health
Department:
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REPUBLIC OF SOUTH AFRICA

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**APPOINTMENT OF THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY (SAHPRA) BOARD**

The Minister of Health, Dr Aaron Motsoaledi, has appointed members of the South African Health Products Regulatory Authority (SAHPRA) Board. SAHPRA replaces the Medicines Control Council (MCC). The scope of the new Authority has expanded to include not only medicines, but also medical devices including *in vitro* diagnostics, and aspects of radiation control.

The Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended by Act 72 of 2008, together with Act 14 of 2015, provides for the establishment of SAHPRA, a Schedule 3A public entity, which will operate as a separate juristic entity, outside of the National Department of Health (NDoH). SAHPRA will be responsibile for monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials, medical devices and related matters in the public interest.

All outstanding work that was being done by the MCC will be continued by SAHPRA. 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. In addition, agreements will be made for recognition of work from recognised international regulatory authorities, resulting in more rapid evaluation timelines.

The Chief Executive Officer of the Authority will be appointed by the Board in consultation with the Minister. In the interim, the Minister and the SAHPRA Board are very pleased to announce that Mrs Portia Nkambule, previously a Director in the Cluster: Food Control, Pharmaceutical Trade & Product Regulation, who acted as secretariat to 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 Medicines Control Council. “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.” said Professor Helen Rees.

The new SAHPRA legislation aligns South Africa with other international regulatory authorities and is designed to support a regulatory framework that addresses the changing needs of the South African public. The Authority aims to become more transparent with better accountability and communication to all its stakeholders including civil society and the general public, healthcare professionals, academia and industry.

**PROFESSOR HELEN REES**
**CHAIRPERSON OF SAHPRA**

**BOARD MEMBERS AND CATEGORY OF APPOINTMENT IN TERMS OF SECTION 2C(1) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965), AS AMENDED**

| No | Name | Category of appoinment |
|---|---|---|
| 1. | Prof. Helen Rees (Chairperson) | Section 2C(2)(a) on account of expertise in the fields of medicine, medical devices, IVD, vigilance, clinical trials, good manufacturing practice, public health or epidemiology |
| 2. | Dr Nonhlanhla Madela - Mntla | |
| 3. | Prof. Shabir Banoo | |
| 4. | Dr Henry Leng | |
| 5. | Dr Thapelo Motshudi | |
| 6. | Prof. Kelly Chibale | |
| 7. | Prof. Aimes Dhai | |
| 8. | Prof. Jeffrey Mphahlele | |
| 9. | Dr Ushma Mehta | |
| 10. | Dr Mphane Molefe | |
| 11. | Adv. Hasina Cassim | Section 2C(2)(b) on account of knowledge of the law |
| 12. | Ms Mandisa Hela (Vice-Chairperson) | Section 2C(2)(c) on account of knowledge of good governance |
| 13. | Ms Lesibana Fosu | Section 2C(2)(d) on account of knowledge of the financial matters and accounting |
| 14. | Mr Norman Baloyi | Section 2C(2)(e) on account of knowledge of information technology |
| 15. | Prof. Craig Household | Section 2C(2)(f) on account of knowledge of human resource management |