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

LOK SABHA
UNSTARRED QUESTION NO. 614
TO BE ANSWERED ON 20th JULY, 2018

MEDICAL IMPLANTABLE DEVICES

614. SHRI SUDHEER GUPTA:
SHRI ASHOK SHANKARRAO CHAVAN:
SHRI BIDYUT BARAN MAHATO:
KUNWAR HARIBANSH SINGH:
SHRI GAJANAN KIRTIKAR:
SHRI DHANANJAY MAHADIK:
SHRI S.R. VIJAYAKUMAR:
SHRI MOHITE PATIL VIJAYSINH SHANKARRAO:
SHRI P.R. SUNDARAM:
DR. HEENA VIJAYKUMAR GAVIT:
SHRI SATAV RAJEEV:
SHRI T. RADHAKRISHNAN:
DR. J. JAYAVARDHAN:
SHRI S. RAJENDRAN:

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

(a) whether most of the medical implantable devices are not regulated by any law in the country and if so, the details thereof;

(b) whether the Government proposes to regulate the sale, manufacture and import of medical implantable devices and if so the details thereof;

(c) whether the Government has consulted various stakeholders in this regard, if so, the response thereto; and

(d) the details of steps taken/being taken by the Government to ensure quality of implant/medical devices made available in the country?

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

(a): The Central Drugs Standard Control Organisation (CDSCO), under the Ministry of Health and Family Welfare, regulates the safety, efficacy and quality of 15 notified category of medical devices under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. Under the said rules, the implantable medical devices like Cardiac stent, Drug Eluting stent, Orthopaedic Implant and Internal prosthetic replacements are regulated as medical devices under section 3(b)(iv) of Drugs and Cosmetics Act, 1940.

(b) & (c): In the 79th meeting of Drugs Technical Advisory Board (DTAB) held on 16th May, 2018, the Board has agreed to include all implantable medical devices under the purview of section 3 (b) (iv) of the Drugs And Cosmetics Act, 1940 as medical devices, with an aim to regulate their import, manufacture, distribution and sale.

Further, a public notice dated 22.06.2018 has been published for inviting comments /suggestions from stakeholders in this regard.

(d): Medical Devices Rules, 2017 have been implemented with effect from 01.01.2018 which have detailed provisions for regulation of manufacture, import, sale and distribution of medical devices covered under the said Act to ensure their quality. Further, as brought out above, the DTAB has agreed to include all implantable medical devices, CT scan equipment, MRI equipment, Defibrillators, Dialysis Machine, PET equipment and X-Ray Machine under the purview of section 3 (b) (iv) of the Drugs And Cosmetics Act, 1940 with the objective of ensuring their quality.