GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 2132
TO BE ANSWERED ON THE 15TH DECEMBER 2023

New Export Policy for Domestically Manufactured Drugs

2132. SHRI SAPTAGIRI SANKAR ULAKA:
ADV. ADOOR PRAKASH:

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 of 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 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) & (d): 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) Under the 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, with a financial outlay of Rs. 6,940

crores and the tenure from FY 2020-2021 to FY 2029-30, under which financial incentive is given for manufacturing of 41 identified products. A total of 48 applications have been selected under the scheme. Out of these, 27 projects have already been commissioned with the installed capacity of 41,881 MT.

(ii) Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. The eligible products under the scheme cover APIs/KSMs/DIs, except for the 41 eligible products already covered under the "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India".

(iii) The Scheme for Promotion of Bulk Drug Parks, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, 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.

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 purpose of drugs, 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 thereunder. Further, the manufacturer is required to meet the requirements of importing country.

(e) & (f): As per Ministry of Health and Family Welfare, in Financial Year 2022-23, total 89729 number of drugs samples were tested. Out of 89729, 422 number of drugs samples were declared spurious/adulterated.

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