Interview: Henk Krebs – Managing Director, MC Pharma Group, South Africa

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The managing director of MC Pharma Group, Henk Krebs illustrates how MC Pharma's new operating structure enables the group to better service its clients, and also highlights the role of strategic partnerships in fueling the company's growth ambitions both domestically and internationally. He also shares his insights on the South African pharmaceutical and medical devices market and how the organization is helping its clients navigate the constantly changing regulatory environment.

To begin, could you please introduce yourself to our readers as well as the strategic direction MC Pharma took since we last met in 2012?

I'm a qualified pharmacist with an interest in regulatory affairs and business development. I'm currently busy with my law degree as well seeing as we engage with various entities like the Department of Health, Medicines Control Council or state agencies and there are many acts and regulations that form the basis of regulatory affairs. I believe an intimate understanding of the law and how to interpret it is of pinnacle importance if you are to truly understand the industry I joined MC Pharma a couple of years ago and since 2012 we've changed our focus and the way we work. We now operate as the MC Pharma Group which consists of five different companies. The mother company is **MC Pharma**, where we assist national and local applicants that do not have the necessary infrastructure for medicine registrations or product licensing with various councils and

authorities and we effectively act as their marketing authorization holder. MC Pharma also fills that role for international clients from all over the word, including the UK, Australia, Israel, India, Japan, Europe, and America that wish to sell, commercialize, and register their products in South Africa. **MC Pharma Consulting** is the regulatory affairs and consulting component acting between industry clients and the Medicines Control Council. This entity offers various services such as dossier registration, Section 21 applications, and lifecycle management of medicines dossiers. We have also created **MC Pharma Training**, which we will officially launch in November 2015 to train regulatory affairs personnel in the industry—addressing the massive shortage of regulatory affairs expertise in this country. We will also offer such training to mid-level executives in sales, marketing and general management.

The platform we are especially excited about is **MC Pharma Global**, a subsidiary based in Singapore that we launched at the beginning of this year that will focus on helping South African companies hoping to launch their products into Africa, Southeast Asia, Europe, and South America. There is a huge interest from European and American companies in coming to Africa, especially South Africa considering its characterization as the springboard into the continent. At the same time, many interesting brands and products in South Africa could do really well on the international level. We are therefore using the MC Pharma Global platform to promote, distribute and commercialize products into other regions of the world. We will soon launch three of our current clients into Southeast Asia and America.

The last company is **Venture Pharmaceutical and Medical products, or "VP",** which is our sales & marketing entity. Through VP we commercialise products in South Africa across various specialities for and on behalf of clients looking for sales solutions Together with the other subsidiaries we are a fully-fledged, backwards integrated company. Instead of having different departments, we split up our activities in different companies because it enables our clients to simply pick the set of services they want from our basket of services. It allows us to give our customers tailor-made service solutions, and we are the only group in South Africa to do that.

With all these developments and imminent changes especially with National Health Insurance (NHI), how are you going to keep up with the work domestically, while also focusing on your global footprint, which seems to be quickly developing right now?

We are currently in the process of opening an office in Cape Town to accommodate the influx of domestic business, and as mentioned earlier, we have just bought over a corporate entity in Singapore that we will use for international markets. The key is to strongly focus on cultivating productive long-term partnerships. We know where our strengths lie and where our limitations are,

especially when it comes to new and unfamiliar markets. Within these types of market, we will strategically partner with experts that have local knowledge and inroads into the Ministry of Health, as well as into local authorities. We do not want to transpose the exact same model we have in South Africa to Nigeria, for example, but really partner through a network and still be able to offer the best services to our existing clients.

Before looking to the dynamics of the pharmaceutical industry here in South Africa and broader Africa, we are interested in gaining your insights on the competitive landscape for regulatory consultancies. How has this profession evolved over the years?

The pharmaceutical industry is relatively small, but as the implementation of NHI rolls out, there will be a bigger need for regulatory support in the industry both from regulatory authorities and local clients. There is enough work for everybody as most consultancies have their own niche focus and 90% of the consultants actually collaborate together on projects at some point. There will still always be a competitive edge and at MC Pharma, we have spread our service offering to focus on many different aspects in order to meet the expectations of our clients. We do have a fantastic team of specialists, some that have worked for international regulatory bodies and understand the needs and requirements of our clients. Soon, there will be some changes in the regulations and laws, in turn, altering the various regulatory requirements and pushing pharmaceutical companies to seek outside help to adequately cope with the changes. Therefore, we are always looking to partner with our customers and build long lasting partnerships and to become an integrated advisor, rather than just a consultant. We aspire to be part of our clients team, not an external consultant. So, with all these changes coming up, the demand for regulatory consultancy will increase, and so will the supply.

Given your expert insights on the industry, what do you think are the biggest entry barriers to foreign companies looking to enter the South African market?

The biggest entry barriers to Sub-Saharan Africa are regulations and logistics. However, logistics are getting their big players that are helping the sector moving forward. We still need that local technical expertise that can align with regulatory specialists such as ourselves and help facilitate registrations with the regulatory authorities. Thankfully, there is a push for harmonization with EU standards in Sub-Saharan Africa in terms of policies, regulations and processes, which is making trade and growth into these African jurisdictions a lot easier. Other organizations like the National Association of Pharmaceutical Manufacturers (NAPM) are also driving this harmonization and improving access to affordable medicines in Africa. We just need to streamline the administrative and regulatory processes that fills the supply of medicine.

How is your focus currently allocated across the group’s operating segments?

My personal focus is to grow our partnership base, which is the role of MC Pharma Global. It is a stand alone company but really integrates into everything we do. While it is a separate entity, it spreads across all our other companies and services. Most importantly our main focus is on the advisory side: We want to make sure our clients know that we will have a long-term relationship. Every two or three years there are massive changes in the regulatory landscape. For example, complementary medicine completely changed the industry two years ago and medical device regulations are imminent and will probably come out next year. Consequently, all the medical devices companies will need more assistance and expertise support. We really want to proactively manage our clients and their expectations. We want to make the process as easy as possible and remove all the headaches from being an applicant—especially in light of all these regulatory changes. As change is coming, requirements are changing, and our duties as well. We take care of the import, the export, the distribution, the registration, and any conceivable problems the clients may have—leaving them able to focus on their core competencies.

South Africa is not a primary consideration for everybody. From your experience, how are South African companies generally perceived abroad?

The industry dramatically changed in the past five years. Aspen, a proudly South African company, is now one of the biggest generics manufacturers in the world. South African companies are actively looking for opportunities outside the borders. Our country is now seen as an access point into Africa. South Africa also has a role to play in increasing trade between the BRICS by contracting out the manufacturing of medicine and buying raw materials from India or China. But we, as a country, are also heavily focused on building local capacity and becoming self-sufficient, as local production brings down the costs of medicine, which increases the availability of affordable medicines to public—the core focus of the NHI. South Africa’s influence on the global market is closely linked to the NHI and it is going to be extremely interesting. We will need to manage cross-border trade into South Africa and work with our BRICS counterparts, while also stimulating local manufacturing. The Department of Health is focusing on making medicines in Africa for Africa and alleviating the country’s import dependency. Indeed, less than 5% of APIs are manufactured in South Africa, as they are mostly imported from India, the EU and China. This helps build up the BRICS, but on the back end of it, the majority of pharmaceutical revenues leave the country and that is not sustainable.

Speaking more about the specificities of the South African market, there is also a lot going on in the medical devices sector, which is much less regulated than the

pharmaceutical industry. Do you see the medical devices sector as an upcoming sector?

The regulations for the medical devices sector are going to be introduced soon with the South African Health Products Regulatory Authority (SAHPRA). While medtech companies have done very well in South Africa, a lot of Chinese or Indian companies that have been able to come to the market and steal quite a bit of the market shares due to price competition will disappear because of stricter regulations. On the contrary, large multinationals such as Zimmer Biomet, J&J Medical, or Medtronic and the like are self-regulated and have products that follow strict quality control processes will survive and see market shares increase.

The dynamics in the medtech sector are very different from pharma but at the same time there are some similarities. Given this, do you see the regulatory scheme in the medtech environment evolving in the same fashion than in pharmaceuticals?

Yes, it probably will. The policies of major funders like Discovery will start treating medical devices, biotech products, and even biosimilars in the same vein as pharmaceuticals. This will slow down the growth as it is easier to grow in a relatively unregulated environment, but, at the end of the day, it all boils down to widespread public access of quality medicines and medical devices. Stringent regulatory controls are good, but it should not become too strict because then very few companies will be able to comply and the sector will invariably suffer. There will be a lot of upfront investments to make sure that the regulation processes are put into place, but ultimately we believe it’ll pay off in the long run.

Considering the fact that the group’s reputation and brand have been steeped on pharmaceutical expertise, did you find it a challenge in approaching and securing business from medical device clients?

Yes and no. Internationally, many pharmaceutical companies have a combination of medical devices and medicines. In South Africa, it is seen differently because of our local legislation. There is a pharmaceutical mind-set and a medical devices mind-set, but in the way the regulations are going, the lines are getting increasingly blurred. It is our job to lead them through and explain that they need our support, especially with the new regulations coming up. About half of our client base is now international medical devices companies. In the next few years, it will be even more important to help them navigate the new regulatory environment and ensure compliance.

Looking forward the next three to five years, where would you like to have positioned MC Pharma Group?

Our main focus in the next five years is to brand MC Pharma as this unique service offering, not only in South Africa but also throughout Sub-Saharan Africa, Southeast Asia, South America, and even America, where we recently started a business association with a consultant there. We have shown fantastic growth in South Africa, but we are now eager to take the successful model and to implement it into other markets to offer our expert services to global clients as well.

Given all your experience in the industry, why exactly did you choose the consulting path?

As a consultant, I constantly juggle a multitude of different clients and products—which keeps me engaged on a daily basis. As consultants, we are forced to remain at the forefront of regulatory changes in the industry and we even have the ability to influence those changes by sitting on different committees, whether it's SAMED or NAPM, RDG etc. The healthcare landscape is quite broad in scope and constantly evolving—requiring us to adapt our services accordingly and tailor them to the specificities of each and every client. Although quite challenging at times, this is what appeals to my interests and strengths as a consultant. I also still practice as a pharmacist, working at a hospital every now and then which allows me to stay in touch with industry developments from a different perspective. .

What would be your piece of advice to someone who wants to enter the consultancy sector?

My advice would be to start as soon as possible because it is a great platform to quickly acquire experience and knowledge—especially when compared to any other sphere in the healthcare industry. That you will need to open up your mind to find innovative and tailored solutions for your clients.

On a more personal note, what keeps you motivated every day?

I absolutely adore my job, as consulting is a great platform to quickly acquire experience and knowledge. I recognize the passion that my clients have for their companies and products and it's infectious. To this end, I thoroughly enjoy developing increasingly innovative solutions to help our clients realize and meet their goals and ambitions.

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