

Who decides how much my Crocin will cost?

- S Srinivasan ("Chinu")

A month ago, the government announced that the price of some 500 essential drugs would rise. How are drug prices fixed in India, and is the latest rise of 3.84 percent a good or a bad thing? Does a Parliamentary panel's recent recommendation that all drugs in India be brought under price control make sense? Here are some answers to questions about drug prices in India.

Who controls the price of medicinal drugs in India?

The [National Pharmaceutical Pricing Authority \(NPPA\)](#) does. It is a regulatory agency under the Department of Pharmaceuticals that implements and enforces the [Drug Price Control Order \(DPCO\)](#) – the most recent order was introduced in May 2013.

The DPCO sets the maximum price of essential drugs sold in India. The drugs under price control cannot be sold beyond the ceiling price (plus taxes).

Which drugs have their prices controlled?

All 348 drugs of fixed strengths (such as 500mg or 4mg, for example) and their approximately 620 presentations (tablets, tonics, capsules, etc) mentioned in the National List of Essential Medicines (NLEM) 2011 are under price control as per the DPCO of 2013.

This means that if a necessary, and frequently used (but highly priced) medicine is not mentioned in the NLEM 2011, then the medicine will not be under price control. For example, atorvastatin 10mg, used to lower cholesterol, is under price control but not its 20mg variant, as the latter is not mentioned in the NLEM 2011. Nor are other statins like rosuvastatin or simvastatin under price control, as they do not find mention in the essential medicine list. Or, to take another example, only 500mg tablets of paracetamol are mentioned in the NLEM – not other strengths. In the absence of a pro-rata formula for strength and price, a 1000mg tablet of paracetamol, for instance, will escape the price control net. Almost all pediatric strengths are not mentioned in the NLEM 2011, and are therefore also out of price control.

Hopefully, the [proposed revision](#) of the NLEM 2011 in 2015 will take these problems into account. A fortnight ago, a [report](#) by the Standing Committee on Chemicals and Fertilizers that was tabled in Parliament said that all drugs should be brought under price control: "[T]he scope of price control needs to be enlarged to make all the drugs available, especially life saving drugs, in all parts of the country." This seems unnecessary, as India has too many drugs (around at least 1,00,000 brands) to control, and a waste of the NPPA's energy – particularly when some of the drugs not on the NLEM are irrational and unscientific (more on this below). While these non-essential and irrational drugs

should be weeded out of the market, all essential and life-saving drugs in all their recommended strengths and presentations, even if not on the NLEM, should be under price control.

How is the ceiling price for medicines decided on?

Drug pricing in India has a long, tortured history. Major milestones in controlling pricing came in 1978, 1986, 1995 and the latest in May 2013. Before May 2013 the ceiling prices of the formulations of only 74 bulk drugs that were under price control were fixed based on a 'cost-plus' formula. This was the sum of the cost of the bulk drug to make one unit, plus the cost of conversion (from, say, powder into a tablet), and the margin that the manufacturer was to be allowed – it was a fairly commonsensical formula.

Since May 2013, the ceiling price has been a market-based one, taking the simple average of the price of a drug sold by brands that have at least 1 percent share of the market. For example, if there are 100 brands selling of 500mg tablets of paracetamol in the market, but only about 15 brands have a market share of over 1 percent, the ceiling is fixed by adding up the price of the 500mg paracetamol sold by those 15 brands, and dividing it by 15.

If the price of the drug that brands are selling is high to begin with, the ceiling price will also be high. This formula has no direct relation to the cost of production or the cost of raw material (and in my opinion, it is nonsense). Take atorvastatin 10mg, the cholesterol-lowering agent – leading brands were selling it at around Rs 100 for 10 tablets before the 2013 DPCO. After price control, this has been brought down to about Rs 60, but even that is highly overpriced. At LOCOST – a non-profit manufacturer of low-cost drugs – where I work, we market it at about Rs 9 for 10 tablets, while our actual cost of production is Rs 3.50. The market-based ceiling price formula is an irrational method. It ends up justifying high prices (and high profits) with no relation to the cost of production.

Are there provisions for increase in ceiling prices?

An increase is allowed in April every year, as per the increase in wholesale price index (WPI) for the previous 12 months. This is to account for inflation and increase in cost of inputs. The WPI increase for 2014-15 was 3.84 percent, so this year, with effect from April 1, 2015, the price of 509 NLEM medicines has been increased by 3.84 percent. A similar WPI-linked increase will be carried out every year in April.

Meanwhile, the DPCO of 2013 allows the price of non-essential drugs to be increased by 10 percent every year!

Is the 3.84 percent rise in the price of essential drugs fair?

The biggest problem with this sanctioned rise is that it does not take into account the percentage rise in the cost of raw material – which often can be more than the percentage increase in WPI. The

ceiling price cannot remain static in this way – frozen at 2013 prices with an annual rise that is too low to keep up with rising prices.

The problem is partly because under the 2013 DPCO, the government does not control the price of active pharmaceutical ingredients (API) or bulk drugs, which are used to make tablets, capsules and other formulations. Nor is the formula for ceiling price linked to the price of the API. In the last 12 months, for instance, the price of folic acid, which is essential for pregnant women as part of iron folic acid tablets, went up from Rs 5,000 a kg to Rs 25,000 a kg. That's a 500 percent rise, compared to the allowed rise of 3.84 percent. Luckily, in this case an iron plus folic acid tablet requires only micrograms (mcg) of folic acid, so manufacturers can manage with this price rise, for now. But for the manufacturers of other drugs (such as doxycycline and norflaxacin), the extraordinary increase in prices has made it almost unviable, even for low-cost manufacturers such as ourselves.

(Incidentally, since folic acid and ferrous sulphate are mentioned separately in the NLEM 2011, the standard prescribed combination of ferrous-sulphate-plus-folic-acid tablet is out of price control!)

The DPCO 2013 does provide for abnormal increases in input costs, but the procedure is inadequate and comes with a time lag, if at all. We need a procedure guaranteed to make useful drugs available, so that there is no scarcity at any time because the cost of manufacturing of a drug makes it unviable.

But isn't it a good thing that prices of essential drugs are kept low? Doesn't it ultimately benefit the consumer?

While some manufacturers may be able to offset the losses they make to manufacture an essential drug by cross-subsidizing it with a non-essential drug, if it is economically unviable even for not-for-profit manufacturers like us, it means bad news.

Whatever price a drug was being sold at in May 2013, it has to be frozen there according to the 2013 DPCO. Even if I, as a manufacturer, have been selling it at much below the ceiling price, I don't have the freedom to adjust the price according to the increase in the cost of raw material. Drugs on the 1995 list such as co-trimoxazole (brand name Bactrim), the already mentioned norfloxacin and doxycycline, have been frozen at that price, to the point that it is uneconomical to continue making them. The ceiling price is so that you can just about make it at cost price, or at a loss.

The cost may be low for the consumer for now, but if it drives manufacturers out of business, who will then produce essential drugs? The consumer is ultimately hit. Price control isn't a bad thing – but the methodology of it has to be fair, based on input costs plus a margin.

How large is the essential drugs market?

The (allopathic/modern medicine) market of medicines sold **domestically** is around Rs 85,000-90,000 crore. A government affidavit filed in the Supreme Court in November 2013 indicated that only 18 percent of the domestic market is under price control. That means about 82 percent of the

market is out of price control. Subsequently the figure of 18 percent has become *even less* as the essential drugs market has not kept pace with the total market growth. (Medicines from other systems of medicine such as Homeopathy and Ayurveda are not under price control.)

Are drugs that are not on the essential medicines list (NLEM 2011) unnecessary? How come they were approved for manufacture in the first place?

There are many useful, scientific and lifesaving drugs (such as montelukast for asthma) not mentioned on the NLEM 2011 that ought to be on it. But yes, in terms of their market share, the majority of the drugs not in the NLEM are indeed non-essential.

Pharmaceutical companies have been given licence to manufacture and market non-essential drugs because of non-application of mind by the state and central drug regulating authorities. And now they are in the market, they are proving to be a legal nightmare to weed them out – again because of lack of bureaucratic, political scientific will to clean up the pharma market.

Non-essential drugs include irrational and unscientific combinations of drugs (such as combinations of painkillers or combinations of antibiotics) as well as popular vitamin and “nutritional” supplements. Most iron tonics for pregnant women such as Dexorange are unscientific and a burden on the consumer – all those that do not contain ferrous sulphate and folic acid in the required strengths are a financial waste and are considered sub-therapeutic. (A *majority* of Indian women have anemia, or iron deficiency.) Indeed, iron and folic acid tablets in the right strengths are generally not available in the retail market! Two of the top-selling cough medicines in the market are of doubtful rationality (there is no clear support for it in respected pharmacological literature). As are fixed-dose combinations of the antidiabetics involving metformin and other drugs. Combiflam, for instance – a combination of ibuprofen and paracetamol – can cause harm – you end up taking two drugs when you need only one. The NLEM document states: “Preference is given to single drug formulations as opposed to fixed dose combinations where appropriate. Hence use of NLEM is expected to improve prescribing practices as well as the health outcomes. The appropriate use of medicines selected in the NLEM promotes rational use of medicines. Such rational use of medicines, especially antimicrobial drugs, reduces development of drug resistance.”

How about drugs of the same therapeutic or chemical class as those on the NLEM 2011? Are they under price regulation?

Drugs of the same therapeutic or chemical class are not under price control. As mentioned above, all statins are not under price control as only atorvastatin 10mg is mentioned in NLEM 2011. Neither are all ACE (angiotensin-converting-enzyme) inhibitors used for cardiac problems – only enalapril 5mg and 2.5mg tablets and an injection are mentioned on the NLEM list, and neither ramipril nor lisinopril find a place (both prescribed frequently by doctors). In crucial areas like diabetes, which affects Indians disproportionately to people of other ethnicities, the NLEM 2011 originally

mentioned – apart from insulins – only two drugs: metformin and glibenclamide. All the other useful and essential antidiabetics like glimepiride (brand name Amaryl) were not mentioned – something the NPPA tried to remedy in July 2014 using special powers mentioned under Paragraph 19 of the 2013 DPCO, which allows the government, in case of extraordinary circumstances and for public interest, to fix the ceiling or retail price of a drug as it sees fit.

The pharmaceutical industry – both Indian companies as well as MNCs – promptly went to court questioning the inclusion of many life-saving drugs not on the NLEM 2011 under price-controlled drugs. But for a change, the pricing authority was doing the right thing. The case is still in the courts – but the central government’s legal counsel (in a classic case of the left hand contradicting the right hand) opined – wrongly, according to many of us – against the future use of Para 19 for such purposes! The industry lobbies **won this round**. A clear case of industry not working for the country’s public health – if proof was needed.

How do India’s neighbors in the developing world control drug pricing? Are there good models to emulate?

Bangladesh has an excellent model for fixing drug prices that protects the interests of both consumers and manufacturers. The cost of drugs is fixed according to different categories of drugs, but takes into account the cost of raw and packing material, production overheads and profit, distribution costs and retailers’ commission to arrive at a drug’s MRP before VAT. And the price is increased every year commensurate to the annual inflation rate. The formula for a tablet would be: if Re 1 is the cost of the raw material in a 500 mg tablet, the ceiling price would be Rs 2.25 – that is 2.25 times the cost of the raw material.

Even though vested interests have succeeded in **diluting** Bangladesh’s price control policy, the country has held on since 1982 – despite pressure from foreign MNC lobbies and their governments.

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