GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA UNSTARRED QUESTION No. 181 TO BE ANSWERED ON THE 05TH DECEMBER, 2023

Import of APIs from China

181 Dr. Amee Yajnik:
Shri Digvijaya Singh:
Shri Dhiraj Prasad Sahu:
Shri Syed Nasir Hussain:
Smt. Phulo Devi Netam:

Will the Minister of Chemicals and Fertilizers be pleased to state:

(a) the details of Active Pharmaceutical Ingredients (API) imported by India, country-wise, especially the quantum of API for drug manufacturing imported from China, since 2018;(b) the amount of APIs domestically produced, since 2018;

(c) the ratio of API import from China and domestic production, in terms of value & quantity; and

(d) the steps taken by Government to avoid such dependency on China for supply of APIs?

ANSWER

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

(a): India's Total Import of Active Pharmaceuticals Ingredients (APIs) [Bulk Drugs, Drug Intermediates] for FY 2022-23 is worth Rs. 36229.15 Cr and the quantity is 402111.18 MT. The details of APIs imported from top 25 countries since 2018 is attached at **Annexure**.

(b) & (c): Domestic production of APIs is not maintained by the Department of Pharmaceuticals.

(d): (I) In order to make the country Atmanirbhar in APIs and drug intermediates, the Department of Pharmaceuticals is implementing the following three schemes to attract investments in the sector to ensure sustainable domestic supply and thereby reduce India's import dependence on other countries: -

(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, 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 product category two covers the 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 to the proposal of setting up Bulk Drug Parks in the states of Andhra Pradesh, Gujarat and Himachal Pradesh were conveyed.

(II) So far as regulatory measures are concerned, the Ministry of Health and Family Welfare and CDSCO have taken following steps 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 1211212018 wherein application fees were increased for grant of import Registration Certificate as well as fees for Overseas inspection.

Import of APIs from top 25 countries for the last five years

			2018-19		2019-20		2020-21		2021-22		2022-23
S.	COUNTRY OF	2018-19 Qty	Value	2019-20	Value	2020-21	Value	2021-22	Value	2022-23	Value
	CONSIGNMENT	(MT)	(INR Cr)	Qty (MT)	(INR Cr)	Qty (MT)	· · · · · · · · · · · · · · · · · · ·	Qty (MT)	(INR Cr)	Qty (MT)	(INR Cr)
	CHINA P RP	202316.645	16777.44	220875.185	16443.1	256608.708	19402.61	264582.478	23273.02	300120.2	25550.91
	U S A	10551.727	1025.54	8432.828	850.83	9831.057	1140.87	7637.176	3096.81	5884.059	1698.69
	SINGAPORE	28781.901	762.8	28310.604	697.11	29538.23	813.97	30621.677	964.28	32482.38	911.74
	ITALY	5298.475	812.35	3868.835	727.21	3637.694	878.65	2834.356	830.04	1932.237	862.65
	SPAIN	2390.95	468.36	2714.854	524.68	3653.445	645.14	3132.973	618.46	2968.207	717.86
6	JAPAN	9488.067	336.44	14169.612	370.16	13819.617	356.27	14474.754	555.42	14596.69	603.32
7	GERMANY	5096.171	417.44	3874.831	445.79	6874.323	489.71	5667.991	549.71	3008.186	497.32
8	AUSTRIA	345.244	117.92	292.922	113.83	1292.503	244.23	1528.902	374.64	1387.928	473.37
	FRANCE	4112.373	352.14	5492.131	376.14	3199.891	366.66	3215.398	351.15	2494.532	443.6
10	HONG KONG	2127.501	514.3	2179.961	303.55	2187.141	399.6	1875.117	492.87	2028.9	397.94
11	TAIWAN	716.713	175.97	172.13	189.93	161.283	241.87	41.168	227.77	143.089	364.14
12	NETHERLAND	16065.48	297.27	16212.241	252.14	6640.08	253.71	3059.477	268.91	1370.061	359.46
13	SLOVENIA	200.38	178.26	37.681	251.51	422.997	442.56	371.455	388.99	528.401	354.16
14	BELGIUM	716.616	235.59	1412.826	301.25	4078.547	344.64	4840.439	266.23	3075.501	313.83
15	SWITZERLAND	364.405	201.29	178.407	179.8	143.775	262.22	200.355	272.85	1079.665	311.42
16	KOREA RP	12084.062	253.89	17515.68	302.2	23123.688	378.51	23797.911	560.33	8184.774	298.72
17	MEXICO	180.936	151.77	204.807	233.16	169.092	197.19	163.737	177.59	163.012	266.07
18	MALAYSIA	5466.814	127.1	5796.711	121.92	5315.539	149.26	6430.327	200.84	5855.919	259.45
19	DENMARK	14.22	293.33	17.174	305.61	17.689	311.46	7.382	345.11	4.928	237.89
20	INDONESIA	24863.55	215.1	22402.809	194.57	15665.914	149.54	19084.812	235.29	11457.97	227.37
21	HUNGARY	23.796	197.8	21.013	159.92	12.665	162.71	19.284	212.22	14.829	211.47
22	U K	183.045	200.73	158.795	154.25	278.3	197.04	287.315	212.91	157.718	193.53
23	PORTUGAL	32.811	116.22	5.876	51.16	8.83	56.27	6.223	33.49	14.699	112.37
24	CZECH										
24	REPUBLIC	2.99	53.95	6.343	81.52	6.885	98.55	9.538	120.09	8.134	87.58
25	MACAO	4.757	13.73	1.674	6.25	15.522	44.87	15.767	45.4	21.304	60.81
	Total imports										
	from top 25	331429.63	24296.73	354355.93	23637.59	386703.42	28028.11	393906.01	34674.42	398983.31	35815.67
	countries										
	Overall total	345944.39	24850.07	364432.49	24171.78	390475.70	28528.97	400642.47	35248.63	402111.18	36229.15
	imports	343744.39	24030.07	304432.49	241/1./0	3904/5./0	20320.91	400042.47	33240.03	402111.10	30449.13

Source: DGCIS, Ministry of Commerce and Industry.