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# Papers

## New pharmaceutical product development: Barriers to overcome and opportunities to exploit

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### Abstract

The pharmaceutical industry experienced an unprecedented rate of increase in the cost of developing new drugs while the number of new drugs that were approved and accepted in the marketplace has reached a very low level. Various factors are responsible for this state of affairs. One of the major opportunities available to the pharmaceutical industry to improve this situation is to collaborate with the biotechnology industry. The future solutions to a host of current diseases as well new strains of existing ones lie in the cooperation between these two industries. The pharmaceutical industry will, however, have to carefully manage challenges such as increased governmental control and the damaged image of the industry. There are many opportunities offered by offshoring, advanced application of information technology, climate change and a new approach to sales and marketing, all of which the pharmaceutical industry can exploit. Should the pharmaceutical industry manage to address the issues responsible for the high costs prevalent in the industry, its role as partner with the biotechnology industry could prove to be very beneficial for both these industries.

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### INTRODUCTION

The past two decades have experienced dramatic changes in the processes utilised by

the pharmaceutical industry to discover and develop new drugs. Biotechnology, especially biologic entities and biological processes, has produced important inputs to develop pharmaceutical products since 1982 when the Federal Drug Administration (FDA) approved the first recombinant biotechnology drug, insulin, for human use. Over time many pharmaceutical products could not have been realised without the availability of

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biotechnologies.<sup>1</sup> In 2004, it was estimated that biotechnology and genomics companies performed about one-fifth of all pharmaceutical research and development (R&D).<sup>2</sup> The dynamics of the pharmaceutical and biotechnology industries, primarily driven by technological changes, have led to knowledge and value creation being moved to a network of firms.<sup>3</sup> In the past, knowledge and value creation took place in the individual firm. The eventual 'partnership' between biotechnology and the pharmaceutical industry has been obvious from the first developments in biotechnology and is now regarded as one of the top eight health industry issues for 2008.<sup>4</sup> Over the past decade, various events have not only complicated the development of new drugs in the pharmaceutical industry, the cost of developing a new product has also escalated at an alarming rate. This hampers to a large extent the potential number of good drugs that the combination of biotechnology and the pharmaceutical industry can produce.

## BACKGROUND

The value, significance and role of the development of new products vary from one industry to another. For some firms their whole future depends on producing new products while others could carry on as much as they have done in the past without developing anything new.

For most firms new products are essential for the progress of the firm. Intensified global and local competition, better-informed and educated consumers, governmental regulations and controls, adverse economic conditions, fast changing technology and the ever decreasing life span of products are typical motives justifying the development of new products. The pharmaceutical industry was subjected to extreme financial constraints in the late 1990s and this led to a large number of mergers and acquisitions with the major aim to improve profitability. Although it was mainly the big firms such as Hoechst, Zeneca and Glaxo Wellcome that made headlines in

the press, a total number of 334 mergers and acquisitions were completed in 2001 and this was only seven less than the number completed in 2000.<sup>5</sup> This consolidation trend was fuelled by a number of factors such as achieving economics of scale, getting access to and operating in important geographic and therapeutic markets, reducing surplus capacity and concentrating market share.<sup>6</sup> In 2000 the top 20 companies, in terms of revenues, were responsible for 64.6 per cent of global sales.<sup>5</sup>

Recent pressures to turn out new products in reduced time periods have led to advances in new processes of new product development that are less streamlined and rigid in comparison with conventional new product development processes. The pharmaceutical industry has particular unique characteristics that dictate the development of new products. It is highly regulated by governments, spends much more than the average of all industries on research and development and new product development is largely determined by the discovery of new clinical entities. The focus of product assessment has also undergone a significant shift towards consumer acceptance. On the one hand, this is the result of better-informed consumers who accept responsibility for decisions concerning their health and medical care. On the other hand, pharmaceutical companies now understand the genetic composition of patients and this enables these companies to segment patients on the basis of pharmacogenomic descriptions.

## PURPOSE OF THE PAPER

The purpose of this paper is to provide an overview of the pressures experienced by the pharmaceutical industry in producing new drugs. These pressures at times almost debilitated the industry and entreated it to partner with and benefit from biotechnological expertise. There are, however, a number of promising developments taking place from which the pharmaceutical industry can benefit and regain its earlier respectability and profitability. The

latter developments are also attended to. For the sake of clarity, the pharmaceutical industry's ability to produce new drugs is discussed with the aid of a conventional SWOT analysis.

## THE NEW PRODUCT DEVELOPMENT PROCESS

To highlight the complexities and their accompanying cost implications of new product development in the pharmaceutical industry, I will briefly compare the new product development process in the pharmaceutical industry with that found in most other industries. Table 1 and Figure 1 illustrate the typical aforementioned processes. Over time the new product development process in nonpharmaceutical industries has also experimented with ways that do not conform to the sequential process illustrated in Figure 1. One such approach followed by the Japanese (which they termed rugby) involved the simultaneous operationalisation of various new product development activities with the purpose to speed up the new product development process and make it more flexible.<sup>7</sup> Apart from a focus on customer needs and wants, the other component that these two processes share is that the closer the product/drug is to finalisation, the more expensive the processes become. This is particularly true for the pharmaceutical



**Figure 1:** The conventional new product development process<sup>10</sup>

industry as a host of regulations that govern the expensive clinical trials in respect of safety and efficacy (and nowadays cost-effectiveness as well) of a drug they have to be adhered to. Clinical trials are responsible for the major proportion of the development cost of a drug. Some new products developed in other industries, for instance, do not have to undergo test marketing if the product concept and business analysis indicated the product to be financially viable and accepted by customers. A recent survey also found that a firm's spending on R&D does not necessarily translate into corporate success; in fact, no significant relationship was found between a firm's R&D spend and corporate success.<sup>8</sup>

**Table 1:** Typical new product development process in the pharmaceutical industry<sup>9</sup>

Pre-clinical studies	Step 1: Screening for new clinical entities
Pre-clinical studies	Step 2: Discovering of new chemical entities
Pre-clinical studies	Step 3: Animal pharmacology: Toxicity and reproductivity
Pre-clinical studies	Step 4: Toxicity studies: Embryo-foetal and peri-natal: Muta-genicity and carcinogenicity
Pre-clinical studies	Step 5: Chemical, pharmaceutical and biological testing
Clinical studies	Step 6: Phase I: Bio-availability: Healthy volunteers
Clinical studies	Step 7: Phase II: Dose ranging – patents
Clinical studies	Step 8: Phase III: Safety and efficacy
Clinical studies	Step 9: LAUNCH

## THE MACRO ENVIRONMENT

An overview of the macro forces that can have an impact on the pharmaceutical industry brings a number of challenging issues to the forefront. An aging population demands new medical needs that have to be met while the diseases encountered in developing countries more and more resemble those of the developed world.<sup>11</sup>

Two major trends affect new product development in the pharmaceutical industry worldwide. On the one hand there are a few good medicines that are in an advanced stage of development. On the other hand, the demand for medicines for a range of 'new'

diseases are increasing all the time – when the effects of global warming on diseases is taken into consideration, one realises the enormous challenges the pharmaceutical industry is confronted with.

## WEAKNESSES WITH REGARD TO THE DEVELOPMENT OF NEW DRUGS

The pharmaceutical industry’s record of the past two decades is one of hardship and mounting challenges.

### Development costs of new medicines

Over the past 20 years the development costs of new drugs have increased at an unprecedented rate, while the number of new drugs that were approved and accepted in the marketplace has reached a very low level.<sup>12,13</sup> The seriousness of this situation has attracted attention of the FDA who published a ‘Critical Path’ document in which the problems encountered in drug development are spelled out.<sup>14</sup> The aforementioned document also appealed for novel approaches to enhance current drug development procedures. In 2002 the FDA approvals of new chemical entities (NCEs) were the lowest for the 1996–2006 decade; only 17 NCEs were approved.<sup>13</sup> In the year 2006, the amount spent in North

America on R&D of pharmaceutical products reached an all time high of \$55.2bn.<sup>11</sup> In the same year the FDA only approved 22 new molecular entities and biologics. The significance of these figures only comes into perspective when it is compared with that of 1996 when the FDA approved 53 new entities and the amount spent on R&D for 1996 was less than half of the money spent in 2006. Figure 2 illustrates these figures.

DiMasi *et al.*<sup>12</sup> analysed 68 randomly selected new drugs from ten pharmaceutical firms and found that the total pre-approval cost estimate for a drug was US\$802m (in 2000 US\$). The amount of US\$802m is the total of pre-clinical and clinical period cost estimates. The out-of-pocket cost per approved new drug is US\$403m and the capitalised total cost is US\$802m. These amounts indicate that the cost of time represents almost 50 per cent of the total cost. The aforementioned figures, as well as those from two earlier comparative studies are illustrated in Figure 3. Figure 3 illustrates that the total capitalised cost per drug in 2000 was, respectively, 2.3 and 2.5 times higher than those in the two previous studies.

The pharmaceutical industry is very aware of the numerous expectations that have to be met. A recent study by Skrepnek and Sarnowski<sup>17</sup> found that regulatory and capital requirements, in addition to investor

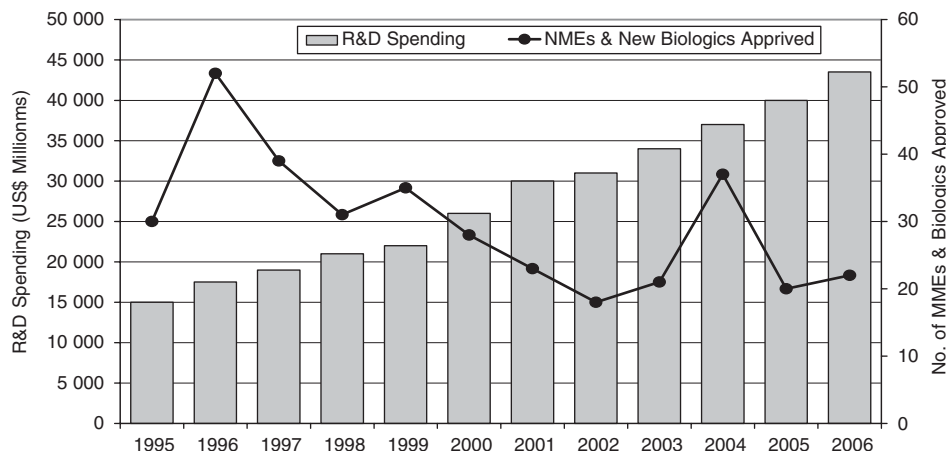
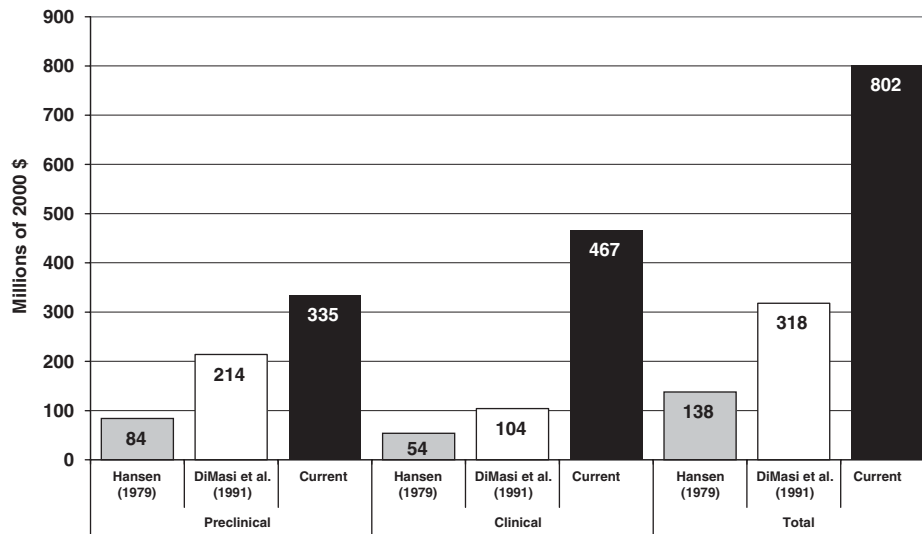


Figure 2: R&D spending and FDA approvals: 1995–2006<sup>11</sup>



**Figure 3:** Trends in capitalized pre-clinical, clinical and total cost per approved new drug<sup>12,15,16</sup>

expectations, were diligently adhered to during the clinical phase trials. To ensure that new drug development meets all the diverse expectations, a range of decision-making techniques such as prior experience/intuition/human judgment, net present value, internal rate of return and pharmaeconomic methods (defined as ‘the description and analysis of the costs of drug therapy to healthcare systems and society’) are utilised at every stage of R&D.<sup>17</sup>

### The pharmaceutical industry’s inability to capitalise on opportunities

Towards the end of the previous century, a number of exciting prospects were on the horizon for the pharmaceutical industry. At that point in time there was an acceleration in the progress in genetic understanding that was seen as a means to empower firms to segment patients on the basis of pharmacogenomic descriptions and to tailor patients’ therapies to their specific needs. The use of such knowledge of an individual’s genetic composition to tailor drugs and significantly enhance the safety and efficacy of drugs within sub-populations showed great promise.<sup>9</sup> Unfortunately, as more and more

knowledge of the human genome has become available, it also became increasingly clear that the human genome was much more complex than any initial indications.

Despite a host of opportunities available to the pharmaceutical industry, the industry will not be able to benefit from these opportunities unless it changes the way it operates.<sup>11</sup> The major obstacle inherent to the pharmaceutical industry appears to be a lack of innovation that makes it ineffective at producing new therapies for the wide range of medical needs that exist all over the world. An often cited statement in a 2000 study states that it took 17 years on average to translate original research to benefits in patient care.<sup>18</sup> Knowledgeable observers identified the following three aspects to be the challenges that require addressing in order to enhance innovation:<sup>19</sup>

- The slow pace of adoption of the best innovations.
- Lack of evidence-based research regarding which innovations are the best.
- Failure to achieve transforming systemic innovations necessary for a sustainable healthcare system.

## THREATS TO THE PHARMACEUTICAL INDUSTRY

A number of threats can complicate the pharmaceutical industry's ability to produce and market new drugs.

### Reluctance of firms to invest in the development of new medicines

The implications of high R&D spend and limited approvals have also impacted on the financial performance of the pharmaceutical industry. The incomes earned have come at a high price. R&D rose from 15 to 17.1 per cent of corporate spending between 1995 and 2005 while the cost of sales and general administration increased from 28.7 to 33.1 per cent.<sup>20</sup> Sales and marketing constituted the biggest component of corporate expenses.

A major concern of this imbalance between R&D spend and approvals is where the attrition takes place in the development pipeline. As indicated earlier, DiMasi *et al.*<sup>12</sup> estimated that the cost of discovering and developing a single new drug was \$804m in 2001. Most of the R&D costs are incurred at a late stage in the development pipeline with the biggest majority of attrition occurring in full clinical development (Phases 11b and 111). Kola and Landis<sup>13</sup> report that the attrition rates vary among phases of development and therapeutic areas. At the registration phase, the average failure rate of compounds is 23 per cent; for women's health the failure rate is as high as 42 per cent while for oncology it is 30 per cent. In Phases 11 and 111 the failure rates of oncology are as high as 70 and 59 per cent, respectively. The implications of these high failure rates of compounds are that the capital market will continue to avoid investments in pharmaceutical companies. Another source of risk in this respect is that the distribution of returns to new drug introductions is highly variable.<sup>21</sup>

### Curbing of promotional activities by pharmaceutical firms

In a survey among executives from the pharmaceutical industry, consumers and various other stakeholders, the pharmaceutical industry emerged with a damaged reputation.<sup>22</sup> More than 94 per cent of the stakeholders surveyed were of the opinion that pharmaceutical companies spend too much on advertising and that industry advertising lacks transparency with respect to drug risks and benefits. Other concerns were that the industry spends too much on sales and marketing and such marketing has a negative influence on physicians' and pharmacists' prescribing habits. Respondents were also of the opinion that marketing should rather focus more on patient treatment and outcomes and less on sales.

Various states in America have taken it upon themselves to regulate the marketing practices of pharmaceutical firms to physicians. These so-called 'gift laws' have been passed in six states while proposals for the introduction of similar legislation are under consideration in 15 other states. These bills require pharmaceutical firms 'to disclose how much they give doctors, hospitals and pharmacists each year ...'<sup>11</sup> The Association of the British Pharmaceutical Industry (2005) has introduced a new code of practice for the pharmaceutical industry which came into force on 1st January, 2006.<sup>23</sup> This code of practice introduced tighter rules on the promotion of medicines. Clause 1.2 of the code defines a long list of activities regarded as 'promotion' while clause 4 sets out all the obligatory information to be provided on promotion material. In 2003, Spain also introduced restrictions on the number of visits that a sales representative can make for promotional purposes.<sup>11</sup>

### The introduction of cost controls on a global scale

Most of the increases in control examples dealt with so far are from the United States.

This situation is, however, not very different in other parts of the world. For instance, both the European Union and Japan have introduced measures to reduce drug prices. The European Union has introduced reference-pricing that will lead to lower the prices. Some governments are prepared to pay for effective new drugs but in exchange demand lower prices for drugs already on the market.<sup>2</sup> The United Kingdom, Japan and Canada now also utilise new criteria for prescriptions. Apart from safety and efficacy evaluations, products and therapies are also now evaluated in respect of their cost-effectiveness. Measures to curb healthcare costs are in place in most countries and these measures are also becoming more and more sophisticated.

It is foreseen that the burden of proof of a drug's safety and efficacy will be subject to greater transparency; even clinical studies that have failed will have to be reported.<sup>11</sup> Monitoring of treatments throughout a drug's lifetime, increased complexity in the analysis of a drug's qualities as well as an assessment of a drug's cost-effectiveness are expected in the future. Figure 4 is a summary of the anticipated new control bodies and processes that future new drug development will be subject to.

### **Limited lifespan of patents**

The limited protection (in terms of number of years) that a medicine patent has makes firms reluctant to invest because the time during which an investment can be recovered is too short. The laws that regulate intellectual property rights should also carry part of the blame for the relative low investments made by pharmaceutical firms to develop new medicines. Patents last 20 years and if the extent of the upfront investment and short period in which to recover such an investment is considered, one can understand the reluctance of firms to invest in the development of new medicines.

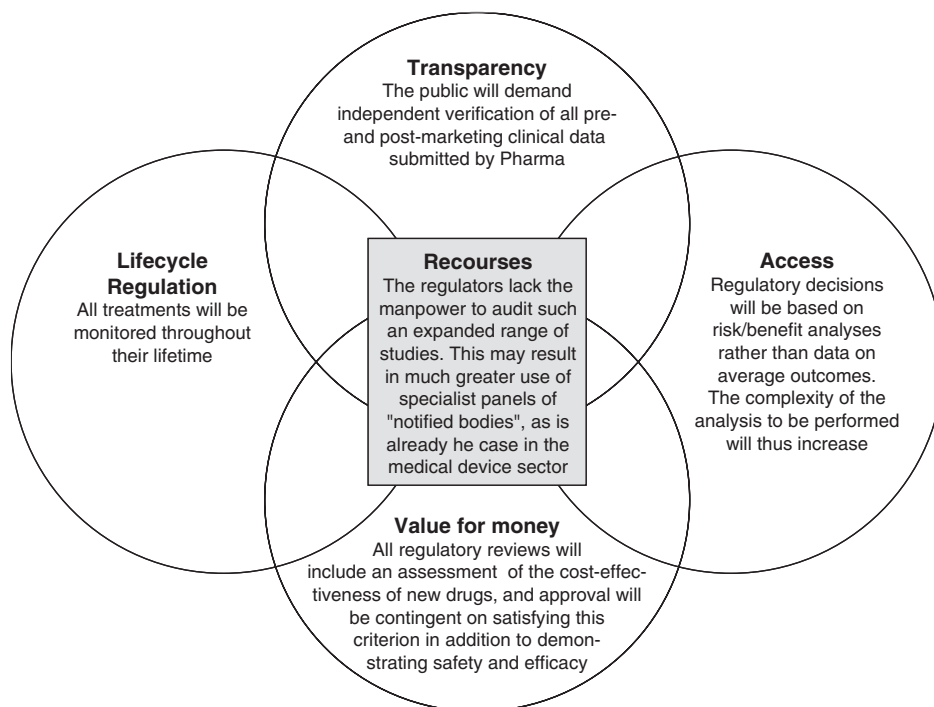
## **OPPORTUNITIES ON THE HORIZON TO IMPROVE THE WOES OF THE PHARMACEUTICAL INDUSTRY**

If the pharmaceutical industry is to benefit from the numerous scientific and technological advances and the increasing opportunities in the marketplace, it will have to refocus and move away from its current dependence on 'one-size-fits-all' drugs. The emphasis should rather be on the development of treatments for specific disease states, that is, a disease-centred approach.<sup>2</sup> The following paragraphs attend to some suggestions as well developments on the horizon that might improve the prospects for the pharmaceutical industry. Some of the expected devastating effects of global warming, for instance, offer both challenges and unprecedented opportunities for the pharmaceutical industry.

### **Global warming**

The current debate on global warming and its implications for health conditions has produced many perspectives and expectations. Although it is highly unlikely to predict with certainty what the eventual full impact of global warming will be, it is possible to make some predictions of particular conditions and their likely impact on the health of human beings. For the purpose of illustrating some possible harmful effects of global warming, malaria, a disease particularly sensitive to changes in the climate, is dealt with here. A few other infections and respiratory diseases that are also susceptible to changes in the climate are referred to.

Of all the vector-borne diseases, malaria is globally the most devastating. It is number one in terms of morbidity, death and productivity losses. Approximately 40 per cent of the world's population is at risk of becoming infected with malaria. About 75 per cent of malaria cases are in Africa. The other areas where malaria is found are southeast Asia, the western Pacific and the Americas.<sup>24</sup> In 2003 the World Health Organization



**Figure 4:** New control bodies and processes for the future<sup>11</sup>

reported that up to 75 per cent of malaria cases occur in children, and over 3,000 children die from malaria each day.<sup>25</sup>

The extent of malaria transmission is generally restricted by climate conditions, while floods (and sometimes droughts) are ideal conditions for epidemic outbreaks. Favourable warm conditions enhance biting and reproductive rates, extend breeding seasons and reduce the maturation of microbes within mosquitoes. Malaria transmission takes place when a mosquito takes a blood ‘cocktail’ from a person suffering from malaria, incubates the parasite and then infects a person by injecting the parasite when it bites that person. In warmer temperatures the rate of maturation of the malarial parasites inside the mosquitoes is quicker.<sup>26</sup> McArthur<sup>27</sup> found that at 20 °C (68 °F) the incubation time of the *Plasmodium falciparum* malarial protozoa is 26 days. At 25 °C (77 °F) the incubation time is halved. Anopheline mosquitoes transmit malaria and they only survive for a few weeks: warmer temperatures

thus make it possible for parasites to fully grow fast enough to be transferred.

Population relocations, deforestation, drug and pesticide resistance, and the deterioration of the public health infrastructure in many countries are changes that take place all over the world. The severity of these changes is amplified by changes in the climate which in turn promote the spread of malaria.<sup>28,29</sup> It is highly likely that warming and weather extremes are going to increase their role in spreading malaria.<sup>30</sup>

The West Nile Virus (WNV) and Lyme disease are two further diseases that are particularly susceptible to changes in the climate. It is suspected that an increase in asthma rates among developing and developed countries is due to the combined effect of air pollution and allergen exposure. In a comprehensive study of the effect of climate changes by the Harvard Medical School it was found that ‘changes in atmospheric chemistry and climate that tend to increase the presence of pollen and fungi in the air therefore



contribute to a heightened risk of allergic symptoms and asthma'.<sup>26</sup>

### **Longer patent protection times**

The limited protection (in terms of number of years) that a pharmaceutical patent enjoys needs to be reconsidered. If firms are granted longer periods of patent protection, the *quid pro quo* could be reduced (and hence more affordable) prices. Apart from the extension of patent protection duration, there are also various other possibilities that governments can pursue to assist pharmaceutical firms in drug development. Vanderbyl and Kobelak<sup>31</sup> mention support of venture capital, allowances to carry forward tax losses and capital gain exemptions, R&D tax credits and drug reimbursement policies as all being possibilities to assist pharmaceutical companies in their drug development endeavours.

### **More communication needed**

As far as the damaged reputation of the pharmaceutical industry is concerned, it is important that the focus of marketing practices and promotional activities be on improvement of treatment of diseases. In this regard it is essential that the pharmaceutical industry team up with stakeholders in healthcare professional associations (such as medical and physician groups) to pursue mutually beneficial activities that improve patient outcomes. Various other stakeholders in the healthcare industry such as medical aid schemes and state pharmaceutical enforcement agencies are also potential partners for teaming up with the purpose of engaging in the promotion of preventive treatment plans. Various consumer misconceptions about chemical and biological innovation and the costs and risks of bio-pharmaceutical product development also need to be addressed by means of communication via continuous press releases. Other stakeholders could be involved in the drafting of such communications to add weight and objectivity to press releases. It is important that these communications are done

on a continuous basis and in media accessible to target markets.

Another very important avenue for pharmaceutical firms to regain credibility is to communicate the broader, that is, socio-economic, benefits of modern drugs. The potential advantages of such communication are twofold: in the first instance it is likely that stakeholders' (especially the general public) opinions of the pharmaceutical companies would be more positive if they understood better the impact of drugs. In the second instance, a more sympathetic attitude among stakeholders might be prevalent when drug prices are announced or adjusted.

### **A new approach to marketing and sales**

The present sales and marketing model was developed to put one-size-fits-all drugs within reach of target markets. This model is, however, not adequate for the marketing and selling of high-density drugs and targeted treatment solutions. Maximum success in the primary care market is the focus of the current marketing approach whereas a specialist approach is required for targeted treatment solutions that cover both primary and secondary care markets. At present marketing efforts strive to differentiate drugs; under targeted treatment solutions the disease will serve as the major differentiating factor. Other areas of marketing that will undergo change are pricing and demand generation. Particularly, it is in pricing where a shift from a relatively low price per dose to premium or 'super' premium prices for targeted treatment solutions is anticipated that will pose a major challenge for pharmaceutical firms. Only time will tell whether the expected superior clinical results of targeted treatment solutions will weigh up against the abilities of healthcare payers to pay for improved treatments. A final comment as far as a new marketing approach is concerned: the current practice of pharmaceutical firms is to maximise

prescriptions whereas the future focus should be on the retention of existing patients and acquisition of new patients.

### **Possibilities offered offshore**

One of the promising possibilities for the pharmaceutical industry to simultaneously harness cost savings and increase the speed at which new compounds are developed is to go offshore. Some of the major pharmaceutical firms, namely Novartis, Merck and Pfizer for instance, have already conducted clinical trials in India and China.<sup>32</sup> A major concern for firms that consider moving some of their business overseas is the poor protection of and the lack of respect for intellectual property in some developing countries that offer labour and other cost savings. Two areas in the operations of a pharmaceutical firm are suitable to benefit from the unique possibilities offered by offshoring. These two areas are clinical trials and improvement in the effectiveness of the sales force.<sup>32</sup> Clinical trials are responsible for 50–60 per cent of the development cost of a new drug. Going global with clinical trials could save costs and improve productivity. A large percentage of clinical trials miss deadlines because patients are not recruited quickly enough. The broad base of patients in lower-cost countries has attracted the attention of a number of major pharmaceutical firms and these firms are recruiting physicians and patients in India and China and countries in eastern Europe. The creation of data-management hubs in lower-wage regions is another possibility to reduce the cost of clinical trials in offshore locations. Novartis established a data-management hub in India, while Pfizer and Wyeth have launched similar operations.<sup>32</sup> As far as the sales and marketing operations are concerned, low-cost labour makes it possible to increase the gathering and analysis of sales and marketing data. Low-cost labour also offers other advantages such as analysing smaller geographic markets and noncore brands in the ‘evening’ of their lifecycle. Early identification of markets trends and competitor’s activities as

well as correlating marketing inputs with prescription writing are further possibilities of low-cost labour. One can thus conclude that cost-oriented offshoring enables a firm to access higher value processes that go further than costs.<sup>32</sup>

### **A greater role for information technology**

Information technology has already made a valuable contribution to speed up the clinical trial process.<sup>33</sup> The first wave of information technology used electronic data capturing to accelerate the collection and analysis of data. Marhawa *et al.*<sup>34</sup> suggest that the second wave of information technology offers even greater savings if a firm implements an end-to-end perspective where the planning process for a number of clinical trials are integrated using modular and reusable tools in the planning process. Despite the culture of independence among clinical trial designers, it has also become clear that the advantages of standardisation and reuse all the way through the design process offer meaningful benefits. Three factors are responsible for this reconsideration.<sup>34</sup> First, it is accepted that integrated planning utilises all the firm’s resources across trials. Reusable models save time in subsequent designs. Secondly, electronic data collection offers incentives for trial designers to modularise the process and thus reduce the development and integration costs of electronic case reports for every trial. The third factor, following logically from the first two, is that the standardisation of data collection enhances the ability to perform analyses early in a trial.

### **CONCLUSIONS**

The pharmaceutical industry is facing numerous challenges as far as new product development is concerned. Events of the past decade have left the pharmaceutical industry with a dented image. Investors regard the industry as too risky for investment and other stakeholders such as consumers and healthcare

providers see greed in the marketing and sales activities of the industry. Governments now demand cheaper prices of existing drugs in order for them to purchase more expensive new drugs. New controls are continually introduced by countries across the globe. These controls not only consume time, but they also have severe financial implications for the pharmaceutical industry. On the positive side there are a number of profitable opportunities that pharmaceutical companies can exploit. The aging population has new medical needs while the diseases found in developing countries are similar to that of the developed world. Climate change such as an increase in the global temperature will lead to an outburst of a disease such as malaria on a scale that never happened before. Other expected effects of climate are increased occurrence of the WNV and the Lyme diseases as well as a heightened risk of allergic symptoms and asthma.

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