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

### RAJYA SABHA UNSTARRED QUESTION NO. 1891 TO BE ANSWERED ON 19<sup>TH</sup> DECEMBER, 2023

#### SEPARATE LAW FOR MEDICAL DEVICES

## 1891: SHRI A. D. SINGH:

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

(a) whether the medical devices are covered under the definition of drugs in the country under the Drugs and Cosmetics Act, if so, the details thereof;

(b) whether there is consistent demand by the industry to frame separate law for medical devices; and

(c) if so, the response of Government?

# ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (DR. BHARATI PRAVIN PAWAR)

(a) to (c): As per Section 3(b) of the Drugs and Cosmetics Act 1940, drugs include "such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government". Comments and inputs have been received from various stakeholders on the draft Drugs, Medical Devices and Cosmetics Bill, 2023 which had been published for public consultation. These have been considered and incorporated.

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