

No. F. 10-01/2016-DDC (Health & OTC)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad, the 1st February, 2016

MINUTES OF THE 7TH MEETING OF ENLISTMENT EVALUATION COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH PRODUCTS

7th Meeting of the Enlistment Evaluation Committee (EEC), constituted under 7 of the Alternative Medicines and Health Products (Enlistment) Rules, 2014, was held in the office of the Chairman of the Committee on 1st February, 2016. Meeting of Committee was attended by the following:-

S. #.	Name & Designation	Position in the Committee
1.	Dr. Noor Muhammad Shah, Director Health & OTC	Ex-Officio Chairman
2.	Abdul Sattar Sohrani, Deputy Drug Controller Health & OTC	Ex-Officio Member / Secretary
3.	Homeopathic Dr. Muhammad Tariq Khan, Assistant Professor, Department College of Pharmacy, Margalla Institute of Health Sciences, Rawalpindi.	Expert Member
4.	Hafiz Muhammad Asif, Assistant Professor Faculty of Health and medical Sciences Department of Eastern Medicines and Surgery, University of Poonch (Rawala Kot), AJ&K.	Expert Member -Not Present-
5.	Dr. Lajbar Khan, Ex-Chief Scientific Officer, Medicinal Botanic Centre, PCSIR Laboratories Complex, Peshawar.	Expert Member
6.	Dr. Farnaz Malik, Chief, DC & TMD, NIH	Ex-Officio Member -Not Present-
7.	Dr. Amjad Ali, Chief, Nutrition Division, NIH	Ex-Officio Member

Item No. 1. Meeting started with recitation of the Holy Quran and Darud on the Prophet (PBUH). Secretary of the Committee presented agenda of the meeting and following decisions were made by the Committee.

Item No. 2. GRANT OF ENLISTMENT CERTIFICATE TO THE MANUFACTURERS

Enlistment Evaluation Committee (EEC) examined and discussed the record / panel inspection reports of the following firms and on the basis of recommendations of the panel of inspectors for the grant of enlistment certificates for manufacturing authorization.

S. No.	Name and address of the Manufacturer	Name of approved Sections
1.	M/s. Zestech Sciences , Plot No. 48, Sector 23, Korangi Industrial Area, Karachi.	1. Soft Gel Capsule 2. Hard Gelatin Capsule 3. Tablet 4. Oral Liquid (Syrup) 5. Cream / Ointment 6. Sachet
2.	M/s. Frontier Botanical Research Laboratories (Pvt) Ltd. (Herbal and Homoeo Division), 107/A, Hayatabad Small Industrial Estate, Peshawar.	1. Tablet 2. Capsule 3. Oral Liquid (Syrup) 4. Sachet 5. Ointment 6. Arq (extract)
3.	M/s. NEUTRA CURE , SB-02 & 15, Sector 6-G, Korangi Township, Karachi.	1. Hard Geltain Capsule 2. Tablet 3. Cream / Ointment 4. Dry Powder 5. Sachet 6. Oral Liquids
4.	M/s FILIX Pharmaceuticals (Pvt) Ltd (H & OTC Division) Plot No. 4-B, Main Road, RCCI Rawat, Rawalpindi. (Dedicated Section)	1. Sachet 2. Cream/ Ointment 3. Capsule
5.	M/s Convell Laboratories (Natural Drugs Division), Saidu Sharif, Sawat. (Dedicated Section)	1. Tablet 2. Capsule 3. Sachet 4. Oral Liquid (Syrup)
6.	M/s Etihad Herbal Industries (Pvt) Ltd. 9.5 Km, Sheikhpura Road, Lahore.	1. Tablet 2. Syrup 3. Capsule 4. Sachet 5. Ointment/ Cream 6. Homoeopathic (Liquid & Drops)

EEC approved that issuance of Homoeopathic sections will be made after satisfactory verification report by Dr. Saleem, Ex-DDG (PCSIR), (Homoeo), Member Advisory Committee.

7.	M/s Tana Netting (Pvt) Ltd, 4 Km, Kana Kacha Road, Off Ferozpur Road, Lahore.	<ol style="list-style-type: none"> 1. Insecticidal Mosquito Netting 2. Enlistment of product Dawa Plus containing insecticidal delta methrin 80 mg per sq. meter for export purpose was approved by the Enlistment Committee because MRP is not required for export purpose. It was also decided that cases of products enlistment may also be brought before the Committee for export purpose after evaluation by the Sub-Committee.
8.	M/s. Himont Laboratories (Pvt) Ltd., 17-KM, Ferozepur Road, Lahore.	<ol style="list-style-type: none"> 1. Tablet 2. Sachet 3. Capsule 4. Oral Liquid 5. Cream/ Ointment 6. Dental preparations
9.	M/s GERISHON INTERNATIONAL , Plot No. 146, St-13/1, Sector 6-B, Abdullah Industrial Estate, North Karachi, Industrial Area, Karachi.	<ol style="list-style-type: none"> 1. Tablet 2. Capsule 3. Sachet 4. Ointment/ Cream/ Balm 5. Oral Liquid (Syrup)
10.	M/s Medwell Pharmaceuticals , 1-Km, Tarbella Road, Lawrencepur District, Attock. (Dedicated Section)	<ol style="list-style-type: none"> 1. Tablet 2. Capsule 3. Cream/ Ointment/ Lotion 4. Oral Liquid (Syrup) 5. Sachet 6. Dry Powder
11.	M/s Modherbs , Plot No. C-596, Sector 2, Ahsanabad, Scheme-33, Opp SITE Super Highway, Karachi.	<ol style="list-style-type: none"> 1. Tablet 2. Capsule 3. Sachet 4. Oral Liquid (Syrup & Drops)
12.	M/s Mektum Homoeo Pharma , Plot No. 122-123, Sector 24, Korangi Industrial Area, Karachi.	<ol style="list-style-type: none"> 1. Oral Liquids (Syrup & drops) 2. Tablet 3. Capsule 4. Mother Tincture/ Potency 5. Cream/ Ointment
13.	M/s Platinum Pharmaceuticals (Pvt.) Limited , A-20, North Western Industrial Zone, Bin Qasim, Karachi-75020	<ol style="list-style-type: none"> 1. Toothpaste/ tooth gel 2. Mouthwash

2.

INSPECTION REPORT WITH NOT RECOMMENDED BY THE PANEL:-

1.	M/s. KAAP Pharmaceuticals (Pvt) Ltd., 18-KM, Ferozepur Road, Lahore. Sections:- 1. Tablet 2. Capsule 3. Syrup	24-11-2015	01. Mrs. Majida Mujahid, FID, DRAP, Lahore. 02. Dr. Saleem, Ex-DG (PCSIR), Member Advisory Committee	Not Good	Committee rejected the application due to the reasons given by the Panel in the Inspection Report.
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Decision

1. EEC rejected the application because panel did not recommend the facility due to the reasons given in the inspection report presented by the Secretary (EEC).
2. **Principal decision:** Committee decided the applicants whose applications have been rejected on the basis of non recommendation by the panel may apply a fresh and his case will be taken on priority basis.

Item No. 3. GRANT OF ENLISTMENT CERTIFICATES TO IMPORTERS AS AN AGENT OF PRINCIPLE MANUFACTURER.

The Enlistment Evaluation Committee considered the applications/ record and evaluated the case of enlistment of the following firms and granted approval for Enlistment Certificates on Form-6

(A) Application for Enlistment as agent of abroad Principal Manufacturer meeting the prescribed criteria

1. M/s Bayer Pakistan (Private) Limited, C-21, S.I.T.E., Karachi.
(Agent of M/s. PT Bayer Indonesia, Cimanggis Plant, Jl. Raya Bogor Km 32, Depok 16416, Indonesia (Human use).
2. M/s. SH Marketing Services (Pvt) Ltd., Shop 2, Bismillah Plaza, Street 67, G-11/2, Islamabad.
(Agent of M/s. Coating Place, Inc. 200 Paoli Street, Verona, WI 53593 USA) (Human use)
3. M/s. Snam Pharma, 61-G, Phase-1, Commercial Area DHA, Lahore-Pakistan.
(Agent of M/s. LABORATORIOS EURISKO, S.L, C/ Mallorca 249, 1º planta, 08008 BARCELONA (ESPAÑA- SPAIN) (Veterinary use)
4. M/s Tarobina Corporation, 226 Ahmed Block New Garden Town, Lahore.
(Agent of M/s K.M.P Biotech Co., Ltd, No. 188/9 Village No. 2, Khalong Tamru Sub-district mueang Chon Buri District chun Buri Province, Postal Code 20000., THAILAND) (Veterinary use)
5. M/s DMG, Diversified Marketing Group, House No. 245, Ground Floor, Saidpur Road, Scheme No. 1, Rawalpindi.
(Agent M/s Tanin Slovenia, D.D. Hermanova Cesta, 1 8290 Sevnica-Slovenia SLOVENIA) (Veterinary use)

6. M/s DMG, Diversified Marketing Group, House No. 245, Ground Floor, Saidpur Road, Scheme No. 1, Rawalpindi.
(Agent M/s Specialty Biotech Co., Ltd. Free Zone Amata Nakom Industrial Park 700/137 Moo 5, Klongtumroo, Muang, Chonburi 20000, THAILAND) (Veterinary use)
7. M/s Bismillah Traders, Quanchi More, Lahore Road, Sargodha.
(Agent of M/s Shandong Soocom Animal Remedy Co., Ltd., Xindakang Road No. 666 Agricultural High & New Technology Development Zone of Jinan, CHINA) (Veterinary use)
8. M/s Vida Laboratory, Plot No. 225, Sector 23, K.I.A, Karachi.
(Agent of M/s Capsugel Japan Inc. 4-3-36 Minamihashimoto, Chuo-ku, Sagamihara, Kanagawa 252-0253 JAPAN) (Human use)
9. M/s Base6 (Pvt) Ltd., E-216, Street No. 6, Cavalry Ground, Lahore. (Agent of M/s Promising Health Inc., 2700-14th Avenue, Unit No. 8, Markham, Ontario, L3R 0J1, CANADA) (Human use)
10. M/s Service Line Private Limited, 21-A, Block-K, Gulberg-II, Lahore. (Agent of M/s Lemasor GmbH, Bergstrasse 19, 66346 Puttlingen GERMANY) (Human use)
11. M/s J&J's Pharmaceuticals, Upper Floor 85/G3, Wapda ECHS (WAPDA TOWN) Lahore.
(Agent of M/s XVET GmbH, Sorthmannweg 20 22529, Hamburg, GERMANY) (Veterinary use)
12. M/s Neucon Pakistan, C-2, Al-Shams Centre, Block-13/A, Gulshan-e-Iqbal, University Road, Karachi. (Agent of M/s Diafarm a/s, Flegmade 11E, Dk-7100, Vejle Denmark) (Human use)
13. M/s Medinowa Pharma (Pvt) Ltd, UG-238, Deans Trade Centre, Peshawar.
(Agent of M/s Qing Dao Double Whale Pharmaceutical Co. Ltd. No. 2, Shuang Jing Road, Liuting Industrial Park, Qingdao, CHINA) (Human use)
14. M/s Sante (Pvt) Limited, 245/2-Z, Block-6, PECHS, Karachi.
(Agent M/s Viva Pharmaceutical Inc. 13880 Viking Place, Richmond, B.C. CANADA) (Human use)
15. M/s Ideal Health Care Products, 1-C-I, LDA Flats, Dubai Chowk, Allama Iqbal Town, Lahore.
(Agent of M/s ZHIVAS LTD, 14, Assen Yordanov Blvd., Sofia 1592, Bulgaria) (Disinfectants)
16. M/s Add Life Pharma, 221/6, Khadim Hussain Road, Tariqabad, Rawalpindi Cantt.
(Agent of M/s Erbex Nutraceutical & Cosmeceutical Co., Via del Laghetto, 110, 45021 Badia Polesine (RO), ITALY)

Decision

The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firms and granted approval for Enlistment Certificates on Form-6

(B) The Firms having agency agreement/ manufacturing authorization of the Principal Manufacturer not attested

1. **M/s M.S. Corporation**, 302, Hashoo Centre, Abdullah Haroon Road, Saddar, Karachi.
(Agent of **M/s Lehning Laboratories**, SAS 3, rue du Petit Marais 57640 Sinte-Barbe, **FRANCE** (Human use))
2. **M/s Tarobina Corporation**, 226 Ahmed Block New Garden Town, Lahore.
(Agent of **M/s Feed Up Ltd**, 21Chungnam-daero, Hongseong-gun, Chungcheongnam-do, **KOREA**) (Veterinary use)
3. **M/s Tarobina Corporation**, 226 Ahmed Block New Garden Town, Lahore.
(Agent of **M/s Insect Biotec Co., Ltd**, 3 Yuseong-daero, 1628 beon-gil, Yuseon-gu, Daejeon, **KOREA**) (Veterinary use)
4. **M/s ICI Pakistan Limited**, ICI House, 5 West Wharf, Karachi.
(Agent of **M/s Inform Nutrition Ireland Ltd**, Whites Cross, Cork, Co Cork, **IRELAND**) (Veterinary use)
5. **M/s Tianshi International Pak. Co. (Pvt) Ltd.** 1st Floor, Banner Store Shopping Plaza, Block 20-A, Main Civic Centre, G-8 Markaz, Islamabad.
(Agent of **M/s Tianjin Tianshi Biological Development Co., Ltd.** No. 16 Xinyuan Road, Wuqing Development Area, Tianjin, **CHINA**) (Human use)

Decision

The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firms and granted approval for Enlistment Certificates on Form-6 subject to provision of manufacturing authorization / attested agency agreement by the abroad Principal Manufacturer.

- (C) **M/s Bristol Mayer Biotech**, 69-A, Guldasht Town, Zarar Shaheed Road, Lahore Cantt. has submitted registration certificate with FDA, USA. Manufacturing authorization from the country of origin not submitted. (Agent of **M/s Officina Farmaceutica Italiana**, S.P.A. -Via Verga, 14-24127-Bergamo **ITALY**) (Human use)**

Decision

The Enlistment Evaluation Committee considered the application/ record and evaluated the application for enlistment of the firm and granted approval for Enlistment Certificates on Form-6 subject to provision of manufacturing authorization from the country of origin.

Item No. 4:- MISCELLANEOUS CASES:-

1. Incomplete Applications:-

List of firms/ companies whose applications are incomplete. Local Manufacturing (**Annex-A**) and Import (**Annex-B**) submitted for consideration of EEC.

Decision:-

The Committee after examination of cases decided to reject the applications under Rule 7 on the grounds that applicant failed to complete their applications as per prescribed criteria under the Rules despite notices of shortcomings/ deficiencies.

Pakistan Zindabad

Disclaimer: -

Any mistake or omission or correction may be reported to the Director (Health & OTC Division) 2nd Floor, TF Complex, Islamabad.