

CHAPTER 2

PHARMACEUTICAL CLASSIFICATIONS

2.1 INTRODUCTION

This chapter covers the different classification systems used by the pharmaceutical manufacturing sector to describe its market, products and clients.

The Pharmaceutical Manufacturing Industry is essentially a part of the Chemical Industry which can be subdivided into Upstream Basic and Fine Chemical Industries. The Upstream Basic Chemical Industry produces large tonnage's of product. The Fine Chemical Industry produces smaller volumes of higher priced products such as dyes and pharmaceuticals.

Act 101 of 1965 and The World Health Organisation (WHO) defines a drug or pharmaceutical preparation (a medicine) as:

“any substance or mixture of substances manufactured, sold, offered for sale, or represented for use in ... the diagnosis, treatment, mitigation, or prevention of disease, abnormal physical state or the symptoms thereof in man or animal; {and for use in} ... restoring, correcting or modifying organic functions in man or animal”.

This would include the distribution of medicines in finished form such as ointments, capsules, tablets, liquids etc. This study concerned only medicines manufactured for human consumption.

The new South African Medicines and Medical Services Regulatory Authority Act (Act No. 132 of 1998) stipulates control of orthodox medicines, complementary medicines, veterinary medicines, devices and scheduled substances. The controls of these products are based upon seven schedules (i.e. from 0 to 6). However, this act is not yet promulgated, and it can take some years before this will happen. This results in ACT 101 still being enforced. **SAMMDRA is still under consideration and may differ from the original Act/Bill. For the purposes of this report Act 101 of 1965 will be taken as the controlling legislation**

but where issues arise relevant to the impending SAMMDRA Act reference will be made in brackets to Act 132 of 1998.

2.2 CLASSIFICATION OF PHARMACEUTICALS BY MARKET

Medicines for human consumption can be classified in different ways, as shown in the table below:

Product Identification	Generics	Branded		
		Non-Patent		Patent
Over the counter (unscheduled and schedules 1 and 2) ^{@@@}	A	Ba	B	Bb
Prescriptions (schedules 3 to 7)	C	Da	D	Db

^{@@@} Refers Act 132, 1998. Act 101 of 1965 which makes provision for schedule 1 - 2 and unscheduled medicines as far as OTC is concerned, and prescription medicines are scheduled from schedule 3-7.

KEY

- A = Generic proprietaries, vitamins, etc.
- B = Branded proprietaries
- Ba = Non-patented branded proprietaries (multi-sourced branded products)
- Bb = Patented branded proprietaries
- C = Unbranded prescription medicines (ethicals)
- D = Branded or true prescription medicines
- Da = Non-patented branded prescription medicines
- Db = Patented branded ethicals
- A + B = Over the counter products for self-medication
- C + D = Prescription medicines
- A + C = Generic medicines
- B + D = Branded medicines

In turn, the terms used in the key above need to be described and are as follows:

OFFICIAL NAME: Name of medicine as it appears in the Pharmacopiea.

GENERIC MEDICINES: Medicines that are identified by a descriptive or official name, as opposed to branded medicines. These types of medicines are mainly of value in the tender market. Pre-packed generics sold in the private sector are usually branded (in the South African context all of these products have to be branded for purposes of registration and is therefore referred to as **multi-sourced branded** products), while bulk packs are sold as true generics by their official name (i.e. paracetamol BP). Generic medicines are sold under branded names. They are not sold under an official name.

BRANDED MEDICINES: Medicines that are identified by a trade name. Aspro, for example, is a trade name for acetylsalicylic acid (the generic name).

PATENTED MEDICINES: Medicines whose sale is protected by patent rights.

OTC'S (OVER THE COUNTER): These are medicines used for self-medication purposes up to Schedule 2 (Act 101) and can be sold without a doctor's prescription. Certain exceptions exist where up to Schedule 4 can also be sold without prescription

PRESCRIPTION MEDICINE: Medicines that may only be supplied to the public on prescription, i.e. Schedule 3 to 7 of Act 101 (Schedule 2 to 6 of Act No. 132 of 1998)

PROPRIETARY MEDICINES: Proprietary medicines are defined as pre-packaged medicines intended for self-medication, which are manufactured, packaged and labelled in accordance with the requirements of the registration authority in the country of distribution and are marketed directly to the consumer. Proprietary medicines should not be confused with home remedies. Registration of certain products is not always required in SA.

ETHICAL MEDICINES: These are basically branded prescription medicines.

The classification system used in the South African Medicines and Related Substances Control Act No. 101 of 1965 categorises medical preparations as either scheduled or unscheduled. Scheduled medicines are further classified into nine subdivisions. Medicines

in Schedules 1 to 7 may only have been obtained from a pharmacist or medical practitioner under conditions laid down by the Act.

Companies in the Industry are usually depicted as either ethical or OTC manufacturers depending on the type of markets they service, i.e. prescription or OTC medicines. Some companies service both sectors.

2.3 CLASSIFICATION OF PHARMACEUTICALS BY METHOD OF PRODUCTION

The pharmaceutical manufacturing industry in the international context and from a production viewpoint (technological criterion) performs the following manufacturing and processing activities:

Bulk manufacture of synthetic organic chemicals, such as vitamins, antihistamines, diuretics and sulphonamides (chemical process). This process is known in South Africa as fine chemical manufacturing.

Bulk manufacture of antibiotics by fermentation, synthesis, or both, which are normally made by the culture of micro-organisms, followed by their extraction and purification (biological process).

Preparation of sera and vaccines by microorganism culture and the extraction and purification of the antibodies or antigens that are formed (biological process).

Production (from naturally occurring animal or vegetable sources) of medicines such as insulin, hormones and alkaloids (originally a biological process, but presently mainly a chemical process).

Processing of bulk medicines into finished forms such as tablets, capsules and ointments. This represents the pharmaceutical manufacturing industry in South Africa.

Production of sterile products such as small and large volume parenterals. This also represents the pharmaceutical manufacturing industry in South Africa.

Two broad aspects of the production of pharmaceuticals have an important bearing on the Industry's structure. Firstly, similarities of production technology provide an incentive for links between pharmaceutical companies and those in other industries, or between

pharmaceutical companies in different sectors of the Industry. Secondly, economies of scale in production affect both the number and size of firms in the Industry.

To consider the importance of these factors it is necessary to recognise the difference between the manufacture of *pharmaceutical chemicals* and *pharmaceutical preparations*, i.e. medicines. The first (manufacture of pharmaceutical chemicals) involves the manufacture of the active ingredients in a chemical plant and is closely similar to - indeed can be considered part of - the fine chemical industry which also covers chemicals for such products as dyes and pesticides. The second (manufacture of pharmaceutical preparations) is primarily concerned with the physical operations required to produce medicines in marketable form : for example, compounding and dispersion of ingredients, granulation, drying, tableting and packaging. Such operations are less akin to those of chemical manufacture than they are to the formulation of certain other chemical-based products such as toiletries.

Although less capital-intensive than some sectors of the Chemical Industry the production of pharmaceutical chemicals, usually by batch processing, is characterised by some economies of scale. For many pharmaceutical chemicals it is possible to employ multi-purpose plants but for others, such as synthetic hormones, special expertise and ancillary plants are required. These factors taken in relation to demand (which for some of today's patent medicines is very small in volume terms, even according to world-wide sales) leads to the concentration of manufacture in a limited number of units in an international context.

Production of pharmaceutical chemicals is undertaken mainly by the larger pharmaceutical companies and by the manufacturers of fine chemicals. These operations, being clearly related to the Chemical Industry, provide a natural means of entry by chemical companies into the Pharmaceutical Industry.

The smaller pharmaceutical companies mainly buy their active ingredients. Economies of scale constitute an obstacle to these companies. Other important obstacles are the substantial working capital required to finance the multi-stage synthesis of high-value pharmaceutical fine chemicals, and the considerable research and development work required to produce new medicines.

Size is less important for producers of pharmaceutical preparations. As a result, the smaller companies in the industry have so far been able to maintain a viable existence by concentrating on pharmaceutical manufacturing of standard prescription medicines (non-patent brands) or OTC products (requiring a relatively low level of research and development and advertising expenditure) or by licensed manufacture of speciality products developed by other manufacturers.

2.4 CLASSIFICATION OF PHARMACEUTICALS BY PHARMACEUTICAL CRITERIA

Medicines can be classified in one of three ways:

- by chemical group, e.g. alkaloids;
- pharmacologically, i.e. the way they work in the body; and
- according to their therapeutic uses.

The general classification used is the MIMS Pharmacological Classification (Ref 2). The categories are accordingly to Regulation 52, Pharmacological Classification Pertaining to Orthodox Medicines, of Act 101 of 1965. An abbreviated list of the MIMS classification is provided below, with a full list appended

ABBREVIATED MIMS PHARMACOLOGICAL CLASSIFICATION

<u>Class</u>	<u>Description</u>
1.	CENTRAL NERVOUS SYSTEM-
2.	ANAESTHETICS
3.	ANALGESICS
4.	MUSCULO-SKELETAL AGENTS
5.	AUTONOMIC
6.	AUTACOIDS
7.	CARDIOVASCULAR AGENTS
8.	BLOOD AND HAEMOPOEITIC
9.	ALCOHOLISM
10.	RESPIRATORY SYSTEM
11.	EAR, NOSE AND THROAT
12.	GASTRO-INTESTINAL TRACT

13. ANTHELMINTICS
14. DERMATOLOGICALS
15. OPHTHALMICS
16. URINARY SYSTEM
17. GENITAL SYSTEM
18. ANTI-MICROBIALS (SYSTEMIC)
19. ENDOCRINE AGENTS
20. VITAMINS, TONICS, MINERALS AND ELECTROLYTES
21. AMINO-ACIDS
22. SPECIAL FOODS
23. CYTOSTATIC AGENTS (see also 19.6.3, 19.8)
24. IMMUNOLOGICALS
25. CHELATING AGENTS, ION EXCHANGE PREPARATIONS
26. BIOLOGICALS
27. ENZYMES (see also 8.3, 12.1)
28. POISON ANTIDOTES
29. OTHERS

2.5 CLASSIFICATION BY MATERIALS USED

Pharmaceutical raw materials may be plant, animal, or other biological products; inorganic elements and compounds; or organic compounds. An important distinction is that between synthetic chemical substances and natural materials of animal, vegetable and micro-biological origin. Another important distinction is that between active and inactive ingredients. Active ingredients are those substances that effect the desired cure, in other words they are active therapeutically. Inactive ingredients, also called excipients, include preservatives, dilutents, stabilisers, etc.

Packaging materials (bottles, vials, cartons, blister packs, plastic containers, aerosol cans, etc.) are important raw materials for the pharmaceutical manufacturing industry.

Whilst the pharmaceutical manufacturing industry's different market sectors - prescription medicines, OTC's, and animal health products - are fairly distinct from one another, in general they require similar raw materials. This has facilitated market sector diversification by companies within the industry.