

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

LOK SABHA
UNSTARRED QUESTION No. 1586
TO BE ANSWERED ON 28th July, 2023

Revenue Earned from Export of Drugs

1586. SHRIMATI APARAJITA SARANGI:

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

- (a) the details of revenue earned by the Government exporting drugs from India in last three years, year-wise;
- (b) whether the Government has taken any measures for promoting export of generic drugs from India and reducing the time cost involved in obtaining necessary approvals;
- (c) if so, the details thereof; and
- (d) the step taken/proposed to be taken by the Government to address the issue of counterfeit drugs in international markets and ensure authenticity of Indian pharmaceutical products throughout the export process?

ANSWER

**MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)**

- (a): The data of India's Pharmaceutical Export for the last three years is as under: -

India's Pharmaceutical Exports (Rs. in crore)				
S. No	DESCRIPTION	2020-21	2021-22	2022-23
1	Bulk Drugs and Drug Intermediates	32,856.71	33,320.93	37,852.77
2	Drug Formulations and Biologicals	1,41,207.04	1,41,634.12	1,56,401.43
	Total	1,81,260.76	1,83,339.97	1,94,254.20
	Year on Year Growth		1.1%	6.0%

[Source: DGCIS, Ministry of Commerce and Industry]

(b) to (c): Under the MAI (Market Access Initiative) Scheme of Department of Commerce, financial assistance is provided to develop new markets, to promote new products and new exporters as well as to consolidate the existing Indian exports markets. The activities supported under the MAI scheme include organising/participating in Fairs, Exhibitions and Buyer Seller Meets abroad. Pharmaceuticals Export Promotion Council of India (Pharmexcil) under Department of Commerce organizes export promotion activities including business delegations to different foreign regions such as ASEAN, Africa, CIS, LAC and Oceania countries and also participates in the prominent pharma events worldwide. The participation in the prominent events enables exporters to showcase their products and services to the potential buyers and

helps in promotion of export of generic drugs. The business delegations to foreign regions provide an opportunity to interact with the Food and Drug authorities in these countries thus enabling networking and facilitating discussion on fast tracking of registration of Indian products. There is already existing arrangement with some of the countries for fast tracking of approvals for Indian pharma products under FTAs such as with Singapore, UAE and Australia. Indian is also negotiating fast track approval for Indian pharma products with EU, UK and Canada under FTA discussions.

(d): As per Department of Commerce, the Government has introduced a policy of track and trace system to ensure the authenticity of the exported finished pharmaceutical products. Under the present system, the barcoding is mandatory on secondary and tertiary packages of export consignments.

As per Ministry of Health and Family Welfare, they have taken various regulatory measures to ensure the quality of medicines in the country: -

(i) The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

(ii) The Drugs and Cosmetics Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

(iii) The Drugs and Cosmetics Rules, 1945 have been amended, making it mandatory that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of manufacturing license by the Authority.

(iv) CDSCO coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

XXXXX