

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

**LOK SABHA
UNSTARRED QUESTION NO.5504
TO BE ANSWERED ON 26TH JULY, 2019**

REGULATION FOR MEDICAL IMPLANT DEVICES

5504. SHRI RAJAN VICHARE:

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

- (a) whether his Ministry has prepared a draft to amend the Act to bring medical implant devices and equipments under the category of drugs enabling the National Pharmaceutical Pricing Authority (NPPA) to determine the maximum prices of medical devices;
- (b) if so, the details thereof; and
- (c) if not, the reasons therefor?

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

(a) to (c): There is no such proposal. However, 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.

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

Medical devices are regulated as drugs notified under section 3 (b) (iv) of the Drugs & Cosmetics Act 1940 from time to time. Such medical devices are regulated under the said Act and Medical Devices Rules, 2017 made thereunder.