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Review Article

Improving Access to New Treatments with Value Based Pricing: An Indian Perspective

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ABSTRACT

The last few years have witnessed significant changes in pharmaceutical pricing model across the world. These changes were driven primarily by payers in an attempt to control rising health care costs. As per the old concept of pharmaceutical pricing model, prices were determined by market forces with hardly any scrutiny by regulatory bodies. These old methods have given way to some of the newer concept such as the Value Based Pricing (VBP), Health Technology Assessment (HTA) and Health Outcomes Analysis (HOA). VBP is an innovative method of pricing medicines wherein both the payers and pharma companies agree to link payment for a medicine to value achieved i.e. actual observed in real-world performance. Pricing is based on willingness to pay or the perceived additional benefit of new drugs relative to established comparator therapies. Value based pricing results in improved patient outcomes and ensures consistent access to medicines. As a result, elements of VBP are commonly embraced in mature pharmaceutical markets viz. Australia, Belgium, Canada, Denmark, France, Germany, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden and the United Kingdom (beginning autumn 2014). However, regulators in India are lagging behind other countries in adopting elements of VBP in their pricing model. This review will discuss various aspects of VBP including its impact on health care system and patients; barriers to the use of VBP; and reasons for its absence in India.

Key words : Treatment Access, Value Based Pricing, Health Technology Assessment, Health Outcomes, Pharmaceutical Pricing.

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PRICING STRATEGY IN PHARMACEUTICAL INDUSTRY

Pricing on medications is a culmination of demand analysis based on market research, account segmentation, health outcomes analysis and evaluation of regulatory constraints, all of which are discussed below.[1,2]

Demand Analysis

To develop an optimal pricing strategy, it is crucial to understand the dynamics of prescription use, which varies across countries and physician types. Willingness to pay for a particular therapy depends on the propensity to use the same. Demand analysis focuses on getting answers to the following three questions: (i) who are the key decision makers for the use of this therapy, (ii) how do price sensitivities of key decision makers affect use and finally (iii) how does the prescribing preference vary across markets of interest?

Segmentation

It is a critical step in the process of pricing strategy that helps determine the optimal price of the medication by identifying opportunities available from those who might purchase or use the medication. This category includes both physicians and patients. Effective segmentation analysis answers the following four questions across the global customer population:

- Segments of the market that are price sensitive?
- How price sensitive are these segments?
- Percentage of the total market that the price-sensitive segments represent?
- Variation in competitor responses depending on the segment?

Parallel trade

Large price differences among countries render it profitable for an arbitrageur to purchase pharmaceuticals in one country market and sell them in another. Liberalization of trades in European Union (EU) has made parallel imports extremely popular. In the EU, costs associated with trade are minimised while disparate regulatory policies have encouraged price differentials across markets. Parallel trade diverts additional product revenues from the manufacturer to those who move the pharmaceuticals from one market to another resulting in the manufacturer losing value of sale in the importing country. Additionally parallel trade enforces other costs such as market forecasting, liability assessment and mitigation and volatile manufacturing requirements on the manufacturer.

Health outcomes

Value of health outcomes and pharmacoeconomic analysis is determined by the structure of the local healthcare system. In countries like France, Spain and Australia, where governments negotiate reimbursement levels, health outcomes research is essential to demonstrate the cost effectiveness of a new therapy. This method however plays a less important role in the United States (US), where reimbursement is traditionally negotiated with non-government payers. An effective health outcomes strategy demonstrates the efficacy of a new drug therapy and speeds up the process of health outcomes research in the market by anticipating the clinical and cost-effective concerns of regulators.

Pricing of pharmaceuticals, biotechnology products and medical technologies/devices is thus a very complex process and needs to cover all the costs while also making profits to invest in future development. Several companies price their products on value based system and invest in considerable amount of research to find out how customers would value their product and assess the benefits and costs.

Value-based pricing – what is it?

Value-based pricing (VBP) is pricing a product or service at the level at which the customer and consumer 'value 'the product relative to others. This is not a new concept and has been in use in several sectors for a long

time, in particular the sophisticated markets like luxury goods, electronics, fashion etc.[3]

The word *value* in purely semantic terms, can be thought of as the amount considered as a fair equivalent for a 'product". The very same word with regard to medical ethics however raises more questions. Ethical issues that must be considered and weighed up against the others are: (i) respect for autonomy with regard to making informed choices, (ii) beneficence for patients along with non-malfeasance, (iii) balancing benefits and risk with financial cost and (iv) finally principles of justice. It is thus very important to remember what value really means in practice for the patient and society at large.[3]

The Centre of Medical Ethics and Health Policy has thus rightly pointed out "the ever-increasing abilities of medicine raise fundamental value questions of how society should use these abilities and how much of them society can afford to use."[3]

VBP for medical treatments

VBP for medical treatments is defined by the 2020 Health.org's as *"The price that reflects the value to patients, carers, society and the economy which delivers health benefits that exceed the health predicted to be displaced both elsewhere in the National Health Services (NHS) and in the welfare economy, due to their additional cost."*[3]

In contrast to cost based pricing that aims to consider profitability as a major factor for valuable products, leading to overpricing of medications in most scenarios, VBP properly reflects the value of a pharmaceutical or medical technology treatment (Figure 1). VBP needs to be welcomed and should be the basis for pricing pharmaceuticals.[4]

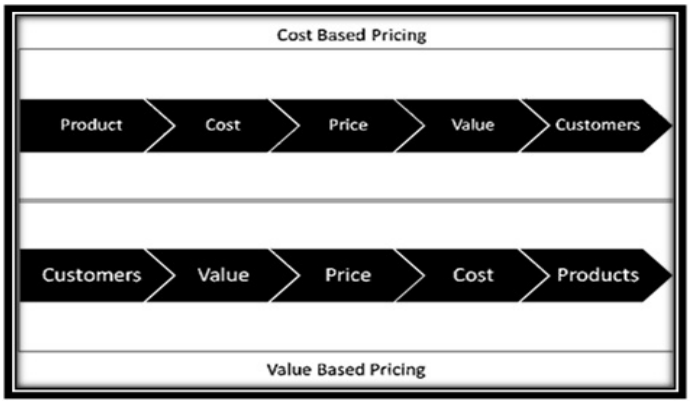

Figure 1: Differences between Cost Based Pricing and Value Based Pricing[4]

Historical background of value based agreement in pharmaceuticals

In pharmaceuticals too, VBP agreements is not a new concept and been in use for a decade. It is only in the last five years that VBP agreements have gained increased popularity.[5] In countries where the governments were involved in pricing and price negotiations of pharmaceuticals, VBP agreements were adopted in response to budgetary pressures.[5] Following are the earliest known examples:

2005

In Denmark, Bayer's entered into a "no cure, no pay" initiative on Levitra (vardenafil). As per this agreement Bayer's had to refund all those patients on treatment with Levitra (vardenafil) who were not satisfied with its response for erectile dysfunction.[6]

2007

In the United Kingdom (UK), Johnson & Johnson agreed to forgo medication charges in all patients with no adequate medication response to Velcade (bortezomib). This offer was proposed by Johnson & Johnson in response to the UK's National Institute for Health and Clinical Excellence (NICE) conclusion that Velcade was too expensive relative to its estimated benefit to the population.[7]

2010

In Sweden a case study on Duodopa (levodopa/ carbidopa) in advanced Parkinson's disease offered meaningful insights into VBP agreements in combination with conditional coverage. The study concluded that all stakeholders can benefit immensely from analysis of real-world (post-market) data in addition to pre-launch, trial-based data. Further it was emphasized that effective risk-sharing (between a payer and pharma company) was possible by conditional coverage as well as sufficient access to pharmaceuticals by consumer.[8,9]

2014

Incyte's use of "Patient- Reported Outcomes" with myelofibrosis was vital element in the decision to approve "Jakafi". Incyte's efforts have been recognised in market place too. Jakafi sells $84,000 a year in US, compared with $40,000-60,000 it was originally expected to fetch.[10]

The above examples indicate suitable candidates for future VBP agreements include products with simple methods for measuring treatment effects (e.g., decreased blood pressure or cholesterol level), or with clearly defined outcomes (e.g., did the tumor respond to treatment or not). Products with high budget impact due to high cost (e.g., oncology treatments) and/ or high volume (e.g., chronic versus acute diseases) can also be good options for VBP.[5]

VBP agreements for pharmaceuticals-a payers' demand

In the US as well as other countries, both private and public payers have encouraged utilization of VBP. Government payers and policy makers have been aligned with the move towards VBP. The following examples are illustrative of payers demand for VBP:[5]

- The Centers for Medicare & Medicaid Services (CMS) in US shifted from a volume-payment to a value-payment system for all medical products. As per this system, reasonable and effective criteria with an emphasis on patient outcomes would be utilized for reimbursing medical devices and pharmaceuticals.
- Alternative pricing agreements were a constant demand of the Australian Pharmaceutical Benefits Pricing Authority (PBPA) and in 2010, approximately 90 alternate pricing agreements (deeds of agreement), including value-based were either in place or in development.
- VBP is in use in Germany and pharma companies are provided with a year's time to prove the value of new pharmaceuticals compared to existing offerings to obtain a premium price compared to the competition. Failing to do so results in a price based on similarly effective, existing (and often generic) pharmaceuticals.
- Since 2014, in UK the existing Pharmaceutical Pricing Regulation Scheme (PPRS) was replaced with VBP for branded medicines sold to the NHS. Initially the basic price threshold, expressed as cost per quality-adjusted life year (QALY) or other outcome metric was adopted. Subsequently the following three factors were included:
  - Burden of illness (BOI) in terms of unmet treatment need or severity of illness;
  - Extent of medication innovation involved; and
  - Wider societal benefits.

In general, payers are more willing to engage in schemes in areas of high unmet need, high cost, variable treatment duration, and uncertain long-term benefits. Manufacturers on the other hand prefer those schemes required for access or in competitive disease areas such as oncology and osteoporosis.[5]

Benefits & Drawbacks of VBP for pharmaceuticals

Value-based pricing provides for a better distribution of risk between payers and pharma companies.[5]

Impact on Pharma

Pharmaceutical companies have knowledge of product feature that are of great value and can be rewarded. Empowered by this knowledge, pharmaceutical companies can maximize their benefits by directing resources and research efforts towards areas likely to achieve higher price/reward (away from unrewarded areas). Further; pharmaceutical companies can benefit from the widespread electronic exchange of health information needed to monitor user outcomes. Access to a broad database facilitates better prediction of effectiveness of new pharmaceuticals, provides important insights into commercial strategy and facilitates and expedite clinical trial recruitment. The greatest advantage of VBP lies in decreasing costs for post market surveillance (combining safety-based, post market research with activities supporting post market value assertions, saves considerable expense), while improving its quality and robustness. Further detection of potential safety signals, if any, is possible by documenting and analysing product safety data during value assertion activities.[5]

The challenge for pharmaceutical industry is that establishing the 'value' of a medicine is a process (or journey) of discovery. Not only is a degree of uncertainty about the expected costs and health gain associated with the indication under review, but there may be other indications that come available in the future. Evidence is the key to reducing uncertainty as to underlying value.[11] Pharmaceutical companies also need a pricing system that gives clear signals about priority areas, so that research efforts are directed to maximum effect. We need a system which can recognise and reward innovation, in particular by encouraging a focus towards breakthrough drugs which address areas of significant unmet need.[12] Development of companion diagnostics to maximise the value of molecule are likely to be mandatory for approval of specialist medicines by 2020.[10]

Impact on payers

The greatest benefit of VBP to payers is the reduction in risk of paying too high a price for a pharmaceutical that may ultimately have low value in the real-world. In VBP, premium pricing would be paid only for high-value pharmaceuticals versus the current day possibility of paying premium pricing for low-value pharmaceuticals. This would permit better allocation of resources towards consumers, who are likely to receive the most benefit. Patient could benefit by accessing the new tools/programs (that assist with value metric attainment and analysis), such as reminders for taking prescriptions or getting lab work done that would in turn facilitate adherence to their treatment plans.[5]

As per the VBP definition, it is a combination of unmet needs and disease severity. Unmet need in a disease is an important attribute from patients and physicians' perspective. In general, diseases with high prevalence attract investment, however if patient numbers are low, even if the unmet need is high, new treatments may not be developed as ROI is low. Hence therapeutic innovation should also be considered as a measure of value of a pharmaceutical product.[13] For instance, Japan is the only country which formally rewards innovation, using several measurements which are primarily driven by therapeutic gain.[12]

Barriers to implement VBP for pharmaceuticals

Major difficulties arise when developing consensus on value metrics and price thresholds (highest price or reward for achieving a value metric and lowest price or penalty for not achieving it) among the payers and pharma companies. Differences in value perception among various groups render the quest for valid and reliable measures of value extremely difficult. Release of new pharmaceuticals can also get delayed by bureaucratic hurdles for pharma companies, due to value metric assessment requirements.[5]

Value metric assessments demands valid, real-time data that in turn requires widespread electronic exchange of health information among stakeholders and disparate sources (e.g., health care providers using electronic health records, consumers operating personal health records). Such extensive network is not currently widespread and needs to be further built. The increased combination of disparate data sources also demands new programming and analysis techniques.[5]

The costs for electronic exchange of value attribute data (e.g., creating or expanding exchanges, inputting data into systems), developing new validated tools for measuring value attributes and data protocols, evaluating value metric performance or performing data reconciliation and adjudication are huge. It is yet to be determined which stakeholder(s) would bear that cost. VBP also leads to additional administrative burdens, requirements, or stipulations (associated with the value metric assessment) on providers and consumers, such as providers' additional monitoring of consumers that becomes a major hurdle to its implementation.[5]

Pricing for pharmaceuticals in India

In India, the government is involved in pricing of pharmaceuticals and since 1970, has adopted various regulatory measures like cost based price control and price monitoring to render medicines affordable to the common man. In case of patented products, the government resorts to price negotiation with the respective companies in an attempt to control the price.[14]

Steps taken by the Government to ensure availability of quality medicines at affordable prices to all are:[15]

- Price control of Scheduled Drugs through the National Pharmaceutical pricing authority (NPPA) in accordance with well-defined criteria and methods of accounting, relating to costs of production and marketing
- Price regulation of Non-Scheduled Drugs through NPPA such that they do not have a price variation of more than 10% per annum.
- Uniform VAT of 4% on medicines
- Reduction in excise duty from 16% to 4%

On not being satisfied with the above regulatory and financial steps for ensuring greater availability of medicines at affordable prices to all, especially the poorer masses, the government decided to launch a country wide Jan Aushadhi Campaign. Accordingly, Jan Aushadhi stores were set up to provide generic drugs at lesser prices but equivalent in quality and efficacy as expensive branded drugs.[15]

Fundamental differences in the overall healthcare system in India compared to the other countries have resulted in adoption of price control policies in India. While in most of the countries, approximately 80% of expenses towards healthcare including medicines are reimbursed either by the governments or health insurance or similar mechanisms, a reverse situation exists in India i.e. 80% of overall healthcare costs including medicines are private or out of pocket expenses (OOP) incurred by the individuals/families.[14]

According to a study by Public Health Foundation (PHF), reducing the cost of drugs translates to improved public health. As drugs form a major portion of OOP, it is emphasized that any reduction in cost of drugs would lead to a concomitant reduction in OOP. The government of India is of the opinion that pricing policy of drug companies has no relation to their actual cost, including research cost and thus recently the NPPA slashed the prices of more than 100 diabetes and cardiovascular drugs under a provision that allows the government to cut prices in extraordinary circumstances.[16]

Thus, fundamental differences in the healthcare system in India as well as opinions have culminated in VBP not being appreciated as a cost-effective measure. In an attempt to make drugs just affordable in India, the government has however failed to acknowledge that a large number

of population does not get access to modern medicines. The approach could thus be a core determinant of healthcare value and regulatory authorities will need to take cognizance of 'outcomes-based' pricing.[14]

Need for VBP for pharmaceuticals in India

India is a country with a population of over a billion. Most individuals in India are unable to bear healthcare costs today. This makes it necessary for the development of a value based healthcare system to cater the needs of such a vast country. However; there are several gaps that makes value based healthcare a distant achievement in India. The healthcare expenses are reimbursed in most countries, however; in India, most healthcare expenses are made out of the pocket. Although new initiatives are being taken by the government to provide medicines at a lower cost, these initiatives still fail to reach out to a larger proportion of people who are unable to have access to modern medicines for reasons other than cost of the medication.[14]

Barriers to implementing VBP for pharmaceuticals in India

Efficient operation of value-based health care systems need certain data standards and IT infrastructure. In a study by the Boston Consulting Group that examined how 12 countries worked toward successful implementing, a value-based health care system the following four factors were identified as critical:[17]

- Developing a national health care infrastructure that includes certain shared IT platforms and unified standards for tracking diagnoses, outcomes, costs and treatments
- Encouraging clinicians to collect and interpret clinical data as part of the exercise to improve patient outcomes,
- Ensuring physicians and insurers track patients' health outcomes using disease registries thereby promoting cost-effective care;
- Spurring changes in care delivery by providing clinicians with incentives based on outcomes data.

Needless to say the above steps need to be adopted in India for value metric assessment and thereby outcomes-based pricing. In addition to these, there are other transformational challenges facing India's healthcare system:[17]

- Insufficient qualified medical professionals in rural areas
- Inadequate health insurance i.e. only one fifth of the population are covered
- 80% of outpatient healthcare managed by unorganized private sector

Achieving a value based healthcare can be made possible with introduction of universal insurance coverage, restructuring the care delivery system, improved data standards and IT infrastructure for tracking diagnoses, outcomes, costs and treatments.[14]

Most importantly, access to modern healthcare is lacking in rural India, although several regions of urban India has access to adequate healthcare most rural regions do not have access to basic healthcare amenities. A recent survey conducted in the state of Bihar revealed that only 31% households with children under the age of 2 yr received immunization while pregnancy care information was received by only 11% households.[18]

Another important factor that is holding Indian healthcare system back is the poor quality healthcare provided in public sector hospitals and high quality healthcare with latest technology provided in private hospitals. Individuals below the poverty line are unable to afford expensive healthcare provided in private hospitals and this sector of rural India is denied of quality healthcare resulting from the cost barrier. Although public sector hospitals are numerous in number, value based healthcare can be achieved if these hospitals are able to provide modern treatment at an affordable price. [19]

Patient Centered Care in India: The Beginning

An ideal value based system in India is required to focus more on value for patients than on just reducing the cost of the medications.[17]Patient centered care mainly focuses on providing the best healthcare at the lowest cost possible. This includes hospitalizations, procedures, tests, physician visits, and medications. A recent report by the Harvard Business Review mentioned regarding distant healthcare provided through telecommunication in rural regions of India. This initiative may be considered as the beginning to providing affordable and apt healthcare required by patients who are unable to have access to specialized healthcare. The system uses live streaming over the internet to connect the patient with the physician. This system has reported to increase access to reproductive health services for patients of 6 million villages in India at a cost of $5.84 per adult for upto 2 years protection from pregnancy.[20] Singh *et al* reported the introduction of handheld tele-electrocardiogram (tele-ECG) which is a non-invasive test to detect underlying heart conditions. The device operated with the help of a phone *via* Bluetooth. A total of 450 individuals participated in the study and ECG was interpreted normal in 70%, left ventricular hypertrophy in 9.3%, and old myocardial infarction in 5.3%. Patient satisfaction was reported to be 95% and the procedure was affordable.[21]

CONCLUSION

In several mature markets, VBP is being increasingly adopted by payers as a way to focus their limited pharmaceutical budgets on drugs that meet genuine clinical needs and better reward manufacturers for developing such medicines. Though it might be a tough time for pharmaceutical industry to get over the challenges of VBP and value based innovation, it definitely would lead to access of basic healthcare to the bottom of the pyramid community.[10] Today value-based health care movement is a growing collection of people, organizations and governments that strongly believe value-of-care should replace volume-of-care. This quest for value in health care is now a global trend and can result in unprecedented impact. It is time that regulator in India become a part of this trend and bring about the necessary change in the healthcare sector for implementing value-based pricing as a core strategy. Adopting the following principles can enable alignment of all healthcare components:[17]

- Shifting the focus from just lowering cost to value for patients; value that is, driven by provider experience, scale and learning at the medical condition level.
- Enabling free flow of information on results and prices that is essential for value-based competition
- Encouraging innovation in healthcare by strongly rewarding any increase in value to the patient or society

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