

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.

(b) The government has fixed the ceiling prices of the 856 scheduled formulations upto 31.12.2018 resulting in the reduction in the prices as follows:—

*Statement showing reduction in ceiling prices of scheduled formulations with respect to maximum price under NELM 2015 as on 31.12.2018*

% reduction with respect to Maximum Price	No. of scheduled formulations
0<= 5%	237
5<=10%	135
10<=15%	98
15<=20%	99
20<=25%	93
25<=30%	65
30<=35%	46
35<=40%	24
Above 40%	59
Total formulations in NLEM 2015	856

(c) The National List of Essential Medicines (NLEM) is a list of essential drugs prepared by the Ministry of Health and Family Welfare. There is no such case as doctors not prescribing medicine from NLEM as essential medicines are those medicines that satisfy the priority healthcare needs of the population.

(d) and (e) There is no such direction of the Hon'ble Supreme Court to stick to cost-based pricing formula.

#### **Sale of unapproved Fixed Dose Combinations**

2608. SHRI SAMIR ORAON:

SHRI MAHESH PODDAR:

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

(a) whether it is a fact that sale of unapproved Fixed Dose Combinations (FDCs) in the Indian markets has been rampant and unchecked, if so, the details thereof;

(b) whether the Government has banned any FDCs for being unsafe to the public, if so, the details thereof; and

(c) the steps taken by the Government to ensure effective and robust post-marketing surveillance programmes of manufacturers of FDCs?