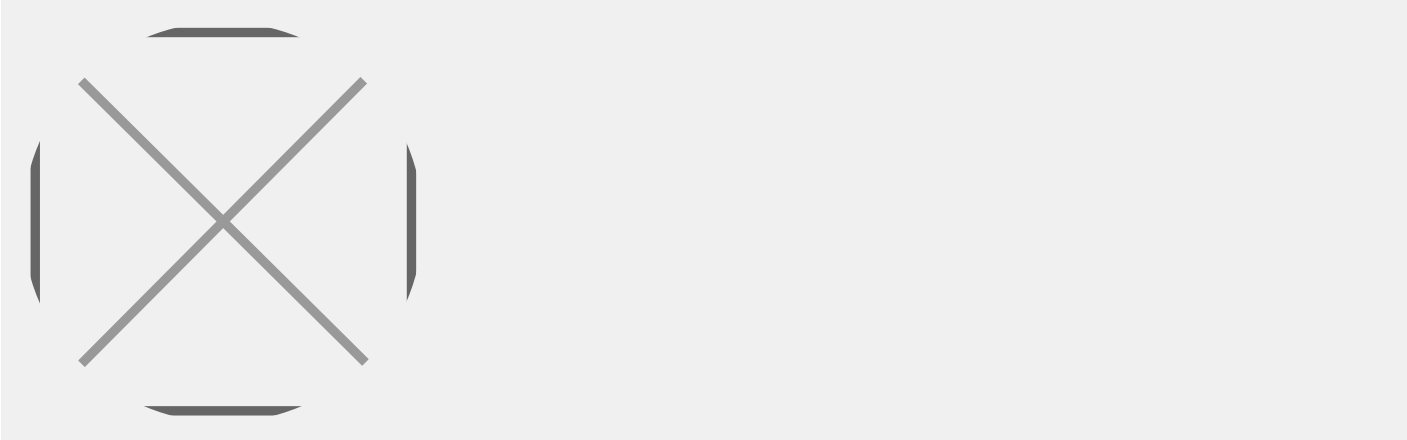
Interview with Val Beaumont, Executive Director, IMSA – Innovative Medecine South Africa



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Ms Beaumont, can you describe the association to our readers and its main objectives?

Innovative Medicines South Africa (IMSA) represents manufacturers of research-based medicines, ie they market the products of their own research. Many of our members do have generic medicines in their product portfolio, and we believe there is an important place for generics in South Africa, but we specifically represent the research-based agenda. We count 12 members, which all happen to be multinationals although we do not specifically represent multinationals in the first place.

What IMSA tries to do is to create a favourable environment for sustainable business opportunities for research-based companies.

Among the key issues that we are addressing, one of them is the regulatory issue, namely the important aspect of reducing the delay in the registration timelines as much as possible. We also obviously try to nurture an environment which respects intellectual property (IP) and there are today certain IP rights that do need to be protected. Another is the regulation of the pricing of medicines and the whole pricing environment. Not to forget probably the over-arching issue that IMSA has to deal with, ie the reimbursement process or access of patients to innovative medicines.

IMSA works towards ensuring that, in the whole debate around access to healthcare, that medicines access is an important challenge and that policy will provide for access to innovative medicines when appropriate.

We know that if there are no medicines then there can be no healthcare. One of our concerns is that politicians appear to think that the issues around access to medicines is just a price issue, but there is actually a lot more to it. It is looking at the needs of the country and the needs of patients and making sure that the right medicines are available.

This event – the International Generic Pharmaceutical Conference (IGPA) – emphasizes on the global growth of generic medicines. But we also talked about the importance of having a pipeline in innovative products. In your view, how does the future for innovative products look like in South Africa?

At the moment there is a lot of change happening in the country in healthcare. We see major decisions being made about how universal access to healthcare can be achieved and also about how medicines will be made available.

The market presents a combination of challenge and opportunity. Theoretically, South Africa is going to be a much larger market for medicines when we move to universal coverage with equal access to healthcare. However, in the same context, there will be new rules, new policies, and new requirements. Therefore we need to make sure that there is an opportunity for patients to access innovative medicines despite, affordability constraints
The government is also starting to talk about wanting to have its own pharmaceutical manufacturing facility. Perhaps in a more pragmatic way, what they could be foreseen is a focus on the production of ingredients for the manufacture of anti-retroviral (ARV). While some people see it as a threat, I don't. Sources of cheap but quality ARV raw materials need to be found and it is likely that the government will play a part in that.

Comparing both situations – in 2005 when Focus Reports first came to South Africa and today – what would you say have been the main improvements and changes in the market?

We have in that period seen quite a big shift to generic medicines in all sectors of the market. That is probably the main difference in the actual market. We have seen a lot of mergers and acquisitions (M&As) among the multinationals, looking at greater efficiencies and newer ways of doing business. That is a whole study on its own.

With regards to the National Health Insurance (NHI) we are getting greater clarity on what exactly is happening. As far as the pricing issues and the overall regulatory environment are concerned, we are right where we were five years ago.

In 2005, we had already brought down the average price of medicines by 21%. since then, we have seen increased controls coming in on medicines as well as on dispensing fees for doctors and pharmacists. There is still some legislation outstanding. Moreover, we have seen a lot more pressure on reimbursement for medicine coming from the medical aids who exert significant

pressure on patients to move to generics and cheaper but not always equivalent alternatives.

A lot is being discussed, we are seeing a lot of NHI initiatives up for debate but not a lot has actually been implemented at this stage.

Our audience knows about the economic conditions of the country recently joining the BRIC, but a lot of issues still need to be tackled in the healthcare sector. Do you think that the government is putting the right incentives out there for the healthcare sector to grow?

There is an interesting dynamic that I see playing out. To my mind there are three key influences on the healthcare policy.

One is the Department of Health (DOH), which has recognized that the healthcare delivery system is somewhat broken and is trying to find ways of fixing it, from infrastructure and human resources to the health insurance.

Another is the Department of Science and Technology (DST), which is a separate government department. The DST is doing a lot of exciting work such as creating an “innovation hub.” This department has put in place a national intellectual property management office to try and help inventors to patent their work and to commercialize it.

Also, the DST has identified a “buyer economy” strategy for health. Officials within the DST are looking at a strategy to ensure self-sustainability in terms of vaccine production for instance, or looking at indigenous medicines, natural plants, trying to develop therapies and molecules out of them in order to ultimately bring them to the market.

So there is definitely, from the scientific side, a significant focus on fostering research to market, rather than trying the main focus being on the research process itself. So now, there is a great support provided to individuals or small businesses to commercialize there search discoveries that may otherwise not have made it to the market.

The third key influence on healthcare policy is the Department of Trade and Industry (DTI). This department champions an investment strategy and a vision to increase the local manufacture of medicines. The DTI has identified pharmaceuticals as a key area for investment despite the impact on manufacturers of health policy. We anticipate the publication of procurement incentives soon to encourage industries to bring production and investment back to this country.

These incentives are favouring local production rather than imports. Many of our members have had manufacturing plants previously in South Africa but they almost all have disinvested. The message today is: “bring your manufacturing back.”

The global industry has moved more to Centers of manufacturing Excellence. They are manufacturing at global sites from which they supply the world markets. The Department of Trade

and Industry would very much like to make South Africa such a hub. It has to put incentives in place, however. Once you have had the disinvestment I do not know how easy it is to get investment back.

To sum up, the DOH is mandated to fix up the healthcare system, they want access to medicines but those medicines must be affordable, the DST is trying to get its own research program going, and the DTI is trying to secure investment in the country.

It also seems challenging for the South African authorities to attract innovators, which is hindering the spread of generics, right?

Indeed, the multinationals bring in huge knowledge on new medicines. They bring them in, get them registered, inform the market about it and get them produced. Then, the generics follow on.

In a branded market, the generics do much better. Where there has not been a product previously launched, generics battle to get it because they do not put the resources behind it. This balance is an interesting dynamic.

What does South Africa have to offer in terms of clinical research?

South Africa is a very good research environment. The country follows international standards of healthcare practitioners. They are trained well and the facilities are good.

Although there is in South Africa a huge potential for research, what is preventing people from coming out here is the long regulatory delays. That goes back to the registration problem. This is where the value of the DST comes in with their alternate mind set the DST brings a dynamic into the field in which they are trying to encourage research and they can influence the system to be more research-friendly, as opposed to the DTI which can be seen to be more investor-friendly.

We talked for years about South Africa being an emerging market but isn't it now an established and stable market?

There are in South Africa very specific provisions in the country's policy and legislation which favour generics, such as the mandatory generic substitution and the payor reimbursement system. As a result, one is constantly seeing the number and volume of generics in the market increasing.

South Africa is an emerging market and because we are part of that emerging market we have become subject to the usual pressures on innovative medicines. However, I think there is a huge place for innovative medicines in the country. We have all the key players and most of the products here, there must be opportunity here. Even though it is not a huge proportion of the global market, it is a very interesting market and a very strategic market.

The South African market is very specific. We have a very sophisticated private sector market and the question will be whether that will continue or not. It is looking like, as we move into NHI, that it will continue. If it does, then we are in the situation where it is an established market. However, if we move onto a total NHI system, the rules will be different.

To what extent do innovators and generics work together in the industry?

Where there are common agendas there is a good relationship and a strong will to work together. You will in any situation, whether at a company level or an association level, come to places where people must agree to differ.

The initiative to adopt the marketing code right across the sector was fantastic because not only did we cover all the associations, but also the over-the-counter products, medical devices and diagnostics. We are all responding voluntarily to things that are happening in the rest of the world and saying we will do it ourselves.

The Consumer Protection Act is another area. There is a lot more cooperation than there was before. When you have good relationships and a good understanding it lays the groundwork for healthy debates.

What are the strategic priorities at the moment on your agenda? To what extent do your members rely on the association?

Our key agenda item at the moment is the regulatory delay – the excessive period it takes to register medicines in South Africa. This is also an issue for generic companies.

We have been working hard collecting data to illustrate the problem and we are making all sorts of offers to the government to assist them. We know they are looking to a new authority and we would very much like to be a part of contributing towards setting up the training, the funding, and whatever is necessary.

There is a significant amount of IP within the industry with regards to the people, their knowledge and experience. The challenge is to have enough trust between government and ourselves to work together.

Moreover, the whole issue of reimbursement for innovative medicines by medical aids is a vexing challenge.

Thirdly, if you think that for a new chemical entity any patent is twenty years, then we lose ten with our research and development (R&D), plus at least another three (and often more) to the regulatory process. So we only have seven years of protection in the market before the generics come in. This period is where all the new treatments have to come through and the delay ids a barrier to access, – it deprives patients of access to those medicines for a three-year period.

What is your final message to multinational pharmaceutical companies that have not come to South Africa yet and who are looking at the business environment?

Nothing happens in South Africa that does not happen in the rest of the world. But it just all seems to happen at once. It is a vibrant and challenging environment.

We are facing huge changes. But with that huge change, comes huge opportunities. Nevertheless, one must not come in assuming that it can be likened to everywhere else. Come in and figure it out and seize the moment.

If what I learned today is still true tomorrow, it will be an easy day, because everything changes so fast. It is constantly changing. It is just a pool of new ideas around every corner.

South Africa is actually doing well in global terms. There are certainly regulatory delays and market barriers but we have 50 million people here who need access to medicines, and there seems to be a lot of energy going in to solving the problem.

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