



AYUSH

Regulation of Ayush drugs

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Drugs & Cosmetics Act, 1940 and Rules thereunder contain exclusive regulatory provisions for manufacturing and licensing of Ayurvedic, Siddha, Unani and Homoeopathic drugs. Section 3(a) and 3(h) of the Drugs & Cosmetics Act, 1940 respectively provide the definition of drugs as mentioned in the authoritative books of Ayurveda, Siddha and Unani systems and the patent or proprietary medicines made differently from the ingredients of those drugs amounting to new formulations. Guidelines for issue of license for the manufacturing of these two categories of Ayurvedic, Siddha and Unani drugs are prescribed under Rule 158-B of the Drugs & Cosmetics Rules, 1945 including the requirement of submission of proof of safety and effectiveness of the drug applied for obtaining manufacturing license from the Licensing Authority appointed by the concerned State Government. Similarly, regulatory provisions for licensing, manufacturing and sale of homoeopathic medicines and new homoeopathic medicine are prescribed in Rules 85B, 85C, 67 A to H and 30-AA of the Drugs & Cosmetics Rules, 1945 respectively. Provisions for Misbranded, Spurious, Adulterated and drugs manufactured or distributed not in accordance with the prescribed standards along with penal provisions are inbuilt in the Drugs & Cosmetics Act, 1940 and Rules thereunder.

States have reported testing of 4349, 3478 and 4107 drug samples of ASU& H drugs, out of which 317, 198 and 251 samples failed during 2013-14, 2014-15 and 2015-16. State Authorities have reported to have issued show cause notices to the defaulters; recalled failed products; suspended/ cancelled licenses in fifty five cases and initiated prosecution in six cases.

As per available information, ten States/UTs viz: Bihar, Jharkhand, Manipur, Meghalaya, Mizoram, Nagaland, Tripura, Dadra & Nagar Haveli, Daman & Diu and Lakshadweep have not reported about the appointment of AYUSH inspectors.

This information was given by the Minister of State (Independent Charge) for AYUSH, Shri ShripadYesso Naik in reply to a question in Rajya Sabha today.

NB/SK/UD

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