

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

LOK SABHA
UNSTARRED QUESTION NO. 3362
TO BE ANSWERED ON 16th March, 2021

Guidelines by NPPA

3362. SHRI SHANMUGA SUNDARAM K.:

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

- (a) whether the Government has given any guidelines for discontinuing the medicines manufactured by the Pharma companies by the National Pharmaceuticals Pricing Authority (NPPA) especially the essential drugs;
- (b) if so, the details thereof;
- (c) whether the Government has any specific proposal to bring guidelines for the uninterrupted supply of essential drugs in the interest of the general public and if so, the details thereof; and
- (d) the number of pharma companies producing essential drugs in Karnataka State along with the details of their discontinuance of production, if any?

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D.V. SADANANADA GOWDA)**

(a) & (b): The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals monitors the production and availability of scheduled formulations, including requests received from manufacturers of Scheduled formulations for discontinuation, as per Para 21 of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). NPPA has issued detailed guidelines on 14.08.2020 for dealing with cases of discontinuation of scheduled formulations. These stipulate a minimum notice of six months to NPPA prior to discontinuation, information through newspaper advertisement to enable other manufacturers to step into production. The period of notice may vary from six to twelve months based on market share of the manufacturer.

(c): Complaints regarding shortage of essential drugs and other drugs received from various sources like individual complaints, State Drugs Controllers, Pharma Jan Samadhan Portal, NPPA Helpline and PMOPG/CPGRAMS are addressed promptly. NPPA has been delegated powers to issue directions under Para 3 of the DPCO, 2013 to achieve adequate availability and to regulate distribution of drugs in case of emergency in public interest. Through rigorous monitoring and liaisoning with all stakeholders, the Government ensured no shortage of Drugs even during the challenging periods of Lockdown and Unlock Phases of COVID pandemic.

(d): License for manufacture, sale and distribution of drugs is granted by the State Licensing Authorities appointed by the respective State Governments. However, as per available information provided by the *Central Drugs Standards Control Organisation (CDSCO)*, as on May, 2020, there are 376 Pharma manufacturing units located in the State of Karnataka. So far, no discontinuation request has been received from these companies by NPPA.
