

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION NO. 4551
TO BE ANSWERED ON 23rd March, 2021

Monitoring Mechanism for Drug Supply

4551. SHRIMATI SAJDA AHMED:

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

- (a) whether the Government has adopted any monitoring mechanism with real-time drug production and supply in domestic market and if so, the details thereof;
- (b) whether the Government has taken note that during the pandemic, supply chain of essential drug was broken in rural areas and if so, the details thereof;
- (c) whether the Government proposes any policy to ensure nationwide sufficient access of drugs including rural areas in view of future pandemic situation and if so, the details thereof; and
- (d) whether there is any existing mechanism to monitor medicine outlets to confirm the availability of drugs and if so, the details thereof?

ANSWER

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

(a): National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP) implements and enforce the provisions of the Drugs (Prices Control) Orders in accordance with the powers delegated to it. There is a mechanism of monitoring the production and availability of the essential drugs/ scheduled drugs under para 21 (1) the Drugs (Prices Control) Order, 2013 (DPCO, 2013) that provides for submission of quarterly return in respect of production/ import and sales of scheduled medicines and Active Pharmaceutical Ingredients (APIs) contained in scheduled formulations as stated in Form-III of Schedule-II of the DPCO, 2013 by a manufacturer/ importer/ marketer. Further, any manufacturer/importer wanting to discontinue manufacture / import of a scheduled formulation has to apply to NPPA in Form-IV of Schedule-II of the DPCO, 2013 at least 6 months in advance, and NPPA can direct the applicant to continue production / import up to one year.

NPPA monitors shortage & non-availability of drugs on the basis of reports received from the State Drugs Controllers and complaints, if any, received from individuals. On receipt of such reports, NPPA immediately takes up the matter with the concerned manufacturer and advise them to rush the stock in the affected area. NPPA under the Consumer Awareness, Publicity and Price Monitoring (CAPP) Scheme has set up Price Monitoring and Resource Units (PMRUs) in the State/ Union Territories. Till now, PMRUs have been set up in seventeen (17) States. Under the CAPP Scheme advertising & publicity campaign/ seminars/ workshops/ webinars etc. are organised from time to time. Apart from this, consumers are made aware about the price fixation and availability of medicines.

(b): As per information provided by the *Central Drugs Standard Control Organisation (CDSCO)* under the Ministry of Health & Family Welfare, the CDSCO has not received any report that supply chain of essential drugs was broken in rural areas during the pandemic. Through greater interaction with the industry associations, manufacturers as well as state authorities, the Department of Pharmaceuticals took steps to ensure that supply chains were not compromised during lockdown and unlock phases.

Further, NPPA constituted an inter-ministerial Committee to monitor trends of export and import of APIs/Formulations and Medical Devices to ensure timely availability of key drugs, assess bottlenecks and impediments in imports of APIs and suggest possible alternative sources & export trend analysis to ensure domestic availability of key drugs and Medical Devices during the pandemic. Control Rooms were also set up by the Department of Pharmaceuticals and NPPA to ensure seamless availability of drugs.

(c) & (d): National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals, as an ongoing process, regularly monitors the production and availability of drugs under para 21 of the DPCO, 2013.
