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

LOK SABHA
UNSTARRED QUESTION NO. 1003
TO BE ANSWERED ON 22ND NOVEMBER, 2019

LEGISLATION TO REGULATE MEDICAL DEVICE

1003. SHRI DIBYENDU ADHIKARI:

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

(a) whether the Government has recently come out with a notification treating all medical devices, including implants or MRI machines as "drugs" under the Drugs and Cosmetics Act;

(b) if so, the details thereof;

(c) whether medical devices can be treated as drugs and whether a new, standalone legislation is needed for regulating medical devices and if so, the details thereof;

(d) whether the Government has any plan to bring in a new, standalone legislation to regulate medical devices; and

(e) if so, the details thereof and if not, the reasons therefor?

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

(a) & (b): The Central Government has prepared a roadmap to bring all the non-notified medical devices under regulation. Further, the Central Government notified the following devices on 08.02.2019, effective from 1st day of April, 2020, vide gazette notification No.S.O.775 (E), namely:-

(i) All implantable medical devices;
(ii) CT scan Equipment;
(iii) MRI Equipment;
(iv) Defibrillators;
(v) Dialysis Machine;
(vi) PET Equipment;
(vii) X-Ray Machine; and
(viii) Bone marrow cell separator

(c): Medical devices notified under the Drugs & Cosmetics Act 1940 are regulated as drugs. Comprehensive provisions aligned with the best international practices exist for regulating such medical devices under Medical Devices Rules, 2017 framed under the said Act.

(d) & (e): No such proposal has been approved by the Government.