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Medical devices: Regulations sorely lacking

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Tanya Vogt, Executive Officer, SAMED

Medical devices are regulated in many countries around the world, but not in SA. Presently, only electro-magnetic medical equipment and radiation-emitting devices have to be registered with Radiation Control. Some combination medical devices (devices that incorporate a medicinal component or biologics) have to be registered with the Medicines Control Council (MCC), as medicines.

According to Tanya Vogt, Executive Officer of the South African Medical Device Industry Association (SAMED), most often in these medical devices the function of the medicinal component is ancillary to the primary intended purpose of the device.

Internationally these devices are classified and registered as medical devices and not medicines. Unfortunately due to a lack of a comprehensive regulatory framework for

medical devices in SA, this means that companies wishing to bring such a product to market often get caught up in a massive medicine dossier submission. It doesn't work at all," said Vogt.

"If you are trying to register a combination medical device in SA, it takes a long time. The reality is these devices have a short shelf-life and before we know it, there is an upgrade to that model. This makes it difficult, you almost have to do a registration on the new model before you have had go-ahead on the first model," stated Vogt.

All other devices, including implants, have no regulations. "This is just another reason why we need appropriate regulation to create certainty for all and standardisation," commented Vogt.

Differences in regulations

"Policy makers and regulators need to take into account that we are quite different to medicines and need to adjust their policies and methodologies in accordance," said Vogt.

Devices are different in terms of manufacturing, classification labelling, training of users, maintenance, storage and regulatory requirements, to mention a few and this needs to be taken into account.

Devices are measured by quality, safety and performance (not efficacy as is the case with pharmaceuticals). Good manufacturing practice (GMP) applies to pharmaceuticals, whereas medical devices are manufactured according to a quality management system. "In the device world, we look at adverse events. Pharmaceuticals look at side effects and adverse drug reactions. With medicines, there is scheduling. Devices are classified according to risk. Risk to the patient and even risk to public health. All methodologies around users of the devices, regulatory pathways, the type of quality management system that one is required to manufacture the device stems from how the device is classified. Devices are categorised into risk categories, starting at Class A, which is low risk, to Class D. We have to get a harmonised definition and risk classification for medical devices written into legislation first off, in SA, and everything else will stem from that," stated Vogt.

Vogt believes the industry needs certainty and specific regulations for medical devices that deal with the idiosyncrasies of combination medical devices as well as separate regulations for in vitro diagnostic medical devices (IVDs).

Separate regulation for medical devices and IVDs

Regulatory authorities in mature regulatory frameworks, regulate medical devices and IVDs as separate because it is a broad range of products – encompassing everything from something as simple as a bandage, to something as complex as laboratory instruments and x-ray machines. "You can't have a one-size-fits-all regulation for those products. If you try to regulate devices as medicines, you end up having to provide data that is required for a bottle of pills that are ingested into the body and data that has been generated to prove safety and efficacy of medicines, which is simply not available for medical devices. It is not how medical devices are designed or tested," stated Vogt.

“You need to look at a framework that is cognisant of the short lifecycle of medical devices and IVDs, and it shouldn’t bear any resemblance to the way that medicines are regulated.”

Why is there no separate regulation for medical devices?

In Vogt’s experience, the National Department of Health (NDoH) is finding it difficult enough to register medicines. Device regulation will require quite a wide spectrum of expertise to look at all the technologies that come through their doors. The WHO estimates that there are 1.5 million different medical devices, in over more than 10 000 types of generic device groups available worldwide. It is a difficult thing to launch into and there needs to be budget, proper infrastructure, appropriate skills and legislation to support it.

The NDoH relies quite heavily on suppliers to sell quality, safe medical devices and doctors in their clinical practice being ethical and making the right choices. The feeling is ‘the doctors know what they are ordering’. However, in practice, more and more, that decision is being taken out of the hands of the clinician and is being put into the hands of procurement officers who are looking for the best prices on tender, and with a lack of an appropriate regulatory framework, resulting in the possibility of ‘nasty’ medical devices and diagnostics of dubious safety and quality coming into the market. The risk is there. “For government, it’s not an easy thing to fix, and until they enact the new amendment to the law, and put in place the South African Health Products Regulatory Agency (SAHPRA); until they put budget and staffing behind that and are serious about medical devices, we are going to continue to fall further and further behind the rest of the world and patients may suffer.”

With no regulatory framework, there is the potential that unscrupulous suppliers will target SA before they target other countries.

“Device companies who have quality management systems, who have internationally accredited standards attached to their products, who have taken the trouble to get their product through stringent regulatory authorities certainly don’t want to compete with companies who haven’t bothered to do that” she commented.

Impact on SA

Vogt pointed out that the vast majority of medical devices are imported, so SA is not the only market in which they trade. For local manufacturers, they won’t be able to sell their product anywhere else in the world, if it has not gone through some authority. At times suspicion is created when a product is sold in another country that is not approved in your own country. Currently credible local manufacturers have to obtain the CE mark or FDA approval for their products at huge cost.

Harmonisation

“We are also now falling behind other African countries. In Africa there are regulations in Kenya, Nigeria, Ethiopia, Ghana and Tanzania. Mozambique and Angola are talking about regulations.

“Good news however is that the East African community that includes Uganda, Rwanda, Burundi, as well as Kenya and Tanzania, both mainland and Zanzibar, are working on a

Pan African Harmonisation Working Party, to get regulations harmonised across the continent.” SA is also a member of this forum.

“Harmonisation is the only viable way to go,” said Vogt.

Harmonisation means to attempt to recognise regulatory frameworks in other jurisdictions. For example, if a regulator has gone to audit a manufacturing site, in a harmonised framework you would accept the audit report from another regulator. This also applies in terms of standards, post market surveillance and the classification and risk profile of devices.

SA has been a member of the Asian Harmonisation Working Party for medical devices since 2006. “These groups are linked to the major regulators in the world and a number of excellent documents and guidelines for regulators have been written. It is SAMED’s hope that the NDoH heed this work and rather than try to regulate medical devices as medicines, as we have seen happen with combination medical devices, develop distinct and harmonised separate regulations for medical devices (including combination medical devices) and IVDs.

In conclusion, medical device and IVD regulation in SA is now urgent and essential to ensure that only quality, safe medical devices and IVDs are available to and for use on patients.

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