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The Growth Potential of the Pharmaceuticals Sector in South Africa

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Authors: Christopher Maloney and Nick Segal

Genesis Analytics (Pty) Ltd
2nd Floor, 4 The High Street, Melrose Arch, Johannesburg
South Africa, 2196.

Post to: Suite 3, Private Bag X1, Melrose Arch, Johannesburg, South Africa, 2076.
Tel: +27 11 214 4080, Fax: +27 11 214 4099
www.genesis-analytics.com

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1. INTRODUCTION

The Accelerated and Shared Growth Initiative for South Africa (AsgiSA) was launched by the government in 2006 as an integrated package of measures aimed at stimulating economic growth and reducing poverty and unemployment. Within this framework, a number of industrial sectors were selected for strategic promotion in accordance with their potential contribution to AsgiSA's targets of growth, investment, employment creation, and poverty alleviation, and several other sectors were preliminarily identified as candidates for priority status.

One of the latter was pharmaceuticals. This arose out of two considerations:

- econometric analysis by a team of specialist outside advisors, which suggested that South Africa should try to develop a competitive advantage in pharmaceuticals manufacturing

- recognition of the importance of pharmaceuticals in the effective provision of healthcare for the population as a whole, especially bearing in mind the high incidence of infectious disease amongst the poorest sections of the community

Accordingly, the government—through the Presidency, which is driving AsgiSA—decided to commission a study into the growth potential of the pharmaceuticals sector including its appropriateness for selection as an AsgiSA priority. To that end, the consultancy Genesis Analytics was appointed in late February 2007 to address two principal questions:

- is the pharmaceutical sector of strategic significance to South Africa?

- does it offer high growth potential?

If the answers to these questions were positive, we were asked to address a third question:

- what are the factors impeding realisation of that potential?

The study was undertaken under the aegis of the Chemical Sector Summit of NEDLAC, whose pharmaceuticals committee steered the study. It was carried out over ten weeks, during which time the consultants met the steering committee three times. A fourth meeting was held in late-May to consider the draft report. The present document – the final report - takes into account the comments, oral and written, made by members of the committee on the draft.

1.1. SCOPE AND APPROACH

The exercise was explicitly conducted at a strategic and policy level. This was partly because a number of technical and economic studies of the sector have

been undertaken in recent years, and there was no need to repeat them. Mostly, however, it was because it was understood that, over and above the dynamics of the local and global market, the key issues affecting the sector in South Africa lay in the domain of public policy with respect to both healthcare and industrial strategy. As will be seen, the future of the sector will depend critically on how these two policy dimensions, each with its own legitimate objectives, are managed and reconciled.

In accordance with the brief, the study stops short of making detailed recommendations. Its thrust, as indicated, is to reach broad conclusions about the strategic significance and growth potential of the sector, and to point to the constraints that will have to be overcome and the preconditions that will have to be met for that potential to be achieved. As such, this report lays the foundation for government to determine whether or not it wishes to accord the sector priority status. If the government were to decide to do so, further and more detailed studies would be needed into the fiscal, institutional and other policy measures required of a sectoral growth strategy.

The consultants carried out the study by reviewing the voluminous literature on the sector (chiefly that literature which the steering committee drew to their attention), and also by interviewing a wide variety of players within industry, as well as other stakeholders from community and government. The list of people consulted is given at the end of this report. We express our appreciation to them for the time and thought they generously gave us—without their input, we as non-experts would not have been able complete the exercise in the short time available.

1.2. NATURE OF THIS REPORT

This report presents our principal findings and conclusions along with the underlying reasoning. It also suggests as to how the matter should be taken forward.

The report is deliberately brief in order to facilitate its being widely reviewed by the numerous stakeholder interests. It is, however, underpinned by a detailed working paper which is being made available separately to the client and the steering committee.

1.3. STRUCTURE OF THIS REPORT

Following this introductory section, section two sets out the current state of the sector in its national and global contexts. Section three analyses the sector's significance and growth potential, while the fourth section explores the determinants of its overall performance. Section five begins with an examination of the preconditions required for the realisation of the growth potential, while the final section offers a way forward by outlining the next steps to be taken.

2. PRESENT STATE OF THE SECTOR

Over the past decade, South Africa's competitiveness in the global pharmaceutical industry has been poor. Despite the presence of 94 registered pharmaceutical operations in South Africa, the majority of firms are operating only as sales and marketing offices, with R&D and production being undertaken overseas. South Africa used to have more firms engaged in production, but with the move towards global 'centres of excellence' where skills, incentives and inputs are in stronger supply, many of these sites have been closed down and/or rendered obsolete.

Today, only ten companies have production factories in South Africa with another six firms using local companies for contract manufacturing and packaging.[1] Since 1994, 35 pharmaceutical plants have closed, mainly belonging to multinational R&D-based companies.[2] Currently, employment stands at 11 000 people, down from 16 000 in 2000.[3] Thus, South Africa's performance in pharmaceuticals appears to be steadily weakening.

2.1. THE GLOBAL CONTEXT

South Africa's declining performance is troubling because the global pharmaceutical industry is currently worth over US$535 billion (R3.7 trillion), and growing at between 5% and 18% per annum depending on the region.[4] While growth is typically highest in the developing world, the global pharmaceutical industry focuses mainly on serving the developed world and its 'lifestyle' diseases such as cardiac conditions, hypertension and depression. This is because ability to pay is higher in wealthier countries, and therefore higher profits arise in these markets.

While estimates vary, the US Federal Drug Administration suggests that the cost of developing a new drug from scratch and bringing it to market is typically in the range US$800 million to US$1.7 billion (R5.5 to R11 billion).[5] Bearing in mind that much, probably the bulk, of R&D does not result in successfully taking new drugs to market, it is financially critical for those companies focused on new drugs that they produce drugs for markets where demand is strong. Hence, new drug development for diseases relevant specifically to the developing world is modest, in contrast to those intended mainly for the developed world. Correspondingly, the pharmaceutical market in the developing world is focused largely on low-cost generic production of off-patent drugs and their inputs, with a move only recently in some developing countries (notably India) to enter the research-intensive segments of the pharmaceutical value chain.

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[1] Figures from PIASA

[2] Figures from DTI

[3] Figures from DTI via the Pharmaceutical Task Group and CSIR/CMCS "Customised Sector Programme—South African Chemical Sector: Pharmaceuticals" and industry interviews.

[4] Bharat Book Bureau. "Global Pharmaceutical Market Estimated to be Worth US$534.8 Billion" (14 Nov 2006) and Pool, Caroline, "Research Report on the Manufacture of Pharmaceuticals" (Who Owns Whom, Feb 2007).

[5] USFDA. "Challenge and Opportunity on the Critical Path to New Medical Products" (Mar 2004).

The global pharmaceutical market can thus be characterised as having a high-value/low-volume component focused on finding and developing new drugs with strong market potential, and a low-value/high-volume component focused on finding more efficient ways of producing already-discovered and marketed drugs. This leads to a split in the type of firms found in the global market: 'innovator' or 'research and development' ('R&D') firms focused on new drug development (multinational examples include Pfizer, Merck and GlaxoSmithKline), and 'generic' firms focused on production (multinational examples include Sandoz, Teva and South Africa-based Aspen).

Beginning in the 1990s, the global pharmaceutical industry has been faced with rising drug development and production costs, as well as a thinning drug pipeline. This has led to a shift in industry dynamics: most companies are consolidating their production and manufacturing activities on 'centres of excellence' in a few countries offering the right mix of skills, incentives and position in the world market, and the companies themselves are engaging in mergers and acquisitions with other pharmaceutical firms in order to achieve better cost-efficiencies and profitability.

This trend towards consolidation has opened up an interesting space for pharmaceutical companies in the developing world, which previously focused only on generic production. Many are now partnering with R&D companies across the pharmaceutical value chain. This includes offering these companies low-cost research facilities and skilled labour, low-cost sites for drug development (especially clinical trials) and low-cost sources for contract or licensed manufacturing, distribution and/or sales and marketing. Hence, like many other industries, pharmaceutical firms are beginning to latch on to the efficiencies found in outsourcing and off-shoring major parts of the value chain to lower-cost firms, mainly in the developing world. India and China have been significant beneficiaries of this trend.

2.2. THE SOUTH AFRICAN CONTEXT: INPUTS

Despite some local generic firms having recently increased their production capacity, South Africa overall has not fared well from this global restructuring - as already noted, the number both of manufacturing plants and of total employment has been shrinking.

One reason is that South African pharmaceutical manufacturers have no option but to import up to 90% of the inputs for their drugs, mainly from India and China in the case of generic firms, or from other overseas manufacturers in the case of innovators.[6] Most of these inputs are active pharmaceutical ingredients (APIs), which include a wide range of fine chemicals. Typically, a single drug requires a single API; however, some analgesics and vitamin combinations, as well as ARV and TB 'cocktails', will require several APIs. While usually it is possible to have one factory produce more than one API, the investment dynamics require strong

[6] Industry interviews.

demand for production of APIs to be cost-effective. Hence, unless there is a large pharmaceutical manufacturing base in place to demand the APIs, there is no business logic for having a critical mass of API producers in-country across a range of different drugs.

Therefore, there is a catch-22. Without a sizeable pharmaceutical manufacturing base in place, South Africa has only modest capacity in API production; conversely, if there were a large API production base, the current size of the pharmaceutical manufacturing industry in South Africa would probably not provide sufficient demand. It is consequently problematic to integrate vertically the entire supply chain of pharmaceuticals in South Africa because one needs to be producing a host of drugs each with high-volume demand. Lacking these essentials, South Africa has been unable to achieve the requisite integration, and so it imports the bulk of its inputs. Thus, the value currently added across the pharmaceutical value chain in South Africa is low.

2.3. THE SOUTH AFRICAN CONTEXT: DRUG POLICY

Compounding the lack of value-adding activities is a controversial policy and regulatory environment. The major policy shifts from 1994 regarding healthcare have led to numerous problems across the sector, mainly related to redistributive policies that did not take into account the possibility of negative spillovers. The policy driver is the government's commitment to increasing equitability in a highly skewed healthcare and pharmaceutical sector where, even today, some 20% of the population is served privately but consumes around R2 000/capita per year, and 80% is served publicly but consumes R80/capita per year.[7]

While roughly half of those served by the private sector are from (in political terms) previously disadvantaged groups, they constitute a small proportion of that community as a whole, which is still served mainly by the public sector. In May 2007, R2 000/capita is equivalent approximately to US$286/year, and R80/capita to US$11/year. The most recent comparators we could find are from 2003, where the upper figure of US$286/capita lay between North America (at US$342/capita) and Europe (at US$147/capita), and the lower figure US$11/year was closer to SE Asia and China (at US$12) and India (at US$9).[8]

The 'first-world, third-world' division in healthcare provision in South Africa is thus stark. As recently evident in the debate on the Health Charter, though stemming back to the Constitution and to the statement on national drugs policy, redressing such inequity in between public and private healthcare in terms of access, quality and distribution of human resources (eg doctors, nurses and pharmacists) is understandably and necessarily a high priority for the government.

However, creating equity in healthcare is not easy to achieve in practice, and much contention has arisen as a result of the efforts to do so. There is little dispute about the broad thrust of government policy since 1994, *viz* to shift resources towards the

[7] Industry interviews.

[8] Figures derives from CSIR/CMCS "Customised Sector Programme for Chemicals: Pharmaceuticals."

drastically under-served bulk of the population. Where the contestation arises is in the nature of the policies, in how they are being implemented and in the capacity to do so. If redistributive policies are so aggressive in that they damage the overall quality of the healthcare sector in South Africa, causing skills and healthcare-related capital to leave the country, the outcome is adverse as it is problematic from the perspectives of both social and industrial policy. Correspondingly, if the redistributive policies are so conservative that they do little to remedy the public-private healthcare disparity, the outcome is unsatisfactory from a social policy perspective. Finding the right balance between the two is vital even if by no means easy.

2.3.1. PHARMACEUTICALS REGULATION

The main regulatory body, the Medicines Control Council (MCC), is beset by internal capacity constraints, leading to inefficiencies in the discharge of its core functions. The Minister of Health has appointed a task team to review the institution and to make recommendations for a new regulatory body for medicines and other health products. We hope that our report will be useful to the task team.

The MCC's times for registration and approval of drugs and clinical trials in South Africa are up to four times higher than international best practice. Such inefficiency is clearly inimical to attracting investment as it reduces the ability of investors to enter the market quickly and, in the case of clinical trials, it disrupts studies occurring in several countries at once. Recently, companies have reported not carrying out clinical trials worth R1m to R5.5m (depending on the trial) due to delays at the MCC.

The MCC's other main function, *viz* licensing producers to carry out manufacturing, is also problematic. There are uncertain expectations and protracted delays as well as unclear implementation of quality standards, which can damage the ability of producers to make sound investment decisions. While few if any disagree with the goal of the MCC's recent move towards requiring international quality standards for manufacturing drugs (Pharmaceutical Inspection Cooperation Scheme or PICS), the way the standards are being defined and implemented by the MCC has created real difficulties for manufacturers. This is especially because there has been no policy, technical or financial assistance to firms to help them make the transition, as well as little understanding of how long the transition period will be and what exactly they will need to do. To our knowledge, two companies have closed directly as a result of this policy shift by the MCC. The quality upgrade to international standards is important as it is a requirement for accessing donor funds (such as PEPFAR), but if it is not accompanied by technical and other assistance there is a real risk of plant closure.

It is evident that the MCC's actions with respect to licensing are not aligned with industrial policy. While the rationale for the shift to PICS standards is fully understood - international quality standards are essential for international competitiveness and for accessing donor funding - the MCC evidently does not recognise that its decisions necessarily have an impact on investment in production

and on employment and, as such, are *de facto* part of industrial policy. The need for effective coordination across government departments and agencies is critical.

2.3.2. MEDICINES PRICING

The Medicines Pricing Committee, set up by government to regulate drug prices in the private sector, has proposed a pricing policy with the express purposes of improving access to drugs by substantially lowering prices and of facilitating the 'migration' of some currently served by the public sector to the private sector. While improving access and lowering prices are broad goals accepted by most stakeholders, the actual proposals are regarded by many as lacking transparency and economic rationale. This is because the proposals have a high risk of impacting negatively on local drug production and development and also have no guarantee of achieving the intended social goals.

The problem is illustrated by the *New Clicks* court case, in which the Constitutional Court said that one must recognise a "balance between the need to make medicine available and accessible to the public at the lowest possible cost, and the need to keep pharmacies in business."[9] While the case was related to the dispensing fee component of medicine pricing (as opposed to the overall prices themselves), the point is clear: if the right balance is not struck by the Pricing Committee between the economics of the industry and the social needs of the country, should a consequence of their policies be a weakening of the industry, access could also falter.

Industry feels the pricing proposals are opaque in terms of how they will be applied in practice, as well as because nobody from its constituency sits on the Committee. The current proposal is to benchmark originator drug prices in South Africa against a basket of four comparator countries (Australia, Canada, New Zealand and Spain), and choosing the lowest price of the five countries as the drug price in South Africa. Generic drugs are then to be priced at 40% of the resulting originator price. There is an 'escape clause' whereby, if the proposal would render provision of the drug uneconomic, a firm can apply to have its particular case reviewed. However, as this would require provision of sensitive and variable cost data, how this would play out in reality is not clear.

The overall pricing policy is also regarded by many within industry as methodologically flawed as it does not take into account the economics of the sector. For example, does is make sense to price a drug in the private sector in South Africa based on the price the drug receives in New Zealand, where almost all drugs are sold in the public sector? Further, the price of an originator drug typically has large sales, marketing and distribution costs built into it; these elements naturally differ across countries. The proposal for generic firms is regarded as defective because it treats drugs in aggregate rather than at the

[9] Constitutional Court of South Africa. *Minister of Health and Another v. New Clicks*, Sep 2005 paragraph 520.

individual level, and it therefore ignores the economics a firm faces given the unique portfolio of drugs it produces. In some cases the drug may be a loss-leader, while other drugs may be low-volume, high-margin drugs. Hence, while few disagree on the need for lower private sector drug prices in South Africa or the right of South Africa to regulate drug prices in general, by not properly taking into account the economics and the dynamics of the industry, how the pricing policy is being executed is widely regarded as deeply problematic. The result increases uncertainty within the industry and the investment climate for pharmaceuticals falters.

Should the Pricing Committee's pricing proposals go forward as they stand, many feel the pricing policy will at best alienate multinational companies who already see little value in having a deeper presence in South Africa beyond sales and marketing, and at worst shut down segments of the industry because the policy will render them economically unviable. This is because the multinationals estimate the proposals will cut their South African revenues by 35%, while generic firms are unable to project the impact until the exact new drug-by-drug prices are released so that they can then see what the 40% price reduction will look like for them in practice after each originator drug is benchmarked.[10] Generic firms maintain they are a commodity industry operating on a model based on high volume and low value; if that value is cut further, some firms argue that their already thin margins will get squeezed and their model will be rendered unviable in South Africa.

Finally, social policy goals may be damaged by the pricing proposal. This is because, as stated by some within industry, most drug companies cross-subsidise the low prices found in South Africa's public sector with the high prices captured in the private sector. If private sector prices are lowered, it is logical that public sector prices will have to be increased, weakening the desired impact of lower prices and greater access for all. Further, another goal of the pricing policy is to limit the rise in private sector medical costs; however, the pharmaceuticals component of a typical medical aid bill has dropped from around 30% to 18% over the past few years.[11] Therefore, without a full study of the drivers and dynamics of costs in private healthcare in South Africa, it is doubtful that focusing on drug prices is an effective way for seeking to lower overall healthcare costs.

Given the wide gap in prices found in the public versus the private sector in South Africa, we have found no evidence to support the idea that the pricing proposals will reduce private sector prices so much that people in the public sector will be able to afford to move to the private sector, resulting in greater social equity. If as seems likely the reduced prices are not low enough for this 'migration' to occur, what will result (from a social policy perspective) will be lower prices for the wealthy cohorts currently served in the private sector, not more access for poor cohorts currently served in the public sector.

We understand that some within the public sector (who are largely very low income) are compelled to purchase their drugs from the private sector because of

[10] Khan, Tamar. "Drug-Price Benchmarks Could Hurt Local Revenue." *Business Day* (10 May 2007).
[11] Industry interviews.

empty public dispensaries and/or the distance and cost of getting to public pharmacies. However, that problem is more a manifestation of systemic problems concerning the public provision of medicine, that will not be solved by lower prices in the private sector. This is why a study that links prices and medicine purchasing behaviour in the private sector is critical in the design of any pricing policy; otherwise, the intended goal and the actual outcome may be completely misaligned.

The current pricing proposals thus remain highly contentious, and their impact uncertain. Industry has recently submitted comments on the proposal, as well as estimates of what will happen financially to the sector in aggregate. Further refinement of the proposals is expected, but when they will actually be implemented and in what form is unclear.

2.3.3. PROCUREMENT

Finally, within the public sector, procurement of ARVs is done on a high-volume three-year competitive tender system, and two years for all other drugs. Preferential procurement is based on a ten-point system with four points awarded for local content, four points for BEE compliance and two points for purchasing from SMEs. Most stakeholders agree that the prices which result from this process are quite competitive. But the point system is easily manipulated in favour of importers, as an overseas-based company can open up a storefront, staff it minimally and receive BEE points, while a local, publicly-traded manufacturer, employing more staff, would not. Further, prices from some importing firms are alleged to be subsidised by home governments (resulting from their own incentive programmes for pharmaceutical manufacturing), reinforcing the cost disadvantage of local producers.

Thus, it is problematic for the industry that the current preferential procurement regime is open to manipulation, and does not measure how much value a firm is actually adding to the economy in terms of employment and contribution to GDP. It is apparent that local industry is not being fostered by government, and is even being disadvantaged relative to importers. Without a full review and resulting change to this regime, local production will continue not to be effectively promoted by government.

2.4. THE SOUTH AFRICAN CONTEXT: RESOURCING

The focus of government on primary at the cost of tertiary healthcare has meant that South Africa’s innovative capacity in the sector has been diminished. The public health sector has become overburdened and under-funded, not least because of the HIV/AIDS epidemic. It is our understanding that the drop in funding of many tertiary activities has put great pressure on university medical faculties and associated research units, and teaching hospitals that were state-of-the-art institutions with strong research capabilities are generally in difficulty.

Private pharmacies have also seen their business models called into question by the various pricing and dispensing fee proposals. As a result, pharmacy as a career has become less attractive: the number of pharmacy graduates per year from South Africa's universities has dropped from 450 students only a few years ago to 320 today. The adverse implications for skills availability are clear.

A further 'distortion' arises in that only 14% of registered pharmacists work in the public sector, despite the far greater volume of transactions relative to the private sector.[12] This arises partly because public sector pharmacies cannot afford graduates, and perhaps also because of the difficult working conditions in that sector.

2.5. CONCLUSION

What has resulted from this overall environment is:

- deep uncertainty in the industry about the government's intentions. This stems back to the procurement issues cited above, earlier pricing proposals that were considered even more extreme (such as a blanket 50% cut in prices) and bitter and uncertain court action continuing over pharmacy dispensing fees

- entrenchment of the mutual distrust between industry and government that began when healthcare transformation started in the 1990s and evolved over time through myriad debates (legal and otherwise) over access and pricing, with the situation being exacerbated by the dwindling regulatory capacity

All of this has served further to weaken a domestic industry already under stress, and contracting because of the global trends to consolidation.

Thus, South Africa's pharmaceutical industry is not competitive at the global level. The weakness can be seen macro-economically in two ways.

First, the ratio of imported to exported pharmaceuticals ready for retail sale rose from around 8:1 in 1998 to 17:1 in 2006.[13] This figure excludes the many APIs and other inputs which also must be imported to produce drugs domestically. If these were included, the overall ratio would be appreciably higher.

Further, an analysis of South Africa's yawning current account deficit found that pharmaceuticals and their inputs are the fifth largest contributor in terms of value.[14] This implies that production is currently more efficient overseas than locally, even for those multinationals with operations here. It also results in a heavy dependence on other countries in meeting South Africa's drug needs, with attendant concerns about security of supply.

[12] Figure from interviews.
[13] Figures from the DTI.
[14] Industry interviews.

Given the high demand for drugs locally, the above observation about the balance of trade highlights the importance of understanding why local pharmaceutical production is so weak relative to overseas competitors and of exploring whether and how the lack of competitiveness can be remedied. Any such study must include examination of the incentives available in countries from which South Africa imports its drugs, in order to ensure that any measures taken here achieve at least a level playing-field.

Second, comparing pharmaceuticals to AsgiSA's existing priority sectors (biofuels/agriculture, tourism and business process outsourcing), there is a deep trade imbalance for the sector (US$830 million in 2005), weak export growth (9% in rand terms between 2005-06 and only 2% in US$ terms), and a demand for high-level skills that are in short supply. Biofuels/agriculture, tourism, and business process outsourcing, on the other hand, all show a positive trade balance for their respective sectors, as well as export growth in double digits. Further, the overall impact on employment and poverty reduction from pharmaceuticals is low—for every R1 million increase in output, only two-five jobs can be expected to be created in the pharmaceutical sector, compared to 12-17 in biofuels, tourism, and business process outsourcing.[15]

In overall summary, the industry has been in difficulty for more than a decade and, on present trends and without changes in public policy, will probably continue to weaken.

[15] Figures from this paragraph are from Genesis Analytics calculations based in part on data from James Thurlow and StatsSA.

3. STRATEGIC SIGNIFICANCE AND GROWTH POTENTIAL

The above section has presented a generally negative picture of recent and current trends in the pharmaceuticals sector in South Africa. This does not, however, gainsay the importance of the sector or its future potential.

3.1. RISING DEMAND

First, improved provision of and access to healthcare are together clearly a public policy priority; pharmaceuticals are a crucial component of this. This is seen, for instance, in the obligations imposed by the Constitution, in legislation such as the Medicines Act of 1997 and the National Health Act of 2003, in the recently agreed plan to combat HIV/AIDS and in the on-going debates over the Health Charter. Reinforcing this national commitment, the African Union has now pledged to improve pharmaceutical capacity and provision on the continent.

Second, the need for pharmaceuticals both within South Africa and regionally into sub-Saharan Africa is large and growing. The picture is dominated by the incidence of infectious diseases: seven million of the 30 million Africans who are HIV-positive require ARVs, yet only one million are on ARVs; 300-500 million cases of malaria occur in Africa each year but few are treated; and there are annually some 2.4 million cases of tuberculosis but treatment is sporadic and poorly managed.[16] Further, the co-infection rate for tuberculosis and HIV/AIDS is nearly 70%.[17] Therefore, the need for drugs to treat Africa-relevant infectious diseases is real, presenting the potential for strong demand. As Africa urbanises and develops, as already evident in South Africa there will also inevitably be increases in the resultant lifestyle diseases, such as cardiovascular and diabetic illnesses, and hence in demand for the appropriate drugs.

While this need for drugs is very real, the lack of ability to pay means that market penetration so far is weak. International funding mechanisms—notably the United States' multi-billion dollar PEPFAR initiative, UNITAID and the multilateral Global Fund for AIDS, Tuberculosis and Malaria—have been set up and will in part be used for buying drugs to help convert this need into effective demand. As a result, pharmaceutical firms that can serve a high-volume/low-value market see a new source of demand opening up - provided they can manufacture to international quality standards, such as USFDA standards in the case of PEPFAR. Aside from HIV/AIDS, new drug development for developing country diseases remains very limited; here too, a company with a cost-effective R&D base may also find a corresponding market opportunity.

[16] Figures from BBC, "One Million Receiving ARVs in Africa" (16 Aug 2006), IFRC website (http://www.ifrc.org), and the WHO, "WHO Declares Tuberculosis Emergency in Africa" (26 Aug 2005).
[17] Industry interviews.

3.2. THE NEED FOR BETTER SUPPLY

The combination of strong policy commitments and rising demand for pharmaceuticals in South Africa and regionally has shifted some attention to the supply side. Currently, as seen in the previous section, South Africa is highly reliant on other countries for the pharmaceuticals themselves as well as for the inputs needed for those pharmaceuticals that are produced at home. Little value is actually directly created in-country.

In the case of South Africa's heaviest disease burden, HIV/AIDS, many of the ARVs and the APIs for domestically produced ARVs come from India and China. Both of these countries have a rising incidence of HIV/AIDS, but their epidemics are still at an early stage. Therefore, there is a fear in some quarters that as domestic demand in India and China increases for ARVs, those countries will not have sufficient production capacity to serve South Africa (and Africa) at the same level as before, which will be all the more serious if demand continues to rise in sub-Saharan Africa.

This possibility is reinforced by the emergence of new trends in India. Pharmaceutical companies there are currently moving up the value chain either by themselves or by partnering with multinational R&D firms to produce on-patent drugs for developed-country markets. These Indian firms are also increasing their production of off-patent generic drugs most relevant to developed markets such as the US. Overall, this may also result in reduced growth in the capacity to produce ARVs and APIs for ARVs (as well as other developing country-relevant drugs) for the developing world.

Thus, there is potentially a supply gap that South African companies could fill themselves or in partnership with other companies based overseas, including firms in China, India and the West. This could be across the value chain: not only in production itself, but also in those specific APIs used in producing the niche of drugs which comprise the potential supply gap. All of this is because of South Africa's unique situation: a high disease burden needing to be addressed (especially in HIV/AIDS and TB), a political and institutional environment that is mandated to provide such drugs and a distinctive position on the continent that itself is seeking greater self-sufficiency in drugs. In doing so, South Africa would lessen its dependency on other countries for its rising drug demand, notably with respect to diseases where it has the greatest need.

In sum, the strategic significance of pharmaceuticals in South Africa is substantial. Not only is there a powerful case for wanting a strong pharmaceutical sector, but that case is wholly in line with broad policy objectives. Further, the argument is backed up by market forces that prima facie present an attractive business proposition—rising demand for pharmaceuticals, and a potential supply gap in meeting that demand.

3.3. PHARMACEUTICALS AS A 'KNOWLEDGE SECTOR'

In addition, there is potential in higher-value components of the pharmaceutical value chain. South Africa's large availability of patients who have never had any sort of treatment (so-called 'drug-naïve' patients) positions the country well to build a competitive advantage in the clinical development phase of pharmaceuticals. This is a large market; in India, for example, this element of the value chain is expected to generate up to US$1 billion (R6.9 billion) by 2010.[18] South Africa already has something of a base in clinical trials - industry estimates that the activity injects R1 billion into the economy annually and that it employs 2 000 people.[19] However, continued inefficiencies on the part of the MCC, lack of skills and strong competing value propositions in other countries together have meant South Africa's advantage in this area is eroding and that it will be difficult to remedy the situation and to scale up quickly. As mentioned previously, millions of rand of expenditure were not spent on clinical trials due to the MCC's inefficiencies.

Development of a clinical trials capability will have a number of wider and beneficial impacts:

- encouragement of researchers and doctors to stay in-country because this research-heavy aspect of the pharmaceutical value chain remains in-country
- inward transfer of knowledge and technology, since trials carried out to international standards will demand extensive monitoring
- patients will have access to the most innovative treatment and care possible, when before they were likely to have received either nothing or basic first-line drugs with little care.

Given that the bulk of clinical trials work is carried out (or outsourced by) innovator firms, if South Africa were to become an attractive location for such activities there could emerge a positive sentiment about the country in the minds of innovator firm investors, which could in turn lead to more investment on their part. Since multinational companies would have a greater local presence, this could contribute to greater investment in development of high-level skills as well as to their retention. It could also result in increased corporate social investment, in which the multinationals have a strong track record.

In short, arising out of the severe disease burden in South Africa and of the need to re-build South Africa's once-vibrant tertiary medical infrastructure, investment in developing competitive capability in clinical trials could stimulate growth in part of the R&D-based segment of the pharmaceuticals value chain, with a variety of spin-off benefits.

[18] BioSpectrum, "India Growth Trends 2006," available at http://www.biospectrum.com
[19] Figures from PIASA.

3.4. CONCLUSION

In conclusion, there is a case for South Africa to seek to grow pharmaceuticals production across the value chain, by focusing initially on certain therapeutic areas that offer strong growth opportunities, notably infectious diseases. The opportunity is to do so not only in low-cost production but also in the clinical trials aspect of the R&D segment of the value chain.

This is different from the strategies followed by China or India, which set out in the 1970s to become self-sufficient in production across most essential drugs, but did little by way of developing new drugs or producing high-value drugs. They each had the market size to allow for such a strategy. It is only in the past few years that India and (more recently) China have started to also serve developed markets with their generic drugs, as well as to move beyond generic production and into more innovative and research-intensive activities, including planning for production and development of high-value drugs.

South Africa's strategic growth opportunity lies in a different approach - developing across the value chain by investing in key aspects of both low-cost production **and** research-intensive clinical trials, with an initial focus on specific therapeutic areas (infectious diseases), and building out into other therapeutic areas over time as and when other therapeutic production and development opportunities arise. South Africa should therefore be fostering stronger capabilities in cost-effective generic production, while building upon existing strengths in (especially Africa-relevant) R&D elements of the value-chain (notably clinical trials) and addressing inefficiencies at the MCC.

While the sector will not itself directly generate large numbers of jobs, because of the high proportion of high-level skills among them the multiplier effects of increased consumption demand will add significantly to the country's employment base. More strategically, beyond the employment-generation impacts, the importance of the pharmaceutical industry's viability in South Africa and its relevance to AsgiSA lie in its high-technology nature, its value to ensuring security of supply and its ability to provide a key tool in helping South Africa's (and sub-Saharan Africa's) people fight its disease challenges.

4. DETERMINANTS OF GROWTH

The previous chapters have shown that while South Africa has a growth opportunity in pharmaceuticals with significant strategic value, the competitive state of the sector is currently weak. It is important to identify the main determinants of achieving global competitiveness, since these will impede potential growth of the sector if they are not properly understood and, as necessary, acted upon. This study has found six such determinants: availability of skills and provision of healthcare, regulatory quality, innovative capacity, intellectual property rights, market scale and cost-competitiveness.

4.1. AVAILABILITY OF SKILLS AND PROVISION OF HEALTHCARE

The pharmaceuticals sector demands relatively skilled labour; a shortage will hinder the ability of the sector to grow. Whether the industry is generic- or R&D-based, chemists, scientists, pharmacologists, engineers and healthcare professionals are all needed for the sector to flourish. Similarly, a government commitment to healthcare ensures a ready market and base of support.

In South Africa's case, there is limited availability of high-level skills: 5.1% of the total unemployed population has a tertiary degree, while in India the corresponding figure is nearly 32%.[20] Further, about 5.2% of GDP is spent on private healthcare in South Africa, whereas 3.2% of GDP is spent on public health; this disparity is telling, especially when more than 80% of the population is served by public healthcare.[21] It reflects the skewed quality, access and resource distribution in public versus private healthcare provision noted earlier. If pharmaceuticals are to grow domestically, the main source of that demand (the public health sector) must be more robust.

4.2. REGULATORY EFFICIENCY AND QUALITY

Because pharmaceuticals are necessarily a highly regulated industry, the regulatory function must be efficient and transparent for the industry to be economically viable. A R&D company will want to get its clinical trials and new drugs approved and registered with minimal delays so as not lose market value, and a generic company will want to be as close as possible to being first-to-market. Excessive and unpredictable delays and other inefficiencies damage both types of firms, introduce uncertainties and make basic business functions such as investment decisions and planning extremely difficult. In an industry as globally competitive as pharmaceuticals, value-adding investment will go elsewhere if the regulatory function is not executed in a thoroughly professional and efficient manner.

In South Africa, as noted earlier, the MCC has a critical role in regulatory oversight. It registers and approves drugs and clinical trials, and it licenses production and

[20] World Development Indicators (World Bank).
[21] World Development Indicators (World Bank).

wholesaling. On all three aspects, the MCC is beset by internal capacity constraints and as a consequence is unable to provide the quality and efficiency of service required for an internationally competitive sector. Indeed, the MCC has a reputation for being a 'black box' where little is known on what happens to an application once it has been submitted, when key decisions will be made and how exactly to implement the MCC's requirements (especially in production). The challenge, ultimately, is to ensure that the regulatory regime is sufficiently connected to industrial policy so that segments of the industry do not shrink, shut down or miss out on new investment. Resolving these problems is a fundamental precondition for having both a competitive pharmaceutical industry and an effective healthcare policy.

The problem of competitiveness being compromised by a weak regulatory environment is also found in the proposed approach to private sector pricing. If predictability and transparency are lacking, the investment climate inevitably suffers. In the case of South Africa, there is little disagreement on the need to marry the social goals of healthcare policy with the economic goals of industrial policy. Where there is disagreement, however, is **how** such reconciliation is to be carried out. Without effective dialogue and relationship-building between the various players, this aspect of regulatory quality will serve only to alienate investors and potentially weaken those investments already in place. It was noted earlier that the principal thrust of healthcare policy has been and remains on improving equity of provision and of access—the challenge is how to do this without damaging South Africa's competitiveness as a location for doing pharmaceuticals business.

As mentioned in earlier sections, South Africa has several deficiencies in its preferential procurement regime, whereby the point-system is open to manipulation and does not take full account of the real value added by a firm. Further, there is nothing in the procurement process that requires the government to go back to local producers with the price at which a foreign firm—which may be in receipt of financial assistance from its own government—has tendered, and ask the local firm if it can match it. Without provisions for looking at how much value-added a company is creating in South Africa, as well as what sort of cost advantages foreign companies may be getting from their own governments, the ability for preferential procurement significantly to boost local production is limited. As such, a review of current preferential procurement regime and how well it is actually working in terms of boosting local production is critical.

4.3. INNOVATIVE CAPACITY

This determinant relates to the ability of a country to add value in the innovative elements of the pharmaceutical value chain, R&D and production. Innovative capacity can be enhanced when the government offers fiscal and policy support to firms investing in such activities. This can come in the form in tax incentives, grants and promotion of linkages with universities and research institutions. Further, programmes which boost innovative capacity in universities and teaching hospitals are vital to ensuring cutting-edge working conditions and thereby to encouraging

specialists to remain in the country and to contribute towards achieving national public health goals.

As matters now stand, the country performs weakly on several measures of innovation. The 2006 Global Competitiveness Report gave South Africa a mediocre score of 3.92 out of 6, versus 5.04 for Singapore and 4.14 for India (but better than 3.44 for China and 3.56 for Brazil). This is seen too in more specific measures of innovation: for example, South Africa spends 0.76% of GDP on R&D, below that of Brazil, India and China.[22] Further, South Africa has only 0.77 physicians per 1 000 people, compared to 2.06 in Brazil, and 1.64 in China.[23] It also has only 50 researchers per million people, compared to 119 in India, 708 in China and 344 in Brazil.[24] It can be inferred from these data that South Africa will find it difficult to operate in the higher-value parts of the drug development and production chain without increased investment in its innovative capacity.

South Africa has recently introduced tax incentives for R&D, across all industries and not specific to pharmaceuticals. Their effectiveness in stimulating R&D is as yet unknown, and consequently their impact on the pharmaceuticals sectors cannot be assessed.

4.4. INTELLECTUAL PROPERTY RIGHTS (IPRS)

This is a complex and controversial area. There is a natural tension between R&D-based (or so-called innovator) companies on the one hand, and generic producers on the other hand. The former want patent protection to be as strong as possible so that they can re-coup their past drug development costs and continue investing in the pipeline of new drugs. The latter want the opposite; as the drivers of competition in the pharmaceutical world, they want patent protection to be weak so that they can enter the market as early as possible.

At the same time, generic companies benefit from the presence of R&D/innovator firms. This is because the latter are the source of the generic firms' new products. An innovator builds a 'culture' around their own on-patent drugs with doctors and patients through marketing and education about their drugs' optimal uses and indications. This is important for generic firms when they launch a substitute, since it means they can offer a substitute product of which doctors and patients are already aware, and therefore do not have to engage in much education and marketing expenditure.

There is another tension too, relevant to social policy. A strict IP regime means patent protection is strong, so that prices will inevitably be high in the period of monopoly. A lax regime, on the other hand, will result in lower prices; however, it may also limit the interest of R&D firms to sell their latest drugs in the market concerned, and it might inhibit their investment in developing new drugs.

[22] World Development Indicators (World Bank).
[23] World Development Indicators (World Bank).
[24] World Development Indicators (World Bank).

South Africa has had a problematic experience with its IPR regime. Given the government's obligation to improve access to drugs, it has focused on using IPRs as potential tools for doing so. The Medicines Act of 1997 has provisions for compulsory licensing and parallel importing (discussed below), as well as mandatory generic substitution unless a doctor or patient says otherwise. Such provisions led to a host of legal challenges by industry.

These issues have been most evident and fiercest in the HIV/AIDS debate. Since most ARVs are expensive and produced by innovator drug companies, licensing to lower-cost producers—whether compulsory or voluntarily—is seen as crucial to their being more accessible. This issue came to a head in a court case in 2000, and since then most pharmaceutical companies have voluntarily licensed out production and/or distribution of their ARV products at very low prices to the South African market. This action is seen by the companies as a major concession and a signal of their commitment to helping address South Africa's health equity problems. Conversely, it is regarded by some within government and the community as evidence of industry's inherent monopoly power and general disregard for helping address government's social healthcare goals without being subjected to serious pressure.

The strength or weakness of an IP regime is seen in four primary ways: patent life, compulsory licensing, parallel importing, and data exclusivity:

- patent life revolves around issues such as whether or not a patent will be extended to make up for the amount of time a drug was off-market when it was being approved and registered. The longer the patent life, the higher the price of the drug. Given the MCC's inefficiency, innovator firms have argued for patent restoration provisions in South Africa

- compulsory licensing revolves around the authority within WTO rules of a government (at the behest either of itself or of a third-party firm), to mandate that a local production company gets the right to produce an on-patent drug resulting in a lower price for the drug. South Africa alludes to such provision in its Medicines Act, though the ensuing regulations do not explicitly mention this because compulsory licensing is already governed by the Patent Act. However, the risk is that compulsory licensing will cause innovator firms to exit the local market since there will be reduced value for them to capture. Were this to happen, however, the grounds for compulsory licensing would then surely increase

- parallel importing revolves around the ability of a government to import a drug that is sold more cheaply in another country, thereby eroding the patent-holder's monopoly position and simultaneously getting drug prices down in its own country. This carries with it concerns about damaging the reputation of the drug if the parallel-imported drug is of poor quality and not a true equivalent. South Africa has legal provision for parallel importing on its law books, but implementation requires the exercise of quality controls

by the MCC. It has yet to be used in practice, and such a move would in any event do nothing to boost local production

- data exclusivity relates to data from the patent-holder being used by regulatory authorities in such a way that generic firms can get more quickly to market once the drug is off-patent. In South Africa, the 'black box' reputation of the MCC has led some innovator companies to fear that their data are not being effectively protected

South Africa's IPR provisions are not in contravention of WTO rules. The Doha Declaration, articulated in late 2001 by most developing country members of the WTO (including South Africa), asserts developing countries' rights to have certain flexibilities within the overall WTO agreement on Trade-Related Aspects on Intellectual Property Rights (TRIPS) regarding access to medicine. These flexibilities include the rights to compulsory licensing and parallel importation in the event of public health crises and national emergencies.

While IPR flexibilities have not been used in South Africa, the perceived threat and uncertainty caused in the minds of R&D companies damage what might be termed the country's value proposition. This refers to the explicit presentation to the investor community of the tangible and intangible factors that a country offers in a certain sector. For example, a robust value proposition to an innovator company in pharmaceuticals would include strong IPR protection, while a value proposition to a generic company would include something weaker.

What has resulted in South Africa with the case of ARVs and TB drugs is voluntary licensing. This has resolved some of the IPR uncertainty. But, the potential threat of parallel importing and compulsory licensing has done little to build confidence among investor companies in South Africa's commitment to recognizing the value of IP.

Further, some of South Africa's regulatory issues manifest themselves as IP issues. If the MCC were more efficient, for example, calls for patent extensions and concerns over data protection might be mitigated. Similarly, if the pricing rules were more transparent and credible to private sector firms, their desire for strong IPR protection might be less of a concern.

Hence, the bottom line is that an unequivocal statement on how IPR-related sections of the Medicines Act is urgently needed. The current regulations imply that only parallel importing will be allowed, and that compulsory licensing will be subject to regulations stemming from the Patents Act. To date, neither authority has been exercised, and it is not clear under what circumstances this would happen. A clear exposition of when and how the government will invoke such provisions will be essential to clarify to prospective investors where South African stands on IPRs and hence to alleviate their uncertainty on this score if they are to enter the market.

4.5. MARKET SCALE

This determinant refers to the attractiveness of a country as a market for a pharmaceutical company. Scale depends on both the volume of need for a drug and the ability to pay for meeting that need. If the market is small, whether for one or both of these reasons, then pharmaceutical firms—which require economies of scale—will find it difficult to become viable. Countries with small markets need actively to address the problem if they wish to be a favoured location for pharmaceutical investment. The possible means of doing so include enlarging the market through regional integration and harmonisation of investment and regulatory regimes, seeking donor funding to help 'convert' need into effective demand, and designing programmes to enable those whose healthcare needs are currently met by the public sector to 'transfer' to the private sector.

In South Africa's case, the private sector market's size has essentially been stagnant throughout the transformation period. Even though it is a high-value market, it reaches only 15%-20% of the population. Therefore, increasing its size means the scale found in the high-value sector will also increase, and provide another aspect of an overall value proposition to an investor. However, currently the majority of South Africans are in a low-value market, unable to pay and hence to increase the value of demand. If policies are put into place whereby some could effectively migrate into the private sector market, and take advantage of it without lowering its high-value nature, then the resulting increase in demand would be a boost to the sector's industrial performance.

Similarly, while efforts are being made to integrate and harmonise the regulatory authorities at least within SADC, progress has been slow, and there are fears this could serve only further to strain the internal capacity of the MCC. Building market scale by integrating regionally is one way to achieve more market value, but if the MCC were required to take the lead in a regional initiative its resources and systems would be severely over-stretched and would have to be greatly strengthened. Hence, proactive efforts to engage with SADC on this effort—perhaps under the recent commitment to improve production and availability across the continent—is essential to make sure that regulatory harmonisation occurs sooner rather than later. Enhancing the capacity of the MCC will be critical to the success of these efforts.

4.6. COST-COMPETITIVENESS

This determinant refers to the costs, internal and external to the firm, that make a country attractive to an investor. Internal costs include those costs which are directly in a firm's control, such as the relative prices of labour and of overheads such as electricity, water, land and buildings. If labour costs are high, there must be a value proposition that makes the premium worthwhile, such as higher quality skills. If there is a premium because the labour market is too rigid when compared to competing countries' labour markets, then the premium will not be worth it from the perspective of the investor. Similarly, if overhead costs are high, the quality of the various components of infrastructure (such as power, water or land) must be

worth the premium. If the case can be made that the premium is worth it, then the cost competitiveness issue is resolved; if, however, the premium seems to have no basis in actual value, then the country's higher internal costs make it uncompetitive.

External costs are those beyond a firm's control. For example, in circumstances where the exchange rate is volatile, if the local company is serving only the domestic market but imports most of its inputs (as is the case in South Africa), currency depreciation will damage profit margins while appreciation will widen them. If volatility is high, revenue predictions are difficult and the firm's ability to make sound investment decisions is impaired. This inevitably compromises the competitiveness of a country.

Another external cost is tariffs. If tariffs exist for some drug inputs (such as APIs) but not for the drugs themselves, such a regime will favour imported drugs over locally produced drugs. There is a lack of clarity on what is occurring at present in South Africa, but some in industry have indicated that there are in fact tariffs on several APIs. As APIs are not a specific trade category, the onus is on industry to prove that specific API inputs they are using are in fact subject to a tariff. Further, up to 140 other (non-API) pharmaceutical inputs of goods not produced in South Africa are also subject to tariffs.[25] Since South Africa has no duties on finished drugs (unlike many countries), these tariffs on inputs mean imports are favoured over locally-produced goods. As an example, if a local producer exports its drugs to India, it will face a duty of at least 15%; conversely, if an Indian producer exports the same drug to South Africa, it will face no duty.[26] As such, the local producer will find it hard to compete. On the flip side, the imposition of tariffs on finished drugs will inevitably raise the price to the consumer—an example of how industrial policy can have a negative impact on social policy. Nevertheless, the point remains that the level and structure of tariffs are critical from a competitiveness standpoint, and designing the 'right' regime requires an intensive dialogue between government and industry.

4.7. CONCLUSION

In sum, these six determinants establish whether or not the pharmaceutical sector in a country will have the ability to grow. As seen above, South Africa has shortcomings on all six constraints, and this is why the country has as yet been unable to find a competitive position in the global pharmaceutical marketplace. Not responding to these shortcomings means that South Africa will continue increasingly to rely on imports at the cost of its own production and R&D activity. A high level of dependency on imports is risky because:

- South Africa has a potentially large market as local demand increases and as international competitors look at higher-value markets

[25] Industry interviews.
[26] Industry interviews.

- South Africa needs to ensure some local supply security and not be completely dependent on other countries for its major drug needs

- local production allows South Africa to seek to reduce its trade deficit in pharmaceuticals, as well as attempt to mitigate its exposure to currency volatility

- local production and some R&D capacity further enhance South Africa's overall policy goals of building and retaining technological expertise in-country

What also emerges from this discussion is the inter-dependence between industrial policy and healthcare policy when it comes to pharmaceuticals. For example, where social goals in healthcare are to be achieved through measures which affect the regulatory and IPR determinants, consideration needs to be given to the economic and investment impacts on industry. As seen in the discussion of the pricing proposals and the efficiency of regulation, the social goal may actually be undermined if the consequences are for the industry to be weakened or for companies to exit. A strategy must consider all of these determinants, seeking to strike a proper and robust balance between achieving the social goals of an equity-enhancing healthcare policy and a growth-oriented industrial policy. In formulating such a strategy it is vital that the country's value proposition, referred to earlier, is clearly and convincingly stated.

5. PRECONDITIONS FOR REALISATION OF THE GROWTH POTENTIAL

To realise the country's growth potential a number of preconditions have to be put in place. South Africa will then be able proactively and strategically to address its shortcomings in the six determinants delineated above, and begin to build a competitive advantage in pharmaceuticals production. We divide these preconditions into four areas: time, commitment, collaboration and reality.

5.1. TIME

A sector as technologically and knowledge-intensive as pharmaceuticals cannot be built overnight. For South Africa's strategic goals to be realised in healthcare and economic growth vis-à-vis AsgiSA, it must be understood that the time-frame is long, probably at least two decades.

India is an instructive example. In the 1970s, it made the choice to become self-sufficient in pharmaceutical production. As this was before the WTO and TRIPS, it recognised patents on processes and not on end-drugs. This allowed it to build up expertise in generic drug production and associated aspects of the value chain. Indian companies have now entered a post-TRIPS world, well-positioned to make the shift from producer to research and developer, either by themselves or in partnership with multinational firms. While South Africa's WTO obligations with respect to IPRs make such an approach infeasible, it is India's long view which is significant; it has over several decades built a world-class industry that is now evolving as the global market and structures have changed.

5.2. COMMITMENT

Given the necessity for a long view, high-level political commitment is required. This means alignment and communication across departments on a common vision on the role pharmaceuticals are to play in South Africa's industrial and social policies. It also implies recognition that the sector cannot grow without overt and (prospectively) substantial government support. Over time, there is no question but that fiscal resources will have to be spent on incentives to attract investment, to build the necessary skills and to enhance innovative capacity.

We recognise that promotion of the pharmaceuticals sector is not the only industrial and social priority that government has. But, given the government's stated seriousness about provision of affordable healthcare, as well as the fiercely competitive international environment for attracting investment in the sector, we judge that government has no option but to commit now to strategically supporting the sector over the long term.

There is another dimension to the requisite commitment. The distinctive opportunity for South Africa in the global pharmaceuticals industry lies in servicing the market for infectious diseases in sub-Saharan Africa. We understand that, because of lack

of harmonisation of regulation across the countries of the region, this is a fragmented market made up of mostly quite small segments. Accordingly, South Africa will have to take the lead, within the framework of at least SADC and ultimately the African Union, to facilitate the necessary harmonisation. It will similarly have to focus on securing sustained donor funding so that the need for drugs in poor countries can be converted into effective demand.

None of the above actions will be easy or quick. This underscores the need for high-level and long-term commitment.

5.3. COLLABORATION

Government will have to ensure collaboration not only across its departments and agencies, but also between itself and industry, along with input from labour and civil society. Since the sector is necessarily highly regulated, the interrelationships between all sides are deep and multi-faceted. This was seen above in the discussion of the inter-dependence between social policy and health policy.

Collaboration requires hard choices. First, within government there will have to be consensus and alignment on how the sector is to be treated. This means a shared understanding across government of what it would like to achieve from having a robust pharmaceuticals sector in South Africa, how that will be achieved through policy and institutional design and what the role will be for each stakeholder. This is to minimise conflicts between departments responsible for social policy and departments responsible for industrial policy. This is not to say one side should dominate the other; rather, both sides must recognise that tradeoffs will have to be made by each and that there is mutual dependence between the social and industrial goals of healthcare policy in South Africa, as argued earlier. In the end, this may well mean reviewing or moderating the position on drastically lowering prices in the private sector, or studying more innovative ways to get private sector prices lower for poorer segments of the population. It may also require stronger coordination within government and a greater willingness for individual departments to recognise that their policies and actions have direct and indirect impacts on other departments.

We have been struck in the course of our consultations by the distrust that pervades the sector. There is no need to attribute blame. Rather, one must acknowledge the government’s commitment to rectifying the deeply unequal availability of healthcare that it encountered in 1994, and equally that some of the measures it has adopted to do so have had unintended and adverse consequences. Similarly, one must recognise, given the history of the international industry, that some of the companies have found it difficult to know how to respond to the intentions of the government.

If the sector is to flourish, which we believe is essential if the government’s healthcare and economic growth objectives are to be met, we believe the way forward lies in an unconditional, multi-stakeholder and multi-departmental review of the pricing, procurement and regulatory policies, followed by swift and decisive

action by government. There is an urgency about this, given the prevailing levels of confusion and uncertainty across the sector.

5.4. REALITY

There is no reason why the pharmaceuticals sector cannot flourish in South Africa, and every reason why it should. But it is hard to imagine that South Africa will become the next India. Rather, what it can aspire to is to become more secure in supply of the drugs it needs most, and also to become a major base for producing and distributing drugs for sub-Saharan Africa. Should it be successful, exports will grow, investment will be attracted, and as the sector becomes more robust, it will be able to move into related activities.

However, it must be recognised that the sector will not directly generate many jobs for the unemployed or the less-skilled, and that its impact on poverty reduction will be indirect and through provision of healthcare rather than through economic growth. Its contribution to the AsgiSA objectives of growth, employment generation and poverty reduction will thus be real, even if mostly indirect.

6. CONCLUSIONS AND WAY FORWARD

Our answers to the two principal questions we were posed are straightforward:

- the pharmaceuticals sector, as a vital element of healthcare provision, is of strategic significance to the country. This arises principally (though not only) out of the high and rising incidence of infectious diseases which constitute one of the critical challenges facing the country, and out of the consequential need for security of supply

- the sector does have the potential to grow. While there is good reason to have a broad-based industry locally, the country's distinctive opportunity lies in positioning itself to be the supplier of choice, in partnership with others as appropriate, for drugs that combat the infectious diseases prevalent in sub-Saharan Africa.

This means that South Africa has to make two sets of choices on where it wants to focus its production and development. The first revolves around defining what the market will be (entirely domestic to entirely export-focused). The second involves defining what the focus of the sector should be (all products and activities of the pharmaceutical value chain, versus building a competitive niche in key products and activities). We present this pictorially below.

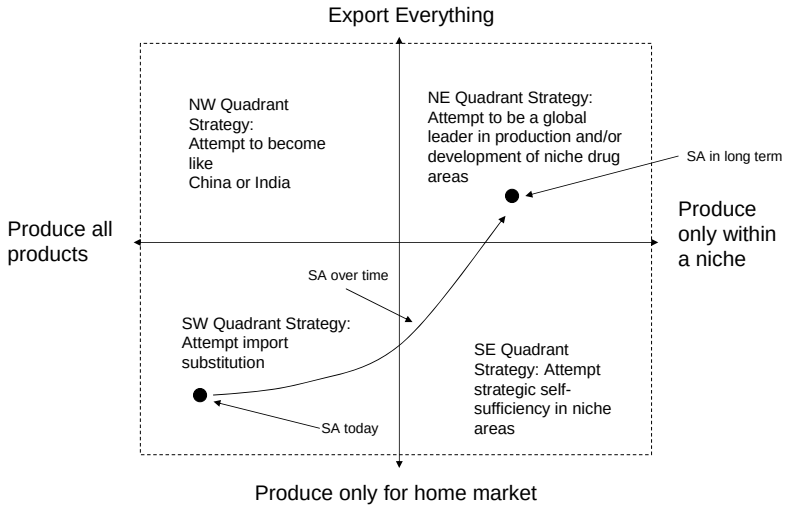

Figure 1: Proposed Way Forward for Pharmaceuticals in South Africa

Source: Genesis Analytics

Currently, South Africa's pharmaceutical industry sits in an uncompetitive position similar to that of an import substitution industry—producing little for export, across a range of products and value-chain activities. However, it adds little value and finds itself inefficient when faced with global competition. Thus, South Africa must create a value proposition that steers the sector to focus increasingly on building a

sustainable competitive advantage in those products and areas of the value chain where it demonstrably has real potential. In doing so, it should begin with its domestic and regional market, and over time expand to the wider export market as the sector becomes globally competitive.

However, as the earlier sections made clear, this statement about the potential for growth must be heavily qualified. The sector is currently not in a healthy state. Apart from much of the industry being internationally uncompetitive, the policy and regulatory framework is not only uncertain and inefficient but is also inimical to the interests of the companies. We have identified a number of factors that need to be resolved, and pre-conditions that must be achieved, if there is to be progress.

None of these difficulties is insuperable. They are amenable to rational analysis and resolution. What is required now is for government to:

- articulate its vision for the sector, leading to a value proposition that makes it clear to investors what South Africa hopes to achieve with its pharmaceuticals sector in economic and healthcare terms

- establish the framework for setting the different roles to be played by its respective departments and agencies, including identifying and properly resourcing the institutional mechanism to design and implement the strategy for attaining this vision

- convene a high-level forum of all stakeholders to review the prevailing policies and regulations, with a view to revising them so that the vision is realisable. Apart from any policy changes that result, such a process if transparently conducted, will go a long way towards overcoming the historically poor relationships, and for creating a positive climate for collaboration across the sector

- in light of all of the above, send out a message to the world that South Africa is serious about being in the pharmaceuticals business, and that it intends to become an increasingly attractive destination for investment in the sector.

In crafting the way forward, government must strike a balance between many contending concerns, each with their own opportunity costs. These immediately reflect back on the determinants of growth discussed throughout the report, and we highlight the main ones here:

- *regulatory quality*. There will have to be a balance between having the lowest possible prices for consumers in the private sector versus having an economically robust local production base. Having a more efficient regulatory body, however, is not a hard choice—it is a necessity

- *IPRs*. There will have to be a balance between having an IPR regime that favours the presence of generic firms and the lowest possible prices for

consumers, versus one which recognises innovator firms' concerns with weak IPRs. Resolving regulatory concerns should help mitigate the opportunity cost in having a more flexible IPR regime favouring generic producers, but it will not resolve it entirely

- *innovative capacity*. There will have to be a balance between having fiscal support for various innovation-focused programmes for pharmaceuticals, and diverting that money to other equally-worthy incentive programmes

- *availability of skills and healthcare provision*. There will have to be a balance between focusing on building skills relevant to pharmaceuticals over other areas of the economy, as well as putting more resources into healthcare relative to other, equally-worthy areas

- *market scale*. There will have to be a balance between depending on the private sector to help off-load some of the burden currently on the public sector through subsidies and other expensive methods, and directly focusing on fixing the public sector itself

- *cost-competitiveness*. There will have to be a balance in choosing which cost-drivers to improve over others, with related social spillovers if such improvements were to expose parts of the value chain to more competition and less protection.

LIST OF INTERVIEWEES

Peter Barber (Fine Chemicals Corporation)

Arthur Barnett (Adcock Ingram)

John Bartlett (Pfizer)

Val Beaumont (IMSA)

Jonathan Berger (AIDS Law Project)

Desmond Brothers (Ranbaxy)

Patsy David (Macquarie Bank)

Vicki Ehrich (PIASA)

Guni Goolab (AstraZeneca)

Joey Gouws (MCC)

Ronnie Green-Thompson (Department of Health)

Noel Guliwe (Novartis)

Matthias Haus (AstraZeneca)

Mandisa Hela (MCC)

Imtiaz Hoosen (Sandoz)

Gregory Hussey (University of Cape Town)

Raseela Inderlall (NAPM)

Elsabe Klinck (IMSA)

Bailey Klinger (South African Growth Initiative at Harvard University)

Andrew Kudlinsky (Department of Trade and Industry)

Mariette Lowes (North West University)

Sipho Moshoane (Biovac)

Stavros Nicolau (Aspen Pharmaceuticals)

Trevor Phillips (NAPW)

Anban Pillay (Department of Health)

Kuben Pillay (Adcock Ingram)

James Ringer (Eli Lilly)

Vikash Salig (Dr. Reddy's)

Kevin Simon (Aspen Pharmaceuticals)

Mpumi Sowazi (Biovac)

Lynda van Niekerk (NAPW)