Insider Analysis From Corporate Law Group New Delhi On India's Drug Pricing Regulations

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Features / Word Count: 2313 / Article # 28120423009

Executive Summary

A new pricing proposal under consideration could extend price controls to 75% of the Indian retail market.

In India, a "drug" is classified as an essential commodity under the Essential Commodities Act (ECA), 1955. The ECA is a pre-liberalization era legislation that provides for stringent Central government control over price, distribution and production of certain commodities that are deemed to be "essential."

The National Pharmaceutical Policies framed by the Central government provides measures for rationalization, quality control and growth of the pharmaceutical industry in India. Price control and price monitoring of drugs has been one of the important components of the National Pharmaceutical Policies as reflected in the Drug Price Control Order (DPCO) by the Central Government of India under Sec. 3 of the ECA.

The DPCO, among other things, provides the list of price-controlled drugs, procedures for price fixing, method of implementation for price fixing by government, and penalties for contravention of provisions. Under the provision of DPCO, the government will fix a maximum sale price for bulk drugs in Scheduled Bulk Drugs and Scheduled Formulations. This is done to regulate equitable distribution and increase supplies of those formulations and make them available at a fair price among different manufacturers.

Whereas the DPCO provides the mechanism for price control, the ambit of applicability of DPCO or the "basket of price-controlled drugs" comes from the essentiality criteria laid down in the National Pharmaceutical Policy (NPP), earlier known as the Drug Policy.

Pharmaceutical products have largely remained under some kind of price regulation in India since 1963. By 1970, almost all drugs were under price control. However, the scope was reduced to a select 347 bulk drugs in 1979, to 142 bulk drugs in 1987 and finally to 74 in 1995. Under the now defunct 2002 policy, the number of drugs under price control was to be further lowered to 37.

The DPCO is usually reviewed every five years. However, the 2002 Policy and the draft DPCO got mired in litigation before the Karnataka High Court and then the Supreme Court of India (SC) and thereafter never saw the light of day. The current DPCO is that of 1995 and based on the 1994 Drug Policy. The draft NPP 2006 is under review by a Group of Ministers (GoM). Meanwhile, in 2011, the National List of Essential Medicines (NELM) 2011 was published and the draft National Pharmaceutical Pricing Policy 2011 (NPPP 2011) was announced and is likely to be placed before the GoM on April 25 ("Wide Criticism Pushes Indian Government To Rethink Its Proposed Pricing Policy" — *PharmAsia News,* Mar. 21, 2012 5:45 PM GMT).

Drug Price Control Order Of 1995

The 74 bulk drugs under the present DPCO (1995) represents roughly 20% of the pharma market in India. Bulk drugs, with a turnover of over Rs. 40 million, are under the purview of DPCO, excluding those drugs with sufficient market competition.

The DPCO in 1995 introduced three parameters to ensure proper market conditions – turnover, market monopoly and market competition.

Any person aggrieved by the decision of the NPPA/Central government may approach a competent Civil Court for injunction or for any other appropriate relief.

The NPPA within the Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers has the power to implementing provisions of DPCO. The NPPA makes decisions on applications for price approvals filed by manufacturers within two months for formulations and four months for bulk drugs. NPPA also monitors the prices of formulations and drugs not under price control and oversees enforcement of the DPCO. The Central government has the power of review.

Any person aggrieved by the decision of the NPPA/Central government may approach a competent Civil Court for injunction or for any other appropriate relief. However, a copy of the notice of the application is required to be given to the government or the concerned officer before the injunction is granted by the Court. Further, any person aggrieved by an order/decision of the NPPA/Central government can file an appropriate writ petition before a High Court under Article 226 or the Supreme Court of India under Article 32 of the Indian Constitution, provided the petitioner satisfies the legal requirements for filing such writ petitions.

The Pharmaceutical Policy 2002 And Its After Effects

In February 2002, a more liberal NPP was released. This policy was immediately challenged in the Karnataka High Court on the grounds that the criteria adopted kept essential drugs out of price control and violated Constitutional provisions (Writ Petition No. 21618 of 2002). The Karnataka High Court upheld the challenge on both counts and stayed the implementation of the 2002 Pharmaceutical Policy by its Nov. 12, 2002 judgment.

Aggrieved, the Central government appealed to the SC, challenging the Karnataka judgment. The Organization of Pharmaceutical Producers of India (OPPI) and the Indian Drug Manufacturers Association (IDMA) filed separate appeals before the SC and became parties to the litigation. Several NGOs including the All India Drug Action Network (AIDAN) also filed a Writ Petition asking the government to include all essential drugs under the price control regime. In March 2003, the appeals were admitted but the SC directed the Central government to consider and formulate appropriate criteria for ensuring essential and life-saving drugs be kept under price control and further directed a review of essential and life-saving drugs.

It is the last part of the Order that has been interpreted in rather extrapolative terms and has become the fulcrum for the debate on drug price control and has been repeatedly used to push for inclusion of all Essential Medicines under the price control regime.

Draft NPP 2006

During the period from 2003 to 2011, numerous developments have occurred on the price control issue. Pharmaceutical Policy 2002 was shelved, and several committees and task forces were established by the

government. Recommendations of the task force under the Chairmanship of Pronob Sen were prominent in this regard, and the draft NPP 2006 was framed based on the Pronob Sen Committee report.

According to the draft NPP 2006, the span of price control was broadened to bring an additional 354 drugs under NLEM 2003 in addition to the 74 bulk drugs already under price control under the DPCO 1995. The Ministry of Chemicals and Fertilizers has admitted that this would result in over 60% of the drugs being brought under price controls. As a modification, it proposed that 354 single ingredient formulations of specified strengths alone would be subject to price controls, and have estimated that this would cover 32% of the market. There has been considerable opposition to this move and the matter has been referred to a GoM for resolution.

Apart from the cost-plus method, other systems of price control like negotiated prices, differential prices, reference prices for patented drugs, bulk purchase prices, etc. have also been proposed.

The draft NPP 2006 was referred to a seven-member GoM under Union Agriculture Minister Sharad Pawar on Jan. 11, 2007, to settle the issue. Under the United Progressive Alliance under the Union government that came to power in 2009, the GoM was reconstituted in March 2011 and is now reviewing the same draft. The policy is still awaiting action by the GOM.

In addition, the government established an inter Ministerial Committee in January 2007 to examine and propose a price-negotiation mechanism for patented drugs. The committee studied such systems in countries like the United Kingdom, Philippines, Brazil, France, Canada, Australia, and Japan, and held consultations with various stakeholders.

2011 Draft National Pricing Policy Criticism

The Writ Petition of AIDAN filed in 2003 was taken up for hearing in October 2011. This petition survived since it was a public interest litigation involving larger issues and questions of law which were not dependent on the Pharmaceutical Policy 2002 or the Judgment of the Karnataka High Court. The SC directed the Secretaries of the Ministry of Health and the Department of Pharmaceuticals (DoP) to inform the Court on steps taken to include the NLEM under price controls.

For its part, in August 2010, the Parliamentary Standing Committee of Health & Family Welfare in its 45th report emphasized bringing NLEM within the ambit of price control under the DPCO. Consequently, the MoH revised the NLEM 2003 and issued the NLEM 2011. While NLEM 2003 had 354 drugs, the current list contains 348 drugs under 27 categories. There are 43 new additions in the NLEM 2011 including eight cancer drugs.

Once the NLEM 2011 was formulated, the DoP came under pressure from three fronts: the MoH; the Parliamentary Standing Committee and the SC to include drugs listed in NLEM 2011 under the span of price controls.

In October 2011, the DoP gave in and formulated the NPPP 2011. The draft NPPP 2011 was framed with a stated dual objective: To put in place a regulatory framework for pricing of drugs to ensure availability of essential medicines at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry ("With Over 348 Drugs In Proposed Pricing Policy, India Aims To Balance Industry Growth With Affordable Drugs" — *PharmAsia News,* Oct. 31, 2011 1:00 PM GMT).

Thus, the draft NPPP 2011 is based on three basic features that are in contrast with the existing 1994 Drug Policy.

First, the draft NPPP 2011 presents an enormous span of price-controlled drugs. The basket of price-controlled drugs as proposed by the draft policy include:

- Drugs with dosages as listed in the NLEM 2011;
- Drugs with strengths and dosages not listed in the NLEM 2011 (nonstandard dosages);
- Formulations containing combination of drugs under NLEM 2011 with other drugs listed in the NLEM 2011; and
- Formulations containing combination of drugs under NLEM 2011 with drugs not listed in the NLEM 2011.

This change from the earlier Drug Policy includes all essential drugs as mentioned in NLEM as well as a combination of such drugs with non-NLEM drugs.

Second, the inclusion under price control in the Drug Policy 1994 was based on economic criteria and market share principle while the proposed criterion under NPPP 2011 is essentiality of drugs. This change is in line with the recommendations of the Pronab Sen Committee.

Third, the proposed regulation of drug prices in the draft NPPP 2011 is based on regulating the prices of formulations only through market-based pricing, where the weighted average price of the top three brands form the ceiling price for a drug. This is different from the earlier principle of regulating the prices through cost-based pricing under the Drug Policy 1994.

The concept of market-based pricing taking the weighted average price of the top three brands as the ceiling price has been rejected because that would then legitimize higher prices.

It is predominantly the latter feature that has come under severe criticism from the NGO community as well as the MoH. The concept of market-based pricing taking the weighted average price of the top three brands as the ceiling price has been rejected because that would then legitimize higher prices. Consequently, the DoP is now tweaking its draft policy before it goes to the GoM where there is expected to be further deliberations and possible finalization of the Policy ("India May Go Beyond Price Control Provisions To Clamp Down On Cancer Therapies" — *PharmAsia News,* Apr. 2, 2012 8:30 AM GMT).

Setback Or Step Forward?

Overall, it may be seen that the NPPP 2011 takes a retrograde policy decision by increasing the span of control, which otherwise has witnessed a steady reduction since the beginning of Drug Price Controls in India. However, the proposed policy does bring in a more realistic and practical approach to the pricing mechanism. By involving market-based pricing and doing away with the cost-based approach, the policy aims to bring in a transparent mechanism.

The estimated value of drugs liable to go under price controls per NPPP 2011 is roughly Rs. 290 billion ($6.3 billion) or 60% of the domestic market. This compares to 20% of the market coverage in the DPCO 1995. However, industry organizations have pegged the impact at around 75% of the retail market. According to the Indian Pharmaceutical Alliance, the NPPP 2011 proposes to add 1,154 drugs and 6,441 formulations, raising the span of control to 75% of the retail market

Industry estimates that about 50% of drugs included in the NLEM 2011 will face a price reduction of 0% to 5% in the current highest-priced brand in the market. An estimated 30% of drugs are likely to face a price reduction of over 20% in the current highest-priced brand in the market, while about 20% of drugs are likely to face between 5% to 20% price reduction in the highest-priced brand.

It is premature to predict the shape of the final policy on pharmaceutical price controls. It is also difficult to assert the direction in which further deliberations could move. Given the uniquely contrasting state of industrial development, economic growth, and the healthcare scenario in India, formulating any policy with respect to drugs is a daunting task and needs much deliberation with all stakeholders involved.

Indeed, India faces an overwhelming burden of meeting its healthcare concerns, and providing access to affordable healthcare is one of the primary functions of a welfare state and drugs are an integral part of any healthcare scheme.

However, it is imperative for the government of a fast-growing economy like India to recognize that price controls alone do little to increase access to medicines. Instead, they limit the scope of access by penalizing the industry that invests in the discovery, manufacturing and distribution of drugs. Medicine is one of many links in the healthcare chain, along with providers, hospitals and clinics, and health insurance. Focusing on one aspect, such as pharmaceuticals, while ignoring the other aspects, will not solve the problem of access to healthcare.

For a country like India, any pharmaceutical policy needs to support the government in its efforts to develop infrastructure, basic supplies and healthcare professionals. Any pricing strategy must be complemented by efforts to lay these critical foundations to ensure that medicines reach the patients who need them most.

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