

**GOVERNMENT OF INDIA  
HEALTH AND FAMILY WELFARE  
LOK SABHA**

UNSTARRED QUESTION NO:3390  
ANSWERED ON:30.08.2013  
REGULATION ON MEDICAL DEVICES AND EQUIPMENT  
Anandan Shri K.Murugeshan

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

- (a) the norms and regulations laid down by the Government to maintain the safety and standards of medical devices and equipment in the country;
- (b) whether instances of use of medical devices and equipment in an unregulated manner have been reported in the country;
- (c) if so, the details thereof and the action taken by the Government thereon;
- (d) whether the Government proposes to make separate provisions to regulate use of medical devices and equipment in the country; and
- (e) if so, the details thereof?

**Answer**

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

- (a): Medical Devices notified under the Drugs and Cosmetics Act, 1940 are regulated as "Drugs" under the Drugs and Cosmetics Rules, 1945.
- (b): No.
- (c): Does not arise.
- (d)&(e): The Drugs and Cosmetics (Amendment) Bill, 2013 has been introduced in the Rajya Sabha. It has a separate chapter on medical devices and has provisions to regulate their use in the Country.