Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services Regulations & Coordination
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Islamabad, the …… 2017

NOTIFICATION

S.R.O. (I)/2016.- In exercise of the powers conferred by section 23 of the Drugs Regulatory Authority Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, with prior approval of the Federal Government, is pleased to make the following rules, namely:-

1. **Short title and commencement. - (1).** These rules may be called the Alternative Medicines and Health Products (Labeling) Rules, 2017.

(2) They shall come into force with immediate effect.

(3) Existing stocks of already manufactured alternative medicines and health products shall remain exempted till 30 June 2017.

(3) They shall extend to whole of Pakistan.

2. Definitions. -(1) in these rules, unless there is anything repugnant in the subject or the context;

(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.

(b) Authoritative Books of Unani Medicines: means recognized books of Unani medicine as prescribed in Schedule-II of these rules, 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.

(c) **Classical Unani medicines** means single or compound formulations recorded in the recognized Authoritative Books of Unani System of Medicines as prescribed in Schedule I to these rules.

(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) **Prescription only medicinal products:** means products which are categorized internationally or in the country of origin or by the Authority to be sold or dispensed only on the written advise of registered medical practitioner(s) or specialist(s)

(j) **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.

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

(l) **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.

(2). The words and expressions used but not defined herein shall have the same meanings as are assigned to them in the Act, DRAP Act& rules frames there under , Codex Alimentarious of Food and Agriculture Organization and World Health Organization or International Conference on Harmonization guidelines for medicines and health products.

3. **Manner of Labeling of Alternative Medicines *(*Except Homeopathic Medicines*):***

(1) 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 Medicines*–

Provided classical Unani 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 "traditional Chinese medicine" or any other category of product as the case may be shall appear on the label of alternative medicines after the brand name or classical name in a box-

(iii) the proper name of the *alternative medicine* 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 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 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 medicines, 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;

(iv) The Principal Display Panel (PDP) shall describe medicinal facts or other facts and 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—

(v) 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;

c) 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:

(vi) The name of the manufacturer and the address of the premises of the manufacture where the alternative medicine 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 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—

(vii) 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'—

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

(ix) Alternative medicine 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)

(x) Alternative medicines 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 are imported, also the enlistment number as importer under which the Alternative medicine is imported, preceded by the words "DRAP Product Enlistment Number":

(xi) **Warning and Caution statements** (when necessary for safe use) must appear on the Information label of the alternative medicine prominently and conspicuously.

(xii) **Directions for Use**: Each alternative medicine must bear adequate directions for use

(xiii) **Pregnancy / Breastfeeding Warnings**: The labels of all alternative medicine 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"**

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

(xv) Every alternative medicine 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 alcohol above 3% by volume the quantity of alcohol shall be stated in terms of the average percentage by volume of absolute alcohol in the finished products.

(xvii) The container of a alternative 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"

(xviii) 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.

4. Manner of Labeling of Food Supplements *(*Nutraceuticals*)*

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 :-

(1) the brand name of the Food Supplement–

(2) the word "food supplement" or "probiotic" or any other category of product as the case may be shall appear on the label of Food Supplement after the brand name in a box–

(3) the proper name of the ingredients of Food Supplements 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 Food Supplement 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 or Codex (Codex Alimentarious or Codex of ingredients of USA, EU, Japan and Australia) 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.

(b) for other Food Supplement, 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 in the principal display panel;

i) A correct statement of supplemental facts indicating there 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—

ii) 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;

c) 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:

(4) The name of the manufacturer and its address of the premises of the manufacture where the Food Supplements 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 Food Supplementis contained in a small container, it shall be enough if only the name of the manufacturer and his principal place of manufacture is shown—

(5) 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'—

(6) Every Food Supplement manufactured in Pakistan shall bear on its label the license number or

enlistment number of the firm or company under which the Food Supplements is manufactured, the figure representing the enlistment number as manufacturer being preceded by the words "Enlistment Number or the registration number"

(7) Food Supplement 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)

(8) Food Supplement 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 Food Supplement is imported, preceded by the words "Import License or DRAP Enlistment Number":

(9) **Warning and Caution statements** (when necessary for safe use) must appear on the Information label of the Food Supplements 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

(10) **Directions for Use**: Each Food Supplement must bear adequate directions for use

(11) **Pregnancy / Breastfeeding Warnings**: The labels of Food Supplement 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"**

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

(13) Every Food Supplement 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.

(14) 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.

***5*. 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.

Provided further that the retail packs of Homeopathic medicines containing alcohol shall not exceed 30ml.

(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.

(4) The labeling of all topical dosage forms, including suppositories, shall state the quantity and attenuation level of the Homeopathic Active Pharmaceutical Ingredients used in their preparation.

(5) Combinations: The label of a mixture or combination of several Homeopathic Active Pharmaceutical Ingredients shall indicate the attenuation of each Homeopathic Active Pharmaceutical Ingredient in the mixture or combination. The quantity or proportion of each Homeopathic

(6) The label shall bear a declaration of net quantity of contents. The net contents for pellets, triturates or tablets shall be stated in terms of numerical count, e.g., 100 pills, or 250 tablets. The statement of quantity of pellets, globules, liquids and ointments shall be stated by weight or volume, e.g. 5 ml (milliliters) of granules, 15 grams (g) of ointment, or 15 ml of dilution or tincture. Directions

(7) Homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed OTC.

(8) Homeopathic products offered for conditions not amenable to OTC use shall be marketed as prescription products.

(9) Each drug product offered for retail sale shall bear adequate directions for use.

(10) A suitable time frame should be included in the statement to consult a physician if symptoms persist. (e.g. "If symptoms worsen or persist for more than 7 days, consult a physician.")

(11) All prescription homeopathic drug products shall bear the prescription legend, prescription only or "Rx only" and a package insert bearing complete labeling information for the homeopathic practitioner shall accompany the product.

(12) For OTC homeopathic products, a statement of the recommended or usual dosage shall be included, meaning:

a) The quantity of the dose for adults and children,

b) The frequency of administration (except with respect to attenuations of 30X and higher), and one of the following:

(i) For single remedies and combination products sold through retail distribution channels, a statement of the conditions, purposes or symptoms and/or indications for which the single remedy or combination product is intended stated in terms likely to be understood by lay persons.

(ii) For single remedies sold directly from a manufacturer or pharmacist to a health professional, one of the following must be included:

1) a statement of the conditions, purposes, symptoms and/or indications for which the drug or combination is intended;
2) the words, "Caution: for manufacturing, processing or repacking ONLY."

(iii) For Homeopathic Pharmaceutical Necessities: Each container must bear the legend, "Caution, for manufacturing or reprocessing only, not to be dispensed or taken."

(13) **Warnings:** OTC homeopathic drugs intended for systemic absorption, unless specifically exempted, must bear a warning statement.

(14) **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 packing(s) or bottles of not more than 100 milliliters.

Provided mother tinctures may be packed in larger packs of 1 liter and dilutions up to 100ml for usage by the registered homeopathic practitioners or enlisted manufacturers.

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

6. 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

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

ii. The amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams 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.

iii. The total quantity of each vitamin, mineral, choline and any other ingredient as listed in 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.

iv. In addition, the declaration of nutrients in i) and ii) per 100 kilocalories (or per 100 kilojoules) is permitted.

4) Date Marking and Storage Instructions.

i. The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in un-coded 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.

ii. 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.

iii. 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.

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

5) Information for Use

i. 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.

ii. 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.

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

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

v. 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.

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

ii. the words "important notice" or their equivalent; the statement
"**Breast milk is the best food for your baby**"

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

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

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

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

vii. 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.

viii. 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.

i. 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.

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

iii. 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.

iv. 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.

7. **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.

8. **Manner of Labeling of Disinfectants**.

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 :-

1) the brand name of the Preparation –

   i. the word "Disinfectant or Antiseptic " shall appear on the label of product(s) after the brand name

   ii. the common name of the active ingredient 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 common name and shall be—

      a) for all products the name given therein;

      b) forpreparationsincluded 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;

2) Subject to these rules, the label on the container shall state-

   (a) the name of the ingredients and their contents,

   (b) the name and full address of the manufacturer or principal manufacturer(s) (for imported drugs),

   (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) DRAP enlistment number, Batch no or lot no

(j) M.R.P

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

9. Misleading Labeling

1) no person shall manufacturer, import or 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.

   c) information except the prescribed or approved one.

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

10. Prescription Medicinal Products. Alternative medicines shall be required to be expressed on the label for prescription-only products. The words "**prescription-only product**" must appear in the blue or red box.

11. Alternative Medicines and Food Supplements labels shall meet the requirements laid down in schedule-I.

12. Exemption: Labels of products intended for export shall meet the requirements of the importing country and may be exempted from the provisions of these rules except following:-

1) Exemption of certain products from certain provisions.— Products meant for exclusively export purpose may be exempted from the manner of labeling except the following:

   i. 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 underwhich the product has been manufactured;

c) batch or lot number;

d) date of expiry, :

2) These rules 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 health care professional 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.

SHEDULE-I

1. 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.

2. LABELLING REQUIREMENTS GUIDANCE;

This Guide provides easy-to-follow guidance on the basic labelling requirements for each type of finished natural product and sustainability certification. This includes all categories of natural products, namely cosmetics, herbal dietary supplement, health food, and herbal drug. The guide also provides references to more in-depth guidance.

Section 1 provides a typology of label used in the Pakistan alternative medicines or health products market and how they fit into a number of regulatory frameworks. These are determined by their

i. Composition,
ii. Dosage form, and
iii. Intended use(s). Each framework has its own unique product labelling requirements. The Authority enforces different labelling regulations for:
    a. Baby milk & food products;
    b. Food supplement products;
    c. Medical food products;
    d. medicated cosmetics products;
    e. Over-the-counter (OTC) alternative medicines (unani,ayuruvedic and homoeopathic drugs); and
    f. Prescription (Rx) only medicinal products.

The Authority's requirements on organic labelling are also explained.

Section 2 requires labels to disclose net contents (weight), identity of the commodity and the name and place of business.

Section 3requires basic information on the labelling requirements for manufacturing and expiry dates, storage conditions, maximum retail price and directions for use.

Section 4 requires recommended conditions for use as defined under the rules.

The **Principal Display Panel (PDP)** is the part of the label most likely to be displayed or seen on the store shelf. The following information must appear on the PDP of an alternative medicine and health product including medicated cosmetic product:

An identity statement: indicating the nature and use of the product, by means of the common or usual name, a descriptive name, fanciful name understood by the public, or an illustration representing the intended cosmetic use. The statement of identity must be shown in bold type and be in a size reasonably related to the most prominent printed matter on the PDP.

Contents: An accurate statement of the net quantity of contents, in terms of weight, measure, numerical count or a combination of numerical count and weight or measure.

The Information Panel: is a label panel other than the PDP that can accommodate label information where the consumer is likely to see it. Since the information must be prominent and conspicuous, the bottom of the package is generally not acceptable for placement of required information, such as the ingredient declaration. The following information must appear on the Information Panel.

i. Name and place of business. This may be the manufacturer, packer, or distributor.8 Distributor statement. If the name and address are not those of the manufacturer, the label must say 'Manufactured for…' or 'Distributed by…'

ii. Material facts. Failure to reveal material facts (e.g. known adverse effects) on the Information Panel is one form of misleading labelling and therefore makes a product misbranded. An example is directions for safe use, if a product could be unsafe if used incorrectly. Other examples of material facts include risk statements (e.g. cautions, contraindications, known side effects, warnings).

Warning and Caution statements (when necessary) must appear on the Information Panel of the finished product label prominently and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background so that the ordinary person can easily read and understood it. The type size of the letters and/or numbers must not be less than 1/16 inch in height.The Ingredients of the product must appear on the Information Panel of the finished product label prominently and conspicuously in descending order of predominance (letters must not be less than 1/16 inch in height).

Finished Attenuation Nomenclature Format For Homeopathic Medicines:

i. When the vehicle used for the dosage form is also the entire diluents for the finished attenuation, (i.e. the previous attenuation step is incorporated in the vehicle in a 1:10 ratio, [or 1:100 ratio] and the whole is successed), the Homeopathic Active Pharmaceutical Ingredient may be declared as the finished attenuation strength. For example, one (1) part of Arnica 2X is added to nine (9) parts [or one (1) part Arnica 5C is added to ninety-nine (99) parts] of ointment base, and the whole is succesed, the final product may be labeled as Arnica 3X [or Arnica 6C].

ii. Ingredient Attenuation Nomenclature Format: When the vehicle used for the dosage form is not used as diluents for a succession step, the quantity of the Homeopathic Active Pharmaceutical Ingredient is declared. For example, one (1) part of Arnica 2X is added to nine (9) parts of ointment base, and no succession is performed, the final product is labeled "Contains Arnica 2X 10%", or "Contains 10% Arnica 2X".

Following guideline for Label (mock-up) for immediate container, outer carton for alternative medicine and food supplement shall be followed.

The following information shall be present on the label of the product on outer unit carton, immediate & blister/ strips.

S.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.	DRAP Enlistment Number of manufacturer or	yes	yes	NA

	importer			
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 country of manufacturer	yes At least name of town/ city and country of manufacturer	NA
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, excipients, and/or capsule shell)	yes	optional	NA
18.	Name and content of the ingredients used.	yes	optional	NA
19.	The words "Keep the product 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.

3. 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.

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

"Protect from light and moisture."

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

Animal part(s):

"This product contains animal part(s)."

Animal origin(s):

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

7) (Porcine / pig." not allowed):

8) Alcohol:

"This product contains alcohol."

(Please declare the percentage of alcohol contained in the product).

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

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

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

4. 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 or recommended use

(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).

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.

5. Ingredient Specific Labelling Requirement (Label & Package Insert).

Specific labelling requirement shall be applicable in patient information leaflets for the products containing following ingredients.

(1) 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.

(2) 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.

(3) ASPARTAME

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

WARNING:

Unsuitable for phenylketonurics

(4) 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.

(5) For product containing: 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.

(6) 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"

(7) For product containing ChelidoniumMajus, please state

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

(8) 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."

(9) 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."

(10) 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."

(11) 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:

(12) **For product containing Propolis** (topical preparation), please state:

"Propolis may cause allergic skin reaction."

(13) 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."

(14) 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."

(15) 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."

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

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

(17) **For products containing Senna (Cassia spp.)** – fruit/ pod/ semen and leaf and Rhubarb/ Radix et Rhizoma Rhei/ 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."

(18) For product containing St. John's Wort, please state:

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

(19) 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."

(21) 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.

(22) INGREDIENTS DERIVED FROM SEAFOOD

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

"DERIVED FROM SEAFOOD"

(23) 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.

(24) 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.

(25) 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."

SHEDULE-II

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 Kanpur,	MatbaNizami	1314 A.H./1896	Persian
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	Delhi Ghulam		Urdu

		AbdusSattarLutfi	Nizamuddin, Delhi		
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	Hyderabad	1988	English

		Department, Govt. of AP			
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 Khan	AinulFuyooz	1883/1301	Urdu
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
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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,	1925	Persian

			Lucknow		
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
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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
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90.	Lawami Al-Shahria Fi IlajAmraz Al Bashria	Ali KausarChandpuri	Al-tabib, Lahore	1939	Urdu
91.	Qanoon Ishrat	Hakim Ishrat	MatbaMunshiNawa	1865	Urdu

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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
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