GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. 3252
TO BE ANSWERED ON 12TH JULY, 2019

LEGISLATION FOR MEDICAL DEVICES

3252. SHRI SISIR KUMAR ADHIKARI:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether it is a fact that the Government had planned to bring in a new legislation for governing the medical devices, and it was scrapped later on;

(b) if so, the reasons therefor;

(c) the laws governing medical devices in the country at present;

(d) whether inspections or audits are carried out on imported as well as indigenous medical devices and if so, the details thereof; and

(e) whether grievance redressal mechanism is available under these laws for a patient if a medical device/implant turns out to be faulty and whether provision for compensation is being included in the Medical Devices Rules, 2017 therein and if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) & (b): The Bill including separate legislative provisions for medical devices called as the Drugs and Cosmetics (Amendment) Bill was introduced in the Rajya Sabha on 29.08.2013 which was referred to the Standing Committee of Parliament. The Standing Committee made certain recommendations for changing the provisions of the Bill.

Accordingly, a proposal regarding withdrawal of the Drugs and Cosmetics (Amendment) Bill, 2013 and introduction of the Drugs and Cosmetics (Amendment) Bill, 2015 was placed on 11.02.2016 before the Group of Ministers for consideration. The Group of Ministers considered the proposal and decided that the Department of Health and Family Welfare may inter alia frame rules for regulation of Medical Devices keeping in view the fact that framing of such rules is feasible in terms of the existing Drugs and Cosmetics Act,1940.

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Therefore, Medical Devices Rules, 2017 were framed and notified on 31.01.2017 which have become effective from 01.01.2018

(c) & (d): Medical Devices are regulated under Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2017 thereunder. The said rules contain provisions for the inspection of imported as well as indigenous medical devices as considered necessary.

(e): If any notified medical device is found to be not in conformity with the provisions of the Act and Rules, the Central Licensing Authority may issue directions that the entire batch of such medical devices may not be sold or offered for sale or may be recalled from the market including hospitals. A proposal for providing compensation in case of injury to patient due to faulty medical device was deliberated in the 81st meeting of Drugs Technical Advisory Board (DTAB) held on 29th November, 2018 and the Board has decided on constitution of a sub-committee.

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