

New authority replaces 'slow' Medicines Control Council

Health Minister Aaron Motsoaledi has appointed members of the South African Health Products Regulatory Authority (SAHPRA) board, which replaces the Medicines Control Council (MCC).



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The MCC was beset by backlogs, taking much longer compared with US or European regulators to approve new medicines and clinical trials.

The scope of the new authority has expanded to include medicines, medical devices including in vitro diagnostics, and aspects of radiation control. Until now, medical devices and complementary medicines had gone unregulated as the MCC could only deal with medicines, *BusinessLIVE* reported last year.

The National Department of Health said SAHPRA would operate as a separate juristic entity, responsible for monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials, medical devices and related matters in the public interest.

The department said there was a plan to speed up the processes.

"The authority will utilise external experts for evaluation of applications, but over time it will actively grow the in-house capacity of the staff to take over the bulk of its work including registration of medicines and evaluations for clinical trials."

While the CEO will be appointed by the board in consultation with the minister, Portia Nkambule, previously a director in the MCC, has been appointed as the acting SAHPRA CEO.

"The chairperson of the SAHPRA board is Professor Helen Rees, who was chairperson of the MCC and has been selected "on account of expertise in the fields of medicine, medical devices, IVD, vigilance, clinical trials, good manufacturing practice, public health or epidemiology," the department said.

"What we are aiming for with the newly constituted SAHPRA is an efficient, relevant and transparent regulatory authority that ensures that South Africans have access to safe, effective, good quality medicines and medical devices, and the information that allows them to use these products with confidence," Rees was quoted as saying.

The other board members are: Dr Nonhlanhla Madela-Mntla, Prof Shabir Banoo; Prof Henry Leng; Dr Thapelo Motshudi; Prof Kelly Chibale; Prof Ames Dhai; Prof Jeffrey Mphahlele; Dr Ushma Mehta; Dr Mphane Molefe; Advocate Hasina Cassim; Ms Mandisa Hela (vice-chairperson); Ms Lesibana Fosu; Mr Norman Baloyi; and Prof Craig Househam.

Source: BDpro

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