

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

**LOK SABHA
UNSTARRED QUESTION NO. 2558
TO BE ANSWERED ON 06TH MARCH, 2020**

NOTIFICATION OF MEDICAL DEVICES AS DRUGS

**2558. DR. T.R. PAARIVENDHAR:
SHRI A. GANESHAMURTHI:
SHRI ASADUDDIN OWAISI:
SHRI SYED IMTIAZ JALEEL:
MS. PRATIMA BHOUMIK:
SHRI DEVUSINH JESINGHBHAI CHAUHAN:**

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

- (a) whether there are no guidelines for medical devices like stents, pacemaker and ortho implants thereby affecting their quality standards and leading to unregulated prices, if so, the details thereof;
- (b) whether the Government has notified the medical devices as drugs bringing a wide range of products under the Drugs and Cosmetics Act, 1940, if so, the details thereof;
- (c) whether approval from the Drug Controller is required to manufacture, import and sell medical devices and the said notification is likely to ensure safety and efficacy for regulation of prices under Drugs Price Control Orders (DPCOs), if so, the details thereof along with the rules framed for any violations;
- (d) whether the stakeholders have raised concerns over proposed rules, if so, the details thereof; and
- (e) the number of Government run embalming centres in the country, State/UT-wise and the manner in which the cost of embalming is regulated?

ANSWER

**THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. HARSH VARDHAN)**

- (a): To have comprehensive regulatory provisions for import, manufacture, sale and distribution of medical devices based on risk based criteria, the Government of India has notified the Medical Device Rules 2017 which have become effective from 01.01.2018. For import or manufacture of any medical device, the applicant is required to submit details of design, specification, non-clinical as well as clinical data of safety and performance of the devices.

As per Medical Devices Rules 2017, the notified medical device shall conform to the standards laid down by Bureau of Indian Standards (BIS) or as may be notified by Central Government from time to time. If such standards are not available then International Organisation for Standardisation (ISO), International Electro Technical Commission (IEC) or any other pharmacopeial standards will be applicable. If none of those are available, then the device shall conform to the validated manufacturer's standard.

Further, National Pharmaceuticals Pricing Authority under the Department of Pharmaceuticals has fixed ceiling prices for Coronary Stents and orthopaedic Knee Implants in the year 2017.

(b): In order to bring the non-notified Medical Devices under regulation, Government of India has, vide S.O. 648 (E) dated 11.02.2020, which will be effective from 01.04.2020, notified all medical devices intended to be used for diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder, etc, as drugs under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.

The Central Government has also amended Medical Devices Rules, 2017 vide G.S.R 102(E) dated 11.02.2020, effective from 01.04.2020, specifying that registration of all such medical devices will be in a phased manner.

(c): As per the Medical Device Rules, 2017, import of all classes of Medical Devices as well as manufacture of Class C & D Medical Devices are regulated by CDSCO, while manufacture of Class A & B Medical devices are regulated by the concerned State Licensing Authorities (SLA) appointed by the State Governments. Sale and distribution of the medical devices are regulated by the State Licensing Authorities.

Pricing of notified medical devices is regulated by National Pharmaceuticals Pricing Authority under the Department of Pharmaceuticals.

(d): The above notifications were finalized with the previous publication of draft and consideration of suggestions/comments of the stakeholders.

(e): The data regarding the embalming centres available in hospitals run by State Governments/UT Administrations is not maintained centrally. As per information obtained from Central Government Hospitals, the Department of Anatomy in Lady Hardinge Medical College is the recognized Government run embalming centre in Delhi. The cost of embalming at the centre is regulated through the Ministry of Health & Family Welfare.

Further, embalming centres are also available in All India Institute of Medical Sciences, New Delhi; Post Graduate Institute of Medical Education & Research, Chandigarh; and Jawaharlal Institute of Postgraduate Medical Education and Research, Puduchery.

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