1. How medical devices industry code of ethics will work

2. The code is based on self-regulation aimed at promoting effective governance and ethical business practice for the medical devices industry

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The South African Medical Device Industry Association (Samed) on Wednesday launched a code of ethics to guide conduct in the medical devices industry. It expects the code will be used as a standardising tool for the sector.

Suppliers of medical devices face an August deadline to seek licenses to operate from the South African Health Products Regulatory Authority, which replaced the Medicines Control Council, on June 1, before they can operate in SA.

At the launch of the Medical Device Code of Ethical Marketing and Business Practice in Johannesburg on Wednesday, Samed chairman Rob Millar said the code was based on a self-regulating approach by the medical device industry, promoting effective governance and ethical business practice between healthcare professionals and suppliers.

"It is an instrument for reconciling professional and business cultures within the medical device and healthcare industries," Millar said, "We hope the code may in future be
recognised by the minister of health as an industry-wide code that encompasses all medical device companies."

He said the recent scrutiny of the sector locally and abroad had encouraged the formation of the code and as custodian of the new code, Samed aimed to ensure medical device companies comply with the highest standard of ethical and marketing practices.

The code has been formulated as a user-friendly reference to facilitate voluntary compliance, which is a condition of Samed membership.

The principles underpinning the code include image and perception, patients’ best interests, and transparency and documentation. They will be applicable to all medical device producers, including manufactures, importers, distributors and agents. It is hoped the national health department also will adopt the code.

The chief director of sector procurement at the National Department of Health, Gavin Steele, commended the code. "We are opting for self-regulation for the time being but it will be followed by more aggressive regulation later," he said.

Steele said the decisions taken by healthcare practitioners should always put patients first. He warned that volume and profit should not drive healthcare professionals’ choices in medical device transactions.

The code also aims to cull corruption and self-gain by healthcare professionals. It allows for anonymous whistle-blowers, and prohibits any and all gifts and kickbacks.

Business ethics specialist at KPMG Dr Schalk Engelbrecht said there was no conflict between biomedical and business ethics but there was a need to develop better business ethics in medicine. He said that while inducements and gifts did not make people malicious, "they do cloud our judgment".

Enforcement against transgressors under the code would be free and complaint driven. Millar said an independent ethics committee would be established. Guilty parties would be subjected to sanctions or fined, depending on the level of infringement.