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

LOK SABHA
UNSTARRED QUESTION NO. 4792
TO BE ANSWERED ON 23rd MARCH, 2018

SETTING UP OF MEDICAL DEVICE TESTING LABORATORIES

4792. SHRI BIDYUT BARAN MAHATO:
SHRI NARANBHAI KACHHADIYA:
SHRI GAJANAN KIRTIKAR:
KUNWAR HARIBANSH SINGH:
SHRI T. RADHAKRISHNAN:
SHRI S.R. VIJAYAKUMAR:
DR. SUNIL BALIRAM GAIKWAD:

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

(a) whether the Government has taken note of the fact that medical equipments especially pre-owned medical electronic equipment is entering the country *via* imports without any safeguards and if so, the details thereof;

(b) whether the Government proposes to bring imaging and endoscopic equipment under the purview of the Drugs and Cosmetics Act, 1940;

(c) if so, the details thereof along with the aims and objectives thereto;

(d) the time by which it is likely to be brought under the purview of the said Act; and

(e) the measures being taken by the Government to set up medical device testing laboratories and make them available at affordable cost 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. However, Medical equipment are not notified as Medical device under section 3(b)(iv) of Drugs and Cosmetics Act, 1940.

(b) to (d)**:** In the 78th meeting of Drugs Technical Advisory Board (DTAB) held on 12th February, 2018, the board has agreed to include ultrasound equipments and similar imaging equipments under the purview of section 3 (b) (iv) of the Drugs And Cosmetics Act, 1940 as medical devices, with a aim to regulate its import, manufacturing, distribution and sale.

(e): As per the Medical Device Rules, 2017, the Central Government may designate any laboratory having facility for carrying out test and evaluation of medical devices as central medical devices testing laboratory. In this regard, CDSCO has requested National Accreditation Board for Testing & Calibration Laboratories (NABL) accredited laboratories on 01.03.2018 which are having capacity and capability for testing and evaluation of the Medical Device including In Vitro Diagnostic, may get registered with CDSCO and inform details of their activities.

It may be mentioned that since Financial Year 2015-16, funds have been approved/disbursed under the erstwhile Assistance to States for infrastructure Development of Exports Scheme and the current Trade Infrastructure for Export Scheme for setting up of testing labs for medical equipment/common scientific facilities etc.