

New regulator will also oversee medical devices

Medical devices will now be regulated, with the newly established South African Health Products Regulatory Authority (Sahpra), replacing the Medicines Control Council (MCC).



Stavros Nicolaou, head of industry association, Pharmaceuticals Made in SA. Photo: [Acumen Magazine](#)

Medical devices and complementary medicines have been unregulated as the MCC only dealt with conventional medicines. Sahpra came into being when the Medicines and Related Substances Amendment Act of 2008 was finally signed. The body is not yet operational as Health Minister Aaron Motsoaledi is yet to appoint a board.

Sahpra came into being to relieve extensive delays at the MCC in approving new medicines and clinical trials.

Sahpra will also regulate foodstuffs, cosmetics, disinfectants and diagnostics.

Stavros Nicolaou, head of industry association, Pharmaceuticals Made in SA (Pharmisa), said the new body would be able to generate its own income, allowing it to use modern systems and retain staff that were often overwhelmed by large volumes of work and prone to being poached by the private sector. "The workload of the MCC had quadrupled but the funding hadn't matched," Nicolaou said.

The new regulator will be clearing a backlog of more than 2,000 applications awaiting registration by the MCC.

Pharma Dynamics CEO Erik Roos said Sahpra could usher in a new and much more effective era for the local pharmaceutical sector.

"Sahpra's new structure will follow a similar model to the US Food and Drug Administration in that it will be more independent than the MCC," Roos said.

Source: *Business Day*

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