Interlink White Paper - 2012

Pharmacoeconomics - Key to affordable medicines

PHARMA | HEALTHCARE | WELLNESS | LIFESCIENCES

INTERLINK
THE BUSINESS PERFORMANCE CONSULTANCY

Contents

Preface

Interlink's Knowledge team is privileged to present this white paper on **'Pharmacoeconomics - Key to affordable medicines'.**

Citizens and physicians worldwide are increasingly facing problems in deciding which treatment is most effective medically and economically. Addressing this dilemma of balancing cost and treatment, President Obama provided a vivid analogy of choosing between a red pill and a blue pill, indicating that the decision is based on the most viable medical and economic options. In order to survive and thrive in this recessionary world, pharma and healthcare businesses will have to rigorously analyse and interpret comparative effectiveness research (CER) results or in other words, perform pharmacoeconomic evaluations.

This white paper first discusses the relationship between Health Economics and Pharmacoeconomics, followed by a brief description of the concept of Pharmacoeconomics. It then focuses on the changing behaviour of today's healthcare consumer and its effect on the industry. Considering the variety of problems faced by the industry today, the paper then focuses on the solutions provided by Pharmacoeconomics to these problems, thus aiming to help our readers understand the significance of Pharmacoeconomics and its relevance today.

This paper also includes a case study of drug selection based on pharmacoeconomic analysis in an attempt to help readers understand the real-time application of Pharmacoeconomics The paper then describes the worldwide presence of Pharmacoeconomics and the current scenario of Pharmacoeconomics in India considering the Indian pharma industry, wherein the challenges, benefits and requirements of boosting Pharmacoeconomics in the Indian system are discussed. The focus then shifts to the role that can be played by governmental, non-governmental organizations, academicians and pharmacists in the introduction of Pharmacoeconomics in India.

Pharmacoeconomic perspectives for Indian CEOs and decision-makers are also a key aspect of the discussion. Country-specific implementation of the Pharmacoeconomics concept is detailed in Annexure I.

We believe that Pharmacoeconomics will provide a comprehensive solution to industry issues and challenges faceds by regulatory bodies. Synchronising efforts to balance the interests of the industry, regulators and consumers is the way challenges can be addressed; hence we consider this white paper to be of utmost interest to our esteemed readers.

Acknowledgements

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We acknowledge the efforts of Interlink team including Mr. Sachin Adawade, for writing this paper, Mr. Pratik Rane, a research intern, for his content-related contribution, Ria Kalghatgi, for editing support & Aarti Paradkar for production.

We believe that this paper will provide clues to policy-makers, industry and other stakeholders for actions to lead India globally.

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Health Economics and Pharmacoeconomics

Economic evaluation is the formal process of weighing benefits and costs in an incremental analysis. It is essentially a framework that draws up a balance sheet between costs and benefits to assist decision-making.

In a world where resources are limited, health economics is used to make informed decisions on which health treatments, medications or technologies to choose and which to avoid in order to maximize health of the overall population of a country. Health economics is gaining importance worldwide as an important decision-making support science. It is a subset of the broader concept of health technology assessment (HTA), which includes not only drugs but also devices, medical and surgical procedures, diagnostics and the systems, processes and programmes that influence healthcare. An important subset of Health Economics is Pharmacoeconomics, which focuses solely on pharmaceuticals.

Economics concepts can be applied to the healthcare industry for assessing healthcare technology, which includes drugs, medical equipment, services and programmes. This specialized application has given birth to Health Economics, a concept that can be further applied to the pharma industry issues, thus giving rise to the concept of Pharmacoeconomics.

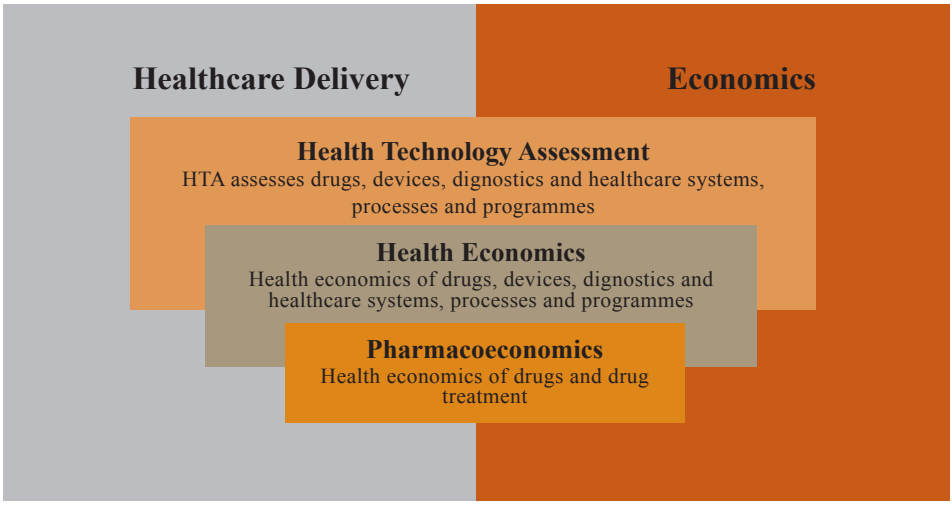

Figure 1: Relationship between Healthcare Delivery and Economics

Introduction to Pharmacoeconomics

Pharmacoeconomics is an economics discipline that evaluates the behaviour of individuals, firms and markets relevant to the use of pharmaceutical products, services and programmes. It focuses on the costs (inputs) and consequences (outcomes) of such a use. It applies the theories and tools of economics, including Managerial Economics, to the science and business of pharmaceuticals.

The purpose of Pharmacoeconomics is to establish the relative worth of a product/service that can be used by decision-makers who face limited budgets.

Operationally, the field of Pharmacoeconomics consists of **analysis and evaluation of outcomes** (clinical, economic, or humanistic), **cost consequences and cost comparison** (for example, considering resource consumption); **identification of alternatives; and decision-making considering limited (fixed) budget/resources.**

Pharmacoeconomics thus addresses critical questions like

- Are there two or more alternatives?
- Do the interventions examine cost and health effects?
- Which drugs should be included in a hospital formulary?
- Which is the best drug for a particular patient?
- Which is the best drug that a Pharma manufacturer can develop?
- How can two clinical pharmacy services be compared?
- Which drug delivery system is the best for a hospital?
- Will a patient's quality of life improve by a particular drug therapy decision?
- Which is the best drug for a particular disease?
- What are patient outcomes of various treatment modalities?

By addressing these questions, Pharmacoeconomics becomes important and relevant to all the different stakeholders of the Healthcare and Pharma industry of any country.

Shift in focus of the healthcare consumer

There has been a distinct shift in the patient/consumer focus and attitude towards health and disease. A few decades ago, patient groups had a 'reactive' approach towards disease wherein patients aimed for a cure by using pharmaceutical products and healthcare services. Based on the consumer needs, the industry shaped accordingly. However, in the last 2 decades, this reactive approach has changed. The focus of both the industry and the consumer is on disease management and prevention. This shift in focus has led both consumers and businesses to diversify their options in order to achieve their respective goals. Apart from offering a wide variety of medicines for disease cure and treatment, the pharmaceutical and healthcare industry has focussed on making preventive measures available to both patients and healthy individuals in order for them to have healthier lifestyles and prevent diseases.

These measures include the following options:

- Genetic and other molecular level tests for determining the probability of contracting a particular disease. Such tests help in taking the necessary preventive measures in advance.
- State-of-the-art diagnostic facilities for diagnosing and treating diseases.
- Wide variety of dietary/nutritional supplements, fitness equipment and gymnasiums with expert guidance for a healthier lifestyle.
- Advanced medical procedures and medicinal treatment options

This shift in consumer attitude and behaviour will change the future direction of the industry and create new opportunities for businesses across the healthcare spectrum. In such an evolutionary scenario, it will be very important to substantiate the costs (inputs) and consequences (outcomes) of a particular product or service, for which pharmacoeconomics is a viable tool.

Healthcare industry challenges and pharmacoeconomic solutions

The pharma industry product pipelines are drying up, leading to a high dependence on existing products for survival. The branded generic drugs segment has become commoditized due to ever increasing and fierce competition.

Price plays a major role in drug prescription and buying decisions. High price may not always assure high quality or more benefits and companies are finding it difficult to substantiate higher prices with commensurate benefits.

Meanwhile government is tightening the regulatory framework in an attempt to curb manufacturing and marketing malpractices. In such a scenario Pharmacoeconomics seems to be a viable tool for balancing the interests of all stakeholders of the industry.

Below is a brief description of the perspectives of each stakeholder in the industry and how Pharmacoeconomics can provide solutions to their problems.

Patient's perspective

Patients are always concerned about the cost of therapy prescribed while doctors are concerned about affordable treatment to ensure compliance and complete recovery. If the pharmacoeconomic profile of a medicine is available, doctors can know and evaluate the additional benefits available from such a medicine over existing medicines and determine whether the incremental price is commensurate with the additional benefits claimed.

Treatment choices

There is always a tension in the minds of patients, doctors and hospital authorities to choose and decide between providing medical services that are technically feasible or available and the patient's willingness to pay for the services from his limited resources. Pharmacoeconomic evaluations can be applied to assess the value of treatments, to compare the medical cost and health outcomes associated with new therapies/medicines to the cost and to determine the outcome of the existing alternative treatment.

Physician's perspective

New medicines are launched very often by pharma companies claiming incremental benefits over existing products available in the market. This incremental benefit comes at an extra cost which is to be paid from the patient's pocket. In this context, performing an economic evaluation of a new medicine and comparing it with existing ones provides significant advantage from the viewpoint of medical practitioners. It will empower physicians to compare medicines on different pharmacological parameters including safety and efficacy.

Health Insurer's perspective

The health insurance business is growing at a rapid rate and individuals today are presented with a wide variety of health insurance options from both government bodies and private insurance companies. Currently, a standardized list or formulary of medicines and their cost is unavailable. This list is essential for determining the eligibility criteria for reimbursement at the insurer and patient levels irrespective of the insurance policy and the insurer. Pharmacoeconomics will prove to be an essential tool in preparing this standardized list or formulary based on cost-effective analyses of drugs, which will benefit both patients and insurers in the process of reimbursement and impart further clarity and transparency to the health insurance system by helping insurers determine the clinical criteria for coverage.

Manufacturer's perspective

For a number of critical diseases like cancer and diabetes, therapy is costly. It is feasible to develop public–private partnership between health insurance companies and pharmaceutical companies manufacturing these medicines for developing a viable business model. Pharmacoeconomics can thus provide a methodology to design a mutually beneficial model.

The principles of Pharmacoeconomics can be extended to taking critical pricing decisions for acute and chronic diseases. These principles can also be useful in preparing the necessary documentation for justifying the proposed prices of beneficial therapeutic treatments and submitting to regulatory authorities for approval.

Researcher's perspective

Pharmacoeconomics concepts were mostly used for the retrospective evaluation of clinical trial data. Implications of efficacy or safety aspects were examined by pharmacoeconomic analyses, data bases were examined, literature was surveyed and expert opinions were solicited. This information was clubbed with retrospective analyses of trial data to develop a decision analysis model.

A recent trend indicates that clinical trial designs explicitly incorporate economic data collection. Some studies incorporate an element of modelling to either adapt the findings of the trial to other settings or to project costs and outcomes beyond the period observed in the trial. Several regulatory agencies are now evaluating the use of pharmacoeconomic parameters as a part of the drug regulatory process. A Pharmacoeconomics study from the researcher's perspective will usually consist of a decision analysis model containing an economic evaluation.

Policy-maker's perspective

Measures of health-related quality of life (HRQOL) are increasingly viewed as important outcomes of medical and surgical interventions.

The expenditure associated with adopting the new medical treatment, including new medicines, will have to be valued in terms of health outcomes. Such outcomes will include, among others, mortality, morbidity, cost, length of hospital stay, quality of care, and most importantly patient satisfaction.

Policy makers are often beset with ethical, financial and political dilemmas. Illustratively, some of the key dilemmas include the following:

- How can finite resources be fairly and appropriately used to cover infinite needs?
- Do costly life-saving prescription therapies offered to one patient population come at the expense of the other?
- Which patients can best benefit from specific interventions?
- Is there a solution that includes humanity and a desire to improve lives apart from employing logic and data?

Pharmacoeconomics provides clues to resolve some of the complex issues in developing a policy framework to balance the economic imperative of industry growth and social need of providing an access to affordable medicines.

It is thus imperative for all players in healthcare to realize and appreciate the utility and contribution of pharmacoeconomics to harmonise the interests of the patient, the provider and other stakeholders.

Stakeholders' Perspectives	Area of Stakeholders' Concerns	Pharmacoeconomic Solution
Patient	• What additional benefit does a new medicine provide over existing medicines? Is the additional price commensurate with the claimed benefit?	Cost benefit comparison between available medicines
Treatment Choices	• How does one determine the value of medicines and treatments, and compare the medical cost and health outcome associated with new therapies/medicines to the cost and outcome of the existing alternative medicine/treatment?	Medical cost and health outcome comparison
Physician	• How does one evaluate new medicines from the viewpoint of medical practitioners, such as safety, efficacy and other pharmacological parameters?	New medicine selection
Insurer	• How does one evaluate the cost and outcome of medicines as well as prepare a list or formulary of medicines for reimbursement eligibility?	Drugs list and reimbursement eligibility
Manufacturer	• How does one take critical pricing decisions? How does one prepare accurate documentation for regulatory authorities to demonstrate therapeutic benefits, which will help in justifying the proposed price and benefits over existing alternatives?	Medicine pricing decision
Researcher	• How does one perform retrospective evaluation of clinical trial data and analyses implications of certain efficacy or safety aspects and develop a decision analysis model for economic evaluation?	New molecule economic evaluation
Policy Maker	• How does one resolve complex issues in developing a policy framework to balance the economic imperative of industry growth and the social need of providing an access to affordable medicines, thus harmonizing the interests of patients, providers and other stakeholders?	Use in policy framework for balancing industry, regulatory and consumer needs

Figure 2: Stakeholders' perspectives and pharmacoeconomic solutions

Drug selection using Pharmacoeconomics: A case study

Physicians worldwide have multiple options for the treatment of pain caused by osteoarthritis. Among these options, the most suitable ones comprise NSAIDs and COX-II inhibitors. However, in order to choose which drug is best in terms of efficacy and price, with minimum side effects, a pharmacoeconomic evaluation was conducted in the US by Spiegel et al. (2003), which is presented below:

1. Etiological and demographical facts about Osteoarthritis

- Pain results in significant disability and resource utilization
- Affects 15% of the US population and is a leading cause of chronic disability in the US
- Affects ~8 million people in the UK and ~27 million in the US
- Results in >100,000 hospitalizations annually
- Most frequent joint disease with prevalence of 22% to 39% in India

2. Comparison of treatment options

NSAIDs	COX-II inhibitors
Effective pain relief	Effective pain relief
24%–30% the cost of Cox-II inhibitors	Substantially expensive than NSAIDs
Associated with a significant risk of adverse effects such as dyspeptic symptoms.	Associated with a lower risk of GI side effects
Their use causes more serious non-dyspeptic effects, symptomatic ulcers, ulcer haemorrhage, and ulcer perforation	

3. How should the physician treat his patient considering cost and side effects?

a. NSAIDs are inexpensive compared to Cox-II inhibitors, but will the more expensive agent pay for itself by preventing an expensive GI bleeding in patients?

- Dyspeptic symptoms are decreased by 15% and clinically significant ulcer complications are reduced by 50%

b. Risk of GI bleeding: how much can it be altered?

- Not all osteoarthritis patients have an equal risk of developing GI bleeding
- Though the relative risk reduction of GI complications with Cox-II inhibitors catches our eye, the actual risk reduction is small, being just 1 to 2% for overall ulcer complications and 1% for serious haemorrhage and perforation.

4. Is paying extra for GI protection justified in all patients? What value is really purchased for the extra cost?

Cost-Effectiveness Analysis using Pharmacoeconomics

Population	Drug	Total Annual Cost	QALYs* Gained	Incremental cost per QALY gained
No History of GI ulceration	Naproxen	$ 4859	15.2613	-
	Cox-II inhibitor	$ 16,443	15.3033	$275,809
History of GI ulceration	Naproxen	$ 14,294	14.7235	-
	Cox-II inhibitor	$ 19,015	14.8081	$55,803

*QALYs-Quality-Adjusted Life Years

5. How do cardiovascular problems affect the choice of using Cox-II inhibitors or NSAIDs?

Population	Drug	Annual Cost	QALYs* Gained	Incremental cost per QALYs gained
All patients	Naproxen	$5,037	15.2539	-
	Cox-II	$16,620	15.2832	$395,324

*QALYs-Quality-Adjusted Life Years

6. Conclusion

1. Risk reduction for GI complications seen with Cox-II inhibitors is unlikely to offset their increased cost in the management of average risk patients with osteoarthritis pain
   - With no history of GI bleeding choosing naproxen
   - With a history of GI bleeding choosing Cox-II inhibitors
2. In all patients with osteoarthritis, the decision to use Cox-II inhibitors should be made with the awareness of the effect of the added risk for cardiovascular events on cost-effectiveness
3. Currently, sufficient information is unavailable about the association between Cox-II inhibitors and cardiovascular events, but it may be prudent to avoid these drugs in patients with a cardiovascular history, especially in patients with history of GI bleeding.

Pharmacoeconomics around the globe

Currently European countries are making the maximum use of pharmacoeconomic data for reimbursement and other financial decisions and most have officially introduced Pharmacoeconomics guidelines in their countries. Australia in comparison with European countries has a relatively well-developed pharmacoeconomic structure. Countries in the North American continent, South American continent and South Africa have introduced the concept of Pharmacoeconomics and outcomes research data lately but its full introduction is not visible until today. Countries in Asia like China, Hong Kong, Japan, Korea and Singapore have a well-developed Pharmacoeconomics and outcomes research structure. However, the Indian healthcare system has not yet undertaken research in Pharmacoeconomics and outcomes. Please refer to Annexure I for details of Pharmacoeconomics in specific markets.

Establishing Pharmacoeconomics in India

The Indian pharmaceutical industry (IPI) is the world's fourth-largest by volume and is likely to lead the manufacturing sector in India. The Indian Patent Act in 1970 played a major role in developing a base for the manufacturing unit in India. The change in law in 2005 has created opportunities for both international firms and local Indian companies for sharing expertise. This has certainly created tremendous job opportunities mainly in the field of clinical research, thus making way for health outcomes research.

In addition, many governments worldwide are seeking to curb their soaring prescription drug costs by greater use of generics, thus giving importance to cost-effectiveness and cost-benefit analysis studies. In other words, they are implementing the concept of Pharmacoeconomics. Unfortunately, even after the availability of tremendous data on health sciences and clinical research, this data is not used for outcomes research and pharmacoeconomic analysis, the reason for this being the quality of primary data available and its suitability for secondary database research. Therefore, the centrepoint for the future of outcomes research and pharmacoeconomic analysis in India is the development of a proper database to be used for comparative effectiveness research.

In India, the concept of Pharmacoeconomics is still not used by the government in order to make reimbursement decisions. Furthermore, the concept of Pharmacoeconomics is not being used in academic research

though cost-effectiveness studies have been performed in various parts of India.

Challenges in using Pharmacoeconomics

1. Great diversity in India namely socioeconomic development and population size make it difficult to adapt to the Pharmacoeconomics research being conducted in other countries.
2. Lack of full appreciation of the potential importance and application of Pharmacoeconomics studies.
3. Poor technical skills of healthcare professionals, especially of pharmacists.
4. Lack of appropriate database of the healthcare system in order to bring about research adaptation from another country.

Benefits of Pharmacoeconomics

1. Optimal use of finances for pharmaceutical expenditure.
2. Provision of job opportunities in the clinical, health economic and market research sectors.

Implementing the Pharmacoeconomics concept – way forward

In a stepwise manner, the following measures can be undertaken to extend Pharmacoeconomics practice in India.

1. Introduction of the Pharmacoeconomics concept at the undergraduate level.
2. Workshops on how to implement the concept of Pharmacoeconomics in pharmacy practice.
3. Use of cost-effectiveness data in the pharmaceutical industry for reimbursement and other financial decisions, thus decreasing pharmaceutical expenditure.
4. Encouragement of pharma students to present posters on Pharmacoeconomics and participate in the student chapters of International Society of Pharmacoeconomics and Outcomes Research (ISPOR).

Pharmacoeconomics and role of governing bodies

At present, there are two International Society of Pharmacoeconomics and Outcomes Research (ISPOR) regional chapters in India, namely ISPOR India and ISPOR Manipal. The National Institute of Pharmaceutical Education and Research (NIPER) is currently India's centre for excellence in pharmaceutical education and research. Collaboration of the existing

and future ISPOR regional chapters and NIPER could accelerate current research and produce quality projects useful for allocation and effective resource utilization in India.

Government's Role

Pharmacoeconomics utilization in India would require the healthcare system to be operated under a single roof in the country. At present, there is no definite healthcare system followed in India; there is no nationalized prescription service as well. The drugs purchased by pharmacies are not via centralized systems such as state associations thus encouraging middlemen and increasing the price a common man would pay had the drug been brought by the pharmacies from state associations at a much cheaper rate. All these increase the expenses paid by the common man as his health expenditure. This indirectly increases the expenditure on the healthcare system of the country.

The government can play a major role by including Pharmacoeconomics in the healthcare system by taking the following measures:

- A government-operated centralized healthcare system is required that would not only regulate government hospitals but would also undertake the regulation of pharmaceutical drugs and services. This action would entertain the usage of pharmacoeconomic studies in evaluating the drugs for its cost-effectiveness and cost minimization, thus optimizing the health expenditure of the country.
- State governments should undertake measures of supplying pharmaceutical drugs to local pharmacies by its direct purchase from the pharmaceutical industries or manufacturers. This would avoid middlemen like super-stockists, authorized stockists and semi-wholesalers, thus lowering the overall cost of the drug in the market.
- Currently the approval of new drugs for marketing is the function of the Central Drugs Standard Control Organization (CDSCO) headed by the Drug Controller General (India). Before approval basic information on chemistry, physicochemical information, complete monograph specifications and data on the formulation including quality control data, animal pharmacology and toxicology and human/ clinical pharmacology are reviewed. During the review process of the new drug by DCGI, pharmacoeconomic evaluation studies should be requested from the manufacturing company, thus giving an idea of cost-effectiveness and cost utility of the newly submitted drug. This would ensure long-term benefits of the newly introduced drug in the market.

Role of National Pharmaceutical Pricing Authority (NPPA)

NPPA, as a part of its monitoring activity, monitors and analyses month-wise price movement of non-scheduled drugs. The prices of these manufacturers are fixed based on various factors like cost of production, market competition and the company's profitability status. NPPA monitors the prices of non-scheduled drugs by various methods such as scrutiny of price lists submitted by manufacturers, analysis of monthly retail store audit reports and complaints/references received from official and unofficial sources. NPPA has the authority to fund relevant studies with respect to pricing of drugs/pharmaceuticals in order to monitor the pricing of various drugs. When NPPA monitors the prices of non-scheduled drugs by accepting the price list from the manufacturers, it should request manufacturers to submit the Pharmacoeconomics study data in order to make optimized decisions with respect to cost and efficacy of drugs.

NPPA could grant funds to universities in order to conduct pharmacoeconomic and health outcomes research studies. This would provide the government with necessary Pharmacoeconomics data of the drugs under scrutiny and give research opportunities to academicians, thereby providing a stronger educational base for pharmacoeconomic and outcomes research studies in the country.

Role of Insurance

Till date, only 3% to 5% of Indians are covered under any form of health insurance. This includes those covered under the Central Government Health Scheme (CGHS; 4 million beneficiaries), the Railway Health Scheme (1.2 million) and the Employees State Insurance Scheme (0.3 million), all examples of social health insurance.

On the other hand, private insurance covers about 11.2 million individuals. Nevertheless, private insurance is not the answer for India's objective of equity, efficiency and quality in health because it tends to cater to the affluent classes, covering the healthiest and the wealthiest thereby resulting in limited social gain.

In order to implement pharmacoeconomic studies in the reimbursement aspect of the Indian pharmaceutical industry, there is a need for the government to undertake a centralized insurance system like other countries in the Asia-Pacific region. Although an initiative was taken by the Indian government in 2003 to implement a Universal Health Insurance Scheme, the initiative failed because of its failure to cover the poor population. However, in April 2008, the Union Ministry of Labor and Employment in India launched a Rashtriya Swasthya Bima Yojna (RSBY) smart card to combat the so-called 'health-based poverty trap' in the country. The RSBY initiative provides health insurance coverage for below poverty line (BPL)

families and there are currently, 28.6 million RSBY card holders and their 115 million family members across India. This initiative has proved to be beneficial for the poor in India.

Although the current insurance companies could make use of pharmacoeconomic studies for the purpose of reimbursement, the entire Indian population will not benefit because of the limited size of the population covered by the current insurance schemes in India. To resolve this issue, insurance companies need to expand their coverage to different economic strata of the society and ensure better health coverage plans for all.

Pharmacoeconomic perspectives for Indian CEOs

Economic evaluations are important for choosing existing alternatives for improving health. They also play a key role in creating incentives for the development of new medicines. If economic evaluations are used for allocation of resources within the healthcare system, it will be possible for firms to develop new medicines and use pharmacoeconomic studies to evaluate different strategies.

The social and economic development of the people is a major concern for policy-makers having a socio-political agenda. It is an equally important concern for the pharmaceutical industry in pursuance of its business agenda. In a market economy, where global competition is intense, pharmaceutical researchers, manufacturers and marketers will have to reckon the need for evaluating resources vis-à-vis outcomes. This could indeed be a valuable instrument in designing and implementing business strategies in the current volatile business world.

Greater challenges in decision-making coupled with improvements in pharmacoeconomic research indicate a greater role for Pharmacoeconomics into the new millennium. This in turn will have consequences for companies in the pharmaceutical industry. More successful access to markets and better commercialization of products will be the rewards for those companies committing to Pharmacoeconomics and to the broader goal of delivering value for money in healthcare.

The opportunities emerging in the Indian Pharmaceutical Industry, changes in patent laws and development of pharmaceutical education specializing in Pharmacoeconomics indicate a promising future for outcomes research and pharmacoeconomic analysis in the country. The knowledge thus developed can be used by government organizations for the reimbursement of pharmaceutical drugs and services aiding profits in the health and pharmaceutical sector.

Annexure I: Implementation of Pharmacoeconomics around the globe

1. Australia

Australia is one of the first countries to incorporate formal guidelines for Pharmacoeconomics and outcomes research.

- It has a national health insurance system (medicare) funded by the state government (funded by income tax and state general revenues) and private hospitals are funded by private insurance. There is a selective list of drugs for drug reimbursement to pharmacists, which is done considering the pharmacoeconomic data in which the cost-effectiveness of the drugs and services is measured.
- Each prescription is charged AUS $ 20 and beneficiaries are charged AUS $2.60 per prescription, which is waived after a threshold.
- Australia operates a Prescription Benefit Scheme (PBS), which reimburses pharmacists for the cost of a selective range of drugs. PBS is operated with the help of an advisory committee called Pharmaceutical Benefits Advisory Committee (PBAS).
- The selective range of pharmaceutical drugs used for reimbursement by the government has been decided on the basis of the therapeutic effectiveness and cost-effectiveness of the drugs.
- According to the Australian guidelines for Pharmacoeconomics, the pharmaceutical company along with drug safety and efficacy data is required to submit the cost effectiveness data for the purpose of reimbursement.

The purpose of pharmacoeconomic data as per Australian guidelines is stated to be:

- Rationalize the use of drugs
- Cost containment (though not considered first)
- Greater health outcome results

2. North America

Considering North America, Canada was among the first few countries to introduce pharmacoeconomic studies for drug economic evaluation. The third edition of Guidelines for the Economic Evaluation of Health Technologies was introduced in 2006. Pharmacoeconomic studies are used by Canadian decision- and policy-makers who are responsible for the funding of decisions for health technologies.

In USA, the healthcare system is mainly managed by the private sector with minimum involvement of the federal government. Even though a

large amount of funds is provided for research in Pharmacoeconomics, the healthcare providers, government, and companies rarely use it. Furthermore, there is a dearth of Pharmacoeconomics research in the US. Research in Pharmacoeconomics is essential for appropriate decision-making as discussed earlier. Therefore, USA needs to conduct appropriate outcomes research of pharmaceutical drugs and services in order to make comparative decisions for the authority.

3. South America

In Latin America, Pharmacoeconomics and outcomes research data has been considered to play an important role in improving the health of people. Latin America is characterized by double burden of diseases: persistence of infectious and parasitic diseases and increased incidence of chronic and degenerative diseases that are otherwise found in developed countries. There is an increase in aging population. With regards to monetary expenditure, Latin America spends a reasonable amount of 7% of GDP on healthcare services. The organization of many healthcare systems in Latin America, except in Costa Rica and Cuba, is characterized by social healthcare insurance for the formally employed population, private insurance for the moderately rich, public insurance for the poor, or a combination.

4. Africa

The early stage of Pharmacoeconomics in South Africa was from 1992 to 1994 as a result of the 'push-and-pull' mechanism: the pull from the Minister of Health and the managed care organizations and the push from multinational drug producers with established departments for Pharmacoeconomics in the US and Europe. In 1996, the National Drug Policy stated the need for Pharmacoeconomics in the rationalization of the pricing structure for pharmaceuticals. To date, there is constant conflict among the ministry, industry and other stakeholders over the pricing of pharmaceuticals, which is exacerbated by the surge of the AIDS epidemic in the country.

Pharmacoeconomics is considered to be a decision-making tool in the Gauteng province healthcare system of South Africa. The private sector in this country is mainly demonstrating the application of Pharmacoeconomics with common uses such as formulary for disease management, funding and comparison studies to rationalize price, whereas the public sector is restricted to training of pharmacy students and in formulary decisions by pharmacy and therapeutics committees.

5. Europe

Compared to other countries in the world, many European countries use pharmacoeconomic data for reimbursement and other funding decisions by the public and private sectors. They have also formally introduced Pharmacoeconomics guidelines for the use of Pharmacoeconomics concepts in the decision-making process.

6. Asia

6.1 Japan

1. At present, Pharmacoeconomics is at an early stage of evolution in the healthcare scenario in Japan, mainly because of the way in which their healthcare policy is formulated. On the other hand, many academic programmes and institutes have been established recently to gather pharmacoeconomic data. Institute for Health Economics and Policy was originally funded by the Ministry of Health in 1993. University of Tokyo established a division of Pharmacoeconomics in Japan in 2000.
2. Previously in Japan, few economic incentives were given to healthcare providers for the cost-effective service provided. However, recently, the need for pharmacoeconomic data has been realized because this data could be used for cost-effective healthcare delivery, which is a means of controlling healthcare inflation.
3. In 1994, pharmacoeconomic data was used for price negotiations for new and approved pharmaceuticals. Although the impact of this data on actual pricing is unclear, companies receive high incentives to conduct these studies.
4. Promising future for Pharmacoeconomics: Many studies on cost-effectiveness have been published academically. The new healthcare reform plans would directly uplift the need for pharmacoeconomic data studies. Health reformation considering the need for evidence-based medicines in Japan has given more importance to the introduction of Pharmacoeconomics studies in the country. The drug pricing organization in Japan has reiterated the point of considering Pharmacoeconomics studies in their decisions.
5. About 44% of drug companies in Japan use pharmacoeconomic data in their drug pricing negotiation processes.
6. Thus, the Japanese government took considerable time in accepting the need for including pharmacoeconomic data in the healthcare benefit plan, but gradually, the plans for its introduction are being

implemented with the current healthcare reformation happening in the country. Many academicians are contributing to and providing pharmacoeconomic data to the government through their research in universities.

6.2 China

1. The share of drug expenditure in overall healthcare expenditure is larger compared to that in US
2. Need of Pharmacoeconomics and outcomes research for wide insurance coverage, policy reform, Pharma pricing and World Trade Organization (WTO) entry.
3. Numerous studies in Pharmacoeconomics have been performed based on 'cost-effectiveness' models.
4. The entry of China in WTO would allow the entry of foreign vendors in important goods, thus making Pharmacoeconomics essential in order to have a competitive advantage, especially for imported drugs, which are relatively costly. Also, since the advertising of prescription drugs is prohibited in public media in China, Pharmacoeconomics is an alternative for foreign investors to gain recognition.
5. State drug administration (SDA) has recently stated that pharmacoeconomic assessments should be considered for the preparation of phase IV clinical trials.

6.3 Hong Kong

The healthcare system is almost 95% provided for by the government

1. Hong Kong hospital authority (HA) is the sole dealer of healthcare products in the country. All decisions are made by the HA in relation to healthcare providers and funding bodies, although the decisions are not made on the basis of pharmacoeconomic data.
2. Pharmacoeconomics was introduced in 1999 at an international meeting with the help of academic papers mostly in the gastrointestinal disease subject area.
3. Many local authorities and healthcare professionals are actively involved in Pharmacoeconomics and outcomes research activities. In December 2000, the first Chinese chapter of the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) was published in Hong Kong, the first regional chapter of the society based on the Asia-Pacific area.

6.4 Korea

1. The healthcare system is market oriented and private sector dominated.
2. Drugs account for 33% of health expenditure. Thus, reimbursement to the physician and healthcare service providers by the national health insurance scheme requires the use of pharmacoeconomic data.
3. A new regulation has been passed by the government: the pharmacoeconomic data of all clinical drugs in Korea and the ones waiting to be introduced in the country should be submitted to Pharmacoeconomics authorities.
4. There is lack of resources in universities, government agencies and pharmaceutical companies for developing pharmacoeconomic and outcomes research data.
5. The problem in Korea is limited insurance coverage especially in cases of major risks. Solution to this is a budgetary cap on expenditures as a long-term strategy and consideration of pharmacoeconomic data as important for future healthcare reforms.

6.5 Singapore:

1. Healthcare system is controlled by the government with the help of three ministries.
2. The government uses a standard drug list to specify the process of drug reimbursement and thus the need of pharmacoeconomic data does not arise.
3. Government offers the concept of Pharmacoeconomics at the undergraduate level of the 4 year pharmacy course.
4. The interest of the Ministry of Health is increasing towards Pharmacoeconomics as its inclusion in decision-making is under consideration. Involvement of the academic community in Pharmacoeconomics studies is evolving.
5. The Singapore government formed a task force in 2001 to review drug prices, and a recommendation of this group was the review of the standard drug list (SDL). This review would consider cost-effectiveness studies. Also, for the SDL review, Pharmacoeconomics studies are recommended.

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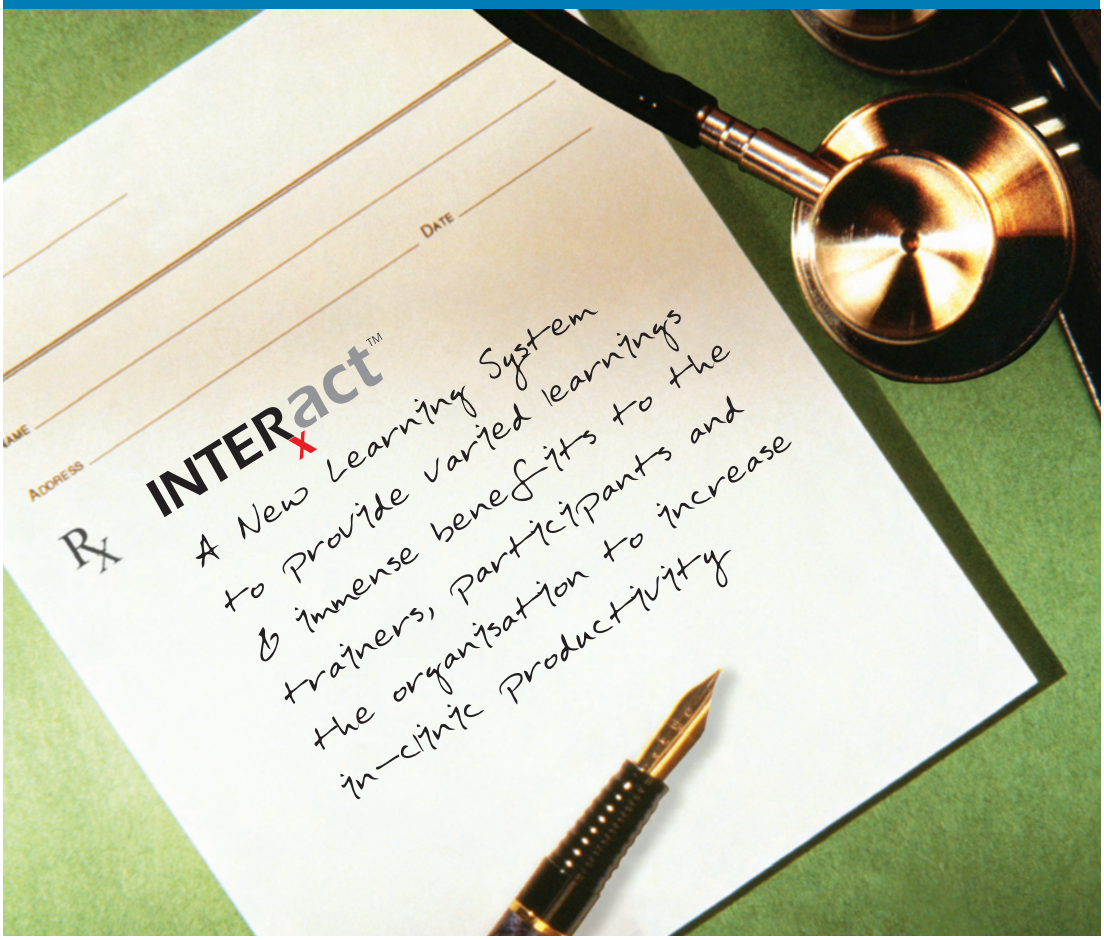

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