SPEED POST

No. 31011/5/2009-PI-II(pt)
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
*****

Shastri Bhawan, New Delhi
Dated 21st February, 2013

To

1. Department of Industrial Policy & Promotion,
2. Department of Commerce,
3. Ministry of Health and Family Welfare,
4. IDMA/BDMA/OPPI/IPA/FICCI/SPIC/CIPI/FOPE and all the other stakeholders.

Subject: Report of the Committee on Price Negotiations for Patented Drugs.

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Sir,

I am directed to refer on the above subject and to say that the Department had setup a Committee to examine the issues of Price Negotiations for Patented Drugs. The said Committee had since submitted its report to the Department which has been uploaded on the website of the Department www.pharmaceuticals.gov.in.

You are requested to provide your comments if any urgently and latest by 31st March, 2013 so that the Department could take a view on the report. The comments could also be sent by e-mail at uspi3-pharma@nic.in

Yours faithfully,

(Raj Kumar)
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Tele: 23071162
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Copy to:

Shri V.K. Tyagi, DIA with the request to upload theCommittee report on the Department's website.

(Raj Kumar)
Under Secretary to Govt. of India

Report of the Committee

On

Price Negotiation for Patented Drugs

Table of Contents

Executive Summary

The erstwhile Department of Chemicals & Petrochemicals (Now Department of Pharmaceuticals) constituted a Committee, in 2007 to suggest a system of reference pricing/ price negotiation /differential pricing etc that could be applied for price negotiation of patented medicines and medical devices before their marketing approval in India. The Committee was to interact with various Pharmaceutical Industry Associations and study the available material on the subject. The Committee had 20 meetings since its inception and in some of them the viewpoints of Industry, NGOs and other stakeholders was also heard.

A second round of consultations was started with the stakeholders (Pharma Industry Associations, FICCI and NGOs) from March 2010. A **Study** was also commissioned at the **Rajiv Gandhi School of Intellectual Property Law, IIT Kharagpur** to find out the mechanisms of price control of patented drugs in various other countries. The Committee went through the Study Report.

After elaborate interactions with various stakeholders and going through various related papers and articles, the Committee is of the view that the prices of the patented medicines, even after negotiation, will remain unaffordable to the majority of the population and therefore the government should expand the coverage of Healthcare and Insurance Scheme (at least for prescription medicines) for all the citizens who are not covered under any other insurance /reimbursement scheme.

The committee deliberated that there could be the three categories of patented medicines(i) A totally new class of medicines which have no therapeutic equivalence,(ii)A medicine that has therapeutic equivalence but also has got a therapeutic edge over the existing one and(iii) A medicine that has similar therapeutic effectiveness compared to the existing one. These three categories are to be treated differently while fixing the price.

The Committee observed that the prices of patented medicines are very high and even if the prices are calibrated on Gross National Income with purchasing power parity, the prices are much beyond the reach of general masses of the country. In case the prices are fixed unilaterally by the Government for open market, it may result in the non availability of the medicine.

Therefore, the Committee recommended that the government should expand the coverage of Healthcare and Insurance Scheme (at least for prescription medicines) for all the citizens who are not covered under any other insurance /reimbursement scheme and the price negotiations be done for the patented medicines for the Government procurement/reimbursement and for Health Insurance Coverage by any other Insurance company.

The committee recommended Reference Pricing keeping in view the Gross National Income and Purchasing Power Parity. The countries to be referred are those where there is strong public health policy and the government has strong bargaining power while negotiating the prices of the medicines. The committee also deliberated upon the methodology of price fixation for such patented medicines which are introduced for the first time in India itself and suggested evidence based cost based pricing.

CHAPTER 1

INTRODUCTION

1.1 Background

During the year 2006, it was decided that a new National Pharmaceutical Policy will be adopted and accordingly a draft Cabinet Note was prepared. One of the elements of the proposed policy is that Patented Drugs launched in India after 1st January, 2005 would be subjected to price negotiations, before being given the marketing approval. The price control on patented drugs is based on the basic premise that the medicines market is not a perfect market and the absence of control on the prices of patented medicines may lead to unaffordable prices for the masses. The other reason is the absence of an effective health insurance system to ensure access and affordability of all medicines to all. It is well known that households are increasingly paying out of pocket for the purchase of healthcare and more so for drugs. As per a WHO study, nearly 21% of total expenditure on medicines in India is accounted for by government or insurance and nearly 79% is paid for privately(out of pocket) in contrast to the scenario in developed countries.

1.2 Composition of the Committee

The erstwhile Department of Chemicals & Petrochemicals, vide letter no 5/80/06-PI.I dated 01.02.2007 constituted a Committee with Shri Gurdeep Singh, the then Director(PI) as Chairman and DCG(I), Dir(NIPER) (or his representative), Director(NPPA), Executive Director (Pharmexcil), Additional Industrial Advisor(Shri P.U.M. Rao) and US(PI-I) as Members. A copy of the letter dated 1st February 2007 is available vide **Annexure I**.

On completion of tenure of Shri Gurdeep Singh, the Committee was reconstituted by replacing him with Shri Paresh Johri, Director as Chairman. Under Shri Paresh Johri's Chairmanship, the Committee consulted almost all stakeholders and submitted an interim report too. After the end of deputation period of Shri Paresh Johri, in December 2009, Shri B. K. Singh joined as Director (PI) and took over as the Chairman of this Committee. The Committee

also co-opted the representatives from Department of Industrial Policy & Promotion (DIPP), Ministry of Health & Family Welfare, Pharmexcil and Shri V.K. Tyagi Deputy Industrial Adviser in the Department as Members. A second round of consultations was started with the stakeholders (Pharma Industry Associations, FICCI and NGOs). The Committee went through the Study Report submitted by the Rajiv Gandhi School of Intellectual Property law, IIT Kharagpur.

1.3 Deliberations of the Committee

As per the mandate, the Committee was to interact with various Pharmaceutical Industry Associations and study the available material on the subject. Based on these, the Committee was expected to propose a system of reference pricing/ price negotiations/ differential prices, which could be applied for price negotiation of patented drugs and medical devices, before their marketing approval in India. The Committee had several meetings since its inception and in some of the meetings, viewpoints of Industry, NGOs and other stakeholders were heard.

A second round of consultation was started with the stakeholders (Pharma Industry Associations, FICCI and NGOs) in March 2010. A **Study** was also commissioned at the **Rajiv Gandhi School of Intellectual Property Law, IIT Kharagpur** to find out the mechanisms of price control of patented drugs in various other countries. The Committee went through the Study Report.

1.4 Context

Prior to 1970, 85% of medicines available in India were produced and distributed by multinational corporations (MNCs) and the prices of drugs in the country were among the highest in the world. However, the trend of high prices tended to reverse after 1970s, in the wake of a series of policy measures and mainly due to introduction of process patents for drugs. But, with the introduction of Product Patent in 2005, a debate has started on the impact of product patent on the Indian Pharmaceutical Industry including the issue of the

prices of the patented drugs and their accessibility. This apprehension has been raised in various fora. The lack of public health policy and absence of health insurance cover to majority, leading to a high ***out of pocket expenditure*** **on** ***medicines*****,** have raised concerns further.

1.5 Patent Drugs Scenario

Indian Pharmaceutical Industry is over US$ 21 billion and the domestic turnover is around US$12 billion. As per an estimate, the total market turnover of patented medicines in India is around US$ 5 million. But the Indian market for patented medicines is expected to grow fast. The main reasons are:

(i) Appreciable upgradation of patent infrastructure in the country over the past few years to support new laws with the addition of patent examiners,

(ii) Decentralization of patent-filing process and digitization of records and lastly;

(iii) The increase of population in highest income group from present 10 million to 25 million in next 5 years.

CHAPTER 2

DRUG PRICE CONTROL ORDER 1995

The prices of drugs in the country are fixed/revised/monitored as per the provisions of Drug Price Control Order (DPCO), 1995 which is based on the existing Pharma Policy of 1994. The policy delineates certain criteria on which price control is based. These criteria include:

(i) Sales turnover,

(ii) Market Monopoly and

(iii) Market Competition.

As per DPCO 1995, drugs are categorized as:

(i) Scheduled Drugs and

(ii) Non-Scheduled Drugs.

2.1 Schedule Drugs: These are the drugs which satisfy the criteria under price control. The prices of Schedule Drugs are fixed on the basis of cost analysis and the formula used to fix the retail price is:

Retail Price = (M.C.+ C.C.+P.M.+P.C.)x(1+MAPE/100)+ Excise Duty

Where M.C= Material Cost, CC= Conversion Cost, P.M.= Packing Material Cost and PC= packing Cost. MAPE denotes Maximum Allowable Post – Manufacturing Expenses and at present it is 100%.

***Imported Scheduled Drugs*:** For imported Scheduled Drugs, the landed cost forms the basis for fixing its price along with such margin, to cover selling and distribution expenses including interest and importer's profit, the maximum limit of which fifty percent of the landed cost.

2.2 Non-Scheduled Drugs: These are the drugs over which there is no control on the Launch Price. However, the prices of these drugs are monitored on monthly basis (based on ORG-IMS data) and actions are taken if there is increase in the price of the drug is more than 10% in one year and certain criteria of turnover and market share is satisfied.

Imported Non-scheduled Drugs: There is no control over Launch Price of the imported drugs and the prices are monitored in the same way as for other non–scheduled drugs.

There is no price control/monitoring for Patented Drugs as per existing provisions of DPCO' 95.

CHAPTER 3
DIFFERENT PRICING MODELS

3.1 Reference Pricing

The prices of the product are fixed on the basis of the prices in other similarly placed countries. The immediate intuitive appeal of reference pricing is clear i.e. to pay a similar price as paid by the buyers in other countries, for products that provide a similar benefit.

However, reference pricing has negative consequences for both patients and pharmaceutical innovation. What it fails to take into account is the variety of both products and patients and their paying parity.

3.2 Differential Pricing

Prices are fixed differently for different type of purchaser, for example, Government procurement and private market. Differentials can take the form of quantity rebates, discounts to key purchasers, concessions for long-term contracts, and so on.

The first advantage of differential pricing is simply that more patients would gain access to essential medicines if they were cheaper. Affordability is not confined to those who can afford everything but also to those who can afford nothing at all. Affordability is graded. Differential pricing brings access to more patients.

The second advantage of differential pricing is that the financial sacrifice is limited, whereas the benefit to recipients can be life-saving. For this reason alone, differential pricing is, in principle, very desirable.

However, there is always an apprehension in differential pricing that the artificially low-priced drugs migrate back into full-price commercial markets.

3.3 Cost based Pricing

The prices are fixed based upon the various input costs and a prescribed trade margin. This method has advantages of easy to calculate, minimal information requirements, easy to administer, insures seller against unpredictable or unexpected costs, simplicity etc. Further price increases can be justified in terms of cost increases.

However, there are problems with this approach. It is not as easy to determine the cost of a product as one might imagine. Companies have fixed and variable costs. The variable costs can usually be directly attributed to each product. However, the fixed costs are divided by the total sales to arrive at the average fixed cost for each item. If the sales increase, the average fixed costs decreases. In other words, up to a certain point, the more you make a good the less it costs you to make it. Likewise, when a company makes more than one product it has to decide which of the overheads of the company as a whole to attribute to each of the products. There are other disadvantages to cost-based pricing in terms of marketing.

3.4 Price Negotiations

Prices are fixed after negotiations with the manufacturer. This methodology has the advantages of proper decision-making by both buyer and seller. But in absence of the details of cost of the input raw material, R&D cost etc. and the volume of procurement to be made, it is very difficult to finalise a negotiated reasonable price.

CHAPTER 4

COMPULSORY LICENSING IN PATENTS ACT

Compulsory Licensing is a system whereby the Government allows third parties (other than patent holder) to produce & market a patented product or process without the consent of the patent owner. This mechanism enables timely intervention by the Government to achieve equilibrium between two objectives- rewarding inventions and in case of need, making them available to the public during the term of the patent. The following are the provisions relating to Compulsory License in the Indian Patents Act.

4.1 Section 84: Compulsory License:

As per this provision of the Patents Act of India, at any time after the expiration of three years from the date of the grant of patent, any person interested, may make an application to the Controller for grant of Compulsory License on patent on any of the following grounds, namely:-

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.

4.2 Section 92: Special provision for Compulsory License on notification by the Central Government:

As per the Section 92 of the Indian Patents Act, if the central Government is satisfied, in respect of any patent in force, in circumstances of national emergency or in circumstance of extreme urgency or in case of public non-commercial use, that it is necessary that Compulsory License should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and thereupon following provisions shall have effect, that is to say:

(i) the controller shall on application made, at any time after the notification, by any person interested grant to the applicant a license under the patent on such terms and conditions as he thinks fit .

(ii) in setting the terms and conditions of a license granted under this section, the Controller shall endeavor to secure that the articles manufactured under the patent shall be available to the public at the lowest price consistent with the patentees deriving a reasonable advantage from the patent right.

4.3 Section 92A: Compulsory License for export of patented pharmaceutical products in certain exceptional circumstances:

As per the section 92A of Indian Patents Act, Compulsory License shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided Compulsory License has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical product from India.

4.4 Section 100: Power of Central Government to use invention for purposes of Government:

As per the section 100 of Indian Patents Act, Central Government has the power to use inventions for the purposes of Government. The provision states that after an application for a patent has been filed at the patent office or a patent has been granted, the Central Government and any person authorized in writing by it may use the invention for the purposes of Government in accordance with the provisions of Chapter XVII of the Patent Act, 1970 (as amended in 2005).

CHAPTER 5
VIEWS OF STAKEHOLDERS

Various Pharmaceutical Industry Associations and NGOs were invited separately for their views on the methodologies of pricing of patented drugs. Department of Industrial Promotion and Policy also sent its written view.

5.1 Department of Industrial Promotion and Policy (DIPP)

The DIPP has commented that *"if it is decided that Price Negotiations on Patented Drugs should be carried out then, the following issues must be ensured:-*

(i) Negotiations should be carried out with caution; as the case for Compulsory License on the ground of unaffordable pricing of drugs [Section 84(b) of the Patent Act] will get diluted.

(ii) Re-Negotiations of the prices at periodic intervals should be an integral part of the negotiation process. "

5.2 Organization of Pharmaceutical Producers of India (OPPI)

The OPPI feels that Price Negotiations for Patented Products should be made only for Government purchases and should not be linked with Regulatory approval.

5.3 Indian Pharmaceutical Alliance (IPA)

The IPA was of the opinion that there should be some form of control over the prices of Patented Drugs as there is an impression in the mind of the public that the prices of such medicines are very high. It was opined that this is mainly because Anti-Cancer/Anti-AIDS drugs which are patented, are being made available in the Indian domestic market at very high price. It was also suggested that the reference pricing should be of the developed countries like UK, Australia and New Zealand where the 80% of the expenditure being incurred on public health is borne by the government. As government is footing the bill of healthcare, they are negotiating the price of Patented Drugs, being

made available in these countries, in a much better way. The IPA was of the view that we should not take the reference prices of patented drugs of South-East Asian Countries as the Indian Pharma Industry is in a much stronger position compared to these countries.

5.4 Federation of Pharma Entrepreneurs (FOPE) & Confederation of Indian Pharmaceutical Industry (CIPI):

The representative of FOPE, submitted the written views to the Committee. Although FOPE supported price negotiation mechanism for patented drugs, it very strongly advocated that it must be ensured that the Compulsory License provisions are not diluted while going for price negotiation.

The representative of CIPI, suggested that the reference on which the price is to be negotiated should also be decided by the Government.

5.5 Indian Drug Manufacturer Association (IDMA)

The representatives of IDMA suggested that there should be price negotiation for all patented drugs. In this connection they suggested that Form 10 of DPCO 1995 could be amended to include an annexure where the importer of the patented drugs could be asked to indicate the price on which they would like the drug to be sold in India. They should also be requested to give the brake up of the cost.

Further, IDMA suggested that the issue of Compulsory License and price negotiation should be dealt separately. Moreover, as it would take lot of time before a Compulsory License is issued, it would be better if the price negotiations are done on patented drugs.

5.6 Lawyer's Collective HIV/ Aids Unit and "Campaign for Essential Medicines" Medecins Sans Frontiers(MSF)-NGOs

The representatives of **MSF Access Campaign** stated that the price negotiation should not weaken the position of Compulsory License of the Patent

Act. As regards the plea of the patent holder that they had spend a large sum on R&D, it was mentioned by them that most of the funds for R&D come from the Governments of their countries. This was seconded by the other members of the NGOs. They further stated that if the cost of production of the patented drugs is not known, it would be impossible to negotiate the price in a proper manner.

5.7 Federation of Indian Chamber of Commerce and Industry(FICCI)

The representative of FICCI informed that price negotiation on medical devices is very difficult as there is a structural change very often in medical devices because of which the patent life of the product is cut short from 20 years as more innovation is made on these devices. It was also mentioned that the higher prices of medical devices were not because of the manufacturers but because of the hospitals/institutions where these are being supplied.

CHAPTER 6
MODELS IN DIFFERENT COUNTRIES

Based on the **Study Report** submitted by **Rajiv Gandhi School of Intellectual Property Law, IIT Kharagpur** and a **Study Report** of ***Institute of South Asian Studies*** on **"Price Control on Pharmaceutical Products in India"**, the models of price control of Drugs (Patented / non-Patented) in various countries are as follows:

6.1 Australia

The healthcare in Australia is provided by publicly funded Medicare System along with private system. The medicine part of the healthcare system is taken care of by Pharmaceuticals Benefit Scheme (PBS). Around 75% of all prescriptions dispensed in Australia are subsidized under PBS which is administered by the Department of Health and Ageing through a body Pharmaceutical Benefit Advisory Committee (PBAC). Pharmaceuticals Benefit Pricing Authority (PBPA) recommends to PBAC that at what price a drug should be listed on PBS. PBPA is an independent non statutory body having an independent chairperson, industry nominee, consumer nominee, representatives from Industry and Health department. It uses information on prices prevailing in UK, New Zealand, price alternatives listed on PBS and expected expenditure to recommend a price for a new drug. Hence, the pricing methodologies used by PBPA are benchmarking pricing, cost plus pricing and average monthly treatment cost. Prices of drugs listed in PBS are reviewed at least once a year. In Australia, the evidence of economic studies is mandatory part of the dossier for the *New Drug Application.*

6.2 Canada

Canada has a public funded Health scheme, known as "Medicare", which provides comprehensive coverage. For the pricing of patented medicine under Medicare, there is Patented Medicines Price Review Board (PMPRB), a quasi-judicial body, which ensures that prices offered by manufacturers of patented

medicines are not excessive. The Board compares the proposed price either to the prices of existing drugs in Canada, or to the prices of seven markets designated in the regulations (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the USA.

Prices of patented drugs that do not provide a significant breakthrough in treating diseases must not exceed the maximum price of other drugs that treat the same disease. Once the introductory price is established, subsequent price increases are limited to changes in the Consumer Price Index. The excessive price criterion used in assessing the price of a new drug depends on the degree of innovation of the new product as categorized by the PMPRB using a three-tiered scale. Category 1 includes the drug products that are a new strength or a new dosage form of an existing medicine. The price is considered excessive if it does not bear a reasonable relationship to the average price of the existing medicine in comparable dosage forms. Category 2 includes drug products that represent a therapeutic breakthrough or provide a substantial improvement (including cost savings) over comparable existing medicines. The price is excessive if it exceeds the prices of comparable products in the therapeutic class and the international median price of the medicine. Category 3 has drug products that provide moderate, little or no therapeutic advantage over comparable medicines. For these so-called me-too drugs, the price is judged excessive if it exceeds the price of comparable products in the Canadian market. PMPRB may use the international median price as a reference when it is impossible or inappropriate to identify comparable drugs in Canada.

The PMRB guidelines indicate that the cost of therapy using a new drug must not exceed the cost of existing therapy in Canada with older drugs. It relies on the prices of the drugs in the same therapeutic category whether patented or generic.

China

In China, the health insurance system is privatized with 29% people having insurance. Another system of insurance is based on premiums paid by

employers and employees. In 2007, China introduced, the New Medical Insurance Policy which covered 86% of the total rural population but the benefits are modest as patients continue to bear large amount out of pocket.

China regulates prices using the cost plus formula and has reimbursement system for listed medicines. There are two methods of drug price regulation in China, direct price control and competitive tendering. In the direct price control method, government directly sets the price of every drug included in the formulatory. Firms need to apply to the government for individual pricing. In competitive tendering, the retail prices of the drugs are made based on the wholesale price plus a constant rate. It is found that the markup between the retail and wholesale price in Chinese market is much bigger than that in European countries.

6.4 France

France has a universal healthcare system, Securite Sociale which includes drug benefits also. The pharmaceutical companies sale their products at any price. If companies want the National Healthcare System to reimburse patients for the cost of the drug, they must agree to a negotiated price. Negotiated prices and reimburse rates paid by the healthcare system are based on the therapeutic value of the drug and the price of the drug in other countries. A new drug is assessed by a two stage process after marketing authorization. In the first stage Commission de Transperance (CdT) assesses the value of the drug to determine whether it should be reimbursed under healthcare system and to assess the extent to which it provides increase in medical benefits (Amelioration du service medicale rendu, ASMR). These are decided based on phase III clinical trial data. The key factors for comparison are presence of market leader in that therapy in France, the product with the lowest treatment cost and recent reimbursed product in the therapy area in France. The reimbursement of new product is based on ASMR recommendation (SMR 1, 2, 3 based on therapeutic value) of the CdT and negotiations with Economic Committee for Health Products (CEPS) with individual companies.

Aspect that affect pricing of a drug are cost of main therapeutic alternatives, the size of target patient regulation and expected cost of new therapy, position of the new therapy (SMR 1, 2, 3) and government budget.

6.5 Germany

Germany has a decentralized healthcare system, with coverage provided by over 700 insurance funds. Reference pricing and spending caps are two main strategies to control drug expenditure in Germany.

Each individual insurance fund can negotiate with pharmaceutical manufacturers on behalf of their covered patients.

6.6 Italy

In Italy, there is a provision for reimbursable drugs. In 2001, reference pricing system was introduced under which pharmaceutical companies are free to set their prices provided it does not exceed 12 countries Average European Price (AEP).

6.7 United Kingdom

The National Health Service (NHS) provides comprehensive healthcare to all United Kingdom residents. The scheme includes a comprehensive drug benefit that pays for most of the drugs prescribed in United Kingdom. The NHS employs a broad range of cost control measures including profit controls, prescribing guidelines, generic substitution, incentives, patient co-payments, pharmacoeconomic guidelines and a negative list. The NHS is funded by UK Government through general taxation, together with national insurance contributions by UK citizens and residents. There is a body, National Institute for Clinical Excellence (NICE) which performs the economic valuation and has responsibility for technology appraisals, clinical guidelines, and assessment of medical procedures. NICE evaluates selected medicines, medical devices,

medical procedures, and public health interventions, and issues recommendations to the NHS and practicing physicians on cost-effectiveness.

6.8 South Korea

In South Korea, there is a public medical insurance under National Health Insurance (NHI). Besides NHI, Korean population is covered for medical illness through Medical Aid Programme (MAD). Price control applies to medical insurance drugs only. After acquisition of a product license a pharmaceutical manufacturer may request its product for listing into the Pharmaceutical Reimbursement Schedule. The drug pricing is determined based on seven country price as reference (US, UK, Switzerland, Japan, France, Germany, and Italy). Now, for the system of price negotiation National Health Insurance Corporation has started taking into account the quantity of drugs consumed or to be consumed.

6.9 Mexico

Mexican healthcare system is a combination of public and private elements. The Mexican government provides healthcare to about 51% of Mexico's population through social security system.

The patented pharmaceuticals continued to be subject to price control but the Mexican government has gradually loosened the control to give industry greater pricing flexibility. The Mexico's Secretariat of Economy has devised a formula for pricing the patented products in which the reference pricing (ex factory price) is taken from the six countries with the largest sale's share of the corresponding pharmaceutical product. The reference price so chosen is multiplied by marketing factor of 1.72 to reach at a Public Sale Reference Price which is a maximum public sale price.

6.10 Philippines

In Philippines, there is a National Health Insurance programme which covers 70% of the population. There is a price control under the Universally Accessible Cheaper and Quality Medicines Act of 2008.

6.11 South Africa

South Africa also has National Health Insurance Scheme and there is also National District Health System. Regarding pricing of drugs, for a transparent pricing system for medicines and scheduled substances, as part of the registration procedure, applicant is required to provide information of the price at which he proposes to sale the medicine in the Republic and the price at which it is being currently sold in any other country by the applicant. Evidence of cost of manufacturing is also required to be submitted.

6.12 Thailand

The healthcare is primarily funded by the Government and nearly 70% of the population in Thailand is covered by the Universal Health Care Scheme implemented by Taxation System. Private sector employees (16% of population) are covered by the Social Health Insurance, Dependants, Government employees and retired group (9%) are covered by Civil Servant Medical Benefit Scheme.

The price control of the drug is partly by the Government. Ministry of Commerce specifies categories of drugs whose prices are to be controlled. A system of medium price is used to control the upper link of drug prices.

6.13 Japan

Japan has provided universal access to health care to Japanese citizens under its National Health Insurance (NHI) system. Patients are allowed to choose hospitals and physicians. Under the NHI, large Japanese corporations are required to provide health care to their employees. The system is funded by employers and mandatory contributions from employees. Government managed insurance programs provide healthcare to employees of small & mid-sized companies, whilst mutual aid associations have been formed to cover the self-employed, farmers, and the unemployed.

The NHI provides a drug benefit covering most drugs approved by the Pharmaceuticals and Medical Devices Agency (PMDA). Once a drug is approved by PMDA, the manufacturer must apply for a NHI listing. Health Insurance Bureau (HIB), under Ministry of Health, Labor and Welfare (MHLW) reviews the drug, negotiates with the manufacturer, and forwards a pricing recommendation to the Drug Pricing Organization (DPO) for review, and for final approval by the "Chuikyo" (Central Social Medical Council). Once a drug is listed on the NHI schedule, it is eligible for reimbursement after being prescribed by a physician.

In pricing drugs, MHLW employs a comparator system, in which new drugs are priced based on a "similar" existing drug. A cost-plus methodology is used when there is no appropriate comparator. Drugs that are deemed innovative or useful are eligible for premiums depending on degree of innovation, usefulness, and marketability–"Innovative", "Useful-I" & "Useful-II." However, the full premiums for innovativeness are rarely approved.

MHLW also employs various corrective rules, including a so-called A-4 (France, Germany, UK, and US) international reference pricing rule, which operates as a floor and ceiling price. After the price has been determined, the Ministry conducts an international price comparison. If the calculated Japanese price is more than 150% higher or more than 75% lower than the average price in the four foreign markets, the price is adjusted upwards for downward using a set formula.

6.14 United States

US do not have a universal health care system. It has Medicare and Medicaid Programmes which are public funded and cater to the cost of healthcare for age group of over 65 and low income group, respectively. United States does not have a Government body to regulate the prices of drugs.

CHAPTER 7

INDIAN SCENARIO

7.1 Capability

Over the last 30 years, India's pharmaceutical industry has evolved from being a marginal global player to becoming a world leader in the production of high quality generic drugs. The Industry is ranked 3rd globally in volume and 14th in value, supplying around 10% of total global production. This also amounts to around 20% of total volume of global generics. All of this growth has been with affordable price to the common man – one of the lowest in the world. However, the Industry is quite fragmented and comprises of nearly 10,500 units with majority of them in unorganized sector. Of these, about 300-400 units are categorized as belonging to medium to large organized sector with the top 10 manufacturers accounting for 36.5% of the market share. India exports pharmaceutical products to more than 200 countries, primarily the United States, Russia, China and the United Kingdom. India's single largest export market continues to be the United States, which is the world's largest generic drug market.

Low production costs give India an edge over other generics-producing nations. In recent years, Indian pharmaceutical companies have invested substantial part (about 30%) of their total global investment in generic manufacturing capacity. Indian firms now account for over 35% of Drug Master File (DMF) applications and 25% of all US Abbreviated New Drug Application (ANDA) filings submitted to USFDA. These filings give Indian generic companies an advantage over other generic producing nations. India also has the largest number of USFDA approved manufacturing sites outside the US.

Today the Indian pharmaceutical sector meets 95% of the country's medical needs. The domestic pharmaceutical industry has evolved from purely reverse engineering focused to being research driven, export oriented and globally competitive.

The Indian pharmaceutical industry consists of both domestic companies and subsidiaries of multinational corporations. Indian companies manufacture a wide range of generic drugs (branded and non-branded), intermediates and bulk drugs/Active Pharmaceutical Ingredients (API). However generic drugs continue to remain the mainstay of the industry.

Recently, Indian pharmaceutical companies have been scaling up their presence in other business segments such as drug discovery & development, contract research & manufacturing and are focusing on developing competencies in several areas of the pharmaceutical value chain.

7.2 Health Insurance

Health insurance in India is just beginning to emerge for select population and prescription drug coverage does not yet exist. The out of pocket expenditure makes up over 79% of the total healthcare spend essentially due to the poor quality of public healthcare facilities and low coverage of private insurance.

However, increasing prosperity has resulted in greater demand for health insurance coverage. The middle income bracket is predicted to include 800 million people by 2015 and this will act as catalyst for health insurance.

7.3 Prices Generic Medicines

The prices of generic medicines in India are very low in comparison to developed countries like USA, UK etc. Various studies have shown that prices of drugs in India are cheaper than Pakistan, Sri Lanka, Malaysia and other developing countries in Asia.

The Committee came across an interesting study on a website; http://www.pharmainfo.net/vijayaratna/drug-prices-international-comparison where a comparison has been made of prices of 10 popular drugs in five countries i.e. USA, UK, Canada, Austarlia & India keeping their GDP in view. Table-I shows the prices of the 10 drugs in terms of rupees in 5 countries. It is clearly seen that for these 3 drugs the prices in USA are maximum, for 3 drugs

in Canada, for 1 drug in UK, and for 2 drugs the Australian prices were maximum. It also shows the Indian prices are lowest for all these drugs.

Table I: February 2007 Price; each product is calculated in rupee value

Per Capita GDP	42,000 $	37,023 $	35,133 $	34,740 $	705 $
Name of the Drug	**USA**	**UK**	**CANADA**	**AUSTRALIA**	**INDIA**
Ciprofloxacin 500 mg	423.26	324.77	132.67	213.8	6
Gliclazide 80 mg	63.7	53.77	28.39	9.15	3.5
Ibuprofen 600 mg	2.2	0.43	6.76	6.67	0.9
Indomethacin 25 mg	3.63	4.87	9.25	10.85	1.5
Insulin 100 IU/ml	124.18	131.05	363.93	219.53	208
Isosorbide Mononitrate 20mg	19.82	59.87	41.55	30.51	3.2
Ofloxacin 200 mg		144.63	109.8	192.15	4
Omeprazole 20 mg	111.47	91.54	201.97	109.15	4
Paracetamol 500 mg	12.55	4.43	2	12.98	1
Propranolol 10 mg	61.41	32.33	11.61	6.49	2

But as shown in Table II, if the price is calculated after being weighted by per capita GDP, the differences in the prices are not much rather higher in six cases in India. Table II shows in each cell, a value obtained by dividing the price with the per capita GDP and multiplying with 100.

Table II: Price per tablet in rupees weighed by per capita GDP

Per Capita GDP	42,000 $	37,023 $	35,133 $	34,740 $	705 $
NAME OF THE DRUG	**USA**	**UK**	**CANADA**	**AUSTRALIA**	**INDIA**
Ciprofloxacin 500 mg	1.008	0.8772	0.3776	0.6154	0.851
Gliclazide 80 mg	0.151	0.1452	0.808	0.0263	0.4964
Ibuprofen 600 mg	0.0052	0.0146	0.0192	0.194	0.1276
Indomethacin 25 mg	0.0086	0.013	0.0263	0.0312	0.2127
Insulin 100 IU/ml	0.2956	0.353	1.0358	0.6319	29.503
Isosorbide Mononitrate 20 mg	0.0471	0.1617	0.1182	0.0878	0.4539
Ofloxacin 200 mg		0.3906	0.3125	0.5531	0.5673
Omeprazole 20 mg	0.2654	0.2472	0.5748	0.3141	0.5673
Paracetamol 500 mg	0.0298	0.0119	0.0056	0.0373	0.1418
Propranolol 10 mgl	0.1462	0.0873	0.033	0.0186	0.2836

7.3.2 Patented Medicines

Efforts were made to obtain the government procurement prices of the patented drugs in developed countries to compare the prices of those patented drugs in Indian Market. Based on the valuable inputs provided by the Indian embassies in Australia, France and New Zeeland a clear picture for two Patented Drugs (Erlotinib HCL & Sunitinib malate) could emerge which shows that prices of these two patented medicines are cheaper by 1/3rd to 1/10th in our country. The prevailing prices of these drugs in India were provided by the NPPA. The data in this connection both in tabular and graphical format is as per Tables III & IV and Charts I & II given below:

Table III

Erlotinib HCL (value in Rs)

Erlotinib HCl	Prices in India	Prices in France	Prices in Australia	Prices in New Zealand
Tab 100 mg	35450	121085.44	121650.3	139500
Tab 150 mg	40300	149180.16	148920.3	177750

Chart I

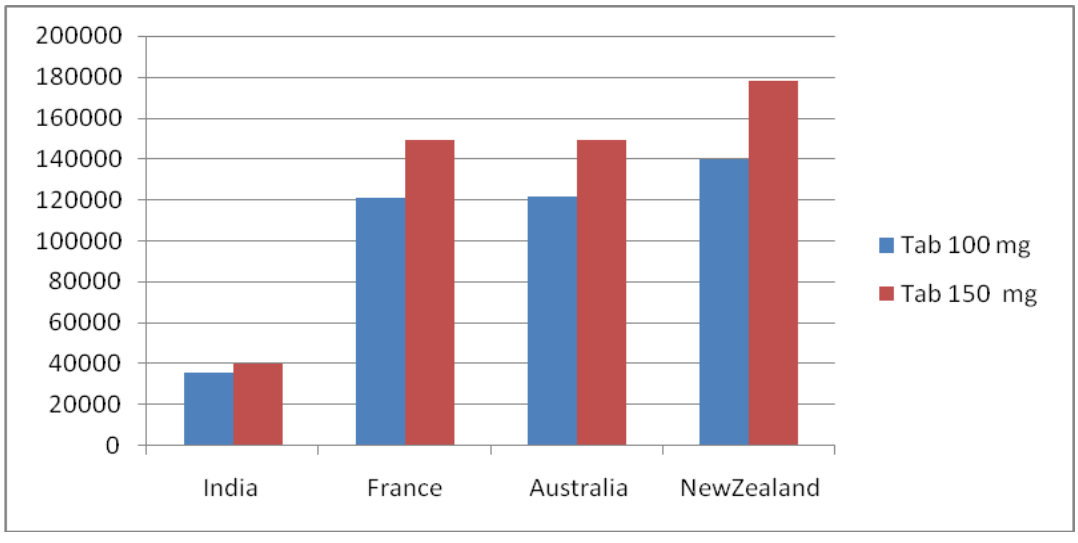

Table IV

Sunitinib malate (Value in Rs)

Sunitinib malate	Prices in India	Prices in France	Prices in Australia	Prices in New Zealand
Capsule 12.5 mg	11731.17	92035.2	82539	104192.1
Capsule 25 mg	23462.86	182428.8	158479.2	208384.65
Capsule 50 mg	46925.72	363216	310384.2	416769.3

Chart II

Inspired by the study on the website, quoted above, an analysis was made for prices weighted with per capita Gross National Income (GNI) for the countries with reference to the Purchasing Power Parity (PPP) as GNI along with PPP provide a better economic picture of the country. These comparisons for both of the above referred medicines are represented in Tables V & VI respectively as follows:

Table V

For Erlotinib:

Per Capita GNI(PCGNI)(US$)* (a)	3260	33940	38510	28050
Ratio of PCGNI of other countries to India (b)	1	10.4	11.8	8.6
Erlotinib HCL (c) (Prices in Rs.)	Prices in India	Prices in France	Prices in Australia	Prices in New Zealand
Tab 100 mg (d)	35450	121085.44	121650.3	139500
Prices weighted in terms of PCGNI (e)=(d)/(b)	**35450**	**11643**	**10309**	**16220**
Tab 150 mg (f)	40300	149180.16	148920.3	177750
Prices weighted in terms of PCGNI (e)=(f)/(b)	**40300**	**14344**	**12620**	**20669**

**Source: Worldbank data 2009*

Table VI

(ii) For Sunitinib:

Per Capita GNI(PCGNI)(US$)(a)	3260	33940	38510	28050
Ratio of PCGNI of other countries to India (b)	1	10.4	11.8	8.6
Sunitinib malate (c)	Prices in India	Prices in France	Prices in Australia	Prices in New Zealand
Capsule 12.5 mg (d)	11731.17	92035.2	82539	104192.1
Prices weighted in terms of PCGNI (e)=(d)/(b)	**11731.17**	**8850**	**6995**	**12115**
Capsule 25 mg (f)	23462.86	182428.8	158479.2	208384.65
Prices weighted in terms of PCGNI (g)=(f)/(b)	**23462.86**	**17541**	**13430**	**24231**
Capsule 50 mg (h)	46925.72	363216	310384.2	416769.3
Prices weighted in terms of PCGNI (i)=(h)/(b)	**46925.72**	**34925**	**26303**	**48462**

From above analysis, it is clear that when we take per capita Gross national Income (with Purchasing Power parity) into account, the **drug prices are on higher side in India compared to most of the countries under reference.**

7.4 Prescription Pattern

Like most of the developing countries, in India also the consumer – i.e. the patient – has virtually no choice that he/she can meaningfully exercise. The decision on the medicine to be taken is made by the doctor or, in some circumstances, the druggist/pharmacist. *Thus, the normal dimensions of consumer choice – product, price and quality – simply do not exist. The only available choice is whether to take the prescribed medicine or not.*

However, with increased awareness and strong base in generic medicines, we may expect, in near future a prescription pattern inclined towards generic medicines.

CHAPTER 8
OBSERVATIONS OF THE COMMITTEE

The Committee deliberated on various issues raised by various stakeholders. The observations of the Committee are as given below:

8.1 Prices of patented medicines

As stated in Chapter-7, the prices of patented medicines are very high and even if the prices are calibrated on Gross National Income with purchasing power parity, the prices are much beyond the reach of general masses of the country. Therefore, it is felt that even after the prices of patented medicines are negotiated by a Government Committee, the same may remain unaffordable to the masses. In case the prices are fixed unilaterally by the Government for open market, it may result in the non availability of the medicine as, at present, the penetration of insurance coverage by Government or any other Health Insurance agency is low resulting in insignificant amount of centralized procurement of patented medicines.

8.2 Price based on the pattern in other developed countries

As mentioned in chapter 6 above, the price regulation in most countries is oriented towards the determination of prices at which the governments procure the medicine for delivery through the public health system or to fix the reimbursement rates against insurance claims as in these countries, the insurance or Public health system covers majority of the population. But in India, although CGHS, Railway, Defence Services and various other Public and Private Insurance companies are operating, still the coverage is around 23% and majority of the population go for out of pocket expenditure for medicines as well as other healthcare services.

In India, expenditure on Health is hovering around 1% of the GDP and it is much lower than the expenditure in most of the developing countries where public health system is strong. The Committee felt that government should go

for coverage of majority of the population under a public health service with coverage of prescription medicines.

8.3 Price based on Reference Pricing with similarly placed countries.

The similarly placed countries are chosen with reference to the size and state /level of the economy, the public health delivery systems, the size of the drug industry i.e. the total volumes and sales. When we compare India with other countries, we find vast differences in one or other parameters. For example, India is far ahead most of developing countries in Pharma sector although India is comparable on other social and economic parameters. Similarly, Public Health System in India is far behind most of the developing countries.

Hence, in Pharmaceutical Sector, it is very difficult to find out similarly placed countries vis-à-vis India.

8.4 Price based on Price negotiation on various input cost.

Under this category, one may think of asking the companies to provide various input costs and then go for a suitable mark up above this cost to cover the R&D expenditure. But the Committee felt that for a new molecule, it is very difficult to find input cost in a transparent way. Secondly, even if we get the input cost in the country of origin, it will have little relevance for price fixation in India as these costs might be incomparable. Thirdly, it is very difficult to evaluate risk factors involved in drug discovery & development.

Further, if price negotiation is considered in an arbitrary manner, one may not reach to a reasonable price and even if the Price Negotiation Committee feels the price to be reasonable, it still may be out of reach of general public in India and may seem unreasonable to them.

8.5 Price based on the Therapeutic effectiveness of the new drug

Under this option, the Committee deliberated upon therapeutic efficiency of the patented medicines. There can be three categories of such patented medicines:

(i) A totally new class of medicines which have no therapeutic equivalence.

(ii) A medicine that has therapeutic equivalence but also has got a therapeutic edge over the existing one.

(iii) A medicine that has similar therapeutic effectiveness compared to the existing one.

For the medicines at category (i) and (ii), the price regulation has to be deliberated upon and for the category (iii), the price has to be same as that of the existing one.

8.6 Compulsory License and Price Negotiation

The Committee deliberated upon the discussions held under the earlier Chairman where it was apprehended that a negotiated price means India will lose the tool of Compulsory License for making the price of patented medicines reasonable.

As stated above in Chapter 4, there is a provision of Compulsory License in the Patents Act 2005 and out of various clauses of the Act for granting the Compulsory License, one of them is that Compulsory License can be granted if the patented medicine is not available to the public at a reasonably affordable price.

Hence, the Committee was of the view that once a Government appointed Committee goes for some form of price regulation of patented medicines and fixes a price of the medicines which is accepted by the government, this fixed price would be supposed to be reasonable and hence it won't be possible for the Government to use the tool of Compulsory License on the ground of reasonableness of the price of the patented medicine.

However, as stated in Chapter 4 above, the Compulsory License can be granted on the basis of other provisions of the patent act. Secondly, if prices of the patented medicines are regulated and thereafter reimbursed through insurance coverage or any public health scheme and the public are not required to pay the same, the apprehension of reasonability of prices can be minimized.

8.7 Price Fixation and Marketing Approval

At present, the public procurement of the drugs is hardly 23% and that also under various agencies that procure or reimburse independently. It means, the procuring agencies are not having much bargaining power. Hence, at this stage, if the marketing approval is linked with price fixation of patented medicines through any method, a situation may arise that the medicine is not introduced in the country. At the time when, the public procurement or prescription reimbursement reaches at a significant portion of total domestic sales, the necessity to link the price negotiation of patented medicine with marketing approval can be considered.

8.8 Patented drugs which are to be manufactured and launched first time in India only.

Presently, Indian companies are also investing in various R&D projects and the Research agencies under Government of India are also working over various new molecules. The Committee deliberated upon a situation where the patented medicine is introduced first time in India itself.

The Committee is of the view that prices of such medicines need to be fixed keeping in view the cost factor, therapeutic efficiency/ efficacy and also the cost of treatment.

CHAPTER 9
RECOMMENDATIONS

In view of the foregoing observations, Committee recommends as follows:

9.1 Public Health Policy and Insurance Coverage

Based on the observations made in para 8.1 above, the Committee is of the view that the government should expand the coverage of Healthcare and Insurance Scheme (at least for prescription medicines) for all the citizens who are not covered under any other insurance /reimbursement scheme.

The Committee recommends the price negotiations for the patented medicines for the Government procurement/reimbursement and for Health Insurance Coverage by any other Insurance company.

9.2 Price Negotiation and Marketing Approval

As observed in para 8.7, the committee is of view that at this stage, the linking of marketing approval with price negotiation may lead to unavailability of the patented medicine in the country. Therefore, at this stage, there is no need to link the price negotiation of a patented medicine with its marketing approval. The linking of price negotiation of patented medicine with marketing approval may be reviewed when the public procurement or prescription reimbursement reaches more than 50% of total domestic sales of the medicine.

9.3 Committee for Price Negotiation

There should be a committee headed by Chairman of NPPA for deciding the price of patented medicines. The committee can be named as Pricing Committee for Patented Drugs (PCPD).The other members of the committee could be from Railway, DGHS, DCGI, Ministry of Finance and Representatives of top 5 (Five) health insurance companies in terms of number of beneficiaries. The committee may co-opt any other members as deemed fit. To have proper

watch on the prices of these patented medicines, a separate set-up may be created in NPPA with adequate staff strength and infrastructure.

9.4 The reference prices of the patented medicines :

The countries like UK, Canada, France, Australia and New Zealand have a wide coverage of health insurance by their governments and therefore have high bargaining power in deciding the price of such patented medicines through negotiations. Therefore, it is recommended that the reference prices of the patented medicines to be used for price negotiations in India will be the procurement prices of those medicines by governments of the aforesaid countries.

9.5 Methodology of Price Negotiation:

(a) For Medicines having no therapeutic equivalence in India: The originator company will submit to the Committee the government procurement price list of UK, Canada, France, Australia and New Zealand. In case the company has not launched its patented medicines in any one of the aforesaid countries, the company will submit the said price lists only in respect of those countries in which the medicines have been launched and are being procured by the respective Governments. The committee will take the per capita Gross National Income (with Purchasing Power Parity) of these countries. The ratio of the per capita income of a particular country to the per capita income of India would be calculated. The prices of the medicine would be worked out for India by dividing the price of the medicine in a particular country by this ratio and the lowest of these prices would be taken for negotiation for further reduction. The process has already been elaborated in Table V and VI in Chapter 7. This methodology would be applicable for medical devices also and all the patented medicines introduced in India after 2005.

(b) For medicines having a therapeutic equivalent in India: If an equivalent medicine already exists (with better or similar efficacy), the pricing committee may deliberate upon the cost of treatment of the disease using the new medicine. While fixing the price of such

medicines, the committee may adopt the methodology of reference pricing as stated in para 9.5(a) above but would ensure that the cost of treatment does not increase w.r.t. the cost of treatment with existing equivalent medicine.

(c) **For medicines introduced first time in India itself**: The Pricing Committee for Patented Drugs will fix the price of new medicines (who are new in the class and no therapeutic equivalence is available) taking various factors into consideration like cost involved, risk factors and any other factor relevant. The regulator may discuss the various input costs with the manufacturer who can produce various documents of evidence. Although this process is complex, but since the medicine is discovered and developed in India and the number of such cases would be very less, the pricing committee would not find it as difficult as in case of medicines discovered and developed outside India.

The prices so fixed will be subject to revision either periodically or if felt necessary by the manufacturer or the regulator as the case may be.

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Annexure-1

S-NO-1(I)

No.5/80/06-PI.I
Government of India
Ministry of Chemicals & Fertilizers
Deptt. Of Chemicals & Petrochemicals

Shastri Bhavan, New Delhi
Dated the 1.2.2007

MEMORANDUM

SUBJECT: **CONSTITUTION OF A COMMITTEE ON PRICE NEGOTIATIONS FOR PATENTED DRUGS.**

It has been decided to constitute a Committee to examine the issue of price negotiations for the patented drugs with following composition:.

(1)	DIRECTOR (PI)	CHAIRMAN
(2)	DRUGS CONTROLLER GENERAL (INDIA)	MEMBER
(3)	DIRECTOR (NIPER) or his representative	MEMBER
(4)	DIRECTOR (NPPA)	MEMBER
(5)	EXECUTIVE DIRECTOR, PHARMEXCIL	MEMBER
(6)	ADDITIONAL INDUSTRIAL ADVISOR (R)	MEMBER
(7)	UNDER SECRETARY (PI-I)	MEMBER

The Committee would interact with various pharma industry associations and study the available material on the subject. Based on this the Committee would 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.

The Committee would submit its report within three months of its constitution.

(J.S. SIDHU)
UNDER SECRETARY TO THE GOVERNMENT OF INDIA

Copy to:

1. Members of the Committee.
2. PS M(C&F&S)
3. PS to MOS(C&F&PA)
4. PPS to Secretary (C&PC)
5. PS to JS(PI)
6. Member Secretary, NPPA.
7. JS(Drugs), Department of Health.