GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 154
TO BE ANSWERED ON THE 2nd FEBRUARY, 2024

Reduction in Import of Raw Materials

154. ADV. DEAN KURIAKOSE:

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

(a) whether the Government has made any progress towards the formulation of new export policy for domestically manufactured drugs in the country;
(b) if so, the details thereof;
(c) the steps taken/proposed to be taken by the Government to reduce dependence on raw material imports for the manufacture of drugs in the country;
(d) the measures taken/proposed to be taken by the Government to ensure the quality, safety and efficacy of drugs being exported to other countries;
(e) whether any incidents of adulteration for profit have been reported in the last few years; and
(f) if so, the details thereof and the action taken/ proposed to be taken by the Government in this regard?

ANSWER

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

(a) & (b): No new export policy for domestically manufactured drugs in the country has been contemplated. However, as per information provided by the Department of Commerce, the new Foreign Trade Policy (FTP) 2023 was announced on 31.03.2023 to facilitate greater trade, boost manufacturing, promote exports, further enable ease of doing business & supporting the government initiative towards internationalization of Indian Rupee, adding further impetus to India's emergence as the global trading hub. The policy would boost local manufacturing and make exports competitive. The new foreign trade policy is a boost to export promotion through collaboration between exporters, states, districts, and Indian Missions to improve the ease of doing business.

(c): The Government strives to minimize country's dependence on imports and to give fillip to indigenous manufacturing. In order to make the country self-reliant in APIs and drug intermediates, the Department of Pharmaceuticals is implementing the following three schemes:

(i) **Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India** - The tenure of the scheme is from FY 2020-2021 to 2029-30 with total financial outlay of ₹6,940 crores. The scheme provides for financial incentive on sales of 41 identified products for six (06) years. 48 projects have been approved under the scheme with a total committed investment of Rs. 3938.57 Crore, against which investment worth Rs 3062.69 cr has

already been realized. 27 Projects have been commissioned so far. The envisioned production capacity under the scheme was 82,270 MT, out of which production capacity for 41881 MT has already been installed.

(ii) **Production Linked Incentive scheme for pharmaceuticals** - The total financial outlay of the scheme is Rs. 15,000 crore and the tenure of the scheme is from FY 2020-2021 to 2028-29. The scheme also provides for incentives on eligible sales of APIs/KSMs/DIs under category 2 of the scheme to the approved participants for a period of 6 years. 1962 APIs/KSMs/DIs are approved for manufacturing under the scheme.

(iii) The **scheme for Promotion of Bulk Drug Parks** has been started with the objective of providing easy access to Common Infrastructure Facilities (CIF) to bulk drug units located in the park, in order to significantly bring down the manufacturing cost of bulk drugs. The scheme has a financial outlay of Rs. 3,000 crores and the tenure is from FY 2020-2021 to FY 2024-25. The scheme provides for financial assistance to three States for establishing bulk drug parks. The Department had received proposals from 13 States. After evaluation of the proposals as per prescribed criteria, the approval was accorded to the proposal of setting up bulk drug parks in the states of Andhra Pradesh, Gujarat and Himachal Pradesh.

(d): So far as regulatory measures are concerned, as informed by the Ministry of Health and Family Welfare and Central Drugs Standard Control Organisation (CDSCO), the following steps have been taken to encourage indigenous manufacturing of drugs: The Drugs Rules,1945 was amended vide G.S.R. 1337 (E), Dated 27 October, 2017 providing that drugs manufacturing license, sale license and approval of drug testing laboratory shall remain valid, if licensee deposits a license retention fee as prescribed, before the expiry of a period of every succeeding five years from the date of its issue, unless it is suspended or cancelled by the licensing authority. The Drugs Rules, 1945 were amended vide Notification No. G.S.R. 1193 (E) dated 12.12.2018 wherein application fees were increased for grant of import Registration Certificate as well as fees for Overseas inspection. Further, Ministry of Health and Family Welfare has informed that for export purposes, the manufacturers are required to obtain license for such manufacturing of drugs from the concerned State Licensing Authority (SLA) under the provisions of Drugs and Cosmetics Act. 1940 and Rules made there under. Further, the manufacturer is required to meet the requirements of importing country.

(e) & (f): As per the Ministry of Health and Family Welfare, details of the actions taken by the Government against the manufacturers and the distributors of sub-standard medicines from 2021 to 2023 are as under: -

Year (1st April of preceding year to 31st March of following year)	**No. of drugs samples tested**	**No. of drugs samples declared not of standard quality**	**No. of drugs samples declared spurious/adulterated**	**No. of prosecution launched for manufacturing, sale and distribution of spurious/adulterated drugs**	**No. of persons arrested**
2020-21	84,874	2652	263	236	164
2021-22	88,844	2545	379	592	450
2022-23	*89,729	2921	422	642	262

*Except from State of Rajasthan

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