GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 3226
TO BE ANSWERED ON 17th DECEMBER, 2021

National Digital Drugs Databank

3226. SHRI D.K. SURESH:
SHRIMATI SUMALATHA AMBAREESH:

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

(a) whether the Competition Commission of India in a recent report has recommended for the creation of a National Digital Drugs Databank to ensure strict enforcement of drug quality standards and boost price competition among generic drugs in India;
(b) if so, the details thereof, whether the Government has taken any steps/proposes to take steps to create the said databank; and
(c) if so, the details thereof and if not, the reasons therefor?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(Dr. MANSUKH MANDAVIYA)

(a) to (c): Competition Commission of India has released a report titled "Market Study on the Pharmaceutical Sector in India: Key Findings and Observations", wherein it has been recommended to create a National Digital Drugs Databank consolidating real-time data on active pharmaceutical manufacturing companies in the country, therapeutic class wise/ formulation-wise approved branded/unbranded products etc.

Drug and Cosmetics Rules, 1945, implemented by the Ministry of Health & Family Welfare, have already been amended in the year 2019 making it mandatory for manufacturing licensees to register with portal SUGAM operated by the Central Drugs Standard Control Organisation (CDSCO) and upload information pertaining to the licences granted for manufacture for sale or distribution of drugs.

National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceutics, in collaboration with the National Informatics Centre (NIC), has set up a Pharma Data Bank (PDB) through an Integrated Pharmaceutical Database Management System (IPDMS). This comprehensive online system provides a platform to the pharmaceutical manufacturer/ marketing/ importer/ distributor companies to file mandatory returns prescribed under the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The application for price approval of 'new drug' in Form–I of DPCO, 2013 can also be filed through this portal. The portal provides industry with a user-friendly mechanism to comply with the mandatory requirement of filing returns and also help NPPA to monitor price compliance. As on 30th November, 2021, about 975 pharma companies have registered themselves under IPDMS and have registered 86,822 products.

*****