Are market-based pharmaceutical price controls the new reality in India?

Three strategic implications for Pharma and Biotech in India

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India’s Department of Pharmaceuticals (DoP) released the Drug Price Control Order (DPCO) in May 2013. It increases the number of medicines on the National List of Essential Medicines (NLEM) from 74 to 348 and offers new paradigms for determining and enforcing price ceilings while maintaining stable drug supply.

The effects of the DPCO are substantial. Pharmaceutical and biotechnology companies that do business in India need to carefully evaluate the consequences of this legislation.

The DPCO uses market-based mechanisms to set price ceilings

The DPCO has three primary aims: expanding the National List of Essential Medicines (NLEM), authorizing the National Pharmaceutical Pricing Authority (NPPA) to regulate prices of India’s NLEM, and authorizing the NPPA to regulate price increases of non-essential medicines.

The DPCO uses market-based mechanisms to set price ceilings. It works differently, depending on how many products are in a category:

1. If a drug is one of many drugs within a given product category, the price ceiling is the simple average of the prices of all drugs that have at least 1% of market share within that product category (plus a 16% pharmacists’ margin).

2. If a drug is the only drug within a given product category, the new price ceiling for that drug category will be a fixed percent, based on price reductions in similar product categories, of the current drug price.

Moving forward, all drugs in a product category must be priced at or below the price ceiling or the manufacturer will face monetary penalties. In the case that a drug’s price is already below the price ceiling, a price increase is prohibited. The NPPA, however, currently has no mechanism to officially penalize an offending manufacturer. For all NLEM-listed medications, yearly price increases must be in-line with or below the wholesale price index (WPI).

The Indian government has also reserved the right to mandate continued production for up to 12 months, to require quarterly drug production reports, and to require 6 months’ notice before production of a given drug ceases.

The regulation also exempts all drugs developed and patented in India from price control as a means of incentivizing India-based research and development.
The DPCO results in three key implications for pharmaceutical and biotechnology companies in India as well as for India as a place for future pharmaceutical/biotech R&D:

1. Fewer “branded generics”
2. No let-up in pricing pressure for non-NLEM drugs
3. No dramatic change in multinational corporations’ (MNC) R&D investment in India

Implication 1: Fewer “branded generics”

To understand how this new policy will impact prices within the Indian market, consider the following three cases:

Case #1: Novartis’ desferrioxamine mesylate is the only product on the NLEM in its category (monopoly category): Nearly 25% price reduction

Because Novartis’ desferrioxamine mesylate is the only drug within its product category, it experiences price reduction as a fixed percentage of its current price. In order to determine the price reduction for desferrioxamine mesylate, the NPAA considers the average reduction in similar product categories. For desferrioxamine mesylate, the price reduction will be 24.80%, the average price reduction for antidotes. This will reduce the price per unit from its current ₹170 to ₹128.

Hepatitis B vaccines’ anticipated price ceiling under DPCO

Source: Simon-Kucher analysis of National Pharmaceutical Pricing Authority of India data
Case #2: GSK’s Hepatitis B vaccine is an expensive branded alternative to a host of low cost generics: A price reduction of about 75% (Fig 1)
GSK’s Hepatitis B vaccine is significantly more expensive than the other seven options. Because the new price ceiling is determined by an arithmetic, and not a weighted, average, the price ceiling for Hepatitis B vaccines will force the price of GSK’s Hepatitis B vaccine significantly down from over ₹300 to a maximum of ₹87. Put simply, GSK’s product will face a price reduction of roughly 75%.

Case #3: A local manufacturer (Pavior) offers a more expensive factor VIII concentrate injection than the only alternative, Baxter’s cheaper version: Market leader (Baxter) unaffected by price reduction (Fig 2)
According to clearly outlined DPCO policy, the new price ceiling for factor VIII concentrates will become the average of current prices, or about ₹5400. Baxter’s factor VIII is priced well below where the new price ceiling would be, and so Baxter will not face mandatory price reduction. This is a particularly interesting case, as the DPCO aims to impact high-priced branded options that compete against a set of generic and “branded generic” alternatives. Given the Baxter product has over 90% of market share, the price ceiling will not have any impact on the category spend.

**Factor VIII concentrates’ anticipated price ceiling under DPCO**

* Price is weighted average of market share and is price to retailers excludes VAT etc. MRP will be attained by adding retailer margins+ VAT
Source: Simon-Kucher analysis of National Pharmaceutical Pricing Authority of India data
In addition, given that Pavior’s drug is currently over ₹6000, it is unclear whether the Indian government will enforce price reduction for a product that was locally developed and launched prior to the DPCO.

In order to understand the reach of the DPCO’s price reduction policies, one must fully understand the India market. Consumers and physicians in India are very brand-conscious, even when it comes to medications. As a result, currently, higher drug prices don’t necessarily lead to lower market share. Indeed, for almost half of product categories under the DPCO (47%), the most commonly used drug is also the most expensive.

Consider the Hepatitis B vaccine market from case #2 (Figure 3). GSK’s product, despite being the most expensive by a wide margin, has a disproportionate 26% market share. This is because market share and price are not inversely related in this product category as would typically be expected. Thus, this category demonstrates the DPCO’s potential success. Though GSK is the only therapy that will face significant price reduction due to its high market share, the weighted average of prices in this category will be slashed in half from ₹140 to ₹70.

**Price vs. market share for Hepatitis B vaccines**

Source: Simon-Kucher analysis of National Pharmaceutical Pricing Authority of India data
On the other hand, the DPCO does not impact all product categories equally: it has a smaller impact on currently economically efficient categories. Under the DPCO, simple price averages will become new price ceilings. This means that for categories for which a low cost alternative to an expensive branded agent has much higher utilization (i.e. economically efficient), the weighted average of prices, and thus actual spend, will not change significantly. Perhaps this is intentional as it will allow the economically efficient part of India’s healthcare market to remain unaffected.

As a result of the DPCO, price differentiation for NLEM-listed medications will become increasingly difficult. More importantly, the DPCO may impact locally-manufactured generic alternatives as it reduces the price of the MNC branded options, thus decreasing the price gap and perhaps making the MNC brand more attractive. This will lead to a decrease in the number of “branded generic” NLEM products. As price differentiation within each product category decreases, so too does the potential for a middle tier, products that are neither the most nor the least expensive in the category, of “branded generics”. As a result, fewer “branded generics” will exist across and within product categories.

**Implication 2: No let-up in pricing pressure for non-NLEM drugs**

An estimated 70% of the India drug market is not listed on the NLEM and will not face new price ceilings or mandatory price reductions. However, medicines not listed on the NLEM will only be permitted a 10% annual price increase. In addition, pricing opportunities remain limited by patient affordability and the threat of compulsory licensing.

The Indian government has a history of implementing compulsory licensing and revoking patents for drugs it considers too expensive (Figure 4). Nine drugs for either cancer or diabetes have faced patent problems ranging from compulsory licensing to revocation of patents to denial of patent infringement in India: Nexavar, Sutent, Pegasys, Herceptin, Glivec, Tykerb, Ganfort, Tarceva, and Januvia. These patent problems have led to cheaper generic alternatives for high cost medicines in India, and have also positioned India as a country in which exceptionally high priced therapies are unlikely to launch successfully.
Implication 3: Multinational corporations’ (MNC) R&D investment in India will not change dramatically

The DPCO incentivizes India-based research and development of drugs. However, the likelihood that this will influence MNC’s investment decisions is negligible. MNCs often have established R&D centers outside of India. Since revenue from NLEM drugs for MNCs in the context of their global revenues is very small, it is very unlikely that many MNCs will make a large R&D investment in India because of the DPCO.

Wrap up

The Indian government is heavily involved in regulating prices for medicines in India by using the DPCO to set price maximums for essential medicines. Going forward the Indian government may also look to other larger areas of the pharmaceutical/biotech market to introduce new and increased regulation to make medicines more affordable. To be successful in a changing India market, manufacturers need to constantly review the changing policy landscape and reassess their India strategy carefully.
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