

APPENDIX 1

SUMMARY OF GENERAL MANAGEMENT VIEW OF ISSUES IMPACTING NEGATIVELY ON FURTHER MANUFACTURING

INTRODUCTION

This appendix presents the views of interviewees in regard to the future direction of the pharmaceutical manufacturing industry, as captured in interview questionnaires. These comments are presented without interpretation or analysis and may contain comments and views that are considered incorrect, uninformed or prejudiced. However, they do add to an understanding of the pharmaceutical marketing sector in terms of how it is being managed and how it sees its future.

The views and comments are split between respondents from locally owned companies and those from multinational companies. In addition, labour has contributed their views on some of these comments from management. These views are shown within blocks at the relevant sections.

Overall

Comments from locally-owned respondents

- Imported generics (certain products/supplies) are believed to be sold in the local public and private market at prices below the existing cost of raw materials. This indicates negative margins for local producers, but also possible dumping activities by importers.
- South African manufacturing sites are believed to have high unit costs of manufacturing caused by various factors such as short runs, labour costs, raw material costs, old equipment, etc.
- Labour is not willing to take responsibility or ownership of their role in the industry. In return labour feel they are being left out of the restructuring process.
- The regulatory process in South Africa as far as the registration of new applications are concerned, is plagued by inefficiencies and uncertainties.

Comments from multinational respondent

- South Africa is not portraying itself at a political level as a foreign-investment friendly countries.
- South Africa's regulatory timetable for registration issues is regarded as the slowest in the world. This prevents timeous market entry for new products, which is a serious business risk. as applicants are deprived from achieving sales.
- Protection of Intellectual Property rights for patented medicines is at risk with the existence of Section 15C of the Medicines and Related Substances Control Amendment Act No 90 of 1997.
- High levels of crime and theft are seriously impacting against the business viability of local operations, as well as creating personal safety fears for foreign staff of multinational companies.
- The focus for lower medicine prices by Government is at manufacturing level, creating further risks for operating margins. However, most inefficiencies and unrealistic pricing occur in the distribution sectors, which is not within the control of the manufacturers.
- There is a poor focus on overall cost-effectiveness of medicines in patients, instead of only looking at the price of medicines.
- Major labour issues are related to legal difficulties to dismiss non-performing workers or workers found guilty of illegal activities (i.e. theft).

Proposals To Improve Viability For Further Manufacturing - Government Issues***Comments locally-owned respondents***

- Focus on outsourcing and private labels to lower cost of production.
- Government to put pressure on International Aid Agencies, such as WHO, UNICEF, etc. to source at least 50% of their medicine requirements from SA for Aid relief in Africa and especially in SADC countries.
- Although COMED is successful in obtaining public sector medicines at globally competitive prices, the poor information feedback and off-take volume control are creating havoc for suppliers. COMED must guarantee volumes and payment terms.

- Theft from public purchases should be minimised by professional control systems. Special markings on products and/or packaging will only have a small prevention effect if total system is not improved. Must look at National Crime Prevention strategy.
- The MCC needs more professional staff and quicker response times. Industry is willing to contribute funding in this regard.
- A quick calculation of the number of applications for registration, new sites etc processed by MCC per annum in relation to the kind of budget necessary to get the best people and equipment for it to run on business lines indicates a fee per transaction of around R 10 000, a cost the industry would willingly pay for an improved service and turnaround time. Another option is to introduce an industry funded fast-track commercial registration option, fully funded by applicants. Applicants would then have the choice to pay a significant fee (i.e. R50k upwards) for those specific new registrations which warrants a quick market introduction.
- It was observed that the MCC places an over-emphasis on their function to secure the release of safe medicines to patients. However, the MCC's main service is actually to the Pharmaceutical industry, and not to patients. A comparison, for example, is the licensing of vehicles for public road use. Although licensing authorities are ensuring that only safe vehicles are licensed, they are actually providing a service to the license applicant. Imagine if an applicant has to wait several months for a road safety test to be completed!
- Investigate the distribution and retail sector as well as servicing of dispensing doctors, to look at options for price reductions at patient level.

Comments from multinational respondents

- Requires consistent approach from Government regarding protection of intellectual property. Conforming to TRIPS is essential, but also need to become part of policy, not only legislation.
- Requires a full professional approach and service from the MCC. This would include more professional people, easier access and communication, as well as performance targets for registrations.
- The focus on primary healthcare and rural clinics may lead to an increase in public sector prices due to complicated distribution. It would be an advantage to outsource public sector distribution to professional private distributors.

- The poor historical COMED information feedback could be overcome by direct interaction with public dispensing units.

Private Health Sector: Proposals To Improve Viability Of Further Manufacturing

Locally-owned respondents

- Focus on outsourcing and private labels to lower cost of production.
- Although COMED is successful in obtaining public sector medicines at globally competitive prices, the poor information feedback and off-take volume control are creating havoc for suppliers. COMED must guarantee volumes and payment terms.
- Theft from public purchases should be minimised by professional control systems. Special markings on products and/or packaging will only have a small prevention effect if total system is not improved. Must look at National Crime Prevention strategy.
- The MCC needs more professional staff and quicker response times. Industry is willing to contribute funding in this regard.
- Investigate the distribution and retail sector as well as servicing of dispensing doctors, to look at options for price reductions at patient level.

Multi-national respondents

- Local prices are high, mainly due to distribution costs. Singular distribution may reduce cost by up to 14%, but could lead to stock problems.
- High number of retail pharmacies and dispensing doctors increases distribution costs. Should look at reducing numbers.
- More realistic fees for private sector medical professionals would lead to a lower dependency on high mark-up on medicines.

Labour Actions To Improve Viability For Further Manufacturing

Locally-owned respondents

- Labour needs to be more informed regarding uncompetitive nature of industry in South Africa. Participation in restructuring process would lead to better understanding that rationalisation now would lead to growth in future.
- Poor communication between union hierarchy and workers regarding threats to industry. For example, Imported Indian products compete locally with no protection for local producers, while an Indian pharmacist earns as much as a SA Grade 3 worker.
- Labour needs to understand need to become competitive, and should not oppose competitive issues such as automation.

Multinational respondents

- Job security is important, but scope must exist to dismiss non-performing workers to build workforce based on excellence and motivation.
- Labour's thinking should be towards globalisation and excellence, which would require a training focus, involving unions.
- Training levy is a good idea, but it would require a proper industry focused evaluation system.

Financial Institutions Actions To Improve Viability For Further Manufacturing

Locally-owned respondents

- Institutions need to understand the dynamics of the industry; whilst some are downscaling sound opportunities for investment exist in areas such as outsourcing, generics, automation, etc.

Multinational respondents

- Local institutions have a very high fee structure for organising financing deals. This is a legacy of the isolation period, but needs to become more competitive.

Other Actions Required To Improve Viability Of Further Manufacturing

Locally-owned respondents

- Investment South Africa could assist in arranging JV's with niche players and SA companies.
- Government needs to ensure outside companies entering the SA market need to commit to adding technology in SA and not use SA as a dumping ground for cheap medicine. In the long term a focus on only cheaper medicine will not be in the interest of the country.
- Develop local actives with generic and patent actives producers to lower currency risks in raw materials.

Multinational respondents

- Multinational companies have done a lot of good in SA that is not appreciated. Underlying mistrust by Government is not conducive to further investment by overseas decision-makers.
- Off-patented brands could be transferred to local operations in a more systematic manner. There is a need for closer co-operation between locally owned and multinationals.
- SA has the basic elements for a thriving industry such as good medical training, history, industry and health/distribution sector, and these have to be exploited.

SUMMARY OF FINANCIAL MANAGEMENT PERSPECTIVES**Financial Issues Impacting Against Further Manufacturing**

- Inconsistency and devaluation of the Rand, especially against the US Dollar, as most equipment and raw materials are purchased in Dollars.
- It is very difficult and expensive for local companies to prove dumping practices.
- For an ethical drug producer it is necessary to continually invest in technology in order to stay competitive.

Proposals Regarding Financial Issues to Improve the Viability of Manufacturing

- Government focus on gradual exchange rate fluctuations.
- Institute proper systems and assistance to protect against dumping actions. The MCC could investigate potential dumping actions together with DTI at registration phase. For Government COMED purchases declarations on tenders could be requested from importers regarding their public sector prices in countries of origin.
- Look at reduction in red tape to improve actives such as narcotics.
- Look at COMED tenders to be awarded for longer periods (i.e. two years), but also spread around a few companies to sustain manufacturing base. The industry sent a delegation to the State Tender Board requesting to keep the tender period for 1 year until other guidelines are put in place to ensure a preference for local manufacturing.
- All tenders awarded to a manufacturing company based outside SA must be shared with a local manufacturing company.
- International approval standards (i.e. FDA, MCA) are over the top, especially for generics. Trade negotiators should be aware that these are subtle methods of developed countries to protect their own industries. However, quality standards protect patients, and this should be the ultimate goal. Quality systems such as ISO9002 also ultimately protect manufacturers and reduce costs.

Proposals for Lower Pharmaceutical Prices at Patient Level

Locally-owned respondents

- Encourage fair competition in production which should lead to more competitors and more price competition (i.e. reduce market risks, dumping protection and fair incentive schemes).
- Consumer education regarding generics substitution. However enforced private sector generics substitution could lead to higher public sector prices as suppliers are looking at recouping margins.
- Need to get a value-added based, transparent pricing in distribution.
- Need good communication between medical funds and suppliers to set realistic list prices. This would take care of affordable prices for most private sector purchases. These list prices could then be enforced for purchases by non-member purchases as well.

Multinational respondents

- Public and private sector must look more carefully at “cost-of-application” rather than direct price alone.
- Minimise distribution chain costs. In South Africa this is estimated at 70 to 100% mark-up on manufacturing level prices, compared to UK 6% and USA 15%.
- Singular distribution chains (i.e. IHD and NASA) could reduce final prices, but may lead to poorer availability.

Distribution Factors Impacting Negatively on the Viability of Manufacturing***Public sector***

- Theft and round-tripping, which have a double negative impact in terms of increasing COMED costs which reduces capacity to purchase more medicines, but also reduces market size and profitability in the private sector for suppliers.
- Poor efficiency and historical information base for public sector distribution.

Private sector

- Illegal trading of stolen medicines give poor control over final prices.
- Influence of wholesalers gives manufacturers poor control over final prices.
- Some wholesalers have not invested in new technologies, and are now threatened due to their low value-adding.
- Some wholesalers provide poor customer intelligence feedback to manufacturers.

Proposals for the Improvement of Distribution to Enhance the Viability of Manufacturing

- Distribution chain mark-ups to be based on value-adding.
- Manufacturers should get closer involved in distribution in order to get “closer-to-the-customer”.

- Public sector should outsource distribution to professional distributors with set performance targets. This should also lead to minimising theft.

Obstacle to Export Growth

- In Africa there is a major problem with regulatory control. Many small markets with different regulatory requirements.
- Local manufacturing cost structure is high, which makes it difficult to export against competing exporting countries.
- Cost to establish export infrastructure in Africa is high, with further problems such as crime, corruption and risky payments.
- Current export focus is opportunistic rather than dedicated. Need framework of co-operation between industry and Government.

Proposals to Improve the Viability of an Export Focus

- Government to focus on speedy implementation of harmonised registration regime for SADC, as well as agreement to participate in EC framework.
- Local operations to focus on supplying multinationals on outsourced basis in areas where competitive such as short-run products.
- Ensure competitiveness of the local manufacturing sector and look at developing guaranteed export off-takes similar to the automotive industry.
- Evaluate successful export based developments such as the Singapore Pharmaceutical Zone (also Ireland). South Africa should provide similar advantages.
- Safeguard against crime and theft of export bound products.

The pharmaceutical industry in South Africa has, in the past, been protected by tariffs and duties but not incentivised by tax breaks and other support. Protection has rendered it inefficient and uncompetitive (in international terms) yet incentives would have been no more costly and would have had a much more desirable effect. It is considered that the previous government never realised the long-term importance of the sector. The consequences of this siege mentality, not just in this sector, are now becoming apparent.

- The DTI I disagrees with this statement. It is based on perceptions, not on facts. In the 1992 SA tariff book three-quarters of tariff lines under headings 30.03 and 30.04 (formulated pharmaceutical products in bulk and in a form ready for retail sale, respectively) were duty free. These free lines even include formulated antibiotics such as penicillins, streptomycines and other beta-lactam, which have been made in SA and always constituted the bulk of imports under Chapter 30.
- Currently all pharmaceutical products are imported duty-free. A moderate level of protection for pharmaceuticals which are manufactured locally is certainly worth considering. We have an abnormal situation in which certain active ingredients are subject to customs duties, but finished products containing the same ingredients are duty-free.
- Partially as a result of this situation, the proportion of pharmaceuticals imported in a form ready for retail sale has been steadily increasing over the past few years, reaching the level of over 80%, by value, in 1999 (imports under heading 30.04 compared to total imports under Chapter 30).
- As far as the effect of incentives are concerned: There is a very negative example from the SA pesticide sector which was the major recipient of GEIS (General Export Incentive Scheme) in the late 1980's and early 1990's. Export markets established with the help of GEIS were lost as soon as the system was phased out.

SUMMARY OF PRODUCTION MANAGEMENT ISSUES

Problems Experienced with Raw Materials

- No real problems experienced with actives (mostly imported) in terms of quality and availability.
- Some quality problems are being experienced with local excipients such as alcohol and starch.
- Major problems are being experienced with packaging (mostly locally sourced). These include;
 - leaking cups, discoloured or damaged containers
 - dirty bottles and caps

- problems and general negligence such as print colour differences
- deviations from specifications/wrong dimensions

Capital Productivity Related Problems

- High cost of capital equipment, which is mostly imported.
- High cost of automation for old plants.
- Small production runs, with frequent changeovers
- High cost of compliance to local and international standards.
- Poor reliability of old equipment, and lack of spares
- Lack of planned maintenance.

Recommendations Regarding Improvement of Capital Productivity

- A Government focus on financial stability and a stronger Rand will make imported equipment more affordable.
- Local standards need to take into account local issues, so that there is no over-regulation that may hinder growth.
- A focus on outsourcing and exports should lead to longer production runs.
- Improve utilisation by 24-hour operation.
- Focus on smaller, more versatile new equipment.
- Look at full automation.
- Standardisation of packaging material sizes to reduce changeovers.
- Planned maintenance.

Labour Productivity Related Problems

- Absenteeism major issue. Sick leave, for example, is seen as “compulsory” to take otherwise “wasted”.
- Workers are perceived not to take responsibility.
- Some resistance to working shifts due to transport problems and personal safety.
- Increased costs of shift work make this opportunity to reduce costs a non-starter and hampers competitiveness against low-cost manufacturers from countries like India.

Proposals Regarding Improvements of Labour Productivity

- Staff training programmes educating people to become more responsible towards issues such as productivity and absenteeism.
- Labour flexibility in negotiating shift work, even regarding substantive issues
- Production related incentive schemes.
- Out-sourcing of non-essential as well as production services.
- Recognition for over and above.

SUMMARY OF HUMAN RESOURCES ISSUES

Problems Related to Human Resources Issues

- The Industry-wide industrial action in 1998 caused major disruptions.
- There is a major shortage of skills in more technically advanced categories.
- Absenteeism of mainly semi-skilled workers.
- Overall work ethic.

Proposals to Improve Human Resources Related Issues

- Action learning programmes.
- Mentorship
- It is difficult to change people's attitude if they are not exposed to wider issues. Inform workers regarding critical nature of pharmaceutical industry's products.
- Conduct multi-skilled training to counter absenteeism.
- Implement a consistent grading system per job throughout industry.
- Unions to play a more active role in educating staff.
- Unions to become more flexible and lateral in dealing with problems, rather than focussing on getting the maximum benefit for their membership, even at the expense of closing the factory.
- Restructuring has led to many unemployed skilled people. Should look at "job pool" to make skilled people available to other employers to prevent skills loss.

SUMMARY OF RESEARCH AND DEVELOPMENT ISSUES

Problems Related to R&D

Locally-owned respondents

- High costs involved with local R&D relative to small size of local market.
- Registration phase for new developments takes too long.
- Existing legislation prevents product development before patent expires.
- Access to raw materials is critical during product development. With TRIPS implementation in India and China, access to actives under patent for product development will be curtailed.
- Insufficient number of suitable scientists.
- Lack of Government incentives.

Multinational respondents

- The approval time for trial protocols from the MCC to conduct clinical trials is too long, and it causes cancellation of South Africa's participation in clinical trials.
- Shortage of qualified doctors to participate in clinical trials.
- Deterioration of hospital infrastructure.
- Safety and security of visiting staff during clinical trials.
- SA has a high potential to develop marketability as a development centre, but overall climate (i.e. Government attitude, crime) must become more welcoming.
- See earlier comments on CRO market in SA.
- The "Brain Drain" has caused the loss of many clinical trial investigators.

Proposals to Enhance R&D

Locally-owned respondents

- Look at a priority system for evaluation by the MCC for locally developed products.
- Eliminate all duties applicable to raw materials required for development work.

- Look at methods to reduce time to market for newly developed generics.
- Other incentives such as tax concessions.

Multinational respondents

- Look at developing vaccines for primary health care.
- Antibiotic developments.
- Look at quicker to market time for breakthrough drugs.
- SA should focus on niche areas of competence such as formulation and tabulating.
- Set out approval times for clinical trials.
- Traditional medicines not seen as a major focus for product development. Internationally New Chemical Entities are systematically being developed with a highly scientific foundation, and traditional medicines are not part of this.