THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) to (c) In the case of Government medical colleges, the respective State Governments are responsible for fixation of fee and in the case of private unaided medical colleges, the fee structure is decided by the Committee set up by the respective State Government under the Chairmanship of a retired High Court Judge in pursuance of the directions of the Hon'ble Supreme Court of India. It is for the Committee to decide whether the fee proposed by an Institute is justified and the fee fixed by the Committee is binding on the Institute. Further, Hon'ble Madras High Court in its order dated 16th June, 2017 in Writ Petition (Civil) No. 14232 of 2017 titled as SBR Menon Vs. Government of Puducherry & Others directed UGC to form a Committee for recommendation regarding Regulation of fee chargeable by self financed Deemed to be Universities in Medical and Dental Courses. However, the above said order of Hon'ble Madras High Court was challenged in Hon'ble Supreme Court of India by the way of a Special Leave Petition No. 19315 of 2017. The Hon'ble Apex Court *vide* its interim order dated 4th August, 2017 has stayed the order of Hon'ble Madras High Court regarding formation of a Committee for fixation of fee chargeable by self financed Deemed to be Universities in Medical and Dental Courses. The matter is *sub-judice.*

Regulatory body for medical devices

1713. SHRI K.C. RAMAMURTHY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of items classified as 'medical device';

(b) whether it is a fact that the latest National Health Policy mandates to set up a regulatory body for medical devices;

(c) if so, what are the reasons that no initiative has so far been taken to set up one such body to oversee various aspects of medical devices in the country; and

(d) by when a national regulator for medical devices would be set up and all medical devices now under Drugs and Cosmetics Act would be brought under the new regulator?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) Presently 15 notified categories of medical devices are regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules 1945 thereunder, as per the details given in the Statement (*See* below).

(b) to (d) The National Health Policy, 2017 recommends strengthening regulation of medical devices and establishing a regulatory body for medical devices to unleash innovation and the entrepreneurial spirit for manufacture of medical device in India. The policy supports harmonization of domestic regulatory standards with international standards.

In line with the above recommendations, Ministry of Health & Family Welfare has notified Medical Devices Rules, 2017 for comprehensive regulation of Medical devices notified under the Drugs and Cosmetics Act, including their import, clinical investigation, manufacture, sale and distribution. The new rules are harmonised with the international regulatory practices and provide comprehensive legislation for the regulation of Medical Devices to foster India specific innovation and provide a fillip to Make in India. A separate and dedicated wing is set up under Drug Controller General of India for effective implementation of new medical Devices Rules, 2017 with effect from 1.1.2018.

Statement

Details of regulated medical devices

Sl. No.	Name of the Device
1.	Disposable Hypodermic Syringes
2.	Disposable Hypodermic Needles
3.	Disposable Perfusior Sets
4.	*In vitro* Diagnostic Devices for HIV, HbsAg and HCV
5.	Cardiac Stents
6.	Drug Eluting Stents
7.	Catheters
8.	Intra Ocular Lenses
9.	I.V. Cannulae
10.	Bone Cements
11.	Heart Valves
12.	Scalp Vein Set
13.	Orthopedic Implants
14.	Internal Prosthetic Replacements
15.	Ablation Devices