

No. F. 12-04/2015-DDC (Health & OTC)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad, the 29th October, 2015.

MINUTES OF 4TH MEETING OF THE ENLISTMENT EVALUATION COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH PRODUCTS.

4th meeting of the Enlistment Evaluation Committee, 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 29th October, 2015.

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
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
7.	Dr. Amjad Ali, Chief, Nutrition Division, NIH	Ex-Officio Member

Item No. 1. The meeting started with recitation of the Holy Quran and Darud on the Prophet (PBUH). Chairman of the committee informed the members about the reasons for early meeting of the Enlistment Evaluation Committee. Secretary of the committee presented agenda of the meeting and following decisions were made by the committee.

Item No. 2. Confirmation of minutes of the Sub-Committee in respect of Product Enlistment (copy of the minutes attached).

AGENDA PART-A

Item No. 3. GRANT OF ENLISTMENT CERTIFICATE TO THE MANUFACTURERS.

The Enlistment Evaluation Committee examined and discussed the record / panel inspection reports of the following firms and on the basis of recommendations of the panel of inspections approved grant of enlistment certificate for manufacturing authorization to them.

S. No.	Name and address of the Manufacturer	Name of approved Sections
1.	M/s. MAC & RAINS, 540-D, Sundar Industrial Estate, Raiwind Road, Lahore.	1. Oral Powder Sachet (General & Probiotics) 2. Oral Powder (Jar Packing) 3. Tablets and Capsules 4. Oral Liquids (Syrups Solutions Suspension) 5. Oral Liquid Drops
2.	M/s. Miksons Healthcare (Pvt) Ltd., Rawalpindi.	1. Tablet Section 2. Syrup Section 3. Capsule Section
3.	M/s. Bio Life Enterprises Nutraceuticals, 14-KM, Adyala Road, Rawalpindi.	1. Tablet Section 2. Liquid Section 3. Capsule Section 4. Cream / Ointment 5. Sachet / Powder

		Section
4.	M/s. Hinucon, Plot No. 12/1, Sector-15, Korangi Industrial Area, Karachi.	1. Sachet / Powder Section 2. Liquid Syrup 3. Oral Chewable Tablets
5.	M/s. Bless Laboratories, Factory # 179, 1.5-KM, Kattar Band Road, Off Multan Road, Thokar Niaz Baig, Lahore.	1. Tablet Section 2. Capsule Section 3. Powder Section 4. Liquid Syrup Section 5. Extraction Section
6.	M/s. Hit Natural Pharma, 25-A, Ammar Block, Nishtar Colony, 18-KM, Ferozpur Road, Lahore.	1. Syrup Section 2. Sachet Section 3. Semi Solid (Balm) Section

Item No. 4. GRANT OF ENLISTMENT CERTIFICATES TO IMPORTERS AS AN AGENT OF PRINCIPLE MANUFACTURER.

The Enlistment Evaluation Committee considered and evaluated the case of enlistment of the following firms and granted approval

01. M/s. La Vie (Pvt) Ltd., Opp. Micro-Electronics, Peco Road, Peco More, Kot Lakhpat, Lahore.

(Agent of M/s. NeoPharm Co., Ltd, 309-8, Techno 2-ro Yuseong gu Daejeon, Korea).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

02. M/s. Nutra Zone Health Care, Suite No. 1, Plot No. 58-C, 25th Tauheed Commercial, DHA Phase-5, Karachi.

(Agent of M/s. Patheon Softgels B.V., De Posthoornstraat 7, 5048 AS TILBURG, The Netherlands).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

03. M/s. Nutra Zone Health Care, Suite No. 1, Plot No. 58-C, 25th Tauheed Commercial, DHA Phase-5, Karachi.

(Agent of M/s. Thompson & Capper Limited, 1 – 13 Hardwick Road, Astmoor Industrial Estate, Runcorn, Cheshire WA7 1PH, United Kingdom).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

- 04. M/s. Orient Traders International, B-10, Airport View Appartment, Opp: Jinnah Airport Shahrah-e-Faisal, Karachi.**
(Agent of M/s. V.M.D. n.v./s.a. Hoge Mauw 900 B-2370 Arendonk Belgium).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

- 06. M/s. Merck Specialities (Private) Limited, 75/1-M, Quaid-e-Azam Industrial Estate, Town Ship, Kot Lakhpat, Lahore.**
(Agent of M/s. Hovid BHD, 121, Jalan Tunku Abdul Rehman, 30010 IPOH, Perak, Malaysia).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

- 07. M/s. Pharma 5 (Pvt) Ltd., 601 & 602, 6th Floor, Mehdi Towers, 115-A, SMCHS, Shahrah-e-Faisal, Karachi-74400, Pakistan.**
(Agent of M/s. Northeast Pharm. Trading Co., Ltd., No. 51 Youth Street, Shenhe District, Shenyang, China). **(Last inspection report of the principal manufacturer is not attached).**

Decision

Committee approved the grant of enlistment certificate as agent of principal manufacturer subject to submission of above mentioned document.

- 08. M/s. Vet Marks International, M-8, 1st Floor, Rahkshanda Heights, 244 Kashmir Block, Allama Iqbal Town, Lahore.**
(Agent of M/s. Pharmaceutical and Veterinary Material Joint Stock Company (HANVET), GMP-WHO FACTORY PhoNoi A industrial zone, Hung Yen, Vietnam).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

Item No. 5. MISCELLANEOUS CASES:-

- i. List of firms / companies who failed to complete their applications despite twice notices.
(Annex-A)

Decision

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

AGENDA PART-B:-

Item No. 6. APPLICATION FOR PRODUCT ENLISTMENT:-

(i) The firms enlisted in the first, second and third meeting of EEC as local manufacturing have applied for the grant of product enlistment certificate. The list is attached at **Annex-A**.

(ii) Firms enlisted in the first, second and third meeting of EEC as importer have applied for the grant of product enlistment certificate. The list is attached at **Annex-B**.

(iii) Enlistment of homeopathy mother tincture and dilutions of M/s. BM (Pvt) Ltd., Lahore (**Annex-C**).

Decision

Committee authorized the sub-committee constituted in 2nd meeting to evaluate the applications and issue letters to the manufacturers / importers included in the agenda subject to fulfillment of criteria. The committee unanimously decided to approve up to thirty (30) products per section. It was suggested by the expert member of homeopathy Dr. Muhammad Tariq Khan to grant approval of hundred mother tinctures and their potencies for the homeopathy manufacturers.

Item No. 7. ANY OTHER ITEM WITH THE PERMISSION OF CHAIR:-

Secretary of the committee explained before the committee that only those applications are brought before the EEC which are complete including re-application by the applicants whose applications are rejected on the basis of non reply within the stipulated time as per practices in vogue or those rejected due to non rectification of short comings. So in this regard principle of first in first out could not be applied because incomplete applications could not be brought before the committee. The committee unanimously agreed to the above proposal.

Disclaimer: -

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