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Decision Modelling Technique: Pharmacoeconomic Approach

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Abstract: In 2012, the pharmaceutical industry spent some 134 billion U.S. dollars on research and development. Pharma companies need to look forward for Decision modelling technique before investing in innovation and technology and technology/research and development sector. A major point of view which is being focussed is to get a new innovation and technology/ molecule/dosage form for a disease Considering various research happening across the world, get it patent and earn money. But would this actually help the industry? There are various alternatives available for treating same disease/symptom, then why would an individual invest more, when similar outcome can be obtained by using a generic version. So a pharmacoeconomic study should be thoroughly done before investing in innovation and technology/research and development sector. Decision tree is a classic structure for decision modelling for existing and innovative products/therapies. A decision model comprises the modelling structure itself (the decision tree), which represents the decision that is being made and the outcomes that can occur as the result of each decision, the probabilities that the various outcomes will occur, and the values of the outcomes if they do occur. Various decision models like Gartner Analytic Ascendancy Model, for change management can also be a crucial study for the pharma industry. Such studies can also improve the forecasting of sales, as it will establish the impact of market value and save millions of money.

Keywords: Pharmaceutical industry, decision modelling, innovation & technology, research & development, decision tree, Gartner Analytic Ascendancy Model, forecasting.

INTRODUCTION

The Indian pharmaceutical industry is ranked third largest in volume terms and 10th largest in value terms. This sector is highly knowledge-based and its steady growth is positively affecting the Indian economy. The organized nature of the Indian pharmaceutical industry is attracting several companies that are finding it viable to increase their operations in the country. The Indian pharmaceutical industry is highly fragmented with about 24,000 players (330 in the organized sector). Indian pharma companies have a large chunk of their revenues coming from exports. While some are focusing on the generics market in the US, Europe and semi-regulated markets, others are turning their attention to custom manufacturing for innovator companies. Biopharmaceuticals is also increasingly becoming an area of interest given the complexity in manufacture and limited competition. [1]

The Indian pharmaceutical sector accounts for about 1.4 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms. The country's pharmaceutical industry is expected to expand at a compounded annual growth rate (CAGR)

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of 14.5 per cent over 2009-2020 to reach $55 billion. With 72 per cent of market share (in terms of revenues), generic drugs form the largest segment of the Indian pharmaceutical sector. Moreover, patented drugs worth around $170 billion is expected to go off by 2015, leading to a huge surge in generic products, which would also provide remarkable opportunities to the Indian companies. Therefore, Indian generic drugs segment is likely to grow at a robust pace in the near future. Referring to other segments, patented drugs represent only 9 percent share, while over the counter medicines, which are sold directly to a consumer without a prescription from a healthcare professional, constitute 19 per cent share in the industry total revenue. [1]

So, when India proves itself to be a hub for generics, what type of investments the firms should make becomes a critical question for the industry. Today due to technology & innovations, new products, processes, and approaches are emerging faster than in the past. This fact has pushed the management of research and development forward as a major focus for both business and society. The impact of new technology on business causes a cascading effect within firms. Competitiveness is built through new technology, if 'successful'. But is it worth to get that technology by spending millions and trillions of rupees still remains a major question. In economic theory, we learn that price is a function of supply and demand. If the technology availed, becomes a success then it will result in more demand and if such demand is achieved then you become the key player in the industry. Similar happenings go with R&D and innovations which happen in industry, but recently it has been observed that most of the R&D centers have been shut down due to various reasons which result in loss for industry in terms of manpower, money, time and revenue. But still India is boosting their power and is in the support of 'Innovations' by 'Digital India'. Sujay Shetty, India Pharma Life Sciences Leader, Partner, PwC 'Innovation is the key to bringing effective treatment at an affordable cost to the market. Indian companies are already climbing the innovation curve for new drug discovery. Further to boost innovation in India, current tax incentives of 200 per cent weighted deduction should be increased to 300 per cent with a validity of 10 years'.

Also, new technology makes more information available to consumers. As more information becomes available, potential buyers become more aware of opportunities to obtain and begin to use the products. This leads to greater demand. But more precise information also leads to pricing being more systematic. Thus, technology leads to better prices.

So the decision of a firm on the investment of products, technology and innovation can be done using the decision modeling technique which can save a lot of wrong investments and can help in generating a revenue.

THEORY

1.1 INNOVATIONS

The process whereby new and improved products, processes, materials, and services are developed and transferred to a plant and/or market where they are appropriate. It is not just a creation or invention but it is a idea that reaches to the society and they will get its benefit. There can be newness of the product or process, newness of the usage, or a combination of both. Management of innovation is a comprehensive approach to managerial problem solving and action based on an integrative problem-solving framework, and an understanding of the linkages among innovation streams, organizational teams, and organization evolution. Fostering creativity is essential to managing innovation. Pharmaceutical innovation focuses on developing drugs about which relatively little is known at the time of their discovery or innovation consists of enhancing drugs that have been on the market for some time by making minor changes to them. Chemical type refers to the compound forming the active ingredient of the product. It may be new, or form the active ingredient of another medicine that has already been approved, or be derived from the active ingredient of an approved drug (e.g. Minoxidil which was used as an antihypertensive vasodilator earlier but now widely used for hair growth). Therapeutic potential refers to the capacity of the drug, based on evidence available at the time of regulatory review, to improve on the clinical performance of products that are already available to diagnose, treat, or prevent the same disease or condition. (e.g. modifying Crocin® to Crocin Advanced®).[2]

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1.2 TECHNOLOGY

Technology, in simple words is the processes used to change inputs into outputs. It can also be defined as the application of science, especially to industrial or commercial objectives; the entire body of methods and materials used to achieve such objectives. The impact of technology on business usually is not one-dimensional, but rather, new technology causes a cascading effect within firms. As seen earlier, technology leads to better prices; a similar cycle has taken place in market. Today, many people now use the Internet to buy automobiles, books, and other products. This has lead to greater numbers of buyers in many cases but also pressures to lower prices. For a firm to make a profit in this environment, it must be more efficient. One of the key means that a firm obtains such efficiency is through technology. Thus, the use of technology in one domain typically leads to greater need for changes in technology in other areas. [2] When considered in case of pharma, in earlier times the product when manufactured involved lot of hands for formulating a product in the production sector. Today, due to technology change hardly people are in direct contact with the product which has exceedingly improved the quality of product available. The use of Radio Frequency Identification (RFID) has helped in detecting many problems in case of packaging and supply chain specially. [2]

1.3 IMPORTANCE OF TECHNOLOGY AND INNOVATION TO SOCIETY

The impact of technology is not simply on individual firms. It also has broader societal impact both positive and negative. Technology helps push firms to lower costs. However, this has led in turn to increased levels of outsourcing by a number of firms to lower cost settings; technology advances in communication and computers help ensure that such outsourcing can be successful. Technology allows many job activities to be done as easily in one part of the world as another. Thus, technology has encouraged and permitted the outsourcing of jobs to these lower cost environments to a degree not seen before. The development of the economies of India, China, Russia, and other similar nations provides new markets for other businesses from developed economies. Thus, technology provides both positive and negative impacts for a society. The interaction between society and technology can be viewed in terms of **pushing** and **pulling.** When we say that technology is pushing society, we mean that new innovations in technology lead to changes in society that were not expected. For example, society was not demanding the development of the Internet. However, when it became a reality, it was quickly adopted and employed. Business can also be pulled by society to create technology. Technology and innovation influence both the firm and society as a whole, and this impact is ongoing. Entire industries can be created or can disappear very quickly because of new technologies. Technology and innovation influence not only the technical aspects of business but also the behaviors and attitudes of individuals and groups within the organization. [2]

1.4 MANAGEMENT OF TECHNOLOGY

Technology is nothing but to change inputs into outputs. Management of technology is defined as linking "engineering, science and management disciplines to plan, develop and implement technological capabilities to shape and accomplish the strategic and operational objectives of an organization." Importance of managing technology includes various aspects such as: 1.The rapid pace of technological change demands a cross discipline approach if economic development is to occur in an effective and efficient manner to take advantage of technological opportunities. 2. The rapid pace of technological development and the increasing sophistication of consumers have shortened product life cycles. The result of these factors is a need for organizations to be more proactive in the management of technology.3. There is a need to cut product development times as well as to develop more flexibility in organizations. The lead-time from idea to market is being reduced by the emergence of new or altered technologies. 4. Increasing international competition demands that organizations must maximize competitiveness by effectively using new technologies. 5. As technology changes, the tools of management must change but the process of determining what those new tools should be is in its infancy. [2]

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1.5 DECISIONS MAKING FOR MANAGING TECHNOLOGY

Decisions initially focus on the strategic posture the firm wants to assume. It is necessary determine that any firm wants to be a leader or follower in its industry. There are benefits to both, but the choice will result in the firm taking radically different steps and developing different processes and structures. It must also determine whether it will develop its own new technology or buy the technology, the scope of products it wants to offer. To create a total **platform** of products and processes, a key element in this determination is how it can leverage its technology and innovations. To manage the technology following things needs to be consider: 1. Analyze the industry structure both domestically and internationally. 2. Understand the firm's capabilities and those of its competitors. 3. Conduct a financial analysis of the product and firm. 4. Forecast future changes. [3]

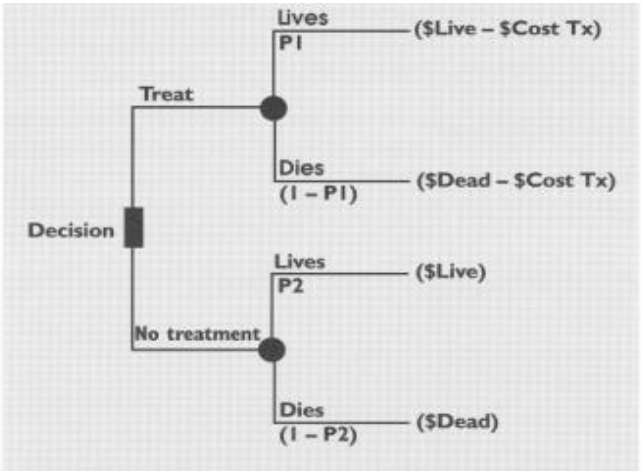

Figure 1: Decision making tree

1.6 STEPS OF DECISION MODELING TECHNIQUE [4]

Many methodologies and modeling types can be used to create and evaluate decision models, and the modeler should use the method most appropriate to the particular problem being addressed. The choice is dependent upon the complexity of the problem, the need to model outcomes over extended periods of time. Steps in conducting a decision analysis are as follow:

***1.6.1 Frame the question*:** The modeler must decide several basic details regarding for whom and from whose perspective the decision is being made. The decision problem must specify exactly who would be affected by the decision. Choosing the perspective of the decision maker is also very important, as it determines the appropriate metric in which to measure the outcomes and costs of the analysis.

***1.6.2 Structure the problem*:** The structuring of the problem represents the particular problem being modeled. The first is that the choices one makes from the decision node must be mutually exclusive; one and only one of the choices can be made.

***1.6.3 Estimate the Probabilities*:** Once the structure of the decision tree has been developed, the probabilities must be estimated for the various chance nodes in the tree. Modelers can use several sources to find and estimate probabilities for various parameters in a decision model. Retrospective Database Analysis, randomized controlled trials are very poor at estimating many other types of the parameters that are important in a decision model. The quality of the evidence that a modeler uses to calibrate a decision model is entirely dependent upon the type of data necessary for a particular parameter in the model. The important concept is that a model requires the best unbiased estimates of the specific parameters in the model; these parameters do not need to come from the same source nor do they all need to be of the same type of study or accuracy of data.

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***1.6.4 Estimate the Values of the Outcomes*:** The modeler needs to assess the values for the outcomes that occur as a consequence of each one of the choices to estimate the probabilities of various events. The appropriate outcome measure will have previously been determined in the framing of the question when the perspective of the analysis is decided. The appropriate outcome measure is usually QALYs in case of choosing a drug/formulation, profit that can be achieved and the risk involved. One of the advantages of developing a model of a pharmacoeconomic problem is that risk and cost outcomes may be evaluated and modeled simultaneously.

1.6.5 Analyze the Tree (Average Out/Fold Back): Goal is to calculate the expected value of the outcomes implied by choosing each branch of the root decision node. Starting with the terminal nodes, each chance node is replaced by the expectation of that chance node (the expected value of the outcome at that chance node), and that process is continued until one is left with the expected value of each branch of the initial decision node.

1.6.7 Test Assumptions (Sensitivity Analysis): One of the most useful steps in modeling is conducting sensitivity analyses after developing, calibrating the model. Sensitivity analyses have several purposes. They can be used to "debug" a model to make sure that the model behaves as it is designed to behave.

***1.6.8Interpret The Results*:** Once the analysis has been completed, the stability of the model has been tested with sensitivity analysis, and a modeler is convinced that the model represents pharmacoeconomic characteristics of the problem adequately, the results must be interpreted and summarized. It is the manner in which the answer varies with changes in underlying parameter estimates and underlying probabilities and values for outcomes that are the most interesting aspect of the interpretation of an analysis.

1.7 MARKOV MODELS [4]

In a traditional branch and node decision tree the terminal nodes are all single outcomes. The value of the outcome might be measured as a life expectancy and quality-adjusted life expectancy, a cost or risk involved. For any model, the outcomes that are expected to occur after each choice are actually quite complex combinations of events that happen in the lives of the people proceeding down that path. The intervention being modeled at a decision node affects the risks of future events. When a model must consider events that occur over time or events that may recur in time, the traditional branch and node structure is an inefficient method for representing these events. Standard decision analytic methods typically use a Markov process to represent events that occur over time.

1.8 SIMULATION MODELS [4]

The decision analytic and pharmacoeconomic investigators have started to rely basically on micro simulation, discrete event simulation, Agent-based simulation. Micro simulation is representing those models in which individual patients are modeled, one at a time, as they proceed through the model. The advantage of micro simulation is that it eliminates a problem with standard Markov process models in that it releases the assumption of path-independent transition probabilities. The basic problem is that in standard Markov decision models, transition probabilities are dependent only upon the state the patient is in the model at any given time in a micro simulation. Discrete event simulation was developed to model production processes in factories, provides the modeler with a set of tools that can represent queues, resource limitations, geographic distribution, and many other physical structures or limitations that constrain the implementation of a particular strategy or therapy. Discrete event simulation has been used for many years to allow for understanding flows and bottlenecks in operating room scheduling, emergency vehicle

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distribution and response time, throughput in emergency rooms, and many other resource constraint problems. The advantage of discrete event simulation is that it has specific structures to allow for the formation of queues, waiting lists, and arrival of both patients and donated organs. Agent-based models, in which each "agent" or component of the model independently contains all of the information it needs to interact with and respond to the actions of the other agents in the model, have been increasingly used to understand and model complex biological systems, from individual cells and organs to populations. One fundamental concept of agent-based models is that the aggregated behavior of multiple individual autonomous agents can replicate and predict very complex social and group behaviors.

1.9 DECISION MAKING TREE [5]

Most decisions involved certain degree of uncertainty. We must constantly choose from several possible courses of action without knowing what the outcome of our decision will be. Pharmaceutical is particularly a risky business. We need to constantly evaluate on the basis of technology, disease state, investment, type of products to manufacture and uncertainty about the prices they'll receive for their products.

Decision analysis uses probabilities and monetary values to provide a guide for what should be done. It uses a decision tree as a pictorial representation of the flow of events in a logical and time-sequenced manner, so that the decision maker can consider the probabilities of each outcome. Decision analysis is is prescriptive rather than descriptive. It is intended to aid the decision maker to decide what should be done under given set of circumstances. The decision is consistent with the problem as it has been laid out logically as a decision tree. The uncertainties involved have been identified and quantified, and relative values placed upon possible outcomes. (Figure 1)

1.10 TECHNOLOGY ACCEPTANCE MODEL (TAM) [3]

Technology Acceptance Model first introduced by Fred D. Davis in 1986 as part of his doctorial dissertation it aims to isolate factors which most affect the integration of new technology into an organization and is used to predict, explain and increase user acceptance of technological systems and applications and to understand why end-users can reject the use of new technological solutions. Perceived Ease of Use (EOU) is the degree to which a person believes that using a particular system would be free of effort and Perceived Usefulness (U) is the degree to which a person believes that using a particular system would enhance their performance. These both the factors are influenced by external variables such as user's experience of the current system and fear of redundancy, popular opinions to the new implementation and pressure from workers unions.

Attitude towards Using (A) is an individual's positive or negative feeling about performing the target behavior and Behavioral Intention (BI) is the measure of strength of ones intention to perform a specified behavior. EOU has a direct effect on U and U has a direct on BI which is having a direct impact on the Actual System Use.

TAM shows that the root cause for the non-acceptance of a technological system or application is the impact of the external variables on its potential users therefore reasons for supporting the adoption of new Technology are Potential benefits, where the expected benefits are at least as great as the risks, Costs of inertia versus costs of change, where new technologies improve on those they replace and Means of managing risks, where potential harms can be managed and reduced through systematic scientific research.

Reengineering of the TAM resembles the notion of Lewin's 3-Step model of Unfreezing, Moving and Refreezing. Unfreezing is related to overcome the habits and inertia of an organization. Making is to change the system and Refreezing is related to making the changes last. Change process is expressed by using a traffic signal lights such as red, amber and green. Red light indicates to stop usage of current technology solution, where as amber light shows the transition period between the old system and the new system, Green light indicates to go ahead if the way is clear. Change management is central to the process of making the transition from old system to new. The need for change, the progress of the project and the benefits of change should be communicated effectively throughout the change project.

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Current technological solution (CTS) exhibits the similar variables identified by TAM is Behavioral Intention Towards using the current solution(BI), Attitude towards using the current technological solution A(c), Perceived Usefulness of the current technological solution U(c) and Perceived Ease of Use of the current technological Solution EOU(c). Whereas the Proposed Technological Solution (PTS) exhibits Behavioral Intention towards using the proposed solution BI(p), Attitude towards using the proposed technological solution A(p), Perceived Usefulness of the proposed technological solution U(p) and Perceived Ease of Use of the proposed technological Solution EOU(p). Change management is required throughout the duration of the change project. The main focus should be to understand the existing culture and skills set and communicate the new vision and plan for the future. The Traffic Light TAM model is made to highlight the existence of acceptance variables in both technological solutions. (Figure 2).

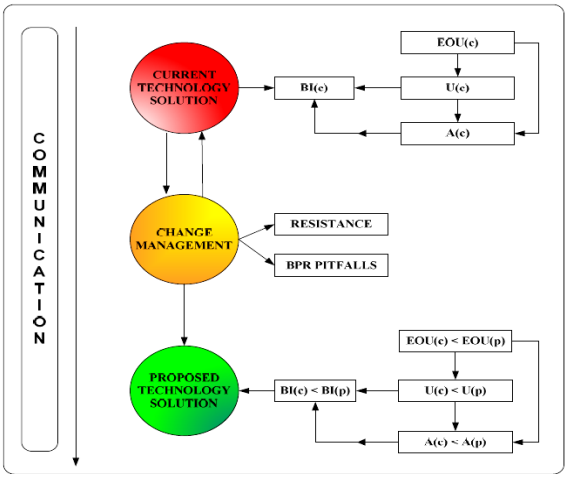

Figure 2: TAM model

1.11 ADKAR MODEL [6]

ADKAR is a goal-oriented change management model that allows change management teams to focus their activities on specific business results. The model was initially used as a tool for determining if change management activities like communications and training were having the desired results during organizational change. The model has its origins in aligning traditional change management activities to a given result or goal.

Awareness of the business reasons for change is a goal of early communications related to a business change. Desire to engage and participate in the change is the goal of sponsorship and resistance management. Knowledge about how to change is the goal of training and coaching. The ADKAR model has the ability to identify why changes are not working and help you take the necessary steps to make the change successful. You will be able to break down the change into parts, understand where the change is failing and address that impact point.

The power of the ADKAR model is that it creates focus on the first element that is the root cause of failure. When change is approach using this model, anyone can immediately identify where the process is breaking down and which elements are being overlooked. (Figure 3)

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	Steps	Enablers
A	***Awareness** of the need for change*	▪ Management communications ▪ Customer input ▪ Marketplace changes ▪ Ready-Access to information
D	***Desire** to participate and support the change*	▪ Fear of job loss ▪ Discontent with current state ▪ Imminent negative consequences ▪ Enhanced Job Security ▪ Affiliation and sense of belonging ▪ Career advancement ▪ Acquisition of power or position ▪ Incentive or compensation ▪ Trust and respect for leadership ▪ Hope in future state
K	***Knowledge** on how to change*	▪ Training and education ▪ Information access ▪ Examples and role models
A	***Ability** to implement required skills and behaviours*	▪ Practice applying new skills or new processes and tools ▪ Coaching ▪ Mentoring ▪ Removal of barriers
R	***Reinforcement** to sustain the change*	▪ Incentives and rewards ▪ Compensation changes ▪ Celebrations ▪ Personal recognition

Figure 3: ADKAR model

1.12 GARTNER ANALYTIC ASCENDANCY MODEL

Descriptive analytics are often a predominant feature on business intelligence dashboards or scorecards and are the most basic transformation of data into information. Descriptive analytics is defined simply as quantitatively describing the main characteristics from a collection of data. For example, how many patients were diagnosed with high blood pressure last year. **Diagnostic analytics** is used to determine "why it happened." For example, why these patients did developed high blood pressure. Once anyone understand the "what has happened" and the "why it has happened," anyone can traverse up the analytics ascendancy model to **predictive analytics**, i.e., "what will happen." Predictive analytics often require the use of statistical methods such as regression models or machine learning algorithms. For example, what are the chances of High blood pressure patients to results in the stroke. Finally, **prescriptive analytics** tells us what decision options we have like patients should be put on some medication to prevent high blood pressure resulting in the stroke. The analytics ascendancy model (descriptive, diagnostic, predictive and prescriptive) is useful constructs for organizations who wish to utilize analytics to address the challenges of population health management and value-based care. [7], [8], [9] (Figure 4).

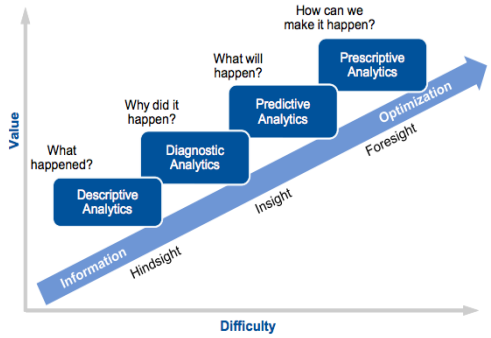

Figure 4: GARTNER ANALYTIC ASCENDANCY MODEL

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CONCLUSION

The growing power of decision models has captured plenty of C-suite attention in recent years. Combining vast amounts of data and increasingly sophisticated algorithms, modelling has opened up new pathways for improving corporate performance. Models can be immensely useful, often making very accurate predictions or guiding knotty optimization choices and, in the process, can help companies to avoid some of the common biases that at times undermine leaders' judgments. It will also give a clear idea about the type of innovation in-need: what is possible with technology, what is viable in market place and what is desirable to users. Pharmacoeconomic decision models will help in preventing the pharmaceutical industry to make wrong investments. The data can give a clear foresight for the industry for its future planning and increasing the profits from the existing products/ technology. It will tell in which area investment can be made and which products should be withdrawn from the market; what will be the outcome of such a change and how much flexible and adaptable will it be.

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