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**INTERVIEW WITH
TANYA VOGT,
COO OF THE SOUTH
AFRICAN MEDICAL
DEVICE INDUSTRY
ASSOCIATION (SAMEDI)**



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INTERVIEW WITH TANYA VOGT, COO OF THE SOUTH AFRICAN MEDICAL DEVICE INDUSTRY ASSOCIATION (SAMED)



Q. Please tell us a little about your background and how you came to be Chief Operating Officer (COO) of SAMED.

A. I have held the position of COO of SAMED since January 2007. Prior to that, I held the position of Director of the Secretariat of the Private Healthcare Forum (PHF), an umbrella association representing key interests in the South African private healthcare sector, whose members include the Board of Healthcare Funders (BHF), the Hospital Association of South Africa (HASA), the South African Medical Association (SAMA), the Pharmaceutical Industry Association of South Africa (PIASA), the National Association of Pharmaceutical Manufacturers (NAPM), Innovative Medicines South Africa (IMSA), the Self-Medication Manufacturers Association of South Africa (SMASA) and SAMED. The PHF was instrumental in forging relationships between the private healthcare sector and government that culminated in deliberations regarding the health charter.

Q. How would you describe the current South African device industry in terms of the types of companies operating in the country, its growth, and the amount of imports versus exports, etc?

A. The South African medical device industry is a dynamic, highly competitive industry with a variety of players: multi-nationals, distributors, agents of varying sizes and a small number of local manufacturers. Approximately 95% of all devices are imported.

Q. SAMED recently brought in a Code of Marketing and Business Practice for its members to follow. Has this initiative been well supported by the industry?

A. Yes, certain of our member companies are

bound by international laws and codes, so we felt it vital to level the playing fields. We have closely aligned our code with that of the AdvaMed and Eucomed codes and we acknowledge the moral obligation in health to ensure that our interactions with healthcare professionals are based on promoting health technology and the safety, quality and efficacy of products.

Q. The Medicines and Related Substances Amendment Act, 2008 – which was published in April 2009 – finally introduces requirements for the registration and control of all medical devices and *in vitro* diagnostics (IVDs) in South Africa. When are these requirements expected to come into force?

A. Officials at the Department of Health estimate that draft regulations needed to implement the Act will be published in the Official Gazette for public comment by the end of this year.

Q. Do these regulatory requirements follow international norms or are there local deviations?

A. A draft document, which has been circulated by Mr Terry Downes, harmonises well with international regulations. However, this document does not address all prescribed regulations in Act 101 because it was finalised prior to the Act being amended. Local deviations in regulation may include controls on sampling, discounting and incentivising in business models for supply of medical devices.

Q. Is SAMED pleased with these legislative changes, or would the industry have preferred some alterations/a different approach?

A. The industry is largely satisfied with the

legislative changes. The industry was successful in participating in the Parliamentary process to substantially amend the original draft of the regulations, which were unworkable and biased towards regulation of medicines.

Our gravest concern is that the South African Health Products Regulatory Authority will not have the capacity to regulate the wide range of medical devices available, and will take too long to provide approvals for entry into the market. The lifecycle of medical devices is much shorter than that for medicines. Long lead times waiting for regulatory approval may mean that South Africans could miss out on the many advancements in medical technology.

Q. There has been some criticism of the structure of the new regulatory Authority that will be established to control medical devices, IVDs and other medical products. In particular, concerns have been expressed about the fact that it will be run by a Chief Executive Officer accountable only to the Minister of Health, and these two people will have virtually unfettered power over a multi billion Rand industry and the Authority will lack transparency and accountability. Does SAMED share these concerns?

A. Yes indeed, those concerns were raised during the period for public comment in Parliament, but the proposed regulatory structure remained in the amendment to the Act.

Q. Why did the South African government decide not to proceed with its proposed separate regulatory framework for medical devices?

A. There was a procedural problem with the introduction of the *South African Medicines and Medical Devices Regulated Authority Act* in the late 1990s, and the Minister of Health was asked to rescind the proposed law. Law experts may be able to provide the exact details, but my understanding is that there

was not sufficient opportunity for public comment and that the Act conflicted with other laws.

Q. Do you think creation of a separate medical device regulatory framework and separate medical device regulatory authority is likely in the future?

A. It is likely that there will be an overarching structure that provides shared services for medicines, other health products, medical devices and *in vitro* diagnostics (IVDs). There will be separate regulations and approval processes for registration of medical devices and IVDs because the industry had asked that medical devices and IVDs be excluded from the term 'product' as defined in the Act, and are therefore distinct from regulation of medicines and other health products.

Q. What do you see as the greatest challenges facing the South African device industry over the next few years?

A. The first is the introduction of innovative technology. There is an increasing drive to bring down the cost of healthcare in South Africa. Decreased cost, however, does not always equate to value, and for the devices industry this means we have to work a lot harder to get new technologies accepted for reimbursement by the medical insurers. Many of these technologies, while appearing at face value to be more expensive, actually offer considerable savings to patients, funders and hospitals in terms of reduced operating time, reduced patient post-operative hospital visits and reduced incidence of re-operation.

The second is National Health Insurance (NHI). How the industry is going to operate in the future depends on the outcome of the current national debate surrounding an NHI scheme. SAMED supports the concept of the introduction of universal health coverage through the NHI. Extending healthcare to more people is in everybody's interest and we look forward to participating in the debate surrounding the exact shape and form that NHI will eventually take.