

Interview with Tracy Burger, Director and Responsible Pharmacist, MC Pharma SA

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Could you introduce to our readers MC Pharma's business model in the South African market as well as the main milestones in the company's development over the recent years?

MC Pharma is a licensed pharmaceutical company and acts as a Holder of the Certificate of Registration (Marketing Authorisation Holder; MAH), importer and exporter. We act as MAH on behalf of local and off-shore Principals, on a contract basis. Our expertise and focus is primarily in regulatory compliance and we act as regulatory consultants for this purpose. Our goal is therefore not to build up our own basket of products, but rather those of the Principal and until such time as we are instructed to cede the products over to the Principal's appointed and licenced Agent or to the Principal's own licenced subsidiary in this country.

In South Africa, the MAH, manufacturer, importer / exporter and distribution facility is required to be a locally registered and licenced company. An application for the registration and importation of a medicine can only be made by a company that is licenced and properly authorised by the medicines Regulatory Authority (RA), currently known as the Medicines Control Council. As the process of setting up a MAH compounded with the time taken to registration submission and regulatory approval can be lengthy, it makes sense to do these activities i.e. setting up the MAH and product registration concurrently and as quickly as possible and this is where MC Pharma can expedite time to market entry.

In the MC Pharma scenario, the application for medicine registration is submitted to the RA with MC Pharma as the MAH allowing the Principal the concurrent time to decide and plan the level of presence and involvement they wish to establish in South Africa i.e. via an Agency, a Subsidiary, whether to have their own marketing sales representatives or not or to contract all activities out to approved licenced facilities, under the regulatory authorisation of MC Pharma. Marketing agencies and or representative sales force companies do not have to be Licenced in the same way as e.g. a MAH or a Distributor of medicines, but are required to conduct their business under the regulatory control of the MAH. This means that a marketing agency may be set up and / or changed without RA notification or pre-approval, provided regulatory compliance is adhered to.

MC Pharma operates and conducts the business of regulatory compliance through enabling contracts and technical agreements with the Principal, manufacturers, distributors and marketing agents. The advantage of this arrangement is that it gives the Principal as much flexibility as they want and allows them to be as involved as they wish. The Principal may wish to establish their own marketing presence by means of setting up their own marketing company in SA or they may opt to choose from the number of contract agencies an agency that best suit their product and MC Pharma will facilitate this arrangement and appointment.

The MC Pharma arrangement offers any module of flexibility that the Principal wishes and it provides for a level of self-determination.

One of our most important milestones was the setting up of our own logistics department in 2006 to manage the import and export of goods, on behalf of the Principal. We now have a well-functioning and managed division handling the paperwork and logistics associated with importing and exporting medicines.

We have an associate company, Venture Pharmaceuticals and Medical Products that handles the commercialisation of medicines on behalf of the Principal. This was established in 2008 and manages national sales and marketing for medicines on behalf of Principals that choose to utilise the services of Venture. MC Pharma Clients are under no obligation to use Venture, it is a sales and marketing vehicle whereby the Principal can self-determine their own marketing strategy under MC Pharma's supervision.

What is driving the growth of MC Pharma and what were the areas of focus in 2011?

We are very pleased with the company's performance of late. We were able to comfortably increase our turnover by 19 percent in 2011, and the interesting dynamic is that a third of that growth comes from Europe. The rest comes from local customers.

We have two kinds of business models:-

- Contract MAH or Applicant responsibility on behalf of the Principal together with regulatory supervision of logistics, and
- Related and on-going adhoc regulatory consultations.

As a service provider, is it natural for pharmaceutical companies to come to see you or do you need to go and try to convince them of the importance and the added value of MC Pharma?

Most of our Clients reach us via “word of mouth”; networking and our involvement with the Industry and the Regulator or from web-page enquiries. We do not actively promote our services through other means.

As a result, companies – mostly overseas Principals – are not always aware of companies like MC Pharma through which they can register and self-determine their medicines.

MC Pharma does not promote its own branding thus allowing the Principal to establish their own brand awareness.

How do you differentiate yourself among your competitors?

We are small, dynamic and enthusiastic. We have a different style at MC Pharma – we like to “partner” with the Principal and to be directed by and work according to their goals and priorities.

Our goal is to be involved in the current and proposed medicines regulatory affairs matters of this market and we have contributed to a number of Industry driven regulatory projects. We are committed to pursuing with these contributions as it gives us, and our Clients, a position of advantage.

I have been in the industry for more than 25 years and have a history in this Industry that includes the public and private sectors, regulatory and registration training, independent consulting and now as a contract MAH / Applicant.

Because of our outsourcing relationship to our accredited partners we can move quickly on projects.

When we interview Mr Fagan of Sanofi has stated that he felt privileged to be a part of the change of the pharmaceutical market. Although this market is one of the most dynamic markets in the world, it is also a challenging market. To what extend MC Pharma can help its Clients to adapt to this unpredictable environment and healthcare reforms?

Because of our involvement in professional and trade associations we are very much “in touch” and “in tune” to current regulatory developments. We make it our business to specialise in regulatory affairs and to communicate new and proposed developments as early as possible to our Clients, together with an interpretation, explanation and recommendations, enabling the Client to act and respond appropriately.

We aim to cultivate a relationship with our contract Clients that allows for quick, easy and effective communication.

Our Clients are enabled to focus on what they do best – commercialisation of their products.

Our philosophy is that as a team, we are as strong as our “weakest link” and for this reason, all staff are trained to be effective and are involved in continuing professional development.

Our Clients are comfortable in the knowledge that we are involved and up to date in terms of current affairs, for instance, if there is a SAPRAA meeting – (South African Pharmaceutical Regulatory Affairs Association), they know that someone from MC Pharma will be attending and will report back on an individual Client basis.

We focus on long-term partnerships – many of our current customers have been with us since 2000/2001.

85% of our business is repeat and contract business, which tells us that Clients are satisfied with our services.

What is the importance of global customers in your Client portfolio? To what extent will International Partnerships be driving the growth in the future?

Global customers are very important for us. 50% of our contract Clients are offshore (Australia, USA and Europe).

Global Clients are increasingly more important to our business model, especially in the light of the proposed National Health Insurance (NHI) and International Tendering and ‘yes’ we would like to broaden our international Client base.

NHI is all about providing cost effective, quality medicines and healthcare to the greater public. My main focus is to take the MC Pharma model to the trade ministries of the BRICS countries, with the intention to promote the MC Pharma business model and to establish a relationship with interested pharmaceutical and healthcare companies in those countries.

I believe that it is partnerships like this that are an important element to the proposed NHI and to effective international tendering.

In the country and customers that you mentioned, the major chunk seems to come from developed countries. Do you expect more relation with the BRIC countries since South Africa joined the alliance?

Yes, I am looking forward to that. We have already made contact with interested parties in Brazil and we hope to facilitate their expansion into South Africa and the southern African market.

As mentioned, it is part of our strategy this year to introduce our business model to the trade ministries of Brazil, Russia, China and India.

It is my wish that, working with interested companies in these countries we will be able to register a basket of essential medicines, ready for public tendering.

Using our service, we can hold these medicine registrations either for the tender market or to out-licensing on behalf of the Principal. That is our intention and I see opportunity for MC Pharma.

How to you see the level of professionalism in South Africa? Do you see the HR factor as an asset or issue for a company established here?

At our level we have good and competent professionals. We however do have a problem of insufficient numbers of professionals to service the industry requirements.

Being a small professional company, and operating through service level and outsource contract agreements with competent, professional and accredited facilities, we do not have an issue with HR. Our MC Pharma staff are all long-standing dedicated staff, we do not have a fast turnover of staff, so we have long-standing embedded knowledge with our staff who in turn have a history with our Clients. Our staff are definitely our best asset.

Opinions are very different: Mr Motsoaledi acknowledged a lack of skills for the development of certain sectors such as R&D, some pharma CEOs said that South Africa has a great labor force. What do you think about it?

I think, honestly, that the level of skills we have in this industry are great, we just lack the head count i.e. number of skilled professionals, and much work needs to be done in order to provide the number of professionals to meet the demands of regulatory controls and the provision of adequate healthcare to all.

The intention to provide adequate professional resources is written into our governments strategic plans, so the requirement to increase the number of professionals is there – we just have to make sure the intentions are realised and adequately provided for.

How do you plan on growing in the next 3 to 5 years?

MC Pharma's plan and goals from last year have been largely achieved, which is fantastic. Looking forward, we will also focus on the "soon-to-be-regulated" complementary medicine and medical device industry. These markets are going to need regulatory guidance and assistance and we are currently working on that. We are a member of the SA Health Products Association (SAHPA) and the National Association of Pharmaceutical Manufacturers and are a regular attendee of meetings.

We are also expecting to grow our global Client base in line with BRICS trade agreements and we anticipate holding a basket of registrations to be used, on the direction of the Principal, for tendering and / or out licensing.

Would you have a final message to Pharmaceutical Executive readers about MC Pharma in South Africa?

The South African pharmaceutical market is a difficult market with its own unique idiosyncrasies, but at the same time, it is, strategically speaking, a very important market and an entrance into Southern Africa.

We work in an exciting, evolving, dynamic and vibrant industry. I have grown with this industry, I've been part of the evolution to where we are now and I am excited about the proposed future changes.

I am excited about MC Pharma's current performance and our commitment to the Industry. I believe that our modular business model is cost effective and provides Client orientated solutions.

I am excited about our future growth and our contribution to the provision of quality, cost-effective medicines in this country. We are definitely here to stay and will continue to provide cost effective solutions and benefits not only to our Clients but also to our staff and ultimately the consumer.

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