

- (c) whether Government intends to check such malpractices?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI ANUPRIYA PATEL): (a) and (b) Health is a State subject. It is the responsibility of the respective State Government to take cognizance of such instances and take action to prevent and control such practices. Therefore, such complaints, as and when these are received, are forwarded to the concerned States. Details of such complaints are, however, not maintained centrally.

(c) Though, health is a State subject, the Government of India has enacted the Clinical Establishments (Registration and Regulation) Act, 2010 for registration and regulation of all clinical establishments (both Government and Private) in the country. Under the Clinical Establishments (Central Government) Rules, 2012 notified under this Act, the clinical establishments (in the States / Union Territories where the said Act is applicable) are required to follow Standard Treatment Guidelines as may be issued by Central/State Governments, display their rates at a conspicuous place, charge the rates for each type of procedures and services within the range of rates determined from time to time in consultation with the State Governments. The National Council for Clinical Establishments has approved a standard list of medical procedures and a standard template for costing of medical procedures and the same has been shared with the States/UTs where the Act is applicable for appropriate action. They are also required to follow Standard Treatment Guidelines as may be issued by Central/State Governments. The implementation and enforcement of the said Act is within the purview of the State/UT Governments.

#### **Fee structure in medical colleges**

1712. SHRI N. GOKULAKRISHNAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the regulatory authority of the fee structure for various courses for private colleges or Deemed-to-be university run medical colleges in a State;

(b) whether the Central Government/ UGC will make it mandatory for the Deemed-to-be universities to follow the fee structure prescribed by Government in view of the fact that at present, the fee structure recommended by the Fee Committee appointed by the State Government is mandatory for all private medical colleges but not for Deemed-to-be universities; and

- (c) if not, the difficulties in doing so?

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).