Minutes of 13th Meeting of Enlistment Evaluation Committee (EEC) held on 05th August, 2016

No. F. 10-09/2016-DDC (Health & OTC)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
DRUG REGULATORY AUTHORITY OF PAKISTAN
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Islamabad, the 5th August, 2016

MINUTES OF THE 13TH MEETING OF ENLISTMENT EVALUATION COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH PRODUCTS

13th Meeting of the Enlistment Evaluation Committee (EEC), constituted under Rules 7 of the Alternative Medicines and Health Products (Enlistment) Rules, 2014, was held in the office of the Chairman of the Committee on **05th August, 2016**. Meeting of Committee was attended by the following:-

S. #.	Name & Designation	Position in the Committee
1.	**Abdul Samad Khan,** 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. Shahzad Hussain,** Chief, DC & TMD, NIH (Ex- Officio Member)	Ex-Officio Member
7.	**Dr. Amjad Ali,** Chief, Nutrition Division, NIH	Ex-Officio Member
8.	**Mr. Muhammad Amin,** Deputy Director (PER Division)	Observer **-Not Present-**
9.	**Mr. Adnan Faisal Saim,** DDC, QC (1&2)	Observer

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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. 1. GRANT OF ENLISTMENT CERTIFICATE TO THE MANUFACTURERS

Enlistment Evaluation Committee (EEC) examined and discussed the record / panel inspection reports of the following firms 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/ Decision
1.	**M/s. Royal Laboratories,** 22-24 Farooq Industrial Estate, 20 Km Ferozepur Road, Lahore.	**Sections:-** 1. Tablet 2. Oral Liquid 3. Encapsulation 4. Cosmetics Preparation 5. Sachet
2.	**M/s. Arshzik (Veterinary),** 23 Km Near Al-Ghani CNG, G.T. Road, Rawat Rawalpindi.	**Sections:-** 1. Oral liquid, 2. Powder
3.	**M/s. SAIA Health Care,** Plot C-167-B, Sector 35-A, Zaman Town, Korangi Township, Karachi.	**Sections:-** 1. Medicated Soap 2. Cream, Lotion & Medicated shampoo .
4.	**(M/s. Novatec Hbm Neutriceutical & Cosmetics)** **M/s. Deforbio Nutraceutical,** 1-Main Canal Road, Harbans Pura, Lahore.	**Sections:-** 1. Tablet 2. Capsule 3. Sachet 4. Syrup 5. Cream / Ointment
5.	**M/s. Trends Pharmaceuticals (Nutraceuticals & Cam Division,** 546-547, Sundar Industrial Estate Lahore. 1.	**Sections:-** 1. Oral Tablet 2. Oral Liquid 3. Sachet
6.	**M/s. Curative Pharmaceutical (Pvt) Ltd,** Plot 34, Street S-5, National Industrial Zone (RCCI) Rawat, Rawalpindi.	**Additional Sections:-** 1. Capsule 2. Tablet

7.	**M/s. Kaap Pharmaceutical (Pvt) Ltd,** 18 Km, Ferozepur Road, Lahore.	**Sections:-** 1. Tablet 2. Capsule 3. Oral Liquid
8.	**M/s. Innovatrium Nutraceuticals,** Opp. Royal Village Restaurant, 8Km Rawat, GT Road, Rawat, Islamabad	**Sections:-** 1. Tablet 2. Sachet 3. Sami Solid 4. Syrups / Oral Drops 5. Capsule
9.	**M/s. Phytotia Laboratory,** 28/28-C, Small Industrial Estate, Kohat Road, Peshawar.	**Sections:-** 1. Tablet 2. Syrup 3. Sachet
10.	**M/s. ARK Laboratories,** Plot 36, Phase 1&2, Industrial Area, Hattar, KPK	**Sections:-** 1. Syrup 2. Tablet 3. Ointment 4. Capsule 5. Sachet
11.	**M/s. Sancura Pharmaceutical Pakistan,** Plot 99/5, Ibrahim Hyderi, Sector-48, Korangi Industrial Area, Karachi	**Sections:-** 1. Capsule 2. Tablet 3. Sachet 4. Softgel 5. Oral Liquid
12.	**M/s. Alomed Curatives ISB,** Plot 253, Industrial Triangle Kahuta Road, Islamabad.	**Sections:-** 1. Topical Liquid 2. Oral Liquid 3. Oral Powder
13.	**M/s. Xecutive Pharma,** 171-S Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore	**Sections:-** 1. Tablet 2. Oral Liquid
14.	**M/s. Viegen Pharma, Plot No. 74-G, Sundar Industrial Estate, Lahore-Pakistan**	**Sections:-** 1. Tablet (Alternative) 2. Oral Liquid (Alternative) 3. Sachet (Alternative)

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A. Not Recommended by Panel

1	**M/s. Innovative Acme Pharma,** Pot 54, Sector 23, Korangi Industrial Area, karachi **Sections:-** 1. Sachet Section 2. Tablet Section 3. Syrup Section 4. Ointment / Cream Section	01-07-2016	01. Area FID, DRAP, Karachi. 02. Analyst, CDL, DRAP, Karachi.		Committee rejected the application due to the reasons given in the Inspection Report by the panel.

B. Observation in the Inspection Report

1. **M/s Himont Laboratories (Pvt.) Ltd.,** 17 – Km, Ferozepur Road, Lahore. As agent of **M/s Matxin Laboratories Pvt. Ltd.,** Plot No. M-11, 7th Cross, 1st Stage, Peenya Industrial Area, Bangalore-560058, **INDIA.**
Inspection Report Observation:-

1. B.M.R is not maintained properly
2. Health Checkup records not found
3. Inspection book (Form 35) is not maintained
4. GMP and Ayurvedic License are not displayed in unit
5. Distribution records not maintained
6. Rejected goods area is maintained
7. D.M water is used for the unit

Decision:-

EEC rejected the application for the grant of enlistment due to above mentioned observations in the inspection report

ITEM:-III GRANT OF ENLISTMENT CERTIFICATES TO IMPORTERS AS AN AGENTS OF PRINCIPLE MANUFACTURERS.

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

1. **M/s. Alpha Omega Integrated Services, Flat No. 12, Al-Hameed Plaza, G-11 Markaz, Islamabad.** As agent of M/s. Alfa Vitamins Laboratories, Inc. 47011 NW 77th Avenue , Miami, Florida, 33166, USA.

2. **M/s. Base 6 (Pvt) Ltd, E-216, Street No. 6, Cavalry Ground, Lahore Cantt.** As agent of M/s. Factor Group of Nutritional Companies Inc., 1550 United Boulevard, Coquitlam, British Columbia, Canada.

3. **M/s. Multi Med Health Care, Plot 17, Street 1, Sector 19, Korangi Industrial Area, Karachi**. As agent of M/s. GBL GUL Biyoloji LaboraturariSanayiveTicaret Limited Siketia, IMES SanayiSitesi C Block 305 Sokak No. 16 EsenehirUmraniye Istabul, Turkey.

4. **M/s. Allmed Laboratories, A-21/3, KDA Scheme No1 (Ext.), Stadium Road, Karachi.** As agent of M/s. Recipharm Parests, S.L. C/Ramo y Cajal, 2, Parests del Valles, 08150 Barcelona.

5. **M/s. Inchem International, Office No.4, Beaumont Plaza, Beaumont Road, Karachi.** As Agent of M/s. Nutri-Ad International NV, Schietstandlaan 2 2300 Turnhout, Belgium

6. **M/s. Angelini Pharmaceuticals (Pvt) Ltd, 221Block CCA, Phase 4, DHA, Lahore.** As agent of M/s. Gelnova Laboratories (India) Pvt. Ltd., C-125, TTC Industrial Area, Mahape, Pawane, Navi Mumbai 400 705, Maharashtra, India

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. It was also decided that product specific free sale certificates shall be required for the Importers who want to import from the principal having multiple agreements with the Pakistani Importers. Only one similar formulation could be enlisted into Pakistan for a particular product by any of the agent.

B. M/s. Add Health Pharma, House 108, Street 26-A, Chaklala Scheme-3 Extension, Rawalpindi. As agent of M/s. Kingherbs Limited 2-603

The court was informed through written parawise comments that:-

"The application is incomplete as informed to the petitioner for fulfillment of legal requirements. Admittedly the herbal products have been included under the definition of drug and petitioner is bound to fulfill legal requirements for obtaining enlistment certificates. Following documents dully issued by the Food and Drug Administration of China and certified by the Embassy of Pakistan are still deficient.

i) GMP certificate.
ii) Manufacturing Authorization.
iii) Agency Agreement with the Principal Manufacturer dully attested from the Embassy of Pakistan.
iv) Application for Danshen Capsule enlistment will be evaluated once the process of company enlistment is completed and petitioner is granted enlistment certificate as agent of Principal

Manufacturer. Hence requirements for the product enlistment have not been so far asked from the petitioner".

The Honorable court after hearing the case dismissed the petition of Mr. Adnan Attaullah of M/s. Add Health Pharmaceutical and passed detailed judgment as the applicant has still failed to complete his application.

Decision:-

The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firm and rejected the case on the basis of being incomplete as per prescribed criteria.

ITEM:-IV

A. Incomplete applications submitted by the contract giver for contract manufacturing.

A number applicant filed applications which are incomplete and does not fulfill the legal requirements as prescribed under the Alternative Medicines and Health Products (Enlistment) Rules, 2014. Deficiencies letter were issued to the applicants but the failed to complete their applications. It is pertinent to mention here that most of the contract acceptors also failed to obtain enlistment as manufacturer.
List of applicants is placed as **(Annex-A).**

Decision:-

1. The Enlistment Evaluation Committee considered the applications/ record and evaluated the application for enlistment of the above firm and rejected the case on the basis of being incomplete as per prescribed criteria.
2. As per policy defined by the Authority the applicants are not licensed / enlisted manufacturers as decided by the Authority.

B. PERSONAL HIRING

3. M/s. Scotmann Nutraceuticals, Plot No. 22, Sector G-6 Markaz, Islamabad. M/s. Scotmann Nutraceuticals, applied for the contract manufacturing as contract giver from M/s. Wilson Health Care, Islamabad as contract acceptor as per policy finalized by the Authority in its 35th Meeting of the Authority held on 18th July, 2016.

   And decided as under:-

   "For Contract Manufacturing of Alternative Medicine and Health OTC Products, same criteria shall be adopted as applicable to the allopathic drugs, that is between manufacturer to manufacturer having either license

of drug manufacturing or enlistment establishment certificate for Alternative Medicines and Health & OTC Products".

M/s. Scotmann Nutraceuticals already approached to the Honorable Lahore High Court, Lahore which has directed to disposed off the application of the petitioner within 02 months period which is going to completed on 07-08-2016. Accordingly personal hearing notices has been issued as under:-

Reference to your applications for the grant of Enlistment of following products on contract bases by M/s. Wilson Health Care, Islamabad. You are hereby required to appear before the Enlistment Evaluation Committee Meeting scheduled to be held on 5-08-2016 at 11:30AM and present your point of view to support your applications.

i. Sunny D STAT Softgel
ii. Sunny D JR Spray
iii. Sunny D 500 Softgel
iv. Emkay-D Softgel
v. Sunny D Drops.

4. You are also advised to bring all the supportive / written documents, which could support your application on contract manufacturing.

Decision:-

Mr. Tipu Sultan presented the case of M/s. Scotman Nutraceuticals. He produced Public Notices issued by the Authority, rules for contract manufacturing and copies of application submitted by the firm. After scrutiny of applications, public notice and going through the Alternative Medicines & Health Products (Enlistment) Rules, 2014, and relevant provisions of the DRAP Act, 2012. The Enlistment Evaluation Committee made following decisions.

"The applications of Sunny D STAT Softgel, Sunny D JR Spray , Sunny D 500 Softgel, Emkay-D Softgel and Sunny D Drops are rejected due to the following reason.

1. "For Contract Manufacturing of Alternative Medicine and Health OTC Products, same criteria shall be adopted as applicable to the allopathic drugs that is between manufacturer to manufacturer having either license of drug manufacturing or enlistment establishment certificate for Alternative Medicines and Health & OTC Products".
2. Sunny-D 3, is the registered brand of M/s. Scotman Pharmaceutical, Islamabad which is a license manufacturer under the Drug Act, 1976.
3. That the public notice referred by the applicants clearly states that "It is further informed that manufacturer, import, marketing, supply and stocking of unapproved alternative medicines and health products with DRAP is an offence under the DRAP Act, 2012.
4. That manufacture, import and sale of un- registered (un-enlisted) products is prohibited under schedules of the DRAP Act, 2012 and the applicant could not claim natural right of manufacturing already.

5. That the enlistment to M/s. Wilson Health Care, Islamabad was granted vide Enlistment No. 0017 dated 21-09-2015, hence earlier eligibility as manufacturer could not be claim under the DRAP Act, 2012 and Rules framed there under.
6. That the applications do not qualify the contract, contract giver, contract acceptor and provision of Rules-6 as defined under the Alternative Medicine and Health Products (Enlistment) Rules, 2014.
7. However the applicants may apply under the name of M/s. Scotman Pharmaceuticals license manufacturing unit which is their sister concern fulfilling the codal formalities as defined under the DRAP Act, 2012 and rules framed there under.

5. **M/s New Shaheen Pharma,** Commercial-13, Block-A, Kazimabad, Model colony, Malir, Karachi.

1		06-05-2016	01. H/Dr. Ahsan Shafi Memon, Assistant Director Homoeo, Sindh Hyderabad. 02. Mr. Abdul Rasool Shaikh, Area FID, DRAP, Karachi.	Good	Panel recommended grant of enlistment certificate for manufacturing authorization. **After verification it was revealed that Area FID of the Malir is Mr. Obaid Ali.**

The case of M/s. New Shaheen Pharma was discussed in 11th Meeting of EEC held on 13-05-2016 and following decision was passed.

> "Deferred for inspection by the panel nominated in the letter issued from the Division of Health & OTC products, because as verified by the DDC, QC (Mr. Adnan Faisal Saim) representing QC Division that Mr. Obaid Ali is Area, FID for Malir, Karachi where the facility exists".

Accordingly the applicant was conveyed the decision of EEC vide this Division letter No. F-1-2358/2015-DDC (Health & OTC) dated 18th May, 2016 and was asked to ordinate with the panel for inspection, but M/s. New Shaheen Pharma submitted presentation vide their letter dated 19th May, 2016 and claimed that Mr. Shaikh Abdul Rasool, FID is Area FID while name of Mr. Obaid Ali, FID District Malir have been wrongly mentioned in the decision. The address of New Shaheen Pharma commercial 13 Block-A, Kazimabad, Model Colony Malir, Karachi is for the purpose of delivery of our postal letters. We mentioned the word Malir because Model Colony is in the jurisdiction of the District East, Karachi. All the judicial matter of the Model Colony heard before the Court of District East, not the in the Court of District Malir. They have also enclosed the notification of federal Election Commission of Pakistan Notification No. F-6(2)/2013-LEG(S) dated 10th November, 2013; whereas per their claimed it is clearly motioned that Model Colony is the jurisdiction of District East.

Decision:-

1.	**M/s New Shaheen Pharma,** Commercial-13, Block-A, Kazimabad, Model colony, Malir, Karachi.	EEC approved the following section after verification of jurisdiction by the DDC (QA) in writing **Section: -** Capsule

ITEM:-V

Agency agreement is require by the importers duly issued by the principal manufacturer as agent in Pakistan. Different applicants file information which sometimes does not fulfill the codal formalities. As the said document is to be legalized and attested by the embassy of Pakistan, this creates problems including delays in the applications. To avoid controversies and delays a uniform format has been prepared as applicable internationally, so that the applicants should forward the same to the principal manufacturers applicable for every importer as under:-

"Power of Attorney to accompany an application for issue of Enlistment for import of Alternative Medicines & Health Products under the Alternative Medicines & Health Products (Enlistment) Rules 2014

Whereas, M/s.----------hereinafter to be known as **Authorized Agent** of us, intends to apply for Enlistment under Alternative Medicines & Health Products(Enlistment)Rules 2014, for the import, use and marketing into Pakistan , of annexed the Alternative Medicines & Health Products**(Annex A).**

1. We, M/s. ---------- hereinafter to be known as the **Principal Manufacturer**, having the **factory premises** at… ……..,
    i. That we are manufacturer authorization holder vide authorization No……dated……..(**Annex B).** and/or
    ii. That we are holder of product marketing authorization vide authorization, free sale certificate or Certificate of pharmaceutical product (COPP) & are owner of product license (**Annex C).**
    iii. That We have been issued Certificate of Good manufacturing Practice based on inspection by the Regulatory Authority of Country of Origin which is valid for …… **(Annex D).**
    iv. That the products are released by my in-house laboratory or private laboratory certified by the …….

v. That my authorized premise remains under periodic inspection by the regulatory Authority & copy of last inspection report is attached **(Annex E).**

vi. That the all the above documents are being attested under my authorized representative Namely ……from the embassy/Consulate of Pakistan

2. Hereby delegate **Power of Attorney** that for a period of ……years:-

(a) The said applicant shall be our Authorized Agent for the Alternative Medicines & Health Products imported into Pakistan under the our brands only, under rule 3 of Alternative Medicines & Health Products (Enlistment) Rules 2014

(b) We shall comply with all the conditions imposed on the Registration Certificate, for import of Alternative Medicines& Health Products as required under the provisions of DRAP Act 2012 & Alternative Medicines & Health Products (Enlistment) Rules 2014

(c) We declare that we are carrying on the manufacture of the Alternative Medicines& Health Products at the premises of the supporting Manufacturers and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.

(d) We shall comply with the provisions of conditions of enlistment laid down under Alternative Medicines& Health Products (Enlistment) Rules 2014.

(e) Every Alternative Medicines& Health Products got manufactured by us for import under the Enlistment Certificate into Pakistan shall conform to the specifications given in Certificate and the Alternative Medicines& Health Products (Enlistment) Rules 2014 as amended from time to time

(f) We shall inform to the Authority within 30 days in the event of any change in variants or in category or in manufacturing location or in labeling original documentation of any of the Alternative Medicines& Health Products pertaining to the certificate to be granted to us.

(g) We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawal regulatory restriction, or cancellation of authorization and/or 'Not of standard quality report' report of any Alternative Medicines& Health Products pertaining to the Enlistment Certificate declared by any Regulatory Authority of any country where the Product is marketed/sold or distributed. The dispatch and marketing of the Alternative Medicines& Health Products in such cases shall be stopped immediately and the Authority shall be informed immediately.

(h) We shall comply with such further requirements, if any, as may be specified, by the Government of Pakistan, under the Act and the rules, made there under.

(i) We shall allow the licensing authority or any person authorized by him in that behalf to take samples of the Alternative Medicines& Health Products concerned for test, analysis or examination, if considered necessary by Authority.

We declare that the M/s……..holds exclusive rights as authorized agent for the products attached with this power of Attorney and no other party holds such rights in Pakistan.

(Signature on behalf of Principal manufacturer, with name, designation, date and place).

NAME:

DESIGNATION:

DATE:

SIGNATURE & STAMP

Manufacturing Address(s): Signature on behalf of Authorized Agent in Pakistan with name, designation, date and place.

NAME:

DESIGNATION:

DATE:

SIGNATURE & STAMP

(To be attested by Consulate or Embassy of Pakistan in the Country of origin after legalization by the authorized law firm)".

Decision:-

The Committee approved the format of the power of attorney by the principal manufacturer for uniform application on the applicants applying after this decision or not submitted duly attested agency agreement.

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ITEM:-VI

Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services Regulations & Coordination
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LABELLING GUIEDLINES

Manner of Labeling

Following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any finished product and on every other covering in which the container is packed, namely :-

(*i*) the brand name of the alternative *medicine or health product*−

Provided classical Unani medicines or classical homeopathic medicines shall be labeled by generic names appearing in the relevant authoritative book.

(ii) the word "traditional medicine" or "Unani medicine" or "herbal medicinal product" or "phytomedicines: or "homeopathic medicines" or :food supplement" or "probiotic" or "traditional Chinese medicine" or any other category of product as the case may be shall appear on the label of alternative medicines or health product after the brand name or classical name -

(*iii*) the proper name of the *medicine or health product* shall be printed or written in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name and shall be—

(*a*) for all products the name given therein;

(*b*) for alternative *medicine and health products* included in the specified publication or the official pharmacopoeias and official compendia the name or synonym specified in the respective official pharmacopoeias and official compendia of standards followed by the letters pharmacopoeia like B.P or USP or 'I.P., or UPI or CP or KP or JP, as the case may be, by the recognized abbreviations of the respective official pharmacopoeias and official compendia of standards;

Provided preparations conforming to specification's monographs (SP) shall bear the words SP instead of any pharmacopoeia.

(c) classical Unani, Ayurvedic , Siddah shall be represented by the proper name or generic name as mentioned in the Authoritative Books of respective system of treatment and such products could not be represented by brand names;

(*d*) for alternative *medicine* and health products included in the National Formulary of USA or British or India, the name or synonym specified therein followed by the letters US NF or'N.F.I.';

(*e*) for other alternative *medicine*s or health products , the international non-proprietary name, if any, published by the World Health Organization or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance;

(*iii*) A correct statement of the net content in terms of weight, measure, volume, number of units of contents, number of units of activity, as the case may be, and the weight, measure and volume shall be expressed in Metric system--

(*iv)* the content of active ingredients shall be expressed−

(*a*) for oral liquid preparations in terms of the content per single dose, being indicated in 5 milliliters:

Provided that where the dose is below 5 milliliters the contents of active ingredients may be expressed in terms of 1 milliliter; or fraction thereof:

Provided further that where the single dose is more than 5 milliliters, the content of active ingredients shall be expressed in terms of minimum single dose as approved by the Authority;

(b) for tablets, capsules, pills and the like, in terms of the content in each tablet, capsule, pill or other unit, as the case may be;

(e) for other preparations, in terms of percentage by weight or volume or in terms of unit percentage per gram or milliliter, as the case may be:

(v) The name of the manufacturer and the address of the premises of the manufacture where the alternative *medicine or health product* has been manufactured or name and address of importer in addition to the name, address and country of origin of the manufacturer:

Provided that if the alternative *medicine or health product* is contained in a small container, it shall be enough if only the name of the manufacturer and his principal place of manufacture is shown--

(vi) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words 'Batch No.' or 'B. No.' or 'Batch' or 'Lot No.' or 'Lot'--

(vii) Every alternative *medicine and health product* manufactured in Pakistan shall bear on its label the license number or enlistment number of the firm or company under which the alternative *medicine* or health product is manufactured, the figure representing the enlistment number being preceded by the words "Enlistment Number or the registration number"

(vii) Alternative *Medicine* or health products and their preparations including combinations with other ingredients shall bear on their labels the date of manufacture, and the date of expiry of potency, and the

maximum retail price (MRP)

(viii) Alternative medicines, *health products* and their preparations including combinations with other ingredients or substances shall bear on the labels

(a) the date of manufacture,

(b) date of expiry of potency fixed by the manufacturer, and

(c) where such alternative medicines or health products are imported, also the number of license under which the *medicine* is imported, preceded by the words "Import License or enlistment number":

(ix) **Warning and Caution statements** (when necessary for safe use) must appear on the Information label of the alternative medicine or health product prominently and conspicuously. For example, the labels of any nutraceutical or food supplement in solid oral dosage form (e.g., tablets or capsules) that contains iron or iron salts for use as an iron source must show the following statement:

WARNING: *Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under the age of six (6.) years Keep this product out ofreach of children. In case of accidental overdose, call a doctor or refer to healthcare facility immediately*

(x) **Directions for Use**: Each alternative medicine or health product must bear adequate directions for use

(xi) **Pregnancy / Breastfeeding Warnings**: The labels of all alternative medicine or health product that are intended for systemic absorption, unless specifically exempted, must contain a general warning under the heading 'Warning' (or 'Warnings' if it appears with additional warning statements) as follows:

"**Pregnant or breast-feeding women shall consult health care professional before use"**

(xii) Imported finished products shall contain Information on halal certification on product labeling from halal certification organizations of the exporting country.

(xiii) Every alternative *medicine or health product* intended for distribution to the medical profession as a free sample shall, while complying with the labeling provisions under clauses (i) to (viii), further bear on the label of the container the words "Physician's Sample—not to be sold' which shall be overprinted.

(xvi) If any preparation contains not less than 3 per cent by volume of alcohol the quantity of alcohol shall be stated in terms of the average percentage by volume of absolute alcohol in the finished products.

(xv) The container of a medicine prepared for treatment of human ailments shall if the medicine contains industrial methylated spirit, or any other poisonous substances for external use shall indicate this fact on the label and be labeled with the words:

"For External Use only and symbol of poison on the label".

(xiv) standard package insert for consumer information as prescribed and approved by the Authority for necessary labeling information shall be included containing product information, posology& administration, recommended indications ,side effects , contraindications ,warnings, precautions , and

interactions etc:

provided warning or contraindication shall be imprinted at prominent place in a more conspicuous manner.

Manner of labeling of Homoeopathic medicines.—(1) The following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any Homoeopathic medicine and on every other covering in which the container is packed—

(i) The words 'Homoeopathic medicine',

(ii) The name of the medicine—

(a) For medicines specified in the Homoeopathic Pharmacopoeias of India or the United States of America or the United Kingdom, or France or the Germany, the name specified in that Pharmacopoeia.

(b) For other medicines, the name descriptive of the true nature of the medicines and approved specifications.

iii) The potency of the Homoeopathic medicine—for this purpose the potency shall be expressed either in decimal, centesimal or millisimal systems.

(iv) In case of Homoeopathic medicine containing two or more ingredients the name of each ingredient together with its potency and proportion expressed in metric system shall be stated on the label.

(v) Name and address of the manufacturer when sold in original containers of the manufacturer. .

(vi) In case the Homoeopathic medicine contains alcohol, the alcohol content in percentage by volume in terms of ethyl alcohol shall be stated on the label:

Provided that in case the total quantity of the pharmacopoeial homoeopathic medicine in the container is 30 milliliters or less, it will not be necessary to state the content of alcohol on the label.

(2) In addition to the above particulars the label of a Homoeopathic mother tincture, trituration or finished products in pharmaceutical dosage forms like tablets, capsules, syrups, external preparations etc.shall display the following particulars: −

(i) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figures representing the batch number being preceded by the words "Batch No." or "Batch" or "Lot Number" or "Lot No." or "Lot" or any distinguishing prefix.

(ii) Enlistment number of manufacturer and of the product.

(iii) Manufacturing date & Expiry date.

(iv) Maximum retail price (MRP).

(v) The name and address of the manufacturer.

(3) No Homoeopathic medicine containing a single ingredient shall bear a proprietary name on its label.

Prohibition of quantity and percentage.–No Finished product of Homoeopathic medicine containing more than 12% alcohol v/v (Ethyl alcohol) shall be packed and sold in packing or bottles of more than 30 milliliters for retail sale, except dispensing packs to be sold to hospitals/ registered homeopathic practitioners or manufacturers of homeopathic dosage forms in packings or bottles of not more than 100 milliliters.

Provided mother tinctures and dilutions to be used by manufacturers as a starting material to manufacture their enlisted or registered products could be packed in larger packings subject to approval by the Authority.

Provided further that traceable records for manufacturing and sale of such consignments shall be maintained by both parties.

Exemption: Exemption of certain Alternative medicines from certain provisions.—

(1) Labels on packages or containers of alternative *medicines and health products* for export shall be adapted to meet the specific requirements of the law of the country to which the finished product is to be exported but the following particulars shall appear in a conspicuous position on the innermost container in which the product is packed and every other covering in which that container is packed:

(a) name of the alternative medicine or health product;

(b) the name, address of the manufacturer and the enlistment or license number and product registration number under which the product has been manufactured;

(c) batch or lot number;

(d) date of expiry, :

(2) This, shall not apply to alternative medicine made up ready for treatment, whether after or without dilution, which is supplied on the prescription of a registered practitioner provided that:

(*i*) the alternative medicine or health product is labeled with the following particulars: –

(*a*) the name and address of the supplier;

(*b*) the name of the patient and the quantity of the alternative medicine;

(*c*) the number representing serial number of the entry in the register;

(*d*) the dose, if the medicine is for internal use;

(*e*) the words "FOR EXTERNEL USE ONLY" shall be printed on the label if the alternative medicine is for external application.

(*ii*) Any other condition applicable under this is satisfied.

Labeling of Baby Milks and Foods

Guidelines for Use of Nutrition and Health Claims apply to infant formula and formula for special medical purposes for infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards. In addition to these requirements the following specific provisions apply:

(1) The Name of the Food

The text of the label and all other information accompanying the product shall be written in the English and Urdu language.

(i) The name of the product shall be either "Infant Formula" or any appropriate designation indicating the true nature of the product, in accordance with national usage.

(ii) The sources of protein in the product shall be clearly shown on the label.

(iii) If cows' milk is the only source of protein, the product may be labelled "Infant Formula Based on Cows' Milk".

(iv) A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

(2) List of Ingredients

(i) A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

(ii) The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

(3) Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information which should be in the following order:

The amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grams or per 100 milliliters of the food as sold as well as per 100 milliliters of the food ready for use, when prepared according to the

instructions on the label.

The total quantity of each vitamin, mineral, choline and any other ingredient as listed in per 100 grammes or per 100 milliliters of the food as sold as well as per 100 milliliters of the food ready for use, when prepared according to the instructions on the label.

In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

(4) Date Marking and Storage Instructions

The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer.

In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon.

Where practicable, storage instructions shall be in close proximity to the date marking.

(5) Information for Use

Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.

Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet.

The label shall carry clear graphic instructions illustrating the method of preparation of the product.

The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

Adequate directions regarding the storage of the product after the container has been opened shall appear on the label and in any accompanying leaflet.

(6) Additional Labeling Requirements

Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

the words "important notice" or their equivalent; the statement

"Breast milk is the best food for your baby"

or a similar statement as to the superiority of breastfeeding or breast milk;

a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use.

The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula.

The terms "humanized", "maternalized" or other similar terms shall not be used.

Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes

(7)Additional Labeling Requirements Formula for medical purpose

Formula for Special Medical Purposes Intended for Infants shall be labeled with the additional information as specified in Sections 4.4.1, 4.4.3, 4.4.4, 4.5.1 and 4.5.5 of CODEX STAN 180-1991.

A prominent statement indicating that the product is intended as the sole source of nutrition shall appear on the label.

In addition, the information specified in Sections 4.5.2, 4.5.3 and 4.5.6 of CODEX STAN 180-1991 shall be included on the label or be provided separately from the package.

Labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended

(8) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figures representing the batch number being preceded by the words “Batch No.” or “Batch” or “Lot Number” or “Lot No.” or “Lot” or any distinguishing prefix.

(9) Enlistment number of the product, Maximum retail price (MRP), the name and address of the manufacturer shall also be printed on the label of the product.

Labeling of medicated cosmetic products

For the purposes of this section, no person shall supply any cosmetic product unless the cosmetic product has a label that sets out the following information:

(1) the name of the cosmetic product;

(2) the function of the cosmetic product, except when it is clear from the presentation of the cosmetic product;

(3) the instructions on the use of the cosmetic product, except when it is clear from the name or presentation of the cosmetic product;

(4) the list of all the ingredients in the cosmetic product, with the exception of the following substances:

(5) impurities in the raw materials used;

(6) subsidiary technical materials used in the preparation of the cosmetic product but not present in the final product; or

(7) materials used in the manufacture of the cosmetic product in strictly necessary quantities as solvents, or as carriers for perfume and aromatic compositions;

(8) the weight or volume of the cosmetic product contained in the immediate container or package, expressed in metric system;

(9) the batch number given by the person who manufactured the cosmetic product to the batch of which it forms a part;

(10) the name and address in of the person responsible for placing the cosmetic product in the market;

(11) the name of the country where the cosmetic product was manufactured;

(12) any special precautions to be observed when using the cosmetic product, or special precautionary information in accordance with any requirements for safety of consumer which are relevant to that cosmetic product;

(13) the date of expiry of the cosmetic product where the cosmetic product has an expected period of durability of less than 30 months between the date of its manufacture and the date of its expiry; and

(14) the date on which the cosmetic product was manufactured, except when the expiry date of the cosmetic product has been specified on the label.

(i) Paragraph (1) (*h*), (*i*), (*j*) and (*k*) shall not apply to an existing cosmetic product available in the market.

(ii) The information specified in paragraph (1) shall appear in the following manner:

a) where the cosmetic product has an outer packaging, the information shall appear on the outer packaging of the cosmetic product;

b) where the cosmetic product does not have an outer packaging, the information shall appear on the immediate container or package of the cosmetic product; and

c) where the size, shape or nature of the container or package does not permit all the information specified in that paragraph to be displayed, the information may appear in a leaflet that accompanies the product or on a display panel placed together with the product, provided at least the information specified in paragraph (1) (*a*) and (*f*) shall appear on the immediate container or package.

(iii) The list of ingredients specified in paragraph (1) (*d*) shall appear in the following manner.

a) where an ingredient appears in the latest edition of any of the standard references listed in the Schedule, that ingredient shall be named according to the nomenclature in that standard reference, except for —

any perfume or aromatic composition, which may be referred to by the term "perfume", "fragrance", "aroma" or any other similar term; and
any flavouring, which may be referred to by the term "flavour" or any other similar term; andthe ingredients shall be listed in descending order by weight, except for —
ingredients, other than colouring agents, present in concentrations of less than 1% (by weight), which may be listed in any order by weight after those ingredients present in concentrations of 1% or more; and

(iv) Colouring agents, which may be listed in any order after the other ingredients?

(v) All information on the label of a cosmetic product shall be provided in the English language, or Urdu(optional) but nothing in this paragraph shall prevent such information from being provided in any other language as well.

(vi) All numbers, letters and symbols used in providing the information on the label of a cosmetic product shall be printed in such a manner as to be legible, permanent, indelible and prominent.

(vii) If a symbol or code (whether in the form of a colour or otherwise) is used in providing the information on the label of a cosmetic product, an explanation of the symbol or colour shall be provided.

Labeling of Disinfectants.

(1) -Subject to these guidelines, the label on the container shall state-

(a) the name of the product,

(b) the name and full address of the manufacturer,

(c) grade, type, R.W. Coefficient of product,

(d) date of manufacture,

(e) quantity present in the container,

(f) indications and mode of use, and

(g) expiry date up to which the product can be used.

(h) enlistment number, Batch no or lot no

(i) M.R.P

The words "for external Use only and symbol of poison on the label" shall appear on the label prominently

Misleading Labeling,

(1) No person shall supply any alternative medicine, health product, baby milk and foods or any cosmetic product with a label which contains any statement, trademark, picture or other sign —

(a) to the effect, whether directly or indirectly, that the supply or use of the product is being promoted or endorsed by the Authority; or

(b) that is likely to create an erroneous impression regarding the formulation, composition, quality or safety of the medicine, health product, baby milk and foods or cosmetic product; or making a false, unapproved or exaggerating label claims or concealing information which is necessary to be included in the labeling for consumer safety.

(d) information except the prescribed one.

(2) No one shall mention any type of certification on the label, unless the Authority have reviewed the information submitted by applicant and necessary sanction has been granted to do so..

NON-PERMISSIBLE INDICATIONS

(1) Following diseases are incurable and could not be claimed to be curable by treating with any alternative medicine or health product.

S.NO.	NON-PERMISSIBLE INDICATIONS
1.	Disease or defects of the kidney
2.	Disease or defects of the heart
3.	Diabetes

4.	Epilepsy or fits
5.	Paralysis
6.	Tuberculosis
7.	Asthma
8.	Leprosy
9.	Cancer
10.	Deafness
11.	Drug addiction
12.	Hernia or rupture
13.	Disease of the eye
14.	Hypertension
15.	Mental disorder
16.	Infertility
17.	Frigidity
18.	Impairment of sexual function or impotency
19.	Venereal disease
20.	Nervous debility or pother complaint of

infirmity arising from or relating to sexual intercourse.

LABELLING REQUIREMENTS

(1) Label (mock-up) for immediate container, outer carton for medicine and food supplement.

Outer Unit Carton, Immediate & Blister/ Strips Labels

The following information shall be present on the label of the product:

No.	Parameters	Outer Carton (Unit Carton)	Immediate Labels	Blister/ Strips
1.	Product Name	yes	yes	yes
2.	Dosage Form	yes	yes	NA
3.	Name of Active Substance(s	yes	yes	yes
4.	Strength of Active Substance(s	yes	yes	yes
5.	Batch Number	yes	yes	yes
6.	Manufacturing Date	yes	yes	NA
7.	Expiry Date	yes	yes	yes
8.	Route of Administration	yes	yes	NA
9.	Storage Condition	yes	yes	NA
10.	Country's Enlistment Number	yes	yes	NA
11.	Name & Address of Product Enlistment Holder (EH)	yes	yes	Name/ Logo of Manufacturer/ Product Owner
12.	Name & Address of Manufacturer	yes At least name of town/ city and	yes At least name of town/ city and	NA

		country of manufacturer	country of manufacturer	
13.	Warnings and/or Specific Labelling (if applicable)	yes	yes	NA
14.	Pack Sizes (unit/ volume)	yes	yes	NA
15.	Name & content of preservative(s) where present	yes	yes	NA
16.	Name & content of alcohol, where present	yes	yes	NA
17.	To declare source of ingredients derived from animal origin, including gelatin (active, excipient, and/or capsule shell)	yes	optional	NA

18.	Recommended daily allowance (RDA) for vitamins/ multivitamins/ mineral preparations used as food supplements	yes	optional	NA
19.	The words "Keep medicine out of reach of children" or words bearing similar meaning in both *Urdu* & English	yes	yes	NA
20.	Other country specific labeling requirements (if applicable)	yes	optional	NA
21.	Security Label (Hologram)	optional	optional	NA

Notes:

NA - Not applicable

(i) For multi-vitamins and minerals preparations it is suggested to label as multi-vitamins and minerals

(ii) If the product is without an outer carton, the inner label shall bear all the information that is required

(iii) Information on the Product Name and Name and Strength of active ingredient(s) must be printed repeatedly.

(iv) In case of no outer carton, the security label shall be applied to the immediate labels. The security label shall not be applied onto outer shrink wrap of a product.

STATEMENTS TO BE STATED ON PRODUCT LABELLING

1) The following statements shall also be stated on the product label, where applicable:

For product with an indication "For general health/ well-being" please state:

"Please consult your pharmacist / doctor before taking this product"

2) For product with an indication "To relieve symptoms for…. (Any illness) please state: "Please consult your pharmacist/ doctor if symptoms persist/ worsen.*"*.

3) Unless otherwise supported, all herbal/ traditional products label shall state the following general cautionary statement, **EXCEPT** for product with indication for men's health or product for children use only:

"Pregnancy and breastfeeding: Insufficient reliable data"

4) For product with an indication to be taken/ used especially for women, please refer Cautionary Statement for Products Specially Used in Women.

"Keep out of reach of children "also in Urdu.

"Protect from light and moisture."

5) Please state the storage condition according to the temperature stated in stability data.

6) For products containing ingredients as specified below, please add the required statements:

i. Animal part(s):

"This product contains animal part(s)."

Animal origin(s):

ii. "This product contains substance(s) from animal origin."

(Porcine / pig." not allowed):

iii. Alcohol:

"This product contains alcohol."

Please declare the percentage of alcohol contained in the product.

k) For the following dosage forms, please add this statement:

i) Topical preparations: "For external use only."

ii) Liquids and suspensions: "Shake well before use"

Patient Information Leaflet

The following information is required to be included in a package insert:

(i) Brand or Product Name and Proper name

(ii) Name and Strength of Active Substance(s)

(iii) Product Description

(iv) Indication

(v) Dose/ Use Instruction

(vi) Contraindications

(vii) Warnings and Precautions

(viii) Interactions with Other Medications

(ix) Statement on usage during pregnancy and lactation

(x) Adverse Effects/ Undesirable Effects

(xi) Overdose and Treatment

(xii) Storage Conditions (may be omitted if the information is stated on the label or outer carton labels)

(xiii) Dosage Forms and packaging available

(xiv) Name and Address of manufacturer/ product registration holder or product enlistment holder.

(xv) Date of Revision of Package Insert

Patient Information Leaflet (PIL)is compulsory for all products.

a) Self-care products;

b) Over-the-Counter,(OTC) products;

c) Food supplements with high claims (disease risk reduction).

d) Alternative Medicine

For details, please refer to:

i. The draft copy of the PIL in both English and *Urdu shall* be submitted for evaluation.
ii. PIL is compulsory to be sold with the product and will be uploaded onto DRAP website as reference for patients or consumers.

Ingredient Specific Labelling Requirement (Label & Package Insert)

a. ALFALFA

The following boxed warning shall be included on the labels of products containing Alfalfa (*Medico sativa*):

This product contains Alfalfa (*Medico sativa*).

Individual with a predisposition to systemic lupus erythematosus shall consult their physician before

consuming this product.

b. ARGININE

The following statement shall be included on the labels and in the package insert of oral preparations containing Arginine for food supplements:

WARNING:

Arginine is not recommended for patients following a heart attack.

c. ASPARTAME

The following statement shall be included on the labels and in the package insert of products containing Aspartame:

WARNING:

Unsuitable for phenylketonurics

d. BEE POLLEN

The following statement shall be included on the labels and in the package insert of product containing bee pollen:

This product contains Bee Pollen and may cause severe allergic reactions, including fatal anaphylactic reactions in susceptible individuals.

Asthma and allergy sufferers may be at greater risks.

For product containing

e.Black Cohosh (*Cimicifugaracemosa*), please state:

Warning: Stop taking this product if signs and symptoms suggestive of liver injury develop such as tiredness, loss of appetite, yellowing of the skin and eyes or severe upper stomach pain with nausea and vomiting or dark urine and consult your doctor immediately.

- Patients using herbal medicinal products shall tell their doctor about it.

f. For products containing Camphor:

i) The following warning shall be stated on the label:

WARNING: "This product is contraindicated in infants less than 2 years of age. Caution must be exercised when older children are treated"

PRECAUTION: "It is dangerous to place any camphor containing product into the nostrils of children. A small amount applied this way may cause immediate collapse"

- Avoid contact with the eyes.
- Do not apply to wounds or damaged skin.

ii) The following warning and precaution shall be stated on product leaflet:

WARNING: "This product is contraindicated in infants less than 2 years of age. Caution must be

exercised when older children are treated"

PRECAUTION: "It is dangerous to place any camphor containing product into the nostrils of children. A small amount applied this way may cause immediate collapse"

g.For product containing ChelidoniumMajus, please state

- Warning: This Product may cause adverse reaction to the liver.

h. For products containing GAMAT/ STICHOPUS spp. for ORAL USE ONLY, please state:

"Please consult your pharmacist, doctor, or other healthcare providers about any other supplements/ medications you are taking and other health care problems. There may be a potential for interactions or side effects."

i. For product containing Ginkgo biloba/ Ginkgo extract, please state:

"As the use of Ginkgo may increase the tendency of bleeding, please consult your physician/ pharmacist if you are on or intend to start using any other medicines and before you undergo any surgical/ dental procedure."

j. For products containing GINSENG (including all PANAX genuses), please state:

- "Contraindicated in pregnant women."
- "Safe use in lactating women and children has not been established."
- "Do not exceed the stated dose."
- "Safety on long term use has not been established."

For product containing MomordicaCharantia, please state:

- "Shall not be used in pregnant and breast-feeding women."
- "Be sure to tell your pharmacist, doctor, or other healthcare providers about any other supplements you are taking. There may be a potential for interactions or side effects."

l. For product containing *Pelargonium sidoides*, please state:

m. For product containing Propolis (topical preparation), please state:

"Propolis may cause allergic skin reaction."

n. For product containing Propolis (for oral use), please state:

- "This product contains propolis and may cause severe allergic reactions including fatal anaphylactic reaction in susceptible individuals."
- "Asthma and allergy sufferers may be at a greater risk."

o. For products containing Psyllium/ Plantago (Seed/ Husk), please state:

- "If the constipation does not resolve within 3 days or if abdominal pain occurs or in case of any irregularity of faeces, the use of psyllium should be discontinued and medical advice must be sought."
- "Please consume a large amount of fluid/ water when taking this product."

p.For product containing Royal Jelly (for oral use), please state:

- "This product contains royal jelly and may cause severe allergic reactions including fatal anaphylactic reaction in susceptible individuals."
- "Asthma and allergy sufferers may be at a greater risk."

q. For product containing naturally occurring SALICYLIC ACID (e.g. Willow *Salix* spp.), please state:

- "People allergic to aspirin/ other NSAID should avoid this product."

X.For products containing Senna (Cassia spp.) – fruit/ pod/ semen and leaf and Rhubarb/ Radix et RhizomaRhei/ Rheum Palmatum / Rheum Officinalis – root part, please state:

- "Do not use when abdominal pain, nausea or vomiting is present."
- "Frequent or prolonged used of this preparation may result in dependence towards the product and „imbalanced electrolytes".."
- "Please consult a healthcare practitioner for use beyond 7 days."

y. For product containing St. John's Wort, please state:

The product may interact with other medicines. Please consult a doctor/ pharmacist before using it.

z. For product containing substance from seafood, please state:

"Derived from seafood."

20. For product with indication "To regulate menstruation/ to improve menstrual flow", please state:

"Contraindicated in pregnant women."

For product with indication „To reduce body weight", please state these statements, (unless proven otherwise):

- "Balanced diet and regular exercise are essential."
- "Safety on long term use has not been established."

ab. For product containing Red Yeast Rice, please state:

"This product contains naturally occurring lovastatin. Please consult your doctor/ pharmacist before using this product."

"Do not take this product if you are already on statin products (lovastatin, atorvastatin, fluvastatin, pravastatin, simvastatin, rosuvastatin,etc)."

"If you experience any allergic reactions or side effects such as lethargy, body and muscle aches, please stop using this product."

"Concurrent use of fibrates may cause severe myositis and myoglobinuria.

ac. INGREDIENTS DERIVED FROM SEAFOOD

The following statement shall be included on the labels and in the package insert of products.

"DERIVED FROM SEAFOOD"

ad. ROYAL JELLY

This product contains royal jelly and may cause severe allergic reactions including fatal anaphylactic reactions in susceptible individuals.

Asthma and allergy sufferers may be at the greater risk.

ae. SODIUM METABISULPHITE (Excipient)

The following statement shall be included in the package insert of products containing Sodium metabisulphite:

WARNING:

This preparation contains Sodium metabisulphite that may cause serious allergic type reactions in certain susceptible patients. Do not use if known to be hypersensitive to bisulphites.

af.CAUTIONARY STATEMENT FOR PRODUCTS SPECIALLY USED IN WOMEN

Special precaution shall be given to ingredients taken during pregnancy. The Authority urges pregnant women to consult their medical/ traditional health care provider prior to taking any herbal or traditional products. Unless otherwise supported, all herbal/ traditional products label shall state the following general cautionary statement:

"Pregnancy and breastfeeding: Insufficient reliable data"

However, for products containing any ingredients as listed in the following lists, i.e. List of Prohibited Ingredients in Pregnancy and List of Restricted Ingredients in Pregnancy, the following cautionary statement shall be stated in the product label:

i) Prohibited Ingredients in Pregnancy:

"Contraindicated in pregnant women."

ii) Restricted Ingredients in Pregnancy:

"To be used with caution in pregnancy."

The list of herbs contraindicated in pregnancy is rarely in agreement as most herbal products are used in combination. The following list has been compiled based on well documented information as an aid to the industry to comply with the labeling requirement for products used during pregnancy.

GLOSSARY

(a)Adequate Intake (AI): Means the recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate. An AI is used when an RDA cannot be determined

(b) Authoritative Books of Unani Medicines: means recognized books of Unani medicine as prescribed in guidelines for authoritative books, which contain traditional regulatory information about single or compound formulas of classical Unani medicines, their method of preparations and recommended conditions for use.

(c) Batch or Lot Number means

(i) In the case of finished products manufactured by a continuous process, the production resulting in one homogenous mix of the finished products shall be considered as one "Batch".

(ii) In the case of powders, liquid orals, ointments etc., one "Batch Number" shall be assigned to all the containers filled from one homogenous bulk.

(iii) In the case of tablets, capsules, lozenges, troches, etc., one "Batch Number" shall be assigned to the products manufactured from one homogenous mix ready for compression or filling.

***Explanation*. —**For the purpose of tests, representative samples from the containers filled from the homogenous bulk should be taken.

(c) **Classical Unani medicines** means single or compound formulations recorded in the recognized Authoritative Books of Unani System of Medicines.

(d) **Classical Homeopathic medicines** means medicines recorded in the recognized homeopathic pharmacopoeia.

(e) **Indian Pharmacopoeia** means official Pharmacopoeias of India approved under the Drugs & Cosmetics Act of India and include Indian Pharmacopoeia (IP), Ayurvedic Pharmacopoeia of India (API), Sidda Pharmacopeia of India and Unani Pharmacopoeia of India(UPI

(f) **Maximum dosage value:** The highest medicinal ingredient quantity which a product can supply in a daily dose**.**

(g) **Minimum dosage value**: The lowest medicinal ingredient quantity which a product can supply in a daily dose.

(h) Pharmaceutical Necessity: means a substance having slight or no therapeutic value, but used in the preparation of various pharmaceuticals, including preservatives, solvents, ointment bases, and flavoring, coloring, diluting, emulsifying, and suspending agents.

(i) **Recommended Dietary Allowance (RDA):** The average daily dietary nutrient intake level sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group.

(j) **Specification Monograph (SM):** means specifications guideline stemplates and standards used as release specifications for finished Alternative medicines and health products adopting methodoly given in specified publications or internationally recognized methods.

(j) **Tolerable Upper Intake Level (UL):** The highest average daily dose or nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase.

Decision:-

The committee recommended the labeling guidelines to be finalized by the Authority. However it was decided that the member may forward the objection about non permissible indications which would also be forwarded to the Authority.

ITEM:-VII

AUTHORITATIVE BOOKS OF UNANI SYSTEM OF TREATMENT

Authoritative Books of Unani System of treatment contain information single or compound formulas of Unani medicines, their method of preparations and recommended conditions for use.

S.No.	Name of the Books	Author	Publisher	Year of Publication	Language
1	AksirKushtajat	Hakim Ghulam Nabi	MushtabaJadid, Delhi	1929	Urdu
2	KhulasaMurakkabat Bu Ali Sina	Mohd. Aziz	Lahore, Bhatia Company	1344 A.H./ 1925	Urdu
3	TibbMakhfi	Hakim Mohd. Yusuf Hasan	Hamdard Kutubkhana, Lahore	1996	Urdu
4	Al Qarabadeen	Hakim Mohd. Hasan Haziq	Meerut, Nami Press	1893	Urdu
5	QarabadeenEhsani	Mohd. Ehsan Ali Khan	MatbaNizami Kanpur	1322 A.H./ 1904	Urdu
6	QarabadeenAhmadiya	Ahmad Ali Khan	Lahore Mohammadi	1896	Urdu
7	QarabadeenRahimi	Rahim Khan Bhadur	Lahore QadarBaksh	1880	Urdu
8	QarabadeenHussaini	Hakim Noor Hussain	Lahore, Hamidiya Press	1909	Urdu
9	QarabadeenHamidiya	Syed Abdul Hamid	Agra KhwajaSiddiq	1928	Urdu
10	QarabadeenMufidAam	Mohd. Sharif	Moradabad, Mohd.Ismail	1920	Urdu
11	KushtajatKamil	Lok Ram Harishchander	Amritsar 2	1932	Urdu
12	Mujarrabat Bu Ali Sina	Bu Ali Sina	Ajaz Publishing House, Delhi	1994	Urdu

13	Masih-ul-MulkkeMurakkabat	Mohd. Ajmal Khan	Gurgaon, Pataudi	-	Urdu
14	MakhzanSulaimani	Shamsuddin	Lucknow, Naval Kishore	-	Urdu
15	QarabadeenHaziq	Hakim Mohd. Hasan Haziq	Meerut	1894	Urdu
16	ZaadGharib	Saadiq Ali Khan	Matba Hind	1895	Persian
17	QarabadeenShifai	Hakim Muzaffar Bin Mohd. HussainiShifai	Delhi	-	Persian
18	GhinaMuna	Nooh Bin Mansoor	Nizami Press, Lucknow	1925	Arabic
19	MujarrabatAzam	Mohd. Azam Khan	Gupta Printing Press, Delhi	1955	Persian
20	GuldastaMujarrabat	Ilah Bakhsh	Delhi, Mujtabai	1923	Urdu
21	Lubb-ul- Mujarrabat	Hakim Delar Hasan Khan	Qudussi Press, Delhi	P.Y.N.M.	Urdu
22.	Rumooz al Atibba	Mohd. Firozuddin	Lahore Cooperative Steam Press, Lahore	1924	Urdu
23.	QarabadeenNawal	Qanoon Ibn Sina	Press, Lucknow	1906	Arabic
24.	QarabadeenAzam-wa-Akmal	Hakim Akmal Khan	Nawal Kishore		Persian
25.	QarabadeenZakai	Zakaullah Bin Ishaq	Lucknow, Matba Hasan	1925	Persian
26.	QarabadeenJalali	JalaluddinAmrohi	Munshi Naval Kishore, Lucknow	1885/1897	Persian
27.	QarabadeenBaqai	Mohd. Ismail	MatbaMustafai	1270 A.H./1853	Persian
28.	QarabadeenQadri,	Mohammad Akbar Arzani	Delhi Matba Ahmadi Na Mohammadi	1270s/1853	Persian
29.	IlajulAmraaz	Mohd. Sharif Khan	Afzal-ul-Matabi, Delhi	1921	Persian
30.	Khulasah-al-Tajarib	Bahauddaula	Mohammadiwa Ahmadi	1283 A.H./1866	Persian
31.	KhazainulMulook	Hakim Shamsuddin	MatbaNizami	1314 A.H./1896	Persian

		Kanpur,			
32.	Kimia-e-Ishrat, Tuhfajahan	Hakim Syed Karam Hussain	Agra	1938	Urdu
33.	Mujarrabat Akbari	Hakim Akbar Arzani w	Munshi Naval Kishore, Luckno	1925	Persian
34.	QarabadeenKaukabiaur MujarrabatShaukati	YaarMohd. Khan Bhopali	Rampur, Hasani	1305 A.H./1854	Urdu
35.	Sadri Mujarrabat	Mohd. Nawaz Chughtai Urdu	Delhi Star Publications, Delhi		Urdu
36.	Marjul Bahrain	Hakim Abdul Hamid Agra	Akhbar Press, Agra	1924	Urdu
37.	QarabadeenLutfi	Hakim AbdusSattarLutfi	Delhi Ghulam Nizamuddin, Delhi		Urdu
38.	BayazWahidi	Hakim Abdul Waheed (died 1901)	Letho Press, Aligarh	1974	Urdu
39.	MatabMurtaish	Hakim Murtaish (died 1841)	Aligarh University Press, Aligarh	1976	Urdu
40.	MujarrabatAzizi (II Edition)	Hakim Abdul Halim (died 1911)	Rama Printing Press, Lucknow	1953	Persian
41.	KifayahMansoori	Mansoor Bin Mohammad	Lucknow, Naval Kishore	1878	Persian
42.	IlajulGhuraba	Hakim Ghulam Imam	Bareilly, Matba Siddiqi	1864	Persian
43.	DustoorulIlaj	Hakim Mohd. Yaqub	Lucknow	1871	Persian
44.	DustoorulIlaj	Sultan Ali Khurasani	Meerut, Ahmadi	1278 A.H./1861	Persian
45.	Yaqooti Kanpur, Nizami	Wakil Ahmad Sikandar Puri	Kanpur, Nizami	1297 A.H./1879	Persian
46.	RisalaKushtaJaat,	Mohd. ShafiMohd. Hussain	Lahore, Mohammadi	1899	Urdu
47.	Misbah-al-Hikmat	Mohd. Firozuddin	Lahore, RafiqulAtibba	1939	Urdu
48.	Jami-al-Hikmat,	Mohd. Hasan Qarshi Lahore	Mushirul Atibba	1935	Urdu

49.	Miftah-al-Hikmat	Hakim Mohd. Sharif Lahore,	RafiqulAtibba	1931	Urdu
50.	Dustoor-al-Atibba	Hakim Mohd. QasimAstarabadi	Amritsar MatbaNanai	1319 A.H./1901	Persian
51.	Dustoor-al-Atibba	Mohd. Hasan Qarshi	Lahore, Mushirul Atibba	1935	Urdu
52.	TibEhsani	Hakim Ehsan Ali	MatbaMustafai, Kanpur	1277 A.H./1860	Urdu
53.	MujarrabatMehdivi	Mirza Mohd. Mehdi	MatbaNami, Lucknow	1905	Urdu
54.	Madin Al-ShifaSikandarShahi	Bahwa Bin Khawas Khan	Nawal Kishore, Lucknow	1877	Persian
55.	QarabadeenSarkari	Indian Medicine Department, Govt. of AP	Hyderabad	1988	English
56.	QarabadeenMajeedi	-	DaftarJamiaTibbia, Delhi	1945	Urdu
57.	Kitab-al-Hawi (Vol: 1 - 23)	ZakariyaRazi	Daaraal-MaarifalUsmania	1957	Arabic
58.	Kitab-al-Taiseer	Ibn Zohr,	CCRUM,NEW DELHI	1986	Arabic
59.	Kitab-al-Abdal CCRUM,	Zakariyarazi	Delhi	1999	Arabic
60.	RumoozAzam	Mohd. Azam Khan	MatbaMustafai Delhi	1320 A.H./1902	Persian
61.	QarabadeenNajmul Ghani Lucknow,	Hakim Najmul Ghani Khan	Naval Kishor	1928	Urdu
62.	Kitab-al-Mukhtarat	MuhazzibuddinAbul Hasan Ali	DairatulMaarif, Hyderabad	1362 H./1943	Arabic
63.	RisalaJoodiya	Ibn Sina (died 1037 A.D.)	CCRUM, New Delhi	--	Persian
64.	QarabadeenMazhari	Hakim Mazhar Ali	MahboobulMatabi, Meerut	1890/1308	Urdu
65.	DustoorulNajat An Masa'ib al Hummayat	Hakim Asghar Hussain	MatbaNawal Kishore	1914	Urdu
66.	MatabAlvi n	Khan Hakim AlviKha	FakhrulMatabi, Delhi	1869	Persian
67.	DusturulIlajMatba	Hakim Ikram Raza	AinulFuyooz	1883/1301	Urdu

		Khan			
68.	DusturulAtibba (Vol.2)	Hakim Mohd. Hasan Qarshi	MushirulAtibba, Lahore	1935	Urdu
69.	Delhi kaSahihMahtab	Hakim KhwajaRizwan	DarulTaleef, Bijnore	1942	Urdu
70.	GuldastaHikmat	Raja Narain Prasad	Matba.....	1885	Urdu
71.	MujarrabatWaliullah	Mohd. Wali-ul-lah Khan	MatbaVidya Prakash, Agra	1890	Urdu
72.	Silk Marwareed (Vol.1)	Mohd. Hasan Qarshi	MushirulAtibba, Lahore	1935	Urdu
73.	IksirulAmraz Syed	Alamdar Hussain	MatbaNamiMunshi Nawal Kishore	1904	Urdu
74.	Asrare	Hikmat Hakim Abdul Aziz	Lahore	1910	Urdu
75.	Tibb Akbar Hakim i	Mohd. Akbar Arzan	MatbaNamiMunshi Nawal Kishore, Lucknow	1925	Persian
76.	TibbFaridi	Hakim Fariduddin	Madrasi	1940	Persian
77.	Tibb Akbar Matba	Hakim Mohd. Akbar Arzani	NamiMunshi Nawal Kishore, Lucknow	1925	Persian
78.	TibbFaridi	Hakim FariduddinMadrasi		1940	Persian
79.	MujarrabatSultani	Hakim Mohd. Yar Khan	Shahpur (4th edn.)	1946	Urdu
80.	Al Asbabwa Al Alamat	NajibuddinSamarqandi	Nami Press, Lucknow	1906	Arabic
81.	Asrar-al-Atibba	Hakim Abdul Majid	Atiqui Delhi	1926	Urdu
82.	Ainul Hayat	Mohd. Bin Yusuf Harwi (died 1542)	Ibn Sina Academy, Aligarh	2007	Persian
83.	IkseerAzam	Hakim Mohd. Azam Khan	MatbaNizami, Kanpur	1869/1286	Persian
84.	Makhazin–al-Taleem	Hakim Mohd. Sadiq Ali Khan	MatbaNamiMunshi Nawal Kishore, Lucknow	1872	Persian

85.	Taksheef-al-Hikmat	Hakim Mohd. Salim Khan	MatbaNamiMunshi Nawal Kishore, Kanpur	1885	Persian
86.	Zia-ul-Absar Fi Had-il-Bah	Hakim Mehmood Khan	MatbaNamiMunshi Nawal Kishore, Kanpur	1871	Urdu
87.	Takmeel-al-Bahrain (Vol.2 & 5)	Hakim Ahmad Ali Khan	RifaahAam/Shamim Press, Lahore	1905	Urdu
88.	QarabadeenRazai	Hakim Mohd. Hadi Raza Khan	MatbaRiasat Rampur	1912	Urdu
89.	BayazKhaas	Hakim Nooruddin	Daftar Hami Al-Sehat, Lahore	1945	Urdu
90.	Lawami Al-Shahria Fi IlajAmraz Al Bashria	Ali KausarChandpuri	Al-tabib, Lahore	1939	Urdu
91.	Qanoon Ishrat	Hakim Ishrat Hussain	MatbaMunshiNawal Kishore	1865	Urdu
92.	Daru-ul- Shifa	Hakim Ghulam Mustafa	MatbaMufeedAam, Lahore	1911	Urdu
93.	Tauzeeh-ul-Adviah	Hakim Mohd. Hasan	Matba Iftekhar, Delhi	1899	Urdu
94.	Mizan-al-Tib	Hakim Mohd. Akbar Arzani	MatbaNamiMunshi Nawal Kishore	1877	Urdu
95.	DusturulIlaj	Hakim Ikram Raza Khan	MatbaAinulFuyooz	1883/1301	Persian
96.	National Formulary of Unani Medicine India First Edition reprint Part I,	Government of India	(AYUSH), Ministry of Health & Family Welfare,	2006	English
97.	National Formulary of Unani Medicine India Part II Volume I First Edition (formulations)	Government of India	AYUSH), Ministry of Health &Family Welfare,	2007	English
98.	National Formulary of Unani Medicine India Part III First Edition	Government of India	AYUSH), Ministry of Health & Family Welfare,	2001	English
99.	National Formulary of Unani Medicine India Part IV First Edition	Government of India	AYUSH), Ministry of Health & Family Welfare,	2006	English

100.	National Formulary of Unani Medicine India Part V	Government of India	AYUSH), Ministry of Health & Family Welfare,	July 2008,	English
101.	National Formulary of Unani Medicine India Part VI	Government of India	AYUSH), Ministry of Health & Family Welfare,	2011	English
102.	National Formulary of Unani Medicine India all parts	Government of India	AYUSH), Ministry of Health & Family Welfare,		English
103	Hamdard pharmacopoeia	Hakim Saeed	Pakistan	1985	English
104	Treatment guidelines for Unani Medicine	Government of Bangladesh	Bangladesh	2012	English

Decision:-

The committee approved the list of authoritative books of Unani System as reference purpose. However addition or deletion of any book could be made after evidence.

ITEM:-VIII

APPROVAL OF LABORATORIES FOR BATCH RELEASE IN THE PRIVATE OR IN THE PUBLIC SECTOR FOR CONTRACT TESTING.

Drug Regulatory Authority of Pakistan has permitted licensing of referral laboratories for contract testing of drugs. All members are requested to forward proposal for finalization of guidelines for approval of contract testing laboratories and good laboratories practices for carrying out contract testing.

Decision:-

EEC recommended the proposal for input the members of EEC in the light of WHO guidelines for herbal medicine testing.

ITEM:-IX

ISSUE OF VARIABLE INSPECTION REPORTS.

It has been observed that inspection report written by various inspection panels vary in the content and sometimes create ambiguity. Sections recommended and documents attached do not match with each other or with the layout plan. Sometimes inadequate facilities are recommended which is congested one. It is proposed as the area of the sections is not defined in the rules expressly, which also creates problems. It is also pertinent that due to unknown reasons the inspections are delayed which not only become problematic for the applicants but also earn bad name for the Authority. It advocates that time frame may be defined by the Enlistment Evaluation Committee to minimize delays. This delay could be due to shortage of technical personnel of the relevant specialties at various stations or unavailability of the DRAP officials due to over occupation. To address this issue it is proposed that experts from the academia, practicing professionals and ex-services men with credibility, integrity and having no conflict of interest could be included fulfilling applicable laws and rules.

Decision:-

The panels who failed to execute inspection with in the period two months would be withdrawn and new panel would be constituted to cope with the delays. New experts of various specialties would be included in the local stations to minimize delays. Common criteria of report should be on prescribed format with clear description to avoid ambiguity.

Minutes of 13th Meeting of Enlistment Evaluation Committee (EEC) held on 05th August, 2016