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ADMA seeks clarification on Rule 158 (B) treating herbal extracts as ayurvedic drugs

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The Ayurvedic Drug Manufacturers' Association (ADMA) has sought clarification from the government regarding some provisions in the recently amended Rule 158 (B) of Drugs & Cosmetics Act under which all herbal extracts or aushadh ghana (medicinal plant extracts either dry or wet obtained from plant including aqueous or hydro-alcohol) have been classified as ayurvedic drugs.

Ayurveda is a well defined traditional science which determines the therapeutic value of an input on the basis of rasa guna veerya vipak and prabhav (RGVV&P) whereas, hydroalcoholic extracts represent a different chemistry than one recognised by Ayurveda through crude powders, decoctions or aqueous extracts of medicinal plants, said Ranjit Puranik, general secretary, ADMA.

He stressed, “We believe that hydroalcoholic extracts represent a manufacturing process which is deviation from the fundamental principles. Therefore, hydroalcoholic extracts in any form should not be allowed for use in formulation that claims to be ayurvedic.”

Puranik informed that the amended rule refers that the patent and proprietary (PP) drugs would now be allowed to be registered as either nutraceauticals, cosmetics or ayurvedic extracts. However he points out that there are certain points that need more clarification like for example the new category created allows all herbal extracts or aushadh ghana ie medicinal plant extracts from any solvents as ayurvedic.

ADMA had been insisting to the government to ensure the supply of standardised and certified raw materials and extracts complying to ayurvedic pharmacopoeia of India (API) standards for all medicinal plants used in Ayurveda. This notification allows for licensing of ayurvedic herbs in the form of extracts as PP drugs.

He points out, “It is understood that in many plants which have been extensively used in traditional medicine would be demanded globally. These medicinal plants would have to be standardised on their phyto chemical profiles and delivery of such products would require extraction with various solvents and not just hydro-ethanolic. This opportunity however needs to be viewed separately and outside the definition and domain of Ayurved.”

There is every possibility of hurting the fledging herbal extract industry by bringing them in the ambit of licensing by extending the scope of the Act to include herbal extract industry which cater to many more industries than just Ayurveda, Siddha and Unani. “It would be a gross error to propose licensing of the herbal extract industry under D&C Act and Rules, when they cater almost 95 per cent of their produce to uses outside of ASU domain and just making a mark in the international trade of botanicals,” he added.

AMDA believes that the ayurvedic principles are clear of an approach in formulation and standardisation and all efforts to update the same with the use of modern technology, without compromising the fundamental principles laid down in the authoritative texts needs to be encouraged and taken forward. Puranik feels that there is need to understand what is herbal extract and define it properly to avoid bottlenecks and hardship otherwise it will be very difficult to manage things and fumbling by insistence of a licensing requires immediate clarification.

ADMA’s stand comes from a consultation on this issue held way back in 2008 itself when permission for use of extracts other than aqueous were under consideration. The other serious dimension of duality this notification suggests is for approvals of nutraceuticals form ASU industry, where the Food Safety & Standards Act, 2006, is also considering licensing for formulations known to be used in traditional systems like Ayurveda, Siddha and Unani. “In a nutshell, you could have a herbal formulation licensed as 'balya poshak' or 'nutraceutical' under the Drugs & Cosmetics Act and a similar formulation as a 'dietary food' under FSSA.”

The looming danger of nutraceuticals going the western way of combination formulations between traditional botanicals, vitamins and other known active-nutraceuticals, are still not clear, he said, “Why do we shun wide spread consultation and the graduation of a regulatory regime has been a question that ADMA has still not configured in actions taken at behest of Department of Ayush,” he added.