Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services Regulations and Coordination
****

Islamabad, the 27th May 2014

NOTIFICATION

S.R.O. 412 (I)/2014.- In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of 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 (Enlistment) Rules, 2014.

(2) They shall come into force at once.

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

(i) "Acceptance Criteria" means numerical limits, ranges, or other suitable measures for acceptance of the herbal substance, preparation ,medicines and health products based on the results of analytical procedures;

(ii) " Act" means the Drugs Act, 1976;

(iii) "Advertisement" means the publication, dissemination, conveyance of information for the purpose of promoting, whether directly or indirectly, the sale or use of any product by any means or in any form including the following namely:-

(a) publication in a news paper, magazine, journal or periodical;
(b) display of poster or notices.
(c) letters addressed to individuals, bodies corporate or uni-corporate;
(d) photographs or documentary or cinematographs films;
(e) sound broad-casting through television or any other media; and
(f) public demonstration for use of the product offer of trial of the product to the member of the public;

(iv) "Adulterated alternative medicine or health product" means alternative medicine or health product shall be deemed to be adulterated if,-

(a) it consists, in whole or in part, of any filthy, putrid or decomposed substance; or
(b) it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
(c) its container is composed in whole or in part, of any poisonous or

deleterious substance which may render the contents injurious to health; or

(d) it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) it contains any harmful or toxic substance which may render it injurious to health; or

(f) any substance has been mixed therewith so as to reduce its quality or strength;

(v) “Adverse Reaction” means a noxious and unintended response to a product that occurs at any dose used to test for the diagnosis, treatment or prevention of a disease or for modifying an organic function;

(vi) “Allersode” means homeopathic preparations of antigens, (substances which, under suitable conditions, can induce the formation of antibodies). Antigens include toxins, ferments, precipitinogens, agglutinogens, opsonogens, lysogens, venins, agglutinins, complements, opsonins, amboceptors, precipitins and most native proteins;

(vii) “Allopathic Ingredients” means ingredients used in allopathic or western system which are chemically defined ingredients and synthetically manufactured, excluding naturally occurring ingredients obtained from natural sources;

(viii) "Alternative Medicine" means medicinal products which include, indigenous or unani medicine, imported medicinal product, homeopathic medicines ,new medicines ,herbal preparation, herbal substance ,proprietary medicines, herbal medicinal product , phyto-medicines or any other product meant for therapeutic or preventive use which have been derived from plant, animal or mineral ingredients alone or their combinations but does not contain chemically defined synthetic ingredients;

(ix) “Authorized Person” means person recognized by the authority as qualified technical person having degree in pharmacy or pharmaceutical sciences and necessary basic scientific and technical background and experience;

(x) "baby milk and foods" means infant formula as a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding and includes infant or baby formulae, follow up formulae, formulae for special medical purposes or complementary foods intended for infants and young children;

(xi) “calibration” means the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a

material measure, and the corresponding known values of a reference standard;

(xii) "clinical trial" means an investigation with respect to a product that involves human subjects and is intended to discover or verify its clinical, pharmacological or pharmacodynamic effects, to identify any adverse events that are related to its use, to study its absorption, distribution, metabolism and excretion, or to ascertain its safety or efficacy;

(xiii) "Common Name" means name for any medicinal or non-medicinal ingredient contained in a product, the name by which it is commonly known and is designated in a scientific or technical references;

(xiv) "Complementary foods for infants and young children" means foods that are intended for infants six months of age and older, and for progressive adaptation of infants and children to ordinary food. Products may be ready to eat or in powder form to be reconstituted with water, milk, or other suitable liquid. These foods exclude infant formulae, follow up formulae, and formulae for special medical purposes like: cereal, fruit vegetable and meat based "baby foods" for infants, "toddler foods," and "junior foods"; for children;

(xv) "Contract Acceptor" means a manufacturer who manufacturers the finished product under the label and brand of contract giver. He is responsible for the following, namely:-

(a) he must have adequate premises and equipment, knowledge and experience, and competent personnel to carry out satisfactorily the work ordered by the Contract Giver. Contract manufacture may be undertaken only by a manufacturer who is the holder of a manufacturing authorization;
(b) he should ensure that all products or materials delivered to him are suitable for their intended purpose;
(c) he should not pass to a third party any of the work entrusted to him under the contract without the Contract Giver's prior evaluation and approval of the arrangements. Arrangements made between the Contract Acceptor and any third party should ensure that the manufacturing and analytical information is made available in the same way as between the original Contract Giver and Contract Acceptor; and
(d) he should refrain from any activity which may adversely affect the quality of the product manufactured or analyzed for the Contract Giver;

(xvi) "Contract" means written agreement which should be drawn up and accepted between the Contract Giver and the Contract Acceptor specifying their respective responsibilities relating to the manufacture and control of the product as under;-

(a) technical aspects of the contract should be drawn up by competent persons suitably knowledgeable in pharmaceutical technology, analysis and Good Manufacturing Practice (GMP);
(b) all arrangements for manufacture and analysis must be in accordance with the marketing authorization and agreed by both parties;
(c) the Contract should specify the way in which the Qualified Person releasing the batch for sale ensures that each batch has been manufactured and checked for compliance with the requirements of Marketing Authorization;
(d) the contract should describe clearly who is responsible for purchasing materials, testing and releasing materials, undertaking production and quality controls, including in-process controls, and who has responsibility for sampling and analysis;
(e) in the case of contract analysis, the contract should state whether or not the Contract Acceptor should take samples at the premises of the manufacturer;
(f) manufacturing, analytical and distribution records, and reference samples should be kept by, or be available to, the Contract Giver. Any records relevant to assessing the quality of a product in the event of complaints or a suspected defect must be accessible and specified in the defect or recall procedures of the Contract Giver; and
(g) the Contract should permit the Contract Giver to visit the facilities of the Contract Acceptor. In the case of contract analysis, the Contract Acceptor should understand that he is subject to Inspection by the competent Authorities;

(xvii) "Contract Giver" means the person who awards the contract of particular products under his brand .Contract Giver is responsible,-

(a) for assessing the competence of the Contract Acceptor to carry out successfully the work required and for ensuring by means of the Contract that the principles and guidelines of GMP are followed;
(b) the Contract Giver should provide the Contract Acceptor with all the information necessary to carry out the contracted operations correctly in accordance with the marketing authorization and any other legal requirements;
(c) the Contract Giver should ensure that the Contract Acceptor is fully aware of any problems associated with the product or the work which might pose a hazard to his premises, equipment, personnel, other materials or other products; and
(d) the Contract Giver should ensure that all processed products and materials delivered to him by the Contract Acceptor comply with their specifications or that the products have been released by a Qualified Person;

(xviii) "counterfeit medicine or health products" means an alternative medicine or health product is an imitation of, or a substitute for,

another drug or medicine or health product or resembles another drug medicine or health product, in a manner likely to deceive or bears upon it or upon its label or container the name of another drug, medicine or health product unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug, medicine or health product;

(xix) "dietetic foods intended for special medical purposes" means foods for special dietary use that are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foods or certain nutrients contained therein, or who have other special medically determined nutrient requirement, whose dietary management cannot be achieved only by modification of the normal diet;

(xx) "Disinfectant" means a health product or ingredient used for destroying or inhibiting micro-organisms that may be harmful to humans or animals. Disinfectants also include ingredients or products having additional antiseptic activity or use;

(xxi) "DRAP Act" means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012).

(xxii) "Drug extract ratio (DER)" means the ratio between the quantity of herbal substance used in the manufacture of a herbal preparation and the quantity of the herbal preparation obtained. The number (given as the actual range) written before the colon is the relative quantity of the herbal substance; the number written after the colon is the relative quantity of the herbal preparation obtained;

(xxiii) "Enlistment" means provisional allocation or entry of proper number to the firm or the product in the enlistment register for the purpose of temporary manufacturing and marketing authorization till the procedure for manufacturing (authorization) license and product registration (marketing authorization) is finalized and enacted ;

(xxiv) "Enlistment Application" means an application in the prescribed form as specified in the Schedule A, accompanied with required information, attachments, data ,evidence to support the claims made in the application and proper fee submitted under the rules to the Division of Health and OTC Products(non drugs) by the manufacturer or importer or another eligible person;

(xxv) "Enlistment Certificate" means a certificate on the form prescribed in Schedule A to the applicant containing an identification number allocated to the firm or product formulation in the enlistment register which enables its holders for temporary manufacturing and marketing

authorizations subject to compliance to the rules and conditions for enlistment;

(xxvi) "Enlistment holder" means proprietor or owner of the company or firm to whom Enlistment of company or product has been granted;

(xxvii) "Expiry date": means earlier of.-

(a) the date, expressed at minimum as a year and month, up to and including which a medicine or a health products maintains its purity and physical characteristics and its medicinal ingredients maintain their quantity per dosage unit and their potency; and
(b) the date, expressed at minimum as a year and month, after which the manufacturer recommends that the medicine and health products should not be used;

(xxviii) "extract" means substances prepared by treating a plant or a plant material, an alga, a bacterium, a fungus, or non-human animal material with solvents or pressure to remove any constituents;

(xxix) "Finished Product" means alternative medicine or health product which is ready for use after release certificate based on conformance to specifications by the quality control department;

(xxx) "Follow up formulae" means food intended for use as a liquid part of the complementary feeding of infants (aged at least 6 months) and for young children (aged 1-3 years).They may be ready to eat or in a powdered form to be reconstituted with water. Products may be soy based hydrolyzed protein or amino acid based, or milk base nutritional vitamins and minerals;

(xxxi) "Food supplements" or "dietary supplement" or "health supplement" or "Nutraceuticals" means products containing vitamins, pro-vitamins, multivitamins, minerals including a mineral salt, a naturally occurring mineral , metals and their salts, a lipid, including an essential fatty acid or phospholipids liproteins,amino-acids, proteins, fatty acids, carbohydrates, a mucopolysaccharide, plant or herbal material (or a synthetic duplicate of that kind), including plant fibers, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll, herbal preparation, resins ,balsams, volatile oils, non-human animal material (or a synthetic duplicate of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates, a microorganism, whole or extracted, except a vaccine expressed juices, exudates etc., alone or their combinations and are presented in pharmaceutical dosage forms intended for health related purpose;

(xxxii) "healthcare professional" means professionals who render their services for betterment of human healthcare and are registered with their respective Council under the law as medical doctor, dentist, pharmacist, homeopathic doctor, hakim or nurse;

(xxxiii) “health products” means health and OTC products (non-drugs) as defined in the DRAP Act and include pro-biotic, pre-biotic, disinfectants, food supplements, nutritional products, baby milk and foods, medicated cosmetics, medicated soaps, medicated shampoos, medicated plasters and derma-care products or any other product which may be notified in official gazette by DRAP as Health and OTC Products;

(xxxiv) “health related purpose” means a therapeutic, curative, preventive, palliative, or cosmetic purpose or for promotion and well being of humans and animal health;

(xxxv) “herbal medicinal products” means any medicinal product, exclusively containing as active substances one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations;

(xxxvi) “herbal preparations” means preparation obtained by subjecting herbal substances to treatment such as extraction, distillation, extraction, fractionation, purification, concentration or fermentation, including comminuted or powdered herbal substances, tinctures, extracts, isolates, essential oil, expressed juices and processed exudates;

(xxxvii) “herbal substances” means all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety);

(xxxviii) “herbal teas” means teas which consist exclusively of one or more herbal substance intended for oral aqueous preparations by means of decoction, infusion or maceration. The preparation is prepared immediately before use. Herbal teas are usually supplied in bulk form or in sachets;

(xxxix) “imported medicinal product’” means Chinese, Ayurvedic or Siddha,or any other herbal medicinal product which has been manufactured into a finished product and contains one or more active substances, all of which are derived wholly from plants, animals or minerals or a combination of any one or more of them, and the medicinal product or all of its active substances have been evaluated for quality, safety and efficacy by the regulatory Authority of the country of origin and any other regulatory authority of other country as per internationally recognized standards of evidence to establish recommended conditions for use ;

(xl) "infant or bay formulae" means a human milk substitute for infants that is specifically formulated to provide the sole source of nutrition during the first months of life up to the introduction of appropriate complementary feeding. Product is in a liquid form, either as a ready to eat product, or is reconstituted from a powder. Products, may be, hydrolyzed protein or amino acid based, or milk based nutritional vitamins and minerals;

(xli) “in-process control or tests” in-process control or tests are tests, which may be performed during the manufacture of either the herbal preparation or herbal medicinal product or any other finished product rather than as part of the formal battery of tests which are conducted prior to product release. In-process tests, which are used for the purpose of adjusting process parameters during manufacturing process within control or an operating range, e.g., hardness and friability of tablet cores, weight variation, disintegration test .etc;

(xlii) “isode” means homeopathic preparations of botanical, zoological or chemical substances, including drugs, excipients or binders, which have been ingested or otherwise absorbed by the body and are believed to have produced a disease or disorder which interferes with homeostasis. They are sometimes referred to as Detoxodes as well;

(xliii) “homeopathic excipient” means substance needed for manufacturing a dosage form (used after potentisation) such as wheat starch and magnesium stearate for tablets. It may also represent the substance of the dosage form;

(xliv) “Homeopathic medicine” include any medicine which is recorded in Homoeopathic proving or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature and which is prepared according to the techniques of Homoeopathic pharmacy and covers combination of ingredients of such Homoeopathic medicines but does not include a medicine which is administered by parenteral route; and a homeopathic product must meet two criteria, that is manufactured from, or contain as medicinal ingredients, only substances referenced in a homeopathic monograph in one of the following homeopathic pharmacopoeias, as they are amended from time to time;-

(a) Homeopathic Pharmacopoeia of the United States (HPUS);
(b) Homöopathische Arzneibuch (HAB) or German Homeopathic Pharmacopoeia;
(c) Pharmacopée française or French Pharmacopoeia (PhF);
(d) British Homeopathic Pharmacopoeia (BHP);
(e) Indian Hoeopatic Pharmacopoeia (IHP);
(f) European Pharmacopoeia (Ph.Eur);
(g) Encyclopedia of Homeopathic Pharmacopoeia (EHP); and

is prepared in accordance with the methods outlined in one of the

homeopathic pharmacopoeias listed above, as they are amended from time to time;

(xlv) "Homeopathic source material" means the original raw material used for the production of Homeopathic medicines. This material is obtained from natural sources, e.g. of botanical, zoological, microbiological, mineral, chemical, animal and human origin, or synthetic procedures. Source materials may undergo preliminary treatment in order to be further processed;

(xlvi) "Indigenous or Unani Medicine" means;-

(a) any substance or mixture of substances, product, or preparations intended for external or internal use in human beings or animals for the treatment, mitigation, or prevention of disease, an abnormal physical state, or the symptoms thereof, or for restoration, correction or modification of organic functions of human beings or animals, which contains as active substances any combination of ingredients, or is in accordance to a formula, prescribed in the authoritative books of Tibb-e-Unani and as prescribed under the rules; and

(b) any substance or material or mixtures thereof as may be prescribed by the Authority in the Official gazette;

(xlvii) "intended purpose" means use for which alternative medicine or health product is intended according to the claim of manufacturer or importer as per recommended conditions for use and stated on any or all of the following, namely;-

(a) label of the product;
(b) instruction for use of the product; and
(c) promotional material in relation to the product;

(xlviii) "isolate" means a purified constituent of a defined molecular structure obtained from a plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material;

(xlix) "label" means any written, printed or graphic presentation that appears on or is attached to the container of the product or active ingredient or herbal preparation or any part of the packaging and includes informational sheet or leaflets that accompanies when finished product or active ingredient or preparation is being supplied;

(l) "label claim" means any representation made on a product in relation to its indication, benefits or actions. Claims could be stated directly or inferred in-directly but not limited to the following:-

(a) graphic or logos on the product packaging;
(b) product or branding;
(c) media advertisement (print, sound, light and sound);
(d) point of sales materials;
(e) product broachers or information sheets distributed with or separately from the product;

(li) "lot or batch" means a quantity of any product in dosage form, a raw material or a packaging material, homogeneous within specified limits, constituting all or part of a single batch and identified by a distinctive lot number which appears on the label of the finished product;

(lii) "manufacture" means all operations of productions involved in the production of medicines and health products or any part of the process of bringing the products to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilizing, testing or releasing for supply of the products or of any component or ingredient of the product as part of the process but does not include dispensing or compounding of products on the advice of healthcare professionals. Single step of manufacture also requires manufacturing authorization or license by the Authority. For example one of the following processes like tablet coating; capsule filling from bulk; aerosol filling from bulk; storage other than for sale; packaging including labelling; sterilization; testing including analysis or testing of batch of medicines and health products and releasing for sale (by a person not involved with actually preparing the finished products);

(liii) "markers" are chemically defined constituents or groups of constituents of a herbal substance, a herbal preparation or a herbal medicinal product which are of interest for control purposes independent of whether they have any therapeutic activity. Markers serve to calculate the quantity of herbal substance or herbal preparation in the Herbal Medicinal Product if the marker has been quantitatively determined in the herbal substance or herbal preparations. There are two categories of markers:

(a) active marker which are constituents or groups of constituents which are generally accepted to contribute to the therapeutic activity.
(b) analytical marker which are constituents or groups of constituents that serve for analytical purposes;

(liv) "master formula" a document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls;

(lv) "medicated cosmetics" means health product used for cleansing, fragrencing, deodorizing, beautifying, preserving, improving, altering or restoring complexion of skin, hair, nail or teeth of human containing ingredients of natural origin;

(lvi) "medicated oil and balm" means any external medicated embrocation, medicated cream, ointment, lotion or inhalant used for soothing purposes containing following ingredients:-

(a) Essential oils;
(b) Fixed oils derived from natural source;
(c) Methyl salicylate;and
(d) Menthol camphor and peppermint;

(lvii) "misbranded alternative medicine or health products" means an alternative medicine or health product which is;-

(a) so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or
(b) not labelled in the prescribed manner; or
(c) label or container or anything accompanying it bears any statement, design or device which makes any false claim for the product or which is false or misleading in any particular;

(lviii) "mother tincture or tincture" means the initial homeopathic preparation made from source material that can be further potentised or sometimes used as homeopathic medicines, is regarded as the most concentrated form of a finished homeopathic medicine. Mother tinctures are obtained classically by maceration or percolation (sometimes also by digestion, infusion, decoction or fermentation) techniques from source materials according to a procedure prescribed by a recognized Homeopathic pharmacopoeia;

(lix) "native extract" means the material consisting only of components present in the original plant or formed during the extraction process, excluding any excipients or other added substances. This term may refer to liquid extracts or semi-solid extracts from which the added solvent has been removed, or may refer to a dry extract or that portion of a finished extract that is comprised solely of plant components;

(lx) "native extract ratio" means the ratio of the mass of herbal material to the mass of the resulting native herbal preparation (= native extract);

(lxi) "new formulation or new medicine" means;-

(a) a formulation, including bulk substance, which has not been evaluated for quality, safety and efficacy nor sufficient standards of evidence have been defined regarding the recommended conditions for use .
(b) a formulation of already approved product for a modified or new claims namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration; or
(c) a formulation of a fixed dose combination of two or more herbal substances or ingredients, individually available earlier for certain claims, which are proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in a marketed combination is proposed to be changed, with certain claims, namely, indications, dosage, dosage form (including sustained release

dosage form) and route of administration;

(lxii) "nosode" homeopathic preparations of pathological organs or tissues, causative agents such as bacteria, fungi, ova, parasites, virus particles and yeast, disease products, excretions or secretions;

(lxiii) "nutritional supplements" means a product that is used to supplement a diet beyond that of normal nutrients to support or maintain the healthy body functions in humans and animals;

(lxiv) "pre-biotics" means the non -digestible nutritional ingredient that stimulates the growth or activity of bacteria in the digestive system and produce health benefits;

(lxv) "production process or manufacturing process" means steps,procedures,instructions and manufacturing technique to convert starting materials into finished product which involves a series of manufacturing operations and process control tests for batch to batch consistency of finished products in terms of quality, efficacy and effectiveness. Manufacturing process also includes process design, process validation and qualification, precautions or process critical parameters which could change the results and in-process controls;

(lxvi) "Principals of Good Manufacturing Practice (GMP)" means that part of quality assurance which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization or product specification. GMP is concerned with both production and quality control. The basic principles of GMP are that,-

(a) all manufacturing processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently manufacturing medicinal products of the required quality and complying with their specifications;
(b) critical steps of manufacturing processes and significant changes to the process are validated;
(c) appropriately qualified and trained personnel;
(d) adequate premises and space;
(e) suitable equipment and services;
(f) correct materials, containers and labels;
(g) approved procedures and instructions;
(h) suitable storage and transport;
(i) instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided;
(j) operators are trained to carry out procedures correctly;
(k) records are made, manually or by recording instruments, during manufacture which demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the product was as expected. Any

significant deviations are fully recorded and investigated;

(l) records of manufacture including distribution which enable the complete history of a batch to be traced, are retained in a comprehensible and accessible form;

(m) the distribution (wholesaling) of the products minimizes any risk to their quality;

(n) a system is available to recall any batch of product, from sale or supply;

(o) complaints about marketed products are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective products and to prevent re-occurrence.

(lxvii) "pro-biotic" means an ingredient or product containing micro organisms that confers health benefits on the host;

(lxviii) "product enlistment holder" an individual with legal ownership of and responsibility for the product. The product enlistment holder may be located in or outside of Pakistan. Product enlistment holders who are located outside of Pakistan must identify a Pakistani representative;

(lxix) "prohibited substance" means a substance that is not permitted to be contained in any medicine or health product and include the following namely;-

(a) allopathic ingredients;
(b) colours and additives, except the prescribed one;
(c) toxic ingredients containing plants or animals or their parts;
(d) restricted ingredients above the prescribed limits;
(e) steroids and anabolic hormones ; or
(f) any other substance which has been declared injurious to health by the Authority, through notification in the official gazette:

Provided that prohibited substances recorded in any recognized homeopathic pharmacopoeia may be may used in homeopathic medicine subject to compliance to the WHO safety guidelines for homeopathic medicines.

(lxx) "proprietary medicines" *means any* substance, ingredient or medicinal product which is not included in any pharmacopoeias or publication available in public domain and its manufacturing process, testing method and clinical data have been generated by the owner of that medicine.

(lxxi) *"*Phyto-medicine" means herbal preparation or herbal products which contain processed or unprocessed standardized materials derived from plants or parts thereof or combination of parts of plants, standardized or quantified extracts or fractions thereof in a dosage form for internal or external use of human beings or animals and intended to be used for the diagnosis, treatment, mitigation or prevention of any disease or

disorder in human beings or animals but does not include administration by parenteral;

(lxxii) *"quality assurance" means* the sum total of the organized arrangements made with the objective of ensuring that alternative medicine and health product are of the quality required for their intended use. The system of quality assurance for the manufacture of alternative medicine and health products should ensure that;-

(a) medicine and health products are designed and developed in a way that takes account of the requirements of Good Manufacturing Practice ;
(b) production and control operations are clearly specified and GMP adopted;
(c) managerial responsibilities are clearly specified;
(d) arrangements are made for the manufacture, supply and use of the correct starting and packaging materials;
(e) all necessary controls on intermediate products, and any other in-process controls and validations are carried out;
(f) finished product is correctly processed and checked, according to the defined procedures;
(g) alternative medicine and health products are not sold or supplied before an authorized person has certified that each production batch has been produced and controlled in accordance with the requirements of the marketing authorization and any other regulations relevant to the production, control and release of medicine and health products;
(h) satisfactory arrangements exist to ensure, as far as possible, that the medicine and health products are stored, distributed and subsequently handled so that quality is maintained throughout their shelf life; and
(i) there is a procedure for self-inspection and/or quality audit, which regularly appraises the effectiveness and applicability of the quality assurance system.,

(lxxiii) "quality control" means that part of Good Manufacturing Practice which is concerned with sampling, specifications and testing, and with the organization, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. The basic requirements of quality control are that;-

(a) adequate facilities, trained personnel and approved procedures are available for sampling, inspecting and testing starting materials, packaging materials, intermediate, bulk, and finished products, and where appropriate for monitoring environmental conditions for GMP purposes;
(b) samples of starting materials, packaging materials, intermediate products, bulk products and finished products are taken by

personnel and by methods approved by quality control;
(c) test methods are validated;
(d) records are made, manually or by recording instruments, which demonstrate that all the required sampling, inspecting and testing procedures were actually carried out. Any deviations are fully recorded and investigated;
(e) the finished products contain active ingredients complying with the qualitative and quantitative composition of the marketing authorization, are of the purity required, and are enclosed within their proper containers and correctly labelled;
(f) records are made of the results of inspection and that testing of materials, intermediate, bulk, and finished products is formally assessed against specification. Product assessment includes a review and evaluation of relevant production documentation and an assessment of deviations from specified procedures;
(g) no batch of product is released for sale or supply prior to certification by an authorized person that it is in accordance with the requirements of the relevant authorizations; and
(h) sufficient reference samples of starting materials and products are retained to permit future examination of the product if necessary and that the product is retained in its final pack unless exceptionally large packs are produced;

(lxxiv) "recall" means any action taken by the manufacturer, importer, supplier or registrant or enlistment holder of a product to remove it from the market or to retrieve from any person to whom it has been supplied because of the reason that the product;-

(a) may be hazardous to health;
(b) may fail to conform to any claim made by its manufacturer, importer, registrant or enlistment holder relating to the quality, safety, efficacy or its usefulness; or
(c) may not meet to the requirement of the DRAP Act;

(lxxv) "recommended conditions of use" recommended conditions of use refer to information about an alternative medicine or health product that enables consumers to make an informed choice regarding its use. It includes the following elements;-

(a) recommended use or purpose;
(b) dosage form;
(c) recommended route of administration;
(d) recommended dose;
(e) recommended duration of use, if any; and
(f) risk information, including any cautions, warnings, contraindications or known adverse reactions associated with its use;

(lxxvi) "review of application" means screening, assessment and evaluation of information and contents included in the application dossiers submitted for the grant of enlistment certificates;

(lxxvii) "risk-reduction claim" which describes the relationship between using a product and reducing the risk of developing a chronic disease or abnormal physiological state by significantly altering a major risk factor or factors recognized to be involved in its development;

(lxxviii) "sub-standard" means alternative medicine or health product, ingredient, raw material or finished product which does not conform to the specifications or prescribed standards of quality, identity, purity and strength as defined in the specified publication or prescribed under the rules or expired medicine and expired health product which has passed its shelf life;

(lxxix) "specified publication" means any of the official publications recognized by the Authority which contain material information regarding the manufacturing, analytical standards or recommended conditions for use of alternative medicines or health products as specified under these rules including British Pharmacopoeia or British Pharmaceutical Codex or British Herbal Pharmacopoeia, United State Pharmacopoeia, American Herbal Pharmacopoeia, European Pharmacopoeia, German Pharmacopoeia, Japanese Pharmacopoeia, Korean Pharmacopoeia, Indian Pharmacopoeia, Chinese Pharmacopoeia and China Drug Standards;

(lxxx) "specifications" means list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a herbal preparation or herbal substance or herbal medicinal product should conform to be considered acceptable for its intended use. Specifications are binding quality standards that are agreed to between the Authority and the applicant. *Conformance to specifications means that the herbal substances or herbal preparation or active ingredients or medicine or health product, when tested according to the analytical procedures listed in the specified publication or rules, will meet the listed acceptance criteria;*

(lxxxi) "spurious alternative medicines or health products" means alternative medicines or health products which;-

(a) is imported under a name which belongs to another product ; or
(b) label or the container bears the name of an individual or company purporting to be the manufacturer of the medicine or health products, which individual or company is fictitious or does not exist; or
(c) has been substituted wholly or in part by another drug, medicine, health product or substance; or
(d) is purports to be the product of a manufacturer of whom it is not

truly a product ; or

(e) contains prohibited substance as ingredient which is originally not part of approved formulation; and

(f) is manufactured without manufacturing and marketing authorizations of the Authority.

(lxxxii) "standards of evidence" means clearly defined criteria used by regulators to evaluate the safety, quality and effectiveness of a claim regarding an alternative medicine, or health product. The criteria define the amount and type of data required to support the safety of a product and all health claims that are associated with it. Although standards of evidence may differ from one type of product to another, they are consistent within a similar category of products like full evaluation of quality, safety and efficacy data shall be required for disease reduction claims or therapeutic claims and simplified evaluation for nutritional, structure function or traditional use claims;

(lxxxiii) "Standard Operating Procedure (SOP)" means an authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation;

(lxxxiv) "stocks" means substances, products or preparations used as starting materials for the production of homoeopathic preparations. A stock is usually a mother tincture or a glycerol macerate, for raw materials of botanical, zoological or human origin, or the substance itself, for raw materials of chemical or mineral origin;

(lxxxv) "Structure-Function Claim" a claim which describes the effect of a product on a structure or physiological function in the human body, or a product's support of an anatomical, physiological, or mental function. This category includes claims of maintaining or promoting health. This claim needs evidence regarding safety and efficacy.

(lxxxvi) "Supply" means to:-

(a) sell the alternative medicine or health product for distribution or retail sale

(b) transfer possession of finished product by exchange, gift,loan,hire or sale; and

(c) transfer product by way of administration to or application in any person in the course of any diagnosis ,treatment or testing;

(lxxxvii) "synthetic duplicate" means a substance that shares an identical chemical structure and pharmacological properties with its natural counterpart. "Natural" means a product that is isolated or comes from a natural source (e.g., plant or mineral). "Synthetic" means a product that is chemically produced. For example, most of the vitamin C in products

marketed in Pakistan is a synthetic duplicate of the ascorbic acid that occurs naturally in plants and animals;

(lxxxviii) "traditional medicine" means the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. Traditional medicine has a long history of usage and has established efficacy and safety for traditional use indications;

(lxxxix) "therapeutic claim" means a claim which relates to the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans;

(xc) *"Validation"* means action of proving, in accordance with the principles of GMP, that any procedure, process, equipment, material, activity or system actually leads to the expected results;

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, Codex Alimentarious of Food and Agriculture Organization and World Health Organization or International Conference on Harmonization guidelines for medicines and health products.

3. Procedure for Enlistment.- (1) The Authority shall enlist alternative medicine and health products, their manufacturers and importers subject to fulfillment of the criteria prescribed below**.**

(2) The following shall be eligible to apply for enlistment namely;--

(a) manufacturers having manufacturing and quality control facilities;
(b) contract giver as prescribed in rule 6;
(c) importers authorized by the overseas principal manufacturer; and
(d) manufacturers holding manufacturing license under the Act may also apply for approval of dedicated sections for manufacturing of alternative medicines or health products and probiotics or food supplements to the Authority and thereafter become eligible to apply for enlistment.

(3) Application for enlistment shall be made to the Authority, addressed to the Director of Division of Health and OTC Products (non-drugs) in the following manner, namely:-

(a) application for the enlistment of manufacturer or any section thereof, and manufacturing on contract basis for contract giver shall be in **Form 1** as prescribed in schedule A;
(b) application for the enlistment of importer shall be made on **Form 2** as prescribed in schedule A;
(c) application for the enlistment of locally manufactured product for general health claim, or traditional use claim, or nutritional claims, or structure- function claims shall be made on **Form 3** as

prescribed in schedule A;

(d) application for the enlistment of locally manufactured product for disease reduction or therapeutic claims shall be made on **Form 4** as prescribed in schedule A;

(e) application for the enlistment of imported product shall be made on **Form 5** as prescribed in schedule A;

(f) application shall be accompanied with a fee of rupees ten thousand for enlistment of manufacturer, contract giver or importer and two hundred and fifty rupees for enlistment of each product of alternative medicine and two thousand rupees for each product of health products; and

(g) application for contracting manufacturing shall be accompanied with fee as prescribed by the Authority, as well as application documents and quality agreement between the contract giver and contract acceptor.

(4) Fee shall be deposited in the head of account of Authority at the designated banks and original receipt of deposit of money shall be attached with the application.

4. **Application evaluation**. - (1) Applications shall be scrutinized by the Division of Health and OTC Products (non-drugs) for conformance to the evaluation criteria.

(2) Applicants shall be required to submit documents with evidence and documentary proof for quality, safety, efficacy or effectiveness and recommended conditions for use as per standards of evidence.

(3) Authority may verify contents or information provided in the application dossier through panel of Inspectors or any authorized Inspector of Authority or Provincial Inspector.

(4) Applicants shall be required to submit a declaration on notarized stamp paper that the contents of the application are correct.

5. Evaluation criteria- (1) Applications shall meet the following criteria, namely:-

(a) applications shall be complete and meet all the criteria prescribed;

(b) applicants shall possess manufacturing and quality control facilities;

(c) applicants shall submit necessary evidence to support applications for manufacturing unit, import or products as defined in the rules;

(d) applicants shall conform to the principles of quality assurance for contract manufacturing or contract testing and analysis;

(e) application containing false, incorrect or misleading information shall be liable to rejection;

(f) the formulation of the applied product shall not contain prohibited substance or ingredient or ingredients that have been declared dangerous or injurious to health by any international body or as may be prescribed;

(g) the formulations as a whole or containing any of its ingredients that have been withdrawn due to safety concerns shall be liable to

rejection;

(h) the applicants of new formulation or new ingredients shall submit safety, efficacy and quality data as per recognized evidence and standards;

(i) applicant shall support applications through necessary proof or evidence, to prove quality, safety and efficacy of the products; and

(j) import documents shall be attested by the regulatory authority of the country of origin and verified by the embassy or consulate of Pakistan in the said country.

6. Contract manufacturing. - (1) The application for enlistment of product for manufacturing on contract basis submitted to the Authority shall be reviewed and decided in the light of fulfillment of criteria prescribed.

(2) Contract acceptor shall have pre-determined surplus capacity in terms of manufacturing facilities, sections, equipment, testing procedures, qualified technical personnel and quality control operations.

(3) Contract acceptor shall be possessing established systems of quality assurance and validation of manufacturing process and testing methods and no major deficiencies or non conformities has been identified during the inspection of manufacturing unit of the contract acceptor.

(4) Every operation of cleaning and sanitization, validation, calibration, manufacturing, in-process controls, quality control, stability protocol, packaging and release shall be clearly defined and documented through standard operating procedures.

(5) Quality control laboratory shall be equipped with Chemistry, Pharmacognosy and Microbiology facilities and equipment, as applicable.

7. Evaluation Committee. - (1) The Enlistment Evaluation Committee shall comprise of the following members, namely:-

(a) Director Health and OTC Products ex-officio
Chairperson/member;

(b) Deputy DG Health and OTC Products
Vice Chairperson/member;

(c) Chief Drug control and Traditional Medicine Division NIH
Member;

(d) Chief Nutrition Division NIH
Member;

(e) One Expert of homeopathy to be nominated by the Authority
Member;

(f) One expert of quality control to be nominated by the Authority.
Member;

(g) One expert of unani to be nominated by the authority
Member;

(h) Deputy Drugs Controller Health and OTC Products
Member;

(2) The Deputy Drugs Controller (Health and OTC products) shall act as Secretary of the Committee.

(3) The Authority may increase or decrease the member through

notification in the official Gazette;

(4) Quorum to constitute a meeting shall be above fifty per cent of the total membership.

(5) The evaluation committee shall evaluate the applications as per criteria and may grant approval or rejection of the application recording reasons thereof.

(6) The secretary shall call the meeting on the direction of Chairperson or Vice Chairperson.

(7) The Vice Chairperson shall preside the meeting in the absence of Chairperson.

(8) The secretary or designated officer of the Division shall sign the correspondence on behalf of the committee.

(9) The committee shall examine and investigate the reports of the inspector and fix the responsibility in case of any violation.

(10) The committee shall issue a show cause notice or a notice for personal hearing prior to decide the cases of violation.

(11) The Committee may make procedure for the conduct of its business subject to ratification by the Authority.

(12) The Committee may pass appropriate orders including referring the case to Drugs Courts for violations of the Act or DRAP Act.

(13) The Committee may direct the applicants for explanation about any matter or refer the matter to experts of relevant specialty for expert opinion.

(14) The committee may call any person for personal hearing or showing cause of violations to the DRAP Act or rules framed there under.

(15) The aggrieved person or party may prefer appeal before the Appellate Board against the decision of committee within a period of one month as per prescribed procedure for appeal.

(16) Enlistment Certificate for manufacturer or importer shall be issued on **Form 6** as prescribed in schedule A.

(17) Enlistment Certificate for products shall be issued on **Form 7** as prescribed in schedule A.

(18) Enlistment Certificate for contract manufacturing shall be issued on **Form 8** as prescribed in schedule A.

8. **Responsibilities of Enlistment Holder**.-(1) Enlistment holder shall be responsible and liable for quality, safety and efficacy of the authorized enlisted product.

(2) The enlistment is an interim arrangement for a specified period and it does not confer any right for unlimited continuation of manufacture, import and export, or grant of manufacturing license or product authorizations.

(3) Relevant provisions of the DRAP Act regarding quality, safety, and efficacy shall be applicable upon all enlisted companies or firms or products.

(4) Enlistment holder shall be responsible for compliance to the conditions of enlistment as defined in the enlistment certificate.

(5) Enlistment holder shall be authorized to procure raw materials for manufacturing of enlisted products at the authorized premises stated in the enlistment certificate as manufacturer and market such products throughout Pakistan under prescribed warranty.

(6) Enlistment holder shall be responsible to follow the principals of good

manufacturing practices.

(7) Finished products shall be supplied after certification and release by the authorized person.

(8) Manufacturing, quality control, sale and distribution records shall be maintained and kept for one year beyond the expiry of the finished product.

(9) Non compliance to fulfillment of responsibilities by enlistment holder shall be liable to revocation of enlistment certificate.

9. "**Certificate of free sale and Compliance to G.M.P.-** (1) Application for award of free sale and Good Manufacturing Practices compliance certificate shall be submitted to the Division of Health and OTC Products of the Authority on **Form 9** as prescribed in Schedule A accompanied by prescribed fee for therapeutic goods.

(2) The certificate for compliance to Good Manufacturing Practices to the manufacturer of alternative medicine and health products shall be issued to enlistment holder on **Form 10** as prescribed in schedule A for compliance to the requirements of Good Manufacturing Practice and conformance to international standard for manufacturing till the time of licensing.

(3) The Division shall issue free sale certificate to the applicant provided the product is freely available in the local market where as the GMP certificate shall be issued after inspection and verification by inspector notified for the purpose.

10. **Manufacturing and distribution.(1)** The manufacturing and testing of alternative medicines and health products shall be conducted in accordance with the criteria laid down in the current edition of specified publication or as may be prescribed and approved by the Authority.

(2) The baby milks and foods, nutritional products and probiotics shall be manufactured and tested in accordance with the internationally recognized standards, codes of practice, guidelines and other recommendations of Codex Alimentarius of Food and Agriculture Organization and World Health Organization.

(3) The enlistment holder or his authorized agent shall issue warranty on **Form 11** as prescribed in schedule A for the supplied alternative medicine and health product warranting that these products does not contravene the any provision of DRAP Act and rules framed there under.

(4) Manufacturer shall use only permitted excipients as prescribed in **Schedule B** complying to the conditions and specifications

(5) Enlistment holder shall authorize distributors as authorized agents for supply and sale on **Form 12** as prescribed in Schedule A to distribute his enlisted finished products and issue warranty on behalf of enlistment holder in their designated area of jurisdiction stated in the authority letter.

11. **Prohibitions.-** (1) No person himself or any other person on his behalf shall issue or cause to be issued any advertisement by any means what so ever, except obtaining permission after review of contents of advertisement material by the Authority.

(2) No person himself or any person on his behalf shall manufacture, import or sell any adulterated, misbranded, spurious, counterfeit or substandard medicine or health products.
(3) Violation of this rule shall be offence under Schedule II and is punishable under Schedule III of DRAP Act.

SCHEDULE A
[See rule 3]

Form 1
[See of rule 3(3)]

APPLICATION FOR ENLISTMENT OF MANUFACTURER OR CONTRACT GIVER
(Attach readable soft copy with application)

I/WE ……..……..
(1)…….. (2)…….(attach list of partners)
Holder (s) of CNIC No. ……..……
Owner of M/S……hereby apply for enlistment of my firm/company established under company/partnership Act..... Having NTN ……. located at the premises as under……..……..

(A) That I am manufacturing following classes of therapeutic goods

1. Alternative Medicines. (Attach detail information as Annex-A)
    a. Herbal Medicinal product or Phytopharmaceuticals(standardized extracts) or phytomedicine
    b. Indigenous or Unani Medicines or traditional Medicines.
    c. Homeopathic Medicines.(mother tincture, sarcode, Nosode , Allersode, Isode or any other homeopathic preparation or dosage form)
    d. Bio-chemic Medicines.
    e. Herbal oils / Balms
    f. Any other alternate/ complementary medicines.

2. Health and OTC Products. (Attach the information as Annex-B)
    a. Food supplements (Neutraceuticals or dietary or health supplements).
    b. Nutritional supplements, pro-biotics and pre-biotics
    c. Baby Milks and Foods (infant or baby formulae, follow up formulae, formulae for special medical purposes or complementary foods intended for infants and young children).
    d. Disinfectants.
    e. Medicated cosmetics, and shampoos containing natural ingredients.
    f. Medicated Soaps containing natural ingredients
    g. Tooth pastes/mouthwashes/throat lozenges/gargles containing natural ingredients.
    h. Medicated cosmetics/Derma-care products/Balms/ patches/ medicated oils natural ingredients
    i. Any other.

3. That my manufacturing unit has following facilities:
(Attach the site master file as Annex-C)

4. Total size of the plot/ building is ……..……..sq/feet.

5. No. of sections are as under: - (Attach list of equipment and instruments available with copy of invoice for each section)

a. Tablets.
b. Capsules.
c. Dry Syrup.
d. Dry powder (s).
e. Liquid Solution, Syrup, emulsion, suspensions, drinking ampoules and Drops.
f. Ointment and Creams.
g. Sachet/herbal teas/joshanda.
h. Eye/ Ear/ Nasal Drops.
i. Packaging and Labeling.
j. Quality Control Lab (pharmacognosy, chemistry and microbiology laboratories).
k. Warehouses.
l. Water purification plant.
m. Sterilization facility.
n. Any other section.

6. Our facility has following staff: (Attach the information as Annex-D)

a. Qualified staff name, qualification, experience and training .State responsibility and attach their CV's.
b. Supportive and non technical staff.

7. List of Manufactured and marketed products and product wise as well as total turnover:
(Attach the information as Annex-E) .

8. Fee deposit bank receipt.

9. I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper.

Name of the owner

Signature

Seal of the Firm/ Company.

Dated.....

Form 2
[(See rule 3(3)]

APPLICATION FOR ENLISTMENT OF IMPORTER
(Attach readable soft copy with application)

I/WE
……..…..
(1)…….. (2)…….(attach list of partners)
Holder (s) of CNIC No. ……
Owner of M/S…….hereby apply for enlistment of my firm/company having NTN ……. located at the premises as under……..……..

(A). that I am importing following classes of therapeutic goods (attach contract if contract manufacturing).

1. Alternative Medicines. (Attach detail information as Annex-A)
    a. Herbal Medicinal Product or Phyto-medicine or Phyto-pharmaceuticals
    b. Imported Medicine
    c. Homeopathic Medicines.
    d. Bio-chemic Medicines.
    e. Herbal oils / Balms.
    f. Herbal preparations
    g. Any other alternate/ complementary medicines.

2. Health and OTC Products. (Attach the information as Annex-B)
    a. Food supplements (Neutraceuticals or dietary or health supplements).
    b. Nutritional supplements, pro-biotics and pre-biotics.
    c. Baby Milks and Foods (infant or baby formulae, follow up formulae, formulae for special medical purposes or complementary foods intended for infants).
    d. Disinfectants.
    e. Medicated shampoos containing natural ingredients.
    f. Medicated Soaps natural ingredients
    g. Tooth pastes/mouthwashes/throat lozenges/gargles natural ingredients.
    h. Medicated cosmetics / Derma-care products / Balms / patches / medicated oils natural ingredients
    i. Any other.

(B). that overseas manufacturing unit has following facilities:

(Attach the site master file as Annex-C)

3. Total size of the plot/ building covered area is ……..sq/feet

4. Storage facilities for storage of imported stocks:- (Attach list of equipment and license of facility from the provincial health department if any.)

5. Type or class of finished products being imported.

a. Tablets.
b. Capsules.
c. Dry Syrup.
d. Dry powder.
e. Liquid Solution, Syrup, emulsion, suspensions, drinking ampoules and Drops.
f. Ointment and Creams.
g. Sachet/herbal teas/joshanda.
h. Eye/ Ear/ Nasal Drops.
i. Quality Control Lab (pharmacognosy, chemistry and microbiology laboratories).

6. The overseas manufacturer has licensed facility from the Regulatory Authority of country of origin. (Attach the information as Annex-D).

7. Detail of manufacturing facility and qualified technical staff

a. Qualified staff name, qualification, experience and training .State responsibility and attach their CV's.
b. Supportive and non technical staff.

8. List of imported and marketed products and product wise as well as total annual turnover. (Attach the information as Annex-E)

9. Manufacturing license and Last inspection report of the overseas manufacturer. (Attach information as Annex-F) .

10. Copy of Agency agreement between the Principal manufacturer and importer.

11. Fee deposit receipt

12. I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper).

Name of the owner

Signature

Seal of the Firm/ Company.

Dated.....

FORM-3

[(See rule 3(3)]

APPLICATION FOR ENLISTMENT OF LOCALLY MANUFACTURED INDIGENOUS UNANI MEDICINE, HERBAL MEDICINAL PRODUCTS (PHYTOMEDICINE) HOMEOPATHIC, MEDICINE OR HEALTH PRODUCTS FOR TRADITONAL USE NUTRITIONAL OR STRUCTURE- FUNCTION CLAIMS

(Attach readable soft copy with application)

I/We…….…… Owner (s) of M/s……hereby apply for enlistment of following products manufactured by my firm/company (has already applied as manufacturer) located at the premises as under

1. Product Profile

S.No	**Brand Name of Product.**				
	List of ingredients With strength	Common Name of ingredients	Recommended use	Pack size	Maximum Retail price

2. Master Formula.
3. Manufacturing process.
3. Testing specifications.
4. Shelf life and storage.
5. Recommended Conditions for use.
6. Packaging and labeling.
7. Maximum Retail price.
8. Fee deposit receipt.
9. I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper).

Name of the owner
Signature

Seal of the Firm/ Company

Dated.....

FORM-4
[(See rule 3(3)]

APPLICATION FOR ENLISTMENT OF LOCALLY MANUFACTURED INDIGENOUS UNANI, HERBAL MEDICINAL PRODUCTS OR PHYTOMEDICINE HOMEOPATHIC, MEDICINE OR HEALTH PRODUCTS FOR THERAPEUTIC OR DISEASE REDUCTION CLAIMS

(Attach readable soft copy with application)

I/We…… Owner (s) of M/s……hereby apply for enlistment of following products manufactured by my firm/company (has already applied as manufacturer) located at the premises as under

1. Product Profile

S.No	**Brand Name of Product.**				
	List of ingredients with strength	Common Name of ingredients	Recommended use	Pack size	Maximum Retail price

2. Master Formula.
3. Manufacturing process and in-process controls
3. Testing specifications for raw material and finished products.
4. Shelf life and storage.(shelf life shall base on stability data)In case data not available then letter of commitment for submission of data be submitted.
5. Recommended Conditions for use (evidence for therapeutic or disease reduction claims as per standards of evidence.
6. Packaging and labeling information.
7. Maximum Retail price.
8. Fee deposit receipt.
9. I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper).

Name of the owner

Signature

Seal of the Firm/ Company.

Dated.....

FORM-5

[(See rule 3(3)]

APPLICATION FOR ENLISTMENT OF NEW MEDICINE (NEW FORMULATIONS) OR IMPORTED PRODUCTS

(Attach readable soft copy with application)

I/We……..… Owner (s) of M/s……hereby apply for enlistment of following products manufactured by M/s…….…… situated at……city……..…. province……..……. Country of origin of principal manufacturer……. firm/company from (has already applied as importer) located at the premises as above

1. Product Profile

S.NO	Brand Name of Product.				
	Common Name ingredients	List of ingredients with strength	Recommended conditions for use	Pack size	Maximum Retail price

2. Batch manufacturing formula or Master Formulation.
3. Manufacturing process and In-process controls.
3. Testing specifications of starting materials and finished products, validation data and certificates of analysis.
4. Shelf life and storage. (Evidence of long term and accelerated Stability data)
5. Recommended conditions for use (with evidence of quality, safety and efficacy data).
6. Evidence of clinical safety and efficacy based on Pre-clinical and clinical studies along with data.
7. Packaging and labeling (label mock up and package leaflet insert approved in the country of origin.
8. Maximum Retail price.
9. Import documents
    a. Manufacturing license of the Principal Manufacturer in the country of origin.
    b. Approval of product registration or marketing authorization in the

country of origin.

c. G.M.P Certificate of Principal Manufacturer by the local regulatory Authority.
d. Free sale certificate in the country of origin and in other countries being marketed (certificate of pharmaceutical product (CPP on WHO Format) as replacement for Free Sale, GMP and Registration or marketing Authorization)
e. Certification with any Organization or Authority.
f. Certificate of Analysis of active ingredients and finished products from the (preferably from Public Sector Laboratory or Independent Accredited Lab).
g. Last three years commercial invoices.
h. Bill of lading and transport documents.
i. Tax or duties payment evidence.
j. Agreement between the importer and principal manufacturer.
k. Last inspection report by the local regulatory Authority.
l. State countries with evidence where product is approved/available/submitted for approval/rejected and approved recommended conditions for use (attach evidence).

10. Fee deposit receipt.

11. I undertake and certify that the contents stated above are correct and true to the best of my knowledge (please attach undertaking on the notarized stamp paper).

Name of the owner

Signature

Seal of the Firm/ Company.

Dated.....

FORM-6

[(See rule 7(16)]

PROVISIONAL CERTIFICATE FOR ENLISTMENT AS MANUFACTURER/ IMPORTER

E.No. …….. Dated: ……..……..
M/s……..…….located at the address ……...……is Agent of ……(applicable for importer only)

Is hereby enlisted in the enlistment register as manufacturer/ importer by the Authority subject to the following conditions namely:-

a. The manufacturer or importer shall be responsible for the quality, efficacy and safety of all the therapeutic goods manufactured and sold by him.

b. He shall abide by all the provisions of the Drug Regulatory Authority of Pakistan Act, (XXI) of 2012 except those exempted under the said Act.

c. He shall immediately recall the defected therapeutic goods within 15 days after intimation to him and report the compliance to the Authority.

d. He shall be responsible to withdraw the unsafe therapeutic goods from the market if so declared by the Authority. He shall also report adverse affect reports, (if any), to the Authority within 15 days period and notify focal person for such reporting.

e. Any other relevant condition imposed by the Authority in future.

f. This certificate shall not be valid after the date notified by the Authority through official gazette.

g. Certificate of enlistment shall be surrendered to the Authority within 7 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

Designated Officer …….
Dated..... Division of Health and OTC Products
Drug Regulatory Authority of Pakistan

FORM-7

[(See rule 7(17)]

PROVISIONAL CERTIFICATE FOR ENLISTMENT OF PRODUCTS

Following products of M/s……located at the address ……..……is / are manufactured by ……..……..

EN	Brand name of the product				
	List of ingredients With strength	Common Name of ingredients	Recommended use	Pack size	Maximum Retail price

Conditions for Enlistment:

a) The product(s) shall be tested for microbial contamination and it is verified that these products does not contain any type of pathogenic microbial contamination.

   Provided that disinfectants and homeopathic medicines containing 50% or above concentration of ethanol shall be exempted from such microbial testing.

b) The content the heavy metals in the finished product shall be within the prescribed limits as defined in the rules.

c) The product shall not contain any toxic or dangerous materials which are injurious to health.

d) The finished products shall be tested and released before sale by the Quality Control Department of the unit or contract laboratory approved by the Authority.

e) The products shall remain safe, effective and retain its quality during the whole shelf life.

f) The product conforms to all the relevant provisions of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI) of 2012.

g) The product is not contaminated with any type of ingredient not enlisted in the formula approved by the Authority.

h) The product does not contain any prohibited substance or Allopathic or any western ingredient which is not part of approved formulation.

i) The manufacturer/ importer shall be responsible for all the liabilities or damage occurred due to usage of enlisted products.

j) The recommended conditions for use shall be permissible only through valid evidence based on standards of evidence as prescribed under the rules.

k) Label claim of prohibited diseases shall not be made in any case, as required under the rules.

l) Maximum Retail Price (MRP) shall be as per policy finalized by the Authority.

m) This certificate shall not be valid after the date notified by the Authority through official gazette.

n) Certificate of enlistment shall be surrendered to the Authority within 7 days if it is suspended, revoked, becomes invalid or its holder winds up his business.

o) Recommended conditions for use as per standard package insert or leaflet shall be reviewed by the Authority which shall be part of finished product label.

Designated Officer …….
Division of Health and OTC Products
Drug Regulatory Authority of Pakistan
Dated.....
.

Form No 8
(See sub-rule 18 of rule 7)

CERTIFICATE FOR CARRYING OUT CONTRACT MANUFACTURING OF ALTERNATIVE MEDICINES OR HEALTH PRODUCTS ON BEHALF OF ENLISTMENT HOLDER OR LICENSEES.

1. Certified that approval number .....granted on the..... day of.....2014..…. for carrying out contract manufacturing of the following *medicines or health product* at the premises situated at ..... has been approved for a period of one year which will expire on the day of .....2015.

2. *List of permitted products to be manufactured on contract basis on behalf of m/s……*
……...for the following finished products.

…….

…….

2. Name(s) of GMP experts and the person-in-charge of production is…….. Expert on test /analysis is ……. and owner of the manufacturing premises is……..

Conditions of approval

i. This approval shall be produced at the request of the Inspectors appointed under the Act.

ii. That the applicant shall inform the Authority in writing in the event of any change of the experts. Where any change in the technical qualified staff of production or the laboratory takes place, the current approval shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh approval has been taken from the Authority in the name of contract manufacturer with the changed constitution otherwise the approval shall stand cancelled after the lapse of this period

iii. That this approval is conditional that the enlistment holder has undertaken to establish his own manufacturing facility.

iv. That the contract manufacturer shall ensure quality assurance of finished product and continuously maintain compliance to the good manufacturing practice as described in the WHO Good Manufacturing Practices for Traditional Medicine 2005.

v. That the contract manufacturer shall forward summary of every manufactured batch of medicine on prescribed format along with certificate of analysis to the Director Quality Assurance, Director

Health and OTC Products and Provincial Quality Control of the concerned province.

vi. That the contract manufacturer and enlistment holder shall comply to the conditions prescribed in the rules.

vii. The Certificate shall be returned to the Authority if it is expired, suspended, withdrawn, revoked or the enlistment holder himself surrenders the business

Date: .....
Signature.....
Place: .....
Designation.....
Seal of Officer Authority

No.....dated.....

FORM NO 9

[See rule 9(1)]

GOOD MANUFACTURING PRACTICES /FREE SALE CERTIFICATE(S)

Certificate of Good Manufacturing Practices (GMP) /Free Sale Certificate to manufacturer of the Alternative Medicine/ Health Products/Baby Milks and Foods/Medicated Cosmetic products etc..

It is certified that manufacturing unit (enlistment holder or licensee), namely.....Situated at ..... ……..... Enlistment No/Licence No..... complies with the requirements of Good Manufacturing Practices of medicines and health products as prescribed by the Authority under the Drug Regulatory Authority of Pakistan Act 2012. or

2. The product namely ……..enlisted with the Authority vide enlistment no……is on free sale in the local market.

This certificate is valid for a period of one year.

Date.....…… Signature……..…...

Place : ..... Designation……..……

Designated Officer …….
Division of Health and OTC Products
Drug Regulatory Authority of Pakistan

FORM NO 10

[See rule 9(2)]

INVOICE/WARRANTY

Invoice no……dated……..20…..
To
M/s…….Situated……
It is certified that I Mr……..s/o Mr…….having NIC NO……..……. being manufacturer or importer or (authorized agent vide authority letter no……/dated……on behalf of M/s……)

1. It is hereby certified that following finished products have been supplied by me.

S.NO	**Total no of items sold.**				
	Name of Product and Pack size	**Batch number (or lot no)**	**No of units sold**	**Distribution price**	**Retail Price**

GrantTotal……

2. It is hereby certified and I undertake that above mentioned finished products of specified batch number (or lot number) supplied by me do not contravene the any provision of the Act and rules framed there under. The Authorized agent (with valid distribution authority letter) shall pass on this warranty to the retailers in his area of jurisdiction during the supply of medicine and health products.

a……..

b……..

Date:....…… Signature……..…...

Place: ..... Designation……..……

Seal of manufacture or /importer

FORM NO 11

[See rule 10(3)]

AUTHORITY LETTER TO THE AUTHORIZED AGENT

NO……..…….dated…….……

It is certified that Mr.……s/o Mr…….having NIC NO…….

Prop of M/S……Situated at ..... …… is hereby authorized as agent to distribute and supply our products (list enclosed) and issue invoice warranty on our behalf within his area of jurisdiction as stated below.

1……..

2……..…

Date…… Signature……...

Place: .....Designation…….……

Seal of manufacturer/importer

SHEDULE B

See rule 10(4)

Permitted Excipients :- Permitted Excipients, i.e. additives, preservatives, anti-oxidants, coloring agents, flavoring agents, alternate sweeteners specified in column (2) of the Table below are permitted in medicines including Unani medicines as per reference standard or grade under the prevention of Food Adulteration Act India (PFA), Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), United States National Formulary (USNF) and others as mentioned in column (3) of the Table, namely:

TABLE

S.No.	**Permitted Excipients**	**Reference Standards/Grade**
(1)	**(2)**	**(3)**
A.	**Additives**	
1.	Gum Acacia	PFA
2.	Activated Charcoal	IP
3.	Agar	PFA
4.	Alginic Acid and its salts	PFA
5.	Arachis Oil	PFA
6.	Beeswax	IP
7.	Bentonite	IP
8.	Calcium Carbonate	PFA
9.	Calcium Phosphate Dibasic	IP
10.	Calcium Phosphate Tribasic	IP
11.	Carbomer	IP
12.	Carnauba Wax	IP
13.	Cellulose and its derivaties	IP
14.	Cetocetyl alcohol	IP
15.	Citric acid and its salts	PFA
16.	Colloidal Silicon Dioxide	IP
17.	Carmellose Sodium	IP
18.	Dextrin and its derivatives	PFA / IP
19.	Dextrose	PFA
20.	Emulsifying Anionic Wax	IP
21.	Gelatin	IP
22.	Glucose	PFA
23.	Glycerin	IP
24.	Guar Gum	PFA
25.	Hard Paraffin	IP
26.	Hydrogenated Vegetable Oil	PFA

27.	Icing Sugar	PFA
28.	Invert Sugar Syrup	BP
29.	Isopropyl myristate	IP
30.	Isopropyl palmitate	BP
31.	Kokam Butter	PFA
32.	Lactose	IP
33.	Lecithin/Soya Lecithin	USNF
34.	Light Magnesium Carbonate	IP
35.	Light Mineral Oil	IP
36.	Liquid Glucose	PFA
37.	Liquid Paraffin	IP
38.	Magnesium aluminium silicate	BP
39.	Magnesium Carbonate	IP
40.	Magnesium Oxide	IP
41.	Malic Acid	PFA
42.	Malt Extract	IP
43.	Maltodextrin	USNF
44.	Mannitol	IP
45.	Methcrylic acid ethylacrylate	USNF
46.	Microcystalline Wax	IP
47.	Pectic Enzyme	In-house specification
48.	Pectin	PFA
49.	Poloxamer	USNF
50.	Polyethylene Glycol	IP
51.	Polymethacrylate	USNF
52.	Polysorbates	IP
53.	Polyvinyl alcohol	IP
54.	Polyvinyl pyrollidone	IP
55.	Polyvinyl acetate phthalate	IP
56.	Potassium Bicarbonate	IP
57.	Povidone and its derivatives	IP
58.	Propylene Glycol	IP
59.	Shellac	IP
60.	Skimmed Milk Powder	PFA
61.	Sodium Bicarbonate	IP
62.	Sodium Chloride	PFA
63.	Sodium Edetate	PFA
64.	Sodium Hydroxide	IP
65.	Sodium Lauryl Sulphate	IP
66.	Sodium Silicate	IP
67.	Sodium Starch Glycollate	IP
68.	Sodium Stearyl Fumarate	IP
69.	Soft Paraffin	IP
70.	Sorbitan Esters	BP

71.	Sorbitol	IP
72.	Starch and its derivatives	IP
73.	Stearic Acid and its salts	IP
74.	Sucrose	IP
75.	Talc	IP
76.	Tartaric Acid and its salts	PFA
77.	Titanium Dioxide	IP
78.	Tragacanth Gum	IP
79.	Wax non-ionic emulsifying	IP
80.	Wax microfine	IP
81.	White petroleum jelly	IP
82.	Xanthan Gum	USNF
83.	Xylitol	USNF
84.	Yeast	PFA
85.	Yellow petroleum wax	IP
86.	Yellow petroleum jelly	IP
87.	Zinc oxide	IP
B.	**Preservatives:**	
1.	Acetic acid	PFA
2.	Benzalkonium chloride	IP
3.	Benzethonium chloride	IP
4.	Benzoic acid and its salts	PFA
5.	Bronopol	BP
6.	Butyl paraben	BP
7.	Cetrimide	IP
8.	Ethyl paraben	BP
9.	Imid urea	In-house specifications
10.	Propyl paraben and its salts	PFA
11.	Methyl Paraben and its salts	PFA
12.	Phenyl mercuric nitrate	IP
13.	Propionic acid and salts	PFA
14.	Sorbic acid and its salts	PFA
C.	**Antioxidants:**	
1.	Ascorbic acid and its salts and esters	PFA
2.	Butylated hydroxyl anisole	PFA
3.	Butylated hydroxyl toluene	PFA
4.	Gallic acid esters	PFA
5.	Potassium metabisulphite	PFA
6.	Sodium metabisulphite	PFA
D.	**Colouring agents:**	**Permissible colors for oral are stated in part 2 of this schedule.**
E.	**Flavouring agents:**	**as per codex Alimentarius**

F.	Alternate Sweeteners:	as per codex Alimentarius

Note:

1. Preservatives, alternative sweeteners and colouring agents shall be mentioned on the label for information of the user.
2. Additives used in various processes and to formulate dosage form shall be mentioned clearly with quantity in the flow sheet and the record shall be maintained by the manufacturing unit.
3. Manufacturers shall be responsible to ensure rationality, safety and quantity of various additives used in the formulation. This will be as per IP/BP/USP/PFA/ or other standard reference book.

Part 2. LIST OF PERMITTED COLOURS FOR ORAL USE.

Colours permitted in medicines for oral use	JECFA name (if different)	Colour number	Index	INS number
Allura Red AC	16035		129	
Amaranth	16185		123	
Annatto	Annatto Extracts (Oil and Alkali-extracted) Annatto Extracts (Solvent-extracted)	75120		160b
Anthocyanins	Grape Skin Extract	-		163(ii)
Beet Red	-		162	
Betacarotene	40800		160a(i)	
Brilliant Black BN	Brilliant Black PN	28440	151	
Brilliant Blue FCF	42090		133	
Brilliant Scarlet 4R	Ponceau 4R	16255	124	
Canthaxanthin	40850		161	
Caramel	**Caramel Colours**			

Class I: Plain Caramel, caustic caramel		150a	
Class II: Caustic sulfite caramel		150b	
Class III: Ammonia caramel		150c	
Class IV: Sulfite ammonia caramel		150d	
Carbon black	Vegetable carbon	77266	153
Carmoisine	Azorubine	14720	122
Carotenes	Carotenes (Algae) Carotenes (Vegetable)	75130	160a(ii)
Chlorophylls		75810	140
Chlorophyllins - Copper Complexes Sodium and Potassium Salts (previous AAN Chlorophyllin - Copper Complex)		75810	141(ii)
Chlorophylls - Copper Complexes		75810	141(i)
Chocolate Brown HT	Brown HT	20285	155
Cochineal		75470	120
Curcumin		75300	100(i)
Erythrosine		45430	127
Fast green FCF		42053	143
Food Orange 6	Beta-apo-8'-carotenal	40820	160e
Food Orange 7	Beta-apo-8'-carotenoic Acid Ethyl Ether	40825	160f
Green S		44090	142

Indigo Carmine	Indigotine	73015	132
Iron Oxide Black	77499		172(i)
Iron Oxide Red	77491		172(ii)
Iron Oxide Yellow	77492		172(iii)
Patent Blue V	42051		131
Phloxine Bb	(none allocated)	45410	-
Quinoline Yellow	47005		104
Riboflavin	-		101(i)
Saffron	75100		-
Sunset Yellow FCF	15985		110
Red 27	45410		-
Titanium Dioxide	77891		171

Director Legal Affairs

Muhammad Arshad Khan

Drug Regulatory Authority of Pakistan

._____

(No. F. 3-5/2013 – DDC (Alt-Med)