New law to regulate drugs, medical devices in age of online pharmacies

NEW DELHI: The government is working to bring a new law to regulate medicines, cosmetics and medical devices in keeping with changes in the pharmaceutical market making the existing law inadequate to monitor new retail avenues and regulatory demands that has emerged in recent years.

The proposed new law will replace the existing Drugs & Cosmetics Act, 1940 and will comprehensively address areas like medical devices, hospital equipments, e-pharmacy, emergency use authorisation as well as compensation norms in case of EUAs and clinical trials etc, an official said.

The health ministry has constituted a committee to examine the existing law and propose a draft for the new law by November 30.

The eight-member panel is headed by the Drugs Controller General of India (DCGI) with representation from various other state drug regulators and health ministry.

"The committee shall undertake prelegislative consultations and examine the present Act, previously framed Drugs & Cosmetics Bills and submit a draft document for a de-novo Drugs, Cosmetics and Medical Devices bill by 30.11.2021," the health ministry said in its order detailing the terms of reference of the panel.

TOI has reviewed the order.

Currently, the Drugs and Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs and cosmetics. Through a recent amendment, the law incorporated regulation of medical devices as well. However, the provisions are limited to govern the rapidly expanding segment which has sophisticated and innovative products entering the market.

A committee under NITI Aayog had earlier suggested a separate law for regulating medical devices.

While the proposed new law is expected to regulate various areas that remain unaddressed in the existing law, the industry is of the view that all stakeholders should be represented in the committee.

Medical device manufacturers also urged the government to have a separate law for regulating medical devices, which are different from drugs.

"The NITI Aayog 2019 draft of a separate Bill to regulate Devices was in the right direction. Such confusing signals confuse potential investors of medical Devices and India will remain import dependent with one step forward two step backward moves " Rajiv Nath , Forum Coordinator, AiMeD, which represents local medical device manufacturers.