**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS & FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

RAJYA SABHA
UNSTARRED QUESTION No. 2739
TO BE ANSWERED ON 25TH MARCH 2025

**Prospects of medical device industry**

**2739 # Dr. Laxmikant Bajpayee:**

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether the medical device industry has the potential to add more than a trillion dollars to the Indian economy;
(b) whether Government is aware that the industry had to suffer over the last two years due to unco-operative and inappropriate behavior of CDSCO officials;
(c) the steps Government proposes to take to reduce human intervention in the licensing of medical devices by completely changing CDSCO officials and medical device regulations in order to promote the growth of the industry; and
(d) if so, the details thereof and if not, the reasons therefor?

**ANSWER**

**THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS**

**(SMT. ANUPRIYA PATEL)**

(a): As per a study report of the Foundation for MSME Clusters, the size of the Indian medical devices market is estimated at US$ 11 billion in 2020 and expected to grow to US$ 50 billion by 2030.

**Export and import of medical devices**

(In million US$)

| | **FY 2021-22** | **FY 2022-23** | **FY 2023-24** |
|---|---|---|---|
| Export | 2,923 | 3,391 | 3,785 |
| Import | 8,540 | 7,492 | 8,188 |

*Source:* Director General of Commercial Intelligence and Statistics

(b): As per the Department of Health and Family Welfare, under whose administrative purview the Central Drugs Standard Control Organisation (CDSCO) comes, there is no report of such suffering.

(c) and (d): The Department of Health and Family Welfare has informed that the Medical Devices Rules, 2017 (MDR) have comprehensively revised the regulations applicable to medical devices, with emphasis on ease of doing business while ensuring the safety and efficacious quality of medical devices. Medical devices are regulated under MDR, which prescribe the specific documents required for the grant of a licence to ensure the quality, safety and performance of medical devices, including *in vitro* diagnostic devices. Applicants need to submit requisite documents as outlined in the said rules. For an application that is

complete in all respects, with all requisite documents as per MDR, the licence is being issued well before the stipulated timeline prescribed in MDR. However, in cases where the required documents are found deficient, compliance has to be ensured with MDR. Opportunities for clarification are provided to applicants.

Further, to streamline regulatory working, measures have been taken as under:

(i) The Medical Device Online Portal has been developed as a single-window system for the submission, processing and approval of various licences in a time-bound manner.

(ii) Phase-wise regulation of all medical devices has been implemented.

(iii) Initially all Class A medical devices were under the licensing regime. *Vide* notification dated 14.10.2022, provision was introduced in MDR for registration of Class A non-sterile and non-measuring medical device.

(iv) *Vide* notification dated 30.9.2022, provision was introduced in MDR for separate registration certificate to sell, stock, exhibit or offer for sale or to distribute a medical device, including *in vitro* diagnostic medical device.

(v) In light of recent development of bringing all medical devices under regulation, a very large number of applications are being received by CDSCO. To address the related capacity requirements, a dedicated Medical Device Vertical has been created in CDSCO, recruitment rules have been notified *vide* notification dated 6.11.2024 for the posts of Drugs Inspector (Medical Devices), Assistant Drugs Controller (I), Deputy Drugs Controller (I), Joint Drugs Controller (I) and Additional Drugs Controller (I), and recruitment process has been initiated to fill the said posts.

(vi) MDR also provide for the registration of medical devices testing laboratories that are responsible for testing medical devices on behalf of manufacturers. Currently, 72 laboratories are registered with CDSCO for this purpose. Further, CDSCO has registered 14 notified bodies to perform the duties and functions concerning Class A and Class B medical devices.

(vii) For ensuring transparency and ease in submission of documents by applicants, various guidance documents, Frequently Asked Questions (FAQs), specimen forms for submission of applications and checklists for various applications have been published.

(viii) Training sessions are conducted on an ongoing process, and stakeholder meetings are held from time to time.

(ix) Dedicated public relations office have been established at the headquarters and zonal offices of CDSCO, to serve as an interface between CDSCO and its stakeholders, including startups and new entrepreneurs, to guide them along the regulatory pathway and for the disposal of their grievances by addressing issues to the level of the Drugs Controller General of India.

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