

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 4215
TO BE ANSWERED ON 13TH DECEMBER, 2019**

MEDICINES UNDER MAKE IN INDIA

4215. SHRI KUNWAR PUSHPENDRA SINGH CHANDEL:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) the details of the medical services and medicines imported during the last three years;
- (b) whether the Government proposes any specific policy measures to reduce the dependency on import for medicines;
- (c) whether the Government proposes special provision for formulation/ manufacturing of medicines under “Make in India” program; and
- (d) if so, the details thereof?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)**

(a): The data regarding category wise imports of medicines during the last three financial years is **annexed**.

(b) to (d): The Government formulates the policies from time to time to promote ‘Make in India’ and reduce country’s dependence on imports.

The Department of Pharmaceuticals has prepared an umbrella Scheme for Development of Pharmaceutical Industry with the objective to ensure drug security in the country by increasing the efficiency and competitiveness of domestic pharmaceutical industry. Under this umbrella scheme, the Department is implementing schemes viz. ‘Assistance to Pharmaceutical Industry for Common Facilities’, ‘Assistance to Bulk Drug Industry for Common Facility Centre’ and ‘Assistance to Medical Device Industry for Common Facility Centre’ for financing common facilities in Pharma Clusters, Bulk Drug Parks and Medical Device Parks respectively in the country.

In addition to these three schemes, umbrella scheme also consists of two other schemes, Pharmaceutical Promotion Development Scheme (PPDS) and Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS). Under Pharmaceutical Promotion Development Scheme (PPDS), financial support is provided for conducting seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments,

conducting studies/ consultancies for facilitating growth and exports. Under 'Pharmaceuticals Technology Upgradation Assistance Scheme' (PTUAS), assistance in the form of interest subvention against sanctioned loan by any scheduled commercial bank/financial institution, both in Public and Private sector, is provided to facilitate Small and Medium Pharma Enterprises (SMEs) to upgrade their plant and machinery to World Health Organization (WHO) Good Manufacturing Practices (GMP) standards so as to enable them to participate and compete in global markets.

Further, the Ministry of Health and Family Welfare has taken various measures to streamline the regulatory process to achieve the mission of “Make in India” with assurance of safety, efficacy and quality of drugs manufactured/marketed in the country. These include perpetual validity of manufacturing and sale licenses subject to certain conditions, implementation of e-governance in Central Drugs Standard Control Organisation (CDSCO) through SUGAM portal, measures to promote scientific and ethical clinical trials in the country, guidelines for similar biologics, framing and implementation of Medical Device Rules 2017, increase in the validity period of Certificate of Pharmaceutical Product (CoPP) under WHO GMP (Good Manufacturing Practices) certification scheme, waiver of the requirement of NOC from CDSCO port offices for export purposes, and delegation of powers to State/UT Drug Controllers for issuance of NOC with respect to unapproved drugs for export purposes only.

The Ministry of Health & Family Welfare has amended the Drugs & Cosmetics Rules, 1945 vide notification No.GSR 1193 (E) dated 12.12.2018 wherein application fees have been increased for grant of various import Registration Certificate as well as overseas inspection.

Annexure

	USD Million		
Category	2016-17	2017-18	2018-19
Bulk Drugs & Drug Intermediates	2725.52	2992.21	3558.07
Drug formulations & Biologicals	1080.38	1489.43	1595.58
Vaccines	294.35	274.22	332.10
Surgicals	70.14	78.18	93.18
Herbal Products	28.08	31.05	42.93
Ayush	25.42	29.88	29.96
Total	4223.89	4894.96	5651.81