New medicines law will change rules on medical devices

When the amendments to the Medicines and Related Substances Act come into operation, it will result in significant changes to the regulatory regime currently in place.

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According to guidelines issued by the department of health and Medicines Control Council (MCC), the new regulations will apply to the manufacturing, importing, exporting and distribution of medium- and high-risk medical devices.

Although proposed licensing requirements will apply to local companies, foreign manufacturers exporting to South Africa will also be affected. “As it stands, the MCC is only responsible for managing the introduction of medicines in all forms into the local supply chain,” says Graham Anderson, Profmed’s CEO and principal office.

Imported devices will also come under scrutiny

He says if the new rules come into play, all medical devices brought into the country will also be properly regulated. “The definition of medical devices in the proposals is quite broad and will cover everything from disposable syringes to MRI scanners,” he adds.

As the law currently stands, anybody can bring any type of machine into South Africa and no legal requirement exists on reporting on its purpose or cost or efficacy. “There is thus no record or proof of what the machine intends to treat, whether

it actually works and what the costs associated with bringing it into operation and maintaining it," says Anderson. "That also means the owners of these machines can charge whatever they want, whether the treatment is effective or not."

Anderson says the lack of transparency in this regard has placed a great burden on both medical schemes and its members over the years, as it has been impossible to sufficiently cater for cost and purpose of some investigations and procedures.

"As a consequence there are instances where both individual and organisation have been left out of pocket and without the knowledge of the specific benefit derived from using a specific device," he adds.

Classification structure

The components of the proposed system include a four-tier, risk-based classification system, as well as requirements for obtaining device licenses for manufacturers, importers and distributors.

It also specifies that full technical documentation on devices need to be submitted to the regulator on request, as well as all required information pertaining to importation, transportation, storage, distribution, marketing and sales.

According to the MCC, domestic manufacturers and distributors will have to apply for local registration as soon as the regulations are enacted. Foreign operators and importers will also need to get their paperwork in order by then.

New regulatory body

Furthermore, the new guidelines stipulate that the MCC will be replaced by a new regulatory authority, called the South African Health Products Regulatory Agency (SAHPRA), which is seen by the industry as an upgraded version of the MCC.

"It has been described as similar in model to the Food and Drug Administration (FDA) in the USA that it will be more independent than the MCC," he says. "It will fall outside of the department of health and funded only partly by government with additional funds raised by way of fees charged and services rendered within its regulatory ambit."

SAHPRA will come into existence only once the amendments have been enacted. Although still very uncertain, it does seem that there is a push to implement and start giving practical effect to the Amendments during 2017.

Of course, if the new authority is up and running, it will also allow for medicines to be approved and be made available at a faster rate and at a more competitive rate, he adds.