The process of medical device regulation only started in South Africa. New recognition and reliance pathways are being tested to ensure that the performance of health products is subject to the control of health care and industry. Health products are essential in supporting the health and welfare of the South African public, its safety, efficacy and quality must be assured at all stages of the product life cycle.

SAHPRA has found temporary office accommodation from several units in the National Department of Health. Several senior management positions have been filled, including the Chief Technical Officer and the senior managers in each of the divisions.

What does SAHPRA do?

SAHPRA is mandated by the Medicines and Related Substance 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 19 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, regulations and laws and includes assessment of the suitability of the product in the South African context.

SAHPRA inspect 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 digitize 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 core founding staff have transferred to SAHPRA from several units in the National Department of Health. SAHPRA has found temporary office accommodation in the CSIR Cambridge building, until such time as a permanent home. Simultaneously SAHPRA is reorganising into a new programme structure:

Programme 1 Corporate Services
Programme 2 Health Product Authorisation
Programme 3 Inspection 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 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 prohibited without charge and this will change in future.

Backlogs

SAHPRA is dealing with a backlog of medical applications comprising both pre-regulation 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 recognize 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 structuring the health authority to work for and with the 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 medical 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 are 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 enthusiasts, self-motivated people with a wide range of professional qualifications and skills. 