# GOVERNMENT OF INDIA <br> MINISTRY OF CHEMICALS AND FERTILIZERS <br> DEPARTMENT OF PHARMACEUTICALS 

RAJYA SABHA<br>UNSTARRED QUESTION No. 181<br>TO BE ANSWERED ON THE $05^{\text {TH }}$ DECEMBER, 2023<br>Import of APIs from China

## 181 Dr. Amee Yajnik: <br> Shri Digvijaya Singh: <br> Shri Dhiraj Prasad Sahu: <br> Shri Syed Nasir Hussain: <br> 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 <br> 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

| $\begin{gathered} \text { S. } \\ \text { No. } \\ \hline \end{gathered}$ | $\begin{array}{\|l\|} \text { COUNTRY OF } \\ \text { CONSIGNMENT } \\ \hline \end{array}$ | $\begin{gathered} \text { 2018-19 Qty } \\ (\mathrm{MT}) \end{gathered}$ | $\begin{gathered} \hline 2018-19 \\ \text { Value } \\ \text { (INR Cr) } \\ \hline \end{gathered}$ | $\begin{gathered} 2019-20 \\ \text { Qty (MT) } \end{gathered}$ | $\begin{gathered} \hline 2019-20 \\ \text { Value } \\ \text { (INR Cr) } \\ \hline \end{gathered}$ | $\begin{gathered} 2020-21 \\ \text { Qty (MT) } \end{gathered}$ | $\begin{gathered} \hline 2020-21 \\ \text { Value } \\ \text { (INR Cr) } \\ \hline \end{gathered}$ | $\begin{gathered} 2021-22 \\ \text { Qty (MT) } \\ \hline \end{gathered}$ | $\begin{gathered} \hline 2021-22 \\ \text { Value } \\ \text { (INR Cr) } \\ \hline \end{gathered}$ | $\begin{gathered} \text { 2022-23 } \\ \text { Qty (MT) } \\ \hline \end{gathered}$ | $\begin{gathered} \hline 2022-23 \\ \text { Value } \\ \text { (INR Cr) } \\ \hline \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1 | CHINA P RP | 202316.645 | 16777.44 | 220875.185 | 16443.1 | 256608.708 | 19402.61 | 264582.478 | 23273.02 | 300120.2 | 25550.91 |
| 2 | U S A | 10551.727 | 1025.54 | 8432.828 | 850.83 | 9831.057 | 1140.87 | 7637.176 | 3096.81 | 5884.059 | 1698.69 |
| 3 | SINGAPORE | 28781.901 | 762.8 | 28310.604 | 697.11 | 29538.23 | 813.97 | 30621.677 | 964.28 | 32482.38 | 911.74 |
| 4 | ITALY | 5298.475 | 812.35 | 3868.835 | 727.21 | 3637.694 | 878.65 | 2834.356 | 830.04 | 1932.237 | 862.65 |
| 5 | 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 |
| 9 | FRANCE | 4112.373 | 352.14 | 5492.131 | 376.14 | 3199.891 | 366.66 | 3215.398 | 351.15 | 2494.532 | 443.6 |
| 10 | HONG KON | 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 | $\begin{aligned} & \text { CZECH } \\ & \text { REPUBLIC } \end{aligned}$ | 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 countries | 331429.63 | 24296.73 | 354355.93 | 23637.59 | 386703.42 | 28028.11 | 393906.01 | 34674.42 | 398983.31 | 35815.67 |
|  | Overall total imports | 345944.39 | 24850.07 | 364432.49 | 24171.78 | 390475.70 | 28528.97 | 400642.47 | 35248.63 | 402111.18 | 36229.15 |

Source: DGCIS, Ministry of Commerce and Industry.

