# CHAPTER II

# THE PHARMACEUTICAL INDUSTRY

This chapter examines the existing situation, challenges and past trends of the pharmaceutical industry worldwide as well as in Malaysia.

## THE INTERNATIONAL PHARMACEUTICAL INDUSTRY

The sales of the world pharmaceutical market in 1994 was US$256.2 billion, having increased by 7.6% over 1993. The growth rate was about 5.1% in 1993 as shown in Table 1.

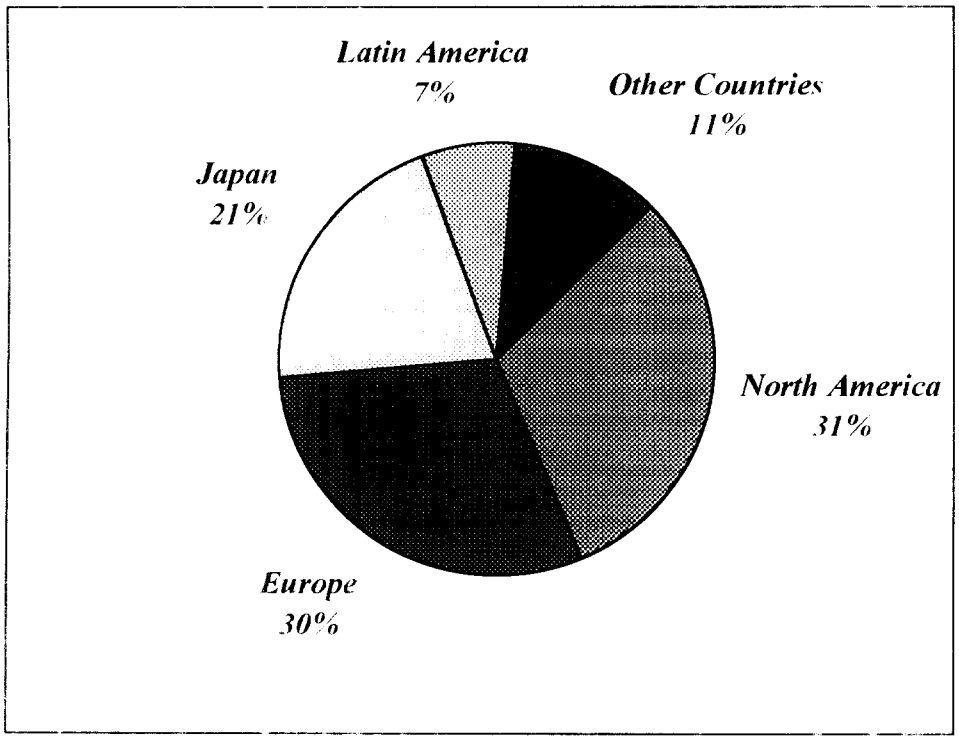
Table 1: World pharmaceutical market performance ($billion)

| Class | 1992 | 1993 | 1994 | Percentage growth rate in 1993 | Percentage growth rate in 1994 |
|---|---|---|---|---|---|
| Pharma | 156.6 | 160.8 | 170.9 | 2.7 | 6.3 |
| Hospital / Institution | 48.3 | 53.5 | 59.2 | 10.8 | 10.6 |
| Others /OTC | 21.7 | 23.8 | 26.1 | 9.9 | 9.7 |
| Total | 226.6 | 238.1 | 256.2 | 5.1 | 7.6 |

Source : PMSI 1995 Global Pharmaceutical Review

Note : The PMSI data are based on sales through all pharmaceutical outlets, hospitals, government agencies, drug stores and tender business, and incorporate sales of both prescription and OTC medicines. Pharma represents all prescriptions for medicines by doctors that are given to patients for treatment of their illness and to be purchased at pharmacies; Hospitals/institutions represent all drugs purchased and dispensed by both institutions and hospitals. Others/OTC are drugs other than the above or over-the-counter medicines that could be purchased without a prescription.

Figure 2 : Regional World Market Shares in US$ (1994)




Source : PMSI 1995 Global Pharmaceutical Review

As shown in Figure 1 the United States, Europe and Japan constitute more than 80% of the world pharmaceutical market.

The pharmaceutical market can be broadly divided as follows :

a. Ethical These are medicines that have been innovated by research-based multinationals and can be dispensed by a medical practitioner or a pharmacist only with a prescription.

b. Generics It is a clone of the original whether it is branded or identified by a company or chemical name. By definition a generic cannot be different in substance or chemical compound from an original (ethical) compound and thus can compete only on price

c. Over-the-Counter Drugs (OTC) These are drugs that can treat ailments and do not require a prescription e.g. cough and cold gastrointestinal, analgesics, vitamins, minerals, tonics, circulatory, dermatological, herbal and homeopathic remedies.

Since 1990 the global pharmaceutical industry is facing numerous challenges. These include the growing cost containment by payers (patients and the government) and downward pressure on prices, generic substitution, higher regulatory barriers, diminishing returns on investment, paucity of innovative and valuable new chemical entities (products). Greater importance of quality driven innovation, speed of developments in technology have been major determinants for gaining a competitive edge in the market. Recently pharmaceutical manufacturers are required to demonstrate the cost effectiveness of the products in addition to their quality, safety and efficacy.

As a response to some of these challenges, the industry has strengthened their product portfolios, improving human resource productivity, improving business processes efficiencies and also adopted cost-cutting measures such as horizontal integration. For example in 1994 and 1995 many companies acquired or set up managed care organisations as a form of diversification.

## THE MALAYSIAN PHARMACEUTICAL INDUSTRY

### Product classification in Malaysia

Pharmaceutical products in Malaysia are broadly classified into two main categories as follows :

1. Scheduled poisons - Drugs that can be purchased, dispensed, stored, or prescribed by licensed practitioners, such as pharmacists and medical practitioners. The number of registered scheduled poisons are 6,438 (61% of the total drugs in Malaysia ) as of December 1994.
2. Over-the-counter/Non-Poison - Drugs that can be purchased, stored and sold by anyone. The number of registered OTC Products are 3,968 (39% of the total drugs in Malaysia) as of December 1994.

### Drug Legislations

The pharmaceutical industry is highly regulated world-wide and this is also true for Malaysia .The sale of drugs in Malaysia is governed by four Acts. These are the Poisons Act 1952, the Dangerous Drugs Act 1952, the Sale of Drugs Act 1952 and the Medicines ( Advertisement & Sales ) Act 1956.

The Control of Drugs and Cosmetics Regulations 1984 was promulgated under the Sales of Drugs Act 1952 with the aim of ensuring that only drugs which meet the required standards of quality, efficacy and safety are registered and allowed to be manufactured, imported, supplied or sold. The Regulations provide for the establishment of the Drug Control Authority which is responsible for the

registration of drugs and cosmetics, and the licensing of manufacturers, importers and wholesalers in the country

Malaysia has the stringent regulations to ensure that drugs used to treat patients meet international standards. Since its implementation in 1985. The Drug Control Authority has registered a total of 10,554 products as of December 1984. (Drug Control Authority, Annual Report 1994)

Market size and growth

The Malaysian pharmaceutical market which is predominantly a dispensing market is estimated by industry sources to be worth RM725 million as of December 1994 (IMS Newsletter June 1995). It has grown by an average of 10% over the last decade and is expected to do so, primarily because of increasing healthcare costs, early awareness of sickness, good economic conditions and a growing health conscious urban population.

Pharmaceutical Industry

The local pharmaceutical industry consists of multinational corporations and local manufacturers. The multinational pharmaceutical organisations control about 70% of the total market value while the local manufacturers control the balance of 30%. Most of the medicines marketed are imported into Malaysia by traders, distributors, and agents. There are only about 59 licensed manufacturers as of December 1994. Local manufacturers are represented by

the Malaysian Organisation of Pharmaceutical Industries (MOPI). Multinational companies are represented by the Malaysian Pharmaceutical Trade and Manufacturers Association (MPTMA) consisting of trading agency houses and principal multinational drug companies involved in marketing and wholesale distribution.

The members of MOPI are engaged in the formulation of generic drugs using imported raw materials, whereas the members of MPTMA deal mainly with imported finished products. There are 35 local manufacturers of Scheduled Poisons and only about 10 non-scheduled or OTC manufacturers (comprising mostly external preparations viz. oils, liniments, lotions, mouth-wash). There are 82 Importers of Scheduled Poisons and 34 for OTC products.

Channels of distribution for pharmaceutical products

All the multinational pharmaceutical corporations have established representative offices in Malaysia with a small field force and administration staff. Their operations are mainly restricted to marketing of their products, while inbound logistics, outbound logistics, inventory control, warehousing, order processing and distribution are handled mostly by distributors

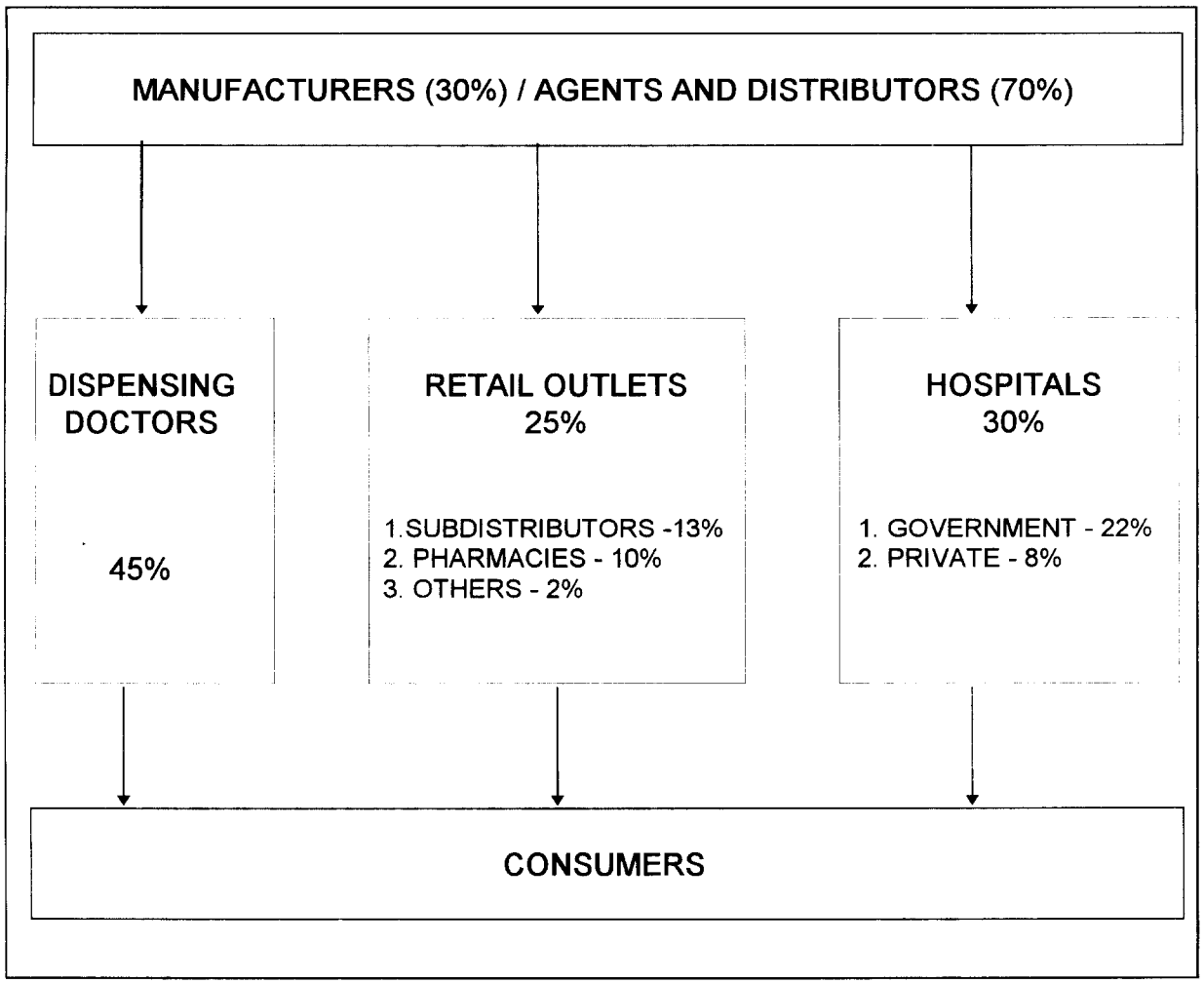
The two largest pioneers in pharmaceutical distribution are

1. Diethelm handles the distribution for companies, such as, Abbott. Hoechst, Bayer, Boehringer Ingelheim, Bristol Meyers Squibb, Johnson & Johnson, Roche, Sandoz and Sterling Drug .
2. Zuellig handles the distribution for companies such as Astra, Ciba. Eli lilly, Glaxo-Wellcome, E Merck. Reckitt and Colman, Rhone Poulenc. Schering Plough, Seven Seas, Smithkline Beecham, and Upjohn

The local manufacturers are involved in all aspects of production. marketing and distribution . The major local manufacturers that produce both poisons and non-poison products are Pharmmalaysia Berhad, Upha Corporation (M) Sdn. Bhd., Xepa Soul Pattinson (M) Sdn. Bhd., Hovid Pharmacy Sdn. Bhd

The flow of the pharmaceutical business in Malaysia is shown in Figure 3. Drugs imported by the multinational corporations, agents and distributors as well as drugs produced by local manufacturers are distributed to dispensing doctors, retail outlets and hospitals About 45% of the total drugs marketed in Malaysia are sold to dispensing doctors i.e. general practitioners and specialists, 25% to retail outlets and 30% to hospitals. Retail outlets comprise of three categories. They are : a) Subdistributors (13%) who may be wholesalers-cum-retail pharmacies or distribution houses such as Harpers and East Asiatic Corporation. b) Pharmacies (10%) such as Guardian Pharmacy, George Town Chemist, Apex Pharmacy and Pharmacare which sell directly to the end user,

Figure 3 : Flow of Pharmaceutical Business in Malaysia




Source : IMS Audit 1994, IMS International

i.e. the patient and c) Chinese Medical Halls, which number 2455 in Malaysia in 1994, supermarkets, sundry, grocery outlets and minimarkets. Hospitals include government hospitals and private hospitals such as Subang Medical Centre and Pantai Medical Centre. Although the final end user in the distribution chain is the patient, the purchasing decision in a dispensing market would solely depend on the doctor who is the primary purchaser and prescriber. The total drug bills of

doctors in terms of volume comprises about 90% generic medicines and 10% innovative drugs. And purchase decisions have been solely on price given that the doctors consider all products manufactured have the same quality and are registered by the Drug Control Authority.

Competition

In Malaysia, there are more than 200 pharmaceutical organisations involved in the sale or marketing of drugs in the different therapeutic categories. Competitive strategies include pricing policies, product promotion and creative advertising. There is intense competition amongst multinational corporations only in a few therapeutic segments rather than the entire product category. Table 2 illustrate the product portfolio of multinational companies and the therapeutic segments that they are active in.

Products marketed by the Research and Development companies for which patents have expired, would fall into the hands of the generic manufacturers. Competition then starts among these manufacturers and the one who is the first to launch the product is able to capture a major portion of the sales volume and market share provided a good pricing strategy is adopted.

Local manufacturers achieve a larger market share than the multinational companies due to their better coverage, more adequate field force, wider

product range, better service, better credit facilities, speedier product development and lower prices.

Table 2 : Product Portfolios of Multinational Pharmaceutical Organisations in Malaysia.

| NAME OF THE COMPANY | NO. OF PRODUCTS | MAJOR THERAPEUTIC SEGMENTS/PRODUCT |
|---|---|---|
| Glaxo | 30 | Gastrointestinal (Zantac)<br>Respiratory (Ventolin) |
| Bristol Meyer Squibbs | 33 | Cardiovascular(Capoten) |
| Pfizer | 18 | Anti-infectives (Zithromax, Vibramycin, Unasyn, Trosyd & Cefobid) |
| Roche | 37 | CNS (Librium, Dormicum & Valium |
| Upjohn | 30 | Hormones (Depo-Medrol, Depo Provera & Dalacin-C)<br>Central Nervous System (Xanax) |
| Wellcome | 33 | Anti-infective (Zovirax & Septrin)<br>Respiratory (Actifed & Sudafed) |
| Zeneca | 22 | Anti-infective (Hibitane & Fulcin)<br>Cardiovascular (Tenormin) |

Products by multinational organisations that have gained a large market share are due to the high level of promotional expenditure of 25-30% of the sales, allocated during the initial launch of the product. Success of an innovative product also depends on prescription by the key opinion leaders - the specialists and the general practitioners in the government hospitals and the

private sector. Although pricing flexibility has been the major advantage for most of the multinational corporations, generics do not enjoy such an advantage as their success has been attributed primarily to low pricing strategy. Most countries have some form of price-controls, whereas, Malaysia hitherto has been free of price-controls

The major challenges constantly faced by local manufacturers are tougher and regular inspections by regulatory authorities for Licensing of manufacturing premises certifying GMP (Good manufacturing practices), storage facilities certifying GLP (Good laboratory practices) and post-registration market surveillance programme to ensure that products conform to specifications submitted to the authority. In addition being a dispensing pharmaceutical market, total prescriptions for products are difficult to assess, inward looking pharmaceutical companies who do not share information makes statistics of product sales volume and value, annual turnover and market intelligence unavailable. Thus strategic planning and decision making becomes a difficult process for the top management.