Minutes of the Meetings of Health & OTC Committee.

(Interim Report) – Phase 1. (To improve operational efficiency).

A committee was constituted vide letter No. F. No. 9-1/2018-CEO (DRAP), dated 27th September 2018, to draft SOPs and proposals to resolve issues related to Health & OTC products. First meeting of the Committee was held on 1st October, 2018, in DRAP Office, Lahore, 2nd meeting was held in DRAP, Islamabad, and third meeting was held on 24th October, 2018 again in DRAP, Islamabad, under the chairmanship of Dr. Sheikh Akhter Hussain, CEO, Drug Regulatory Authority of Pakistan, for drafting SOPs / resolving issues of Health & OTC Division for bringing improvement in efficiency, and for recommendations to address the issues pertaining to alternative medicine and health products.

Following were the participants of the meetings:-

Representatives from DRAP:-

- Dr. Sheikh Akhter Hussain,
  CEO, DRAP.
- Mr. Asim Rauf
  Additional Director, DRAP, Lahore.
- Prof. Dr. Mahmood Ahmad
- Sayyad Hussain Khan,
  Deputy Director, DRAP, Islamabad

Representative from Stakeholders

- Mr. Hamid Raza — Member
  Former Chairman Pakistan Pharmaceutical Manufacturers Association.
- Mr. Muhammad Naeem — Member
  COO Indus Pharma Pvt. Ltd., Karachi

- Mr. Waseem Sarwar — Member
  Neutraceutical Association of Pakistan
- Mr. Nadeem Khalid — Member
  Pakistan Tibbi Pharmaceutical Manufacturers Association
- Mr. Kamran Atif — Member
  Director RA/R&D, CCL Pharmaceuticals (Pvt) Ltd, Lahore.

Following were the provisional recommendations for Phase 1.

I. Disposal of work of Health & OTC Products:-

The members stressed that a time period needed to be defined for **disposal of various issues of alternative medicine and health products**, as detailed below. It was further urged to enhance pace of the work from now to onward, based upon FIFO Policy, record to be maintained accordingly in the Division, and cases be processed as per their respective submission date. The automation should be used as a tool in order to ensure efficiency & transparency.

Suggested Timeline:

(i)	Manufacturer / Importer Enlistment (Form 6):		**within 90 days**
(ii)	Product Enlistment (Form 7)	:	**within 90 days**
(iii)	Contract Manufacturing (Form 8) (where manufacturer already has (Form 6)	: :	**within 90 days**
(iv)	Export matters	:	**within 48 hours**

In order to facilitate business development opportunities for the new licenses / sections and to create new jobs opportunities, fifteen products per section may be considered without any queue, and afterward FIFO system may be followed strictly as is already practiced for registration of pharmaceuticals. The combinations of one ingredient may be treated as one product. Moreover, different strengths of one ingredients may also be treated as one for the purposes of enlistment.

Contract manufacturing (Form 8) may be issued for a period of three years instead of one year. However, applicable fee shall be three times of the current fee, and may be renewed as per rules / practice in vogue.

Pending approved products (Form-7) by the Enlistment Evaluation Committee shall be issued immediately within a month without any conditionality except for those facilities, which are located in the residential or commercial area.

(II) Agenda and Minutes of Health & OTC Meetings.

Minutes of the meetings be uploaded on the website of the DRAP, in order to ensure transparency of the proceedings.

(III) Export Related Issues.

Matter has already been addressed vide CEO office letter F.No. 16-1/2017-CEO (DRAP) dated 15th October, 2018, and 22nd October, 2018, wherein it has been directed by the CEO, DRAP to issue Enlistment Certificate (Form 7) for export purpose within 05 working days and issuance of CoPP, GMP and free sale has also been de-centralized to facilitate export.

(IV) Minimum Area Requirement.

Presently no minimum area is defined for establishment of manufacturing units of alternative medicines. Units having 5 marlas or 10 marlas area were also enlisted in the past. In order to provide safe manufacturing environment, it was decided to define minimum area requirements as 2 kanals. A transitory period of 02 years would be given

to existing manufacturers having Form 6 for transforming their units to new approved size, however these manufacturing units must be located in non-residential and non-commercial areas. This transitory period of 02 years will not be applicable to those units which are located in residential and commercial areas. Meanwhile, for units having area less than 2 kanals area, no further Form-7 may be issued, in case unit is already having enlisted products. However, in case, enlisted manufacturer is not having any enlisted product, only five products per section may be granted. Furthermore, such manufacturers may be allowed contract manufacturing for export purpose only on production of a valid export order in order to boost export opportunities and earn foreign exchange.

(V) Contract Testing Laboratory for Health & OTC Testing.

DRAP is mandated to establish laboratory to ensure quality of alternative medicines and Health and OTC products in the market. Central Drug Laboratory (CDL), Karachi may be equipped with logistics to make it operational for testing / analysis of all such products. The services of prequalified/ approved other labs may also be utilized in order to cater the work load.

(VI) Manufacturing in the Existing Units.

Issue of manufacturing of alternative products in the same premises, where allopathic formulations are manufactured, also came under discussion. It was decided to discourage such practice in order to avoid cross contamination and other hazards to the public health.

Allopathic manufacturers, who have already established such manufacturing facilities after approval from DRAP, may be advised to make immediate shifting

arrangement, and a reasonable period may be allowed to establish separate dedicated facility. No further Form-7 may be issued, in case the unit is already having enlisted products. However, in case, enlisted manufacturer is not having any enlisted product, only five products per section may be granted. Furthermore, such manufacturers may be allowed contract manufacturing for export purpose only on production of a valid export order.

If dedicated alternative manufacturing units is located / established in the same vicinity along-with dedicated allopathic facility (in addition to 4 kanals), the testing lab may be shared provided if testing facilities are made available for both categories. No other common usage will be permitted.

(VII) Spurious Herbal Products

Strict Action should be taken by DRAP to curb this menace, as mandated under the DRAP Act, 2012 and Alternative Medicines and Health Products (Enlistment) Rules, 2014. Culprits involved in spurious / counterfeiting alternative medications be dealt as per DRAP Act, 2012 may be denied continuity of their business in case of confirmation of commission of such heinous offence.

(VIII) Categorization of Health & OTC Products as per Global Guidelines

a. Category for **Food supplements and Vitamins and other Nutraceuticals** should be handled separately as per global guidelines, e.g. food supplements. The objective of regulations for this category should be to ensure truthful labelling, safety & efficacy of the ingredients and to strictly discourage manufactures / distributors from making any therapeutic claims about cure or

prevention of disease as per global guidelines. The enlistment procedure in this regard needs to be made simple by limiting only to essential required data such as formulations, labelling etc., especially for those products which have been declared as safe (GRAS).

b. The Committee also endorsed the view point that the pure / raw herbs should be dealt with separately in a segregated / dedicated facility to avoid cross-contamination, sanitation, hygiene, etc . However, the standardized extracts and its further processing may be considered for allowing in the neutraceutical manufacturing facility as applicable under rules.

c. DRAP is in the process of developing a software to cater the enlistment of the alternative medicines as per practice of stringent regulatory bodies. The preliminary presentation in this regard would be given to the CEO, DRAP, after a period of two weeks. The Committee appreciated this joint effort of all the stake holders.

(IX) Irresponsible Advertising with False/Exaggerated Claims

DRAP may handle these matters under the relevant provisions of the DRAP Act, 2012 / Drugs Act, 1976, and the Drugs (L, R & A) Rules, 1976.

(X) Import of Raw Materials etc.

Presently, the import of raw materials related to the alternative medicines are being dealt with reference to the letters No. F.4-3211/2016-DD (Health & OTC), dated 11th April, 2017 and No. F. 4-3211/2016-DDC (Health & OTC), dated 24th July, 2018, of the DRAP, Islamabad (copy attached).