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New medicines could be added to the 'essential' list

The National Pharmaceutical Pricing Authority (NPPA) has been able to fix ceiling prices of about 90% of the drugs in the National List of Essential Medicines (NLEM), in accordance with the new Drug Price Control Order (DPCO) 2013, despite concerns raised by industry. NPPA chairman CP Singh, in an interaction with **Jayati Ghose**, *explains how affordable medicines go a long way in boosting the nation's healthcare. Edited excerpts:*

How are ceiling prices fixed under the new DPCO 2013?
Under the new DPCO, we have fixed a ceiling price of a drug (molecule) as listed in the NLEM, but not that of any brand. The cap is based on a market-price linked criteria as opposed to a cost-plus basis that prevailed earlier.

How much of the market has been covered so far?
We have covered more than 90% of the volume of the market which is under price control. (Around 60% of the overall ₹80,000 crore domestic pharma market is under price control.) For about 108 drugs, there are no reliable data as to the number of manufacturers, price, quantum of drugs produced, etc. Many of these drugs may no longer be in circulation.

The Department of Pharmaceuticals (DoP) has started the process of revising the NLEM. So, drugs which are not being manufactured anymore will be removed. There is also the scope of adding some new essential and common medicines such as painkillers and anti-diabetic drugs to that list.

What was the impact on drug prices following the notification of new ceiling prices?
Prices of many essential drugs have fallen by 30-70% due to the new policy. As many as 106 drugs saw price reduction of over 40%. For instance, Cetrizine (10 mg tablet), which is a commonly prescribed anti-allergic medicine, saw its maximum price fall by 50%, from ₹3.7 to ₹1.81 per tablet; painkiller Diclofenac (50 mg tablet) became cheaper by 53% with companies restricted to selling it at ₹1.95 per tablet or less. Carboplatin, which is used to treat ovarian and lung cancers, saw companies like Dr Reddy's, Pfizer and Alkem bring down the rate to ₹789 (for a 150 mg injection), a 56% reduction over the current prices.

Has the industry accepted your logic of taking simple average price of all the brands having marketshare more than or equal to 1% of the total market turnover of that medicine?
Our formula is based on the fact that the same company is selling the same drug in the same dosage under different brand names and at widely different prices. For instance, popular painkiller diclofenac (50 mg dosage) sold as Voveran by Novartis is available at ₹3.49 and ₹2.64 per tablet (for a pack of 15 tablets). Novartis also sells the same drug as Voltaflam, which is priced at ₹2.58 per tablet. This fragments the market and creates artificial competition while retaining (and entrenching) bigger market shares with a few players, undermining real competition.

When we were undertaking the exercise to determine ceiling prices of essential medicines under the new DPCO, pharmaceutical companies had insisted that if a company held a 1% market share or above that in the premium range, then that price should be taken into consideration while calculating the ceiling price. However, we considered all brands of a particular drug marketed by a company as one brand, even if any one held less than 1% market share, to calculate the ceiling price. This led to a higher reduction in the ceiling prices set for essential medicines, giving more relief to customers.

What is the outstanding demand in overcharging cases and how much has NPPA recovered till date?
The total overcharging amount demanded from the pharma industry till January this year is ₹3,312 crore. This includes interest on the initial demand. Of this, we have recovered around ₹274 crore from the industry.

How does NPPA plan to deal with the overcharging issue? Many of these cases are also being challenged in court. Will you be able to recover the entire demand raised?
Overcharging happens when a company's drug or any active ingredient (bulk drug) in the final medicine is under price control, but the retail price of the drug is higher than the ceiling price set for that drug.

Initially, whenever an overcharging demand would be raised, companies would argue that the drug under consideration is not under price control. They would argue that either the name of the active pharmaceutical ingredient or raw material used is different or that the composition is different, so the final product is outside the purview of price control. To overcome this problem, we issued a circular stating that these cases fall under two categories—either the price has been fixed without NPPA approval or it amounts to overcharging. I also made it clear to the companies that as per DPCO it is the responsibility of the pharmaceutical company to get prices fixed by the pricing regulator.

When a bulk drug comes under price control, using it in any proportion puts the final product also under price control. Hence, the price of this final drug needs to be fixed by NPPA. We told the companies that in case of non-approval of price by NPPA the entire sales of that drug from the time it came under control till the date the overcharging demand was raised as unauthorised sale. So, 100% sales from this drug needs to be returned to the government. If there is an overcharging case, then the difference between the sale price and the ceiling price would have to be returned to government.

People who argue against drug price control say that medicine prices do not account for the major portion of disease treatment and hence it should not be controlled. Your opinion.
Maybe, they are talking about healthcare as a holistic concept that includes education, hygiene, etc. You may say that in the absence of good neighbourhood hygiene, what is the point of controlling medicine prices. However, that is not a correct argument. Affordable medication for the masses under the public healthcare system boosts the country's overall health and economy. It is very necessary to keep essential medicines under price control.

Another argument is that the government can increase distribution of subsidised generic drugs through public distribution system instead of controlling price of branded drugs?
That is a good argument, the only flaw being that the production of generic drugs is paltry. Moreover, doctors do not prescribe generic drugs, it is always a brand name.

The government is pushing for Jan Aushadhi programme. Will that help?
It should, except there are some conceptual flaws in that scheme. Under the scheme, low-priced, high quality unbranded generic medicines are made available through Jan Aushadhi stores. However, these stores are situated in government hospitals and district general hospitals where patients anyway get free medicines. Moreover, these stores have only a handful of common drugs. So, if a patient is suffering from a complex disease for which, say, 10 medicines have been prescribed, she will not be able to purchase all of them at these stores. Why should she travel to any Jan Aushadhi store for a few medicines?

The government has now decided to enlarge the basket of medicines available at Jan Aushadhi stores. They will purchase generic medicine from private pharmaceutical companies and sell them at subsidised rates through these stores. Moreover, seed money is also being given to the shop owners.

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Chairman, National Pharmaceutical Pricing Authority


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