GOVERNMENT PRICE CONTROLS FOR PATENTED MEDICINES IN INDIA

History

The first price-control order in India was issued under the Defence of India Act in 1963. In 1970, the Drug Price Control Order (DPCO) was introduced almost simultaneously with the amendments to the Patents Act 1970 that derecognized product patents.

The policy on patented drug-price controls evolved from the Pranab Sen Committee Report of 2005, leading to the National Pharmaceutical Policy in 2006 and subsequently the report of the BK Singh Committee in 2013.

2013: BK Singh Committee Recommendations

- Price negotiations to be restricted to government purchases and insurance procurements, leaving the open market free of controls
- Price negotiations not to be linked with marketing approvals
- Once priced are fixed, following negotiations with government, a CL may not be issued on grounds of affordable price, though other grounds for CL may be invoked

Barring these positive recommendations that were specific asks of the research-based pharmaceutical industry, the report has many downsides:

- The inherent and primary drawback is the suggested methodology, which seems to be driven by a need to arrive at the lowest price at which medicine may be sold in India. The recommendations do not give weightage to IPR and the investments that might have gone into developing a drug.
- The prices for medicines already introduced in developed countries would be worked out for India by dividing the price of the drug in a particular country by the ratio of per capita income of that particular country to the per capita income of India.
- For medicines with an equivalent alternative, the pricing committee would ensure that the cost of the treatment does not increase beyond the cost of treatment with existing equivalent medicines.
- The pricing committee would fix the price of medicines introduced in India (which have no therapeutic equivalent) after considering factors such as costs involved, risks and any other relevant factors.

2014: The New Inter-ministerial Committee for Patented Product Pricing

In February 2014, the Ministry of Chemicals & Fertilizers formed an Inter-Ministerial Committee under the Chairmanship of the Joint Secretary, Department of Pharmaceuticals (DoP), to look into the issue of price negotiations of patented drugs.

It was suggested that while framing a policy for price negotiations of patented drugs, the Committee should factor in the growth of the industry and changes in the disease profile of the country. Also, the healthcare systems of Sri Lanka, Thailand, Malaysia and countries with similar problems to India could be studied. The Committee was also tasked to study the feasibility of bulk purchasing and reduction of commission paid to middlemen.

However, certain sections of the Committee have strong views that patented drugs, with the exception of those that qualify for exemption from price control under Para 32 of DPCO 2013, should be compulsorily brought under the price control mechanism prior to grant of marketing approval. They also opined that price control of patented drugs will not affect Compulsory Licensing (CL) provisions if done carefully, as most EU countries follow a strict price control regime for patented drugs and they resort to parallel import from other EU countries. There is a divergent view within the Committee that a pricing policy on patented drugs might affect the CL provisions under the Patent Act and the CL system under the Patent Act must not be compromised.
OPPI’s position

- In order to create an operative and impactful pricing mechanism there is a pressing need to engage and evaluate recommendations and point of views of key industry stakeholders OPPI strongly believes that competitive market conditions are the most efficient way of allocating resources and rewarding innovation. However, we recognize the unique circumstances in India and are committed to engaging with the Government to discuss pragmatic public policy approaches that will enable the development of government pricing systems that reflect the value of products, include the patient perspective, and reward innovation. Should the Government pursue international reference pricing (IRP), OPPI’s proposed approach to a pricing scheme for Government procurement of patented medicines is described below. IRP should be used as a reference mechanism to facilitate confidential negotiations with individual manufacturers, rather than a rigid or even singular determinant of a product’s price. More specifically: We believe a pricing scheme for patented medicines should be limited to government-procurement schemes. World over, where prices of patented drugs are controlled or negotiated, such control/negotiation is backed by government reimbursement policies and manufacturers get the benefit of bulk volume procurement to offset the price reduction. This is not the case with private markets. Applying economic principles workable in public procurement to private markets will make private markets commercially unviable.

- The BK Singh report recommends referring to government-procurement prices in the UK, Canada, France, Australia and New Zealand, but if India were to consider an IRP system, it would be important to define a balanced basket of comparable countries, such as China, Brazil, Russia, Mexico, and Indonesia, that are “peers” in relation to similar economic size with similar healthcare systems and can serve as a more appropriate reference.

- It is imperative to take into account the value of innovative pharmaceuticals, including the high investment required to develop pharmaceuticals, when determining pricing for patent drugs. To focus only on the price of medicine while ignoring its value to the patient is a short sighted approach. The share of expenditure on medicines is oftentimes a small component of the total cost of healthcare for an individual patient, particularly with the availability of lower cost generics. This can and should be covered through adequate health insurance.

- A pricing scheme, based on therapeutic equivalents and comparison with generic products, will not be an effective price-determination methodology. Government pricing policies should be developed in the context of India’s health system’s objectives and recognize the value of innovation as critical to expanding access and availability of innovative medicines for Indian patients.

- We believe that as GNI/PPP weighting has not been used in any market for any sector, such weighting would result in unreasonably low prices. OPPI suggests the use of ex-factory prices, provided by manufacturers, as the basis for comparison across countries. If a single reference price as a starting point of negotiations is necessary, we suggest a simple average of ex-factory prices without import duties in reference countries.

- Individual OPPI members may be willing to offer further discounts to the resulting reference prices for Government procurement based on purchase volume commitments. Price negotiations must be held confidentially with the patentee.

The Inter-ministerial committee is looking at the issue afresh, and is open to discussing alternate models other than that suggested by the B K Singh Committee. OPPI recognizes the unique nature of the Indian market and is committed to discussing with the government possible solutions that will enable the development of simple, transparent and sustainable government-pricing mechanisms.