

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 751
TO BE ANSWERED ON 07th FEBRUARY, 2025

Import of Refurbished Medical Devices

751. Shri Magunta Sreenivasulu Reddy:

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

- (a) the details regarding the total number of medical devices imported into the Country over the last five years, year-wise and country of origin-wise;
- (b) whether the Government has conducted any study/survey of refurbished/reconditioned medical devices in India over the last five years;
- (c) if so, the details regarding the total number of such refurbished/reconditioned medical devices that are presently being used in the country;
- (d) whether the Government has considered/introduced and/or implemented any specific policy/standard for refurbished and/or reconditioned medical devices in the country over the last five years, if so, the details thereof and if not, the reasons therefor; and
- (e) whether the Government has set any timeline for the proper implementation of policy/guidelines regarding the use and sale of refurbished/reconditioned medical devices in the country, 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): The details of imports and exports of medical devices over the last five years, as per data of the Directorate General of Commercial Intelligence and Statistics, are as under:

(In million US\$)

	FY 2019- 20	FY 2020- 21	FY 2021- 22	FY 2022- 23	FY 2023- 24
Exports	2,293	2,532	2,923	3,391	3,785
Imports	5,845	6,242	8,540	7,492	8,188

Country-wise details regarding the imports and exports of medical devices over the last five years, as per the data of the Directorate General of Commercial Intelligence and Statistics, in respect of major countries, are as under:

Imports

(In million US\$)

Country	FY 2019-20	FY 2020-21	FY 2021-22	FY 2022-23	FY2023-24
USA	1,190.08	984.08	1,464.73	1,418	1,519
China	622.2	1,110.92	1,657.67	1,246.82	1,332
Germany	732.07	668.5	782.35	797.49	908
Netherlands	347.51	228.51	398	416	460
Japan	280.08	236.99	343.08	321.77	372

Exports

(In million US\$)

Country	FY 2019-20	FY 2020-21	FY 2021-22	FY 2022-23	FY2023-24
USA	521.85	600.01	631.48	714.12	714.30
Germany	123.74	133.7	127.29	176.63	199
China	130.27	133	146.94	144.574	166
Netherlands	33.78	43.87	93.68	110.44	145
Japan	30.63	27.21	31.84	38	42.17

(b) and (c): As informed by the Ministry of Environment, Forest and Climate Change (MoEFCC), it has notified the Hazardous and Other Waste (Management and Transboundary Movement) Rules, 2016. The import or export of hazardous and other waste is regulated by the said rules. The import of 'Used Electrical and electronic assemblies' falls under Schedule III Part B (Basel No. B1110), and the same can be imported by the actual user only after obtaining necessary permission from MoEFCC. Further, used critical care medical equipment is covered under Basel No. B1110 of Schedule VI of the said rules and is prohibited for import for re-use.

MoEFCC amended the said rules on 23.12.2022 to allow the 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 (OEMs) or Indian Subsidiary of OEM or Trader on behalf of actual user for re-use. These items fall under Schedule III Part B of the said rules and, therefore, import of such equipment is restricted and cannot be done without permission from MoEFCC and is subject to such conditions as may be imposed in the permission letter and the license issued by the Directorate General of Foreign Trade.

(d) and (e): The Department of Health and Family Welfare has informed that all medical devices are regulated by the Medical Devices Rules, 2017. As per Chapter V of the said rules, medical devices are imported in the country against a valid import licence issued by the Central Drugs Standard Control Organisation. Under the said rules, there is no specific provision for regulation of refurbished medical devices. Any importer possessing a valid licence is permitted to import a medical device under the Drugs and Cosmetics Act, 1940.
