Chapter - VIII

RECOMMENDATIONS FOR ACHIEVING COMPETITIVENESS AND FUTURE OF HIGH TECH PHARMA BUSINESS

8.1 Introduction
During much of the 1980s and 1990s the pharmaceutical industry provided one success story after the other: Ever bigger blockbusters were hitting the market. Although industry growth rates were modest but stable, further success seemed unlimited due to extending the limits of R&D driven innovation. Furthermore, the industry was considered recession proof, as human mankind would continue to depend on medicines even more with a growing ageing population in the rich western world.

The beginning of the 21st century saw first and second generation biotech drugs with much more efficient clinical profiles entering the market, the mapping of the human genome would not only allow tailoring of drugs to individual patient profiles but catapult medicines into an entirely new age of finally understanding and preventing disease. All in all, it definitely seemed like an industry with a bright future ahead!

Yet, all of a sudden the bubble burst dramatically. Nowadays, companies are throwing ever more R&D funds into their development machinery but the output is slowing down and additionally the discovery of NCE’s has not really increased over the last 20 years.

Are we just confronted with a temporary shortage of pipeline output or a true structural deficit of the industry which requires entirely new approaches on product development, approval and marketing?

8.2 Challenges within a tougher market place
The pharmaceutical industry is currently facing important challenges from within. Increasing research and development costs combined with falling
returns, as well as an increasingly competitive market place are the main factors calling into question the wisdom of the ‘blockbuster drug’ strategic approach traditionally followed by the large pharmaceutical companies\textsuperscript{160}. These firms have now reached a critical size, whereby their only strategy of getting bigger via new blockbuster drugs in unrelated disease and therapeutically categories is now questionable. Lack of focus in some specific disease areas is seen as one of the key reasons for the slow growth of large pharmaceutical companies, whereas niche market companies tend to perform better comparatively.

Many pharmaceutical companies are experiencing problems with their research and development departments, with product pipelines for blockbuster drugs drying-up despite rising research costs in this area.

Since most of the body’s enzymes have already been exploited by the industry, those problems which have not yet been solved require more complex solutions. These solutions will inevitably continue to add to the costs of R&D. In addition, the movement away from chemistry toward nuclear biology has necessitated expensive technology platforms which have further added to R&D costs. These new technologies should eventually allow more complex problems to be solved but it will be many years before the investments start to pay off for the companies involved. In a number of cases, products which were expected to become blockbusters have received disappointing labelling / market authorisation in the approval process. The European Agency for the Evaluation of Medicinal Products (EMEA) recently announced that, in 2003, it expects the lowest ever number of new product applications.

It is clear that the blockbuster drug game is changing; while pharmaceutical companies still strive to produce drugs that can hit the magic $US 1 billion in

\textsuperscript{160} Changing this strategic approach and producing more generic products, bulk drugs and Active Pharmaceutical Ingredients (APIs) will strengthen Indian companies through larger profits and will help to acquire regulated and semi-regulated international markets.
peak-year sales, the appearance of super blockbusters (such as Pharmacia's Celebrex, which generated $US 1 billion in its second year after launch) has raised the bar. Although the number of drugs achieving blockbuster status ballooned during the 1990s, it has been forecasted that the cost-containment efforts of reimbursement agencies, skyrocketing drug development costs, and an increasingly competitive marketplace will seriously impede the industry's ability to produce blockbusters in the next ten years.

At the same time, large pharmaceutical companies are faced with an increasingly competitive market place. Competitors are always quicker to put "me-too" (or almost identical) drugs into the market and exclusivity for the length of the patent is increasingly rare.

Generics companies are growing faster and developing their portfolios considerably in a general context of favourability towards generics. In an attempt to combat this, companies tend to increase their spending on sales and marketing, further reducing their profitability.

8.3 Facing new external pressures

The pharmaceutical industry’s external business environment has been changing rapidly. Regulatory approval processes and requirements are being tightened and, in recent years, national health authorities have reviewed their pricing and reimbursement policies. Budgetary constraints of national governments have also led to the growth of the generics market, even in countries where penetration levels were previously very low (the most relevant example being France). In addition, the marketing environment is moving toward a new focus, with patients taking an increasing interest in, as well as greater responsibility for, the choice of treatment available to them. Public demands for companies to act as “Good Corporate Citizens” and to live up to their promises on corporate social responsibility are also increasing.
Business success in the pharmaceutical industry is increasingly being driven by external factors, in particular speed and conditions of regulatory approval of new products, as well as pricing and reimbursement decisions. Given the dual pressures of short follow-up time on innovative products by competitors and limited patent life span, the importance of these factors is heightened.

In recent years, the current product approval systems in Europe and the US have been tightened. Despite efforts to speed up the process in many countries, the approval process is lengthy and there is greater scrutiny of the data and underlying studies used.

On the consumer side, pharmaceutical companies must also respond to new challenges posed by more knowledgeable patients. An increasing number are becoming more educated about diseases and are starting to seek knowledge via other sources (especially the Internet) in addition to their doctors. At the same time, patients’ price awareness of medicines and consciousness of generic medicines as alternatives to branded drugs are increasing.
This obliges pharmaceutical companies to review their marketing strategies and to consider patients as a true target separate from doctors. Considering these different elements together, it is clear that the pharmaceutical industry's external environment is becoming increasingly complex, with a greater number of interlinked stakeholders than ever before.

Developments in policy are also contributing to this, creating a more challenging environment that is harder to control.

These changes in the external environment create new challenges for the industry. Traditionally, many pharmaceutical companies have focused their resources in relation to the promotion of a favourable regulatory environment at the national level, because product approvals have been handled via the mutual recognition procedure, and pricing and reimbursement issues are the competence of national healthcare systems. This system is gradually being replaced by a multi-layer system, whereby different political institutions,
scientific and regulatory bodies and social actors work together and interact in parallel at different levels. As a result, pharmaceutical companies have to operate in a more system-based, web-like environment.

8.4 The Rationale for a new integrated communication and lobbying approach

The critical success factor for the pharma industry will be to regain focus in order to optimise resources. This applies across the board, from R&D, product development, lobbying to marketing and corporate communication. Companies have to redefine the ‘life line’ of their business existence. Therefore, we firmly believe that the successful pharma company of the future will be built around the concept of therapeutical areas. The number of therapeutical areas in which a company has expertise, may vary, from a niche player with a very narrow specialisation to a big player, who tackles several areas with the same excellence. All company functions will gravitate around the therapeutical area(s) of choice - be it in structural or informal terms. Our assumption is that this will result in more focused and efficient product pipelines, optimise product development and trials and overall lead to better output for the marketing process.

In this context communication shifts from a supporting to a core ability as the quality of communication will directly contribute to business success. Scientific research and development remains at the core of excellent business performance but developing a successful stakeholder communication and lobbying model may help significantly to convert this into real business results.

Communication will define how successfully different company functions can be aligned and to what extent their external activities can be leveraged for the overall product strategy. It is therefore believed it is time for pharmaceutical companies to review their communications model and adopt a more integrated communication and lobbying approach. This should be directed at building relationships and reputation with a variety of stakeholders of the
company (both internally and externally) in a comprehensive way and would therefore allow pharmaceutical companies to outperform the competition on a number of product related aspects (approval / pricing / reimbursement / marketing), leading to better business results.

The basic assumptions around which such an integrated communication model is to be built are that:

Improved internal communication between development, regulatory and marketing functions will help optimise the strategy for product development, approval and launch. Further, relationship and corporate reputation building – both in broad corporate, political as well as therapeutical sense – better understanding of regulatory and stakeholder concerns can be obtained, as well as goodwill generated. This initiative can be leveraged for product approval, launch as well as marketing.

8.5 Making the business case for a new integrated communication approach
Pursuing an integrated communication approach will improve company performance on a range of product related aspects (approval / pricing / reimbursement / marketing), leading to better business results. The advantages to be generated relate to the various aspects, which are of key
importance to pharmaceutical companies. In this context, past cases of product lobbying have been reviewed to identify where best/worst practice resulted in a tangible impact on company business performance.

- **Getting better conditions for product approval** (via less critical lead time, preferable labelling and indications comprehensive thanks to more tailored files for submissions).

Not only that better coordination between R&D, product development and regulatory affairs will result in a better file for approval submission but longterm relationship building with decision-makers (regulatory authorities, evaluators) and indirect (patient groups, learned societies, healthcare NGOs) influencers in the approval process will speed up discussions and create goodwill. To this mix add corporate and therapeutical reputation building which will create additional goodwill and trust, resulting in authorisation of more favourable labelling.

- **Better price and reimbursement conditions**

Long-term relationship building with public health authorities will improve intelligence about requirements and criteria for pricing and reimbursement decisions, enabling companies to tailor submissions to local circumstances, while maintaining a Pan-European pricing strategy. Therapeutical and corporate reputation building with third parties involved in the area, like insurers, hospitals, patient groups will build up additional goodwill/pressure that can be leveraged to achieve better price and reimbursement conditions.

- **Improving the company’s corporate reputation and brand awareness in certain therapeutical areas** (via more substantive media coverage, relationships building etc.) leading to higher patient demand, higher doctor faithfulness and finally quicker market penetration and take-up.
Increased good-will in case of adverse effects and in crisis situation, long-term relationship building with a broad range of stakeholders (scientists, regulatory authorities, patient groups etc.), supported by corporate and therapeutical reputation building, will lead, over time, to increased goodwill. In cases of crisis or adverse effects, well-established relationships will help companies to rapidly respond to concerns and channel information to the right people. Goodwill will contribute to damage limitation, facilitate dialogue with regulators and help regaining trust with the different audiences in the aftermath of the crisis.

8.6 The ideal type model of integrated communication and lobbying
What would be an ideal type communication and lobbying model look like? Most certainly it must be company-specific as it has to reflect internal company structures, corporate and business culture as well as the specific business priorities. Nevertheless, any ideal type model must integrate the relevant company functions as well as co-ordinate and leverage communication with stakeholders at and between different levels.

The ideal type of integrated communication and lobbying approach would incorporate a clear strategic direction by corporate headquarters, commitment
and involvement of top executives and integration of different communication / lobbying dimensions (e.g. policy, corporate communication, and pricing/reimbursement) and the elements that work across these (e.g. relationship building and therapeutic reputation building) into one overarching concept. In addition, marketing and R&D functions need to be aligned with relationship and reputation building activities, so all can be leveraged as necessary.

It is essential to look into the overarching structure and principles of communication / lobbying, followed by a description of activities to be undertaken by the different functions. The marketing and R&D/product development issues will be touched upon, where relevant.

• **Structures and processes**

A best practice company implementing an integrated lobbying approach would be structured in such a way that senior levels of the company provide overall guidance and direction. The organisational model should integrate the different lobbying aspects into a more co-ordinated and coherent approach with the aim of improving business performance. A company would fully integrate lobbying around its regulatory, policy and corporate departments. Additionally, clear communication lines between lobbying and marketing
would be established to ensure synergies between the two, particularly in the pre-launch phase. A best practice company would also take therapeutical reputation into account in terms of structure, both in broad terms and regarding specific business units.

**Progress of pharmaceutical industry in India during 35 years from 1965 to 2000**

1) Compared to 1965-66, capital investment has increased by 17.8 times; from Rs. 1400 crores to Rs.25000 crores in the year 2000 A.D. Especially after Uruguay Round in late 1980s and during the economic reforms era, the progress has become tremendously faster. India's membership of WTO and advantage of manufacturing world class medicines by adopting independent processes up to 2005, specially helped to boost up the production and exports to both developed and developing countries. Indian drug prices remained competitive because of the comparative cost advantage of cheaper scientific and skilled labour, moreover, Indian companies also maintained the quality of their products.

2) By 1965, the number of formulation of drugs produced in India was 1500 only which increased to a very high figure of 1 lakh, 59 thousand six hundred (159600). This growth accounts for 106 times during the period of 35 years. On an average, about 3500 new formulations were added within a year from 1965 to 2000. It should be noted that due to adoption of globalization, reforms and WTO regime, pharma industry in India has made miraculous progress during the period of post-reforms compared to that of pre – 1990s.

3) Industrially advanced countries have established their monopoly in production of 'bulk drugs' which require excellent facilities of R & D. Indian pharma industry used to produce only 180 bulk drugs in one year 1965-66. It is a marvelous achievement for them that by the end of the year 2000, they produced world-class 37,770 bulk drugs having great demand in developed countries. The cost of bulk drugs per unit in
India is far less than that of advanced countries; thus India could capture overseas markets especially in U.S., Japan and Europe. Just like the Software and IT industry, the Pharma Industry in India has emerged as another 'Knowledge Powered Industry'. Indian pharma industries are very prompt in adopting recent biotechnology techniques in the production of drugs. The use of chemistry has been overshadowed by the use of biotechnology in world's pharmaceutical business. Along with gems and jewellery, textiles, IT and software, automobiles, fisheries and basmati rice, India's pharmaceutical industry has emerged as a big dollar – earner.

4) In 1965, India used to import drugs worth Rs. 8.5 crores only; in the year 2000, its imports have gone up to Rs. 3441 crores, which is more than 430 times! Since India's standard of living and national per capita income have improved over the last 40 years. Indian doctors and hospitals are using world class life-saving drugs. No wonder, that during the last three to four decades, the death rate in India has declined to 8 from 16 and average life expectancy has risen to 62 years from about 45 years. A bulk share of the imported drugs and compounds are used for new processes and medicines, which again are re-exported and rake in foreign exchange.

5) As far as export earnings of pharma industry are concerned, India's success in this field has become a reason for envy to other upcoming countries like China, Brazil, Mexico etc. India used to earn a partly sum of Rs.3 crores by its exports of pharma products. In the years 2000, the export earnings of pharma products have gone up to a whopping Rs. 6631 crores, which is around 2210 times! It should also be noted that in the year 2000, India earned Rs 6631 crores from exports. While expanding only Rs. 3441 crores on imports. In the year 1965, India had a trade balance deficit but in the one year 2000, India has in garnering a trade balance surplus of Rs. 3190 crores. The Indian pharma industry, therefore, contributes net surplus in its trade earning.
6) Lastly, the Indian pharma industry could afford very little amount of Rs.3 crores only on R & D activities. In the year 2000, companies like Ranbaxy, Cipla, Dr Reddy's Laboratory etc. have spent Rs. 320 crores on R & D. This rise is about 107 times than the previous amount. To sum up, the Indian pharma industry has progressed amazingly, during the post-reform era and is now one of the most admirable success stories in pharma business.

Modern drugs in India faced competition from other traditional medical treatments such as Ayurveda, homeopathy, Unani, and Acupuncture. The central government remained a key influence and a controlling factor in the direction of India’s pharmaceutical industry. The inward-looking policies adopted by India’s politicians since independence had slowed foreign direct investment into India’s industry, and pharmaceuticals were no exception. The Drug Price Control Order (DPCO) was established in 1985, enabling the government to dictate drug prices for 143 basic drugs, with the purpose of ensuring the availability of medicines at low prices. Currently, 76 drugs fall under the DPCO.

India’s lack of product patent laws further hindered foreign direct investment and deterred the MNCs from investing in India. The Indian Patents Act (IPA) of 1970 only recognized process patents resulting in a highly competitive market with extremely low drug prices. Drug prices in India were normally ten times less than that of U.S. prices.