

## **CHAPTER 7**

### **SUSTAINABILITY ANALYSIS**

#### **7.1 INTRODUCTION**

Chapter 6 undertook a market attractiveness analysis of the South African pharmaceutical manufacturing industry in order to identify those products that were most in demand by the market. This chapter examines the sustainability of further pharmaceutical manufacturing. Sustainability depends upon the relative competitiveness of the local manufacturing industry, as well as the impact of the external environment upon the industry. This include aspects such as the overall Health Policy, Investment Incentives, image of the industry amongst the Public and investment communities, etc..

#### **7.2 APPROACH**

In order to stimulate further pharmaceutical manufacturing in South Africa it will be necessary to address those areas of competitiveness that the benchmarking exercise has highlighted as problematic. In addition, the external factors impacting negatively onto the industry also needs to be addressed.

The benchmarking exercise highlighted a number of competitiveness issues that are mitigating against further manufacturing. These are discussed under the following topics:

- feedstocks and raw materials
- manufacturing
- marketing and distribution

#### **7.3 RESULTS**

##### **7.3.1 FEEDSTOCK AND RAW MATERIALS ISSUES IMPACTING UPON SUSTAINABLE PHARMACEUTICAL MANUFACTURING**

The benchmarking data indicated that purchasing of raw materials, especially actives, is based upon:

- low order quantities
- poor focus on bulk purchases
- wide fluctuation in product cost per unit

Taking into account that raw materials constitute by far the major cost component to the industry, it is paramount that efficient purchasing systems are employed. Sourcing should be focused on obtaining suitable quality product at the lowest possible cost, rather than buying from a convenience point of view. It is therefore recommended that manufacturers institute a serious effort in evaluating and approving more approved suppliers of raw materials, as well as a focus on minimising costs by evaluating issues such as bulk discounts. Another option would be for manufacturers to evaluate co-operative sourcing of actives in order to negotiate better prices.

It would be costly and difficult to have several active raw material suppliers approved by the Regulatory Authority because of problems in establishing the same quality for material obtained from each supplier and such quality differences could be crucial to the bio-equivalence of the final product. Strategically this would be desirable.

It is further recommended that the industry set up a task team to evaluate purchasing opportunities offered by the global movement towards Internet-based commerce. This option would be easier for commodity excipients, but could also be used for active ingredients

Another raw material aspect which is seriously impacting against the competitiveness of local manufacturing operations is the poor quality standards of packaging materials. It is recommended that the industry in a combined manner take up this issue with the packaging sector in order to develop globally competitive quality standards.

It was found that the majority of actives, as well as many excipients and inerts are being imported by the industry. Although companies indicated that they could import products competitively, it was found that fully integrated Indian manufacturers have distinct price

advantages for end-products. In this regard a focus on a local active manufacturing industry would not necessarily constitute an advantage to the pharmaceutical formulation industry, unless this is conducted in a fully-integrated or co-operative manner to transfer cost advantages to the formulation level. India did not observe patent rights until TRIPS in 1995 and has until the year 2005 to comply. .

API production typically requires multi-step chemical synthesis. Some of these synthesis steps could be utilised to synthesise a variety of different intermediates, which could lead to various API's. Multinational companies are moving strongly towards outsourcing of API's. An option to ensure cost-competitive API production is to explore outsourcing opportunities with multinational companies. A multi-purpose API facility geared towards certain outsourced API's, but also utilising productive capacity for other generic API's could result in cost advantages to the local industry.

### **7.3.2 MANUFACTURING ISSUES IMPACTING UPON SUSTAINABLE PHARMACEUTICAL MANUFACTURING**

There is a global trend by multinational companies to focus on manufacturing at a few, strategically located, so-called "centres of expertise". These centres are large low-cost units, located at logistically well-located areas to service major global markets. South Africa, unfortunately, does not offer an attractive package to multinational companies as a location for these "centres of expertise", and this is subsequently driving a number of plant closures and rationalisation actions by multinational companies in South Africa. The legislative environment, a poor image of the industry, as well as the lack of a sound investment incentive scheme exacerbates this. The lack of drug product formulators is also not an incentive to create API manufacturing abilities for the South African market.

In order to enhance the manufacturing viability for multinational companies in South Africa, these issues have to be addressed. What is of particular interest is a harmonised registration regime for the Southern African Development Community (SADC), as well as the trade advantages within SADC. Where South Africa constitutes less than 1% of the Global

pharmaceutical market, the SADC trade block has the potential to offer manufacturers 3% of the market, based upon population data, not current purchasing power. By a clear focus on this aspect, regional manufacturing should become more viable again.

Another aspect seriously affecting South African operations is the high cost of compliance. There is also a perception that unduly high quality and manufacturing standards are set by bodies such as the FDA and MCA. The fact is that minimum standards for cGMP by the WHO are not dissimilar to these standards. The major issue is that the inspectorates of bodies such as the FDA have extremely stringent approaches, creating the impression that standards are much higher, requiring higher cost of compliance. The high cost is only relevant to those companies intending to supply product in the highly regulated markets. A comment from Fine Chemicals Corporation states that standards set by the regulated market are designed to ensure the safety of a specific drug usage.

Regulatory authorities in different countries tend to enforce manufacturing standards at different levels. It is therefore possible that for relatively similar standards, the cost of compliance can be significantly different between countries.

Other pharmaceutical formulation issues that should be looked at to enhance viability of manufacturing are:

***Production Related:***

- Plants are relatively old with poor efficiencies and high maintenance costs. New investment in plant and equipment is not encouraged due to high financial risk profile of the sector.
- Machine utilisation rates are low, and focus should be placed on achieving large production runs. It would also be advisable to evaluate an enabling model for companies to move towards multi-shift production
- Planned maintenance has a low priority and this should be given a high priority. Availability of spares for old equipment is also a problem.
- A focus on outsourcing and export promotion could lead to production run increases.
- Smaller versatile equipment with a high level of automation should be evaluated.

***Labour Related:***

- High labour turnover as well as rationalisation is causing a loss of skills to the industry. A process to create a “job pool” should be looked at to keep redundant skilled people available to the industry.
- Absenteeism is a problem in the industry, and education programmes should be instituted focusing on this issue.
- Labour productivity can be improved and positive actions such as reward and incentive schemes could be looked at.
- Provision of transport and recreation facilities are lacking in South Africa and could be used to improve labour team spirit.

***Finance Related:***

- Cost of sales, both raw materials and labour are high in South Africa based on information supplied from India.
- Relative high levels of fixed and current assets are required to generate turnover.
- Debtor collection days, especially public and exports, are too long.
- SA companies continue to hold unnecessarily high levels of stock.
- Costs to comply with FDA and MCA standards are high and Government needs to introduce some incentive, as it will add to export potential.

***Business Strategy:***

- Strategic planning by locally-owned companies was found to be focused on short-term budgeting rather than longer term objectives. This is caused partly by the legislative environment as well as poor management of Government purchasing.
- Succession planning specifically at management level is not well exercised.
- Communication at especially lower levels in companies is not good and needs to become more formalised.
- Performance evaluation of both management and workers is regarded as poor, and a need exist to develop (industry-wide) objectives and scientific measurements.

***Business Development:***

- South Africa will not become a competitive base for novel New Chemical Entity development, but existing competitive advantages in regulated clinical trials should be nurtured, in order to entrench and develop associations with innovator multinational companies.
- Local research and development must focus on products with regional importance, such as vaccines.
- With the major emphasis on off-patented or generic drugs, product development must be focused on quicker-to-market times.
- Niche areas of competence for business development should be developed (i.e. formulation, tableting).
- Upstream manufacturing of actives should focus on areas where cost benefits can be transferred to downstream formulators.

### **7.3.3 MARKETING AND LOGISTICAL ISSUES IMPACTING UPON SUSTAINABLE PHARMACEUTICAL MANUFACTURING**

#### ***Government/Legislation***

In South Africa the Government is in an unfortunate position of being accountable for the control of registration process of medicines, the overall health policy framework, as well as the responsibility of being the single biggest customer of industry. A number of serious risk factors for the sustainability of pharmaceutical manufacturing have been identified.

- The registration process for new medicines by the Medicines Control Council (part of the Department of Health) is regarded as unduly long and unappreciative of the commercial sensitivity of time-to-market in the industry. The long registration process is delaying cash flow to companies that have developed products at high cost. In this regard the actual registration cost in many instances is insignificant relative to the opportunity loss in the market place. A serious consideration should be given to improve the efficiency of registrations without increasing patient risk.
- Overall health policy in South Africa is geared towards affordable health care to all people including the poor. Although this policy is admirable from a humanitarian

perspective, the policy focuses efforts on the lowering of the cost of medicines. This ultimately is threatening the profitability of the industry, resulting in the lowering of manufacturing and investment levels. A core focus on generic substitution is perceived to lower cost to the private and public sector. New innovator drugs may result in overall cost savings in terms of total health care cost. For example, a cheaper drug may only be administered under controlled conditions (i.e. in a hospital), whilst a more expensive innovator product may be self-administered at home. Generic substitution removes differentiation as a marketing tool and subsequently commoditises medicines and erodes margins. It is recommended that a greater focus be placed upon the cost structure in the total value adding chain, inclusive of the distribution and retailing pipeline, rather than manufacturing only.

- Due to high relative business risks in the manufacturing of medicines (imported feedstocks, imported cheap competitive end-products, high domestic interest rates, poor market structure, etc.) it is necessary to allow the industry reasonable profit margins or else it will lead to further curtailment of manufacturing activities.
- The Government as the largest single customer through COMED should also address the responsibilities this dominant market position carries with it. The large volumes associated with COMED tenders often dictates production scheduling, and the poor control over planned off-take volumes is seriously affecting production facilities. Payments from State organs are also regarded as poor. COMED should also look at reducing its paying times to the actual official period. The cost to COMED for paying on time could easily be off-set by lower prices which suppliers can offer with secure payment times.
- Due to the tendering system used, companies have difficulty in forward planning, as existing tenders can easily be lost to aggressive competitors. A smoothing out process for tenders, whereby they are awarded over longer periods, and also more evenly spread out between suppliers, should be looked at.

- The relatively small size of the South African local market is a serious constraint for sustainable manufacturing. The Government should take cognisance of this fact in discussing agreements with trade blocs such as SADC and the EC. All efforts should be made to offer the greater SADC market as a whole to manufacturers.
- Current local requirements for labelling are also restraining export promotion, especially to Africa, where different print and packaging runs are required (that normally increase costs).
- This issue could have been addressed more than two years ago when the MCC placed the SEAMRAC\* initiative on hold. Adoption and implementation of the SEAMRAC recommendations would have addressed this problem adequately. It is recommended that the Minister of Health give serious consideration to re-instating SEAMRAC. SEAMRAC is the Southern and Eastern African Medicines Regulatory Authorities Conference which is an attempt to harmonise regulatory requirements between the participating countries to facilitate exports and trade between the member countries. Government wanted to make the SEAMRAC process more inclusive as the body representing all local manufacturers (NAPM) was significantly absent from the process until only recently.

There are further round of TRIPS negotiations upcoming, and it is recommended that the Government take special care in identifying issues which may have a negative impact on South African pharmaceutical producers.

- As was pointed out before, it will be critical for the future development of the pharmaceutical industry to have a viable and growing API manufacturing industry. In this regard COMED tenders could support this issue by providing preference to local raw materials content of raw materials.
- It is also critical for Government to critically access Counter-trade opportunities for the pharmaceutical sector emanating from the Arms and aircraft purchasing for the SANDF and SAA. There are possibilities where certain supplier consortia have pharmaceutical

interests. There are, however, serious reservations from Labour and other parties regarding the true benefits of these measures.

#### **7.3.4 PRIVATE HEALTHCARE SECTOR**

Marketing and selling costs in South Africa are relatively high. This is due to the large number of decision-makers (doctors, specialists, etc.), the large number of pharmaceutical service providers which have to be serviced, as well as general cost of sales. In addition, actual costs for sales representatives are also high (i.e. five times more than in India). A focus should be placed upon these aspects to determine cost saving measures.

Private health care organisations are dominating the prescription sector of the private market, and they are also focusing on achieving cost savings in the sourcing of medicines. These actions can also be expected to place further pressure on the profit margins of manufacturers. It is recommended that E-Commerce solutions should be evaluated to minimise distribution costs. Some attention needs to be given to perverse incentives in the putting together of formularies where listing fees are charged to become a profit centre and little of the savings are actually passed on to the consumer. Perverse incentives are incentives offered to healthcare professionals to encourage them to use a particular medical facility. The term implies a need from the payer for the doctor to either increase the number of patients referred and/or the amount of work per patient. This again highlights the need to look at the costs across the total value-adding chain, rather than only at a manufacturing level.