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Some Approaches to Pricing Controls for Patented Drugs in India

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Summary

The Government of India has constituted a Group of Ministers (GOM) to finalise the National Pharmaceutical Policy. One of the issues before the GOM is the question of price controls for patented drugs and formulations. Though such controls are distortionary, it appears that there is a direction to propose such controls. This paper examines the features of price control mechanisms in different countries and suggests two alternatives. The first is a Vietnam-like approach where prices are negotiated for government purchases, and are merely intimated and approved for public markets. The second is a mechanism where the price fixed is not higher than the lowest in any of the comparator countries. The paper describes the processes involved in making this mechanism work.

Introduction

In 2006, the Indian government announced that it would adopt a National Pharmaceutical Policy, and circulated a draft policy outlining its intentions. To finalise this policy, a Group of Ministers (GOM) was set up by the government in 2007. The GOM has met several times, and the National Pharmaceutical Pricing Authority (NPPA) has also made a presentation to the GOM in April 2008. One of the elements of the proposed policy is that patented drugs (formulations under the Product Patent protection) that were launched in India after 1 January 2005 would be subjected to price negotiations before approval is given for them to be marketed. A Committee (hereinafter called the Committee), under the chairmanship of Director (Pharmaceuticals) in the ministry, was also formed to propose a system of reference pricing/price negotiations/differential prices which may be applied for price negotiations of patented drugs and medical devices before their marketing approval in India.[1] It should be noted that only a few medicines in India are patented, with the vast majority not covered by any patents.

Under the Drug Prices Control Orders, the government has been regulating prices of drugs and formulations since 1970. Initially, there was a 100-percent control on all drugs and formulations. However, progressive liberalisation reduced it to 74 bulk drugs in 1995. An

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1 Letter from Under Secretary, Ministry of Chemicals and Fertilizers 5/80/2006-PI I dated 22 February 2007.

attempt to reduce it further to 25 bulk drugs in 2002 was unsuccessful, with litigation against the move. The United Progressive Alliance government that came to power in 2004 has been leaning towards greater controls over pricing and, of late, the NPPA has been fairly stringent in monitoring retail prices of drugs and has attempted to levy fines on manufacturers that have transgressed. These issues are in dispute at various forums and relate entirely to generic drugs and formulations. However, it is clear that the government is concerned about the availability of drugs at reasonable prices and this is a key issue for the Committee that is considering approaches to pricing of patented drugs.

The approach of the Committee in its deliberations so far has been towards finding a suitable model of pricing control to apply to patented drugs. This is based on the basic premise that the absence of controls would subject the availability as well as the use of these drugs to market forces which may set prices at unaffordable levels. The Committee has been examining drug price regimens in use in several countries such as Canada, France, the United Kingdom, Australia, Egypt, Brazil, South Africa, Philippines, etc., to find a model that would be replicable in the conditions prevailing in India. An important element in India is the fact that the majority of the drug costs are privately paid for, in the absence of an effective health insurance system that provides access and availability to all. As per the World Health Organization data, only 21.3 percent of the total expenditure on medicine in India is accounted for by the government or insurance, with the balance of nearly 78.6 percent paid for privately. In the United Kingdom, public health and insurance takes care of 83.4 percent of the spending on medicine, and in Germany, it is 78.5 percent. Price regulation in most countries is, therefore, oriented towards the determination of prices at which governments purchase the medicine for delivery through the public health system or to fix the reimbursement rates against insurance claims, but seldom to fix prices prevailing in the open market. The task of the Committee is made more onerous by the need to work out a policy and a process that would be easy to implement in India and, at the same time, be monitorable, effective and efficient.

Price Control of Patented Drugs – Considerations

Several countries have adopted a model at arriving at pre-determined prices for drugs and pharmaceuticals, and at the forefront are those that have a well established national health system such as the United Kingdom, Australia and Canada. However, the determination of prices that manufacturers would be entitled to is invariably arrived at through a transparent, public process, and there is recourse to remedy decisions through appellate forums. Prices in general reflect an understanding of the need to reward innovation and the critical nature of research and development (R&D).

At the same time, it is important to examine some of the concerns that have been expressed about the concept of price control for patented drugs in order to take note of the limitations to this approach. In academic literature as well as industry analyses, there is a consensus that there is no acceptable way to set prices to reward innovation in life sciences and that those who set prices do so with a focus on reducing costs rather than providing incentives for innovators to continue their R&D endeavours.[2]

[2] Caffee, John, Pharmaceutical Market Competition Issues; American Enterprise Institute, Washington, June 2008.

There is a wide body of published literature[3] whose conclusions can broadly be summarised into four major themes.

First, R&D investment in the pharmaceutical industry is motivated by the size of the potential market, as determined by volumes and prices, and the opportunities of risks and rewards on proposed investments. This has led to facile complaints that the industry only seeks to maximise profits and does not have improved health outcomes as a primary concern. It is also maintained that where the size of the market is small, in terms of volume as well as ability to pay, there is little incentive for innovation, and non-government organisations (NGOs) have been quick to point out that there is very little R&D in respect of several known so-called "neglected" diseases. The answer perhaps is in treating R&D in these diseases as a public good and providing for public expenditure through government-supported institutions such as the Council for Scientific and Industrial Research and the Indian Council of Medical Research. This would have two positive consequences. One, there would be national mission to develop drugs that are considered a priority for a country. Two, the costs of R&D would become open and transparent, and thus subject to public scrutiny.

Second, there is sufficient evidence to show that the combination of regulation and economic disincentives, for example, mandatory price reductions, tend to discourage both rapid entry of generics as well as price cutting after entry. Controls[4] appear to affect openness of competition as well as the availability of alternatives.[5]

Third, evidence from European Union (EU) markets indicates that the EU drug price controls have brought a reduced number of drugs to the market, and that these markets offer significantly lower rewards for R&D.

Finally, there is adequate evidence to indicate that the introduction of new drugs tend to yield important offsets in the form of savings in health-care expenditure elsewhere in the system through reduced hospitalisation, after-care, doctor's fees and the like.

In addition to the above are the worries that the future of new discoveries may be less in the realm of chemicals and much more in the area of biotechnology. This is because the biopharmaceutical industry is not in the business of catering to the tastes of the market looking for the next-generation cell phone, but rather it is trying to decipher the intricacies of complex diseases such as diabetes and cancer which require ever more sophisticated scientific techniques. It is not impossible to imagine region-specific and even patient-specific drugs in the future, all of which would be hard put to fit into any standardised price-discovery mechanism.

Any policy on price controls over patented drugs is, therefore, fraught with the above concerns. Ostensibly, the government and public policy initiatives are focused on providing cutting-edge drugs at affordable prices. At the same time, there is strident media and NGO comment[6] about the supposed profits that multi-national corporations (MNCs) are making,

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3 For example, Danzon and Li-Wei Chao (2000); Does regulation Drive out Competition in Pharmaceutical Markets?; Journal of Law and Economics, Vol. 32, No. 2, pp 311-357.

4 Danzon and Furakawa; International Prices and Availability of Pharmaceuticals in 2005; Health Affairs, Vol. 27, No. 1, pp 221-233l.

5 Danzon and Furakawa; Prices and Availability of Pharmaceuticals – Evidence from Nine Countries; Health Affairs Web Exclusive; 2007l.

6 For example, Francis, P.A.; Pricing Patented Drugs; Pharmabiz; 19 November 2008.

that is to say, that there is a justification for controls simply because, according to the writers, MNCs make huge profits. It is fervently hoped that the Committee recognises these arguments as being particularly uninformed and that the sale of patented drugs will, for the foreseeable future, constitute a miniscule proportion of all drugs sold in India and a small fraction of the total sales worldwide. Any form of government pricing controls need to be justified only on the basis of improving affordability to the majority of Indians and there must be mechanisms to ensure that prices finalised are implemented in the form of availability in the general market, outside government purchases, at these prices. Without this, the entire exercise would be futile.

Pricing of Patented Drugs – Suggested Approaches

The mandate for the Committee, therefore, comes down to a determination of how prices might be negotiated, who would be responsible for the negotiations and how to monitor the availability of the drugs in the open market at the negotiated prices. Arising from this are several issues that need to be addressed:

- Who would constitute the decision-making group?
- Are price controls to apply to all patented drugs or only selected ones? Can those below a certain threshold level be left out?
- What inputs would the group need?
- What criteria are to be adopted?
- What should be the principles for arriving at the pricing?
- What will be the period of controls? When would they take effect and how often would they be negotiated?
- If using an international reference pricing system, what should be the comparator countries?
- How are the prices and volumes to be monitored post-introduction?

In this context, the Committee has been studying the practices prevailing in several countries, including Canada, the United Kingdom, France, Germany, Egypt, South Africa, Brazil, Malaysia, Vietnam, Pakistan, etc. As already pointed out, in almost all the countries, price controls apply to those drugs that are purchased for delivery through the public health systems and as a benchmark, for insurance, reimbursement claims, and there is no clear methodology available for ensuring the monitoring of open market prices. In that respect, the initiative is likely to be unique to India.

Constitution of the Group

The approach of the Committee has been to examine the practices prevailing in several developing and developed countries to identify approaches that would be relevant for India. The common feature of all the countries is that there is a body or group, duly constituted, either by law or by executive orders, that is authorised to act on this. The constitution of the group varies but the Canadian concept of the Patented Medicines Prices Review Board[7] appears to be relevant. In the case of France, the United Kingdom and in most European countries,[8] the concerns are primarily with reimbursement of medicine costs through insurance and the public health system.

[7] Global Insight Report: Health Infrastructure; Canada; 2008 www.globalinsight.com.
[8] Global Insight Report: Health Infrastructure; 2008 (relevant countries) www.globalinsight.com.

In India, pricing is approached as a direct intervention in the market and is likely to affect supply and demand. Therefore, the constitution of the group becomes important, for it has to be relevant, transparent and objective. The important constituents should include representatives from the NPPA and Drug Controller General of India. The Department of Pharmaceuticals, as such, may like to keep out of the group as decisions of the group are likely to be debated, discussed, and, sometimes, disputed. It would, therefore, lend greater credibility to the group if it were to be headed by an eminent public figure such as a scientist. The group should contain representatives of the medical profession as well.

Practices in other Countries

In brief, free pricing is available in the United States and in some European countries including Denmark.[9] Malaysia also adopts a free pricing system. In France,[10] there is an agency for market authorization called the Comité économique des produits de santé (CEPS) that decides on the entry of new drugs after an expert-based examination of their therapeutic values. The CEPS sets the reimbursable medicinal costs which are adopted by all the insurers and the public health authorities. The CEPS ensures that prices set are similar to those in Germany, Italy, Spain and the United Kingdom which are taken as the comparator countries for this purpose. In the United Kingdom,[11] prices for patented products are set through a voluntary agreement between manufacturers and the Pharmaceutical Price Regulation System, and these prices remain in force for a period of five years. At the other end of the spectrum are Brazil and Egypt, where price controls are arbitrary. Brazil has introduced a price freeze for the last three years. In Vietnam,[12] the companies submit a price list to the Ministry of Health (MOH) that needs to be approved. There is a two-tier arrangement whereby government purchase prices are negotiated by the ministry separately, with an undertaking on volumes, while open market prices could be different, though they need the approval of the MOH. The prices of patented drugs in Canada are subject to capping and should not exceed the maximum price in seven reference countries, namely, France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. The Price Monitoring and Review Committee is committed to transparency, and publishes the prices every month on its website.

There are, as such, three different models. At one end are countries where there are no price controls and, at the other, where they are arbitrary price freezes from time to time. Among the countries that do try to apply principles to pricing of patented products, the overwhelming majority is concerned with costs of reimbursement for its own government insurance schemes, and not with market prices per se. In other words, companies are free to price their drugs as they see fit in the open market. Evidence from a study of prices in nine countries (Danzon and Furakawa 2007 indicates a range of between 6 and 23 percent from the prices prevailing in the United States for the same drugs). As argued earlier, in the context of India, it is important to recognise that only 20 percent of the drug delivery is through the public health system and that insurance is not yet widespread. Therefore, a substantial quantity of medicines is purchased directly from the market.

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[9] Pharmaceutical Pricing and Reimbursement and Information; European Union reports- Directorate of Health and Consumer Protection; Denmark; February 2007.

[10] Pharmaceutical Pricing and Reimbursement and Information; European Union reports- Directorate of Health and Consumer Protection; France; October 2007.

[11] Global Insight Report: Health Infrastructure; U.K. 2008 www.globalinsight.com.

[12] Global Insight Report: Health Infrastructure; Vietnam 2008 www.globalinsight.com

Issues before the Group

The basic issues that need to be settled *ab-initio* are whether all drugs that are granted patents after 1 January 2005 would be subject to price negotiations, and what would be the criteria that would be applied. In the initial stages, it does not appear to be feasible for the group to engage itself in negotiations over a very large number of products – it would delay the introduction of the products and prolong the process. There may be drugs that would have only small volumes and of limited relevance. In most countries, the drug companies prepare estimates of the likely volumes of the drug in the market before its introduction. These could be used to determine whether price controls need to be applied or not. The deciding group could arrive at a threshold of forecasted sales of a particular medicine. If the sales are less than a specified threshold of volume, in terms of quantities sold (for example, one million doses a year), there is little purpose in bringing the drugs under control. Price control mechanisms could, therefore, work above a particular pre-set threshold in terms of volumes and revenues. The total volumes would then be monitored annually to ensure that the drugs move into the price control regime when the volumes cross the threshold. There could be a simple criteria for the applicants to submit anticipated volumes of sales in the first five years, and drugs that have a threshold of actual sales below a particular volume could be excluded,[13] with the stipulation that if the actual sales are higher than that threshold in any year, the companies would be up for negotiations in the following year.

The group would need inputs from the manufacturers that should include anticipated volumes of sales, the price and strength of formulations in other countries, details on dosages and clinical administration to determine the quantities required for treatment (this would help determine total patient cost). There is little purpose served in looking at company balance sheet data to arrive at R&D costs, overheads and profits – these would be subject to interpretation and dispute, and, in any case, vary from company to company and even from country to country. It is important to reiterate that the purpose of the price controls would be to ensure availability and affordability, not to question the commercial operations of the manufacturers. The group should be satisfied that the prices are lower than those in comparator countries and this could be a simple and straightforward approach to adopt. The Canadian example of using the seven reference countries and ensuring that the prices in Canada are not above any of those could be used in reverse to ensure that the prices offered are the lowest among the comparator counties. Once the price for a dosage is available, then alternate dosages or formulations could broadly be based on the per unit prices to ensure that they are not excessive. In short, since the focus is on costs to the patient, it needs only to be ensured that the costs are lowest, as compared with the comparator countries. Any attempts at averaging, or mean or median pricing are likely to be difficult to interpret.

The group should always consider inflation or increases in prices on an annual basis, and this should be in reference to all drugs and formulations, and not to the patented ones alone.

An important consideration would be whether the drug is “first-in-class”, or alternative drugs or clinical regimen are available. The group would need to satisfy itself about this from medical experts. In the case of a “first-in-class” drug, the price should be fixed simply as at the lowest prevailing price in the comparator countries, and in the case of drugs where alternatives are available, with reference to the price of the alternatives.

[13] Similar approaches are available in other countries.

Comparator Countries

There has been an argument that the practices in developed countries such as the United Kingdom, France, etc., are not relevant in the Indian context. There have been some arguments in favour of the Canadian model, primarily because of its simplicity of approach – the manufacturers are required to give information about prices in other countries, the volumes expected and alternative formulations. As an approach, its simplicity is its elegance while, at the same time, the price levels arrived at may not be relevant for India. Perhaps a combination of the Canadian approach to the prices prevailing in similarly-placed countries could be considered relevant for comparison. The comparator countries need to be chosen carefully with reference to the size and state of the economy, the public health delivery systems, the size of the drug industry and the total volumes and sales. At the bottom end, there is no merit in arguing for price levels that are even lower than in other South Asian countries such as Pakistan and Bangladesh, for Indians pride themselves as being better off.

Post-price Fixing Activities

There are two issues here. The first is data collection on the efficacy of the drugs, volumes sold and comparable therapy, and the second is the monitoring and implementation of the prices set. In a large country such as India, with a federal set-up, this is possible only through the cooperation of state governments. It is important to include them as stakeholders in the exercise; though involving them at the level of price negotiations would be cumbersome and would lead to complaints of bias. It is possible to conceive of a mechanism whereby the notified prices are applicable all over the country, with only variations being due to local taxes. The concept of Maximum Retail Price-based pricing exists in many products and needs to be extended to patented products as well. Once this is done, it is important that the state governments do not engage in fresh discussions and negotiations with the manufacturers for their government purchases, for this would fragment the market and distort prices more than they would be already.

Finally, a two-price format for government purchases as well as for the open market is still an option to be considered, with the pre-set prices being determined as per suggestions above. These preset prices would be applicable to all government purchases, state or centre, while the sale in the open market could be free from controls. A system modelled on that of Vietnam, where open market prices are not negotiated but intimated in advance to the government, could also be considered.

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