CHAPTER V

CRITICAL SUCCESS FACTORS

The data collected from the industry through their in-house publication and communications of the Malaysian Organisation of Pharmaceutical Industries and the data obtained from the Malaysian Pharmaceutical Trade and Manufacturers Association were scanned. Some data was obtained from the National Pharmaceutical Control Bureau. Personal interviews were conducted with some key personnel in the local manufacturing industry to obtain their views and opinions on the success factors for the industry. As the industry is a highly competitive one information was not easily forthcoming. It was observed that not much research data was available on the industry.

Based on my experience in the industry combined with the data obtained a qualitative analysis was done to identify the critical success factors for the industry at present and for its future growth

The local manufacturers only control 30% of market share while the balance of 70% is held by foreign companies (Second Industrial Master Plan 1996-2005). As the local manufacturers hold only 30 % they have an opportunity to capture a part of the 70% balance. They have not been able to increase market share due to their difficulty in

matching the overseas companies bringing out new drug entities or new products thus they are left contented to play second fiddle to the multinationals.

Major world pharmaceutical companies undertake large scale R&D to maintain a competitive advantage Eight to ten percent of their total turnover is invested for R&D which actually is a large amount. The Malaysian Pharmaceutical industry at it's present state of development cannot afford large scale of expensive research or development on it's own. It does not have the capacity, financially and technologically to venture into New Chemical Entity research. Industry reports indicate it would need a battery of 1000 scientist and US$300 to US$400 million for a multinational company to introduce a successful new chemical entity. This kind of R&D will only be possible when the industry is large and viable enough to support primary manufacturers of raw materials. This requires the industry to achieve the required size by Import Substitution and Active Exports.

Clearly research to develop new chemical entities is beyond the financial resources of local companies but this should not deter us from looking into our indigenous plants and herbs on which we have a vast body of knowledge and experience. Lurking among our forest or "herbarium" we may find molecules which can provide cures for some incurable diseases. This research could be done when the industry joins hand with the local universities and government laboratories.

The other form of research which can be carried out now is based on the "Old Wine New Bottle" approach. Here we find better ways of utilising existing drug entities. Research can be devoted to developing novel drug delivery systems which are capable of controlling the rate of drug absorption and administration over extended periods of time. This type of research are relatively cheaper and entails less development time and will be profitable.

There is a need to improve the product quality and also the product range. This would necessitate investment in R&D which would be helped if government incentives are forthcoming. Another problem with regards to R&D is the acute shortage of scientist to carry out R&D

The local industry currently is only involved in R&D activities in product formulation including very limited development of novel or sustained release dosage form. Product development includes formulation development and improvement, stability studies, dosage form innovation and dosage improvement. R&D to develop products in preparation for drug registration upon expiry of patents should be recognised and incentives be given.

The grant given by I.T A F of RM. 30,000 to RM 100,000 is too small and insufficient for meaningful research as facilities are limited in Malaysia. Incentives should be given for overseas R&D. Another proposal is to lure the large drug companies (multinationals) to locate their manufacturing or research activities in Malaysia which will provide spin-off benefits in the form of Technology Transfer.

Due recognition and incentives should be awarded for all the above mentioned R&D activities and such incentives should include a risk sharing feature. The Singapore government for instance bears 50% as incentives and helps to share the risk.

The current state where each manufacturer carries on with their own R&D with resources available to themselves is not ideal as R&D equipment and facilities are very expensive and decentralised R&D is inefficient and does not allow maximum utilisation of the limited R&D resources and there is wasteful duplication of resources and efforts

To avoid such inefficient and wasteful practice it is proposed by the manufacturers that the government initiate and establish a risk sharing pharmaceutical research and development centre which will eliminate the current wasteful duplication with proper focus on projects which can be capitalised upon by the local manufactures. This pharmaceutical R&D centre should be modelled after PORIM (Palm Oil Research Institute of Malaysia) or RRI (Rubber Research Institute).

The facilities and findings must be available to all manufacturers. An important R&D niche for this centre will be in-depth investigation into native medicinal plants which may give rise to the identification and commercialisation of a number of useful compounds. Thus from this one of the critical success factors is research and development which is neglected and should be developed

The local pharmaceutical industry is highly regulated. The industry has become very capital intensive which gives slow returns. The start up cost for a new pharmaceutical factory manufacturing a modest range of medicines is estimated at approximately RM 20 million. The operations cost is high due to stringent regulatory controls and enforcement of this industry. To meet this strict terms of Good Manufacturing Practice imposed by regulators, investments in excess of RM 100 million by manufactures have been made in both "software" and "hardware". Hardware in the form of new factories, plant upgrading, acquisition of high technology production equipment such as automatic machines, computers and sophisticated analytical equipment software in the form of good documentation and EDI for registration.

The slow return is due to the long gestation period of 3 years before production, it takes 2 years to register products before manufacturing can start, 7 years to see profit and 12 years for recovery of investment capital. Due to this the industry needs some kind of tax concession or incentives and low interest loans .

As there is a long gestation period for exports due to the time taken by the importing country to register the product, incentives should be given, it is suggested that the government set up a fund to assist in export of pharmaceuticals. The development of a long term export market requires a long gestation period about two years and expensive, payment made upfront for two years before the product is registered and allowed to be sold. Registration fees can range from US$300 to US$1000 per product and if 10

products are registered in 10 countries the fees alone would amount to US100,000. To this scenario the government should help to reduce the burden of the local manufacturers by giving some financial incentives for export.

At present there is a double tax allowance for promotion of Malaysian made products overseas for export purposes. It is proposed that this allowance be made available for local export promotion of Malaysian made pharmaceutical products. This would help the small and medium manufacturers who do not have the resources to undertake promotion overseas.

Multinational companies have ready and better access to overseas markets and local companies can form strategic alliance with the multinational companies to gain access to their market for local brands and for this co-operation it is proposed that financial aid be arranged by the government. Incentives must be made available for overseas joint ventures for exports.

Finished products imported is completely free from tariffs and duties whilst duty and sales tax is paid for imported packaging material e.g. glass containers, aluminium containers, tubes and foils as well as plastic packaging material. Even though exemption is possible it is cumbersome and not granted in all occasion. There is also duty and sales tax on equipment used in pharmaceutical manufacture like sealers, spare parts like punches and dies and other laboratory equipments. The Malaysian Organisation of Pharmaceutical Industries propose to level the domestic playing field, and suggest that at least a 50%

import duty be charged for products imported that could be manufactured in Malaysia and they believe that this will promote translocation of manufacturing to Malaysia.

The Malaysian pharmaceutical industry needs soft loans with low interest for relocation and Good Manufacturing Practice upgrading as well as adoption of higher technology or automation in pharmaceutical manufacture. The Taiwan government for example gives loan at 3% interest for relocation purposes.

Another suggestion by the Malaysian Organisation Of Pharmaceutical Industries is the setting up of the Third Board in the stock exchange and inclusion of the pharmaceutical industry in the Third Board which will provide access to cheap funds for growth and development. Thus from the above discussion it has been found that financial support in the form of soft loans, incentives and reduced duty is needed for the industry and is one of the critical success factors for the industry.

The local industry is facing a multitude of problem, one is the acute shortage of scientist in the pharmaceutical or related fields hindering R&D. In 1995 there was only one school of pharmacy which had produced 1500 graduates till date, most were first degree holders who preferred to work in the pharmacy service sector, few have ventured into the ıdustrial sector and lesser to post graduate degrees. Attempts have been made by some ɔmpanies to recruit foreign scientists but the immigration legislation makes it difficult as ey are not able to work on a long term basis and this hinders the recruiting of the best ıins from outside to help in the industry.

There is a shortage of trained personnel in both the manufacturing and marketing division of the pharmaceutical industry. Manufacturing has a shortage of trained pharmaceutical technicians as there is no institution presently catering for this kind of training. Only the government trains technicians for its own placement.

In the industry the technical training is given by the individual firm i.e. they learn as they work. This type of training is not structured and does not allow the trainee to gain full knowledge.

In an effort to create a viable pharmaceutical industry in Malaysia it is imperative that the limited supply of personnel especially in the manufacturing and R&D (e.g. Pharmacist, Microbiologist, Engineers etc.) and other needs to be addressed. It is crucial that the industry needs to work closely with government and institutes of higher learning to tailor curriculum and train personnel that could meet the need of the industry.

The shortage of pharmacist has been addressed with the setting up of three new schools of pharmacy while there is still shortage of skilled technicians. As the Malaysian Organisation of Pharmaceutical Industry says that the program could be funded by the Human Resource Development Fund and the organisation could train the personnel through co-operation with some foreign organisation strong in pharmaceutical technology. For the curren shortage, requirement of experienced personnel from overseas is proposed but th procedure for requirement has to be simplified. The training institutes can be linked to th

R&D research centre mentioned earlier. Thus Human Resource need for the industry is a critical success factor which has to be addressed urgently before it worsens.

The industry, as mentioned, earlier is highly regulated, stringent Good Manufacturing Practice conditions have been erected and it is mandatory to follow. Non compliance of this requirement can cause the shut down of the manufacturing facility and suspension of the manufacturing licence (see Table 6 and Table 7 below) and it can only resume if cleared by

Table 6 : Punitive Action - Degree Of Product Recall 1995

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	
DEGREE OF PRODUCT RECALL													
Degree I	-	-	-	-	-	-	-	-	-	-	-	-	
Degree II	-	-	-	-	1	1	2	-	-	-	-	-	4
Degree III	-	5	-	1	2	6	10	5	1	1	-	-	31
	-	5	-	1	3	7	12	5	1	1	-	-	35

Source : National Pharmaceutical Control Bureau, Annual Report 1995

the National Pharmaceutical Control Bureau and reissued with a licence to operate. A manufacturer can only manufacture products that have been registered. The manufacturing premises are regularly inspected by inspectors from National Pharmaceutical Control Bureau who check on all aspects of the operations. Post market sampling is also done by

the National Pharmaceutical Control Bureau which obtain samples from the market to test its quality safety and its efficacy. Over the years a number of factories have been shut down for non compliance to Good Manufacturing Practice causing great loses to the manufacturers.

Table 7 : Punitive Action - Product Source 1995

Month SOURCE	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	
Local	-	2	-	1	3	3	6	-	1	1	-	-	17
Imported	-	3	-	-	-	4	6	5	-	-	-	-	18
Total	-	5	-	1	3	7	12	5	1	1	-	-	35

Source : National Pharmaceutical Control Bureau, Annual Report 1995.

The National Pharmaceutical Control Bureau is the government regulatory agency for implementing the control of Drug and Cosmetics Regulations 1984. Its task is to ensure the safety, quality and efficacy of pharmaceutical, health and personal care products marketed in Malaysia.

Ten years since the implementation of regulation governing the industry, the continually evolving rules imposed by the regulators has without doubt given rise to problems. To meet this stringent Good Manufacturing Practice regulation, investments in excess of RM 100 million by the manufacturers, has been made in upgrading the facilities. The strict enforcement has caused the industry to evolve into a modern industry capable of

producing a wide range of products of internationally accepted standards in compliance to the World Health Organisation standards of Good Manufacturing Practice.

The delay in processing of applications for registration is usually blamed on lack of staffs. This could be overcome by corporatizing the National Pharmaceutical Control Bureau. It could generate more funds and offer better remuneration for the staff and this would lead to a symbiotic relationship between the industry and the National Pharmaceutical Control Bureau for the betterment of both.

A major problem in the industry is the sudden changes in Good Manufacturing Practice requirements and the frequent changes in the GMP basic reference which is very disruptive and expensive for the industry leading to much waste and inefficiency. GMP standards and compliance is the mainstay of the industry. It needs planning and is expensive. The Malaysian GMP is based on WHO code of GMP, sudden incorporation of other codes from other countries can be confusing and disruptive. As such the GMP standards have to be clearly defined.

One form of non tariff barrier affecting export of our products is the non recognition of our GMP certification even though Malaysia is recognised as a reference centre for GMP by WHO. This problem is encountered with countries like Indonesia, Korea, Taiwan, the US and European Union. The Ministry of Health and the Government has to convince the regulatory authorities to accept Malaysian GMP as certified by NPCB

The government should adopt an international standard like WHO's standard of GMP. Imposing a higher standard on local manufacturers is detrimental as it would make both exports and import uncompetitive.

The question of product registration for contract manufacture which is a huge and lucrative business should be expedited so that the local manufacturer can tap the market, and not lose out to others due to the product registration delay The registration of products by the NPCB is to safeguard the consumers so that only safe and effective medications are marketed The time taken to register a product can be two or more years. NPCB should simplify the process and shorten the lead time.

The question of patent has always been around. A new drug entity is patented for 20 years so that the manufacturer can reap the benefit from their discovery. The government should have a reliable patent system that would encourage research and stimulate trade. A strong enforcement of this would create the right environment to promote R & D rather than promote a generic industry.

The problem with regulatory enforcement arises when the patent expires. Presently local manufacturers thrive on post patent product development. But the regulatory agency does not allow the local manufacturers to produce for pre registration before patent expire. As the registration takes about 2 years the MNC's are allowed this additional two years to get patent protected prices. The manufacturers propose that permission should be granted for pre registration two years prior to patent expire so that the generics can be marketed the

day after the patent expires. The US FDA allows "provisional registration" to facilitate short and long-term exports. In Canada the patent protection period is only 17 years compared to the norm of 20 years giving the local manufacturers opportunity to develop/register the product domestically and internationally.

From the above facts it is imperative that we cannot take regulatory matters lightly and this is accepted to be a critical success factors for the local manufacturer.

Another concern for local manufacturers of pharmaceutical is the advent of AFTA, the Asean Free Trade Agreement which was to be implemented in 2008 which is now been moved forward to 2003, which is only six years away. The implementation of AFTA would herald significant changes, i.e. Tariffs will drop to 0-5% only. and very large market consisting of 330 millions consumers will be available, competition will come in from cheaper products produced by countries with comparatively cheaper labour or material cost or abundant natural resources. This factor will be one of the critical success factors. The only way to protect our local manufacturers from competition against other Asean products is to allow our local manufacturers to dominate the domestic market and only then can they be assured of a secured local base as the large domestic base would give rise to better economy of scale resulting in lower cost and competitive in exports.

This can be obtained through the prudent use of GMP and drug registration and also promote the use of locally manufactured drugs by import substitution through the listing of local manufactured drugs in the essential drug list. Finally it will all depend on how we

manage change to adapt to trade liberalisation in AFTA. Last but not least is the question of acquiring advanced technology as mentioned earlier the R & D capability of local manufacturers are not adequate. To be competitive, companies must always develop new products and services to maintain the advantage.