Import of Bulk Drugs/APIs

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

(a) whether India imports around 70 per cent of its total bulk drugs or Active Pharmaceutical Ingredients (APIs) from China;
(b) if so, the details thereof along with the percentage of raw material imported for the manufacture of antibiotics;
(c) whether the current coronavirus outbreak has limited such import, if so, the steps being taken by the Government to ensure that stocks last for the foreseeable future;
(d) whether the Government is considering restrictions on export of paracetamols, other key drug ingredients and their formulations and if so, the details thereof; and
(e) whether the Government has any proposal to develop bulk drug parks in the country to reduce dependence on imports, if so, the details thereof and the progress and timeframe for completion of the bulk drug parks?

ANSWER

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

(a) & (b): The Indian Pharmaceutical industry is 3rd largest in the world in terms of volume and 14th largest in terms of value. India exported medicines worth US $14389 mn in Financial Year 2018-19. India also exported Bulk Drug/Drug Intermediates worth US $ 3911mn in Financial Year 2018-19. However, the country also imports various Bulk Drugs/Active Pharmaceutical Ingredients (APIs) for producing medicines. Two-thirds of the total imports of Bulk Drugs/Drug Intermediates is from China. The imports from China are mainly due to economic considerations. The details of India’s imports of Bulk Drugs/Drug Intermediates (including from China) are as under:

<table>
<thead>
<tr>
<th>Year</th>
<th>Total imports (US $ mn)</th>
<th>Imports from China (US$ mn)</th>
<th>Percent of Imports from China</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018-19</td>
<td>3560.35</td>
<td>2405.42</td>
<td>67.56%</td>
</tr>
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</table>

As per the information received from the port offices of CDSCO, the quantity of raw materials imported for the formulation of antibiotic medicines in the country during each of the last three years is as follows:
<table>
<thead>
<tr>
<th>Year</th>
<th>Quantity of raw materials imported for the formulation of antibiotic medicines in the country (in MTs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>11230.50</td>
</tr>
<tr>
<td>2018</td>
<td>12006.11</td>
</tr>
<tr>
<td>2017</td>
<td>5591.44</td>
</tr>
</tbody>
</table>

(c) & (d): Department of Pharmaceuticals has constituted a Committee under the chairmanship of Dr. Eshwara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO) to address the issue of drug security in the country in the context of novel coronavirus outbreak in China. Based on the recommendations of the Committee, the department has issued necessary instructions to National Pharmaceutical Pricing Authority (NPPA), Drugs Controller General of India (DCGI) and State Governments to ensure adequate supply of APIs and formulations at affordable prices in the market and to prevent black-marketing, illegal hoarding, creating artificial shortages in the country. In this regard, Department of Pharmaceuticals has written to DGFT to restrict exports of 13 API and formulations made out of these APIs which includes paracetamol. NPPA has also written to Chief Secretaries of States with copies to Principal Secretaries Health and State Drug Controllers requesting them to closely monitor the production and availability of APIs and formulations to prevent the black marketing and hoarding in their States and UTs as well as to ensure that there is no violation of provisions of Drugs (Prices Control) Order, 2013 with regard to compliance of ceiling prices/ permissible increase in prices of scheduled/ non-scheduled formulations respectively.

(e): The Department of Pharmaceuticals has formulated a Scheme namely ‘Assitance to Bulk Drug Industry for Common Facility Centre’ for providing assistance of upto Rs. 100 crore for creation of Common Facility Centre (CFC) in any upcoming bulk drug park promoted by State Governments/State Corporations. The department has given ‘In-principle’ approval to the following proposals under this scheme:

1. Govt. of Andhra Pradesh (AP Economic Cities Promotional Corporation Ltd.)
2. Govt. of Telangana (Telangana State Industrial Infrastructure Corporation Ltd.)
3. Govt. of Himachal Pradesh (HP State Industrial Development Corporation Ltd.)

As per the said scheme the time frame for development of a CFC is 2 years from the date of final approval.