Interview with Vicki St Quintin, COO, PIASA. Pharmaceutical Industry Association of South Africa

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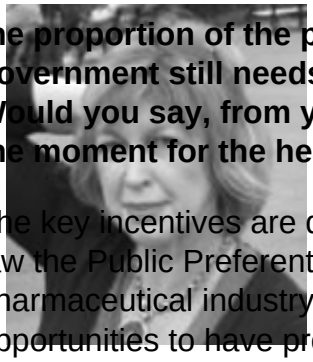

ly achieved the 1st Millennium Development Goal (MDG) â?? reducing the proportion of the population living on less than 1 USD a day by half â?? but the government still needs to tackle issues such as providing adequate public health services. Would you say, from your perspective, that the government is putting the right incentives at the moment for the healthcare sector to grow?

The key incentives are directed very much at local manufacturers. In fact, the authorities just put to law the Public Preferential Procurement (PPP) Act, which favours local manufacturers. In that, the pharmaceutical industry has become a designated industry. Local manufacturers will be given the opportunities to have preferences over importers â?? the preferences still need to be defined.

For instance, Adcock Ingram is currently setting up a factory under the Strategic Industrial Projects (SIP) governmentâ??s incentive. When comparing South Africa with the incentives that are given to the industry internationally that countries like Puerto Rico, Singapore, or Ireland have done in order to attract investment, South Africa is lagging behind.

In the 1980s, there were around 45 manufacturing facilities in the country; there is only a handful remaining today. The government is trying to stimulate local manufacturers. Almost only local generic companies are manufacturing in South Africa, as opposed to multinationals, which either import finished products, have some packaging done locally, or they have it done through contract manufacturing.

An increasing generic penetration is a global trend, not only in South Africa: In 2010, generics accounted for just 27% of the global drug market, and experts estimate this will reach 39% by 2015. How do you see this evolving in South Africa?

At the moment, the generic use is exceptionally high in South Africa. Since 2005, a mandatory generic substitution system is in place in the private sector. As a result, generic products in the private sector are 60% of prescription medicines by volume, while originators â?? original branded > schedule 3 â?? represent 40%. Generic medicines outstrip by far originators in the private sector. In value, originators represent 68% of the market, while generics represent 31%, again for the private sector.

There is of course also a very large portion of generic use in the public sector.

The generic penetration in South Africa is a growing phenomenon: for instance, last August, generics grew by 8% in volume, versus 0% for original products.

In September 2010, the ruling African National Congress (ANC) released its current proposals for the National Health Insurance (NHI), which aims to provide health coverage for all South Africans. From your perspective, what are the implications of the introduction of a NHI and the potential impact on both the economy and the population?

The Cabinet has released the NHI Green Paper for public discussion. Nevertheless, the information published is very top line, there is very little details. One mention only of pharmaceuticals is stated in the paper. Unfortunately, I lack information on what is exactly intended. What would be interesting to see, is the pilot studies they intend to do next year in a few districts of South Africa.

We hope that it would ultimately lead to a greater access to medicines and therefore greater benefits to the patients by retaining access to innovative medicines. In other words, we would be very concerned if the system introduced would involve an â??always the cheapestâ?? type of approach, restricting choice to the patient.

PIASA advocates for some kind of diversification, that the selection is done responsibly, that the patients do continue to have access to innovative medicines.

It would be demanding towards the South African population to finance the NHI trough taxation, as a fourth of them are unemployed and represented by a tiny middle class,. Do you have concerns about this and when do you see the first benefits of this program happening?

That is the biggest challenge that everyone has been criticizing. The introduction of the NHI is a decision that has been made and that is going to happen. The question of its financing is therefore not something that will make it go away. The government has committed to make it work.
As there is no exact time frame for the introduction of the NHI, what we are working on is what we would like to suggest to the government in terms of pharmaceuticals; that is what we think PIASAâ??s role can be. It is important that we comment on the pharmaceuticals, considering a lot of people will already be commenting on the funding aspects.

Focus Reports came in South Africa in 2005 and interviewed you, what would you say have been the most important changes implemented in the country since then in the pharmaceutical sector and how have these changes affected your agenda over the years?

On the positive side, what has been achieved by the associations working together has been the development of a code of marketing practices, which is very important for the ethics of the industry to be aligned with the worldwide movement.

The code has been agreed in-between South African various associations in this sector, and we entered a pilot phase two months ago that will last six months. We will then move into actual implementation of the code. There is a person that has been appointed at the head of the proper code authority, whose purpose is to open cases and fine offenders.

In fact, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) in Geneva has been very much impressed with what South Africa has done because this is the only country where all the associations have worked together including generics. Many of the other countries have worked only with the innovators associations. They keep on highlighting this idea of working altogether as a real achievement.

As far as the regulatory environment is concerned, we are still working on the pricing regulation, which we put on the table in 2004 and there has not been much progress since then. What was pending in 2004 is still pending today.

In 2004, the Single Exit Price had been introduced (2004). In order to adjust the SEP, the government has implemented three or four price increases since 2004. The adjustments have been erratic, but the commitment from the pricing committee is that they will move to a regular schedule, and it seems that the effort has been made to start the process this year.

On the other hand, what has not been finalized is for example the regulation of the logistics fees, which was supposed to be done when the SEP was initially set up. We again submitted comments earlier this year. We also had opportunities to comment on proposals relating to the methodology for international benchmarking of medicine prices in the private sector.

What are PIASAâ??s strategic priorities at the moment?

As we go forward, we will be dealing more and more with the NHI, and try to constructively solve issues around the registration of medicines. Indeed, in South Africa, it takes about four years to get your medicines registered. That is one of the blocks we are trying to work on constructively.

Moreover, companies in South Africa are subjects to the Black Economic Empowerment (BEE) score card, which defines how well you are doing as a company promoting the BEE. This score card counts towards whether you get the tenders or not. As an association, PIASA facilitates and assists its members with a tool kit, involving consultants who advice them, as well as running workshops to better apprehend the BEE situation.
Also, we have been looking at the rest of Africa. As an association, we have really been working on our membersâ?? interests in South Africa.

Things have become increasingly difficult for them in neighbouring territories, particularly with regards to regulatory issues.
In some of the countries, authorities have insisted that the product comes in only with the registration details on the pack. Volumes in such markets are so small that it is not worthwhile running separate production range to market in a particular country.

Even though you look at South Africa being the most important market in the continent, it has not been in the past the logical spring boat to the rest of Africa. South African companies have only marketed to the immediate surrounding territories most commonly, in the like of Namibia, Botswana, and Zimbabwe, not much further than that. Normally, the marketing to the rest of Africa has been done from corporate offices in the Middle East for instance.

There is today a shift, considering some South African companies are now looking to set up offices in the rest of Africa.

South Africa is a very well established market, where the growth rate of originator products is 0%. Some of our members are battling with these expectations: South Africa is seen as a developing market, out of which you could get massive growth, whereas South Africa has been a well established market for years. The rest of Africa should be looked at to see whether the environment is changing, the market has more potential, etc. South Africa companies have been given more responsibilities compared to the rest of Africa.

What is the level of clinical research in the country?

Even though South Africa is small â?? the country represents 1% of the worldâ??s market â?? the amount of research done by particular companies has been way ahead of what we legitimately think it could be.

In South Africa, the research has been affordable and of hard quality. Nevertheless, because of the increasing competition from Asia, there has been a campaign to reinforce the idea that South Africa is a good target for clinical research.

The country has gone through a massive clinical research drive. It is part of our governmentâ??s ten-point plan for health to drive clinical research. The Department of Science and Technology (DST) have a ten year plan for the stimulation of clinical research. A statutory party has been appointed by the Parliament, called the Technical Innovation Agency (TIA), which works under the DST to facilitate intellectual property, to attract, bring in technology transfer, and to turn any research done in South Africa into commercialisation.

The National Health research council will direct all the research activities in South Africa, including that of the Medical Research Council (MRC).
Clinical research is a massive potential area, which directly relies to us, as they will need researchers. It gives our members the opportunity to train researchers.

What is your final message to the readers of Pharmaceutical executive?

PIASA strives towards a value proposition, which really drives the value of the industry towards healthcare, far beyond the actual medicines. Medicines are the easy target where to cut prices. Our industry needs a better understanding of the value to be seen, the relevance particularly of multinational companies and originator products, because very often, people do not realize they are a crucial part of the cycle.

One of the most important arguments for our market is that you need to attract investment from the innovators in the market to bring the new products in the market, which then creates the pipeline for the generics to exist.

If you disincentivize the local presence of multinationals, you dry up your pipeline towards generics, which could be a threat in the long term. If regulation is too punitive and too focused on just cutting prices, which is happening around the world, then you donâ??t have any flexibility and sustainability in the sector.

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