Annual Report
2018/19

SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

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Part: A
General Information

1. PUBLIC ENTITY'S GENERAL INFORMATION

Registered name of public entity	South African Health Products Regulatory Authority
Registration numbers and/or other relevant numbers	
Registered office address	CSIR Campus Reception Building 38A 1 Meiring Naude Road, Brummeria Pretoria 0002
Postal address	Private Bag X828 Pretoria 0001
Contact telephone numbers	+2712 842 7582/3
Email address	enquiries@sahpra.org.za
Website address	www.sahpra.org.za
External auditor's information	Auditor-General of South Africa
Bankers information	Absa
Company secretary	Advocate Teboho Peter Nthotso

2. LIST OF ABBREVIATIONS AND ACRONYMS

ADR	Adverse Drug Reaction
AIDS	Acquired Immune Deficiency Syndrome
APP	Annual Performance Plan
BAU	Business-as-Usual
CEO	Chief Executive Officer
COID	Compensation for Occupational Injuries and Diseases
CSIR	Council for Scientific and Industrial Research
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GRAP	Generally Recognised Accounting Practice
GTAC	Government Technical Advisory Centre
GVP	Good Vigilance Practice
GWP	Good Wholesaling Practice
HIV	Human Immunodeficiency Virus
ICT	Information and Communication Technology
KPI	Key Performance Indicator
MCC	Medicines Control Council
MoU	Memorandum of Understanding
MRA	Medicines Regulatory Authority
MTEF	Medium Term Expenditure Framework
MTSF	Medium Term Strategic Framework
NCE	New Chemical Entity
NDoH	National Department of Health
NHA	The National Health Act, 2003
NHI	National Health Insurance
OHS	Occupational Health and Safety
PFMA	Public Finance Management Act
PIL	Patient Information Leaflet
PSUR	Periodic Safety Update Report
QMS	Quality Management Systems
RAG	Risk, Audit and Governance Committee
SAHPRA	South African Health Products Regulatory Authority
SCM	Supply Chain Management
SA GAAP	South African Statements of Generally Accepted Accounting Practice
TORS	Technical Oversight and Regulatory Strategy
TB	Tuberculosis
TGA	Therapeutic Goods Administration, Australia
WHO	World Health Organization

3. FOREWORD FROM THE CHAIRPERSON

"Despite the troubleshooting that had to take place in the past year, the catchwords for the regulator during this period have been re-envisioning and re-engineering."

It is globally accepted that a well-functioning drug regulatory authority is an essential component of an effective health system. In February 2018, the South African Health Products Regulatory Authority (SAHPRA) was established based on the platform set up by South African Medicines Control Council. Aligned with global trends, SAHPRA transitioned from being part of the National Department of Health (NDoH) to becoming an autonomous Schedule 3A public entity accountable to the Minister of Health. As a new entity, SAHPRA aims to be a transparent and effective regulator, sensitive to the context in which it operates whilst being independent of public, commercial and political pressures. Through a patient centred approach, SAHPRA aims to safeguard the health and wellbeing of all who live in South Africa, both human and animal. Its regulatory scope has expanded to include all medicines, medical devices, radiation emitting devices and radioactive nuclides. SAHPRA has a key role to play in achieving universal health coverage and in the planning for National Health Insurance. Ensuring equitable access to safe, effective and quality medicines and health products is an essential pillar to a revamped and reinvigorated health system.

With this background, SAHPRA has started to make good progress but the birth of this new public entity has not been without challenges. At the outset, SAHPRA should have been regarded as a 'start-up' organisation and have been provided with adequate corporate service support and adequate technical staff to deliver on its expanded mandate and inherited problems. Neither of these essential underpinners were provided to SAHPRA. This transitional period coincided with industrial action in the NDoH's Civitas building where SAHPRA was still housed, and this limited the support that these NDOH departments could offer SAHPRA.

The SAHPRA staff themselves were affected by the industrial action so at the beginning of 2019 the regulator had to precipitously move out of Civitas and into new premises on the campus of the Council for Scientific and Industrial Research (CSIR), to allow work to resume. Lack of IT and phone connectivity further hampered the regulator's work and the spread of its activities across five remotely situated buildings within the CSIR campus continues to make SAHPRA's work challenging. This entire experience process put enormous strain on the existing and newly appointed staff at a time when they have been asked to undertake many turnaround processes. Despite these challenges, a team of committed and resilient staff and Board members rolled up their sleeves and led SAHPRA through this difficult period to emerge as a growing organisation, into a good and positive space.

Despite the troubleshooting that had to take place in the past year, the catchwords for the regulator during this period have been re-envisioning and re-engineering. SAHPRA will soon have more fit for purpose premises, supported by new IT systems designed for the complex needs of a regulatory authority that aims to become fully digitalized within the next year. The authority is in the process of employing over 100 new and much needed staff at all levels and in all departments of the organisation. Established SAHPRA mandates such as pharmacovigilance are receiving renewed attention, while new portfolios including Radiation Control and medical devices are receiving priority attention to address identified shortcomings. Radiation Control, a service that is essential both for public health and for heath security, will see major changes and improvements in the coming

year aimed at streamlining its mandate and addressing backlogs. Registration of medical devices will continue to be aligned with global best practices and its staff contingent will be bolstered to implement new strategies. The new vision for pharmacovigilance, which is key to ensuring the safety of all health products, includes proactive multi-stakeholder communication. A new communication strategy is being introduced that places at its core the wellbeing of individuals and communities. The next year will see redesigning of the website, and the use of all forms of media to proactively and interactively communicate with the public, professionals and industry.

The critical priority for SAHPRA since its launch in February 2018 has been the clearance of the medical products backlog. SAHPRA inherited the backlog from the Medicines Control Council but at the outset the backlog size and scope were unclear. With the skilled support of the Boston Consulting Group, recruited to assist SAHPRA by the Bill and Melinda Gates Foundation, it was established that the Backlog consists of 16 000 applications. Of these applications 50% are over five years old and 90% are generic medicines. Using the current strategies, it would take eight years to clear the backlog even if no new applications were received. It is impossible to achieve SAHPRA's vision of establishing a state of the art, world class regulatory authority while this burden of the backlog continues to weigh us down. To address this immense challenge, SAHPRA required and received the buy-in of the pharmaceutical industry who agreed to adopt fundamentally different ways of doing business.

The SAHPRA leadership would like to thank all members of industry who patiently supported this process, and for their willingness to embrace the many changes that have taken place over the past eighteen months. The SAHPRA team have put a roadmap in place to clear the backlog within a period of two years, using totally re-engineered approaches for medicines registration. This includes digitalisation, reliance procedures that allow SAHPRA to exchange information with recognised regional and international regulatory authorities, and standardisation of evaluation processes allowing applicants and regulators alike to know what's excepted of them and how long it should take. The same processes are now being introduced for 'business as usual' applications. These radically different strategies will reduce the timelines for the registration of both cutting-edge, innovative medicines and of generic medicines. This means that these new processes will increase access to affordable medicines and to medicines of public health importance, while simultaneously supporting the growth of a thriving local pharmaceutical industry.

The Board and senior management are acutely aware of the importance of good corporate governance and of the medium and long term sustainability of SAHPRA. Given the trying circumstances of the past eighteen months, we acknowledge there have been shortcomings in some aspects of our functioning, but these can be excused against the challenging operational backdrop. Our aim in the next year is to strengthen the executive and senior management team and their supporting departments, and to continue on the steady path already started, of stabilising SAHPRA, its outputs and its oversight. To ensure financial sustainability, fees will be reviewed and fee adjustments will be proposed based on a proper evaluation of the work required to produce a quality output.

Restructuring a regulatory authority is not a small task and the turnaround has required many inputs including political support and vision, an effective Board that understands good governance, and extraordinary staff with skill, commitment and dedication.

I would like to sincerely thank the previous and current Ministers of Health and the Director-General of Health for the support they have offered SAHPRA during this challenging transition. My immense appreciation goes to my fellow Board members who have gone way beyond the call of duty to ensure that SAHPRA has proper oversight as it pursues its mission, and to Dr Nicholas Crisp, Ms Mandisa Hela and the BCG group who provided critically important technical support to SAHPRA throughout this period. And finally, my enormous gratitude goes to the acting CEO, Ms Portia Nkambule, the SAHPRA Executive, Management and staff members for their outstanding resilience and dedication throughout the year. This determination has sustained the collective vision that SAHPRA is destined to become a world-class regulatory authority.

Prof Helen Rees
Chairperson: SAHPRA Board
Date: 19 September 2019

4. ACTING CHIEF EXECUTIVE OFFICER'S OVERVIEW

"SAHPRA rapidly and successfully re-engineered the delivery of Section 21 permits. These are permits allowing, seriously ill patients suffering from life-threatening conditions access in emergencies to currently unregistered medicines."

In February 2018, I was entrusted with the responsibility of leading the South African Health Products Regulatory Authority (SAHPRA) as the Acting Chief Executive Officer through its first year as a Schedule 3A public entity, an appointment that I accepted with humility and executed with diligence and integrity. The aim of the first year of SAHPRA was to revitalise the national medicines regulator and reshape it into a world class authority that would benefit and improve the health of all South Africans.

This is SAHPRA's first Annual Report and Audited Financial Statement for 2018/19 presented as a 3A public entity. The purpose of this report is to give an account of the Authority's performance in line with its public health mandate and reflect upon some of its key achievements and challenges experienced in this year under review. However, this first transitional year of SAHPRA has proved to be challenging and the authority had to deliver in a complex environment.

This financial year was marked by prolonged labour unrest culminating in an emergency relocation from the Civitas building to the CSIR campus. This labour unrest adversely affected the delivery of a Memorandum of Understanding (MoU) between SAHPRA and the NDoH. This arrangement was designed to lend support to SAHPRA during its transitional period and the lack of delivery on this MOU has negatively affected SAHPRA's ability to achieve a seamless transition. Furthermore, the forced and rapid relocation into emergency new promises in the CSIR Campus adversely affected SAHPRA's delivery due to the geographic and communication limitations of the new premises.

While these challenges inevitably affected SAHPRA's overall delivery, certain areas of its work were improved through new visions and innovation, including the Backlog Clearance Project which is aimed at addressing the backlog inherited from the Medicines Control Council. Because of the public imperative, during the industrial action, SAHPRA rapidly and successfully re-engineered the delivery of Section 21 permits. These are permits allowing individual, seriously ill patients suffering from life-threatening conditions to have access in emergencies to currently unregistered medicines. These include permits necessary to allow hospitals to maintain supplies of unregistered medicines required for emergency treatment of critically ill patients. In addition, plans were established to ensure that SAHPRA's overall public health mandate to promote health, wellbeing and safety of the public, through ensuring access to safe, efficacious and quality health products, was not compromised.

To this end SAHPRA has developed, approved and commenced implementation of a re-engineered framework to eradicate the backlog of health product registrations. SAHPRA's organisational structure to support this re- engineered operation was developed and approved, equipping the organisation to advertise and recruit 109 new employees across the five programmes from executive management, technical and professional staff to administrative and support staff.

SAHPRA has also promulgated a policy shift to adopt reliance models with other regulatory authorities that will be utilised in both the backlog clearance project and business-as-usual (BAU) operational processes. To achieve this, SAHPRA engaged with the pharmaceutical industry and other stakeholders to ensure bilateral and transparent communication

and strengthened collaborative relationships, thereby building support for the policy shift towards increased reliance models utilised in the authority's operations. Efforts to improve vigilance and reporting of adverse events was also undertaken, resulting in more active reporting from professionals and the public.

SAHPRA developed, approved and implemented systems and frameworks to address new areas of health product regulation for medical devices and has commenced the same process for radiation emitting devices and radioactive nuclides. These regulatory functions were inherited from the NDoH and this is work in progress.

Towards the end of re-shaping the organisation and ensuring better alignment with its values, the entity worked to ensure it was properly supported by adequate leadership and successfully appointed the Company Secretary, Chief Financial Officer, and the Director: Information Technology.

At the inception of SAHPRA, the Authority did not have a full staff complement. Staff were transferred from the NDoH to the newly established Authority by way of a section 197 transfer which was effected in October 2018. The industrial action meant that over 80% of SAHPRA staff were unable to properly carry out their duties in the Civitas building. Administration and recruitment could not be properly delivered and some critical positions were only filled towards the end of the year. As a result, a saving of R30 million was realised from the budget for the compensation of employees. Further recruitment will be done in the next financial year.

From the financial perspective, SAHPRA received a government grant of R125.1 million for the 2018/19 financial year through the budget vote of the NDoH. Revenue generated from fees amounted to R72 million and interest received amounted R4.9 million. A surplus of R31.2 million was generated in this financial year. In view of the pending operational requirements, the Authority will request that National Treasury grant permission for the surplus funds to be retained for the 2019/20 financial year. The Authority was very grateful for the help of the Bill and Melinda Gates Foundation who offered significant financial support for the funding of the Backlog Clearance Project which has been invaluable in moving this programme along.

In the next year SAHPRA will focus on improving administrative and management systems to limit internal control deficiencies and have developed the requisite policies and procedures for effective supply chain management (SCM), as well as establishing the necessary committees to evaluate and adjudicate procurement issues. The appointment of a Chief Financial Officer in March 2019, Mr Molatlhegi Kgauwe has contributed to stabilising the entity, eliminating capacity constraints, and is ensuring that the Authority complies with financial and supply chain regulations.

For reasons beyond its control, SAHPRA has had an unsteady start in this first year. However, this year was a year of great learning opportunities for the fledgling entity. The evolution of SAHPRA to becoming a seamless and agile medicines regulatory environment for South Africa is moving closer.

The momentum of change increases daily and initiatives begin to bear fruit through the groundwork already completed and the relentless efforts of our dedicated staff.

I would like to thank the SAHPRA Executive, management and staff for their dedication and enthusiasm in ensuring that SAHPRA continues to do its best in executing its mandate despite the challenges experienced in this first year. I believe that there are many exciting opportunities ahead of us. In a special way, I thank the SAHPRA Board Chairperson, Prof Helen Rees, Vice Chairperson, Ms Mandisa Hela and members of the Board for their guidance and support.

Ms Portia Nkambule
Acting CEO: SAHPRA
Date: 19 September 2019

5. STATEMENT OF RESPONSIBILITY AND CONFIRMATION OF ACCURACY OF THE ANNUAL REPORT

To the best of our knowledge and belief, we confirm the following:

All information and amounts disclosed in the annual report are consistent with the annual financial statements audited by the Auditor-General of South Africa.

The annual report is complete, accurate and free of any omissions.

The annual report has been prepared in accordance with the guidelines on the annual report as issued by the National Treasury.

The annual financial statements (Part E) have been prepared in accordance with Generally Recognised Accounting Practice Standards applicable to the public entity.

The accounting authority is responsible for the preparation of the annual financial statements and for the judgment made in this information.

The accounting authority is responsible for establishing and implementing a system of internal control, which has been designed to provide reasonable assurance as to the integrity and reliability of the performance information, the human resources information and the annual financial statements.

The external auditors were engaged to express an independent opinion on the annual financial statements.

In our opinion, the annual report fairly reflects the operations, the performance information, the human resources information and the financial affairs of the entity for the financial year ended 31 March 2019.

Ms Portia Nkambule
Acting CEO: SAHPRA
Date: 19 September 2019

Prof Helen Rees
Chairperson: SAHPRA Board
Date: 19 September 2019

6. STRATEGIC OVERVIEW

6.1 Vision

To strive towards excellence in health product regulation with the aim of promoting and protecting human and animal health in South Africa, and being recognised and respected both nationally and globally as a leading and exemplary health product regulator.

6.2 Mission

To safeguard the health and wellbeing of all who live in South Africa and to support human and animal health through scientific and ethical regulation of medicines, medical devices, radiation emitting devices and radioactive nuclides.

6.3 Values

SAHPRA has identified the following values as the principles that will underpin the policies, procedures, code of conduct and culture of the organisation:

Table 1: Values and Principles Governing SAHPRA

No.	Value	Description
1	**Care**	Caring about society and the environment: for humans and animals. This involves consideration of our impact on individuals, local communities and on the environment, acting with diligence and sensitivity.
2	**Ethical conduct**	Commitment to ethical conduct by promoting and protecting the health of all who live in South Africa and of its animals through relevant, scientifically sound and ethical regulatory practices.
3	**Unity of purpose**	Ensuring that all policies, guidelines and procedures are underpinned by the core principles and values of the organisation that are known to all SAHPRA staff, Board members and stakeholders; united by a common vision, facilitating collaboration and support, thereby contributing to a beneficial, safe and effective working environment. Achieving collaboration through pooling of resources, work-sharing and effective communication, as teamwork and cohesion are key. Fostering professionalism, trust and honesty in interactions with colleagues and stakeholders. Cultivating an environment where all contributions are valued, everyone is treated consistently and fairly, diverse viewpoints are heard and capitalised on and conflicts are resolved effectively. Making SAHPRA goals a priority, by targeting and carefully using SAHPRA resources to ensure effective delivery of our work.
4	**Service excellence**	Valuing good work ethics and striving towards service excellence and extroversion. This represents being committed to working with stakeholders and building good relationships with them by understanding their needs, responding quickly to their needs and providing appropriate solutions that are underpinned by the core mission and values of the organisation. Treating stakeholders with respect at all times; being helpful, courteous, accessible, responsible and knowledgeable in our interactions; ensuring that all communication is clear, effective and tailored to the needs of the target audience. Developing robust performance measures, allowing for benchmarking and monitoring challenges and opportunities for growth. Ensuring that SAHPRA, its Board and relevant stakeholders have clarity on the mandate of the organisation, policies and procedures that underpin their work and on the roles they perform.

No.	Value	Description
5	**Transformation**	Investing in the professional growth of staff by sharing knowledge and experience, peer networking, education through training and creating opportunities for development. This includes creative problem-solving, informed risk-taking, learning from our mistakes and experiences and behaving professionally. Career pathing, skills development and performance in the workplace to be managed with the aim of introducing greater diversity. Working with academic and training agencies to identify and develop new opportunities for regulatory science training. Enabling leaders to develop innovative approaches and drive continuous improvement as well as effective and smooth organisational change initiatives. Influencing and supporting the global regulatory network in which we operate, and promoting harmonisation, whilst ensuring local responsiveness to the evolving needs of our country.
6	**Innovation**	Promoting the sharing of ideas and supporting innovation, research and development in the public's interest. Identifying needs and challenges present in society. Creating an enabling environment for sound, ethical research and backing new ideas by bringing them to the market. Pursuing cost-effective solutions in operations, research and training. Monitoring and evaluating the impact of interventions on the challenges faced. Applying new ways of doing things at all levels of the Authority. Encouraging out-of-the box thinking and rewarding ground-breaking initiatives.
7	**Integrity**	Working with integrity and responsibility: setting and achieving goals, consistently delivering business results, while complying with standards and meeting deadlines. Ensuring efficiency in the best use of public resources. Creating a work environment underpinned by a culture of fairness, impartiality, independence, accountability and transparency. Aligning the Authority's operational ethos with the principles set out in the WHO Good Regulatory Practice Guideline.

7. LEGISLATIVE AND OTHER MANDATES

7.1 Legislative mandate

Mandated obligations and functions of SAHPRA

The South African Health Products Authority (SAHPRA) is the regulatory authority of South Africa responsible for the regulation of health products intended for human and animal use; the licensing of manufacturers, wholesalers and distributors of medicines, medical devices, radiation emitting devices and radioactive nuclides; and the conduct of clinical trials.

The legislative mandates of SAHPRA are derived from the Constitution; the National Health Act, 2003 (Act No. 61 of 2003); the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended (hereinafter referred to as "the Medicines Act"); and other relevant legislation, regulations and policies.

Further, SAHPRA's mandate has expanded to include the regulation and control of radiation emitting devices and radioactive nuclides under the Medicines Act and the Hazardous Substances Act, 1973 (Act No. 15 of 1973).

The Constitution of the Republic of South Africa, 1996

In terms of the constitutional provisions, the Authority is, amongst other, guided by the following sections and schedules:

The Constitution of the Republic of South Africa, 1996, places obligations on the state to progressively realise socio-economic rights, including access to healthcare.

Section 27 of Chapter 2 of the Bill of Rights of the Constitution states the following with regard to healthcare, food, water and social security:

- Everyone has the right to have access to healthcare services, including reproductive healthcare; sufficient food and water; and social security, including appropriate social assistance if they are unable to support themselves and their dependents.
- The state must take reasonable legislative and other measures within its available resources to achieve the progressive realisation of each of these rights, and no one may be refused emergency medical treatment.

The National Health Act, 2003 (Act No. 61 of 2003)

The Act provides a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on national, provincial and local government with regard to health services. The objectives of the National Health Act (NHA) are to:

- Unite the various elements of the national health system in a common goal to actively promote and improve the national health system in South Africa;
- Provide for a system of co-operative governance and management of health services, within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality healthcare services;
- Establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourage participation;
- Promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans;
- Create the foundations of the healthcare system.

The Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended

The Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), which was amended by Amendment Act, 2008 (Act No. 72 of 2008) and Amendment Act, 2015 (Act No. 14 of 2015) and enacted in May 2017, enabled, amongst others, the establishment of SAHPRA, the licensing of manufacturers and importers of active pharmaceutical ingredients, and the regulation of medical devices.

In terms of the Medicines Act, the objectives of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, medical devices, radiation control, clinical trials and related matters in the public interest. It also provides for registration and control of veterinary medicines in such a way as to ensure that they are produced, distributed and used without compromising human and animal health. Antimicrobials intended for use in animals and registered under the Medicines Act may only be administered or prescribed by a veterinarian.

As per section 2B (1) of the Medicines Act, the Authority must, in order to achieve its objects:

- Ensure the efficient, effective and ethical evaluation or assessment and regulation of medicines, medical devices, radiation emitting devices and radioactive nuclides that meet the defined standards of quality, safety, efficacy and performance, where applicable;
- Ensure that the process of evaluating or assessing and registering of medicines, medical devices, radiation emitting devices and radioactive nuclides is transparent, fair, objective and concluded timeously;

- Ensure the periodic re-evaluation or re-assessment and ongoing monitoring of medicines, medical devices, radiation emitting devices and radioactive nuclides;
- Ensure that evidence of existing and new adverse events and reactions, interactions, and signals emerging from post-marketing surveillance and vigilance activities are investigated, monitored, analysed and acted upon;
- Ensure that compliance with existing legislation is promoted and achieved through a process of active inspection and investigation; and
- Ensure that clinical trial or clinical performance study protocols are assessed according to prescribed scientific, ethical and professional criteria and defined standards.

In executing its functions, the Authority may:

- Liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority or institution in respect of:
  - matters of common interest; or
  - a specific investigation; and
- Enter into agreements to co-operate with any regulatory authority in order to achieve the objectives of the Medicines Act.

Hazardous Substances Act (Act No. 15 of 1973)

Within the Medicines Act, "medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) (hereinafter referred to as "the Hazardous Substances Act").

The Hazardous Substances Act provides for the efficient, effective and ethical evaluation and registration of non-ionizing radiation emitting devices and radioactive nuclides.

It also prohibits and controls the importation, manufacture, sale, use, operation, application, modification, disposal or dumping of substances and (electronic) products that may cause injury or death due to their detrimental direct or indirect effects. The Hazardous Substances Act classifies such substances and products in groups according to the risk associated with them.

A Group I, Group II, Group III or Group IV hazardous substance means a substance, mixture of substances, product or material declared in terms of section 2(1) of the Hazardous Substances Act to be a Group I, Group II, Group III or Group IV hazardous substance, including:

- Any substance or mixture of substances which, in the course of customary or reasonable handling or use, including ingestion, might, by reason of its toxic, corrosive, irritant, strongly sensitising or flammable nature or because it generates pressure through decomposition, heat or other means, cause injury, ill-health or death to human beings, declared to be a Group I or a Group II hazardous substance;
- Any electronic product, declared to be a Group III hazardous substance; and
- Subject to the approval of the Minister of Mines, any radioactive material, declared to be a Group IV hazardous substance.

Related legislation impacting on and influencing the functioning of SAHPRA

Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)

Provides for the registration of fertilizers, farm feeds, agricultural remedies, stock remedies, sterilising plants and pest control operators. The aim of the Act is to regulate the importation, sale, acquisition, disposal or use of fertilisers, farm feeds, agricultural remedies, stock remedies. Furthermore, it governs the use of antimicrobials for growth promotion and prophylaxis/ metaphylaxis and the purchase of antimicrobials over the counter (OTC) by the lay public (chiefly farmers).

Animal Diseases Control Act, (Act No. 35 of 1984)

Provides for the control of animal diseases and parasites, for measures to promote animal health, and for matters connected therewith.

Veterinary and Para-veterinary Professions Act, 1982 (Act No. 19 of 1982)

Provides for the establishment, powers and functions of the South African Veterinary Council; for the registration of persons practising veterinary professions and para-veterinary professions; for control over the practising of veterinary professions and para-veterinary professions; and for other related matters. It further makes provision for the compounding and or dispensing of any medicine, which is prescribed by the veterinarian for use in the treatment of an animal, which is under his or her professional care.

Drugs and Drugs Trafficking Act, 1992 (Act No. 140 of 1992)

Provides for the prohibition of the use or possession of or the dealing in drugs and of certain acts relating to the manufacture or supply of certain substances or the acquisition or conversion of the proceeds of certain crimes; for the obligation to report certain information to the police; for the exercise of the powers of entry, search, seizure and detention in specified circumstances; for the recovery of the proceeds of drug trafficking; and for matters connected therewith.

Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) (as amended)
Provides for the regulation of foodstuffs, cosmetics and disinfectants, in particular the quality standards that must be complied with by manufacturers, as well as the importation and exportation of these items.

Environmental Management Act: Waste Management Act, 1998 (Act No. 107 of 1998)
Provides for co-operative, environmental governance by establishing principles for decision-making on matters affecting the environment, institutions that will promote co-operative governance and procedures for coordinating environmental functions exercised by organs of state, and to for matters connected therewith.

Health Professions Act, 1974 (Act No. 56 of 1974)
Provides for the control over the education, training and registration of as health professionals registered under the Act, and for matters incidental thereto.

Nursing Act, 1978 (Act No. 50 of 1978)
To consolidate and amend the laws relating to the professions of registered or enrolled nurses, nursing auxiliaries and midwives, and to provide for matters incidental thereto.

Pharmacy Act, 1974 (Act No. 53 of 1974)
Provides for the regulation of the pharmacy profession, including community service by pharmacists.

Occupational Health and Safety Act, 1993 (Act No. 85 of 1993)
Provides for the requirements that employers must comply with in order to create a safe working environment for employees in the workplace.

Child Care Act, 1983 (Act No. 74 of 1983) Provides for the protection of the rights and well-being of children.
Provides for the protection of the rights and well-being of children.

Customs and Excise Act, 1964 (Act No. 91 of 1964)
Provides for the prohibition and control of the import, export or manufacture of certain goods, and for matters incidental thereto.

The Protection of Personal Information Act, 2013 (PoPI) (Act No. 4 of 2013)
To ensure that all South African institutions conduct themselves in a responsible manner when collecting, processing, storing, sharing another entity's personal information.

Promotion of Access to Information Act, 2000 (PAIA) (Act No. 2 of 2000)
Amplifies the constitutional provision pertaining to accessing information under the control of various bodies.

Promotion of Administrative Justice Act, 2000 (PAJA) (Act No. 3 of 2000)
Amplifies the constitutional provisions pertaining to administrative law by codifying it.

Public Finance Management Act, 1999 (Act No. 29 of 1999)
Regulates financial management in the national government and provincial governments. Furthermore, it ensures that all revenue, expenditure, assets and liabilities at all levels of government are managed efficiently and effectively and provides for the responsibilities of persons entrusted with financial management to support, among others, sustainable access to healthcare and medicines.

Basic Conditions of Employment Act, 1997 (Act No. 75 of 1997)
Provides for the minimum conditions of employment that employers must comply with in their workplaces.

State Information Technology Act, 1998 (Act No. 88 of 1998)
Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) (as amended)
Provides for the creation and administration of an institution responsible for the state's information technology system.

Labour Relations Act, 1995 (Act No.66 of 1995)
Establishes a framework to regulate key aspects of the relationship between employer and employee at individual and collective levels.

The Division of Revenue Act, 2003 (Act No. 7 of 2003)
Provides for the manner in which revenue generated may be disbursed.

Skills Development Act, 1998 (Act No. 97 of 1998)
Provides for the measures that employers are required to take to improve the levels of skills of employees in workplaces.

Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000)
To give effect to section 217(3) of the Constitution by providing a framework for the implementation of the procurement policy contemplated in section 217(2) of the Constitution, and to provide for matters connected therewith.

Employment Equity Act, 1998 (Act No. 55 of 1998)
Provides for the measures that must be put into operation in the workplace in order to eliminate discrimination and promote affirmative action.

The Copyright Act, 1998 (Act No. 98 of 1998)
Regulates copyright, and to provide for matters incidental thereto.

Broad-Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003)
Provides for the promotion of black economic empowerment in the manner in which the State awards contracts for services to be rendered, and incidental matters.

State Information Technology Agency Amendment Act, 2002 (Act No. 38 of 2002)
Provides for the establishment of a company that will provide information technology, information systems and related services to, or on behalf of, participating departments, and in regard to these services, act as an agent of the South African Government, and provides for matters connected therewith.

Electronic Communication and Transaction Act, 2002, (Act No. 25 of 2002)
To provide for the facilitation and regulation of electronic communications and transactions; to provide for the development of a national e-strategy for the Republic; to promote universal access to electronic communications and transac¬tions and the use of electronic transactions by SMMEs; to provide for human resource development in electronic transactions; to prevent abuse of information systems; to encourage the use of e-government services; and to provide for matters connected therewith.

Competitions Act, 1989 (Act No. 89 of 1998)
To provide for the establishment of a Competition Commission responsible for the investigation, control and evaluation of restrictive practices, abuse of dominant position, and mergers; for the establishment of a Competition Tribunal responsible to adjudicate such matters; for the establishment of a Competition Appeal Court; and for related matters.

Consumer Protection Act, 2008 (Act No. 68 of 2008)
To promote a fair, accessible and sustainable marketplace for consumer products and services and, for that purpose, to establish national norms and standards relating to consumer protection; to provide for improved standards of consumer information; to prohibit certain unfair marketing and business practices; to promote responsible consumer behaviour; and to promote a consistent legislative and enforcement framework relating to consumer transactions and agreements.

7.2 Policy mandates

The Authority, as an organ of the state, is obliged to discharge its policy mandate in a coherent manner, which is consistent with the National Development Plan (NDP) Vision 2030, Medium Term Strategic Framework (MTSF) priorities and the policy of the National Department of Health (NDoH).

The following table reflects NDP goals, MTSF priorities and NDoH strategic goals that are aligned with the SAHPRA strategic goals.

Table 2: Health Strategic Issues and Priorities

NDP Goals 2030	MTSF Priorities	NDoH Strategic Goals 2014–2019
Average male and female life expectancy at birth increased to 70 years	HIV/AIDS and Tuberculosis (TB) prevented and successfully managed Maternal, infant and child mortality reduced	Prevent disease and reduce its burden and promote health
TB prevention and cure progressively improved	N/A	N/A
Prevalence of non-communicable diseases reduced	N/A	N/A
Health system reforms completed	Healthcare costs reduced	Improve financial management by improving capacity, contract management, revenue collection and supply chain management
	Efficient health management information system for improved decision-making	Develop an efficient health management information system for improved decision-making
	Improved quality of healthcare	Improve the quality of care by setting and monitoring national norms and standards, improving systems for user feedback, increasing safety in healthcare and improving clinical governance
Primary healthcare teams deployed to provide care to families and communities	Re-engineering of primary healthcare	Re-engineer primary healthcare by increasing the number of ward-based outreach teams, contracting general practitioners and district specialist teams, and expanding school health services
Universal health coverage achieved	Universal health coverage achieved through implementation of National Health Insurance	Make progress towards universal health coverage through the development of the National Health Insurance Scheme, and improve the readiness of health facilities for implementation

8. ORGANISATIONAL STRUCTURE

8.1 Introduction

SAHPRA was operationalised as a Schedule 3A public entity with operational autonomy and accountability on 1 February 2018. It is responsible for the regulation of all medicines, complementary medicines, medical devices and in vitro diagnostics, radiation emitting devices and nuclides. This includes the regulatory compliance functions and oversight of clinical research and vigilance. The Medicines Control Council (MCC) is largely focused on the regulation of medicine and therefore SAHPRA is a different entity in terms of breadth of function and potential size.

SAHPRA is accountable to the Minister of Health through a Board appointed by the Minister and in line with the prescripts of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended. The committees of the Board as delineated are made up in the main by the Board members. The committees assist with oversight of performance in the functional areas of finance, internal risk, audit and governance, human resources and remuneration, information technology and communication, technical oversight, and regulatory strategy.

The Board was appointed by the Minister on 2 October 2017. The Medicines Regulatory Authority (MRA) and the MCC were dissolved on 31 January 2018, the day preceding the first meeting of the Board. The functions of the MCC were absorbed into the Authority and restructured to best meet the required regulatory objectives.

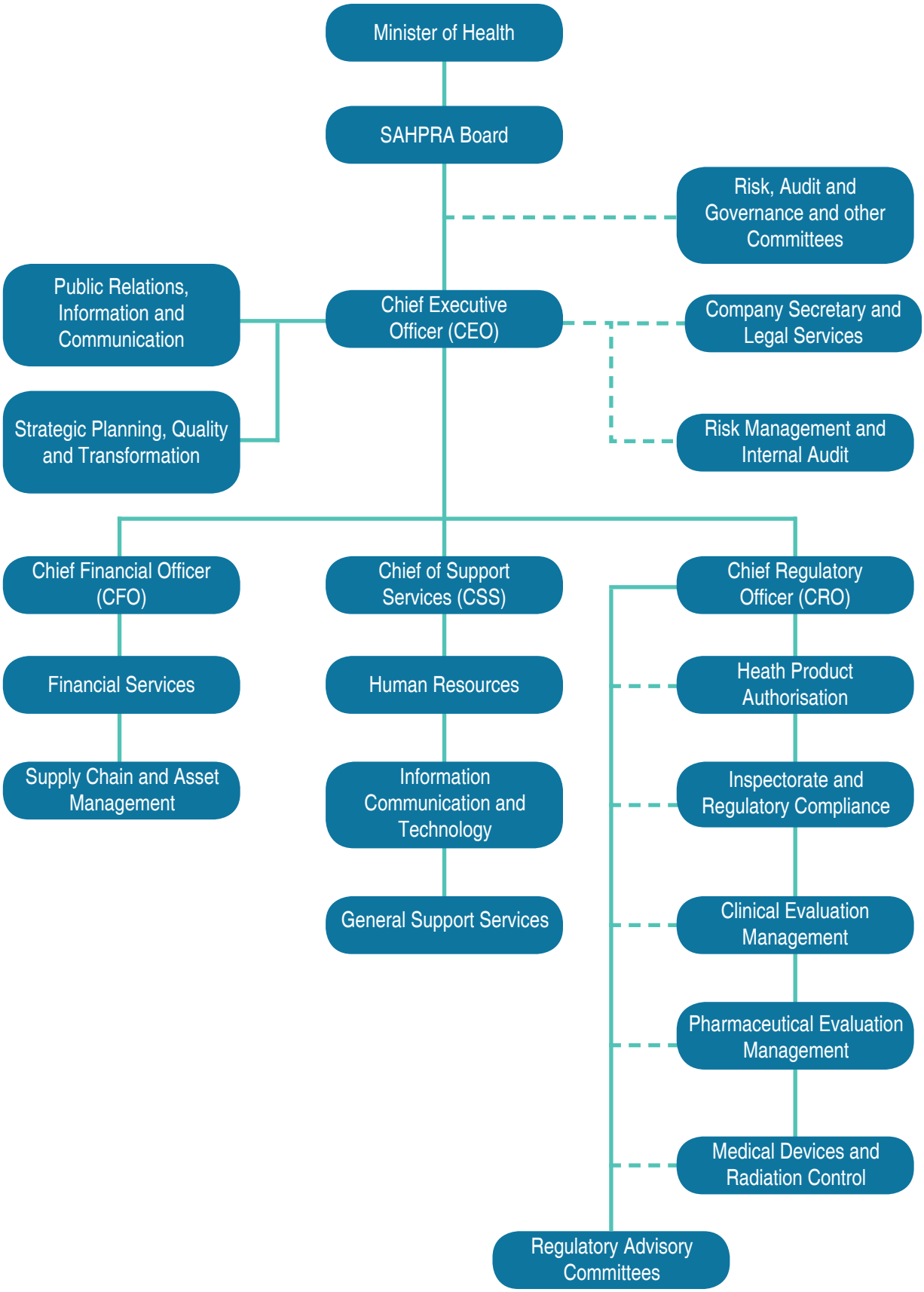
The SAHPRA Board includes Prof Helen Rees and Ms Mandisa Hela, as the new chairperson and vice-chairperson respectively. The remaining 13 members comprise experts from various sectors of health, including global and South African public health, medicines registration and regulation as well as medical research fields, law, governance, ethics and finance. The members have extensive experience in both public and private management. This depth and diversity of experience and qualifications have been crucial in supporting the entity at its inception.

The SAHPRA Board is responsible for appointing the Chief Executive Officer (CEO) after consultation with the Minister of Health and for overseeing the performance of the CEO and the Executive Management of SAHPRA.

The key Executive Management of SAHPRA, as represented in Figure 1 that follows, includes the CEO, the Chief Financial Officer, the Chief Regulatory Officer, the Chief Manager of Support Services and the Company Secretary.

Senior management roles within the organisation are represented by the heads of the core functional areas contained within Programmes 2 to 5, namely Health Products Authorisation, Inspectorate and Regulatory Compliance, Medicines Evaluation and Registration (Clinical Evaluation Management and Pharmaceutical Evaluation Management), and Medical Devices and Radiation Control. The Management from within Programme 1: Corporate Services includes Managers in Information Technology, Communications and Public Relations, Human Resources, Legal, Strategic Planning, Quality and Transformation, Finance, Supply Chain Management, General Services and Risk.

Figure 1: SAHPRA Macro-structure



8.2 OUR LEADERSHIP

SAHPRA Board

Chairperson:
Prof Helen Rees

Vice-Chairperson:
Ms Mandisa Hela

Member:
Mr Tinyiko Baloyi

Member:
Prof Shabir Banoo

Member:
Adv Hasina Cassim

Member:
Prof Ames Dhai

Member:
Ms Lesibane Fosu

Member:
Prof Craig Household

Member:
Dr Edith Madela-Mntla

Member:
Dr Ushma Mehta

Member:
Dr Mphane Molefe

Member:
Dr Thapelo Motsudi

Member:
Prof Jeffrey Mphahlele

Member Resigned:
Prof Kelly Chibal

Member Resigned:
Prof Henry Leng

SAHPRA Executive Management

Chief Executive Officer (Acting):
Ms Portia Nkambule

Chief Financial Officer:
Mr Molatlhegi Kgauwe

Company Secretary:
Adv Teboho Nthotso

Chief Manager: Support Services: VACANT

SAHPRA Senior Management

Senior Manager: Medical Devices and Radiation Control	Senior Manager: Clinical Evaluation Management	Senior Manager: Pharmaceutical Evaluation Management
Senior Manager: Medical Devices and Radiation Control	Senior Manager: Clinical Evaluation Management	

Part: B
Performance Information

9. AUDITOR-GENERAL REPORT: PREDETERMINED OBJECTIVES

The Auditor-General of South Africa currently performs the necessary audit procedures on the performance information to provide reasonable assurance in the form of an audit finding. The audit findings on the performance against predetermined objectives is included in the report to management, with material findings being reported under the Predetermined Objectives heading in the Report on other legal and regulatory requirements section of the Report of the Auditor-General.

Refer to page 91 of Report of the Auditor-General, published as Part E: Financial Information.

10. SITUATIONAL ANALYSIS

10.1 Service delivery environment

The health service delivery environment

The Institute of Medicine has defined quality healthcare as "the degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge".

It is imperative to note that this definition indicates that quality healthcare should be effective, efficient, equitable, patient-centred, safe and timely. This is especially important in the increasing public demand for access to and use of new technologies and new medicines with higher expectations of quality and safety.

Health reform and envisaged impact of SAHPRA towards quality and safety

The National Department of Health has been implementing several initiatives towards reform in the health sector, including universal healthcare in the form of the planned National Health Insurance (NHI). The focus of these initiatives is to ensure that the public and private health sectors deliver on key expectations and requirements of providing the right healthcare at the right time under the safest conditions.

SAHPRA was established as part of these initiatives with the mandate to promote the health, wellbeing and safety of the public by ensuring access to safe, efficacious and quality health products.

Initiatives of relevance to the work of SAHPRA include:

- Development, approval and implementation of a re-engineered framework to eradicate the backlog of health product registrations.
- Promulgation of a policy shift towards increased reliance models with other regulatory authorities that will be adopted in both the backlog and business-as-usual operational processes.
- The review of both operational and technological systems to ensure timeous delivery of this operational mandate within the ambits of internationally established best practice.
- Development, approval and implementation of systems and frameworks to address new areas of health product regulation, including medical devices and radiation emitting devices and radioactive nuclides.
- Actively working to improve vigilance and reporting of adverse events, resulting in more active reporting from professionals and the public, and securing patient safety when engaging health products, both registered and unregistered.

A total number of 26 key performance indicators were relevant for the period under review		
Achieved	15/26	58%
Not achieved	11/26	42%

Towards this end and through the work of SAHPRA, the following outputs were achieved in the performance year 2018/19.

Within the core programmes fulfilling the mandate of the organisation, the following performance outputs were noted for the entity:

Issued a consolidated **5 910** licences, permits and certificates from its Authorisation Management unit	**20** new chemical entity and biological health products were registered.
169 establishments were inspected for good manufacturing practice, good clinical practice, and good wholesale practice compliance	**181** generic and biosimilar health products were registered.
64 permit holders, establishments and sites of narcotic and psychotropic substances were inspected.	Reports of new adverse events and signals that have been assessed, actioned and concluded were published every quarter and included eight media releases and **12** 'Dear Healthcare Professional' letters.
147 human and animal clinical trials were reviewed within the predefined timeline.	**349** medical device establishments were licensed.
682 clinical trials amendments were reviewed within the predefined timeline.	**2 960** new licences were issued for radiation emitting devices and radioactive nuclides
10 808 human, animal and complementary medicines – Section 21 applications – were reviewed within the predefined timelines in 2018/19	Developed, approved and began implementation on the backlog framework to ensure the eradication of the backlog inherited from the previous MCC.
Engaged with industry and other stakeholders **64** times to ensure bilateral and transparent communication	Strengthened **19** collaborative relationships with relevant stakeholders, and built support for the policy shift towards increased reliance models to be utilised within the entity's operations.

These achievements were significant in lieu of the strained organisational environment under which SAHPRA performed in the year 2018/19.

10.2 Organisational environment

The 2018/19 reporting period represents SAHPRA's first year as a Schedule 3A public entity. SAHPRA was in a unique position in this transitional period as it had inherited a functioning and mostly capacitated core programme. The corporate services capabilities were previously fully provided for by the NDoH and needed focused attention to grow and develop within the newly established public entity framework.

A balanced approach was used to address the operational difficulties of the entity derived from the medicines backlog and newly adopted functions of medical device and radionuclide control, while simultaneously growing a brand-new corporate services programme. The programme needed both skills and functionality, to provide the necessary administrative support to SAHPRA's core programmes, to enable compliance with both the mandate and legislative frameworks.

The Board's initial strategic direction opted for a phased-in transition of corporate services by commencing the process of filling key critical posts first, thereby allowing these new executives to extend the efforts of the entity in the area of building corporate services capacity. The key critical posts were identified as the Chief Executive Officer, the Chief Financial Officer, the Chief Operations Officer, the Director: Human Resources, the Director: Information Technology, and the Company Secretary. These were subsequently re-engineered in the 3rd quarter to the needs of the organisation by changing the Chief Operation Officer to the Chief Regulatory Officer and by including a Director: Communications and Public Relations in the list of critical roles.

A Memorandum of Understanding (MoU) that was entered into between SAHPRA and the NDoH in April 2018 predicated the assumption that the NDoH would provide continued support related to corporate services during the transitional period, enabling this phased-in approach.

As a result, the Board elected to focus the efforts of the newly appointed Acting CEO, Ms Portia Nkambule, and her team on developing and implementing strategies to address the backlog of applications for product registrations and to re-engineer methods of operation that will prevent such re-occurrences.

Critical stakeholder engagements that informed the framework, and crucial donor funding and public health expertise engagements characterised this initial period, resulting in the development of a re-engineered operational framework that would address the inherited backlog and refresh the operations in the BAU functional areas. This framework was approved and implementation commenced in this financial year.

This initial phase was characterised by the development and implementation (where possible) of a corporate services framework, resulting in the creation and approval of policies and procedures to support corporate services and good governance functions of the entity.

In this period, the entity remained on par with performance targets set out in key performance areas of health product registration, clinical trials, inspections and licensing to support the public health agenda.

The 1st quarter, however, marked the onset of a year-long labour unrest, linked to the wellbeing of staff housed in the NDoH, Civitas building. The labour unrest began with limited working hours in April 2018 and progressed to a 'stay away' by August 2018. This culminated in the building shutdown on 30 October 2018. The impact of this protracted labour unrest was a diminished workforce of between 10–15% that severely impeded workforce productivity and impacted work output significantly in the 2nd and 3rd quarters.

Corporate services activities, that relied on the NDoH through the MoU that was signed, were plagued with obstacles to implementation and stilted operations as a consequence of this lack of capacity, with both SAHPRA staff and NDoH staff participating in the labour unrest action.

A direct consequence of the ineffective MoU, was that SAHPRA's tender and recruitment initiatives to set up its own crucial administrative support services were impeded, with no access to supply chain and human resources technical support. Measures were taken to engage with the Government Technical Advisory Centre (GTAC) to secure a mechanism to capacitate SAHPRA. This, however, did not transpire in the preferred timeframes, to have a significant impact as the SLA between the GTAC and SAHPRA was only signed in December 2018. SAHPRA took further steps in the 4th quarter to implement its own procurement process, aligned with the National Treasury guidelines to secure key corporate services support. This culminated in Finance, HR and Supply Chain Management (SCM) service providers being secured in the 4th quarter.

With the workforce productivity diminished, an executive decision was taken in the 2nd quarter to focus the entity's efforts on areas of work with the greatest public health priority to ensure that safety and access were not compromised. Where possible, automated digital solutions to support certain functions were created. A key area where this strategy was effective was in the processing of applications for sales of unregistered medicines that went from the hundreds to the thousands in capacity capability.

A second executive decision was taken to relocate SAHPRA, following the building shutdown in the 3rd quarter, as the conclusion of the prolonged labour unrest remained uncertain. This necessitated a once-off emergency dispensation from the Office of the Chief

Procurement Officer at National Treasury to relocate SAHPRA to new premises, thereby bypassing the tender process. A 6-month to 8-month short-term lease agreement was signed on 8 December 2018 between SAHPRA and the Council for Scientific and Industrial Research (CSIR). The process to tender for more permanent fit-for-function premises was simultaneously initiated as a condition of this emergency dispensation. SAHPRA's relocation commenced in mid-December 2018 and the process was finalised in February 2019.

The move saw a workforce attendance increase of up to 80% and a more 'business-as-usual' state of affairs was re-established. Work productivity and work output increased satisfactorily in this last quarter.

The move to CSIR was not without its teething issues and disruption to services such as internet and email, typified this initial period in the 4th quarter.

Access to ICT hardware was severely compromised during this time, without options to properly resolve this critical matter, the entity was forced to resort to what may be termed, wasteful expenditure. Bedding down of ICT infrastructure at this juncture would be derived at a great cost and it would be lost when final relocation occurred. The ICT strategy therefore would remain a living document evolving with the process to secure a final home for SAHPRA.

Office space at the temporary CSIR premises was unfortunately also not optimal, with the entity now occupying five different buildings scattered across the vast campus. This became a serious obstacle to operations and communication. These difficulties were addressed by means of intensified staff engagements. These increased engagements paved the way for a more formalised, harmonious labour relations environment.

In the 4th quarter, the Acting CEO focused on engaging labour and establishing a workplace forum, which created a formal platform for labour and SAHPRA to formally engage on issues of mutual interest. The workplace forum is now running efficiently and is an effective mechanism to guide the organisation through the remaining transition with more bi-directional labour-informed initiatives.

The Board resolved in the 4th quarter to capacitate the office of the CEO with more resources as the process of recruiting executives intensified. In this regard, the Board, in consultation with the Minister, requested the Vice-Chairperson to step down from the Board and render support to the CEO in her capacity as technical strategic executive within SAHPRA. The Board further resolved to appoint Dr Nicholas Crisp, the public health specialist who was instrumental in developing the initial SAHPRA business case, to give much needed support to the office of the Acting CEO during this transitional phase.

Both Ms Hela and Dr Crisp helped the entity to focus on building corporate services, finalising the staff establishment and consolidating the core functioning, whether it be re-energising operational functions in medicine and radiation control, guiding the backlog project or building capacity in new fledgling spaces such as medical devices.

Dr Crisp put together a few solutions to propel the entity towards its envisioned operational space. This included providing much needed guidance for stabilising SAHPRA's Programme 1, by finalising the organogram and staff establishment, lending support to the relocation process, engaging labour, and advising the Acting CEO on HR matters. The Board adopted the new staff establishment, which comprises 477 posts.

A total of 209 staff members were absorbed in terms of section 197 of the Labour Relations Act and would need to be placed into this new staff establishment. This process remains ongoing.

The Authority advertised six senior management posts and authorised the filling of 89 posts in the 1st quarter of 2019/20. These posts are primarily to strengthen the corporate functions in Programme 1 and the Radiation Control and Medical Device functions in Programme 5.

Further, the senior management of SAHPRA was reinforced by the appointment of the Chief Financial Officer, the Company Secretary and the Director: ICT. Interviews for the position of Director: Public Relations and Communications were held in this quarter and the successful candidate will assume duty at SAHPRA in the 1st quarter of the 2019/20 financial year.

The process of recruiting the CEO and Chief Regulatory Officer is ongoing and should be finalised in the 1st quarter of the 2019/20 financial year. Simultaneously the re-engineered detailed organogram identified up to 100 posts, ranging from management, pharmaceutical, medical device and radiation control, administration and support for the backlog project. These posts will be advertised in the first quarter of the 2019/20 financial year. Approximately 20 of these will include crucial senior and middle management posts across all programmes. This will ensure that the organisation is fully established and working toward self-sufficiency.

The year 2018/19 was a year filled by tremendous and unforeseen obstacles. Despite these difficulties, the strong resolve to fulfil its mandate and serve the public remained, and initiatives to continue to pursue SAHPRA's strategic goals in the next reporting period, persisted. SAHPRA remained committed to setting a solid foundation to anchor the re-engineering of operations and fulfilling its core mandate.

The focus of the Authority remained on strategies to address the inherited backlog and refresh the BAU operations to both eliminate this backlog and initiate methods of operations that will prevent a recurrence.

Foundations to build capacity in the new functional areas of medical devices and radiation control also remained a crucial priority. Work within these functions to license establishments; enabling a system to register medical devices and maintain gains in the unit responsible for regulation of radiation emitting devices and radioactive nuclides commenced.

Enhanced stakeholder communication and reactiveness to the public needs around health products also remained a primary focus area of the entity and saw it not just addressing the difficulties experienced in this first year, but growing, learning and strengthening itself towards a more self-reliant, professional entity, capable of benchmarking itself against a globally recognised platform.

This was evident in two key success areas, during this reporting period the entity with a limited staff capacity was able to ensure registration of the Tenofovir/Lamivudine/Dolutegravir (TLD) antiretroviral combination within a period of less than 180 days. This quick response to public health need and alignment with public health mandates within its parent department demonstrated the entities ability to remain agile under difficult circumstances and not lose focus of its primary mandate and public service focus.

The challenges of 2018/19 highlighted opportunities for growth and reform and have paved the way forward for SAHPRA to embrace the potential to change, a much-needed trait in a strained public sector environment. The entity commenced its organisation-wide re-engineering and whilst it remains acutely cognisant that this change must be deliberate, monitored and well supported, it has also embraced the process with enough vigour and enthusiasm to remain undeterred from the ultimate outcome of becoming a high functioning national medicines regulator and a critical pillar in the greater focus of NHI and medicine access, patient safety and South Africa's wellbeing.

11. STRATEGIC OUTCOME-ORIENTED GOALS

Goal 1:

Publicly demonstrate responsiveness and accountability as an effective and efficient high-performance organisation

SAHPRA places prominence on good management, from well-considered planning to effective performance measurement.

SAHPRA aims to be an effective and efficient high performing organisation that is responsive and publicly accountable.

Achievement of this goal rests to a large extent on sound financial and human resources management and the effective use of information technology to support business processes and the interface with stakeholders.

Goal 2:

Timeous regulatory decisions taken on medicines and medical device applications to ensure compliance to defined standards of quality, safety, efficacy and performance

The Authority strives to make timeous regulatory decisions based on defined standards for quality, safety, efficacy and performance.

Goal 3:

Re-evaluate and monitor medicines and medical devices periodically

The Authority endeavours to establish a framework to ensure that registered products are periodically re-evaluated in accordance with the defined standards of quality, safety, efficacy and performance.

Goal 4:

Investigate, monitor, analyse and act upon existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance

The Authority seeks to ensure that evidence of existing and new adverse events, interactions, signals emerging from post-marketing surveillance and vigilance are being solicited, investigated, monitored, analysed and acted upon, and that supportive national and global partnerships are established.

Goal 5:

Ensure regulatory compliance through a process of active inspections and investigations

The Authority undertakes to inspect and investigate establishments and permit holders in accordance with the defined guidelines and standards.

Goal 6:

Evaluate clinical trial protocols in accordance with defined standards

The Authority seeks to safeguard the public and data integrity by evaluating clinical trials in accordance with the defined standards.

Goal 7:

Evaluate the applications for sale of unregistered health products in accordance with defined standards

The Authority endeavours to ensure that unregistered health product applications are evaluated in accordance with defined standards of safety, efficacy and quality for unregistered health products.

Goal 8:

Establish and strengthen collaborative initiatives with any other regulatory authorities or institutions in order to achieve the objectives of the Medicines Act

The Authority seeks to liaise with any other regulatory authority or institution with a view to exchange information with and receive information from any such authority or institution in respect of (i) matters of common interest, or (ii) a specific investigation, and to enter into agreements of collaboration with any other regulatory authority or relevant organisation.

Goal 9:

SAHPRA is capacitated by adequate, competent and motivated human capital

A functional SAHPRA with a budget and personnel to implement the Authority's mandate effectively is phased in and will be fully operational by 2022.

12. PERFORMANCE INFORMATION BY PROGRAMME

12.1 Programme 1: Administration

Programme purpose

To provide the leadership and administrative support necessary for SAHPRA to deliver on its mandate and comply with the relevant legislative requirements.

The Administration Programme plays a crucial role in the delivery of SAHPRA's services through the provision of a range of support services, such as organisational development, HR and labour relations, information technology, property management, security services, legal, communication and the integrated planning functions. SAHPRA is highly dependent on the effective management of financial resources and procurement processes as administered within the Financial and Supply Chain Management Department. Generating sufficient revenue remains a critical focus area for SAHPRA to ensure financial viability and sustainability.

There are four sub-programmes, namely:

Sub-Programme 1: Financial and Supply Chain Management

The purpose is to serve all business units in SAHPRA, the senior management team and the Board by maintaining an efficient, effective and transparent system of financial and risk management that complies with the applicable legislation. The Internal Finance Unit also serves the Risk, Audit and Governance Committee, Internal Auditors, Finance Committee and NDoH, National Treasury and Auditor-General by making available to them information and reports that allow them to carry out their statutory responsibilities. Furthermore, this sub-programme must seek to improve the cash flow position of SAHPRA.

Sub-Programme 2: Governance and Compliance

The purpose is to provide support services and ensure compliance with relevant legislation and achieve an unqualified audit outcome by ensuring consistent management practices through compliance with standard operating procedures and systems within SAHPRA. Furthermore, the purpose is to review existing operational processes and recommend new or changed processes and work methods to ensure optimal organisational effectiveness, and to measure and monitor the Authority's performance.

This sub-programme is supported by three functional work programmes residing within SHAPRA's corporate services. They comprise the functions found within the Office of the Board Secretary and Legal Services, the Office of Strategic Planning and Monitoring, and the Office of Quality Management.

The purpose of the each of these programmes and their corresponding contribution to the Governance and Compliance sub-programme are as follows:

- **Board Secretary and Legal Services:** To manage the corporate governance framework and legal risk of the Authority and be held legally accountable to the Authority.
- **Strategic Planning and Monitoring:** To review existing operational processes and recommend new or changed processes and work methods to ensure optimal organisational effectiveness and to measure and monitor the Authority's performance.
- **Quality Management Systems:** To ensure SAHPRA has effective, efficient and transparent quality management policies, programmes and systems in support of achieving the Authority's objectives.

Sub-Programme 3: Information Technology and Communication

The purpose is to develop and implement an ICT-integrated governance framework by focusing on the business continuity plan and supporting the needs and requirements of the end users. Furthermore, the purpose is to manage public relations, and information and communication services to ensure proper management and dissemination of information to internal and external stakeholders, and to ensure a seamless, harmonious operational platform by building strong and sustainable relationships with all its stakeholders.

Sub-Programme 4: Human Resource Management

The purpose is to provide human resources and organisational development systems and solutions that meet the needs of the organisation and support the achievement of the Authority's strategic objectives.

Table 3: Programme 1: Annual Performance

KPI	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	QTR 1	QTR 2	QTR 3	QTR 4	Annual Achievement 2018/19	Variance	Reasons for Variance
1	1	Establish, in a phased approach, a fully functional Authority suitably staffed to execute the mandate and goals of SAHPRA	% of funded positions filled	70%	94%	93%	92%	91%	91%	+21%	Target exceeded During the year under review, the former MCC structure was utilised as the SAHPRA organogram was not yet finalised. The output therefore reflects staff as per this previous staff establishment. The new micro-organogram was approved in April 2019 and will be reported on during the 1st quarter of 2019/20.
2	1	Establish, in a phased approach, a fully functional Authority suitably staffed to execute the mandate and goals of SAHPRA	% of staff trained as per annual performance plan	60%	0%	0%	0%	0%	0%	-60%	Target not met Training planned through the National Department of Health Sector Education Training Unit (NDoH SETU) was not completed due to the labour unrest at the workplace and lack of staff in both SAHPRA and NDoH HR to facilitate and attend training. The critical HR Director position could not be filled, despite a recruitment initiative during the period under review. This position was subsequently re-advertised. Therefore, there was no training plan in place against which this KPI could be measured. However, staff have been undergoing informal training within various programmes.

KPI	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	QTR 1	QTR 2	QTR 3	QTR 4	Annual Achievement 2018/19	Variance	Reasons for Variance
3	1	Maximise performance to improve organisational efficiency	% of employee performance agreements signed no later than 31 May of each year	100%	–	–	–	xx	24%	-76%	Target not met. As at 31 May 2018, 51/211 performance agreements were signed. After 31 May 2018, 108/211 were signed. 52/211 were unsigned and they are being addressed. Part of the difficulty in achieving this target was the labour unrest and relocation of SAHPRA that hampered this signing process.
4	1	Develop a communication strategy to support improved external stakeholder interactions and relations	Communication strategy developed, approved and published	Approved communication strategy published on website				Communication Strategy developed	Communication strategy developed but not yet approved and published	–	Target not met A draft Communications Strategy was finalised in the 1st quarter of 2019/20 and will be tabled for approval in the 2nd quarter of 2019/20. The delay is attributable to the anticipated support from the Government Communication and Information system (GCIS) not being secured to lend support to the development of the communication strategy. The Communications Committee was established in the 4th quarter to facilitate this KPI output. The appointment of the Director: Communications has been made. The post will be occupied on 1 June 2019 of 2019/20. ICT infrastructure and web development to support this KPI is also in process.

KPI	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	QTR 1	QTR 2	QTR 3	QTR 4	Annual Achievement 2018/19	Variance	Reasons for Variance
5	1	Create public and stakeholder awareness about the mandate of SAHPRA	Number of media and communication events and stakeholder meetings	4	8	37	7	12	64	+60	Target exceeded There was a significant increase in initiatives aimed at ensuring that stakeholder communication was effective, particularly during labour unrest and building shutdown. Moreover, communications that had a significant public health impact (such as safety advisories) were prioritised. There were also increased stakeholder engagements with regards to the development of the backlog framework. This KPI will be revised to better delineate engagements per stakeholder constituency.
6	1	Implement good governance, oversight and accountability through appropriate delegation, including Financial Management and compliance with PFMA requirements	Audit Outcome	Unqualified Audit Report					Qualified Audit Report		Target not met. This is mainly due to lack of and limited internal controls as a result of capacity constraints

KPI	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	QTR 1	QTR 2	QTR 3	QTR 4	Annual Achievement 2018/19	Variance	Reasons for Variance
7	1	Ensure that the monitoring and inspection of information stored on SAHPRA Information and Communication Technology (ICT) facilities and services are performed in an appropriate and responsible manner	ICT policy developed and approved	Approved ICT policy		Draft ICT policy developed		ICT policy approved	ICT policy developed and approved	–	Target met
8	1	Ensure a comprehensive plan is in place that outlines how technology should be used to meet IT and SAHPRA goals	ICT strategy developed and approved	Approved ICT strategy		Draft ICT strategy developed		ICT strategy developed	ICT strategy developed and approved	–	Target met
9	1	Share, co-operate and strengthen collaborative initiatives with relevant stakeholders to support the mandate of SAHPRA	Number of collaborative relationships strengthened	2 MoUs	11	1	7	19	19	+17	Target exceeded The significantly increased number of MoUs is due to a policy shift towards increased reliance models with other regulatory authorities that will be adopted in both the backlog and business-as-usual operational processes.
10	1	Enter into agreements with contract laboratories to support quality assurance and control function of Regulator	Number of service level agreements in place with contract laboratories	1	–	–	–	1	1	–	Target met Contract signed with National Control Laboratory for Biological Products.

KPI	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	QTR 1	QTR 2	QTR 3	QTR 4	Annual Achievement 2018/19	Variance	Reasons for Variance
11	1	Maintain medicine and medical device registers	Updated medicine and medical device registers published on website quarterly	Quarterly update report published	Yes	Yes	No	No	Quarterly update reports published for 2 quarters	-2 quarters	Target not met. SAHPRA is currently using the old MCC notification of registration system to publish quarterly reports. SAHPRA is in the process of developing an electronic register for publication on the website. 3rd and 4th quarter updates were unpublished owing to issues with labour unrest, which affected staff capacity, and relocation, which affected access to the ICT infrastructure.

Finance and Supply Chain Management

The Authority managed SAHPRA's finances under the direction of the Public Finance Management Act (PFMA) through the Office of the CFO. The CFO position was successfully filled in the 4th quarter. With the incumbent (Mr Molatlhegi Kgauwe) joining late in the reporting period and entering into the first audit of the entity, the MoU with the NDoH is still being utilised to support the provision of financial information until full capacity can be established with SAHPRA's own financial systems. Monthly reconciliations were submitted to SAHPRA and this in turn was reported to the SAHPRA Finance Committee and the Board.

The protracted labour unrest and subsequent relocation to the CSIR delayed the compilation of financial information throughout the year; however, measures have been taken to address this lag by strengthening the temporary ICT infrastructure at the CSIR and access to NDoH servers to ensure that access to performance and finance information is guaranteed to be more timeous and efficient as reporting progresses from the 1st quarter of 2019/20.

Interim emergency temporary finance and supply chain support was acquired (on a month-to-month basis) in the 4th quarter to support the unit, to assist with the completion of related functions, to help set up SAHPRA in its own system, and to ensure self-sufficiency moving forward. The specified terms of reference requested from the service providers was to facilitate the training of SAHPRA's administrative staff in financial and supply chain administrative tasks through job shadowing and experiential learning.

The Supply Chain Management (SCM) service provider acquired and mobilised several requests for quotations, proposals and bids that were being bottle necked in the NDoH SCM system. These included but were not limited to media advertisements, a tender for new premises, recruitment agencies, internal audit and risk service support, strategic planning support, financial systems and other goods and services as deemed necessary to support both corporate services as well as core functions during the transition period.

Governance and Compliance

A crucial appointment in the 4th quarter was that of the Company Secretary (Adv Peter Nthotso). Under his guidance, the opportunity to activate and adhere to the framework established for compliance is now fortified, lending the entity the much-needed guidance in this new area of compliance.

SAHPRA mobilised the tender process for expertise to inform, develop and implement the internal audit and risk management system to support the internal audit and risk framework approved by the Risk, Audit and Governance Committee (RAG). The process to secure external members for the RAG was also re-energised following the move from the NDoH Civitas building. The incumbents will most likely assume office in the 1st quarter of the 2019/20 reporting period.

SAHPRA's management also formally engaged the Auditor-General of South Africa in the last quarter in preparation for its first audit. In order to add rigour to the reporting completion, in the absence of internal audit and risk experts, the CFO and Company Secretary secured the support of the NDoH internal audit function to give feedback on the quarterly reporting process to date.

Risk registers are currently being crafted by management and will be reviewed and refined following the appointment of a service provider to review and implement the organisational risk management system. This will thereafter be presented to the Board for approval.

Information Technology and Communication

During the 4th quarter the position of Director: ICT (Mr Teboho Ramosangoane) was successfully filled. The Director set about the mammoth task of stabilising the entity in its temporary premises and setting out a plan to support the digitisation of the operational processes for both the backlog project and the BAU Unit. Regular scoping meetings were held with managers in the 4th quarter to establish the way forward with regard to digitisation of all business processes. The IT plan was approved in the last quarter and will be implemented as part of the solution when SAHPRA moves to its new premises, which is expected to happen by November 2019.

The move to the CSIR resulted in severe disruption to all ICT-related functions and the immediate focus was on interim solutions to achieve partial functionality until permanent premises are secured. Permanent plans were deferred to avoid wasteful expenditure on infrastructure that could not be taken to the new premises. This affected the functioning of the entity somewhat in the last quarter. Temporary measures were undertaken in the 4th quarter of 2018/19 and 1st quarter of 2019/20 to address ICT infrastructure, and ICT functionality has improved in the current space of SAPHRA within the CSIR.

A draft communications strategy was finalised in the 1st quarter of 2019/20 and will be tabled for approval in the 2nd quarter. The delay in developing and approving the communication strategy is attributable to the anticipated support from the Government Communication and Information system (GCIS) not being secured to assist in developing the communication strategy. The Director: Communication and Public Relations was interviewed in the 4th quarter and the post will be occupied 1 June 2019.

Notwithstanding these difficulties, there was a significant increase in initiatives: 64 media and stakeholder engagements were supported by SAHPRA in the

2018/19 reporting period, ensuring that stakeholder communication was effective, particularly during labour unrest and building shutdown. Moreover, communications that had a significant public health impact (such as safety advisories) were prioritised. There were also increased stakeholder engagements with regard to the development of the backlog framework.

Human Resources

The post of Director: Human Resources was not successfully filled in the reporting period, despite extensive recruitment efforts. This has, to some extent, affected the efficient roll-out of the HR administrative services support. Interim HR administrative services were secured as was done for Finance and SCM.

Dr Nicholas Crisp, a public health specialist, was secured to give guidance in many critical areas of work that impacted SAHPRA's transition. Subsequently, significant strides were made in the 4th quarter to advance the human resources requirements as part of the transition. Meetings between managers and Dr Crisp helped to evolve the comprehensive SAHPRA organogram to make the organisation fit for functioning and bring alignment to the transforming operational processes.

The staff establishment was also scrutinised towards these same objectives and the immediate HR needs of the organisation were determined. The resultant list of approximately 100 posts and comprehensive organogram were presented to the HR and Remuneration Committee and accepted for tabling at the next Board meeting. These posts were advertised in the 1st quarter of 2019/20 and approximately 5 655 applications were received for processing by the middle of the 1st quarter of 2019. By the 2nd quarter of 2019, the first round of posts should be filled. This process will be managed by five recruitment agencies according to the categories of management, corporate services, pharmaceutical, administration and support, and backlog.

12.2 PROGRAMME 2: HEALTH PRODUCT AUTHORISATION

Programme purpose

To provide administration support necessary for SAHPRA to deliver on its mandate and comply with the relevant legislative requirements.

The specific purpose of this programme is to coordinate the process of registration and/or licensing or amendment of applications in respect of medicines within a legislative framework that defines the requirements necessary for application to the Authority, to receive record and distribute all documents submitted to SAHPRA, and to manage and maintain SAHPRA's main registry.

There are five sub-programmes, namely:

Sub-Programme 1: Document reception and helpdesk

The purpose of this sub-programme is to receive, record and/or direct all documents submitted to SAHPRA.

Sub-programme 2: Records management

The purpose is to manage SAHPRA's main registry system to ensure the completeness of records, ease of retrieval and compliance with the National Archives Act and relevant organisational policies.

Sub-programme 3: Project office – regulatory decision for medicines

The purpose is to coordinate the process of the making of a regulatory decision of medicines (screening, dispatch to evaluators, coordinating reports, recommendations, responses, arranging peer and product review meetings). It is also involved in ensuring that regulatory decisions made at the time of registration are in the public interest throughout the products' lifecycle through post-marketing vigilance of registered products. Vigilance includes the soliciting of data through various approaches, monitoring, analysis and responsive action, including the provision of feedback. In addition, a fully staffed backlog project team led by a senior project manager and linked to this sub-programme will be established.

Sub-programme 4: Project office – clinical trials, section 21 portfolio management

The purpose is to coordinate the vigilance process and authorisation of clinical trials and Section 21 applications for medicines and devices within a legislative framework that defines the requirements necessary for application to the Authority. Details on the assessment procedure and the grounds for approval or rejection of the application, and also the circumstances where authorisation already granted may be cancelled, withdrawn, suspended or revoked, are also catered for.

Sub-programme 5: Licensing, permits and certificates portfolio management

The purpose is to manage and coordinate the process of licensing and amendments in respect of medicines manufacturers, wholesalers and medical device establishments and the issue of permits and registration certificates within a legislative framework that defines the requirements necessary for application to the Authority. Details on the assessment procedure (based on quality, efficacy and safety criteria) and the grounds for approval or rejection of the application, and also the circumstances where registration/licence/authorisation already granted may be cancelled, withdrawn, suspended or revoked, are also catered for.

Table 4: Programme 2: Annual Performance

KPI	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 per APP	QTR 1	QTR 2	QTR 3	QTR 4	Annual Achievement 2018/19	Variance	Reasons for Variance
12	2	Take regulatory decisions on all backlog applications	Backlog framework developed	Backlog framework developed and implemented	Backlog framework developed	Backlog framework approved	Backlog framework implemented	Backlog framework implemented	Backlog framework developed, piloted and implementation commenced		Target met
			% of backlog applications with regulatory decisions taken	Not applicable for 2018/19	–	–	–	–	Not applicable for 2018/19		Not applicable for 2018/19
13	2	Issue of licence, permits, registration certificates, certificates of establishments and health products for applications received for medicines and medical devices within a specified timeline after regulatory decision taken	% of licences, permits and certificates issued within predefined timelines on quarterly basis	70%	38%	22%	97%	90%	47 %	-2 quarters	Target not met The non-compliance can be attributed to the labour unrest and relocation in the 2nd and 3rd quarters. This resulted in a lack of staff to support targeted output. Strategies to address this backlog are now being implemented successfully. 5 910/12 648 certificates, permits and licences were issued in 2018/19

Health product authorisation

Health Product Authorisation is home to the backlog project and BAU operations. As such, the programme is the central point of business transformation. In this reporting period, the programme has been active in the rollout of the re-engineered operational model whilst continuing to coordinate the current operational model so that the core mandate of the organisation is not disrupted during this business transformation process. The recruitment for BAU commenced in the 2nd quarter, including the approval of policies and procedures which will be mirrored in the BAU. The change in organisational structure was greatest in this programme and staffing will increase the unit number to 88. Upskilling this programme and ensuring digitisation remain crucial to it and to the organisation's successful transition in this re-engineering process. The senior manager of the unit retired in the 1st quarter and takes with her a wealth of institutional knowledge. There will be an anticipated re-stabilisation phase whilst this programme is re-capacitated. This post exists as one of the 89 advertised in the 1st quarter of 2019/20.

The backlog negatively impacts applicant business and as such creates a huge reputational risk for the Authority. The Boston Consulting Group (BCG)-managed backlog project proposal has been reviewed by the Board and the Technical Oversight and Regulatory Strategy (TORS) Committee, and will be implemented to address this risk to permit a sustainable solution to both addressing and preventing a recurrence of the backlog. Programme 2 should be capacitated with competent trained individuals and digitising the system. Infrastructure issues that plague the unit will be addressed by focused consideration of relocation premises suitable to the needs of the registry.

SAHPRA as a Schedule 3A entity is now partially reliant on its own revenue for funding. Any prolonged disruption of services will result in a decrease in revenue generated and affect the financial sustainability and stability of the organisation. Digitisation and a stable operational structure are key to sustaining an adequate inflow of applications.

Backlog clearance programme

Special mention is made of this Programme as the SAHPRA Board committed to clearing the inherited backlog of +/- 16 000 applications within 2 years as they are acutely aware of the impact that this backlog has on the Authority and South Africans in general.

A diagnostic project was launched in May 2018 in order to draw up the Backlog Clearance Strategy. From February to July 2019, the Backlog Clearance Strategy was brought to life in preparation for 'go-live', with significant progress made on each of the three formative pillars as follows:

1. **Reduce the number of backlog applications for evaluation by partnering with industry and other stakeholders:** To ensure SAHPRA's focus on the highest priority, most relevant applications, industry was required to 'opt in' for applications submitted before 2014, resulting in a withdrawal of +/- 3 000 applications (+/- 35%). From 1 August 2019 to 30 November 2020, applicants will be required to update and resubmit their applications in designated resubmission windows.

2. **Segment and prioritise the applications for evaluation by public health need and risk:** All new registration backlog applications have been classified by therapeutic area, and therapeutic areas of unmet public health need are being prioritised for resubmission. Once resubmitted, the extent of evaluation required is determined by public health risk, i.e. the level of prior scrutiny by SAHPRA's recognised regulatory authorities.

3. **Improve efficiency of evaluations through the implementation of new policies and processes, including ensuring digital systems and sufficient staff capacity are in place:** SAHPRA has implemented streamlined processes end-to-end, including with the best practice of the European Medicines Agency. SAHPRA's improved processes have resulted in 1 800 variation certificates in the backlog of 3 450 (+/-50%) being finalised to date. In addition, new digital systems for submission and tracking will culminate in an online, industry-facing tool, which will go live by the end of September 2019, allowing applicants to track their own applications A dedicated Backlog Clearance Team was recruited, on boarded and trained, and will be supported by team leaders from various units to ensure that SAHPRA remains 'one regulator' throughout the duration of the Programme.

SAHPRA's transformative Backlog Clearance Programme will be launched in August 2019, after only 15 months since it was first conceived.

12.3 PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE

Programme purpose

The main purpose of this programme is to ensure public access to safe health products through inspections and regulatory compliance. This programme focuses on assessment of site compliance, with good regulatory and vigilance practices, including:

- Good Manufacturing Practice (GMP);
- Good Clinical Practice (GCP);
- Good Wholesaling Practice (GWP);
- Good Distribution Practice (GDP);
- Good Laboratory Practice (GLP); and
- Good Vigilance Practice (GVP).

The purpose is achieved through the conducting of inspections at Active Pharmaceutical Ingredient and medicine and medical device manufacturers, wholesalers, laboratories and clinical trial sites, located both locally and internationally, as well as inspections and monitoring of compliance with applicable legislation as mandated (Medicines Act and Hazardous Substances Act).

There are three sub-programmes, namely:

Sub-Programme 1: Inspections

The purpose of to ensure that good practice (GxP) inspection activities are actively managed to facilitate the running of an effective inspection programme monitored against predefined timelines and commitments communicated to stakeholders.

Sub-Programme 2: Regulatory Compliance

The purpose is to ensure public access to safe medicines through regulatory compliance and monitoring of compliance with applicable legislation as mandated.

Sub-Programme 3: Laboratory Services

The purpose is to oversee the quality control testing of medicines, including biological medicines and vaccines, for compliance with predefined quality standards.

Table 5: Programme 3: Annual Performance

KPI	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 APP	QTR 1	QTR 2	QTR 3	QTR 4	Annual Achievement 2018/19	Variance	Reasons for Variance
14	3	Inspect establishments to ensure compliance with relevant GxP and established standards within predefined timelines	% of establishments due for inspection inspected annually	45%	45%	22%	32%	50%	37%	8%	Target not met The annual target overall was underachieved by 8% due to a drop in performance in the 2nd and 3rd quarters. During these quarters, the workforce was limited because of labour unrest and building shutdown affecting inspectorate functioning. The relocation of SAHPRA in the 3rd and 4th quarters further affected delivery. This trend has now been reversed with the backlog of inspections being addressed in Q1 2019/20. 169/463 establishment inspections were conducted in 2018/19.
15	3	Inspect permit holders/ establishments of narcotic and psychotropic substances to ensure compliance with established standards within predefined timelines	% of permit holders, establishments and sites of narcotic and psychotropic substances inspected annually	20%	33%	18%	77%	30%	34%	14%	Target exceeded The focus in the 3rd and 4th quarters was on cannabis sites and applications. Inspectors were mobilised out of the office during labour unrest and relocation. Routine work was deferred with minimal risk as these sites were GMP-compliant. This KPI target will be revised to better align to international best practice norms. 64/190 narcotic and psychotropic inspections were completed in 2018/19.

The Inspectorate and Regulatory Compliance Programme progressed satisfactorily in the reporting period, maintaining adequate targets despite having the highest attrition rate of staff since the transition to a public entity. The difficulties experienced in this programme arose during the labour action when control and integrity of data information were compromised as a result of the labour unrest and relocation and problems in ICT infrastructure to properly track work completed. Development of an internal control framework to manage this is crucial for this moving this programme forward. In 2019/20 a key manager within regulatory compliance retired. Stabilisation of staffing also needs to be a focus of the programme to ensure this programme's functioning is optimised.

Adequate funding to meet mandates is crucial, as are the continued efforts to increase revenue generation to supplement funding from National Treasury in this unit. This needs to be properly managed to ensure the funding received from this unit remains on par with or higher than costs and expenses. Inspections are both national and international. The costs to complete international inspections can fluctuate and need to be adequately resourced to ensure planned inspections are completed.

To attract and retain qualified and experienced staff, implementation of a well-designed rewards and remuneration strategy is needed to decrease staff attrition, stabilise inspectorate HR capital and build long-term sustainability.

Laboratory infrastructure needs to be secured for SAHPRA. Development of a priority capital expenditure plan is crucial to securing this space for the sake of sustainability.

12.4 PROGRAMME 4: MEDICINES EVALUATION AND REGISTRATION

Programme purpose

To evaluate the safety, quality and therapeutic efficacy of medicines and register them for use as per delegated authority in terms of relevant legislation as listed in the legal mandate of part 1A of the annual performance plan.

The functions include:

- Management of the evaluation of applications to ensure safety, quality and efficacy of products;
- Management of the registration and control of medicine;
- Management of regulations pertaining to the sale of medicines;
- Establishment of surveillance mechanisms to detect, assess and prevent adverse reactions to health products; and
- Management of the authorisation of sale of unregistered medicine for specified purposes in terms of relevant legislation.

There are seven sub-programmes, namely:

Sub-programme 1: Clinical evaluation

The purpose is to evaluate the safety and efficacy of orthodox medicines.

The functions include:

- Evaluation of new chemical entities and generic medicines with respect to safety and efficacy;Evaluation of post-registration amendments;
- Safety updates (USRNs, SR-PINs, PSURs and other major safety amendments);
- Evaluation of new indications package inserts and Patient Information Leaflet (PIL) updates;
- Preparation of reports on clinical evaluations;
- Preparation of peer review committee recommendations on applications;
- Ensuring the safety and efficacy of new products;
- Ensuring the safety and efficacy of marketed products;
- Handling of technical/scientific queries referred by Authorisation Management;
- Evaluation of applicant responses (both pre- and post);
- Development and/or updating of relevant guidelines; and
- Interaction with industry representatives, the NDoH, international agencies and other relevant stakeholders to establish co-operative agreements, and disseminate and exchange information.

Sub-programme 2: Clinical trials

The purpose is to evaluate clinical trial applications of orthodox medicines, complementary medicines and medical devices to ensure that the trial to be conducted is scientifically sound in accordance with the South African Good Clinical Practice guidelines and to ensure safety and the protection of the rights of patients.

The functions include:

- Evaluation of new clinical trial applications for orthodox medicines, complementary medicines, medical and radiation emitting devices, including bioequivalence studies;
- Evaluation of safety reports and line listings;
- Updating policy documents on the conduct of clinical trials;
- Evaluation of study documentation updates (informed consent documents, investigator brochures, certificate of analysis, study insurance, shelf life extensions, etc.);
- Evaluation of completed study reports and synopses;
- Evaluation of additional site, site staff and investigator applications;
- Evaluation of protocol amendment applications of approved protocols;
- Evaluation of progress reports of ongoing clinical trials, protocol deviations, protocol violations and waiver;
- Evaluation of the Data Safety Monitoring Board reports on clinical trials and making recommendations;
- Preparation of reports on completed evaluations;
- Preparation of peer review committee recommendations on applications; and
- Promotion of vigilance by collecting, managing and assessing serious adverse events reports in clinical trials.

Sub-programme 3: Pharmaceutical evaluation

The purpose is to perform pharmaceutical and analytical evaluations of new and registered medicines, inclusive of clinical aspects of veterinary medicines and biologicals.

The functions include:

- Oversee and direct evaluation of data sets submitted by applications in the pharmaceutical industry for the registration and amendments of medicines to ensure quality, safety and efficacy;
- Preparation of reports on biological and veterinary clinical evaluations for submission to the Expert Committee;
- Handling of technical/scientific queries referred by Authorisation Management;
- Interaction with industry representatives, the NDoH, international agencies and other relevant stakeholders to establish co-operative agreements, and disseminate and exchange information; and
- Development and updating of relevant guidelines.

Sub-programme 4: Vigilance and post-marketing surveillance

The purpose is to establish a regimen of vigilance for the collection and evaluation of information relevant to the benefit-risk balance of medicines and medical devices on the South African market, the continuous monitoring of the safety profiles of these products and taking appropriate action where necessary.

The functions include:

- Creating awareness amongst healthcare professionals regarding the significance/importance of reporting adverse drug reactions (ADRs);
- Monitoring benefit-risk profiles of medicines and medical devices;
- Generating independent, evidence-based recommendations regarding the safety, efficacy and quality of medicines and medical devices;
- Promoting vigilance by collecting, managing and assessing adverse reaction and medication error reports, including post-marketing surveillance and research data;
- Collaborating and harmonising with local and international cohorts monitoring ADRs;
- Implementing post-market surveillance for adverse events related to medical devices and complementary medicines and developing and/or updating relevant guidelines;
- Handling of technical/scientific queries referred by Authorisation Management;
- Investigating adverse events related to medicines and medical devices;
- Evaluating of vigilance reports and enforcing corrective actions where applicable; and
- Providing relevant and user-friendly feedback to stakeholders, particularly health professionals and the public.

Sub-programme 5: Complementary and medicines

The purpose is to perform evaluations of new and registered complementary medicines in order to determine their safety, quality and efficacy and to register and/or regulate them for use where applicable.

The functions include:

- Evaluation of data sets submitted by applicants for the registration of complementary medicines to ensure safety, quality and efficacy;
- Preparation of reports on evaluations for submission to the Expert Committee;
- Interaction with industry representatives, the NDoH, international agencies and other relevant stakeholders to establish co-operative agreements, and disseminate and exchange information;
- Development and/or updating of relevant guidelines.

Sub-programme 6: Veterinary medicines

The purpose is to evaluate the safety, efficacy and quality of veterinary medicines.

The functions include:

- Evaluation of all applications for registration of veterinary medicines, including new chemical entities and generic veterinary medicines, with respect to safety, efficacy and quality;
- Evaluation of post-registration amendments, safety updates, package insert amendments and updates;
- Preparation of reports on clinical and quality evaluations;
- Preparation of peer review committee recommendations on applications;
- Handling of technical/scientific queries referred by Authorisation Management;
- Evaluation of applicant responses (both pre- and post-registration);
- Development and/or updating of relevant guidelines; and
- Interaction with industry representatives, the NDoH, international agencies and other relevant stakeholders to establish co-operative agreements, and disseminate and exchange information.

Sub-programme 7: Laboratory services

Access to international standard quality control laboratory services is essential for post-marketing surveillance of medicines via pharmaceutical analysis. Under the current provisions of the Medicines Act, SAHPRA is obliged to test all biological medicines and vaccines for batch release purposes. Under the MCC, pharmaceutical samples were submitted on an *ad hoc* basis to contract laboratories, while biological (batch release) samples were submitted to the contract laboratory, with which the MCC has a contract under the NDoH tender. Given the current resource constraints, the creation of in-house analytical laboratory facilities, however desirable, would not be feasible, and therefore, the short- to medium-term approach would be to continue the outsourcing of pharmaceutical and biological analysis and all laboratory services. A contract would need to be drafted with a suitable institution through an open tender process.

Table 6: Programme 4: Annual Performance

KPI	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 per APP	QTR 1	QTR 2	QTR 3	QTR 4	Annual Achievement 2018/19	Variance	Reasons for Variance
16	4	Evaluate clinical trial protocols received in accordance with defined standards	% of clinical trial applications evaluated within an evaluation cycle	85%	100%	100%	100%	88%	95%	10%	Target exceeded Work output was supported by community service pharmacists deployed to the unit. 147/154 clinical trials were reviewed within the predefined timeline in 2018/19.
17	4	Evaluate clinical trial protocol amendments in accordance with defined standards	% of permit holders, establishments and sites of narcotic and psychotropic substances inspected annually	72%	94%	52%	59%	74%	73%	1%	Target exceeded Work output was supported by community service pharmacists deployed to the unit. 682/929 clinical trial amendments were reviewed within the predefined timeline in 2018/19.
18	4	Evaluate the applications received for sale of unregistered health products in accordance with defined standards	% of applications for the sale of an unregistered health product evaluated within a specified timeline	75%	50%	68%	92%	89%	80%	5%	Target exceeded Digitisation and deployment of community service pharmacists allowed for faster processing over the last two quarters. 10 808/13 433 applications for the sale of an unregistered health product evaluated within a specified timeline.
19	4	Scientific evaluation of all NCE/biological applications submitted for regulatory decision	40%	0%	0%	0%	0%	0%	0%	-40%	Target not met Labour unrest, relocation and ICT difficulties hampered improved output. The 275-day timeline was not yet achievable. The impact of the backlog and re-engineering will only be evident in 2020/21. 20 NCEs and biologicals were registered in the year 2018/19. The range of time taken to register an NCE/biological was 395-3188 working days.

KPI	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 per APP	QTR 1	QTR 2	QTR 3	QTR 4	Annual Achievement 2018/19	Variance	Reasons for Variance
20	4	Scientific evaluation of new health product amendments submitted for regulatory decision	% of NCE/ Biological amendments evaluations concluded with a regulatory decision within 120 working days. (time spent at regulator)	40%	0	0	0	0	0%	-40%	Target not met Labour unrest, relocation and ICT difficulties hampered improved output. The 120-day timeline was not yet achievable. The impact of the backlog and re-engineering will only be evident in 2020/21.
21	4	Scientific evaluation of generic/biosimilar applications submitted for regulatory decision	% of generic/ biosimilar application evaluations concluded with a regulatory decision within 180 working days (time spent at regulator)	40%	0%	0%	15%	0%	3%	-37%	Target not met Labour unrest, relocation and ICT difficulties hampered improved output. The 180-day timeline was not yet achievable. The impact of the backlog and re-engineering will only be evident in 2020/21. 181 generics and biosimilars were registered in the year 2018/19. The range of time taken to register a generic/biosimilar was 167-3 354 working days. Five products in the 3rd quarter were registered over a period of 167 working days.
22	4	Scientific evaluation of generic/biosimilar amendments submitted for regulatory decision	% of generic/ biosimilar amendment evaluations concluded with a regulatory decision within 120 working days (time spent at regulator)	40%	0%	0%	0%	0%	0%	-40%	Target not met The 120-days timeline was not yet achievable. The impact of backlog and re-engineering will only be evident in 2020/21. Labour unrest, relocation and ICT difficulties hampered improved output.

KPI	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 per APP	QTR 1	QTR 2	QTR 3	QTR 4	Annual Achievement 2018/19	Variance	Reasons for Variance
23	4	Investigate, monitor, analyse solicit and act upon existing and new adverse events, interactions and signals emerging from post-marketing surveillance and vigilance	Published quarterly reports of new adverse events and signals that have been assessed, actioned and concluded	Bi-annual reports to the public	1	1	1	0	Quarterly reports to the Public for three quarters	+1	Target exceeded SAHPRA is actively working to improve vigilance and reporting of adverse events, resulting in more active reporting from professionals and the public. SAHPRA is moving towards consolidated vigilance quarterly reports in the 2019/20 performance year. This KPI will be revised to better delineate quarterly reporting of adverse events and signals.
				No applicable for 2018/19	–	–	–	–	Not applicable for 2018/19		
			An inclusive vigilance framework for all health products developed and approved								Not applicable for 2018/19

Programme 4 is the key unit that fulfils the greatest part of SAHPRA's mandate. The re-engineering process and digitisation of operations will have a significant business transformation impact in this unit. The unit is to be upstaffed to 118 persons as per the new organisational structure, with the greater focus being on building in-house technical skills and enabling the BAU to function at full capacity and prevent the creation of a new backlog.

The unit has been drawn thin in 2018/19, given the demands on the unit to participate in the refinement of the backlog project, interviews for the backlog personnel as per the organogram and ensuring readiness for the 2018/19 audit.

Programme 4 is a key programme aligned to the core functions of SAHPRA. The risk of accumulating a backlog with each subsequent year will result in a serious impact with regard to the public health space. The backlog project as part of the mitigation process must address both the current backlog and structure the registration process to prevent this year-on-year accumulation.

Critical factors that must be considered are to ensure adequate funding is sourced to support the project in its entirety. Implementation must address reviewing operations to ensure long-term sustainability, and a natural consequence of the backlog project must be a resultant increase in human capital capacitation and competencies.

12.5 PROGRAMME 5: MEDICAL DEVICES, DIAGNOSTICS AND RADIATION CONTROL

Programme purpose

- The main purpose of Programme 5: Medical Devices, Diagnostics and Radiation Control is to develop and maintain regulations and guidelines pertaining to the regulatory oversight of medical devices, ionising and non-ionising radiation emitting device, and radioactive nuclides. The core functions for this programme include:
  - Licensing of medical device establishments;
  - Registration of medical devices and radiation emitting devices and radioactive nuclides;
  - Designation and supervision of conformity assessment bodies;
  - Conducting inspections of medical device establishments;
  - Post-marketing surveillance and vigilance; and
  - Approval of clinical trials.

There are two sub-programmes, namely:

Sub-programme 1: Medical devices

The purpose is to implement and strengthen the regulatory oversight of medical devices through the development and maintenance of relevant regulations and guidelines.

Sub-programme 2: Radiation control

The purpose is to efficiently, effectively and ethically evaluate and register non-ionising radiation emitting devices and radioactive nuclides.

Table 7: Programme 5: Annual Performance

KPI	Prog.	Strategic Objective	APP Key Performance Indicators	Target for 2018/19 per APP	QTR 1	QTR 2	QTR 3	QTR 4	Annual Achievement 2018/19	Variance	Reasons for Variance
24	5	License medical device establishments that are compliant with prescribed reference standards	% of medical device establishment licence applications finalised within predefined timelines	35%	82%	59%	48%	66%	70%	35%	Target exceeded Work output was supported by community service pharmacists deployed to the unit to address the backlog accumulated from 2017/18 due to a large number of applications received in that period. 349/500 medical device establishments were licensed in 2018/19.
25	5	License medical device establishments that are compliant with prescribed reference standards	A system to register medical devices has been developed and implemented	72%					73%		Target met A system for certain medical devices is in place for group 3 and 4 devices. Further, a system exists in the radiation control unit. The system will be re-engineered to improve the scope and capability of medical device registrations in 2019/20.
26	5	Evaluate radiation emitting devices and radioactive nuclides for regulatory decision	Evaluate radiation emitting devices and radioactive nuclides for regulatory decision	35%	100%	100%	100%	96%	An approved system to register medical devices have been implemented	+64%	Target exceeded Targets in radiation control are passively determined by applications received from applicants. Currently, three of the four units within this area of work process 100% of the licences. The 4th unit (ionising radiation devices) has a three-month backlog. Review and re-engineering of operations are being undertaken in radiation control to bring alignment to the mandate of the Act and will be implemented in the 2019/20 performance year. This KPI will be revised to better delineate this change. 2 960/2 978 new licences were issued for radiation emitting devices and radioactive nuclides.

The Medical Device Unit met and exceeded its target in 2018/19 as the unit was capacitated with community service pharmacists. This is a temporary measure and the unit will anticipate a growth to 17 from its current post establishment in the new organisational structure. Digitisation and upskilling are also key to ensuring this unit runs efficiently as the process to rollout medical device registrations proceeds.

The process for registration of medical devices is being looked at to build on the existing operations that co-exists to a limited degree in the radiation control unit. A new road map will be looked at to include the established functionality that exists in the radiation control unit in Cape Town.

Radiation control was given closer inspection in 2018/19 by Dr Crisp so as to streamline the business functions aligned to SAHPRA's mandate, to properly understand the work sharing or joint venture space with the Department of Energy and to ensure that the unit is properly capacitated with staff upskilling and digitisation so as to enable the unit to function at a more optimal output aligned to its mandate.

The success of the unit is dependent on ensuring competent human resource capital to meet the unit's requirements, which are crucial to completing the work of the two new functional areas of regulation for the Authority. Failing such, the work in these units could easily fall into the already burdened backlog. Digitisation of the system in radiation control is also crucial to keeping proper account of all work completed and for recording purposes. Digitisation is further crucial to supporting a proper quality management system for policy development and for building efficiency and accountability into operations. Work is currently completed in 'silos' with little system harmonisation across units. This does not support adequate monitoring and evaluation and traceability. Licences are renewed on a risk-based schedule which varies between one and four years. Licence holders are also legally obliged to submit annual returns (inventories of the radioactive sources that they possess and use and verification of contact details). Unfortunately, many licences were not renewed, and many licensees do not submit annual returns any more. Due to the persisting critical staff shortage, this could not be followed up. In addition, the database is inaccurate. These facts pose a risk for future collection of licence fees. The Sub-directorate: Electronic Generators of Ionising Radiation does not renew licences. Licences are updated only when licensees apply for additional equipment to be added to the licence or in cases where equipment is relocated. This also poses a risk for the future collection of licence fees.

Part: C
Governance

13. INTRODUCTION

Corporate governance embodies the processes and systems by which any public entity is directed, controlled and held to account. SAHPRA was established in November 2017 in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended. The enabling legislation was extended to include the Hazardous Substances Act, 1973 (Act No. 15 of 1973), with the integration of the radiation control function into the ambit of regulation of this national regulator.

In addition, the Authority is directed in its corporate governance compliance by the precepts of the Companies Act, 2008 (Act No. 71 of 2008), the Public Finance Management Act, 1999 (Act No. 1 of 1999), as amended, and the King Code of Governance and the King Report on Governance IV (King IV).

Parliament, the executive authority (Minister of Health) and the accounting authority (SAHPRA Board) are responsible for corporate governance.

14. PORTFOLIO COMMITTEE

The Parliamentary Portfolio Committee on Health provides oversight of the service delivery of SAHPRA.

In March 2018, SAHPRA briefed the Portfolio Committee on Health on its five-year Strategic Plan (2018/19–2022/23) and its Annual Performance Plan (2018) as well as its progress in the transitional phase of SAHPRA from a unit within the Department of Health to a Schedule 3A public entity. Further, the entity, through its Chairperson and Acting CEO, responds in writing to any queries via the Office of the Public Entities in the National Department of Health.

15. EXECUTIVE AUTHORITY

SAHPRA as a public entity within the sphere of entities within the NDoH reports through the Public Entities Oversight Office to the Minister of Health. For the reporting period covered in this annual report, the Minister reported to was the Honourable, Dr Aaron Motsoaledi.

SAHPRA submitted all four (4) quarterly reports for the 2018/19 financial year. The Authority was granted extensions in the 1st and 3rd quarters. The submission compliance date was met for the 2nd and 4th quarters. All reports were approved.

16. ACCOUNTING AUTHORITY

SAHPRA's accounting authority is the Board appointed by the Minister. The Board comprises 15 members appointed by the Minister of Health.

The Board has an appropriate mix of technical, governance, corporate and public health skills, competencies and talents, as members are drawn from a cross section of society. The composition of the Board displays a clear commitment to transformation and gender diversity. The Board members are leaders in their personal careers and this bodes well for the organisation as it has the advantage of not only tapping the best talent, but also a diversity of cultures, backgrounds and ways of thinking.

Meetings of the Board as listed in Table 8 that follows reflect face to face meetings only, Teleconferences were not included in this number.

Table 8: SAHPRA Information

Name	Designation	Date Appointed	Date Resigned	Number of Board Meetings Attended
Prof Helen Rees	**Chairperson**	**17 November 2017**		**8**
Prof Rees holds the following qualifications: GCOB, OBE, MB BChir, MA (CANTAB), MRCGP, DCH, DRCOG She is the Chairperson of the Board of the newly established SAHPRA. Prof Rees is also the Executive Director of the University of Witwatersrand's Reproductive Health and HIV Institute (Wits RHI) where she is serves as a Personal Professor in the Department of Obstetrics and Gynaecology and Co-Director of Wits University's Flagship Centre for Vaccinology (ALIVE). She is an Honorary Professor at the London School of Hygiene and Tropical Medicine (LSHTM) and a member of their Visiting Committee. Professor Rees has been involved in medicines regulation for many years. She was appointed to the Medicines Control Council in 1995 and chaired the Council from 1997 until 2001. During that time, she also chaired the MCC's Clinical Trial Committee and the Pharmacovigilance Committee. From 2013 to 2015, she chaired the SAHPRA Transitional Task Team responsible for finalising the new SAHPRA legislation and in 2015 was again appointed as Chair of the MCC. She has served on numerous national and international structures relating to medicines regulation and clinical research. Professor Rees is known for her global expertise in HIV prevention, reproductive health and vaccines. She has over 200 publications, has delivered over 200 plenary and keynote addresses, has chaired over 100 national and international scientific and policy committees, and served at or chaired more than 100 conferences. Prof Rees has received many national and international awards for her contribution to global health. She was made an Officer of the British Empire by Queen Elizabeth II, and was awarded one of South Africa's highest awards, the Order of the Baobab, for her contribution to the South African health sector. She received Lifetime and Gold achievement awards for her distinguished contribution to science, global health and women's health by the South African Academy of Science, the South African Medical Association, the South African Department of Science and Technology, BHP Billiton and the Oppenheimer Foundation. She received the London School of Hygiene and Tropical Medicine's International Heath Clark Lecturer award as an outstanding global health practitioner. She also received a lifetime achievement award from the African NGO Amanitare, for her contribution to African women and children's health and rights.				
Ms Mandisa Hela	**Vice-Chairperson**	**17 November 2017**		**7**
Ms Hela has extensive experience in medicine regulation and pharmaceutical policy development and implementation. She actively promoted the introduction and implementation of the Essential Medicines Programme in South Africa. She is a former Registrar of the MCC and the mandate of the regulator was expanded under her leadership to include all medicines and medical devices. She is passionate about access to medicines and currently serves as a trustee of the Health Systems Trust. She is a pharmacist and holds a Master's degree in Public Health from the University of Hawaii.				
Prof Mohamed Shabir Banoo	**Member, Chairperson (TORS)**	**17 November 2017**		**8**
Shabir Banoo holds the position of Chief Technical Specialist and Head: Pharmaceutical Policy and Programmes within Right to Care, a donor-funded non-profit organisation linked to the University of the Witwatersrand. In this role, he oversees Right to Care's pharmaceutical technical assistance, research and support programmes to ministries of health in South Africa and several African countries. This focus is aimed at strengthening pharmaceutical policy, regulation and governance in public health programmes through implementation of best practices to improve patient management and care, particularly for HIV and related diseases. Shabir graduated with a degree in pharmacy from Rhodes University in 1986, later obtaining a doctorate in pharmacology from Rhodes University in 1992. He has previously held senior positions in government as well as in the private and NGO sectors. He has also held positions in academia and research at the University of the Witwatersrand, and at Rhodes University as associate professor of pharmacology. Shabir has worked as a technical consultant for the South African Ministry of Health and has served on a number of advisory panels and task teams on national drug policy, medicine regulation, pharmaceutical pricing and public health. He has actively contributed to the development of national standard treatment guidelines and management policies including those for HIV, TB, maternal, child and woman's health (MCWH) and malaria programs. Shabir currently serves as a Board member of the South African Health Products Regulatory Authority (SAHPRA). He has previously served as a member of the former Medicines Control Council (MCC) of South Africa and on a number of its technical committees and task teams. He has contributed, in this role, to the modernization of the legislative and governance framework for medicine regulation, streamlining procedures and processes for registration, and developing guidelines and policies to support the registration of medicines and regulation of clinical trials. He also serves as a member of the South African National AIDS Council (SANAC) Treatment Technical Task Team. He is also a member the Central Drug Authority (CDA) of South Africa and has served on the National Essential Medicines List Committee (NEMLC). Shabir serves on a number of international panels and is regularly called upon as a technical advisor to the World Health Organization (WHO) and other international organisations and programmes. His technical areas of expertise include basic and clinical pharmacology, public health, pharmacoepidemiology and pharmacovigilance, health products and clinical trials regulation, health technology assessment, evidence-based medicine and rational medicine use, and pharmaceutical and commodity security.				

Name	Designation	Date Appointed	Date Resigned	Number of Board Meetings Attended
Dr Edith Nonhlanhla Madela-Mntla	**Member**	**17 November 2017**		**8**
Dr Madela-Mntla is an academic and independent consultant on transdisciplinary research, health management, medicines regulatory affairs and mental health. She holds a doctoral degree in Mental Health Nursing and a year course in Research Methodology from the University of Johannesburg, in addition to numerous qualifications in various healthcare and management fields. She has vast experience in South Africa's public health systems and policies, including research, as well as in the academic context. She served as the Data Champion for the Gauteng Mental Health Relocation Project of the previous Life Esidimeni patients, consultant to the National Department of Health, and Regional Director of the International Council for Science (ICSU), heading its Regional Office for Africa (ROA). One of the highlights of her career was driving the establishment of the Future Earth initiative in Africa, which has finally seen two coordinating offices being launched in two countries on the continent (S.A. and Rwanda). Prior to this role, she served as the Executive Manager for Human Capital Management and Development of the South African Medical Research Council, Director for Mental Health and Substance Abuse at the National Department of Health, lecturer in Departments of Family Medicine (postgraduate) and Nursing (undergraduate) at the then Medical University of Southern Africa (MEDUNSA) and worked as a Psychiatric Nurse Specialist both in a child and adolescent development institute and a provincial tertiary hospital. Apart from serving as a SAHPRA Board Member, she has been the Deputy Chair of the Clinical Trials Committee since 2005 and a member of the National Health Research Committee since 2010, which she has chaired since 2017.				
Dr Henry Martin John Leng	**Member**	**17 November 2017**	**7 June 2018**	**2**
Dr Henry Leng holds bachelors' degrees in science and pharmacy as well as a master's degree in the pharmaceutical and medical sciences from the Universities of the Western Cape (UWC) and Stellenbosch (US). He also obtained a Ph.D (Pharmacology) from the University of Cape Town and an MBA from the University of Stellenbosch. Dr Leng's major research focus has been in pharmaceutical biotechnology. His current research is in the area of access to medicines. Dr Leng has served on several expert committees of the Medicines Control Council (MCC) of South Africa, since 2000, until its transformation into the South African Health Products Regulatory Authority (SAHPRA) in February 2018. In addition, he has served on several working groups which reviewed and wrote guidelines for the registration of medicines in South Africa and has also participated in technical working group meetings of the World Health Organisation. He is a former professor of pharmaceutical chemistry at the University of the Western Cape.				
Dr Thapelo Montgomery Motshudi	**Member**	**17 November 2017**		**6**
Dr Motshudi is a co-founder and managing partner of two private radiology practices based in Gauteng. He completed his undergraduate medical degree at the University of Pretoria, and he qualified as a diagnostic radiologist from the University of the Witwatersrand and The Colleges of Medicine of South Africa. Prior to studying radiology, he spent a few months as a registrar in nuclear medicine at Steve Biko Academic Hospital. In addition to clinical practice, he is also the Chairperson of the Board of the National Nuclear Regulator (NNR). Dr Motshudi has a special interest in radiation protection and has completed a course in radiation protection in medical applications in Madrid, Spain.				
Prof Kelly Chibale	**Member**	**17 November 2017**	**13 March 2019**	**4**
Kelly Chibale is a full Professor of Organic Chemistry at the University of Cape Town (UCT) in South Africa. He is also a Full Member of the UCT Institute of Infectious Disease & Molecular Medicine (IDM), a Tier 1 South Africa Research Chair in Drug Discovery, founding Director of the South African Medical Research Council (SAMRC) Drug Discovery and Development Research Unit at UCT and the Founder and Director of the UCT Drug Discovery and Development Centre (H3D). Kelly obtained his PhD in Synthetic Organic Chemistry from the University of Cambridge in the UK (1989–1992). This was followed by postdoctoral stints at the University of Liverpool in the UK (1992–94) and at the Scripps Research Institute in the USA (1994–96). He was a Sandler Sabbatical Fellow at the University of California San Francisco (2002), a US Fulbright Senior Research Scholar at the University of Pennsylvania School of Medicine (2008) and a Visiting Professor at Pfizer in the UK (2008).				
Prof Ames Dhai	**Member**	**17 November 2017**		**5**
Prof Dhai holds the following qualifications: PhD, MBChB, FCOG, LLM and PGDip Int Res Ethics. She is the Director of the Steve Biko Centre for Bioethics, which she established in 2007. Prof Dhai has served on several policy-making bodies in the country, including being a past president of the South African Medical Association and serving two terms as Deputy Chair of the National Health Research Ethics Council. She also serves regularly as a consultant/expert advisor for WHO, and is on the WHO's African Advisory Committee for Health Research. She served on the World Medical Association's (WMA) Working Groups on international policy development and has been pivotal in bringing the African voice to The Declaration of Taipei on Health Databases and Biobanks and the current Declaration of Helsinki. Other appointments include those as member of the Ministerial Advisory Committee for Medical Litigation, the Ministerial Advisory Committee on Unrelated Organ Transplants, the National Commission for the Lancet Commission on Global Health, the ASSAf Panel on Genetics and Genomics: ELSI and the DST/MRC Genomic and Precision Medicine Think Tank. She is Editor-in-Chief of the South African Journal of Bioethics and Law and an Associate Editor of the South African Medical Journal. Prof Dhai can be credited with entrenching bioethics as an integral aspect of health sciences at the Wits Faculty of Health Sciences and further afield in SA. She supervises a number of students in the Bioethics and Health Law postgraduate programs, serves as external and internal examiner and has published widely in the field.				

Name	Designation	Date Appointed	Date Resigned	Number of Board Meetings Attended
Prof Jeffrey Mphahlele	**Member, Chairperson (HR& Remco)**	**17 November 2017**		**6**
Prof Mphahlele holds the following qualifications: PhD, MSc, BSc Med Hons, BSc, and MASSAf). He has been the Vice President for Research at the South African Medical Research Council (SAMRC) since October 2014. Prof Mphahlele has served on numerous boards and governance structures He also serves on ministerial-appointed committees of the National Department of Health, including the National Advisory Group on Immunisation (NAGI), the South African National Task Force (NTF) for Laboratory Containment of Wild Poliovirus and Potential Infectious Materials and the National Certification Committee on Polio Eradication (NCC) . He is a member of the WHO Scientific Advisory Group of Experts (SAGE) on Polio Working Group. Prof Mphahlele is a member of the Academy of Science of South Africa (ASSAf), a Co-Director of the SAMRC/Diarrhoeal Pathogens Research Unit, a WHO Rotavirus Regional Reference Laboratory for Africa. Previous services include those as Professor and Academic Chair of the Department of Virology, National Health Laboratory Service (NHLS) at the University of Limpopo and Head of the South African Vaccination and Immunisation Centre (SAVIC) at the same institution. Prof Mphahlele's research interests in prevention and control of human viral diseases cover a wide range of topics, including viral hepatitis, gastrointestinal viral infections, human papillomaviruses, molecular epidemiology of HIV, genomics of infectious diseases, vaccination control of hepatitis B, rotavirus and HPV, and strengthening immunisation services and policies. He is actively involved in developing the next generation of scientists, and to date has trained, supervised and mentored several PhD and Master students. He published widely and achieved a C1 NRF rating.				
Dr Ushma Mehta	**Member**	**17 November 2017**		**7**
Dr Mehta has been involved in medicines regulation since 1996. She started her career as the manager of the National Adverse Drug Event Monitoring Centre and has assisted WHO in developing regulatory and programmatic pharmacovigilance systems in several countries. She completed her Doctor of Public Health degree in Australia focusing on the development of pharmacovigilance systems within public health programmes. She is currently a senior researcher at the Centre for Infectious Disease Epidemiology and Research at the University of Cape Town's School of Public Health and Family Medicine, supporting the creation of a pregnancy exposure registry as well other surveillance systems aimed at assessing the safety of health products.				
Dr Mphane Molefe	**Member**	**17 November 2017**		**5**
Dr Molefe qualified as a veterinarian from the Medical University of Southern Africa in 1995. He did a short stint as a veterinary clinician in private practice in Johannesburg after qualifying and later joined the University of North West as a senior lecturer in Animal Health. He held the position of Head of the Department of Animal Health for a period of 6 years. His professional life in academia included being a member of the faculty board, senate, council, institutional forum, convocation, quality assurance committee and honorary degrees committee. In 2007 he joined government veterinary services at provincial level responsible for veterinary public health. After 6 years, he transferred to the national veterinary office of the Department of Agriculture, Forestry and Fisheries and was appointed as Director of Veterinary Public Health in 2017, a position he is still currently occupies.				
Adv Hasina Cassim	**Member**	**17 November 2017**		**6**
After completing her BPharm degree in 1990, Adv Cassim pursued studies in pharmaco-economics (pharmaco-epidemiology, Newcastle University Australia) and completed an executive leadership programme through Oxford's Said School of Business. She also served on several representative fora such as the PSSA, the PCMA and the Council of Medical Scheme's committee for the development of algorithms for the PMB-CDL conditions. After completing a certificate course in Medicine and Law through Unisa, she continued with her studies in law and completed her LLB in 2011. In 2015, Adv Cassim joined the Johannesburg Bar having passed the Bar exam for advocates and is an admitted Advocate of the High Court and a qualified mediator. She has served in various positions in the health sector including hospitals, the pharmaceutical sector, managed healthcare, risk management and as a consultant. Adv Cassim also serves on the Department of Health's Pricing Committee and has recently been appointed to the SAHPRA board.				
Ms Lesibana Fosu	**Member, Chairperson (Finance)**	**17 November 2017**		**5**
Ms Fosu is a chartered accountant and holds an MBA from the International Institute for Management Development (IMD) business school. Through her career, she acquired extensive experience of over 18 years in the public sector, private sector, non-governmental organisations and international financial institutions. In the private sector, she had the opportunity of acquiring subsector experience in the following areas, amongst others: pharmaceuticals and health services, industrial manufacturing, financial services, mining sector, transport sector, enterprise development, social service and constitutional institutions. Ms Fosu has served on various boards, board sub-committees, ExCo and ExCo committees, making contributions at both strategic and operational levels and gaining valuable governance and oversight experience. She acquired competencies and skills in the following areas: finance, strategy development and implementation, people and business management, business process mapping, enterprise resource planning, financial accounting, costing and management accounting, business reporting, and auditing.				

Name	Designation	Date Appointed	Date Resigned	Number of Board Meetings Attended
Mr Tinyiko Baloyi	**Member, Chairperson (ICT)**	**17 November 2017**		**6**
Mr Baloyi holds numerous qualifications in Commence, Business and Management, Science, Technology and Engineering as well as in IT. He has extensive knowledge, education, experience and expertise in research and the finance sector. He has filled positions such as Chief Operations Officer, Executive Director, General Manager, Director, and Senior Manager in a number of organisations in South Africa. He is qualified in commerce, business, engineering, and management. His skills set includes but are not limited to accounting, financial management, development finance, human resources, investment, information technology, auditing and risk management. His extensive experience as a member of the board of directors of various companies gives him corporate governance clout.				
Prof Craig Household	**Member, Chairperson (RAG)**	**17 November 2017**		**7**
Prof Household holds the following qualifications: MB ChB University of Cape Town MD University of Cape Town FCP (Paediatrics) SA Colleges of Medicine of South Africa DCH SA Colleges of Medicine of South Africa. He is a specialist paediatrician and holds an honorary professorship from the University of the Free State where he headed the Department of Paediatrics and Child Health until January 1995. Thereafter, he became the Head of the Free State Health Department in February 1995, a post which he held until 2001. In 2002, he was appointed as Head of the Western Cape Department of Health, until his retirement on 31 March 2015. During his term of office, health services in the Western Cape underwent significant restructuring with the implementation of Healthcare 2010 by the Western Cape Government. As Head of Health in the Free State and the Western Cape, Prof Household served on various national and provincial bodies and management structures. Since his retirement, Prof Household has been contracted by Advanced Health and Deloitte South Africa on a consultant basis, and in addition he has undertaken various other private sector consultant briefs. Prof Household also served on a national ministerial task team related to hospital performance from 2015 to 2017. From December 2017 to April 2018 he was a member of the intervention task team appointed to assist the management of the Gauteng Department of Health.				

The Medicines Act outlines the Board's primary and secondary responsibilities, including accountability to the executive authority in so far as the mandate of the Authority which includes regulation of health products intended for human and animal use, the licensing of manufacturers, wholesalers and distributors of medicines and medical devices, radiation emitting devices and radioactive nuclides, and the conduct of clinical trials in a manner compatible with the national medicines policy, namely the National Drugs Policy.

The Board also has traditional duties as a governing board over and above the statutory duties and responsibilities. These duties include:

- The evaluation and approval of the five-year strategic plan;
- The evaluation and approval of the annual performance plan;
- The evaluation and approval of financial information and reporting;
- The oversight of Executive Management performance;
- Determining of policy processes; and
- Ensuring compliance with applicable laws, regulations and government policy.

The Authority has demonstrated its commitment to good corporate governance for the reporting period despite severe limitations experienced in the year that ranged from an extended protest action to a building shutdown where the Authority was housed and a relocation, with the anticipated teething problems.

While there has been a commitment to good governance, difficulties in securing an internal control and risk management system due to problems in securing support through the MoU signed with the NDoH, have compromised the standards of integrity and accountability somewhat. Efforts to support the fledgling entity towards this end through the transition and labour unrest and relocation resulted in the Board assuming a more operational role to ensure delivery of the mandate despite the circumstances. Recognising that this challenging environment was a detour from normal practice, the Board ensured that business-as-usual progressed with transparency and fairness in the way it conducts its business and in engaging actively with the entity's various stakeholders.

The Board does not view corporate governance as an abstract system of compliance and box ticking, but rather as a mechanism through which it expresses its value-laden leadership. The Board therefore seeks to re-establish good corporate governance through the following existing and planned rehabilitative mechanisms:

Existing Mechanism	Planned Rehabilitative Mechanisms
• A devolution of its work into six committees of which all have approved terms of reference and defined responsibilities, allows for checks and balances	• A charter and code of conduct which regulates its functions will be solidified in 2019/20.
• A system for declaration of conflicts of interests and registers.	• Regular learning and development as well as annual evaluation, including that of committees.
• Regular sittings of up to four times a year as provided for in the Medicines Act and additional special meetings when necessary.	• A robust risk management system which is monitored and updated on regular basis will be established in 2019/20.
• Full and unfettered access to the organisation's information, including records of any nature.	• Development and application of the voluntary corporate governance instruments in its business.
• Corporate governance in the Board to be audited by the Auditor-General of SA.	• Corporate governance in the Board to be audited by internal auditors (external service provider) in 2019/20.

The Board is assisted and supported by the Acting CEO and her management team who offer guidance to members collectively and individually on their duties, responsibilities and powers. The management of SAHPRA apprises the Board of developments in legislation, regulations, good governance, ethics and compliance. The recording of minutes of meetings, resolutions of the Board training and development, induction and annual evaluations are carried out by the entity management.

Key Board resolutions taken in 2018/19 include:

- Relocation of SAHPRA to the CSIR as an emergency measure responding to the shutdown of the Civitas building;
- Approval of the backlog project, and approval of re-engineering of the business processes in both the backlog and BAU units;
- Approval of the new SAHPRA organisational structure;
- Appointment of key Executive Managers;
- Approval of the 2019 Annual Performance Plan and budgets; and
- Approval of the quarterly performance reports.

17. GOVERNANCE COMMITTEES

The following committees were in place to support the Board in the Performance year 2018/19. Meetings of the sub-committees as listed in Tables 9 to 13 that follow reflect face to face meetings only. All teleconferences were not included in this number.

17.1 Finance committee

The primary purpose of the Finance Committee is to review SAHPRA's financial policies, strategies and capital structure and take such action and make such reports and recommendations to the Audit and Risk Committee and SAHPRA Board as it deems advisable.

The Finance Committee met on 5 April 2018, 25 May 2018, 13 August 2018 and 25 September 2018

Table 9: Finance Committee Membership and Meeting Attendance:

No.	Name	Designation	Number of meetings attended
1	Ms L Fosu	Chairperson	Four
2	Prof J Mphahlele	Member	Four
3	Mr N Baloyi	Member	Four
4	Prof C Household	Member	Four
5	Ms M Hela	Member	Two
6	Prof S Banoo	Member	One
7	Adv H Cassim	Member	One

The Finance Committee in this financial year:

- Recommended the budgets for approval;
- Recommended finance and supply chain policies for approval;
- Provided oversight on quarterly financial information; and
- Monitored the financial environment of the public entity.

17.2 Human resources and remuneration committee (HR and REMco)

This committee is responsible for ensuring that SAHPRA has a transparent, ethical and professional human resources management framework, acts in good faith, and takes care of the total wellbeing of employees, develops, promotes and maintains fair practices and procedures that ensure a climate of mutual trust, co-operation and commitment, and creates a culture of excellence.

The Human Resources Committee met on 6 June 2018, 7 August 2018 and 5 October 2018. Prof H Leng resigned from the Board and the committee on 6 June 2018.

Table 10: HR and REMCO Membership and Meeting Attendance:

No.	Name	Designation	Number of meetings attended
1	Prof J Mphahlele	Chairperson	Three
2	Ms M Hela	Member	Two
3	Dr E Madela-Mntla	Member	Three
4	Prof H Leng	Member	0ne

Key outputs from this committee for the reporting period include:

- Recommended for approval six critical Executive Management posts in 2018/19;
- Recommended for approval the macro-organisational structure of the organisation;
- Recommended for approval the emergency appointment of Dr Nicholas Crisp to support development of the comprehensive organisational structure; and
- Recommended human resource policies for approval.

17.3 Information, Communication And Technology Committee (ICT)

The role of this committee is to advise the SAHPRA Board and Chief Information Officer on how the communication and ICT strategic goals and their related service delivery will be aligned with SAHPRA's strategic goals, monitored and reported on to the relevant stakeholders.

The committee also advises the Board on all ICT and communications-related spending and overall management of related resources and staff as well as overseeing the delivery of ICT value by ensuring that the ICT contribution effectively achieves SAHPRA's strategy.

This committee will develop and monitor performance measures for ICT and communication, using standard regulatory benchmarks and assessing ICT and communication performance.

The ICT Committee met on 22 March 2018, 28 June 2018, 13 August 2018 and 13 March 2019. Prof K Chibale resigned from the Board and the committee on 13 March 2019.

Table 11: ICT Committee Membership and Meetings

No.	Name	Designation	Number of meetings attended
1	Mr TN Baloyi	Chairperson	Four
2	Dr E Madela-Mntla	Member	Four
3	Dr T Motshudi	Member	Three
4	Prof K Chibale	Member	Three
5	Dr U Mehta		Three

17.4 Risk, audit and governance committee (RAG)

The role of this committee is to provide independent assurance and assistance to the Board as the accounting authority on control, governance and risk management.

The committee is an oversight committee and not an executive committee. The committee does not replace established management responsibilities, accountability and delegations. Rather, the committee will provide the accounting authority with prompt and constructive reports on its findings, especially when issues are identified that could present a material risk to the SAHPRA.

The report from the RAG Committee can be reviewed on page 82.

The Risk, Audit and Governance Committee met on 5 April 2018, 13 May 2018, 27 September 2018, and 12 March 2019.

Table 12: RAG Committee Membership and Meetings

No.	Name	Designation	Number of meetings attended
1	Prof C Household	Chairperson	Four
2	Ms L Fosu	Member	Three
3	Prof A Dhai	Member	Two
4	Dr T Motshudi	Member	Four
5	Adv H Cassim	Member	Three
6	Dr M Molefe	Member	Three
7	Prof S Banoo	Member	Three

Key outputs from this committee for the reporting period include:

- Recommend for approval the five-year Strategic Plan 2018–2022; Annual Performance Plan 2018 and Annual Performance Plan 2019;
- Recommended for approval the quarterly performance reports and compliance check lists;
- Oversight of the compliance framework; and
- Monitoring of the compliance environment of SAHPRA.

17.5 Technical oversight and regulatory strategy committee (TORS)

The role of this committee is to provide assistance to the Board on all technical, operational and regulatory matters. The committee is an advisory committee to the Board and not an executive committee. The committee does not replace established management and operational responsibilities, accountability and delegations. Rather, the committee will provide the Board with prompt and constructive reports on its findings and recommendations.

The TORS Committee met on 7 June 2018, 13 July 2018 and 31 October 2018. Prof H Leng resigned from the Board and committee on 7 June 2018. Prof Chibale resigned from the Board and committee on 13 March 2019.

Table 13: TORS Committee Meetings and Minutes

No.	Name	Designation	Number of meetings attended
1	Prof S Banoo	Chairperson	Three
2	Prof H Leng	Member	Two
3	Adv H Cassim	Member	Two
4	Dr U Mehta	Member	Three
5	Prof K Chibale	Member	One
6	Dr M Molefe	Member	One
7	Prof A Dhai	Member	Two

Key outputs from this committee for the reporting period include:

- Recommended for approval the backlog strategy and re-engineering operational model for both the backlog and BAU operational environments;
- Provided oversight and monitoring of the technical environment and output to ensure compliance to the core mandate; and
- Responded to public health issues where appropriate.

18. INTERNAL AUDIT RISK MANAGEMENT STRATEGY

For the year under review, the entity was reliant on the NDoH to assist with corporate services support under the auspices of the MoU signed between SAHPRA and the Director-General of the NDoH.

A crucial function of this support was access to procurement processes to assist in securing key service providers of corporate services, namely Internal Audit and Risk Management as well as human resources support. The difficulties experienced with the extended labour unrest prevented completion of the process initiated with the NDoH, which was also adversely affected.

Alternative conduits to crucial corporate services via the Government Technical Advisory Centre (GTAC) were explored; however, the process via this agency was lengthy and onerous. GTAC did however provide SAHPRA access to its vendor listings via its Procurement Unit, permitting SAHPRA to run its own independent procurement process.

In January 2019, SAHPRA was able to secure SCM services and a request for quotation was successfully issued for risk management. This service will be outsourced for the year 2019/20. The organisational structure was also finalised in the beginning of 2019/20 and a Risk Officer position was established within the Office of the CEO to be filled in this 2019/20 financial year.

19. INTERNAL CONTROL

SAHPRA's ability in 2018/19 to provide a stringent and focused approach to ensure effective internal controls was compromised by the extended labour unrest and protracted relocation to the CSIR.

The road map for 2019/20 is focused on filling newly created and vacant posts. A focused training programme for managerial, technical and administrative staff will be planned with the Human Resources Development unit regarding internal controls. IT will be aligned towards a digitised information monitoring system that enables tracking and tracing of all business activities.

The continuous strengthening of internal controls remains a commitment of the Authority.

20. COMPLIANCE WITH LAWS AND REGULATIONS

SAHPRA reviews its regulatory environment on a quarterly basis and has incorporated all applicable laws, regulations and policies. The PFMA-compliance checklist is submitted quarterly as a section of the quarterly report to the executive authority. The internal compliance with the laws and regulations that inform the mandate are monitored as a function of the office of the Acting CEO and will be an extension of the office of the Company Secretary who was appointed in the last quarter of the reporting period. In addition, the Board, Risk, Audit and Governance will ensure more stringent oversight of this area.

The reporting period 2018/19 was year one of the entity's transitional period. This period is characterised by development of the administration function of the entity (Programme 1) and re-engineering of the operational model to support the core functions of the Authority. As such, the framework to support reporting on the compliance universe is an evolving space and in the process of maturation which will be substantially progressed in the 2019/20 reporting period.

During the period under review, SAHPRA, through its Board and Executive, exercised stringent oversight over all laws and regulations impacting on its business and took remedial measures when there were deviations.

21. ANTI-FRAUD AND CORRUPTION

No fraud and corruption investigations were completed in 2018/19.

22. MINIMISING CONFLICT OF INTEREST

SAHPRA has processes in place to determine whether any of the Board members have any vested interests in matters deliberated by the entity or in the procurement, governance and operational aspects of SAHPRA. The declaration of interest of the staff is an extension of the same signed with the NDoH until such time as SAHPRA develops full capacity in human resources and labour to develop its own.

Annually, all Board members declare their specific current interests, whether financial or otherwise, which may result in a conflict of interest. Conflict of interest forms are completed at each meeting of the Board and committees. Conflicts that may arise are referred to the Board Chairperson for a decision before all proceedings continue. In the event of a conflict, the conflicted party is recused during a discussion of the item on which they are conflicted.

The way forward for the organisation is to secure full oversight of whether any of the Board members or staff are directors or shareholders in companies which might cause conflicts of interest in respect of service level agreements and/or adjudication by conducting searches through the Companies and Intellectual Property Commission.

This will be facilitated in 2019/20 by the office of the Company Secretary.

23. CODE OF CONDUCT

SAHPRA Board members adhere to a formal Code of Conduct and Conflict of Interest Policy. Staff at SAHPRA once more adhere to the Code of Conduct for employees as set up by the NDoH and exercised as an extension of the MoU signed by the NDoH and SAHPRA.

Through the Code of Conduct policies, Board members and staff members are expected to align their behaviour with the values of the entity. The Code also addresses disclosures relating to conflict of interest, financial disclosures as well as gifts received. In the event of a breach, the internal disciplinary process of the NDoH is followed.

24. HEALTH, SAFETY AND ENVIRONMENTAL ISSUES

Requirements of the Occupational Health and Safety (OHS) Act, 1993 (Act No. 85 of 1993) fall primarily under the ambit of the HR and Facilities Manager who guides and advises the organisation on OHS matters. For the 2018/19 reporting period, the OHS requirements were undertaken on behalf of SAHPRA by the NDoH. The NDoH oversight was in place during the labour unrest which resulted in the reduced hours of all staff housed in Civitas, the shutdown of the Civitas building and subsequent relocation of SAHPRA.

This fulfilment of this requirements has experienced a partial gap in the governance of SAHPRA since the relocation. This gap is being addressed as both the Director HR and Facilities Manager will be appointed in the 2019/20 reporting period. For the time being, SAHPRA adheres to the OHS interventions of the CSIR campus as a default mechanism to meet this need. SAHPRA staff, acting as OHS officers within the NDoH, are still active within the new premises and adhere to the OHS policy as set out by the NDoH for organisational specific requirements.

25. SOCIAL RESPONSIBILITY

SAHPRA's corporate social responsibility programme has not yet been developed and will be a focus of the Executive Management in 2019/20 as the entity seeks to establish its footprint.

26. RISK, AUDIT AND GOVERNANCE COMMITTEE REPORT

The Committee was provided with an overview of the SAHPRA Final Management Report 2019 and Audit Report by the representatives of the Auditor-General of South Africa which concluded in summary with the following findings:

- Annual Financial Statements: Qualified audit opinion;
- Compliance: Paragraphs on material amendments of financial statements and non-compliance with procurement and contract management practices; and
- Annual performance report: Audit of Predetermined Objectives (AOPO) revealed material findings on Programmes 2, 3 and 4 and a paragraph on material amendments of the annual performance report, which resulted in a qualified opinion of Programmes 2 and 4 and a disclaimer on Programme 3.

The key recommendations arising from the audit were, that the Board should:

- Ensure that signed copies of the Board documents including minutes and policies are placed on record.

That management should:

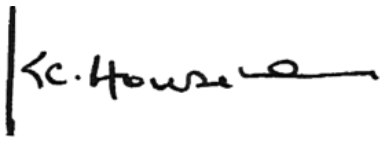
- Implement proper record keeping;
- Prepare accurate and complete financial statements;
- Review and monitor compliance with applicable legislation;
- Ensure that internal audit is functional;
- Ensure oversight over performance management reporting and compliance;
- Ensure that there are business continuity and disaster recoverability plans;
- Ensure adequacy of general IT control around IT governance and security; and
- Ensure that SAHPRA has a robust M&E Unit to evaluate both the indicators and the data collected.

The committee raised the following issues related to the audit:

- Concern that adequate documentation and registers could not be provided by SAHPRA to the Auditor-General of South Africa to enable a more satisfactory audit outcome. This had resulted in both limitations of scope in the audit of the financial statements and the qualifications and a disclaimer related to the audit of predetermined objectives which was of concern to the committee.
- Supply chain findings indicated the need for SAHPRA to establish an effective and fully functional supply chain management capacity and internal audit capacity as a priority.
- Concern that the implications of the difficulties related to the establishment of SAHPRA and the labour unrest at Civitas building had not been taken fully into account by the Auditor-General.
- Concern related to the AOPO where it appeared that SAHPRA was unable to provide information to substantiate the performance reported.
- That the implication of qualified audits for the AOPO of Programmes 2 and 4 and a disclaimer for Programme 3 was that the credibility of the information provided by SAHPRA in the annual report negatively affected.
- Concern that the findings reflected in the audit report created a very negative impression of the organisation unless the background and context of a newly established entity and the difficult circumstances surroundings its inception were provided.

The Risk, Audit and Governance Committee resolved that:

- The findings contained in the Final Management Report of the SAHPRA and the Final Audit Report of the SAHPRA were noted.
- The recommendations contained in the Final Management Report and Audit Report were accepted and recommended to the SAHPRA Board for implementation of an action plan to address the shortcomings identified.



Prof Craig Household
Chairperson: Risk, Audit and Governance Committee SAHPRA
Date: 19 September 2019

Part: D
Human Resource Management

27. HR OVERVIEW

27.1 Introduction

During the reporting period, the entity relied predominantly on the human resources unit of the National Department of Health (NDoH) for all its human resources functions. This was enabled by the Memorandum of Agreements (MoUs) signed between the NDoH and SAHPRA in November 2017.

While SAHPRA commenced with the development of its own human resource policies, these could only be provisionally approved as the human resources unit faced challenges in appointing an HR executive despite focused recruitment and making offers to two potential candidates. SAHPRA secured a short-term service provider from February 2019 through its own procurement processes using the GTAC database.

The protracted labour unrest, the prolonged shortage of staff which impacted work productivity, and the subsequent difficulties in evoking the MoU resulted in this unit's challenges adversely affecting the entity's transitional progress.

Emergency measures were taken to lend the necessary support to the entity, including the Board at times taking on more operational roles. For instance, Ms Mandisa Hela took a leave of absence from the Board to give operational and technical support within the office of the Acting CEO. Further, Dr Nicholas Crisp was appointed as a public health specialist to support progress in key issues around human resources.

The new HR Director will need to lead the entity in:

- Setting HR priorities for the year and delineating the impact of these priorities;
- Developing a workforce planning framework aligned to the key strategies identified in the five-year Strategic Plan and 2019/20 APP to attract and recruit a skilled and capable workforce. While this has been set in motion with the appointment of Dr Crisp, it is recognised that this will be an ongoing process and will need to remain dynamic. Whereas Dr Crisp focused on recruitment, the new incumbent will need to include training and change management as part of the HR operational strategy to lead the organisation through its workforce;
- Developing an employee performance management framework that is rigorous and encompasses consequence management and parity for the worker;
- Developing employee wellness programmes to ensure the workforce is adequately cared for in an environment responsive to the needs of the workforce whilst ensuring optimal productivity; and
- Ensuring policy developments are aligned to the evolving business processes of the entity.

27.2 HR priorities for the year and its impact

The key priorities for 2018/9 were to stabilise SAHPRA following the labour unrest at the NDoH and relocation, through finalisation of the organisational structure, appointment of critical executives to provide the necessary leadership and stabilising the environment through active engagements with labour independent from the NDoH processes.

27.3 Workforce planning framework

Towards finalisation of the organisational structure, SAHPRA secured the services of a public health specialist (Dr Nicholas Crisp) in January 2019 to support the office of the Acting CEO. A key output of this engagement was to stabilise the entity with regards to its HR capital.

The services Dr Crisp rendered at SAHPRA resulted in the development of the complete organisational structure. Subsequently, advertisements of 109 posts on this new structure were placed on 8 May 2019. The result of this exercise was as follows:

Groups	Posts	Applications Received
Senior Management	18	766
Medical Device Regulation and Radiation Control	29	240
Medicines Regulation	21	1 680
Support Services	22	1 676
Medicines Backlog Project	19	1 293
Total	**109**	**5 655**

Four HR roles were identified in the new organogram and final placements are expected in the second quarter.

The appointment of five recruitment service providers through procurement processes run by SAHPRA was made in June 2019 to support the screening and short-listing of all 5 655 applications received.

The creation of SAHPRA's workplace forum ensured that labour consultations were undertaken in parallel during this entire process. The organisational structure was created in conjunction with the management of SAHPRA through intensive scoping of business processes and interviews.

There is a temporary HR system in place using a service provider that administers the four new staff (payroll). This HR system 'Sage 300 People' was finally procured to support payment of the staff appointed.

SAHPRA was able to secure key executive placements in 2018/19.These included Mr Molatlhegi Kgauwe as the Chief Financial Officer, Adv Peter Nthotso as the Company Secretary, and Mr Teboho Ramosangoana as the Director: ICT.

At the time of the publication of this annual report, though after the reporting period, the following offer and appointments were made: Chief Executive Officer, offer made, the Chief Regulatory Officer, Ms Portia Nkambule, and the Director: Communications and Public Reslations, Mr Yuven Gounden. The backlog project and senior management interviews were underway and internal staff members on the Section 197 transfer were being reviewed for inclusion into the new structure.

Additionally, preparatory work was done to establish what data from Persal needs to be loaded on Sage 300 People (besides the loading of the new personnel). It is important to get the structure of the posts in the organogram loaded so as to establish approval hierarchies, as this is critical for Employee Self Service (ESS).

27.4 Employee performance management framework

For this reporting period, the entity managed its performance framework under the policy approved by the NDoH. This was managed by the NDoH HR unit.

27.5 Policy development

The Human Resources Policy Manual covering various components was developed by Management and reviewed by the SAHPRA Board. This manual is extensive and encompasses the full ambit of the HR universe of policies to guide the entity towards its staff wellbeing and optimised productivity. The appointment of the HR Director and capacitation of this unit will be the stimulus for the adoption and implementation of these policies.

28. HUMAN RESOURCES OVERSIGHT STATISTICS

Below follows key information on human resources in alignment with the financial statements.

28.1 Personnel cost by salary band

Table14: Personnel Cost by Salary Band

Level	Personnel Expenditure (R)	No. of Employees	Average Personnel Cost per Employee (R)
Top Management	3 568 014	3	1 189 338
Senior Management	2 182 233	5	1 091 117
Professional Qualified	74 492 709	103	72 230.20
Skilled	7 958 334	31	256 720.50
Semi-Skilled	11 882 670	69	172 212.60
Unskilled			
TOTAL	100 083 960	211	

28.2 Training

Informal training has been given to the new employees but it is anticipated that a proper training and development program will be put into place once the new HR unit is in place. The new HR Director faces the responsibility of putting in place a proper HR strategy as well as change management, as old and new employees need to be orientated to the new SAHPRA organisational arrangements.

28.3 Employment and vacancies

Table 15: Employment and Vacancies

Level	No. of Employees	2018/19 Vacancies
Top Management	3	2
Senior Management	5	8
Professional Qualified	103	17
Skilled	31	2
Semi-Skilled	69	1
Unskilled		
TOTAL	211	30

SAHPRA embarked on a mass recruitment drive to fill 89 positions after finalising the new organisational structure. A further 19 posts were opened for the Medicines Backlog Project in a bid to clear an inherited backlog of applications and certificates.

28.4 Employment changes

Table 16: Employment Changes

Salary Band	Appointments	Terminations
Top Management	0	
Senior Management	0	
Professional Qualified	5	29
Skilled	0	5
Semi-Skilled	0	19
Unskilled	0	
TOTAL	5	53

With the implementation of the new organisational organogram, vacant posts were identified and interviews and appointments are still under way.

28.5 Labour relations: misconduct and disciplinary action

No statistics were available from the NDoH at the time of reporting.

28.6 Equity target and employment equity status

Table 18: Equity Target and Employment Equity Status

Category	Targets	Current	Gap (entity representivity targets)
Top Management	3 568 014	3	1 189 338
Senior Management	2 182 233	5	1 091 117
Professional Qualified	74 492 709	103	72 230.20
Skilled	7 958 334	31	256 720.50
Semi-Skilled	11 882 670	69	172 212.60
Unskilled			
TOTAL	100 083 960	211	

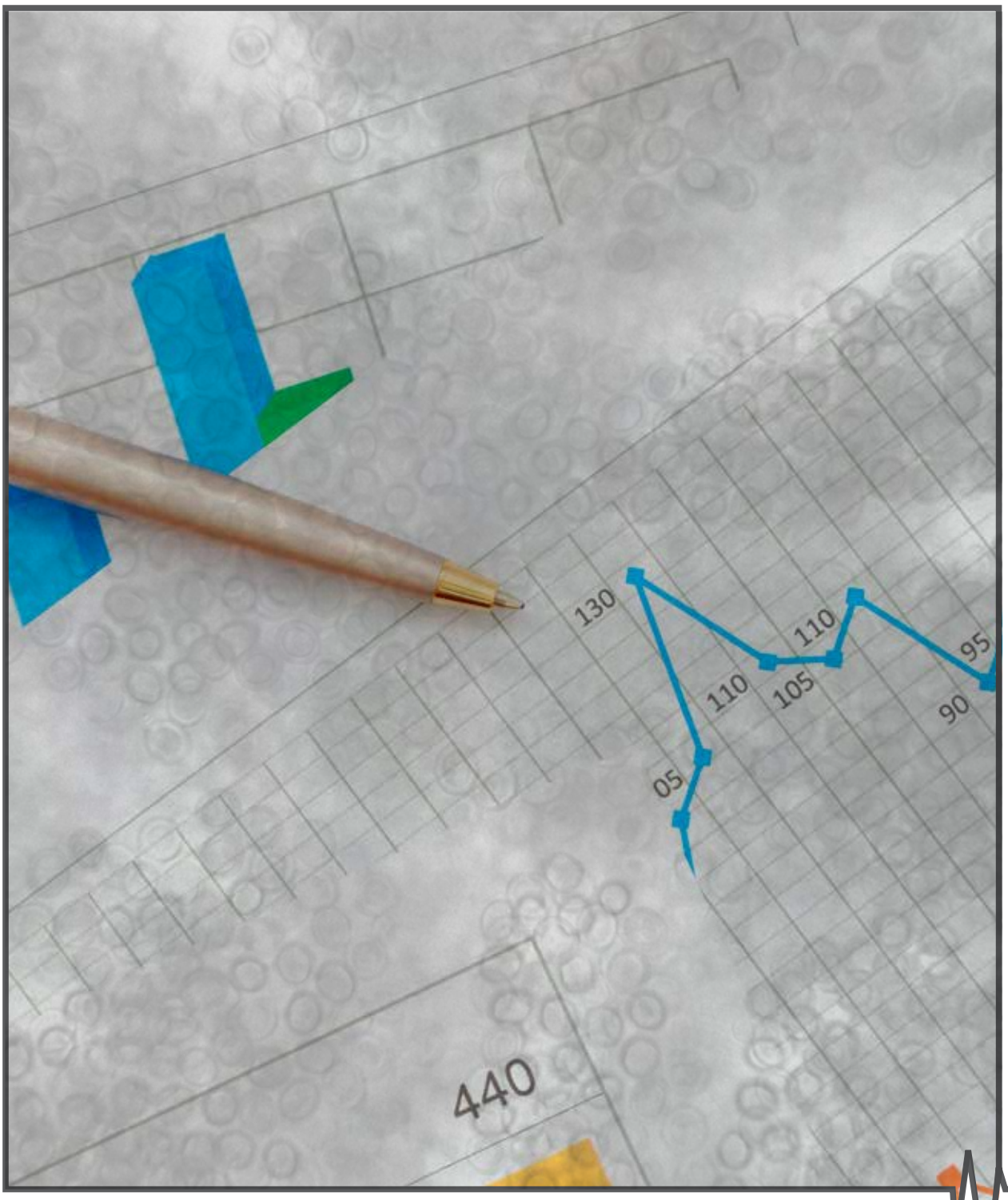
The employment equity status is listed as reported to the NDoH against the % equity targets set by the department.

This policy will be reviewed by the entity to ensure its own targets are set and enumerated.

In the category for Black employees, SAHPRA employs 71% African, 7% Coloured and 6% Indian employees as a percentage of its full staff complement.

In the category for female employees, 44% African women make up the workforce, 4% Coloured and Indian women and 5% White women compromise the SAHPRA workforce.

SAHPRA has 1 disabled staff member.



Part: E
Financial Information

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29. REPORT OF THE AUDITOR-GENERAL TO PARLIAMENT ON THE SOUTH AFRICAN HEALTH PRODUCT REGULATORY AUTHORITY

Report on the audit of the financial statements

Qualified opinion

1. I have audited the financial statements of the South African Health Products Regulatory Authority (SAHPRA) set out on pages 98 to 126, which comprise the statement of financial position as at 31 March 2019 the statement of financial performance, statement of changes in net assets and cash flow statement for the year then ended, as well as the notes to the financial statements, including a summary of significant accounting policies.

2. In my opinion, except for the possible effects of the matters described in the basis for qualified opinion section of this auditor's report, the financial statements present fairly, in all material respects, the financial position of the SAHPRA as at 31 March 2019, and its financial performance and cash flows for the year then ended in accordance with the South African Standards of Generally Recognised Accounting Practice (SA Standards of GRAP) and the requirements of the Public Finance Management Act of South Africa, 1999 (Act No. 1 of 1999) (PFMA).

Basis for qualified opinion

Deferred Income

3. I was unable to obtain sufficient appropriate audit evidence that deffered income for the current year has been properly accounted for, as the entity did not have adequate systems of internal control for the recording of all transactions and events and could not reconcile the transactions and events to the financial statements. I could not confirm whether all deffered income had been recorded by alternative means. Consequently, I was unable to determine whether any adjustment was necessary to deferred income stated at R35 589 600 and the related fee income stated at R72 059 772 in the financial statements.

Revenue

4. I was unable to obtain sufficient appropriate audit evidence that fee income for the current year had been properly accounted for, due to the status of the accounting records. I was unable to confirm the fee income by alternative means. Consequently, I was unable to determine whether any adjustment was necessary to fee income stated at R72 059 772 in the financial statements.

Operating expenditure

5. I was unable to obtain sufficient appropriate audit evidence that the operating expenses for the current year as management did not provide information requested for the audit. I was unable to confirm whether operating expenses by alternative means. Consequently, I was unable to determine whether any adjustment was necessary to operating expenses stated at R29 209 137 in the financial statements.

Context for the opinion

6. I conducted my audit in accordance with the International Standards on Auditing (ISAs). My responsibilities under those standards are further described in the auditor-general's responsibilities for the audit of the financial statements section of this auditor's report.

7. I am Independent of the department in accordance with sections 290 and 291 of the International Ethics Standards Board for Accountants' Code of ethics for professional accountants (IESBA code), parts 1 and 3 of the International Ethics Standards Board for Accountants' International Code of Ethics for Professional Accountants (including International Independence Standards) and the ethical requirements that are relevant to my audit in South Africa. I have fulfilled my other ethical responsibilities in accordance with these requirements and the IESBA codes.

8. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my qualified opinion.

Responsibilities of the accounting authority for the financial statements

9. The accounting authority is responsible for the preparation and fair presentation of the financial statements in accordance with SA Standards of GRAP and the requirements of the PFMA ,and for such internal control as the accounting authority determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

10. In preparing the financial statements, the accounting authority is responsible for assessing the SAHPRA's ability to continue as a going concern, disclosing, as applicable, matters relating to going concern and using the going concern basis of accounting unless the appropriate governance structure either intends to liquidate the entity or to cease operations, or has no realistic alternative but to do so.

Auditor-General's responsibilities for the audit of the financial statements

11. My objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes my opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

12. A further description of my responsibilities for the audit of the financial statements is included in the annexure to this auditor's report.

Report on the audit of the annual performance report

Introduction and scope

13. In accordance with the Public Audit Act of South Africa, 2004 (Act No. 25 of 2004) (PAA) and the general notice issued in terms thereof, I have a responsibility to report material findings on the reported performance information against predetermined objectives for selected programmes presented in the annual performance report. I performed procedures to identify findings but not to gather evidence to express assurance.

14. My procedures address the reported performance information, which must be based on the approved performance planning documents of the entity. I have not evaluated the completeness and appropriateness of the performance indicators/measures included in the planning documents. My procedures also did not extend to any disclosures or assertions relating to planned performance strategies and information in respect of future periods that may be included as part of the reported performance information. Accordingly, my findings do not extend to these matters.

15. I evaluated the usefulness and reliability of the reported performance information in accordance with the criteria developed from the performance management and reporting framework, as defined in the general notice, for the following selected programmes presented in the annual performance report of the entity for the year ended 31 March 2019:

Programmes	Pages in the annual performance report
Programme 2 – Authorisation Management	46 – 49
Programme 3 – Inspectorate and Regulatory Compliance	50 – 55
Programme 4 – Medicines Evaluations and Registration	56 – 64

16. I performed procedures to determine whether the reported performance information was properly presented and whether performance was consistent with the approved performance planning documents. I performed further procedures to determine whether the indicators and related targets were measurable and relevant, and assessed the reliability of the reported performance information to determine whether it was valid, accurate and complete.

17. The material findings in respect of the usefulness and reliability of the selected programmes are as follows:

Programme 2: Authorisation management

Indicator: % of licence/permits/certificates issued within predefined timelines on quarterly basis

18. The source information and method of calculation for achieving the planned indicator was not clearly defined

19. I was unable to obtain sufficient appropriate audit evidence for the reported achievement of target 70%. This was due to inadequate technical indicator descriptions, proper performance management systems and processes with formal standard operating procedures that predetermined how the achievement would be measured, monitored and reported. I was unable to confirm that the reported achievements of these indicators were reliable by alternative means. Consequently, I was unable to determine whether any adjustments were required to the achievement of 47% as reported in the annual performance report.

Programme 3: Inspectorate and Regulatory compliance

Indicator: % of establishments due for inspection inspected annually

20. The source information and method of calculation for achieving the planned indicator was not clearly defined.

21. I was unable to obtain sufficient appropriate audit evidence for the reported achievement of target 45%. This was due to inadequate technical indicator descriptions, proper performance management systems and processes with formal standard operating procedures that predetermined how the achievement would be measured, monitored and reported. I was unable to confirm that the reported achievements of these indicators were reliable by alternative means. Consequently, I was unable to determine whether any adjustments were required to the achievement of 37% as reported in the annual performance report.

Indicator: % of permit holders/establishments/sites of narcotic and psychotropic substances inspected annual

22. The source information and method of calculation for achieving the planned indicator was not clearly defined.

23. I was unable to obtain sufficient appropriate audit evidence for the reported achievement of target 20%. This was due to inadequate technical indicator descriptions, proper performance management systems and processes with formal standard operating procedures that predetermined how the achievement would be measured, monitored and reported. I was unable to confirm that the reported achievements of these indicators were reliable by alternative means. Consequently, I was unable to determine whether any adjustments were required to the achievement of 34% as reported in the annual performance report.

Programme 4: Medicines evaluation and registration

Indicator: Published quarterly reports of new adverse events and signals that have been assessed, actioned and concluded

24. The target approved in the annual performance plan was 2 reports published. However, the target reported in the annual performance report was bi-annual reports to the public.

25. The source information and method of calculation for achieving the planned indicator was not clearly defined.

Various indicators

26. I was unable to obtain sufficient appropriate audit evidence for the reported achievements in the annual performance report of the indicators listed below. This was due to inadequate technical indicator descriptions and a lack of an adequate record keeping system that will enable reliable reporting. I was unable to confirm that the reported achievements of these indicators were reliable by alternative means. Consequently, I was unable to determine whether any adjustments were required to the reported achievements.

Indicator description	Planned Target	Reported achievement
% of clinical trial applications evaluated within an evaluation cycle	85%	95%
% of clinical trial protocol amendment evaluated within predefined timelines	72%	73%
% of applications for the sale of an unregistered health product evaluated within a specified timeline	75%	80%
% of Generic / Biosimilar application evaluations concluded with a regulatory decision within 180 working days (time spent at regulator)	40%	3%

Various indicators

27. I was unable to obtain sufficient appropriate audit evidence to support the reported achievements below. This was due to inadequate technical indicator descriptions, proper performance management systems and processes and formal standard operating procedures or documented system descriptions that predetermined how the achievement would be measured, monitored and reported. I was unable to confirm the reported achievement of the indicator by alternative means. Consequently, I was unable to determine whether any adjustments were required to the achievements as reported in the annual performance report.

Indicator description	Planned Target	Reported achievement
% of NCE/Biological applications evaluations concluded with a regulatory decision within 275 working days	40%	0%
% of NCE/Biological amendments evaluations concluded with a regulatory decision within 120 working days (time spent at regulator)	40%	0%
% of Generic/ Biosimilar amendments evaluations concluded with a regulatory decision within 120 working days. (time spent at regulator)	40%	0%

Other matter

28. We draw attention to the matter below.

Achievement of planned targets

29. Refer to the annual performance report on pages 33 to 69 for information on the achievement of planned targets for the year and explanations provided for the under/overachievement of a significant number of targets. This information should be considered in the context of the qualified and disclaimer of opinions expressed on the usefulness and reliability of the reported performance information in paragraphs 18 to 27 of this report.

Adjustment of material misstatements

30. We identified material misstatements in the annual performance report submitted for auditing. These material misstatements were on the reported performance information of Programme 2: Authorisation management, Programme 3: Inspectorate and regulatory compliance and Programme 4: Medicines evaluation and registration. As management subsequently corrected only some of the misstatements, we raised material findings on the usefulness and reliability of the reported performance information. Those that were not corrected are included in the basis for qualified and disclaimer of opinion paragraphs.

Responsibilities of the accounting authority for the reported performance information

31. The board, which constitutes the accounting authority is responsible for the preparation of the annual performance report in accordance with the prescribed performance management and reporting framework, as set out in annexure D to this report and for such internal control as the accounting authority determines is necessary to enable the preparation of performance information that is free from material misstatement in terms of its usefulness and reliability.

Auditor-General's responsibilities for the reasonable assurance engagement on the reported performance information

32. Our objectives are to obtain reasonable assurance about whether the reported performance information for the selected programmes presented in the annual performance report is free from material misstatement and to issue a management report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that the assurance engagement conducted in accordance with the relevant assurance standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if they could reasonably be expected to influence the relevant decisions of users taken on the basis of the reported performance information.

33. Our procedures address the reported performance information, which must be based on the approved performance planning documents of the entity. We have not evaluated the appropriateness of the performance indicators established and included in the planning documents. Our procedures do not extend to any disclosures or assertions relating to planned performance strategies and information relating to future periods that may be included as part of the reported performance. Accordingly, our opinion does not extend to these matters.

34. A further description of our responsibilities for the reasonable assurance engagement on reported performance information is included in annexure E to this report.

Report on the audit of compliance with legislation

Introduction and scope

35. In accordance with the PAA and the general notice issued in terms thereof, I have a responsibility to report material findings on the compliance of the entity with specific matters in key legislation. I performed procedures to identify findings but not to gather evidence to express assurance.

36. The material findings on compliance with specific matters in key legislations are as follows:

Annual financial statements, performance and annual reports

37. The financial statements submitted for auditing were not prepared in accordance with the prescribed financial reporting framework and supported by full and proper records, as required by section 55(1) (a) and (b) of the PFMA.

38. Material misstatements of liabilities, revenue, expenditure, disclosure items identified by the auditors in the submitted financial statements were corrected and the supporting records were provided subsequently, but the uncorrected material misstatements and supporting records that could not be provided resulted in the financial statements receiving a qualified opinion.

Procurement and Contract Management

39. Sufficient appropriate audit evidence could not be obtained that quotations were accepted only from bidders who submitted a declaration on whether they are employed by the state or connected to any person employed by the state, which is prescribed in order to comply with treasury regulation 16A8.3.

40. Some of the goods and services with a transaction value below R500 000 were procured without obtaining the required price quotations, as required by treasury regulation 16A6.1.

41. Some of the goods and services of a transaction value above R500 000 were procured without inviting competitive bids and deviations were approved by the accounting officer but it was practical to invite competitive bids, as required by treasury regulations 16A6.4.

42. Some of the contracts were awarded to bidders who did not submit a declaration on whether they are employed by the state or connected to any person employed by the state, which is prescribed in order to comply with treasury regulation 16A8.3.

43. Some of the contracts were awarded to suppliers whose tax matters had not been declared by the South African Revenue Services to be in order as required by treasury regulations 16A9.1(d).

Other information

44. The accounting authority is responsible for the other information. The other information comprises the information included in the annual. The other information does not include the financial statements, the auditor's report and those selected programmes presented in the annual performance report that have been specifically reported in this auditor's report.

45. My opinion on the financial statements and findings on the reported performance information and compliance with legislation do not cover the other information and I do not express an audit opinion or any form of assurance conclusion thereon.

46. In connection with my audit, my responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements and the selected programmes presented in the annual performance report, or my knowledge obtained in the audit, or otherwise appears to be materially misstated.

47. I did not receive the other information prior to the date of this auditor's report. After I receive and read this information, and if I conclude that there is a material misstatement, I am required to communicate the matter to those charged with governance and request that the other information be corrected. If the other information is not corrected, I may have to retract this auditor's report and re-issue an amended report as appropriate. However, if it is corrected this will not be necessary.

Internal control deficiencies

48. I considered internal control relevant to my audit of the financial statements, reported performance information and compliance with applicable legislation; however, my objective was not to express any form of assurance on it. The matters reported below are limited to the significant internal control deficiencies that resulted in the basis for the qualified opinion, the findings on the performance report and the findings on compliance with legislation included in this report.

Oversight responsibility

49. The entity did not have sufficient monitoring controls to ensure proper implementation of the overall process of implementation and reporting of financial and performance management reporting, compliance and related internal controls.

Financial and performance management

50. Implementation of proper record keeping was not done to ensure that complete, relevant and accurate information is accessible and available to support financial and performance reporting.

51. Management did not design suitable internal controls to reliably report performance against predetermined objectives.

52. The entity did not properly review and monitor the requirements for compliance with legislation.

53. Sufficient and appropriate controls were not in place to ensure the completeness of revenue and differed income.

Governance

54. The entity did not ensure that it has a functioning internal audit function.

Auditor - General

Pretoria
21 September 2019

AUDITOR-GENERAL
SOUTH AFRICA

Auditing to build public confidence

ANNEXURE – AUDITOR-GENERAL'S RESPONSIBILITY FOR THE AUDIT

1. As part of an audit in accordance with the ISAs, I exercise professional judgement and maintain professional scepticism throughout my audit of the financial statements, and the procedures performed on reported performance information for selected programmes and on the entity's compliance with respect to the selected subject matters.

Financial statements

2. In addition to my responsibility for the audit of the financial statements as described in this auditor's report, I also:

    - identify and assess the risks of material misstatement of the financial statements whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control
    - obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control
    - evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by accounting authority.
    - conclude on the appropriateness of the accounting authority use of the going concern basis of accounting in the preparation of the financial statements. I also conclude, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the SAHPRA ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the financial statements about the material uncertainty or, if such disclosures are inadequate, to modify the opinion on the financial statements. My conclusions are based on the information available to me at the date of this auditor's report. However, future events or conditions may cause an entity to cease continuing as a going concern
    - evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation
    - obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated financial statements. I am responsible for the direction, supervision and performance of the group audit. I remain solely responsible for my audit opinion

Communication with those charged with governance

3. I communicate with the accounting authority regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

4. I also confirm to the accounting authority that I have complied with relevant ethical requirements regarding independence, and communicate all relationships and other matters that may reasonably be thought to have a bearing on my independence and, where applicable, related safeguards.

ACCOUNTING AUTHORITIES' RESPONSIBILITIES AND APPROVAI

The accounting authorities are required by the Public Finance Management Act (Act No.1 of 1999), to maintain adequate accounting records and are responsible for the content and integrity of the financial statements and related financial information included in this report. It is the responsibility of the accounting authorities to ensure that the financial statements fairly present the state of affairs of the entity as at the end of the financial year and the results of its operations and cash flows for the period then ended. The external auditors are engaged to express an independent opinion on the financial statements and was given unrestricted access to all financial records and related data.

The financial statements have been prepared in accordance with Standards of Generally Recognised Accounting Practice (GRAP) including any interpretations, guidelines and directives issued by the Accounting Standards Board. The financial statements are based upon appropriate accounting policies consistently applied and supported by reasonable and prudent judgements and estimates.

The accounting authorities acknowledge that they are ultimately responsible for the system of internal financial control established by the organisation and place considerable importance on maintaining a strong control environment. To enable the accounting authorities to meet these responsibilities, the sets standards for internal control aimed at reducing the risk of error or deficit in a cost effective manner. The standards include the proper delegation of responsibilities within a clearly defined framework, effective accounting procedures and adequate segregation of duties to ensure an acceptable level of risk. These controls are monitored throughout the entity and all employees are required to maintain the highest ethical standards in

ensuring the entity's business is conducted in a manner that in all reasonable circumstances is above reproach. The focus of risk management in the entity is on identifying, assessing, managing and monitoring all known forms of risk across the entity. While operating risk cannot be fully eliminated, the entity endeavours to minimise it by ensuring that appropriate infrastructure, controls, systems and ethical behaviour are applied and managed within predetermined procedures and constraints.

The accounting authorities are of the opinion, based on the information and explanations given by management, that the system of internal control provides reasonable assurance that the financial records may be relied on for the preparation of the financial statements. However, any system of internal financial control can provide only reasonable, and not absolute, assurance against material misstatement or deficit.

The accounting authorities have reviewed the entity's cash flow forecast for the 12 months to 31 March 2020 and, in the light of this review and the current financial position, they are satisfied that the entity has or has access to adequate resources to continue in operational existence for the foreseeable future.

Although the board is primarily responsible for the financial affairs of the entity, they are supported by the entity's external auditors.

The external auditors are responsible for independently reviewing and reporting on the entity's financial statements. The financial statements have been examined by the entity's external auditors and their report is presented on pages 91 to 97.

The financial statements set out on pages 98 to 126, which have been prepared on the going concern basis, were approved by the on 19 September 2019 and were signed on its behalf by:

Ms Portia Nkambule
Acting CEO: SAHPRA
Date: 19 September 2019

Prof Helen Rees
Chairperson: SAHPRA Board
Date: 19 September 2019

Statement of Financial Position

as at 31 March 2019

	Note(s)	31 March 2019 R'000
Assets		
Current Assets		
Receivables from exchange transactions	3	3 367 301
Prepayments	4	269 927
Cash and cash equivalents	5	103 656 936
		107 294 164
Non-Current Assets		
Property, plant and equipment	6	7 213 490
Total Assets		**114 507 654**
Liabilities		
Current Liabilities		
Payables from exchange transactions	7	33 036 195
Conditional grant	8	1 441 170
Provisions	9	9 463 516
Deferred income	10	35 589 600
		79 530 481
Total Liabilities		**79 530 481**
Net Assets		**34 977 173**
Accumulated surplus		34 977 173

Statement of Financial Performance

for the 14 months ended 31 March 2019

	Note(s)	14 months ended 31 March 2019 R'000
Revenue		
Revenue from exchange transactions		
Fee income	11	72 059 772
Interest received	12	4 907 134
Total revenue from exchange transactions		**76 966 906**
Revenue from non-exchange transactions		
Transfer revenue		
Transfer payment received	13	125 189 000
Goods and services in-kind from National Department of Health	14	29 124 227
Total revenue from non-exchange transactions		**154 313 227**
Total revenue		**231 280 133**
Expenditure		
Employee related costs	15	(119 066 656)
Depreciation	16	(836 240)
Lease rentals on operating lease	17	(1 857 473)
Contracted services	18	(19 992 200)
Goods and services in-kind from the National Department of Health	14	(29 124 227)
Loss on disposal of assets		(21 968)
Operating Expenses	19	(29 209 137)
Total expenditure		**(200 107 901)**
Surplus for the 14 months		**31 172 232**

Statement of Changes in Net Assets

for the 14 months ended 31 March 2019

	Accumulated surplus R'000	Total net assets R'000
Balance at 01 April 2018	–	–
Changes in net assets		
Surplus for the 14 months	31 172 232	31 172 232
Assets and liabilities transferred from NDOH	3 804 939	3 804 939
Total changes	**34 977 171**	**34 977 171**
Balance at 31 March 2019	**34 977 171**	**34 977 171**

Note(s)

Cash Flow Statement

for the 14 months ended 31 March 2019

	Note(s)	14 months ended 31 March 2019 R'000
Cash flows from operating activities		
Receipts		
Fee income		69 399 275
Government grants		125 189 000
Interest received		4 907 134
Deferred Income		35 589 600
Conditional grant		1 441 170
		236 526 179
Payments		
Employee related costs		(104 310 872)
Suppliers		(28 369 849)
		(132 680 721)
Net cash flows from operating activities	20	**103 845 458**
Cash flows from investing activities		
Purchase of property, plant and equipment	6	(188 522)
Net cash and cash equivalents		**103 656 936**
Cash and cash equivalents at the end of the year		**103 656 936**

Statement of Comparison of Budget and Actual Amounts

for the 14 months ended 31 March 2019

	Approved budget R'000	Adjustments R'000	Final Budget R'000	Actual amounts on comparable basis R'000	Difference between final budget and actual R'000	Reference R'000
Statement of Financial Performance						
Revenue						
Revenue from exchange transactions						
Fee income	90 681 000	-	**90 681 000**	72 059 772	**(18 621 228)**	27.1
Interest received	-	-	**-**	4 907 134	**4 907 134**	27.2
Total revenue from exchange transactions	**90 681 000**	**-**	**90 681 000**	**76 966 906**	**(13 714 094)**	
Revenue from non-exchange transactions						
Transfer revenue						
Government grants	125 189 000	-	**125 189 000**	125 189 000	**-**	
Goods and services in-kind from the National Department of Health	-	-	**-**	29 124 227	**29 124 227**	
Total revenue from non-exchange transactions	125 189 000	-	**125 189 000**	154 313 227	**29 124 227**	
Total revenue	215 870 000	-	**215 870 000**	231 280 133	**15 410 133**	
Expenditure						
Employee Related Costs	(149 145 380)	-	**(149 145 380)**	(119 066 656)	**30 078 724**	27.3
Administration	(135 000)	-	**(135 000)**	-	**135 000**	
Depreciation	-	-	**-**	(836 240)	**(836 240)**	27.4
Lease rentals on operating lease	(1 120 000)	-	**(1 120 000)**	(1 857 473)	**(737 473)**	
Contracted Services	-	-	**-**	(19 992 200)	**(19 992 200)**	27.5
Goods and services in-kind from the Department of Health	-	-	**-**	(29 124 227)	**(29 124 227)**	
General Expenses	(65,469,620)	-	**(65 469 620)**	(29 209 137)	**36 260 483**	27.6
Total expenditure	(215,870,000)	-	**(215 870 000)**	(200 085 933)	**15 784 067**	
Operating surplus	-	-	**-**	31 194 200	**31 194 200**	
Loss on disposal of assets and liabilities	-	-	**-**	(21 968)	**(21 968)**	
Surplus before taxation	-	-	**-**	31 172 232	**31 172 232**	
Actual Amount on Comparable Basis as Presented in the Budget and Actual Comparative Statement	-	-	**-**	31 172 232	31 172 232	

ACCOUNTING POLICIES

1. Presentation of financial statements

The financial statements have been prepared in accordance with the Standards of Generally Recognised Accounting Practice (GRAP), issued by the Accounting Standards Board in accordance with Section 91(1) of the Public Finance Management Act (Act No.1 of 1999) and National Treasury issued guidelines, Instruction notes and practice notes.

These financial statements have been prepared on an accrual basis of accounting and are in accordance with historical cost as the basis of measurement, unless specified otherwise.

In the absence of an issued and effective Standard of GRAP, accounting policies for material transactions, events or conditions

were developed in accordance with paragraphs 8, 10 and 11 of GRAP 3 as read with Directive 5 issued by the Accounting Standards Board.

Assets, liabilities, revenues and expenses were not offset, except where offsetting is either required or permitted by a Standard of GRAP.

A summary of the significant accounting policies, which have been consistently applied in the preparation of these financial statements, are disclosed below.

1.1 Presentation currency

These financial statements are presented in South African Rand.

1.2 Going concern assumption

These financial statements have been prepared based on the expectation that the entity will continue to operate as a going concern for at least the next 12 months.

1.3 Materiality

Material omissions or misstatements of items are material if they could, individually or collectively, influence the decisions or assessments of users made on the basis of the financial statements. Materiality depends on the nature or size of the omission or misstatement judged in the surrounding circumstances. The nature or size of the information item, or a combination of both, could be the determining factor.

Assessing whether an omission or misstatement could influence decisions of users, and so be material, requires consideration of the characteristics of those users. The Framework for the Preparation and Presentation of Financial Statements states that users are assumed to have a reasonable knowledge of government, its activities, accounting and a willingness to study the information with reasonable diligence. Therefore, the assessment takes into account how users with such attributes could reasonably be expected to be influenced in making and evaluating decisions.

1.4 Significant judgements and sources of estimation uncertainty

The use of judgment, estimates and assumptions is inherent to the process of preparing annual financial statements. These judgements, estimates and assumptions affect the amounts presented in the annual financial statements. Uncertainties about these estimates and assumptions could result in outcomes that require a material adjustment to the carrying amount of the relevant asset or liability in future periods.

In the process of applying these accounting policies, management has made judgements that may have a significant effect on the amounts recognised in the financial statements..

Estimates are informed by historical experience, information currently available to management, assumptions, and other factors that are believed to be reasonable under the circumstances. The estimates shall be reviewed on a regular basis. Changes in estimates that are not due to errors are processed in the period of the review and applied prospectively.

In applying the entity's accounting policies estimates shall be made on items such as the following:

Impairment testing

In testing for, and determining the value-in-use of non-financial assets, management is required to rely on the use of estimates about the asset's ability to continue to generate cash flows (in the case of cash-generating assets).

For non cash-generating-assets, estimates are made regarding the depreciated replacement cost, restoration cost, or service units of the asset, depending on the nature of the impairment and the availability of information.

Other provisions

Provisions shall be measured using the estimated future outflows required to settle the obligation. In the process of determining the best estimate of the amounts that will be required in future to settle the provision management considers the weighted average probability of the potential outcomes of the provisions raised.

This measurement entails determining what the different potential outcomes will be for a provision as well as the financial impact of each of those potential outcomes. Management then assigns a weighting factor to each of these outcomes based on the probability that the outcome will materialise in future.

ACCOUNTING POLICIES(continued)

The factor is then applied to each of the potential outcomes and the factored outcomes are then added together to arrive at the weighted average value of the provisions.

Leave provision

Leave Provision shall be measured using the accumulated leave days on the assumption that all days will be taken within the stipulated timeframe per applicable leave policy.

Effective interest rate

The entity shall use an appropriate interest rate, taking into account guidance provided in the standards, and applying professional judgement to the specific circumstances, to discount future cash flows. The entity shall use the prime interest rate to discount future cash flows.

Depreciation and amortisation

Depreciation and amortisation recognised on property, plant and equipment and intangible assets shall be determined with reference to the useful lives and residual values of the underlying items.

The useful lives of assets are based on management's estimation of the asset's condition, expected condition at the end of the period of use, its current use, expected future use and the entity's expectations about the availability of finance to replace the asset at the end of its useful life. In evaluating the condition, the use of the asset informs the useful life. Management considers the impact of technology and minimum service requirements of the assets.

1.5 Property, plant and equipment

Property, plant and equipment are tangible non-current assets that are held for use in the production or supply of goods or services, rental to others, or for administrative purposes, and are expected to be used during more than one period..

The cost of an item of property, plant and equipment is recognised as an asset when:

- it is probable that future economic benefits or service potential associated with the item will flow to the Authority; and
- the cost of the item can be measured reliably.

Property, plant and equipment is initially measured at cost.

The cost of an item of property, plant and equipment is the purchase price and other costs attributable to bring the asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Trade discounts and rebates are deducted in arriving at the cost.

Where an asset is acquired through a non-exchange transaction, its cost is its fair value as at date of acquisition.

Where an item of property, plant and equipment is acquired in exchange for a non-monetary asset or monetary assets, or a combination of monetary and non-monetary assets, the asset acquired is initially measured at fair value (the cost). If the acquired item's fair value was not determinable, it's deemed cost is the carrying amount of the asset(s) given up.

When significant components of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment.

Costs include costs incurred initially to acquire or construct an item of property, plant and equipment and costs incurred subsequently to add to, replace part of, or service it. If a replacement cost is recognised in the carrying amount of an item of property, plant and equipment, the carrying amount of the replaced part is derecognised.

Property, plant and equipment are depreciated on the straight line basis over their expected useful lives to their estimated residual value.

Property, plant and equipment is carried at cost less accumulated depreciation and any impairment losses.

The useful lives of items of property, plant and equipment have been assessed as follows:

Item	Depreciation method	Average useful life
Furniture and fittings	Straight line	10 –14 years
Computer equipment	Straight line	5 – 7 years
Computer software	Straight line	7 years
Other assets	Straight line	10 years

Items of property, plant and equipment are derecognised when the asset is disposed of or when there are no further economic benefits or service potential expected from the use of the asset.

The gain or loss arising from the derecognition of an item of property, plant and equipment is included in surplus or deficit when the item is derecognised. The gain or loss arising from the derecognition of an item of property, plant and equipment is determined as the difference between the net disposal proceeds, if any, and the carrying amount of the item.

ACCOUNTING POLICIES(continued)

1.6 Financial instruments

Initial recognition

The entity recognises a financial asset or a financial liability in its Statement of Financial Position when, and only when, the entity becomes a party to the contractual provisions of the instrument.

Upon initial recognition the entity classifies financial instruments or their component parts as a financial liabilities, financial assets or residual interests in conformity with the substance of the contractual arrangement and to the extent that the instrument satisfies the definitions of a financial liability, a financial asset or a residual interest.

Initial measurement of financial assets and financial liabilities

When a financial instrument is recognised, the entity measures it initially at its fair value plus, in the case of a financial asset or a financial liability not subsequently measured at fair value, transaction costs that are directly attributable to the acquisition or issue of the financial asset or financial liability.

Subsequent measurement of financial assets and financial liabilities

The entity measures all financial assets and financial liabilities after initial recognition using the following categories:

- Financial instruments at fair value.
- Financial instruments at amortised cost.
- Financial instruments at cost.

All financial assets measured at amortised cost, or cost, are subject to an impairment review. Financial instruments at fair value comprise financial assets or financial liabilities that are combined instruments that are designated at fair value;

Financial instruments at amortised cost are nonderivative financial assets or nonderivative financial liabilities that have fixed or determinable payments, excluding those instruments that the entity designates at fair value at initial recognition

Financial instruments at cost are investments in residual interests that do not have a quoted market price in an active market, and whose fair value cannot be reliably measured.

The entity assesses which instruments should be subsequently measured at fair value, amortised cost or cost, based on the definitions of financial instruments at fair value, financial instruments at amortised cost or financial instruments at cost as set out above.

Gains and losses

A gain or loss arising from a change in the fair value of a financial asset or financial liability measured at fair value is recognised in surplus or deficit.

For financial assets and financial liabilities measured at amortised cost or cost, a gain or loss is recognised in surplus or deficit when the financial asset or financial liability is derecognised or impaired, or through the amortisation process.

Impairment and uncollectibility of financial assets

The entity assesses at the end of each reporting period whether there is any objective evidence that a financial asset or group of financial assets is impaired.

Financial assets measured at amortised cost:

If there is objective evidence that an impairment loss on financial assets measured at amortised cost has been incurred, the amount of the loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows (excluding future credit losses that have not been incurred) discounted at the financial asset's original effective interest rate. The carrying amount of the asset is reduced directly. The amount of the loss is recognised in surplus or deficit.

If, in a subsequent period, the amount of the impairment loss decreases and the decrease can be related objectively to an event occurring after the impairment was recognised, the previously recognised impairment loss is reversed directly. The reversal does not result in a carrying amount of the financial asset that exceeds what the amortised cost would have been had the impairment not been recognised at the date the impairment is reversed. The amount of the reversal is recognised in surplus or deficit.

Financial assets measured at cost:

If there is objective evidence that an impairment loss has been incurred on an investment in a residual interest that is not measured at fair value because its fair value cannot be measured reliably, the amount of the impairment loss is measured as the difference between the carrying amount of the financial asset and the present value of estimated future cash flows discounted at the current market rate of return for a similar financial asset. Such impairment losses are not reversed.

Derecognition

Financial assets

The entity derecognises financial assets using trade date accounting.

The entity derecognises a financial asset only when:

- the contractual rights to the cash flows from the financial asset expire, are settled or waived;

ACCOUNTING POLICIES(continued)

- the entity transfers to another party substantially all of the risks and rewards of ownership of the financial asset; or
- the entity, despite having retained some significant risks and rewards of ownership of the financial asset, has

transferred control of the asset to another party and the other party has the practical ability to sell the asset in its entirety to an unrelated third party, and is able to exercise that ability unilaterally and without needing to impose additional restrictions on the transfer. In this case, the entity :

- derecognise the asset; and
- recognise separately any rights and obligations created or retained in the transfer.

Financial liabilities

The entity removes a financial liability (or a part of a financial liability) from its statement of financial position when it is extinguished – i.e. when the obligation specified in the contract is discharged, cancelled, expires or waived.

An exchange between an existing borrower and lender of debt instruments with substantially different terms is accounted for as having extinguished the original financial liability and a new financial liability is recognised. Similarly, a substantial modification of the terms of an existing financial liability or a part of it is accounted for as having extinguished the original financial liability and having recognised a new financial liability.

1.7 Leases

Leases are classified as finance leases where substantially all the risks and rewards associated with ownership of an asset are transferred to the entity through the lease agreement. Assets subject to finance leases are recognised in the Statement of Financial Position at the inception of the lease, as is the corresponding finance lease liability.

Assets subject to operating leases, i.e. those leases where substantially all of the risks and rewards of ownership are not transferred to the lessee through the lease, are not recognised in the Statement of Financial Position. The operating lease expense is recognised over the course of the lease arrangement.

The determination of whether an arrangement is, or contains, a lease is based on the substance of the arrangement at inception date; namely whether fulfillment of the arrangement is dependent on the use of a specific asset or assets or the arrangement conveys a right to use the asset.

Finance leases – lessee

Assets subject to a finance lease, as recognised in the Statement of Financial Position, are measured (at initial recognition) at the lower of the fair value of the assets and the present value of the future minimum lease payments. Subsequent to initial recognition these capitalised assets are depreciated over the contract term.

The finance lease liability recognised at initial recognition is measured at the present value of the future minimum lease payments. Subsequent to initial recognition this liability is carried at amortised cost, with the lease payments being set off against the capital and accrued interest. The allocation of the lease payments between the capital and interest portion of the liability is effected through the application of the effective interest method.

The finance charges resulting from the finance lease are expensed, through the Statement of Financial Performance, as they accrue. The finance cost accrual is determined using the effective interest method.

Any contingent rents are expensed in the period in which they are incurred.

The finance lease liabilities are derecognised when the entity's obligation to settle the liability is extinguished. The assets capitalised under the finance lease are derecognised when the entity no longer expects any economic benefits or service potential to flow from the asset.

Operating leases – lessee

The lease expense recognised for operating leases is charged to the Statement of Financial Performance on a straight-line basis over the term of the relevant lease. To the extent that the straight-lined lease payments differ from the actual lease payments the difference is recognised in the Statement of Financial Position as either lease payments in advance (operating lease asset) or lease payments payable (operating lease liability) as the case may be. This resulting asset and / or liability is measured as the undiscounted difference between the straight-line lease payments and the contractual lease payments.

The operating lease liability is derecognised when the entity's obligation to settle the liability is extinguished. The operating lease asset is derecognised when the entity no longer anticipates economic benefits to flow from the asset.

1.8 Impairment

Cash-generating assets are assets used with the objective of generating a commercial return. Commercial return means that positive cash flows are expected to be significantly higher than the cost of the asset.

Impairment is a loss in the future economic benefits or service potential of an asset, over and above the systematic recognition of the loss of the asset's

ACCOUNTING POLICIES(continued)

future economic benefits or service potential through depreciation (amortisation).

Carrying amount is the amount at which an asset is recognised in the statement of financial position after deducting any accumulated depreciation and accumulated impairment losses thereon.

A cash-generating unit is the smallest identifiable group of assets used with the objective of generating a commercial return that generates cash inflows from continuing use that are largely independent of the cash inflows from other assets or groups of assets.

Costs of disposal are incremental costs directly attributable to the disposal of an asset, excluding finance costs and income tax expense.

Depreciation (Amortisation) is the systematic allocation of the depreciable amount of an asset over its useful life.

Fair value less costs to sell is the amount obtainable from the sale of an asset in an arm's length transaction between knowledgeable, willing parties, less the costs of disposal.

Recoverable amount of an asset or a cash-generating unit is the higher its fair value less costs to sell and its value in use.

Useful life is either:

- the period of time over which an asset is expected to be used by the entity;

1.9 Impairment of non-cash-generating assets

Recognition and measurement

The entity assesses at each reporting date whether there is an indication that an asset may be impaired. Where the carrying amount of an asset exceeds its recoverable amount the asset is considered impaired and is written down to its recoverable amount. An assets recoverable amount is the higher of the fair value less costs to sell, and the value-in-use of the asset.

This recoverable amount is determined for individual assets, unless those individual assets are part of a larger cash generating unit, in which case the recoverable amount is determined for the whole cash generating unit.

An asset is part of a cash generating unit where that asset does not generate cash inflows that are largely independent of those from other assets or group of assets.

In determining the recoverable amount of an asset the entity evaluates the assets to determine whether the assets are cash generating assets or non-cash generating assets.For cash generating assets the value in use is determined as a function of the discounted future cash flows from the asset.

Where the asset is a non-cash generating asset the value in use is determined through one of the following approaches:

Depreciated replacement cost approach – The current replacement cost of the asset is used as the basis for this value. This current replacement cost is depreciated for a period equal to the period that the asset has been in use so that the final depreciated replacement cost is representative of the age of the asset.

In assessing value-in-use for cash-generating assets, the estimated future cash flows are discounted to their present value using a discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. In determining fair value less costs to sell, other fair value indicators are used.

Impairment losses of continuing operations are recognised in the Statement of Financial Performance in those expense categories consistent with the function of the impaired asset.

An assessment is made at each reporting date as to whether there is any indication that previously recognised impairment losses may no longer exist or may have decreased. If such indication exists, the Entity makes an estimate of the assets or cash-generating unit's recoverable amount.

Reversal of an impairment loss

A previously recognised impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognised. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognised for the asset in prior years. Such reversal is recognised in the Statement of Financial Performance.

1.10 Employee benefits

Short-term employee benefits

Short term employee benefits encompasses all those benefits that become payable in the short term, i.e. within a financial year or within 12 months after the financial year. Therefore, short term employee benefits include remuneration, compensated absences and bonuses.

Short term employee benefits are recognised in the Statement of Financial Performance as services are rendered. These short term employee benefits are measured at their undiscounted costs in the period the employee renders the related service or the specific event occurs.

ACCOUNTING POLICIES(continued)

Post-employment benefits: Defined contribution plans

Contributions made towards the Government Employees Pension Fund are recognised as an expense in the Statement of Financial Performance in the period that such contributions become payable. This contribution expense is measured at the undiscounted amount of the contribution paid or payable to the fund. A liability is recognised to the extent that any of the contributions have not yet been paid. Conversely an asset is recognised to the extent that any contributions have been paid in advance.

1.11 Other provisions

Provisions shall be measured as the present value of the estimated future outflows required to settle the obligation.

Leave Provision shall be measured using the accumulated leave days and the cost of salaries.

1.12 Revenue from exchange transactions

Revenue from exchange transactions refers to revenue that accrues to the entity directly in return for services rendered or goods sold, the value of which approximates the consideration received or receivable, excluding indirect taxes, rebates and discounts.

Recognition

Revenue from exchange transactions is only recognised once all of the following criteria have been satisfied:

- the entity retains neither continuing managerial involvement to the degree usually associated with ownership nor
- effective control over the goods sold;
- the amount of revenue can be measured reliably; and
- it is probable that the economic benefits or service potential associated with the transaction will flow to the entity and the costs incurred or to be incurred in respect of the transaction can be measured reliably

Revenue arising out of situations where the entity acts as an agent on behalf of another entity (the principal) is limited to the amount of any fee or commission payable to the entity as compensation for executing the agreed services.

Measurement

Revenue is measured at the fair value of the consideration received or receivable, net of trade discounts and volume rebates.

Fair value is the amount for which an asset could be exchanged, or a liability settled, between knowledgeable, willing parties in an arm's length transaction.

Rendering of services

When the outcome of a transaction involving the rendering of services can be estimated reliably, revenue associated with the transaction is recognised by reference to the stage of completion of the transaction at the reporting date. The outcome of a transaction can be estimated reliably when all the following conditions are satisfied:

- the amount of revenue can be measured reliably;
- it is probable that the economic benefits or service potential associated with the transaction will flow to the entity;
- the stage of completion of the transaction at the reporting date can be measured reliably; and
- the costs incurred for the transaction and the costs to complete the transaction can be measured reliably.

When the outcome of the transaction involving the rendering of services cannot be estimated reliably, revenue is recognised only to the extent of the expenses recognised that are recoverable.

1.13 Revenue from non-exchange transactions

Non-exchange transactions are transactions that are not exchange transactions. In a non-exchange transaction, an entity either receives value from another entity without directly giving approximately equal value in exchange, or gives value to another entity without directly receiving approximately equal value in exchange.

Recognition

An inflow of resources from a non-exchange transaction recognised as an asset is recognised as revenue, except to the extent that a liability is also recognised in respect of the same inflow.

As SAHPRA satisfies a present obligation recognised as a liability in respect of an inflow of resources from a non-exchange transaction recognised as an asset, it reduces the carrying amount of the liability recognised and recognises an amount of revenue equal to that reduction.

Measurement

Revenue from a non-exchange transaction is measured at the amount of the increase in net assets recognised by SAHPRA.

When, as a result of a non-exchange transaction, SAHPRA recognises an asset, it also recognises revenue equivalent to the amount of the asset measured at its fair value as at the date of acquisition.

1.14 Fruitless and wasteful expenditure

Fruitless and wasteful expenditure means expenditure which was made in vain and would have been avoided had reasonable care been exercised.

All expenditure relating to fruitless and wasteful expenditure is recognised as an expense in the statement of financial performance in the reporting period that the expenditure was incurred. The expenditure is

ACCOUNTING POLICIES(continued)

classified in accordance with the nature of the expense, and where recovered, it is subsequently accounted for as revenue in the statement of financial performance.

A register of Fruitless and Wasteful Expenditure is maintained.

1.15 Irregular expenditure

Irregular expenditure as defined in section 1 of the PFMA is expenditure incurred in contravention of or that is not in accordance with a requirement of any applicable legislation, including PFMA.

National Treasury practice note No. 4 of 2008/2009 which was issued in terms of sections 76(1) to 76(4) of the PFMA requires the following (effective from 1 April 2008):

Irregular expenditure that was incurred and identified during the current financial and which was condoned before year end and/or before finalisation of the financial statements must also be recorded appropriately in the irregular expenditure register. In such an instance, no further action is also required with the exception of updating the note to the financial statements.

Irregular expenditure that was incurred and identified during the current financial year and for which condonement is being awaited at year end must be recorded in the irregular expenditure register. No further action is required with the exception of updating the note to the financial statements.

Irregular expenditure that was incurred and identified during the current financial year and which was not condoned by the National Treasury or the relevant authority must be recorded appropriately in the irregular expenditure register. If liability for the irregular expenditure can be attributed to a person, a debt account must be created if such a person is liable in law. Immediate steps must thereafter be taken to recover the amount from the person concerned. If recovery is not possible, the accounting officer or accounting authority may write off the amount as debt impairment and disclose such in the relevant note to the financial statements. The irregular expenditure register must also be updated accordingly. If the irregular expenditure has not been condoned and no person is liable in law, the expenditure related thereto must remain against the relevant programme/expenditure item, be disclosed as such in the note to the financial statements and updated accordingly in the irregular expenditure register.

1.16 Budget information

Budget information in accordance with GRAP 1 and 24, shall be provided in a separate disclosure note to the annual financial statements.

The approved budget is prepared on a accrual basis and presented by economic classification linked to performance outcome objectives.

The approved budget covers the fiscal period from April to March annually.

The financial statements and the budget are on the same basis of accounting therefore. A comparison with the budgeted amounts for the reporting period have been included in the Statement of comparison of budget and actual amounts.

1.17 Related parties

A related party is a person or an entity with the ability to control or jointly control the other party, or exercise significant influence over the other party, or vice versa, or an entity that is subject to common control, or joint control.

Control is the power to govern the financial and operating policies of an entity so as to obtain benefits from its activities.

Joint control is the agreed sharing of control over an activity by a binding arrangement, and exists only when the strategic financial and operating decisions relating to the activity require the unanimous consent of the parties sharing control (the venturers).

Related party transaction is a transfer of resources, services or obligations between the reporting entity and a related party, regardless of whether a price is charged.

Significant influence is the power to participate in the financial and operating policy decisions of an entity, but is not control over those policies.

Management are those persons responsible for planning, directing and controlling the activities of the entity, including those charged with the governance of the entity in accordance with legislation, in instances where they are required to perform such functions.

Close members of the family of a person are considered to be those family members who may be expected to influence, or be influenced by, that management in their dealings with the entity.

The entity is exempt from disclosure requirements in relation to related party transactions if that transaction occurs within normal supplier and/or client/recipient relationships on terms and conditions no more or less favourable than those which it is reasonable to expect the entity to have adopted if dealing with that individual entity or person in the same circumstances and terms and conditions are within the normal operating parameters established by that reporting entity's legal mandate.

Where the entity is exempt from the disclosures in accordance with the above, the entity discloses narrative information about the nature of the transactions and the

ACCOUNTING POLICIES(continued)

related outstanding balances, to enable users of the entity's financial statements to understand the effect of related party transactions on its financial statements.

1.18 Events after reporting date

Events after reporting date are those events, both favourable and unfavourable, that occur between the reporting date and the date when the financial statements are authorised for issue. Two types of events can be identified:

- those that provide evidence of conditions that existed at the reporting date (adjusting events after the reporting date); and
- those that are indicative of conditions that arose after the reporting date (non-adjusting events after the reporting date).

The entity will adjust the amount recognised in the financial statements to reflect adjusting events after the reporting date once the event occurred.

The entity will disclose the nature of the event and an estimate of its financial effect or a statement that such estimate cannot be made in respect of all material non-adjusting events, where non-disclosure could influence the economic decisions of users taken on the basis of the financial statements.

Notes to the Financial Statements

for the 14 months ended 31 March 2019

2. New standards and interpretations

2.1 Standards and interpretations issued, but not yet effective

The entity has not applied the following standards and interpretations, which have been published and are mandatory for the entity's accounting periods beginning on or after April 1, 2019 or later periods. The below standards will be applied when they become effective:

Standard/ Interpretation:	Effective date: Years beginning on or after	Expected impact:
• GRAP 32: Service Concession Arrangements: Grantor	01 April 2019	Unlikely there will be a material impact
• GRAP 104: Financial Instruments	to be confirmed	Unlikely there will be a material impact
• GRAP 108: Statutory Receivables	01 April 2019	Unlikely there will be a material impact
• GRAP 109: Accounting by Principals and Agents	01 April 2019	Unlikely there will be a material impact
• IGRAP 17: Service Concession Arrangements where a Grantor Controls a Significant Residual Interest in an Asset	01 April 2019	Unlikely there will be a material impact

3. Receivables from exchange transactions

	14 months ended 31 March 2019 R'000
Trade debtors	2 660 447
Rental deposit	706 854
	3 367 301

Trade debtors relates to inspectorate services provided and not yet invoiced as at year end.

Trade and other receivables pledged as security

None of the trade and other receivables were pledged as security for any obligation

4. Prepayments

	14 months ended 31 March 2019 R'000
Prepayments	269 927

The balance relates to licence fee, membership fees

5. Cash and cash equivalents

	14 months ended 31 March 2019 R'000
Cash and cash equivalents consist of:	
Bank balance held at ABSA bank	103 656 936

Credit quality of cash at bank

The credit quality of cash at bank held at ABSA Bank that are neither past due nor impaired can be assessed by reference to external credit ratings of AA was ascribed by the financial institution. The entity's maximum exposure to credit risk as a result of the bank balances held is limited to the carrying value of these balances as detailed above.

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

6. Property, plant and equipment

	2019		
	Cost /Valuation	Accumulated depreciation and accumulated impairment	Carrying value R'000
Furniture and fittings	3 140 934	(234 895)	2 906 039
Computer equipment	3 220 767	(446 606)	2 774 161
Other fixed assets	1 684 334	(151 044)	1 533 290
Total	**8 046 035**	**(832 545)**	**7 213 490**

Reconciliation of property, plant and equipment – 2019

	Opening balance	Additions	Transfers received	Depreciation	Disposals	Total R'000
Furniture and fittings	–	53 979	3 086 955	(234 895)	–	2 906 039
Computer equipment	–	134 543	3 111 889	(450 301)	(21 970)	2 774 161
Other fixed assets	–	–	1 684 334	(151 044)	–	1 533 290
	–	**188 522**	**7 883 178**	**(836 240)**	**(21 970)**	**7 213 490**

Pledged as security

None of the property plant and equipment were pledged as security for any obligation. There are no future contractual commitments for acquisition of property plant and equipment.

7. Payables from exchange transactions

	14 months ended 31 March 2019 R'000
Trade payables	29 964 711
Refunds due	443 519
Salary accrual	2 346 285
PAYE	261 453
UIF	7 733
SDL	12 494
	33 036 195

Trade payables principally comprise amounts outstanding for trade purchases and ongoing costs. The majority of trade payables relate to amount due to the National Department of Health for expenditure incurred on behalf of SAHPRA. TheAuthority considers that the carrying value of trade and other payables approximates the fair value.

Salary accruals relates mainly to travel and inconvience allowance due to employees.

Refunds due are those payments received by the Authority in error, duplicate or for services not required from the Authority.

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

8. Conditional grant

	14 months ended 31 March 2019 R'000
Clinton Health Access Initiative Grant	1 441 170

This relates to funding provided to SAHPRA by Clinton Health Access Initiative (a non-profit organization) to support the backlog reduction project to be implemented in the 2019/2020 financial period. The funds are specifically to support expert review and registration of medicine and devices deemed to be national priorities and public health imperative such as those related to HIV/AIDS, TB, Maternal and Child Health and Non-Communicable Diseases.

9. Provisions

	14 months ended 31 March 2019 R'000
Leave provision 6,263,516	6 263 516
Performance management and development system provision	3 200 000
	9 463 516

Leave provision

The Authority does not have an unconditional right to defer settlement of its leave liabilities and its policies stipulate that leave is forfeited if not used within 6 months after the start of a calendar year, except for capped leave. A significant part of the leave provision balance relates to take on balance for employees who were transferred from the National Department of Health to SAHPRA.

	Current Cycle Pro-Rata R'000	Previous Cycle R'000	Capped Leave R'000	Total R'000
As at 1 April 2018	1 703 963	1 495 356	878 921	4 078 240
Movement for the year	621 201	1 560 485	3 590	2 185 276
As at 31 March 2019	**2 325 164**	**3 055 841**	**882 511**	**6 263 516**

Performance management and development system provision

The Performance management and development system (PMDS) bonus individual assessment process for 2018-19 was not concluded at the time of finalisation of the financial statement. Management has made a provision based on a constructive obligation as a result of past performance bonus payments. The provision was calculation was based on the data for 2017-18 PMDS cycle.

10. Deferred income

	14 months ended 31 March 2019 R'000
Deferred income	35 589 600

The deferred income relates to revenue received in advance for the backlog reduction project to be implemented in the 2019/2020 financial period.

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

11. Fee Income

	14 months ended 31 March 2019 R'000
Section 21	3 747 690
Section 21 Veterinary	240 755
Screening	1 256 280
Clinincal trials	4 273 603
License fees	11 890 319
Post screening	19 219 590
Permits	4 928 311
Veterinary	45 000
Amendments	2 158 190
Inspection Fees	5 777 656
Fast Track	232 160
Retention fees	12 584 337
Certificates	630 820
Registration Fee	5 075 061
	72 059 772

Fees received per function

Medicines evaluation, registration and product lifecycle	40 570 619
Inspections, permits and licences issued	23 227 105
The use of unregistered medicines	8 262 048
Total	**72 059 772**

12. Interest received

	14 months ended 31 March 2019 R'000
Interest received	4 907 134

Interest received from current account held at ABSA Bank at an average interest rate of 5.25% per annum.

13. Transfer payment

	14 months ended 31 March 2019 R'000
Government grants	
Transfer payment from the National Department of Health	125 189 000

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

14. Good and services in-kind from NDOH

	14 months ended 31 March 2019 R'000
Revenue from non exchange transactions in-kind donation	(29 124 227)
Expenditure relating to in-kind donation	29 124227
	–

At the commencement of SAHPRA's independent operations following the first Board meeting, NDOH paid for its expenses for the period between 1 February 2018 to 31 March 2018 which were not refunded by SAHPRA. As the result SAHPRA accounted for the expenditure during that period as an in-kind donation by the NDOH. The expenses were made up of salaries, goods and services.15. Employee related costs

Sundry HR costs relates to the inconvenience allowance for SAHPRA staff members relating to the additional travel between SAHPRA's previous and current interim offices.

Basic and non-pensionable salaries	90 622 649
Service and perfomance bonus	11 063 433
Medical aid	2 484 515
UIF	7 733
SDL	12 494
Bargaining council	14 724
Pension fund	8 652 606
PAYE	321 830
Travel allowances	5 850
Overtime payments	90
Housing benefits and allowances	2 419 396
Leave accrued	2 436 039
Sundry HR Costs*	920 140
Standby allowances	105 157
	119 066 656

16. Depreciation

	14 months ended 31 March 2019 R'000
Property, plant and equipment	836 240

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

17. Lease rentals on operating lease

	14 months ended 31 March 2019 R'000
Premises	
Contractual amounts	1 857 473

Rental of office space at the CSIR campus in Pretoria. The contract was entered into in December 2018 and expires in July 2019. The Authority has an option for a month-to-month renewal up to November 2019.

Outsourced Services	
NCL Laboratory	19 992 200

18. Contracted services

The NCL Laboratory is an outsourced services for testing of biological medicine and vaccines on behalf of the Authority.

19. Operating expenses

	14 months ended 31 March 2019 R'000
Advertising	637 629
Bank charges	55 304
Board Costs	1 022 550
Catering	217 962
Communication	750 774
Computer expenses	548 648
Conferences and seminars	13 500
Consulting and professional fees	551 857
Expert committees	7 351 581
General expenses	9 787
Membership fees	36 318
Motor vehicle expenses	7 436 229
Photocopiers rental expense	450 623
Postage and courier	197 768
Printing and publication	169 158
Printing and stationery	418 015
Psychometric assessments	107 470
Refunds processed	15 147
Relocation of SAHPRA	1 117 379
Repairs and maintenance	8 097
Research and development costs	49 214
Staff relocation	35 076
Staff training	78 067
Staff welfare	8 897
Travel - local and overseas	7 449 437
Travel local and overseas – SAHPRA Board	471 550
Venues and facilities	1 100
	29 209 137

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

20. Cash generated from operations

	14 months ended 31 March 2019 R'000
Surplus	31 172 232
Adjustments for:	
Depreciation and amortisation	836 240
Loss on disposal of assets and liabilities	21 970
Movements in provisions	5 385 279
Changes in working capital:	
Receivables from exchange transactions	(3 367 301)
Prepayments	(269 927)
Payables from exchange transactions	33 036 195
Conditional grant	1 441 170
Deferred income	35 589 600
	103 845 458

21. Commitments

- Extension of NCL contract	3 028 548
- Single supplier of eCTD software	2 700 000
- Supply of IT equipment and related IT expenditure	1 201 902
- Consultant	1 130 384
- Open orders	997 192
- Legal services	85 000
	9 109 684

Authorised expenditure

The following commitments were made during the financial year. Services and goods were secured but not yet rendered and delivered as at the end of the financial year:

This committed expenditure will be financed by allocated operational budget of future years.

Operating leases – as lessee (expense)

Operating lease payments represent rentals payable by the entity for leased office space. No contingent rent is payable.

Minimum lease payments due	
– within one year	1 859 211

22. Comparative figures

No comparative figures have been presented as these are the first financial statements of the entity.

23. Risk management

Financial risk management

The entity's activities expose it to a variety of financial risks: market risk, credit risk and liquidity risk.

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

23. Risk management(continued)

Liquidity risk

The entity's risk to liquidity is a result of the funds available to cover future commitments. The entity manages liquidity risk by monitoring forecasted cashflows and ensuring that the necessary funds are available to meet any commitments which may arise.

Exposure to liquidity risk

The following table reflects the commission's exposure to liquidity risk from financial liabilities:

	Carrying amount	Total Cashflow	Contractual Cashflow within one year	Contractual Cashflow between two and five years
Payables from exchange transactions	24 953 836	24 953 836	24 953 836	–

	Neither past due nor impaired	Past due but not impaired – less than two months	Past due but not impaired – more than two months	Carrying amount
Cash and cash equivalents	103 656 936	–	–	103 656 936
Receivables from exchange transactions	3 367 301	–	–	3 367 301
	107 024 237	–	–	107 024 237

Credit risk

The entity's services are paid for in advance with exception of revenue from inspections. Revenue from inspection is done on request by the customer and is a regulatory requirement., Receivables balances are monitored on an ongoing basis with the result that the entity's exposure to bad debts is not significant. The maximum exposure is the carrying amounts as disclosed. There is no significant concentration of credit risk within the entity. With respect to credit risk arising from the other financial assets of the entity, which comprise cash and cash equivalents, the entity's exposure to credit risk arises from default of the counterparty, with a maximum exposure equal to the carrying amount of these instruments. The entity cash and cash equivalents are placed with high credit quality financial institutions therefore the credit risk with respect to cash and cash equivalents is low. Trade and other receivables are not rated.

	14 months ended 31 March 2019 R'000
Financial instrument	
Cash and cash equivalents	103 656 936

Financial assets exposed to credit risk at 14 months' end were as follows:

Market risk

Interest rate risk

As the entity has no significant interest-bearing assets, the entity's income and operating cash flows are substantially independent of changes in market interest rates.

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

24. Going concern

The financial statements have been prepared on the basis of accounting policies applicable to a going concern. This basis presumes that funds will be available to finance future operations and that the realisation of assets and settlement of liabilities, contingent obligations and commitments will occur in the ordinary course of business.

25. Reconciliation between budget and statement of financial performance

Reconciliation of budget surplus/deficit with the surplus/deficit in the statement of financial performance:

	14 months ended 31 March 2019 R'000
Net surplus per the statement of financial performance	31 172 232
Adjusted for:	
Decrease in Fee Income	18 621 228
Increase in interest received	(4 907 134)
Under expenditure on Employee related costs	(30 078 724)
Under expenditure on Administration fees	(135 000)
Over expenditure on operating lease	737 473
Under expenditure on operating expenses	(36 260 484)
Over expenditure on depreciation	836 240
Over expenditure on contracted services	19 992 200
Over expenditure on Loss of disposal of assets	21 969
Net surplus per approved budget	–

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

26. Related parties

Relationships

Members of key management	Members of the Executive Authority
National Department of Health	National Department in National sphere
Council for Scientific and Industrial Research	Public entity in National sphere
Provincial Department of Health – Western Cape	Provincial Department
Provincial Department of Health – Limpopo	Provincial Department

	14 months ended 31 March 2019 R'000
Related party balances	
Amounts included in trade payables regarding related parties	
National Department of Health	26 719 222
Related party transactions	
National Department of Health	
Government grant received	125 189 000
Provincial Department of Health – Western Cape^	
Inspection depot	5 500
Provincial Department of Health – Limpopo^	
Inspection of depots	11 000
Council for Scientific and Industrial Research	
Rental expense	1 857 473

^ During the period under review only medical depots in Western Cape and Limpopo provinces were inspected.

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

26. Related parties (continued)

Remuneration of Executive Authority and Management

Board fees*****

2019

	Board Fees	Travel	Total R'000
Prof H V Rees – Chairperson	81 661	10 568	92 229
Ms M Hela – Deputy Chairperson***	132 658	5 565	138 223
Prof M S Banoo – Member	35 737	3 685	39 423
Dr E N Madela-Mntla – Member	101 234	6 282	107 516
Dr H M J Leng *	72 736	4 397	56 168
Dr T M Motshudi – Member	25 684	3 095	28 779
Prof K Chibale – Member **	24 207	–	24 207
Prof A Dhai – Member	12 872	–	12 872
Prof M J Mphahlele – Member ****	–	–	–
Dr U Mehta – Member	78 582	–	78 582
Dr M S M Molefe – Member ****	–	–	–
Adv H Cassim – Member	84 561	5 988	90 549
Ms L J Fosu – Member	91 862	7 387	99 248
Mr T N Baloyi – Member	69 988	50 018	120 006
Prof K C Household – Member	111 853	–	111 853
	902 670	**96 985**	**999 655**

* Resigned 15 August 2018

** Resigned 27 March 2019

*** Ms Hela was seconded from the Board to support the Acting CEO to execute her duties from 1 February 2019

**** Prof J Mphahlele and Dr MSM Molefe are employees in the public sector – no fees claimed

***** The board fees reflects the actual claims submitted. At times board members opt not to claim for meetings attended

Executive management

2019

	Basic salary	Pension Fund	Other benefits received	Total R'OOO
P Nkambule – Acting Chief Executive Officer *	918 912	94 785	25 920	1 039 617
M.K. Kgauwe – Chief Financial Officer **	74 060	–	–	74 060
	992 972	**94 785**	**25 920**	**1 113 677**

* Appointed - 01 February 2018

**Appointed - 15 March 2019

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

27. Budget differences

Material differences between budget and actual amounts

27.1 Fee Income

Fee income is below budget due to services that could not be rendered as a result of industrial action at the NDOH premises were SAHPRA was accommodated.

27.2 Interest Received

Interest is higher than budget due to more funds in the bank than expected.

27.3 Employee Related Costs

Employee related costs are lower than budget due to vacancies.

27.4 Depreciation

Depreciation is higher than the budget due to change of accounting basis from modified cash to accrual basis.

27.5 Contracted Services

Contracted services is higher than budget as it was provided for under operating expenses.

27.6 Operating Expenses

Operating expenses is more than budget due to less transactions as a result of the industrial action and the contracted services above.

28. Contingent liabilities

Claim against SAHPRA

A medical device company instituted a legal action amounting to R3,82 million against the National Department of Health

(NDOH) and SAHPRA for the recovery of money that the company had paid in respect of the Section 21 applications from June 2009 to September 2014. The claim is based on the alleged communication issued by MCC in 2014, saying that a Section 21 fee should be paid in respect of each medical practitioner application as opposed to individual application. At this stage the possible outcome is inconclusive.

29. Donor funding

29.1 Bill and Melinda Gates Foundation

During the year under review, SAHPRA received an in-kind donation from the Bill and Melinda Gates Foundation (BMGF). There is an in principle agreement in place between SAHPRA and the BMGF to financially support the “Backlog Reduction Project”. The support is specifically for:

- Provide ongoing backlog clearance programme leadership and support to SAHPRA’s Board and Incoming Executive team to drive and assure smooth implementation by SAHPRA on the required activities.
- Develop detailed strategy to leverage new evaluation policies and processes from the backlog reduction project for “Business-as-usual” to ensure SAHPRA has a fundamentally new way of doing business, improving its absorption capacity and preventing any future backlog development.
- Enable the sustainability of the project management office (PMO) beyond conclusion of the support, identifying and training experienced project managers to deliver expected results with required visibility and transparency to SAHPRA’s board, executive team and other public health stakeholders.

Included in this support is consulting and project management services led by the Boston Consulting Group. The maximum benefit for the period under review amounts to R27.6 million.

29.2 Public Health Enhancement Fund

During the year under review, SAHPRA received an in-kind donation from the Public Health Enhancement Fund (PHEF) to assist SAHPRA with crisis project management support. The objectives of this support are:

- Support the Office of the CEO with a systematic approach to triage, assess and crisis manage the operations of urgent regulatory functions - preventing avoidable loss of lives
- Develop strategies to support sustainable, efficient management of these urgent regulatory functions
- Work in a complex stakeholder environment to identify broader risks within SAHPRA’s day- to-day operations and develop plans to address those risks before they impact public health
- Develop rigorous project governance, provide transparency to the Board, and build capacity in SAHPRA staff to foresee, prevent and manage possible future crises.

The benefit received for the period under review amounts to R2,58 million

29.3 Right to Care

During the year under review, SAHPRA received an in-kind donation from the Right to Care to assist SAHPRA with office accommodation to host the Backlog Reduction Project team at their offices in Centurion. The benefit received for the period under review amounts to R94 204.00

Notes to the Financial Statements(continued)

for the 14 months ended 31 March 2019

30. Transfer of functions between entities under common control

Nature of transfer

Entities involved in the transfer of functions were the NDoH (transferor) and SAHPRA (acquirer). The functions relating to the regulation of health products intended for human and animal use; the licensing of manufacturers, wholesalers and distributors of medicines, medical devices, radiation emitting devices and radioactive nucleides; and the conduct of clinical trials were transferred to SAHPRA. The transfer was in terms of the transitional provisions of the Medicines and Related Substances Act, (Act 14 of 2015), as amended. The transfer became effective following the 1st meeting of the SAHPRA Board on 1 February 2018.

Value of the assets acquired and liabilities assumed

During the 2019-20 further assets and liabilities will be transferred from the NDOH to SAHPRA.

	14 months ended 31 March 2019 R'000
Assets acquired	
Property, plant and equipment	7 883 178
Liabilities assumed	
Provision for leave	4 070 241
Difference between assets and liabilities transfered	3 804 939

31. Irregular Expenditure

	14 months ended 31 March 2019 R'000
Opening balance	–
Add: Irregular expenditure - current year	1 206 785
Less: Amount condoned	–
	1 206 785

Details of irregular expenditure

The irregular expenditure relates to non-compliance with Supply Chain Management regulations. Management will attend to the irregular expenditure in line with the guideline issued by National Treasury.

SAHPRA
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HEALTH PRODUCTS
REGULATORY AUTHORITY

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