Nanyang Business School

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The Pharmaceutical Industry

B6015: Corporate & Business Strategy

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1 ENVIRONMENTAL FORCES

The development of the modern pharmaceutical industry is inevitably affected by various environmental forces. Those forces affecting the competitive environment around the discovery, development, production, distribution and marketing of prescription and non-prescription drugs can be categorised using the PESTEL framework.

1.1 Political

- Government intervention: The government was the only powerful purchaser in the 1980s and focused upon pharmaceuticals as a politically easy target in their efforts to control rising healthcare expenditure. The government usually interferes in areas such like "black list", "de-list" and managed competition, and this involvement will not stop in future if the government continues to act as the only one powerful buyer. Such behaviour is very distinctive in countries like the UK or Germany where large parts of the population participate in government-managed healthcare insurances.

  The government policy regarding price and reimbursement control and funding system will decide the purchasing power in the end, whether it will still reside with government or it will extend further to patients. If a shift to the patients themselves occurs, the pharmaceutical industry will have to target individual customers in their marketing efforts.
- Government Policy: In order to stipulate the development of the pharmaceutical industry, the government may grant favourable tax rate to support the development of pharmaceutical industry. We can identify such behaviour in Singapore which sees biotechnology as a future core industry in the country and consequently tries to support the creation of a corresponding industry landscape.
- Political Stability: Political parties may use healthcare reform as a weapon to gain votes in elections. The strength change of opposite parties, the suppression of state political power, combined with the lobbying capability and pressure from different benefit groups will influence the industry. Such effects can seriously affect the ability to conduct long-term planning in the pharmaceutical industry.

1.2 Economic factors

- Business cycles: Healthcare spending will partly follow the track of business cycles, booming as economics prospered and dropping during recession. However, we must distinguish between sectors of the pharmaceutical industry. While sectors which deal with

diseases that have to be cured anyway (like cancer, urgent surgeries, etc.) will likely experience only a small drawback in a declining business cycle, sectors which are more elastic like cosmetic (plastic) surgery or artificial teeth are effected to a much higher degree.

- Disposable income: With increasing affluence of consumers, more money will be spent on healthcare. This is especially true for the "nice to have" treatments as compared to the "necessary" treatments. Consumers with higher income typically also take more interest in healthcare and are willing to spend more on maintaining their health, or on lifestyle. This benefits especially sectors that treat with lifestyle diseases like erectile dysfunction ("impotence"), hair loss, artificial teeth, cosmetic surgery.
- Economic development status: The relative healthcare spending of developing countries is much less than that of developed countries due to the different economic development status. This is a different issue from *disposable income*. When we highlight *economic development status*, then we must consider that in many countries like India, China or Latin America, large groups of consumers simply cannot afford any treatment even if that treatment is necessary to survive. These consumers are therefore not yet customers of the pharmaceutical industry. However, we must also see that the emerging markets in China, India, Latin America constantly increase the share of wealthy consumers and consequently provide growing opportunities for companies which are able to address the specific needs of these customers with more targeted products and services**.**
- Ease of Finance: Ease of finance will give rise to more new entrants into pharmaceutical industry because heavy investment is needed for player to enter this market. In that aspect, financial markets that provide venture capital or that allow start-up companies to raise funds easily, will have an advantage.
- Exchange Rate Risks: Countries with a high exchange rate risk, that is, with an unstable exchange rate, are disfavoured in two aspects. First, such a risk discourages R&D or production facilities in the respective country because it renders reliable financial planning for the investing company difficult. Secondly, it tends to retard parallel import of medicines to that country and thus inhibits one channel that may have a decreasing influence on the market prices and benefit the customers.

1.3 Sociocultural factors

- Demographics: The trend of an aging population is well documented in the Western economies whereas the average population in Asian countries is much younger. Drugs aimed at the ageing population have grown in importance in the West, therefore. Since

old people need medical treatment more often than young people, this provides opportunities for the pharmaceutical industry. On the other side, this tendency also introduces pressure for governments to control the growing healthcare expenditures in the affected countries.

Another factor is the distribution of the population in a country and the living standard in urban and rural areas. While in the U.S. and Europe, the living standard and the disease pattern are not different between urban and rural areas, countries like India or China may have vast differences. Large and overcrowded cities may have a different disease pattern from rural areas. In Thailand and Vietnam, for example, urban areas are almost Malaria-free while in rural swampy areas, this disease accounts for a substantial part of infection diseases. The R&D efforts of the pharmaceutical industry normally targets on diseases specific to urban areas, when population is denser and usually more affluent than in rural areas.

- Customer behaviours: Final customers used to have little or no say in the choice of drugs and treatments in the 1980s. But in recent years, more purchasing power has shifted to individual customers because of better education of the patients due to the increasing diffusion of information via internet, TV and print media. Consumers are also more concerned about their health nowadays and try to maintain their health by prophylactic treatments.
- *Lifestyle changes*: Modern medicine allows even patients with chronic diseases like diabetes to spend a fulfilled life with only minor restrictions. But niche areas such as erectile dysfunction (“impotence”), obesity, hair loss, cosmetic surgery, remain at the focus of customers who are spending more and more in these fields to improve the their personal life and image. Viagra, an effective treatment of erectile dysfunction, is one of the best selling medicaments and has provided large benefits for the manufacturer *Pfizer*. In Singapore, fashion magazines advertise numerous treatments and medicaments to lose weight and enhance the body shape. Plastic surgery like breast implants are a growing business in Asia and Latin America (especially Venezuela and Brazil). Especially in Korea and Taiwan, many women opt for changes in the eyelids and nose to look more “western”. Thailand which has an elevated percentage of transgender, has gained reputation for gender transformation.
- Religion & beliefs: Traditional beliefs and religion can have a substantial impact on medicaments. For example, many elder Chinese still prefer Chinese herbal medicine over Western medicine. On the other side, Chinese medicine is increasingly becoming popular

in Western countries, especially in the treatment of chronic diseases where Western medicine has so far not achieved satisfactory results, like in neurodermatitis. Acupuncture is more and more offered in Europe while Western medicine increasingly is applied with younger generations in Asia.

Some religions forbid medicaments that are made of certain ingredients. In Islamic countries, for example, the pharmaceutical industry cannot sell treatment of vaccines that result from pigs. Similarly, medical syrups that contain alcohol cannot be applied there. Other religions forbid the use of medicaments that are made of animal blood (like certain vaccines).

- Education: The health consciousness increases with the level of education as it can be observed in developed countries. Consequently, with increasingly better education in underdeveloped countries, there is a growing amount of health-conscious customers that are suitable customers for the pharmaceutical industry.

1.4 Technological

- Government support on research: R&D is crucial for the pharmaceutical industry, and some governments explicitly support and sponsor pharmaceutical research because they believe that the thriving of this industry is important to the country. Singapore is a good example where the government deliberately sponsors biotechnology because it believes that biotechnology is a major growth area in future and an aggregation of skilled talents in Singapore can benefit the country in various aspects.
- Research Infrastructure: R&D is not only done within companies, but also at universities, scientific institutes, and even hospitals. The existence of a sufficient number of universities and research institutes with a good reputation also serves to grow local talents and to attract foreign talents, and this aggregation of skilled researches may create synergies.
- Technological Advances: Clearly, technological advances are one of the major drives for the development of the pharmaceutical industry. The result of such advances are new products, cheaper manufacturing processes, medicaments with less side effects, medicaments with a larger therapeutic bandwidth. Currently, many industry players hope for advances in genetic engineering. An advance in this area can be in two directions. One aspect is that genetic engineering can be used to produce medicaments that so far can only be manufactured by costly processes. We have witnessed such a development in the production of insulin which initially was extracted from the pancreas of pigs and

which can now be generated genetically which is cheaper and safer. The other aspect is that maybe genetic engineering can help us to identify humans which are susceptible to certain diseases by their genetic structure, like diabetes, cancer, etc. In that aspect, these patients could already be treated with prophylactic medicaments before the actual disease breaks out. Continuing this idea, it may be possible in future that we can generate customized treatments or medicaments for these patients, again by genetic engineering that neutralize these latent diseases. That clearly is the "best case" scenario of genetic engineering whereby customized medicaments can help to avoid latent diseases in certain patients. Of course, this would be a highly profitable market for the pharmaceutical industry because such treatment could command a premium over standard medication.

- Speed of Technology transfer: The speed of technology transfer from universities and research institutes is a crucial advantage in this business, although in many countries, this issue is still not resolved in a satisfactory manner. Too often, universities do not understand the needs of the industry, and industry players do not understand how universities function.
- Information and communication technology: The advance of information technology (IT) has benefited the pharmaceutical industry in several aspects. First of all, R&D, manufacturing and marketing can be connected fast and efficiently, like in any other industry, too. But especially for the R&D intensive pharmaceutical industry, knowledge exchange is very important, and electronic communication of course helps a lot in this aspect. But IT also helps to manage patients' records. In Singapore, for example, all hospitals share the patient record so that doctors can immediately collect data from previous treatments. Finally, IT helps customers to inform themselves better about diseases or treatments. IT can cut down costs for the consumers because the available medicaments can be listed and in the treatment of branded medicaments can be substituted by generic medicaments if available.

1.5 Environmental

- Waste & Pollution Disposal: Pressure from environmental protection organization and more stringent waste disposal law can increase the cost of pharmaceutical industry as a whole. Sometimes, people object to genetic engineering or to genetically modified plantations which may mean that a production site has to be relocated abroad. Even consumers can be directly affected. Some countries like Germany insist that non used

medicaments are disposed of in "special waste" which is apart from household waste, because of the possibly toxic ingredients that medicaments may have.

1.6 Legal

- Regulatory control on development (clinical trials): The regulatory control on clinical trials can greatly influence the time-to-market and development cost of new medicaments. Sometimes, even complete research disciplines like stem-cell research are highly controversial and ethically loaded. Some countries like Germany ban the use of aborted embryos or of remaining inseminated ovum that result from in-vitro insemination, others like China don't.
- Regulation and supervision between countries: Typically, every country has its own procedures for admitting a medicament to the market. However, we also can see harmonization attempts in certain regions like the European Union (EU). Such a harmonization could lead to an accelerated introduction of medicaments in the whole region. Similarly, cross-country or cross-region regulation is thinkable, at least between countries or regions with a similar admission standard.

  Another question is whether parallel imports are allowed. This can develop an industry of mediators who buy and sell medicaments between countries, but in general reduced the profits of the pharmaceutical industry who currently can use price discrimination as a means to take leverage on the different purchase power in different countries.

  Then, finally, regulations on which medicaments can be sold over-the counter (OTC) and which can only be sold with a prescription, have an impact on the pharmaceutical industry. In countries like Germany, the OTC medicaments are further subdivided into medicaments that can be sold in supermarkets (like vitamins) and medicaments that can only be sold in pharmacies (Aspirin). Related to this is how these laws are enacted. While antibiotics can only be sold on prescription in Brazil, in reality anybody can buy antibiotics in most of the pharmacies.
- Trade Policies: Free bilateral or multilateral trade agreements like FTA will increase the foreign trade of medicines. But regulations on parallel imports, will have significant influence on the industry since so far, no country is willing to allow unrestricted access to the market just based on an FTA.
- Patent protection: Companies maybe hesitate to conduct R&D or to introduce new pharmaceuticals into countries where the protection of intellectual property (IP) is not well established or enforced. Estimates in China claim that 30% of the medicaments are

actually fake ones, and that the quality of the fake ones can be everything from "effective" via "not effective" to "poisonous". The introduction of "generic medicaments" after the expiry of the patent protection period is reflected through substantial increases in R&D spending because once a patent expires, the same drug is often produced by many companies and becomes essentially a commodity which is sold at much lower prices and does not yield substantial profits. Consequently, pharmaceutical companies must try to recoup their R&D investment during the time of the patent protection period in order to remain profitable. Similarly, the expiry of IP forces the pharmaceutical industry to constantly come out with new medicaments which can be sold at a premium during the patent protection period.

A very recent and new tendency is the exemption of patents for certain drugs by governments. Countries like Thailand and South Africa demand either an exemption of patents for AIDS treatment or the delivery of medicaments at prices that are affordable to larger parts of the population.

- Regulation on Horizontal/Vertical Integration: Mergers and acquisitions will be very much influenced by regulations. Many countries have legal barriers in the sense that they do not allow pharmaceuticals and healthcare providers to merge or to ally in order to maintain competition.
- Ban on DTC Advertising: Direct-to-the-customer (DTC) sales and marketing are a useful tool for pharmaceutical companies that truly understand the needs of the market. However, DTC is currently banned in major markets, like the EU which locks the door to this kind of sales. Furthermore, certain restrictions apply to advertisements of medicaments in TV and the print media which otherwise could be used to stipulate consumption of medicaments. However, such stipulation can also lead to the unnecessary consumption of medicaments which is an ethically questionable development.

1.7 Other

- New Diseases: The breakout of SARS in 2003 is only one example of the disastrous impact of new diseases. Epidemics like SARS and Ebola bring to mind that the treatment opportunities of viral infections is still very unsatisfactory. Consequently, there are still plenty of opportunities, and the pharmaceutical industry must build up the ability to combat these diseases and to deal quickly with any new upcoming diseases in terms of R&D, manufacturing and distribution. This ability is not easy to be achieved because it may signify a rapid and small-scale roll-out of new medicaments in the case

of local epidemics or the deployment of a large scale roll-out in the case of large epidemics like SARS.

- Catastrophes: Catastrophes like earthquakes, floods, famines are also challenging the pharmaceutical industry. Typically, during times of catastrophes, diseases like typhus, amoebiasis or cholera surge, due to decreasing hygienic conditions. While such catastrophes are terrible from the human viewpoint, they challenge the pharmaceutical industry in the sense that the industry has to ramp um production for medicaments that are only needed in small amounts during normal times.

2 RELEVANCES OF VARIOUS FRAMEWORKS

Organizations today live in an environment with high complexity and high speed of changes. In order to cope and compete in the business field, it's important for managers to analyze the tendencies of the industry, within which they are directly competing, and formulate strategies to cope with uncertainties. The following diagram, Figure I, illustrates different drivers that affect the business environment.

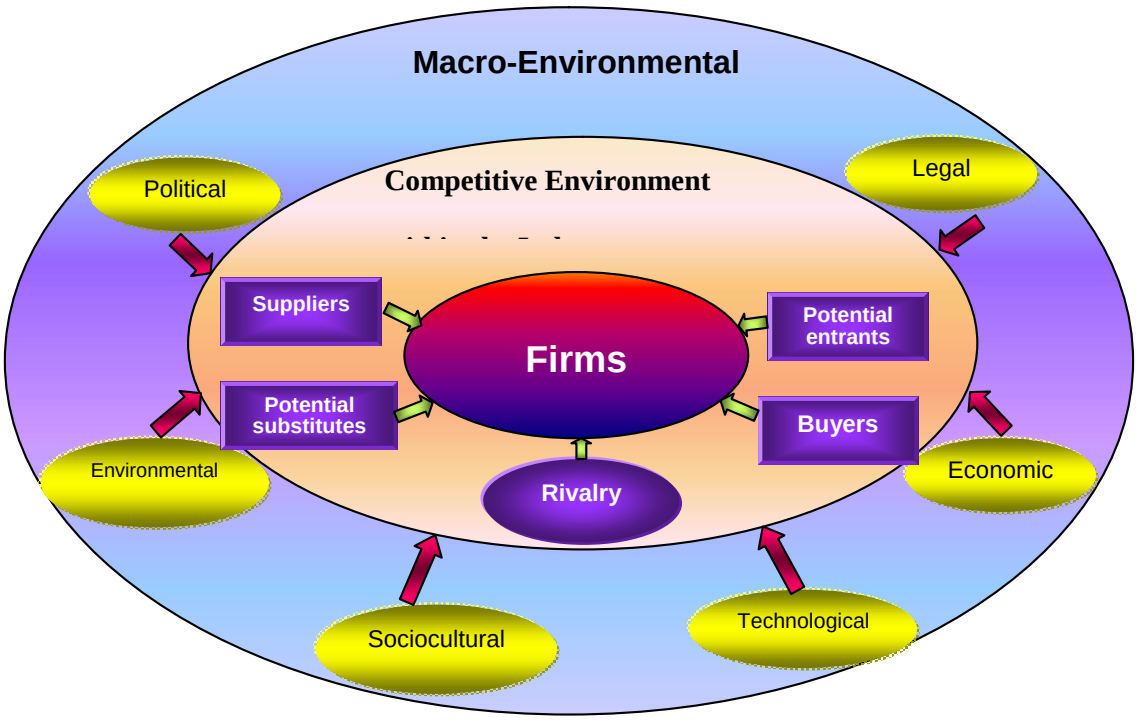

Figure 1: Environmental Factors & Competitive Forces

As discussed in 'Exploring Corporate Strategy' by Gerry Johnson and Kevan Scholes (J&S), there are a few layers surrounding the organization, which constitute the 'environment'. The immediate layer outside the organization is the competitive environment, where in our views,

Michael Porter's five-forces framework is an ideal model to analyze different drivers within this environment for a specific industry and assist manager to cope with severe competition. In 1960s, when the pharmaceutical industry was bound under limited regulatory controls like tax, "muscle marketing", a competitive strategy that focused on the buyer (i.e. specialists and general practitioners), was proven to be successful approach. In view of such, when the macro-environmental factors remained relatively steady in the time horizon of origins, five-forces framework was a useful tool for strategy formulation. During such a time, the impact of environmental factors on pharmaceutical industry was insignificant.

A broader layer of the environment is often referred to as the macro-environment. PESTEL framework identifies six factors that drive industry in this environment. The change of an environmental factor will be on industry as a whole, and then be transformed into its implications on one or more forces as in MP's framework. In our case of pharmaceutical industry, we believe that environmental forces are of special importance. For instance, as we discussed in the first part, the government policies and regulations, the technology advancement, the funding system of a society, emerge of new disease, and validity of patent, are of significance in the future trend of the pharmaceutical industry.

One good example in the case is of the introduction of much tighter regulatory controls on clinical trials in 1970s, greatly increasing time-to-market and development costs, and enactment of legislation allowing 'generic' medicines. Such changes caused many pharmaceutical companies' strategic move into outsourcing production, as well as R&D centers. Assuming we were in the 1970s and tries to figure out the future development of this industry, MP's five-forces could not identify a trend like this, until we used PESTEL to focus on political factors.

However, the layers of environment are not mutual exclusive, since scope of pharmaceutical industry will evolve in a long run, i.e. there may be convergence of verticals and also divergence of product offerings, as well as consolidation of marketplaces arising as a result of globalization. And the difference between macro-environment and competitive environment is not explicit. Furthermore, environmental factors and competitive forces are interactive and inter-relative. Therefore, other planning framework like scenario planning will be of increasing relevance. Scenario planning technique emphasizes on factors that are of high impact and high uncertainty. There are numerous uncertainties having high impact on the pharmaceutical industry, such as society funding system, new diseases and how technology will advance in this industry. Hence, with the degree of uncertainty increase, scenario planning becomes an increasingly useful tool.

Figure II illustrates our evaluations of PESTEL, MP's five-forces frameworks and scenario planning technique.

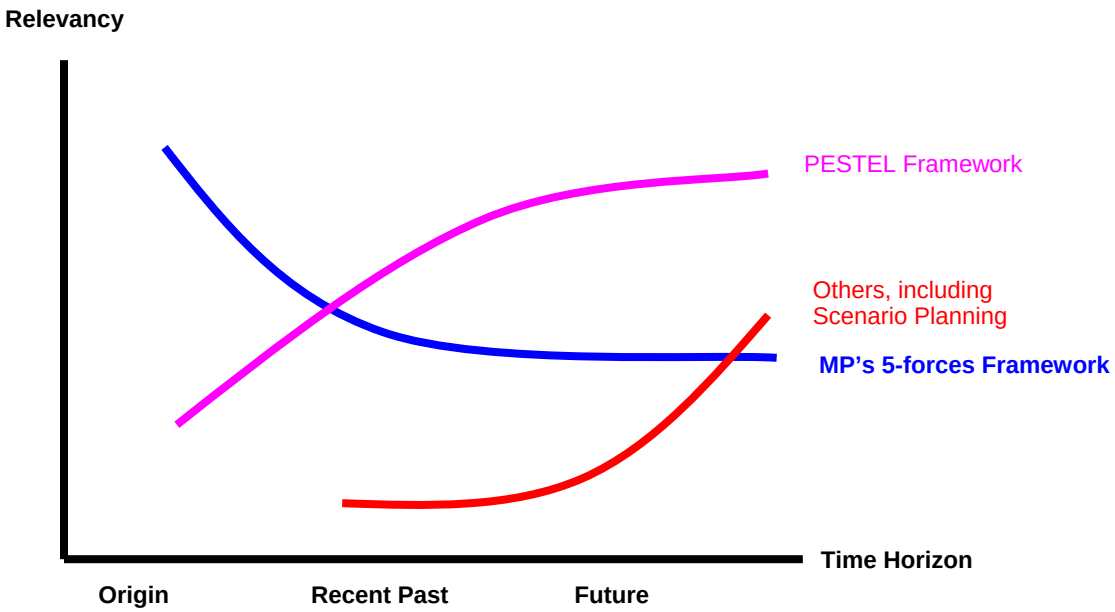

Figure 2: Relevancies of Various Frameworks

3 SCENARIO PLANNING

In Scenario Planning, the underlying assumption is that a scenario is the result of the outcome of a series of variables that assume certain values. In 1, environmental factors as to the PESTEL framework were identified. Some of these factors will follow an almost pre-determined development in future. For example, in Europe, we will surely see that the average age of citizens will increase within the next years. Any other development is unrealistic and anyway not achievable in a short time frame. Other variables like the technological progress are, however, undetermined since a technological breakthrough could theoretically come at any time, or maybe – not at all. In Scenario Planning, one identifies a small set of variables or *factors* that are highly uncertain (that cannot be predicted) and whose outcome (value that the factors assume) have a high impact on the resulting scenario. For a reasonable scenario planning, it is important that only a few variables are selected, especially if these variables are non-numerical and their value and the resulting impact has to be evaluated subjectively. Nevertheless, with the upcoming of adequate software tools, scenario planning can be done with a larger set of (numerical) variables. The selection of the suitable variables comprises the *first step* in scenario planning. In the case of the pharmaceutical industry, our team has identified the four variables:

- *New Diseases*
- *Technological Progress*
- *Consumer Buying Pattern*
- *Healthcare Funding System*

The *second step* in scenario planning is that different values for the variables are assumed. Especially with non-numerical and ambiguous variables, this can be a difficult task as the value of the variable may assume values that cannot be ordered on a linear scale. In our case, we assume the extreme values of the variables to:

Variable	Worst Case	Best Case
New Diseases	no new epidemics.	New epidemics like SARS, Ebola…
Technological Progress	no breakthrough development	new effective treatments
Consumer Buying Pattern	restrictive use	active interest in health & lifestyle
Healthcare Funding System	government	purely private

Table 1: Variables for Scenario Planning

We see the variable *New Diseases* as important because despite the fact that new epidemics are a plague to mankind, they offer new and broad business opportunities for the pharmaceutical industry. Obviously, the more persons become sick, the more healthcare is needed. The worst case for the pharmaceutical industry as to this variable is surely that there are no new epidemics,

but that does not necessarily lead to a lack of business opportunities because there are still plenty of diseases that do not have effective treatment like AIDS, SARS, Ebola, Hepatitis C, Cancer, and which can be highly profitable once a company can develop an effective treatment for them.

This remark leads to the *second variable*, probably the one with the highest uncertainty and impact among the four variables chosen. *Technical Progress* is a development that in fact cannot be predicted. A breakthrough development can occur at any time, or it can never occur, despite heavy investment in R&D. In the worst case for the pharmaceutical industry, there are no or only marginal new technological developments, at least none, that lead to new markets like the treatment of new diseases or of widespread diseases that so far do not have an effective treatment. The best case for the industry is, of course, technological breakthrough in one of the major issues. Such a breakthrough can occur in various sectors, and therefore, this variable is so difficult to handle. One idea is a major breakthrough in an effective treatment of an already widespread disease by conventional, that is, chemical treatment. Let us assume that a company develops an effective vaccine against AIDS. Clearly, such a breakthrough invention, once patented by the company, will lead to a large scale production of the agent, and a worldwide-distribution network would have to be set up. But technological breakthrough can also occur in genetic engineering, like already nowadays, some insulin is product by genetic engineering rather than the old way which was extracting the insulin from the pancreases of pigs. Similarly, some vaccines which are expensive now (like Hepatitis B), may experience a drastic decline in manufacturing costs and a higher production level once they can be produced in a cheap and genetically engineered way. But genetic engineering can also be more than just a cheaper method of producing agents for old diseases. We could think of a very advanced technology which can screen humans as to their genetic susceptibility to certain diseases, maybe diabetes. In that case, humans could get to know this at a very early stage, even before the illness manifests itself. The advanced medicine could then genetically engineer a medicament that is adapted specifically to the body of this person and that prevents or delays an outbreak of the disease in this person. This would lead us to a world of totally customized medicaments. It cannot be stated whether in such a world, the price of such a medicament will be affordable for everyone or maybe only for the upper class or whether certain persons can be put into a group. Depending on this, there are clearly differences as to how a supply chain would have to look like.

Our *third variable*, *Customer Buying Pattern*, already slowly moves into the direction of more interest in health & lifestyle. In fact, nowadays we can already some tendencies in the consumer behaviour. Patients are more savvy nowadays and want to have a say in their therapies and eventually in the choice of medication. Patients at least in the developed countries have become

more of a partner of the physician rather than an unknowing person that accepts everything without asking. We also see a growing interest in supplementary medicine like vitamins, tonics, creams, etc. And finally, we can identify a growing demand for the cure of lifestyle diseases that in former times were accepted as inevitable or even ignored like erectile dysfunction ("impotence"), loss of hairs, artificial teeth, etc. Finally, some customers go even further and seek to modify their body because they are not satisfied with their appearance. In Asia, for example, many women opt for a surgery of the eyelids to appear more "westernized" or seek to modify their nose. A growing number of women in Asia and Latin America also opt for breast enlargements by breast implants. Nevertheless, this trend does not indicate whether it will enforce in future or whether we will see completely different patterns of behaviour. Consumer Buying Pattern is a variable that can be influenced by a range of underlying forces like public opinion on healthcare, new trends, influences from abroad. Consequently, consumer behaviour can correctly be labelled as a highly uncertain variable. For example, it may become fashion to buy medicaments via the internet bypassing pharmacies in the near future. That would have a substantial impact on the pharmaceutical industry as the companies would have to go for the "DELL model", that is for a disintermediation of the downstream channel. In the worst case, however, things do not evolve further or at slow pace, and the behaviour does not change substantially.

Finally, our *fourth variable* is the *Healthcare Funding System*. Again, it may sound strange to include this variable since we encounter so many different systems in the world. Countries like the UK or Germany have a largely government funded system or a system that largely comprises public health insurance systems. Countries like the U.S. are largely dominated by private health insurances. Countries like India or China have a vast population that cannot even afford the rates of a private insurer, yet alone pay the prize of medicaments. And a further question arises when we ask why should a switch from a government funded healthcare system to a privately funded healthcare system in countries like Germany or the UK have a big impact? The population then would opt for private insurances, and maybe they could then enjoy slightly better treatment in the hospital or in their medication, but since such luxury comes at an increased rate of the insurance premium, it is not sure whether such practice would be widely accepted. Clearly, a shift to a government funded system in countries like China or India would have a large impact, but is this really probable? Rather not, since these countries have growth on their agenda, and government funded health care drains from government funds and ultimately slows down growth substantially. So why did we include this variable then? The reason is that in some cases, we may see a shift in funding for certain diseases. Let us assume that a company develops a vaccine

against AIDS which is effective, yet affordable. Some governments may then consider to apply such a vaccine to their whole population. Or a similar move may come from a supranational organization like the WHO. Similarly, the WHO once funded programs to reduce Leper or Malaria, albeit the latter without success. When would a government undertake such a shift in behaviour? If we assume a non-humanistic view of governments and take a realist's stance, then governments would at least undertake such a move if the costs for the vaccination of the whole population is less than the costs incurred by the disease. While such a shift may be expected at a very late stage in the case of AIDS, diseases like SARS are much more likely to see such a shift. In the case of the highly contagious SARS, the costs of an epidemic are high, and the economy is directly impacted. So governments have a high interest to provide effective protection of their citizens from a possible vaccine. There, a decision of the government to vaccinate the whole population, has a large impact on a possible manufacturer's business. Similarly, a manufacturer who researches on such a vaccine, may be able to achieve funding from a government in certain countries. In that aspect, the Healthcare Funding System is a suitable variable for a scenario analysis.

The *third step* of scenario planning comprises the build of plausible scenarios of the different combinations of the variables. This again involves a certain selection of the outcomes of the variables. If we only look at the two extreme values that each of the *n* variable assumes, we can have 2^n different scenarios. However, not every variable influences each scenario equally, and some scenarios may effectively be similar. In the case of the pharmaceutical industry, we chose to select three scenarios that I will highlight subsequently:

3.1 Scenario 1: No great Changes

no epidemics

no breakthrough development

restrictive use

no changes in funding

This scenario is a continuation of current slow moving trends that we can currently observe. We do not experience epidemics in this scenario, nor do we see technological breakthrough developments in the healthcare sector. Consumers maintain the slow growing trend to a more active role which is labelled here as "restrictive use" because we do not see a major shift to a largely increased consumption of medicaments or treatments. Clearly, this scenario looks unfavourable for the pharmaceutical industry because the industry has only a few limited growth options. It can integrate vertically or horizontally, at least as to the limit of what is legally permitted in the respective countries or regions. It can also enlarge the product spectrum to a certain extent by introducing complementary products or products that will be in a higher demand by an ageing population in Europe or by a growing

young population in India. But this does not offer huge profits. The only move that could generate substantial profits is to enlarge the business to so far undeveloped markets like China and India. But then, also, there is the question of the market size. Who will be able to afford treatment or medication in countries where the majority of the population does not even have a health insurance and sometimes not even enough money to sustain the life of their family.

The economic outlook is aggravated by the expiry of patents that will bring additional manufacturers to the market that will sell the expired patented drugs as generic drugs soon. All these developments show that the only feasible way for the pharmaceutical industry in this scenario is to reduce costs which essentially means mergers, relocation of production and even R&D facilities to countries with a cheaper salary structure and a good scientific level (China, India). A further consolidation of manufacturers can be expected, too. This will lead to structural changes, but not to abrupt ones. Rather than that, the structural changes will be a mere extrapolation of trends that we currently can see already in this industry.

3.2 Scenario 2: Age of Plagues

In this scenario we see the rise of new epidemics, but without any major technical breakthroughs in the pharmaceutical industry. As terrifying as this scenario may see for mankind, it provides opportunities and business for the pharmaceutical industry even without any major new medicament developments. As we could verify in the case of SARS where an effective anti-viral treatment is still not available, the treatment and isolation of patients requires an enormous medical effort. Infected patients are treated with supporting medicaments for their immune system, vast parts of the population starts wearing masks, people increase their purchases of vitamins and prophylactic medicaments, etc. Hence, such a scenario purely means business. Inevitably, a rise of epidemics comes along with an increased interest of the public in health & lifestyle as newspapers will cover the epidemics even on their front pages. In this scenario, we do not see much of government spending going on, at least not for the direct benefit of the healthcare sector. Such a situation could change, however, as soon as a medical treatment or a vaccine is found against one epidemic.

In this scenario, the pharmaceutical industry should focus on an increased R&D effort in order to come out quickly with treatments or vaccines. Here, a first mover advantage guarantees rock-solid profits and the company who develops such medication, can label itself as a true benefactor to the society thus even enhancing brand value for the company. Increased R&D efforts consume

funds, and the pharmaceutical industry must strongly lobby governments for funds in order to combat the plagues. Similarly, companies must lobby for easing the regulations on field trials in order to be able to rapidly test new medicaments. At the same time, sales of supplementary material like facial masks, vitamins, latex gloves, etc. will increase and can provide reasonable growth opportunities for enterprises. Nevertheless, the biggest growth would surely come from an effective treatment, and companies must do everything to try to come out with treatments. This also involves planning as on how to roll out a large scale production of agents like vaccines or medicaments in case that the company really succeeds in finding an effective agent. That means, speed is essential. Strong companies should associate with R&D facilities at universities or hospitals and buy smaller companies that seem to have developed prospective agents for treatment.

3.3 Scenario 3: Golden Age of Healthcare

This scenario describes the "Golden Age of Healthcare" and sees the rise of new epidemics in combination with breakthrough technologies in medical progress. Huge profits wait for the pharmaceutical industry which is able to take leverage on the new technological developments to combat the new epidemics as well as the old diseases like diabetes, AIDS, cancer, etc. Effective medicaments can be manufactured at low cost thanks to genetic engineering, and even personalized medication is possible enhancing greatly the efficiency in treatments of diseases and offering a value-add compared to the "standard" market. Companies secure the intellectual property rights (IPR) in the form of patents and can yield substantial premiums during the validity period of their patents. Personalized medication caters for the high-end market in developed countries and for the rich in undeveloped countries and leads to exceptional profits in this sector. At the same time, research in this field benefits the genetic engineering of "standard" medicaments similar to the "trickle down" effect of innovative security features from luxury car models to low-class models over the time. In this scenario, speed is essential, similarly to the second scenario. But while in the previous scenario speed was targeted to R&D in order to develop a medicament, here, speed is an inherent constant in R&D, production, marketing, product line planning, etc.

This scenario also sees extensive government funding in the way that enlightened governments realize the benefits of cost-effective vaccination and treatment in a macroeconomic sense and decide to subsidize preventive medication rather than bearing the costs for a population burdened

by frequent outbreaks of epidemics. Nevertheless, the pharmaceutical industry must nourish this behaviour and try to get funding for new projects that target new epidemics and diseases.

At the same time, the pharmaceutical industry must lobby intermediaries like doctors to apply their newly developed genetically engineered treatments. Eventually, according to the legal situation, the industry will have to disintermediate in the high-profit segment of personalized medication and market the treatments to prospective customers themselves, in order to reach the customer directly and to speed up marketing. Such efforts must go hand in hand with brand-building exercises which themselves can draw substantial benefits from the benefactor issue when a company develops new treatments against the threatening epidemics. Brand awareness also requires that the companies carefully observe the market and fight plagiarism and copy cats wherever possible.

As to the structure in the pharmaceutical industry, the accelerated developments obviously means utmost flexibility in R&D, production and marketing. Continuous change in the only constant in the business, and speed is as important as in the previous scenario. At the same time, companies are challenged by the need to market their products in markets that are as large as possible, at very different quantities, ideally worldwide. This poses huge challenges to the downstream supply chain that has to remain flexible, without too many assets, yet expandable at any time.

4 LIKELY IMPLICATIONS OF CHANGING BUSINESS ENVIRONMENT

Until now, we have seen how the macro-environmental factors (PESTEL framework) are affecting and changing the business framework of the pharmaceutical industry. In this section, we will see how these changes will impact the industry considering some of the major factors.

4.1 Increasing market potential in Asia

With approximately 2.8 billion populations, Asia is one of the fastest growing healthcare markets. Asian governments and private healthcare facilities are either forming regulations or programs to make their countries attractive for foreign investments in terms of healthcare manufacturing and research segments. Frost & Sullivan estimates that the total pharmaceutical market in Asia pacific to be more than US$95 billion in 2001, and this is approximately 28% of the world market. Please refer to Figure 3 on pharmaceutical market in Asia (in billion USD)

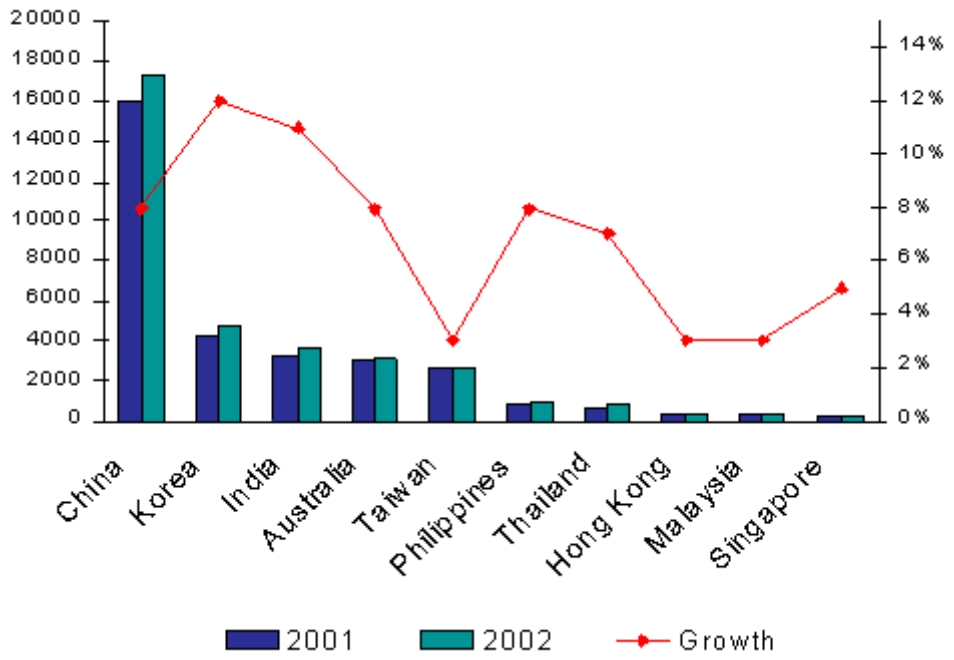

Figure 3: Overview of the pharmaceutical markets in Asia (billion USD)

Likely implication of the growing market potential in Asia is the change in focus in terms of drug development and targeted customer segment. Till now top tier multinational companies (MNC) in the pharmaceutical industry were mainly focussing their research and marketing towards developed countries like U.S., Europe and Japan. The high population growth in India, China and a constantly aging population in countries like Australia, Singapore, in addition to increases in lifestyle make top companies to refocus their strategy in terms of customer segment, diseases and demographic changes.

4.2 Focus on Speed and R&D

The pressure on the pharmaceutical companies to develop and launch new drugs has never been so great. CGE&Y estimates that US$100 billion of products face patent expiry by 2004. Of this, US$37 billion of blockbuster drugs will see a dramatic fall in revenue as generic drug take market share.

In contrast, the biotechnology industry is getting stronger and stronger and it is building its pipeline drug inventory, which is threatening the conventional pharmaceutical industry. Biotech companies are bringing new and superior drug much faster to the market. So the traditional pharmaceutical companies not only face the problem of patent expiry but they will also see their newly launched products being eclipsed by designer drugs.

Even we could see the implication driving towards more focus on R&D, the future growth of pharmaceutical companies is no longer dependent only on their ability to replace declining products or expiring patents. As the pressure mounts, the ability to speed up is synonymous with success – from the acceleration of the development pipeline to the rapid commercialisation of new products to increase in their lifetime economic value. To sum up, the era of a faster pharmaceutical industry has already arrived.

4.3 Advances in Technology

Researchers now believe that eight of the ten leading causes of death in the U.S. have genetic components. Genomics science promise to deliver a step change in our understanding and treatment of diseases at every stage of its cycle – from risk analysis through to treatment. Today, there are 76 approved biotechnology medicines and more than 360 in the pipeline targeting over 200 diseases like AIDS, diabetes, etc. So biotechnology is creating an explosion in potential treatment options as well as exciting new possibilities in predictive and diagnostic medicine. Also advances in informational technology mean treatment delivery will be revolutionised through concepts such as telemedicine and biochips.

These trends are combining to change the focus of healthcare from treating illness to managing wellness, and are speeding the blurring of traditional boundaries between various industries – pharmaceutical, biotechnology and medical devices – in healthcare. As the product changes, so too will the manufacturers, or they find themselves being sidelined by emerging players.

Information technology trends like the internet are driving the change in consumer knowledge about health facts and industry path. This forces change in consumer behaviour and buying pattern. After the introduction of DTC in the U.S. in 1987, patients and consumers have been driving the market rather than the pharmaceutical companies driving the customers, to a certain extent. In face of this, pharmaceutical companies need to re-evaluate the traditional role of their sales force alongside other, more innovative, promotional channels to market their products.

4.4 M&A and Outsourcing

Alliances and outsourcing provide a reliable approach to establish missing capabilities and capacity. In the past, outsourcing was done primarily in the manufacturing of drugs to low cost countries like India and China, but now the focus is on outsourcing R&D phases like clinical trials and pre-clinical trials to their partners. In many cases, these services are provided at low cost and to a higher standard than they could be provided in-house. Some pharmaceutical companies have already started the move toward a more sophisticated outsourcing approach – engaging in collaborative relationships with outsourcing partners from R&D to create high

performance capability support. Thus, there are two different kinds of partners have emerged within R&D – drug discovery and platform technology companies. Drug discovery companies specialise expertise within the drug discovery and development value chain often specialising within a specific therapeutic area. Platform technology companies have emerged in response to rapid changes in technology. They develop specific technology within a particular segment of drug discovery and product development value chain. Pharmaceutical companies benefit from these different categories of partners in the long run. Time-to-market is the one of the biggest challenges of the present day pharmaceutical companies. It is predicted that from inception to final release of the drug could almost take 12 years. The major implications of outsourcing various phases of R&D to their partners, is to reduce the time-to-market. The resources and capabilities could take years to build for these partnering companies and so as in the past M&As will become the norm of the industry even in future.

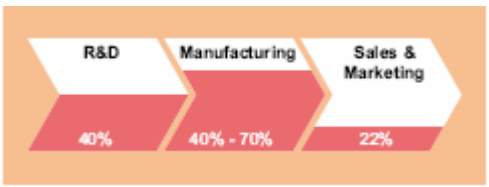

Figure 4: Outsourcing forecast by 2005

4.5 New diseases

Major epidemics like SARS have really changed the way people perceive their health life style. It also created a great impact in the pharmaceutical industry in terms of speed and rapid development of new drugs to future uncertain diseases. It also impacted the way pharmaceutical companies' time-to-market and supply chain issues of the required drugs. After the SARS impact, the focus of pharmaceutical R&D is more towards Asian countries and their people' health style. New unforeseen and unpredictable diseases or epidemics will play a prominent role in terms of strategic thinking of these companies who will foresee to reap the benefits at the given amount of time. As we have seen before, *scenario planning* will play a significant role in tackling these highly unpredictable and high impact factors. One of the major implications we could foresee due to these unpredictable diseases is the change in supply chain and logistic issues of reaching the market with right drugs in the right time.

4.6 Terrorism

Every industry is either directly or indirectly affected by terrorism, and the pharmaceutical industry is no exception. Post 9/11 terrorism has forced manufacturers to reconsider their

strategies in terms of location bases. More and more MNCs are trying to relocate their R&D and manufacturing bases from potential terrorist target location to safe locations like Singapore. Although there is a trade-off between low cost manufacturing places and unsafe countries, pharmaceutical companies are trying to spread their risk across the globe. They surely do not want to put "all the eggs into one basket", especially not in this terrorist hit world. Pharmaceutical companies are those companies, in which the resources – patents, human resources – takes years to build and so it should be preserved for future successes. Therefore, companies are increasingly choosing their locations taking into consideration all aspects of safety measures and potential threats.

4.7 Increase in competition and outlook to the future

Overall, the successful companies will be those who manage the integration of functional areas from discovery through to marketing by increasing the speed of decision making and customer focus. Pharmaceutical companies are facing the challenge of becoming faster, leaner, agile and more integrated. Competition is very intense in this industry as in IT. Home-grown companies, although not having the big muscle power compared to large MNCs, will engage in fierce fights with their big counterparts in their homelands. In most cases, outsourcing and collaboration are ad-hoc and inconsistent with their strategy. Truly customer focus is a very long way off, but surely will be the trend in future.

Looking into the future, in the new pharmaceutical industry model, the line distinguishing in-house capabilities from outsourcing partners will blur as companies of different strength and capabilities partner to target, develop, produce and sell drugs. We should see some shift from capital investment to intellectual investment, in-house production to contract manufacturing and from long-term market to speed and agility. Market research will become a pre-requisite for timely and successful launch of new products.

5 A CLOSER LOOK TO SINGAPORE

5.1 Relation to the development of the industry in Singapore

Singapore sees these developments as an opportunity for her to attract pharmaceutical firms to invest in Singapore.

Firstly, Singapore can provide some form of solutions to issues like terrorism threats, political unrest and deadly epidemic like SARS. This year, Singapore had demonstrated its ability and leadership in managing SARS epidemic very effectively, gaining global commendation from both the medical fields and corporate world. The Singapore government's resolution and effectiveness in dealing with the terrorist threat also gave assurance to many firms. Further, Singapore stable political scene provides another strength.

By positioning itself to be a safer haven in Asia , Singapore would be a compelling location for international firms to be in as spreading the business risk is one of the prime consideration in face of the changing and uncertain macro environment.

Secondly, Singapore has strengths and advantages as well as being able to provide the necessary environment for the industry to flourish.

Thirdly, Singapore recognizes this industry as a growth sector in the global market. As the focus is turning towards Asia, Singapore is seizing this opportunity to tap on this new growth engine to sustain itself in the face of a weakening economic growth. Indeed, there is the political will and commitment for Singapore to get a bite of the global pharmaceutical industry.

Below are some of the major strengths and advantages, which Singapore has:

- political stability
- responsive government
- robust infrastructure
- extensive trade links
- good IP protection framework
- leading financial centre
- R&D resources
- educated workforce
- vibrant cosmopolitan lifestyle

5.2 The Singapore Vision

Singapore is positioning herself to be the *Biopolis* of Asia where international reputable biomedical sciences companies will locate their manufacturing, R&D, clinical development and headquarter activities here. Pharmaceutical industry is one of the four sectors under the biomedical sciences cluster. The other three industries are medical technology, biotechnology and healthcare services.

Singapore clearly aims to be become a global hub for both large companies with extensive market reach as well as small technology intensive companies with the ability to innovate with speed.

5.3 Approaches

The Singapore government is very committed to this vision. Many initiatives, actions and efforts had been made to get to this path:

1. Top level ministerial involvement and support
2. Establishment of councils, regulatory bodies, legal framework
3. Establishment of physical infrastructure
4. Provision/ availability of funds
5. Establishment of robust ethical framework
6. Establishment of a regime for protection of intellectual property rights
7. Attraction, retention and nurturing of talents
8. Financial & economic incentives
9. Creating an environment for the R&D to flourish – like conventions, exhibitions, collaboration between institutes, scholarships and internship programs, university faculty and curriculum
10. More vibrant lifestyle

Indeed their efforts seem to have paid off, as is evidenced by their success in attracting firms like GlaxoSmithKline, Merck & Co, Pfizer, Wyeth, Baxter, Johnson and Johnson Medical, Eli Lilly.

5.4 Singapore is not alone

Asia is currently perceived as one of the fasting growing healthcare markets in the world and the pharmaceuticals industry is no exception. Frost & Sullivan estimates that the total pharmaceutical market in Asia Pacific stood at more than US$95 billion in 2001 and this represents approximately 28% of the world market in terms of manufacturers' revenues.

By 2005, manufacturer revenues in this region are expected to surpass US$110 billion. Baring any unforeseen circumstances, Asian pharmaceutical markets are forecast to experience growth

in the 2000-2005 period with a compound annual growth rate of 5.8% (10.4% if excludes Japan). The strongest growing markets are China, India, South Korea, Australia and Taiwan.

Indeed Singapore is not alone in this race as Figure 3 shows. To tap into this growing sector, many countries like China, India, Korea, Taiwan and Australia are also gearing themselves up to tap on this business opportunity. The respective governments, like Singapore, are also making efforts and taking actions to position itself as a prominent pharmaceutical player in the global arena.

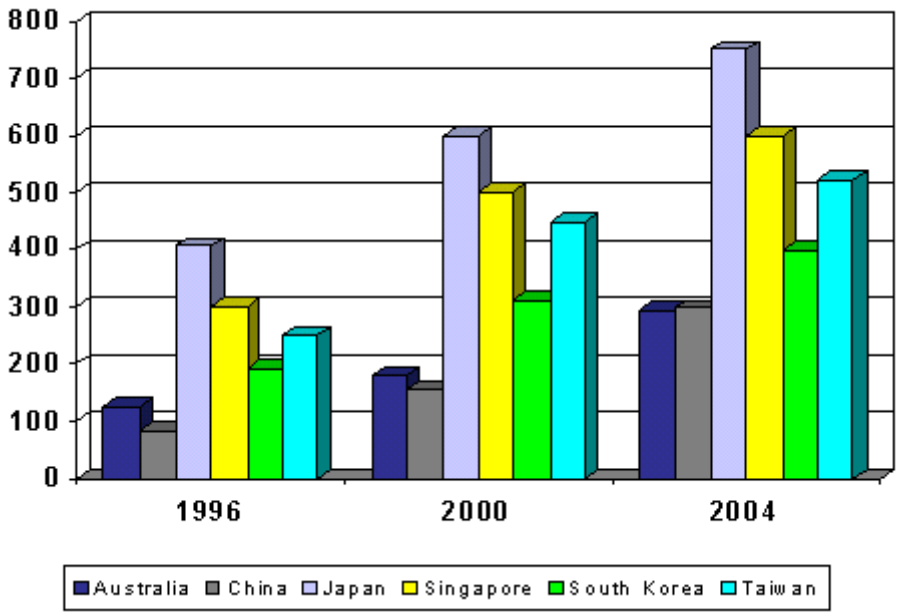

Figure 5: Government Investment in Biotechnology since 1996, forecasts for 2004

According to Figure 5, Japan is clearly the leader. Singapore's R&D investment is rather high, ranking second but Taiwan appears to be catching up rather fast.

Obviously, Asian countries realized that the future in pharmaceutical is based on medical research, development and biotechnology research. Genetic knowledge and expertise would be the next medical revolution and governments are aggressively pushing for it to develop in their countries.

The major regional competitors like Japan and China have the following advantages over Singapore:

- Huge domestic market
- Larger talent pool

The huge domestic market has two major implications:

Firstly, there is a huge domestic demand for pharmaceutical products and firms would naturally want to set up a manufacturing base to cater to the demand.

Secondly, the huge population base attracts firms to conduct local clinical trials in China. It is estimated that over 40 clinical trails for Class I new drugs sponsored by around 30 multinational pharmaceutical firms are currently being conducted throughout China. This will boost growth opportunities.

In spite of that, we believe that Singapore can still find a niche in R&D, clinical development and perhaps headquarter activities although we seriously doubt that she can compete well in the manufacturing aspect.

The “hardware” can be duplicated and catch up by competitors easily but the real acid test lies in the breakthroughs in R&D and clinical development. Currently, the U.S. is deemed to be the dominant player and leader in the global pharmaceutical market with 35 potential blockbusters lined up in the next five years. Japan is currently the leader in Asia but China is rapidly catching up. If Singapore could line up a series of potential blockbusters soon, it would be a player to be reckon with, despite her seemingly young experience in the industry. However, one critical resource is talent.

Whereas the bigger competitors has a larger talent pool to tap from, Singapore’s small talent pool means that the government has to aggressively import foreign talent which is not easy to attract and may not be interested in staying permanently. However, this is an issue that Singapore can be manage and overcome.

Having the “hardware” and talent in place is still not sufficient. There needs to be a conducive culture or environment for the R&D to flourish. In the IT industry, many attempts failed to duplicate the success of Silicon Valley despite investments in the infrastructure. The reason is simply the combination of critical factors like the buzz , the chemistry and the network which are present at Silicon Valley. They cannot be imitated or duplicated as easily. In this respect, Singapore may have a slightly better edge over its competitors (listed in Figure 5) but she still needs to work on it.

Furthermore, the management of business ethics is also crucial in this industry and perhaps, Singapore has proven in its recent sacking of a top scientist at the *Institute of Molecular Biology* when he breached ethical rules in his research in Singapore. There must be the discipline and commitment to maintain the standard of ethics. Singapore’s reputation as a clean and corrupt free government give her an edge over its competitors.

To be a global player, Singapore also needs to build its reputation in the field of biotechnology. This can be built only with the successful combination of breakthrough results and a conscious branding of Singapore's position as the *Biopolis* of Asia. Indeed Singapore has the potential to be a global player but it would not be an easy task.

6 LITERATURE

1. EDB website
2. A*Star website
3. www.medisourceasia.com
4. MTI website