

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

**LOK SABHA  
UNSTARRED QUESTION NO. 1945  
TO BE ANSWERED ON 12<sup>TH</sup> FEBRUARY, 2021**

**SELF RELIANCE IN MEDICAL DEVICES**

**1945. SHRI MANOJ KOTAK:  
SHRI MANNE SRINIVAS REDDY:**

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

- (a) whether India currently imports 80 to 90 percent of its medical devices and the vast majority of which are unregulated for quality and safety, if so, the details thereof;
- (b) the details of the such country/countries which export high technology medical equipment to India;
- (c) whether the Government has set up a roadmap for India's self-reliance in medical equipment, medical devices, medical lab kit sector;
- (d) if so, the details thereof and progress made so far; and
- (e) the funds sanctioned/utilized so far for the purpose?

**ANSWER**

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI ASHWINI KUMAR CHOUBEY)**

(a) & (b): India currently imports approx. 80% of its requirement of medical devices. USA, Germany, China, Singapore and Netherlands are the top exporters of medical devices to India.

Central Drugs Standard Control Organisation (CDSCO) is presently regulating 28 categories of notified medical devices under the provisions of Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2017 thereunder.

Further, in order to regulate all medical devices, Ministry of Health & Family Welfare has issued notification vide S.O. 648 (E) dated 11.02.2020 defining medical devices and G.S.R 102(E) dated 11.02.2020 specifying mechanism for regulation of all non-notified medical devices in a phased manner to ensure the quality safety and performance of medical devices.

(c) to (e): Various schemes/initiatives have been formulated to promote domestic manufacturing of medical devices/equipments and to attract large investment in the sector; such as:

- (i) National Biopharma Mission.
- (ii) DBT-AMTZ COMManD [Covid-19 Medtech Manufacturing Development] Consortia launched by Department of Biotechnology (DBT) with Andhra Pradesh Med-tech Zone (AMTZ).
- (iii) Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices.
- (iv) Scheme for "Promotion of Medical Devices Parks"

A scheme called "Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices" has been approved by the Government of India with a total financial outlay of the Scheme of Rs.3,420 crore.

A scheme called "Promotion of Medical Device Parks" has also been approved by the Government of India with a financial outlay of Rs.400 crore.

The National Biopharma Mission, with an outlay of Rs.148.79 crore is meant for establishment of infrastructure and facilities for manufacturing and testing of medical devices. 9 such facilities have been funded and Rs.105.42 crore have been utilized.