluation, Licensing Division issued reminder for completion of application with following shortcomings;

i. Attested copies of CNIC of partners.
ii. Late fee of Rs.5,000/- for one day.
iii. Attested copy of approved layout plan.
iv. Fee for approval of technical staff i.e Production Incharge and QC Incharge.
v. Attested copies of appointment / job acceptance letters of proposed Production Incharge and QC Incharge.
vi. Attested copies of CNIC of proposed Production Incharge and QC Incharge.
vii. Attested copy of Undertaking as whole time employee of Production Incharge and QC Incharge.
viii. Attested copies of resignation letter of previously appointed Production Incharge and QC Incharge.
ix. Attested copies of resignation letter of proposed Production Incharge and QC Incharge from previous firm.

3. With reference to above reminder, the firm submitted some shortcoming documents. Upon evaluation, it was observed that there was change of management and accordingly Licensing Division issued another reminder for completion of application with following shortcomings;

i. Requisite fee Challan of Rs. 50,000/- alongwith documents for change of title has not been submitted, but the title of the firm has been changed from private limited company to partnership firm.
ii. The detail of previous management (as per Form-29) has not been submitted.
iii. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP has not been submitted.
iv. Attested copy of CNIC of proposed Production Incharge Mr. Abid Hussain, is not attached.
v. Attested copy of appointment letter of proposed Production Incharge is not attached.
vi. Attested copy of resignation of proposed Production Incharge from the previous firm is not attached.
vii. Attested copy of resignation of previously approved Production Incharge is not attached.
viii. Undertaking as whole time employee by proposed Production Incharge is not attached.
ix. Attested copy of appointment letter proposed QC Incharge Mr. Muhammad Yasir is not attached.
x. Attested copy of resignation of proposed QC Incharge from the previous firm is not attached.
xi. Attested copy of resignation of previously approved QC Incharge is not attached.
xii. Fee Challan of Rs.5,000/- for approval of proposed QC Incharge is not attached.
xiii. Undertaking as whole time employee by proposed QC Incharge is not attached.

4. With reference to above reminder, the firm submitted some documents. Upon evaluation, Licensing Division issued final reminder for completion of application with following shortcomings;

i. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.
ii. Form-29 & Form-A of SECP showing the detail of previous title and management.
iii. Dissolution certificate from SECP showing that the M/s Yousaf Ali Shah Chemical Industries (Pvt) Ltd., has been dissolved.

5. With reference to above final reminder, the firm submitted some documents. Upon evaluation, following shortcomings have still been observed;

i. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why theDML No. 000371 by way of formulation of M/s Yousaf Ali Shah (Pvt) Ltd, Plot No.191/1, Street L-10, Gadoon Amazai, Swabi may not be suspended under Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund.

Case No.23 **M/S SIBRO PHARMA LTD., PLOT NO.230, INDUSTRIAL AREA, NOWSHERA – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.**

M/s Sibro Pharma Ltd, Plot No.230, Industrial Estate, Nowshera submitted the application for renewal of DML No. 000036 by way of formulation on 27-04-2015 for the period of 03-05-2015 to 02-05-2020, which was well on time. **The firm submitted only fee challan with covering letter.**After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued advising the firm to submit complete application on prescribed Form-1A with its all enclosures.

2. With reference to above letter, the firm as per record of Licensing Division no response has been received from the firm and a final reminder was issued advising again to the firm to submit complete application on prescribed Form-1A with its all enclosures.

In response to the final reminder, the firm replied as under;

> *"In this connection, we humbly want to inform you that we have already submitted the License Renewal challan of Rs. 50,000/- Dated 23-04-2015.*
>
> *Our production is still remained closed but we are under negotiation with the bank for Running Finance in order to restart our Pharma production.*
>
> *Therefore, we will instantly inform you as soon as our deal with the Bank become finalize to restart the factory."*

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000036by way of formulation ofM/s Sibro Pharma Ltd, Plot No.230, Industrial Estate, Nowshera may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No.24 **M/S LAWARI INTERNATIONAL, VALLEY ROAD, GULKADA, SWAT – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.**

M/s Lawari International, Valley Road, Gulkada, Swat submitted the application for renewal of DML No. 000658 by way of formulation on 27-01-2014 for the period of 30-01-2014 to 29-01-2019, which was well on time.After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued advising the firm to submit complete application on prescribed Form-1A with its all enclosures.

2. With reference to above letter, the firm has submitted DML renewal application on Form-1A with some attachments. Upon evaluation, Licensing Division issued letter for completion of application with following shortcomings;

i. Classes of Drugs.
ii. Name of drugs.
iii. Copy of approved layout plan with sections letters issued by Central Licensing Board (CLB)
iv. Approval letters of technical persons i.e. Production Incharge and Quality Control Incharge or provide documents as per checklist (enclosed).
v. Updated nothing due certificate (CRF) from STO (R&D) DRAP Islamabad.
vi. Legal status of the firm with the names of directors, owners or partners.

3. With reference to above letter, as per record of Licensing Division no response has been received from the firm and a final reminder was issued on 16th February, 2017 advising again to the firm to rectify following shortcomings;

i. Attested copy of classes of drugs to be manufactured.
ii. Attested copy of name of drugs to be manufactured.
iii. Attested copy of approved layout plan with approval letter(s) of all approved sections.
iv. Approval letter of Production and QC Incharge and if technical persons have been changed then provide attested documents as per enclosed checklist.
v. Up-to-date nothing due certificate (CFR) from STO, DRAP.
vi. Legal status of the firm with the names of directors / owners / partners.

4. With reference to above final reminder, as per record of Licensing Division no response has been received from the firm till to date.

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000658by way of formulation ofM/s Lawari International, Valley Road, Gulkada, Swat may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 25 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S UNIPHARMA (PVT) LTD, LAHORE.**

M/sUniPharma (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahore had applied for renewal of DML No. 000412 by way of formulation for the period of 19-06-2015 to 18-06-2020.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 8th June, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form 29 Attested from SECP
2. Copies of CRF / N.O.C Nothing Due Certificate
3. Copy of approval Layout plan
4. Proof of all licensed section granted by CLB.
5. Proof of approval of QC Incharge (Mr. M. Amjid as per application 1A)

2. The firm submitted the reply of our letter on 18-07-2016. But the application for renewal of DML was not complete and Reminder-I was issued on 3-11-2016 to the firm with following shortcomings: -

1. Attested of copies of CNIC of all directors.
2. Proof of approval of QC incharge (Mr. M. Amjid as per application 1A).

3. Firm submitted documents on 06-12-2016 in reply to Reminder-I but following documents were still deficient /short and same were convened to the firm vide letter issued on 2-2-2017. The firm did not reply and Final Reminderwas issued on 1-06-2017 to the firm with following shortcomings: -

1. Appointment letter.
2. Job acceptance letter by the appointee.
3. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not less than 10 years).
4. Resignation / retirement of earlier QC Incharge.
5. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
6. Undertaking as whole time employee.
7. Approval letter of Production Incharge in case of change then submit complete set of documents as per check list
8. All documents should be duly attested.

4. The firm has submitted following documents in response to aforesaid Final Reminder.

1. Appointment letter.
2. Job acceptance letter by the appointee.
3. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
4. Approval letter of Production Incharge in case of change then submit complete set of documents as per check list.
5. The firm has submitted unattested experience certificates and relevant experience of proposed Quality Control Incharge is less than 10 years (7 year 6 month).

5. Following documents are still short:-

1. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
2. Resignation / retirement of earlier QC Incharge.
3. Undertaking as whole time employee.

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000412by way of formulation ofM/sUniPharma (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahore may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 26 <u>RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000656 OF M/S USMAN ENTERPRISE, KARACHI.</u>

M/s Usman Enterprise, Plot No. 116, S.I.T.E (SHW) Phase-I, Karachi, has applied for renewal of DML No. 000656 by way of formulation for the period of 30-01-2014 to 29-01-2019 on 29th October, 2013. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 7th March, 2014 and 20th February, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

a) Complete attested enclosures of Form-1A.
b) NOC of CRF issued from statistical officer of DRAP (Updated).
c) Complete set of attested documents of proposed QC Incharge / Production Incharge along with prescribed fee(as per checklist).
d) Attested copy of CNIC of proprietor.
e) Attested land ownership document.

2. Later on with reference to above shortcomings / deficiencies a final reminder letter was issued on 4th April, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

1. All enclosures of Form-1A must be attested.
2. Detail of premises including approved layout plan / Proof of Sections from CLB.
3. Nothing due certificate regarding CRF from STO (Updated).
4. Documents of proposed Quality Control Incharge who does not fulfills the requirements of Rule 16 of Drugs (L, R, &A) rules 1976 in terms of qualification.
5. Prescribe fee of Rs.10,000/- for change of Quality Control Incharge and Production Incharge.
6. Complete Set of documents for Proposed Quality Control Incharge and Production Incharge as (per check list).

7. All documents should be duly attested.

3. Now, the firm has submitted documents for approval of QC incharge but still following shortcomings are required to be completed.

i. Updated nothing due certificate regarding CRF from STO.
ii. Resignation / retirement of earlier Production Incharge.
iii. Approval letters of section issued from CLB.

Decision of Central Licensing Board in 254th meeting.

4. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of DML No. 000656 by way of formulation of M/s Usman Enterprise, Plot No. 116, S.I.T.E (SHW) Phase-I, Karachi, may not be rejected by Central Licensing Board or their Drug Manufacturing License may not be suspended or cancelled by Central Licensing Board.

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

5. The Show Cause notice dated 23rd June, 2017 was issued to the M/s Usman Enterprise, Plot No. 116, S.I.T.E (SHW) Phase-I, Karachi

6. Reply of the show cause is received from the firm and documents were evaluated. Firm has submitted all the required documents for renewal of DML No. 000656 and application for renewal of DML is complete.

7. Case is placed before the Board for ceasing the enforcement the show cause notice issued to the firm forviolation of Rule 5 (2A) of Drugs (Licensing, Registering and Advertising) Rule, 1976.

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to cease the enforcement of the operation of the show cause notice issued to the firm with immediate effect.

Case No.27. **M/S MEDICON PHARMACEUTICAL INDUSTRIES (PVT) LTD., B-1/11, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.**

Case Background

M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar submitted the application for renewal of DML No. 000215 by way of formulation on 26-05-2016 for the period of 14-06-2016 to 13-06-2021, which was well on time. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. To submit renewal of Drug Manufacturing License application on prescribed Form-1A (copy enclosed).
ii. To submit detail of management / owners with attested copies of CNIC's and Form-29 (previous and current).

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

i. To submit renewal of Drug Manufacturing License application on prescribed Form-1A (copy enclosed).
ii. To submit detail of management / owners with attested copies of CNIC's and Form-29 (previous and current).

3. No response of the firm was received with reference to above mentioned letter and final reminder and case was considered in 253rd meeting of the Central Licensing Board.

Decision of CLB in its 253rd meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medicon Pharmaceutical Industries (Pvt) Ltd. Hayatabad, Peshawar DML No. 000440 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

4. The Drug Manufacturing Number of the firm was erroneously written as "**000440**" instead of the correct Drug Manufacturing License Number i.e. "**000215**".

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record decided to correct the mistake for mentioning the Drug Manufacturing License Number i.e. "**000215".**Accordingly, ShowCause Notice shall be issued.

Case No. 28. <u>RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FARMACEUTICS INTERNATIONAL, KARACHI.</u>

M/s Farmaceutics International, F-1,A-3, S.I.T.E, Karachi had applied for renewal of DML No. 000554 by way of formulation for the period of 03-11-2014 to 02-11-2019 on 02-12-2019.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 21st March, 2016under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

f) Proof of approval of sections/dosage form
g) N.O.C. of CRF
h) Copy of approval Layout plan
i) Proof of all licensed section granted by CLB.
j) Names and Attested copies of CNIC of all Directors.
k) Proof of approval of Q.C incharge and Production incharge or complete set of documents of technical staff.

2. Firm did not submit the shortcoming documents and a Final Reminder letter was issued on 19th June, 2017 under Rule 5 (2A) of Drugs (Licensing, Registering &Advertising) Rules, 1976 of following shortcomings.

a) Proof of approval of sections/dosage form
b) N.O.C. of CRF
c) Copy of approval Layout plan
d) Proof of all licensed section granted by CLB.
e) Names and Attested copies of CNIC of all Directors.
f) Proof of approval of Q.C incharge and Production incharge or complete set of documents of technical staff.

3. Firm has not submitted the required above mentioned documents till date and application for renewal of DML No.000554 for the tenure 03-11-2014 to 02-11-2019 is **still incomplete**.

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000554by way of formulation ofM/s Farmaceutics International, F-1,A-3, S.I.T.E, Karachi may not be rejected by Central Licensing Board or the Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 29. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ANEEB PHARMACEUTICALS (PVT) LTD, LAHORE

M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-Km, Bedian Road, Lahore had applied for renewal of DML No. 000555 by way of formulation for the period of 01-11-2014 to 31-10-2019.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 25th June, 2015 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. List of total licensed sections involved in manufacturing of drugs and their letter for grant from CLB.
ii. Status of the construction of section according to approved layout plan dated 15-12-2012 and status of production.
iii. Latest copy of form-29 issued and attested by S.E.C.P.
iv. CNIC copies of all directors of the firm.
v. To furnish documents of proposed Production Incharge as per checklist.
vi. To provide information of QC Incharge of the firm and approval letter form competent authority.
vii. To furnish Nothing Due certificate valid upto 31-12-2015.
viii. To provide detail of registered products of the firm.

2. Firm submitted documents on 23-07-2015 but following documents were still deficient /short and same were conveyed to the firm Final Reminder letter issued on 09-06-2017.

i. Attested of copy of Form-29 from S.E.C.P.
ii. Nothing Due certificate of CRF (Updated).
iii. Attested documents of proposed Production and QC Incharge as per checklist.
iv. Declaration that there is any change in management of firm or not with detail of management.

3. The firm has submitted documents in response to aforesaid Final Reminder but Following documents are still short:-

1. There seems to be change of management but the firm has not deposited fee of Rs. 50,000/-. Detail of Management / Directors of M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-KM, Bedian Road, Lahore is as under: -

Management at the time of Previous Renewal of DML As per Form-29 of SECP	**Retiring Management As per Form-29 of SECP**	**Management As per Form-29 of SECP**
1. Ch. Shahid Sharif S/o Muhammad Sharif, CEO/Director, CNIC No. 35201-5391544-4 2. Mr. Atif Sharif S/o Muhammad Sharif, CNIC No. 35201-6971651-5, Director 3. Mr. Umair Sharif S/o Muhammad Sharif, CNIC No. 35201-9735350-1Director.	1. Mr. Umair Sharif S/o Muhammad Sharif, CNIC No. 35201-9735350-1 Director	1. Ch. Shahid Sharif S/o Muhammad Sharif, CEO/Director, CNIC No. 35201-5391544-4 2. Mr. Atif Sharif S/o Muhammad Sharif, CNIC No. 35201-6971651-5, Director

4. M/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-KM, Bedian Road, Lahore has submitted documents for approval of proposed Production Incharge Muhammad Imran S/o Muhammad Hashim (M.Phil Pharmacology) CNIC No. 36602-2076151-7 QC Incharge Miss NaurinaMaqbool D/o Ch. Maqbool Ahmad Tajwar (M.Sc Chemistry) CNIC No. 35202-4519743-4 but it is observed from the documents that the earlier production Incharge of the firm had resigned 30-06-2016 and the firm appointed new production Incharge on 01-06-2016 and applied to this Division for approval on 12th May, 2017. Similarly, proposed Quality Control Incharge was appointed on 06-12-2016 after the resignation of previous QC Incharge on 15- Nov, 2016 and the firm applied for approval on 12-05-2017. Firm has been manufacturing and selling medicines with supervision and quality checks by approved qualified staff.

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000554by way of formulation ofM/s Aneeb Pharmaceuticals (Pvt) Ltd, 24-KM, Bedian Road, Lahore may not be suspended or cancelled by Central Licensing Board.

Case No. 30 RENEWAL OF DRUG MANUFACTURING LICENCE OFM/S KAILGON AGRO INDUSTRIES (Pvt) Ltd, HUB.

M/s Kailgon agro industries(Pvt) Ltd , Hub, Balochistan had submitted application dated 10-02-2016 for the renewal of DML No. 000277 for the tenure 11-02-2016 to 10-02-2021 . After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings/attested documents dated09-09-2016: -

(i) Fee for change of management/Directors.

(ii) Proof of all licensed sections issued from CENTRAL Licensing Board.

(iii) N.O.C for C.R.F.

2. Firm did not submit the reply of the above shortcoming letter; accordingly a reminder was issued by Secretary CLB dated 09-03-2017 to submit documents for renewal of DML .Firm did not submit reply along with deficient documents against the reminder for the completion of their DML renewal application. In the meanwhile firm also applied for change of both technical personsand letter dated: 27-03-2017of shortcomings was issued to the firm to submitdocuments for approval of Production Incharge & Q.C. incharge.

3. A Final Reminder dated 16-06-2017 was issued to the firm to submit following documents for renewal of DML& for approval of technical staff(Production Incharge & Q.C. Incharge):

i. Attested form-29 along with Form -A from SECP(Updated).
ii. Approval letters of sections issued from CLB.
iii. Nothing Due certificate(Updated)
iv. Prescribed fee of Rs.50,000 for change of management.
v. N.O.C from previous management to new management.
vi. Prescribed fee of Rs.5000 for change of Q.C. Incharge
vii. Attested academic certificates of Q.C. Incharge.
viii. Resignation of Production Incharge & QC incharge from previous firm.
ix. Attested CNIC copy of QC incharge.
x. Resignation of earlier appointed Production Inchage.

4. Firm submitted documents on 29-06-2017 in reply to Final Reminder but following documents are still deficient /short;

i. Attested form-29 along with Form -A from SECP(Updated).
ii. Prescribed fee of Rs.50,000 for change of management.
iii. Resignation of earlier appointed Production Incharge.
iv. Relevant Experience certificates of Production Incharge & QC Incharge.
v. Prescribed fee of Rs.5000 for change of Q.C. Incharge
vi. Attested academic certificates of Q.C. Incharge.
vii. Resignation of Production Incharge & QC incharge from previous firm.
viii. Attested CNIC copy of QC incharge.

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Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000277by way of formulation ofM/s Kailgon agro industries(Pvt) Ltd , Hub, Balochistanmay not be rejected by Central Licensing Board or the Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 31 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 bailable 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 issue N.B.W of arrest of the accused for 20-11-2015 and again forward 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 disagreeable. 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 sealed under intimation to this Court.
Announced
03-11-2015

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

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

i. Division of (QA/LT) 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 received from FID, Lahore 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 taken in its 245th meeting held on 30 December, 2015:
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 Hon'rable 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 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 complete the proceedings and submit report before the court on 28-01-2015.

- On 28-01-2016 again FID appeared before the Hon'rable 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 further stated that the Hon'rable 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 before the Central Licensing Board (CLB) in its 247th meeting held on 31-04-2016.**

Proceedings of 247th meeting of CLB

Muhammad Fahim Regulatory Manager of the firm M/s M/s Medi-Markers Hyderabad 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 RaheelaSaleem 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 assure 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.

Further 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 Hon'rable Drug Court Lahore passed on 01-06-2016 and Nonbailable warrants of accused for execution.

The State Versus
Medimarker'setc
Present: DDPP for the State
Accused absent
Sheikh Abdul Rasheed Federal Drug Inspector Present

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 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 attendance. 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 inform this court for the proceedings of suspension of license.

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.

Announced
01-06-2016

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-Lic 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 placed in agenda of upcoming meeting of CLB for consideration.

Court Orders dated 17-06-2016:

Another letter No.9157/2016-DRAP(L-I) dated 21-06-2016 was received from Federal Inspector of Drugs, Lahore 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 orders of the Drug court following actions were 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 were placed in agenda of 248th 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 of Central Licensing Board:

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

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

Action taken by Licensing Division:

i. Show cause notice to the firm was issued for suspension/cancellation of Licence on 30th August, 2016 and copy of the same was also forwarded to Chairman, Drug Court, Lahore.

ii. Meanwhile, hearing of the case was held on 31.8.2016 at the Drug Court, Lahore. The order of the court is reproduced as under:

> "***The order dated 1.06.2016 was passed by this Court to procure the attendance of the accused for facing the trial. Now they have surrendered themselves before the Court. In these circumstances, application in hand is thereby accepted and Federal Drug Regulatory is directed to stop the proceedings of the cancellation of licence of Medimarker's under intimation to this Court."***

Now another order passed by Honourable, Chairman, Lahore Drug Court Lahore dated **19-10-2016** is received through FID, Lahore. Orders of the Court are re-produced as under: -

> *"The case in hand is pending before the court since 16-04-2014 and during that period, accused played hide and seek with the Court even Court passed strict orders for the suspension of drug manufacturing license of the company through Drug Regulatory Authority of Pakistan, Islamabad and premises was sealed, then after adopting all the coercive measures, accused made appearance and moved application for cancellation of the NBW already issued against the accused by this Court. No doubt case of the accused is private complaint and after attending the Court, accused remained absented themselves again and again by playing hide and seek with this Court. Keeping in view the attitude of the accused toward Court orders, court is left with no option accept taking serious notice and passing strict order for procuring the attendance of accused persons attracting issuance of NBW of both the accused and forfeiture of their sureties and service be executed through DIG Karachi. Separate notices to their sureties also be issued to show cause or to pay the penalty.*
>
> ***Drug Regulatory Authority of Pakistan, Islamabad is directed to seal the premises of M/s Medimarker's Pharmaceutical A-104 SITE Area Hyderabad Pakistan, through Federal Drug Inspector Karachi and suspend its Drug Manufacturing License by convening special meeting under intimation to this Court till further order****. Ahlmad is*

directed to convey this order to Sheikh Abdul Rasheed Federal Drug Inspector for onward transmission to quarter concern for immediate compliance.

Re-list for 27-10-2016*".*

The firm has been called for personal hearing

Proceeding of 250th meeting of Central Licensing Board held on 27th October, 2016.

Mr. Rashid Ali, Manager Regulatory Affairs, appeared before the Board on behalf of the company. He contended that he was authorized to appear before the Board. He presented the Medical certificate issued in the name of Dr. Abdul Shakoor S/o Muhammad Usman issued by Dr. Anoop Kumar of M/s Dr. Ziauddin Hospital, Karachi. The contents of Medical certificate are reproduced below:

"*This is to certify that Dr. Abdul Shakoor s/o Muhammad Usman 43 years old was admitted on 18-10-2016 with reference # 00048933/2016 under care of Dr. Imran Bashir and Dr. Saad Niaz Consultant Gastroenterlologist with complaint of epigastric pain for 2 days for which he is investigating for his diagnosis."*

Decision in 250th meeting of Central Licensing Board held on 27th October, 2016.

The Board heard the representative of the firm who was called on the orders of the Drug Court, Lahore and decided to suspend the Drug Manufacturing Licence of M/s Medimarker's Pharmaceutical A-104 SITE Area Hyderabad Pakistan till further orders.

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

Accordingly order for suspension of the License were issued on 28-11-2016.

Later on, Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore-I, has forwarded the copy of the Order dated 10-03-2017, passed by Hon'rable Chairperson Lahore Drug Court, Lahore along with original summon of M/s Madimarker's Pharmaceuticals (Pvt) Ltd. He has further stated that next date of hearing is fixed by the Court on 13-04-2017. The Order of Hon'rable Court is as under:

"Learned counsel moved an application on behalf of the applicant / accused Shakoor Sheikh, praying to recall the order which was passed by this court on 19.10.2016 and restoration of manufacturing of drug sale license. Court heard the full arguments early in the morning.

In view of above the court has decided to de-seal the premises subject to furnishing fresh surety bonds in the sum of Rs 5,00,000/- with two sureties for satisfaction of this court. As far as second request for restoration of manufacturing license, we are inclined to refer the matter to the Central Licensing Board consider its previous decision and act in accordance with law.

They will de-seal the premises for conducing GMP in inspection.

The attendance of the accused Shakoor Sheikh may be exempted if he admitted in Hospital but produce the medical Certificate".

The case of de-sealing of premises M/s Medimarker's Pharmaceuticals (Pvt) Ltd, A-104 SITE Area Hyderabad was related to QA / LT Division, Islamabad and same was forwarded on 06-04-2017.

Decision of Central Licensing Board in 253rd meeting.

The Board considered and deliberated on the background in the light of orders of the Honourable Lahore Drug Court, Lahore and decided to:

i. Withdraw the suspension of Drug Manufacturing Licence of M/s Medimarker's Pharmaceuticals (Pvt) Ltd, A-104 SITE Area Hyderabad with immediate effect.

ii. Detailed GMP inspection of the firm shall be conducted as per laid down procedure.

iii. The firm shall not conduct production till successful GMP inspection with good rating and approval of the Competent Authority.

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

In the light of decision of Central Licensing Board mentioned above, the suspension of DML of firm was withdrawn with immediate effect. GMP inspection report was received from area FID Karachi in which area FID has informed that overall conditions of firm were found satisfactory during the inspection. On the basis of the report from the office of Federal Inspector of Drugs, Karachi, production was allowed for registered drugs.

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board endorsed the proceedings taken by the Licensing Division.

Case No. 32 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MARVI PHARMACEUTICALS KARACHI.**

M/s Marvi Pharmaceuticals, Plot No. 70, Sector 24, Korangi Industrial Area, . Karachi had applied for renewal of DML No. 000148 by way of formulation for the period of 09-07-2015 to 08-07-2020. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 5-06-2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Copy of Form-D from Registrar of firms.
2. CNIC copies of management / Partner.
3. Approved Master Layout Plan / Proof of licensed section from CLB.
4. Nothing due certificate regarding CRF from STO (Updated).
5. Prescribe fee of Rs. 10,000/- for change of proposed Production Incharge and Quality Control Incharge.
6. Complete set of documents for Proposed Production Incharge and Quality Control Incharge as (per check list).
7. All documents should be duly attested

2. The firm submitted their reply on 15th June, 2017 After evaluation of the submitted documents, final reminder was issued on 10th July 2017 to the firm with following shortcomings: -

1. Nothing due certificate regarding CRF from STO (Updated).
2. Complete set of documents for Proposed Production Incharge and Quality Control Incharge as (per check list).
3. All documents should be duly attested.

3. The firm has not submitted the above mentioned documents till date and application for renewal of DML is **still incomplete**

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000148by way of formulation ofM/s Marvi Pharmaceuticals, Plot No. 70, Sector 24, Korangi Industrial Area, . Karachi may not be rejected by Central Licensing Board or the Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 33 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S SURGICAL FIBRE, LAHORE.

M/s Surgical Fibre, 1-Km, Katar Bund Road, Thoker Naiz Baig Off Multan Road, Lahore had applied for renewal of DML No. 000466 by way of formulation for the period of 19-08-2014 to 18-08-2019.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 25th May, 2015 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. CNIC copies of all Directors of the firm.
ii. On letter hear of the firm, provide information of all directors in terms of name, address, contact Number.
iii. List of total sections of the firm and their letters of grant from CLB.
iv. Documents / information submitted for proposed Production Incharge i.e. Fiza does not fulfills the requirements of Rule 16 of Drugs (Licensing, Registering and Advertising) rules 1976, as minimum experience required under rule is 10 years after academic qualification whereas proposed production incharge is graduate of Pharmacy in year 2008 and proses 6 years' experience only. Therefore, firm is required to submit documents / information of proposed production incharge who shall proses minimum 10 years' experience after academic qualification and complete the documents / information of the request according to the check list enclosed herewith.
v. To provide photocopy of degree and contact detail of Mr. Muhammad Nadeem (M.Sc. chemistry).
vi. Nothing due certificate regarding CRF from STO valid upto 31-12-2015.
vii. To submit photocopy of master layout plan of the firm mentioning all the sections in licensing facility and which be approved by competent authority, in case if not approved then to regularize the master layout plan of the firm.

2. The firm did not submit their reply. Final Reminder was issued on 1stJune 2017 to the firm with following shortcomings: -

i. Detail of management at the time of pervious renewal of DML and present renewal of DML along with CNIC copies.
ii. CNIC copies of all Directors / Partners.
iii. Approved Master Layout Plan / Proof of licensed section from CLB.
iv. Nothing due certificate regarding CRF from STO (Updated).
v. Prescribe fee of Rs. 5,000/- for proposed Production Incharge.
vi. CNIC copy of appointee (Production Incharge).
vii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not less than 10 years in relevant field for proposed Production Incharge).
viii. Resignation / retirement of earlier Production Incharge.
ix. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Production Incharge).
x. Undertaking as whole time employee (Production Incharge).
xi. All Documents should be duly attested.

3. Firm submitted documents on 21-06-2017 in reply to Final Reminder but following documents are still deficient /short and application for renewal of DML is still incomplete.

i. Detail of management at the time of pervious renewal of DML and present renewal of DML along with CNIC copies.

ii. CNIC copy of appointee (Production Incharge).
iii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not less than 10 years in relevant field for proposed Production Incharge).
iv. Resignation / retirement of earlier Production Incharge.
v. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Production Incharge).
vi. Undertaking as whole time employee (Production Incharge).
vii. Documents should be duly attested.

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000466 by way of formulation ofM/s Surgical Fibre, 1-Km, Katar Bund Road, Thoker Naiz Baig Off Multan Road, Lahore may not be rejected by Central Licensing Board or the Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 34 <u>RENEWAL OF DRUG MANUFACTURING LICENCE OF M/SSEAGULL PHARMA, JHANG.</u>

M/s Seagull Pharma, Tower Point, Beg Colony, Gojra Road, Jhang had applied for renewal of DML No. 000482 by way of formulation for the period of 19-12-2015 to 18-12-2020.The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 9th August, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Proper on form 1-A duly attested, sign & stamped by the management of firm
ii. Nothing due certificate CRF from STO.
iii. Classes of drugs / Dosage form of drugs / name of all resisted drugs

2. The firm submitted their reply on 19th December, 2016 After evaluation of the submitted documents, Final Reminder was issued on 2nd March 2017 and again Final Reminder 19th June 2017 to the firm with following shortcomings: -

i. Nothing due certificate CRF from STO (Updated).
ii. Complete set of documents for change of management (as per checklist) along with prescribe fee of 50,000/-.
iii. All documents should be duly attested.

3. Firm submitted documents on 14-07-2017 in reply to Final Reminder and submitted Nothing due certificate regarding CRF from STO valid upto 31-12-2017 and stated that Mr. Muhammad Umar Farooq S/o Ghulam Nabi is the sole proprietor / Managing Director of the firm since the issuance of DML and there is no change in the management of the firm. But as per available record in Licensing Division, following were the partners of the firm at the time of grant of DML (page 68/ Corr).

i. Mr. Muhammad Umer Farooq S/o Ghulam Nabi.
ii. Ms. Ghulam Zahra D/o Sher Muhammad.
iii. Mr. Muhammad Usman Farooqi S/o Ghulam Nabi.
iv. Mr. Hafiz Irfan Mujahid S/o Ghulam Nabi.

4. Now Mr. Muhammad Umar Farooq S/o Ghulam Nabi is sole proprietor as per application of renewal of DML so there is change of management.

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000482by way of formulation ofM/s Seagull Pharma, Tower Point, Beg Colony, Gojra Road, Jhang may not be rejected by Central Licensing Board.

Case No. 35. <u>M/S MAKSON PHARMACEUTICALS, INDUSTRIAL AREA, I-10/3, ISLAMABAD – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.</u>

M/s Makson Pharmaceuticals, Industrial Area, I-10/3, Islamabad submitted the application for renewal of DML No. 000560 by way of formulation on 12-11-2015 for the period of 07-12-2014 to 06-12-2019, as due date of renewal of said DML was 18-12-2014. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. Name of total sections of licensed facility and their letters of grant issued after approval in meeting of Central Licensing Board and also submit copy of approved master layout plan.
ii. Approval of Production Incharge and Quality Control Incharge from the competent authority. In case if not approved then to submit documents / information of proposed Technical Experts according to check list enclosed herewith and with respect to Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules 1976 after promulgation of SRO 1134 (I)/2014. The technical experts shall possess minimum 10 years experience after academic qualification.
iii. Attested photocopies of CNICs of all the Directors of the firm their contact numbers, mailing addresses and email addresses.
iv. Details of the section wise machinery and equipment of production department.
v. Details of machinery / equipment in Quality Control Department.

vi. Nothing due certificate regarding deposition of Central Research Fund updated.
vii. All documents should be duly attested.

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

i. Name of total sections of licensed facility and their letters of grant issued after approval in meeting of Central Licensing Board and also submit copy of approved master layout plan.
ii. Approval of Production Incharge and Quality Control Incharge from the competent authority. In case if not approved then to submit documents / information of proposed Technical Experts according to check list enclosed herewith and with respect to Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules 1976 after promulgation of SRO 1134 (I)/2014. The technical experts shall possess minimum 10 years experience after academic qualification.
iii. Attested photocopies of CNICs of all the Directors of the firm their contact numbers, mailing addresses and email addresses.
iv. Details of the section wise machinery and equipment of production department.
v. Details of machinery / equipment in Quality Control Department.
vi. Nothing due certificate regarding deposition of Central Research Fund updated.
vii. All documents should be duly attested.

3. In reply to final reminder, firm has submitted documents which have been evaluated and it found that application for renewal of Drug Manufacturing Licence is still short of the the following documents:

1. Name of total sections of licensed facility and their letters of grant issued after approval in meeting of Central Licensing Board.
2. Nothing due certificate regarding deposition of Central Research Fund updated.
3. Detail of management at the time of previous renewal and present renewal.

Production Incharge.

1. Fee of Rs. 5,000/- for proposed Production Incharge.
2. Appointment letter.
3. Job acceptance letter.
4. Registration Certificate from Pharmacy Council.
5. Resignation / retirement of earlier Production Manager.
6. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.

Quality Control Incharge.

1. Approval letter of quality Control Incharge in case of change than submit requisite documents with Fee of Rs. 5,000/- for proposed Quality Control Incharge.

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and

Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000560by way of formulation ofM/s Makson Pharmaceuticals, Industrial Area, I-10/3, Islamabad may not be rejected by Central Licensing Board or the Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 36. <u>M/S GOODMAN LABORATORIES, PLOT NO. 5, STREET NO.S-5, NATIONAL INDUSTRIAL ZONE, RAWAT ISLAMABAD – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.</u>

M/s Goodman Laboratories, Plot No. 5, Street No.S-5, National Industrial Zone, Rawat Islamabad submitted the application for renewal of DML No. 000613 by way of formulation on 27-01-2017 for the period of 21-03-2017 to 20-03-2022, as due date of renewal of said DML was 20-03-2017. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. Nothing due certificate regarding CRF from STO.
ii. Detailed of Management at the time of previous renewal and present renewal.

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

i. Nothing due certificate regarding CRF from STO.
ii. Detailed of Management at the time of previous renewal and present renewal.

3. Later on with reference to above shortcomings / deficiencies a final reminder letter was issued on 26th April, 2017 under Rule 5{2A} of Drugs (Licensing, Registering& Advertising) Rules, 1976. With reference to above final reminder, the firm did not submitted documents till date and the following shortcomings still have been observed.

i. Nothing due certificate regarding CRF from STO.
ii. Detailed of Management at the time of previous renewal and present renewal

Proceedings and Decision of Central Licensing Board in 255th meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000613by way of formulation ofM/s Goodman Laboratories, Plot No. 5, Street No.S-5, National Industrial Zone, Rawat Islamabad may not be rejected by Central Licensing Board or the Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No.37 M/S RAYMOND PHARMACEUTICALS, 16-KM, MULTAN ROAD, LAHORE.

Brief History of Case:

1. Production of the firm was stopped by CLB due to GMP non-compliance as reported during an inspection by FID conducted on 13.04.2013. Firm was served a show cause notice and case was placed in 232nd meeting of the Board, wherein the Board decided that the production of the firm will remain stopped till the final decision of the Board and firm will be re-inspected by a panel. A panel was constituted accordingly to re-inspect the firm. But firm informed that they were not ready and requested more time for rectification of shortcomings.

2. FID then again visited the firm on 07.05.2014 to check the status of the firm. The firm was found closed. Mr. Kashif, Son of Mr. Asif Chaudhary CEO was present at the premises and informed that they were renovating the firm and will intimate for panel inspection when ready. The firm also submitted an undertaking in this regard.

3. The firm informed the licensing section on 21.09.2015 that they were ready for inspection and Directorate of QA constituted a new panel to conduct inspection. Accordingly, panel inspection was scheduled on 15.12.2015 and the firm was also intimated. However, Mr. Muhammad Asif, CEO of the firm submitted a request to defer the inspection as the renovation work was not completed and they were not ready for inspection.

4. FID again made a surprise inspection of the firm on 07.04.2016 to check the status of the firm. It was reported that the firm was closed. Main gate was locked and no person was seen inside the premesis. Mr. Muhammad Asif, CEO, was contacted on his mobile No. but no response was received. Later on son of Mr. Muhammad Asif, CEO was contacted who arrived at the premises and informed that his father Muhammad Asif, CEO of the firm was severely ill and the firm was closed and they were not yet ready for panel inspection

Findings of Instant Inspection (07-11-2016):

5. Keeping in view the above situation and unwillingness of the management of the firm for panel inspection, the panel decided to make a surprise inspection, therefore the panel visited the firm on 07.11.2016. At the time, it was found that Mr. Akif (son of Mr. Asif, CEO) was present at the premises. He informed the panel that the firm was non-functional since 2013 and his father, CEO of the firm was severely ill and did not come to factory.

6. The panel visited the production areas along with Mr. Akif. The firm possessed two sections namely Tablet section and Oral liquid section. Both the sections were closed. There was no production and there were no signs for any kind of production activities since long. Both the sections for production were very dirty. There was dust, cobwebs everywhere in these areas.

Machines in tablet section were not cleaned. In oral liquid section the mixing tanks were dirty having remains of previously manufactured batches and not cleaned. Both the areas were not maintained and sanitation & hygienic conditions were worst. Some of the machines were dismantled.

Conclusion:

7. Keeping in view the brief history of the manufacturing activities and GMP status of the firm since 2013, and findings of this inspection and apathy and non-serious attitude of the management of the firm, the panel was of the opinion that firm did not maintain the GMP requirements and licensing conditions as required under Rule 16, 19 & 20 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

Recommendations:

8. As the firm is non-functional since 2013 and failed to meet the requirements of drug manufacturing license (DML) in spite of the repeated directions and show cause notice issued by DRAP and commitments given by management of firm from time to time. In the light of observations and above submission the panel recommends that the Drug Manufacturing License of the firm bearing No. 000201 may be cancelled in accordance with the law.

Decision of 252nd Meeting of CLB:

9. The Board after considering the facts on the record and thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16, 19 & 20 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of Drug Manufacturing Licence No. 000201 by way of formulation M/S Raymond Pharmaceuticals, 16-Km, Multan Road, Lahore may not be suspended or cancelled by Central Licensing Board.

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

10. The Show Cause notice dated 21st April, 2017 was issued to the M/s Raymond Pharmaceutical, 16-Km, Multan Road, Lahore. No reply from the firm was received. The firm had been called for personal hearing vide Licensing Division letter date 08-05-2017. The Board received a letter from M/s Raymond Pharmaceutical, 16-Km, Multan Road, Lahore through fax wherein the firm had requested that owner was diabetic and was not in position to travel therefore, he may be another date for appearance before the Board.

Decision of the Central Licensing Board in 253rd meeting

11. The Board after perusal of request made by the firm decided to defer the case till next date of meeting. Next hearing would be treated as final chance to firm to appear before the Board.

12. Now, the firm has been called for personal hearing.

Proceedings and Decision of Central Licensing Board in 253rd meeting

A letter is received form the Federal Inspector of Drugs that letter of personal hearing has been conveyed to the firm on 11th August, 2017 and same was received by the representative of the firm on 15 August, 2017. The Board after perusal of facts on record and not appearance of the firm before the Board subsequent second time decided to **cancel** the Drug Manufacturing LicenceNo. 000201 by way of formulation of M/S Raymond Pharmaceuticals, 16-Km, Multan Road, Lahore with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16, 19 & 20 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No.38. **ORDERS OF HONORABLE LAHORE HIGH COURT, LAHORE REGARDING WRIT PETITION NO. 10988/2007 FILED BY M/S MICKO INDUSTRIAL CHEMICALS CO. (PRIVATE) LIMITED, 28-KM FEROZEPURROAD, LAHORE.**

The complete case background is narrated in chronological order as follows:

1. M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore submitted application for renewal of Drug Manufacturing Licence (DML) # 000183 (Formulation) for the period 17-11-2005 to 16-11-2010 for which a panel was constituted on 23-09-2005. The panel conducted inspection on 20-07-2006 of the Company for renewal of DML and submitted report on 17-08-2006 wherein a number of observations/shortcomings were reported. The Company submitted an undertaking that it would remove the shortcomings as pointed out by the panel within 15 days.
2. The Licensing section of Ministry of Health (Defunct) issued a letter to Federal Inspector of Drugs, Drugs Control Administration (now DRAP), Lahore, wherein it was stated that the firm has submitted an under taking to the panel stating that it will rectify the shortcomings as pointed out by the panel dated 20-07-2006, but the compliance report concerning the same was not been received, therefore, the Area FID was requested to verify the same and submit report within 07 days positively.
3. The Area Federal Inspector of Drugs (FID), inspected the premises on 30-10-2007, along with Mr. Ghazanfar Ali Khan, Assistant Drug Controller (ADC), Lahore to check the rectification of shortcomings as pointed out by the panel during its inspection dated 20-07-2006. The Area FID submitted inspection report wherein a number of serious GMP non-compliance were observed and it was suggested by the Area FID, that production of the firm be stopped and renewal of DML may not be considered in the light of critical shortcomings

observed and due to failure of the commitment given by the Company to remove the deficiencies as pointed out by the panel during its previous inspection.

4. During the inspection, Area F.I.D took the samples of drugs, for the purpose of test and analysis and reported that the owner of company snatched the box of samples along with form- 3 from the driver (Mr. Ismail) of Area FID. Area F.I.D along with ADC, MrGhazanfar Ali Khan launched a F.I.R in the concerned police station (Khana) and also sealed the premises on the violation of provisions of Drug Act, 1976 and rules framed there under, with the assistance of police.

5. The Company was then served a Show Cause Notice on 19th November 2007 by the Central Licensing Board (CLB) and was directed to submit reply to the Show Cause within 15 days.

6. However, in the meanwhile, Mr. KhurshidAlam Sheikh filed a Writ Petition No. 10988/2007 in Honorable Lahore High Court, Lahore through his counsel against the sealing of his premesis of M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore requesting the Court to declare the **sealing order illegal and for award of cost incurred on this petition**. The Court issued Order dated 07-11-2007 wherein the Court suspended the sealing order of the Area FID till next date of hearing without hearing the respondent (Area FID). The Court also ordered for submission of reply and para-wise comments.

7. In compliance to the Court Order dated 07-11-2007, Area FID along with Mr. Ghazanfar Ali Khan ADC visited the premises on 14-11-2007 to de-seal the factory but surprisingly found that the seals were already broken and production of drugs was already in process. The Area F.I.D reported the same to the honorable High Court, Lahore and to the Central Licensing Board.

8. The Secretary Licensing Section of the Central Licensing Board, issued a letter on 05th December 2007, to the Company wherein it was stated that the Board has been informed by the Area FID about the unlawful de-sealing of premesis and resumption of production by the Company upon its inspection dated 14-11-2007. The same is a violation of Rule 13 of the Drugs (Licensing, Registering & Advertising) Rules 1976. Therefore, the Company was directed to suspend the production with immediate effect till removal of the deficiencies and re-inspection by the panel and approval of Central Licensing & Registration Board.

9. Meanwhile, M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore filed another Writ petition No. 11889/2007 whereby orders for suspension of production by the Central Licensing Board were challenged.

10. The honorable Lahore High Court, Lahore passes an Order dated 23-04-2015 in Writ Petition # 10988/2007 & 11839/2007 which is reproduced as under :

Mr. Bashir Ahmad Tariq, Advocate for the Petitioner.
Ms. SaadiaMalik, learned Standing Counsel for Pakistan along with Ayesha Irfan, Federal Inspector Drugs.
Through this single order I intend to dispose of writ petition Nos. 10988 and 11889 of 2007 as both are based on common facts.
2. In W.P NO. 10988/2007 order dated 30-10-2007 is challenged whereby the factory of the petitioner was sealed for violation of Section 27 (3) and other provisions of the Drugs Act, 1976 and also for the reason that owner of the factory namely KhurshidAlam Sheikh had snatched samples taken from the factory premises by the Federal Drug Inspector.
3. Facts, which have surfaced after arguments from both sides, are that he inquiry report was being prepared by the Federal Drug Inspector when samples of some illegal drugs were allegedly snatched by the owner of the factory. Stately, due to violation of the statutory provisions and the illegal act by the owner, the factory premises were sealed. As per learned Standing Counsel's assertions, the factory was de-sealed illegally and production was commenced by the petitioner, therefore, another order for suspension of production was passed.
1. Due to multiplicity of litigation, facts of the case are confused. It is asserted by the petitioner that its factory is sealed and production is suspended whereas learned Standing Counsel submits that the production is being carried out illegally at the sealed premises.

5. Be that as it may, it is settled proposition that this Court cannot look into factual controversies in exercise of its constitutional jurisdiction. For resolution of dispute on facts as well as on legal side, this matter is referred to Central Licensing Board, before which report has already been filed by the Federal Drugs Inspector. The Board shall provide opportunity of being heard to the petitioner and shall pass a speaking order within 45 days positively under intimation to the Deputy Registrar (Judicial) of this Court.
Till decision no coercive measures shall be taken

11. Against the aforementioned order of the honorable High Court, M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore filed Inter Court Appeal.
The Orders of the Honorable Court in Intra Court Appeal are as under: -

"For what has been discussed above this Court is of the view that present appeals have not been filed by an authorized person therefore they being incompetently filed are not maintainable and are thus dismissed".
"For the reasons recorded in judgment of even dated passed in ICA No. 653-2015, this Intra Court appeal is dismissed". (Announce Date 26-01-2016)

12. <u>Proceedings of Licensing Division:</u>

Licensing Division placed the case before the Central Licensing Board and the Board deliberated the case in its 241st, 243rd, 247th, 250th, 251st and 252nd meetings. The Board deliberated the case in detail and issued notice for personnel appearance/hearing to the petitioners, Federal inspector of Drugs and witnesses Mr. Ghazanfar Ali Khan (ADC), and Mr. Ismail (Driver).

13. <u>The statement of Mrs. Aisha Irfan, Federal Inspector of Drugs is reproduced as under</u>;

"The inspection of M/s. Micko Chemical Industries (Pvt.) Ltd., was conducted on 30-10-2007 alongwith Mr. Ghazanfar Ali Khan, Assistant Drugs Controller, Lahore vide the defunct Ministry of Health, Islamabad letter No. F.1-16/85-Lic (Vol-II), dated 29-07-2007 to check the rectifications of shortcomings pointed-out in previous inspection conducted for the renewal of DML.

It was noticed at the time of inspection that the firm did not rectify the shortcomings and overall condition of the firm was very deplorable, hence clear violations of GMP were observed.

Meanwhile, the samples of the drug Gentian Violet Paint Batch No. G/000404, Wax Aid, Batch No. SG/0142 and Tincture Iodine Batch No. TID/003156, were taken for test / analysis purpose. Mr. KhurshidAlam the owner of the firm behaved in a very harsh manner and snatched the samples alongwith form-3 from the driver of the undersigned. He created obstruction in the official duty of the Federal Inspector of Drug, and took away the box of samples and Form-3 with him and left the factory with his wife Mrs. RubinaKhursheed, Chief Pharmacist of the factory. He did not provide the inspection book on demand. The Drugs Controller and Deputy Director General (E&M), Lahore at that time were informed and the Drugs Controller directed, to lodge FIR immediately and seal the factory.

FIR No. 1257/07 dated 30-07-2007 was lodged against Mr. KhurshidAlam, under section 27(3) of Drug Act, 1976 with section 186/506PPC at Police Station, Khana. The factory was sealed in the presence of Assistant Sub Inspector and Head Constable.

The firm had taken interim order from High Court for de-sealing of premises. The undersigned visited the factory on 12-11-2007 as per High Court order in writ petition No. 10988/2007 to de-seal the factory. It was noticed that the seals were already broken and the factory was already opened and illegal production was going on. The order of the court was just to de-seal the factory and the production of the factory was not allowed. The undersigned informed the High Court and the Chairperson, Central Licensing and Registration Board of the above position. The case was referred to Chairperson Central Licensing & Registration Board.

The show cause notice to the firm was issued vide Ministry's letter No. 1-16/85-Lic (Vol-II) dated 19th November, 2007. The production of M/s. Micko Chemical Industries (Pvt.) Ltd. was suspended vide Ministry's letter No. F.1-16/85-Lic (Vol-II) dated 30th November, 2007.

The owner of the firm Mr. KhursheedAlam filed Writ Petition No. 10988/2007 in the High court and three cases of damages against the undersigned in the civil court just to create harassment. The cases are still at different stages in courts as cited below.

S.No.	*Name of Court.*	*Title of Case*	*Nature of case*
01	*In the Court of Qazifi Bin Zair Civil Judge, Lahore.*	*Mrs. RubinaKhurshid Wife of KhurshidAlam, Chief Pharmacit, MickoIndu. Chemical Co., (Pvt.) Ltd., Ferozepur Road, Lahore Vs. Mst. Aisha Khalil, FID, Lahore.*	*For damages Rs. Ten Million.*
02	*In the Court of Mr. Khalid Mehmood, Civil Judge, Lahore.*	*KhurshidAlam, Sh. R/o/ 50-C, F.C.C., ChZahoorElahi Road, Gulberg, Lahore Vs. Mst. Aisha Khalil, FID, Lahore.*	*For damages Rs. 150,40,000/-*
03	*In the Court of Mr. HymoonPervaiz, Civil Judge, Lahore.*	*KhurshidAlam, Sh. R/o/ 50-C, F.C.C., ChZahoorElahi Road, Gulberg, Lahore Vs. Mst. Aisha Khalil, FID, Lahore.*	*For damages Rs. 130,40,000/-*

One case of complaintwas filed by Mr. KhursheedAlam in Special Judicial Magistrate Lahore, Cantt which the undersigned won and acquitted, the judge gave 08 page judgment in the favor of undersigned stating that the acquittal of the accused is accepted as being on merit and complaint is herby dismissed.

It is pertinent to mention here that the firm is involved in the illegal manufacturing of drugs to date, as the production of the firm was suspended and the firm's Drug Manufacturing License was not renewed as two times the panel inspected the firm for the Renewal of DML in year 2007 and 2011 and in both the inspections serious short comings were pointed out by the panel. Moreover, it is asserted by the petitioner in the High Court that his factory is sealed and production is suspended, where as learned standing counsel submits that the production is being carried out illegally at the premises, as mention in the Lahore High Court order dated 23-04-2015. Moreover, the drugs manufactured by M/s. Micko Industries are freely available in the market.

It is submitted that all the actions were taken on the directions of the Central Licensing & Registration Board as per Drugs Act, 1976 and rules framed there under, hence no malafide intentions were involved, and the actions were taken in Good Faith by the undersigned. The undersigned was not given counsel in the damages cases and in the case of complaint filed by Mr. KhursheedAlam in Special Judicial Magistrate Lahore, Cantt and the lawyers were hired by the undersigned personally and fees paid to them from own pocket. The purpose of Mr. KhursheedAlam owner of M/s. Micko Industries is being fulfilled by creating harassment to the undersigned for the last 09 years, while he is doing illegal business without any fear, hence endangering public life.

It is therefore humbly requested that strict action against Mr. and Mrs. KhurseedAlam owner/Chief Pharmacist of M/s. Micko Industrial Chemical Co., be taken such as the plaintiff be given due punishment under provision of Section 27 (3) and (4) of Drugs Act, 1976 with imprisonment of five years and fine, his DML be cancelled as he is involved in the illegal manufacturing of drugs. Hence in order to curtail these type of illegal practices in future such as taking law in their own hands by creating harassment and hurdles in the official duties of FIDs stringent action is required. Moreover, it is also requested to give counsel to the undersigned in all the damages cases filed by Mr. KhurseedAlam as the actions were taken in official capacity and in good faith. The damages suits are barred under Section 38 of Drugs Act, 1976 and also liable to be dismissed under Section 07 Rule 11 of the CPC and the compensation of Rs: 200,000/- be given to the undersigned for the fees already paid to lawyers in the last 09 years till to date."

14.* The statement of *M/s. Micko Chemical Industries (Pvt.) Ltd., which was represented by the following persons.

1. Mr. KhursheedAlam, Director Admn

2. Mr. ShahyarAlam, Assistant Production Manager

Mr. KhursheelAlam, (Director Admin) in his verbal statement before the Board stated that he did not snatched the box of samples but has voluntarily provided same to the Federal Inspector of Drugs, however later he asserted that the Federal Inspector of Drugs was not authorized to inspect his factory and the action of Federal Inspector of Drugs was totally unlawful and illegal.

Mr. KhursheedAlam further stated that he has obtained a suspension Order against the decision of the Central Licensing Board from the High Court, Lahore. However, he was unable to provide the copy of the said Order but committed that same will be provided upon his return to Lahore. The Board advised that he may submit the copy of the Order within 07 days. He also admitted before the Board that the production in his factory is continued till date.

The Board requested to submit his asserted facts in writing but he has refused to accede to Board's request. Further, he has not provided such orders of the High Court till date.

15. Statement of Mr. Ghazanfar Ali Khan is as under:-

With reference to Secretary, Central Licensing Board (CLB) letter No. F.1-16/85-Lic (Pt) dated 08-03-2016, the undersigned appeared before the CLB for recording statement in subject mentioned case. Accordingly, the written statement is as under:-

1) That the undersigned being ADC, Lahore accompanied Mrs. Aisha Irfan, FID, Lahore to assist her in inspection of M/s Micko Industrial Chemicals Company (Pvt) Ltd, 28-KM Ferozepur Road, Lahore on 30-10-2007.
2) That during inspection of the manufacturing unit critical MP non-compliance of the firm was observed for which a detailed report was written / forwarded by FID.
3) That the FID, took drug samples for test / analysis from the premises of the company and Mr. Muhammad Iqbal (Naib Qasid) handed over them to Mr. Muhammad Ismail, Driver to keep them in the official jeep parked nearby the manufacturing area.
4) That the FID and the undersigned asked the owner / management namely, Mr. KhurshidAlam to provide the inspection book so as to write the inspection report in the premises but he flatly refused to accede t despite repeated requests.
5) Meanwhile Mr. Ismael, driver rushed in to the premises where the undersigned and the FID were standing and informed that the owner Mr. KhurshidAlam took the samples from him on the pretext to see the stamp on the samples and on handing over the drug samples, Mr. KhursheedAlam fled away in his car from the premises of the manufacturing unit.
6) Later, on the same day, an application was given in Police Station KahnaNau and subsequently an FIR was lodged and the factory was sealed with the assistance of the police at around 9:00 pm.
7) After few days the undersigned accompanied the Area FID to the premises of aforementioned company for de-sealing and found out that the sealed were already broken and the production was in progress.

16. Statement of driver Ismail is as under: -

1) That the undersigned being driver of the FID, Lahore, namely, Mrs. Aisha Irfan accompanied her along with Dr. Ghazanfar Ali Khan, ADC to M/s Micko Industrial Chemicals Company (Pvt) Ltd, 28-KM Ferozepur Road, Lahore on 30-10-2007.
2) That the FID, took drug samples from the premises of the company. Mr. Muhammad Iqbal (Naib Qasid) brought the samples and handed over to me for keeping the same in the official jeep.
3) While FID and ADC were busy in inspection in the Production Area, the owner Mr. KhurshidAlam in the presence of Mr. Muhammad Iqbal asked the undersigned to handover the drug samples to him in order to see the stamp on the drug samples. I handed over the drug samples and he kept them in his car and fled away from the premises of the company.
4) I rushed inside to inform the FID and ADC.
5) Later on FIR was lodged in KahnaNau Thana and factory was sealed with the assistance of the police.

Decision of 252nd meeting of CLB :

17. The Board provided a fair opportunity of being heard in person to both the Parties i.e M/s. Micko Chemical Industries (Pvt.) Ltd. represented by MrKhurshidAlam (Director Admin) and the Area Federal Inspector of Drugs (FID) Mrs. Aisha Irfan along with their witnesses. After a great deal of deliberations on the facts and in the light of the statements made by the Parties and their witnesses, the Board concludes as follows:

i) That the allegation leveled by the Area FID against Mr. KhurshidAlam, Director Admin / owner of the firm that he has behaved in a very harsh manner and snatched the samples along with form-3 from the driver (Mr. Ismail) at the time of inspection.

ii) This fact is corroborated by the verbal as well as written statement of the Driver (Ismail) who has confirmed that Mr. KhurshidAlam, took away the box of samples along with Form 3 from him by deceptive means by saying that he only wants to check the stamp on the samples.

iii) MrGhazanfar Ali Khan ADC, who accompanied FID at the time of inspection, also confirmed in his statement that after the samples were taken away by Mr. KhurshidAlam, the driver (Ismail) came rushing to FID and informed her that Mr. KhurshidAlam took away the samples from him on the pretext to see the stamps but did not return and took them away.

iv) Mr. KhurshidAlam in his verbal statement admitted before the Board that he got the box of samples along with form 3 from the Driver. His refusal to narrate the facts and his verbal statement into writing, confirms the fact that he got hold of the box of samples along with Form 3 without any lawful cause which tantamount to causing resistance in the lawful authority of the public servant in the discharge of public functions. Further the refusal to give statement in writing, leaves the Board with no option except to draw a negative inference against Mr. KhurshidAlam.

v) The other allegations that the seals of the factory were unlawfully broken and production was in progress at the time the Area FID visited to de-seal the factory in compliance with the order of the Honorable High Court.Mr. KhurshidAlam admitted verbally during the course of personal hearing that the production was in progress when the Area FID visited the factory.

vi) Moreover, there are no orders as to the resumption of production passed by the Board after same was suspended. Resumption of production without orders by competent authority amounts to violations of the provisions of the Drug Act, 1976 and Rules framed thereunder.

vii) In consideration to the foregoing facts the Board is of unanimous view that violations of the provisions of the Drugs Act 1976 and the Rules framed there under have been

committed. So, a SHOW CAUSE NOTICE should be issued to provide an opportunity of being heard as required by the Drugs Act 1976 and the Rules framed there under.

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

18. The Licensing Division has conveyed the above decision of Central Licensing Board to firm in the form of Show Cause Notice dated 21st April, 2017and report has been submitted into Honorable Lahore High Court, Lahore.No reply of the Show Cause Notice has been received till to date. Further letter has been issued to firm for personal hearing dated 8th May, 2017. Case was submitted for consideration of the Board.

Decision of the Central Licensing Board in 253rd meeting

19. The Board after perusal of request made by the firm decided to defer the case till next date of meeting. Next hearing would be treated as final chance to firm to appear before the Board.

Reply of the Firm was received after meeting which is as under

20. Since the factual controversies could not be resolved by the High Court in Constitutional Petition under the law therefore, matter was referred to the Central Licensing Board for resolution of dispute on facts as well as on legal side. Our Writ Petition No. 10988 and 11889 of 2007 were disposed of according by Mr. Justice Shahid Jameel Khan, Judge of Lahore High Court on 23-04-2015, but the learned central Licensing Board has proceeded to suspend or cancel our manufacturing license for one reason or another instead of resolving the factual controversies contained in the above said petition. The moot question which boils down in the writ petition are : - Whether Mrs. Ayesha Khalil, FID could legally seal our factory and lodge FIR u/s 186/506 P.P.C read with section 27(3) of drug Act, 1976 when she visited our factory on 30-10-2007 for carrying out inspection and (ii) Whether Khurshid Alam (Director Admin) of our organization actually snatched samples from Ismail, driver on the stipulated date.

21. The Central Licensing Board was pleased to prob into the matter with regard to snatching of samples only, whereas the legal aspects of the matter with regard to sealing of the factory and lodging of FIR remained unattended which comes under the ambit of factual controversies. The board was inclined to give shelter to Mrs. Ayesha Khalil, FID who violated the permission of Sub-Section (7) of Section (19) of Drug Act, 1976 and proceeded to put Mr. Khurshid Alam, Director Admin of our organization into mail by registering a false case against him at PS Kahna, Lahore. The board recorded the statement of Ayesha Khalil, Ismail, Driver and Ghanzfar Ali Khan, ADC at the back of our representative and has issued the instant Show Cause Notice illegally, which is perver, capricious, inoperative and malafide, although in his report, the investigating Officer, in challan u/s 173 Cr: Pc submitted to Judicial Magistrate has specifically jotted down that samples were not snatched by the accused, but only hot words were exchanged Mehr Muhammad Yousaf, Addl. Session Judge, Lahore also arrived at the similar conclusion, when application u/s 22-A (6) (iii) Cr: Pc filled by Khurshid Alam came up for hearing before him. It was held by him that no offense u/s 27(36) of Drug Act, 1976 was committed by Khurshid Alam and he declined to issue directions to Ayesha Khalil to file

compliant u/s 27(3) of drug Act in the Drug Court for prosecution of Khurshid Alam. The above referred two documents patently show that offence u/s 27(3) was no committed, but the Board after recording statements of Ayesha Khalil, Ismail and Ghazanfar Ali has proceeded to reopen the case which is contempt of Court under section 3 of Contempt Act 1976. Copy of challan order of Addl. Sessions Judge are attached as Annex-A&B. The Show Cause Notice thus runs Counter to the directions Mr. Shahid Jamil Khan, Judge of Lahore High Court contained in his order dated 24-04-20145. The show Cause Notice is thus not warranted under the law and needs to be struck down.

22. Mrs. Ayesha Khalil, FID is not above the law and deserves punishment for degenerating a director of our organization by lodging FIR against him intentionally by violating the provision of Drug Act, 1976, she is not fit for retention in government services and the High Court is thus being moved for her dismissal from service by filling a constitutional petition for the purpose.

Accordingly in continuation to Show Cause Notice a letter for personal hearing has been issued to the firm dated 8th May, 2017. The Board received a letter from M/s Micko Industrial Chemicals Co. (Pvt) Ltd 28-KM Ferozpur Road, Lahore through TCS wherein the firm has requested that they have received letter for personal hearing on 13.5.2017 and requested for affording them an other opportunity for personal hearing

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board As per decision of 253rd meeting of CLB, firm has been issued letter for personal hearing as final opportunity before CLB in 255th meeting of CLB.

ProceedingsandDecision of the Central Licensing Board in 255thmeeting

It was brought into the notice of the Board that a letter and an sms have been received from the area Federal Inspector of Drugs, Lahore wherein he has stated that letter of personal hearing was sent to Micko Chemical Industries but factory was closed and person at gate did not receive the letter. Mr. Khurshid claiming to be CEO of the firm called me and said that he is in UAE and factory is closed hence letter can not be received. Moreover, in letter Federal Inspector of Drugs has enclosed letter of the firm wherein it is stated that unit will remain close for annual summer holidays from 26-07-2017 to 26-08-2017.

Keeping in view the facts mentioned above, the decided to afford one more opportunity to the firm M/s Micko Industrial Chemicals Co. (Pvt) Ltd 28-KM Ferozpur Road, Lahore for personal hearing.

Case No.39 RENEWAL OF DRUG MANUFACTURING LICENCE M/S HUMAYUN INTERNATIONAL PHARMA (PVT) LTD, FAISALABAD.

M/s Humayun International Pharma (Pvt) Ltd, 20-KM Satiana Road, Faisalabad has applied for renewal of DML No. 000443 by way of formulation for the period of 26-11-2014 to 25-11-2019 on 14th November, 2014. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 12th December, 2014 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Nothing Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of CRF valid upto 31-12-2014.

ii. List of total sections f the firm as per approved layout plan by the competent authority.

iii. List of sections under construction / not constructed as per approved layout plan by the competent authority.

iv. As per available record of licensing Division, DRAP, Islamabad, CLB in its 130th meeting held on 10th November, 1997 approved the grant of DML No. 000443 (formulation) to your firm for manufacturing of Injectable (ampoule only). I t has been noticed in your application for renewal of DML that firm also possess registrations of products for (i) Sterile Dry Powder Injectable Vials (General) (ii) Injectable Dry Powder Vials (Cephalosporin) (iii) Sterile Liquid Vials/Infusion (General) therefore you are required to furnish proof of grant of above mentioned sections form CLB.

v. Copy of latest Form-29 issued and attested by Security Exchange Commission of Pakistan along with attested photocopies of CNICs of all the Directors as per Form-29.

2. Later on with reference to above shortcomings / deficiencies a reminder letter was issued on 3rd November, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976. The firm has submitted their reply on 22nd November, 2016 which is evaluated and still found following shortcomings / deficiencies:-

i. Updated Nothing Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of CRF.

ii. Proof of sections from CLB.

Decision of CLB in 252nd meeting.

3. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of Drug Manufacturing Licence No. 000443 by way of formulation M/s Humayun International Pharma (Pvt) Ltd, 20-KM Satiana Road, Faisalabad may not be rejected by Central Licensing Board.

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

4. Accordingly, a Show Cause Notice has been issued to the firm dated 21st April, 2017 and yet no reply has been received from firm till to date, Moreover a letter for personal hearing has been issued to the firm dated 8th May, 2017.

Proceedings andDecision of Central Licensing Board in 253rd meeting

5. No person appeared before the Board on behalf of the firm.

6. The Board observed that letter might not have been received to the company and therefore, case may be deferred till next meeting and Licensing Division may ensure delivery of letter of personal hearing along with copy of Show-cause notice through concerned Federal Inspector of Drugs, Lahore.

7. Firm has submitted reply of personal hearing stating they received personal hearing letter on 20-05-2017.

> *"Due to sudden death of his wife ,the factory was closed during those days, that's why they could not receive intimation letter in time. Due to this reason , they could not receive intimation letter in time.Due to this reason they could not attent the personal hearing in time"*.

8. As per decision of 253rd meeting of CLB, firm has been issued letter for personal hearing as final opportunity before CLB in 255th meeting of CLB through concerned F.I.D

Proceedings and Decision of Central Licensing Board in 255thmeeting

Mr. Tahir Humayun Syed, Chief Executive, M/s Humayun International Pharma (Pvt) Ltd, 20-KM Satiana Road, Faisalabad appeared before the Board. He contended that Dry Powder Injectables (Ceph), Liquid Ampoules and Capsule (Ceph) are being manufactured at the facility of his company. He further contended that he has submitted documents with Budget and Accounts Division of Drug Regulatory Authority of Pakistan. The Board inquired about providing proof of sections he contended that he would submit Lay out plan for regularization. Keeping in view, contention of Mr. Tahir Humayun Syed, Chief Executive, M/s Humayun International Pharma (Pvt) Ltd, 20-KM Satiana Road, Faisalabad and facts on record the Board decided to suspend the Drug manufacturing Licence No. 000443 by way of formulation of M/s Humayun International Pharma (Pvt) Ltd, 20-KM Satiana Road, Faisalabad with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976till settlement of Central Research Fund (CRF) and submission of application for regularization of Lay out plan.

Case No 40. **M/S SPADIX PHARMACEUTICAL, PLOT NO. 17, STREET NO. S-5, NATIONAL INDUSTRIAL ZONE, RAWAT, ISLAMABAD – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.**

M/s Spadix Pharmaceutical, Plot No. 17, Street No. S-5, National Industrial Zone, Rawat, Islamabad submitted the application for renewal of DML No. 000675 by way of formulation on 10-12-2014 for the period of 18-12-2014 to 17-12-2019, as due date of renewal of said DML was 18-12-2014. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. Submit application for Renewal of Drugs Manufacturing License on prescribed Form 1A provided in Schedule A of Drugs (Licensing, Registering & Advertising) Rules, 1976 and mandatory according to Rule 5(1) of Drugs (Licensing, Registering & Advertising) Rule, 1976. The prescribed Form 1A should be properly filled for all the requisite information and shall be signed and stamped by Director / Owner / Authorized person of the firm.

ii. Nothing Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of Central Research Fund up 31-12-2015.

iii. Provide proof of sections involved in manufacturing of drugs, being licensed by Central Licensing Board.

iv. Clearly mention names of registered products of the firm along with registration number, pharmacological class (es) of Drugs, Dosage Form(s) of drugs as requisite in prescribed Form 1A.

v. Provide details of Director (s) of the firm along with their residential addresses, contact numbers and CNIC along with supported legal documents.

vi. Provide the details of approved technical experts (Q.C Incharge & Production Incharge) of the firm.

vii. Provide details of premises including approved copy of layout plans from the competent authority and to provide list of sections currently involved in manufacturing of drugs.

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

i. Provide details of Directors of firm mentioning legal status of firm alongwith copies of CNIC.
ii. Any change in management of firm supported by legal documents. NOC from previous management in case of change.
iii. Provide details of premises including approved copy of layout plans from the competent authority and to provide list of section alongwith approval letters.
iv. Nothing due certificate from STO.
v. Form 1 A duly signed by authorized person.
vi. All documents attested as per check list.

Decision of 253rd meeting Central Licensing Board.

3. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Spadix Pharmaceutical, Plot No. 17, Street No. S-5, National Industrial Zone, Rawat, Islamabad DML No. 000675 by way of formulation may not be rejected by Central Licensing Board.

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

4. The Show Cause notice dated 19th June, 2017 was issued to the M/s Spadix Pharmaceutical, Plot No. 17, Street No. S-5, National Industrial Zone, Rawat, Islamabad

5. Now the firm has submitted the required shortcoming documents but following documents are still deficient and application for renewal of DML is still incomplete.

1. Details of Directors of firm mentioning legal status of firm alongwith copies of CNIC.
2. Any change in management of firm supported by legal documents.
3. NOC form previous management in case of change.
4. Provide details of premises including approved copy of layout plan from the competent authority and to provide list of section along with approval letters.
5. Nothing due certificate regarding CRF from STO.

The firm has been called for personal hearing.

Proceedings and Decision of Central Licensing Board in 255thmeeting

Mr. Aimal Khan, Director Operations, M/s Spadix Pharmaceutical, Plot No. 17, Street No. S-5, National Industrial Zone, Rawat, Islamabad appeared before the Board. He contended before the Board that Mufti Ibrarul Haq, Owner of the firm is under NAB custody in Modarba Scandal. Moreover, Accounts of the firm are sized therefore he was not in position to submit latest documents for Management and Central Research Fund. He further contended on the enquiring from the Board that he was not in position to submit the statement in writing. Keeping in view, contention of Mr. Aimal Khan, Director Operations, M/s Spadix Pharmaceutical, Plot No. 17, Street No. S-5, National Industrial Zone, Rawat, Islamabadand facts on record the Board decided to reject the application of renewal of the Drug manufacturing Licence No. 000675 by way of formulation ofM/s Spadix Pharmaceutical, Plot No. 17, Street No. S-5, National Industrial Zone, Rawat, Islamabadwith immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 41. M/S VETEC LABORATORIES, 51-INDUSTRIAL TRIANGLE KAHUTA ROAD, SIHALA, ISLAMABAD.

M/s Vetec Laboratories, 51-Industrial Triangle Kahuta Road, Sihala, Islamabad, submitted the application for renewal of DML No. 000320 by way of formulation on 26-05-2015 for the period of 30-05-2015 to 29-05-2020, as due date of renewal of said DML was 30-05-2015.After evaluation of the renewal application of the firm, a letter for completion of application for renewal under rule 5 (2A) of the Drug (L,R&A) Rules, 1976 was issued for following shortcomings: -

1. Name of Drugs registered / approved.
2. Details of premises including layout plan.
3. Name & qualification of Production Incharge.
4. Name & qualification of Quality Control Incharge.
5. Nothing due certificate regarding CRF.
6. Approvals of new Management documents are required to submit as per check list.
    a. CNIC copies of Directors.
    b. Deposit fee of Rs. 50,000/- for approval of new management.
    c. Partnership deed.
    d. Transfer deed.
    e. Form 29 in case of Pvt. Ltd.

2. With reference to above letter, the firm submitted following documents:-
    1. Copy of CNIC un-attested.
    2. Form 1A un-attested.
    3. Detail of equipment and machinery for manufacture and quality control un-attested.
    4. Partnership deed un-attested.

3. Upon re-evaluation of submitted documents following shortcomings were still observed in the DML renewal application;

    1. Form 1A duly signed and stamped.
    2. Approved Layout plan.
    3. Proof of licensed sections from CLB.
    4. Nothing Due Certificate regarding CRF from STO (updated).
    5. Approval of new management documents are required to submit as per check list.
    6. CNIC copies of Directors.
    7. Deposit fee of Rs. 50,000/- for approval of new management.
    8. Partnership deed (attested).
    9. Approval letter of QC Incharge & Production Incharge in case of change then submit complete set of documents as check list.

4. In the meanwhile M/s Vetec Laboratories, 51 industrial Triangle Kahuta Road, Islamabad has informed that they are stopping the manufacturing activities from 10th March, 2017 and change of site of M/s Vetec Lab. DML No. 000320 at Plot 51 Industrial Triangle Kahuta Road, Islamabad to move our to the new premises with the same name.

Decision of Central Licensing Board in 254th meeting.

5. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of

Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Vetec Laboratories, 51 industrial Triangle Kahuta Road, Islamabad DML No. 000320by way of formulation may not be rejected by Central Licensing Board or Licence may not be suspended or cancelled by Central Licensing Board.

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

6. The Show Cause notice dated 19th June, 2017 was issued to the M/s Vetec Laboratories, 51 industrial Triangle Kahuta Road, Islamabad. No reply from the firm is received yet. **The firm has been called for personal hearing.**

Proceedings and Decision of Central Licensing Board in 255th meeting

No person appeared before the Board. Keeping in view the facts on record the Board decided to reject the application of renewal of the Drug manufacturing Licence No. 000320 by way of formulation ofM/s Vetec Laboratories, 51 industrial Triangle Kahuta Road, Islamabadwith immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976for not complying the provision of Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No.42. M/S EVEREST PHARMACEUTICALS, PLOT NO.124, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

1. M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad has submitted the application for renewal of DML No. 000535 by way of formulation on 28-03-2014 on time as due date of renewal of DML was 31-03-2014.After evaluation of the renewal application of the firm a letter for completion of application for renewal of DML was issued on 7th May, 2014. With reference to above letter the firm has submitted one page reply on 3rd June, 2014 and stated that requisite documents / information have already been provided vide their earlier request letter.

2. It is mentioned that in available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. On 25th February, 2015 Licensing Division issued another letter for completion of application of renewal of DML to the firm in which mentioned that no correspondence from your side had been received in this Division regarding receipt of documents / information deficient in your application for renewal of DML and advised to the firm to furnish the required information / documents to this office within 20 days of issuance of this letter in case of failure to rectify the application within the specified period, the application for renewal of DML may be rejected by the Central Licensing Board.

3. On 17th March, 2015 the firm has submitted their one page reply and stated that an FIR in FIA is lodged on misunderstanding of DRAP and their production Manager and Q.C manger were arrested. They will be able to reply the letter of Licensing Division after resolution of the case. They requested to hold any proceeding / any further order till resolution of the case.

Proceedings of CLB

4. Case was submitted for consideration and orders of the Board. Chairman Quality Control (CQC) informed the Board that recently there were two FIRs which have been now quashed by Islamabad High Court.

Decision of Central Licensing Board in 247th meeting:

5. The Board in the light of information provided by CQC that the said FIRs have been quashed, so Board decided to direct the firm to provide the requisite information / documents for the purpose of renewal of Drug Manufacturing License.

Action by Licensing Division

6. Licensing Division communicated the above decision of the Central Licensing Board to M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad 15th June, 2016 but envelope returned with the following remarks:

The same letter were communicated to the firm through Federal Inspector of Drugs, Islamabad on 22nd November, 2016 and 29th November, 2016 but those letters were also returned back with following remarks:

7. Now, final reminder has been issued to the firm and copy of the same was send to area Federal Inspector of Drugs to deliver the letter by hand and report. The report by the area Federal Inspector of Drugs is as under:

> "***It is hereby report that I, Hasan Afzaal (FID-III, Islamabad) was informed by Dr. Fakharuddin Aamir (additional Director-QA&LT-II) on direction of Dr. Sheikh Akhtar Hussain (Director- QA/LT) on Friday 2nd june, 2017 at 4:00 pm to report to the Licensing Division for delivery of a letter to Everst Pharmaceuticals. The letter was handed over by Mr. Manzoor Bozdar (Additional director- Licensing) at 5:00 pm. I was accompanied by Mr. Sarfarz (driver-Admin) to the firm. We reached the firm at 6.00PM, where Mr. Waqar (Employee everest Pharmaceuticals) refused to receive the letter. We pasted a copy of the letter alongwith that day's newspaper and video graphed the proceedings. A short summary of this report was conveyed via Whats App alongwith the video was forwarded to the Director (QA/LT), Director (Licensing), Additional Director (QA/LT-II) and Additional Director (Licensing).***"

8. Following shortcomings have been communicated to the firm under Rule 5(2A) in the above said letter:

i. Complete document / information of your proposed Quality Control Incharge Mr. Imtiaz Ahmed & Production Incharge Mr. Muhammad Arshad as per checklist enclosed herewith for your guidance. All documents should be attested by gazette officer or Notary Public and also signed by CEO / Director / Authorized person with seal / stamp of the firm.

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

iii. Attested photocopy of latest Partnership deed within CNICs of all the Directors as per partnership deed and certificate of Registration with Registrar of the firm.

iv. Details of the premises i.e. approval letter of sections issued by Secretary Central Licensing Board & to also furnish copy f approval layout plan of the building.

v. Details of equipment / machinery for Quality Control Laboratory.

vi. Name of the drugs registered / approved.

Decision of Central Licensing Board in 254th meeting.

9. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad DML No. 000535 by way of formulation may not be rejected by Central Licensing Board or License may not be suspended or cancelled by Central Licensing Board.

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

10. The Show Cause notice dated 22nd June, 2017 was issued to the M/sEverest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad. The said Show Cause Notice is returned un-delivered. Consequently, Show Cause Notice was published in Print Media dated 22nd July, 2017.

11. Now a letter is received from M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad through legal Counsel M/s Farooq Law Associates, Advocates and Attorneys, Islamabad. They had stated that his client M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road, Islamabad owned by Ch. Muhammad Usman have shown him the show cause notice published on 22.07.2017 in the daily “Dunya”, Islamabad calling upon them to answer the show cause notices issued to them regarding their application for renewal of their Drug Manufacturing License. He has further stated that he has instruction to state at the outset that no notice purportedly sent by Secretary Central Licensing Board to his client was received. The notice of 15-06-2016, 22-11-2015 and 02-06-2017 were never received by his client. However, the notice of 25-02-2015 was duly replied and necessary information provided to Secretary Central Licensing Board. His client has the apprehension that the Central Licensing Board is working against his interest on which Chief Executive Officer of DRAP was removed by the Hon’rable Islamabad High Court. The publication of notice and other proceedings are based on malafide intension of DRAP. His client has never neglected

or refused to comply with the necessary information required by DRAP for renewal of his license. He has, therefore, requested to desist from taking any illegal action against his client without providing him right of hearing. He has requested for providing him copies of the notices said to have been issued to his client on 15-06-2016, 22-11-2015 and 02-06-2017 as same did not reach his client. He has further, requested to provide a copy of Minutes of 253rd meeting of Central Licensing Board held on 15-16th May, 2017 so as to enable his client to meet the objection, if any, to the renewal of his license.

He also further stated that please note that any adverse action taken against his client without providing rights of hearing will be illegal. A copy of this notice has been retained in his office for further action.

Proceedings by Licensing Division

12. It is submitted that M/s Farooq Law Associates, Advocates and Attorneys, Islamabad has been provided all copies of correspondence made with M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad and he has been assured that Central Licensing Board is a statutory body working independently and not takes influence from any quarter. More over, letter of **personal hearing** has been served to M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad on his company address and through legal counsel M/s Farooq Law Associates, Advocates and Attorneys, 201, Dosal archade, 47-W, Blue Area, Islamabad. No reply from the firm is received yet.

13. Meanwhile, a copy of the Orders of the Islamabad High Court, Islamabad in Writ Petition No. 2836 of 2017 are received which are reproduced as under:

> "*The learned counsel, inter-alia, contends that the petitioner had earlier filed a constitutional petition in this Court whereby appointment of the Chairman, Drug Regulatory Authority (hereinafter referred to as the "Authority") had been challenged. The learned counsel further contends that for malafide reasons the impunged proceedings have been initiated. The learned counsel has stressed that the Drug Regulatory Authority is aware of the address of the petitioner yet a show cause notice has been published in a daily newspaper. The learned counsel has further argued that application for renewal of the license is pending before the Authority since 28-03-2014, which has not been processed. The leaned counsel has stated that there is no reason, whatsoever, in the facts and circumstances of the case for publication of the show cause notice in the daily newspaper.*
>
> *Let notice be issued to the respondents for filing of report and parawise comments within a fortnight.*
>
> *Relist after a fortnight.*
>
> *C.M. No.01 of 2017*

Notice. Final order shall not be passed till the next date fixed. However, the petitioner shall appear before the competent authority. The latter shall afford an opportunity of hearing to the petitioner.

C.M. No. 02-E of 2017.

Exception sought for is allowed, subject to all just and legal exceptions."

Proceedings and Decision of Central Licensing Board in 255th meeting

14. Right of hearing was provided to M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabadas per direction of the Honourable Islamabad High Court, Islamabad. The letter of personal hearing has also been served to M/s Everest Pharmaceuticals, 124, Industrial Triangle, Kahuta Road Islamabad on his company address and through legal counsel M/s Farooq Law Associates, Advocates and Attorneys, 201, Dosal Archade, 47-W, Blue Area, Islamabad.However, petitioner failed to appear before the Board himself or through legal counsel on the date and time of hearing without any intimation. The Board did not pass any orders as per Orders of the Honourable Islamabad High Court, Islamabad. The Board however, decided that facts/ proceedings would be made part of the parawise comments to be submitted before the Honourable Islamabad High Court, Islamabad.

Case No.43. M/S DANAS PHARMACEUTICALS (PVT) LTD., 312 INDUSTRIAL TRIANGLE KAHUTA RAOD, ISLAMABAD CHANGE OF MANGEMENT – VIOLATION OF SECTION 34 OF DRUGS ACT, 1976 THEREOF.

M/s Danas Pharmaceuticals (Pvt) Ltd., 312 Industrial Triangle Kahuta Raod, Islamabad Licence No. 000569 by way of formulation was granted licence in 2005. The company/ firm informed for change of Chief Executive vide letter No. Danas /L&A/2014 dated 08-07-2014. Some observations were noted and conveyed to firm on 26th December, 2014 and reminder to this effect was issued on 12January, 2015. The observations which were conveyed to the firm are as under:

i) It seems that management of the firm has been changed number of times without intimation to Central Licensing Board. It is not clear that who has purchased the licensed premises of M/S Danas Pharmaceuticals (Pvt) Ltd, DML No.000569 (Formulation) located at Plot # 312, Industrial Estate, Kahuta Triangle, Islamabad from Mr. Ansar Farooq, who was Chief Executive Officer of the firm according to available record of Licensing Division, DRAP, Islamabad.

ii) With respect to the deed of sale dated 09-09-2011 submitted by your firm, it has been observed that one of the present Directors of your firm i.e Mr. Imran Khan S/o Muhammad Khan holding CNIC # 3602-0489641-7 has purchased this licensed unit from Mr. Rizwan Khan S/O Muhammad Khan holding CNIC # 36302-5064463-5. Mr. Rizwan Khan was not the Director of the firm as per available record of Licensing Division DRAP Islamabad and in any of Form 29 provided by your firm. Therefore you are required to submit sale deed / agreement made between Mr. Ansar Farooq, previous CEO of the firm & Mr. Rizwan Khan and to also submit copy of Form 29 issued and attested by SECP wherein Mr. Rizwan Khan was appointed as Director of the firm and also for retirement / resignation from directorship of the firm.

iii) You are also required to submit attested photocopy of Form-29 issued by SECP wherein Mr. Usma Lahooti was appointed as director of the firm.

2. The firm replied that we are still waiting for the fresh Form—29 and annual return i.e Form-A for the year 2014-15 from SECP, which is expected to receive with fortnight. Meanwhile Anti Narcotics Force, Rawalpindi has also issued a letter on 26th October, 2015 wherein they referred to FIR 40/2011 ANF Police Station, Rawalpindi and directed to not to accept Form-A and 29 till finalization of said case in Supreme Court of Pakistan.

3. Danas Pharmaceuticals, Islamabad has filled writ petition through Mr. Mohammad Mustafa purported Chief Executive in the Islamabad High Court, Islamabad vide writ petition No. 1174/2016, wherein above referred letter of ANF has been contested. The court has not yet granted any relief to petitioner.Moreover, firm has been concealing information and changing their management time and again without seeking approval from the Board as under:

DETAILS OF THE DIRECTOR OF THE FIRM FROM THE TIME OF GRANT OF DML TO TILL DATE

At time of grant of first DML in year 2005. The name of the Directors of the firm on prescribed Form 1 for application for grant of DML (Page 87/Corr.) of main volume	At the time of submission of renewal of DML of the firm dated 29-03-2011	Form 29 issued on 30-12-2012 (Page 50-52/Corr.)	Form 29 issued on 31-10-2013 (Page 53-54/Corr.)	Form 29 issued on 16-04-2014 (Page 48-49/Corr.)	Form 29 issued on 02-07-2014 (Page 45-47/Corr.)
1. Mr. Ansar Farooq 2. Mr. Muhammad Naveed Akhtar 3. Mrs. Azra Parveen 4. Mr. Nadeem Ahmed Khan 5. Mrs. Mehreen Nadeem 6. Mrs. Tahira Tasneem	Mr. Ansar Farooq CEO of the firm.	1. Imran Ahmed Khan – Appointed 2. Usman Bashir - Appointed 3. Najam-ul-Ghafar- Appointed 4. Tariq Haneef Sole proprietor of Tariq Hanif and Co. Chartered Accountant- Retired	Tariq Haneef Sole proprietor of Tariq Hanif and Co. Chartered Accountant- re-appointed`	1. Mudasir Farooq- Appointed 2. Kaleem Arshad - Appointed 3. Usama Lahooti - Resigned 4. Fawad Rasheed- Retirement	Muhammad Mustafa has been appointed by Board of Director as Chief Executive Officer upto the conclusion of AGM in 2015.

4. In the circumstance mentioned above, section 34 of the Drugs Act, 1976 and Rule 5(6) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 is not being complied. Any contravention / illegality committed by M/s Danas Pharmaceuticals (Pvt) Ltd., 312 Industrial Triangle Kahuta Raod, Islamabad would create trouble for the DRAP to nominate accused in the case.

DECISION.

5. The Board deliberated on the case matter in detail in the light of steps taken by the Licensing Division and facts of the case decided to show-cause the company under Section 41 of the Drugs Act, 1976 and Rule 12 of the Drug (Licensing, Registering and Advertising) Rules,1976 as to why their Drug manufacturing Licence may not be cancelled or suspended for violation of Section 34 of the Drugs Act, 1976 and Rule 5 (6) of the Drug (Licensing, Registering and Advertising) Rules,1976.

Action by Licensing Division

6. Accordingly, show cause notice was served to the firm through Chief Executive (claimant) and Director (claimant).

Reply by Mr. Muhammad Mustufa,
Managing Director & Chief Executive

7. Reply of **Mr. Muhammad Mustufa**

1. With due respects and apologies, aggrieved and resented with the observations given and further issuance of show cause notice dt.02-03-2017 acknowledged by us dt.07-03-2017 in the above referred meeting . In replying to show cause notice would like to bring the following points for your kind consideration that justify if dully considered, will remove all the ambiguities and issuance of un-warranted show-cause notice should be vacated .

i. That first of all, present management took the control of the company in 2014 by purchasing shares at a juncture when it was at a "Crash situation"
ii. That with the restructuring, the present management team set a goal to reinvigorate the image and business of the company which was tarnished / spoiled by the misdeeds of erstwhile members. Through dedication and fairness the company is gaining confidence in the business community and today IMS Data ranks it at #123 (listing of 2016). We are not just stopping here , rather we have set target to be within top 100 companies by the end of current year.
iii. That currently, we are also proud to be one of the companies,chosen by the KPK Government in its campaign to purchase quality drugs from the Market at competitive prices.
iv. That with the staff strength of 50 peoples and revenue generation of forty millions, In 2016 we are looking with 185 people and revenue generations two hundred Eighty five Million plus per annum.
v. That is discussed earlier, In th transitional period of 2014,we took control of the management/the undersigned being Chief Executive office of the Company appointed in July 2014, and upon receipt of certified copy of Form-29 from SECP, intimated the licensing Division vide letter No. Danas L/A/2014 dated 08-07-2014, 18-11-2014 and 24-11-2014 including the paid free Challan of Rs.50,000/- dt.18-11-2014 for change of management (copy of letter enclosed herewith as Annexure-A,B&C.)
vi. That besides, the share Holders and management Team, as mentioned in preceding para, no change has been brought in the formation of the company , but re-elected till 2019.Therefore, there exists no element of concealment from the licensing Division, Whatsoever, on the part of the present Management has dully submitted to your good office vide our letter dt.10-01-2017 dully acknowledged by you dt.10-

01-2017(Attached herewith certified copies of Form-29 and Form-A for the year 2016 for your kind perusal as Annexure-D)

vii. That the above fact clearly revealed that at the part of the present management there is no concealment at all from the Licensing Division .

viii. That it is also pertinent to mention here that , we did queried the then Licensing Division officer that since Januray,2014 we were continuously observing the name of Mr. Imran Ahmed Khan the then C.E.O of the company not only signatory on all documents related to Ministry /DRAP, but specifically with the Licensing Division for submission of details of technical staff, layout plan, etc, for which we have seen due acknowledgements from Licensing Division, including but not limited to dealing with Area FID, DDG(E&M)/ Chairman QC for CGMP inspections, imports of material (API's) but no objection was ever raised upon the same. Therefore, we requested the then Licensing Division to recheck/verify the record for change of management .However, despite assurance to do the needful, we had no reply or response.

ix. That in view of our aforesaid observation, it is once again requested to re-check this aspect as the same is needed to be rectified being an act done by the erstwhile Management While dealing with the then members of Licensing Division.

x. It is also stated that if some illegality ,irregularity or concealment has been committed by the previous Management between the period of 2011 up to july - 2014, the same is not attributable to us we have already submitted that we took control of the affairs of the company in July 2014.

xi. That however, being the present custodian of the affairs of the company for the last three years, we are extremely apologetic for the same and are ready to rectify any error done / caused by the previous Management with the hope that the error caused previously and prior to our inclusion in the Company may be condoned.

xii. That in edition to the aforesaid, through the subject Meeting, it has also been observed by the Board that we promised to submit the certified copies of Form-29 for 2014 and 2015 but remained silent about the submission. It is submitted that the same has been furnished to the licensing Division vide our letter No.L&A/DANAS/SECP/01 & DANAS/L&A/2014.(copy of letters enclosed herewith as Annexure-E)

xiii. That apart from above submission, your attention is also drawn towards our meeting with the then Honourable Secretary Licensing Board Mr. Abdullah dt.**22-03-2016.** In result of that meeting a detailed and elaborated /comprehensive letter/reply explaining all the happenings/events and objections /observations in chronological order since our inclusion in the affairs of the company in the year 2014 annexed with all necessary supportive documents including mentioned at aforesaid para was re-submitted to your good office vide our letter dt.24-03-2016 duly acknowledged by the Licensing Division dt.25-03-2016 (copy of letter along with all annexure enclosed herewith for your ready reference as Annexure-F)

xiv. That however, about the pending certified copies of Form-A (of present management) for the year 2014 and 2015 have been dully submitted vide letter dt.08-08-2016 acknowldged by your good office on dated 09-08-2016. (Copy of letter enclosed herewith as Annexure-G).

xv. That regarding ANF's letter dt. 26-10-2015 is concerned, it was about directions (in our opinion beyond their legal scope) to our two main regulators i.e SECP and DRAP i.e not to issue certified copies of Form-A and Form-29 for the year 2014 and 2015 for SECP and not to entertain the same by DRAP respectively.

xvi. That initially the issuance of certified copies of Forms A and 29 for the year 2014 and 2015 were g egretted by the SECP while acting upon the direction of the ANF. That we have approached and explained our stance to SECP vide our letter dated 19-11-2015. (Copy of letter enclosed herewith as Annexure-H).

xvii. That in this connection, we also approached and explained our stance to ANF Authorities as well vide our letter dated 11-12-2015 and a copy of the same was also submitted to the license Division vide our letter No.CEO/DP/01 dated 25-12-2015. However, the ANF Authorities did not reply that letter. (Copy of letter enclosed herewith as Annexure-I).

xviii. That to contest our statuary rights vis a vis management of the Company, we were constrained to approach the Court of Law and filed a Constitutional Petition bearing No. 1174/2015, titled "M/s Danas Pharmaceuticals (Pvt) Ltd. etc. Vs. Federation of Pakistan etc", pending adjudication before the Honourable Islamabad High Court, Islamabad.

xix. That the above scenario has also been brought to your kind notice vide our letter No. dated 13-04-2016 dully acknowledged by your good office dated 14-04-2016 (copy of letter enclosed herewith as Annexure-I).

xx. That after initial few hearings and arguments raised in the above refereed case, The SECP admitted / felt their wrong footings on acting upon the directions of ANF's letter.

xxi. That therefore, during the pendency of the case, SECP has issued all the pending certified copies of Form-A and Form-29 i.e for the year 2014, 2015 and later for the year 2016.

xxii. That the same have been dully submitted to the licensing Division vide our letter dated 08-08-2016 acknowledged by your good office dated 09-08-2016 and for the year 2016 vide our letter dated 10-01-2017 dully acknowledged by you dated 10-01-2017 (Attached herewith copies of letters alongwith certified copies of Form-A and Form-29 enclosed herewith as Annexure-K and L).

xxiii. That although the same impugned letter in question contained direction for you as well, but it is appreciated by saluting your wisdom that the Authority has not aided any illegality on the Directions of ANF. We also appreciate this very fact that the Authority has trusted in our words and acts and confided us. Therefore, keeping in view of the stance, the Drug Regulatory Authority has been arrayed as Proforma Respondent, as no relief has been sought against the Authority.

xxiv. Therefore, the undersigned while acting for and on behalf of the Company and rest of the Sharre Holders / Management assures you that ever since our inclusion, no illegality has ever been committed. However, the concerns raised by the Board in the Meeting can only be attributable to the past Management.

xxv. That in the light of foregoing, we at present believe have no issues with our main regulators i.e SECP or your good office. Further the main relief we were looking for have already obtained.

2. That in the light of above submission, it would be crystal clealr that the present management haven's concealed anything from the competent authority, the main argument of that licensing board meeting. Hence, otherwise, all other formalities are being fully complied by us So, at this juncture, we can fairly say that there is no justification and plausible reason to serve us a Show Cause Notice and it needs earnest reconciliation and revocation. Therefore your early response to safeguard our valuable interests are dire needed, and the same shall also

be highly appreciated. Your precious time is also sought in furthereance of this communication for a personal hearing and we hope to hear from you soon in this regard at your earliest convenience.

3. He has also written an other letter where in he has made submission that we further would like to inform you that in response to ANF's letter No. dated 02-03-2017 a comprehensive and well elaborated reply vide our letter dated 06-03-2017 has been dully submitted to ANF Authorities. Acknowledgement to our above refered letter ANF authorities is enclosed herewith for your kind perusal. We are looking forward to receive their appropriate reply with in fortnight inshAllah. We are very much hopeful through that expected reply / letter our last issue pertaining to the directions given to SECP and your good office will also be resolved amicably. You are also aware of the fact that regarding issue of management and shares holding, we have already submitted up-to-date Form-A and Form-29 for the year 2016-2019.

4. He has further responded through legal consel M/S AJURIS, Advocates & Corporate Counsel, Islamabad, Where it is stated :-

i. We have been instructed by M/S Danas Pharmaceuticals (Pvt) Limited (company) and act for and on behalf of the Compnay and Mr.Mustafa/Chief Exective Officer of the Company (Clients). This response is with refrence to Show Cause Noted 02-03-2017 issued in the name of M/s Danas Pharmaceuticals (Pvt) Limited .

ii. The Show Cause Notes alleges that the company has been concealing information and changing their management without approval of Central Licensing Borad in violation of section 34 of the Drugs Act,1976 read with Rule 5(6) of the Drugs (L,R&A.) Rule,1976.Our client have been required to show cause in writing within 15 days of issuance of the Show Cause Notes as to why the Compnay's Drug Manufacturing License No.000569 should not be cancelled or suspended .

iii. You will appreciate that our Clients have filed Writ Petition No.1174/2016 titled 'M/s. Danas Pharmaceutics (Pvt.) Limited etc. vs. Federation of Pakistan etc.' ("Petition") before the Honorable Islamabad High Court in which notices have been served to the Drug Regulatory Authority of Pakistan ("DRAP"). You will further appreciate that in the Petition our Clients have impugned all letters of the Anti Narcotics Force that form the foundation of the baseless allegations leveled against the Clients. Our Clients have also filed an application for interim relief in the Petition, which is pending adjudication before the Honorable Islamabad High Court.

iv. It is emphasized that during the pendency of the application for interim relief, any adverse action against the Clients would be tantamount to interference with the proceedings of the Honorable Islamabad High Court. In this regard, reliance is placed on the case of **Saifur Rehman Vs. Muhammad Ayub** and 2 others **(1998 CLC 1872)** which states "Needless to

point out that there is sound logic behind the proposition that a party to the proceedings cannot, while an application for interim relief is bona fide pending, blatantly so act as to pre-empt its lawful disposal because that, in given set of circumstances, may amount to doing things calculated "to interfere with or obstruct or interrupt or prejudice the process of law or the due course of a judicial proceeding" and thus fell within the mischief of section 3 of the Contempt of Court Act, 1976." Reliance is also placed on the case of **Arif Khan and 7 others Vs. Federation of Pakistan** and others **(2002 CLC 601)** which states that "There appears to be prima facie force in the contention of Mr. K.M. Nadeem that while notices of a lis are issued to the other side, the latter is expected to maintain a status guo."

v. The basis of the SCN is a matter in dispute pending adjudication which is ripe for final arguments and strong likelihood of success exists in favour of the Clients. Any continuation of proceedings in pursuance of the SCN while the Petition is pending may not only cause serious prejudice and loss to the Clients it may also tantamount to interference with pending proceedings before the Hononorable Islamabad High Court.

In view of the facts as stated and the law on the subject, you are requested to desist from taking any coercive action against our Clients in relation to matters pending adjudication before the Honorable Islamabad High Court. Your cooperation in this regard shall be highly appreciated.

Reply by Mr. Usma Lahoti, Director.

8. Reply of Mr Usama Lahooti is as under:

1. It is submitted that I hold 66666.66 shares in Danas Pharmaceuticals (Pvt) Ltd. Since 2012, which previously were held by Tahir-ul-Wadood Lahoti (my father) since 2007. I alongwith shareholding was also the Director of the company, the title which I still hold as per the record of Security Exchange commission of Pakistan (SECP), till date. Meanwhile a case was registered against the company by ANF with regard to allotment of ephedrine to the company. During the period 2012 to 2014 due to hectic commitment in the case and subsequently the health issue of my father, which resulted into his CABG procedure, I remained mostly busy there. During 2012, the then Chief Executive, illegally prepared Form 29 against me for removal from the Board of Director and submitted the same to the SECP. The same was turned down by the SECP by declaring it as an illegal document prepared contrary to the relevant rules spelled out in the Companies Ordinace 1984. After this I was re-elected as director in 2013 by the company and my name was endorsed in the Form 29 of 2013.

2. During July, 2014, Mr. Imran Ahmad Khan resigned from the post of Chief Exeuctive and Mr. Muhammad Mustafa, on the same date took over as Chief Executive. This

act was a gross irregularity of the companies Ordinance, 1984. I was neither informed nor asked to vote, as per rights authorized to me by the Companies Ordinance, 1984.

3. During the stay of my father in the company, he had loan an amount approximately around 40 Million to the company at various stages, for various activities, from his personal account. During last quarter of 2013 when the company was asked to pay back the loan, they hesitated in one form or the other, saying that financial position of the company at this point is not in a condition to pay back such a heavy loan. Since we were in dire need of the money so the company was requested for grant of loan from the personal accounts of any of the shareholder. This request was acceded to and a resolution was passed during the Board of Director meeting held on 30th January, 2014, wherein Mr. Muhammad Mustafa and Mr. Mudassar Farooq agreed to give the loan amounting to 30.25 Millions against pledging of my shares. For which as a guarantee I had given blank dated shares deed and resignation signed and submitted the same to the company for keeping it as a pledged record. Contrary to the agreement, Mr. Muhammad Mustafa fraudulently submitted my these documents to the SECP for transfer of shares in his name. On getting this information about of his this malafide act I immediately approached SECP for non transfer of my shares in anyone name without my personal appearance.

4. Meanwhile, ANF had also frozen the shares of mine and my family through a letter to SECP during December, 2012, February, 2015 and October, 2016. In the light of these letters, SECP, paid no heed to fraudulently submitted documents for transfer of shares. After having the knowledge about this act of Mr. Muhammad Mustafa, I initiated a correspondence with the SECP mentioning about the irregularities taking place in the company, also highlighted the illegal occupation of Mr. Muhammad Mustafa as Chief Executive of the company. In response to my letter SECP gave me a comprehensive reply in February, 2016 mentioning therein that statutory documents of the company are frozen at the time of 2011 and also clarified that Form 26 submitted by the company against me stands null and void after being withdrawn by the company. Thereby confirming me back to the status of Director of the company till date.

5. After having received detail reply from the SECP about the status of self declared chief Executive by Mr. Muhammad Mustafa, I approached Drug Regulatory Authority's (DRAP), staring from Federal Inspector of Drugs, Chairman Quality Control, Director Licensing, Director Quality Assurance and the Chief Executive Officer of the DRAP through nth numbers of time. Similarly I had been corresponding through normal letters as well as through legal notices with Mr. Muhammad Mustafa and Mudassar Farooq cautioning them about all the illegalities being performed by them as per DRAP lay as well as, as per

Companies Ordinance, 1984 but unfortuneately nothing could put them right. Finally as a result of my various personal meetings with Licensing Directorate Officials in DRAP resulted in taking this case in the board meeting.

6. To summarize the present management sitting in the company and corresponding with DRAP is totally illegal and unauthorized. As per the record of SECP according to the directions of ANF about freezing of assets. The only authorize Director is myself which has been confirmed by the SECP through their letter of February, 2016. Since the present management could not g et any headway from SECP through a marathon correspondence by their counsel and even putting all kind of pressure on the Regulators of SECP, finally they filed a writ petition No. 1174/2016 in Islamabad High Court, Islamabad. In this petition, Mr. Muhammad Mustafa and party has made ANF, SECP and DRAP as the respondents but have not made me or Ansar Farooq Ch. As respondents in the same petition. The concern of the petitioners is evident from the court record that for the past more than 4 months, the petitioner's counsel is seeking adjournment for the one reson or the other. Moreover, the Honourable Islamabad High Court, Islamabad has not passed any restraining / supporting order in favour of petitioner. The respondents ANF as well as SECP have submitted their replies to the Islamabad High Court, Islamabad wherein they have clearly mentioned their legal position about freezing of shares and making the same non transfereable in the SECP.

7. Just for record and for demand of justice, I am attaching copies of all letters sent to SECP and their reply to me, letters / legal notices sent to Mr. Muhammad Mustafa and Mudassar Farooq and copies of letter sent to FIDm CQC, DD Licensing, Director Licensing and the CEO of DRAP, Going through these letters will give a clear idea that how much effort I have put in to stand beside the law and knock each door to get the justice. The copies of reply by ANF and SECP as respondents to the Islamabad High Court, Islamabad.

8. Keeping in view, the above brief history and seeing my efforts through correspondence with Mr. Muhammad Mustafa, SECP and DRAP, I have no doubt in conformingly mentoning that the management is illegal therefore, they should not be entertained in seeking any approval, sanctions and any other facility from the DRAP. If the company has to proceed on a legal way then all the correspondence reaching DRAP should have my signature since I am the only legitimate director as per law. It is also submitted that as per Drug Act relevant rules quoted in your show cause notice, I am being legitimate Director be authorized to take on as Chief Executive of the company.

9. In response to para 3 of your show cause notice dated 02-03-2017, I hereby confirm that Mr. Tahir-ul-Wadood Lahoti will like to be heard by the Central Licensing Board

on the date of its assembly in person. You are requested to intimate about the date and venue of Board Meeting at Cell No. 0332-5555532 and 0316-5555532

Proceedings Central Licensing Board in 254th meeting

9. Mr. Osama Lahooti, Director (claimant) or his representative could not appear before the Board.

10. Mr. Muhammad Mustafa, Chief Executive (Claimant), Mr. Muhammad Mudassir and Ahmad Junaid Advocate appeared before the Board. They pleaded their case reiterated the facts already submitted in reply to the Showcause Notice and set of documents presented before the Board. During the pleadings they apprised the Board that till March, 2016 Security and Exchange Commission of Pakistan has been issuing Form-29 and has been refusing to issue Shareholdings. They also apprised the Board that they have signed a "Sale Deed" with Mr Osama Lahooti while "Transfer Deed" is signed without date of execution. They also apprised the Board that they have contested against the letter of the ANF in the Islamabad High Court, Islamabad through Constitutional Petition bearing No. 1174/2015 whereby Drug regulatory Authority of Pakistan was directed not to accept Form-A and Form 29. A number of hearings has been held and no relief to the plaintiff has been awarded by the Honourable Court and no restraining orders are passed by the Honourable High Court.

Decision of the Central Licensing Board in 254th meeting

11. The Board after hearing the one party decided to defer the case for giving final opportunity of personal hearing to the Mr. Osama Lahooti in the next meeting of the Board.

12. After 254th meeting of the Central Licenisng Board Mr. Muhammad Mustafa through his legal counsel M/s Ahmed Junaid Advocate addressed to Secretary Central Licensing Board has alleged as under:

i. that he have acted on for and on behalf of M/s Danas Pharmaceuticals (Pvt) Limited (the Company) and this refers to the hearing dated 15-06-2017, under Show Cause Notice dated 02-03-2017. With regard to the same, you are being conveyed utmost disappointment on behalf of the Company, as serious observations and concerns causing grievance to the Company have been made/found during the course of the subject Meeting. **It has been explicitly observed/witnessed that, you had deliberately kept the Respectable Members of CLB in dark,** regarding certain aspects of our case, which are validly and legally favoring the Renewal of License. Further, in a deliberate and blatant manner, you have concealed from the minutes of CLB meeting the very aspect/fact that the present management (those who are reflecting from the updated/later/recent Form-29 issued from the SECP) are the legitimate sole owners of total 200,000 shares of the Company out of which 133,334 (66.67%) shareholding (an absolute majority) in the company holds PERFECT TITLE, and only 66,666 (33.33%) shares with the freezing status by ANF Authorities. The said aspect was supported by

documentary evidences/facts as has been submitted by the Company from time to time in your good office.You have not only deliberately concealed from the respectable members of the CLB but also from the minutes of CLB meeting the fact that the company has been submitting all forms A and Forms 29 since 2014, which do not reflect Mr. Lahooti as Director of the company.

ii. You have also deliberately concealed from the respectable members of the CLB, but also not recorded in the minutes of CLB meeting the contents of letter dated 10-01-2017, wherein you were informed by the company that as per relevant provisions of governing law i.e. companies ordinance, 1984, through elections in the AGM of the company, as was due in October, 2016, the present Management has been elected for the period of next three years i.e. for the term 2016-2019, which do not reflect Mr. Lahooti as Director of the Company for the said term.

iii The company and its present Management in therefore highly indignant and in deep dejection, which further observing the unacceptable/unwarranted biasness on the part of the Secretary Licensing Board, as it has been witnessed beyond and shadow of doubt that you have reflected a mindset to deteriorate the very interests of the company, as you have brushed aside the contents of reply to the show cause Notice, which was mainly rebutting the alleged concealment of change of Management. Through the said reply it has been maintained that it was committed/ mis-doing of the then Management, however you only discussed, to our understanding supported mostly the allegations leveled by Mr. Usama Lahoti against the present management of the company.

iv Therefore, being the stake holders of the situations, they therefore, hold right to query us with expectations of an immediate/without any delay response from your side. Needless to state that you and us are fortified by the provisions of the Drugs Act, 1976 and Drugs (Licensing, Registration and Advertising) Rules, 1976, for the purpose of renewal of license. Without prejudice, it seems to us that we have sat to argue/defend the so-called and irrelevant concerns of an outgoing share holder and previous director of the company i.e. Mr. Lahooti. Therefore, in view of the same, please clarify that haven’t you created a norm/history that the Central Licensing Board is also authorized to turn its ears to any complaint, if raised and agitated regarding the title of share holdings or any dispute, if raised thereon? Or you are broadening the scope of the aforesaid legislations by acting as a Judge of your own cause? Please, write to us that which provision of the said laws warrants you to travel beyond the scope of your permitted authority.

v To the best of their knowledge and understanding, if you could prove otherwise, our perusal of the aforesaid laws reveals that renewal of license of a company is only dependent to what is required under Rule-5 thereof and also disclosure of mandatory information i.e. name of management only, as required to be placed through Form-1-A. Therefore, if you are privy to

any other piece of legislation, which does warrant you to arbitrate and adjudicate any correspondence/complaint as a judge, whereby a previous share holder has raised any objection regarding transfer of shares, or his directorship, then you are requested to share the said law with us as well.

vi. You are also reminded that during the hearing of show Cause Notice, we have referred to plethora of decisions given by the Central Licensing Board's Meetings, wherein the Board while renewing the License/Change of management has only resorted to Form-29 of the company which the company has been dully submitting since 2014. We are also keen to know that what made you convinced to contradict and deviate from the previous decisions passed/taken by the Board, whereby the Licenses have been renewed on the basis of the information available through Form-29, issued by the SECP.

vii All the aforesaid events and those out of our previous hearing, transpire beyond any shadow of doubt that you have taken steps ahead to facilitate the concern of Mr. Lahooti and that too in such a manner that you forget to follow the law governing your ambit and preview/authority. This is also to state that the Show Cause Notice only levels an allegation of concealment on our part, which we clarified and rebutted through convincing/tangible and reliable evidence.

viii Knowingly well that you are not empowered to do so under the law, but to our extreme astonishment, we are unable to understand as to what personal interests/fringe benefits, or simply what urgency was existing on your part that made you to adjudicate upon. We are also unable to understand, what exactly barred you that even you didn't even bother to make it part of show cause notice or call an explanation/justification/from the company prior to discussion in the CLB, which you are under an obligation to. But rather, you seem completely biased to the Company, whereas it should not be based on personal grievances, rather it is about legal proceedings against a legally licensed company and the company and its present management owe all its rights and reservations, but given your KNOWINGLY/DELIBERATELYRENDERING AN UNJUST JUDGMENT/FAVORITISM/NEPOTISM in favour OF AN ALIEN TO THE PRESENT MANAGEMENT, YOU EVEN have given him another opportunity of hearing to fulfill his suspicious plans. Although Show Cause Notice was very clear and candid that if nobody appears, the decision with made ex-parte.

ix As matter of fact, you must understand that this is the licensed company duly licensed under Drugs(Licensing, Registration and Advertising) Rules, 1976, in particular you are dealing with, and not merely the Shareholder of the Company and this is THE COMPNAY which takes full responsibility of th records and documents attached with or contents declared thereof submitted through statuary documents/ forms from time to time dully certified by the SECP, wherein your role is mere an employee and the law applicable on the subject make you

a PUBLIC SERVANT, who as the custodian of law, is not only required to maintain the norms of justice and equity, but is expected to deal with the affairs fo the Companies without any fear, favour or nepotism.

x That although you are not in your legal capacity to play the role of an adjudicator under various provisions and sections of the Drugs (Licensing, Registration and Advertising) Rules, 1976 as we have every reason to believe that you have acted in excess of your legal jurisdiction. It was your moral but definitely a legal obligation to first enquire the stand of the Company by sharing the documents/claim submitted by Mr. Lahooti, and in the light of that submissions you should have questioned us or ask any reply after testimonial of the evidences, heard/seen from both end.

xi. It is also strange that you have failed to advice Mr. Usama Lahooti that SECP under the preview of various PROVISIONS of Companies Ordinance 1984, i.e. Section-76, Section 152 and Section-290, DRAP is not the competent Authority to adjudicate such matters but only Civil Court has jurisdiction to adjudicate thereon. Further, if any Shareholder is aggrieved of omission of his name from the register of Share Holders, it is only for the Company Judge of High Court to decide and adjudicate the said issue/matter under Section-152 of the Companies Ordinance, 1984. On the contrary by agitating this matter in the CLB, you have rendered him favour, which is highly unbecoming of a man of your stature.

xii Even worse than this, you seem to favor/show fidelity to Mr. Usama Lahooti, as YOU deliberately concealed our letters written a year ago dated 21-03-2016 and 24-03-2016 from the CLB in the hearing, wherein we have explicitly explained/clarified/informed your good office that Mr. Lahooti was removed from directorship of the company in year, 2012 and was never re-instate or re-elected by the board of the company, you not only turned a deaf ear to our aforesaid letters, but miserably failed to convey our advice to Mr. Lahooti that DRAP is not competent forum to adjudicate upon his grievance, if any.

xiii Further, you have deliberately concealed from the Respectable Members of CLB that the Company has submitted the dully certified Form-29 dated 04-10-2012 issued by SECP wherein Mr. Lahooti having tendered his willful resignation from the said office on 19-09-2012, in lieu of his forced removal from the directorship through Board Resolution passed by the then management and by the vast majority of the shared holders on 19-09-2012 (copy of the said resolution is re-enclosed for your kind perusal and understanding) the same was duly acknowledged by him on 05-12-2012. Afterwards he was never restored neither re-appointed nor elected by the company since 2012 copy of Form-29 dated 04-10-2012 (Fresh copy of the said Form-29 dated 04-10-2012 re-attested and re-certified on dated 14-07-2017 by SECP is enclosed herewith for your kind perusal and understanding) .

xiv **We have already reached to the conclusion that having your sympathies for him**, **Mr. Usama** has been knitting a plan against the Company and its Management, and having got

your illegal support, while playing a dubious role, you mysteriously portrayed this whole matter suspicious in front of CLB, by referring to a Form-29 dated 31-10-2013, wherein Mr. Usama is shown re-elected as Director till 2016, as becoming a part and parcel of Mr. Lahooti's intrigue thinking you kept a dreadful and criminal silence at your part of justification, to the fact that the said form-29 is not issued/certified by the SECP.

xv We have strong apprehension about accepting/entertaining of the said Form, though knowingly well that the same has no legal sanctity and is a sheer violation of your lawful duty, rather we consider it the mischief/misconduct on your part while acting as the Secretary Licensing Board. The said act of yours in unfathomable and incomprehensible to the company and its management and needs immediate clarification/legal footing, if any, from your side. At the same time, we reserve the right to question the validity of the said Form in the court of law.

xvi Further, you have also deliberately concealed from the respectable members of CLB that the company has been submitting all Form A and Forms 29 since 2014, which don not reflect Mr. Lahooti as Director of Company.**Let the company make it very clear that the aforesaid on your part is your acts of duality and it further give rise to a simple question about your conduct and your impartiality as The Secretary Licensing Board.**

xvii. It is hard to understand that, what made you to sit and act as a judge and term Mr. Usama's so-called complaint a Dispute. This leads to the conclusion that either **you are unable to understand the scope of your duties inside the Central Licensing Board**, or you are acting in flagrant disregard of the same. Therefore, to justify your part, we shall also await to see, when you will write a letter to Mr. Usama clearly stating therein that he should approach the appropriate forum, if he has any objection of the transactions inside the Company OR OTHERWISE WE SHOULD BE CALLED UPON WHEN HE WILL BE HEARD IN THE UP COMING MEETING OF CLB TO COUNTER HIS CLAIMS/DOCUMENTS. And in case, you fail to do so, it will lead to the conclusion, as drawn aforesaid, that you are acting hands in gloves with Mr. Usama under the garb of his evil designs coupled with your personal interests.

xviii You must be already privy to the fact that we have issued a letter dated 21-03-2016 in the name of Mr. Usama Lahooti to withdraw from his evil designs or at-least approach the Court of law against us to prove the same. You are also therefore, as we consider the same malicious and unproductive attempts and futile efforts on your part, advised to forthwith withdraw your un-lawful objection/arbitration or else, we shall be within our rights to hold you answerable before the Courts of law to prove your legal standings and footings, and in case of your failure to prove the same, you shall also be liable to face our claim of damages.

xix. **We have also seen that during the hearing of show cause notice you told us that letter dated 26-10-2015 written by ANF has tied your hands and you have expressed**

your inability to acknowledge the change of Management due to the same, But more surprisingly, for un-known reason you had deliberately concealed from the minutes of CLB in dark about ANF's letter dated 30-05-2017 in which ANF's Authorities have shown their inability to respond to their earlier letter dated 26-10-2015, as the matter is prejudice before the Honourable Islamabad High Court, which raises a very serious question that if ANF's Authorities couldn't stand to their stance, how you could react to the same? (Copy of the said letter is enclosed herewith for your kind perusal and understanding)

xx. But even to settle this issue, when you were asked to give us the same in writing that enable us to place the same before the Honourable Court to get directions thereof, you simply flare up and used abusive language with Representative of the Company, who came to your office for the letter. The company and its management reserve right to place on record of the appropriate forum, the recorded/documented version of your conduct, as you have shown to the company's representative.

xxi. You are further directed, as well as required, through this communication to forthwith and in any case within FIVE DAYS of receipt of the instant letter, do the needful done, as required through preceding paras, failing which we reserve our rights and, therefore, shall be at liberty to initiate legal proceedings against you. In that eventuality, this is to inform you further, that **we might feel obligated to divulge to the Court of Law** or any other competent forum to secure our rights. Looking forward to hear from you soon.

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

13. Mr. Osama Lahooti has been called for personal hearing.

Proceedings and Decision of Central Licensing Board in 255th meeting

14. The Secretary, Central Licensing Board separated himself from the proceedings of the case in the light of allegations from legal counsel of Mr. Muhammad Mustafa as reproduced at para 12 above and went out of the Committee Room. The honourbale members of the Board brought him back and posed confidence on him being Secretary of the Central Licensing Board. The Board also condemned in stronger terms the contents of the letter written by legal counsel of Mr. Muhammad Mustafa. The Board also reiterated that decision taken and recorded in minutes are taken by the Board and not by any individual and allegations leveled against the Secretary, Central Licensing Board are baseless and of infected mind. The observers on the Board also condemned the contents of the letter written by legal counsel of Mr. Muhammad Mustafa in stronger terms.

15. Col. (R) Tahir ul Wudood Lahooti father of Mr Osama Lahooti appeared before the Board as representative of Mr Osama Lahooti. He contended that:

i. I, hold 33% shares of the company till date.

ii. I am the legitimate director of the company till date as clarified by the SECP during their letters.

iii. All documents submitted by Mr. Muhammad Mustafa to your office against my share holding and directorship are false, fabricated and have been turned down by the SECP, being the regulator of private limited companies as per the Company Ordinance, 1984.

iv. Since July 2014 onward, every activity took place in the company related to purchases, obtaining sanctions from DRAP related to the active and inactive materials are illegal and also are in total violations of Drug Act.

v. All relevant restrictions imposed by the Anti Narcotics Force (ANF) have also been communicated to your office since October, 2015 which clearly directs that sharing capacity of mine cannot be changed.

vi. I have been communicating with all relevant offices in the Drug Regulatory Authority, Pakistan starting from FID, CQC, DDG Licensing, Director Licensing and the CEO of DRAP.

vii. Mr. Mustafa and party have not been able to prove their legal position in front of all legal Regulators.

viii. Restriction imposed by the ANF on transfer of my shares have been communicated to all the concerned regulators since October, 2015.

ix. I definitely have apprehension about illegal activities in the company which may harm me, being a director, and not being a part of management physically.

x. Drug Act paras quoted in the show cause notice if read and viewed, it allows the board to handover the management to me being the legitimate director in all legal documents.

xi. If the DRAP accepts the direction of ANF conveyed then it must accept my shares holding and directorship. Similarly if DRAP and the Licensing Board do not accept the ANF direction then it must be conveyed to me in clear words so as enabling me to approach the appropriate forum regarding this decision of Drugs Licensing Board.

The Board after hearing the versions of both Parties, is of the unanimous view that the dispute between the Parties is regarding the share holding of the Company i.e M/s Danas Pharmaceuticals (Pvt) Ltd., 312 Industrial Triangle Kahuta Raod, Islamabad which is purely of civil nature and not within the mandate and jurisdiction of the Board. The Parties therefore, may be advised to have it resolved from the Court of competent jurisdiction.

Meanwhile, since the important question before the Board is that who will be responsible for any irregularity / illegality during the time the question of ownership is resolved by the Court. It was resolved that the Secretary Licensing Board, may write a letter to Anti Narcotics Force, in reference to their last received letter stating therein that the Board has received an application from one of the Parties, who has allegedly acquired the major share holding in the Company and same has been endorsed by the Securities and Exchange Commission of Pakistan (SECP), but the Board is unable to process their application due to the impeding instructions issued by the Anti Narcotics Force vide their letter No. F. 2 (132) Assets/ANF/IR/2011-4143 dated 26th October, 2015, F. 2 (132) Assets/ANF/IR/2011-4143 dated 02 March, 2017. Therefore, ANF, may advise the Board the course of action required to be taken in this regard.

Case No. 44. **M/S HASSAN PHARMACEUTICALS (PVT) LTD, 99A, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.**

M/s Hassan Pharmaceuticals (Pvt) Ltd, Industrial Estate, Hayatabad, Peshawar submitted the application for renewal of DML No. 000357 by way of formulation on 07-09-2015 for the period of 18-09-2015 to 17-09-2020, which was well on time. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. Proper application on prescribed Form-1A.
ii. Class(es) of Drugs
iii. Dosage form(s) of drugs
iv. Updated nothing due certificate (CRF) from STO (R&D) DRAP Islamabad.
v. Legal status of the firm.
vi. Any change in management / owner of firm, details of management i.e. name, CNIC (in case of partnership then partnership deed).
vii. To provide approval letter of Production and QC Incharge, if technical persons are changed then provide attested documents according to Rule 16 of Drugs (Licensing, Registering & Advertising) Rules, 1976, after promulgation of S.R.O 1134(i)/2014 and submit documents according to checklist (check list enclosed) with requisite fee.
viii. List of total section of the firm and their letters of grant which were approved in meetings of Central Licensing Board.

2. With reference to above letter, the firm submitted following documents;

i. Application on Form-A with attached documents.

Upon evaluation following shortcomings were observed and conveyed to the firm vide final reminder dated 17th February, 2017;

i. Up-to-date Nothing Due Certificate from Statistical Officer, DRAP.
ii. Fee challan for approval of proposed QC Incharge Mr. Mujahid Sher.
ii. Attested copy of resignation of previously approved QC Incharge.

3. With reference to above letter, the firm submitted following documents;

i. Copy of Fee Challan for approval of proposed QC Incharge Mr. Mujahid Sher.
ii. Attested copy of resignation of previously approved QC Incharge.
iii. Copy of application to STO, DRAP, Islamabad for issuance of Nothing Due Certificate (CRF).

Upon evaluation, following shortcomings are still present in the DML renewal application;

i. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad, has not been attached.
ii. Copy of Fee Challan for approval of proposed QC Incharge (Mr. Mujahid Sher) is unattested.

Decision of CLB in its 253rd meeting.

4. The Board considering the facts on the record and after thread bare deliberation decided to serve ShowCause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs(Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why theirapplication for renewal of M/s Hassan Pharmaceuticals (Pvt) Ltd, Industrial Estate, Hayatabad,Peshawar DML No. 000357 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Reply of Firm to Show Cause Notice

5. The firm has replied that :

i. We have applied for CRF clearance certificate for a long time but due to change of status of the company the case is still pending. All the CRF dues are cleared and up-to-date.
ii. We have applied for the change of status of the company and management on 29th May, 2017 copy of the letter regarding this matter attached.
iii. As the status of the company changed we will provide all the required documents.
iv. We also want to have a meeting with you so as to discuss the case in detail.
v. Therefore, you are required to kindly gave us an appointment in order to discuss the case.

6. The case for change of management is also on agenda. Certificate from Budget and Accounts is received.

Proceedings and Decision of Central Licensing Board in 255th meeting

Mr. Muhammad Nawaz, Managing Director of of M/s Hassan Pharmaceuticals (Pvt) Ltd, Industrial Estate, Hayatabad, Peshawar appeared before the Board and contended that all codal formalities has been completed by him for the purpose of renewal of Drug manufacturing Licence of his company therefore, Show Cause Notice issued to the company may be recalled. After hearing the representative of the company and facts on record the Board decided to cease to enforce the operation of the ShowCause Notice issued to company earlier.

Case No.45. <u>M/S CHERWEL PHARMACEUTICALS (PVT) LTD, PLOT NO.20, PHASE-IV, HATTAR INDUSTRIAL ESTATE, HATTAR – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.</u>

M/s Cherwel Pharmaceuticals (Pvt) Ltd, Hattar Industrial Estate, Hattar submitted the application for renewal of DML No. 000606 by way of formulation on 22-12-2016 for the period of 30-12-2016 to 29-12-2021, which was well on time. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

iii. The initial part of Form-1(A) is missing and form is un-signed.
iv. Copy of list of approved /registered drugs is un-attested.
v. Latest Form-29 showing the list of directors is not attached.
vi. Copy of layout plan is not clear and letter(s) of approval of sections is not attached.
vii. Details of section wise equipment and machinery is not attached.

viii. The names of technical staff mentioned on Form-1(A) is different from those mentioned on previous renewal certificate and fee Challan as well documents for approval of new staff are not attached.

ix. Up-to-date Nothing due certificate from statistical officer is not attached.

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

x. The initial part of Form-1(A) is missing and form is un-signed.

xi. Copy of list of approved /registered drugs is un-attessted.

xii. Latest Form-29 showing the list of directors is not attached.

xiii. Copy of layout plan is not clear and letter(s) of approval of sections is not attached.

xiv. Details of section wise equipment and machinery is not attached.

xv. The names of technical staff mentioned on Form-1(A) is different from those mentioned on previous renewal certificate and fee Challan as well documents for approval of new staff are not attached.

xvi. Up-to-date Nothing due certificate from statistical officer is not attached.

3. With reference to above final reminder, the firm has submitted reply as under;

xiv. Form 1-A.

xv. List of Directors.

xvi. List of equipment and machinery.

xvii. Copy of application to STO, DRAP, Islamabad for issuance of Nothing Due Certificate (CRF).

xviii. Copy of appointment letter of proposed Production Incharge.

xix. Copy of appointment letter of proposed QC Incharge.

xx. Copy of approved L.O.P.

4. Upon evaluation of documents following shortcomings have still been observed;

iii. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad, has not been attached.

iv. Fee Challan of Rs.50,000/- alongwith requisite documents for change of management, has not been attached but the management seems to be changed as under;

Previous Management as per Form-1A (Page-210/Corr)	**Current Management as per Form-1A (Page-314/Corr)**
i. Imdadullah S/o Muhammad Inam CNIC No.17201-2115379-1	i. Abdul Wahab S/o Zar Muhammad CNIC No.OR130671
ii. Abdul Wahab S/o Zar Muhammad CNIC No.OR130671	ii. Tahir Ahmed S/o Nisar Ahmed CNIC No. 16101-6321648-5
iii. Tahir Ahmed S/o Nisar Ahmed CNIC No. 16101-6321648-5	iii. Kashfadduja S/o Badrudduja CNIC No.16101-1635177-9

iv.	Shabir Ahmad S/o Kashfadduja CNIC No.16101-6456368-3	

Proposed Production Incharge (Dr. Qazi Irfan ul Haq)

v. Fee Challan of Rs.5,000/- for change of Production Incharge, has not been attached.

vi. Attested copy of CNIC, has not been attached.

vii. Attested copies of academic certificates, have not been attached.

viii. Attested copy of registration certificate from Pharmacy Council, has not been attached.

ix. Attested copy of resignation of proposed Production Incharge from previous firm, has not been attached.

x. Attested copy of resignation of already approved Production Incharge, has not been attached.

xi. Undertaking as whole time employee, has not been attached.

Proposed QC Incharge (Miss Robina Kausar)

xii. Fee Challan of Rs.5,000/- for change of QC Incharge, has not been attached.

xiii. Attested copy of CNIC, has not been attached.

xiv. Attested copies of academic certificates, have not been attached.

xv. Attested copy of job acceptance letter of proposed QC Incharge, has not been attached.

xvi. Attested copy of resignation of proposed QC Incharge from previous firm, has not been attached.

xvii. Attested copy of resignation of already approved QC Incharge, has not been attached.

xviii. Undertaking as whole time employee, has not been attached.

Decision of CLB.

5. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Cherwel Pharmaceuticals (Pvt) Ltd, Hattar Industrial Estate, Hattar DML No. 000606 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Reply of Firm to Show Cause Notice

6. We M/s Cherwel Pharmaceuticals (Pvt) Ltd., Plot No.20, Phase 4, Industrial Estate, Hattar, having manufacturing license # 000606, state that they received letter No.F.3-9/2005-Lic regarding the

Showc Cause Notice, and their technical person will appear before the Central Licensing Board to answer any queries and the hurdles at our end that are the causes of stoppage of renewal inspection at your demanding time.

Proceedings and Decision of Central Licensing Board in 255th meeting

Mr. Irfan Qazi, Production Incharge appeared before the Board. He contended that audit reports have been submitted to the Budget and Accounts Department for issuance of NOC for central Research Fund (CRF). He admitted that firm has not submitted fee of Rs. 50000/- for change of management. While discussing the case he was approved that no documents for approval of Quality Control Incharge are received. Moreover, documents for approval of Production Incharge are also deficient.After hearing the representative of the firm and facts on record, the Board decided to suspend the Drug Manufacturing Licence of M/s Cherwel Pharmaceuticals (Pvt) Ltd, Hattar Industrial Estate, HattarDML No. 000606 by way of formulation for the period of six months with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No.46. <u>M/S ONYX PHARMACEUTICALS, 30-A, SMALL INDUSTRIAL ESTATE,MANSEHRA – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.</u>

M/s Onyx Pharmaceuticals, Small Industrial Estate, Mansehra submitted the application for renewal of DML No. 000440 by way of formulation on 13-06-2016 for the period of 15-06-2016 to 14-06-2021, which was well on time. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. Application on prescribed Form-1A (enclosed).
ii. List of class(es) of drugs.
iii. Dosage forms of drugs.
iv. Updated nothing due certificate (CRF) from STO (R&D) DRAP Islamabad.
v. To provide approval letter of Production and QC Incharge, if technical persons are changed then provide attested documents according to Rule 16 of Drugs (Licensing, Registering & Advertising) Rules, 1976, after promulgation of S.R.O 1134(i)/2014 and submit documents according to checklist (check list enclosed) with requisite fee (Rs.5000/-) for each.
vi. Attested and readable copies of CNIC's of all Directors / partners.
vii. Requisite fee for change in management (Rs.50,000/-) as the management is changed.

2. With reference to above letter, the firm submitted following documents;

i. Documents for approval of technical staff.
ii. Copy of previous application and Fee Challan submitted for renewal of Drug Manufacturing License.
iii. Unattested copy of list of products.
iv. Unattested copy of transfer of Lease Deed.
v. Unattested list of Machinery.
vi. Unattested copy of application for issuance of Nothing Due Certificate (CRF).

3. Upon evaluation of firm's reply, a reminder with following shortcomings was issued to the form;

i. Application on prescribed Form-1A (enclosed).
ii. List of class(es) of drugs.
iii. Dosage forms of drugs.
iv. Updated nothing due certificate (CRF) from STO (R&D) DRAP Islamabad.
v. To provide approval letter of Production and QC Incharge, if technical persons are changed then provide attested documents according to Rule 16 of Drugs (Licensing, Registering & Advertising) Rules, 1976, after promulgation of S.R.O 1134(i)/2014 and submit documents according to checklist (check list enclosed) with requisite fee (Rs.5000/-) for each.
vi. Attested and readable copies of CNIC's of all Directors / partners.
vii. Requisite fee for change in management (Rs.50,000/-) as the management is changed.

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

Upon evaluation of documents following shortcomings have still been observed;

i. Application on prescribed Form-1A (enclosed).
ii. List of class(es) of drugs.
iii. Dosage forms of drugs.
iv. Updated nothing due certificate (CRF) from STO (R&D) DRAP Islamabad.
v. To provide approval letter of Production and QC Incharge, if technical persons are changed then provide attested documents according to Rule 16 of Drugs (Licensing, Registering & Advertising) Rules, 1976, after promulgation of S.R.O 1134(i)/2014 and submit documents according to checklist (check list enclosed) with requisite fee (Rs.5000/-) for each.
vi. Attested and readable copies of CNIC's of all Directors / partners.
vii. Requisite fee for change in management (Rs.50,000/-) as the management is changed.

5. In response to final reminder, the firm submitted following documents;

i. Application on prescribed Form-1A.
ii. Fee Challan for change in technical staff alongwith documents.
iii. Fee Challan for Change in management.
iv. List of Directors.
v. Copies of CNICs of Directors.
vi. Copy of Partnership Deed.
vii. List of Products
viii. Copy of Nothing Due Certificate Valid upto 31-12-2016.
ix. Copy of layout plan.

6. Upon evaluation of submitted documents, following shortcomings were still observed;

i. Experience of proposed Production Incharge is less than prescribed experience of ten (10) years.
ii. Fee Challan of Rs.5000/- for change of Production Incharge, has not been attached.

iii. The proposed QC Incharge has resigned from M/s Onyx Pharmaceuticals, Mansehra w.e.f. 30-06-2016 and has been approved as QC Incharge in M/s Perk Pharma (Pvt) Ltd, Swabi dated 06-04-2017. But the firm has not submitted documents alongwith fee of Rs.5000/- for approval of new QC Incharge.

iv. The sale agreement between previous and current management includes five (5) persons as current management (page 86/Corr) while partnership deed shows only four (4) current partners (page 91/Corr).

v. Transfer deed in the name of new management issued from the Industrial Estate, has not been attached. But only application for the same to Industrial Estate, has been attached.

Decision of CLB in its 253rd meeting.

7. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Onyx Pharmaceuticals, Small Industrial Estate, Mansehra DML No. 000440 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Reply of Firm to Show Cause Notice

8. The firm has submitted reply as under

i. Transfer of lease deed showing five (05) partners.
ii. Complete set of attested documents of proposed QC Incharge.
iii. Attested copies of experience certificates of proposed Production Incharge.
iv. Attested copy of revised partnership deed showing five (05) partners.

9. All requirements have been completed. The firm has been called for personal hearing as Show Cause Notice was issued by the Board.

Proceedings and Decision of Central Licensing Board in 255thmeeting

10. Mr. Muhammad Abdullah, Director (Administration) of M/s Onyx Pharmaceuticals, Small Industrial Estate, Mansehra, appeared before the Board and contended that all codal formalities has been completed by him for the purpose of renewal of Drug manufacturing Licence of his company therefore, Show Cause Notice issued to the company may be recalled. After hearing the representative of the company and facts on record the Board decided to cease to enforce the operation of the Show Cause Notice issued to company earlier.

Case No. 47. **M/S MED ASIA PHARMACEUTICALS (PVT) LTD., PLOT NO.7, NOWSHERA INDUSTRIAL ESTATE, RISALPUR – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.**

M/s Med Asia Pharmaceuticals (Pvt) Ltd. Risalpur submitted the application for renewal of DML No. 000690 by way of formulation on 18-08-2016 for the period of 12-07-2015 to 11-07-2020, which was 38 days late. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. Proper application on Form-1A signed & stamp by authorized person.
ii. Class(es) of Drugs.
iii. Dosage form(s) of drugs.
iv. Detail of premises including approved layout plan of the factory.
v. Details of the proprietor / directors / partners etc with CNIC copies and latest Form-29 attested by SECP.
vi. To provide approval letter of Production and QC Incharge if technical persons are changed then provide documents according to Rule 16 of Drugs (Licensing, Registering & Advertising) Rules, 1976, after promulgation of S.R.O 1134(i)/2014 and submit documents according to checklist
vii. Updated nothing due certificate (CRF) from STO(R&D) DRAP Islamabad.
viii. Details / letters of approved sections by Central Licensing Board.
ix. Requisite fee for change of Management / Directors of firm.
x. Late fee @ Rs.5000/- per day as renewal application is 38 days late.

2. With reference to above letter, it is mentioned that as per available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. Licensing Division issued reminder with the same shortcomings.

With reference to above reminder, the firm submitted following documents;

i. Fee Challan of Rs.1,90,000/- as late fee.
ii. Application on Form-1A alongwith attached documents.

3. After evaluation of the submitted documents, final reminder was issued to the firm with following shortcomings: -

i. Deposited Fee Challan of Rs. 50,000/- for approval of change in management, has not been attached.
ii. Copy of Form-A dully attested by SECP, showing complete detail of current management, has not been submitted.
iii. Copy of Form-A dully attested by SECP, showing complete detail of previous management, has not been submitted.
iv. Attested Copy of CNICs of all Directors, has not been attached.
v. Attested Copy of Nothing Due Certificate (CRF) from STO, DRAP, has not been attached.

4. In response to final reminder, the firm has replied as under;

> "It is informed that codal formalities regarding renewal of Drug Manufacturing License is under process with the SECP, Tax Consultant and FBR. As and when the same is completed the case will be submitted to your office immediately."

Decision of CLB.

5. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Med Asia Pharmaceuticals (Pvt) Ltd. DML No. 000690 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Reply of Firm to Show Cause Notice

6. In this regard, it is informed that due to changes of previous managements of this factory, income tax returns and audit reports for the last few years were not traceable in this office which were basic requirements for obtaining of central research fund certificate from CRF section. For this purpose a tax consultant was hired and all required auditable documents were handed over to him accordingly to do the needful well in time but in the meantime unfortunately, suddenly the tax consultant proceeded abroad for medical treatment of his wife, who was suffering from chronic disease. Keeping in view this situation, the undersigned once again approached to the tax consultancy office to collect the auditable documents and hire another suitable tax consultant for this matter but the available staff of the respective office did not allow me to do so and saying the words "in absence of tax consultant this is impossible". On the receipt of show cause notice, the matter deeply discussed with concerned consultant stating that all supporting documents have already been completed in all respects and lying in his office and he is coming back shortly within a week time. Furthermore, it is also mention here that all dues as per policy have been deposited along with supporting documents except CRF certificate, which will be obtained from CRF section, as and when income tax returns, audit reports and central research fund is deposited. Only due to non availability of CRF certificate, the renewal of DML is being delayed for which the reason as shown above.

7. In view of above, it is humbly requested that delay submission of this case may kindly be regretted, please. Furthermore shortcoming documents as per requirements will be handed over personally on arrival of tax consultant very shortly but not later than one month.Your kind cooperation in this matter is requested please and your points are also noted for future compliance.

8. The firm has been called for personal hearing

9. Mr. Kifayatullah, General manager and Mr. Saeed ur Rehman, Quality Control Manager appeared before the Board. He contended that documents have been submitted to the Budget and Accounts Department for issuance of NOC for central Research Fund (CRF). He admitted that firm has not submitted fee of Rs. 5000/- and other documents for change of management. After hearing the representative of the firm and facts on record, the Board decided to suspend the Drug Manufacturing Licence of M/s Med Asia Pharmaceuticals (Pvt) Ltd. Risalpur DML No. 000690 by way of formulation with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of CRF and other codal formalities.

Case No. 48. M/S IMCO PHARMACEUTICAL LABORATORIES (PVT) LTD., 73-INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.

M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd. Peshawar submitted the application for renewal of DML No. 000317 by way of formulation on 11-02-2015 for the period of 16-02-2015 to 15-02-2020, which was well on time. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. Form-1A is not submitted with signature and stamp of firm's director.
ii. Remaining some documents are printed on one side of already used papers without any sign/stamp or letter head.
iii. Form-29 (Attested) from SECP as firm is Pvt Ltd.company.
iv. Attested photocopies of CNIC of managment.
v. Details of technical staff as per check list attached.
vi. Detail/proof of all licensed sections.
vii. Current NOC for CRF.

2. With reference to above letter, it is mentioned that as per available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. Licensing Division issued final reminder with the following shortcomings.

i. Form-1A with signature and stamp of firm's Director.
ii. Attested copy of list of classes of the Drugs to be manufactured.
iii. Attested copy of list of Dosage forms to be manufactured.
iv. Attested copy of list of section wise equipments.
v. Attested copy of CNIC's of all Directors.
vi. Form-29 attested by SECP as the firm is (Pvt) Ltd company.
vii. Attested copy of approval letter(s) of Production and QC Incharge and if technical persons have been changed then provide attested documents as per enclosed checklist.

viii. Attested copy of approval letter(s) of all approved sections.

ix. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.

3. In response to final reminder, the firm submitted following documents;

i. Form-1A alongwith attached documents.

4. After evaluation of the submitted documents, following shortcomings were still observed: -

i. Attested copy of Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad, has not been attached.
ii. Attested copy of approval letter(s)/approved L.O.P.(s) showing all approved sections, has not been attached.
iii. Proof of approval of Production and QC Incharge (Mr. Imtiaz Khan and Mr. Inamullah Khan), has not been attached.

Decision of CLB.

5. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd. Peshawar DML No. 000317 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Reply of Firm to Show Cause Notice

6. Reply of the firm to the Show Cause Notice is as under:

i. Copy of up-to-date Nothing Due Certificate (CRF).
ii. List of sections and copy of approved layout plan.
iii. Proof of approval of Production Incharge (Mr. Imtiaz Khan).
iv. Fee Challan and documents for approval of proposed QC Incharge (Mr. Rafiq Ahmad).

7. Upon evaluation of submitted documents following observations have been noted;

i. Attested copy of CNIC of proposed QC Incharge, has not been attached.
ii. Appointment letter of proposed QC Incharge is of 04-05-2015.
iii. The experience of proposed QC Incharge is less than prescribed experience of ten (10) years.

Proceedings and Decision of Central Licensing Board in 255thmeeting

8. Mr. Imtiaz Khan, Chief Executive M/s IMCO Pharmaceutical Laboratories (Pvt) Ltd. Peshawarappeared before the Board and contended that all codal formalities have been completed by him for the purpose of renewal of Drug manufacturing Licence of his company therefore, Show Cause Notice issued to the company may be withdrawn. He also presented copies of the documents before the board. After hearing the representative of the company and facts on record the Board decided to cease to enforce the operation of the Show Cause Notice issued to company earlier.

Case No. 49. M/S ATLANTIC PHARMACEUTICAL LABORATORIES, 89-D, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.

M/s Atlantic Pharmaceutical Laboratories, Peshawar submitted the application for renewal of DML No. 000273 by way of formulation on 27-10-2014 for the period of 30-10-2014 to 29-10-2019, which was well on time. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings: -

i. Revised partnership deed mentioning change in directors / owners if any.
ii. To provide approval letter of Production and QC Incharge if technical persons are changed then provide documents according to Rule 16 of Drugs (Licensing, Registering & Advertising) Rules, 1976, after promulgation of S.R.O 1134(i)/2014 and submit documents according to checklist (check list enclosed).
iii. No Objection Certificate for Central Research Fund (CRF) by Statistical Officer DRAP, Islamabad.

2. With reference to above letter, it is mentioned that as per available record of Licensing Division, no correspondence received in respect to shortcomings in application for renewal of DML of the firm. Licensing Division issued final reminder with the following shortcomings.

i. Partnership Deed(s) mentioning the detail of the previous and current management.
ii. Attested copy of CNIC's of all partners.
iii. Up-to-date Nothing Due Certificate (CRF) from STO, DRAP, Islamabad.
iv. Attested copy of list of section wise equipments.
v. Complete set of attested documents of proposed Production Incharge Mr. Sikandar Sohail as per check list attached.
vi. Fee challan of Rs.5000/- for change of technical staff.

3. In response to final reminder, the firm submitted following documents;

i. Copy of partnership deed.
ii. Copy of Form-H.
iii. Copies of CNIC's of Directors.
iv. Copy of application for issuance of Nothing Due Certificate (CRF).
v. Copy of list of section wise equipments.
vi. Docuemnts of proposed technical staff alongwith fee Challan.

4. After evaluation of the submitted documents, following shortcomings were still observed: -

i. Up-to-date Nothing Due Certificate from STO, DRAP, Islamabad.
ii. Proof of all approved sections.
iii. The experience of proposed Production and QC Incharge is less than ten (10) years.

Decision of CLB.

5. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Atlantic Pharmaceutical Laboratories, 89-D, Industrial Estate, Hayatabad, PeshawarDML No. 000273by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board

6 Accordingly, show Cause Notice was served to the firm. No reply from the firm is received yet. Now, firm has also been called for personal hearing.

Proceedings and Decision of Central Licensing Board in 255th meeting

Mr. Humayun Khan, Director and Mr. Hameed ur Rehman, Quality Control Manager appeared before the Board. They contended that they have completed documents for approval of Quality Control Incharge. They also contended that documents for issuance of NOC for CRF has also been submitted with Budget and Accounts Division.After hearing the representative of the firm and facts on record, the Board decided to suspend the Drug Manufacturing Licence of M/s Atlantic Pharmaceutical Laboratories, 89-D, Industrial Estate, Hayatabad, PeshawarDML No. 000273 by way of formulationfor the period of three (03) months with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case NO. 50 M/S HAFIZ PHARMA INDUSTRY , 44-KM, (GHANIYA)KAMOKE, DISTRICT GUJRANWALA – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.

M/s Hafiz Pharma Industry, Kamoke had submitted application dated 04-07-2016 for the renewal of their Drug Manufactuing Licence period from 07-07-2016 to 06-07-2021. After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings/attested documents dated 23-08-2016:

i) Detail of Management / Directors / Partners.
ii) Proof of sections from Central Licensing Board / approved layout plan.
iii) Approval letter of Production and QC Incharge.
(iv) No Objection Certificate for Central Research Fund (CRF) updated issued by Statistical Officer DRAP, Islamabad.

2. Firm did not submit the reply of the above shortcoming letter, however firm had applied for the approval of Production Incharge, which was approved. Accordingly a final reminder was issued for the completion of DML renewal application dated 20-04-2017 for following shortcomings;

i) Detail of Management / Directors / Partners.
ii) Proof of sections from Central Licensing Board / approved layout plan.
iii) Approval letter of QC Incharge.
iv) No Objection Certificate for Central Research Fund (CRF) updated issued by Statistical Officer DRAP, Islamabad.

3. Firm has submitted following documents /copies in reply to above final reminder ;

(i) Copy of L.O.P
(ii) Incomplete documents of Quality Control Incharge

(iii) Incomplete documents of C.R.F

(iv) Name of Managing Director.

4. Following documents/information is still short/deficient.

(i) Updated Nothing Due Certificate for C.R.F from S.T.O

(ii) Complete set of attested documents for approval of proposed Q.C Incharge as per check list.

Proceedings and Decision of Central Licensing Board in 254th meeting.

5. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of M/s Hafiz Pharma Industry, 44-KM, (Ghaniya) Kamoke, District Gujranwalaby way of formulation may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board

6. Reference Para 113/N, Central Licensing Board in its 254th meeting held on 15th June, 2017 decided to serve show cause notice to the firm for violation of Rule 16 and Rule 5(2A) and accordingly show cause notice was issued to the firm dated 24-07-17(Page #211/Corr).

7. Firm has submitted reply to show cause notice but firm has not submitted the following required documents for renewal of DML No 000595(Formulation) and application for renewal of DML is still incomplete.

i) N.O.C OF CRF (Updated)
ii) Complete set of documents of Q.C. Incharge.

Firm has been called for personnel hearing to explain its position on the above subject matter.

Proceedings and Decision of Central Licensing Board in 255thmeeting

8. Mr. Hafiz Abdur Rehman, owner of the firm and Mr Waheed Akhtar , Manager appeared before the Board. They contended that documents for issuance of NOC for CRF has also been submitted with Budget and Accounts Division. After hearing the representative of the firm and facts on record, the Board decided to suspend the Drug Manufacturing Licence of M/s Hafiz Pharma Industry, 44-KM, (Ghaniya) Kamoke, District GujranwalaDML No000595by way of formulation for the period of three (03) months with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case NO.51 M/S HELICON PHARMACEUTEK PAKISTAN (PVT) LTD., MODEL TOWN ROAD,FAISALABAD – VIOLATION OF RULE 5(2A) OF DRUGS (L,R&A) RULES, 1976.

M/s Helicon Pharmaceutek Pakistan (Pvt.)Ltd, Faisalabad had submitted application dated 06-11-2015 for the renewal of DML No. 000117 . After evaluation of the renewal application of the firm, a letter for completion of application for renewal of DML was issued for following shortcomings/attested documents dated 28-12-2016: -

i. Details of management/Form-29 from S.E.C.P. Previous Form-29 and any change in management, CNIC copies of all Directors.
ii. Details of premises including approved L.O.P
iii. Approval of technical staff or proposed documents for technical staff as per check list
iv. Proof of all licensed sections.
v. N.O.C for C.R.F

2. Firm did not submit the reply of the above shortcoming letter; accordingly a final reminder was issued by Secretary CLB dated 17-02-2017.Firm submitted reply alongwith deficient documents against the final reminder for the completion of their DML renewal application as under:

i. Unattested form-29 from SECP
ii. Copy of L.O.P
iii. Nothing Due certificate UPTO 31-12-2005
iv. Mr. Rafaqat Ali , production Incharge
v. Miss ZahidaMaqsood, Q.C Incharge

3. Following documents /information is still deficient /short;

i. Firm submitted the name of Miss ZahidaMaqsood as Q.C. Incharge, However it is revealed from record that she had resigned from her post on 2-1-2009 and her resignation was accepted by the management of firm. According Mr. Muhammad Rafiq Khan S/o Sultan Jan Khan was approved as Q.C. Incharge vide this office letter of even Number dated 21-07-2009 Firm did not reply for approval of approved of Q.C. Incharge Miss ZahidaMaqsood to this office was submitted resignation of Mr. Muhammad Rafiq Khan till to date as per available record of licensing Division.
ii. Firm submitted form-29 (un-attested) and seems change in management, however fee Challan for change of management is not provided
iii. Letter of approved Section from CCB is not provided.
iv. Latest nothing due certificate for C.R.F from S.T.) is not provided. Firm submitted certificate up to 2015.

Proceedings and Decision of Central Licensing Board in 254th meeting.

4. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000117 by way of formulation ofM/s Helicon Pharmaceutek

Pakistan (Pvt.) Ltd, Faisalabad may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

5. The Show Cause notice dated 21st July, 2017 was issued to the M/s Helicon Pharmaceutek Pakistan (Pvt.) Ltd, Faisalabad.Reply of the show cause is received from the firm which is as under:-

"This show cause notice is seem to be a result of misreading/ non reading of our reply received on dated 20.03.2017 and reply to your letter dated 28.12.2016 and 17.02.2017.We were required to provide following five information's/ queries

i. *Detail of management form-29 duly attested from S.E.C.P. previous Form-29 and any change in management. CNIC copies of all direction.*
ii. *Detail of premises including approved layout plan.*
iii. *Proof of all licensed sections.*
iv. *Approval of technical staff or proposed documents for technical person as per check list.*
v. *Nothing due Certificate for CR.F.*

We have already thoroughly replied all these queries/ observations by providing all requisite information and by attaching the requisite documents. We reproduce for your kind information along with the extract of requisite reply para wise as below. Which proves that this show cause/notice is unwarranted and liable to withdrawn forth with

***Query 1**. Detail of management form-29 duly attested previous Form-29 and from S.E.C.P. any change in management. CNIC copies of all directors.*
***Reply:** Form 29 duly certified on 06 August 2016 diary no. 918622 from joint registrar S. E.C.P. Faisalabad elaborating he following information of all the directors.*

***Query 2**. Detail of premises including approved layout plan.*
***Reply:** The detail of premises including layout plan is attached here with again. This factory was licensed in 1962 and then under Drug Act 1976 and since then continuing at this premises duly inspected and approved and renewed as per layout plan.*

***Query 3**.Proof of all licensed sections.*
***Reply:** The license sections have been duly inspected while granting the registrations and while renewing the drug manufacturing license. This is the sufficient proof of licensed section. More over all our registrations are current and renewed.*

***Query 4**. Approval of technical staff proposed documents for technical person as per check list.*

***Reply**: The following approved technical staff is working continuously without any interruptions*

After fulfillment of all requisite qualifications. As under

Sr. No	*Name*	*Job assigned*	*Qualification*
1.	*Mr. Rafaqat Ali*	*Production Manager*	*B. Pharmacy*
2.	*Ms. ZahidaMaqsood*	*Quality Control Manager*	*B. Pharmacy*

copy of approval letter of Ministry of Health is attached for ready reference.

***Query 5**. Nothing due certificate for C.R.F,*

***Reply:** Letter dated 20th March 2015 issued by the statistical officer DRAP Islamabad narrating this "Nothing due certificate is valid up to 31.12.2015" copy attached.*

We are amongst the pioneer manufacturing units serving the country. In the recent past we have donated 50% of our registered drugs to a charity. Thus we are not working for profit.

it is not out of place to mention that in line with the suggestions of the inspection panels, we have closed down few sections and are intending to shift the production to a third party arrangement till such time that we have alternative manufacturing facility to under take these by our self for which we have made positive arrangements. We have sufficiently replied to your queries on the basis of which we were issued this un warranted show cause notice. We therefore request personal hearing to clarify our stance for ends of justice as poor patients are likely to suffer incase of any adverse consequences arising out of misreading's

We may be accorded some convenient date with sufficient lead time for personal hearing as well".

Observations of the Licensing Division

6. Observations of the Licensing Division are as under:

Query 1. Detail of management form-29 duly attested previous Form-29 and from S.E.C.P. any change in management. CNIC copies of all directors.

Observation: The firm has submitted copy of form-29 which is not duly attested from S.E.C.P. and not provided CNIC copies of all directors.

Query 2. Detail of premises including approved layout plan.

Observation: The firm did not submit **approved** layout plan.

Query 3.Proof of all licensed sections.

Observation: Not provided by the firm

Query 4. Approval of technical staff proposed documents for technical person as per check list.

Observation: It is revealed from the record that Ms. ZahidaMaqsood (approved Quality Control Incharge) had resigned from her post on 02-01-2009 and her resignation was accepted by the management of firm (page 56/Corr). Accordingly Mr. Muhammad Rafiq Khan S/o Sultan Jan Khan was approved as Quality Control Incharge vide this office letter of even number date 21-07-2009 (page 69/Corr). Afterwards, the firm neither applied for approval of Ms. ZahidaMaqsood as Quality Control Incharge nor submitted resignation of Mr. Muhammad Rafiq Khan till date to Licensing Division.

Query 5. Nothing due certificate for C.R.F,

Observation: The Nothing due certificate for C.R.F. is valid upto 31-12-2015.

The firm has been called for personal hearing

Case is placed before the board for its consideration in light of previous proceeding of the Board.

Proceedings and Decision of Central Licensing Board in 255th meeting

7. No person appeared before the Board. Letter issued to the firm for personal hearing is received undelivered. The Board therefore, decided to defer the case till next meeting of the Board.

Case No. 52. <u>RENEWAL OF DRUG MANUFACTURING LICENCE M/S ALKEMY PHARMACEUTICAL LABORATORIES (PVT) LTD, HYDERABAD.</u>

M/s Alkemy Pharmaceutical Laboratories (Pvt) Ltd, P-9, S.I.T.E, Area Hyderabad, has applied for renewal of DML No. 000131 by way of formulation for the period of 02-11-2015 to 01-11-2020 on 30th September, 2015. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 8th November, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Copy of latest Form-29 issued and attested by Security Exchange Commission of Pakistan along with attested photocopies of CNICs of all the Directors as per Form-29.
ii. Nothing Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of CRF valid upto 31-12-2016.
iii. List of total sections of the firm as per approved layout plan by the competent authority.
iv. Approval letter of both Production Incharge and Quality Control Incharge.

2. The firm did not submit the shortcomings documents mentioned above and later on with reference to above shortcomings / deficiencies a final reminder letter was issued on 13th March, 2017

under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976. The firm has submitted their reply on 19th April, 2017 which is evaluated and still found following shortcomings / deficiencies:-

i. Latest Nothing Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of CRF.

ii. Detail of management at the time of pervious renewal of DML and present renewal of DML along with CNIC copies and Prescribe fee of Rs. 50,000/- for change of management as management is changed.

iii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not less than 10 year for proposed Production Incharge).

iv. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (proposed Production Incharge).

v. Complete Set of documents of proposed Quality Control Incharge along with prescribe fee.

Decision of 253rd meeting of CLB .

3. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Alkemy Pharmaceutical Laboratories (Pvt) Ltd, P-9, S.I.T.E, Area Hyderabad, DML No. 000131 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

4. The Show Cause notice dated 22nd June, 2017 was issued to the M/s Alkemy Pharmaceutical Laboratories (Pvt) Ltd, P-9, S.I.T.E, Area Hyderabad

5. No reply of the show cause is receive from the firm till date. Instead firm submitted documents for approval of production incharge and following documents are still deficient and application for renewal of DML is still incomplete.

1. Nothing due certificate regarding CRF from STO (Updated).
2. Prescribed Fee of Rs. 50,000/- for change of management.

The firm has been called for personal hearing .

Case is placed before the board for its consideration in light of previous proceeding of the Board.

Proceedings and Decision of Central Licensing Board in 255thmeeting

Mr. Faraz Ahmed Sheikh, owner of the firm appeared before the Board. He contended that documents for issuance of NOC for CRF has also been submitted with Budget and Accounts Division. He also contended that he was un aware for fee for change of management and assured the Borad that he

would submit required fee within few days. After hearing the representative of the firm and facts on record, the Board decided to suspend the Drug Manufacturing Licence of M/s Alkemy Pharmaceutical Laboratories (Pvt) Ltd, P-9, S.I.T.E, Area HyderabadDML No000131 by way of formulation with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976till settlement of CRF and other codal formalities.

Case No. 53. <u>RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S SPENCER & COMPANY (PVT) LTD, KARACHI.</u>

M/s Spencer & Company (Pvt) Ltd, D-105, S.I.T.E, Karachi, has applied for renewal of their DML No. 000272 by way of formulation for the period of 19-07-2015 to 18-07-2020 on 22nd July, 2015. The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 21st March, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Application on letter head along with its related documents dully attested by authorized person.
ii. Proof of management i.e. Form-29.
iii. Proof of approval of section.
iv. Proof of last renewal of Drug Manufacturing License.
v. Latest Nothing Due Certificate issued by Statistical Officer, DRAP, Islamabad regarding deposition of CRF.
vi. Proof of approval of technical staff.

2. Later on with reference to above shortcomings / deficiencies a reminder letter was issued on 31stJanuary, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976. The firm has submitted their reply on 27th February, 2017 which is evaluated and still found following shortcomings / deficiencies:-

i. Due date of renewal application was 19-07-2015 and renewal application was received on 22-07-2015 which are 4 days late. According to Rule 6 of Drugs (Licensing, Registering &Advertising) rule 1976 the additional surcharge 5,000/-for each day and total Rs. 20,000/- = (4x5000) should be deposited.
ii. Updated nothing due certificate regarding CRF from STO.
iii. Updated Form-29.
iv. Approval letters of section issued from CLB.
v. Fee of Rs. 10,000/- for proposed Quality Control Incharge and Production Incharge.
vi. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not less than 10 years for proposed Quality Control Incharge and Production Incharge).
vii. Resignation / retirement of earlier Production Incharge / QC Incharge.

3. Later on with reference to above shortcomings / deficiencies a final reminder letter was issued on 13th March, 2017 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

The firm has submitted their reply on 3rd April, 2017 which is evaluated and still found following shortcomings / deficiencies:-

i. Updated nothing due certificate regarding CRF from STO.
ii. Updated Form-29.
iii. Approval letters of section issued from CLB.

Decision of 253rd meeting of CLB .

4. The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Spencer & Company (Pvt) Ltd, D-105, S.I.T.E, Karachi, DML No. 000272 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

5. The Show Cause notice dated 23rd June, 2017 was issued to the M/ Spencer & Company (Pvt) Ltd, D-105, S.I.T.E, Karachi.

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

"M/s spencer & Company (Pvt) Ltd, Karachi, wherein the firm has informed that they have received Show Cause on 7th July, 2017 at their factory address. The firm investigated the whole correspondence related to application of the renewal of manufacturing license but was unfortunately not able to identify any such problem which may be potential root cause of this Show Cause Notice. Kindly consider:-

i. On 15th July 2015 firm applied for renewal of our manufacturing license.
ii. On 21st April 2016 frim applied to our letter of 21st March 2016 and submitted all the documents as you advised.
iii. Frim again sent reminder on 13th December 2016.
iv. On 27th February 2017 firm replied to our letter of 31st January 2017 and covering all requirements & queries as per direction.
v. On 31st March 2017 firm reported to our letter of 13th March 2017 in full as advised.
vi. As required firm applied for change of technical staff vide their letter of 31st March 2017 and received approval from DRAP on 4th May 2017.
vii. On 11th April 2016 firm applied to the Central Research Fund for clearance and received letter of 19th April 2017 asking for clarification. The said clarification was responded vide their letter of 18th May 2017.

Based on above we have been chasing the renewal of their License and have responded to all the requirements, queries and taken all actions as required by DRAP. Owing to the above they do not

understand the reasons for the said Show Cause notice and request that we be informed for the reasons. Additionally firm request a personal hearing to put across their and discuss the matter to mutual satisfactory. The firm, therefore, request personal hearing any time after 24th July 2017 as their Executive Director is travelling and will be available at our convenience after the said date".

7. The firm has been called for personal hearing.

Case is placed before the board for its consideration in light of previous proceeding of the Board.

Proceedings and Decision of Central Licensing Board in 255th meeting

Mr. Abdur Rehman, Manager North, Mr. Mujeeb Ur Rehman, Regional Manager and Mr. Tanveer appeared before the Board. They contended that documents for issuance of NOC for CRF has also been submitted with Budget and Accounts Division. He also contended that they have form-29 issued by SECP and would submit soon. After hearing the representative of the firm and facts on record, the Board decided to suspend the Drug Manufacturing Licence ofM/s Spencer & Company (Pvt) Ltd, D-105, S.I.T.E, Karachi, DML No. 000272 by way of formulation with immediate effect under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976till settlement of CRF and other codal formalities.

Case No. 54. CONSTITUTION OF PANEL FOR GRANT OF LICENCE, GRANT OF ADDITIONAL SECTION AND RENEWAL OF DRUG MANUFACTURING LICENCE

The Chairman, Central Licensing Board is empowered by the Central Licensing Board to constitute panel of experts under Rule 8 (17) the Drugs (Licensing, Registering and Advertising) Rules, 1976for the purpose of grant of licence, grant of additional sections and grant of renewal. The Board after considering the cases of M/s N.S Pharma, Plot No. 576-577, Sunder Industrial Estate, Lahore, M/s Sunrise Pharma (Pvt) Ltd, Plot No. 594-A, Sunder Industrial Estate, Raiwind Road, Lahore and M/s Himont Pharmaceuticals (Pvt) Ltd, 17-Km, Ferozepur Road, Lahoreobserved that panels have been altered at will without giving due consideration to the panel constituted by the Chairman, Central Licensing Board. The Board therefore, compelled to issue directions that in future orders of the Board shall be followed in letter and spirit and no officer/ expert should sign the report who is not the member of the panel constituted by the Chairman.

Case No. 55. ITEMS WITH THE PERMISSION OF THE CHAIR

It was appraised during the meeting that expert members of the Board who are entrusted with the mandate to inspect the pharmaceutical units for the purpose of grant of licence, grant of additional sections and grant of renewal has to spend whole day from his busy schedule for inspection. These services are provided honorary. Furthermore, cost of hotel accommodation has increased. Members of

the Board apprised that as their nominations are honorary therefore, extra cost of hotel stay has to be paid from their pocket as government is only paying ceiling rate. The Board after considering the their valuable contribution of the expert members recommended as under:

i. an honorarium of Rs. 10000/ per inspection within city may be approved for expert members.

ii. an honorarium of Rs. 10000/ per inspection out of city in addition to TA/DA. Moreover, the Board recommended that ceiling rates of hotel charges may be increased to Rs. 12,000/- per day.

QUALITY ASSURANCE CASES

Item No. I (Old Cases)

Case No. 1. **M/s Medipak Limited Lahore**

Case Background

Mr. Abdul Rashid Shaikh, FID, Lahore conducted inspection of M/s Medipak (Pvt) Ltd, Lahore on 13.04.2016 to verify the GMP compliance and production activities. The FID noticed number of observations which are reproduced as follows:

- Ø Replace the wooden fixture and doors from the premises.
- Ø Appoint qualified person in all sections as per the requirement of Drugs Act, 1976 and Rules framed there under.
- Ø Ensure the availability of qualified person in their stores as well.
- Ø Review SOPs for manufacturing and sterilization of the batch as per available capacity and maintain their proper BMR.
- Ø Ensure the proper clean and lint free uniforms for all workers.
- Ø Take the safety measures regarding the exposure of hazardous solvent used for the assembling of IV sets components.
- Ø Ensure the airtight closed containers for the storage of their raw materials with proper identification to avoid any mixing.
- Ø Ensure the separate dispensing hood for the steroidal materials to avoid any cross contamination.
- Ø The buffer of the area needs repair maintain and paints.
- Ø Ensure the emergency alarm system.
- Ø Review and upgrade the SOPs for the maintenance of cold chain from manufacture till user end along-with documented evidence.
- Ø Ensure the placement to data logger for the mentoring of storage from manufacture to user end.
- Ø Improve the improvers' storage areas.
- Ø Ensure the separate bags for different products to avoid to cross contamination of floor bed dryer.
- Ø Ensure the filtration of the air which is being used for the dryer.
- Ø Ensure the availability of proper dispensing booth.
- Ø Ensure the closed trolleys for the transportation of dispensed material from dispensing area to the production floor.
- Ø Review the SOPs for the storage of post dispensed material.
- Ø Review the organogram of the organization by avoiding the conflict of interest.
- Ø Make the GC functional as at the time of visited was out of order due to some technical reasons.
- Ø Proper install the newly purchased liquid particle counter.
- Ø Ensure the data backup system for the records.
- Ø 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.

- Ø Improve the storage condition of their finished foods stores by installation of AC and monitored their proper record without fail.
- Ø Develop the proper and regular internal and external training program for workers and other technical staff and maintain their records.
- Ø Get the medical certificate of all workers and maintain their record.
- Ø Maintain the proper record of changing of all filters placed on different lines and maintain their record.
- Ø Get the certificate from the concerned authorities' boilers and get calibration of all the gauges and maintain their record.
- Ø Buffers of solution preparations and filling areas need repair and maintenance.

2. Accordingly, show cause notice was served to the firm on 25.05.2016. The firm vide letter No. Nil dated 03.06.2016 submitted detailed reply of show cause notice including compliance status. **(Annex-A)**

Proceedings of the 248th Meeting of CLB

1. The case was placed before the 248th meeting of CLB held on 13.07.2016.

2. 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

A. 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

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

Updated Status

The constituted panel conducted inspection of the firm on 17-01-2017. The inspection report was received in this office on 11-05-2017 which contains the comparative statements of updated status with observations noted during previous inspection. ***(Annex-B)***

The panel concluded as under:-

" in view of all the above, it is observed that the management has addressed most of the shortcomings, which were pointed out during the last inspection, which leads the panel of

inspectors to the conclusions that the firm is presently operating at the good level of GMP compliance, hence it is advised to the management to continue their efforts to further upgrade their systems."

Proceedings of the 255th Meeting of CLB

The Board during scrutiny of the case noticed that panel has submitted brief report of the firm M/s Medipak in tabulated form only and the cGMP inspection report has not been submitted on the approved format under schedule B-II of drugs (LR&A) rules, 1976 as was decided in 248th meeting of CLB.

Board was apprised that QA section already has sent a letter to area FID for compliance of orders of CLB in its letter and spirit. Board endorsed the letter No. F.4-109/89-QA dated 26-05-2017.

Further, Board took serious notice of late submission of the inspection report after 4 months of conducting the inspection.

Decision of the 255th Meeting of CLB

After thorough deliberation took seriousnote of the delayed submissions of report fom the office of Federal Inspector of Drugs, Lahore andafter perusal of the letter of Quality Assurance and Laboratory Testing (QA/LT) Division decided:

i. to defer the case and constituted new panel comprising following members who will conduct cGMP inspection of the firm on approved format under Schedule B-II of Drugs (Licensing Registering and Advertising) Rules, 1976.

   - Dr. Ikram Ul Haq, Member CLB
   - Chief Drug Controller, Government of Punjab, Lahore.
   - Area FID, DRAP, Lahore.

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

iii. The board further directed that, the inspection of the firm will be conducted within one month of the communication of the decision of CLB and report of the firm shall be placed before the board in next meeting.

Case No. 2. M/s Lahore Chemical and Pharmaceuticals Works, Lahore

Recommendations for Cancellation / Suspension of Drug Manufacturing License (Referred by PQCB, Lahore)

Background

Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab vides letter No. PQCB/F-42/2016 dated 08th August 2016 informed that provincial teams of experts/Drug Inspectors conducted GMP inspections of various pharmaceutical manufacturing units and reported the violations found there by Provincial Quality Control Board, Punjab. He added that the Board after due deliberations recommended cancellation/suspension of Drug Manufacturing Licenses of the firms who were involved in violations of Good Manufacturing Practices (GMP), conditions of license and were involved in manufacturing / selling of substandard drugs. It is worth mention here that M/s LCPW was

one of the firms whose DML cancellation/suspension was recommended by PQCB, Punjab besides other. Mr. Abid Saeed Baig further requested to look into the matter and direct the concerned authority to take action in the best interest to curb the menace of spurious and substandard drugs.

1. Accordingly the case was placed before the CLB in its 249th meeting held on 29.08.2016.
2. As per decision of CLB in its 249th meeting, the case was referred to the Secretary, Provincial Quality Control Board, Punjab vide letter dated 03.10.2016, for clarification.

Decision of the 249th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, the Board considered the recommendations of the Secretary, PQCB, Punjab and observed that laid-down procedure as provided under the rule 5(3) of the Punjab Drugs Rule, 2007 has not been observed. Therefore it has been resolved by the Board that following information / documents / record is required in order to proceed further:-

i. Copy of the notification of the Provincial Inspector of Drugs under Section 17 of the Drugs Act, 1976
ii. Copy of the inspection report of the firm
iii. Copies of the test reports of the samples of the firm (if any)
iv. Show cause notice issued to the firm.
v. Reply of the firm.
vi. Letter of personnel hearing issue to the firm under Section 41 of the Drugs Act, 1976.
vii. Copy of the minutes of the meeting.
viii. Copy of the permission for prosecution (if any).
ix. Copy of the report of the appellate testing Under Section 22 (5) of the Drugs Act, 1976 (if any).
x. Enquiry report (if any).
xi. Reason for imposing both penalties including prosecution and recommendation for cancellation / suspension of DML of the firm. Even the Rule 5(3) of the Punjab Drugs Rules, 2007 states that "*The provincial and district Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the rule, issue a show cause notice to the personal and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority.*"

2. The Board further decided that the representative of the firm shall also be asked to submit the reply on the observations of the PQCB and may be given an opportunity of personnel hearing in the forthcoming meeting of CLB.

Reply by the M/s LCPW, Lahore

In response to this office letter No. F. No.F.8-19/2016-QA (M-249-CLB) dated 03.10.2016, the firm vide letter No. Nil dated 21.10.2016 submitted detailed reply including the proceedings of PQCB, Punjab with reference to the recommendations for cancellation / suspension of DML by PQCB, Punjab.

2. The firm further requested to grant opportunity for personal hearing before the Central Licensing Board.

Reply by PQCB.

In response to this office letter No. F. No.F.8-19/2016-QA (M-249-CLB) dated 03.10.2016, Mr. Abid Saeed Baig, Secretary PQCB vide letter No. PQCB/F-42/2016 dated 28.10.2016 submitted reply as under:-

(Reply of the PQCB is reproduced on next page in tabulated form).

Name of Pharmaceutical Manufacturer	Documents Required	Reply by Secretary PQCB, Lahore
M/s Lahore Chemical and Pharmaceuticals Works, Lahore	i. Copy of the notification of the Provincial Inspector of Drugs under Section 17 of the Drugs Act, 1976	Copy of notification of Mr. Muhammad Jamil has been provided by the Secretary, PQCB, Punjab.
	ii. Copy of the inspection report of the firm	The Secretary PQCB did not provided copy of the inspection report. However letter of the Drug Controller, Data Gunj Bux Town Lahore is provided.
	iii. Copies of the test reports of the samples of the firm (if any)	Copies of following test reports provided:- Inj. Ceftacin 250 mg Batch No. 65118 Inj. Gentamycin 80mg Batch No. 55250 Inj. Bupicain 2 ml Batch No. 65043 The Government Analyst has declared all the samples as of standard quality.
	iv. Showcause notice issued to the firm.	Copy of showcause notice issued to the firm on 30.06.2016 provided
	v. Reply of the firm.	Reply of the firm to PQCB, Lahore provided.
	vi. Letter of personal hearing issue to the firm under Section 41 of the Drugs Act, 1976.	Copy of personal hearing issued to the firm on 30.06.2016 provided
	vii. Copy of the minutes of the meeting.	Copy of the Minutes of the 137th Meeting of PQCB dated 14.07.2016 provided
	viii. Copy of the permission for prosecution (if any).	Copy of permission for prosecution dated 14.07.2016 provided
	ix. Copy of the report of the appellate testing Under Section 22 (5) of the Drugs Act, 1976 (if any).	N/A
	x. Enquiry report (if any).	N/A
	xi. Reason for imposing both penalties including prosecution and recommendation for cancellation /	The Rule 5(3) of the Punjab Drugs Rules, 2007 quoted specifically in this case not legally interpreted. The rule is rephrased as under:-

	suspension of DML of the firm. Even the Rule 5(3) of the Punjab Drugs Rules, 2007 states that *"The provincial and district Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the rule, issue a showcause notice to the personal and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."*	*"The provincial and district Board shall examine a case referred to it by an inspector and shall, if an action is proposed to be taken against a person under the Act or the rule, issue a showcause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority."* The exact legal interpretation of this rule is that the Provincial Quality Control Board is bound to issue show cause notice and personal hearing notice to the accused persons before taking any action / decision in terms of prosecution or recommendation for suspension or cancellation of license. Under above-mentioned provision of law there is no bar for imposing both penalties. In the instant case the PQCB has fulfilled the codal formalities. The case referred for cancellation / suspension of DML of M/s LCPW, Lahore is as per law and within jurisdiction of PQCB, Punjab.

The case was placed before the CLB in its 251st meeting held on 18.01.2017 and opportunity of personal hearing was granted on firm's request.

Proceedings of the 251st Meeting of CLB

Deputy Director QA Section apprised the Board that reply of the Secretary PQCB has been received. The record provided by Secretary, PQCB showed that during inspection three samples of injection were taken and all the samples has been declared as of ***Standard quality*** by the Government Analyst.

2. Mr. Waqar Azeem Quality Control Manager and Mr. AhsanUllah Manj, Legal Counsel of the firm M/s Lahore Chemical and Pharmaceutical Works, Lahore appeared before the Board for personal hearing. Legal Counsel of the firm informed the Board that they filled a review petition in the Provincial Quality Control Board and the hearing was held on 27.09.2016. Decision of the review petition by the PQCB is still awaited. Member of the Board raised a query regarding the expired active raw material and storage of water in open steel tank. Mr. Waqar Azeem QCM informed to the Board that the lead of the tank was screw caped at the time of inspection; however the inspector was of the view that it should be sealed. The samples were taken during the inspection and all the samples have been declared as of standard quality. The drug inspector also seized stock during inspection and after receiving of standard report of the samples from DTL, Lahore, the drug inspector sent letter to the firm and released all the seized stock. He also provided copy of the said letter. He further added that as far as issue of expired raw material is concerned, the date of expiry of the raw material was 17.05.2016 and it was wrongly written by Provincial Drug inspector as 17.05.2015.

Decision of the 251st Meeting of CLB

A: After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the record submitted by Secretary, PQCB and factual position of the case, 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. Ikram ul Haq, Member CLB.
ii. Ch. Zeeshan Nazir, Deputy Director (QA)
iii. Mr. Muhammad Jamil, Provincial Drug Inspector, Lahore
iv. Area FID, Lahore

B: The panel inspection report shall be placed in the next meeting of CLB

Current Status:

The above mentioned panel inspected the firm on 12.04.2017 and 17.05.2017 and submitted report as per decision of the CLB. The panel concluded as under:-

In view of the inspection proceedings, the panel concluded that:-

1. *The firm had rectified the shortcoming pointed out by Mr. Muhammad Jamil, Provincial Drug Inspector.*

2. *Required dedicated area for cephalosporin section hence production in the cephalosporin dry powder section / capsule sections would remain stop, till the firm develop the new area.*
3. *Regularize the layout plan for narcotic capsule section and install HVAC system. However the production of general capsules would be stopped as the management manufacture narcotic capsule in the section.*
4. *Segregated areas for narcotic/ hormone / steroid liquid injectable were not provided and the management was advised to stop manufacturing of those products. The management informed that they would de-register those products in future.*
5. *Submit compliance report in tabulated form within one month time period for the observations pointed out by the panel of experts in the inspection.*

Compliance Report of the Firm:

On the directions of the panel, firm has submitted a copy of compliance report having reference No. 011 dated 10-07-2017.
The compliance report of the firm is reproduced as under:

ADVICES	***COMPLIANCE***
A separate dispensing hood was provided for cephalosporin: however it was not proper as returns were not provided.	*Dispensing hood replaced.*
Separate dispensing area for narcotics were provided	*A **segregate** for narcotic will be established soon after approval of submitted layout plan*
It was advised to install computerized data base system in store, indicating expiry of raw material.	*The system already installed*
HVAC system working and validated.	*HVAC system validated and validation certificates submitted.*
Provision of dedicated cephalosporin area.	*State of the art dedicated area will be established soon after approval of submitted layout plan.*
Availability of TOC/LPC in QAD.	*L/C established under dispatch now.*
Regularize the layout plan for narcotic capsule section and install HVAC system. However, the production of general capsules would be stopped as the management manufacture narcotic in the section.	*As we submitted the layout plan for approval the **segregate** area will be established. Moreover HVAC system already validated.*
Segregated areas for Narcotic/Hormone/Steroid liquid injectable were not provided and the management was advised to stop manufacturing of those products. The management informed that they would de-register those products in future.	*Narcotic/Hormone/Steroid all areas **segregated.***

Proceedings of the 255th Meeting of CLB

The Board during scrutiny of the case noticed that provincial drug inspector had forwarded a brief inspection report and based upon the findings of the inspector, PQCB Punjab has already granted permission for prosecution of the firm and the matter is in the court of law.

The Board discussed the panel inspection report of the firm and took serious notice of the observations pointed out by the panel. It was also noticed that the panel had advised the form to stop production in certain areas that includes Cephalosporin Dry Powder Suspension / Capsule Sections, General Capsule Section, and Narcotic / Hormone / Steroid Liquid Injectable Sections but compliance report submitted by the form does not reflect such an action.

Decision of the 255th Meeting of CLB

After thorough discussion/deliberations, the Board took serious note of the observations reported by the panel and therefore, the Board decided to:-

i. Issue show cause notice to the M/s Lahore Chemical & Pharmaceutical Works, Lahore under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing , Registering and Advertising) Rules, 1976 for cancellation or suspension of the Licence of M/s Lahore Chemical & Pharmaceutical Works, Lahore based upon findings of panel inspection report dated 12.4.2017 and 17.5.2017 and for manufacturing drugs in Cephalosporin Dry Powder Suspension / Capsule Sections, General Capsule Section, and Narcotic / Hormone / Steroid Liquid Injectable Sections despite the panel had directed to stop production in these areas.

ii. Direct the Area FID to ensure that production is not carried out in the sections as advised and mentioned by the panel.

Case No. 3. M/s Ali Noor Industries, Okara.

Background

Mrs. Aisha Irfan, FID, Lahore conducted inspection of the firm M/s Ali Noor Industries, Depalpur Road, Okara on 11.02.2016 to check the GMP compliance and production activities of the firm. The FID noticed number of critical observations, which are as under:-

i) At the time of inspection, Production In-charge and QC In-charge were not present.
ii) Doors of executive entry were widely opened.
iii) No concept of changing prevailed.
iv) Workers were in street clothes/shoes.
v) Rejected bundles of crept bandage were placed in the crepe bandage section instead of rejection store.
vi) Gauze section was sealed by army as armed forces pledged gauze / bandages were stored there.
vii) Finished goods store was also sealed by army.

viii) QC was locked from outside, QC In-charge was not present hence could not be checked.
ix) Documentation needs improvements.
x) The FID further concluded that the management was advised to rectify short comings pointed out and the technical staff presence should be made mandatory during working hours.

Action Taken by DRAP:-

Accordingly, a show cause notice was issued to the firm for above mentioned violations on 08.03.2016.

Reply of the firm:-

The firm vide letter No. Nil dated 17.03.2016 has informed that all observations have been rectified. They further requested for re-inspection

Proceedings of the 247th Meeting of CLB

The case was placed in the 247th meeting of CLB held on 29-04-216 and opportunity of personal hearing was granted to the firm vides letter no F.8-17/2016-QA (M-247) dated 25-04-2017.

2. Mr. Ahsan Ali Noor, Managing Director of the firm M/s Ali Noor Industries, Okara appeared before the Board for personal hearing. The Board inquired about the reason for such observations and non availability of production manager and quality control manager at the time of the visit. He replied that they are supplying their products only to Army or Institutions and have a very minimum market shares. Production was not carried out at that day, due to non availability of market orders, that's why production manager and quality control manager were not present. He requested that a panel may be constituted and re-inspection may please be conducted.

Decision of the 247th 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. Mr. Zia Husnain, FID, Lahore
iii. Mrs. Aisha Irfan, 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.

Panel Inspection

According in compliance to CLB decision, the panel was informed about the decision of the panel vides letter No. F.8-17/2016-QA (M-247-CLB) dated 07-06-2016.

2. The panel comprising of Dr. Abdul Rashid, Chairman CQC and Syed Zia Husnain, FID Lahore conducted inspection on 16-01-2017 received in this office on 07-02-2017.
3. The panel concluded as under.

Firm has made most of the rectifications as pointed out in previous inspection. Firm was directed that immediately QC-Incharge with required experience under the law should be appointed. In addition to advises given in the above performa as part of report, following advises was also given for further up-gradations.

i. *Exhaust system be designed in such a way that contamination from outside cannot be happened.*
ii. *SOPs of QC need to be focused in letter and spirit.*
iii. *Official; books such as BP and USP should be arranged.*
iv. *Complaint and recall system required to be established.*
v. *Improve the lightening in the stores.*
vi. *Develop the master validation plan.*

Firm shown their positive response towards compliance to the advises given for rectifications of shortcomings. Panel is of the view that re inspection of the unit is required to verify the rectifications' of shortcomings and implementation of the advises given above in the report.

Follow up:

Accordingly, Secretary CLB was requested vides letter No. F.4-20/987-QA dated 14-02-2017 to take further necessary action regarding the matter of appointment of the QC-Incharge and Firm was directed vides letter no. F.4-20/987-QA dated 14-02-2017 to rectify the observations.

Reply by the Firm:

Accordingly, the firm was submitted the compliance letter vides letter No. Nil dated 03-03-2017 and stated that they rectified all the observations.
2. The FID was directed to verify the compliance status of the firm vides letter No. F.4-20/98-QA dated 08-03-2017
3. Accordingly, Mrs. Aisha Irfan, FID, Lahore conducted inspection of the firm on 10-07-2017 to check the rectifications with reference to DRAP's letter No. F.4-20/98-QA dated 08th March 2017. The FID informed that all previous observations have been complied and in addition, she noticed some other observations.

i. The firm was advised to follow labeling requirements properly.
ii. The management informed that they are not manufacturing gauze due to pricing issue.
iii. It was advised to install smoke detectors and fire alarms as well.

Proceedings of the 255th Meeting of CLB

The Board during scrutiny of the case noticed that all previous observations have been rectified as confirmed by Mrs. Aisha Irfan, FID, DRAP, Lahore in its latest inspection report dated 10-07-2017.

Decision of the 255th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, the Board decided to:-

i. Seize to enforce the show cause notice as no further action is warranted.
ii. Direct the area FID to inspect the firm M/s Ali Noor Industries Okara on quarterly basis (for a period of 3 quarters) on approved format under Schedule B-II of Drugs (Licensing , Registering and Advertising) Rules, 1976 for thorough cGMP evaluation and to monitor the continuation of cGMP compliance.
iii. Licensing Division will process the matter related to appointment of QC Incharge on urgent basis.

Case No. 4. M/s Ashraf Surgical Cotton Bandage, Okara
(Change of Panel Member)

M/s Ashraf Surgical, Okara was inspected by the Aisha Irfan on 11-02-2016 to check the GMP compliance. The FID noticed some observations and accordingly firm was served with showcause notice. The firm submitted the reply to the showcause notice vides letter No. Nil dated 11-03-2016 and stated that they have rectified all the shortcomings and requested for re-inspection.
The case was placed in the 247th meeting of CLB held on 29-04-2017 wherein the board had decided as under:-

Sr. #	Name of the firm	Decision of the CLB
1.	M/s Ashraf Surgical Cotton Bandage, **Okara**	1. After thorough discussion, considering all the pros and cons of the case, keeping in view the available record, compliance report of the firm and request from CEO 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, the panel will submit report within fifteen days, in tabulated form identifying the previous observations and the current status, by the following members:- i. Dr. Abdur Rashid, Chairman, Quality Control ii. Mr. Zia Husnain, FID, Lahore iii. Mrs. Aisha Irfan, Area FID, Lahore 2. The Board also decided to direct the panel to submit brief report in tabulated form identifying the previous observations and the current status.

Updated Status

Accordingly, Mrs. Aisha Irfan, FID, Lahore vide letter No. 11993/2016-DRAP (L-III) dated 22.08.2016 requested Additional Director (QA&LT) to give convenient date and time for the inspection of following firm as per decision of the CLB made in its **247th meeting of CLB held on 29-04-2016**

2. The additional Director (QA&LT) requested to the CEO, DRAP to allow him to conduct inspection of the firm wherein the CEO, DRAP has directed as under:-

"The CLB may nominate another inspector or board member instead of Dr. Abdur Rashid, as many urgent issues are being affected."

Proceedings of the 255th Meeting of CLB

The Board during scrutiny of the case took serious notice for delaying and for not conducting the inspection of M/s Ashraf Surgical Cotton Bandages, Okara by the panel as was decided in 247th meeting of CLB. The board endorsed the recommendation of the CEO, DRAP for replacing the name of Dr. Abdul Rashid in the said panel.

Decision of the 255th Meeting of CLB

After thorough discussion/deliberations and after considering all the pros and cons of the case, the Board decided to:-

1. Following panel will conduct cGMP inspection of the firm on approved format under Schedule B-II of Drugs (Licensing , Registering and Advertising) Rules, 1976.

    i. Dr. Farzana Chaudhary, Director, Institute of Pharmaceutical Sciences, UVAS, Lahore
    ii. Mr. Syed Zia Husnain, FID, DRAP, Lahore
    iii. Mrs. Aisha Irfan, FID, DRAP, Lahore.

2. The panel will submit report within one month of communication of decision of the board and the report will be submitted in tabulated form identifying the previous observations and the current status. This report will be in addition to the cGMP inspection report on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976,

Item No. II (New Cases)

Case No. 1. M/s Eros Pharmaceuticals (Pvt) Ltd, Karachi

Background of the case:

Dr. Abdur Rashid, Additional Director (QA&LT), Dr. Najam-us-Saquib, Area FID, Karachi, Dr. Muhammad Kashif, AD, Karachi and Dr. Krishan, AD, Karachi conducted inspection of the firm M/s Eros Pharma (Pvt) Ltd, Karachi on 04.04.2017 to verify GMP compliance / production activities of the firm.

2. The panel noticed critical observations, which may endanger the public health at large and need urgent attention and rectification. The observations include:-

xi) Firm was being supervised by Mr. Ahmed Raza Jilani Msc, Chemistry, QC Manager and by Mr. Muhammad Imran, B-Pharmacy, Manager Production. Both technical persons were not approved by the DRAP authorities, Islamabad, as the firm could not present any approval.

xii) Very poor hygienic conditions observed throughout the firm including production and ware houses areas,
xiii) Storage of various raw materials, packaging materials and bottles and holding finished drugs and finished drugs for market release were also stocked in a common hall in haphazard way.
xiv) Firm also seen involved in up-gradation / construction work without any prior information / approval from DRAP authorities including DRAP, Karachi.
xv) Highly inadequate lighting arrangements seen in firm, in general.
xvi) In adequate technical personal were present in the firm that was also not well conversant with technical knowledge.
xvii) Production record and quality control record was also not produced by the management. Responsible persons also failed to produce the required record pertaining to technical operations.
xviii) HVAC system not seen operational.

xix) Temperature / humidity of the ware houses and corridors and production areas were not being controlled and monitored.
xx) Powder (unknown) seen in various production cubical that were also not labeled with any operation performed previously or being performed.
xxi) Firm bas tablet section and syrup section on the ground floor that were observed in very unhygienic conditions.
xxii) Tablet section cubicles were observed in lock and key and despite of several directions and advises management failed to open these cubicles.
xxiii) Firm has informed that they had applied for renewal of DML as well, as the renewal is due since long.
xxiv) Cephalosporin and eye drop area and capsule (general) and ointment cream sections are located at first floor and shares common corridors. Firm's management informed that they are not manufacturing cephalosporin since long.
xxv) In general most of the manufacturing equipments seen non-operational and out of order.

Conclusion of Panel.

Keeping in view the above stated facts panel observed that firm failed to observe the conditions of DML (No. 000147) as mentioned in section 16 of Drug (LR&A) rules, 1976 of the Drugs Act, 1976. Panel seals the manufacturing facility as it can cause endanger to the health of the public, if remain operational, in larger public interest to safe guard the public health. This report along with detail report will be submitted to the Chairman Central Licensing Board for further necessary action / further directions into the matter.

Action taken by DRAP:

Accordingly show cause notice / suspension of production activities was issued to the firm on 01.06.2017. The area FID was also directed to ensure the delivery of this order and compliance of orders in its true letter and spirit and area FID provided the receiving of the letter by the firm.

However, the firm did not submit reply to the show cause notice/suspension of production order' till date.

Proceedings of the 255th Meeting of CLB

Mr. Asif Iqbal, Director, M/s Eros Pharmaceuticals (Pvt) Ltd along with his brother Mr. Abid Iqbal, Director, M/s Eros Pharmaceuticals (Pvt) Ltd appeared before the board for personal hearing.

Mr. Asif Iqbal informed the Board that when panel visited the firm on 04-04-2017, the up-gradation and renovation was under process and he claimed that he had intimated the DRAP, Karachi about the renovation process on 31-03-2017. He also presented a letter dated 31-03-2017 regarding intimation of renovation process, however there was no official stamp of DRAP Karachi showing receipt of the letter.

Furthermore, Mr. Asif Iqbal presented some documents along with written reply of personal hearing to the Board in which one letter with the title of "permission for renovation & improvement of areas" was attached. The said letter was dated 10-04-2017 addressed to the Additional Director, DRAP Karachi and there was no official stamp of DRAP Karachi showing receipt of the letter.

Mr. Asif Iqbal informed that Dr. Abdul Rashid, Additional Director (QA/LT) and Dr Najam us Saquib, Additional Director DRAP, Karachi came together for inspection on 04-04-2017 and after sometime, Dr. Abdur Rashid went and Dr Najam us Saquib came back again along with Mr. Krishan Das, Assistant Director, & Mr. Kashaf, Assistant Director and sealed the company.

Further, Mr. Asif Iqbal informed that already approved technical staff has left and approval of new technical staff is under process in the Division of Licensing. He further informed that there was no renovation in finished goods store and already manufactured batched for placed there for distribution to market. Mr. Asif Iqbal prayed to the Board that the firm may be de-sealed and one month time may be given to him for completion of renovation work.

The Board asked from Mr. Asif Iqbal that whether he read the report before signing the inspection report. Mr. Asif Iqbal informed that he signed without reading the report as Federal Inspector of Drugs has asked him to sign it. He also informed that he requested Federal Inspector of Drugs to provide a copy of the report but could not provided to him.

The Board looked into the matter in detail and noticed that the panel has not submitted the detailed inspection report and sealing memo despite of lase of more than four months. It was also observed that on the inspection report, signatures of one of the member of the panel, Dr. Abdul Rashid, Additional Director, DRAP were not available. The Board deliberated on the issue and took serious notice in the matter. The Board further observed that the capacity in which Dr. Adul Rashid, Additional Director, DRAP visited the firm was not clear the same may be sought from the Federal Inspector of Drugs, Karachi.

Decision of the 255th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, the Board decided to:-

i. De-Seal the firm by Area FID so that the firm can start rectifying the deficiencies pointed out by the panel.
ii. The firm will complete all the renovation work within one month time after de-sealing and a panel inspection will be conducted by the following members on approved format under Schedule B-II of Drugs (Licensing, Registering and Advertising) Rules, 1976.

    i. Mr. Syed Muid Ahmed, Member CLB
    ii. Chief Drug Inspector, Sindh
    iii. Area FID, DRAP, Karachi.

iii. The panel will also submit report in tabulated form identifying the previous observations and the current status.
iv. Production will remain suspended during this period and orders for resumption of production will be issued by CLB based upon the findings/ recommendations of the inspection panel.
v. Area FID will be asked to submit his reply as to why detailed report and sealing memo was not forwarded in time and inspection report was not signed by one of the members of the panel. Further, Central Licening Board will also be intimated about the approval of composition of the panel for conducting said inspection.

Case No. 2 M/S PRIME LABORATORIES (PVT) LTD, LAHORE

Background of the case:

Mrs. Aisha Irfan, area FID, Lahore conducted inspection of the firm M/s Prime Laboratories, Lahore on 15.05.2017 to verify GMP compliance / production activities of the firm.

2. The FID noticed a number of major and critical observations, which needs urgent attention and rectification. The observations include:-

i) Inspection book was not available at the time of inspection and was not provided on demand.
ii) No production activity was seen at the time of inspection however some very serious observations were noted.
iii) The factory condition was very deplorable. Birds' nests were seen inside air / curtains and when it was switched on dust and dirty air started coming out.
iv) The conditions of stores / sections were very deplorable and the QC charge and consultant informed that renovation work was under process however paint work was seen in tablet section.
v) Raw materials were stored without temperature / humidity requirements.
vi) It was noticed and confirmed by Production In-charge that different products were manufactured again and again in such conditions.
vii) Batch of gentian violet was manufactured on 13.05.2017 in verandas / outside the building, where manufacturing and mixing tasks were seen installed under open sky.
viii) The stains of gentian violate were also seen on floors.

ix) No record of that batch was provided.
x) Similarly dirty bottles were being washed outside in open, required for syrup filling.
xi) The HVAC system was not functioning properly and was not validated.
xii) During inspection a light went off and there was not facility was alternate arrangement
xiii) Only QC was provided with light
xiv) The oral liquid section was not maintained to filled and packed bottles of al-hydrochloride syrup was seen in filling line.
xv) The room contained filling machine was in very dirty condition.
xvi) No renovation / paint work was seen in this section.
xvii) However paint work was going on in tablet section.
xviii) There was no light and the factory was full of cobwebs, litter of lizards and mice were also seen at various places.
xix) In the QC lab some wood work was under process as wooden slabs and dust was seen on QC floor.
xx) However the sensitive QC instruments / equipments were placed on shelves without any protective covering from the dust.
xxi) The packaging material store was also full of dust and waste materials were also stored beside packaging materials
xxii) The outside of the corridors of the factory also contained wastes.
xxiii) The bottle stores were also full of dirt.
xxiv) The firm did not inform that the factory is under renovation/maintenance.
xxv) It was noticed that various products were produced in such dirty /unhygienic conditions as confirmed by production In-charge (Mr. Qamar)
xxvi) BMRs / QC testing of these batches were not in record, as CPM powder was seen in one of the drum of tablet section.
xxvii) The firm was previously also indulged in such practices of non compliance of GMP guidelines.
xxviii) Just recently a product “Tincture Benzoin” Batch No. M.F 84 manufactured by M/s Prime Lab Lahore was declared substandard by the CDL and the firm was asked to recall the substandard product from the market. However, no response in this regard was received from the firm and the management did not submit any document / information regarding detail of technical staff which was also violation of section 23 (i) (f) of Drugs Act 1976 and section A (I) (a) (v) of Schedule II of DRAP Act 2012. The matter was referred to registration board.
xxix) The firm has been involved in malpractices i.e. manufacturing products in dirty conditions in open areas i.e. in verandas outside the main premises using dirty bottles in syrup sections and marketing without QC tests.
xxx) Mr. Qamar Zaman very old age production In-charge (above 70) was the only person hired in the production.
xxxi) There was no other technical staff in the production and QC. Hence clearly violation of Drugs Act, 1976.
xxxii) The condition of the factory was not that of a pharmaceutical unit running in lines of the GMP guidelines.
xxxiii) As per past history and previous record of the firm it appeared that the management of the firm is habitual of this practice of violating GMP guidelines, manufacturing products in such un-hygienic dirty environment.
xxxiv) No section was found functional and the machinery was dismantled in syrup section.

xxxv) The production / QC In-charge informed that he has manufactured gentian violet batch outside of main building in open area on the direction of Mr. Zaheer the owner of this Pharma and the BMR is not written. CPM tablets are manufactured without BMR in the month of May and marketed without QC testing. Mr. Zaheer the owner of this Pharma is manufacturing drugs on his own wish.

The FID concluded that:

Keeping in view above finding it is recommended a very strict action against the firm may be taken such as cancellation of DML in violations of various condition of Drugs Act, 1976.

Action taken by DRAP:

Accordingly show cause notice / suspension of production activities was issued to the firm on 05.06.2017

Reply by the firm:

The firm vides letter dated 17.06.2017 submitted reply of the showcause notice which is reproduced as under.

1. That the FID, in question, is not aware about the title of our unit because she is writing Prime Pharma, while actually it is Prime Laboratories (Pvt) Ltd.
2. That the said FID may be well versed with theoretical knowledge but have no working experience.
3. That the FID is not authorized to take away inspection book from the premises but also kept in her custody for 15 days for recording after thoughts.
4. Mention of Tr-Benzoinco in inspection report is irrelevant and throw challenge to contest the same with our consultant.
5. That the said FID is not aware about Aluminium Hydroxide Syrup, our consultant is ready to contest the same with her under impartial umpire.
6. That FID is not concerned with alternate arrangements of electric supply. Her concern is with the end result of the drug.
7. Section 41 deals with cancellation/suspension of DML and can be cancelled if there is any health hazard caused by the use of our manufactured drugs.
8. The order for stoppage of production cannot be issued for unspecified period (copy of authority attached) nor we can be condemned un-heard.
9. Issuance of stoppage of production with show cause notice is not maintainable simultaneously.
10. That we have employed two technical staff as required by Drug (L.R & A) Rules 1976.
11. That FID has no power to take into consideration of Age Factor of the Technical Staff, the age limit not applicable for private service.

In circumstances, it is requested that the inspection may kindly be ignored, because her observations cannot by pass the observation of panel of experts.

Mr. Bashir Ahmed, Advisor of M/s Prime Laboratories along with Sheikh Zubair Iqbal, Director of M/s Prime Laboratories and his son Jahanzeb Zubair appeared before the board for personal hearing.

Mr. Sheikh Zubair Iqbal informed that renovation work was under process during inspection and he admitted that he did not inform any concerned quarter of DRAP about renovation process.

The board asked from Mr. Sheikh Zubair that why inspection book was not provided by him in reply of which Mr. Sheikh Zubair Iqbal said that inspection book was present in the premises but he was away from the firm. Therefore, employees did not handover inspection book to the panel.

Decision of the 255th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, the Board decided to:-

i. Suspend the Drug Manufacturing License for a period of 03 months.
ii. During suspension period, the firm will take necessary measures to rectify all the shortcomings pointed out by Area FID and to ensure cGMP compliance and conditions of license as defined under Drugs Act 1976 and rules framed there under.
iii. The firm will submit compliance report after rectification of deficiencies after 03 months or earlier.
iv. A panel comprising following members will inspect the firm on approved format under Schedule B-II of Drugs (Licensing Registering and Advertising) Rules, 1976 after report of rectifications.

    i) Dr Farzana Chaudhary, Director, Institute of Pharmaceutical Sciences, UVAS, Lahore.
    ii) Chief Drug Inspector, Baluchistan (Member CLB).
    iii) Deputy Director (QA), DRAP, Islamabad
    iv) Area FID, DRAP, Lahore.

v. The panel will also submit report in tabulated form identifying the previous observations and the current status.
vi. This comprehensive report will be placed before CLB in its forthcoming meeting for decision in the matter.

Case No. 3. M/s Renacon Pharma Limited, Lahore

Case Background

Inspection of the firm M/s Renacon Pharmaceuticals, Lahore was conducted by Mr. Syed Zia Husnain FID along with Mrs. Aisha Irfan, FID, DRAP, Lahore on 29.05.2017 & 30.05.2017.

2. The panel of inspectors noticed following number of observations, which needs urgent attention and rectification:-

Workers & Executive Entrance:

- Executive entrance was not as per GMP guidelines.
- No shoe covers were available.
- Entry is through office.
- Air curtains were not functional at entry.
- SOPs not displayed.

Raw Material Store & Packaging Material Store

- Very poor condition of raw material stores.
- No control of temperature and humidity seen.
- Packaging material was placed in the raw material store and also in the solution preparation area of main production area.
- Identification slips on the most of raw materials were not placed.
- Overall condition was not satisfactory.
- There was repeated electricity breakdown and generator was also not working.
- Firm is on about 02 kanals land and over all stores were very congested.

Finished Goods Store:

- Overall condition was very poor.
- Door of finished goods store open into main road directly.
- During the inspection finished goods were being loaded on a truck and opened door was source of contamination of the main finished goods store.
- Store was very congested.

PRODUCTION AREA:

Liquid Dialysis Concentrate Area:

- Packaging material was also placed in main production area.
- Stocks of empty bottles were so huge that it has covered the returns of HVAC supply. HVAC was also not operational.
- Fumes of production concentrate were contaminating the small production room.
- No concept of temperature and humidity control seen.

Powder Section:

- HVAC was not working.
- Consistent electrical breakdown observed.
- No concept of double door hatches. Hence pressure differentials could not be maintained in case of operational HVAC.
- Two double cone mixers installed in a room.
- Sifter was also in place.
- Filling and sealing of dialysis powder was being done in separate room, however HVAC was not operational and there was no proper ventilation and lighting.
- Overall conditions were very unsatisfactory.
- Areas were also very congested.

Internal Audit report:

- Firm does not have proper record of internal audits. It was advised to time to time conduct the internal audits and keep records.

Validation and Calibration:

- Process validations were not proper. Firm was advised to properly validate the processes as per master validation plan and keep records.

Quality Assurance:

- Condition of quality assurance was very un-satisfactory.

- Ø Temperature and RH monitoring charts were not displayed.
- Ø In stores, temperature was 34 C and 33 C in two adjacent rooms. Firm was advised to up-grade the quality assurance.

Quality Control Department:

- Ø It was very small room.
- Ø In the same room, office, fume hood, glassware and instruments were placed. FTIR was not available.
- Ø Titrations were being done in the same room.
- Ø Area was very congested with limited space.
- Ø Microbiology section was provided, however, area monitoring was not being performed.

Personnel Safety:

- Ø Space is very congested. Corridors were very congested.
- Ø Emergency exits were not proper.
- Ø Packaging material was also stored in production area.
- Ø Safety measures were very poor.

Trainings:

- Ø Firm was advised to develop training manual and give training to staff on regular basis.

Water Treatment

- Ø Firm was advised to test the in process water quality and keep records

Documentation:

- Ø Documentation needs up-gradations.
- Ø SOPs were not displayed.
- Ø Training manual required to establish.

The FID further concluded that most of the above findings were due to limited space. Firm informed that CLB has given time of three years vide letter no. F1-13/97-Lic (Vol-I) dated 09-06-2016 to shift the unit at new premises.

ACTION TAKEN BY DRAP:

Accordingly an explanation letter vides letter No. F.4-5/2005-QA dated 21-07-2017 along with suspension of production orders was issued to the firm after taking approval from the competent authority. The area FID was also directed to ensure the delivery of this order and submission of compliance report by the company.

REPLY BY THE FIRM:

The firm vides letter No. Nil dated 24-07-2017 submitted compliance report and requested to resume the production.

FURTHER ACTION TAKEN BY DRAP

Accordingly the competent authority made following panel vides letter No.F.4-5/2005-QA dated 31-07-2017 for follow up inspection of the said firm before allowing resumption of production activities.

i. The Director DTL (Punjab), Lahore.
ii. Mr. Asim Rauf, Additional Director (E&M), DRAP Lahore.
iii. Area FID, DRAP, Lahore.

CURRENT STATUS:

Mr. Syed Zia Husnain, FID DRAP Lahore along with Mrs. Mahwish Butt, Assistant Director (I&E) DRAP, Lahore visited the firm on 01-08-2017 and ordered for not to dispose of the following drugs on form-I under section 18 of Drugs Act, 1976 for a period of 28 days as production of the firm has been suspended by the DRAP vide letter No. F. 4-5/2005-QA dated 21-07-2017, however the firm was involved in manufacturing of the drug which is violation of section 23 of Drugs Act 1976 and Sche3dule II of DRAP Act 2012 and which is punishable under schedule III of DRAP Act, hence case is being forwarded under section 19 (7) of Drug Act 1976 and section 7 of schedule V of DRAP Act 2012 to seek further orders of CLB as to action to be taken against the above mentioned firm in respect of contravention of DRAP Act.

2. FID further informed that case is under investigation therefore it is also requested to extend the time period of not to dispose of the above mentioned stocks till the decision of the case please.

Sr. No.	Name of Product (s)	Batch No.	Mfg Date	Exp. Date	Manufactured By	Quantity.
1	White powder in cone mixer (small)	Nil	Nil	Nil	M/s Renacon Pharma, 18-Km Ferozpur Road, Lahore	200 Kg
2	White powder in large cone mixer	Nil	Nil	Nil	-DO-	450 Kg

Proceedings of the 255th Meeting of CLB

The Board during scrutiny of the case evaluated and decided as under.

Decision of the 255th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record,, the Board decided to:-

i. Grant permission to the Federal Inspector of Drugs, Lahore on his request for not to dispose-off the material till 03 months

ii. Direct the Federal Inspector of Drugs, Lahore to complete the investigation and send names of persons prima facie responsible.

iii. Issue show cause notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing , Registering and Advertising) Rules, 1976 for cancellation or suspension of the Licence M/s Renacon Pharmaceuticals, Lahore for GMP non- compliance as per inspection report dated 29-05-2017 &30-05-2017 and manufacturing of drugs despite suspension of production orders from QA section.

QUALITY CONTROL CASES

Case No.01

Subject: - **Manufacture/Sale of De-Registered Drug – Rumin Suspension - Contravention of Provisions of the Drugs Act 1976 and rules framed there under. F. No. 3-17/2014-QC**

The case was placed before the Board in its 246th meeting held on 22nd February 2016 as under:-Brief of the case:

The Federal Inspector of Drugs (FID), Karachi-III vide his letter dated 21-04-2014 informed that he alongwith Dr. Shahid Hussain, FID Karachi and others raided the premises of M/s Ankaz Pharmax (Pvt) Ltd., Karachi on 19-04-2014 at 07.45 AM. The raid was conducted on the source information of FIA Crime Circle Karachi. Deputy Director FIA Mr. Fakeer Muhammad headed the raid alongwith his team. Ten samples of different products were taken from the manufacturers premises for test/analysis on the prescribed Form-3.

· The FID vide his investigation report of the case intimated that eight samples of the drugs taken have been declared to be substandard by the Federal Government Analyst, CDL Karachi. In the light of the same, the FID issued explanation letter regarding the matter of manufacture and sale of substandard drugs to the firm. As per documents provided by the FID, the firm challenged the test reports and requested to get the samples retested from the Appellate Laboratory, NIH Islamabad.

· The FID vide his investigation report of the above case also reported that the firm was found manufacturing its one of de-registered product namely syrup Rumin mentioning the old manufacturing date on the label. It has been intimated that Syrup Rumin was found stored in bulk in big vessel placed in liquid manufacturing areas of the firm. A huge quantity of finished goods of same de-registered syrup was also seen placed in finished good wear house.

· The FID concluded that the manufacturer is guilty of manufacturing substandard drugs and de-registered drug in violation to the provisions of Drugs Act 1976 and rules framed there under. He has requested for cancellation DML of the firm or permission to lodge the prosecution against the firm.

· Following persons of the firm were held responsible for committing the offence by the FID.

i. Ali Abbass, Managing Director of the firm.

ii. Akbar Ali, Production Incharge.

iii. Safdar Alam, Quality Control Incharge.

· As per record of Quality Control Section, registration of this product was cancelled by DRB in its 237th meeting held on 26-02-2013, which was communicated of the firm vide their officer letter bearing No.03-16/2012-QC, dated 22-03-2013.

· The Appellate Laboratory declared 04 samples as Substandard and one of these as Misbranded whereas 03 samples were declared as of Standard quality by the Appellate Lab (NIH) Islamabad.

· As per procedure Show cause notices were issued to the firm and other accused, in the light of the test reports of the Appellate Lab and report of the FID, offering them opportunity of personal hearing before the Drug Registration Board.

246th meeting of Registration Board:-

· The case of manufacture and sale of substandard and de-registered drugs by M/s Ankaz Pharmex (Pvt.) Ltd, Karachi was considered by the Drug Registration Board in its 246th meeting held on 10th& 11th December 2014. Mr. Saleem Isharat Hussain, Technical Consultant of the firm, appeared before the Board on behalf of the firm on 11-12-2014. The Drug Registration Board after hearing the representative of the company, deliberations made, available record and facts of the case decided as under:-

I. "To cancel the registration of the following products of the firm:-

i. Rumin (Ibuprofen) 400mg Tablet, Reg. No. 007545.

ii. Rumin (Ibuprofen) 200mg Tablet, Reg. No. 007543.

iii. Tab. Biprim (Co-Trimoxazole) DS, Reg. No. 008409.

II. The Board further decided to recommend to the Central Licensing Board for cancellation of the Drug Manufacturing License of the firm on the violation of manufacturing of already De-registered product i.e. Rumin Suspension Reg. No. 008526."

239th meeting of Central Licensing Board:-

. The case was accordingly placed before the Central Licensing Board (CLB) in its 239th meeting held on 22nd January 2015, for consideration of recommendation of the Drug Registration Board regarding cancellation of Drug Manufacturing License (DML) of M/s Ankaz Pharmex (Pvt.) Ltd, Karachi and request of the area Federal inspector of Drugs, Karachi for cancellation of DML of the firm or permission to lodge the prosecution against the firm as narrated above.

Decision of 239th meeting of the CLB:-

The Board was apprised about the case. The Board after deliberations, taking into consideration all the facts of the case and available record decided as under:-

"To Issue show cause notice to the firm for cancellation of Drug Manufacturing License (DML) of M/s Ankaz Pharmex (Pvt.) Ltd, Karachi as per Section 41 of the Drugs Act 1976 and also for prosecution of the above named firm and the accused persons in the Drug Court for Sindh, Karachi".

Accordingly a show cause notice along with giving the opportunity of personal hearing, was issued to the following accused persons as nominated by the FID Karachi.

i. Ali Abbass, Managing Director of the firm.
ii. Akbar Ali Production Incharge.
iii. Safdar Alam, Quality Control Incharge.

246th meeting of Central Licensing Board:-

Proceedings:-

The firm and its nominated persons were called for personal hearing before the CLB in its 246th meeting held on 22-02-2016. Mr. Ali Abass S/o S.M Abass (MD of the firm) was appeared before the CLB and informed that there is writ petition in the Sindh High Court wherein the firm has challenged the decision of the Registration Board for cancellation of the registration of the Rumin suspension and he further informed that there is also stay order in the favor of the firm vide Sindh High Court order dated 18-12-2014. The order of the Court dated 18-12-2014 was read out before the Board. On the question regarding availability/presence of any other order of the Court relevant to this case after 18-12-2014, he negated and further informed that next date of hearing of the case in Honorable Sindh High Court was not yet fixed.

Decision:-

The Board after detailed discussions, deliberations, considering point of view of person appeared before the Board, taking in account the legal/codal provisions and keeping in view the facts of the case and as per available record decided **defer the case for clarity of the case and to take the opinion from legal affairs Division of DRAP, that whether the CLB may proceed or not in the case in the light of order of the Honorable Sindh High Court dated 18-12-2014 which is reproduce as under:-**

"Till the next date of hearing, respondents are directed to conduct themselves strictly in accordance with law and not to take any action against the petitioner without due process of law".

Proceedings of 255th meeting of Cental Licening Board

Central Licensing Board discussed the case in detail and deliberated on the matter in depth keeping in view the recommendations of Registration Board in 246th meeting for cancellation of Drug Manufacturing License of the firm. The Board observed that the firm was involved in the manufacturing of substandard drugs and unregistered drug which is an offence under the Sections 23 and 27 of the Drugs Act, 1976 and the rules framed there under. The Board also discussed the Honorable Sind High Court's order dated 18.12.2014 wherein the Honorable Court passed the order as under.

> **"Till the next date of hearing, respondents are directed to conduct themselves strictly in accordance with law and not take any action against the petitioner without due process of law."**

On the direction of Central Licensing Board in its 246th meeting, opinion of Legal Affairs Division, DRAP was obtained on the above orders of the court. The Legal Affairs Division was of the opinion that there is no need for legal opinion from the Legal Affairs Division since the court's orders are self-explanatory, very clear and without any ambiguity. Even if court order not direct, it is our responsibility to take strictly accordance with law and not to take any action without due process of law.

As the subject Writ Petition was lying pending in Sind High Court Karachi since 2014, therefore opinion Legal Affair Division, DRAP was also obtained as to whether CLB should proceed further or the matter should remain pending till honorable court passes final order in the matter. Legal Affairs Division was again of the same opinion that there is no need for legal opinion from the Legal Affairs Division since the court's orders are self-explanatory, very clear and without any ambiguity. Even if court order not direct, it is our responsibility to take strictly accordance with law and not to take any action without due process of law.

The Board also obtained opinion/comments from the legal expert/representative of the law division, Islamabad. The honorable member also endorsed the opinion of Legal Affair Division, DRAP and stated that there is no bar on taking a lawful action against the firm to protect the public health from the hazards of substandard and unregistered drugs. The board also observed that, to comply with legal provisions, the firm was served with show cause notice on 7th December, 2015 under section 41 of the Drugs Act, 1976 and opportunity of personal hearing was also provided to the firm.

The Board also discussed the reply to show cause notice submitted by the firm and also referred the statement of the representative of the firm during the personal hearing in 246thCLB meeting. The Board did not get satisfied with the point of view of the firm.

Decision of Central Licencing Board

The Board after through deliberations and observed that ample opportunity was proided to M/s Ankaz Pharmex, (Pvt), Karachi to defend his caseand decided to:

i. Cancel the Drug Manufacturing License of M/s AnkazPharmex, (Pvt), Karachi under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing , Registering and Advertising) Rules, 1976 due to poor GMP compliance that resulted in manufacturing of substandard drug and for manufacturing the unregistered drug i.e Rumin suspension registration no. 008526.
ii. grant the permission to the Federal inspector of Drugs, Karachi for prosecution the firm under section 23 and 27 of Drug Act. 1976 and rules framed thereunder in the Court of Law.

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