AYUSH

Drug Control Cell is functioning in M/o AYUSH to coordinate with States and CDSCO to enforce quality control of drugs: Shri Shripad Naik

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The regulatory and quality control mechanism for Ayurvedic, Siddha, Unani and Homeopathic drugs has been established in the country in accordance with the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. Exclusive provisions exist in the Drugs & Cosmetics Act, 1940 and rules thereunder for the licensing, manufacturing, labeling, shelf-life and testing of these drugs. Central Government is vested with the powers to make and amend the legal provisions and to give directions to the State Governments. State Governments are responsible to enforce the legal provisions for AYUSH drugs, for which Licensing Authorities/Drug Controllers are appointed in the states. Good Manufacturing Practices and Quality Standards for manufacturing of Ayurvedic, Siddha, Unani and Homeopathic drugs as prescribed in the Drugs & Cosmetics Rules, 1945 and the respective pharmacopoeias are mandatory for the manufacturers to follow. Quality and authenticity of the drugs is checked on the basis of standards of identity, purity and strength prescribed in the pharmacopoeia. For this purpose Central Government has set up Pharmacopoieal Laboratory of Indian Medicine and Homoeopathic Pharmacopoeia Laboratory in Ghaziabad, Uttar Pradesh and there are 27 State Drugs Testing Laboratories and 44 laboratories approved under the provisions of Drugs & Cosmetics Rules, 1945 for testing of medicines and raw materials. Pharmacopoieal Commission of Indian Medicine & Homoeopathy and Pharmacopoiea Committees are in place to lay down quality standards and Standard Operating Procedures for the manufacturing of ASU&H drugs.

Both AYUSH and allopathic drugs are regulated under the provisions of the same Act, the Drugs and Cosmetics Act, 1940 and the regulatory provisions are framed on more or less similar lines. However, AYUSH drugs differ from allopathic drugs in respect of legal definition, nature, reference books, ingredients, methods of preparation, quality standards, dosage forms, Good Manufacturing Practices requirements, shelf life, labeling provisions, penal provisions, analysis parameters for drugs testing, mechanism of action and licensing requirements. Moreover, AYUSH drugs are not allowed to be administered by parenteral route i.e. injectable form.

Drug Control Cell is functioning in the Ministry of AYUSH to co-ordinate with the States and the Central Drug Standards Control Organization (CDSCO) for enforcement of the regulatory provisions and quality control of AYUSH drugs. The Drug Control Cell is also the secretariat for the Ayurvedic, Siddha and Unani Drugs Consultative Committee, which is a statutory body comprising of representatives of all States and constituted under the provisions of Drugs & Cosmetics Act, 1940 to advise the Central Government, State Governments and Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) in technical matters related to AYUSH drugs for harmonization in enforcement of the regulatory provisions. The meetings of ASUDTAB and ASUDCC are held at regular intervals to discuss the issues related to inter-alia quality control of AYUSH drugs. The meetings of State Licensing authorities are also held to review the quality control status of ASU drugs in the States.

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

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