No. F. 1-2/2013-Director, Health & OTC Products
Drug Regulatory Authority of Pakistan
M/o National Regulations and Services
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Islamabad, the 14th February, 2013

OFFICE ORDER

Subject:- **Constitution of Advisory Committee for Furnishing Recommendations to Develop Rules regarding Health & OTC Products**

I am directed to inform you that the Chairperson, Policy Board, Drug Regulatory Authority of Pakistan, has been pleased to constitute Advisory Committee for Furnishing Recommendations to Develop Rules regarding Health & OTC Products:

a.	Director Health & OTC Products	Chairman
b.	Dr. Mahmood Abbasi (Policy Board)	Member
c.	Mr. Hakim Rizwan (Policy Board)	Member
d.	Dr. Masood-ur-Rehman, DDG(Alt/Med)	Member
e.	Amanullah Bismil (Homoeo) Industry	Co opted Member
f.	Mr. Abdul Qayyum (Herbal Industry)	Co opted Member
g.	Mr. Iqbal Ahmad Importer / PCDA	Co opted Member
h.	Mr. Muhammad Asad M/s Global Pharma	Co opted Member
i.	Mr. Naveed Anwar, Drug Inspector Rwp	Co opted Member
j.	Mr. Habibullah Cheema M/s Cheema Lab	Co opted Member
k.	Dr. Fahim Ashraf Qureshi, COMSATS	Co opted Member
l.	Dr. Muzafar, Qarshi Laboratories	Co opted Member
m.	Mr. Hakim Mansoor M/s Ashraf Lab	Co opted Member
n.	Mr. Sadiq Anees Wasay Dawakhana KPK	Co opted Member
o.	Hakim Abdul Waheed, Afghani Dawakhani, KPK	Co opted Member
p.	Mr. Abdul Sattar Sohrani DDC (Alt / Med)	Coordinator

2. The said Committee will furnish its recommendations under the following terms of references.

A. To determine its scope from amongst the following items alongwith the phases / stages

a. Homeopathic and Biochemic medicines
b. Unani and Ayuruvedic medicines
c. Nutaceuticals (Health Supplements) and OTC Products
d. Medicated cosmetics, medicated shampoos and soaps including tooth pastes containing ingredients of natural origin
e. Baby Milks and cereals
f. Disinfectants

No. F. 1-11/2013-DDG (Alt / Med)
Drug Regulatory Authority of Pakistan
M/o National Regulations and Services
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Islamabad, the 20th February, 2013

Subject: - **1st Meeting of Advisory Committee for Furnishing Recommendations to Develop Rules regarding Health & OTC Products**

I am directed to inform you that the 1st meeting of Advisory Committee is scheduled to be held on **25th February, 2013 at 11:00 AM** in the Committee Room of Ministry of National Regulations and Services G-5, near State Bank of Pakistan, Islamabad. The Advisory Committee is supposed to develop recommendations regarding Health & OTC Products Rules 2013.

2. The said Committee will function and propose recommendations under the following terms of references.

A. To determine its scope from amongst the following items alongwith the phases / stages

a. Homeopathic and Biochemic medicines
b. Unani and Ayuruvedic medicines
c. Nutaceuticals (Health Supplements) and OTC Products
d. Medicated cosmetics, medicated shampoos and soaps including tooth pastes containing ingredients of natural origin
e. Baby Milks and cereals
f. Disinfectants

B. *The time frame within which above said items will be brought through under the regulatory regimen through Licensing, Registration and Pricing.*

C. *Well defined and elaborate standards of Licensing, Registration and Pricing in respect of each of the above said items.*

D. *The Committee is expected to conclude its recommendations within one month period.*

E. Every expert member of the Committee is required to submit conflict of interest declaration at the time of meeting.

(Abdul Sattar Sohrani)
DDC (Alt / Med) / Coordinator
Advisory Committee

LIST OF PARTICIPANT OF 1ST MEETING OF ADVISORY COMMITTEE

DIRECTORATE OF ALTERNATIVE MEDICINE (HEALTH & O.T.C. PRODUCTS.)

DRUG REGULATORY AUTHORITY OF PAKSITAN
MINISTRY OF NATIONAL REGULATIONS AND SERVICES

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WORKING PAPER FOR

1ST MEETING OF ADVISORY COMMITTEE ON HEALTH & OTC PRODUCTS.

A new division in DRAP has been created with the following mandate:

Division of health and OTC products (non-drugs) shall be responsible for the assessment, licensing and registration of alternative medicines such as Ayurvedic, Chinese, Unani and Homeopathy, enlistment or registration of nutritional products and food supplements for human beings, animals and to perform other functions connected therewith;

Definition of **drugs**: The Alternative Medicines have now been included in the definition of drugs in the Schedule I of the DRPA Act, 2012, as:

(a) **any substance or mixture** of substances that is manufactured, sold, stored, offered for **sale or represented for internal or external use in the treatment, mitigation, prevention or diagnosis of diseases**, an abnormal physical state, or the symptoms thereof in human beings or animals or the restoration, correction, or modification of organic functions in human beings or animals, including substance used or prepared for use in accordance with the **Ayurvedic, Unani, Homoeopathic, Chinese or biochemic system** of treatment except those substances and in accordance with such conditions as may be prescribed;

(b) abortive and contraceptive substances, agents and devices, surgical ligatures, sutures, bandages, absorbent cotton, **disinfectants**, bacteriophages, adhesive plasters, gelatin capsules and **antiseptic** solution;

(c) such substances intended to be used for the destruction or repulsion of such vermin, insects, rodents and other organism as cause, carry or transmit disease in human beings or animals or for disinfection in residential areas or in premises in which food is manufactured, prepared or kept or stored;

(d) such pesticides as may cause health hazard to the public;

(e) **any substance** mentioned as monograph or as a preparation in the Pakistan Pharmacopoeia or the Pakistan National Formulary or the International Pharmacopoeia or the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United States, **whether alone or in combination with any substance exclusively used in the Unani, Ayurvedic, Homoeopathic, Chinese or Biochemic system of treatment**, and intended to be used for any of the purposes mentioned in sub-clauses (a), (b) and (c); and

(f) any other substance which the Federal Government may by notification in the official Gazette, declare to be a drug for the purpose of this Act.

Item No.1. Introduction of the alternative Medicines etc. that are to be regulated.

a). **Homeopathic and Bio-chemic products.** These products are being manufactured by various units under the International Pharmacopeias as under:

i. German Homeopathic Pharmacopoeia
ii. British Homeopathic Pharmacopoeia
iii. United State Homeopathic Pharmacopoeia
iv. Chinese Homeopathic Pharmacopoeia
v. Japanese Homeopathic Pharmacopoeia
vi. Indian Homeopathic Pharmacopoeia

b). **Unani and Ayurvedic products.** These products are being manufactured under the following Pharmacopoeias.

i. British Herbal Pharmacopoeia
ii. Chinese Herbal Pharmacopoeia
iii. United States Herbal Pharmacopoeia
iv. German Herbal Pharmacopoeia
v. Indian Herbal Pharmacopoeia
vi. Japanese Herbal Pharmacopoeia
vii. International Pharmacopoeia (WHO Herbal Monographs)
viii. In India some authoritative books of ayurvedic system of medicine have been published which are used as reference books.

c). **Nutraceuticals (Health Supplements or Food Supplements).** These are the product which contain Vitamins, Minerals, Metals, Animals origins or Standardized plant extracts, Enzymes, Amino acids and/or their combination and their converted into Pharmaceutical dosage form and used for Health, Nutrition or therapeutic purpose in or Human or Animal. Majority of these products are registered under the Drug Act 1976 and consequently fall under the Regulatory Regimen. These products are included in various Pharmacopeias as monographs and the stakeholders are already following Pharmacopeias Standards.

d). **Medicated Cosmetics, Shampoos and Soaps including Tooth Pastes.** These products are also been manufactured through various standards. In India Bureau of Standards for Cosmetics gives the set of standards to be followed.

e). **Disinfectants.** These products are being manufactured and regulated under various standards the Indian model is simple one.

f). **Baby Milks and Cereals.** These products are required to food standards as these are fortified foods for infants and convalescence.

All the above items will be required to conform the any of the above mentioned approved publications/International Standards/Authoritative books till the Pakistani Pharmacopoeia / Standards are published by the Authority.

Item No.2: Regulation of Natural Health & Otc Products

Under the DRAP ACT 2012, The Directorate of Natural Health and OTC Product is mandated to regulate the Licensing, Registration and other regulatory affaires of Alternate Medicines, Natural Products like Health Supplements (Nutraceuticals), including Cosmetics containing Natural Ingredients, Baby milks and Cereals as well as disinfectants etc.

The Committee input is solicited before draft rules are formulated Health & OTC Products Division.

i. **ENLISTMENT.**
It is proposed that newspaper advertisement may be published in the English and Urdu newspapers having national circulation to inform the stakeholders about the enlistment of manufacturers, locally manufactured products, importers, imported products. The same information will also be routed through relevant associations for awareness of every person involved in this business to submit applications for enlistment with in the devised timeframe. The applications would be entered in a register and a serial number of application would be allotted. A proper enlistment number would be provided to these applications after verification of manufacturing & testing facilities and/or import documents.

ii. **LICENSING.**
Advisory Committee may recommend the timeframe and requirements for licensing of units. The applications will be processed after the Rules are notified. The input from the technical members is solicited.

iii. **REGISTRATION / MARKET AUTHORIZATION.**
The applicants who would obtain a particular type of Manufacturing License shall be eligible to apply for the grant of Registration of new medicines. The criteria of application shall be as per approved guidelines of the Authority.

Item No.3: Enlistment Form of Natural Health & OTC Products

The enlistment procedure would require a Form to be filled by the applicant and submit it to the office of the Directorate. The fee for the enlistment is to be decided.

LIST OF PARTICIPANT OF 1ST MEETING OF ADVISORY COMMITTEE

Form – 1EN

Form of Natural Health & OTC Products

1. **Purpose of Application:**
   1.1. Application for the enlistment of Local Manufacture of (tick the type of application type):
      1.1.1. Herbal Medicines
      1.1.2. Homeopathic Medicines
      1.1.3. Biochemie Medicines
      1.1.4. Unani Medicines
      1.1.5. Ayurvedic Medicines
      1.1.6. Chines Medicines
      1.1.7. Any other type of alternative or complimentary medicines
2. Particulars of the applicant:
   2.1. Name of the applicant:_____
   2.2. Name of the Firm:_____
   2.3. Name of Partners:_____
   2.4. Site of the Manufacturing site:_____
3. Details of the Manufacturing sites:_____
   3.1. Manufacturing area:_____ sq feet
   3.2. Number of Sections:
      3.2.1. Tablet
      3.2.2. Capsule
      3.2.3. Paste
      3.2.4. Liquid
      3.2.5. Quality control
      3.2.6. other
   3.3. Number of employees_____
4. Any other information