CHAPTER II

THE MALAYSIAN PHARMACEUTICAL INDUSTRY

The industry is highly regulated world-wide and the same holds true for Malaysia. The industry is governed by four acts. They are The Poison Act 1952, The Dangerous Drugs Act 1952, The Medicine (Advertisement and Sales) Act 1956 and the most important of all The Sale of Drugs Act 1952 under which was promulgated the Control of Drugs and Cosmetics Regulation 1984 which gave rise to The Drug Control Authorities (DCA) in 1984 which is the Regulatory Agency for this industry. The DCA's aim is to ensure that the medicine manufactured or sold in Malaysia are registered, there by meeting required standards of quality, efficacy and safety. This is enforced by registration of the products and licensing of the manufacturing premises.

Product classification in Malaysia is broadly grouped into two groups.

Schedule Poison :

Drugs that can be purchased , dispensed and stored and prescribed by licensed practitioners such as pharmacist, doctors and veterinarians . The number of schedule poison products available in the market is 6687 which is 60% of the available medicinal preparation as of December 1995.

Non Poison / Over the counter (OTC) :

Drugs that can be purchased and stored by anyone. The number of registered OTC products are 4036 as of December 1998 which translates to 40 % of drug preparation in the market. (Refer to Table 4)

Table 4 : Registration Status of Application Till 1995

REGISTRATION STATUS	TYPES OF PRODUCT				
	Schedule Poison	Non Poison	Traditional	Cosmetics	Total
Registered	6687	4036	339	168	11230
Deferred / Rejected / Cancelled*	4614	2870	1224	92	8800
Being Evaluated	333	402	13830	65	14630
Total Number Of Application	11634	7308	15393	325	34660

** Deferred until compliance to GMP*
Source : National Pharmaceutical Control Bureau Annual Report 1995.

The industry is represented by two organizations

1. The Malaysian Organization of Pharmaceutical Industries (MOPI)

2. Malaysian Pharmaceutical Trade and Manufacturers Association (MPTMA)

The first comprises of all the licensed manufacturers in the country who number 62 presently of which 42 manufacture scheduled poisons and the rest are involved in the manufacture of nonpoison or herbal preparations.

The second, MPTMA is comprised of multinational companies who are importers except for Sanofi Winthrop which manufactures OTC items.

This study is relevant for MOPI and does not involve MPTMA who are not in the manufacturing sectors but are competitors as they hold 70% of the domestic market share.

The type of products manufactured by local manufacturers include tablets both coated and plain capsules, creams, ointments, powders, small volume injectables, sterile ear / eye drops and infusions fluids under a wide spectrum of pharmaceutical classification - they are branded generics.

The National Pharmaceutical Control Bureau is the organization which licenses manufacturing facilities. There are three types of licensed premises; manufacturing, wholesale and importers.

The licensed manufacturers numbering 62 are located all our the country.(Refer to Table 5). Stringent regulation are in force to ensure that internationally accepted standard are maintained by the manufacturers.

The National Pharmaceutical Control Bureau ensures that by regular audits at the manufacturing facilities to see Good Manufacturing Practice. Good Laboratory Practice and Good Storage Practice standards as required are adhered to by the manufacturers. from time to time the manufacturers are supposed to acquire new Good Manufacturing Practice grade machines and upgrade their processes.

In a tight labour market like Malaysia there is always a problem of trying to get competent staffs and there is a natural shortage of technical staffs in the industry. At present the technology used by the local manufacturers is comparable to other countries the productions processes, quality control and quality assurance is of acceptable standards

based on the World Health Organization 's standards. Research and Development is still in the infant stages where local manufacturers are only involved in product development and product formulations and not so much in new chemical entity research.

Table 5 - Distribution Of Pharmaceuticals Manufactures In Malaysia, 1995

	Poison	Non Poison
Wilayah Persekutuan	3	3
Selangor	13	9
Negeri Sembilan	1	0
Melaka	3	1
Johor	2	4
Pahang	0	0
Trengganu	0	0
Kelantan	1	0
Perlis	0	0
Kedah	4	0
Pulau Pinang	11	1
Perak	1	4
Sabah	0	0
Sarawak	0	0

Source : National Pharmaceutical Control Bureau Annual Report 1995

The marketing expertise of the local manufacturers who usually promote and distribute their product themselves is quite well developed.

Drug registration was implemented in1984. The Malaysian implementation of the drug registration is very stringent . In Phase 1- Scheduled Poisons were registered, Phase2 - Over The Counter or Non Poison, Phase 3 - Herbal preparations, Phase4 - Cosmetics.

Phase1 to 3 registration has been completed. The strict enforcement in evidenced by the registration of Over The Counter and herbal products which is not mandatory in the US and the Asean nations, thus putting us at a disadvantage. The National Pharmaceutical Control Bureau samples products from the market in a post market surveillance to ensure that the products are safe and effective.