Regulatory Framework

on

Health and OTC Products

January 2013

DRAFT

Therapeutic Goods

(Medicine, Health Supplements and Health Products)

Rules 2013

Presented by

Division of Health and OTC Products

Drugs Regulatory Authority of Pakistan

Government of Pakistan, Islamabad

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Therapeutic Goods (Medicine, and Health Products) Rules 2013

In exercise of powers conferred under section 23 of Drugs Regulatory Authority of Pakistan Act 2012 and after approval of Federal Government, Drugs Regulatory Authority of Pakistan (DRAP) is pleased to make the following Rules namely:-

Chapter I

1. Short title and Commencement:

(i) These Rules may be called Therapeutic Goods (Alternative Medicines, Health Supplements and Health Products) Rules, 2013

(ii) They shall come into force at once for whole of Pakistan

2 Definitions:

1) "Act" means Drug Regulatory Authority of Pakistan Act 2012, (Act No. XXI of 2012).
2) "Active Ingredient" means substance or compound that is useable in the manufacture of Alternative Medicine, Health Supplements or Health Products as a pharmacologically active constituent.
3) "Adverse Effect" means any debilitating, harmful, toxic or detrimental effects which have been found or likely to have on the body or health of human or animals when such products is used or administered to the human or animals.
4) "Adulterated" a products shall be deemed to be adulterated
   a) If it contains in whole or in part of any filthy, putrid, or decompose substance; or
   b) If it has been prepared packed or stored under unsanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
   c) If its container is composed in whole or part of any poisonous or deleterious substance which may render the contents injurious to health: or
   d) If it bears or contains a color or flavoring agents other than which is prescribed; if it contains any harmful or toxic substance which may render it injurious to health; or if any substance have been mixed so as to reduce its quality or strength.
5) "Advertisement" means the publication, dissemination, conveyance of any information for the purpose of promoting whether directly or indirectly the sale or use of any medicine or health product by any means or in any form including the following:
   a) Publication in a news paper, magazine, journal or other periodicals;
   b) Display of poster or notices;
   c) Circular, handbills, broachers, pamphlets, books or other documents;

d) Letters address to individual, bodies, corporate or unincorporated;
e) Photographs or documentary or cinematographs film;
f) Sound broadcasting television or other media;
g) Public demonstration for use of the products;
h) Offer of trial of products to the member of public;

vi. "Allopathic Ingredients" means ingredients of drugs used in allopathic or western system which contains chemically defined synthetically manufactured ingredients.

vii. "Analyst" means a person of prescribed qualification and experience appointed by the Authority or Federal or Provincial Governments, for the supervising test/ analysis of the samples of therapeutic goods and verification of analytical methods. He/ She will also issue Certificate of Analysis as prescribed.

viii. "Appellate Board" means Board of expert constituted under section 9 of the Drugs Act 1976 for the disposal of appeals preferred by the person aggrieved with the decision of Medicine, and Health products Licensing and Registration Boards.

"Appropriate non-proprietary name" means

a. where the medicinal product or ingredient is described in a monograph in a specified publication which was last published before the date on which the medicinal product was supplied or dispensed, any name or abbreviation of that name or synonym at the head of that monograph
b. where the medicinal product or ingredient is not described in a monograph in a specified publication but has an international non-proprietary name, that international non-proprietary name; or
c. where the medicinal product or ingredient is not described in a monograph in a specified publication and does not have an international non-proprietary name, the accepted scientific name or other name descriptive of the true nature of the medicinal product or ingredient.

"APPROPRIATE QUANTITATIVE PARTICULARS" MEANS

a. the quantity of each active ingredient, identified by its appropriate non-proprietary name, in each dosage unit of the medicinal product expressed in terms of weight, volume, capacity or units of activity; or
b. where there is no dosage unit, the quantity of each active ingredient identified by its appropriate non-proprietary name, in the container of the medicinal product expressed in terms of weight, volume, capacity or units of activity or percentage by weight or volume of the total quantity;

ix. "Authorized Person" means a focal person having degree of pharmacy nominated by the manufacturers or importers for correspondence including timely submission of Pharmacovigilance updates and adverse effects to the Authority.

x. "Certificate of Registrations" means certificate granted by the Authority regarding Medicine and Health Products in accordance with the rules.

xi. "Clinical Trial" means an investigation in respect of Medicine, and Health Products that involves human subjects and that is intended to

a) Discover or verify its clinical, pharmacological or pharmacodynamic effects;
b) Identify any adverse effect that may arise from its use;
c) Study its absorption, distribution and excretions;
d) Ascertain its safety and efficacy;
e) Dosage regime calculation;

xii. "Constituent" means chemically defined substances or group of substances which are generally accepted to contribute substantially to the therapeutic activity of a medicine product or medicinal preparation

"Counterfeit" means if it is imitation of resemble in a manner likely to deceive or bear upon its label or the container the name of another product of medicines or allopathic drugs or nearly resembles to the products of another manufacturer or importer with a view to deceiving the public.

xiii. "Disinfectant" means a health product used for destroying or inhibiting microorganism that may be harmful to the human or animals

"dispensed medicinal product" means —

a. a medicinal product supplied by a healthcare professional to his patient or to a person under whose care that patient is; or
b. a medicinal product dispensed by a pharmacist in any premises registered under the Act for carrying on a retail pharmacy business;

xiv. "Efficacy" means ability of product to properly carry out the intended purpose

xv. "Expert" means a person with post graduate relevant qualification and at least 15 years experience in the relevant field.

"Expiry date" means the date after which, or the month and year after the end of which, a medicinal product should not be used, or the date before which or the month and year before the beginning of which, a medicinal product should be used;

xvi. "Export" with its grammatical variation and cognate expressions means to take out of Pakistan by sea, land or air route.

xvii. "General sale" means sale of a medicinal or health product to a pharmacy or in any outlet which is not pharmacy and it is a product which has been exempted under these rules.

xviii. "Health Products" means any formulation or preparations that is represented for use by human solely or principally for health related purpose and it includes the following

a) Medicated Cosmetics, Shampoos and Soaps containing natural active ingredients

b) Medicated plaster
c) Disinfectants
d) Medicated Oil and Balm

xix. "Health Related Purpose" means a therapeutic, preventive, palliative or cosmetic purpose or any other purpose for promotion or wellbeing of human or animals and also including destroying or inhibiting microorganism that may be harmful and cleansing, fragrencing, deodorizing, beautifying, preserving, improving, altering or restoring complexion, skin, hair, nail and teeth of human.

xx. "Health Supplement (Neutaceuticals)" means finished product containing active ingredient (s) like vitamins, minerals, amino acids,enzymes, fatty acids (natural and synthetic), baby milk and foods, cereals, prebiotic and probiotics including herbal preparations in the form of extracts, isolates and concentrates intended for health related purpose and are presented into pharmaceutical dosage form to be administered in small unit doses. These dosage forms includes

a) Hard gel and Soft gel Capsules
b) Tablets
c) Drops, Liquid and syrups
d) Creams and Ointments
e) Powders and Sachets
f) External Preparations
g) Oral ampoules or
h) Any other dosage form as prescribed

xxi. "Herbal Medicinal Product" means any medicinal product exclusively containing as active ingredient 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.

xxii. "Herbal Preparations" means preparation obtained by subjecting herbal substances to treatment such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

xxiii. "Herbal Substance" means all mainly whole, fragmented or cut plants, plants parts, algae, fungi, lichen in an unprocessed usually dried form but sometimes fresh. Certain exudates that have not been subjected to specific treatment or also considered to be herbal substances. Herbal substances are precisely defined by the plant parts used and the botanical name.

xxiv. "Homeopathic Medicine" means any substances used in the system of therapeutic in which diseases are treated by the use of minute amount of such substance which are

capable of producing in healthy person symptoms similar to those of the disease being treated, and finished product may contain a number of principal prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by any of the following pharmacopeias;

a) German Homeopathic Pharmacopeia
b) US Homeopathic Pharmacopeia
c) European Homeopathic Pharmacopeia
d) British Homeopathic Pharmacopeia or
e) Any other pharmacopeia prescribed

xxv. "Import" with its grammatical variation and cognate expressions means to bring into Pakistan by sea, land or air route.

xxvi. "Inspector" means a person of prescribed qualification and experience appointed by the Authority or Federal or Provincial Governments for the purpose of DRAP Act 2012.

xxvii. "Intended Purpose" means use for which medicine or health product is intended according to the claim of manufacturer or importer as stated on any or all of the following

a) Label of the product
b) Instructions for use of the product
c) Promotional Material in relation to the product

"International non-proprietary name" means a name which has been selected by the World Health Organisation as a recommended international non-proprietary name and in respect of which the Director-General of the World Health Organisation has given notice to that effect in the WHO Chronicle

xxviii. "Label" label in relation to product or ingredient or preparation means any written, printed or graphic representation that appears on or is attached to the container of product or active ingredient or preparation or any part of its packaging and includes any informational sheet or leaflets that accompanies when finished products or active ingredient or preparation is being supplied.

"Label Claim" means any representation made on a product in relation to its indications, benefits or action. Claims could be stated directly or inferred indirectly through, but not limited to, the following:

- Graphics or logos on product packaging
- Product and/or Brand Name
- Media advertisements (print, sound and light & sound)
- Point of sales materials
- Product brochures or information sheets distributed with/separately from the product.

xxix. "Licence " means any type of licence issued under these rules

"Loan Licence" means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another licensee.

xxx. "Manufacture" means all operations involved in the production including processing, compounding, formulating, filling, packing, repacking and labeling with a view to storage, sale and distribution.

xxxi. "Manufacturer Licence" means a licence issued under these rules authorizing the holder thereof to manufacturer, registered Medicine and Health Products for distribution and sale.

"Markers" means chemically defined constituent of herbal medicine which are of interest for control purpose independent of weather they have any therapeutic activity or not. Marker servers to calculate the quantity of herbal medicinal products or preparation in the finished products.

"Maximum Retail Price" means retail price of a finished product fixed by the Authority

xxxii. "Medicated Cosmetic" means health product used for cleansing, fragrencing, deodorizing, beautifying, preserving, improving, altering or restoring complexion, skin, hair, nail and teeth of human containing active ingredient of natural origin and include

a) Antidandruff preparation
b) Medicated cosmetic for treating pimple and acne
c) Medicated soap
d) Sweets for reliving cough and throats infections
e) Sunscreen and sustan preparations
f) Medicated toothpaste

xxxiii. "Medicated Oil and Balm" means any external medicated embrocation, medicated cream, ointment or inhalant used for soothing purposes and contains following active ingredients

a) Essential oils
b) Fixed oil derived from plant
c) Methyl Saliscylate
d) Menthol, Camphor and Peppermint

xxxiv. "Medicine and Health Product Licensing Board" means a board established under these rules for the grant/ renewal/ revocation of various type of licence s for Medicine and Health Product

xxxv. "Medicine and Health Product Registration Board" means a board established under these rules for the grant/ renewal/ revocation of registration of Medicine and Health

Product.

xxxvi. "Medicine" means a finished product pertaining to homeopathic, Ayruvedic and Tib Unani which contains as an active ingredient any isolated constituent of plants, animals, or minerals or a combination of any of one or more of them but shall not include

a) Any medicinal product to be injected into the human body
b) Any item of allopathic substances
c) Any vaccines to be used by the human being
d) Any product derived from human blood
e) Any chemically defined substance except vitamin and mineral products

xxxvii. "Misbranded" a finished product shall be deemed to be misbranded;

a) If it is so colored, coated, powdered or polished that the damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or
b) If it is not labeled in the prescribed manner or
c) If its label or container or anything accompanying the product bears any statement, design or device which makes any false claim for the product or which is false or misleading in any particular; or
d) If its label or container or package leaflet do not accompany any information or precaution or side effect or adverse effect, which is otherwise to be mentioned under these rules.

xxxviii. "Nutritional Supplement" means a product that is used to supplement a diet, with benefits beyond those of normal nutrients, and / or to support or maintain the healthy functions of the human body.

"Package leaflet" means a leaflet containing information for the consumer which accompanies the finished product

xxxix. "Pharmacist" means a health care professional having university education and registered under the Pharmacy Act 1967.

xxxx. "Pharmacy" means a shop being lawfully kept open for dispensing or compounding of medical prescription and includes the pharmacy of a hospital.

xxxxi. "Prebiotics" means the non digestible nutritional ingredient(s) that stimulate the growth and/ or activity of bacteria in the digestive system in ways claim to be beneficial to health

xxxxii. "Probiotics" means the product containing live microorganism that may confer health benefits on the host.

xxxxiii. "Prohibited Substance" means a substance that is not permitted to be contained by any medicinal or health products and includes

a) Allopathic Ingredients
b) Colors except the prescribed

c) Any substance or herb declared harmful to animals or human beings

d) Any other substance prescribed

"Proprietary designation" means the word or words used in connection with the sale or supply of medicine and health products for the purpose of indicating that they are the goods of a particular person by virtue of manufacture, selection, certification, dealing with or offering for sale or supply;

xxxxiv. "Raw Material" means active ingredient (s) including all additives and excipients

"Recall" means any action taken by manufacturer, importer, supplier or registrant 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 product which

a) may be hazardous to health

b) may fail to conform to any claim made by its manufacturer, importer or registrant relating to the quality, safety or efficacy

c) may not meet the requirement of the DRAP Act 2012

xxxxv. "Reference Products" means innovator products used for comparison for verification of therapeutic equivalence of generic product.

xxxxvi. "Registered Hakeem" means a health care professional registered by the National Council for Tib to practice under the Unani and Ayurvedic system of medicine.

xxxxvii. "Registered Homoeopathic Medical Practitioner" means a health care professional registered/enlisted with the National Council for Homeopathy to practice under the homeopathic/~~(~~Biochemic~~)~~ system of medicine.

xxxxviii. "Registered Medical Practitioner" means a health care professional registered with the Pakistan Medical and Dental Council.

"Registered Products" means a medicinal or health products dully registered by the Authority under the DRAP Act 2012.

xxxxix. "Review of pharmaceutical dossiers" means screening, assessment and evaluation of data included in the pharmaceutical dossiers submitted for the grant of registration, renewal and approval for variation including addition and deletion of labeling claims.

"Sales promotion" means any sales campaign (including door to door sales), exhibition, competition or any other activity for the purpose of introducing, publicising or promoting the sale or use of any medicinal product or any device, instrument, apparatus or contrivance used or represented to be used for a medicinal purpose.

xxxxx. "Schedule" means schedule under these rules

"Standardization" means adjusting the herbal drug preparation to a defined content of a constituent or a group of substances with known therapeutic activity respectively by adding excipients or by mixing herbal medicine or herbal medicinal preparation. E.g.

Standardized extract of the European pharmacopeia

"Sound Advertisement" means any advertisement broadcast over radio, or any audio recordings.

"Sound and Light Advertisement" any advertisement with light and sound effects, e.g. television, cinema advertisements, film lets, videos.

"Specified publication" means any of the following:

(a) European Pharmacopoeia;

(b) British Pharmacopoeia or British Herbal Pharmacopoeia;

(c) US Pharmacopoeia or National Formulary;

(d) Pharmaceutical Codex (British); or British Herbal Codex

(e) British National Formulary.

(f) International Pharmacopoeia

(g)Any other publication approved by the Authority for this purpose.

"Still Advertisement" means any advertisement in print media, e.g. newspapers, magazines, leaflets, brochures, billboards, posters, banners, shelf talkers, wobblers, stickers, display racks, stands or trays, lighted boxes, mail order announcements or calendars.

xxxxxi. "Storage" means storage for sale, to "store", or "stored" shall be construed accordingly.

xxxxxii. "Substandard" means a product is substandard

a) It is not in conformity as regard strength, quality, purity with specifications mentioned in the official pharmacopeias or prescribed authoritative books or specification approved by the Authority
b) It has strength which differs from standard of purity or quality and falls below as represented on the label.
c) It contain any substance in excess of the prescribed permitted concentration
d) It has passed its expected shelf life or its expiry date mentioned on the label

xxxxxiii. "Supply" means

a) To sell the product through retail sale, wholesale or auction
b) To expose or display the product as an intimation to treat
c) To transfer possession of product by exchange, gift, leased, loan, hire or sale
d) To transfer product by way of administration to or application in any person in the course of any diagnosis, treatment or testing.

xxxxxiv. "Therapeutic goods" means both finished product of medicines and health product or their active ingredients for the purpose of these rules

"Traditional Use Medicine" means a finished product having long history of usage, which is authorized for use through certificate of registration after manufacturing for sale and includes

a) Ayruvedic Medicine
b) Tib-E-Unnani Medicine
c) S

Chapter II

Manufacture of Medicine and Health Products

3. **Types of Licenses s:** licenses to manufacture Medicine and Health Products shall be of the following type
   i. to manufacture Ayurvedic Medicine & Tib-E-Unani Medicine
   ii. Licence to manufacture Health Supplements(Nutraceuticals)
   iii. Licence to manufacture Bulk Herbal Preparations
   iv. Licence to manufacture Health Products
   v. Licence to manufacture Homeopathic/Biochemic Medicine
   vi. Loan Licence
   vii. Licince to manufacture Therapeutic goods for experimental purpose

3 Licensing Board:

4. **Licensing Authorities:**
   i. Director, Health and OTC Product to perform the various functions of licensing on behalf of Medicine and Health Product Licensing Board shall be Licensing Authority for the purpose of these rules.
   ii. licensing authority may with the approval of the CEO of Authority by an order in writing delegate the power to sign licences and such other powers as may be specified in the order to any other person under his control
   iii. Secretary to the health department of Province(s) or his nominated officer (s) shall be Licensing Authority for the provinces or such and such areas as may be prescribed for the purpose of licensing of pharmacies at provincial level or district level as the case may be.
   iv. Qualification of licensing authorities shall be at least graduation in Pharmacy or Pharmaceutical Chemistry or Medicine with specialization in clinical pharmacology from a recognized University and having at least 10 years experience in the manufacture or testing of therapeutic goods or drugs or relevant enforcement of various provision of the Act.
5. **Manufacture on more than one set of premises:** If the therapeutic goods are manufactured on more than one set of premises, a separate application shall be made and separate licence shall be issued in respect of each licence
6. **Application For Licence to Manufacture Medicine and Health Products**
   i. An application for the grant or renewal of a licence to manufacture for sale for any

Ayurvedic or -Unani, health supplements, herbal preparations or health products shall be made in prescribed form for the medicine and health products to the licensing authority

ii. An application under sub rules (i) shall be accompanied by the prescribed fee as specified in schedule I

iii. On receipt of application for grant or renewal of a licence, any objection or short coming in the application observed by the directorate may be intimated to the applicant and he shall be given a time period of thirty days for rectification or completion of application. In case, the applicant fails to rectify or complete the application within the specified period, the application may be rejected.

iv. In case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry

v. It shall be the responsibility of licence holder to apply for renewal of licence before its expiry.

vi. The applicant may apply for renewal after the expiry of one month, but within six months of such expiry with the fee as may be prescribed.

vii. If the licence holder fail to submit application for licence renewal after the expiry of six months, the licence shall stand cancelled.

viii. A fee as prescribed shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.

ix. A fee as prescribed shall be payable for each section, if the applicant applies for more than one section

x. An inspection report of fitness of the premises for manufacturing by the panel of inspectors shall be mandatory for the consideration of the Board

xi. For change of the name of licencee, a fee as prescribed in schedule shall be paid along with complete particulars as prescribed.

7. **Certificate of Licence ;** The licensing authority shall issue Certificate of Licence to the applicant on the prescribed form XXXX

8. **Certificate of Renewal of Licence:** The certificate of renewal of a licence in form XXX shall be issued.

9. **Certificate of award of GMP:** The certificate of good manufacturing practices to manufacturers shall be issued to licencee who comply with the requirements of Good Manufacturing Practice regulations as laid down in schedule

10. **Duration of Licence :** An original licence in form or a renewed in form, unless sooner suspended or cancelled shall be valid up to five(5) years from the date of issue:

Provided that if the application for the renewal of a licence is made before its expiry or within one month of its expiry after payment of the prescribed fee, the licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to

have expired, if the application for its renewal is not made within six months of its expiry.

11. Licencing Board:

i. Licencing board shall consist of following members namely;
   a. Director, Health and OTC Product ex officio Chairperson
   b. Additional Director as Ex-Officio Member / Secretary
   c. Analyst of government drugs testing laboratories deputed for testing of medicine and health products nominated by respective provincial government.
   d. One expert member of Unani Medicine, nominated by the Authority
   e. One expert member of Homeopathic medicine nominated by the Authority
   f. One Professor of Pharmacy from any public University nominated by the Authority
   g. Concerned Deputy Drugs Controller (s) as ex-officio member (s)

ii. Three representatives from the stakeholders may also attend the meeting of the Licencing Board as observer to be notified by the Authority.

iii. Any matter pertaining for legal opinion shall be referred to the Director, Legal Affairs, the same shall be considered by the Licensing Authority or Board as the case may be.

iv. The quorum to constitute a meeting shall be 50% of the total membership.

v. No act or proceeding of the Board shall be invalid merely on the ground of existence of any vacancy or any defect in constitution of the Board.

vi. After show cause notice and personal hearings, the Licencing Board shall fix the responsibility of offence and grant sanctions for prosecution or otherwise as the case may be.

viii. Every member shall sign a declaration of conflict of interest that he/she does not hold any conflict of interest.

ix. The concerned Deputy Drugs Controller (s) shall submit brief of inspection report of manufacturing facility to be considered by the Board.

x. Liciencing Board may co-opt any other person who is expert of any speciality for the disposal of relevant cases

xi. Secretary shall call the meeting of the Board on the direction of Chairperson of Board.

xii. Vice Chairperson shall act as Chairperson in absence of Chairperson.

xiii. No act or proceeding of the Board shall be invalid merely on the ground of existence of any vacancy or any defect in constitution of the Board.

xiv. After show cause notice and personal hearings, the Licencing Board shall ascertaining the responsibility of offence and grant sanctions for prosecution or otherwise as the case may be.

xv. Licencing Board may grant, renew, suspend or revoke Certificate of Manufacturing Licence or approval of particular section (s) after evaluation of facts presented before.

xii. Vice Chairperson on behalf of Registration Board may extend the "note to dispose of" and "sealing Period" on the request of Inspector (s).

xiii. Vice Chairperson on behalf of Licencing Board may constitute inspection panel for inspection and investigation as and when required.

xiv. Licencing Board may initiate evaluation process against any manufacturer who is established non compliant by the Registration Board or on its own motion.

xv. Licencing Board shall follow and adhere to the policy guidelines approved by the Authority.

xvi. Members of the Licencing Board shall not be included any panel for inspection constituted by the same Board.

12. Procedure for Licincing Board:

(1) the licensing board shall, before issuing a licence, cause the premises in which the manufacture is proposed to be conducted to be inspected by a panel of inspector or experts appointed by it for the purpose, which may examine all portions of the premises and the plant and appliances, inspect the process of manufacture intended to be employed and the means to be employed for standardizing, if necessary, and analysing substances to be manufactured and enquire into the professional qualifications of the technical staff employed

(2) where inspection under sub-rule (1) is carried out by panel of experts or inspectors appointed under the said sub-rule it shall forward to the licensing board a detailed report of the result of the inspection on prescribed format.

(3) if the licensing board, after' such further enquiry, if any, as it may consider necessary, is satisfied that the requirements of the rules have been complied with, it may issue a licence in form xxx.

(4) if the licensing board is not so satisfied, it shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a licence may be issued.

(5) No application shall be entertained within three months of the rejection of an application under sub-rule (4).

(6) if after the expiry of three months but within six months of the rejection of an application under sub-rule (4), the applicant informs the licensing board that the

requirements of the rules have been fulfilled, the board may if after causing a further inspection to be made, is satisfied that the conditions for the grant of a licence have been complied with, issue a licence and prescribed fee shall be required to be deposited for such an application.

(7) in case an application for licence to manufacture is made after the expiry of six months from the date of rejection of an application under sub-rule (1), such application shall be treated as a new application.

Special provisions regarding grant of a licence:

(1) where a manufacturer intends to manufacture a product a part of the process of which is of specialised nature and would be uneconomical for him to conduct it, the licensing board may permit such process to be undertaken at another licensed premises specialised for this purpose, subject to such conditions, if any, as may be specified in this behalf.

(2) if a person is conducting a part of the process of the manufacture on behalf of another manufacturer in accordance with the permission granted under sub-rule (1), and he is not responsible for the quality of the final product, the licensing board may not require him to establish an independent quality control laboratory for such products.

(3) if a person possesses, or applies for, more than one type of licences to manufacture therapeutic good in the same premises, he may establish one quality control department for the purpose of both the licences.

(4) Licencing Board may approve an application for the testing and issuance of certificate of analysis of any product from the approved laboratory on contract basis,

Provided released responsibility shall be shared according to the contribution defined in the written contract.

Provided further that the contract giver shall have a Quality Control Department who shall ensure compliance of contract laboratory by reviewing their laboratory information file and practice of contract quality control laboratory.

11. Conditions for the grant or renewal of a licence in form xx: before a licence in form xx is granted or renewed in form xx the following conditions shall be compiled with by the applicant, namely: —

i. The manufacture of medicine shall be carried out in such premises and under such hygienic conditions as are specified in schedule xx. [1-a for getting a certificate of 'good manufacturing practices' of medicine, the applicant shall made application on prescribed form, providing the information on existing infrastructure of the manufacturing unit, and the licensing authority shall after verification of the requirements as per schedule 'xx' issue the certificate within a period of 3 months in form xx]..

ii. The manufacture of Health Supplements shall be carried out in such premises and under such hygienic conditions as are specified in schedule B, BI, BI-A and BII of Drugs (Licensing, Registering and Advertising) Rules 1976 of Drugs Act 1976. [1-a for getting a certificate of 'good manufacturing practices'of Health Supplement, the applicant shall made application on prescribed form, providing the information on existing infrastructure of the manufacturing unit, and the licensing authority shall after verification of the requirements as per above said schedule issue the certificate within a period of 3 months on prescribed format.

iii. the manufacture of therapeutic goods shall be conducted under the direction and supervision of competent technical staff consisting at least one person as production in-charge and one as quality in-charge, who are whole time employee and who possess the following qualifications, namely—

a) A master degree in pharmacy with pharmacognosy or phytochemistry as major subject, conferred by a recognized university and at least 5 years experience in manufacturing of therapeutic goods shall act as Production Incharge. A graduate of Unani medicine having experience of at least 5 years in the manufacture of medicines for supervising respective manufacturing activities as Section Incharge.

b) A graduate in Pharmacy or Pharmaceutical Chemistry or Master in Chemistry or Master in Botany of a recognized University shall act as Quality Control In-Charge and at least 5 years experience in testing of therapeutic goods. In case microbiological testing is required and lab facilities are available, a microbiologist/ pharmacist having master degree in Microbiology or pharmacy respectively with 5 year relevant experience, to supervise the microbial testing

iii. Every section of the manufacturing facility shall have independent qualified In-Charge to supervise manufacturing activities.

12. Conditions of Licence: A licence in form xx shall be subject to the conditions stated therein and to the following further conditions, namely

i. the licence e shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or by any other person on his behalf, of the raw material (s), packaging material (s) and finished products

ii. The licence e shall allow an inspector appointed under the Act or authorized person (s)

to enter any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises, facilities, utility service, to take samples of the raw material as well as finished products, and to inspect the records maintained under these rules and to make copies as extract of records.

iii. The licence e shall maintain an inspection book provided by the Authority to enable an inspector to record his impressions and the defects noticed.

iv. A manufacturer licence does not authorized the holder thereof to supply any of manufactured product (for testing) unless the product so manufactured is registered by the Authority and he is allowed to sale.

v. The licence shall not used any premises or facility for the manufacturer of any therapeutic goods unless the premises facility is authorized by the authority for such used under the manufacturer licence and areas have been approved for particular type of manufacturing.

vii. The licence shall ensure manufacture of registered product is carried out in accordance with such requirement as may be prescribed.

viii. Manufacturing of registered products is carried out in accordance with the condition of licence and complying with the standard of good manufacturing practice applicable on the product.

ix. The licence shall not procure, supply arrange for manufacturing of any therapeutic goods which is

a) Adulterated
b) Spurious
c) Misbranded
d) Substandard
e) Counterfeit
f) Which falls in violation to any provision of DRAP Act 2012

x. The licence e shall not sell or supply any finished products which contains any allopathic ingredient of western medicine.

xi. Licence e shall ensure that finished product complies that

a) the content of Arsenic, Copper, Lead and Mercury are within the prescribed limit
b) Where the finished product is for oral consumption, test result on the content of Escherichia coli, Salmonella, Staphylococuss aureus, total yeast and mould counts and total aerobic microbial content per gram or mille litre shall be within permissible limit.

Provided such microbial testing not necessary, if the finished products contain any active substance which is derived from plant, animals or a combination thereof and which has been produced by the fermentation process.

c) Where the finished product is for external preparation test result on the content of Seduomonas aureginesa, Staphylococuss aureus total yeast and mould counts and total aerobic microbial content per gram or mille litre shall be within permissible limit.

Provided such microbial testing not necessary, if the finished products contain any active substance which is derived from plant, animals or a combination thereof and which has been produced by the fermentation process.

xii. The licence e shall conduct all manufacturing operations in such a way as to ensure that the finished product or of correct identities and confirms the standards of strength, quality, purity applicable to them.

xiii. The licence e shall inform the licensing authority before making any material alteration to the premises or plant used under licence or in the operation for which they are used.

xiv. The licence e shall inform the licensing authority before making any change that purposes to make in any personnel named in his licence application form responsible for supervising production operation or the quality control operations and get approval from the Authority for such change.

Xv Licence e shall recall the defective finished products and notify the compliance to the Authority along with detail of actions taken by him within ten days.

xvi. The licence e shall return the original copy of licence to the licensing authority within seven days of the date on which the licence has been suspended or revoked.

xvii. The licence e shall not use the licence for advertising purpose

13. Cancellation and suspension of licences

i. the licensing authority may, after giving an opportunity to show cause within a period which shall not be less than fifteen days from the date of receipt of such notice, why such an order should not be passed, by an order in writing stating the reasons therefore, cancel a licence issued under this rules or suspend it for such period as he thinks fit, either wholly or in respect of some of the therapeutic goods to which it relates, if in his opinion, the licence e has failed to comply with any of the conditions of the licence or with any provisions of the DRAP Act 2012 and the rules made there under.

ii. A licence e whose licence has been suspended or cancelled may appeal before the Appellate Board within a period of three months from the date of cancellation or suspension of licence as the case may be.

14. Identification of raw materials: Raw materials used in the preparation of medicine, health supplements and health products shall be identified and tested, wherever test are available for their genuineness, and records of such tests as are carried out for the purpose and the methods thereof shall be maintained.

15. Licence to manufacture homoeopathic medicines: Licence for manufacture of Homoeopathic

medicines is a licence to manufacture mother tincture/trituration/potentised/and biochemic medicines preparations from back potencies by Pharmacies who are already licence–d to sell Homoeopathic medicines by retail and shall be granted by Provincial Governments.(to be separated for sale and manufacturing)

16. **Additional conditions for the grant or renewal of a licence to manufacture homoeopathic medicines** : Before a licence in prescribed Form is granted or renewed, the following conditions shall be complied with by the applicant :____

i. The manufacture of Homoeopathic medicines shall be conducted under the direction and supervision of competent technical staff consisting at least of two person who is a whole time employee to carry out independent production and quality control activities

a) a Pharmacy graduate or Master in Science with Chemistry as one of the subjects with five years' experience in manufacture and quality control of Homoeopathic Medicines for supervision of manufacturing and quality control activities respectively with additional qualification of the relevant field.

Provided one homeopathic graduate shall also be employed for supervision of activities related to their speciality.

ii. The factory premises shall comply with the requirements and conditions specified XXX

Provided that where the Licensing Authority considers it necessary or expedient so to do, it may having regard to the nature and extent of manufacturing operations, relax or suitably alter the said requirements or conditions in any particular case for reasons to be recorded in writing.

iii. The applicant for manufacture of Homoeopathic mother tinctures shall either;

a) provide and maintain adequate staff, premises and laboratory equipment for identifying the raw materials and for testing the mother tinctures wherever possible, or

b) For those who do not have the inhouse arrangement may make arrangements with some institution or contract laboratory approved by the Licensing Authority under these rules for such tests, to be regularly carried out on his behalf by that institution.

iv. The premises where Homoeopathic medicines are manufactured shall be dedicated, distinct and separate from the premises used for any other purposes

v. Homoeopathic medicines shall not be manufactured simultaneously with drugs pertaining to other systems of medicine

vi. The applicant shall make arrangements for proper storage of Homoeopathic medicines manufactured by him.

Provided that in case potentised preparations are made in a Pharmacy holding

licence, the conditions (ii) and (iii) shall not apply. The licence e shall ensure to the satisfaction of the Licensing Authority that the products manufactured by it, conform to the claims made on the label

vii. the licensee shall comply with the following conditions in respect of mother tinctures manufactured by him

a) the crude drug used in the manufacture of the mother tincture shall be identified and records of such identification shall be kept for a period of five years.

b) the total solids in the mother tincture shall be determined and records of such tests shall be kept for a period of five years.

c) the alcohol content in the mother tincture shall be determined and records of the same shall be maintained for a period of five years.

d) the containers of mother tinctures shall preferably be of glass and shall be clean and free from any sort of impurities or adhering matter. The glass shall be neutral as far as possible.

e) in the p.rocess of manufacture of mother tinctures hygienic conditions shall be scrupulously observed by the licensee. Storage and handling conditions shall also be properly observed by the licensee according to Homoeopathic principles

f no colour shall be added to any Homoeopathic medicines:

Provided that caramel may beaded to combination of Homoeopathic preparations with syrup base

17. Inspection before grant or renewal of licence to manufacture homoeopathic medicines: Before a licence under this Part is granted or renewed, the Licensing Authority shall cause the establishment, in which the manufacture is proposed, to be conducted or being conducted, to be inspected by one or more Inspectors or experts appointed under these Rule. The Inspector or Inspectors/ experts shall examine all portions of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the substances to be manufactured and inquire into the professional qualifications of the technical staff to be employed. He shall also examine and verify the statements made in the application in regards to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipments and the requirements of plant and equipment as laid down in Schedule XXXX read with the requirements of maintenance of records as laid down in Schedule XXX.

18. Inspection and Inspection report for grant or renewal of licence to manufacture homoeopathic medicines: The inspection team shall forward a detailed descriptive report giving his or their findings on each aspect of inspection along with his or their recommendations after completion of their inspection to the Licensing Authority.

19. Grant or refusal of licence to manufacture homoeopathic medicines:

i. If the Licensing Authority after such further enquiry, if any, as he may consider necessary is satisfied that the requirements of the rules under the Act have been complied with and that conditions of the licence and the rules under the Act shall be observed, he shall grant or renew a licence in Form xx or Form xx

ii. If the Licensing Authority is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a licence can be granted or renewed and shall supply the applicant with a copy of inspection report

20. Further application after rejection: If with a period of six months from the rejection of an application for a licence under section 19, the applicant informs the Licensing Authority that the conditions have been fulfilled and deposits prescribed inspection fee, the Licensing Authority may, if, after causing further inspection to be made, he is satisfied that the conditions for the grant of licence have been complied with, issue a licence on prescribed format.

21. Appeal against rejection of application: Any person who is aggrieved by the order passed by the Licensing Authority refusing to grant or renew a licence under this rules 19 may within ninety days from the date of receipt of such order, appeal to the Appellate Board and the Appellate Board may, after such enquiry into the matter as is considered necessary and after giving the said person an opportunity for representing the case, pass such order as it thinks fit.

22. Loan Licences.

i. Application for the grant or renewal of loan licences to manufacture for sale or for distribution of Therapeutic goods shall be made up to ten items for each Therapeutic goods categories accompanied by prescribed fee to the licensing authority.

Provided that if the applicant applies for the renewal of a licence after, its expiry but within six months of such expiry, the fee payable for renewal of such licence shall be accompanied by a prescribed licence fee and an inspection fee.

ii. The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture, and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan licence.

iii. If the Licensing Authority is satisfied that a loan licence is defaced, damaged or lost or otherwise rendered useless, he may, on payment of prescribed fee issue a duplicate licence.

23. Conditions for the grant or renewal of a loan licence.- Before a loan licence is granted or renewed, the all GMP conditions shall be complied with by the applicant. All the conditions of licence shall be applicable on the licence of loan.

24 Duration of loan licence.- An original loan licence in Form xx or a renewed loan licence in Form

xx, unless sooner suspended or cancelled, shall be valid for a period of five years on and from the date on which it is granted or renewed.

Provided that if the application for the renewal of a licence is made before its expiry, or if the application is made within six months of its expiry, after payment of prescribed fee, the licence shall continue to be in force until orders are passed on for its renewal is not made within six months of its expiry.

25 Licence to manufacture therapeutic goods for experimental purpose:

i. If person intending to manufacture therapeutic good for experimental purpose does not hold a licence to manufacture therapeutic goods, he shall before commencing such manufacture apply in prescribed form for the grant or renewal to the licensing authority.

ii. The application shall be countersigned by the head of the institutions or the director or manager of the company of the firm by which product will be manufactured.

iii. The licence for manufacture therapeutic goods for experimental purpose shall be in Form XXX

26 **Conditions of Licence to manufacture therapeutic goods for experimental purpose:** A licence issued shall be subject to the following conditions namely

i. The licence shall use therapeutic goods manufactured under the licence exclusively for experimental purpose and shall carry on the manufacturer on the premises specified in the licence.

ii. Licencee shall allow the licensing authority or the quality control board or an inspector to entere with or without notice the permsed where therapeutic goods are manufactured and to satisfy himself that the manufacture is being conducted for experimental purpose only.

iii. The licencee shall comply with the further requirements if any as may be specified by the licencing authority.

27. Labelling of therapeutic goods manufactured for experimental purpose:

i. Any therapeutic good manufactured for experimental purpose shall be kept in containers bearing the label indicating the purpose for which it has been manufactured.

Ii. If any therapeutic good manufactured for experimental purpose is supplied by the manufacture to any other person the container shall bear a label on which shall be stated name and address of the manufacturer, scientific name of the therapeutic good if known or if not known a reference which will enable it to be identified and the purpose for which it has been manufactured.

2~~8~~2. Accreditation/ Certification of Laboratories for contract testing

i. Contract testing of Medicine, Health Supplements and Health Products will be allowed for the purpose of release of raw material, finished goods and stability testing from the dully accredited and certified laboratories by the Authority both in private and public

sector.

ii. There shall be signed contract between the both parties for contract testing. Liability for quality, safety and efficacy of the drug shall rest on the both parties unless either party proves himself innocent.

iii. ~~The~~

23. Application for grant of approval for testing Medicine, Health Supplements and Health Products. – Application for grant or renewal of approval for carrying out tests for identity, purity, quality and strength of Medicine, Health Supplements and Health Products or the raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of the said Medicine, Health Supplements and Health Products shall be made in xx to the Licensing Authority under these rules, and referred to Board and shall be accompanied by prescribed fee.

Provided that the applicant shall furnish to the Board such additional information as may be required by it in connection with the application in Form xx.

Provided further that if the applicant applies for renewal of approval after is expiry but within six months of such expiry, the fee payable shall be as per schedule 4.

24. Conditions for grant and renewal of approval for contract testing:

i. Approval for carrying out such tests of identity, purity, quality and strength of Medicine, Health Supplements and Health Products as may be required under the provisions of these rules, on behalf of licensee for manufacture of Medicine, Health Supplements and Health Products shall be granted in Form xx

ii. The premises where the tests are carried out shall be well lighted and properly ventilated except where the nature of tests of any Medicine, Health Supplements and Health Products warrants otherwise. Wherever necessary, the premises shall be air-conditioned and Laminar flow so as to maintain the accuracy and functioning of laboratory instruments or to enable the performance of special tests such as sterility tests and microbiological tests

iii. The applicant shall provide adequate space having regard to the nature and number of samples of drugs proposed to be tested. He should also possess testing procedure at authoritative reference books and pharmacopeias.

Provided that the approving authority shall determine from time to time whether the space provided continues to be adequate.

iv. Separate section shall be provided for

(i) Chemistry,

(ii) Pharmacognosy,

(iii) Microbiology,

(iv) Sample Room,

(v) Office-cum-Record Room with proper partitions and minimum required area is 2000 sq. ft.

v. The applicant shall provide a list of persons who may be full time employed with him as experts, such as Chemist, Botanist, Microbiologist or Pharmacist who should have at least a graduation in Pharmacy or master in Pharmaceutical Chemistry or Pharmacognosy or Master in Chemistry or Master in Botany from recognized University with minimally 5 years experience in testing of therapeutic goods.

vi. The applicant shall provide adequate equipments essential for carrying out tests for identity, purity, quality and strength of Medicine, Health Supplements and Health Products as per pharmacopoeial standards or other available standards as per schedule 5

vii. The applicant shall provide and maintain suitable equipment having regard to the nature and number of samples intended to be tested which shall be adequate in the opinion of the Board

viii. The testing of Medicine, Health Supplements and Health Products, as the case may be, for identity, purity, quality and strength shall be carried out under the active direction of person-in-charge of testing, who shall signed test report and shall be held responsible for the reports of test issued by the applicant.

ix. The testing of Medicine, Health Supplements and Health Products, as the case may be, for identity, purity, quality and strength shall be carried out by persons whose qualifications and experience of testing are adequate as prescribed

x. The applicant shall provide list of standard Medicine, Health Supplements and Health Products (Reference standards and samples) recognized under the provisions of the Act and rules made there under and such reference samples kept in the laboratory may be required in connection with the testing or analysis of the products of which approval is applied for.

25. **Duration of approval**. – An approval granted in Form xx or renewed in Form xx unless sooner suspended or withdrawn, shall be valid for a period of three years from the date on which it is granted or renewed.

26. **Conditions of approval.** – An approval in Form 41 shall be subject to the following conditions, namely: -

i. The contract testing laboratory granted approved under this Part (hereinafter referred to as the approved laboratory) shall provide and maintain adequate staff and adequate premises and equipment as prescribed.

ii. The approved laboratory shall provide proper facilities for storage so as to preserve the properties of the samples to be tested by it.

iii. The approved laboratory shall maintain records of tests for identity, purity, quality and strength carried out on all samples of Medicine, Health Supplements and Health Products and the results thereof together with the protocols of tests showing the readings and calculation in such form as to be available for inspection and such records shall be retained in the case of substances for which date of expiry is assigned; for a period of two years from such date of expiry and in the case of other substances, for a period of three years.

iv. The approved laboratory shall allow the Inspector appointed under the Act to enter with or without prior notice the premises where testing is carried out and to inspect the premises and the equipment used for test and the testing procedures employed. The laboratory shall allow the Inspectors to inspect the registers and records maintained under these rules and shall supply to such Inspectors such information as they may require for the purpose of ascertaining whether the provisions of the Act and rules made there under have been observed.

v. The approved laboratory shall from time to time report to the approving authority any changes in the person-in-charge of testing of Medicine, Health Supplements and Health Products or the expert staff responsible for testing, as the case may be, and any material alterations in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the approving authority before the grant or renewal of approval.

vi. The approved laboratory shall furnish reports of the results of tests or analysis in Form 50 to the contract giver and one copy to the Authority.

vii. The approved laboratory shall comply with the provisions of the Act and rules made there under and with such further requirements, if any, as may be specified in the rules made from time to time under the DRAP Act 2012 not less than 4 month notice with the authority has been given.

viii. The approved laboratory shall maintain an inspection book to enable the Inspector to record his impression or defects noticed.

27. Inspection before grant of approval. Before an approval in form xx is granted, the approving authority shall cause the laboratory at which the testing of Medicine, Health Supplements and Health Products as the case may be, is proposed to be carried out to be inspected jointly by the Inspectors appointed or designated by licensing Authority for this purpose, who shall examine the premises and the equipment intended to be used for testing of drugs and verify into the professional qualifications of the expert staff who are or may be employed by the laboratory

28. Report of inspection. – The Inspectors and panel appointed by the Authority under DRAP 2012 shall forward a detailed report of the results of the inspection to the Board

29. Procedure of approving authority

i. If the approving authority after such further enquiry, if any, as it may consider necessary, is satisfied that the requirements of the rules made under the Act have been complied with and that the conditions of the approval and the rules made under the Act have been observed, it shall grant approval in Form 48.

ii. If the approving authority is not satisfied, it shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which shall be satisfied before approval could be granted.

iii. If within a period of six months from the rejection of an application for approval, the applicant informs the approving authority that the conditions laid down have been satisfied and deposits inspection fee of two thousand rupees, the approving authority may, if, after causing a further inspection to be made and after being satisfied that the conditions for grant of approval have been complied, with grant the approval in Form xx

iv. On an application being made for renewal, the approving authority shall, after causing an inspection to be made and if satisfied that the conditions of the approval and the rules made under the Act have been complied with, shall issue a certificate of renewal in form xx

v. The approving authority may, after giving the approved laboratory an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, withdraw an approval granted under this Part or suspend it for such period as it thinks fit either wholly or in respect of testing of some of the categories of Medicine, Health Supplements and Health Products to which it relates, if in his opinion the approved laboratory had failed to comply with any of the conditions of the approval or with any provision of the Act or the rules made there under.

vi. Any approved laboratory, whose approval has been suspended or withdrawn, may, within three months of the date of the order of suspension or withdrawal, appeal to the Appellate Board which shall dispose of the appeal in consultation with a panel of competent persons appointed by the Authority.

Chapter xcxxxxx

Government Analysts, Inspectors and Controlling Authorities

30. **Qualifications of Government Analyst:** A person appointed as a Government Analyst under these rules shall be a person who

i. is a post graduate in pharmaceutical chemistry or pharmacy or pharmaceutical sciences from a university recognized by the HEC a~~. A~~nd has had not less than 10 years' post-graduate experience in the testing of drugs in a laboratory or in a Institution or testing laboratory approved for the purpose by the appointing authority, [or has completed

training on testing of therapeutic goods or,

ii. for purpose of examination of items microbiological or pharmacological or toxicological testing

a. The persons having postgraduate degree in Pharmacology, Microbiology, Pharmacy with at least ten year's experiences in the relevant field.

31. Duties of Government Analysts.

i. the government analyst shall cause to be analyzed or tested such samples of therapeutic good as may be sent to him by inspectors or other persons under the provisions of DRAP Acts and shall furnish Certificate of test/analysis in accordance with these rules (for in case of homeopathic drugs ~~,~~as per approved PHP and others)

ii. Government Analyst shall from time to time forward to the Government report (s) giving the result of analytical work and research with a view for Public Alerts, further regulatory action and their publication at the discretion of Authority.

32. **Procedure on receipt of sample.** On receipt of a package from an Inspector containing a sample (s) for test or analysis, the Government Analyst shall compare the seals on the packet or on portion of sample or container with the specimen impression received separately and shall note the condition of the seals on the packet or on portion of sample or container. After the test or analysis has been completed, he shall forthwith supply to the Inspector a report in quartiplicate in prescribed Form o the result of the test or analysis, together with reference of approved specification/protocols of the tests or analysis applied

33. Specification and Protocol of Test/Analysis applicability:

i. for pharmacopoeial therapeutic goods, where tests or methods of analysis described in the official pharmacopoeia are followed, references to the specific tests or analysis in the pharmacopoeias are given in the report;

ii. for patent or proprietary therapeutic goods for which the tests and methods described in any of the official pharmacopoeias are applicable and are followed, references to the specific tests or analysis in the pharmacopoeias are given in the report;

iii. for patent or proprietary therapeutic goods containing pharmacopoeial drugs for which the official tests or analysis or methods of assays are modified and applied, a description of the actual tests or, as the case may be, analysis or methods of assays so applied is given in the report.

iv. for patent or proprietary therapeutic goods for which no pharmacopoeial tests or methods of analysis are available or can be applied but for which tests or methods of analysis given in standard books or journals are followed, a description of such tests or methods of analysis applied together with the reference to the relevant books or journals from which the tests or methods of analysis have been adopted, is given in the report

v. for those therapeutic goods for which methods of test are not available manufacturer

specifications which have been approved by the Authority or evolved by the Government Analyst, a description of tests applied is given in the report.

34. An application from a purchaser for test or analysis of therapeutic goods shall be made in prescribed form and the report of test or analysis of the therapeutic goods made on such application shall be supplied to the applicant in prescribed Form.

35. Prescribed fees shall be paid by a person submitting samples to the Government Analyst for test or analysis of any therapeutic goods purchased by him.

36. **Qualifications of Inspectors**. A person who is appointed an Inspector under the DRAP Act 2012 and these rules shall be a person who has ~~post~~ graduation in pharmaceutical sciences with basic degree in Pharmacy under Pharmacy Act 1967 and at least 10 years post graduate experience in testing or manufacturing or regulation in therapeutic goods relevant filed/experience.

37. **Controlling authority**. All Inspectors appointed by the Authority shall be under the administrative control of Director, Health and OTC Products for the purpose of these rules.

38. **Duties of Inspectors specially authorized to inspect the manufacture of therapeutic goods:**

    i. It shall be the duty of an Inspector authorized to inspect the manufacture of therapeutic goods.

        a. to inspect twice a year all premises licensed for manufacture of therapeutic goods within the area allotted to him to satisfy himself that the conditions of the licence and provisions of the Act and Rules there under are being observed.

        b. in the case of establishments licensed to manufacture products to inspect the plant and the process of manufacture, the means employed for standardizing and testing the therapeutic goods the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishment likely to affect the potency or purity of the product;

        c. to send forthwith the controlling authority after each inspection a detailed report indicating the conditions of the licence and provisions of the Act and Rules there under which are being observed and the conditions and provisions, if any, which are not being observed

        d. to take samples of the therapeutic goods manufactured on the premises and send them for test or analysis in accordance with these Rules;

        e. To investigate the violations and submit complete case within 90 days period to the controlling authority seeking sanction for prosecution to launch the case in the court of law. Provided if the inspector, is unable to complete the investigation due to the reasons beyond his control within 90 days he shall obtain extension from the controlling authority stating reason (s) for a period not more than 60 days.

        f. to call any person in respect of investigation for the purpose of interview as accused or witnessed in accordance with provisions of the Act

g. To call law enforcement agencies for assistance in case obstructions are produced in discharge of his/her duties.

h. To apply for registration of FIR against the defaulters of cognizable offences with law enforcement agencies.

i. to institute prosecutions in respect of breaches of the Act and Rules there under

j. Local inspector shall conduct regular and on direction inspections but he/she shall not be included in the inspection panels responsible for renewal of manufacturing licences.

k. To conduct surveillance of marketed therapeutic goods for ensuring quality control and compliance of various provisions of the Act and rules framed there under.

l. To assist in organizing and conducting the programme for monitoring of adverse reaction of therapeutic goods.

m. Any other function deputed by the Authority or Controlling Authority.

ii. A Inspector shall for the purpose of schedule V of the Act take approval or inform the Registration Board or Licensing Board in all cases as the case may be.

39. **Prohibition of disclosure of information:** Except for the purposes of official business or when required by a Court of Law, an Inspector shall not, without the sanction in writing of his official superior, disclose to any person any information acquired by him in the course of his official duties.

40. **Form of order not to dispose of stock:** An order in writing by an Inspector under sub-clause (i) of clause 1 of schedule V of the Act requiring a person not to dispose of any stock in his possession shall be in prescribed Form.

41. **Prohibition of sale:** No person in possession of a therapeutic goods in respect of which an Inspector has made an order sub-clause (i) of clause 1 of schedule V of the Act shall in contravention of that order sell or otherwise dispose of any stock of such therapeutic goods.

42. **Forms of receipts for seized therapeutic drugs, record register, document or any other material object:** A receipt by an Inspector for the stock of any therapeutic goods or for any record, register, document or any other material object seized by him under Schedule V of the Act shall be in Form 16.

43. **Manner of certifying copies of seized documents:** The Inspector shall return the documents , seized by him under schedule V or produced before him under the Act, within a period of 30 days of the date of such seizure or production, to the person from whom they have seized or, as the case may be, the person who produced them, after copies thereof extracts there from have been singed by the concerned Inspector and the person from whom they have seized , or, as the case may be , who produced such records.

44. **Form of intimation of purpose of taking samples:** When an Inspector takes a sample of therapeutic goods for the purpose of test or analysis, he shall intimate such purpose in writing in

prescribed Form to the person from whom he takes it.

45. **Procedure for dispatch of sample to Government Analyst.**
    i. The portion of sample or the container sent by an Inspector to the Government Analyst for test or analysis under schedule V of the Act shall be sent by registered post or by hand in a sealed packet, enclosed together with a memorandum in Form XX, in an outer cover addressed to the Government Analyst.
    ii. A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst separately by registered post or by hand.
46. **Central Drugs Laboratory:** The Authority shall, as soon as may be, established a unit in Central Drugs Laboratory, for testing of medicines, health supplements and health products to carry out the functions entrusted to it by these rules. Central Drugs Laboratory shall perform following functions namely:
    i. to test and analysis of such samples of Medicine, Health Supplements and Health Products as may be sent to it under these rules.
    ii. To analysis such samples as may be sent to it by the registration board, the licensing board and the Inspectors.
    iii. To carry out such other function as may be entrusted to it by the Authority or with the prior approval of the Authority.
47. **Appellate Laboratory,** Drugs Control and Traditional Medicine, National Institute of Health, Islamabad or any other laboratory notified by the authority shall function as Appellate lab for the purpose of these rules and shall have following functions namely
    i. to test and analyze such samples Medicine, Health Supplements and Health Products as may be sent to it by the Authority.
    ii. to carry out such other function as may be entrusted to it by the Authority with the prior approval of Federal Government.
48. **Signature of the Certificate of Analysis:** Certificate issued under these rules shall be signed by the Government Analyst and Officer In-charge of the Laboratory for the Central Drugs Laboratory and Appellate Laboratory respectively.
49. **Fee:** Fee for test analysis of sample of Medicine, Health Supplements and Health Products shall be those specified in schedule. Xxxxx.
50. **Inspection of Laboratory Information and Quality System:** In-house and external inspection of quality system and practices shall be conducted annually.

Chapter XX

Registration of Therapeutic goods

51 Registration Board:

i. Registration Board shall consist of the following members namely:

a. CEO of the Authority, who shall be its ex-officio Chairperson

b. Director, Health and OTC Products, who shall be its ex-officio Vice Chairperson
c. Four expert members from the field of Pharmacognosy, Phytochemistry, Traditional Medicine, etc to be nominated by the provincial government, one from each province.
d. One expert member of Unani Medicine, nominated by the Authority
e. One expert member of Homeopathic medicine nominated by the Authority
f. One Professor of Pharmacognosy/ Phytochemistry from public sector University nominated by the Authority
g. One Professor of Pharmacognosy/ Phytochemistry from private sector University nominated by the Authority
h. One professor of Pharmacology/Toxicology
i. One expert having background of Manufacturing of medicines(formulation Expert)
j. One expert having background of testing of medicines
k. Reviewer (s) of pharmaceutical dossier of the concerned sections as ex-officio member (s)
l. Additional Director, Health and OTC Products, who shall be its ex-officio Secretary cum member
m. One member from the Consumer organization nominated by the Authority

ii. Three representatives from the stakeholders may also attend the meeting of the registration board as observer to be notified by the Authority.
iii. Every member shall sign a declaration of conflict of interest that he/she does not hold any conflict of interest.
iv. The concerned reviewer (s) shall submit brief review report of pharmaceutical dossier to be considered by the Board.
v. Registration board may co-opt any other person who is expert of any speciality for the disposal of relevant cases
vi. Secretary shall call the meeting of the board on the direction of Chairperson of Board.
vii. Vice Chairperson shall act as Chairperson in absence of Chairperson.
viii. The quorum to constitute a meeting shall be 50% of the total membership.
ix. No act or proceeding of the Board shall be invalid merely on the ground of existence of any vacancy or any defect in constitution of the Board.
x. After show cause notice and personal hearings, the Registration Board shall ascertaining the responsibility of offence and grant sanctions for prosecution or otherwise as the case may be.
xi. Registration Board may grant, renew, suspend or revoke Drug Registration Certificate after evaluation of facts presented before.
xii. Vice Chairperson on behalf of Registration Board may extend the "note to dispose of"

and " sealing Period" on the request of Inspector (s).

xiii. Registration Board may in public interest restrict or stopped the import of any therapeutic good which is sufficiently produced within the country.

xiv. Vice Chairperson on behalf of Registration Board may constitute inspection panel for inspection and investigation as and when required.

xv. Vice Chairperson or any other person authorized by the chairperson shall act as Licensing Authority on behalf of Registration Board and dispose off relevant matters connected thereto.

xvi. Registration Board shall follow and adhere to the policy guidelines approved by the Authority.

xvii. Members of the Registration Board shall not be included any panel for inspection constituted by the same Board

xvi. Any matter requiring legal opinion shall be referred to the Director, Legal Affairs, the same shall be considered by the licensing Authority or Board as the case may be.

52 **Form and manner of application for Registration Certificate:** (1) An application for issue of a Registration Certificate shall be made to the licensing authority in Form 40, either by the manufacturer himself, having a valid whole sale licence for sale or distribution of drugs under these rules, or by his authorized agent in Pakistan, either having a valid licence under the rules to manufacture for sale of a drug or having a valid whole sale licence for sale or distribution of Therapeutic goods under these rules, and shall be accompanied by the fee specified in Schedule XXX and the information and undertakings specified in Schedules D-I and D-II duly signed by or on behalf of the manufacturer.

53. A fee of one thousand and five hundred US dollars shall be paid alongwith the application in Form xx as registration fee for his premises meant for manufacturing of therapeutic good intended for import into and use in Pakistan

54. A fee of one thousand US dollars shall be paid along with the application in Form xx for the registration of a single drug meant for import into and use in Pakistan and an additional fee at the rate of one thousand US dollars for each additional drug.

55. The applicant shall be liable to pay expenditure as may be required for inspection or visit of the manufacturing premises or therapeutic good, by the Registration board or by any other persons to whom powers have been delegated in this behalf by the authority.

56. The applicant shall be liable for the payment of testing fees directly to a testing laboratory approved by the Authority in Pakistan or abroad, as may be required for examination, tests and analysis of therapeutic goods.

57. fee of xxx US dollars shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.

58. No Registration Certificate shall be required under these rules in respect of an inactive bulk

substance to be used for a drug formulation with pharmacopoeal conformity

59. Condition to be satisfied before a licence to import.

i. the premises, where the imported substances will be stocked are equipped with proper storage accommodation for preserving the properties of the drugs to which the licence applies

ii. the occupation, trade or business ordinarily carried out by the applicant; Provided that the licensing authority may refuse to grant a licence in Form xx in respect of any applicant where he is satisfied that the applicant has not complied with the provisions of the Act or these rules.

60 **Registration Certificate for import of therapeutic goods manufactured by one manufacturer:**

A single application may be made, and a single Registration Certificate in Form 41 may be issued in respect of the import of more than one therapeutic goods or class of therapeutic goods, manufactured by the same manufacturer:

Provided that the therapeutic goods or classes of therapeutic goods, are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit:

Provided further that if a single manufacturer has two or more factories situated in different places manufacturing the same or different therapeutic goods, separate Registration Certificates shall be required in respect of the therapeutic goods manufactured by each such factory

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61. **Conditions of Registration:**

The Registration holder shall forth with inform the authority any change in his name and in any address at which there is carried on the business to which registration relates.

ii. The Registration holders shall forth with inform the authority of any material change that has been made or that purposes to make in particulars contained in his applications in relation to any therapeutic good to which registration relates that is to say:-

a. the specification of the product
b. specification of any constituent
c. composition of the products or any of its constituents
d. In the method of manufacturer or any of its constituents
e. In method and the procedure describe in the applications for ensuring compliance with specifications relating to the products.
f. In the arrangement describe in the applications for storage of product
g. In the indications for use of products
h. In the contents of any label affixed to a displayed on the container or package of the product or in the content of any leaflets relating to the products enclosed in the container

iii. The registration holder shall forthwith inform the Authority of any information received by him that caused doubt on the continued validity of data which was submitted with or in connection with his application for registration for the purpose of being taken into account in assessing the safety, quality or efficacy of any products to which registration relates.

iv. The registration holder shall inform the Authority within seven days upon receipt of any report of with he is aware of adverse effect in one or more human being or animals associated in that report resulting from the use of any product to which registration relates which shall be open to a inspection by a panel authorized by the registration board who may take copies thereof and if registration boards so direct the registration holder shall furnish Authority with a copy of any such reports of which he has record or of which he is are subsequently become aware.

v. When the holder of registration has been informed by the Authority that any batch of any product to which registration relates found to be harmful or unsafe or not to conform as regard strength, quality or purity with the specifications of that products, the registration holder shall if so directed withhold such batch from sale, supply or exportation for such period as may be specified by the authority and withdraw the defective product from the market immediately if Authority request him to do so.

vi. Registration holder shall ensure that finished product complies that

a) the content of Arsenic, Copper, Lead and Mercury are within the prescribed limit

b) Where the finished product is for oral consumption, test result on the content of Escherichia coli, Salmonella, Staphylococuss aureus, total yeast and mould counts and total aerobic microbial content per gram or mille litre shall be within permissible limit.

Provided such microbial testing not necessary, if the finished products contain any active substance which is derived from plant, animals or a combination thereof and which has been produced by the fermentation process.

c) Where the finished product is for external preparation test result on the content of Seduomonas aureginesa, Staphylococuss aureus total yeast and mould counts and total aerobic microbial content per gram or mille litre shall be within permissible limit.

Provided such microbial testing not necessary, if the finished products contain any active substance which is derived from plant, animals or a combination thereof and which has been produced by the fermentation process.

63. Registration of Medicines, Health Supplements and Health Products:

i. an application for the registration of a health product shall —

a. be made to the authority by such person and in such form and manner as the

authority may require;

b. state the category (and, where applicable, the class within that category) under which the applicant is seeking to have the product registered; and

c. **be accompanied by —**

i. such particulars, information, documents and samples as the Authority may require; and

ii. if required by the Authority, a declaration by the applicant verifying any information contained in or relating to the application

ii. Upon receiving an application under **sub rules** (i), the Authority may

a register the health product if it is satisfied that

i. the such registration; applicant is a fit and proper person to be granted

ii registration of the health product will not be contrary to the public interest; and

iii. the health product complies with such requirements as may be prescribed; or

b. refuse to register the health product

iii. The Authority may register a product under the category and class stated in the application for its registration if the Authority is satisfied, after an evaluation of the product under these rules, that the product is suitable to be so registered

iv. If the Authority finds that a product is not suitable for registration under the category or class stated in the application, it may

a. recommend to the applicant that the product be registered under a more suitable category or class as determined by the Authority; or

b. refuse to register the health product and the reasons shall be communicated.

v. If the applicant accepts the recommendation of the Authority under **sub rules** (iv)(a), the Authority shall subject to the payment of the appropriate prescribed fee by the applicant, register the health product under the category or class recommended by it.

vi. If the applicant does not wish to register the product under the category or class recommended by the Authority under **sub rules** (iv)(a), he may

a. within such time as the Authority may allow, submit to the Authority such additional information, documents and samples as the Authority may require in support of his application to have the product registered under the category or class stated in his application

b. Or withdraw the application.

vii. Upon considering the additional information, documents and samples submitted by the applicant under **sub rules** (vi)(a), the Authority may do any of the following

a. register the health product under the category and class stated in the application if it is satisfied that it is appropriate to do so

b. subject to the payment of the appropriate prescribed fee by the applicant, register the health product under the category or class recommended by the Authority under **sub rules** (iv)(a) if the applicant is agreeable thereto

c. refuse to register the health product.

viii. Upon registering a health product under this Act, the Authority shall assign a registration number to the product and shall enter in the Register of Products the prescribed information pertaining to that product

ix. Where the Authority refuses to register a health product under subsection (ii)(b), (iv)(b) or (vii)(c), the Authority shall, if requested to do so by the applicant, state in writing the reasons for the refusal.

x. Any person who, in making an application for the registration of a product

a. makes any statement or furnishes any document which he knows to be false or does not believe to be true; will be liable to dealt under law as prescribed and same shall be rejected.

62. **Registration of New Homeopathic medicine:**

i. Notwithstanding the provisions of rules which relate to the requirements for pre-clinical tests and clinical trials, the Board may grant a registration in respect of a homeopathic medicinal product.

ii. For the purposes of obtaining registration in accordance with rules applicant shall demonstrate to the satisfaction of the Board:

a. that the product is a homeopathic medicinal product which conforms with the principles and characteristics of homeopathy as practised in accordance with authoritative books of homeopathy.

b. that the indication sought is appropriate to such a homeopathic medicinal product

c. that any such indication shall be suitable for use without the intervention of a registered medical practitioner for diagnostic purposes or for prescription or for the monitoring of treatment;

d. that the efficacy of the product shall be established on the basis of evidence that the particular class of homeopathic medicinal product has been in use as a homeopathic treatment for the indication sought; and

e. that the safety of the homeopathic medicinal product has been established in the manner set out in paragraph iii

iii. For the purpose of this rule the safety of the homeopathic medicinal product shall be demonstrated

a. by reference to relevant published literature or original data having regard to the proposed route of administration and the dilution involved; or

b. in the case of stocks derived from substances commonly used in food, by means of

a statement setting out the homeopathic nature of the product and the absence of any change to the route of exposure for the substance concerned; or

c. in the case of an active principle used in allopathic medicinal products, by establishing that the dilution of the stocks is at least 1 in 10,000 of the mother tincture or not more than one hundredth of the smallest dose of the said active principle as used in allopathy; or

d. by establishing that the medicinal product contains not more than one part per 10,000 of the mother tincture.

iv. In regard to the active principles referred to in subparagraphs (iii)(c) and (d), the Board may refuse to grant an registration, where it is satisfied that the active principle concerned is toxic and as such would present concerns in regard to the safety of the product. For the purposes of this subparagraph, the Board may publish and update from time to time a list of the substances that it considers to be in this category.

v. A homeopathic medicinal product that is placed on the market on foot of a marketing registration granted in accordance with this rule shall, in addition to compliance with the requirements relating to labeling and package leaflets, be presented in such a manner as to show

a. that the product is a homeopathic medicinal product in respect of which a registration has been granted in accordance with this rule;

b. that any evidence of efficacy on the part of the product has not been based on the outcome of clinical trials;

c. that use of the product is only intended for the symptomatic relief of the condition to which the indication specified relates; and

d. that the user is advised to consult a Homeopathic doctor or other healthcare professional if the symptoms persist.

63. **Duration of registration:** The registration of a health product under this Act shall remain in force for so long as**.**

i. the registrant of the health product continues to pay to the Authority within the prescribed time, such retention fee as may be prescribed for the retention of the registration of the health product in the Register of Products; and

ii. the registration is not otherwise suspended or cancelled by the Authority under these rules

64. Conditions of registration: The Authority may attach such conditions to the registration of a health product as it thinks necessary, and may from time to time vary such conditions by notice in writing given to the registrant of the health product.

65. **Evaluation of health products:**

i. In order to ascertain that a product is suitable for registration under this Act or for registration under any particular category or class, the Authority may

a. subject samples of the health product to an evaluation by an analyst

b. require the applicant for the registration of the health product to send samples of the health product for evaluation by an analyst and thereafter submit the evaluation report to the Authority; or

c. consider the evaluation report of any body or rganization, whether in Singapore or elsewhere, that has evaluated the health product

ii. The evaluation of a health product shall include such tests and examination of the health as the Authority thinks necessary to determine the following matters:

a. whether the quality, safety or efficacy of the health product for the purposes for which it is to be used has been satisfactorily established

b. whether the presentation of the health product is appropriate, given its formulation, composition or design specification and intended purpose;

c whether the health product complies with such requirements as may have been prescribed in relation thereto; and

d. such other matters relating to the health product as the Authority thinks relevant.

iii. The requirements that may be prescribed for the purposes of **sub rules** (ii)(c) include the following:

a. that the health product should not have in its composition

i. any prohibited substance; or

ii any particular substance in excess of the prescribed permitted concentration; and

b. that the manufacture of the health product

i. If carried out in Pakistan, should comply with such requirements as may be prescribed; and

ii. if carried out elsewhere, should comply with such standards that are acceptable to the Authority.

iv. In determining whether a product complies with the standards referred to in **sub rules** (iii)(b)(ii), the Authority may consider such evidence as it thinks sufficient from a relevant overseas authority establishing that the manufacture of the health product is of the acceptable standard.

v. The costs of and incidental to the evaluation of a health product shall be borne by the applicant for the registration of the health product

66. Maintained of Records:

i. The Authority shall keep and maintain in such form and manner as it thinks fit a Products for the purpose of compiling information in relation to all registered health

products.

ii Any person may, during the office hours of the Authority and upon payment of the prescribed fee, inspect such parts of the Register Products as the Authority may determine and obtain extracts therefrom.

iii. Any extract from or copy of an entry in the Register of Health Products shall be prima facie evidence of the information stated therein if the extract or copy is certified under the hand of the an officer of the Authority duly authorised by the Chief Executive to be a true extract or copy.

iv. The Authority may, from time to time, prepare and publish in such form and manner as it thinks fit a list of all registered products.`

67. Suspension and cancellation of registration:

i. The Authority may suspend or cancel the registration of a health product if the Authority has reasonable grounds to believe that:-

a. the registration has been obtained by fraud or misrepresentation

b. the registrant of the health product has contravened or is contravening —

i. any provision of this Act;

ii. any condition attached to the registration; or

iii. any other prescribed requirement;

c. the formulation, composition, design specification, quality, safety or presentation of the product has changed such as to render it unsuitable to continue to be registered;

d. the health product no longer complies with a prescribed requirement; or

e. it is in the public interest to do so.

ii. The Authority may cancel the registration of a health product if the registrant of the health product fails to pay the prescribed retention fee under the rules within the prescribed time.

iii. The Authority may, upon the application of the registrant of a product, cancel the product.

iv. Before suspending or cancelling the registration of any health product under sub rules (i) or (ii), the Authority shall

a. give to the registrant of the product notice in writing of its intention to do so; and

b. in such notice, call upon the registrant of the product to show cause within such time as may be specified in the notice as to why the registration of the product should not be suspended or cancelled.

v. If the registrant of the health product:-

a. fails to show cause within the period of time given or such extended period of time as the Authority may allow

b. fails to show sufficient cause, as to why the registration of the product should not be suspended or cancelled, the Authority shall give notice in writing to the registrant of the health product of the date from which the suspension or cancellation of the registration of the health product is to take effect.

69. Appeals:

i. Any person who is aggrieved by the decision of Authority may, within such time as may be specified in the notice informing him of the refusal, suspension, revocation or cancellation, as the case may be, appeal in writing to the Appellate Board whose decision shall be final, against;

a. the refusal of the Authority to register a product under these rules

b. any condition attached by the Authority to the registration of a health product under these rules

c. the decision of the Authority to suspend or cancel the registration of a health product under the Act or rules

ii. Before making a decision under subsection (i), the Appellate Board may refer the matter to an Expert Committee and, in making his decision, the Appellate Board shall have regard to any report made to him by the Expert Committee

iii. Notwithstanding that any appeal under sub rules (i) is pending —

a. Any condition attached by the Authority to the registration of a health product under rules.

b. the decision of the Authority to suspend or cancel the registration of a product under rules, shall take effect from the date specified by the Authority, unless the Appellate Board otherwise directs

Chapter XXX

Duties of manufacturers, importers, etc.,

70. The duties imposed on manufacturers, importers, suppliers and registrants of products shall apply in addition to any other duty imposed on them under these rules regarding manufacturing, registration and imports as the case may be.

i. Keeping of records: The Authority may, by notice in writing, require the manufacturer, importer, supplier or registrant of a
health product

a. to keep such records as the Authority may determine in relation to the manufacture, import, supply, use or administration (as the case may be) of the health product; and

b. to produce such records for inspection by the Authority or an inspector as and when required by the Authority or Inspector.

ii. The records referred to in sub rules (i) shall be kept in such form and manner and for

such period as the Authority may stipulate, and shall contain such information in relation to the manufacture, import, supply, use or administration (as the case may be) of the health product as the Authority may require

72. Reporting of defects and adverse effects to Authority

i. Where the manufacturer, importer, supplier or registrant of a health product becomes aware of :-

a. any defect in the health product; or

b. any adverse effect that has arisen or can arise from the use of the health product, it shall be the duty of such person to inform the Authority within the prescribed time of the defect or adverse effect.

ii. Where the Authority receives any information under sub rules (i) concerning any defect in, or adverse effect of, a health product or becomes aware of any such defect or adverse effect through any other means, it may take any one or more of the following actions:

a. by notice in writing require the manufacturer, importer, supplier or registrant of the health product to investigate into the defect or adverse effect and make a report of his findings and recommendations to the Authority;

b. by notice in writing require the manufacturer, importer, supplier or registrant of the health product to issue or cause to be issued to such persons as the Authority may specify or to the general public a statement informing them of the defect or adverse effect and the measures that should be taken for addressing such defect or adverse effect;

c. by notice in writing require the manufacturer, importer, supplier or registrant of the health product to recall the health product and take such measures as the Authority may specify to secure the immediate stoppage of the manufacture, import, supply, use or administration (as the case may be) of the health product;

d. by notice in writing prohibit any person from using or administering the health product and require such person to take such measures as the Authority may specify to address any adverse effect that may have arisen from any previous use or administration of the product;

e. by notice in writing require the manufacturer, importer, supplier or registrant of the health product to take such other measures as the Authority thinks necessary in the circumstances.

iii. The Authority may also in any notice in writing given under sub rules (ii) require the person to whom the notice has been given to submit to the Authority in such form and manner and within such time and for such period as the Authority may specify, a report containing information on —

a. the measures that he has taken under the notice;

b. the results of the measures so taken; and
c. other matter as the Authority thinks necessary or relevant in the circumstances

iv. A statement under sub rules (ii)(b) shall be issued in such form and manner as the Authority may require, including —
   a. by publication in any one or more daily newspapers circulating in Pakistan; or
   b. by dissemination in such alternative medium within such time and for such period as the Authority may determine

v. Any person who —
   a. fails to comply with sub rules (i) or a notice given to him by the Authority under sub rules (ii) or (ii); or
   b. in compliance or purported compliance with sub rules (i) or a notice given to him by the Authority under sub rules (ii) or (iii), furnishes the Authority with any information or document which he knows is false or misleading, shall be guilty of an offence and shall be liable for legal proceedings.

vi. For the purposes of these rules, a product has a defect if
   a. it has or has possibly been adulterated or tampered with;
   b. it is or is possibly a counterfeit or an spurious product;
   c. is or is possibly of inadequate quality or unsafe or inefficacious for its intended purpose; or
   d. it fails or could possibly fail to satisfy such other standards or requirements as may be prescribed.

73. Verification of quality, safety and efficacy of health product

i. Where the Authority has reasonable grounds to believe that a product may no longer be of adequate quality, safe or efficacious when used for the purpose in respect of which it has been registered under this Act, the Authority may, by notice in writing, require the manufacturer, importer, supplier or registrant of the product to take such measures as the Authority may specify to verify the quality, safety or efficacy (as the case may be) of the product

ii. The measures that the Authority may require under sub rule (i) include —
   a. subjecting the product to an evaluation in accordance with these rules and
   b. furnishing the Authority with such evidence of the quality, safety or efficacy of the health product as the Authority may require.

iii. Any person who, in compliance or purported compliance with a notice given to him by the Authority under sub rule (i), furnishes the Authority with any information or document which he knows is false or misleading, shall be guilty of violation of these rules.

72. **Safety & Quality Specifications:** The Manufacturer or importers shall ensure safety and quality

limits of heavy metals and Microbial Contamination Limits as under.

Limits of Heavy Metals

Substance	**Quantity (by weight)**
1. Arsenic	5 parts per million
2. Copper	150 parts per million
3. Lead	20 parts per million
4. Mercury	0.5 parts per million

Microbial Contamination Limits

Total aerobic microbial count:	Not more than 105 per gram or ml
Yeast and mould:	Not more than 5 x 102 per gram or ml
Escherichia coli, Salmonellae and Staphylococcus aureus:	Nil in 1 gm or ml of the product

73. Notification to Authority concerning recall of health product

i. Where the manufacturer, importer, supplier or registrant of a product recalls or intends to recall the product, he shall, within the prescribed time, notify the Authority of the recall or intended recall and the reasons therefor.

ii. On being notified of the recall or intended recall of a product under sub rule (i), the Authority may, by notice in writing, require the manufacturer, importer, supplier or registrant of the product to issue or cause to be issued to such persons as the Authority may specify or to the general public a statement informing them of the recall of the product and such other matter as the Authority considers necessary.

75 Regulation of manufacture, import, supply, etc., of active ingredients

i. The Authority may, make regulations to control and regulate the manufacture, import, supply, transport, possession and storage of active ingredients.

ii. Regulations made under subsection (i) may —

a. prohibit the manufacture, import, supply, transport, possession or storage of any active ingredient except under and in accordance with the conditions of a licence issued by the Authority; and

b. prescribe the requirements to be complied with by any person who manufactures, imports, supplies, transports, possesses or stores any active ingredient.

iii. The requirements that may be prescribed for the purposes of subsection (2)(b) include the following:

a. that the manufacture, import, supply, transport or storage of any active ingredient should be carried out only by certain specified persons;

b. that the manufacture, supply or storage of any active ingredient should be carried out only at certain specified premises;

c. that the manufacture, import, supply, transport or storage of any active ingredient should or should not be carried out in any specified manner;
d. that the packaging of any active ingredient should comply with certain standards or specifications;
e. that the labels on the packaging of any active ingredient should conform to certain specifications and contain certain specified information;
f. that the supply of any active ingredient should only be made to certain specified persons and for certain specified purposes; and
h. that proper records should be kept in relation to any supply made of any active ingredient

iv. Any person who contravenes any regulation made under this section shall be guilty of an offence and shall be liable for legal proceedings.

v. In any proceedings for an offence under sub rules (iv), if any person is proved to have kept or had in his possession or under his control any active ingredient, he shall be presumed to have done so knowingly unless the contrary is proved by him.

Chapter

Advertisement & Sales Promotion

76 Any advertisement or sales promotion that relates to or is likely to cause any person to believe that it relates to any medicinal product, health supplements and health requires prior approval from the Authority in the form of permit and includes still, sound, sound and light advertisement.

77 **Types of Applications:**

78. **Permit of advertisement:** Except as provided in these rules, no person shall:-
a. issue or cause to be issued any medical advertisement; or
b. conduct any sales promotion, without first obtaining a permit from the Authority

79. **Application for permit:** An application for a permit under these rules shall be on prescribed form or as the Authority may require.

80. **Period of validity of permit:** Any permit granted by the Authority under rules shall, unless sooner revoked, be valid for a period of one year from the date on which it was granted.

81. **Permit subject to terms and conditions:** A permit may be granted subject to such terms and conditions as the Authority may think fit to impose

82. **Refusal, etc., of permit:** The Authority may, without assigning any reason, refuse to grant a permit or may suspend or revoke any permit already granted.

83. **Appeal against refusal:** Any person aggrieved by such refusal, suspension or revocation may appeal to the Appellate Board whose decision shall be final.

84. **Duty of printer or publisher**: No person shall print or publish or cause to be printed or published any medical advertisement unless he has first ascertained that a permit has been granted by the Authority in respect of that advertisement.

85. **Gifts or prizes**: No person shall, in conducting any sales promotion, offer any thing in cash or kind or gift or prize to promote the sale of any Therapeutic Goods.

86. **Exception for trade, business or profession:** these rules shall not apply to any medical advertisement, sales promotion or representation directed exclusively to a person in his business premises who may lawfully sell or supply any medicinal product in the course of his trade, business or profession.

87. **Exception for trade, advertisement and public authority**

i. These Rules shall not apply to —

a. a reference advertisement or a trade advertisement; and

b. any medical advertisement issued or published by any public authority or any person authorised to issue or publish such advertisement by the Federal or Provincial governments as the case may be.

ii. For the purposes of this rule

Explanations:

"commercially interested", in relation to a Therapeutic goods used for a medicinal purpose, means to be involved in the sale of or to deal in that product, as a manufacturer, supplier, retailer, importer or exporter;

"reference advertisement" means an advertisement containing a brief description of a product, its use, any contra-indications and warnings relating thereto or of any product used or represented to be used for a medicinal purpose appearing without charge in a publication consisting mainly of such advertisements where the publication is sent or delivered to practitioners and pharmacists by a person not commercially interested in the product;

"trade advertisement" means an advertisement relating to a medicinal product used or represented to be used for a medicinal purpose which is issued by means of a catalogue, price list or other document for the purpose of a sale by way of wholesale dealing but which does not contain any recommendation relating to the use of the same other than as part of the name of the medicinal product as part of any heading or sub-heading indicating a therapeutic classification.

77 **Permit number:** Every medical advertisement issued or published shall have printed legibly thereon the number of the permit granted in respect of the advertisement

78. **Alteration, etc., of advertisement** No person shall alter or amend any medical advertisement for which a permit has been granted unless —

i. he has made an application in such form as the Authority may require to amend the permit to reflect such alteration or amendment; and

ii. the application is approved by the Authority.

79. **Fees of permit for advertisement and sales promotion**

i. The fees payable for

a. an application for a permit;

b. a permit; or

c. an application to amend a permit, shall be as specified in the Schedule.

ii. No refund shall be made in respect of any fee paid under these Rules

Chapter XX

~~Labeling~~Labelling and Health Claims

80. The product Label should be prominently and conspicuously displayed on the product. Where the size, shape or nature of the final product or package does not permit the full listing of labelling information, the use of inserts, leaflets, hang tags, in appropriate format, will be allowed.

80. The name of the product, the recommended dosage, the batch reference and relevant precautionary statements should be displayed on the final product or package

80. Expiry date, batch number and name of product shall be mentioned on immediate label affixed with the product.

80. The information shall be in English and shall be printed in a clear and legible manner. It should also be adequate and truthful in its content.

80. The names of the ingredients on the label may be the Scientific names, Latin botanical names or Common names. Companies should use acceptable international nomenclature for ingredient names.

80. **Particulars to be shown on label:** Where a product is a Health Supplement, the container of the product shall be labelled to show the following particulars:

i. Name of the health supplement product

ii. Names and quantities of all the active ingredients

Names of inactive ingredients including sweeteners, preservatives, colorants and other additives, if present

Recommended daily allowance (RDA) based on approved local standards or authoritative international standards (to specify the standard used) applicable only for vitamins etc.

Recommended daily dosage

Instructions on proper usage

Pack Size

Manufacturing Date

Expiry date (or “Use by”, “Use before” or words with similar meaning)

Batch Number

Name and address of the manufacturer & packer (or local Assembler)

Name and address of dealers (or Importer, Wholesale dealer where appropriate

Manufacturing Licence number

Product Registration number

Mandatory Precautionary Label / Statement, where necessary

Maximum Retail Price

75 Evidence of Claims for Health Supplements: the claims made must be consistent with the definition of health supplements i.e. a product that is used to supplement a diet, with benefits beyond those of normal nutrients, and / or to support or maintain the healthy functions of the human body.

76 Nutritional Supplement may make Nutritional (General) Health Claims or Functional Health Claims.

Nutritional Health claims are permissible for products provided that they contain well-documented ingredients, where the function of each ingredient is supported and documented in standard reference texts.

Nutritional Health claims include Nutrient-Support claims and General Health claims that are intended for:

- General health maintenance and well-being.
- Vitamin and/or mineral supplementation, such claims are permitted only when the relevant vitamin and mineral used in the product amounts to >30% the RDA value.
- Nutritional supplementation beyond normal nutritional value from food

77 The manufacturer or importer should hold evidence to support these claims, and provide this to the Authority when required to do so.

Nutritional Supplements could make claims that include:

i) Support good health and growth

ii) Supplementing nutrition

iii) Nourish the body

iv) Strengthen the body (without reference to body organs)

v) Relieve general tiredness, weakness

79 **Functional Health Claims:** Functional Health claims must be adequately substantiated through ingredient-based evidence, and when necessary product-based evidence. The manufacturer/ importer must hold evidence to support these claims, and provide this to the Authority when required to do so.

80 Functional Health claims include:

- General support maintenance of healthy functions.
- Supports healthy function of the human body such as maintaining healthy joints, support natural physiological processes e.g. immune system, circulation, etc.

- Manage mild discomfort associated with menopausal symptoms.
- Assist in maintaining joint mobility.

81 Nutritional supplements shall not be labeled, advertised or promoted for any specific medicinal purpose that is treatment or prevention, implied or otherwise.

82 Health Supplement shall not claim prohibited diseases or conditions unless evidence through demonstrated clinical trial for such claims and necessary permit is obtained from the Authority, namely: Blindness, Cancer, Cataract, Conception and pregnancy, Dangerous drug addiction, Deafness, Diabetes, Epilepsy or Fits, Frigidity, Hypertension, Infertility, Insanity, Impotency, Kidney diseases, Leprosy, Menstrual disorder, Paralysis, Sexual function and Tuberculosis.

83 Objectionable terms and claims shall not be used, which includes; Miraculously , The only product to use, World's best, 100% safe, No side effects, Guaranteed, Other drugs / products cannot compare with it, Sensational relief, The No. 1 (unless substantiated), Efficacious/Effective, Perpetual youth, Anti-aging, Longevity, Anti-stress, Boost immunity, Enhance immunity, Breast enhancement, enlargement, growth, Height growth, Enhance intelligence / Increase IQ, Increase / improve memory, Memory enhancement, Hormone releaser/enhancer/amplifier, Regulate hormone, Enhancement of sexual organs, Sexual powers
Arousal and Libido.

85 ~~Labeling~~Labelling of medicinal products:

i. Following Particulars are required to be shown on container, package and leaflet of medicinal products.
   a. the trade or brand name under which the proprietary medicine is sold;
   b. the appropriate non-proprietary name of the proprietary medicine;
   c. the batch reference given by the person who manufactured the proprietary medicine to the batch of which it forms a part;
   d. Expiry date after which the proprietary medicine should not be used;
   e. the name and address of the wholesaler of the proprietary medicine or, if the proprietary medicine is imported, the importer thereof;
   f. the name and address (including the name of the country of manufacture) of the manufacturer of the proprietary medicine;
   g. the name and address of the person who assembled the proprietary medicine, if any;
   h. the appropriate non-proprietary name of the ingredients of the proprietary medicine;
   i. the appropriate quantitative particulars of the ingredients of the proprietary medicine;
   j. the recommended dosage of the proprietary medicine;
   k. the purpose or purposes for which the proprietary medicine is to be used;

l. the purpose or purposes for which the proprietary medicine should not be used;
m. the possible side effects that the proprietary medicine may have on persons to whom it is administered; and
n. directions as to how the proprietary medicine is to be used (including the time and method of administration).
o. Maximum Retail Price

ii. Where the container of a proprietary medicine is too small for it to be reasonably practicable to state thereon the particulars as specified in paragraph (i) (*h*) and (*i*), such of those particulars as there is space for shall be stated on that container in accordance with the following criteria

a. precedence shall be given to the particulars in accordance with the order in which they appear in paragraph (i);and
b. the other particulars not stated on the container shall be stated on the package in which the container is immediately enclosed

iii. Where any proprietary medicine is sold or supplied without any package, the particulars specified in paragraph (i) (*e*), (*f*), (*g*) and (o) shall be stated on the container of the proprietary medicine.

iv. Where any proprietary medicine is sold or supplied without any leaflet, the particulars specified in paragraph (i) (*j*), (*k*), (*l*), (*m*), (*n*) and (o) shall be stated on the container or the package of the proprietary medicine in any order.

v. **Exception for clinical trial:** Rules (ii) shall not apply to any proprietary medicine for administration in a clinical trial which is labeled with the particulars specified in under the clinical trial rules.

vi. **Certain substances to be labeled.** Any proprietary medicine which contains any substance like Tartrazine, Benzoic acid and Sodium benzoate, shall be labeled with a statement in English declaring the presence of that substance.

vi. **Prohibition of certain labels and leaflets:**

a. No person shall sell or supply any proprietary medicine if the container or package of the proprietary medicine contains any statement or other representation which, directly or indirectly, claims, indicates or suggests that the proprietary medicine will prevent, alleviate or cure any disease or condition specified in the Schedule XXX
b. No person shall supply, with any proprietary medicine, or have in his possession for the purpose of so supplying, any leaflet which contains any statement or other representation which, directly or indirectly, claims,

indicates or suggests that the proprietary medicine will prevent, alleviate or cure any disease or condition specified in the Schedule XXXX

81 Manner in which particulars are to be stated:

i. The particulars required by rule (ii) to be stated on the container or package of, or on any leaflet supplied with, any proprietary medicine shall

a. be printed in letters not less than 1.5 millimetres in height;

b. be clearly legible;

c. be printed in an indelible manner; and

d. appear conspicuously in a prominent position on such container, package or leaflet so as to be easily read by an intending purchaser or user of the proprietary medicine under normal conditions of purchase or use

ii. Notwithstanding sub rule (i), the particulars required by regulation 3 to be stated on the container or package of, or on any leaflet supplied with, any proprietary medicine may be printed in reduced size where such container, package or leaflet is so small as to prevent the use of wording of the size specified in said rules provided the particulars are clearly legible.

iii. Where a container which is in the form of a bubble, blister or other sealed unit is part of a continuous series comprising a sheet or strip of like containers, said rules shall be deemed to have been complied with if the particulars required by that regulation to be stated are displayed at regular intervals on the sheet or strip of such containers.

iv. Where the package immediately enclosing a container referred to in said rule is itself in the form of a bubble, blister or other sealed unit and is part of a continuous series comprising a sheet or strip of like packages, said rule shall be deemed to have been complied with if the particulars required by the said rules to be stated are displayed at frequent intervals on the sheet or strip of such packages.

83 **Language in which particulars are to be stated:** The particulars referred to in these rules shall be stated in the English language.

83 **Additional information to be shown on container of proprietary medicine for general sale:** the statement "***Allowed for sale as a Proprietary Medicine based on information submitted to the Authority. Consumer discretion is advised***." Shall be printed on the label in a boxed area which does not contain any other information or particular.

84 Traditional use claim for Unani and Ayurvadic medicine may be allowed by the Authority on the

basis of evidence as approved by any International Regulatory Authority or published in the specified scientific literature or authoritative book.

85. **Manner of labeling of Homoeopathic medicines.**

i. 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

a. The words 'Homoeopathic medicine'

b. The name of the medicine

i. For medicine included in the any specified publication of Homoeopathic Pharmacopoeias of India or the United States of America or the United Kingdom, or the German Homoeopathic Pharmacopoeia, the name specified in that Pharmacopoeia.]

ii. For other drugs, the name descriptive of the true nature of the drug

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

d. 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.

e. Name and address of the manufacturer when sold in original containers of the manufacturer. In case a Homoeopathic medicine is sold in a container other than that of the manufacturer—the name and address of the seller.

f. 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 that the total quantity of the pharmacopoeial Homoeopathic medicine in the container is 30 milliliter or less, it will not be necessary to state the content of alcohol in the label.

ii. In addition to the above particulars the labels of a Homoeopathic mother tincture shall display the following particulars

a. 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.

b. Manufacturing licence number, the number being preceded by the words

"Manufacturing Licence Number" or "Mfg. Lic. No." or "M.L.".

Explanation:-- This clause shall not apply to a Homoeopathic mother tincture manufactured outside Pakistan

iii. No Homoeopathic medicine containing a single ingredient shall bear a proprietary name on its label.

85 **Prohibition of quantity and percentage**.- No Homoeopathic or biocemic medicine containing more than 12% alcohol v/v (Ethyl alcohol) shall be packed and sold in packing or bottles of more than 30 millilitres, except that it may be sold to hospital/dispensaries in ~~packings~~pickings or bottles of not more than 12~~0~~0 millilitres, however this shall not apply to mother tincture packing.

86 **Manner of ~~labeling~~labelling of Cosmetic:** Subject to other provisions of the rules, a cosmetic shall contains.

i. On both the inner and outer labels
   a. The name of the cosmetic
   b. The name of the manufacturer and complete address of the premises of the manufacturer where the cosmetic has been manufactured.

   Provided that if the cosmetic is contained a very small size container where the address of the manufacturer cannot be given, the name of the manufacturer and his principal place of manufacture shall be given along with PIN code.

ii. On the outer label, a declaration of the net contents expressed in terms of weight for solids, fluid measure for liquids, weight for semi solids, combined with numerical court if the content is sub-divided:

   Provided that this statement need not appear in case of a package of perfume, toilet water or the like the net content of which does not exceed 60ml or any package of solid or semi-solid cosmetic the net content of which does not exceed 30 grams.

iii. On the inner label, where a hazard exists
   a. Adequate direction for safe use.
   b. Any warning, caution or special direction required to be observed by the consumer
   c. statement of the names and quantities of the ingredients that are hazardous or poisonous.

iv. 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 letter "B", provided that this clause shall not apply to any cosmetic containing 10grams or less if the cosmetic is in solid or semi-solid state, and 25 milliliters or less if the cosmetic is in a liquid state.

Provided further that in the case of soaps, instead of the batch number, the month and year of manufacture of soap shall be given on the label.]

v. manufacturing licence number, the number being preceded by the letter 'M'.

vi. Where a package of a cosmetic has only one label, such label shall contain all the information required to be shown on both the inner and the outer labels, under these Rules

85 **Prohibition against altering inscriptions on containers,** *labels or wrappers of cosmetics.*- No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any cosmetic.

Provided that nothing in this rule shall apply to any alteration, inscription or mark made on the container, label or wrapper of any cosmetic at the instance or direction or with the permission of the licensing authority

86 **Labelling of Hair dyes containing Dyes, Colours and Pigments.—**Hair dyes containing Para-Phenylenediamine or other Dyes, Colours and Pigments] shall be labeled with the following legend in English and these shall appear on both the inner and the outer labels.

"Caution—This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to the accompanying direction should first be made. This product should not be used for dyeing the eye-lashes or eye-brows; as such a use may cause blindness".

Each package shall also contain instructions in English on the following lines for carrying out the test

"This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow it to dry. After twenty-four hours, wash the area gently with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. This preparation should on no account be used for dyeing eye-brows or eye-lashes as severe inflammation of the eye or even blindness may result".

86 Special provisions relating to toothpaste containing fluoride;

i. Fluoride content in toothpaste shall not be more than 1000 ppm and the content of fluoride in terms of ppm shall be mentioned on the tube and carton.
ii. Date of expiry should be mentioned on tube and carton.

85 **Pharmacovigilance**

i. A person responsible for placing a medicinal product on the market shall

a. have appointed permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance, who shall reside in the Pakistan;

b. make and retain a detailed account of any suspected adverse reaction as required under these rules;

c. promptly report to the Authority any suspected serious adverse reaction, or submit to the Authority any records of suspected serious adverse reactions, as required under the rules. Such report shall be made to the Authority no later than 10 days following receipt of the information concerned;

d. promptly report to the Authority, any suspected serious unexpected adverse reaction and any suspected transmission via a medicinal product of any infectious agent occurring in the territory of a third country. Such report shall be made to the Authority, not later than 15 days following receipt of the information concerned;

e. except where other requirements are laid down as a condition for the granting of the certificate of registration, or subsequently, submit to the Authority, reports of adverse reactions in the form of a periodic safety update report. Such report shall be submitted immediately upon request or at least every six months after the date of grant of the registration certificate and until the placing on the market. Such reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the market and once a year for the following two years. Thereafter, the reports shall be submitted at three yearly intervals or immediately upon request. The periodic safety update reports shall include a scientific evaluation of the risk benefit balance of the medicinal product; and

ii. A person employed or engaged as an appropriately qualified person responsible for pharmacovigilance for the purpose shall—

a. establish and maintain a system for collecting and collating information about suspected adverse reactions;

b. prepare for the Authority a report on any such reactions, including a periodic safety update report and a scientific evaluation of the risk benefit balance of the medicinal product, as required by Authority;

c. ensure that a request from the Authority for the provision of additional information for the evaluation of the benefits and risks afforded by a medicinal product is answered fully and promptly, including the provision of information about the volume of sales or of prescriptions for the medicinal product concerned; and

d. provide to the Authority any other information relevant to the evaluation of the benefits and risks afforded by a medicinal product, including appropriate information on post authorisation safety studies.

iii. Where a report is required to be made to the Authority under this Rules, such report shall, except in exceptional circumstances, be communicated to the Authority and shall be in the form of a report prepared and presented in accordance with published regulatory guidelines.

Information on Pharmacovigilance concerns for the general public.

i. A person who is the registration holder, or certificate of traditional-use registration, in respect of a medicinal product, shall not communicate information relating to Pharmacovigilance concerns about that product to the general public without giving prior or simultaneous notification to the Authority.

ii. In any case where information of the nature referred to in paragraph (i) is communicated by any such person, the said information shall be presented objectively and shall not be misleading.

Obligation to ensure that supplies continue to be available to meet the needs of patients: A person who is the registration holder or and any person acting on behalf of such a person, in respect of a medicinal product actually placed on the market in the Pakistan, and within the limits of his responsibility, shall ensure appropriate and continued supplies of that product to pharmacies and other persons authorised to supply such products, so that the needs of patients in the Pakistan in respect of any such medicinal product are catered for.

91. **Central Research Fund:** The licence holder or the registration holder shall by 30th June and 31st December each year whichever is immediately after the financial closing of the company or the

firm contribute 1% of his gross profit before the deduction of income tax towards Central Research Fund to be maintained and utilized by the Authority in accordance with Drugs (Research) Rules of DRAP Act 2012.

i. The Authority may allow a portion of such contribution to be spent by the firm or company for Research and development of new therapeutic goods or for establishing Research Laboratories or upgrading the existing laboratories owned by the Authority, when it is fully satisfied that such expenditure will be utilized for the said purpose effectively and properly and falls in public interest.

ii. The licence or the registration holder shall on or before 31st July year submit a dully signed statement of balance sheet indicating profit and loss, as per prescribed Proforma along with an evidence of deposit of 1% of profit towards Central research Funds.

Chapter

Import and Export of Therapeutic Goods

51. Form and manner of application for import licence. An application for an import licence shall be made to the licensing authority in Form 8 for Therapeutic goods, either by manufacturer himself having a valid wholesale licence for sale or distribution of drugs under these rules, or by the manufacturer's agent in Pakistan either having a valid licence under the rules to the manufacture for sale of a therapeutic goods. or having a valid wholesale licence for sale or distribution of drugs under these rules, and shall be accompanied by a licence fee as prescribed for a drug and by an undertaking in Form 9 duly signed by or on behalf of the manufacturer:

52 Any application for import licence in prescribed Form xxx or Form xxxx, as the case may be, shall be accompanied by a copy of Registration Certificate issued in Form 41.

53 The authorization by the manufacturer of his agent in Pakistan shall be documented by a power of attorney executed and authenticated either in ~~Paksitan~~Pakistan before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Pakistani Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate

Import of finished Products. Finished Products may be imported subject to the following conditions, namely

(i) the importer possesses an import licence and Pharmacy Licence to sell by way of retail/wholesale, the product or Active ~~Ingridient~~Ingredient intended to be imported and has adequate facilities for proper storage to preserve its properties

(2) The importer shall, within fifteen days of establishing the letter of credit, intimate such action on Form I to an officer authorised by the Authority in this behalf;

(3) the finished products shall be imported in containers intended for retail sale or supply to hospitals, dispensaries or such other institutions; and

(4) the finished products / active ingredients shall be imported against indents issued by the authorised indentors or local agents of the manufacturers.

Types of licences to import drugs. Licences to import therapeutic goods shall be of the following types, namely

(i) licence to import drug other than the finished product; and

(ii) licence to Import small quantities of therapeutic goods for the purpose of clinical trial, examination, test or analysis.

Licences for import of therapeutic goods manufactured by one manufacturer. A single application shall be made, and a single licence shall be required, in respect of the import of more than one therapeutic goods or class of therapeutic goods manufactured by the same manufacturer:

Provided that if a manufacturer front whom the products are to be imported has two or more premises manufacturing the same or different products. a separate application shall be made, and a separate licence shall be required, in respect of the products manufactured in each such premises.

Application for licence to import therapeutic goods

(1) An application for licence to import therapeutic goods/ Active Ingredient shall be made to the licensing authority in Form 2 and shall be accompanied by a prescribed fee and by an undertaking in Form 3, signed by or on behalf of the manufacturer

(3) An application for a licence to import small quantity of therapeutic goods for the purpose of clinical trial, examination, test or analysis shall be made to the licensing authority in Form 4; and the licensing authority may require such other particulars to be supplied as it may consider necessary

(4) Any fee deposited under sub rule (1) shall in no case be refunded.

Licence to import drugs. A licence to import therapeutic goods in the form of Active Ingredient shall be issued in Form 5 and for the import of small quantity of therapeutic goods for clinical trial, examination; test or analysis shall be issued in Form 6.

Duration of licence to import therapeutic goods. Licence to import therapeutic goods, unless earlier suspended or cancelled, shall be valid for two years.

Licensing authority. For the purpose of this Chapter, "licensing authority" means the authority appointed by the Director, Health and OTC Products to issue licences to import

therapeutic goods and includes any person subordinate to it to whom such authority may, with the approval of the Authority by an order in writing, delegate the power to sign licences and such other powers as may be specified in the order.

Grant of licence to import therapeutic goods. On receipt of an application fern licence to import therapeutic goods the licensing authority shall. on being satisfied that, if granted, she conditions of the licence will be observed issue an import licence.

Conditions of licence to import therapeutic goods other than finished product: A licence to import therapeutic goods or Active ingredient other than finished product shall bc subject to the following conditions, namely :--

(1) the manufacturer shall at all times observe the under-taking given by him or on his behalf in Form 3

(2) the license shall allow the licensing authority or any person authorised by it in this behalf to enter, with or without prior notice. any premises where the imported therapeutic goods is stocked to inspect the means, if any, employed for testing the therapeutic goods and to take samples;

(3) the licensee shall on request furnish to the licensing authority from every batch of each therapeutic goods or from such batch or batches as the licensing authority may from time to time specify as sample in such quantity as the licensing authority may consider adequate for any examination, test or analysis required to be made, and the license shall, if so required furnish full protocols of the tests, if any which have been applied;

(4) the licensee shall ensure proper storage facilities for preserving the properties of the imported therapeutic goods;

(5) the licensee shall maintain a complete record of utilization of the imported therapeutic goods, showing particulars of the substance manufactured from it and such further particulars, if any as the licensing authority may specify and such record shall be open to the inspection of licensing authority or any person authorised in this behalf by the licensing authority.

(6) the licensee shall comply with such further requirements, if any applicable to the holders of import licences, as may be specified in any rules subsequently made under the Act in this behalf and of which the licensing authority has given to him not less than three months notice.

Conditions of licence to import small quantities of therapeutic goods for clinical trial, etc : A licence to import small quantities of therapeutic goods including therapeutic goods

the import of which is otherwise prohibited under the Act for the purposes of clinical trial, examination, test or analysis shall be subject to the following conditions, namely:-

(1) the licensee shall exclusively use the therapeutic goods for the purpose for which it has been imported and at the place specified in the licence, or at such other plate as the licensing authority may from time to time authorise;

(2) the licensee shall allow the licensing authority or any person authorised by it in this behalf to enter, with or without prior notice, the premises where the therapeutic goods are kept and to inspect the premises and investigate the manner in which the drugs are being used and to take samples thereof;

(3) the licensee shall keep record of, and shall report to the. licensing authority, the therapeutic goods imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer;

(4) the licensee shall comply with such further requirements if any, applicable to the holders of licences for clinical trial, examination, test or analysis as may be specified in any rules subsequently made under the Act and of which the licensing authority has given to him not less than .one month's notice.

Import of therapeutic goods for personal use: Small quantities. of therapeutic goods including drugs the import. of which is otherwise prohibited tinder the Act may be imported for personal use subject to the following conditions. namely :--

the therapeutic goods shall form part or a passenger's bona fide baggage and shall be intended for the exclusive .personal use. of the passenger;

the quantity of any single therapeutic goods so imported shall not exceed one hundred average doses:

Any therapeutic goods imported for personal use but not forming part of bona fide personal baggage may be allowed to be imported subject to the following conditions, namely

(1) the licensing authority on an application being made to it prior to the import, and. being satisfied that the therapeutic goods is for bona tide personal use has granted permission for the import of the said therapeutic goods; and

(2) the quantity to be imported is, in the opinion of the licensing authority, reasonable and is covered by a prescription from a registered medical practitioner

General provisions regarding import: An importer of therapeutic goods. except where such import is for personal use, shall comply with the following general provisions,

namely:-

(1) the importer shall allow any person authorised in. this behalf to enter, with or without prior notice, any premises where the imported therapeutic goods are stocked, to inspect the storage facilities and to take samples for testing ;

(2) the importer shall, on being informed by the Registration Board or the licensing authority or an officer authorised by it in this behalf or the Chairman .of the Provincial Quality Control Board that any part of any batches of a therapeutic goods has been found to be in contravention of the provisions. of the Act or the rules made thereunder and on being directed so to do, withdraw the remainder of that batch from sale and, so far as practicable, recall the issues already made from that batch and dispose of in such manner as the Board or, as the case may be, the authority, may direct;

(3) the importer shall maintain a record of all sales by way of wholesale made by him of the imported therapeutic goods, and such record shall be open to the inspection by any person authorised in this behalf;

(4) the importer shall ensure that the import of each batch of a therapeutic goods is accompanied by--

a) a batch certificate in form 7 from the competent health authority or any other such agency of the country of export or from the manufacturer;

b) a copy of the test report of the drug from the competent health authority or any other such agency of the country of export or from the manufacturer;

(5) the importer shall maintain an inspection book on which a member of the registration board or of the licensing authority or an inspector shall record proceedings of each of his visits, his impressions and the defects notified by him and such inspection book shall be signed by him as well as the. licensee or his authorised agent;

(6) the importer, shall on receipt of information of arrival of the consignment of therapeutic goods at the port of importation report in form 8 alongwith three copies of the invoice to the officer authorised by the authority grant clearance under these rule.

Procedure at Customs-Ports

(1) No therapeutic goods shall be released from the customs unless a clearance certificates has been obtained by the importer from an officer authorised in this behalf by the authority.

(2) if the collector of customs or an officer authorised by him has reason to suspect that any therapeutic goods does not comply with the provisions of the act or the rules made thereunder, he may, or if requested by as officer authorised in this behalf by the federal government shall, take samples of any therapeutic goods from the consignment and forward them to the officer-in charge of the laboratory appointed for the purpose by the authority and may detain the therapeutic goods from the consignment of which samples have been taken until the report of the officer-in charge of the said laboratory on such samples is received:

Provided that if the importer gives an undertaking in writing not to dispose of the therapeutic goods without the consent of the collector of customs and to return the consignment or such portion thereof as may be required, the collector of customs shall make over the consignment to the importer.

(3) if an importer who has given an undertaking under the proviso to sub-rule (2) is required by the collector of customs to return the consignment or any portion thereof. he/she shall return the consignment or portion thereof within ten days of receipt of the notice.

if the officer-in-charge of the laboratory appointed for the-purpose by the authority reports to the collector of customs that the samples of any drug in a consignment do not conform to the specification or that the therapeutic goods contravenes in any other respect the provisions of the act or the rules made thereunder and that the contravention is such it cannot be remedied by the importer, the collector of customs shall communicate the report forthwith to the importer who shall within two months of his receiving the communication, either export all the drugs of that description in the consignment to the country from which they were imported or surrender them to the authority for disposal in such manner as it may deem fit.

Provided that the importer may, within fifteen days of the receipt of the report make a representation against the report to the collector of customs who shall forward the representation with a further sample to the licensing authority or, as the case may be, the registration board which after obtaining, the report of the .officer-in-charge of the appellate laboratory, shall pass orders thereon which shall be final.

(5) if he officer-in- charge of the laboratory appointed for the purpose by the authority reports to the collector of customs that the samples of any drug

contravene in any respect the provisions of the act or the rules made thereunder and that the contravention is such that it can be remedied by the importer, the collector of customs shall communicate the report forthwith to the importer and permit him to import the therapeutic goods on his giving an undertaking in writing not to dispose of that drug without remedying the said contravention.

(6) A Federal or Provincial inspector or a person authorised in this behalf by the authority may physically inspect the consignment and draw samples from each batch for test and analysis as may be necessary and, if the consignment has been released by the customs, may order the importer not to sell or offer for sale or dispose of the drug for a reasonable period not exceeding one month with a view to obtain a test report:

Provided that the Federal or Provincial inspector or such authorised officer may prohibit the disposal of a therapeutic goods for a longer. period if he has sufficient reason to believe that the import, in any way, is in contravention of any or the provision of the act or these rules in which case. the importer shall not dispose of that therapeutic goods until a certificate authorising the sale of the batch has been issued to him.

suspension and cancellation of licence to import therapeutic goods: if the manufacturer or licensee fails to comply with any of the conditions of a licence to import therapeutic goods or violates any of the provisions of the act or the rules made thereunder, the licensing authority may, after giving the licensee an opportunity of being heard, by an order in writing stating the reason therefor, suspend or cancel the licence for such period as it thinks tit or cancel for all times either wholly or in respect of some of the therapeutic goods. to which it relates or, if the nature of offence is so serious that it is likely to endanger the public health, .may prohibit the import of all other therapeutic goods of the said manufacturer:

Provided that a person, who is aggrieved by the suspension or cancellation of his licence, may within sixty days of the receipt of such order, appeal to the appellate board.

Export of Finished Product: finished product may be exported subject to the condition that the exporter possesses a licence to manufacture or sell by way of retail sale or wholesale.

Licences for Export Therapeutic Goods: a licence to export Therapeutic Goods shall be required in form 9 for the export of Therapeutic Goods other than the finished product.

Licences for Export of Therapeutic Goods Manufactured by One Manufacturer: a

single application shall be made, and a single licence shall be required in respect of the export of more than one therapeutic goods or class of therapeutic goods manufactured by the same manufacturer:

Provided that if a manufacturer has two or more premises manufacturing the same or different therapeutic goods, a separate application shall be made, and a separate licence shall b~~e~~e required, in respect of the therapeutic goods manufactured in each such premises.

Application for Licence to Export Therapeutic Goods:

(1) An application for licence to export therapeutic goods shall be made to the licensing authority in form 10 alongwith an undertaking on form 11 signed by the manufacturer and shall be accompanied by a prescribed fee

(2) an application for a licence to export small quantity of therapeutic goods, including drugs the export of which is otherwise prohibited under the act, for the purpose of clinical trial, examination, teat or analysis shall be made to the licensing authority in form 12; and the licensing authority may require such other particulars to be supplied as it may consider necessary

(3) Any fee deposited under sub-rule (i) shall in no case be refunded.

Duration of a Licence to Export Therapeutic Goods: a licence to export therapeutic goods, unless earlier suspended or cancelled, shall be valid for two year.

Provided that if application for a fresh licence, is made three month, before the expiry of the existing licence, the current licence shall continue to be in force until orders are passed on the application.

Licensing Authority: for the purpose of this chapter. "licensing authority" means the Authority appointed by the Director, Health and OTC Products to issue export licences and includes any person subordinate to it to with such authority may, with the approval of the Authority by an order in writing, delegate the power to sign licences and such other powers as may be prescribed in the order.

Grant of Export Licence: on receipt of on application for an export licence, the licensing authority shall, on being satisfied that, if granted, the conditions of the licences will be observed, issue an export licence.

conditions of licence to export therapeutic goods: a licence to export therapeutic goods other than finished therapeutic goods shall be subject to the following conditions, namely:-

(1) the licensee shall allow any person authorised by the licensing authority in this behalf to enter, with or without prior notice, any premises where the therapeutic goods to be exported is stocked to inspect the means, if any employed for testing

the therapeutic goods and to take samples;

(2) The licensee shall on request furnish to the licensing authority from every batch of each therapeutic goods or from such batch or batches as the licensing authority may from time to time specify samples in such quantity as the licensing authority may consider adequate for any examination, test or analysis required to be made and the licensee shall, if so required furnish full protocols of the tests, if any, which have been applied;

(3) If the licensing authority so directs, the licensee shall not export or offer for export any batch in respect of which a sample is, or protocols are, furnished under clause (ii) until a certificate authorising the export of the batch has been issued to him by or on behalf of the licensing authority:

(4) The licensee shall, on being informed by the licensing authority that any part of any batch of a drug has been found by the licensing authority not to conform to the required specifications and on being directed so to do, withdraw the remainder of that batch from export and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that batch;

(5) The licensee shall maintain a record of all exports made by him of each drug showing particulars of the drug and of the person to whom exported and such further particulars, if any, as the licensing authority may specify, and such record shall be open to the inspection of any inspector authorised in that behalf by the licensing authority and such records shall be preserved for three years from the date of the export of the therapeutic goods;

(6) The licensee shall cause the therapeutic goods to be packed and labelled in conformity with the requirements of the consignee.

(7) the licensee shall ensure proper storage facilities for preserving the properties of the therapeutic goods to be exported during storage;

(8) The licensee shall comply with such further requirements, if any, applicable to the holders of export licenses, as may be specified in any rules subsequently made under the act in this behalf and of which the licensing authority has given to him not less than three months' notice.

Export of Therapeutic Goods for the Purposes of Clinical Trial, Examination, Test Analysis or Personal Use: small quantities of therapeutic goods, including therapeutic goods the export of which is otherwise prohibited under the act, may be exported for the

purposes of clinical trial examination, test, analysis or personal use with the written permission of the licensing authority.

Statement to Accompany Therapeutic Goods for Export: all consignments of therapeutic goods sought to be exported shall be accompanied by an invoice or other statement showing the name and address of the manufacturer and the names and quantities of the therapeutic goods.

General Provisions Regarding Export: an exporter of therapeutic goods, except where such export is for personal use, shall comply with the following general provisions, namely:-

(1) the exporter shall allow any person authorised in this behalf to enter with or without prior notice, any premises where the therapeutic goods to be exported are stocked, in inspect the storage facilities and take samples for testing.

(2) The exporter shall, on being informed by the registration board or the licensing authority or an officer authorised by it in this behalf or the chairman of the provincial quality control board that any part of any batch of a drug has been found in contravention of any of the provisions of the act or the rules made thereunder and on being directed so to do, withdraw the remainder of that batch from export and so far as practicable, recall the issues already made from that batch and dispose of it in such manner as the board, or, as the case may be, the licensing authority, may direct.

(3) The exporter shall maintain a record of all exports of therapeutic goods made by him and such record shall be open to inspection by any person authorised in this behalf.

(4) The exporter shall maintain an inspection book on which a member of the registration board or the licensing authority or an inspector shall record proceedings of each of his visits, his impressions, and the defects noticed by him and such inspection book shall be signed by him as well as the licensee or his authorised agent.

Procedure at customs port:

(1) if the collector of customs or an officer authorised by him has reason to suspect that any drug does not comply with the provisions of the act or the rules make thereunder, he may, and if requested by an officer appointed for this purpose by the authority shall, take samples of any therapeutic goods from the consignment and forward them to the officer-in-charge of the laboratory appointed for the

purpose by the authority and may detain the drugs from the consignment of which samples have been taken until the report of the officer-in-charge of the said laboratory on such samples is received:

Provided that if the exporter gives an undertaking in writing not to export or dispose of the therapeutic goods without the consent of the collector of customs and to return the consignment or such portion thereof as may be required, the collector of customs shall make over the consignment to the exporter.

(2) If an exporter who has given an undertaking under the proviso to sub-rule (i) is required by the collector of customs to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of the receipt of the notice

(3) If the officer in-charge of the laboratory appointed for the purpose by the authority reports to the collector of customs that the samples of any dug in a consignment do not conform to the specifications or that the therapeutic goods contravenes in any other respect the provisions of the act or the rules made thereunder and that the contravention is such that it cannot be remedied by the exporter, the collector of customs shall communicate the report forthwith to the exporter who shall cause them to be destroyed or surrender them to the authority for disposal in such manner as it may deem fit.

Provided that the exporter may, within fifteen days of the receipt of the report, make a representation against the report to the collector of customs who shall forward the representation with a further sample to the licensing authority or, as the case may be, the registration board which after obtaining, if necessary, the report of the officer-in-charge of the appellate drugs laboratory, shall pass orders thereon which shall be final.

(4) If the officer-in-charge of the laboratory appointed for the purpose by the authority reports to the collector of customs that the samples of any therapeutic goods contravene in any respect the provisions of the act or the rules made thereunder and that the contravention is such that it can be remedied by the exporter, the collector of customs shall communicate the report forthwith to the exporter and permit him to withdraw the drug on his giving an undertaking in writing not to export that therapeutic goods without remedying the said contravention.

Suspension and Cancellation of License to Export Therapeutic Goods: if the

manufacturer or licensee fails to comply with any of the conditions of license to export drugs or violates any of the provisions of the act or the rules made thereunder, the licensing authority may, after giving the licensee an opportunity of being heard, by an order in writing stating the reasons therefor, suspend or cancel it for such period as it thinks fit or cancel for all times, either wholly or in respect of some of the therapeutic goods, to which it relates or, if the nature of offense is so serious that it is likely to endanger the public health, may prohibit the export of all other therapeutic goods of the said manufacturer:

Provided that a person who is aggrieved by the suspension or cancellation of his license, may within sixty days of the receipt of such order, appeal to the Appellate Board.

Explanation: Therapeutic Goods includes finished product, active ingredient and herbal preparations for the purpose these rules**.**

Sale Rules: Provincial Governments shall be competent for making Sales Rules to regulate the sale of Health and OTC Products.