80% of medicines not covered by price control order

Rema Nagarajan, TNN | Dec 1, 2013, 10.41 AM IST

About 38 million people in India (which is more than Canada's population) fall below the poverty line every year due to healthcare expenses, of which 70% is on purchase of drugs. Yet, the much-awaited drug price control order (DPCO) 2013, meant to control the price of medicines does not cover over 80% of the medicines in the market. Many drugs crucial for India's disease profile have been left out, which means people are unlikely to see any significant reduction in expenditure on medicines.

In 2003, the Supreme Court, while hearing a case on the National Pharmaceutical Pricing Policy, had directed the government to formulate appropriate criteria to identify essential and life saving drugs and ensure that they came under price control. It took over a decade for the government to announce the DPCO in May 2013.

By the government's own admission in an affidavit filed in court, the market value and share of medicines covered by DPCO is just 18% of the country's pharma market. Many life-saving medicines including anti-cancer drugs, expensive antibiotics and drugs needed for organ transplantation have been left out.

The government merely lifted the entire National List of Essential Medicines (NLEM) 2011, comprising 348 medicines, and placed it under price control. "The literal translation of the NLEM into DPCO 2103 has been done without a thought of its implications. The companies have been provided a convenient escape route. A 500 mg Paracetamol tablet is under price control but its 650 mg strength is not; individual anti-TB drugs are under price control but their combinations which outsell single ingredient preparations are not. This undermines the entire objective of making essential medicines more affordable to Indians," explained Dr Anurag Bhargava, associate professor at the Himalayan Institute of Medical Sciences. He stressed the need to expand the scope of price control to include all dosages and combinations, as was the case in the previous DPCO of 1995.

With the current DPCO not covering combinations of drugs, a lot of drugs for diabetes and hypertension and many other conditions will move out of price control as they are used in combination. The combinations not covered under NLEM account for Rs 31,866 crore or almost 45% of the total pharma market of Rs 71,226 crore in 2012.

An independent evaluation of the National Pharmaceutical Pricing Policy, by the Public Health Foundation of India (PHFI) and the Institute for Studies in Industrial Development (ISID) for a forthcoming report explains why it is important to expand the scope of price control. According to their evaluation, the market value of anti-infectives under price control is Rs 4,636 crore, just 6.5% of the total market. Anti-infectives, which include antibiotics, have the biggest chunk of India's pharma market.

"Our evaluation shows that if price control was expanded to combinations, additional strengths and dosages of just the anti-infectives included in the NLEM, the total market value would be worth more than Rs 10,500 crore, about 15% of the total pharma market, a vast improvement over the current coverage of just 6.5%," said Malini Aisola of PHFI.

The essential medicines list does not seem to have taken into account India's disease profile as it leaves out several drugs crucial for treating many common conditions, pointed out Dr Bhargava. The government's own affidavit admits that only 18% of anti-diabetics, 19% of anti-TB medicines and 6% of the respiratory therapeutics segment are under price control. This is despite India being the diabetes and TB capital of the world, and facing high prevalence of asthma and chronic obstructive pulmonary disease (COPD).

There's good reason why we need price controls. The MRP charged by companies is often many times the cost of production leaving them with profit margins unheard of in any other sector. Price control was meant to address this problem, particularly in medicines important for India. But it has failed to make any significant difference.

One reason is the way prices are determined under the current DPCO. Under the 1995 DPCO, the drugs prices under controls was decided by taking the cost of manufacture and fixing a certain percentage as mark-up, which included packaging and distribution costs, retailers' margin, excise duty and profit. But the current DPCO uses a new formula under which the price is fixed by taking the average price of brands having one per cent or more of market share and adding 16% as retail margin.

S Srinivasan of LOCOST, a company producing drugs for use by NGOs to treat the poor, explained how the cost of manufacture, including retail margin, for Cetrizine, an anti-allergic, is just Rs 1.20 for ten tablets. The ceiling price under the DPCO is Rs 18.10, the same as the price charged by the market leader GSK. This allows a price that is 15 times the cost of manufacture. In the case of Albendazole, a drug used to treat worm infections, the cost of manufacture including retail margin is Rs 8.90 per 10 tablets, while the DPCO ceiling price is over Rs 91, a ten-fold mark-up, pointed out Srinivasan. The price charged by the market leader in Albendazole, GSK, was Rs 140 per ten tablets. In this case, while price control should bring down the market leader's price, it still allows a huge profit margin. In fact, the PHFI-ISID evaluation shows that in 43% of drugs studied, the sales leader will face little or no impact from price control.

To show how effective DPCO has been, the government has compared the price reductions due to DPCO with the highest price of a drug. However, PHFI and ISID point out, it makes more sense to use the price charged by the company with the highest market share for comparison. Out of the 390 formulations for which prices have been notified, in 212 the company with the highest sales does not have the highest price. So, the price reduction achieved by DPCO is nowhere as dramatic as claimed by the government. PHFI and ISID have conducted an independent analysis using the same data as used by the government. Their calculation for 396 formulations shows that the effective average price reduction would be just 11% and the impact on the pharma market as a whole would be a mere 1.8%.

In sum, coming in 2013, a decade after the Supreme Court asked for it, the DPCO is clearly late. But even worse, as the PHFI-ISID study reveals, it is too little. Given how much rides on this for the aam aadmi, that is a tragedy of mammoth proportions.
80% of medicines not covered by price control order - The Times of India

India has the highest number of MDR-TB cases. Cost of MDR-TB treatment: Rs.5,000 per month. Number of drugs under price control: 60 million diabetics in India. Number of oral anti-diabetic drugs under price control: Two (8% of the market).

Newer vaccines in WHO list of Essential Medicines: Seven. In essential medicine list or under price control: Zero.

Severe malaria kills thousands annually. Artesunate injection that treats this is not under price control.

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