

Interview: Vivian Frittelli - CEO, The National Association of Pharmaceutical Manufacturers (NAPM) - South Africa



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The CEO of

NAPM reveals how the main challenge facing his members is the length of time needed to register a generic product, taking up to four years and acting as a significant block on investment, discusses the benefits that come with being part of the International Generic Pharmaceutical Alliance and why re-unification of the two South African generic association would be an advantage for the industry.

NAPM is the oldest association representing the pharmaceutical manufacturing industry in South Africa. What have been some of the latest developments since 2012 when we met with your then President Muhammed Bodhania?

There has been a lot of change within the numerous South African associations. Around four years ago the association Pharmisa was formed, leading to fragmentation within the industry. Unfortunately, the two largest local companies, Aspen and Adcock, are not members of NAPM. Back in 2013 the South African research-based pharmaceutical companies that previously belonged to either Innovative Medicines SA (IMSA) or the Pharmaceutical Industry Association of South Africa (PIASA), integrated to form a new association, the Innovative Pharmaceutical Industry Association South Africa (IPASA). With the formation of IPASA, local companies producing generics, such as

Adcock, were excluded. We had been hoping Adcock would join NAPM, but instead they decided to remain independent, but in December 2014 joined Pharmisa.

NAPM works with the government and regulatory bodies to ensure a fair playing field for generics. How important is your relationship with the government? Do they appreciate the importance of generics to the South African pharma industry?

There are a number of areas that indicate the government's willingness to assist in the growth of generics. As part of changes to the Medicines Act, the legislation states that if there is a generic option available, the pharmacist is obliged to inform the customer. Then it is up to the customer to decide. I believe the government is serious in its stated ambition of increasing access to drugs. To a large degree, most of the government tenders utilize generic products. Generics in South Africa undergo exactly the same registration process as originators. In terms of quality related issues, both are equal. Our role is to convey this point to the general public, and in particular to doctors.

As an association that represents a wide variety of both local and international generic companies, what do you see as some of the main challenges for generic companies in South Africa?

One issue that frequently comes up is the length of time it takes to register a generic product. Our members report that the process is taking up to four years. When the active pharmaceutical ingredient is changed, it also has to be examined by the Medicines Control Council (MCC), something which can take up to two years. If anything has changed within the four year period that it takes to register a product, the consequence is that you can only release your product on the market in six years' time. This is a major block on investment.

The MCC is also severely underfunded. Currently a new Bill is before parliament, to bring into being an organisation called SAHPRA (the South African Health Products Regulatory Agency), which would replace the MCC. The MCC is part of the Department of Health and receives its funding from the government's budget. The fees that we as an association pay are not used by the MCC but go to the Treasury. Instead, the MCC is given a set allocation from the National Department of Health's budget. SAPRAH will function like the FDA, and any income it receives will be used solely for its benefit.

Do we know yet when SAPRAH is due to be established?

The formation of SAHPRA was legislated prior to the year 2000. However there were some technical issues which caused the founding legislation to be repealed and the Bill was rewritten and

is being considered by the Parliamentary Portfolio Committee on Health. We are hope full that the legislation is passed soon as the MCC has advertised for applications for 52 posts which will be incorporated into the new regulatory authority. .

When we were last in the country the government's National Health Insurance (NHI) was a big talking point. What have been some of latest developments concerning this issue?

The NHI was a fourteen year plan, which began in 2011. We are still waiting for the White Paper, which was due three years ago. It is difficult for the pharmaceutical industry to express an opinion on the matter, as we still do not know what the set up will look like. This is an area, where there is a lack of communication between industry and the authorities.

NAPM is a full member of the International Generic Pharmaceutical Alliance (IGPA). How beneficial is the relationship with this organization? What can the South African generics industry learn from other countries?

The IGPA is not a formal association yet, but will be incorporated in Switzerland later this year, as the representative association from all the continents. The IFPMA (International Federation of Pharmaceutical Manufacturers), representing the originators, has a permanent secretariat in Geneva with 19 people. The NAPM as the representative of South African generics has the benefit of an international network and the information shared among members of the Alliance.

The IGPA has four subcommittees. Local staff can learn a tremendous amount from the expertise shared in the meetings. The IGPA committee on Biosimilars assisted us in giving technical comment to the Regulatory Authority when the pathway for Biosimilar registration was proposed in South Africa. We are also a member of SAGMA (The Southern African Generic Medicines Association). The aim has been to increase harmonization amongst the Southern African states. The recent announcement of a common market that is to be established across Africa could help in expanding the pharmaceutical market in the region.

Do you have a five year vision for the future of NAPM?

We need to increase our membership. It would be a real achievement if we could re-amalgamate the larger South African companies. As an association we have much in common with Pharmisa and if we could re-unite, it would benefit us all, acting as a united generics industry. As a generics association, increasing patients' access to treatment, is at the heart of what we do.

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