

Govt proposes separate post for medical devices controller

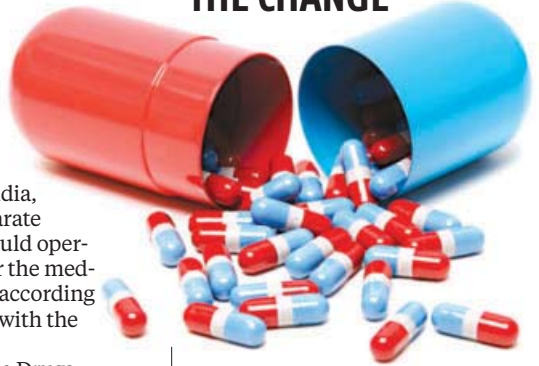
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The Union health ministry has proposed the creation of a separate post for a drugs and medical devices controller general in India, under whom a separate wing of officials would operate as regulators for the medical devices sector, according to sources familiar with the development.

On Thursday, the Drugs Controller General of India (DCGI) convened a meeting in Delhi to deliberate on matters related to the draft New Drugs, Medical Devices and Cosmetics Bill, 2023, said people in the know.

Key features of the proposed Bill were discussed in the meeting. The ministry has recommended

GEARING UP FOR THE CHANGE



Drugs and Cosmetics Act, 1940

- ▶ Director General of Health Services (DGHS)
- ▶ Drugs Controller General of India (DCGI)
- ▶ Joint Drugs Controller India (JDCI)
- ▶ Deputy Drugs Controller (DDC)
- ▶ Assistant Drugs Controller (ADC)
- ▶ Drugs Inspector

Drugs, Medical Devices and Cosmetics Bill, 2023

- ▶ Director General of Health Services (DGHS)
- ▶ Drugs and Medical Devices Controller General
 - Controller General Drugs
 - Joint Controller Drugs
 - Deputy Controller Drugs
 - Assistant Drugs Controller
 - Drugs Control Officer
 - Controller General Medical Devices
 - Joint Controller Medical Devices
 - Deputy Controller Medical Devices
 - Assistant Medical Devices Controller
 - Medical Devices Control Officer

WHAT THE MOVE MEANS

- ▶ Medical devices will be dealt with in a manner distinct from drugs
- ▶ Specific provision for recall of drugs and medical devices
- ▶ Creation of quasi-judicial authorities to adjudicate certain minor offences
- ▶ Provisions related to powers to prohibit, restrict sale of drugs, cosmetics, medical devices through online route

constituting medical devices officers independent of drug control officers and creation of medical devices testing laboratories and the

appointment of medical devices testing officers, a source said. *Business Standard* has seen a copy of the presentation detailing

these aspects. The medical devices manufacturing lobby has been pressing for a separate Bill and a separate pro-

posal for medical devices. It has also written to the ministry requesting a recall of the proposed Bill that is likely to be tabled in the monsoon session of the Parliament.

An industry source disclosed that the testing report of a medical devices testing officer would be considered conclusive evidence in any judicial matter.

The source added: "Medical devices officers will have the power to inspect, take samples and so on, and can also seek police assistance as and when required."

This apart, the proposed Bill recommends the establishment of a separate AYUSH board for drugs, cosmetics, and medical devices. It includes specific provisions for the recall of drugs and medical devices, as well as regulations pertaining to the power to prohibit or restrict the sale of drugs, cosmetics and medical devices through online channels.