

No. F. 12-01/2015-DDC (Health & OTC)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad. The August, 2015.

MINUTES OF 1ST MEETING OF THE ENLISTMENT EVALUATION COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH PRODUCTS.

1st 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 31st August, 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	Expert Member

	Laboratories Complex, Peshawar.	
6.	Dr. Farnaz Malik, Chief, DC & TMD, NIH	Ex-Officio Member
7.	Dr. Muhammad Amjad, Chief, Nutrition Division, NIH	Ex-Officio Member

2. The meeting started with recitation of the Holy Quran and Darud on the Prophet (PBUH).

3. Chairman of the committee welcomed the members and briefed them regarding the regulation of the subject of Alternative Medicines and Health Products by the Authority under the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) after the 18th Amendment in the Constitution of Pakistan. The Chairman informed the members that membership of the committee is great honour entrusted upon the members due to their expertise in the subject of Alternative Medicines and Health Products. Better performance of the duty and fulfillment of responsibilities however go side by side with authority and honour and same is applicable for the members of the committee. The Chairman hoped that the members will evaluate, in appropriate time, the large member of applications for enlistment of the manufacturers, importers and their products lying pending for a long time, keeping in view the provision of safe, effective and of quality Alternative Medicines and Health Products to the patients at affordable cost. The Chairman also appreciated the willingness of the expert members for the committee for evaluation of the applications and thanked them for attending the meeting on a short notice.

4. The members of the committee thanked the Authority for giving them the opportunity to utilize their professional expertise in the field for the well being of the public.

5. The chairman apprised the committee for making its conduct regarding its functioning in just and proper way. The committee accordingly proceeded for preparation of procedures for conduction of its functioning, placed at **Annexure-A**.

6. Secretary of the committee presented agenda of the meeting and following decisions were made by the committee.

Item:- I. **Resolution of Commitment.**

The committee unanimously passed the resolution that all the members of the committee will strive hard for fulfillment of the responsibilities enshrined with full real and zest by utilizing their professional skill with honesty and integrity for the betterment of public at large. It was also resolved that the industry will be facilitated in terms of up-gradation in quality to promote business in the subject field so that safe and effective medicines are provided to patients and also to promote the export of these products.

Item:- II. **Inspection of Manufacturing Units.**

The committee nominated following specialties to be panel members for inspection of the manufacturing units.

1. Member of Enlistment Evaluation Committee / Advisory Committee
2. Federal Inspector of Drugs
3. Provincial Drug Inspector
4. Expert in the relevant field.

2. It was decided that the panel of inspectors will be comprising of two to three members. The committee also decided the names of panel inspectors for the manufacturing units ready for inspection placed at **Annexure-B**.

3. The committee authorized the chairman to nominate panel of inspectors from the above specialties for the manufacturing units and importers ready for inspection. This will result in quick disposal of cases lying pending in the division.

Item:- III. **Grant of Certificate of Enlistment to the Manufacturing Units.**

The committee discussed the panel inspection reports of following units in detail and in the light of the reports that the firms are fulfilling the requirements including manufacturing and quality control facilities and procedures and recommendation of the inspecting panels, decided to approve grant of certificate of enlistment to the following manufacturing units:-

S. No.	Name and address of the Manufacturer	Name of approved Sections
1.	M/s. Herbion Pakistan (Pvt) Ltd., Plot # 30, Sector-28, Korangi Industrial Area, Karachi.	1. Tablets 2. Capsules 3. Granules 4. Extraction & Liquid Manufacturing 5. Sachets
2.	M/s. Glorious Laboratories, Plot # 136, Industrial Triangle, Kahuta Road, Islamabad.	1 Tablets 2. Capsules 3. Sachets 4. Powders 5. Liquid Preparations (Syrup, Suspension and Drops Sections) 6. Semisolid Preparations 7. Extract Manufacturing (Semi Basic)
3.	M/s. Nutra Biotics Nutritional Life Sciences, Plot # 32-33, Small Industrial Estate, Kohat Road, Peshawar.	1. Tablet 2. Syrup 3. Sachets 4. Cream / Ointment
4.	M/s. High Noon Laboratories (Pvt) Ltd., 17.5-KM, Multan Road, Lahore.	1. Dedicated Ointment Section

Item:-IV.

GRANT OF ENLISTMENT CERTIFICATE TO IMPORTERS AS AGENT OF PRINCIPLE MANUFACTURING

- 01. M/s. Abbott Laboratories Pakistan Limited, Karachi**
(Agent of M/s. Magrina Laboratorios, Barcelona, Spain for Melagyn Gel, Melasept, Melagyn Junior and Melagyn Pediatric)

- 02. M/s. Abbott Laboratories Pakistan Limited, Karachi**
(Agent of M/s. Abbott Granada Spain for Nepro HP Vanilla Powder, Similac Total Comfort, Stage-I, Similac Total Comfort, Stage-II and Similac Total Comfort, Stage-III)

- 03. M/s. Abbott Laboratories Pakistan Limited, Karachi**
(Agent of M/s. Abbott Laboratories B.V. Zwolle Netherland for Isomil Powder, Ensure Liquid Plus, Ensure Powder Strawberry, Ensure Powder Chocolate, Ensure Powder Vanilla, Ensure Chocolate, Glucerna Liquid and Ensure Advance Nutrivigr)

- 04. M/s. Abbott Laboratories Pakistan Limited, Karachi**
(Agent of M/s. Abbott Laboratories Cootehill, Ireland for Similac 1 and Similac 2)

- 05. M/s. Abbott Laboratories Pakistan Limited, Karachi**
(Agent of M/s. Abbott Manufacturing Singapore Private Limited for Powder formula products, Pediasure NG vanilla, Pediasure NG chocolate, Pediasure NG strawberry and Similac Mom tin packs)

- 06. M/s. Glaxo SmithKline Pakistan Limited, Karachi**
(Agent of Smith Kline Beecham (Pvt.) Ltd., Colombo, Srilanka for Herbal Iodex)

- 07. M/s. Vida Corporation, Karachi**
(Agent of Weihai Baihe Biology Technological Co. Ltd. Rongcheng City, China Tablets, Hard capsules, Powder, Granules, Softgels and pill)

- 08. M/s. Asian Consumer Care Pakistan (Pvt.) Limited, Karachi**
(Agent of Dabur India Limited, disputed territory Jammu and Kashmir India for Hajmola Regular Tablet, Hajmola Pudina Tablet, Hajmola Imli Tablet, Hajmola Nimbu Tablet, Hajmola Anardana Tablet, Hajmola Saunf Tablet and Hajmola Kachha Aam Tablet)

- 09. M/s. Schiwo Pakistan, Multan**
(Agent of Asifac Vet Pharma, Vietnam for Oral Powders for veterinary products)

10. M/s. Sindh Medical Stores, Karachi

(Agent of B-Jain Pharmaceutical (Pvt.) Ltd., India for Specialities, Mother Tinctures, Single Remedies, Bio Chemics, Bio Combination Numbers, Trituration, Lithotherapy and Gemmotherapy)

11. M/s. Matrix Pharma, Karachi

(Agent of B-Jain Pharmaceutical (Pvt.) Ltd., India for Pro-biotics)

Item:-V. **GRANT OF PRODUCTS ENLISTMENT CERTIFICATE TO THE MANUFACTURER AND IMPORTERS AS AGENT OF PRINCIPLE MANUFACTURING**

The manufacturers mentioned in agenda item-III and importers mentioned in agenda item-IV have also applied for Enlistment of products under the Alternative Medicine and Health Products (Enlistment) Rules, 2014. It is proposed that upto twenty priority products per sections from the already submitted applications may be considered for the grant of product Enlistment Certificate subject to verification of applications. It is also proposed that a sub-committee comprising of at least three members of Enlistment Evaluation Committee may be constituted for this purpose to verify the applications and ancillary matters connected there with.

2. Likewise upto ten products per sections or applied products from the overseas manufacturers may also be allowed for the grant of Products Enlistment Certificate after verification of applications by the above mentioned subcommittee.

Item:- VI. **PRICING OF ENLISTED PRODUCTS**

The product approved for enlistment under the rules will also be required to have MRP fixed by the Authority under section 7 of the DRAP Act, 2012, otherwise issuance of product enlistment certificates would be delayed. This is mandate of pricing section under section 4 of DRAP Act, 2012.

Item:-VII **MISCELLANEOUS CASES**

1. Request for withdrawal of Applications:-

Applicants at (**Annex-B**) have requested for withdrawal of their applications submitted before the authority for enlistment certificates due to their own problems.

2. Incomplete Applications and Non Reply of the Applicants:-

Applications deficient in documents and information (**Annex-C**) were issued notices for rectification of shortcomings but they did not reply. Reminders were also sent but majority of them have once again not replied.

3. Notices Returned back to the Division:-

In some cases the notices sent to applicants were returned back to the Division undelivered.

Disclaimer: -

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