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No small price to pay

We need to think deeper on how to make drugs more affordable

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THREE months from now, India's new drug pricing regime will turn a year old. Last May, the Union ministry of chemicals and fertilisers brought 354 drugs under price control, up from 74, via the new Drugs (Prices Control) Order, 2013 (DPCO). The new DPCO had severe teething troubles and its implementation preoccupied bureaucrats and companies alike for many months.

But there are equally thorny issues that loom on the horizon. Indeed, the national discourse on drug pricing and affordability is just warming up. First, some background on the new regime. It has two main objectives. First, to address the argument put forward by civil society groups that the earlier price-control regime was outdated and ineffective, the ministry has created a new, longer list of drugs that mirrors India's National List of Essential Medicines (NLEM). Second, it has consigned the production cost-linked pricing method, a tedious procedure repeatedly denounced by the drug industry, to the dustbin. The new method fixes the final price as the simple average of the prices of the top three brands of a drug by value market share.

None of this was sudden. It took 10 years. During this time, there was much wrangling, including inter-ministerial, as various interest groups fought to influence policymaking. However, India is still far from finding a panacea to make drugs affordable. For one, consider the drugs outside the list. Some are not on the list because they are patented. That is, their producers have a legal monopoly on the market and so the question of applying a "top-three-by-share" formula does not arise. They need a different approach, which is yet to be formulated.

Then there are those off-patent drugs that do not figure in the NLEM and are therefore outside the purview of price control. What does this mean for a patient suffering from a life-threatening disease who is prescribed a drug that is not on the list? Consider one such product, the breast cancer drug trastuzumab. For months, a civil society group has been campaigning for lower prices for the drug, which has a list price of Rs 75,000 per 440-mg vial (but is reportedly available at a discounted price of approximately Rs 55,000). Patients have to take multiple vials.

A recent Bloomberg report observed that the list price is 15 times India's per capita monthly income. The drug only works on a subset of breast cancer sufferers — about a quarter of the 1,45,000 women diagnosed annually with breast cancer in India. That's 36,000 mothers, wives, sisters and daughters — not a small number. This month, a rival brand was launched at a 25 per cent discount. But most women cannot afford that either, say spokespersons for the Campaign for Affordable Trastuzumab. According to the campaign, ideally, the price should be below Rs 5,000 for a vial.

Cancer is just one example. There are similar problems with drugs for other rare diseases being priced out of reach of most patients, forcing them either to go without treatment or rely on charity, which is unpredictable and finite. Over the last decade, thanks to the improvement of infrastructure, the diagnosis of diseases such as cancer is on the rise. Imagine the irony: scores of new patients are diagnosed early enough to survive if they are given treatment. Only to realise that treatment is beyond their means. How does that work? Going forward, more patients will demand answers.

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Then, there is the question that has refused to go away — are we using the right approach? Consider once again the list of price-controlled drugs. The DPCO uses "brand" prices to arrive at a ceiling. Branding helps companies stand out in a market full of "me-toos". Also, in a market traditionally plagued by sub-standard or spurious drugs, brands have been linked to quality. Brands incur more costs — of promotions to doctors etc. Imagine that industry could pare those by selling large amounts of unbranded drugs to an efficient and transparent government procurement and distribution mechanism where cost and quality are paramount. The ministry is attempting just this through the Jan Aushadhi scheme. It did not take off initially but has been relaunched with some much-desired improvements.

Not surprisingly, price-controlled drugs in Jan Aushadhi stores cost less than the price ceiling fixed by the DPCO even though there is no subsidy. Given the government's track record in procurement, the jury is still out on the scheme. A successful scale-up would beg the question: is it better to focus on such a scheme rather than tinker with lists?

These are just some points to ponder. Doubtless, there are many more. The new DPCO is not the end, it is merely another beginning.

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