

GOVERNMENT OF INDIA  
MINISTRY OF COMMERCE & INDUSTRY  
(DEPARTMENT OF COMMERCE)

**LOK SABHA**  
**UNSTARRED QUESTION NO. 260**  
**TO BE ANSWERED ON 03<sup>rd</sup> FEBRUARY, 2021**

**EXPORT BY PHARMACEUTICAL MANUFACTURE RS**

260. DR. AMOL RAMSING KOLHE:  
DR. SUBHASH RAMRAO BHAMRE:  
SHRI SUNIL DATTATRAY TATKARE:  
DR. DNV SENTHILKUMAR S.:  
SHRI KULDEEP RAI SHARMA:

Will the Minister of **COMMERCE & INDUSTRY** (वाणिज्य एवं उद्योग मंत्री ) be pleased to state:

- (a) whether majority of small and medium pharmaceutical manufacturers in the country are working for bigger pharmaceutical units which export pharmaceutical products under their brand names;
- (b) if so, whether there is any proposal to boost the exports of pharmaceutical products by small and medium Pharmaceutical manufacturers under their own brands under Atmanirbhar Bharat initiative;
- (c) whether the export of pharmaceutical items from India have declined drastically and if so, the details thereof and the reasons therefor and the steps taken to overcome it;
- (d) the present policy of the Government on Foreign Direct Investment(FDI) in the Pharmaceutical sector; and
- (e) whether the Government has any regulations for the export of pharmaceutical products and if so, the details thereof and the extent to which these regulations have impacted the volume of exports from the country?

**ANSWER**

वाणिज्य एवं उद्योग मंत्रालय में राज्य मंत्री (श्री हरदीप सिंह पुरी)

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY  
(SHRI HARDEEP SINGH PURI)

**(a) & (b):** Manufacturers are required to obtain a license for manufacturing drugs for export from the concerned State Licensing Authority (SLA) under the provision of Drugs and Cosmetic Act,

1940 and Rules made thereunder. Further, the manufacturer is required to meet the requirements of the importing country.

In the global pharma supply chain, there are small, medium and large manufacturers from India, who are engaged at different levels of the value chain. The measures taken by Government of India to promote exports, including those of small and medium pharmaceutical manufacturers, include various schemes under the Foreign Trade Policy (FTP), assistance under the Market Access Initiative (MAI) scheme, setting up district export hubs, Transport and Market Assistance Scheme etc. Trade delegations/buyer-seller meets with various countries are regularly organized for the benefit of exporters. Airfare support is also provided to the exporters with a turnover of Rs.30 crore and below to encourage participation in business delegations/trade fairs.

(c) India's exports of Pharmaceutical products have not declined and they are growing consistently. During the year 2019-20, India's exports of Pharmaceuticals were USD 20.58 billion with a growth rate of 7.57% over the previous year. Total pharma exports during Apr -Dec 2020-21 were USD 17.57 billion, registering a growth rate of 12.43% over the same period of the previous year.

(d) As per the extant FDI Policy, 100% foreign investment is allowed under the automatic route in Medical Devices. Foreign investments in pharmaceuticals in greenfield projects are allowed upto 100% under the automatic route and for brownfield pharmaceutical projects, foreign investment beyond 74% to up to 100% Government approval is required.

(e) The manufacturers are required to obtain license for manufacturing of drugs for export under the provision of Drugs and Cosmetic Act, 1940 and Rules made thereunder. The current policy pertaining to the pharmaceuticals products is outlined in chapter 30 of the ITC(HS) Export Policy 2018. Currently, restrictions are placed on export of RT-PCR Kits, VTM Kits, RNA Extraction kits and 12 other laboratory reagents in the context of COVID-19 in accordance with Notification no. 09/2015-2020 dated 10<sup>th</sup> June 2020.

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