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

LOK SABHA
UNSTARRED QUESTION NO. 3537
TO BE ANSWERED ON 16TH MARCH, 2018

REGULATORY BODY FOR MEDICAL DEVICES

3537. DR. BOORA NARSAIAH GOUD:

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

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

(b) whether the National Health Policy mandates to set up a regulatory body for medical devices and if so, the details thereof;

(c) the initiatives taken to set up one such body to oversee various aspects of medical devices in the country; and

(d) the time by which a national regulator for medical devices would be set up and all medical devices now under Drug and Cosmetics Act would come under the purview of the new regulator?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(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 in the **Annexure**.

(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.

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Annexure

S.No.	Name of the device	Notification Date
1.	Disposable Hypodermic	17-03-1989
2.	Disposable Hypodermic	17-03-1989
3.	Disposable Perfusion Sets	17-03-1989
4.	In vitro Diagnostic Devices for HIV, HbsAg and HCV	01-09-2002
5.	Cardiac Stents	06-10-2005
6.	Drug Eluting Stents	06-10-2005
7.	Catheters	06-10-2005
8.	Intra Ocular Lenses	06-10-2005
9.	I.V. Cannulae	06-10-2005
10.	Bone Cements	06-10-2005
11.	Heart Valves	06-10-2005
12.	Scalp Vein Set	06-10-2005
13.	Orthopedic Implants	06-10-2005
14.	Internal Prosthetic	06-10-2005
15.	Ablation Devices	25-01-2016