

CHAPTER 1

INTRODUCTION & BACKGROUND TO STUDY

1.1 INTRODUCTION

This chapter covers the background to the Pharmaceutical Manufacturing Sector Study, the scope of the study and approach used, and the project arrangements

The global pharmaceutical industry is going through a period of unprecedented restructuring. This is most evident in mergers between research based multinationals (e.g. Glaxo & Wellcome and Sandoz & Ciba Geigy {the latter pair forming Novartis}, as well as many more). The latest development is the mega-merger between Glaxo Wellcome and SmithKline Beecham. These have been driven to a large extent by the need to cut the costs of product research and development, marketing and production. Of equal importance is the increasing role of non-research based companies, which focus on the production of off patent (generic) drugs, in supplying pharmaceutical markets. A large number of blockbuster drugs will come off patent in the next few years, providing a greater range of products for these companies to supply.

Against this backdrop of global restructuring, domestic pharmaceutical companies have had to adapt to a completely re-oriented market environment, shaped by the Department of Health's policy focus on cost effective primary health care, as well as significantly intensified competition from imports, brought about partially by the total removal of tariff protection on finished pharmaceutical products in the early 1990's. There has also been in recent years a changing legislative environment which has been strongly impacting both manufacturing and distribution of medicines.

This new environment clearly presents major opportunities and threats for domestic manufacturers. In response to this, the Fund for Research into Industrial Development Growth and Equity (FRIDGE), and the Chamber of NEDLAC initiated a study into pharmaceutical manufacturing in South Africa in 1999, with specific emphasis on the

Generics sub-sector of the industry but not, however, excluding the broader industry and including patented and/or branded products. The stated objectives of the study were to:

- Establish the drivers of competitiveness in the market for generic pharmaceuticals, pinpointing relative strengths and weaknesses of domestic manufacturers, and thereby opportunities and threats which could affect the competitive performance of the local industry;
- Propose collective and individual actions by labour, government, industry associations and individual companies to address the competitive issues identified in the course of the study; and
- Build capacity and co-operation between stakeholders in the pharmaceutical sector.

In addition, it was agreed during the course of the study that it was critical to identify specific categories in the off-patent or generic pharmaceutical sector where competitive manufacturing could be stimulated pro-actively, with a specific focus on the Essential Drugs List (EDL);

1.2 SCOPE

There are numerous steps in the process of producing and distributing pharmaceuticals. Many terms, which hold different meanings for different groups, are used to describe these steps. To ensure that there is clarity on the scope of the study some definitions of pharmaceutical manufacturing are described below, followed by a description of the scope which the study was to cover.

The South African Medicines and Medical Devices Regulatory Act of 1998 (SAMMDRA Act) defines “manufacture” as:

All operations, including purchasing of material, processing, production, packaging, quality control, release and storage of medicinal products and related control.

The Standard Industrial Classification of all Economic Activities (SIC) used by Statistics South Africa in gathering economic data classifies pharmaceutical manufacturing under code 3353 with the description:

Manufacture of pharmaceuticals, medicinal chemicals and botanical products.

The Customs and Excise Tariff classifies pharmaceutical imports and exports under 3 separate Chapter headings:

- I. Chemically defined inorganic chemicals (chapter 28);
- II. Chemically defined organic chemicals (chapter 29); and
- III. Pharmaceutical products (chapter 30).

The study was to be conducted into pharmaceutical manufacturing as defined in the SAMMDRA Act but excluding production of chemically defined raw materials and focussed on the manufacture of generic (“off patent”) products. The study would thus not include production of Active Pharmaceutical Ingredients (APIs) although the strong inter-relationship between this manufacturing activity and the manufacture of complete drugs as listed in the EDL could not be ignored.

1.3 APPROACH

The study included:

- I. A brief literature survey, covering trends and developments in the global and local pharmaceutical industry;
- II. A sample survey of manufacturing companies;
- III. The acquisition of international data for product benchmarking; and
- IV. The identification of growth and development opportunities for the domestic manufacture of pharmaceuticals.

The terms of reference for the study were compiled by the Department of Trade and Industry’s Chemical Directorate in consultation with major industry associations and unions in the pharmaceutical sector, as well as the Industrial Development Corporation (IDC), the Department of Health and the Pharmacy Council. The study was managed by a Counterpart group drawn from these groups of stakeholders (labour, industry, government) in line with

the approach of the National Economic Development and Labour Council (NEDLAC), the manager of FRIDGE.

Labat Africa and Chemical Marketing and Consulting Services were appointed to conduct the study. Their proposed method of approach to the study was to take cognisance of the structure of the pharmaceutical market and industry, specifically pertaining to the generics sub-sector. Although the term “generics” generally refers to off-patent medicines, it should be realised that there is also a distinction between prescription medicines and so called OTC (Over The Counter) drugs. The marketing issues between these two categories differ greatly and thus had to be addressed separately.

1.4 GLOSSARY OF TERMS

This report uses a large number of terms and has provided definitions wherever possible. However, for the ease of use of the reader, a consolidated glossary of key terms is given at this early point in the report.

GLOSSARY

Drug or pharmaceutical preparation (a medicine)	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..
Pharmaceutical manufacture	All operations, including purchasing of material, processing, production, packaging, quality control, release and storage of medicinal products and related control
Generic Medicine	Medicines that are identified by a descriptive or official name, as opposed to branded medicines
Branded Medicines	Medicines that are identified by a trade name
Patented Medicines	Medicines whose sale is protected by patent rights.
Over the Counter (OTC) Medicines	Medicines used for self-medication purposes up to Schedule 2 (Act 101) and can be sold without a doctor's prescription
Prescription Medicines	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	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.
Ethical Medicines	Branded prescription medicine
Pharmaceutical chemicals	Production 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
Pharmaceutical preparations	primarily concerned with the physical operations required to produce medicines in marketable form
Active Ingredients	Those substances that effect the desired cure, in other words they are active therapeutically
Inactive Ingredients	Also called excipients, and includes preservatives, diluents, stabilisers, etc
Innovator Drug	A drug that receives a patent on its chemical formulation or manufacturing process, obtains approval from the FDA or any regulatory authority after extensive testing, and is sold under a brand name.
Breakthrough Drug	The first brand name drug to use a particular therapeutic mechanism - that is, to use a particular method of treating a given disease.
Me-Too Drug	A brand-name drug that uses the same therapeutic mechanism as a breakthrough drug and therefore competes with it directly.
Single-Source Drug	A brand-name drug that is still under patent and thus is usually available from only one manufacturer.
Multiple-Source Drug	A drug available in both brand name and generic versions from a variety of manufacturers.
Official Name	Name of medicine as it appears in the Pharmacopoeia.