

MCC's new licensing requirements for medical devices

New regulations relating to the import and distribution of radiology equipment will start to bite in 2017, when revised Medicines Control Council (MCC) licensing requirements come into effect.

In terms of the regulations, distributors and local manufacturers of medical devices have to comply with six general and at least eight design and construction principles related to their safety and efficacy. Importantly, licence applicants cannot just claim to comply with the requirements, they actually have to demonstrate compliance.



© 123rf.com

“Effectively, it will become illegal to import and distribute potentially sub-standard, ‘pirate’ equipment,” says Nicolene Voget product manager at Bidvest Medical.

In addition, any device – apart from those categorised as being totally without risk to the health and safety of the user or patient – must have already obtained registration or approval from at least one of the internationally recognised regulatory authorities in Australia, Brazil, Canada, the European Union, Japan or United States before they can be registered for use in South Africa.

“Until now, radiology equipment sold in South Africa has not been subjected to these pretty stringent regulations by the MCC. The new regulations should effectively shut down what has become a worrying trend where low-cost, potentially low-standard radiology equipment is increasingly being imported into South Africa. This is finding its way not only into private practices but also into government institutions,” Voget explains.

“In many instances, the specifications of this ‘pirate’ equipment appear to match that of registered equipment. However, because it has not been subjected to the same rigorous testing, there is no way for local radiography practices to determine whether what they are installing meets the high safety and quality standards their patients deserve.”

She notes that all radiology equipment, including equipment already in use in South Africa will have to be subjected to the MCC’s scrutiny every five years to ensure it complies with the latest safety and efficacy regulations.