GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No.2309
TO BE ANSWERED ON THE 3rd December, 2019

Active Pharmaceutical Ingredients

2309. SHRI DEVUSINH JESINGHBHAI CHAUHAN:

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

(a) whether it is a fact that India is very much dependent on China and European Union for Active Pharmaceutical Ingredients (APIs) and if so, the details thereof;
(b) whether any meeting has been held recently with the officers of Ministry of Health, Commerce and Industry, Chemicals and Fertilizers to draw a comprehensive plan to produce APIs in the country;
(c) if so, the details thereof;
(d) whether it is true that India does not have the latest sophisticated infrastructure and funds to ensure adequate quality control;
(e) whether it is true that pricing is a big issue for manufacturing APIs in India, as Chinese APIs are low-priced;
(f) if so, the details thereof; and
(g) the steps being taken by the Government to manufacture APIs in the country and maintain the pricing at Chinese API level?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a): Many bulk drugs are imported from China and European Union, for manufacturing of medicine. As per available data from the various Port Offices of CDSCO, the details of the percentage of bulk drugs imported from China and European Union are as under:

	Percentage (in terms of value)	
Year	**API Import from China**	**API Import from European Union**
2016	56.62%	16.78%
2017	68.62%	15.91%
2018	66.53%	11.76%

(b)&(c): An Inter-Ministerial Task Force has been constituted under the Chairmanship of the Hon'ble Minister of State (Chemicals & Fertilizers) on 18.04.2018 to formulate a roadmap for the enhanced production of Active Pharmaceutical Ingredients (APIs) in the country. The Task Force also includes the members from Ministry of Health & Family Welfare, Ministry of Commerce and Industry and members from Ministry of Chemicals and Fertilizers. Last meeting of the Task Force was held on 19.06.2019

(d): No, Sir. The fact is India pharma industry has been granted the highest accreditations from United States Food and Drug Administration (USFDA), United Kingdom's Medicines and Healthcare products Regulatory Agency (UKMHRA), Therapeutic Goods Administration (TGA), Pharmaceuticals and Medical Devices Agency (PMDA), European Medicines Agency (EMEA) which are considered as the stringent regulatory authorities globally. As regard to adequate quality control of imported drugs, it may be mentioned that for import of any drug the foreign manufacturing site and the drug are required to be registered as well as import license is required to be obtained from Central Drugs Standard Control Organization (CDSCO) under the provisions of the Drugs and Cosmetics Act, 1940 and rules made there under. As per the requirements no drug shall be imported unless it complies with the standard of strength, quality and purity and the test prescribed under the provision of the Drugs and Cosmetics Act, 1940 and rules made there under. The port offices of CDSCO verify the consignments at the port and draw samples for testing of drugs from imported consignments as per the defined criteria.

(e) & (f): The feedback from the Industry is that the cost involved in manufacturing the APIs in China and India are more or less the same these days and China could do it low-priced mainly due to its large volumes of production.

(g): With the objective to ensure drug security in the country by increasing availability and affordability of the bulk drugs in the domestic market, the Department of Pharmaceuticals has prepared a scheme namely 'Assistance to Bulk Drug Industry for Common Facility Centre'. Under this scheme, financial assistance would be provided for creation of common facilities in any upcoming Bulk Drug Park promoted by State Governments/State Corporations. Further, Department of Commerce has convened series of meetings with stakeholders, Pharma Associations and Research Institutions for evolving strategy for indigenous development of manufacturing of APIs, KSM and Drug Intermediates. Department of Commerce has commissioned a study in this regard on "Strategies to reduce import dependence of APIs, KSMs and Intermediates aimed at developing the Detailed Project Report (DPR)". Also, the Ministry of Health and Family Welfare has taken various measures to streamline indigenous manufacture of drugs. Details are as under:-

- G.S.R. 1337 (E), Dated 27 October, 2017: Drug 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. Also, it is 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. The licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach.
- The Ministry of Health and Family Welfare, Government of India has amended the Drugs and Cosmetics Rules, 1945 vide Notification No. G.S.R. 1193 (E) dated 12/12/2018 wherein application fees have been increased for grant of various Import Registration certificate as well as Overseas Inspection.