

## Substantial changes to South Africa's medical device regulations have far-reaching impacts

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Although medicines have always been heavily regulated in South Africa, medical devices have not. Recently, however, Medical Device Regulations have been issued to bring medical devices into the regulatory fold. Medical devices must eventually be registered, and entities that manufacture, sell, or distribute devices must hold specific licences.

In this [hoganlovells.com](http://hoganlovells.com) interview, Hogan Lovells partner Vaughn Harrison and associate Mandi Krebs discuss the scope of these nationwide legislative changes.

### What are some of the material changes in medical device legislation and regulation in South Africa?

**Harrison:** Until now, medical devices have not been regulated. But regulatory changes were brought in recently, and they will have far-reaching effects not only on what clients do, but also on the costs of doing business and complying with regulations in South Africa.

Normally, the words “medical device” imply something like an MRI, a scanner, or a machine, such as a Stryker saw in an operating theater. But the definition is so wide in South Africa as to cover issues such as apparatus and material. For example, items such as a bandage, suture, or needle can be classified as a device. So this new legislation has brought uncertainty within very short time periods.

In addition, it hasn't been tested in the courts. They've also brought in very tight time limits on licencing, so certain licencing activities will need to be completed by 24 August and other activities by early 2018.

**Krebs:** Because of the introduction of this new regulatory framework, medical devices will now be subject to certain prescribed requirements when it comes to labeling, advertising, marketing, sampling, and discounting issues, which has never historically been the case. This will have a profound impact on how business models are structured, and will carry certain cost implications for industry participants.

### How is a person or entity classified as a manufacturer, distributor, or wholesaler of medical devices?

**Krebs:** The way people have traditionally viewed these categories, with reference to pharmaceuticals, is different in terms of medical devices. Medical device industry participants will now be required to licence themselves as a manufacturer, distributor, or wholesaler. But there's confusion as to what constitutes the activities of each category. For example, in terms of pharmaceuticals, somebody who holds a manufacturer's licence may also be permitted to import or export medicines. But somebody who wishes to import or export medical devices may have to apply for a distributor's licence. Everyone who needs to submit licencing applications must make sure that they understand what type of licence they're applying for, and particularly in light of the activities and proposed activities conducted by the applicant.

**Harrison:** It's not clear to a client who might be an importer, wholesaler, or manufacturer of a medical device, or exactly where the lines are drawn between the various categories. Are they a manufacturer and/or a wholesaler and/or a distributor, and do they apply for one or more licences?

**Krebs:** If you're going to apply for a manufacturer's licence, for example, you're looking at activities including labeling, packaging, reprocessing, and refurbishing.

My advice is to carefully consider your activities in light of the definitions included in the regulations, as that will guide you in terms of which applications you should be submitting.

## What are the deadlines for submitting licencing applications?

**Harrison:** For manufacturers and distributors, the deadline is 24 August 2017. Wholesalers have a slightly longer lead-in time: that deadline is 24 February 2018.

They took a very long time to introduce the legislation, but have stipulated unreasonably short time limits for compliance, and particularly in light of the lack of clarity in this new regulatory environment. I think a lot of industry participants are not fully aware of the enormity of the changes and the regulatory demands being made on them.

From a professional and advisory point of view, and unfortunately for the clients, compliance is going to have a cost implication, and clients will need to carefully consider the legislation and regulations in conjunction with people such as ourselves in order to ensure that they are compliant.

## What other related submissions must be made to the local regulatory authority by those deadlines?

**Krebs:** Before submitting licencing applications, the applicant must have appointed an "authorized person." Fortunately, the regulations do not stipulate what this person's qualifications need to be, but essentially, they would be likened to those of a responsible pharmacist in terms of a pharmaceutical company. The regulations do provide that the person needs to be "suitably qualified" when it comes to the medical device or categories of medical devices held by,

imported by, or manufactured by the applicant. If an applicant has multiple sites of manufacture and distribution, an application must be submitted per site, with an authorized representative appointed in respect of each site.

In addition, they must ensure that they have adequate quality management (QM) systems in place, with ISO 13485:2016 being the benchmark. The good thing is that applicants can decide whether or not they wish to have a QM system for each of their sites or just one system that will apply to multiple sites.

## Are there other challenges facing manufacturers, distributors, and wholesalers of medical devices arising out of the implementation of the new legislation?

**Harrison:** An interesting issue is that, previously, medical representatives could keep stocks of medical devices at regional locations or their homes, and not have to go back to a central location. They could then deliver those devices to their customers. Now, if they want to continue to do that, they'll have to submit a licence application in order to hold the medical devices at their private premises, which is an additional cost and additional regulation. Also, in terms of labeling and advertising, while some of the products may be imported bearing compliant labeling, if they want to change or add labeling once the item is in the country, that will need additional compliance, and of course the requisite licence to do so.

**Krebs:** When we talk about labeling, the concern is not only that the labels need to be compliant with local legislation, but the way that our legislation reads at present. Some people have adopted the interpretation that each medical device is required to have the appropriate labeling — and we're talking about medical devices such as sutures and needles. How practical is it to individually label each of those items? Potentially, and again it hinges on your interpretation of the legislation, this may open a Pandora's box of practical considerations, and also commercial implications.

Once applicants have put their QM system in place, they will also have to undertake a review of any related agreements that they have in place with third parties. For example, if you require courier services in respect of your medical devices, you need to ensure that your courier company — for example, DHL or FedEx — adheres to your QM system, and that they have all of the controls and checks in place to ensure compliance for the safe transportation, and certainly adherence to the environmental conditions, required for those devices.

**Harrison:** We've gone from almost a totally unregulated space to an over-regulated one. Clients need to be urgently paying attention to this, whatever their size, and even multinational groups. Our role is to tell clients what the law is, how to comply with it, and how best to interpret it.

In addition, and as the process evolves, we will need to monitor how the South African courts interpret and apply the new legislation.

### About Vaughn Harrison

Partner Vaughn Harrison focuses on corporate law. His strength lies in managing large and complex transactions for multinationals in multiple jurisdictions, involving a variety of issues (such as due diligence, tax and restructuring, HR, IP, regulatory matters, and merger approvals).

### **About Mandi Krebs**

Associate Mandi Krebs focuses on healthcare and pharmaceutical law, the food industry, as well as advertising law. Her experience includes advising various pharmaceutical manufacturers, complementary medicine manufacturers, medical device manufacturers, and pharmaceutical distributors and wholesalers on a range of issues. These include regulatory requirements relating to marketing authorizations; manufacturing, import, and wholesale dealer licenses; and the sale and advertising of pharmaceutical products in South Africa.

### **For Additional Information**

For additional information on this topic, read "[Medical devices – South Africa's changing landscape.](#)"

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