5 PRICE, AVAILABILITY & QUALITY OF GENERICS

5.1 SURVEYS IN OTHER COUNTRIES

High costs of medicines have always been an area of great concern to the health authorities in providing healthcare to the mankind. Efforts are made globally to provide quality medicines to the ailing mankind at affordable prices. To achieve this goal, states are moving towards the use of cost effective generic medicines at a very fast pace, in view of their advantage over innovator/patent drug products.

The use of generic medicines has been steadily increasing internationally as a result of economic pressure on pharmaceutical budgets and the expiry of patents on widely used medicines. Generic drugs are indispensable in the world over, including the developed nations like United States, UK, etc.; the actual costs associated with these medications are less than 13% compared with their branded counterparts (Shrank et al., 2009).

Generic medicines provide the opportunity for major savings in healthcare expenditure because of its substantially lower cost than the counter-part innovator (Janodia et al., 2007). Further, in view of the high cost of patented medicines and the fact that most of the essential medicines are going off patent, generic medicines are replacing the patented one speedily throughout the world including the developed countries like U.S. The extent to which generic medicines are prescribed and dispensed varies widely among the countries throughout the world. The countries with highest penetration of generics are the United States, United Kingdom, Denmark, Germany, Netherlands, Canada, etc., where generics are promoted and are considered as a tool to contain rising healthcare costs. In other countries like Spain, Greece, Italy, France etc. where the prices are low, generic products are not actively promoted by the health insurance organizations (http://www.imshealth.com/ims/portal/front/article/02777, 6599_6245190300.html).

Brazilian law requires that generic medicine price be at least 35% lower than the reference price and such prices have to be pre approved by a governmental committee. In Canada, generic drugs on an average provide 45% savings when compared to brand equivalents (canadiangenerics.ca/en/issues/pre_budget_jan03.pdf). Average price difference between generic and branded medicines as well as generic market share in
leading European countries is tabulated in Table 5.1 (www.piribo.com/tocs/sample_V1024.pdf).

FDA evaluated 2070 human studies conducted between 1996 and 2007. These studies compared the absorption of brand name and generic drugs in to a person’s body. The average difference in absorption in to the body between the generic and brand name was only 3.5% (Davit, 2009).

Although the generic medicines are bio-equivalent to their innovator counterparts and are produced in similar facilities according to good manufacturing practices (Davit, 2009), yet it is widely believed and perceived, even in developed world by patients, as inferior in their therapeutic efficacy and quality to branded products (Hassali et al., 2004). Apprehensions about their quality and therapeutic efficacy also found haunting minds of the prescribing physicians throughout the world (Hassali et al., 2010). Marketing practices adopted by the manufacturers of branded medicines also propagate the belief that generics are of inferior quality, as reported from countries in Central and Eastern Europe and independent countries emerged from former Soviet Union (Joncheere et al., 2003).

Lack of effectiveness of generic policies in terms of lowering the prices and in turn increasing the market share of the generic medicines is particularly attributed to their inability to consistently demonstrate medicine quality. The misconception among the public as well as the physician that the innovator/branded medicine is safer and better than generic; further exaggerate the situation and tends to result in greater use of expensive branded product. The most common opinion held by the physicians is their apprehensions about the quality of generic drugs (Hassali et al., 2010).

In developing countries today medicine accounts for 25-70% of overall health expenditure, compared to less than 10% in most high income countries. Up to 90% of population in low and middle income countries must pay for the medicines out of pocket due to lack of social insurance and inadequate publicly subsidized services. The medicines thus are not only unaffordable for large sector of global population; they are a major burden on government budgets.

Many direct and indirect pharmaceutical price regulations remain in effect in member countries of the Organization for Economic Co-operation and Development
However, in many low and middle income countries, national medicine pricing policies have been shifting from price controls to deregulation under the influence of structural adjustment and reform programs. The mechanism of price control usually differs from country to country and it might be regulated by one or more of following criteria.

- Clinical performance
- Economic evaluation (cost effectiveness ratio)
- Cost of existing treatment for the same conditions or disease
- Cost plus (cost of production plus a profit margin)
- International prices of product
- Innovative character of product

Most developed countries implement price regulations for pharmaceuticals that cover the majority of population. Majority of developing countries do not regulate prices of medicines.

**5.1.1 PRICE CONTROL SYSTEM IN OECD COUNTRIES**

The following is an overview of the span of the price control in different countries:

- Price control used for reimbursement pharmaceuticals: Austria, Finland, France, Ireland, Italy, Latvia, Lithuania, Poland, Slovenia, Spain.
- Price control used for all products: Belgium, Cyprus, Hungary, Greece, Slovakia.
- Price control used for all products (except OTC): Norway, Portugal, Romania.
- No (direct) product price regulation: Denmark, Germany, The Netherlands, Malta, Sweden, UK.

Throughout the OCED countries, free or market based pricing is commonly used in markets for products sold over the counter (OTC), usually with exceptions in cases where the OTC products are reimbursed by the cover scheme. Germany and the United Kingdom are unusual among OCED countries in that pharmaceutical firms are free to sell their products (prescription medicines as well as OTC products) there at any price once they have been approved for marketing, irrespective of any reimbursement price decision (i.e., there is neither price regulation nor de facto price regulation).
5.1.2 METHODS OF PRICE REGULATION IN OCED COUNTRIES

1. Direct price regulation: The most direct method is for governments to set the sales price and prohibit sales at any other price. France, Italy and Spain require that prices of new products and price changes of existing products be approved if they are to be reimbursed by the social insurance system. Wholesale and retail distribution margins are also regulated, such that governments control the retail prices charged to insurers or consumers.

2. Cost-plus pricing system: Under this system, prices are based on the R & D, manufacturing, sales and marketing costs for each product, as estimated by the authorities.

3. International comparison: The prices are set according to the prices prevailing in several other reference countries. Since 1993, Italy has used international price comparison as a basis for setting the domestic prices. Prices of pharmaceuticals are not allowed to exceed a level known as the “average European price”, corresponding to the prices in France, Germany, the UK and Spain. In Canada, the Patented Medicines Prices Review Board (PMPRB) sets a maximum “factory gate” price for new, patented drugs, based on the median price in seven OCED nations (France, Germany, Italy, Sweden, Switzerland, the UK, and USA).

4. Reference pricing: In this system a reimbursement price is set for a therapeutic category of drugs and patients pay the difference, if any, between the costs of the product prescribed and the reference price. The reference price may be the average price of drugs in a category (Germany, the Netherlands), the lowest priced drug (New Zealand), or the lowest priced generic drug plus some amount (10% in Sweden). New and innovative drugs are not covered by this system.

5. Rate of return regulation (profit controls): Some countries impose profit controls on drug manufacturers. The controls limit the amount of profit a company may earn per product or within a specified period of time. The UK Pharmaceutical Pricing Regulation Scheme (PPRS) places limits on the profit that a company can gain from sales to the UK National Health Scheme (NHS). If the limit is exceeded, the company may be required to either compensate the government for any excess profits or accept a price cut.
6. **Cost-effectiveness controls:** Australia pioneered this approach within its Pharmacy Benefit Scheme (PBS), a system of regulated prices and subsidies.

7. **Other methods:** In Norway negotiations are conducted with the manufacturer until an acceptable price is agreed upon. The prices of new products are compared with those of similar products in other European countries, particularly in the country of manufacture. Pre-approval of prices from the government is must before marketing of prescription only medicines.

### 5.1.3 PRICE CONTROL IN SOME SELECT OCED COUNTRIES

**UNITED KINGDOM:** In UK prices of all prescription medicines supplied to the NHS are controlled, branded medicines through the Pharmaceutical Price Regulation Scheme (PPRS) and generic medicines through the Drug Tariff. The retail prices of over the counter (OTC) medicines are not controlled. The PPRS comprises of two main components: Profit Controls and Price Controls.

Profit Controls set a maximum level for the profits that a company may earn from the supply of branded drugs to the NHS. Exceeding this level will require a repayment of excess profits to the Department of Health (DH). The maximum and minimum level of profits are based on a target rate of return, which is the higher of 21% return on capital employed (ROC) and six percent return on sales to the NHS.

Price Controls: Under the PPRS, the companies have freedom of pricing for New Active Substance (NAS) within the constraint of their profit target. Where a new product has not been subject to a new active substance marketing authorization, companies must seek the department’s agreement to the price of the new product.

Reimbursement Prices for Generics: Reimbursement prices for generics are set and published monthly in the Drug Tariff (DT). The DT has three main categories, namely category M, A and C. The reimbursement prices of category M are set quarterly based on manufacturers’ prices after discount. Category A prices are based on list prices of a basket of 2 main full line wholesalers and 3 manufacturers. Category C prices are not readily available and their prices are based on a particular brand or manufacturer.
CANADA: Canada established a system to regulate prices of patented medicines in 1987. The regulation limits the prices that a manufacturer can charge according to a formula that differs depending on which one of the three categories the drug is assigned to. The categories define whether the drug represents an innovation or improvement over existing products.

UNITED STATES: In USA manufacturer set list prices for new products freely at market entry. However, the US government uses de facto price regulation in case of federal purchases (e.g. Veterans Health Administration) and in the Medicaid social assistance program that provides coverage for about 19% of the US population.

AUSTRALIA: Australia pioneered the cost-effectiveness controls approach within its Pharmacy Benefit Scheme (PBS), a system of regulated prices and subsidies. Approximately 95% of prescriptions issued in Australia are subsidized under the PBS. It has two categories of recipients of PBS subsidized medicines: “general” patients and “concessional” patients (the elderly, disabled, unemployed, and low-income workers). To ensure that pharmaceutical firms participate in the scheme, the Pharmaceutical Benefits Pricing Authority (PBPA) determines a list of agreed prices which pharmacists pay the pharmaceutical firms for their drugs. If the agreed price is above the price paid by the customers, then pharmacists claim the difference from the government, and thus the consumption of medicines is essential subsidized. To be listed, a drug must meet efficacy, safety and quality standards. Generally the drugs that are cost effective are listed at the agreed price.

5.1.4 WHO-HAI METHODOLOGY TO MEASURE MEDICINE PRICES

Globally, medicine prices are often high and unaffordable not only for large sectors of the population in low- and middle- income countries, but also for sizeable segment of the population without adequate social protection or insurance in high income countries. Too little is known, however, about the actual prices people pay for medicines and how these prices are set. Patients, and even government authorities dealing with medicines, often do not know what the lowest prices are and how they vary (Creese, 2003). Sound national medicine pricing policy needs to be evidence based and grounded in reality, requiring empirical data about the real affordability of medicines for the whole population.
Moreover, drug has to be available at dispensing site; not out of stock, back ordered or expired. The drug has to be affordable by the intended patient. Access and availability are meaningless, if the patient does not have financial resources to enable attaining possession of the product. The availability as well as affordability of essential medicines is the key challenge for the health-care providers specially, in developing and transitional countries. Access to healthcare and therefore, essential medicines is a fundamental right, enshrined in international treaties and recognized by governments throughout the world and it cannot be fulfilled without equitable access to essential medicines.

National policies, medicine pricing and procurement strategies are required to ensure that medicines are affordable. High medicine prices are one of the biggest obstacles to access medicines. The difficulty in finding reliable information on medicine prices and availability and therefore analyzing their components hinders government in constructing sound medicine pricing policies or evaluating their impact. Prices of some medicines frequently vary between countries (Wagner et al., 2004). Some countries have publicly available prices but the information’s use is obstructed by country specifics that apply and language barriers.

The prices of medicines are also influenced by factors such as whether the country observes patents and the level of flexibility allowed under international treaties- which is eventually incorporated in to national patent law, the level of domestic production, national policies on protecting local industries, the level of competition between pharmaceutical manufacturer and price regulation policies.

Therefore, in order to monitor the prices and cross country comparison of medicine prices WIHO-IIAI recognized the need for a standard methodology to measure medicine prices in different countries so that a clear picture of what patients actually pay for medicines in low and middle income could be obtained. These two organizations published jointly a manual (www.haiweb.org/medicineprices) which describes a methodology for collecting data and measuring medicine prices in various countries. Following pilot testing in Armenia, Brazil, Cameroon, Ghana, Kenya, Philippines, South Africa and Sri Lanka, the methodology was launched at the 2003 World Health Assembly for field testing. The methodology was kept under review and further developed in collaboration with the survey managers during the field surveys undertaken. This enables
international comparison to be made, since all surveys have used the WHO/HAI standardized approach.

Till date, over 60 surveys had been undertaken across the globe, from Cameroon and the Cook Island to El Salvador; South Africa and the Syrian Arab Republic. These surveys provided reliable evidence showing for the first time, some startling facts about the affordability and availability of medicines. The results of these surveys revealed that in many low and middle income countries:

- Medicine prices are high, especially in private sector (e.g., over 80 times an international reference price).
- Availability is low, particularly in public sector (even no stocks of essential medicines).
- Treatments are often unaffordable (e.g., requiring 15 day’s wages to purchase 30 day’s treatment).
- Government procurement system inefficient (buying expensive originator as well as cheaper generics).
- Mark-ups in the distribution chain are excessive.
- Numerous taxes and duties on medicines.

The results confirm that in many countries access to essential medicines is hindered by low availability and unaffordable prices. For example, Salbutamol inhaler—an important medicine for asthma was found missing in public sector of many countries and when purchased from private sector, cost the lowest paid government worker several days wages (Table 5.1.4.1). The price of Atenolol 50 mg. tablets was found over 20 times the international reference price except India, where it is still high at 5 times the reference price (Gelder, 2006). Retail price of Ranitidine 150 mg (Zantac) is higher in Vietnam than Australia, New Zealand and Pakistan (Bala et al., 1998). Low price generic Ceftrixone one vial daily for seven days costs 15.9 days wages while 83 days wages extra for its branded counterpart (Ngyuen et al., 2009). Because of lack of medicine pricing policy in Thailand same generic medicines were procured and sold at different prices. The median mark-ups in private sector in innovator is 22% while it is 31% in public sector, while it is 80% and 96% for generic respectively (Sooksriwang et al., 2009).
The underlying purpose of the price and availability survey is to bring about changes that will result in lower prices and improved availability to patients and, hence increased access to needed medicines. The low availability may be the result of under-budgeting or spending the available money on high cost originator products when a quality assured generics are available or using the funds for hospital and not for primary care medicines. In private sector low availability may be due to price regulations or there may be limited demand. A range of policy options is open to improve availability like prioritizing the drug budget with particular emphasis on essential medicines. Further, procuring low cost quality generics to treat more patients with the same resource allocation and providing essential chronic disease medicines through private sector at public sector procurement prices in case of poor public sector and dominating private sector.

In case of single source products, for which no generic versions are available in a country, a monopoly situation exists - the government may go for therapeutic substitution, direct price negotiations, or use of the flexibilities compatible with the TRIPS Agreement. One of these flexibilities is to issue compulsory licenses to import or to manufacture the generic version of patented medicines. In case of multi source generic products price control free market will ensure their availability and patient can purchase the best value generic product if generic substitution is encouraged. The government can further regulate to ensure that the generic medicines on the market are of good quality with controlled mark-ups and free from duties and taxes.

Most of the initial medicine price surveys have drawn attention to poor availability in the public sector suggesting a widespread need to focus on this vital issue. Some countries have acted on the evidence generated through these surveys to improve the availability and affordability of essential medicines. The Government of Indonesia reduced the prices of 458 generic drugs from 50%-70% and implemented regulations to standardize prices for all public purchasing; the Government of Lebanon reduced prices of a quarter of medicines and introduced regressive mark-ups. Government of Nigeria has drafted a medicine policy based on its survey findings and Government of Tajikistan has abolished 20% VAT on medicines. The cost of medical care impoverishes or is simply beyond the reach of many people in developing countries. Amid the gloom, however, there is some light. Simply collecting data and presenting it to the government can stimulate action (Richards, 2006).
5.2 SURVEYS IN INDIA

5.2.1. INDIAN SURVEY AS PER WHO-HAI METHODOLOGY

India is well known for its growing pharmaceutical industry that offers low cost generics to the world. At home India faces the challenge of equal access to affordable and quality essential medicines for its own people (Kotwani et al., 2007). Despite tremendous pharmaceutical growth in last two decades, access to essential medicines remains an issue for common citizens. Affordability continues to be an important barrier to access of medicines for the poor population (Falkingham et al., 2007). A comparison of prices of medicines in India vis-à-vis other countries indicate that medicine prices in India are the lowest, as compared to rest of the world (Table 5.2.1.1) (Singh, 2010).

Medicines prices in India are among the lowest in the world; still, the Indian patients do not have access to ‘cheaper’ generics. In India, generic products are not required to be labeled with lower MRP as compared to their branded counterpart (as in Brazil). These are sold at their labeled prices, which are usually exorbitant and comparable to their branded counterpart. Generic medicines, therefore, in India, do not provide any affordable alternative to their branded counterpart.


The drug companies were found selling generic products to retailer at much less price than their labeled maximum retail price, allowing them to earn multifold trade margins out of sale of generics. Such unethical marketing practices were not found in other countries. Comparative price structure of branded and branded generic medicines (maximum retail price, price to retailers and profit margin) for some common medicines in India is tabulated in Table 8.1.1

To assess medicine prices and availability of essential medicines in India six surveys were undertaken simultaneously in five States of the country using the World Health Organization and Health Action International methodology between October 2004 and January 2005 (i) to measure the price patients pay for certain common medicines in different states and price variations in the States (ii) to know difference in prices of innovator and their generic equivalents (iii) to compare the prices in public and private
sector (iv) to know the procurement price in public sector and to assess availability of medicines in public and private sectors (Kotwani et al., 2007). This was the first such study conducted simultaneously at six different sites in one country using same methodology. \textit{The task of conducting this study in the State of Haryana was entrusted to the research scholar by the WHO-HAI. The results of the study were presented by the research scholar in the 38th annual conference of Indian Pharmacological Society held at Chennai in December 2005 (Singal et al., 2005).} The methodology was field tested in many other countries and one such survey had already been conducted during April-June 2003 in the State of Rajasthan (Kotwani, 2006).

Median availability of any generic medicine in public sector was poor in all the States with 0 % in West Bengal and 30 % in Chennai as detailed in Table 5.2.1.2. The corresponding results for the availability in private sector are given in Table 5.2.1.3. The State Governments were found procuring medicines at public facilities for distribution to the patients at reasonable prices. The median MPR for all surveyed medicines was lowest for Chennai (0.27) and highest for Karnataka (0.48) implying that all State Governments were buying medicines at much lower prices than the MSH reference price (Kotwani et al., 2007). There was also little variation in the selling prices of the same medicine among different States indicating effect of mandatory labeling of MRP on medicine pack in India. Medicines were also found being sold at their printed maximum retail price in most of the outlets. \textit{The results of the study carried out in the Haryana State were presented by the researcher in the 38th Annual Conference of Indian Pharmacological Society held at Chennai in December 28-30, 2005.}


\textbf{CONCLUSION}

The prices of the medicines are regulated by adopting various price control mechanisms like direct price regulation, cost plus pricing, international comparison, reference pricing, profit control and similar other methods throughout the world to ensure availability and affordability of medicines to their people. The price control regulations in India on medicines to ensure their availability and affordability exist since last more than fifty years but it failed to achieve its purposes as per the medicine price surveys carried out
in different parts of the country during 2004 by the WHO-HAI. As per these surveys the availability of generic medicines in government facilities was negligible with lowest in West Bengal. The availability of generic medicines in the private sector was although found satisfactory yet unaffordable to the larger section of the society. The study provides baseline data for interventional studies which can be planned to improve the availability of medicines in the public facilities of concerned State and general affordability to the consumer. Surveillance of medicine prices using the WHO-HAI methodology is a useful tool for international price comparisons of medicines and designing appropriate corrective system to improve the availability and affordability of medicines.