ISAS Working Paper

No. 20 – Date: 19 March 2007 (All rights reserved)

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PRICE CONTROLS ON PHARMACEUTICAL PRODUCTS IN INDIA

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Introduction

In revising its drug pricing policies, the Government of India needs to balance its core responsibility to protect the health and welfare of the Indian people and the Nation's interest in sustaining the continued development of a world-class Indian life sciences capability. It is vital that the citizens of India, particularly the common man, have access to affordable medicines for treating the most common and important disease conditions. This is a core mission for any government. At the same time, unlike most nations, including even the most advanced OECD economies, India is a global competitor in the advanced life sciences. Our pharmaceutical industry is a world leader in international generics markets and has begun making serious inroads in innovative drug discovery. Indian scientists, doctors, and medical researchers have developed important, commercially-successful treatments for disease, including biopharmaceutical inventions which have been patented in the United States and Europe. Indian scientists and researchers populate the laboratories of the major U.S. and European multinational drug companies, and increasingly are being drawn home by opportunities in our own country. Accordingly, any pharmaceutical pricing policy must also advance India's capability to discover and develop advanced medicines. Our global competitiveness in the life sciences represents a long-term national technological asset and a

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potential cornerstone of our Nation's future economic prosperity. Achieving a balance between access and innovation will not be easy.

The development of innovative pharmaceutical products plays a critical role in ensuring health gains and longevity through the provision of adequate amounts of effective drugs to treat the most important and common disease conditions. Governments play a vital role in encouraging development of new drugs though economic incentives like direct and indirect government funding, effective intellectual property laws and other policies that favour innovation. It is the responsibility of the Government to ensure that consumers benefit both from technological breakthroughs and the competition that further innovation generates. The changes in the Patents Act of 1970 in India have now provided for the recognition of product patents and opened the door for a new era of advanced biopharmaceutical discovery, but such gains need to be nurtured through the creation of an enabling environment that would encourage R&D spending and new drug discovery. Even now, the investment in R&D by Indian firms is only a fraction of R&D spending by leading multinational companies, and could pose a barrier to the emergence of a globally-competitive Indian life sciences industry which can compete on an equal basis with leading U.S. and European research-based biopharmaceutical companies.

Given India's unique circumstances as a developing country which is globally-competitive in the biopharmaceutical arena, these challenges can only be addressed through a "third way" approach to drug pricing. Simply copying existing Western European price controls or the U.S. free market approach would not address India's special role as both a developing country with tens of millions who lack adequate access to health care and as a future leader in global drug discovery. By formulating a new approach to pharmaceutical pricing, India can offer viable solutions to other developing countries that aspire to expand access to basic health for their rural and urban poor, avoid an uncontrolled expansion of government spending, and at the same time exploit the full economic potential of the 21st century life sciences.

The paper is organised in four sections. In the first part, the historical evolution of pricing regulations in India is discussed, as also the international experience of price control mechanisms, followed by a discussion of the limitations of price control systems. The second part deals with the reach of the health care system in India, and examines the private-public health interface. It emphasizes that public health delivery is not a matter of drug pricing alone. The third part deals specifically with price control mechanisms proposed for patented drugs, and the limitations to the approach. Alternate approaches are considered in conclusion, which

outlines potential elements of an Indian "third way" which avoids the pitfalls of European price control systems; the inequities of the U.S. free market approach, and the complete lack of access to drugs or health care in many developing countries.

I Price Regulations on Pharmaceutical Products in India

Price controls for drugs and formulations have a long history in India. The first price control order was issued under the Defence of India Act in 1963. Price control orders have been issued under the Essential Commodities Act, from 1970 onwards. The Drug Price Control Order (DPCO) in 1970 was a measure to safeguard the interests of the consumer, while providing for a restricted but reasonable return to the producers. Simultaneously with the negation of product patents in 1970, the measure brought about an era of cheaper medicines in India, albeit at the expense of diluting intellectual property rights. The DPCO has been amended thrice since then, the last being in 1995. The DPCO in 1995 has introduced three parameters to ensure proper market conditions – turnover, market monopoly and market competition. Under this, prices of 74 bulk drugs and their formulation are being controlled representing approximately 20% of the pharma market. Bulk drugs, with a turnover of over Rs.40 million, are under the purview of the DPCO, excluding those drugs with sufficient market competition. Sufficient market competition is defined as the presence of at least five bulk producers and 10 formulations, with no producer's market share exceeding 40 per cent. In case a single producer controls about 90 per cent of the market for a drug, which has a turnover in the range of Rs.10-40 million, the drug is considered to be under the purview of the price order (ICRA, 2000).

Industrial licensing has been abolished for all drugs, formulations and drug intermediates except for the five drugs which are reserved for public sector. Moreover, price controls have been waived for a period of five years for drugs which have been developed indigenously. The pricing methods for imported bulk drugs were based on the landed cost (inclusive of import and customs duty), which was the maximum permissible selling price. In case of a bulk drug manufactured locally, the price has been fixed based on the capacity and cost data of a particular production unit like post-tax returns or pre-taxed return on total capital employed or internal rate of return based on the long-term marginal cost.

In the case of pricing of imported formulations, the price has been fixed based on the landed cost and the selling and distribution expenses, which would not exceed 50 per cent of the landed price. In the case of locally produced formulations, the price has been determined

using the retail price.[2] It implies that the DPCO monitors and fixes the price of 74 bulk drugs and all the formulations which uses these bulk drugs. Therefore, the government controls under DPCO 50 per cent of the pharmaceutical market in India (ICRA, 2000). The impact of prices of drugs during post-DPCO (1995) period evaluated by the ORG (1996) found that there had been a 4.6 per cent increase in drug prices in the 12 months following the announcement of the 1995 DPCO compared to an increase in the Consumer Price Index (CPI) of 9.8 per cent for the same period. The study also showed that the index of prices on products that had moved from the controlled to the decontrolled category under the DPCO had also registered around 10.7 per cent increase. Though there is a price controls under DPCO, still a majority of drugs in the market are not regulated and the price rise during this period is still considered to be minimal. In short, while the DPCO has evolved in a step-by-step ad hoc fashion, it has managed to strike a rough balance between regulating prices to ensure adequate access to essential medicines for the rural and urban poor, while allowing the emergence of a globally competitive Indian domestic drug industry.

A new pharmaceutical policy was approved by Government in 2002 wherein the number of drugs under price control and span of price control was sought to be reduced. However, before this policy could be implemented it was stayed by the Karnataka High Court in a PIL filed before the Court on the ground that a large number of essential drugs would go out of price control. An SLP was filed by Government in the Supreme Court against the order of the Karnataka High Court. The Supreme Court vide its interim order on 10th March, 2003, stayed the order of the Karnataka High Court. However it also ordered that "the petitioner shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control, and to review the drugs which are essential and life saving in nature till 2nd May, 2003,

After consideration, the government announced a new pharmaceutical policy in 2005, wherein it was proposed to bring an additional 354 drugs under a National List of Essential Medicines (NLEM) under price control.[3] It is also proposed that patented drugs would be

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[2] Retail price equals to (material cost + conversion cost + packing material and its cost) x (maximum allowable post manufactured expenses (MAPE) + excise duty).

[3] The ministry has admitted that this would result in over 60% of the drugs being brought under price controls. As a modification, they have now proposed that 354 single ingredient formulations of specified strengths alone would be subject to price controls, and have estimated that this would cover 32% of the market. There has been considerable opposition from local industry to this move, and the matte has been referred to a Group of Ministers for resolution.

subject to price negotiations, prior to grant of marketing approvals. A system of reference pricing is to be evolved for these, based on prevailing practices in other 'comparable' countries.

The concern in this paper is the approach proposed to be taken for the fixing of prices for patented medicines. Since only a small number of new biopharmaceutical discoveries receive marketing approval each year and the revenues of even largest multinational U.S. and European drug companies often rest on only a handful of products, even a small expansion of price controls could have a damaging impact on India's industrial competitiveness in new drug discovery and the viability of India's globally-oriented domestic pharmaceutical companies. In addition, while the initial number of products subject to controls may appear limited, the reorganization of the drug-pricing process and establishment of new government agencies to impose controls on medicines deemed "essential" appears likely to lead to further expansion of controls over time. This has been the pattern in most of the markets studied in this paper, since artificially holding the price of a good below its market price necessarily leads to an expansion of consumer demand for the so-called "free good."

Review of International Experience on Pricing of Pharmaceutical Products

The draft Pharmaceutical Price Policy indicates that the models of other countries could be followed for the pricing of pharmaceutical products. Price control mechanisms for pharmaceutical products are a common form of intervention in many countries to contain costs of healthcare. The principal methods employed in many countries include pharmacoeconomics, various forms of reference pricing, comparator pricing, restrictions on dispensing and prescribing, and reimbursement restrictions. Canada uses the two-tiered pricing system based on negotiated prices while France follows new price notification procedure - to be set up with reference to prices based on a European average.

Since the draft Pharmaceutical Price Policy indicates that international price control models, such as Canada and France, are being studied, it is imperative to review the leading international price control models, such as the United Kingdom, Canada, France, Australia, and Japan, as this can provide a framework for identifying potential strategies for pricing pharmaceutical products in India. Mexico is also examined closely because it is a developing country which has recently liberalized its drug price control system, and faces some of the economic and social challenges confronting India.

Overview

In the OECD economies, there are a wide range of price regulations, ranging from product-to-product pricing to partial price freedom. Authorities also try to control pharmaceutical expenditure through across the board price cuts, profit controls, delays in approving new products, and budgetary devices. Price freezes very often supplement mandated price reductions and have been commonplace in Europe in the recent years and apply to patented medicines as well as those off patent. Fourteen out of sixteen European countries are fixing prices of new products by reference to prices applied in other EU countries. The selection of price levels is designed to suit the price levels that are considered desirable by the authorities.

Some form of reference pricing currently applies in Belgium, Denmark, Germany, Italy, the Netherlands, Norway, Portugal, Spain, France, Sweden, Australia, and New Zealand. Implementing arrangements vary in practice: the statutory health insurance system reimburses the cost of a medicine up to a fixed amount known as the reference price that is communicated by the authorities. When the market price exceeds the reference price, the patient pays the difference. In most countries, this system is applied at the reimbursement level, and not at the market price level, though market prices do get determined by reference prices. Netherlands has gone in for an index pricing system which is again a price at which insurers can reimburse clients.

A large number of countries, including France, Canada, Belgium, Finland, Norway, the UK, Hungary, Netherlands, Portugal, Sweden, Australia, and New Zealand, have adopted pharmacoeconomic evaluation as a mandatory part of the price setting mechanism.[4] Data sharing on cost-effectiveness of medicines is also becoming more prevalent, since the establishment of NICE in 1999, and there is a move to share data across nations. Attempts to develop data banks and use economic modeling are under way in Europe. The application of a pharmacoeconomic or cost-effectiveness standard requires extensive, high-quality clinical, economic, and health care cost data, and well-defined methodologies for national costs and benefits. Otherwise, it can become highly politicized decision process or turn into a case-by-case negotiations that lack any rational scientific justification.

[4] Michael Drummond, PhD., "Using Economic Evaluation in Reimbursement Decisions for Health Technologies: Lessons from International Experience," (Paper Presented at International Conference on Pharmaceutical Innovation, Taipei, May 2005).

Other approaches to price controls include fixing growth targets for public pharmaceutical spending: several countries legally fix an overall budget or seek to impose percentage limits on growth in pharmaceutical spending. Many countries exclude medicines from the reimbursement list, especially those that are adjudged to be of little therapeutic or clinical value. Control over costs is also achieved through scrutiny of companies' promotional expenditures and marketing practices.

Most of the OECD countries with drug price controls employ multiple pricing tools. The individual systems, moreover, differ how these tools are employed and how their decision-making processes are organized and structured. Other important systemic factors include the transparency of the price-setting process, the availability of independent review mechanisms to ensure some level of bureaucratic accountability, and the strength or weakness of patient groups with an interest in access to advanced medical treatments, who can provide a political balance to budgetary or fiscal concerns. Given these important differences, it is helpful to briefly examine the leading foreign price control systems to understand how they are organized and to begin to evaluate their potential suitability in an Indian context.

A variety of pricing models for pharmaceuticals are used internationally:[5]

- Free pricing—no regulatory intervention at the pricing level. The government or health care provider tries to influence drug costs on the demand side through restricted reimbursement and /or market mechanisms such as public tenders or supply contracts.
- Country of origin based pricing—the manufacturer or importer provides data on the price in the country in which the drug is manufactured. This price is either the basis for negotiations or is entered into a formula to set the list price for the given country. This model has proved to be economically ineffective.
- External reference pricing—the manufacturer provides price information from a number of countries that have been selected as a reference standard. Then a formula is applied to compute the list price. This model is used in many middle income countries.
- Volume/price contracts have been used in several markets to counteract the growth I prescription volume. If a certain volume is exceeded, the administration can impose a price reduction.

[5] World Bank; HNP Brief # 7; ibid.

- In the UK, the industry operates under a profit control agreement. Prices are set so that the manufacturers reach an agreed profit margin. This model tries to balance the interests of the local research-based industry within the limitations of government financed health system.
- Some countries have introduced compulsory rebates to counteract growing pharmaceutical expenses. For example, Germany introduced a temporary social insurance rebate of 6% and later 16% for innovative drugs that do not fall under a reimbursement limit. This created a rebound effect with a 20% increase of drug expenditure in the first half year after the rebates ran out; leading to a search for more sustainable cost containment strategies.

The following table provides an overview of the key elements of some of the leading foreign drug price control systems. As the table demonstrates, national price control systems are complex, and differ in important respects. It is also important to note that virtually all of the OECD drug price control systems are an integral part of a comprehensive national universal health care system. These national schemes provide universal access to health care for all citizens; are funded in whole or in part by the government through taxes, budgetary contributions, household payments, or employer mandates; and cover a wide range of advanced medical treatments. As a result, according to the OECD and virtually all analysts, Western European governments and other advanced industrial economies with comprehensive drug price control schemes have experienced great difficulty controlling the growth of drug spending.[6]

Artificially suppressing the price of any good, including medicines, below market levels necessarily boosts consumer demand. In addition, the existence of any "free good" means patient groups and consumers inevitably will use the political system to demand access to more advanced and more expensive treatments, undermining government efforts to control spending through price controls alone. Accordingly, public drug price control programs exhibit a clear tendency toward increasing administrative complexity and budgetary cost over time.

[6] Danzon, pp. 37-41

Table 1: Key Elements of Foreign Drug Price Controls Systems

	UK	Canada	France	Australia	Japan	Mexico
National Health Insurance	NHS	Medicare	Securite Sociale	Medicare	NHI	Limited + Private Mt.
Drug Benefit	Yes	Provincial	Yes	PBS	Yes	PROMIF
Drug Price Controls	No-Initial launch	Yes	Framework Agreement	Yes	Yes	Yes
Prescriptions Covered	80%	45%	83%	95%	100%	50%
% of Cost Covered	100%	Varies	65-100%	80%	70%	N/A - Private Mkt
Profit Controls	Patented	No	Yes	No	No	No
Private Insurance	Yes-Suppl.	Yes-Suppl.	Yes-Suppl.	Limited	Limited	Limited
Co-Payment	$11.75	Yes-Prov.	No	$23.70	30%	N/A
Core Methodology	PE	Comparator + IRP	PE + IRP	PE + Comparator + TRP	Comparator	IRP + Price Notification for Patented
Administering Agency	PPRS	PMPRB	CT	PBAC	MHLW + DPO	SECOFI
Pharmacoeconomics (PE)	NICE	CDR + CEDAC	ASMR-6 pt. scale + SMR	Yes – 1992	No	No
Approx. QALY	?	$50-70,000	?	$39,000	N/A	N/A
Reimbursement Restrictions	NICE Clinical Recommend	Prov. Formularies	Yes	Restricted Indications	No	Positive List-Govt. Programs
Intl Reference Pricing (IRP)	N/A	Median A-7	Yes/A-4	Yes	A-4	A-6 for patented
Therapeutic Ref.	N/A	Provincial, e.g. B. Col.	Yes	Yes	No/Comparators	N/A
Corrective Rules	N/A	Yes	Yes	Yes	Extensive + Premiums Rule	N/A
Price Negotiations	Yes	Yes– Prov.	Yes	Yes	Yes	N/A
Budget Measures	Yes	Provincial	Global Budgeting	Yes	Ad Hoc	N/A
Price-Volume Restrictions	N/A	Provincial	Price + Vol. Rebates	Yes	Repricing	N/A
Other Measures	?	“Excessive” Price Reductions	Spending Targets + Year-End Clawbacks	Ad Hoc Price Cuts	Biennial Price Revisions + Repricing	Govt. Plans - Generics
Generic Incentives	Yes	Yes	Yes	Yes	Under Consideration	Yes
Approval Delays	No	Significant	Significant	Significant	Serious	?
Transparency	Good	Minimal	Minimal	Improving	Improving	Good
Independent. Appeal Mechanism	Yes	No	No	PBPA + Convenor	No	N/A
Per Cap. Drug Spend	?	$507	$606	$353	$393	$125
Globally-Competitive Industry	Yes	No	Declining	No	Declining	No

Summary Descriptions of Key National Pricing Systems

Europe: United Kingdom Pricing and Reimbursement

The National Health Service (NHS) provides comprehensive health care to all United Kingdom residents.[7] The NHS includes a comprehensive drug benefit that pays for most drugs prescribed in the UK. 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 the UK government through general taxation, together with national insurance contributions by UK citizens and residents.

The NHS's main cost containment tool is profit control. Price controls were initially established in 1957 through a Voluntary Price Regulation Scheme. In 1978, the scheme was renamed the Pharmaceutical Price Regulation Scheme (PPRS) and converted into a joint arrangement between the Department of Health (DOH) and individual firms to control excess profit-making. The DOH periodically reviews the terms of the PPRS and renegotiates health spending targets with the industry. Under the PPRS, the DOH sets company profit levels by evaluating a variety of factors, including long-term risk, UK investments, rate of return on capital, the company's relationship with the NHS, level of exports, and level of UK manufacturing.

The initial launch prices of pharmaceuticals are not controlled, but cannot be increased without official permission. Each year, firms participating in the NHS must file a confidential Annual Financial Return (AFR). The allowable rate of return on "allowable" capital varies between 17 and 25 %, with an automatic 25 % tolerance. If a company's profits on sales to the NHS exceed the PPRS limit, it can be forced to reduce prices or repay the excess profit directly to the PPRS. In addition to controlling profits and price increases through the PPRS, the Department periodically freezes prices or reduces the total health care budget to achieve budgetary goals. While the PPRS does not cover generic medicines, rapid price and expenditure increases for generics led to a maximum price scheme for generics in August 2000. These prices are recalculated monthly by the Prescription Pricing Authority.

Patients are required to pay an annual fee for a "Prescription Pre-Payment Certificate" for unlimited prescription costs or to pay a co-payment for prescriptions. The fee, however, is frequently waived, so the cost of most prescriptions is funded entirely by the NHS.

[7] Kullman, "United Kingdom Pharmaceutical Pricing and Reimbursement Policies."

To further limit pharmaceutical spending, the DOH has established programs to encourage physicians to control drug expenditures and prescribe generics, including a Prescribing Analysis and Cost Information system, which allows physicians to compare their prescriptions to those of a practice with similar patient demographics. It has also adopted voluntary drug budgets for general practitioners.

The UK is a leader in economic evaluation. The National Institute for Clinical Excellence (NICE) was established in 1999 with 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.[8]

Europe: French Pricing and Reimbursement System

France has a universal health care system, Securite Sociale, which includes a drug benefit. In 1994, the French Government's Comite Economique de Medicament (CEM) and SNIP, the French pharmaceutical industry association, entered into a "Framework Agreement" based on voluntary agreements ("conventions") between CEM and specific companies. Under the conventions, a company would agree that, in exchange for an agreed reimbursement price, it would supply only "medically justified" quantities of a drug and limit promotional spending to an agreed percentage cap.

In 1999, a revised Framework was negotiated. It was also based on conventions negotiated between the CEM -- renamed the Economic Committee for Health Products (CEPS) -- and individual companies, subject to a 10% limit on promotional spending and annual targets for spending on major categories of medicines. By 1999, such conventions covered over 97% of French prescriptions.

France has also adopted global budgeting. In its annual Social Security Financing bill, the French Parliament sets a target for pharmaceutical expenditure growth each year. If the target is exceeded, the government can seek an "exceptional contribution" from the pharmaceutical industry under a "safeguard clause," based on the national target for health care expenditure (ONDAM). Under the "conventions," pharmaceutical companies have agreed to pay "voluntary" rebates to CEPS to avoid application of the safeguard clause. As a

[8] Redgwood, "The Use of Cost-Effectiveness Analysis of Medicines in the British National Health Service: Lessons for the United States" (April 2006).

result, the industry has been regularly subjected to special year-end rebates or levies, *e.g.* FF 1,200 million in 1999, E 440 million in 2000, and E 183 million in 2001.

In France, reimbursed medicines are first evaluated by a Transparency Commission (CT), which decides whether a product should be eligible for reimbursement. The CT bases its evaluation on an Amelioration du Service Medicale Rendu (ASMR), which rates new medicines on a 6-point scale from "major therapeutic progress" to "reimbursement unadvisable" The CT also examines a product's medical benefit (SMR) compared to existing products within its therapeutic class, and determines a level of reimbursement (100%, 65%, or 35%). Then, a price is negotiated between the CEPS and the company, taking into account the expected volume of sales, prices of other drugs in the therapeutic class, and prices in other European Union markets. Thus, unlike Mexico, the French CT and CEPS calculate a reimbursement price based on the ASMR, SMR, and other factors, and can include volume limits, programmed price reductions, and other restrictions.

In 2003, the Social Security Financing Law introduced a new fast-track price notification procedure designed to speed up access to certain "innovative medicines." Under this system, once an innovative product has been evaluated by the CT and given an ASMR, the sponsoring company may notify a suggested price to the CEPS. If the price is acceptable, the drug would be automatically registered as a reimbursable product. If the price is not acceptable, the company can either cut the price or enter into price negotiations with CEPS.

In July 2004, the French Parliament approved legislation to replace the CT with a new "High Authority of Health," which will have an enhanced role. The reform legislation is designed to initiate a more active and systematic policy on product pricing during the product life cycle, including bringing the prices of innovative medicines closer to the European average. The current SMR (medical benefit) will likely be replaced by both SMA (expected medical value) and SMRR (observed medical value) based on clinical experiences after 2-3 years on the market.

Despite longstanding price controls, France still has the second largest per capita drug consumption in the OECD at $606 in 2005,[9] trailing only the U.S. The deteriorating competitiveness of the French biopharmaceutical industry has also become a concern. The French Government has sought to support French industry by promoting mergers, e.g. Sanofi-Aventis, of French firms, and promising to bring prices closer to the OECD median.

[9] OECD Health Data 2005.

In sum, France operates a classic European-style pharmaceutical price control system where the government determines or negotiates a maximum reimbursement price and strictly controls spending. While the reforms are designed to boost French industrial competitiveness in the life sciences, they also appear to contemplate a greater emphasis on pharmacoeconomics, and re-evaluations of prices based on post-launch clinical data.

Americas: Canadian Pricing and Reimbursement System

In Canada, the providers provide health care to their citizens under a broad federal mandate that establishes general benefit and eligibility standards. Because the actual provision of health care is handled at a provincial level, health care and drug access programs vary significantly by province. All of the provinces provide a public pharmaceutical benefit for the elderly and social assistance recipients and persons with special needs. The levels of public drug coverage vary by province. The remaining two-thirds of the Canadian population purchase drugs through private insurance plans sponsored by their employers or purchased on an individual basis.

Canada regulates the prices of patented pharmaceuticals at a federal level through the Patented Medicines Prices Review Board (PMPRB). The PMPRB was created in 1987 to prevent pharmaceutical firms from abusing their monopoly position. It is a quasi-judicial body with the power to impose sanctions and enforce price reductions. The PMPRB has issued guidelines that set out criteria for determining whether a drug's price is "excessive." Under its published criteria, the Board determined the introductory price of a patented medicine with the price of an existing comparator drug in Canada and to prices in the "A-7" countries – France, Germany, Italy, Sweden, Switzerland, the UK, and the U.S. The price in Canada cannot be higher than the median of the ex-factory price in the A-7 basket. Prices are monitored throughout the patent life of the product, and price increases are capped at the level of changes in the consumer price index in line with inflation.

While the Canadian federal authorities set an upper limit on the price of a patented drug through the PMPRB, the provinces also set limits under provincial drug plans. The provinces employ a wide range of cost-containment tools, including formularies, reference pricing, therapeutic groupings, co-payments, deductibles, reimbursement restrictions, and generic substitution. In British Columbia, a reference pricing scheme limits prices to a single reimbursement price for all drugs that are grouped in a therapeutic class. Thus, in British Columbia, the level of reimbursement is capped below the PMPRB price, leaving the patient responsible for the difference.

The Canadian Government established the Common Drug Review (CDR) process in 2003 to evaluate new drugs and issue official recommendations as to whether drugs should be included in provincial formularies. The Canadian Expert Drug Advisory Committee (CEDAC), which evaluates clinical studies regarding safety and effectiveness, therapeutic advantages and disadvantages relative to existing drugs, and a drug's cost- effectiveness compared to existing treatments, and issues recommendations to the provincial authorities, which are incorporated in provincial formularies.

Despite this array of cost-containment measures and price controls, Canada has the third-highest drug consumption in the OECD at $507 per capita annually, well above the OECD average.[10] Between 1999 and 2003, Canadian pharmaceutical expenditures grew by 6.9% annually, exceeding the OECD average of 5.6%.

Americas: Mexican Pharmaceutical Pricing

Mexico's health care system combines public and private elements. The Mexican Government provides health care to about 51% of Mexico's population through the Social Security System. This system is financed by the government, employers, and compulsory contributions from employees. Public health care is provided through various institutions, including the Mexican Institute for Social Security, the Institute for Health and Social Security for State Workers, PEMEX, and the Mexican armed forces. Federal and state ministries of health also support basic health care to the uninsured. Pharmaceuticals provided through the Social Security System consist of older off-patent generic medicines, which are acquired through bulk purchasing schemes. In 2000, seven of the top 20 drugs purchased by the Social Security System were over 40 years old, in part because purchasing decisions involve lowest price criteria.[11]

Mexico also has a large private health care market. Private health care is provided primarily through hospitals and clinics, and financed through out-of-pocket expenditures and private insurance schemes. Patented pharmaceuticals are sold almost exclusively in the private health care market. Accordingly, Mexico has evolved toward a 2-tier health care system with public institutions providing basic care for government workers and uninsured urban and rural populations, while the expanding Mexican middle-class purchases health care on the private market.

[10] OECD – Canada, 49.
[11] USITC.

While patented pharmaceuticals continue to be subject to price controls, the Mexican Government has gradually loosened the controls to give industry greater pricing flexibility. In 1991, Mexico adopted a "Program to Modernize the Pharmaceutical Industry" (PROMIF), which established a system of pharmaceutical price control guidelines. The PROMIF system was amended in 1996 in a Prices Coordination Agreement, which established a Medicines Price Self-Regulation System to boost competition, increase consumer supplies, and promote the Mexican industry.

On October 1, 2004, Mexico's Secretariat of Economy and CANIFARMA, which represents the Mexican pharmaceutical industry (including U.S. research-based companies), signed an "Addendum" setting out major changes to the Mexican pharmaceutical price control system. Key changes include the following:

International Reference Pricing. For patented products (new and old), pharmaceutical companies will determine the maximum retail price based on the weighted average ex-factory price from the immediately preceding calendar quarter in the 6 countries with the largest sales share of the corresponding pharmaceutical product. This information must be submitted under oath, and ratified by an independent auditor. If the product is not sold in 6 countries, the report must provide the number of countries where it is sold.

Public Sales Reference Price/Maximum Public Sales Price. The reference price of the patented product must be multiplied by a marketing factor of 1.72 to reach a Public Sale Reference Price (PRVP). This represents the Maximum Public Sales Price (MPSP). The Mexican price cannot exceed the MPSP, which operates as a retail price control cap.

Notification/Registration. For patented medicines which have been sold in Mexico prior to the Addendum, a company must register the price of the product as of May 31, 2004 with the General Directorate of Basic Industries of the Secretariat of Economy. For newly-registered products, a company must register the price with the General Directorate. The registered price cannot exceed the PSRP. Thereafter, companies must file an annual notification with the General Directorate of the Basic Industries Head Office.

Adjustments. A pharmaceutical company can modify the MPSP at any time, provided it does not exceed the PSRP.

By October 30, 2004, each company was required to sign a letter stating its desire to adhere to the Addendum. Within 90 days thereafter, companies were required to present the Secretariat of Economy with their international reference prices. These prices must be certified by an independent auditor.

The new Addendum focuses on self-regulation of maximum prices by companies. Unlike many price control systems, the individual company, not the Mexican Government, calculates and notifies the maximum reimbursement price. While the system involves international reference pricing, it is based on existing prices in the product's 6 largest markets, and thus will typically involve a weighted-average of the U.S., Europe, Japan, and other advanced industrialized countries. The Addendum gives companies broad flexibility to raise and lower prices, subject to the MPSP limit, and to respond to competitive conditions.

In sum, the Mexican reflects[12] a steady loosening of drug price controls over time, increased pricing flexibility for industry, and the gradual emergence of a private health care market to meet the needs of an expanding middle-class, alongside a public health care system for government workers and low-income households.

Asia: Australian PBS Pricing and Reimbursement System

Australia's Medicare national health care system provides subsidized access to prescription medicines for Australian residents under the Pharmaceutical Benefit Scheme (PBS). The PBS aims to improve the health of the Australian people by providing universal and equitable access to necessary and life-saving medicines at an affordable price. It funds approximately 93% of Australian prescriptions. A small private market exists for drugs which are not covered by the PBS, e.g. anti-impotence medicines or other drugs that are not regarded as "necessary" for patient health, or cost less than the co-payment.

Australia helped pioneer the use of pharmacoeconomics in 1992, and relies heavily on pharmacoeconomic analysis in determining eligibility for listing and the scope of PBS reimbursement. The PBS operates as a "positive list" system providing reimbursement to medicines approved through pharmacoeconomic evaluation. Prescriptions are subject to maximum co-payments of $23.70 for most patients and $3.80 for concession card holders, i.e.

[12] A comparison of systems in countries in Africa, Middle Eastern Countries and developing countries in Asia indicates that most of the countries with price controls favored cost-effectiveness analysis for determining pharmacoeconomic guidelines. However, understanding for such analysis was limited and often the preference in fact, was for a cost analysis.

low-income workers, unemployed, disabled, and seniors. Co-payments are adjusted annually every January 1 in line with inflation.

The process of obtaining a PBS listing is complex and involves multiple steps by different administrative bodies. Before listing, a drug must be approved by the Therapeutic Goods Administration (TGA). Once the TGA finds that a drug is safe and effective, a sponsor (typically a pharmaceutical company) applies to the Pharmaceutical Benefits Advisory Committee (PBAC) for a PBS listing. In applying for a listing, a company must identify a comparator drug, which is already listed on the PBS, and show that the new drug is more cost-effective than, or at least as cost-effective, as the listed drug. Based on a report from an outside evaluator, the PBAC evaluates the drug's effectiveness, including its cost effectiveness, and advises the Minister of Health and Aging whether the drug should be approved for listing and whether restrictions should apply.

If the Minister accepts the PBAC's recommendation, the Pharmaceutical Benefits Pricing Authority (PBPA) negotiates a price with the manufacturer. The PBS employs a variety of cost-containment tools, including therapeutic reference pricing, price-volume agreements, and generic substitution incentives. PBS listings are frequently subject to reimbursement restrictions.

The Minister of Health and Aging must approve the final listing, except drugs with a potential outlay over A$10 million, which must be approved by the Cabinet. The PBS listing process takes a minimum of 8 months from TGA approval, and often much longer. On occasion, the Australian Government has imposed across-the-board price cuts on pharmaceuticals to reduce pharmaceutical spending and achieve budgetary targets.

The U.S.-Australia Free Trade Agreement contains a Pharmaceuticals Annex, which sets out specific steps to improve the transparency and accountability of the PBS process. The FTA also provides for independent review of PBS decisions though an "independent convenor."

Asia: China's Evolving Health Care and Drug Pricing Systems

Like India and Mexico, China is a developing country with both a rapidly expanding economy and a large population of urban and rural poor. From the 1950s to the 1970s, China experienced major gains in life expectancy, childhood mortality, and other health indicators. These gains reflected underlying improvements in basic public services (e.g. sewage facilities), improved nutrition, and a high level of access to basic health services (e.g.

vaccines) though rural health clinics. During this period, China's Cooperative Medical System (CMS) used "barefoot doctors" to provide free preventative and primary care services. As China embarked on sweeping free market economic reforms starting in the 1980s, public subsidies were cut, hospitals were allowed to retain additional patient revenues, and the CMS deteriorated.

Today, public expenditures are low, while private expenditure is much higher than the worldwide average.[13] According to the World Bank, Chinese public expenditure as a share of total health care spending totals approximately 11% -- well below the rest of the world, e.g. India (13%), the U.S. (23%), Brazil (49%), and the OECD average (72-80%). While the national government subsidizes health care through various programs, about 60% of public expenditure is borne by provincial and local governments. Both national and provincial public expenditures focus on hospital construction, purchase of equipment, and staff salaries, leaving hospitals to fund many individual health care services through fee-for-service payments by patients and households.[14]

As a result, the Chinese system relies heavily on cash payments by patients. Even patients with private health insurance typically must pay over one-third of the cost of medical services out-of-pocket.[15] Chinese hospitals use the prescription and sale of pharmaceuticals as a profit center, contributing to high prices and widespread over-prescription. The mark-ups on pharmaceuticals average 70% over the ex factory price, one of the highest margins in the world.

Because the governments typically sets the prices of basic or preventative health care procedures below the cost of providing such services, Chinese hospitals and physicians tend to focus on high-profit tests and medical procedures, leading to excessive use of expensive diagnostic tests, excessive spending on advanced technology, e.g. MRI machines, and lengthy hospital stays.

China has a large number of uninsured urban and rural poor. Since hospitals operate on the basis of cash payments, the system imposes a large burden on low-income households, who lack private insurance or financial resources to finance urgent care for family members. Accordingly, many poor Chinese households have been forced to borrow to pay for catastrophic medical care for a family member.

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[13] Public Expenditure and the Role of Government in the Chinese Health Sector (World Bank 2005).
[14] Elaine Wee-Ling Ooi, "The World Bank's Assistance to China's Health Sector," p.3 (World Bank 2005).
[15] China's Health Sector – Why Reform is Needed, p. 2 (World Bank 2005).

The Chinese Government reimburses essential medicines listed on the "National Reimbursement List" (NRL). The NRL is revised periodically by adding new medicines. Because of the de-centralized structure of the Chinese health care system, each province typically maintains a provincial formulary.

China maintains national and provincial price controls on certain drugs, including those listed on the NRL, provincial formularies, monopoly drugs, and other special drugs (e.g. immunization, psychiatric products, birth control drugs, and narcotics). The legal authority for such price controls arises from Order No. 25 from the State Development and Planning Commission,[16] and the Price Law of the People's Republic of China. In Notice No. 2141, the State Development and Planning Commission (SDPC) published a list of drugs subject to national and provincial price controls.[17] Price controls were revised in 2000 with the aim of gradually expanding market mechanisms, removing OTC products from price controls, and eliminating differences between the pricing formulas for imported and domestic drugs. The principal form of price control is a ceiling retail price. The pricing formulas vary for different drug classes including innovative, generic, GMP, brand v. non-brand, and market entry. The National Development and Reform Commission (NRDC) periodically cuts the maximum retail price for certain classes of listed medicines to address discounting. Free market pricing is used for drugs which are not subject to government controls.

The Chinese pharmaceutical industry is highly fragmented with large numbers of small Chinese companies often producing hundreds of low-quality generic copies of patented and branded drugs. Intellectual property piracy is rampant. However, China is seeking to build a globally-competitive life sciences industry, and Chinese companies are becoming serious competitors in developing country generic markets around the world. While China has focused to date on low-cost generic products, it is seeking to develop more advanced generic products and beginning to invest in biopharmaceutical research and development. At both a national and provincial level, the Chinese Government has established subsidy programs and government incentives for multinational pharmaceutical companies that are prepared to locate production facilities or research laboratories in China.

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[16] Order from State Development and Planning Commission, Number 25 (Nov. 1, 2002).

[17] SDPC Notice on the Issuance of "List of Drugs Priced by SDPC" (Urgent, Ji Jia Ge [2000] No. 2141). *See also* SDPC Notice on Issues Relating to the Setting and Adjustment of Prices of B List Drugs, (Urgent, Ji Jia Ge [2000] No. 2143 (Nov. 21, 2000)); SDPC Notice on the Issuance of "List of Drugs Priced by SDPC" (Urgent, Ji Jia Ge [2000] No. 2144 (Nov. 21, 2000)); and State Development and Planning Commission's Publication of Notice of Prices for 383 Drugs (Urgent, Planning Price No. 2661 [2001]).

Asian: Japan's National Health Insurance System

Japan is the world's second-largest pharmaceutical market with annual sales of over $50 billion, trailing only the U.S. Since 1961, 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 health care to employees of small- and mid-sized companies, whilst mutual aid associations have been formed to cover the self-employed, farmers, and the unemployed. All of the programs are supervised by the Ministry of Health, Labor, and Welfare (MHLW). NHI spending totaled $268.1 billion in 2002.

The NHI provides a drug benefit covering most drugs approved by the Pharmaceuticals and Medical Devices Agency (PMDA).[18] Once a drug is approved by PMDA, the manufacturer must apply for a NHI listing. MHLW's Health Insurance Bureau (HIB) 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. The patient is responsible for a 30% co-payment.

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 the degree of innovation, usefulness, and marketability – "Innnovative," "Useful I," and "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 upward or downward using a set formula.

[18] Certain "lifestyle" drugs are excluded.

Special rules apply to pricing of me-too drugs (zoroshin). Generics are priced at a fixed percentage of the originator's price, with the percentage declining with the number of generic competitors approved. While MHLW has encouraged manufacturers to submit pharmacoeconomic data since 1992, it does not play a major role in MHLW's pricing decisions.

One peculiarity of the Japanese system is biennial price revisions. Until the 1990s, Japanese physicians were permitted to both prescribe and dispense. In addition, drugs were reimbursed at an official price, rather than an actual transaction price. This meant the Japanese market was characterized by widespread discounting ("yakassa"), which allowed physicians to profit from the discount margin on medicines that they prescribed and dispensed. In the 1990s, MHLW separated prescribing and dispensing, and began sharply reducing the level of permitted discounts (R-zone). The R-zone was set at 2 % in 1998, and has remained at this level. Every two years, MHLW surveys drug prices and calculates whether the discounts on classes of drugs have exceeded the permissible level of discount (R-zone). On April 1, 2004, for example, MHLW announced that the survey had resulted in an average price cut of 6.2%. Some classes, however, received larger or smaller price revisions depending on the survey.

MHLW also employs a repricing process, in which the price of a drug can be reduced because of market expansion or approval of new indications. The industry has criticized the repricing rule for punishing successful products that experience high demand from patients.

The Japanese generic market is extremely small, roughly 7% of consumption. Japanese physicians and patients are highly brand-conscious and pharmacists are not permitted to engage in generic substitution. The Japanese public tends to associate generics with questionable quality and reliability. Finally, biennial price revisions also have had the perverse effect of undermining generic markets, because prices are unstable and discounts, which are required to sell generics, are punished in the next two-year revision.

Because of the age and declining value of comparators, Japanese drug prices have been spiraling downward for over a decade. As a result, the A-4 rule plays a critical role in ensuring viable prices and keeping Japanese prices for innovative drugs aligned with international prices.

Japan is also experiencing a major drug lag, because its slow drug approval process and low prices. Even leading Japanese drug companies have begun launching their most innovative products in the U.S. and Europe, and shifting an increasing share of their most advanced research and development abroad. MHLW has responded by developing a detailed

"vision" forth measures designed to boost Japan's competitiveness in the life sciences, but thus far progress toward implementing the vision has been mixed.[19]

Because of the rapid aging of Japanese society, NHI spending has soared, leading to a multitude of cost-containment initiatives. To date, MHLW has focused on curbing drug spending, by containing the number of me-toos and the high prices of non-innovative products. Despite these initiatives, per capita drug consumption remains extremely high compared to other OECD markets.

Worldwide: Key Conclusions Regarding National Drug Pricing Systems

Price control regimes for pharmaceuticals sometimes attempt to set higher prices for more innovative drugs (as in Canada, France, Japan, and elsewhere.) That action requires price controllers to outguess the market in deciding which research areas are most promising and which new types of drugs would be most useful.[20] The current American dominance of global life sciences discovery suggests that government subsidies and planning are not a viable substitute for the market in new drug development.

A study[21] examined the drug price regulatory systems of 11 OECD countries and found that all rely on some form of price controls to limit spending on pharmaceuticals. It also found that under the reference pricing, governments often are the dominant market participant and may negotiate favorable prices with manufactures by leveraging this monopsonistic power based on the sales prices. Such negotiations generally result in prices lower than they would be in a free market. The study also found that reimbursement price generally functions as the *de facto* market price where such mechanisms are employed, since there is no real private market. There was also evidence that some OECD governments regularly cut the prices of drugs for budgetary or cost-containment reasons.

A study of nine countries[22] (Canada, Chile, France, Germany, Italy, Japan, Mexico and the UK), indicates that other than Japan, other countries' prices are 6 percent to 33

[19] "Toward Reinforcing the Global Competitiveness of the Pharmaceutical Industry, Mainstay of the 'Century of Life' – Outline of a Vision of the Industry," Ministry of Health, Labor and Welfare (April 9, 2002).

[20] J. E. Caffee; ibid.

[21] USDCITA (2004) "Pharmaceutical Price Controls in OECD countries: Implications for US consumers, pricing, research and development and innovation", Washington DC: U.S. Department of Commerce International Trade Administration.

[22] P. M. Danzon & M.F.Furukawa; Prices and Availability of Pharmaceuticals: Evidence from Nine Countries; HEALTH AFFAIRS – Web Exclusive; 29 October 2003.

percent lower than in the United States. A related study[23] found that in OECD countries, government mandated controls on price, volume and overall spending do result in reduced prices, but also in reduced access to innovative medicines. Launch delays of one to two years are typical, adoption rates are slower and even peak penetration rates lag US rates by 15% to 20%, and therefore patients are unable to receive the full therapeutic benefits of these drugs. There is evidence that cost control policies in OECD countries have contributed to the migration of R&D activities out of these countries to the United States. Using counterfactual data, the researchers estimate the negative consequences in the form of fewer medicines, missed opportunity for lower pricing from incremental competition and lower jobs. Other studies have validated the hypothesis that replacement of older drugs by new drugs resulted in reductions in total medical expenditures. Estimates indicate that a reduction in age of drugs utilized reduces non-drug expenditures substantially, including hospital expenditure and physician office- visit expenditures.

A review of key national drug pricing systems underscores the close inter-connection between price controls and government-sponsored universal health care systems. In most of the European systems, price controls are used to regulate the prices at which pharmaceuticals are reimbursed as part of a national health care system, which is operated and funded, or closely-regulated, by the government, and provides universal access to health care for all citizens or residents. Such systems also tend to be found in OECD countries. Most developing countries do not provide universal health care. While some developing countries have programs to provide basic health care to the most vulnerable members of society, and also some type of drug price controls, such systems tend to be much more flexible and to cover only a limited range of essential medicines.

Economic studies have repeatedly confirmed that price controls have had only limited effectiveness in controlling drug spending. As a developing country, India has much more limited fiscal and economic resources alongside a much larger population of low-wage urban workers and small farmers. As a result, establishing a European-style drug reimbursement scheme, even with a combination of public and private financing, would require a vast expansion of public subsidies by the Indian Government.

Although reference pricing is the most common international cost-containment tool, adopting a European drug pricing system and referencing prices to foreign prices also would have serious disadvantages in an Indian context. Even if Indian prices were referenced to

[23] Boston Consulting Group; Adverse Consequences of OECD Government Interventions in Pharmaceutical Markets on the Economy and the Consumer; July 1, 2004, mimeo.

even the lower end of the OECD, the prices of most advanced drugs would still be prohibitively high and likely well beyond the reach of the common man. While a European-style universal health insurance system and a comprehensive public drug benefit could be used to alleviate the burden on the common man through a public subsidy, it would impose a massive long-term fiscal burden on the Indian Government. According to the OECD, in 2003 per capita drug expenditures averaged $606 in France, $507 in Canada, $393 in Japan, $353 in Australia, $284 in the Czech Republic, and $225 in Poland.[24] Even if these costs were partially subsidized by the Indian Government or the states, the cost would be prohibitive and would likely displace other vital government programs.

On the other hand, if the prices of advanced drugs were referenced to other developing countries, or domestic generic drug prices, such controls would keep drug prices lower, but undermine the global competitiveness of India's world-class pharmaceutical companies, and deter future private sector investments in advanced biopharmaceutical discovery. In such a situation, research by Indian companies and patenting activity of scientists would likely shift offshore, probably to the U.S. or to the U.K.

If a government sets the same price for generic and patented medicines, consumers naturally tend to choose the more advanced product, since it provides better value or greater quality assurance. Accordingly, demand for unbranded generics in price controlled markets tends to be artificially reduced, e.g. Japan (13%),[25] Australia (28.4%), and France (23.56%).[26] This has led OECD governments to adopt measures to boost demand for cheaper unbranded generics. The Sen Commission report sought to address this phenomenon by wholly restructuring the Indian market to focus on low-cost unbranded "generic" generics, but this would also undermine the globally-competitive segment of the Indian industry and with it any prospect of building an innovative life sciences capability.

Limitations and Problems in the Price Fixing Approaches

Price determination efforts attempt to reduce costs of public health care. Therefore, price fixing has been concerned with the reimbursement burden that the public health system would have to bear, and to improve cost-effectiveness of that expenditure. There has been little or no attempt to control the market price of the drugs and formulations, only of the price

[24] OECD Health Data (2005).
[25] ABPI, Generic Market Share by Value for Selected Countries at ABPI.org.
[26] U.S. Dept. of Commerce.

at which patients would be able to access these drugs in the public health system, or, at best, receive reimbursement from the medical insurance providers. Price negotiations for NHS in the UK and the negotiations in Australia are intended to determine the prices for access through the national health systems. The important underlying factor of the existence of a national health care system, with some measure of universal coverage assurance is the basis on which these reference price systems work. In most developing countries, and certainly in India, there is no such universal health care system. In theory, the public health delivery systems are accessible to the entire population at low or no cost, but in practice, the growth of the private sector in health care, and its share in providing clinical care, has been growing over the years. There is a growing market of health care that is outside the government system, and indeed, outside any organized system of reimbursement. There have been considerable investments in private health care facilities in India in the last two years. Current investments in high end hospitals across the country are likely to add an additional 30000 hospital beds by 2010. These hospitals charge market rates for health care, and are supported by the medical insurance industry as well as corporate health plans, and cater to the growing affluent market. Patients demand superior care and attention, and are willing to pay. This important difference, coupled with the fact that unlike Australia, India is a large market for pharmaceutical products, and has, at the same time, a thriving pharmaceutical industry, would have a considerable impact on policies and practices in pricing of pharmaceutical products.

At the implementation level, a common feature of all price regulatory mechanisms is the large amount of data that needs to be processed, and the transparency of the process. Pharmacoeconomic criteria are adopted by almost all countries in Europe. Data on cost effectiveness in the form of analysis of alternate regimens of drug delivery and effectiveness of the drugs themselves, are gone into in considerable detail to determine the range of drugs that would be taken up for reference pricing. The data base at NICE is increasingly accessed by other countries, and recent G 8 discussions on health care have focused on the need to create, and to pool together, information on drug delivery effectiveness, and cost benefit data that could be used by member countries in a transparent manner. The system in France provides for a transparent methodology that closely interacts with the producing firms at every level. Governments tend to regulate prices, but some of these regulation models are economically not very effective. Lack of negotiation skills or information sometimes makes it difficult for public sector negotiators. The lack of transparency in the process is likely to

distort the process and lead to rent seeking.[27] Lack of competition or market access may also drive providers away from such markets.

In short, the price fixing mechanisms in the developed countries presuppose capability for a sophisticated degree of analysis, evaluation and transparency in methodology and approach, that focuses on objective criteria and results. It is an organizational challenge to create a mechanism that would duplicate these in India. There are several reasons for this. First, data and information on cost effectiveness is not collected in a systematic manner by institutions, and hence the exercise is reduced to cost analysis rather than cost- effectiveness analysis. Second, due to difference in income levels, standard comparisons of reference level populations of other countries to determine capacity to pay becomes difficult. Third, with a large local industry, comparison between international costs of production and indigenous costs are not always possible to make in an objective manner. Therefore the entire exercise has several limitations.

These problems are exacerbated in the case of patented medicines, that is, those pharmaceutical products that enjoy product patent protection. It is universally acknowledged that drug discovery is an extremely expensive process; that for every molecule that finally makes it into a product, there are several that are abandoned on the road to discovery; that the patenting system provides an opportunity to recover developmental costs over the patent period. The new research environment has added important new elements to the risk environment of pharmaceutical research as a byproduct of the dramatic exploration of entirely new areas of application. Manufacturers that venture into new territory are less certain of what they will find and less confident of what it will be worth when they find it—they face new uncertainties over both supply and demand.

Of the numerous factors that create uncertainty over the demand for new drugs, two stand out. First, many new drugs address conditions that have not been systematically treated. Data on the prevalence, health consequences, and social costs are sparse because conditions that are not treated tend not to be studied. Second, even if one does know the number of those suffering from a condition and the health consequences of that condition, we still may have only a vague idea of what people are willing to pay for the drugs that alleviate those conditions. Uncertainty over the health benefits from a new drug is therefore one problem, and uncertainty over what consumers are willing to pay for those benefits is another.

[27] World Bank; HNP Brief #7; 35560; Pharmaceuticals: Cost Containment, Pricing, Reimbursement; Washington, August 2005.

On the supply side, the costs of developing new treatments are also shrouded in uncertainty. New research tools notwithstanding, failures are still the norm when researchers attack problems that have remained unsolved for decades.

There are indeed, a very large number of studies[28] that have examined the impact of price controls on patented products and R&D. The underlying comparison is with the US, where market prices for pharmaceutical products are free to operate, and pharmaceutical companies do attempt, in the short period of time that exclusivity is available, to defray the humungous costs of Research and Development that go into drug discovery. On the impact of price controls by OECD countries, studies indicate that Europe's free-ride on US R&D is costly, in terms of delayed access to medicines, poorer health outcomes, and lower investment in R&D. If the OECD governments did not control pharmaceutical prices, an additional $ 17-22 billion would have been spent on R&D in 2003, resulting in a 50% increase in new chemical entities. Studies unequivocally suggest that a regulation of prices in the US could lead to a decline in R&D intensity of between 23 and 33 percent. The impact of price controls on pharmaceuticals in OECD countries also documented[29] that without price controls; revenues available for R & D could be significantly higher. The higher revenues would mean more R & D and new drugs. Based on an estimated cost developing a new drug, an increase in R & D of $ 5 billion to $ 8 billion could lead to three or four new molecular entities annually once markets fully adjust. It also reveals that in the absence of drug price controls, average prices in the OECD countries for innovative pharmaceuticals would be equal to U.S. prices adjusted for differences in per capital income. These adjusted prices were used to estimate revenues in the absence of drug price controls. Even, the economic models also indicate that benefits of lower prices to consumers were less than the benefits to society of new drugs foregone.

The summary review clearly demonstrates that price controls on pharmaceutical products produce a variety of negative consequences for national health systems and reduce social welfare by depressing the number of new drugs added to the global pharmacopoeia. It can also reduce the availability of some innovative medicines in foreign countries, with the effect of limiting competition and requiring national health system to forgo the benefits of those innovations in reducing health care costs.

[28] See bibliography for an illustrative list of studies referred to
[29] USDCITA (2004) ibid.,

II Is Price Control on Pharmaceutical products compatible with the existing provision of health care system?

The negative consequences of price controls on pharmaceutical products are related to the health system administration and level of market size of the pharmaceutical industries in respective countries. Therefore, it is imperative to review the existing healthcare system and its compatibility with the proposed price controls on pharmaceutical products in India.

The healthcare system in India consists of primary, secondary and tertiary care institutions and managed by medical and paramedical personnel at different levels of the State government. There are also specialized institutions and hospitals set up by the Central government in different parts of the country. The on-going health programs are managed at the Central, State, and district levels. The process of public sector funding to health care commences from the Central Ministry of Finance based on recommendations from the Planning Commission and flows to the Ministry of Health and Family Welfare at the Central level and in turn to the respective State governments. The Central Health and Family Welfare Ministry plays a major role in allocation of funds to various programs to the States, as they are responsible for implementation of family welfare, and public health programmes.

Despite the fact that India is a signatory to the Alma Ata Declaration of 1978 aimed at 'Health for All' by 2000, the Government of India spending on health was hardly 0.9 per cent of GDP in 1999-2000. Health being a predominantly a State subject, 81 per cent of total health expenditure is borne by the respective States and the balance 19 per cent by the Central government through its own funds or through external assistance. It is interesting to note that health expenditure has always hovered around 3% of the plan allocations, and it is only in the tenth plan that there is an effort to increase it to nearly 4 %. The significant growths in private health expenditure, particularly after the 90s, is indicative of alternates to public health being available and affordable for a larger section of the population. Based on the NSSO 52nd survey round data, the total health expenditure of the country was around Rs.26, 281 crore out of which the public sector accounted for only 21 per cent and the balance by the private sector.

Table 2: Pattern of investment and expenditure on health and family welfare (Rs in billions) and selected health outcomes

Plan period	Public health investment and expenditure						Private health		Total health	
	Health & FW plan expenditure	Health & FW as % of plan	Health & FW expenditure – plan + non plan	% of health & FW of total govt expenditure	% of health & FW of GDP	% of plan H&FW expenditure	Private health expenditure	Private health as % of GDP	Total health expenditure	Public as % of total health
First Plan (Actuals)(1951-56)	0.65	3.33	2.27	3.74	0.44	28.63	7.5	1.46	9.77	23.2
Second Plan (Actuals) (1956-61)	1.46	3.12	3.93	3.52	0.56	37.15	13.2	1.88	17.13	22.9
Third Plan (Actuals)(1961-66)	2.51	2.92	6.68	2.65	0.62	37.57	26.89	2.53	33.57	19.9
Annual Plans (Actuals) (1966-69)	2.11	3.18	6.84	2.8	0.69	30.85	26.92	2.71	33.76	20.3
Fourth Plan (Actuals)(1969-74)	6.14	3.89	19.91	3.35	0.84	30.84	67.02	2.83	86.93	22.9
Fifth Plan (Actuals)(1974-79)	12.53	3.18	34.33	2.86	0.81	36.5	148.21	3.52	182.54	
Annual Plan(1979-80)	3.84	3.3	11.29	3.19	1.04	34.01	45.85	4.21	57.14	19.8
Sixth Plan (Actuals) (1980-85)	34.12	3.12	95.72	3.15	1.1	35.64	354.64	4.06	450.36	21.3
Seventh Plan (Actuals) (1985-90)	68.09	3.11					556.05	3.35		
Annual Plans(1990-91, 1991-92)	37.71	3.06	109.95	2.94	0.99	34.3	307.63	2.8	417.58	26.3
Eighth Plan (Actuals)(1992-97)	141.1	2.9	434.34	2.52	0.93	32.49	1352.23	2.88	1786.57	24.3
Ninth Plan (Budget Estimates) (1997-2002)	299.96	3.19	847.69	2.65	0.97	35.38	3054.24	3.49	3901.93	21.7
Tenth Plan (draft outlay) 2002-2007	589.2	3.86	1785	2.5	1	33	7500	4.28	9285	19.2

Source for plan data: 1. 'Indian Planning Experience -- A Statistical Profile', Planning Commission, GOI, New Delhi, 2000; 2. Ninth Five-Year Plan, Planning Commission, GOI, New Delhi, 1998; 3. Draft Tenth Five-Year Plan, www.planningcommission.nic.in/ ; for total public health expenditure (ministries of health and family welfare: 1. Up to 1986 -- combined finance and revenue accounts, respective years, GOI, New Delhi; 2. 1987–2002 -- finance accounts of states and Union government, respective years; and RBI -- finances of the state governments, respective years, RBI, Mumbai; for private health expenditures and GDP data -- national accounts statistics, CSO, 2003; for health outcomes -- Registrar General of India, respective years. Projections estimated by author

Table 3 below gives the nature of health expenditure in terms of revenue and capital expenditure. It clearly illustrates the low capital formation that is taking place. Table 4 below is also evidence that some of the States (for example, Andhra Pradesh, Karnataka, Maharashtra, Tamil Nadu and, Gujarat) have increased allocations to health significantly in the last decade, while in others (Assam, Orissa, Uttar Pradesh) the increases are smaller. It is also important to note the decline of health related revenue expenditure in almost all the states after peaks in the seventies and the early eighties. The reasons for this lie elsewhere, in the fiscal contractions that took place in the first wave of the reforms of the nineties, and are a pointer to the increased attention being paid now.

Table 3: Total public health expenditure (revenue + capital) trends 1975-2003 and selected ratios

Year	Total public health expenditure	Percent of GDP	% of total govt expenditure	Per capita (rupees)	Capital as ratio to revenue expenditure
1975-76	6.78	0.9	3.13	11.16	0.11
1980-81	12.86	0.99	2.96	18.94	0.08
1985-86	29.66	1.19	3.29	39.28	0.09
1991-92	56.4	0.96	2.96	65.89	0.08
1992-93	64.64	0.74	2.71	74.13	0.04
1993-94	76.81	0.98	2.89	86.21	0.04
1994-95	85.65	0.93	2.33	94.33	0.05
1995-96	96.01	0.89	2.47	103.57	0.04
1996-97	109.35	0.88	2.43	115.96	0.04
1997-98	127.21	0.92	2.5	132.65	0.05
1998-99	151.13	0.94	2.66	155.01	0.04
1999-00	172.16	0.96	2.61	173.72	0.05
2000-01	186.13	0.98	2.69	182.66	0.04
2001-02 RE	211.06	1.02	2.72	203.53	0.05
2002-03 BE	219.59	1	2.6	208.54	0.05

Source: 1. Up to 1986 -- combined finance and revenue accounts, respective years, GOI, New Delhi; 2. 1987–2003 -- finance accounts of states and Union government, respective years; RBI -- finances of the state governments, respective years, RBI, Mumbai; 3. GDP and population data -- national accounts statistics, CSO, 2003

Table 4: Percentage of total government revenue expenditure in Health for Union and State governments

Union and State governments	1950-51	1960-61	1970-71	1980-81	1985-86	1990-91	1994-95	1999-00	2000-01
Union government	0.5	2.5	0.58	0.48	0.5	0.5	0.5	0.5	0.75
Andhra Pradesh	—	8.9	8.74	7.55	6.6	5.9	5.9	6.06	5.57
Assam	6.7	7.5	6.2	6.51	6.8	5.8	5.9	5.25	5.39
Bihar	6.3	9	6.53	5.72	5.7	5.5	5.5	6.3	6.95
Gujarat	—	6.2	9.75	7.11	7.5	5.8	5.5	5.21	4.05
Haryana	—	—	8.09	5.94	7	4.2	*	4.08	4.05
Jammu and Kashmir	—	8.6	6.68	7.35	7.6	6.1	6.2	5.54	5.45
Karnataka	0.4	5.8	6.32	6.74	6.6	6.1	6.3	5.7	5.42
Kerala	—	9.7	9.16	8.55	7.9	7.5	6.8	5.95	5.67
Madhya Pradesh	2.5	8.4	9.66	6.77	6.7	5.8	5.7	5.18	5.55
Maharashtra	6.2	7.6	8.38	6.53	6	5.5	5.1	4.59	4.27
Orissa	5.8	7.3	7.69	7.47	7.4	5.4	5.4	5.03	4.9
Punjab	3.8	7.1	7.22	7.04	7.2	5.5	3.7	5.34	5.44
Rajasthan	—	9.9	9.64	8.28	8.1	7.2	6.8	6.39	5.84
Tamil Nadu	7.1	9.1	8.66	7.66	7.7	6.7	6.3	5.51	5.34
Uttar Pradesh	5.8	5.1	6.79	6.5	9.8	6.5	5.8	4.42	4.54
West Bengal	9.9	9.5	8.8	9.83	8.9	8.4	6.9	6.3	6.23
Other states									
Arunachal Pradesh	—	—	—	6.86	5.9	6.6	6.4	6.57	5.9
Goa, Daman and Diu	—	—	15	10.3	8.2	8.7	7.6	5.33	4.82
Mizoram	—	—	—	7.03	6.8	4.9	5.6	6	5.27
Pondicherry	—	—	14	10.6	9.1	8.9	7.8	8.65	8.75
Himachal Pradesh	—	—	6.39	8.24	7.9	7.4	7.2	6.48	6.01
Manipur	—	—	7.17	7.68	6.2	5.6	5.6	5.55	5.87
Meghalaya	—	—	11	11.1	9.2	6.7	6.7	6.11	6.53
Nagaland	—	—	7.24	6.11	7	5.9	5.5	5.31	5.92
Sikkim	—	—	—	4.17	4.8	6.2	2.7	2.23	4.16
Tripura	—	—	7.91	5.07	6.5	5.6	*	4.87	4.77
Delhi	—	—	—	—	—	—	—	11.1	11.9
Chhattisgarh	—	—	—	—	—	—	—	—	4.78
Jharkhand	—	—	—	—	—	—	—	—	—
Uttaranchal	—	—	—	—	—	—	—	—	3.75
All India	2.7	5.1	3.84	3.29	3.3	3	2.7	2.97	3.13

Note: — = Not applicable; * = Not available

Source: Up to 1985-86 -- combined finance and revenue, Accounts Comptroller and Auditor General of India, GOI, respective years; other years -- finance accounts, respective states, respective years; RBI -- finances of the state governments, respective years

Table 5 disaggregates expenditure on public health by national programmes. The increase in proportion of revenue expenditure on health and the decreases in programme expenditure are apparent.

Table 5: Disaggregation of national public health expenditure by major programs

Particulars	1950-51	1960-61	1970-71	1980-81	1985-86	1990-91	1994-95	2000-01
Disease programmes	10.9	26.1	13.6	13	11.7	10.9	10.4	7.86
Hospitals and dispensaries	44.0	39.7	37.3	43.3	37.8	30.1	26.4	22
ESIS, CGHS	--	2.69	4.54	8.42	--	5.29	5.24	4.69
Medical education training and research	4.99	5.6	7.15	9.07	8.67	11.2	11.7	10.7
Family welfare*	—	—	—	11.4	17.4	15.5	15.5	13.5
MCH services*	—	—	—	0.51	0.5	0.91	1.82	2.77
Health administration	14.0	11.1	20.1	4.91	4.73	4.51	4.53	5.25
Capital expenditure on health*	__	__	__	7.54	8.45	4.69	4.56	4.09

Note : The sub-heads do not add up to the total as some sub-heads like public health training, health statistics, health transport, public health laboratories, etc, are not included here. Percentages for all programmes are a proportion of total revenue health expenditure, except for capital, which is a proportion of total health expenditure

* (i) Family welfare and MCH from 1950-51 to 1970-71 included in medical and public health account heads (ii) Capital expenditure on health is shown separately only from the '70s, prior to which it was under the ministry of works

Source: Up to 1985-86 are combined finance and revenue accounts, Comptroller and Auditor General of India, respective years. Other years -- finance accounts, respective states

Note: From the mid-'90s, external funding for hospital sector reforms and for select disease programmes has increased sharply and these are recorded under separate budgetary heads and hence the decline we see in the budget head ‘hospitals and dispensaries' and ‘disease programmes' may not be really so

Table 6 is an example from Maharashtra[30] of the proportion of rural versus urban expenditure, and indicates the urban bias to health care that persists. The picture is similar across states.

[30] Data is for 2001. Information for 2004indicates a similar distribution.

Table 6: Maharashtra public health expenditures (Rs in millions)			
Type of expenditure	Rural	Urban	Combined
Medical care*	259.55 (4.09)	7,457.24 (74.59)	7,716.79 (47.22)
Public health	4,514.34 (71.15)	1,947.33 (19.48)	6,461.67 (39.54)
Family planning	677.57 (10.68)	61.70 (0.62)	739.27 (4.52)
MCH	136.91 (2.15)	58.68 (0.58)	195.59 (1.20)
Other FW	672.34 (10.60)	167.77 (1.68)	840.11 (5.14)
Capital	84.41 (1.33)	305.04 (3.05)	389.45 (2.38)
Total	6,345.12 (100.00)	9,997.76 (100.00)	16,342.88 (100.00)
Percent to combined	38.82	61.18	100
Per capita	113.85	243.73	168.92
* Includes teaching hospitals, medical education and ESIS; figures in parentheses are column percentages			
Note: In addition, urban areas have municipal health expenditures, which can be substantial in bigger cities; for instance, Mumbai city alone has a municipal health budget equivalent to the entire medical care budget of Maharashtra state			

Table 7 suggests that the Hospitalisation expenses both in rural and urban Karnataka are higher than the National average, but the growth rate between the two rounds in the state is less than the country growth rate. The per hospitalization expenses had increased by 226% in rural areas, whereas it has gone up by 191% in urban Karnataka.

Table 7: State wise trends in total expenditure per Hospitalisation in Rupees

State	Rural		Urban	
	42nd round	52nd round	42nd round	52nd round
Andhra Pradesh	754	6428	901	4886
Kerala	464	2293	487	1927
Tamil Nadu	684	2840	1032	3934
Karnataka	919	2997	1231	3593
India	853	3202	1183	3921

Source: 42nd and 52nd rounds of National Sample Survey Report- Volume on Morbidity Pattern and Health

In fact, the hospitalization expenses in urban Karnataka during the 42nd round was highest among Southern states, but the next round figures indicate that with huge increase in expenditure over time, Tamil Nadu and Andhra Pradesh have overtaken Karnataka in the

spending. It is noteworthy to understand that Kerala, which stands high in Health infrastructure and Human Development Index, has the lowest expenditure for hospitalization in both the rounds for both urban and rural areas. However, it implies that most of the higher spending on health is taking place in the rural areas, where there has been a significant growth of middle income groups.

Table 8: Trend in total expenditure per Hospitalisation in Rupees

Survey round	Rural			Urban		
	Govt. Hospital	Private Hospital	All	Govt. Hospital	Private Hospital	All
42 nd	706	1241	853	969	1792	1183
52 nd	2080	4300	3202	2195	5344	3921

Source: 42nd and 52nd rounds of National Sample Survey Report- Volume on Morbidity Pattern and Health

It is obvious from the Table 8 that, over time, the average health expenditure has increased three fold in the urban as well as in rural areas. The other notable factor is the increasing difference between the public and private hospitals indicating that the public subsidies are high in Government Hospitals as they are targeted for the poor.

It is also important to note that the share of drugs and medicines to the total health expenditure of the State in Karnataka was ranging from 3 per cent to 8 per cent during 1997-98 and 2003-04 as in the Table 9. However, most of the States in India spend less than 5 per cent of total health expenditure for drugs and medicines. In principle the drugs and medicine provided in the hospitals and dispensaries are free of cost or very nominal rate. However, there is no universal coverage of health insurance scheme or health plan in India.

Table 9: Percentage trend in Non wage components as Percentage of Total Health Expenditure

Year	1997-98	1998-99	1999-00	2000-01	2001-02	2002-03	2003-04
General Expenses	1.59	3.61	2.18	2.48	2.03	1.61	3.57
Machinery & Equipment	0.08	0.00	0.01	0.01	0.00	0.61	0.56
Building Expenses	2.23	2.02	2.54	3.73	2.62	3.05	4.80
Transport Expenses	0.00	0.25	0.19	0.32	0.50	0.25	0.51
Scholarship & Incentives	0.38	1.00	0.50	1.02	0.67	0.95	0.96
Drugs & Chemicals	2.95	5.73	6.15	6.22	6.38	6.87	7.68
Equipment & Accessories	6.47	4.36	8.44	3.93	5.64	2.46	1.55
Maintenance	0.08	0.07	0.15	0.31	0.63	0.62	0.51
Publicity Expenses	0.06	0.03	0.02	0.09	0.12	0.01	0.00
Grants-In-Aid	8.45	8.69	7.82	10.55	10.05	11.65	9.70
Land and Buildings	0.46	0.30	0.23	0.40	0.59	0.89	1.99
GIA for ZP	1.80	1.32	1.34	1.52	1.78	1.89	2.02
Block assistance to ZP	6.16	5.93	5.44	5.48	5.17	5.42	5.34
Total Non-Wages	30.72	33.30	35.01	36.05	36.15	36.29	39.20
Total Wages	57.46	53.22	53.91	53.83	54.53	58.68	56.57
Capital Expenditure	11.86	13.43	11.06	10.15	9.19	5.03	4.23

Source: Mathiyazhagan, M.K. (2004) Health Sector Public Expenditure Review, A background paper for World Bank's IDA Mission for Government of Karnataka, Bangalore

There are several studies on the expenditure on health care among rural households in India. In a seminal study on total health expenditure in proportion to annual income of the morbid rural households across India, Mathiyazhagan[31] estimates the total costs including the fee, the opportunity cost of travel and waiting time (Table10)

The study also found that health expenditure tends to rise less rapidly in lower income groups than in higher income groups. On events of long-term morbidity (LTM), lower income groups tend to spend more as income increases. It implies that the rural households especially of lower income groups are spending a very high proportion of their household income on health.

[31] Mathiyazhagan, M.K, Rural Household Characteristics and Health Expenditure, *Journal of Economic and Social Development*, (Jan-June 2003)

Table 10: Total Health Expenditure in proportion to Annual Income

States	Total Health Expenditure to Income %
Andhra Pradesh	19
Bihar	17
Gujarat	25
Haryana	10
Himachal Pradesh	15
Kerala	33
Maharashtra	18
Madhya Pradesh	11
Orissa	13
Rajasthan	29
Tamil Nadu	29

A World Bank survey in 2002 on the impact of the Indian pharmaceutical policy on the health sector, found that there were considerable variations in the availability, affordability and quality of drugs across states. States such as Tamil Nadu have been able to set up fairly strong pharmaceutical systems while others such as Uttar Pradesh have tended to lag behind. However, in areas such as the implementation of a programme on rational drug use, almost all the states have room for improvement.[32] Most of the variations among the states are attributable to differences in the quality of human resources and institutions, with differences in socioeconomic development and political stability also contributing. The broad conclusion is that, despite the impressive growth in the Indian pharmaceutical industry over the last 25-30 years described above, problems with the availability, affordability, and rational use of good quality, cost-effective, essential drugs have persisted in most parts of India, and that these health-related issues need be addressed as apriority.

The Bank's recommendations focus on strengthening the implementation and regulation of the pharmaceutical sector at the state-level, rather than on simply introducing new regulations. Adequate pharmaceutical quality assurance needs to be particularly emphasized as, in its absence; other reform measures could be rendered moot. Similarly, the rational use of drugs needs to be emphasized as it is likely to yield significant cost savings to the government and to consumers, in addition to its positive impact on health. Interestingly, the recommendations on drug affordability are for:

[32] World Bank Discussion Paper No 437: The Indian Pharmaceutical Sector – Issues and options for Health Sector Reform; Govindaraj, R and Chellaraj, G: (2002).

- improvements in the budgetary procedures at state-level, such as allowing switching of funds between various budget heads, to alleviate the problem of low per capita consumption through the public sector,
- targeting mechanisms for better access to good quality drugs that ensure that the poor are not left without a safety net, and,
- consideration for the creation of pooling mechanisms through the establishment of social insurance programs, most likely at the state level.

A survey[33] was carried out in Karnataka to examine the willingness to pay for a viable rural health insurance scheme through community participation in India, and the policy concerns it engenders. Most of the people stated they are willing to join and pay for the proposed rural health insurance scheme. However, the probability of willingness to join was found to be greater than the probability of willingness to pay. Indeed, socio-economic factors and physical accessibility to quality health services appeared to be significant determinants of willingness to join and pay for such a scheme. The main justification for the willingness to pay for a proposed rural health insurance scheme is attributed from household survey results: (a) the existing government health care provider's services are not quality oriented; (b) is not easily accessible; and, (c) is not cost effective.

III Price fixing and controls for patented products - Issues and Suggestions

The new pharmaceuticals pricing policy envisaged that all patented drugs that would be launched in India after 1 January 2005 would be subject to price negotiations before granting them marketing approval, and that the Drugs and Cosmetics Act 1940 would be suitably amended to provide for this. The Department of Chemicals and Petrochemicals in consultation with the Department of Health would lay down necessary guidelines for determining the negotiated prices. The ministry is already looking at practices in other countries like Canada, France and Australia. Government has, on 18 January 2007, notified a committee to examine the issue of price negotiations for patented drugs. The committee consists of officials from the ministry of chemicals and petrochemicals, the Drugs Controller General and others. The committee is to interact with industry and to propose a system of reference pricing/price negotiations/differential prices that could be used for price

[33] K. Mathiyazhagan, Willingness to Pay for Rural Health Insurance through Community Participation in India; International Journal of Health Planning and Management Vol13, pp 47-67 (1998).

negotiations of patented drugs and medical devices before their marketing approval in India. The committee is to submit its report in three months, by mid April 2007.

There is as yet no clear indication about how the prices are likely to be determined. Among the considerations that could weigh with the committee could be:

1. An approach that would determine the price premium enjoyed by the drug in the lowest price market abroad compared with the closest therapeutic equivalent in the same country, and to apply that same premium to the closest therapeutically equivalent prevailing in the domestic market. That is to say, the same premium factor prevailing in the domestic market would become one of the markers.
2. Another approach under consideration is the principle of purchase parity pricing being used in Europe between member countries. Under this methodology, the price arrived at could be at a substantial discount to the U.S. prices, even less than 50%.
3. There is a push towards looking at prices charged abroad with a view to determining the lowest of the prices charged overseas.

Every one of these approaches is market distorting, and suffers from several shortcomings:

1. The National Pharmaceutical policy suggests that all patented drugs that would be launched in India after 1 January 2005 would be subject to price negotiations before granting them marketing approvals, and that the Drugs and Cosmetics act would be amended for this purpose. Legislative amendment is a cycle of almost two years in India, and this would mean that marketing approvals would be available only after the act is amended, which may take until 2008. Further, the methodology of price fixing is left vague, and the development of guidelines left to the committee formed recently. Practices of Canada, France and Australia are to be studied to evolve guidelines. As has been pointed out above, the examples of these countries would be quite unsuitable for India for the reasons earlier discussed. For example in Canada, the pricing system in Canada is two-tiered system that relies on negotiated prices. Federal prices act as a ceiling on prices nationally and further discounts are negotiated by the provincial and territorial governments. In the case of British Columbian provincial government sets a reimbursement price for all products that are grouped in a specified therapeutic classification. This leaves the manufacturer free to charge any price below the

PMPRB price, but it requires the individual patient to pay the difference between the provincial price and the PMPRB price. The system helps for both government and pharmaceutical companies. Pharmaceutical companies fix the price, which is market determined price with their expect profit margin and it allows pharmaceutical companies share more allocations for the development new drugs. Under this system, government may also able to allocate more budget share to health sector. These things are possible only when there is a universal health insurance schemes or specified health plans, which are virtually missing in Indian context. Though there are voluntary health insurance schemes with public and private partnerships of insurance companies in India, which covers less than 10 per cent population, the price negotiations are taking place only between the insurance companies and pharmaceutical companies.

2. There is also the problem of data and determination of cost-effectiveness. A spectrum of data collection inputs would have to be created to make the system transparent and objective. Given the strong presence of both in indigenous industry and the foreign companies, debates on appropriate pricing are likely to arise frequently, and can be resolved only if the system, ab initio, is a transparent one. It is also evident from the existing DPCO (1995) that there are many administrative problems with DPCOs that have been worsening as the Indian drug industry expands. The government often fails to update the financial data on which it bases its criteria for inclusion, aggravated by the long time lag between the collection of data and announcement of new pricing policy. As a result, basis data for determining prices is at least three months old at the time of approval, and the price benchmarks used end up being historical instead of prospective. Furthermore, there are serious problems with the way the government calculates the fixed prices for many drugs. For example, it does not take raw material price volatility or exchange fluctuations into account when calculating prices. The government determines drug prices solely upon cost, not quality, of production (no distinction in pricing is made, therefore, between a drug produced under Good Manufacturing Practices (GMP) and one that is not.

3. Any reference pricing model, if adopted, would have to take account of prevalent practices in developing countries of the region, not on developed country experiences. In countries that do adopt a price control regime, these are meant as limits to reimbursement under public health/ medical insurance programmes, not as market markers.

4. Given the high number of pharmaceutical firms in the informal/unorganized sector, domestic and foreign drug companies in India have therefore run a large risk that their patented drugs will be pirated even with protected product patent system.
5. The suggestion for creation of gold standard companies that would be entitled to a higher MAPE of 50% is a process that could easily be considered as partisan and not fair. A requirement of 200 scientists in India being employed as a touchstone for gold standard recognition is clearly a tilt away from multinational firms that do their research globally.
6. The condition of development through indigenous R&D qualifying for exemption from price control for five years is an invidious one as the definition of the term R&D would be subject to administrative interpretation.
7. There are a large number of studies that establish that price controls for patented drugs results in lower R&D expenditure, slower access to new drugs and lower drug discoveries.
8. Price controls benefit health delivery in countries that have a well regulated public health delivery system. Public health expenditures in Indian states continue to be low, with a wide disparity in effectiveness of delivery between states. There is a large private sector and unorganized access to medicines. In these circumstances, price controls would lead to market distortions, excessive regulation and the development of grey markets. Prices should be considered in the context of the total regimen of the treatment, where several alternatives may be available, that could be as effective as any measure of cost control.
9. High duties and transaction costs impose a heavy burden on the consumer—there are examples where these distort prices enormously, against imported drugs. A mindset that creates negativity towards imported drugs needs to be changed.

IV Conclusion: Urgent Need for a "Third Way" Approach

The above analysis makes clear that India should develop a new approach that avoids the costs of European-style drug price controls, while also avoiding the inequities of a U.S.-style free market.

The issue of drug availability is to ensure that:

- the latest clinical treatment and drugs must be available,
- these should be accessible to the entire population, and,
- there should be incentives for development of new drugs through R&D that would require adequate compensation for development costs.

All the price control systems described earlier suffer from limitations. The systems practiced in OECD are integral to a universal health care and delivery system that is funded through insurance, employer benefits, and the national budget. The UK system for patented drugs does not impose price controls at the beginning, but seeks to regulate profit levels by insisting on annual disclosures by companies. In Canada, trends in public health pricing vary by provinces. Prices for patented drugs are on the basis comparable prices in seven developed countries, with the median price being adopted. The system adopted in Mexico, where public health care covers around 51% of the population, uses the weighted average ex factory price in the preceding calendar year in six countries that have contributed to the largest sales of the product. The retail price is determined as 1.72 times the reference price. Private health care charges market prices for drugs.

Pricing control over patented drugs presupposes existence of cost-effectiveness information, comparator models, and, most importantly, a reimbursement mechanism that limits cost of reimbursement. Intervention in the market to fix free market prices for drugs is not a practice that is adopted by any of these countries.

India therefore presents a unique situation. Absence of product patents for over three decades, a large indigenous industry, coupled with political economy requirements of a welfare state, require a balance between incentives and control. It is important that the latest drugs and formulations are available, that they can be reached to all, whether in the public health or the private health systems. It is equally important that there be an environment for industry and research to grow, and that global firms are comfortable using the talent pool in India for R&D and drug discovery, assured of reasonable returns.

Given wide income disparities, a range of public health and private care systems, and freedom of choice, and the distortions likely to be caused by the price fixing for patented products, it is important to consider creative solutions that would suit a developing country like India. A possible alternative that could be adopted in India for patented drugs is the adoption of a two tier price system. Some form of this system is prevailing in Mexico.

For example, in some states like Tamil Nadu, drug purchases for public hospitals by the government are negotiated with the companies. Each tablet carries a distinctive mark and the strips are separately labeled to indicate that they are not for sale, but part of the public health care system. The same drugs are available in the open market at market prices. Such a twin pricing system has the advantage of delivering drugs at low costs to the public health care system without distorting the market mechanism. In the case of patented drugs it is conceivable that producers may be willing to accept prices that are close to marginal costs of production plus fixed returns, if allowed to access the market for pricing that covers development costs. In this approach, the Department of Petrochemicals would finalize a list of patented drugs that it intends to be used in the public health system. Using this approach, the producing companies would be invited to convey the prices at which these drugs would be made available to government hospitals and dispensaries. These would be distinctively packaged and labeled and supplied to the health departments of the states against invoices raised by them, and accepted terms of payment. Outside this, firms would be free to charge market prices, and enjoy IP protection in full for their products. Such a mechanism would require:

- identification of the government/publicly supported hospitals that are eligible for lowered prices
- putting in place a complete procurement system for each state, that would cater to the needs of these hospitals
- supplies to be made direct to the hospitals
- creating a special packaging for supplies to these hospitals
- setting up tracking and monitoring system that confirm end use and detect diversions if any
- clear commitments on payments

Such an approach might offer a short term solution to drug access concerns, while longer term structural reforms are explored. In the long-term, any solution to India's drug access problem requires major structural reforms to the health care system. In formulating such reforms, a balance must be struck between the markets for free sales and government supplies. The government cannot supply the entire demand for drugs unless it is prepared to commit to massive public subsidies and drastic price controls. A fresh approach is needed.

In developing a new approach to pharmaceutical pricing, the Government of India faces unique challenges. The Government has an overriding responsibility to ensure that the citizens of India – especially the common man -- have access to affordable medicines for treating the most common and important disease conditions. At the same time, any new policy must maintain a world-class Indian life sciences capability. India is a world leader in the advanced life sciences. The Indian pharmaceutical industry dominates global generics markets and has begun making serious investments in innovative drug discovery. Given adoption of the Product Patents Act and increasing competition from Chinese generic companies in the international generics marketplace, the future of the Indian biopharmaceutical industry rests on its ability to innovate. Thus, any new policy must balance improved access to key medicines for the common man with support for India's continued capability to discover and develop advanced medicines, which represents a long-term national asset.

Such a solution requires a two-track approach. First, the government should strengthen the public health infrastructure to ensure that rural and urban poor have universal access to treatments for basic medical needs. Such a system should be built around government bulk purchases of low-cost generic medicines. While such medicines are older and may not incorporate some of the latest advances, they provide a low-cost solution to expanding access to basic medical treatment, and are often quite effective in treating disease. Accordingly, instead of seeking to provide the latest state-of-the-art treatments for the rural and urban poor, the focus should be on the low-cost delivery of high-quality, essential care for all. By keeping drug costs low, more care can be provided to more people, providing hope and help to the common man. Such an approach would facilitate a dramatic expansion of public access, particularly for low-income workers, subsistence farmers, the unemployed, and rural and urban poor. Any co-payments should be kept low to maintain affordability for the most vulnerable elements of Indian society. While patients in the public health system should be free to purchase more expensive patented or branded drugs, this could be achieved through a "balanced-billing" arrangement in which the government would subsidize only the cost of the basic generic drug, with the remainder being contributed by the patient. Such an approach would avoid the prohibitive cost of have the Central or State governments subsidize state-of-the-art foreign medicines, allowing government funds to be allocated to an expansion of basic care to a larger number of people.

Second, the government should aim to facilitate the continued evolution of private health care markets, including private hospitals, private insurance, and high-cost patented

drugs. India already has an extensive system of private hospitals. Creating a separate private market would ensure that India's expanding middle-class, which now comprises roughly 200-300 million people, would have access to sophisticated world-class health care. It would also ensure that the cost of such advanced care would be borne by middle-income households who can afford private insurance or out-of-pocket payments, and would not have to be subsidized by the public treasury. This two-track system would avoid the bureaucratic complications and prohibitive cost of transferring a European-style government health care system to a developing country like India. The "third way" would address the expanding needs of the Indian middle-class for world-class health care, whilst creating a strong domestic home base for Indian biopharmaceutical companies to launch their new innovative patented products. And it would offer a new and creative third-way drug pricing model for developing countries around the world, which look to India for continued leadership.

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