Determination of Ceiling Prices of Drugs – Regarding

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1. The Government has been examining the Drugs (Prices Control) Order, 2013 (DPCO) with a view to enhancing the accessibility and affordability of essential medicines at reasonable prices to the poor and needy while providing sufficient opportunity for innovation and competition to support the growth of the Pharmaceutical Industry. The Government has been actively interacting with the Industry and other stakeholders on these issues. **Any impression regarding tightening of price control is both misleading and misplaced.**

2. Under the provisions of DPCO, the prices of only those medicines are fixed which are in the National List of Essential Medicines (NLEM), numbering about 850 against more than 6,000 medicines available in the market of various strengths and dosages. This constitutes approximately 17% of the total pharmaceuticals market, in value terms. There is an Expert Committee which continuously evaluates the list of Essential Medicines.

3. **Important issues under consideration of the Department** are i) treating the drugs which have become non-scheduled as non-scheduled drugs without any freezing of their prices for a further year; ii) revision of the list of scheduled medicines on the basis of revision of NLEM by incorporating only additions and deletions to the list so that the prices of only "new medicines" which are added to the NLEM will be fixed by NPPA; iii) limiting the determination of overcharged amount of a medicine found to be sold at higher than the ceiling price to the stock available with the defaulter; iv) In case of negative WPI, mandating the NPPA to change the ceiling price of scheduled drugs and not require the individual drugs to also reduce their MRPs if they are already lower than such revised ceiling price; etc. Other issues include new provisions for using Institutional price data for fixation of prices of those scheduled medicines which are being supplied directly to the Healthcare Institutions.

4. Any changes in the methodology of calculating ceiling prices of scheduled medicines are presently not under consideration.

5. As regards "**new drugs**" as defined in DPCO 2013, the Government is considering a change in the method of approving their prices. The Government is in consultation with the Industry to explore doing away with the present practice of deciding a new price for each applicant of "new drug", which is causing considerable time delay in launch of the new drugs in the market by the manufacturers.

6. The Department has constantly interacted with stakeholders and would further consult all concerned before finalising these proposals.

Department of Pharmaceuticals

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