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Evolving Operational Decision Models in the Pharmaceutical Industry

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The pharmaceutical industry is unraveling the business and operational models across the value chain to create a new industry picture. The current operational decision model of vertical integration from the laboratory to the pharmacy is more of an art than science. Some of the critical issues such as price pressures, increased regulatory scrutiny, reducing drug development costs and time, managing patent expirations and leveraging technology and emerging global markets will influence the industry strategies, which need to be steered and implemented for continued growth and profitability. This paper presents the different options and strategies that are rationally derived and/or practically interpreted from other industries.

Keywords: Operational Strategies, Decision making options, Pharmaceutical business models

1. Introduction

The pharmaceutical industry is unraveling the business and operational models across the value chain to create a new industry picture now as several other industries did in the past -- oil in late 1970's, automotive in mid 1980's, electronics in late 80's, chemicals/ specialties in early 1990's and personal care in mid 1990's.

The current business model of vertical integration from the laboratory to the pharmacy is moving to a more fragmented model with various players active in each section of the value chain. The business and operating models of pharmaceutical industry are highly complex. The technologies leading to drug discovery and development are at the limits of human knowledge. The huge size of the companies and the complexities of their processes and technologies presents many organizational and management challenges. The distribution system development and management is complex and highly costly.

However excellence in managing the distribution system development is a necessary condition for the survival of the global pharmaceutical companies. The uncertainty of the discovery process generates lot of risk for a potentially huge return from the discovery of a single drug. Much of the thinking about business strategy in the industry is how best to cope with this uncertainty. The highly skewed nature of the returns from the drug discovery and development process means that a single drug cannot deliver corporate success at least in the short to medium term. As

Scherer (2000) has pointed out, in these conditions, the normal principles of large numbers in which diversified portfolios produce predictable returns does not apply to this industry. Due to these reasons, returns from pharmaceuticals are highly volatile.

Figure 1 *Industry Drivers and Business Model Changes*

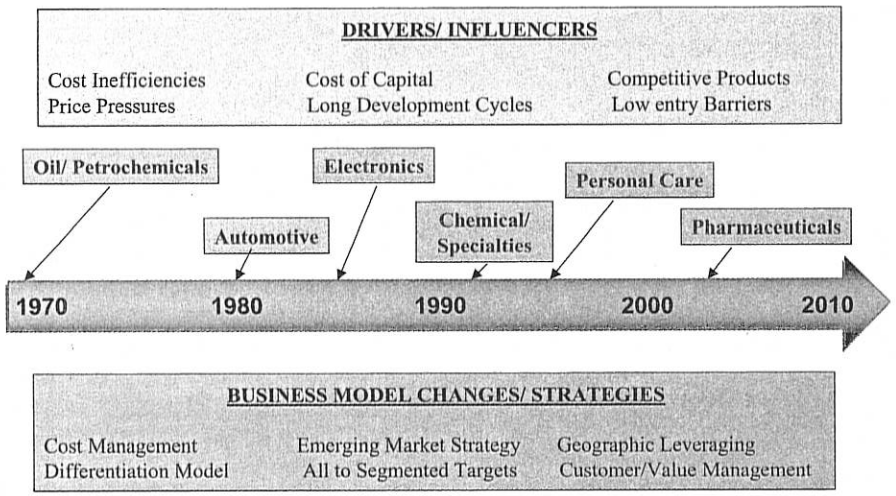


Figure 1 shows the factors that influenced various industries to change their business and operating models. Similar forces are influencing the big pharmaceutical companies to change their status quo. Some of the most critical influencing the pharmaceutical industry includes:

- Risk Mitigation of Increased Regulations
- Managing the Price Pressures
- Reducing drug Development Costs and Time
- Managing Patent Expirations –
  - Alternatives to Blockbuster Model
  - Competition from Generics
- Leveraging Technology & Emerging Global Markets

This is the time for the industry to address some of these issues and their influence on the strategies, which need to be steered and implemented for continued growth and profitability.

2. Current Pharmaceutical Industry Situation

2.1 Business Model and Strategies

One of the repeated mantras of pharmaceutical company strategy over the past decade has been increasing scale. Companies can only afford the considerable costs of drug development and distribution by growing larger. This is well summarized in the Price Waterhouse Coopers report *Analysis and Opinions on M&A Activity* (Price Waterhouse Coopers, 1999). The three observed business models from this broad strategy are:

I. Blockbuster model involving the discovery and distribution of a small number of drugs that achieve substantial global sales (usually in excess of $1 billion). The success of this model depends on achieving large returns from a small number of drugs in order to pay for the high cost of the drug discovery and development process for a large number of candidates.
II. Diversification model in which a larger number of drugs are marketed to smaller niche markets. The success of this model is not dependent on sales of a small number of drugs. However, the model only works for small markets where distribution costs are low, particularly without a blockbuster to help pay for the high development costs.
III. Intermediate model with some of each of (I) and (II).

Industry analysts have recognized the blockbuster model as the dominant model (Mercer Management Consulting, 2001). However interest in alternative models is growing as consideration is being given to the marketing of biotech drugs with smaller markets and higher treatment costs and the expectation of more personalized medicine.

The Primary strategy of the big established pharmaceutical companies has been to increase scale through mergers and acquisitions. By Building scale, the latter stages of their product pipelines have at least a handful of highly prospective blockbuster drugs. Scale also offered the capacity to both fund in house research and draw in external research through a variety of licensing arrangements and alliances.

Since the number of New Chemical Entities (NCEs) at the latter stage is so small and returns are so uncertain these solutions may last a very short duration. The gaps in the pipeline, expiration of existing blockbuster patents, and the failure of the expected blockbusters are producing another round of Merger & Acquisitions. The expected growth rates by the financial markets to sustain current valuations require a significant and questionable expansion in the number of new large selling drugs. Another strategy has been for pharmaceutical companies to diversify their business activities into lower risk activities. For example, Merck went into Medco or Johnson & Johnson expanded into household health products. As Merck recently spun off its Medco unit, it is not clear that the financial markets have rewarded this strategy.

Another diversification strategy is to focus on a comparatively large number of niche market drugs rather than blockbusters. A number of European companies have followed this strategy. While their total sales of pharmaceuticals place them in the top rank of pharmaceutical companies they have only one or two blockbuster drugs. This diversification strategy lessens dependence on the discovery of new blockbusters, but development and marketing costs need to be minimized for the smaller markets to be profitable.

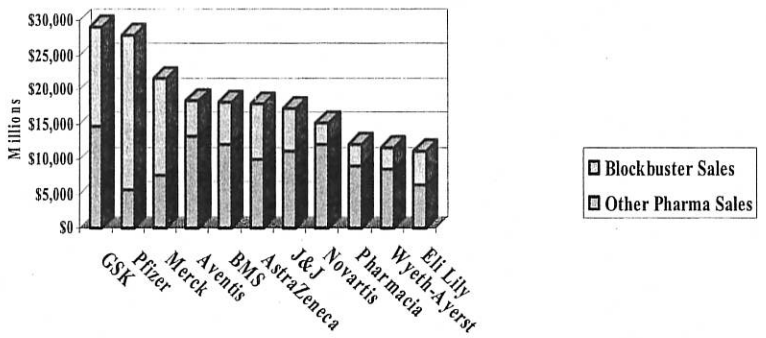
On the other hand, some biotech firms used a discovery breakthrough to develop a blockbuster of their own, and eventually succeeded in marketing through an alliance with a global pharmaceutical company. In some instances, biotech firms also have funded independent drug discovery through direct access to the venture capital market. In other cases, large pharmaceutical companies through alliances and licensing have supported their research. Very small number of biotech companies rose to the top ranks from a single successful blockbuster drug. On the other hand, many biotech companies fail to realize these goals and become contract research

organizations or go out of businesses. There is a strong need for alternate business models due to the instability and unsustainability of current pharmaceutical business strategies and structure. Details of the blockbuster model are presented below.

The Blockbuster Business Model

Due to its complex and uncertain nature of drug development and distribution system, the industry's economics call for few high selling drugs to mitigate the risks and enhance the profitability. Figure 2 presents the 10 largest global pharmaceutical companies by sales of pharmaceuticals for 2002 together with total sales of those drugs with global sales exceeding $US1 billion ('blockbuster'). There are only 40 blockbusters highly concentrated with the three largest companies representing on average 41% of pharmaceutical sales of these companies.

Figure 2 *Blockbuster Sales by Major Pharmaceutical Companies (Credit Suisse First Boston, 2002)*



The blockbuster model requires that the later stages of the development pipeline always contain drugs of blockbuster potential. This also requires a consistent and dedicated approach to drug R&D with considerable in house research expertise and successfully utilizing public domain research or using various alliance strategies and licensing arrangements to bring prospective drugs into the later stage drug development. The risk involved in this strategy is that there may not be new blockbusters to replace those losing patent protection since the number of blockbuster drugs at any point in time is relatively small. Some companies failed to invest adequately in the pipeline resulting in lack of blockbusters to keep sales growing as in the case (Gambardella , 1995)of SmithKline, which failed to reinvest the proceeds of its Tagamet success in upstream research, and it was forced to merge with Beecham in 1989. Some companies have combined mutually supportive capabilities such as the ability to develop valuable drug development pipeline and a strong sales and distribution infrastructure as in the case of the merged company AstraZeneca – Astra with the blockbuster drug Losec and Zeneca with the financial strength and scale to underwrite further R&D.

The blockbuster model requires cost improvements in the developmental costs to reduce the uncertainty in the model. In 19990s, Ely Lilly's efforts to improve in efficiency of its drug development pipeline for its blockbuster drugs through quality, speed and value (QSV) concept. Lilly emphasized to improve speed to market, leveraging existing products and establishing a global and focused therapeutic area presence. Their focused activities and more disciplined approach of the drug discovery and development process (Burgleman, Maidique and Wheelwright, 2001) resulted in a remarkable performance in share price. Despite these improvements, the cost of R&D per drug has climbed exponentially over the last 30 years (Grabowski and Vernon, 1994). Recent estimates put the cost of R&D per drug at $802M whereas the equivalent study conducted 10 years previously and adjusted to 2000 dollars put the cost at $318M (DiMasi, 2001).

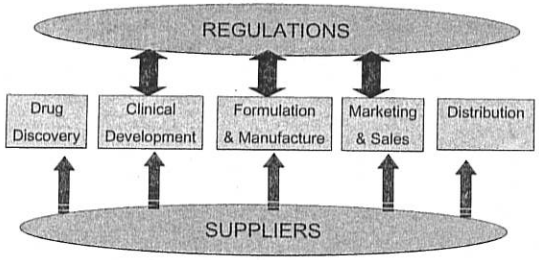
Series of consolidations in the industry increase the risks in the blockbuster model and uncertainty of the economics of new drug development as it is difficult to achieve stable and predictable returns when less number of blockbusters are replenished in the portfolio while the facing the constantly emerging competition from follower drugs. The industry data shows that the follower drug competition has cut market exclusivity from 4 years in the 1980s to less than 1 year in the 1990s (Pharmaceutical Research and Manufacturers of America, 2001). From the lesions learned from the other industries such as automotive, chemical, and personal care industries the pharmaceutical industry need to leverage its value chain to gain efficiencies in supply chain costs.

2.2 Operational Model and Supply Chain Management

In the changing pharmaceutical landscape, all the supply chain components need to gain efficiency in order to sustain the growth and profitability of the past performance. Recent market withdrawals of products in COX-2 inhibitors and regulatory disappointments of several promising drugs, big pharmaceutical companies that continue to rely on old investment and commercialization model based on the blockbuster drugs will face the challenge of shifting the drug development to specialty products. About 75 of the new chemical entities (NCEs) entering the market are specialty products and/or biologics produced by the small to medium size biotech companies. The challenge of being profitable through smaller chemical entities needs to be managed by developing more niche products either internally or through partnerships. One element of this new model, as learnt from the other industries such as the specialty chemicals and personal care is the cost and resource management. Efficiencies need to be gained in minimizing the costs and resources until these products have large growth potential. Timing is also an important factor in bringing these products into the market as quickly as possible.

Figure 3 presents the pharmaceutical supply chain, which integrates the processes from drug discovery to distribution to create value for the patients. Drug discovery and clinical development can be enhanced in this supply chain by leveraging the technology. Currently, the process is very lengthy, labor-intensive and highly regulated. The legacy IT systems and multiple, disparate data sources that are resident internally and externally in many companies is hampering the improvement in this area.

Figure 3 *Pharmaceutical Supply Chain*



Marketing and Sales is another area where scale delivers clear advantage. Sales per representative typically rise with company size (Walton, 2001). About 35% of pharmaceutical revenues are allocated for Marketing, where as less than 20% for R&D. Any efficiencies gained in this area of supply chain can have a major impact on company value. A survey of US pharmaceutical companies suggests that marketing and sales capability accounts for 42% of the variation in financial performance (George and Perone, 2001 and Blumberg and Perone, 2001). Most of the new blockbuster drugs are launched with a comprehensive and expensive global marketing campaign that involves the full range of marketing tools including media advertising, comprehensive information packs, special events for doctors, conference presentations, dedicated sales forces and the Internet.

Sales and distribution activities in the supply chain is emerging as a major issue for pharmaceutical companies. Traditionally in the US, clinical settings (hospital, in-patient facilities) have accounted for about 25% of pharmaceutical sales while the remainders have been distributed through various wholesale and retail channels. Typically the manufacturer sold the drugs to a wholesaler which distributed the drug to retail pharmacies. In this relationship the doctor, who has been the focus of marketing campaigns, had an unrestricted ability to prescribe drugs as he saw fit.

Traditionally marketing to physicians involves sending more sales reps to the doctors with each new drug launched. Accordingly, the number of sales reps has been rising rapidly, at 20%, compared with physicians at only 3%. Pharmaceutical companies are seeking ways around the doctor channel such as direct-to-customer (DTC) and various forms of the Internet delivery.

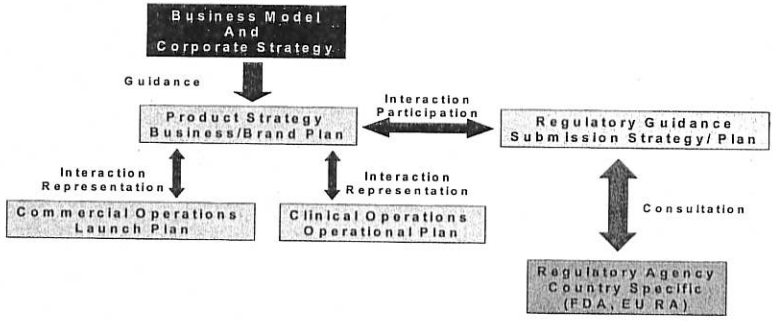
2.3 Decision Making Process and Models

The decision making process in the traditional large pharmaceutical companies has been hierarchical in nature. Figure 4 below shows the general decision making process in the pharmaceutical industry.

Once the business model and corporate strategy has been developed (typically in the past Block-Buster model is the predominantly used in Big Pharmaceutical companies), Product strategy decisions are made with product teams in consultation with regulatory authorities through an internal regulatory team. These decisions are usually in team environment with cross-functional participation such as commercial and clinical operations. The regulatory teams provide guidance to the product strategic plan upon interactions and agreements from the regulatory authorities in various regions of the world where the product is been submitted for approval and

commercial launch. Depending on the product team leader and the facilitator this decision making process can have several other interactions and representations from various other groups/teams.

Figure 4 *General Decision Making Process in the Pharmaceutical Industry*



Although these processes with various variations have been tried in different large pharmaceutical environments, the outcomes were not good in recent years as the failure in product introductions and safety concerns after the launch of the products. In addition to the different processes involved in making decisions, groups/teams can also have different decision rules and biases. Some of these biases can be identified as the following (Dickerson and Flanagan, 1990):

- **Conservatism and Inertia:** Unwillingness to change thought patterns that we have used in the past in the face of new circumstances. As the business models and operational model are changing in the industry this has been a predominant bias in the industry
- **Experiential limitations:** Unwillingness or inability to look beyond the scope of our past experiences; rejection of the unfamiliar. Pharma industry is so much used to the blockbuster model, the current decision making is still based on the same approach.
- **Wishful Thinking or Optimism**: We tend to want to see things in a positive light and this can distort our perception and thinking. In the blockbuster model traditionally the groups/teams always plan for success, which is a positive morale booster for the teams. But, too much optimism with out willingness to adapt to the dynamic external environment leads biased decision and failed outcomes.
- **Group Think:** Peer pressure to conform to the opinions held by the group. As the Block Buster model was successful in the past, groups are dominated by the few who had successes in the past business/operational model.
- **Underestimating uncertainty and the illusion of control:** Groups tend to underestimate future uncertainty because they tend to believe they have more control over events than they really do. Groups also believe they have control to minimize potential problems in their decisions. In the past the blockbuster drugs have less competition in the market place and the uncertainty was less as the threshold for risk/benefit was low fro drug development.

In general, Politics is one of the predominantly used approaches to make decisions in the current pharmaceutical industry. This approach is very useful when used without any biases mentioned above.

3. Preparing for the Change and Future Industry Trends

3.1 Emerging Business Models and Strategies

In order to prepare for the future, integrated pharmaceuticals companies have a variety of strategic alternatives to position themselves in the future market. They can leverage the value chain and recapture the value like the personal care and chemical industries have done in the 1990's (Chitra, 1999 and 2000). They can concentrate on individual slices of the integrated value chain, such as cardiology, urology or CNS. Another option is to focus on individual functions of the value chain such as lead identification, drug development, production or marketing & sales. Finally, integrated firms can continue to follow the current strategy of acquire and integrate the newly acquired companies into current organizational structures with elimination of redundancy.

The primary strategic alternative is to concentrate on integrated slices of the value chain. This will require companies to separate their existing business structures into multiple fully integrated organizations focussing on specific segments or markets with focus on market orientation from process orientation. The responsibility lies with individual organizations for research, development, production and marketing and sales. Resources can be obtained from internal service providers (e.g., central headquarters) or external service firms based on competitive pricing.

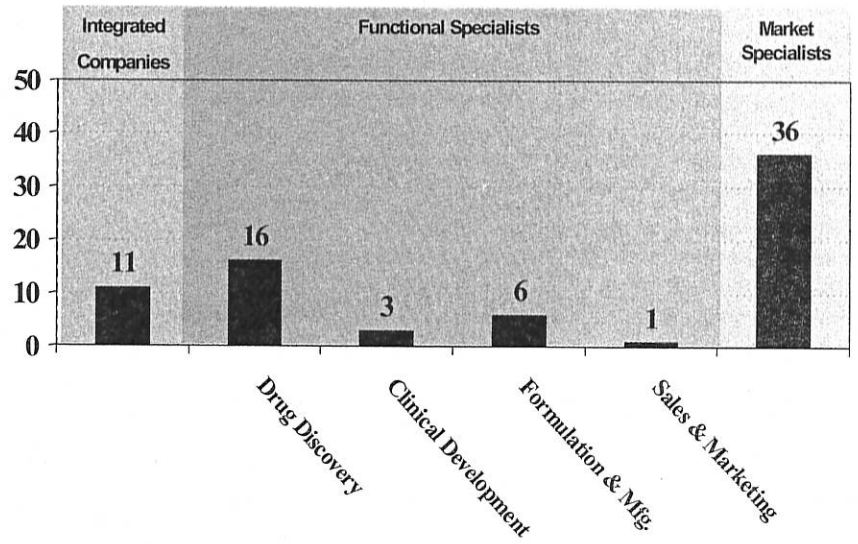
A secondary strategic alternative for large integrated pharmaceutical companies is to focus on the individual functions of the supply chain or the individual segments of the value chain, which provide a clear sustainable benefit to profitability. Companies must decide regarding which functions the firm should retain internally, which functions the firm should source to outside partners and which technologies the company will need to retain and grow. In addition the companies develop strategies to select and orchestrate synergistic partners. As a result of this strategy value chain segments can be separated into independent units, which can be divested or maintained as profit centers.

The final strategic alternative, acquire and integrate smaller firms, is the current strategy followed by the industry. An example of this strategy is the acquisition of Vicuron Pharmaceuticals by Pfizer recently. However, this strategy becomes increasingly competitive and difficult as the industry continues to consolidate. Sooner it will become hard to follow this strategy as the few remaining firms will be too large acquire to maintain the current growth. Just like in the other industries such as oil and chemical industries, the integrated firms will begin to yield to the specialists of one segment or a function. Already, the market is beginning to reward the segment and market specialists as shown in Figure 5.

The current blockbuster model is very risky, expensive and time and resource intensive. The alternative to the blockbuster model is to consider the other options used by the biotech companies and the generic drug manufacturers. Some smaller biotech companies approach is to focus on specialty products and/or biologics. In 1996, 25% of the NDAs targeted specialty products and 75% targeted the primary

care products. Where as in 2003, the trend is the reverse with 75% for the specialties and 25% for the primary care. This approach can reduce the risk compared to the current blockbuster model, since these NCEs are targeted for very specific target patient populations. But the drug development cost is very high and time to market these drugs is still very long.

Figure 5 *Ratio of Market Value to Sales for Pharmaceutical Companies*



As the competition in the generic market is increasing due to many smaller players, the generic producers are also targeting the NCE development. Their approach is to conduct R&D at lower cost geographic areas (such as Eastern Europe, Russia, China and India) and later phases of the clinical development to be done in western regions with alliances with other generic companies I the region. This approach will reduce the initial costs of development and may reduce the time to market these drugs. The risk for this approach probably is the same, as these companies are not experienced as much as the big pharmaceutical companies.

3.2 Evolving Operational Models

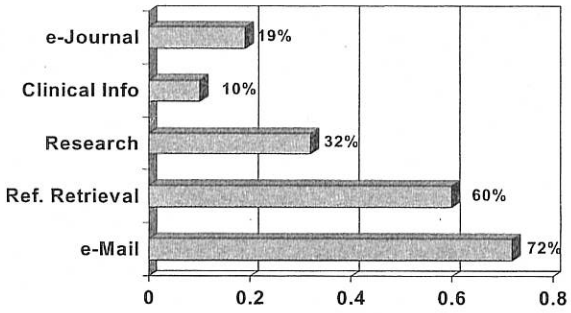
As the business pharmaceutical business models are changing the operational models are also evolving into more efficient and dynamic models. An evolving opportunity for the improvement in cost and speed in the discovery and clinical development is to maximize the potential of emerging markets such as India and China. Nearly a dozen U.S. pharmaceutical companies are currently operating in India and others are expected to follow. Several companies have migrated clinical trials to these regions because it is less expensive and easier to access drug naive patients. India also has a highly educated, English speaking scientific population, which offers huge potential for in-country drug discovery and development.

Additionally, China, in turn, offers a cost-effective population to staff drug manufacturing facilities and a huge consumer/patient population. More and more U.S. companies are trying to expand their manufacturing and sales operations in China.

Other evolving opportunities in the value chain are leveraging Electronic Data Capture (EDC), remote site monitoring and management, computer modeling of clinical side effects, and other technologies that have a potential to bring significant savings and speed to drug discovery and development. The industry can improve the productivity by utilizing the emerging electronic research organization (eRO) methodology (Pratt, 2005). An eRO leverages the best of both the CRO and EDC to effects substantial cost-savings through efficiencies and speed to market. As pointed by Hindin (2004), industry is developing new types of strategic partnerships that are changing the rules and reinventing the clinical trials process. The CRO industry is rapidly growing with the rise of genetics and genomics and the push toward partnering and post approval research (Glilings, 2004).

The evolving marketing and sales approach to reach the consumer is through the Direct-To-Consumer (DTC) techniques. The current DTC techniques include special purpose Internet sites providing information to both physicians and patients about a particular drug. Each expected major drug is now launched with its own dot.com site. In addition to attracting the attention of doctors, the objective is to alert potential patients to the attributes of the drug and encourage them to seek prescription from their physician. Increasingly media, including TV advertising, is being used to announce the arrival of new drugs. The current DTC is still a challenge for pharmaceutical companies since the patients need a script from a physician to obtain the drug.

Figure 6 *Internet Usage Type and Extent by the Physicians*



Some Internet sites have been established to give physicians the opportunity to call highly qualified sales reps and discuss the drug attributes via live videoconference. This so-called e-Detailing has been found to be an effective way of raising product awareness amongst doctors. According to the 1999 Healtheon survey of provider practice physicians, 72% of physicians claim to use the Internet (home and/or office) and 89% have been impacted by patients accessing healthcare information. Figure 6 shows the usage type and the extent for the physicians. Managing customer interactions electronically is one of the most significant factors in sales.

3.3 Evolving Decision Making Processes

The pharmaceutical processes are very complex with several functions involved. In recent years various companies are trying to revamp the entire drug development process by simplifying the overall structure. This simplification may not reduce the complexity of decision making, as the people involved in the process are still the same manger who have grown along the lines of blockbuster model. In this simplification the decision process described in Figure 4 still valid with improvement in communications and interactions. These improvements are partly due to evolving developments in the value chain operations such as e-clinical efforts as mentioned above in the clinical development and utilization of DTC and Internet technologies for marketing and sales. Still the decision process can have the same biases unless the groups evolve away from the blockbuster thinking.

A critical aspect for decision-making in groups is the ability to converge on a choice (Butler and Rothstein, 2004). Politics is one approach to making decisions in groups. This process revolves around the relative power or ability to influence of the individuals in the group. Some relevant ideas include coalitions among participants as well as influence and persuasion. The use of politics is often judged negatively, but it is a useful way to approach problems when preferences among actors are in conflict, when dependencies exist that cannot be avoided, when there are no super-ordinate authorities, and when the technical or scientific merit of the options is ambiguous.

The evolving decision making approach is to utilize sub-committees. Sub-committee process involves assigning responsibility for evaluation of a decision to a sub-set of a larger group, which then comes back to the larger group with recommendations for action. Sometimes a sub-committee includes those individuals most affected by a decision, although at other times it is useful for the larger group to have a sub-committee that involves more neutral participants. These subcommittee membership is usually involves key stakeholders from functions such as commercial, research, clinical development and regulatory. Sometimes these include external key opinion leaders as well.

The groups are also separating the decision making process from outcome by explaining that a good decision-making processes does not guarantee a good outcome, and that a good outcome does not presuppose a good process. Thus managers interested in good decision-making are encouraged to put good decision-making processes in place. Although these good decision making processes do not guarantee good outcomes, they can tip the balance of chance in favor of good outcomes.

4. Conclusions and Recommendations

From the review of the current business and operational models and the future trends in the industry, the pharmaceutical industry can prepare for the future growth and sustained profitability in several ways. The following list can provide different options to explore for the industry:

1. It may become increasingly risky and difficult to ensure long-term growth and profitability of pharmaceutical companies, as there are only a limited number of products in their pipelines following the blockbuster model. Rather, companies can seek to develop and market products that are more innovative, even if the potential sales of the drug are lower than what most pharmaceutical companies currently expect. The decision-making processes need to adapt to this change.
2. Decisions should also include innovating targeted therapeutics for smaller market segments, which are still profitable, while harvesting existing products by maximizing the revenues from products that they currently market.
3. Pharma companies are working on the due diligence type of decision making tools to license or arrange for equity share with the specialist biotech and other research companies by leveraging the value chain.
4. Decision to improve speed to market with minimizing costs and providing great values to the customer with CSV (Cost, Speed and Value) approach by geographic utilization of skills and resources need to be utilized.
5. Utilizing the decision techniques evolving due changes in the industry pharmaceutical industry needs to maximize the potential of emerging global markets such as Eastern Europe, South East Asia and China to gain the cost and efficiency advantage.
6. Lastly, the decision processes can respond quickly to the external market forces by transforming the resources and implementing flexible business/operating models.

Finally, the pharmaceutical industry can look at the experiences learned from other R&D intensive industries, such as telecommunications, aerospace, specialty chemicals, personal care and automotive industries. There may be some value in the technologies that are developed using disciplines that lie outside traditional pharmaceutical R&D (i.e., mathematics, operations research, physics, and engineering) and use the flexible technologies to close the uncertainty in the profitability gap (Karis, 2005). Some of the decision technologies utilized by these various sectors can be adapted to changing pharmaceutical business and operational models.

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