SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

WHO OR WHAT IS SAHPRA?

SAHPRA is the South African Health Products Regulatory Authority. It is a Section 3A public entity that was formed by the South African government to oversee the regulation of health products which includes medicines, medical devices, in-vitro diagnostic tests and devices, radiation emitting products and devices used in health care and industry. SAHPRA replaces the Medicines Control Council (MCC) as well as the Directorate of Radiation Control (DRC).

Board and Management

SAHPRA has a Board, appointed by the Minister of Health. The Chief Executive Officer (CEO) is appointed by the Board after consultation with the Minister of Health.

Several senior management positions have been filled, such as Chief Finance Officer, Director IT and the Company Secretary. Others are all being filled for the first time, including the Chief Regulatory Officer and the senior managers in each of the divisions.

What does SAHPRA do?

SAHPRA is mandated by the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) to regulate (i.e. monitor, evaluate, investigate, inspect, register and review) all health products and their use in South Africa.

SAHPRA has also been delegated the task of overseeing radiation control in South Africa. This function is governed by the Hazardous Substances Act (Act 15 of 1973) which aims to protect the public (workers, patients, etc) against radiation used in both health settings and in industry.

SAHPRA's function is therefore to promote public health and safety by ensuring that all medicines and medical devices that are available and used in the country are safe, effective and of good quality.

All functions are already operational but some, such as medical device registration and vigilance, oversight of clinical trials for medical devices and in-vitro diagnostics, are new and the full scope of activities will only be implemented over the coming years.

In summary SAHPRA ensures that
- Medicines
- Complementary Medicines
- Medical Devices and In Vitro Diagnostic Medical Devices (IVDs)
- Radiation Control

are safe, effective and of good quality and in the interest of the public throughout their life cycle.

Medicines

Before a health product is made available or sold to the South African public, its safety, efficacy and quality is rigorously assessed by SAHPRA. This evaluation process complies with international and local standards, regulation and laws and includes assessment of the suitability of the product in the South African context. SAHPRA inspects the manufacturing plants where all medicines that are sold in South Africa are made, even those abroad. Once marketed, SAHPRA encourages health professionals to report any adverse events or product quality problems through their national spontaneous reporting system. In addition, SAHPRA continually monitors the local and international performance of health products to ensure that the availability and use of these products continues to be in the public's interest.

New recognition and reliance pathways are being tested by several countries including South Africa. SAHPRA has also embarked on an exciting re-engineering process that will digitise and automate procedures while expanding its technical staff complement in order to build much-needed regulatory capacity and expertise in South Africa.

Medical Devices and In Vitro Diagnostics (IVDs)

The process of medical device regulation only started in June 2017. Three types of licences may be issued for medical device establishments: manufacturer (manufacture, pack, label, service, import, export), distributor (import, export, distribute) and wholesaler (storage, transportation, delivery). Currently, all companies who manufacture, distribute or wholesale medical devices in the market, and who have submitted a licence application to SAHPRA, are trading legally and may continue trading.

A distributor licence only applies where imported devices bear the name and address of the registration holder in South Africa. Addition of a label with the registration licence holder name is classified as a manufacturing activity.

Registration of medical devices is planned to follow later in 2019/2020. A Registration Call-Up Plan will be published to inform stakeholders of the phased approach in which medical devices will be called up for registration. This plan will specify the type and class of medical devices that will be prioritised and called up sequentially as the road map for registration of medical devices is rolled out.

In order not to prevent duplication of regulatory effort in South Africa, SAHPRA will implement reliance pathways in the registration of medical devices based on recognised verification of registration of medical devices in some other jurisdictions including: Australia, United States, European Union, Brazil, Canada, Japan and/or pre-qualification of IVDs by the World Health Organization.

Radiation Control

Radiation and radioactivity are natural phenomena and natural sources of radiation are features of the environment. Ionizing and non-ionizing radiation and radioactive material may also be of artificial produced. Ionising radiation refers to X-rays and gamma-rays. Non-ionising ranges from radio waves, through infrared- and the visible spectrum, to ultraviolet-rays. Radiation and radioactive material have many beneficial applications, ranging from uses in medicine, industry, research and agriculture. The radiation risks to people and the environment that may arise from these applications have to be assessed and, if necessary, controlled without unduly limiting the beneficial use thereof. The risks associated with facilities and activities involving ionizing radiation, such as the medical uses of radiation, the production, transport and the management of radioactive waste must therefore be subject to standards of safety. All aspects of ionizing radiation are regulated according to the international standards of the International Atomic Energy Agency (IAEA). Non-ionizing radiation is regulated in accordance with the Guidelines issued by the International Commission on Non-ionizing Radiation Protection. SAHPRA is the competent authority mandated to regulate all applications of radiation protection used outside the nuclear fuel cycle in South Africa.

SAHPRA is reorganising radiation protection functions into Radiation Control and Radiation Device Control. Radiation Control regulates radionuclides and electronic generators of ionising radiation (mainly X-rays). Radiation Device Control regulates equipment (medical and industrial) that produce radiation or contain radioactive sources. Radiation Control's inspectorate has branches in Cape Town, Pretoria and Durban.

SAHPRA's operational model

The core founding staff have transferred to SAHPRA from several units in the National Department of Health. SAHPRA has found temporary office accommodation at the CSIR Campus in Pretoria. Plans are in motion to secure a permanent home. Simultaneously SAHPRA is reorganising into a new programme structure:

Programme 1	Corporate Services
Programme 2	Health Product Authorisation
Programme 3	Inspectorate and Regulatory Compliance
Programme 4	Evaluation for Registration
Programme 5	Medical Devices and Radiation Control

Programme 1 is new and includes the Office of the Chief Executive Officer, Chief Financial Officer, and Chief of Support Services (including ICT and Human Resources).

Programme 2, Health Product Authorisation, will form the heart of the regulatory functions. Applicants will interact with Portfolio Coordinators, whose roles will be to steer a 'portfolio' of applications through the prescribed processes. Even though applications will be more and more electronically managed, these coordinators will be responsible for ensuring their timeous passage through the relevant processes. This unit will manage the archives and the central data base of all certificates, licences and permits.

Programmes 3 and 4 will encompass the management of all medicines regulation while Programme 5 will include regulation of devices, IVD regulation and radiation control.

How is SAHPRA funded?

SAHPRA receives a portion of its funds from the national fiscus through the National Department of Health budget. The balance of SAHPRA's funding is raised through charges for services rendered in the conduct of its mandates. The entity may also receive donations in accordance with the National Treasury Regulations.

Over time it is expected that SAHPRA will receive most of its funds from fees. The objective is to deliver better, faster services and therefore justify increased tariffs. Several functions (like radiation control in its entirety) are provided without charge and this will change in future.

Backlogs

SAHPRA is dealing with a backlog of medicine applications comprising both pre-registration and post-registration amendment (variation) applications., and has committed to clearing this backlog within 2 years. The backlog clearance strategy comprises three pillars: (1) reducing the number of applications that require evaluation, (2) segmenting and prioritising applications on the basis of public health need, and (3) implementing new models for evaluation that recognise work done by other national regulatory agencies.

What is the scope for employment at SAHPRA?

The relative autonomy of a public entity provides flexibility that is not possible in a government department. Today's advertisement for the filling of over 100 vacant posts is just the start of the process of truly establishing the authority as a public health agency that works to support public health. This recruitment drive will establish the core of the corporate services required to support the line functions.

The erosion of capacity to manage radiation control is being addressed with a drive to recruit competent professionals to this programme. Several key managerial positions, and some technical operational positions, are advertised for the other line functions. The fixed-term contracts for staff to support the backlog project will ensure that full-time staff are not distracted from the day to day work as the backlog is addressed.

In due course SAHPRA will fill further vacancies. These are exciting times. SAHPRA works closely with the medicine and medical devices industries and in health facilities and many factories and other plants where radiation emitting devices are used.

Perhaps the most exciting opportunities lie in the impact of the 4th Industrial Revolution on SAHPRA. Information systems and digitisation will become more important than ever. SAHPRA is working closely with different groupings of international regulators across the globe and all are being drawn into the digital age.

A variety of Jobs are available for enthusiastic, self-motivated people with a wide range of professional qualifications and skills.