



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce, Govt. of India)

COPY

Date : 07-07-2010

News / Story reproduced with thanks:- **Pharmabiz**

Dept of Ayush issues draft notification on licensing conditions for ASU drugs under new rules 158(B)

Wednesday, July 07, 2010 08:00 IST

Nandita Vijay, Bangalore

Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=56272§ionid=>

Department of Ayush has issued a draft gazette notification amending the licensing conditions for ASU medicines and proprietary ASU medicines. The draft notification introduces new rules 158(B) which has opened up a new category for cosmetics exports among others.

In this regard, the Government has published a draft amendment to the Drugs & Cosmetic Rules. This rule retains the current definition of ASU medicine which is referred as classical or grantha formulations. However, the draft notification has amended the proprietary ASU medicine to introduce four categories instead of the current one single category. These include Current Proprietary Ayurvedic Medicine (PAM) category which are ingredients mentioned in the texts.

The new category which primarily relates to "Ayurveda or Unani or Siddha Health Supplements". The terms officially used in the notification are - Balya - nutrition and strength giver: Poshak - health promoter: positive health promoter, formulations and ayurvedic ingredients that are recommended in official books for promotional and preventive health.

Further, the new category created primarily relates "Ayurveda or Unani or Siddha Cosmetics". The terms officially used in the notification are 'Soundarya Prasadak' which deals with formulations having ingredients that are recommended in official books. These drugs are recommended to promote 'Soundarya' or beauty related to Skin, Hair & Body Care. In fact the the notification clearly mentions the four body parts for which the 'Soundarya Prasadak' are meant for use.

In the case of Ayurveda or Unani or Siddha Extracts, the terms officially used in the notification are 'Aushadh Ghana' extracts obtained from plants mentioned in the official books including Aqueous (water) or hydro-alcohol (water + ethanol).

It is for the first time that the department of Ayush has officially allowed the three new categories of ayurvedic supplements, ayurvedic cosmetics & ayurvedic extracts. The Ayurveda Drug Manufacturers Association (ADMA Technical Committee had been instating to the government through the ayurvedic Pharmacopoeia Committee to ensure the supply of standardized extracts of ayurvedic herbs. The new category created allows extracts as ayurvedic. The government has also allowed use of proportions of ethanol along with water for extraction purposes. Ayurveda most often used only water to extract components from herbs, either as infusions (phanta) or decoctions (kwatha or kadha).

There are also detailed requirements regarding safety study/data, evidence or experience of efficacy from published literature, evidence or experience of efficacy in the form of "proof of effectiveness by published data or pilot clinical trials".

In cases where an ayurvedic formulation from an official book is to be marketed for a new indication other than those given in the books, published data and proof of efficacy are pre-requisites for licensing.

For ayurvedic supplements & ayurvedic cosmetics, photocopy of references from official texts are required to get a license. If the indication is different from those mentioned in the official texts, safety and effectiveness study submissions are needed.

For water extract of herbs mentioned in the official texts, no special data is required. However, if the indication is new, then proof of effectiveness is to be generated and submitted for issue of a license. For all hydro-alcoholic extracts of herbs mentioned in the official texts, in addition to textual references, safety data, published literature data and proof of effectiveness data are required as a pre-requisite for licensing.

According to JSD Pani, president, Karnataka Indian Medicine Manufacturers Association, the draft amendment is a progressive step by the government. The scientists and industry of Ayush support the effort.