



## PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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### **Union govt ready with draft guidelines for 5th amendment of the D&C Rules 2010 for Ayush drugs**

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**Nandita Vijay, Bangalore**

Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=55706&sectionid=>

Union government has issued a draft copy of the Drugs & Cosmetics (Fifth Amendment) Rules 2010 for the Ayush industry seeking to introduce licensing for production of herbal formulations. The new rules would be issued under Section 33- N of the Drugs & Cosmetics Act 1940.

The fresh rules are for Ayurveda, Unani and Siddha drug manufacturers under Section 3 (A), patent or proprietary drugs under section 3(H), 'Balya, Poshak, Muqawi and Unavuporutkal' which are positive health promoter formulations having ingredients mentioned in the books of the First Schedule of the D&C Act and recommended for promoting and preventive health. The formulations under Saundarya Prasadak and Azhagh-sadan having ingredients recommended for oral, skin, hair and body are also provided with a set of procedures for production.

In a communiqué from the Ministry of Health and Family Welfare, department of Ayush, via GSR 377(E) No. K11020/02/2010 DCC Ayush, comments were sought from the industry on the draft before the end of June, 2010. The rules will be finalised then and will be approved for publication in the Gazette.

The new set of rules will be introduced after Rule 158 (A) as 158 (B) of the Drugs and Cosmetics Act 1940.

According to the draft, the drugs for Ayurveda, Unani and Siddha will not require data submission on safety study and evidence of effectiveness but the use of ingredients should be according to the Indian System of Medicine texts.

For the issue of licenses for patent and proprietary drugs, safety study report is not required but manufacturers will need to submit a pilot study according to the protocol of Ayurveda, Siddha and Unani drugs.

For the medicines prepared using ingredients listed in Schedule E(1) of the Drugs & Cosmetics Act 1940, companies will need to furnish the safety data and proof of effectiveness.

The drugs coming under the purview of 'Balya and Poshak category, the applicant should provide a copy of the textual references of ingredients in the formulation listed in Schedule E(1), but need not conduct the safety studies.

For issue of licenses of Saundarya Prasadak products, the applicant seeking license should submit the photo copy of textual references of ingredients used in the formulation and conduct safety studies.

With regard to Aushadh Ghana drugs, which are dry and wet extracts of medicinal plants, safety and proof of effectiveness reports are not required for the aqueous based drugs, but adequate information of the same is required for the Hydro-alcoholic-based medicines.

The draft of the fifth amendment of Drugs & Cosmetic Rule 2010 was finalized by the department of Ayush secretary S Jalaja after intensive deliberations with the herbal industry and its associations Ayurveda Drug Manufacturers Association (ADMA) and Karnataka Indian Medicine Manufacturers Association (KIMMA).

JSD Pani, president, KIMMA said, “We had a difference of opinion on permitting the aqueous based drugs to be approved for production without submission of safety and proof of effectiveness data. However, since the department of Ayush is convinced about this parameter, we agreed on the same.”

“There is need for a similar guideline to be issued for herbal drugs coming under non- aqueous and non Hydro-alcoholic category. Industry experts are here to assist in the formation of a set of laws for the same which is critical. The extensive research carried on in the herbal arena should not go futile in the absence of guidelines,” stated Dr K Venkateshwarlu., medical advisor (Ayurveda), R&D Centre, Natural Remedies Pvt. Ltd.