

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

**RAJYA SABHA
UNSTARRED QUESTION NO.3153
TO BE ANSWERED ON 28TH MARCH, 2023**

REGULATION OF MEDICAL DEVICES AND COSMETICS

**3153: SHRI SYED NASIR HUSSAIN:
DR. AMEE YAJNIK:**

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

- (a) whether Government has taken any steps to amend the laws relating to regulation of medical devices and cosmetics, if so, the status of such amendment and if not, the reasons therefor;
- (b) whether Government has received any feedback/comments on the draft Drugs, Medical Devices and Cosmetics Bill, 2022, if so, the total number of responses received and a summary thereof; and
- (c) whether Government proposed any time limit for introducing the Bill in the Parliament?

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

(a) to (c): Government of India published new Medical Device Rules, 2017 for regulation of manufacture, import, clinical investigation and sale of medical devices on 31.01.2017 which came into effect on 01.01.2018. The Rules contain various provisions for improving transparency and accountability & promote research and development of new medical devices. Further, in order to regulate all the medical devices and phase-wise regulation of the all non-notified medical devices, these Rules have been amended vide notification No. G.S.R. 102(E), dated 11.02.2020.

Additionally, rules pertaining to regulation of cosmetics have been separated from Drugs and Cosmetics Rules, 1945 and a New Cosmetics Rules, 2020 has been published vide notification no. G.S.R. 763(E) dated 15.12.2020.

Comments/suggestions/objections have been received.
