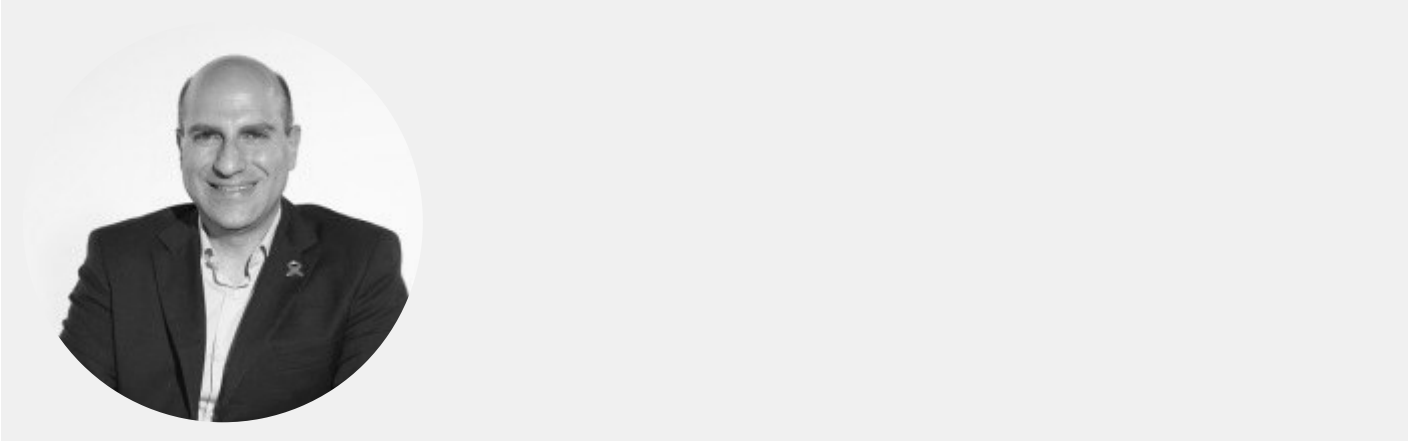
Interview: Stavros Nicolaou – Chairman, PHARMISA (Pharmaceuticals Made in South Africa)



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The chairman of PHARMISA reveals how pharmaceuticals has been designated as one of eight priority sectors of South African Government's Industrial Policy Action Plan (IPAP), how South African life expectancy has increased by around eight years over the last decade, placing further strain on the public healthcare system, and why the vision is to turn South Africa into a formulation powerhouse for emerging markets, helping to close the pharmaceutical trade deficit with a strong export orientation and import substitution strategy.

Back in 2012, PHARMISA was only just starting out, now you have cemented your role as one of the key South African associations. What have been some of PHARMISA´s achievements since then?

There has been some consolidation among the multinationals (MNCs) trade groupings. Previously there were two associations representing MNC's, now they have merged into a single association. Back in 2012 PHARMISA was the fourth largest association, by market share value; today we are the second largest. We have overtaken the National Association of Pharmaceutical Manufacturers (NAPM) and Self Medication Association (SMASA) in terms of value market share and represent the strongest Pharmaceutical Manufacturing base in the country.

There have been three considerable achievements. We have seen an expansion in the government's preferential procurement policy. Local producers are provided some preference under the preferential procurement policy framework. Industrialisation is at the forefront of SA Economic policy and is a key imperative for the Zuma administration's second term. A procurement policy has been introduced called "designation", which sets out a requirement for government, under certain conditions, to award a fixed percentage of any tender to a local producer. This has to be within certain conditions. Rent seeking, when prices are artificially inflated, is prohibited. You have to be within a particular price band to qualify for designation status. While this policy has not yet been implemented to its fullest extent and there remain some weaknesses in the system, it is an important breakthrough for local producers.

The second major achievement was to have pharmaceuticals assigned as a priority sector. The first iteration of IPAP (Industrial Policy Action Plan) came out in 2007, and we have now had the fifth iteration released, with pharmaceuticals entrenched as one of Government's eight priority sectors. It is not a traditional manufacturing sector for South Africa. The fact that pharmaceuticals are one of the most prominent sectors within this plan is a considerable achievement and consistent with the SA government's approach of diversifying its economy. Thirdly, we have successfully advocated to our government on the need to establish manufacturing incentives, particularly for capex investments.

The South African government, together with social partners, has put significant effort and investment into re-positioning the South African economy to be less dependent on imports, and gradually improving its export orientation. What has been behind the government's change of emphasis?

South Africa has one of the worst Gini coefficients in the world, in other words we have an unequal society, together with peer countries such as Colombia or Brazil. We need to entrench social and political stability. To achieve this we need our economy to grow at 5 percent or more, creating the requisite number of jobs in the process. Quality jobs are needed and you want jobs that are going to be sustainable in the future. The National Development Plan (NDP) captures these objectives. It is a blueprint document for the government on economic growth. During the mid-2000s South African growth peaked at 5.4 percent. We had sound fiscal management and ran budget surpluses. However, this was not translating into sustainable jobs, the reason being that it was largely consumption-led economic growth. Those economies that have been in a similar post-democracy transition to South Africa, with significant job deficits and an under-skilled and under-developed population, increasingly and successfully moved into manufacturing economies. A strong

manufacturing sector is key to achieving our desired economic growth levels.

Our government was looking for sectors in which we could develop a significant manufacturing presence. As a local industry we argued that there was a strong rationale, given South Africa´s disease burden, to prioritise pharmaceuticals. The authorities did.

What do you see as some of the major challenges for the South African healthcare system?

Our country has only been a democratic one since 1994. Prior to 1994, we had a healthcare system that was largely geared for the servicing of 4 million white citizens. Fast-track 21 years, and we have roughly the same system, having been consolidated, that now has to care for 52 million people. As an additional challenge, we have had a significant worsening of our disease burden, primarily brought on by HIV/Aids, TB and the proliferation of non-communicable diseases (NCD's) such as diabetes. Today there are six million infected HIV patients in our country. These often require a long hospitalisation period because of secondary infections. We have also seen a shift into non-communicable diseases**.**

Over a decade ago our life expectancy went down to an average of around 53 years. It is now back up to 61. Having a life expectancy increase of around eight years over the last decade brings further challenges as more patients need to be treated in an already overburdened system. Our healthcare system has to cope with funding challenges and even fewer human resources, particularly in the public sector. Forecasting how many ARVs you need in the country is extremely difficult. If there is regional political instability amongst our neighbouring countries, and you suddenly have 400 thousand migrants entering South Africa, it places a significant extra strain on our already under-resourced healthcare system and makes volume quantification more difficult.

In recent times we have received some criticism that the country is not realising its economic potential. We need to place this in perspective. There are not many countries in the world that have had to contend with the explosion in healthcare needs that we've had to as South Africa. The MCC (Medicines Control Council) is a good case in point, where resources and capacity have remained roughly the same as 1994 in relative terms, yet the number of product filings has quadrupled. While there are numerous remaining challenges, we have achieved much. We now have 3 million people on ARV treatment, around seven times the size of the next large ARV public programme, the Brazilian one. The challenge remains that of leveraging all of your existing health resource to optimise health outcomes for all South Africans, regardless of whether they reside in the public or private sector.

Why has the South African market historically been an extremely open one, highly vulnerable to pricing pressures?

As the world has become more globalized, and our democratic order ushered in, more and more entrants entered the South African market. South Africa has one of the five most highly vulnerable emerging market currencies. Within this group of countries you have Brazil, India, Turkey, South Africa and Indonesia. The rand has gone from 8.10 to the dollar in 2012, to almost 14 today. This has placed significant margin pressure on pharmaceutical businesses in the country as most components are imported.

At the same time more and more people are demanding and consuming healthcare services. The public sector has had to considerably increase the number of patients that are being treated. In 2008 there were around 300 thousand people on ARVs, today that number stands at 3 million, a 10 fold increase. The cost of such an increase is significant. Unless there was significant downward pricing pressure, the authorities would not be able to ramp up to 3 million patients. The plan is to reach 4.8 million patients by the start of 2017. An ambitious target, but at current rates of conversion, certainly attainable. Consequently manufacturers have had to make themselves more competitive. This means changing API sources and more competitive manufacturing sites which in itself places significant regulatory pressure on businesses and the MCC.

On the private sector side, like the rest of the world, we are starting to see the use of customized drugs, primarily for diabetes and oncology. We are starting to see increased use of monoclonal antibodies (mAbs). Treatment on mAbs can cost up one and a half million rand (110K USD) per patient per year. This stretches the financial resources of private health funds. The private sector is around 75 percent of the market in value terms. If you are a small or medium-sized private health insurance scheme and you receive 20 such patients per month, this could place you in financial difficulties. Consequently the administrators of these schemes have become very vigilant in trying to drive medicine prices down. We do not have many biosimilars in South Africa as we don’t have a clear regulatory pathway for biologics/biosimilars. With generics, you can change prescribing behaviour and drive demand, pushing prices down as well as price referencing products.

What are some of the challenges with regards to drug regulation in the country?

Many of the regulatory challenges we raised in our interview in 2012 remain unresolved. The issue of international benchmarking has still not been settled. In 2004 we had the introduction of a transparent pricing system called single exit pricing. This meant that prices were set at a price net of discounts and that government sets the pricing increase only once a year regardless of macro-

economic conditions. This becomes a challenge when our currency becomes volatile or suddenly devalues. In the last couple of years the minister has set the increase at below the real increase in costs. There is a dispensation called Regulation 9, which allows you in exceptional circumstances, to seek an increase beyond the increase granted by the minister. The experience of the industry is that in reality this dispensation has been hugely onerous to implement and often this special increase is not granted.

With fiscal constraints and a depreciating currency, the government is having to become a lot more efficient around procurement. Today the authorities have to procure for an increasingly large number of people. This is causing a re-configuring and realignment of the supply chain in the public sector. Aligning the industry while migrating to a new system, and still preserving your supply chain sustainability, is a particular challenging, but necessary to secure long term sustainability..

Do you have a five year vision for the future of the South African pharmaceutical sector?

The vision is to turn South Africa into a formulation powerhouse for emerging markets. This will allow us to close the significant pharmaceutical trade deficit. Having a strong export orientation into other emerging markets and beyond is an important part of this vision. Aspen has proven that it can be done, having in a short space of time become one of South Africa's most globalised companies.

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