

No. F. 12-03/2015-DDC (Health & OTC)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad, the 19th October, 2015.

**MINUTES OF 3RD MEETING OF THE ENLISTMENT EVALUATION
COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH
PRODUCTS.**

3rd 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 12th 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. Lajber 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. Muhammad Amjad, Chief, Nutrition Division, NIH	Ex-Officio Member
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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.

Item No. 2. Secretary of the committee presented agenda of the meeting and following decisions were made by the committee.

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
01	M/s. Nutra Biomed (Pvt) Ltd., Plot No. 01, Behind Allied Bank, Air Port Road, Mangral, Rawalpindi.	<ol style="list-style-type: none"> 1. Tablet Section 2. Oral Liquid (Suspension / Drops / Syrup) 3. Sachet Section 4. Powder Section 5. Capsule Section 6. Topical Preparations (Creams / Ointment / Gel)
2.	M/s. BM (Private) Limited, 22-Anam Road, Industrial Estate (Glaxo Town), 20-KM, Ferozpur Road, Lahore.	<ol style="list-style-type: none"> 1. Mother Tinctures 2. Homoeopathic Dilutions (Potencies) 3. Tablet Section & Granules 4. Oral Drops Section & General 5. Trituration & Biochemic (Tablets) 6. Syrup Section
3.	M/s. Global Laboratories, Plot No. 224, Street No. 1, Sector I-10/3,	<ol style="list-style-type: none"> 1. Topical Preparations (Cream, Lotion,

	Industrial Area, Islamabad.	<p>Solution and Ointments) in Sachet and tube</p> <ol style="list-style-type: none"> 2. Tablet Section 3. Capsule Section 4. Oral Liquid Section 5. Dry Powder Sachet 6. Oral Powder 7. Liquid Solution
4.	M/s. Nugen, 28-KM, Ferozepur Road, Lahore.	<ol style="list-style-type: none"> 1. Tablet Section 2. Capsule Section 3. Cream / Ointment / Gel Section 4. Sachet / Powder Section
5.	M/s. Evergreen Pharmaceutical (Natural Division), 20-KM, Ferozepur Road, Lahore.	<ol style="list-style-type: none"> 1. Oral Liquid General (Natural) 2. Capsule Section (Powder Natural) 3. Sachet Section (Powder Natural)

Item No. 4. GRANT OF ENLISTMENT CERTIFICATE 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. Acti Health Food, Suite # 1 Shireen Arcade Plot # A-41, K.U.C.H.S Block 7 & 8, Karachi.**
(Agent of M/s. Thompson & Capper, 9-13 Hardwick Road, Astmoor Industrial Estate, Runcorn, Cheshire, WA7 1PH).

Decision

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

- 02. M/s. Graton Pharma, Suit#102, 1st Floor, The Plaza, Block-09, Clifton 2-Talwar, Karachi, Pakistan.**
(Agent of M/s. ESSENTIAL PHARMACEUTICAL, CORP. 1906 W. Holt Avenue Pomona, CA 91768). The firm has submitted two different distribution certificates. The latest one deem to be issued by the same person which seems to be differing in terms of signatures of the chief executive and chief executive officer with same name Dr. Bruce Y Lin. Moreover, in the first one it is only named as Essential Pharmaceutical Corp. and in the latest one it is for Essential Pharmaceutical Corp. moreover the site master file of the principal manufacturer does not

reflect facility for gelatin capsules while the list contains a number of soft gelatin products.

Decision

Committee approved the grant of enlistment certificate as agent of principal manufacturer subject to verification of agency agreement and facility for soft gel manufacturing by the principal manufacturer.

- 03. M/s. PharmEvo (Private) Limited, Plot A-29, North Western Industrial Zone, Port Qasim Karachi-75020, Karachi-Pakistan.**
(Agent of M/s. Chr. Hansen A/S BogeAlle 10 - 12 DK-2970 Hørsholm Denmark).
- 04. M/s. ICI Pakistan Limited, ICI House, 5 West Wharf, Karachi-74000, Pakistan.**
(Agent of M/s. Chr. Hansen A/S BogeAlle 10 - 12 DK-2970 Hørsholm Denmark).
- 05. M/s. Vida Laboratories, Plot 225, Sector 23, Korangi Industrial Area, Karachi, Pakistan.**
(Agent of M/s. Chr. Hansen A/S BogeAlle 10 - 12 DK-2970 Horsholm Denmark).

Decision

Committee approved the grant of enlistment certificate as agent of M/s. Chr. Hansen A/S BogeAlle 10 - 12 DK-2970 Horsholm Denmark for the following subject to the conditions that same product would not be permitted to the other agent.

- (i) M/s. PharmEvo (Private) Limited, Plot A-29, North Western Industrial Zone, Port Qasim Karachi-75020, Karachi-Pakistan.
 - (ii) M/s. ICI Pakistan Limited, ICI House, 5 West Wharf, Karachi-74000, Pakistan.
 - (iii) M/s. Vida Laboratories, Plot 225, Sector 23, Korangi Industrial Area, Karachi, Pakistan.
- 06. M/s. Vida Laboratories, Plot 225, Sector 23, Korangi Industrial Area, Karachi, Pakistan.**
(Agent of M/s. BioGrowing CO., LTD. No.10666, Songze Rd, Qingpu, Shanghai, 201700, China).

Decision

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

- 07. M/s. Binsadiq International, 89-A, Canal View Housing Society, Lahore.**

(Agent of M/s. Diamond V South Plant, P.O. Box 74570, 2575 60th Avenue SW, Cedar Rapids Iowa 52404, USA).

Decision

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

08. M/s. Meezab Z International, Fareed Abad, Jahanian District Khanewal.

(Agent of M/s. ALREEF COMPANY FOR MANUFACTURING VETERINARY DRUGS AND AGROCHEMICALS (REEFCO) ALHASSAN INDUSTRIAL ESTAE-IRBID-JORDAN).

Decision

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

09. M/s. Getz Health (Pvt) Ltd, 29-30 Sector-27, Korangi Industrial Area, Karachi

(Agent of M/s. Xuancheng Braveiy Bioengineering Co. Ltd, China).

Decision

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

10. M/s. The Searle Company Limited, First Floor, N.I.C.L. Building abbasi Shaheed Road, Karachi.

(Agent of M/s. Shandong Kexing Bioproducts Co., Ltd., No.26666 CHUANGYE ROAD, MINGSHUI DEVELOPMENT ZONE, ZHANGQIU, JINAN, SHANDONG-250200, China).

Decision

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

11. M/s. Schiwo Pakistan, Office No. 10, 1st Floor, City Plaza, Khanewal Road, Multan.

(Agent of M/s. NFA Ilac Kimya Sanayi ve Tic. Ltd. Sti. (Tuzla Kmya Sanayicileri Org. San. Bol. Melek Aras Bul. Analitik Cd. No: 92 Tuzla Istanbul TURKEY).

Decision

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

12. M/s. Galaxy Pharma (Private) Limited, D-180, Rojhan Street, Block-5, Clifton, Karachi-75600, Pakistan.

(Agent of M/s. Lo. Li Pharma International, ROMA – 00156 – VIA dei LUXARDO, 33 – VAT. 0678051002, Italy).

Decision

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

13. **M/s. Synapse Chemicals (Pvt) Ltd., 298-H/3, Johar Town, Lahore.**
(Agent of M/s. Laboratories Lyocentre, 24 Avenue Georges Pompidou BP429, 15004Aurillac, France).

Decision

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

14. **M/s. Harum Pharma, 12-F-1, Aleem Centre (1st Floor), Main Rashid Minhas Road, Gulshan-e-Iqbal, Block-5, Karachi.**
(Agent of M/s. Advanced Agrochemicals and Veterinary Products Industrial Co. (CHEMVET) P.O. Box: 294, Abdullah II Bin Al-Hussein Industrial Estate, Sahab, Amman - 11512 - Jordan). **(The original Agency Agreement and Drug Sale License are unavailable with the application).**

Decision

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

Item No. 5. MISCELLANEOUS CASES:-

1. Request for withdrawal of Applications:-

- i. Applicants have requested for withdrawal of their applications submitted before the authority for enlistment certificates due to their own problems. The list of the firms is mentioned below:-

S. No.	Name of the Firms
1.	M/s. MSAN Natural Products®, Multan-Pakistan
2.	M/s. Sadiq Herbal Pharma, Multan

Decision

Committee acceded to the request subject to verification by the applicant.

- ii. List of firms / companies whose letters have been returned backed un-delivered. (**Annex-D**)

Decision

Committee decided to reject the applications under Rule 7 because the applicant failed to complete the application as per prescribed criteria under Rule 5.

- iii. List of firms / companies who did not replied to official correspondence. (**Annex-E**)

Decision

Committee decided to reject the applications under Rule 7 because the applicant failed to complete the application as per prescribed criteria under Rule 5.

- iv. List of firms / companies who have requested twelve months extension. (**Annex-F**)

Decision

Committee decided that final notice may be issued to the firms.

AGENDA PART-B

Item No. 6. APPLICATION FOR PRODUCT ENLISTMENT:-

(i) The firms enlisted in the first and second 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 and second 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. Dr. Masood Homeopathic, 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 homoeopathy Dr. Muhammad Tariq Khan to grant approval of hundred mother tinctures and their potencies for the homoeopathy manufacturers. It was also indicated by the chief nutrition that recommended use of baby milks and foods shall be in conformance to the guidelines of Codex Alimentarius Commission of FAO / WHO. It was also agreed that recommended conditions for use for vitamin preparations, multivitamin preparations, multivitamin & mineral preparations and mineral preparations shall be in accordance with the multivitamin-mineral products monograph. The enlistment committee decided that shelf life shall be two years for all products except vitamin mineral liquid preparations. However, request for enhancement in shelf life shall be entertained on the basis of stability data generated in compliance with the WHO stability guideline for the relevant products.

Item No. 7. APPLICATION FOR CONTRACT MANUFACTURING:-

The list of applications for contract manufacturing along with products is placed for consideration of the EEC. (**Annex-C**)

Decision

The committee also authorized sub-committee to evaluate the application for contract manufacturing and issue letters subject to the following conditions.

1. Contract manufacturing by enlisted manufacturer up to one hundred products per section subject to the following conditions.
2. Payment of fee to be prescribed by the authority for contract manufacturing of products.
3. Number of products shall not exceed the limit fixed by the enlistment evaluation committee.

Item No. 8. GUIDELINE FOR EXPIRY DATE, BRAND NAME RECOMMENDED CONDITIONS FOR USE AND SPECIFICATIONS

- (i) SOP's for expiry date,
- (ii) SOP's for brand name,
- (iii) Monograph for vitamin preparations, multivitamin preparations, multivitamin & mineral preparations and mineral preparations and their recommended conditions for use and
- (iv) Specifications monograph which is integral part of the product marketing authorization. Therefore procedure and guidelines have been prepared and placed for consideration of EEC. (**Annex-D**)

Decision

Committee agreed to the sop's and monographs to issue product enlistment certificate in the light of sop's and above monographs.

Disclaimer: -

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