



Pricing and reimbursement policies in mature pharma markets: A comparative evaluation

Vipin Choudhary, SK Gupta

Department of Clinical Research, DIPSAR, New Delhi, India

Abstract

Objectives: To understand overview and evaluate the pricing & reimbursement policies of USA, UK, Germany, Japan and France.

Methods: A desk research was carried out. Data was collected from published materials, such as published articles, government publications, press releases, and news articles, online portals of regulatory agencies and relevant keyword searches. This data was then evaluated on the basis of several parameters.

Results: Japan follows international reference pricing where it gains the reference from US, UK, Germany, and France. France follows ASMR evaluation and then it negotiates the price with company. In USA, there is a free pricing policy. USA has a robust reimbursement system under Medicare, Medicaid and CHIP. There is mutual understanding between companies and payers. Therefore, companies keep the price controlled. In UK, there is Value Based Pricing for branded and Reference to market prices in case of generics. In Germany, there are different pricing policies for different types of products. However the sponsor is free to set the price of a product initially for a period of 12 months.

Conclusions: Pricing is expected to be based on an equitable, transparent and lucid system. Pricing policies should vary country to country depending upon various factors like economy, population and patient burden.

Keywords: reference pricing, medicare, medicaid, value based pricing

1. Introduction

The priorities of global pharmaceutical companies are changing. Growth of MNCs in pharmaceutical market is saturated and Global Pharmaceutical Companies want to increase their presence in the lives of more and more consumers as companies seek to expand and promote their products to a still wider range of markets globally. Therefore firms are shifting more of their focus to finding new sources of revenues and profitability in markets.

In developed economies, market access is chiefly concerned with pricing and with satisfying local conditions, such as obtaining the appropriate ASMR and SMR ratings in France.

Mature markets offer advantages like huge population, technological advancement, increasing insurance coverage and high growth rate. However, they also pose several challenges like:

- Increasing chances of diseases
- Rising customer expectation
- Diverse regulatory environment
- Uncertainty in pricing and reimbursement
- Complex taxation structure
- Slowed market growth
- Policy reforms
- Drug approval stagnation

Among all the above given challenges, Uncertainty in pricing and reimbursement is considered as one of the most difficult challenge. Pricing and reimbursement policies affect not only access and affordability of medications, but they are intimately linked to other areas of the healthcare system, including insurance coverage, drug quality and hospital reform.

This study takes a look on the pricing and reimbursement policies of developed pharma markets. In order to gain an understanding on different markets:

USA, UK, Japan, Germany and France

This study attempts to find out whether the pricing and reimbursement policies of a defined geography are imposing any kind of burden on healthcare system of that country. Additionally, a comparison is made between different pharma developed markets and pharmaemerging markets. Analysis of these 10 countries is done to get the deeper insights.

In importance, this study contributes to the understanding of what pricing and reimbursement policies government of these 10 countries follows with the challenges they faced. Also, the study tries to answer very critical question that what needs to be done in future in order to help the patients of the emerging markets. [Fig 1]

2. Background

This is an era of changing status quo for global pharmaceutical companies, as mature markets in many areas of the developed world become saturated. Global life sciences companies are aware that growth and sustained competitive advantage may be increasingly dependent on the effective planning and execution of markets strategy. As growth patterns in developed markets continue to saturate, firms are switching more of their focus to come up with new sources of revenues and profitability in emerging markets. Collectively the mature markets generate 59% of the total revenues but they are becoming more difficult places to prosper. They are demanding better results as a prerequisite for paying for new medicines. Financial pressures have played a part in hardening

healthcare payers' policies. Crushing demographic and epidemiological factors have compounded these economic woes. Aging populations, chronic/lifestyle diseases, emerging-market expansion, and treatment and technology advances are expected to spur life sciences sector growth in 2015. However,

efforts by governments, health care providers, and health plans to reduce costs, improve outcomes, and demonstrate value is dramatically altering the health care demand and delivery landscape [1].

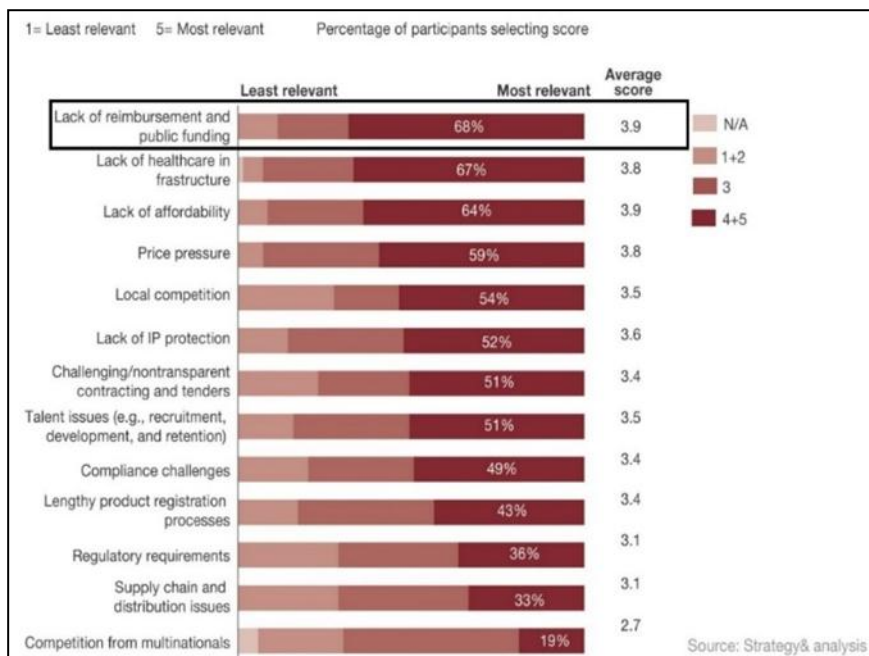


Fig 1: Key challenges to growth in Pharma market

It is becoming increasingly evident that the global life sciences sector is working in an era of substantial transformation. Pharmemerging nation developing countries where use of pharmaceuticals is growing rapidly are expected to see the fastest growth in total drug spending in coming years, making them attractive targets for drug makers. Demand for drugs in pharmaemerging markets will expand at a compound annual growth rate of as much as 11% through 2018, according to a report by the IMS Institute for Healthcare

Informatics. Pharmerging markets will account for nearly 50% of absolute growth in drug spending in 2018 [2]. If the above situation continues to supervene, there will be a huge deprivation in mature. On the first hand where pharmaemerging markets offers such a great platform to expand and the mature markets are declining, pharma company are moving towards emerging markets which is not healthy for mature market.



Source: IMS heakth report, May 2012. Spending in USS with variable exchange rates.

Fig 2: Top 10 pharma country in the world (all figures in US \$ Billion)

2.1 What are developed/mature pharma markets

There is no established formula for the designation of “developed” and “developing” countries or areas in pharma world. However, the economic criteria have tended to dominate the categorization of a nation as developed, developing or under developed. Also IMS defined Pharmaemerging countries as those having per capita income below \$ 2500 per annum. Per capita income as well as Gross Domestic Products (GDP) per capita is also important criteria for categorization. In case of pharma industry, on economic background, following countries are considered as developed countries:

USA, Germany, Italy, UK, Japan, France, Canada, Australia etc.

However, we have considered only 5 main countries for evaluation.

2.2 What is status quo of these markets

USA

The U.S. pharmaceutical market is the world’s most important pharma market. Along with Canada and Mexico, it stages the largest continental pharma market worldwide. The United States alone reserve over 45 percent of the pharmaceutical market worldwide. In 2016, the market of USA was valued around \$446 billion. Numerous global top pharm companies are from the United States. In 2016, six out of the top 10 companies were from the USA.

Considering medical research and development, the U.S. has always been on pinnacle and a promoter for the global pharmaceutical industry. Almost \$60 billion are spent annually on pharmaceutical R&D purposes in the USA ^[3].

UK

The pharmaceutical market in the UK is expected to spring up from \$28.8 billion in 2015 to around \$43 billion by 2020, exhibiting a compound annual growth rate (CAGR) of 8.4%, driven majorly by a robust life sciences industry. The National Health Service (NHS) accounts for more than 98% of the UK prescription medicines market, which is the sixth largest pharmaceutical market in the world. The pharmaceutical industry was the sixth largest contributor to the UK’s balance of trade, imparting \$46.9 billion (£32.4 billion) to the economy in 2014, according to the Association of the British Pharmaceutical Industry. R&D investment arrived at \$5.9 billion (£4.2 billion) in 2013 in the UK ^[4, 5].

Japan

The pharmaceutical market in Japan is expected to climb from approximately \$70 billion in 2016 to \$72 billion by 2021, exhibiting a low CAGR of 0.3%. [6]

The Japanese healthcare market is controlled primarily by increasing levels of affordability and access to healthcare facilities. The increasing burden of the old population and delineated regulatory guidelines will drive the growth of the pharmaceutical market in the future [8]

France

The pharmaceuticals market in France is expected to decline from \$35.5 billion in 2017 to \$34.16 billion in 2021, exhibiting a negative CAGR of 1%.

Latest report states that regardless of France’s robust public health insurance system and elevating elderly population, increasing pressure on pharmaceutical selling prices, expiration of patent of branded drugs and foreign exchange fluctuations are suppressing ^[9].

Germany

German pharmaceutical market is expected to rise from \$67.9bn (€52.9bn) in 2016 to around \$86.3bn (€67.2bn) in 2021, putting it on course for a CAGR of 4.9%.

Germany is a mature healthcare market, the largest in the EU will be driven by an elderly population and associated disease burden, but government initiatives to reduce healthcare expenditure will put a bridle on its growth ^[11].

3. Methodology

A desk research was carried out on existing P&R policies mature Pharma markets at DIPSAR through literature review, report analysis, and data analysis. Data were derived from published materials, such as journal articles, government publications, press releases, and news articles.

The results obtained were evaluated on the basis of various parameters like extent of price control, price control mechanism, pricing norms for generics, channel margins etc. economy of that country was also considered while evaluation. Results were then concluded into a strategy that can be used by government and companies for approaching in markets and help patients by increasing accessibility and affordability of medicines.

4. What policies are followed by federal agencies

USA

The US is the largest market for pharmaceuticals in the world. It is also one of the few countries in the industrialized world that does not regulate pharmaceutical prices. This shows the dominance of competing private health insurance plans in USA. Although the public insurance programs, mainly Medicare and Medicaid, now account for more than 40% of total health expenditures in the US. The 340B Drug Discount Program is a US federal government program that necessitates drug manufacturers to supply outpatient drugs to entitled health care organizations at substantially attenuated prices.

In USA, insurance that provides financial protection to consumers thereby also tends to make consumers insensitive to prices. For patented biopharmaceuticals, this enables producers to charge higher prices than they would in the absence of insurance ^[3].

Public Sector

Formulary evidence dossiers sum up the key clinical and economic evidence for a product. These are employed as a reference document by P&T committee for their formulary decision making process. Pharmaceutical sponsors have to develop dossier for their product and submit it to AMCP ^[12].

The dossier is uploaded on the AMCP portal and is made accessible to health care decision makers (health plans, Pharmacy Benefit Managers (PBM), government agencies, etc.) without request. This information is used to support reimbursement decision making.

Private Sector

Decision for coverage of private health insurance plans are customized according to individual health plan. Most of the health plans use evidence dossiers and/or conduct their own clinical and economic review to ascertain coverage for a

particular drug. Reimbursement varies according to individual health plans. Hospitals constitute their own P&T committee to develop and manage the hospital formulary as well as act as the liaison between pharmacy and medical staff.

Table 1: Federally Funded Health Insurance Programs ^[14]

	Coverage is sub-divided into four parts (Part A to D).
Medicare	People who are eligible for Medicare are all entitled to Part A. Those covered by Part A can enroll in Part B voluntarily. Around 95% of Part A participants also enroll in Part B benefits. Those covered by Part B can enroll in Part C voluntarily, so on and so forth.
Part A	Covers inpatient hospital services including inpatient and hospital prescriptions.
Part B	Covers payment for physician, outpatient, home health, and preventive services.
Part C	Medicare Advantage Prescription Drug Plans (MA-PD) are offered by private plans, HMOs, and PPOs with lower copayment than the "standard" plans that are approved by Medicare.
Part D	Covers outpatient prescriptions.
Medicaid	Eligibility requirements are based on income status, age, pregnancy status, disability, and citizenship status.
	Covers hospital stays, doctor visits, emergency room visits, prenatal care, prescription drugs, and other treatments.
Child Health Insurance Plan(CHIP)	Benefits are very similar to that of Medicare Part A.

Similar to the AMCP dossier, hospitals frequently formulate their own evidence dossier by collecting information including clinical trial data, package inserts, and published literature to conduct their own assessment to make formulary decisions. Furthermore, they consider acquisition cost of the drug as well as budget impact.

Range of matrices used to calculate the reimbursement prices:

1. WAC: Wholesale Acquisition Cost
2. AWP: Average Wholesale Price
3. AAC: Average Acquisition Cost
4. ASP: Average sales price
5. AMP: Average manufacturer price
 - 28 states in US rely on AWP as their means of calculating pharmacy reimbursement prices for Medicaid patients.
 - 13 states use WAC for Medicaid drugs
 - 6 use AAC for drugs dispensed to medical beneficiaries.

France ^[25]

France has a direct price control.

Pharmaceuticals are enlisted in two steps:

Step 1 is the technical assessment by la *Haute Autorité de Santé* (HAS) which hosts a commission previously known as the *Commission de la Transparence* and now *Commission d'Evaluation des Médicaments*.

Step 2 is the enlisting on the lists with price fixing by the *Comité Economique des Produits de Santé* (CEPS) and reimbursement rate fixing by the Union Nationale des Caisses d'Assurance Maladie (UNCAM)

All registered pharmaceuticals are subjected to Evaluation of Therapeutic Benefit (Amélioration du Service Medical Rendu, or ASMR), that is expressed as a classification between 1 & 6, as follows:

1. Innovative product of significant therapeutic benefit

2. Product of therapeutic benefit, in terms of efficacy and/or reduction in side effect profile
3. Already existing product, where equivalent pharmaceuticals exist; moderate improvement in terms of efficacy and/or reduction in side effect profile
4. Minor improvement in terms of efficacy and/or utility
5. No improvement but still granted recommendations to be listed
6. Negative opinion regarding inclusion on the reimbursement list ^[26].

The prices of reimbursable pharmaceuticals are determined by the inter-ministerial Economic Pharmaceutical Committee *Commission d'Evaluation des Médicaments* (CEM) after negotiations with the manufacturers and can be fixed in contracts between the CEM and the pharmaceutical company in question.

The price depends upon:

- the ASMR evaluation
- the relevance of the respective pharmaceutical in the market (valuated by the number of packs sold)
- the research expenditure, and
- the advertising costs of the manufacturer

According to the assessment of these five criteria, the *Commission d'Evaluation des Médicaments* CEM appraises a Medical Benefit level. There are five levels:

- Major
- Important
- Moderate
- Weak

Insufficient to justify a reimbursement

In UK and Germany, there is a positive and negative list available for reimbursement purpose. But the price control is applied to reimbursable drugs only ^[16].

Germany

The German health insurers have different instruments of pharmaceutical budget impact control. In Germany, different pricing policies are followed for different type of products [12].

A. New patented products: Price negotiated with payers (GKV-SV) based on early benefit assessment (AMNOG)

B. Old patented products

1. Price set by pharmaceutical company
2. Price freeze and mandatory discounts
3. Price negotiated with payers by individual contracts (optional)

C. Generic products (and some old patented)

1. Reference pricing
2. Price freeze and mandatory discounts

D. OTC product

1. Price set by pharmaceutical company
2. No reimbursement by SHI statutory health insurance (beside exception list)

The initial price for a product can be freely set by the manufacturer for a period of 12 months after market launch. This initial price must be officially declared and subsequently applies to all sales of the product in Germany. After the 12 month, the retail price for prescription-only pharmaceuticals dispensed by pharmacies is fixed. Fixed margins are added to the manufacturer's price [17, 18].

Reimbursement [24]

There are different pharmaceutical reimbursement pathways that must be used in outpatient care. There are certain limitations for reimbursement.

1. Drugs for trivial diseases are legally excluded from the benefits package for insurant over 18 years.
2. Inefficient drugs can be included to a negative list and will not be reimbursed
3. Pharmaceuticals prescribed for off-label use are not reimbursable unless no authorized product is available for this indication or using it aims at treating a life-threatening disease, and/or scientific data indicates good prospects of treatment success as well as a positive risk/benefit balance
4. Prescribing limitations to specific indications, to specific usage requirements (after failed nonmedical treatment, second-line, third-line), can be defined by the FJC Federal Joint Committee using self-assessment or an IQWiG assessment (but the FJC is free to decide independently).
5. Reference prices can be fixed for a group of therapeutic or generic substitutes.
6. Maximum prices can be set for drugs protected by patent, if a negative cost benefit-assessment supports such a decision

Organizations related to pricing and reimbursement in Germany and their roles

A. The Federal Joint Committee (FJC)/G-BA (Gemeinsamer Bundesausschuss)

1. Decides on coverage and reimbursement of most health care services in Germany (SHI only)
2. Decides on early benefit assessment of innovative pharmaceuticals

B. The German Institute for quality and efficiency in health care (IQWiG) is responsible for the scientific evaluation of

the benefits and harms as well as the quality and efficiency of health care services.

C. SHI (Statutory Health Insurance) Funds/ GKV(Gesetzliche Krankenversicherung)/ Public health insurance

1. Price negotiations after early benefit assessment
2. Decides about pharmaceutical reference prices and maximum amounts

D. The Arzneimittelmarkt

Neuordnungsgesetz (AMNOG)

“Pharmaceuticals Market Reorganization Act”) is a German law relating to the marketing of pharmaceutical products in Germany. It requires drug manufacturers to submit evidence to the Federal Joint Committee to show that their new products are more effective than previous products

E. Private Health Insurance PHI Association/ PKV (Private Krankenversicherung)

1. Effective lobbying (PHI only)
2. Contract negotiation

UK

UK uses Pharmaceutical Pricing Regulation Scheme (PPRS) to ensure that NHS has access to good quality medicines at reasonable price. The PPRS is voluntary agreement between government and pharmaceutical industry with the dual aim of seeking to create an environment that ensures safe and effective medicines are available to the NHS and that maintains a strong, efficient and profitable pharmaceutical industry [19].

Patient Access Schemes (PAS)

Are designed to ensure patients can gain access to medicines which are likely to have high cost and might not be deemed cost-effectiveness by payers. Patient access schemes are proposed by pharmaceutical company and referred by the Department of Health to the Patient Access Schemes Liaison Unit (PASLU) within the Centre for Health Technology Evaluation (CHTE) at NICE who then provide advice on the feasibility of implementing the patient access schemes in the NHS in England and Wales [13].

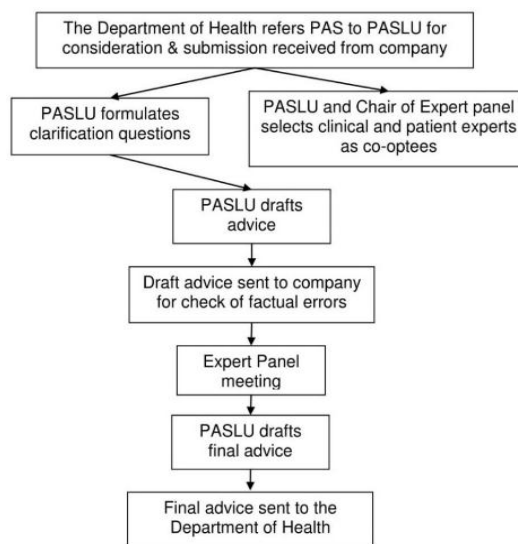


Fig 3: Summary of PASLU process [7, 19]

Types of PAS ^[10]

- Discounted price scheme
- First cycle free scheme
- Rebate for non-response scheme
- Free after x cycles scheme
- One-off payment scheme

Japan

Japan is the world’s largest price-controlled market for prescription drugs. Under the National Health Insurance (NHI) system, the government stringently regulates prescription drugs. Drug prices are laid down both according to standardized formulas and via negotiations between government officials and applicant companies on a product-by-product basis ^[20].

Reimbursement process ^[21]

The reimbursement price of a drug is laid down by the government as an official price, and almost all new drugs that were approved by the Ministry of Health, Labour and Welfare (MHLW) have been subjected to reimbursement.

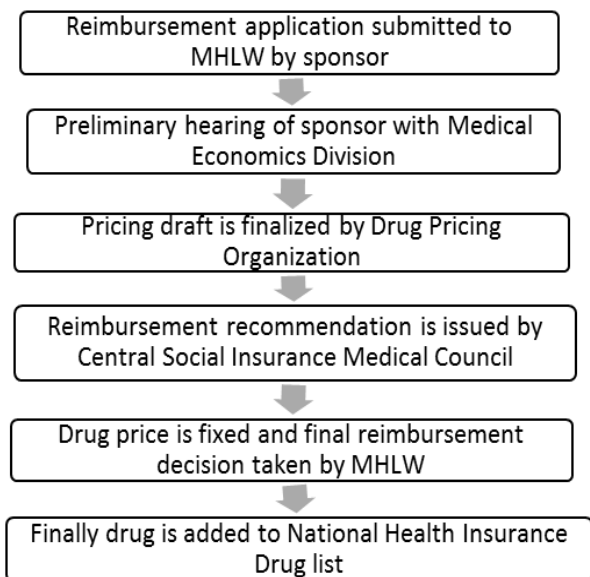


Fig 4: Japan drug reimbursement approval process

National Health Insurance (NHI) ^[15]

Every Japanese citizen and resident can subscribe to NHI, unless:

1. They are 75 years of age or older
2. They receive health insurance from their employer (such as through a health insurance association, mutual aid association, or seafarers’ insurance organization), or
3. They receive public assistance (System of medical insurance for the whole nation). Single application is submitted for each household, every member of the family is covered under this application. (Fig 5)

NHI Price Calculation Method ^[22]

In principle, the price of a new drug is calculated by reference price of similar drug in the market (comparable drug). This

calculation method is called “similar efficacy comparison method”. A comparable drug is selected from existing, reimbursed drugs from viewpoint of similarity in indication, mechanism of action, molecular formula, dosage form and route of administration. As a rule, new drugs that are within 10 years after NHI drug price listing for which generic drugs have not been listed are used as the comparison drugs. Second, the daily price of new drug is set as the same daily cost of the comparable drug to ensure competition in the market. (Fig 6)



Fig 5: NHI listing procedure

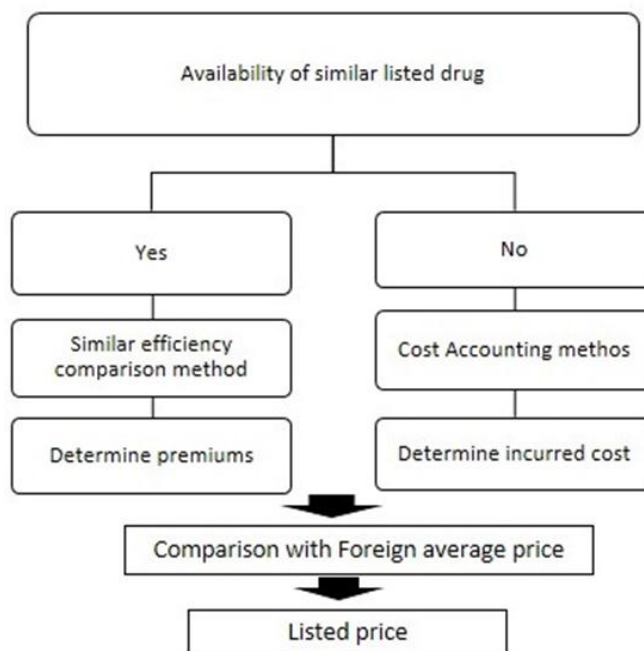


Fig 6: National health insurance price calculation method

Table 2: Comparative Analysis of P&R related aspects of Mature Pharma markets

Pricing	USA	UK	Germany	France	Japan
Extent of price control	None	All branded medicines	Almost all products	All retail pharmacies reimbursable drugs	All drugs included in NHI price list
Price control mechanism	Absent	Value Based Pricing	Variability exists depending upon the product	ASMR evaluation and negotiation with company	International Reference Pricing (US, UK, Germany, and France)
Pricing norms for generics	Absent	Reference to market prices	Reference pricing and mandatory discounts	40% below the innovator drug	50% - 70% less than innovator drug
Price Increases/trends for price controlled products	Not controlled	Generally reduced each year by an amount set out in the Regulations	Cost-benefit-assessment is done	Prices lowered based on volume, dosage and cost clauses	Prices revised periodically based on drug price survey
Pricing trends for non-controlled products	Absent	Controlled by market competition	Cost benefit assessment	Based on ASMR rating	Assessment of proposed drug price by DPO
Pricing for government purchases	340 B Drug pricing program	Local made products enjoy a 15% price premium over similar imported products	Distribution margins are dropped	Distribution margins are dropped	Average tender price drops by 2% to 3% each year
Channel margins	Gross margin averages 71% incl. manufacturers, insurers, pharmacies, PBM and wholesaler	Average wholesaler margin is 12.5%	Generics have higher margins Average wholesaler margin 4%-6.1%	Average wholesaler margin 6.2%	NDRC applies maximum margins based on manufacturer's price

5. Discussion and Findings

This paper describes the existing P&R policies in mature pharma countries so that providers and payers can use that information in their decision making process. The market analysis of major developed markets were done to find out the complexity in pricing and reimbursement environment that are specific with these markets.

It was found that there is lot of differences in mature markets *inter alia*. Therefore, most of the developed countries are not getting the desired success in providing growth to healthcare services as they might not be fully aware of lacunas in their policies. Though the existing pricing and reimbursement policies of various countries are quite good. But, the execution lacked the connectivity. Broadly, the major problems with their P&R policies of mature markets are:

- 1. USA:** Major lacunae in existing price control mechanisms of USA is skewed incentives to the health practitioners, non-transparency of federal Medicare and Medicaid program and inability of government healthcare program to negotiate with drug companies. This is the reason for outrageous cost of drugs in USA. However, reimbursement system of USA is very strong which makes customer insensitive to price.
- 2. UK:** Price of all branded prescription drugs have been regulated in UK since 1957 pursuant to PPRS. This is to ensure the availability of pharmaceutical products at reasonable price as well as a fair return for company to encourage innovation. Main loophole in British pricing system was that there is no regulation of price of generics. However, Health Service Medical Supplies (Costs) Act 2017 approved on April 2017 will enable government to control the hike priced of generics. This act might prove very significant for UK Pharma market.
- 3. France:** In France, pharmaceutical pricing depends upon pre evaluation of drugs and then negotiations with the

pharma companies. The ASMR evaluation done for pricing is very strict. Average wholesaler margin and distribution margins are also comparatively low in France. Although this kind of evaluation ensures the entry of quality product in market but it sometimes discourages sponsor also. These are the reason for the declining growth of Pharma market in France.

- 4. Germany:** Pricing system in Germany is one of the most complicated in the world. Initially it allows company to set price of innovative product for 1 year and then the product comes under the price regulation process. We cannot comment directly whether this pricing regulation is affecting the market because the growth of market in past decade has remained stable. Maintaining least growth at higher pressure from other European countries as well as government's initiative to reduce healthcare expenditure is good. However dropping distributor's margin is discouraging for the supply chain.
- 5. Japan:** Pricing and reimbursement system in Japan is strictly regulated by various agencies. Price of drugs can also be revised depending upon the sale of a particular product. According to government this increases affordability of drugs however it is criticized by pharma trade groups. These sudden price cut have gravely affect the stock market. This price cut may also make the pharma companies reluctant to spend in the pharma sector. This is probable cause of very slow growth of Japanese pharma market despite being developed.

6. Conclusion

Healthcare sector is one of the most important sector strategically. It is essential for providing care for sick, and for instituting measures that promote wellness and prevent disease. It is also evident that improving health of a nation also increases the economic growth of the country. Therefore

for the economic, social and health development of the country, the need of growth in healthcare sector is prime requirement. Pricing and reimbursement policies of a country play a major role in the growth of Pharma sector in that country. Pricing policies may vary country to country. However, sound analysis of these policies is required. Although there are other factors like lack of infrastructure, untenable regulatory requirements, patent cliff, lack of IP protection, lack of skilled task force etc. which requires the government to shift focus towards healthcare sector in order to promote the development of health of its citizen thereby the ultimate development of the country.

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