Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
DRUG REGULATORY AUTHORITY OF PAKISTAN
TF Complex, Sector G-9/4, Islamabad
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Islamabad, the 2nd September, 2019

NOTIFICATION

F.No.1-78/2018-DD (H&OTC) (Pt).- In exercise of the powers conferred by section 7(c)of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, is pleased to issue the following guidelines for Provisional Enlistment of Manufacturers of Alternative Medicines and Health Products:-

1) **Minimum Area Requirement**

i. A minimum area of 2 kanals is required for establishment of Alternative Medicines & Health Products manufacturing unit. The existing manufacturers, holding Provisional Enlistment Certificate (Form-6) are required to transform their units to new approved size within a transitory period of 02 years, 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. Such manufacturers are required to submit an immediate shifting plan within 30 days of issuance of this notification.

ii. Meanwhile, for units having less than 2 kanals area, no further Form-7 shall 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 shall be granted. Furthermore, such manufacturers shall 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.

2) **Manufacturing of Alternative Products in Allopathic Manufacturing Facilities.**

i. In order to avoid the cross contamination and other hazards to the public health, allopathic manufacturers, who have already established manufacturing facilities after approval from DRAP in the same premises, where allopathic drugs are manufactured, are advised to make immediate shifting arrangements and a transitory period of two years is given to establish separate dedicated facility.

ii. No further provisional product enlistments (Form-7) shall be issued to such manufacturers, if the unit is already having enlisted products. However, in case, enlisted manufacturer is not having any enlisted product, only five products per section shall be granted. Furthermore,

such manufacturers shall be allowed contract manufacturing for export purpose only on production of a valid export order.

iii. If dedicated alternative manufacturing unit 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. However, no other common usage will be permitted.

3) Category for Food supplements and Vitamins and other Nutraceuticals shall be handled separately as per global guidelines, e.g. food supplements. The objective of regulations for this category is to ensure truthful labeling, 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 pure / raw herbs shall be dealt separately in a segregated / dedicated facility to avoid cross-contamination, sanitation, hygiene, etc. However, the standardized extracts and its further processing shall be considered for allowing in the nutraceutical manufacturing facility as applicable under rules.

4) DRAP may handle the matters of irresponsible advertising with False/Exaggerated Claims under the relevant provisions of the DRAP Act. 2012, Drug Act, 1976, and the Drugs (L, R & A) Rules, 1976.

(Muhammad Abdul Ghaffar)
Additional Director,
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