

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

LOK SABHA
UNSTARRED QUESTION NO. 1891
TO BE ANSWERED ON 06th DECEMBER, 2024

Import of Refurbished Medical Devices

1891. Shri Balashowry Vallabhaneni:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) whether the import and use of refurbished devices create a risk to patients safety and is also violation of medical regulatory framework, if so, the details thereof and the reasons for permitting import of such devices;
- (b) the reasons for adopting a policy which permit import of refurbished medical devices into the country; and
- (c) whether the Government proposes to recall the said policy looking at risks for patients' health and safety, if so, the details thereof and if not, the reasons therefor?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SMT. ANUPRIYA PATEL)**

(a) to (c): Ministry of Health and Family Welfare has informed that the Medical devices are regulated under Drugs and Cosmetics Act, 1940 and the Medical Device Rules, 2017. Under the said Rules, there is no specific provision for Regulation of Refurbished Medical Devices. Further, Central Drugs Standard Control Organization (CDSCO) has not issued any license/permission for import of such devices to the country.

Further, Ministry of Environment, Forest and Climate Change (MoEFCC) has notified Hazardous and Other Waste (Management and Transboundary Movement) (HOWM) Rules, 2016 as amended from time to time. The import/export of hazardous and other waste is regulated thorough the said HOWM Rules, 2016. The import of 'Used Electrical and electronic assemblies' falls under Schedule III Part B (Basel No. B1110)] which can be imported by the actual user only after obtaining necessary permission from MoEFCC. Further, used critical care medical equipment covered under Basel No. B1110 of Schedule VI of the HOWM Rules, 2016 and is prohibited for import for re-use.

The MoEFCC amended the HOWM, 2016 on 23rd December, 2022 to allow import of High End and High Value Used Medical Equipment other than Used Critical Care Medical Equipment by the actual user or by Original Equipment Manufacturers (OEM) or Indian Subsidiary of OEM or Trader on behalf of actual user for re-use. This items falls under Schedule III Part B of HOWM Rules, 2016, hence import of these equipment is restricted and cannot be imported without permission from MoEFCC and with conditions imposed in the permission letter and DGFT license, if applicable.
