GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 2174
TO BE ANSWERED ON THE 31st July, 2018

Drug Pricing Policy

2174. SHRI RAJESH KUMAR DIWAKER:

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

(a) whether there is any policy regarding pricing of new drugs and their supply in the country and if so the details thereof;
(b) whether the Government has taken any fresh measures to expedite the pricing of new drugs to ensure adequate supply of drugs in the market; and
(c) if so, the details thereof

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a): New Drugs are regulated under Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945. Permission for grant of new drugs licenses is given by Central Drugs Standard Control Organization (CDSCO). However, in case of an existing manufacturer wanting to launch a new drug which is a variation of a drug scheduled under Drugs (Prices Control) Order-2013, the pricing of such a new drug is decided by National Pharmaceutical Pricing Authority (NPPA). Out of 855 applications received by NPPA, notifications fixing the retail prices of 770 applications for new drugs have been issued till 30th June, 2018.

(b) & (c): Under the provisions of DPCO, all drug manufacturers are under obligation to issue a price list to Distributors, State Drug Controllers and the Government. An initiative was taken by the government for online filing of the mandatory information for creation of an Integrated Pharmaceutical Database Management System (IPDMS).As per government decision, the new drug applications of only those manufacturers/marketers were put on hold who had either not submitted the complete information for IPDMS or had prima facie launched new drugs without prior price approvals. Some pending cases have been because of non-submission of necessary data by that industry. New drug have become a practice by pharma companies with prime objective of going out of price control.

The Government continuously monitors to ensure that there are sufficient numbers of the manufacturers in the market for various formulations and there is sufficient flow of medicines in the market. The Government also monitors that such manufacturers continue the production of concerned scheduled formulations. After delinking the necessity of compliance with IPDMS, new applications are being disposed off expeditiously.

xxxxx