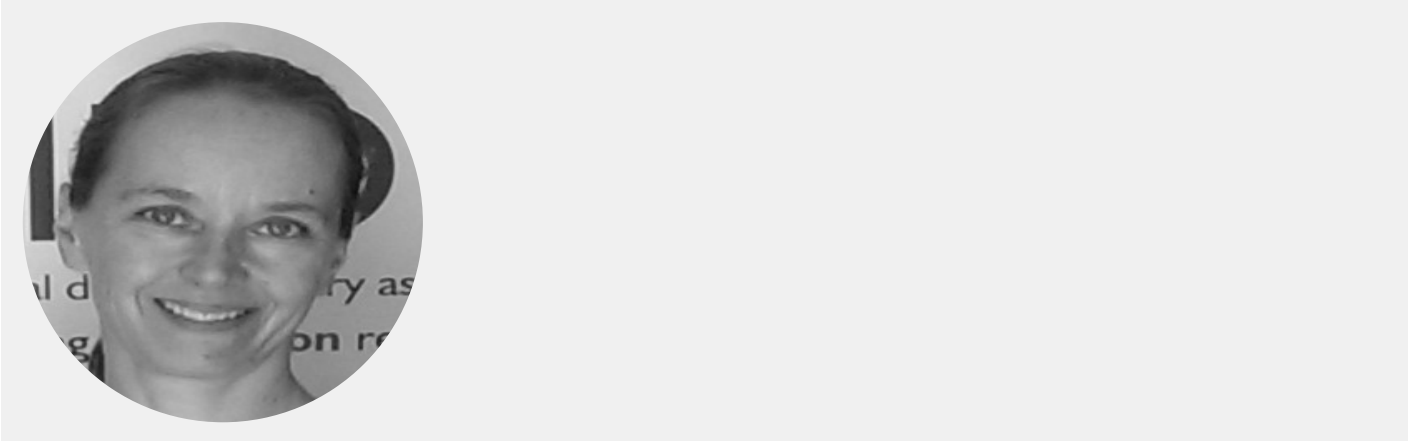
Interview: Tanya Vogt – Executive Officer, The South African Medical Device Industry Association (SAMED)



23.10.2015

Tags: Pharma, Pharmaceuticals, South Africa, Africa, Medical devices, Government Relations, Global Markets

The EO of SAMED discusses recent regulations surrounding the medical device industry in South Africa, why South Africa remains the hub and the major gateway to Africa for medical devices and In Vitro Diagnostics and talks about recent focus by government on supporting local manufacturing

What have been the main trends and dynamics in the South African medical devices market since we last met with you in 2011?

Impending Regulations are undeniably one of the main fields where important changes have taken place these past few years. New government drafts demonstrate the extent to which industry viewpoints are now being taken into account, by highlighting more specifically the nuances and the differences between the medical devices and pharmaceutical industries. To reach such a position, SAMED has worked constructively at different levels, including public hearings, committees, and position papers, putting forward the primary matters of concerns within our industry whilst maintaining an open dialogue with the Medicines Control Council (MCC) and the Ministry of Health. We have also had an educational role with regards to policy makers, by reiterating clearly the differences between pharmaceuticals and medical devices, to both the Ministry of Health's procurement department and National Treasury (in charge of many national tenders) levels, in order to raise awareness on the specificities of the medical devices industry. I believe we are closer than we have ever been to some form of regulation, even if it will be a long process until we reach

final implementation. The main reason being that there are plans to move from the MCC structure to the new South African Health Products Regulatory Authority (SAHPRA), a transition that cannot be completed until numerous legislation and infrastructural developments are completed. At the same time, the National Department of Health has embarked on a new project to create a Regulatory Training Institute that will provide ongoing training of medical devices regulators in South Africa. Companies will also have to deal with a Quality Management System that they will have to acquire and be accredited to, in order to get a license to sell medical devices in South Africa. The new system will also rely on new Assessment Entities that will accredit companies and give them the standard certification to receive the license to sell products.

Investors often see Africa as the next frontier in the global healthcare industry. The sub-Saharan Africa medical devices market is expected to grow, boosted by new investment, to reach $25–$30 billion in the total healthcare market over the next few years. What potential do you see for South Africa, as the most developed market in the continent, to potentially capitalise on such growth and become a medical devices hub for the region?

Beyond South Africa, in the past five years we have seen tremendous developments in the medical devices industry throughout the whole continent, not only in terms of offices opening, but also regarding partnerships between public or private stakeholders within different African countries. We have also noticed a lot of momentum in the regulation of medical devices in some geographical areas. In East Africa, Tanzania, Ethiopia and Kenya we have seen a process towards the harmonization of documentation required for registration of medical devices, and this kind of achievement is extremely helpful to industry. There is also the new Pan-African Harmonization Working Party, which aims to address the harmonization of regulation of medical devices and diagnostics in Africa, and which is committed to listen to industry views. One of the industry’s most pressing concerns is related to the cost of registration, which is generally labelled in dollars. In some countries, product registration is extremely expensive, and this is clearly a challenge that African governments need to review in order to improve the accessibility of medical devices in Africa.

Regarding South Africa, our country undeniably remains the hub and the major gateway to Sub Saharan Africa for medical devices. The new Regulatory Training Institute may assist in strengthening our position in terms of training and expertise. Nevertheless, some challenges need to be addressed, notably in relation to infrastructure and resources.

How does the South African medical devices environment compare to other emerging markets, such as the other BRIC countries? What are the particularities present within the South African medical devices industry?

In terms of regulations, South Africa still lags behind Brazil, even if government is undoubtedly trying to address such shortcomings. On the other hand, South Africa has tremendous potential to further develop its own local market. The focus for such local products seems to be on diagnostic devices, in the areas of TB, HIV and trauma, all of which are a real burden in South Africa. The Strategic Health Innovation Partnerships (SHIP), funded to a large degree by the Department of Science and Technology, is currently conducting multi-disciplinary and multi-institutional product research and development, looking into local needs and for local consumption.

There has also been a recent focus by government on supporting local manufacturing. After commissioning a report from Deloitte into the challenges faced by the local industry, the Minister of Trade and Industry is now formulating a development strategy. A new association has also been created, the Medical Devices Manufacturers of South Africa (MDMSA), and they have become members of SAMED. With regards to ethical principles and practices, thanks to the recently established Marketing Code (common to health products) and to the SAMED Code of Business Practice, South African industry strictly follows European and North American trends in terms of transparency. Finally, we continue to work on the reimbursement of payers and funders in the private sector and private hospitals, which put substantial pressure on the industry to reduce their prices. Again we try to educate policymakers and raise awareness around the specificities of the device world, specifically around scientific evidence and the shortening of delays to obtain approval for reimbursements.

On the pressure to reduce prices, we see that increasing access is one of the priorities of the government. What impact might the new South African National Health Insurance (NHI) system have on SAMED and its members?

From the documentation we have been able to scrutinize, it seems that government is still conducting a lot of “framework building” for NHI, implementing a large number of training programs and renovating current facilities. Government is also starting to pay more attention to waste and corruption with regards to procurement and the processes around payment. The situation has clearly improved from a couple of years ago, when hundreds of millions of Rands were owed to suppliers.

Do you have a five-year vision for the future of the South African medical devices industry?

Firstly, I think that if we get the expected regulations, we can foresee a reduction in the number of companies operating in our industry. My hope is that regulations will reduce the number of companies that are enrolled in tenders, but vanish without training employees or maintaining equipment once they have sold their products. Regulations should help us to reach our objective of having only quality, safe and effective medical devices and credible suppliers active in South Africa. We expect companies will spend more focus and money on product training whilst continuing to furnish greater efforts with regards transparency. I foresee a rationalization in pricing, given that The Department of Health wants to manage this field more closely and is embarking on a system of centralized procurement.

The ever weakening exchange rate and ongoing pressure by medical schemes to reduce prices will continue to be a challenge to Industry. Year on year however the Medical Device Market does show favourable growth.

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