Interview with Stavros Nicolaou, Chairman, PHARMISA South Africa

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of the worldâ??s most disproportionate disease burdens, the worst of so-called westernised diseases, such as cardiac disease, diabetes etc on the one hand and the developmental infectious diseases, such as HIV, AIDS and TB on the other. South Africa represents 0.4% of the worldâ??s population, yet it carries 17% of the global HIV burden.

This disproportionate disease burden, supply security concerns and the opportunity to begin leveraging large domestic infectious disease volumes for potential export growth, particularly into developing and emerging markets, led to an industrial introspection by the local pharmaceutical sector a few years ago. I believe that as PHARMISA we were party successful in shaping the future industrial landscape of the pharmaceutical sector.

This position, although it is in its infancy and significant roll out still needs to happen, the new industrial direction of the local industry represents a refreshing departure from the previous two decades. The last 15 years in particular, had seen the closure and / or downsizing of close to 40 manufacturing plants in South Africa, particularly as multinationals shifted their production to either more industrial friendly destinations, or those where global manufacturing had been centralised for long run, dedicated, campaign manufacturing.

This is also a refreshing departure, as the South African industry traditionally has been largely import biased, with the pharmaceutical sectors trade deficit growing year on year to the point where in todayâ??s terms the ratio of imports to exports is over 15:1.

Moreover, pharmaceuticals and medical devices are the fifth largest contributor to South Africaâ??s current account deficit, with an obvious focus, as there is in other economies, for pressure to shrink deficits.

South African Government, together with its social partners, has placed significant effort and investment in repositioning the South African economy into one that is less import dependent and one which can gradually improve its export orientation. PHARMISA has been able to successfully position itself in this social partnership and future economic positioning. To this end pharmaceuticals have been positioned as one of the key priority sectors for industrialisation and technology development, in the South African governments industrial policy action plan.

Local industryâ??s case for inclusion as a priority sector was most certainly bolstered by a number of factors. These include a number of visionary pharmaceutical entrepreneurs such as Aspenâ??s Stephen Saad, who have leveraged existing market strengths and who, through challenging existing

mindsets, were able to use a South African platform, to build what is today a multinational business operated largely out of South Africa. Iâ??m pleased to say that there are a number of other smaller emerging players, many of them from previously disadvantaged backgrounds, who are beginning to position themselves for volume growth and potential exports into Africa.

Other factors included the need to ensure consistency and security in supply, particularly for epidemiologies where sustainable supply is critical. Linked to supply security is managing the risk of material downward currency movements, which push up the cost of imported products and can fuel imported inflation. It is therefore important to bring parity to the trade ratio and mitigate the risk of downward shifting currency by enhancing local capacity.

The growing pandemic of HIV, AIDS and AIDS associated diseases presented a case, both for the investment in local capacity, but also the opportunity to leverage the scale that these diseases present, for more domestic stimulus, export orientation and diversification into other dosage forms and formulations. For example Bodene, the local subsidiary of Fresenius-Kabi exports hormonal injectable products into various export geographies. Similarly the empowered company, Specpharm, has been able to use domestic stimulus to diversify and manufacture ARVs. Lastly, empowered company Litha Healthcare, through its subsidiary, Biovac will commence the manufacture of vaccines by 2013.

In our discussions with Government, we have represented that although Pharmaceuticals, being high tech, high value add products are more capital rather than labour intensive, there will be some job creation as the sector grows, however the real value in promoting local manufacture is in providing supply certainty in a country with one of the most disproportionate global disease burdens, skills retention and diversification, new technologies, the reduction of current account financing by deficit reduction and future export potential.

What have been PHARMISAâ??s main achievements over the past few years?

One of the key issues that local industry has strongly advocated, with South African Government is the need to balance the trading playing fields. In many cases the playing fields are lopsided in favour of importers, as they are subsidised by the export destination, through tax holidays and other instruments, or the export destination has defensive tariffs, which provide a significant advantage to exporters exporting to South Africa. The South African Pharmaceutical sector has no duties on finished product imports making the South African market an extremely open one and one which is highly vulnerable to import substitution and displacement. Fronting by local empowered players who import into South Africa exacerbates the import bias and negates true Black Economic Transformation in the country.

Working together with Government, PHARMISA has made significant progress in addressing these industry threats and particularly the need for a more level playing field. To this end, SA Government is in the process of tabling legislation that will provide stiff sanctions, for fronting as it was described above. This legislation is due to be introduced shortly.

In terms of the unlevel trade environment, PHARMISA has successfully incorporated pharmaceuticals in the revised preferential procurement framework regulations. It was particularly important for PHARMISA to achieve this, as these amended regulations provide for the designation of the pharmaceutical sector and the recognition of the value add established by local production as opposed to the importation of these same products.

PHARMISA is made up of local South African producers and Black Empowerment companies. Our singular interest is to promote local production, create empowerment opportunities and boost local capacity whilst some of the other trade associations have some interest in this, there are others, that

primarily represent importers and it would not have been possible to achieve this should the PHARMISA members have been part of the one of the other trade associations that presently exist in South Africa. We required an organisation that had express focus on promoting local manufacture. PHARMISA represents this.

The previous preferential procurement framework was ineffective and in many cases, as described, with tender fronting earlier, the framework landed up favouring an importer, rather than a local producer, negating the very core of the framework. We are relieved and welcomed both the revised preferential procurement framework and the imminent changes to empowerment legislation that will short circuit fronting.

Since its establishment, PHARMISA has focused on three priorities; these included preferential procurement, the development of productive incentives to boost local manufacture and addressing tariff and non-tariff barriers to entry. Our focus has been on the first two areas and once these are bedded down we will place more attention on the third.

In respect of the first two priorities, we have had reasonable success around the capital incentives and as indicated earlier pharmaceuticals are due to become one of the first sectors legislated for designation.

Designation means that an agreed list of products will be set aside only for public sector procurement from local companies. A draft list of approximately 180 molecules is presently being finalised between the Departments of Trade & Industry, and the Department of Health for the purpose of local procurement.

Local procurement infers that a certain percentage of local activity has to take place in South Africa. This will be determined by a local standard administered by the South African Bureau of Standards. Moreover the social partners, being Government, Labour and Business have signed a local procurement accord, in which the pharmaceutical sector has been included. This places further impetus to our goal of boosting local manufacture.

What is better: to secure cheap drugs for the population or to Industrialise? And can pharma really help to fix the trade deficit?

One of the debates that has presented over local procurement, is what happens with those medicines that are cheaper if imported and whether this is cost efficient to procurement budgets.

The answer to this is simple. Firstly, not everything that is imported is cheaper, in many cases a locally produced product costs less than that of an imported one. Furthermore, preferential procurement applies only to the public sector and public sector procurement is funded through the national fiscus. Therefore, the cheapest price is not necessarily the most cost efficient to the fiscus. For example, a locally produced product might contribute 20c more back into the economy out of every R1 publically procured, when compared to an imported product, if the import is 10c cheaper, you are clearly better off, as the fiscus purchasing the locally produced one, in fact you are 10c better off.

In addition, aside from the cost benefit example described above, where the locally produced product represents best value for money, there are a number of other benefits to supporting local production.

The absolute national imperative for South Africa is the need to grow our economy at levels of around 7% of GDP. This is important in order to close the income disparity gap and create long term political stability. Local manufacture, with its multiple spinoffs, such as an increased tax base,

enhanced education, job creation and improved service delivery are all closely interwoven to this national imperative.

The case for boosting local manufacture is an extremely solid one.

All of the above factors are interwoven with the South African Governmentâ??s New Growth Plan (NGP). The NGP is the overarching growth plan for South African Cabinet. The current administration is going to be largely judged by its delivery on the NGP. Industrialisation is a key component of the NGP.

What are your thoughts on National Health Insurance (NHI)?

NHI is very much in a conceptual stage at this point in time. NHI is the South Africanâ??s Governmentâ??s way of addressing the skewing in healthcare funding and resources between the private and the public sectors and also its way of lifting standards in the public sector and enhancing treatment access, particularly in the resource challenged settings.

NHI is at the inceptual stage of a â??Green Paperâ?•, released by Government last August. A â??Green Paperâ?• is a high level attempt at providing a first view of the NHI architecture.

As with something that is conceptual, the document is deliberately and understandably light on the details, including the details on the future direction of pharmaceuticals. Much of the NHI architecture needs to be agreed, before we can zero down into the detail of for example, pharmaceutical supply and provision.

As PHARMISA and also in my role at Aspen, it is a priority right now to build confidence and co-operation between the private and the public sectors. We are doing this through an initiative which although conceptual at present, aims to set up a compact between the private and public sectors. These discussions are taking place together with a number of other partners from Pharma, Hospital groupings, Funders, other parts of the Healthcare supply chain and Government.

We have discussed this conceptually with the Deputy President of the Republic and the Health Minister and they are excited at the prospects of the two sectors working together. As discussed earlier, this is in conceptual phase, however should it come off, it is likely to focus on Human Resourcing and Management Capacity Building, both areas which will make a significant difference to public sector healthcare outcomes.

How is the international benchmarking affecting the industry at the moment?

When you were last in South Africa, In 2005, the Government was looking to apply benchmarking for the entire private pharmaceutical market. Government has subsequently proposed various benchmarking methodology changes and the latest proposal is that benchmarking would apply only to originator patent protected products. This excludes generic products. This would mean the latter would be excluded from an economic impact point of view and most of the impact with the present methodology lies mainly with R&D based multinational companies.

Furthermore, the current methodology, which incidentally has not been legislated and is still the subject of discussion between industry and Government provides for the lowest price in a five country basket, as the benchmark. The five country basket includes Australia, Canada, New Zealand, South Africa and Spain.

What criteria did the DoH apply in determining the benchmarking basket?

It is difficult to comment on the criteria used, other than to say Government attempted to incorporate a basket of countries with similar developing economics, similar regulatory standards and some degree of similarity in disease profiles. Industry has subsequently contended that it would have found a different basket to be more appropriate to these criteria. It is however difficult to say because these criteria have never been outlined officially in a document.

The industry is not adverse to benchmarking per se, as long as Government adheres to benchmarking as it is defined in the Regulations. There is concern that benchmarking does not imply the lowest in the basket and that this is inconsistent with the regulations. It is hoped that Government and Industry can thrash out common ground here, such that a moderated form of benchmarking is able to achieve the mutual objective of increasing access to healthcare and at the same time not unfairly economically prejudicing multinational companies.

Mr Nicolaou, we talked mainly about what has changed over the past five years. What would you say has remained the same?

As the saying goes, the more we change, the more we stay the same. Seriously though, although a number of new challenges and opportunities present, many of the previous challenges remain with us. One of these challenges remains in drug regulation in South Africa. The Medicines Control Council (MCC), is a highly thought of global Regulator, which has established PIC/S Accreditation. Its workload has increased significantly in recent years and it continues to be underinvested, particularly at a human resource level, with skilled staff retention being a particular challenge.

The solution to resolving the MCC conundrum lies in a Government plan to overhaul the MCC and turn it into a type of state-owned enterprise. This overhaul requires legislative amendment and would have to serve before Parliament, but would seemingly address a number of the present structural weaknesses of the MCC and would enable it to futuristically retain skilled employees and resources.

Why do we have five trade associations in South Africa, whereas most countries have only two?

If you go back 20 years, there were two: Pharmaceutical Manufacturerâ??s Association (PMA) and National Association Pharmaceutical Manufacturers (NAPM) in those days, when the generic penetration was low, NAPM was made up of two or three companies. The market opened up in 1994 and a number of generic companies, mainly Indian generic companies, came into the market. These companies are largely importers. Of course these importerâ??s interests were not necessarily aligned to local producers, and local companies such as Aspen and Adcock Ingram soon found themselves within the minority in the NAPM and their domestic interests were not necessarily represented here. In the case of Aspen, together with other partners, we established PHARMISA. Adcock Ingram moved to PIASA.

The other trade association, which represented most of the market in value terms, 20 years ago, namely the PMA existed in that form until the late 1990s. In the late 1990s, following the so-called IP Rights landmark court case a split occurred in the PMA. Some of its members, all multinationals, defected and set up their own organisation, Innovative Medicines South Africa (IMSA). The PMA subsequently renamed itself to Pharmaceutical Industry Association of South Africa (PIASA).

The members of PIASA are mostly multinationals, however, Adcock Ingram, the second largest South African company after Aspen are members of PIASA.

In addition, South Africa has a robust self medication market, which has necessitated the establishment of a dedicated self medication trade organisation, called the Self Medication Association of South Africa (SMASA). We therefore have five trade associations. The members of

SMASA also belong to one or other of the other four trade associations.

In terms of market share, PIASA and IMSA represent around 65% of the market, PHARMISA around 22% and the NAPM around 13%, all in value terms.

Whilst each of these associations has its own unique interests, there are interests which are common and aligned across the five trade associations. In those cases where there is common ground, these five trade associations cooperate through an umbrella organisation on specific common issues. The PTG is not a binding association, but rather one that looks to leverage common issues and presents a united front on these issues. This approach is particularly useful in reducing duplication and streamlining discussions with Government. This makes it more efficient for both Government and Industry.

What is the vision you have for this country and the role PHARMISA will play?

What does PHARMISA want to do? PHARMISA would like to create an environment where South Africa becomes a leading emerging market player in pharmaceuticals, both with regards to production and distribution.

Over the years there have been a number of successful South African pharmaceutical entrepreneurs, some of which left the country 25 or 30 years ago and were able to establish successful global generic businesses. The Tabaznik family and Isaac Key are good examples of this. Although South Africans have this track record, traditionally global pharmaceutical businesses have not been established outside of South Africa. As indicated earlier, Aspenâ??s Stephen Saad has bucked this trend and it is an express wish of ours that South Africa will futuristically be seen as a pharmaceutical power house in pharmerging markets.

What I aspire to as a South African is a balanced perception of the challenges and opportunities that exist in our country. I find far too often that the international media, do not necessarily present an accurate picture of South Africa, often leaving would-be investors with incorrect perception. Not all about South Africa is bad and in fact there are a number of world-class products and services that exist here that donâ??t necessarily exist elsewhere. You will find really passionate business people and very committed South Africans from all walks of life who want to drive economic development, who aspire to a better future for their children and who want to improve service delivery.

Our markets are growing, there is a lot of economic energy around and if everyone pulls together we can make a real difference on the African continent and beyond.

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