

CHAPTER 10

CONCLUSIONS AND RECOMMENDATIONS

10.1 INTRODUCTION

What does South Africa need to nurture and develop the locally and foreign owned pharmaceutical industry, and in particular the generic manufacturing sector of this industry? This question needs to be answered first before embarking on an analysis of the problems and opportunities of this industry.

The global pharmaceutical market is approaching \$250 billion, or around twice the South African GDP. This market is growing in volume terms at 7.5% annually, with the generic sector growing at an even faster rate, increasing its relative slice of the pharmaceutical pie continuously (sales value performance has been more varied, with world-wide growth fluctuating between +4 % and -1% in recent years). An industry of this magnitude and potential for future growth should be of interest to any country wishing to develop its industrial base. There are not many, if any, other industrial sectors that have such attractive characteristics and can hold such strong investment potential (particularly if supported by appropriate legislation).

Apart from the general attractiveness of the global pharmaceutical market, South Africa already possesses a well-developed pharmaceutical sector, in particular at the formulation level. This industry thrived in a strongly protected environment and became the largest and most advanced on the African continent.

Globalisation and restructuring in the industry, as well as the meteoric rise of countries such as India (especially in the generic sector), has affected the South African industry severely, slashing employment to half that in the 1980's. The multi-national companies have been particularly visible in the closure of manufacturing operations as part of global strategies. The pharmaceutical industry is a growing employer once again, however, with employment levels increasing at around 2 % p.a. in 1998 and 1999 (due mostly to increases in staff involved in

packaging, sales and marketing, rather than production). Currently the industry produces around R 5 - 6 billion of scheduled pharmaceuticals (mostly from imported APIs) out of a total South African consumption of R8 billion and employs more than 18 000 people. There are around R3 billion imports (1999) of pharmaceutical products in a form ready for retail sales, as well as around R2-2.5 billion imports of API's. Exports of pharmaceuticals were around R420 million in 1998. The overall trade balance for the sector is therefore biased towards imports.

There is clearly a need to ensure the survival of an already significant industrial sector in South Africa, as well as to restructure and refocus the industry to become globally competitive in this exciting, growing business. This scenario briefly sets the background to this study.

The market in South Africa is dominated by multinational companies which account for three-quarters of sales by value. There are 79 manufacturing sites, as well as 4 sites where packaging only is done. The market is highly fragmented, with no one company controlling more than 5% of the total market. However, dominance exists in specific therapeutic categories.

This chapter presents the conclusions and recommendations of the pharmaceutical manufacturing sector study, including recommendations on the way forward. The conclusions have been discussed in terms of the key stakeholders of the sector - Government, Business and Labour. The recommendations are clustered according to main themes arising from the study and are thereafter prioritised in terms of urgency of action.

10.2 VALUE OF THE PHARMACEUTICAL MANUFACTURING SECTOR IN SOUTH AFRICA

International evidence and local experience indicates that the pharmaceutical manufacturing industry in South Africa has the potential to play a considerable role in the development of the economy and society. All stakeholders involved in this study (Government, Labour and

Business) unreservedly support this sector, believing a viable pharmaceutical manufacturing industry can make the following contribution to the country:

- Well managed and resourced pharmaceutical companies, whether locally-owned or multinational, have the opportunity to compete in the supply of pharmaceuticals to a strong, stable and diverse local market, as well as export to the African sub-continent and globally (in the 1995 – 1999 period 78 % of South African pharmaceutical exports were destined for the rest of Africa). Good levels of profitability can be realised and growth can be sustained off a sound platform of infrastructure, skills and resources. Linkages to other sectors and industries deepen the quality and competitiveness of the locally owned generic manufacturing industry and encourage skills and technology transfer;
- A sound and stable sector provides sustainable employment opportunities for large numbers of skilled and semi-skilled workers. Technological advances in the field imply an increasingly more educated workforce with transportable skills and higher standards of living;
- Export markets for high value added pharmaceutical products meeting international regulatory standards provide considerable revenue to South Africa, as well as improving the quality of products for the local market. A diverse and well serviced range of products for the local market enhances public health care, ensuring the poorer sections of the population have an improving quality of life;
- Progressive and pragmatic legislation and well managed regulations provide an environment for sector development and job creation and encourages positive long term investment decisions (as long as there is compliance with TRIPS to which South Africa is a signatory);
- Long-term economic opportunities for the previously disadvantaged are promoted in a sector that is decentralised, linked to the local economy, and technology driven. Particular opportunities for small business development exist in an industry appropriately regulated and characterised by multi-stage processing and widespread outsourcing and contract work. It should be noted that outsourcing and contract work is not supported by organised labour because it is perceived to directly threaten the organisational reach and collective bargaining power of the unions.

10.3 CURRENT STATUS OF PHARMACEUTICAL MANUFACTURING IN SOUTH AFRICA

The key drivers of competitiveness in the South African market for pharmaceuticals (in particular generics) are the:

- Size of the South African market and its composition in terms of public sector and private sector consumption by volume and value
- Sourcing of Active Pharmaceutical Ingredients (APIs) at lowest cost and with highest quality and assurance of supply
- Legislative and regulatory framework for business operation, in particular registration of new products and patent protection; and
- Cost structure of the industry, particularly the composition and relationship of the different parts of the pharmaceutical value chain.

In this regard the domestic manufacturing industry is in the following position:

Size of the South African market and its composition in terms of public sector and private sector consumption by volume and value

The size of the total pharmaceutical market in South Africa is not accurately known but was estimated at around R 8 billion in 1998 at manufacturing level, excluding the manufacture of Active Pharmaceutical Ingredients (APIs). APIs are incorporated in the manufacturing statistics for the chemical sector, while their imports form part of the pharmaceutical sales figure at the manufacturer level. In real terms (excluding inflation) there has been no increase in the market over the past 10 years. This is primarily a function of the overall state of the South African economy, but also somewhat due to the increasing prominence of medical aids that tend to hold prices down in the private market sector. In this regard the actual growth in volumes, or prescriptions, has been positive over the same period.

Between 1990 and 1998, sales at the manufacturer level and household consumption have increased in both nominal and real terms [deflating the series by the CPI or other inflationary index such as PPI]. However when accounted for in real terms, household consumption

growth and sales growth and the manufacturer level have been taking place at considerably lower rates than when the data is examined in nominal terms. An index (with base 1995 = 100) reflecting real household consumption and real manufacturer level sales is presented below to illustrate the case.

Year	Real Pharmaceutical Consumption Index	Real Pharmaceutical Sales Index
1993	66,83	85,15
1994	88,76	86,70
1995	100,00	100,00
1996	106,26	106,26
1997	109,79	106,06
1998	115,80	103,55

The above table clearly shows that pharmaceutical consumption is growing by volume much faster than by value, a consequence of the increased penetration of generic pharmaceuticals into the market. There has also been the impact of increasing efforts by medical aids to hold prices down in the private market sector using co-payments by patients and other techniques.

The South African population stands at 42 million, of whom 62 % earn less than R 1 500 per month. Pharmaceutical consumption per capita per annum is around US\$ 33, considerably higher than the average of US\$ 7.5 for Africa, but only 75 % of the world average of US\$ 44.

The South African market accounted for over 1 % of the world market 10 years ago, but is around 0.6 % of the global market now. Despite this the South African pharmaceutical market is larger than that of most EU Nordic states (when measured at the manufacturer's price level) and makes up about one-third of all pharmaceutical sales in Africa. With the opening up of the South African economy there has been an increase in imported drugs into the market. Wholly imported drugs now account for around 30 % of the local market, up from 15 % ten years ago.

It is assessed that generic pharmaceuticals (in terms of volume) account for more than half of the total market (public and private sector) although accurate figures are not available and definitions of terms vary. Industry believes that more than half of pharmaceuticals by volume in both private and public sector markets are generics (branded and non-branded) but account for only about 20 % by value.

South Africa is a small and not very wealthy market. It has a general inability to achieve economies of scale in production. Production runs are short in South Africa for the local market and the higher unit costs can only be countered through higher output. However, because of poor economic conditions much of the equipment has not been replaced or even particularly well maintained and is unable to deliver this level of production. Over 30 companies have closed plants over the past 5 years due to downsizing/rationalisation/mergers and imports, as well as other cost reasons [such as medicines registration approval times].

The State purchases pharmaceuticals through a medical provisioning system. [The State Tender System] which serves to secure good prices. However this system has had the effect of prompting suppliers to recover public sector bulk discounts through much higher prices to the private sector. The size of public sector orders has also engendered a somewhat boom or bust operation by suppliers – short term planning, poor cost control etc. Medicine purchases by the State account for around 10 % of the total health care budget and was around R 2 billion in 1998. The rate of generic consumption in the public health sector is expected to accelerate due to the impact of the DOH's Essential Drugs List, which mainly lists generics, as well as legislative encouragement of generic substitution.

Sourcing of Active Pharmaceutical Ingredients (APIs) at lowest cost and with highest quality and assurance of supply

APIs are high unit value, downstream chemicals made in small quantities typically using multi-step batch synthesis. Whilst not an absolute pre-condition of competitiveness the study has established that in all cases world-wide where there is a successful **generic** pharmaceutical manufacturing sector, manufacture of **generic** APIs occurs locally and provides competitively priced and regularly supplied product for the downstream industry.

The situation in South Africa is that API manufacture does exist but it is extremely limited and has few linkages with formulated drug manufacturers in the country. South African manufacturing of API's is around US\$ 15 million (around 0.06 % of the global figure of US\$ 25 billion) and only for the generic market. Local manufacturers thus import most of their API requirements. However, whilst the development of the API sector may be desirable for a variety of reasons, the cost of establishment of these facilities is extremely high and investment decisions need to be done on a careful, in-depth evaluation basis.

Legislative and regulatory framework for business operation, in particular registration of new products and patent protection

A predictable and well-managed legislative and regulatory framework is vital for the pharmaceutical industry, as it is a highly regulated industry that has to meet the requirements of a myriad of health, safety, quality and commercial legislation. Particularly important for generic manufacturers are the patent law and the registration process for new products, as this industry is extremely sensitive in terms of time to market for new products. Also important is the removal of tariff protection that has protected South African manufacturers from competition in the past but has now rendered the industry vulnerable in an open globalising market, resulting in escalating imports and local job losses (an issue particularly important to organised labour). South Africa's tariff regime, under pressure from various parties to achieve affordable medicines, is currently below that required by GATT.

South Africa post 1994 has sought to update and modernise key health care legislation to bring it in line with international best practice and ensure delivery of health care services to the public. A 1997 amendment to the original Medicines and Related Substances Control Act No. 101 of 1965 was opposed by the pharmaceutical manufacturing sector around the issues of patent protection/parallel importing, and by the Medicines Control Council around safety. South Africa was for some time placed on a United States Trade Representative [USTR] Watch List of countries where intellectual property rights were deemed to be under threat. Opposition to these South African legislative amendments and other factors led to the establishment of a Task Team that recommended that the MCC should cease to exist and a new regulatory authority be formed. In 1998 a completely new Act, the South African

Medicines and Medical Devices Regulatory Authority Act,[No. 132 of 1998] was introduced, which repealed most of the original Act No. 101 of 1965. However this Act was flawed, having been promulgated without a replacement body for MCC in place, and without new regulations or schedules to replace those in the repealed 1965 Act. Confusion arose and the Act was finally rescinded and the legislation reverted back to Act 101 of 1965, still currently in force.

A related issue is the performance of the Medicines Control Council (MCC), tasked with approval of new drug registrations, as well as control of all aspects of medicines including approval of the sites of medicine manufacture. A fairly rapid turnaround time for new registrations is desirable as:

- Innovator drug companies need to recover their research and development costs as soon as possible, and fully utilise market exclusivity time given to them by patent protection.
- Generic manufacturers need to get their products to market post patent expiry before existing patent holders secure the market with branded derivatives or other competitors remove all the profit (this window of opportunity for generic manufacturers is open for no more than 2 years after expiry of the patent of the patented product)

The current situation is that the MCC has been taking up to 3 years to approve new applications for registration and a considerable backlog has developed. This deviates from the median drug approval times of 20,4 months in the European Union and 11,4 months in the USA in 1998. The situation is alleged to be so bad that local companies are registering new products with US, UK or other registration authorities first and then using this to try and fast track the registration process in South Africa (MCC has a 'fast track' process for products already registered by reputable authorities like the US Food and Drug Administration (FDA)). Slight improvements in the situation have been reported recently, however the net effect has been to increase uncertainty in the sector.

Cost structure of the industry, particularly the composition and relationship of the different parts of the pharmaceutical value chain.

There are a number of elements to the cost structure of the pharmaceutical manufacturing industry that have a direct bearing on competitiveness, as well as on affordability of drugs to

the general public. The first one is the manufacturing cost, including R&D expenditure and multi-national transfer pricing. A second contributory cost factor is the one relating to retailing and distribution costs. A third one is regulatory and compliance costs.

Research and development costs are very considerable in pharmaceutical manufacturing and many products fail to recover their costs of development. R&D costs have risen considerably over the past 20 years and R&D expenditure among major multinational suppliers is estimated to be around 20 % per annum of revenue for the industry. R&D currently is focused on major needs such as Hepatitis B and C (which affect over 600 million people world-wide), as well as lifestyle drugs and improved drug delivery systems (patches, dosages, slow release etc). The extremely high cost of R&D means that it is not viable for South African manufacturers to undertake this, except in areas such as delivery systems and in association/partnership with international pharmaceutical manufacturers. Local manufacture is, and will continue to be, based on production of:

- generics that require no further research and little further development, or
- branded or patented drugs owned by multinational companies with local production and packing facilities.

The situation, however, should not be considered static. Adcock Ingram has planned a R 25 million research facility in the next few years to develop new products for the treatment of tuberculosis.

Considerable debate is occurring around the degree to which manufactured cost determines final selling price. Ex-factory manufacturing prices in South Africa account for ± 50 % of the final consumer price, considerably lower than that of many EU member states. Domestically more than half of the final consumer price of pharmaceuticals is composed of wholesaler and retailer margins and VAT. This results in domestic manufacturers receiving among the world's lowest percentage of the final selling price of medicines. Whatever the view on this, pharmaceutical manufacturing companies (particularly multinational ones) can create an artificial price not reflective of the true cost of production but used to transfer non-recoverable expenses (such as R&D) from one country to another. Transfer pricing issues include artificial price setting between local subsidiaries of multinational concerns and other overseas operations for API's and complete product imports.

The second area is retailing and distribution costs. The pharmaceutical producers do not carry the actual cost of distribution. They are supplying to the wholesale sector that distributes to the final reselling points. These distribution costs are regarded as relatively high in South Africa, and contribute significantly to the final cost of medicines to patients. The issue is also important for this country, as there is a perception that recent legislation has sought to drive down manufactured prices in the interests of public health care and failed to pay sufficient attention to the substantial cost component in the distribution of pharmaceuticals.

Pharmaceutical manufacturers have significant marketing and selling expenses. The pharmaceutical manufacturing sector is extremely competitive and requires vast amounts of product and marketing information be relayed to a huge variety of role-players (e.g. medical professionals, pharmacists, patients) using a broad variety of media. This has led to highly developed marketing policies and practices by many manufacturers that has inevitably increased the cost of this part of the value chain (in the private sector where current legislation precludes manufacturers from using direct to consumer advertising). This is deemed to be particularly the case in South Africa, where these marketing and selling costs in percentage terms are up to 5 times that of India (although in line with similar costs in comparable markets). However, the comparison with figures for India could be misleading since wages are much lower in India.

The last area is cost of compliance. There is certainly a cost to comply with current and impending legislation, as well as the requirements of regulatory authorities. However, what is of greater importance for South Africa as a potential exporter is the cost of compliance with regulations of other countries (such as the US). Minimum standards applied by different national regulatory authorities may not appear to differ very much, however the stringency with which they are applied does differ. The point of this is that the effort and cost to move from 90 % compliance to 95 % is much more than the extra 5 % and may be more like an extra 25 % cost.

10.4 RECOMMENDATIONS

The pharmaceutical manufacturing sector in South Africa is in crisis – declining investment, legislative and regulatory chaos, plant closures. If it is to survive and develop into the kind of sector envisaged earlier all stakeholders must be involved. Positive actions by one particular group, whether Government, Business or Labour, will have little effect in the absence of active support of the other parties. For this reason, the recommendations flowing out of the conclusions are clustered according to themes rather than interest groups. This places responsibility for action to implement recommendations with multi-disciplinary teams not individual parties. This approach is in the spirit of the work done by the Counterpart Group over the period of this project. It also reflects the complexity of this sector.

There are two over-riding dimensions to this study –

- The pharmaceutical manufacturing industry itself, in terms of the value chain by which pharmaceuticals are manufactured, distributed and consumed; and
- The environment in which the industry operates – resources, infrastructure, values, systems

The key components of the pharmaceutical manufacturing value chain are broadly:

- Sourcing
- Production
- Packaging
- Sales & Marketing

The key components of the environment are:

- Research and development
- Legislation & contracts
- Human resources
- Finances
- Organisations

The recommendations emanating from this study are thus discussed under these headings. They will also be classified in terms of degree of urgency, as follows:

- **Urgent** actions that are of the highest priority and justify resources being shifted

- Less urgent actions that are **important** but do not justify resources being moved from other areas
- **Longer term** actions that can be attended to over the course of the next few years.

10.4.1 Value Chain – management and business strategy

- The legislative environment in South Africa, effects of global restructuring as well as issues such as State Tender Board practices have resulted in South African management focusing on short term budgeting, rather than long- term goal setting and objectives. Such short-term focused strategies and tactics are clearly not conducive to the long-term sustainability of the industry. All efforts should be made by all role-players to create a business environment, which would enable management to introduce long-term strategic plans and objectives, essentially through much more consultation and information sharing, as well as public-private partnerships and other mechanisms;
- Succession planning at all levels, and in particular management levels, is not well exercised. It is recommended that industry promote higher levels of succession planning, integrated with their human resource development plans;
- Performance evaluation of both management and workers is regarded as poor. It is recommended that industry-wide objectives and scientific measurement is evaluated.

10.4.2 Value Chain – sourcing

IMPORTANT

- The decline in the value of the Rand and growth in imports makes the pharmaceutical manufacturing sector extremely vulnerable. International evidence is that local API production is a highly important factor in formulator sustainability, particularly in the generic sector. However, there is only one generic API producer in SA with little or no connection to the downstream sector. This study was not focused on API production and it is imperative that opportunities to stimulate the API sector in South Africa are

investigated. This could include establishment of a globally competitive multi-purpose API facility in SA. Such a facility could be geared towards certain outsourced patented APIs as well as off-patented generic APIs. Preferential tendering for local raw materials, tax rebates and other investment incentives can be used to encourage those willing to stimulate production in the local industry.

- Cost and availability of raw materials are major cost factors and particularly problematic for SA. In particular the generic sector is vulnerable to low cost imports from countries such as India. Manufacturers need to minimise these costs by co-operation to obtain bulk discounts. Co-operative purchase of actives from single sources would be desirable. Industry should set up a task team to evaluate opportunities for Internet-based commerce. Manufacturers should look at licensing arrangements to secure raw materials and reduce market entry period for local generic producers without prejudice to patent and trademark owners. Alternatively local producers should have the appropriate environment to build strategic alliances and pursue licensing and joint venture arrangements to act as a catalyst for market access of international firms. This should, however, be closely examined as it can negatively affect direct foreign investment by multinationals.

10.4.3 Value Chain – production

IMPORTANT

- Expansion and restructuring options for the industry involving all parties need to be considered. Options could include private sector driven restructuring, public-private partnerships, or state-led restructuring. Each of these options implies a different driver of investment and provides different restructuring outcomes or scenarios;
- Industry needs to invest in new machinery to become globally competitive and this requires a substantial level of exports, given small local market. As in the car industry, this can only be done by rationalising and limiting production to a few large, competitive and strategically located plants that produce large numbers of standard products. The State should play a supportive role in providing financial infrastructure to encourage this

process but firms that are active in the industry are usually best placed to determine the structure of the market. Such firms are more aware of the market conditions in which they operate and hence are better able to judge what products to produce and which will not be viable;

- Production runs are short and unproductive. It is recommended that possible incentives be evaluated to stimulate longer production runs within operations. Multi-shift production is very limited in the industry, but introducing multi-shifts is not easy due to many problems – travelling at night etc. It is recommended that a valuation of an enabling model for multi-shift introduction is conducted;
- Planned maintenance is currently a low priority. This should be made a much higher priority. Availability of spares for old equipment is also a problem. It is recommended that the possibility of an Internet site for advertising of second-hand equipment and spares is evaluated

10.4.4 Value Chain – finances

- Cost of sales in South Africa, including both raw materials and labour, is relatively high compared to India. A major reason for this is undoubtedly the relatively higher living standards (thus salaries) in South Africa, but is also due to relatively lower levels of productivity (small market size, small production runs, old equipment, high absenteeism etc) in our industry. It is recommended that all efforts be made by industry to become more competitive in this regard;
- Relatively high levels of fixed and current assets are required to generate turnover by South African companies. All efforts should be made to improve productivity of fixed assets, either by introducing more productive new technologies, or by increasing production runs. Wherever possible new technology should be introduced in a manner that enhances work skills, as well as output;

- Costs of compliance with FDA or MCA standards are relatively high. However, such compliance is critical for export development. It is recommended that DTI evaluates incentive options to assist companies to obtain such compliance;
- South African companies are carrying unnecessary levels of stock, while debtors collecting days are also long for both private and public sector sales. These are basic issues for sound business practises, and industry together with the public and private healthcare sectors should work together to improve the situation;
- Shrinkage and distorted demand schedules (particularly prevalent in the public sector - State purchasing, warehousing and distribution) also create problems for proper financial management.
- Improvements in information technology such as electronic management information and inventory systems could correct the majority of problems faced in the public sector.

10.4.5 Value Chain – packaging

IMPORTANT

- Engage packaging sector to improve relative poor quality of packaging materials

10.4.6 Value Chain – sales and marketing

IMPORTANT

- Experience in India by generic manufacturers indicates that the local manufacturers have no option but to obtain a foothold in high growth potential export markets – through associations, joint ventures or acquisitions in such export markets. This requires local firms making the effort to identify those markets and the best ways to position themselves there. Brand focusing as a means of product differentiation is essential. Backward integration into API production would bring cost savings and establish key competitive skills. This could however face problems from Competition Authorities, which could

deem such practices as anti-competitive in nature. Finally, rather than trying to develop New Chemical Entities (NCEs), there are many opportunities in product improvement and differentiation as ways to become competitive exporters. Recent market conduct by Adcock Ingram, Afrox, Aspen and Alliance suggests that major South African pharmaceutical companies are trying to build competitive advantage by means of acting as a catalyst for market access by multinational companies and their products, or to establish themselves as niche developers investing in areas that refine existing medicine.

- Costs may be saved in sales and marketing where these are above international norms, using E-Commerce solutions
- The SA Government should formally commit to participation in the South East African Medicines Regulatory Authorities Conference (SEAMRAC) initiative. This initiative seeks to harmonise the regulatory requirement between participating countries to facilitate trade and export opportunities for South Africa. This conference has been on hold for the last two years awaiting action by the Department of Health to renew South African participation. This would help to overcome the constraint of the small domestic market;

10.4.7 Value Chain – distribution

IMPORTANT

- The distribution and retailing section of the pharmaceutical sector is adding significantly to the final cost of medicines to patients, or healthcare providers in the private sector. Although not directly part of manufacturers cost structure, this is impacting negatively on the sector as a whole. Payment to pharmaceutical service providers should be based upon the level of service provided rather than a percentage mark-up. A range of alternative forms of payment should be considered and allowed to develop as efficiency and demand dictate. Furthermore, all measures related to reducing costs in the distribution pipeline should be supported. The relatively large number of service points (pharmacies,

prescribing doctors, etc.) is also a significant factor in increasing logistical demands and hence higher than original costs.

- It is recommended that an investigation into the limitation of prescription medicine points of supply be instituted. This is not contrary to Government's declared intention of providing more points of supply for medicines in remote rural areas where poor people can receive their required medicines although they do not have transport. The issue is to reduce the excessive number of supply points in the relatively well-supplied urban areas.

10.4.8 Environment – Research and Development

IMPORTANT

- The cost of primary research and development for NCEs is extremely high, mainly due to a high number of products that must be investigated for therapeutic benefit, rather than the specific cost of a singular new entity. In other words, the few successes have to pay for a large number of failures (molecules investigated for potential therapeutic benefit without success). This is a high risk/high return type of investment. This makes it difficult for South Africa to participate in development of NCEs. However, in the area of biochemistry, a number of smaller concerns are doing groundbreaking work, and then selling off good ideas to multinational companies for further development when significant expense occurs (i.e. costly clinical trials). South Africa has a significant biochemical resource base hosted by the academia and the CSIR and this group should explore this possible opportunity. R & D funding could come from tax-based incentives and government grants [being awarded by bodies such as the National Research Foundation] through a less rigid and performance-based process.
- It is recommended that local research must focus on products with regional importance, such as vaccines and AIDS related problems, rather than lifestyle diseases. Currently 78 % of South African pharmaceutical exports go to Africa. Zimbabwe alone accounts for 25 % of the total amount of pharmaceuticals exported, with SADC countries consuming most of the rest.

- Opportunities to capitalise on existing competitive advantages in new product development can be nurtured in order to entrench and develop associations with innovator companies developing NCEs. Opportunities exist for South Africa to become the global source of specified ranges of innovative medicines provided the infrastructure, legal and business environment attract investment. Companies involved in clinical trials should give serious thought to establishing API production facilities for new drugs in South Africa, or to outsource such NCEs to local operations. Related to this is development of niche expertise in products with regional importance such as vaccines, as well as short production run niche products based on local resources.

- It has been shown in the study that generic manufacturers have a critical need to start selling generic substitutes as soon as possible after patent expiry. In this regard it is necessary to promulgate Bolar type legislation (for “springboarding” of generics) in South Africa to assist generic companies to conduct basic process development and bio-equivalence tests before patent expiry.

10.4.9 Environment – Legislation and State Purchases

URGENT

- The legislative disorder has to be addressed as probably the top priority. A new amended SAMMDRA Act must be promulgated as soon as possible with relevant regulations and schedules. This will create stability in the sector and provide the platform upon which to address one of the key bottlenecks for the industry – the long registration times of the Medicines Control Council. An Industry Task Group (ITG) is addressing application backlogs with the Medicines Control Council. Industry expertise and resources has been offered and must be used to alleviate this situation

- If Government deems it appropriate in the context of job creation to retain a degree of protection of the pharmaceutical industry it may reconsider parallel imports (i.e. rescind parallel importing under condition that patent holders manufacture in South Africa) and

use of tariffs. However, the wider implications of this approach in terms of international trade agreements, as well as public health policy, need to be considered as:

- South Africa would be in breach of the TRIPS Agreement to which it is a signatory (thereby weakening confidence in the country in business and political circles); and
- South Africa is a net beneficiary of R & D work done in other countries and therefore contributes to R & D funding.

IMPORTANT

- Allow split tenders, longer periods or other smoothing out processes for COMED to reduce the boom and bust situation of suppliers to the public sector. Address lengthy payment times by provinces to suppliers;
- Allow direct interaction between pharmaceutical dispensing units (hospitals and clinics) and suppliers to overcome problem of poor information feedback via provinces and COMED. Some suppliers are reportedly addressing market issues directly with hospitals and clinics. The improved flow of market information is apparently working to the benefit of both parties;
- In order to stimulate further local manufacturing at API/excipient level as well as formulation, incentives should be instituted to increase local content of both formulation and raw materials. In this regard multinational companies should be able to score 'credits', e.g. preference point for State tenders for products manufactured in South Africa for export into their global markets. A specific issue here is drugs focused on the African market, such as anti-retroviral drugs for AIDS.

10.4.10 Environment – Human Resources

URGENT

- Labour relations in the pharmaceutical industry are regarded as relatively healthy and both labour and management have a grasp of the realities of globalisation. However, they

differ on how this should be addressed and it is recommended that alternatives to deal with the impact of globalisation be considered jointly. It is also necessary to communicate to everyone that globalisation necessitates a high level of competitiveness, as well as an utmost thrust towards excellence;

- Labour turnover is high, and with the large number of plant closures a tremendous number of skilled workers is lost to the industry. It is recommended that a 'labour pool' database be created of jobless, skilled pharmaceutical workers. This pool could be utilised by companies wishing to expand or start-up in South Africa. Labour supports this approach but does not want this to open up extensive atypical employment such as temporary and part-time contracts and would like the labour pool to be for permanent employees.

IMPORTANT

- The global trend in pharmaceutical investment is towards capital-intensive operations. South Africa is in dire need to upgrade and invest in new manufacturing technology, but although this is necessary to become competitive, it will result in relatively few new jobs, or even job losses. It is futile to believe that this technology trend can be ignored in South Africa. It is therefore necessary to focus on development of the labour force to cope with advanced technologies, or to look at multi-skill training of workers, in order to utilise workers from redundant operations in other functions. Development of export markets should be looked in conjunction with the introduction of new technologies, as larger production volumes could counter the need for fewer workers;
- Training in the industry should be harmonised with the standards and institutional arrangements of the Skills Development Act;
- Management and labour unions should be encouraged to support the development of technical skills in production techniques and processes through the Pharmaceutical Production Technology courses run by the Pharmaceutical Manufacturers' Association and accredited by the South African Pharmacy Council.

- Absenteeism and the attendant disruption to production is a major issue from a management point of view although labour does not share that perspective. Management and labour unions should work together to obtain a common approach to this issue;
- Provision of transport and recreation facilities are lacking in South Africa, and could be used to improve quality of life and team spirit.

10.4.11 Environment – Financing

IMPORTANT

- High interest rates, together with the declining value of the Rand, are creating a seriously negative business environment for companies. Imported raw materials account for around half of total cost of production. In addition long payment terms and large stockholding aggravate the financial position of companies. Low levels of exports also alleviate the potential for Rand hedging. Companies can correct for this cost [to their trade volumes] by means of purchasing forward cover to insure their business risk of exchange but is considered expensive. These financial issues, together with all the other negative issues impacting upon the industry, make it difficult for the financial sector to provide capital for upgrading, expansion or new investment. The industry has significant growth potential should it be able to address the problems identified in this study. However, it can be expected that the financial sector will continue to regard the sector as high risk for some time to come. An additional burden will continue to be placed upon state organs such as the IDC to finance investment in this sector, especially by smaller and medium players (it should be realised, however, that the IDC is as concerned with the sustainability and commercial viability of projects as any commercial financial institution). State led industrial planning and active support of the sector by the State may entice more development finance than is presently forthcoming, however the costs and policy consequences of this need to be considered.

- Industrial planning by the State should centre on fostering that legislative and business climate which can generate the finance that the sector needs. This would transfer the cost of financing from the State to the private enterprise, which is better equipped to generate the finance and manage it.

10.4.12 Environment – Organisations

URGENT

- There are two main industry associations, namely the NAPM and PMA, to service the pharmaceutical industry. This is not uncommon worldwide for this sector but is unusual within South African industry. These associations have a good working relationship, although the focus of their membership differs from locally-owned companies (NAPM) to multinationals (PMA). It is, however, of utmost importance that these organisations embrace the issues identified in this study, and work together in implementing recommendations;
- The two leading trade unions in the industry – SACWU and CEPPWAWU – have been working closely together within the research process for this project. A close relationship has been forged which should be consolidated for further dialogue and policy engagement with the industry.

IMPORTANT

- There are a number of other associations and organisations that could have an impact in securing the sustainability of the industry. These include the Chemical and Allied Industries Association (CAIA), in whose ambit API production falls; packaging associations (to address packaging problems); SACOB/other (export promotion and other issues); CSIR (research capabilities, especially in multi-step chemical synthesis and biochemistry); and other. It is recommended that such organisations are actively involved in the way forward to ensure the implementation of all recommendations