

Medical device industry gets new ethics code

The new Medical Device Code of Ethical Marketing and Business Practice allows for self-regulation by the industry, and seeks to ensure that members, and medical devices companies in general, do not offer inducements to healthcare providers or other customers in order to sell, lease, recommend or arrange for the sale or lease of their products.



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The development is in recognition of the unique features of the medical device industry. It is characterised by rapid technological advancement and frequent introduction of new products and product lines. Continual innovation requires that healthcare professionals be properly trained in order to use medical devices safely and appropriately, and companies provide demonstration, training and practice sessions on an ongoing basis.

"There is close scrutiny over the healthcare industry in South Africa and globally. The code is an instrument for reconciling professional and business cultures within the medical device and healthcare industries, said Rob Millar, chair of the South African Medical Device Industry Association (Samed) code committee said. The association is the custodian of the code.

"Our industry has a social and moral responsibility not only to customers, but to patients and society at large. Samed members need to have close working relationships with healthcare professionals to provide optimal value to patients and customers. The code directs how this should be done responsibly and by avoiding potentially perverse practices."

The code is formulated as a user-friendly reference to facilitate voluntary compliance – which is a condition of Samed

membership. It is Samed's hope that in the future, the code may be recognised by the minister of health as an industry-wide code that encompasses all medical device companies.

Some of the provisions of the code are:

- Sponsorship of healthcare professionals at conferences organised by third parties will be prohibited from 1 January 2018 – aligning South Africa to European and other jurisdictions;
- .Hosting of product and procedure training, or other company events for professional and marketing purposes, needs to have a suitable programme and be held in venues of reasonable hospitality; and
- All gifts from suppliers to healthcare providers or organisations are considered inappropriate, while specific regulations guide the provision of items for promotional or medical purposes.

A code with teeth

“The code also has teeth in the form of complaint-lodging procedures with a provision for independent investigation of alleged transgressions,” explains Millar. “It views suspected infringements through the lens of individuals with a sound knowledge of the industry, while introducing experts with an understanding of legal principles and investigational methods.”

The range of sanctions is set out in a schedule which forms part of the code. Sanctions include options of restitution, monetary fines and publication of confirmed infringements together with the name of the company or individual transgressing the code.

The code applies directly to Samed member companies, and their agents and contractors.

Applies to healthcare practitioners

Millar says that the code also applies to healthcare practitioners and organisations in the public and private health sectors in their role as customers of medical device companies – although their conduct is subject to the provisions of other professional codes or legislation. All healthcare providers who make medical product-related decisions, whether clinical or non-clinical staff including procurement officers and supply chain managers, need to be familiar with the code, and avoid infringements or report occasions when it has been transgressed.

In formulating the Code, Samed has aimed to align it with international best practice regarding value-based procurement, as well as with the relevant South African legislation and ethical codes.

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