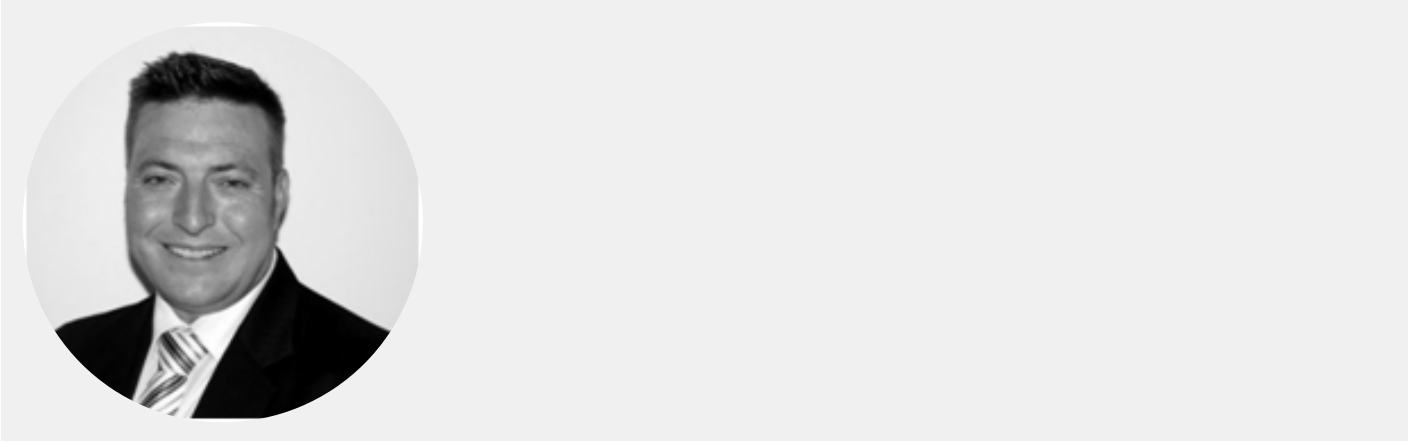
Interview: Gaby Simaan Jnr. – Managing Director, Trinity Pharma, South Africa



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The managing director of Trinity Pharma, Gaby Simaan (Jnr) depicts Trinity's evolution from a regulatory consultancy into a fully commercialized pharmaceutical company, and how their unique position in the private label space has allowed the company to significantly expand its pipeline of products and presence in the market.

To begin, Gaby, can you please describe the main focus of your strategic directives since assuming the position of MD in 2011, and what impact they've subsequently had on the company's performance?

When I joined in 2011, our focus was to move Trinity Pharma from a regulatory consultancy into a fully commercialized pharmaceutical company. That involved in-licensing products from various international manufacturers, with many of them now coming through to market. Considering that we only recently entered the South African generics sector in 2011 with a small basket of products, it would've been hard to directly compete against the industry giants such as Aspen or Adcock Ingram. As such, we've decided to concentrate more on private label generics—specifically targeting retail chains in South Africa, including Dischem, Unicorn Pharmaceuticals (owned by Clicks), Medirite, and Pick n Pay.

Our regulatory consulting practice, which provides pre-registration and post-registration regulatory services for both international and local companies, is still a fundamental component of Trinity Pharma. With this part of the business, we're exposed to a vast spectrum of collaborative opportunities with international pharma companies, at least much more so than if we were solely focused on commercial pharmaceuticals. Strategically speaking, it also helps us build partnerships with local pharma companies from a confidence and reliability standpoint—producing further business development opportunities on the commercial side.

The third division of Trinity Pharma is exports. We actively participate in buyouts in numerous African countries that are less regulated by nature, which are contingent upon sourcing a wide range of different products that isn't' necessarily restricted to our South African portfolio. Specifically, we procure these products from well-established and highly reputable overseas pharma companies and launch them in these African countries on an emergency basis—a function that is effectively supported by our regulatory consulting network. Fundamental to our export model, is registering and establishing a portfolio of products across Sub Saharan Africa.

Which of these segments will serve as the primary growth driver for the company moving forward?

The growth will come from the in licensing of pharmaceutical products—not only with a strong focus on South Africa, but also Sub-Saharan Africa (SSA). This region exhibits completely different dynamics and warrants special considerations when it comes to the prevalence of private labels, retail chains, and the maturity of the market. Our current private label strategy in South Africa simply wouldn't fit into these Sub-Sahara territories, but we do have a specialized portfolio that specifically aligns with the dynamics of these countries.

In the context of other African countries, what future opportunities is Trinity looking at?

SSA is a big growth area for us—strategically and financially. In terms of partnerships, companies find more appeal in partners with a presence in the broader Sub-Sahara region, in addition to South Africa. Furthermore, there is a lot of market opportunities for financial growth. With our regulatory team's experience and knowledge in SSA, the high quality of our manufacturers, and our understanding of these markets, we are well positioned to expand in these territories.

Highlighting a prominent country that's currently within the scope our export initiatives, Namibia exhibits a regulated environment that only incorporates products that are registered in PIC/s countries—allowing us to avoid direct competition with low cost manufacturers. Botswana also offers similar dynamics, but exhibits longer registration times; though regulatory approval

timelines in both Namibia and Botswana are still shorter than in South Africa.

Approximately 20 to 25 percent of our turnover is currently attributed to exports. Considering our strong growth forecast in South Africa specifically, that structure is projected to remain constant moving forward.

Considering the influx of partnerships and in-licensing agreements with leading international pharmaceutical companies, how has Trinity adapted its therapeutic portfolio of products to address the clinical needs of South African citizens?

We're fortunate to have a niche positioning within the South African pharmaceutical market. We're focused on our own branded products and are the only pharma company in South Africa that is specializing on private labels. We're interested in any product that can be sold in a retail pharmacy. Regardless of whether or not the molecules are saturated, our unique position in South Africa's private sector and specialized business model allow us to accommodate demand fluctuations and produce a steady stream of product flow. Moving forward, we're looking at more local alliances to not only expand our portfolio of products, but also to penetrate other market segments where we're not currently active, such as independent pharmacies or dispensing doctors.

How has the country's current disparity between public and private healthcare sectors shaped the company's marketing approach and interactions with pharmaceutical retailers?

We've chosen at this stage to focus on the private sector, but there are still opportunities within the public sector that we're eventually looking to capitalize on—especially with the increasing accessibility of drugs. That being said, however, we do help fulfill our social obligation with regards to section 21 drugs, which have to be reported on a patient-named basis. Section 21 normally applies to extremely sick patients with rare diseases that require life saving drugs currently unavailable in South Africa. Due to the scarcity of these products around the world, the costs for these drugs are sometimes astronomical. In this regard, we assist in the importation and supply of these drugs at heavily discounted and much more affordable prices, as least compared to some of the other pharma companies that are more profit driven in this area.

Further demonstrating our commitment to the welfare of South African citizens, we possess a level 2 BBBEE certification—allowing us to effectively participate in public sector tenders. We have worked hard to obtain our level 2 status – not only allowing us to effectively participate in government tenders but also to show that we are truly a South African company, playing our part in the Pharma industry and for the greater benefit of our country. As the MA holder, we were also

recently involved in a successful tender for oral contraceptives on behalf of Mylan Pharmaceuticals. Although it's not our core focus at the moment, we're looking to eventually build up our public sector business as the company becomes more established in the industry.

From your perspective as managing director, what were the main challenges that you've helped Trinity Pharma overcome in its evolution from a regulatory consultancy into a fully commercialized pharma company?

Despite our large number of in-licensing agreements, the bottleneck has primarily come from product registration. Especially from the perspective of a startup, without proper market authorizations, we're not able to scale up our commercial activities. To mitigate the lengthy regulatory approval timelines, we've partnered with a few local companies that have had duplicate registrations or non-core molecules, and integrated these types of products in our own marketing channels.

Looking at Trinity's other profile as regulatory consultant, what are a few of the most fundamental regulatory considerations for pharmaceutical companies looking to ensure commercial success here in South Africa?

Aside from patience, the most pivotal component is ensuring that dossiers are of the highest quality, which can otherwise cause significant delays. From a quality control standpoint, it's great that South Africa is such a heavily regulated environment, but personally, I hope that regulatory stakeholders are able to find the optimal balance between efficiency and quality standards with minimal trade-offs.

We've lost customers on the regulatory consulting side that attempt to circumvent, bypass, or shortcut regulations. In this regard, our reputation and philosophy of providing quality medication into the South African environment far outweighs any short-term revenue gains from those types of clients.

Spanning your tenure in the pharmaceutical sector, how has the regulatory environment in this country evolved alongside the industry's evolution? Do you believe it's headed in the right direction?

The government is keen on bringing down prices in South Africa to make medicine more accessible. The easiest way to do that is by speeding up the registration process. If the industry was getting more products registered without affecting quality standards, then there would be more competition in the market—causing an overall decrease in prices and increase in

accessibility. Recently, there's been a shortage of public tender suppliers. By having better registration times, and in turn more competition, this entire scenario could be prevented, with more competitors to pick up the pieces when a supplier goes out of stock

As managing director, what sort of legacy do you envision Trinity Pharma leaving on the South African community?

When I joined the company, there were only three people that were solely focusing on the regulatory consulting side of the business. Although we're still a small company, we've grown significantly from our modest roots in terms of headcount—now with 18 people on staff and the vast majority of them performing regulatory work. We've got a satellite office in Potchefstroom, South Africa, with three people sitting there. But the bulk of the team is located in Johannesburg—primarily focusing on servicing the additional clients that we've acquired over the last four years and also pushing our products through registration.

Moving forward, I hope to have positioned the company as a pivotal provider of high quality and affordable medicines into South Africa. Focusing on the private label space goes a long way in reducing the overall cost of medicine—effectively supporting the country's own ambition on increasing widespread access of pharmaceutical treatments, which also applies to other African countries as well. We've got a pipeline of just over 100 products pending registration. We'll soon begin to experience accelerated momentum once market authorizations start flowing through.

What are your personal motivations?

I thrive on the fact the ever-changing and challenging nature of this industry. Having grown up in pharmaceuticals, I've never seen a dull moment in this sector. Furthermore, we're not only able to make a difference in patients' lives, but also in doctors' and pharmacists'. Overall, I find it sincerely rewarding to play a role in the development of South Africa's healthcare system and the potential to positively impact every citizen in this country.

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