

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

**LOK SABHA  
UNSTARRED QUESTION NO. 525  
TO BE ANSWERED ON 18<sup>TH</sup> NOVEMBER, 2016**

**MEDICAL DEVICES REGULATIONS**

**525. SHRI DEVJI M. PATEL:**

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

- (a) whether various organizations and associations have raised certain objections on the second draft of the Medical Devices Regulations notified recently;
- (b) if so, the details thereof; and
- (c) the corrective steps taken by the Government to boost manufacturing of medical devices in the country?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI FAGGAN SINGH KULASTE)**

(a) & (b): The draft Medical Devices Rules have been e-gazetted on 17.10.2016 for inviting comments and suggestion from all stakeholders. Till now, comments and suggestion have been received from some organization. The last date for receipt of comments was 16.11.2016

(c): Availability of a transparent, objective and predictable regulatory framework for medical devices is a pre-requisite for boosting domestic manufacture of medical devices. Draft Medical Devices Rules have been framed keeping this in view. Further, the Government is providing some facilities for medical devices parks such as Andhra Pradesh Med Tech Zone (AMTZ) to set Up common facilities.