

## **CHAPTER 8**

### **EXPORT DEVELOPMENT**

#### **8.1 INTRODUCTION**

This chapter provides background information on export development for the generic pharmaceutical manufacturing sector, as it has become apparent from the study that there is a close correlation between successful pharmaceutical exporting and a competitive and sustainable local manufacturing base.

#### **8.2 APPROACH**

The focus of this project is on the formulation of pharmaceutical end-products, rather than the chemical synthesis of pharmaceutical active ingredients (API's). However, it is clear that there is close interaction between API synthesis and formulation, especially in the generics sector. The development of export-focused generics formulation sub-sector within the pharmaceutical industry would be dependent upon the establishment of a competitive base in the local market first. In other words, it will be difficult to become successful in exports until the negative aspects identified by this study have been addressed and improved. In addition, it will be necessary to evaluate the viability of integrated API production on a competitive basis. However, it is possible to evaluate the conditions and strategies required for a successful export focus for specifically generic pharmaceuticals.

A case study based on the experiences of the successful export-based Indian Company Ranbaxy is available. The Managing Director of Ranbaxy, D. S. Brar had published an article in Chemical Management Review, dated November/December 1999. This article provides a background on strategies available to generic pharmaceutical producers to develop international business.

A summary of this article is provided below, as well as conclusions regarding the relevance for the South African generic industry.

### 8.3 CHARACTERISTICS OF THE GLOBAL GENERIC MEDICINES INDUSTRY

Historically the overall pharmaceutical industry has not been highly exposed to new entrants, due to highly localised competition and fragmentation. Suppliers did not have much bargaining power due to backward integration, and buyers could not influence the industry due to the lack of generic alternatives. This resulted in a state of continuous growth, little competitive rivalry, high brand loyalty and weak generic penetration.

This situation is drastically changing. Major mergers between multinational companies are the order of the day, driven by the need to achieve economies of scale, as well as to rationalise excess production and high cost research and development capacities.

The influences of buyers are increasing due to buying pressures created by the healthcare sector. Supplier influence is also increasing, as is competition from substitutes. This situation created a major trend towards generic substitution globally. This broadening in generic demand calls for generics suppliers to cope with increasing diversity of cultural and social requirements, caused by a broader customer base. Increasingly more stringent regulatory requirements also limits generics producers to source from various suppliers.

Global healthcare cost was estimated at 2,3 trillion US dollars in 1997, with nearly a half of that (\$1,1 trillion) spent in the USA (*OECD Health Data, 1999*). Expenditure on pharmaceuticals (\$ 300 billion) contribute less than 15% to the total figure. In South Africa the total public healthcare budget is around R 23 billion, of which only R 2 billion (less than 10%) is spent on medicines. Despite this relatively low share, it appears, that a general attitude of governments and healthcare providers is to focus the cost-containment policies on the reduction of the bill on pharmaceuticals. Methods employed include:

- ✧ price control by governments (among others: in North America - Canada and Mexico, in Europe - the UK, Switzerland, the Netherlands, Italy and Spain; in Asia - Japan, India and China; in Australasia - Australia). USA is a notable exception from price control policy.

- ✧ legislating compulsory generic prescribing (in Europe - in Denmark, in South America - in Mexico).
- ✧ use of formularies by Health Maintenance Organisations (HMOs), (a prevalent practice in the USA),

The generic market is estimated to account for nearly 50% of all prescriptions, globally. In the UK, generic prescribing accounted for over 60% of all prescriptions in 1997 (*Scrip* 2355, 24 July 1998)

Globally, the generics' sector is benefiting from favourable governmental policies and legislation. These include: the Bolar exemption and the Waxman-Hatch Act in the USA, which allow development work on generic copies before the expiry of a patent. The US law even allows a generic company to make several trial production runs at a commercial scale, which are needed to qualify for marketing authorisation.

A large generics' industry developed in Canada, benefiting from a system of compulsory licensing. This system was seen by the Canadian government as a method of controlling the cost of drugs, by allowing cost-saving generic drugs onto the market after the innovator companies had received a fair period of market exclusivity. It also helped to foster the growth of the domestic pharmaceutical industry. After Canada became member of NAFTA, compulsory licensing was eliminated by Bill C-91 which came into force on 15 February 1993.

Under the current Canadian patent law, generic manufacturers are allowed not only to conduct development work before a patent expires, without the consent of a patent-holder, but also to manufacture and stockpile commercial quantities of an product (the provision for stockpiling was contested by the USA and the EU, as non-compliant with GATT/TRIPS, and was subsequently ruled as illegal).

As a result of the above-mentioned regulations, a generic equivalent can start competing with the original (innovator's) drug almost immediately after the patent has expired. It is visible in years when none, or a few, of "blockbuster" drug patents' expire. Sales and revenues of

generic manufacturers stagnate as a result of fierce competition and rapidly falling prices of drugs which came off-patent earlier. Such depression occurred in the USA during the period 1996-1997.

Harmonisation of the legislation and regulations of medicines are in the interest of the generics' industry. This include the formation of the International Generic Pharmaceutical Alliance (IGPA), in March 1997. The funding members were: The European Generic Medicines' Association (EGA), three US associations (the National Association of Pharmaceutical Manufacturers (NAPM), the National Pharmaceutical Association (NPA) and the US Generic Pharmaceutical Industry Association) and the Canadian Drug Manufacturers Association (CDMA).

#### **8.4 CRITICAL SUCCESS FACTORS FOR GLOBAL GENERICS COMPETITION**

According to Ranbaxy, the drivers that will determine the success of a generics company in the International Market are:

- ✧ **PRODUCT RANGE:** Need to have breadth and depth in product portfolio; Wide therapeutic coverage.
- ✧ **BRAND RECOGNITION:** Effective detailing through a network of field representatives in each market covered; Strategic and efficient channel management; Being first.
- ✧ **ACCESS TO RAW MATERIALS:** Backward integration for strategic control; Strong supplier arrangements; Source with regulatory cover at low costs.
- ✧ **TECHNICAL CAPABILITIES:** Process development skills; Rapid ramp-up of products; Innovative products and/or delivery systems; Sound technical management.
- ✧ **FLEXIBLE PRODUCTION SYSTEMS:** Leveraging capacities to customise production plans; Location advantages.
- ✧ **REGULATORY EXPERTISE:** Experience spread around various markets; Strong compliance/conformance mechanisms.

## **8.5 STRATEGIC MODELS AVAILABLE TO INTERNATIONAL GENERICS COMPANIES**

There are broadly speaking four categories of positioning models available for generics companies competing in the International Market:

### **8.5.1 BRAND DEVELOPER**

Aggressive sales and marketing with a high focus on promotion in order to establish access to prescribers and the distribution channel. The focus is on differentiation with high sales and marketing costs.

### **8.5.2 SPECIALIST/NICHE INNOVATOR**

Offer difficult to manufacture or high value-added products. The focus is on a narrow, research-based product line. Selective products/formulation. This implicates higher technology and clinical research costs.

Licensing by a generic company from the originator company before the patent's expiry: Usually production / sales are restricted to areas less attractive to the innovator company. While this initially may not be profitable for the licensee, he gains a significant advantage over its generic competitors during the first critical months after the drug comes off-patent.

### **8.5.3 BROAD LINE GENERIC SUPPLIER**

Offer wide range of products to provide customer base with "complete" generics product range. The focus is on scope economies, with a portfolio/basket approach, resulting in complex logistics. Could utilise franchised sales force.

### **8.5.4 CONTRACT SUPPLIER**

Become preferred supplier to large companies. Volume led operations striving for cost leadership. The focus is on scale economies, low and thin margins, absence of sales and marketing infrastructure and the ability to customise production per buyer needs.

## **8.6 RANBAXY'S APPROACH TO INTERNATIONAL GENERIC COMPETITION**

Ranbaxy Laboratories is the largest Indian owned pharmaceutical company. They have been successful in developing export markets to the extent that they are selling in forty-five countries, and manufacturing in six. As a case study, it is of interest to analyse Ranbaxy's approach to International generics competition. They have developed a multi-pronged approach, which is more or less a hybrid of the available basic strategic models.

All Ranbaxy's processes for products exported to the US hold FDA accreditation's. With sales estimated at US\$ 435 m per year (1997 data) Ranbaxy is among the world's 10 largest generic manufacturers.

Their approach focuses on four key aspects:

- ❖ Multiple markets
- ❖ Brand development
- ❖ Research and development
- ❖ Backward integration

### **8.6.1 MULTIPLE MARKETS**

Ranbaxy identified that completely new demand structure are developing through expanding health care systems, increased government focus on facilities and increased government purchasing power. These developments are creating the potential for developing economies such as China, India, Russia and Brazil to become the major markets of the future, with a high generics focus. Ranbaxy therefore used acquisitions, strategic alliances and supply arrangements to establish themselves in these markets.

### **8.6.2 BRAND DEVELOPMENT**

Ranbaxy developed a focus on brand development as a means of differentiation in a fiercely competitive home market. Brand development is based upon marketing, process technology, innovative drug delivery systems, line extensions and improved dosage requirements. Ranbaxy is developing a range of global brands over a wide range of therapeutic categories. Ranbaxy uses focussed sales and marketing teams for specific therapeutic classes. Ranbaxy brands through it's own sales and marketing teams in twenty-six of the countries they operate in.

### **8.6.3 BACKWARD INTEGRATION**

Backward integration gives Ranbaxy strategic control over key raw materials, which is key to global brands. They manufacture thirty actives and are adding 3-4 annually. Backward integration provides a way to reduce costs but also achieve greater efficiency in research and development and manufacturing. It creates a strong skill base in chemistry and chemical processing. In addition backward integration assist in overcoming regulatory hurdles in the supply chain, especially when supplying to developed markets. The ability to sell actives globally also provided Ranbaxy with an entry-point into export markets, to be followed by sales of value-added end-products.

### **8.6.4 RESEARCH AND DEVELOPMENT**

Ranbaxy used it's strategy of brand building to focus on new drug delivery products from a Research and development point of view. From this base, research and development has now developed to encompass:

- Pharmaceutical development
- Drug delivery
- Chemical synthesis
- Fermentation / biochemistry

Ranbaxy is one of the few generics focused companies, which has successfully developed a product development strategy, which includes new chemical entities. New chemical entities have traditionally been the domain of the multinational patent-based companies.

## **8.7 IMPLICATIONS FOR THE SOUTH AFRICAN GENERIC PHARMACEUTICAL SECTOR**

The Ranbaxy model identifies a number of critical areas for the South African generics pharmaceutical sector to reposition itself as an export-focused sector:

- ✧ Firstly, there is clearly a need for South African products to obtain a foothold in high-growth potential export markets. Ranbaxy clearly indicates its intent in these markets by means of joint ventures, acquisitions, own sales and marketing, etc. It will therefore be necessary for South African producers to identify those export markets which have potential for them, and then to take bold steps to obtain a foothold in them. The opportunity to use South Africa's position in SADC as a mechanism to develop SADC / Africa-based exports must be fully exploited.
- ✧ Secondly, brand focusing as a means of differentiation in an increasingly competitive generics market should be embraced and developed into export markets, with the necessary sales and marketing back-up required by such a brand focus.
- ✧ Thirdly, backward integration is more or less totally neglected by South African producers. The Ranbaxy example indicates that well-defined backwards integration into API production not only provides cost savings for an international generics producer, but also establish key competitive skills in chemistry, processing and compliance.
- ✧ Fourthly, Ranbaxy is defying the conventional wisdom that research and development for New Chemical Entities can only be done by the well-established multinational patent-focused companies. By a means of a dedicated effort on product improvement and differentiation, Ranbaxy has expanded capabilities into the sphere of New

Chemical Entities. It is therefore imperative for South African generics producers to have a major research and development focus on product improvement and differentiation, in order to become competitive exporters. However, developing research and development capabilities offer the opportunity to expand over time into new chemical entities, utilising for example the local base of traditional remedies and the bio-diversity of plant material.

It is interesting to note that the generic pharmaceutical industry in Israel benefited from a local law which enabled companies to obtain compulsory licences under the innovator's patent. Furthermore, under this law, companies could not only manufacture for the domestic market but also for export. An Israeli company, Teva, became the world's second largest generic manufacturer (after the Swiss company Novartis), with global sales estimated at US\$ 875 million in 1997. The provision for compulsory licensing was recently abolished in Israel as it contravened the TRIPS agreement.