

Drug Regulatory Authority of Pakistan

PUBLIC NOTICE

All manufacturers and importers of Alternative Medicines including products used exclusively in homeopathic, unani, ayurvedic, biochemic, Chinese or any other system of treatment; and Health Products including probiotics, disinfectants, nutritional products, food supplements, baby milks & foods, medicated soaps and medicated shampoos are hereby informed, these medicines and products have been brought under the regulatory control of DRAP, through the Drug Regulatory Authority of Pakistan Act 2012.

For the purpose of regulation of Alternative Medicine and Health products as mentioned above, as a first step the DRAP has promulgated the Alternative Medicines and Health Products (Enlistment) Rules, 2014 vide SRO No 412 (I)/2014, dated 29.5.2014. These rules can be downloaded from the DRAP's website www.drap.gov.pk and shall apply to the following business:-

- (a) Manufacturers, having manufacturing and quality control facilities.
- (b) Contract giver, as in rule 6 of Enlistment Rules;
- (c) Importers, authorized by the overseas principal manufacturer; and
- (d) Manufacturers holding manufacturing license for therapeutic goods under the Act.

Those who are involved in the business of the above said medicines and health products by local manufacture or import, are hereby informed through this advertisement, that the manufacture and market authorization has become mandatory under DRAP Act 2012. Therefore applications for enlistment of manufacturers, contract manufactures, and importers are invited under the said rules on the prescribed forms within 60 days of this advertisement.

- I) Application forms can be downloaded from the DRAP's website or can also be obtained free of cost from the office of the Division of Health & OTC Products, 10 D West, Taimour Chambers Blue Area Islamabad.
- II) Application complete in all respect and addressed to Director, Health and OTC Products are to be submitted in the same office through recorded post or in person or through the representative against a receipt.
- III) Prescribed application fee can be deposited through (pre numbered and preprinted deposit slips) of DRAP in the Account No "**0010008463700018**" in designated branches of Allied Bank of Pakistan.
- IV) New manufacturer or importer of Alternative Medicines and Health Products may also submit applications under the rules.
- V) All applications shall be evaluated as per laid down criteria. Applications fulfilling the criteria of safety, efficacy and quality as per Alternative Medicines and Health Products (Enlistment) Rules, 2014 shall be granted provisional manufacture, import and product market authorizations.
- VI) It is further informed that manufacture, import, marketing, supply and stocking of unapproved alternative medicine and health products with DRAP is an offence under the DRAP Act, 2012.

Abdul Sattar Sohrani
Dy. Drugs Controller (Health & OTC Products)
Drug Regulatory Authority of Pakistan,
Islamabad.