

| 1           | 2             | 3   | 4   | 5   |
|-------------|---------------|-----|-----|-----|
| 20.         | Odisha        | 0   | 0   | 0   |
| 21.         | Punjab        | 0   | 4   | 2   |
| 22.         | Rajasthan     | 1   | 15  | 11  |
| 23.         | Tamil Nadu    | 0   | 0   | 1   |
| 24.         | Telangana     | 0   | 1   | 0   |
| 25.         | Tripura       | 1   | 12  | 1   |
| 26.         | Uttar Pradesh | 0   | 0   | 121 |
| 27.         | Uttarakhand   | 2   | 17  | 29  |
| TOTAL       |               | 86  | 236 | 225 |
| GRAND TOTAL |               | 547 |     |     |

#### **Delay in pricing process of new drugs**

2606. SHRI B.K. HARIPRASAD: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that present practice of deciding price for new drugs is causing delay in launch of the new drugs in the market by the manufacturer;

(b) if so, the details thereof and the reason therefor; and

(c) the course of action for expeditious pricing of new drugs as it is the main driver of growth of the industry and provides scope for innovation?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH MANDAVIYA): (a) and (b) No Sir, there is no such inordinate delay in fixing the prices of new drugs. Out of 979 applications received till 30th November, 2018, notifications for fixing the retail prices of 920 applications for new drugs have already been issued. Under the provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013), all drug manufacturers are under obligation to issue a price list to distributors, State Drug Controllers and the Government. The new drug applications of only those manufacturers/marketers were temporarily put on hold by National Pharmaceutical Pricing Authority (NPPA), who had either not submitted the complete information for Integrated Pharmaceutical Database Management System (IPDMS) or had *prima facie* launched new drugs without prior price approvals. Other cases have been pending because of non-submission of necessary data by the industry.

(c) The Government regularly monitors the number of manufacturers in the market for various formulations and that there is sufficient flow of medicines in the market.

The Government also checks whether such manufacturers continue the production of concerned scheduled formulations. The Government has issued instructions to NPPA that new drug approvals need not be linked to IPDMS compliance or any such other conditionalities which are strictly not ordained according to the DPCO, 2013 and directed NPPA to revisit all pending applications of pharma companies including those for new drugs expeditiously. NPPA has also been directed to take a decision within 30 days from the receipt of the “New Drug” application and within 7 days if drug of similar composition has been approved earlier or the manufacturer is offering lower price than decided for similar drug earlier. Also, in cases where drug of higher strength is being offered at the ceiling price of drug of lower strength, then the approval may be given within 7 days. In case of negative decision, a reasoned order should be given.

### **Pricing of essential medicines**

2607. SHRI HARNATH SINGH YADAV:

SHRI VIJAY PAL SINGH TOMAR:

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

- (a) the details of the methodology adopted to fix the prices of essential medicines;
- (b) the likely impact on the prices of essential medicines due to the new drug policy;
- (c) the steps taken/being taken by Government to ensure that doctors in private clinics are prescribing medicines from the National List of Essential Medicines;
- (d) whether Government has taken steps to implement the Supreme Court directive to stick to cost-based pricing formula; and
- (e) if so, the details thereof and if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH MANDAVIYA): (a) Under the Drugs (Prices Control) Order, 2013 (DPCO, 2013), ceiling price of scheduled medicines is fixed based on the market based data, *inter alia*, by taking simple average price to retailer (PTR) of all those manufacturers who have market share more than or equal to 1% of total market turnover on the basis of Moving Annual Turnover (MAT) of a specified medicine. The ceiling price is derived by adding 16% margin on the simple average price to the retailer (PTR) for the specified medicine. As provided for under the Order, the local taxes if actually paid, wherever applicable on actual basis, will be added with the ceiling price to arrive at the Maximum Retail Price to the consumers.