SAHPRA

South African
Health Products
Regulatory Authority

ANNUAL REPORT 2019/20

CONTENTS

PART A:

GENERAL INFORMATION

1. PUBLIC ENTITY'S GENERAL INFORMATION

REGISTERED NAME:	South African Health Products Regulatory Authority (SAHPRA)
REGISTRATION NUMBER (if applicable):	Not applicable
PHYSICAL ADDRESS:	Building A Loftus Park 402 Kirkness Street Arcadia Pretoria
POSTAL ADDRESS:	South African Health Products Regulatory Authority Private Bag X828 Pretoria 0001
TELEPHONE NUMBER/S:	012 501 0300
E-MAIL ADDRESS:	enquiries@sahpra.org.za
WEBSITE ADDRESS:	www.sahpra.org.za
EXTERNAL AUDITORS:	Auditor-General of South Africa 300 Middel Street New Muckleneuk Pretoria
BANKERS:	ABSA 240 Vermeulen Street Pretoria Central Pretoria
COMPANY/BOARD SECRETARY:	Advocate Teboho Peter Nthotso

2. LIST OF ABBREVIATIONS/ACRONYMS

4 IR	Fourth Industrial Revolution
AA	Accounting Authority
ADR	Adverse Drug Reaction
AGSA	Auditor-Genaral of South Africa
API	Active Pharmaceutical Ingredient
APP	Annual Performance Plan
BAU	Business-as-Usual
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CMs	Complementary Medicines
COVID-19	Coronavirus Disease
CRO	Chief Regulatory Officer
CSP	Community Service Pharmacist
CSIR	Council for Scientific and Industrial Research
CTC	Clinical Trials Committee
DHCPL	Dear Healthcare Professional Letter
DMRE	Department of Mineral Resources and Energy
eCTD	Electronic Common Technical Document
EOI	Expression of Interest
EXCO	Executive Committee
ERM	Enterprise Risk Management
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GL	General Ledger
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GRAP	Standards of Generally Recognised Accounting Practice
GRP	Good Regulatory Practice
GVP	Good Vigilance Practice
GWP	Good Wholesaling Practice
GXP	Good Manufacturing, Laboratory, Wholesaling, Distribution, Clinical and Vigilance Practices
HIV/AIDS	Human Immunodeficiency Virus, Aquired Immunodeficiency Syndrome
HPA	Health Product Authorisation
HR	Human Resource

HR&Remco	Human Resources and Remuneration Committee
ICT	Information and Communication Technology
IESBA	International Ethics Standards Board for Accounts
IMS	Information Management System
ISAs	International Standards on Auditing
ITG	Industry Task Group
IVDs	In Vitro Diagnostics
KPI	Key Performance Indicator
MCC	Medicines Control Council
MOU	Memorandum of Understanding
MRA	Medicines Regulatory Authority
MTSF	Medium Term Strategic Framework
NDoH	National Department of Health
NDP	National Development Plan
NHA	National Health Act
NNR	National Nuclear Regulator
OTC	Over the Counter
PAA	Public Audit Act
PAIA	Promotion of Access to Information Act
PAJA	Promotion of Administrative Justice Act
PFMA	Public Finance Management Act
PMDS	Performance Management and Development System
POPIA	Protection of Personal Information Act
PPE	Personal Protective Equipment
PTG	Pharmaceutical Task Group
RAG	Risk, Audit and Governance
Remco	Remuneration Committee
SAHPRA	South African Health Products Regulatory Authority
SIU	Special Investigations Unit
TB	Tuberculosis
WHO	World Health Organisation

3. FOREWORD BY THE CHAIRPERSON

Prof. Helen Rees

Medicines regulation is a critical pillar of a country's health sector, ensuring that health products are safe, efficacious and of high quality, and that the framework guiding regulatory decisions is one of public health benefit. This Annual Report covers the period between 1 April 2019 to 31 March 2020 which included the onset of the Coronavirus (COVID-19) pandemic. The pandemic has challenged SAHPRA in a way that no one could have anticipated. Although the pandemic occurred only at the end of the reporting year under review, I nonetheless want to take the opportunity of this Chair's report to offer my wholehearted appreciation of the work being done by the SAHPRA Chief Executive Officer (CEO), her staff and SAHPRA Board members, to address the COVID-19 emergency. This has included SAHPRA developing emergency strategies to review, approve, license and regulate new products including lab tests, personal protective equipment, ventilators, Section 21 requests, and rapid approval of clinical trials. The structures, personnel and commitment that have evolved since SAHPRA was established in 2018 have provided the backdrop for SAHPRA's response to the current emergency.

Overall, the year has seen continued forward momentum in the establishment of an effective national regulator. In January 2020, the new SAHPRA CEO, Dr Boitumelo Semete-Makokotlela, was appointed and through her office a full executive and senior management team is being recruited. Dr Semete took over SAHPRA at a critical time with many important changes already underway but with many challenges, including Information Technology (IT) infrastructure and sub-optimal office space, requiring ongoing attention. The reins of the authority are now firmly in the hands of the CEO and her team. The CEO has introduced a new organisational structure and appointments are being made to support the new staff organogram. In addition, a process is underway to place existing staff transferred from the National Department of Health (NDoH) and the old Medicines Control Council (MCC) either into new positions or to be upskilled within existing roles. In the next year, Board members anticipate that the more 'hands on' approach that they have been required to take until now, including during the COVID-19 pandemic, will be replaced by a predominant focus on strategy and governance.

In parallel to staff changes, SAHPRA has continued to work on improving core outputs required for regulatory excellence and organisational efficiencies. Key to the establishment of SAHPRA as an effective regulator has been the 'Backlog Project'. In February 2018, the newly appointed SAHPRA Board and its acting CEO recognised that unless SAHPRA addressed the backlog of products awaiting licensure, it would never get out of the starting blocks. An ineffective regulator is first and foremost a threat to the integrity of the health sector and to its users, but it is also a threat to the pharmaceutical industry that relies on the efficiency of the regulatory authority to facilitate its core business. The subsequent priority that the SAHPRA Board and Executive has placed on rebuilding the regulatory authority in the context of changed legislation, has started to pay dividends. By the end of March 2020, I estimate that that we are about 58% of the way towards dealing with the backlog, and although we will not achieve this in the optimistic timeline of two years, we are hopeful that it will be substantially addressed by mid-2021. The partnership with industry in formulating the approach to

the backlog has been critical to its success to date. This flagship programme is supported by the Bill and Melinda Gates Foundation whose insight into the importance of SAHPRA's re-engineering project and confidence in SAHPRA's ability to transform has been unstinting.

The lessons learnt from the Backlog Project are being transferred into the 'Business as Usual' programme and efficiencies and revised timeframes for registration are being introduced. This includes the implementation of a new IT and Communications Strategy, and completely different ways of doing business including embracing the concept of reliance that formally takes into account decisions of other recognised regulatory authorities.

The complementary medicines programme has continued to expand in staff numbers and outputs, and given the overwhelming interest in the use of these health products, this is a focus that will require more attention over the next year. There continues to be significant national interest in the potential uses of cannabis products against the backdrop of the Constitutional Court ruling on private recreational use and the potential that cannabis in all its forms can provide a sustainable source of income for small farmers. To accommodate the Constitutional Court ruling, SAHPRA amended the schedules of cannabis-containing products which will also have the effect of facilitating the development of the local cannabis industry. To support these national efforts SAHPRA continues to be part of a multi-ministerial cannabis working group, recognising that our contribution is one element of a comprehensive national strategy.

The Medical Devices and in vitro diagnostics (IVDs) department has, of necessity, expanded its size and scope and is playing a critical role in SAHPRA's response to the COVID-19 pandemic. Alongside this, the use of Section 21 for unlicensed products has also been of critical importance for the pandemic response. However, the use of Section 21 legislation to solve questions of access to expensive medicines is an issue that SAHPRA continues to grapple with because of the legal framework in which it operates, and this will require ongoing consideration over the next year.

Another area of focus is Radiation Control. This was a new responsibility given to SAHPRA which has required the overhaul of its organogram and a revision of the legal framework that governs Radiation Control in consultation with the National Nuclear Regulator. This is work in progress and more needs to be done over the next year to ensure that this very important portfolio has proper oversight and management.

Lastly, attention is being paid to the importance of monitoring health product safety and of communicating information timeously to all stakeholders, including the public, about appropriate use of health products. SAHPRA has prioritised both these areas and a pharmacovigilance and communication strategy has been approved and is beginning to be introduced. But more work and creativity is required if we are going to achieve our ambition of being a 'go to' source of information and support to the public about all matters relating to health products.

In summary, this annual report reflects a period in which there has been continued re-engineering of SAHPRA. The SAHPRA Board has been outstanding throughout this challenging period both in their support for SAHPRA senior management but also in their willingness to use their respective skills and wisdom to support the development of SAHPRA. The building of a new style regulatory authority has been embraced and supported by both Minister Motsoaledi and Minister Mkhize, who continues to push SAHPRA to reflect upon and expand its role and effectiveness. At this point, SAHPRA is progressing well as an organisation, and with Dr Semete and her executive firmly at the helm, I am confident that we will ensure that SAHPRA becomes a truly fit-for-purpose national regulatory authority.

Chairperson of the Board

Prof. Helen Rees

Date: 30 October 2020

4. CHIEF EXECUTIVE OFFICER'S OVERVIEW

Dr Boitumelo Semete-Makokotlela

Since assuming the role of Chief Executive Officer of the South African Health Products Regulatory Authority in January 2020, I have embraced the challenge of re-positioning this critical entity so that it functions optimally as a world-class and an independent health products regulator.

I must thank the SAHPRA Chief Regulatory Officer (CRO) for acting as CEO of the entity since its inception. She has done a sterling job at ensuring that while SAHPRA transitions from MCC, it continues to ensure that South Africans have access to safe, efficacious and quality health products. This is SAHPRA's 2nd Annual Report and audited Financial Statements for the 2019/20 Financial Year presented as a Schedule 3A public entity. This report presents the Authority's performance in accordance with its mandate.

Being a newly established schedule 3A public entity, ensuring that SAHPRA complies with good governance practices was important. A number of SAHPRA policies, frameworks and guidelines were developed with the subsequent approval by the Board. Ministerial approval of the 2020-2024 Strategic Plan and the 2020-2021 Annual Performance Plan was secured. However, the presentation to Parliament, originally scheduled to take place in March 2020, was deferred owing to the national lockdown announced by the President of the Republic of South Africa.

The financial sustainability of SAHPRA remains to be an area that as a schedule 3A public entity, has to be closely monitored and supported. SAHPRA received a government grant of R183.3 million for the 2019/20 financial year. Revenue generated from fees amounted to R54 million and interest received amounted to R8.1 million. The new revised fees were developed and will be implemented in the 2020/21 financial year. This will go a long way to ensuring that SAHPRA has the resources required to offer the world-class service it aims to.

A key aspect in ensuring a world-class regulator, is creating a human capital base that is fit for purpose with the required skills sets to ensure delivery on our mandate. In working towards this objective, a phased-in approach was put in place to capacitate the organisation and a greater focus on the completion of the transfer of employees from NDoH to SAHPRA. The second critical aspect is ensuring that SAHPRA performs its role efficiently, through the implementation of global best practices approaches such as Reliance and continuously collaborating with international regulators. The 2019/20 financial year, saw the Reliance approach being piloted within the backlog project and an optimised Reliance model will continue to be implemented in the 2020/21 financial year. In addition, ensuring SAHPRA's processes are re-engineered and digitised will go a long way in achieving the objective of being a world-class, efficient regulator. In the age of the Fourth Industrial Revolution (4IR), SAHPRA is embracing digital technology and streamlining its processes, thereby gradually moving away from a traditionally paper-based approach to digitised systems. The strategy of digital technology to address the inherited medicines backlog will also be applied rigorously to the Business-as-Usual (BAU) processes, ensuring that SAHPRA does not create any further backlogs. In the 2019/20 financial year, SAHPRA met and in some instances exceeded 16 of its 28 organisational Key Performance Indicators (KPIs). This is commendable considering the challenges that the organisation faced including, but

not limited to, relocating from the Civitas building to the Council for Scientific and Industrial Research (CSIR) and implementing the new operating model.

SAHPRA enjoys favourable relationships with industry partners. Important platforms such as the Pharmaceutical Task Group (PTG) and the Industry Task Group (ITG) are valuable platforms that not only generate robust debate, but also to arrive at solutions that are realistic and mutually beneficial. The users of the health products that SAHPRA regulates are key stakeholders that SAHPRA engages with through its Pharmacovigilance programs and many others. Greater focus in the areas of post market surveillance and pharmacovigilance will be critical to ensuring that SAHPRA implements its mandate.

A key step towards providing a safe and conducive work environment that builds positive staff morale, was securing a fit for purpose accommodation to adequately support the functioning and well-being of the regulator's staff. Occupancy in the new premises took place in August 2020.

Clear and lucid communication is the backbone to any entity that strives to have an interactive relationship with its stakeholders. SAHPRA has embarked on a new corporate identity and this has been applied consistently on all of its platforms, a move that is a precursor to the move to SAHPRA's new home in Loftus Park. The newly designed website has been kept updated with "fresh/ new" content and boasts live feeds from SAHPRA's social media platforms. SAHPRA engaged the media proactively and these agents of mass communication view SAHPRA as a credible knowledge broker. The media has been important in supporting SAHPRA's knowledge dissemination process.

As SAHPRA re-engineers its processes and seeks definition through a new brand and new digital efficiencies at its new home, the stage is set for regeneration and growth for the Authority.

I wish to thank the SAHPRA Executive Management for their leadership and direction and their unstinting support in being a part of the evolution of SAHPRA. SAHPRA staff members must also be thanked for their hard work, dedication and commitment to the ethos that makes up SAHPRA. SAHPRA is also grateful to all its stakeholders who work with SAHPRA and who contribute in ways that ensure that SAHPRA executes its mandate for the benefit of all who live in South Africa. Finally, I must say thank you to the Board Chairperson, Professor Helen Rees, the Vice Chairperson, Ms Mandisa Hela and the rest of the Board members for their valuable guidance and support as SAHPRA encounters both challenges and accolades on the road to infinite success.

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer
Date: 30 October 2020

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

To the best of my knowledge and belief, I confirm the following:

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

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

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

The Annual Financial Statements (Part E) have been prepared in accordance with the Standards of Generally Recognised Accounting Practice (GRAP) applicable to the public entity.

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

The accounting authority is responsible for establishing and implementing a system of internal control that 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 are 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 resource information and the financial affairs of the public entity for the financial year ended 31 March 2020.

Yours faithfully

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Dr Boitumelo Semete-Makokotlela
Chief Executive Officer
Date: 30 October 2020

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Prof. Helen Rees
Chairperson of the Board
Date: 30 October 2020

6. STRATEGIC OVERVIEW

6.1 Vision and Mission

VISION

An agile, conscientious and socially transformative, globally positioned health products regulator with sustainable positive impact on long and healthy lives of all those living in South Africa

MISSION

To safeguard public and animal health by licensing of safe, effective and good quality medicines, medical devices, IVD's, radiation devices and radioactive materials. Further, to monitor clinical trials maintain vigilance and ensure regulatory compliance of these health products in South Africa

6.2 Values

- Care and Service Excellence
- Unity of Purpose
- Transformation
- Innovation
- Ethics and Integrity

7. STRATEGIC GOALS AND OBJECTIVES

The strategic goals and objectives for the 2019/20 financial year included:

GOAL 1: Demonstrate responsiveness and accountability as an effective and efficient high-performance organisation	• SAHPRA is an effective and efficient high-performing organisation that is responsive and publicly accountable • INDICATOR: UNQUALIFIED AUDIT OUTCOME
GOAL 2: Timeous regulatory decisions taken on applications to ensure compliance with defined standards of quality, safety, efficacy and/or performance	• Timeous regulatory decisions based on defined standards for quality, safety, efficacy and performance • INDICATOR: REGULATORY DECISIONS TAKEN WITHIN A SPECIFIED TIMELINE
GOAL 3: Re-evaluate and monitor medicines and medical devices periodically	• Establish a framework to ensure that registered products are periodically re-evaluated in accordance with defined standards of quality, safety, efficacy and performance • INDICATOR: FRAMEWORK FINALISED AND APPROVED WITHIN A SPECIFIED TIMELINE
GOAL 4: Investigate, monitor, analyse, solicit and act upon existing and new adverse events, interactions and information with regard to post-marketing surveillance and vigilance	• Ensure that evidence of existing and new adverse events, interactions, signals emerging from post-marketing surveillance and vigilance is being solicited, investigated, monitored, analysed and acted upon; and establish supportive national and global partnerships • INDICATOR: UNQUALIFIED AUDIT OUTCOME
GOAL 5: Ensure regulatory compliance through a process of active inspections and investigations	• Inspect and investigate establishments and permit holders in accordance with the defined guidelines and standards • INDICATOR: PERCENTAGE OF ESTABLISHMENTS INSPECTED WITHIN SPECIFIED TIMELINES
GOAL 6: Evaluate clinical trial protocols in accordance with defined standards	• Clinical trial protocols are evaluated in accordance with the defined standards to ensure participant safety and data integrity • INDICATOR: PERCENTAGE OF CLINICAL TRIAL PROTOCOLS EVALUATED WITHIN A SPECIFIED TIMELINE
GOAL 7: Evaluate the applications for sale of unregistered health products in accordance with defined standards	• Ensure that unregistered health product applications are evaluated in accordance with defined standards to ensure access only to safe, efficacious and quality unregistered health products • INDICATOR: PERCENTAGE OF APPLICATIONS OF AN UNREGISTERED HEALTH PRODUCT EVALUATED WITHIN A SPECIFIED TIMELINE
GOAL 8: Establish and strengthen collaborative initiatives with any other regulatory authority or institutions in order to achieve the objects of the Medicines Act	• 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 enter into agreements of collaboration with any regulatory authority or other relevant organisations • INDICATOR: ESTABLISH AT LEAST NINE COLLABORATIVE RELATIONSHIPS TO SUPPORT THE FUNCTIONS OF SAHPRA
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 fully operational by 2023 • INDICATOR: PERENTAGE OF FUNDED POSITIONS FILLED

8. LEGISLATIVE AND OTHER MANDATES

8.1 Constitutional Mandate

In terms of the provisions of the Constitution of the Republic of South Africa, 1996, the Authority is guided by the following sections and schedules, among others:

- The State has an obligation 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;
    - 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.

8.2 Legislative and Policy Mandates

8.2.1 Legislative Mandate

The South African Health Products Authority is responsible for the:

- Regulation of health products intended for human and animal use;
- Licensing of manufacturers, wholesalers and distributors of medicines, medical devices, radiation emitting devices and radioactive nuclides; and
- Conduct of clinical trials.

Since its establishment in February 2018, as a Schedule 3A public entity as per the Public Finance Management Act, 1999 (Act No. 1 of 1999) (PFMA) there have been no updates to its legislative and policy mandates. The cornerstone legislative mandates of SAHPRA are derived from the Constitution of the Republic of South Africa, the National Health Act, 2003 (Act No. 61 of 2003) (NHA) and the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended (herein after referred to as "the Medicines Act").

Pursuant to the expansion of SAHPRA's mandate to incorporate, inter alia, the regulation and control of radiation-emitting devices and radioactive materials, the following are various pieces of legislation that define the legislative framework within which SAHPRA executes its mandate:

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 NHA are to:

- Unite the various elements of the national health system into 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; and
- Create the foundations of the healthcare system.

The NHA must be understood alongside other laws and policies that relate to health.

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

Amended by Amendment Act, 2008 (Act No. 72 of 2008) and Amendment Act, 2015 (Act No. 14 of 2015) and enacted in May 2017, the Act enabled, among others, the establishment of SAHPRA, the licensing of manufacturers and importers of Active Pharmaceutical Ingredients (APIs), and the regulation of medical devices. In terms of the Medicines Act, the objects 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.

The Act 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 can only be administered or prescribed by a veterinarian.

As per Section 2b (1) of the Medicines Act, the Authority must ensure the following in order to achieve its objects:

- 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;
- 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;
- The periodic re-evaluation or re-assessment and ongoing monitoring of medicines, medical devices, radiation emitting devices and radioactive nuclides;
- 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;
- That compliance with existing legislation is promoted and achieved through a process of active inspection and investigation; and
- 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, request and receive the necessary information from and exchange information with 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 objects of the Medicines Act.

Hazardous Substances Act, 1973 (Act No. 15 of 1973)

The Hazardous Substances Act provides for the efficient, effective and ethical evaluation and licensing of electronic generators of ionising radiation and radionuclides. The Hazardous Substances Act classifies such substances and products in groups according to the risk associated with them. SAHPRA is only responsible for the regulation of Group III and Group IV hazardous substances.

Section 3 of the Hazardous Substances Act refers to regulation of Group III hazardous substances which are electronic generators of ionising radiation. Section 3A refers to regulation of Group IV hazardous substances, which are radionuclides.

Other Related Legislation

Due to the complex environment in which SAHPRA operates, a series of related legislation impacts on and influences the functioning of SAHPRA, as set out below:

- **Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)**

Provides for the registration of fertilisers, farm feeds, agricultural remedies, stock remedies, sterilising plants and pest control operators. To regulate or prohibit

the importation, sale, acquisition, disposal or use of fertilisers, farm feeds, agricultural remedies and 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 Act, 1984 (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 matters connected therewith. 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 quality standards that must be complied with by manufacturers, as well as the importation and exportation of these items.

- **National Environmental 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 co-ordinating environmental functions exercised by organs of state, and for matters connected therewith.

- **Health Professions Act, 1974 (Act No. 56 of 1974)**

Provides for the control over the education, training and registration for and practising of health professions 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.

- **Customs and Excise Act, 1964 (Act No. 91 of 1964)**

Provides for the prohibition and control of the importation, export or manufacture of certain goods, and for matters incidental thereto.

- **Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000) (PAJA)**

PAJA gives effect to the right to administrative action that is lawful, reasonable and procedurally fair as well as to the right to written reasons for administrative action as contemplated in section 33 of the Constitution of the Republic of South Africa, 1996.

- **The Promotion of Access to Information Act, 2000 (Act No. 2 of 2000) (PAIA)**

The legislation allows access to any information held by the State, and any information held by private bodies

that is required for the exercise and protection of any rights. It applies specifically to South Africa, but is part of the global drive towards freedom of information.

- **The Protection of Personal Information Act, 2013 (Act No. 4 2013) (POPIA)**

Section 14 of the Constitution of the Republic of South Africa provides that everyone has the right to privacy, hence the enactment of POPIA. The commencement date of the Act was 1 July 2020. The purpose of POPIA is to promote the protection of personal information processed by public and private bodies, to introduce certain conditions so as to establish minimum requirements for the processing of personal information, and to provide for the establishment of an Information Regulator to exercise certain powers and to perform certain duties and functions in terms of this Act.

- **Companies Act, 2008 (Act No. 71 of 2008)**

The Companies Act established the term "state-owned company", which is defined as an enterprise that is registered as a company in terms of this Act, and is either listed as a public entity in terms of Schedule 2 or 3 of the PFMA, or is owned by a municipality. Section 66 (1)2 of the Act requires a state-owned entity to have a Board of Directors, which has the authority to exercise all of the powers and perform any of the functions of the state-owned entity, except if limited by the Companies Act or Memorandum of Incorporation. The Board of Directors is accountable to the shareholder for the performance and affairs of the state-owned entity.

SAHPRA's Role in the Legislative Context

A favourable legislative environment is fundamental to the operations of a regulator, such as SAHPRA, in supporting an effective execution of its mandate. In the 2019/20 financial year, there have been a few notable developments in SAHPRA's operating environment that have necessitated a review of its legislative and policy framework.

In the first instance, SAHPRA's role exists amid an extremely complex legislative context where there is a series of other players involved where SAHPRA has only a limited yet important regulatory role. A case in point is a role SAHPRA fulfils through its representation at key ports of entry, where there are goods that come into the country that fall within its legislative obligations, for their inspection, as per the Customs and Excise Act.

One of the key new responsibilities emanating from SAHPRA's extended mandate relates to radiation control, which has crucial elements falling within the jurisdiction of the Department of Mineral Resources and Energy (DMRE).

Another responsibility concerns cannabis regulation, which cross-pollinates multiple ministries, to give impetus to the country's focus on enhancing access to this medicinal product.

As SAHPRA continues to mature into its role, it is becoming increasingly evident that there is a critical need to harmonise roles and responsibilities so as to avert the risk of an internal leadership vacuum or duplication of efforts and subsequent potential "conflict".

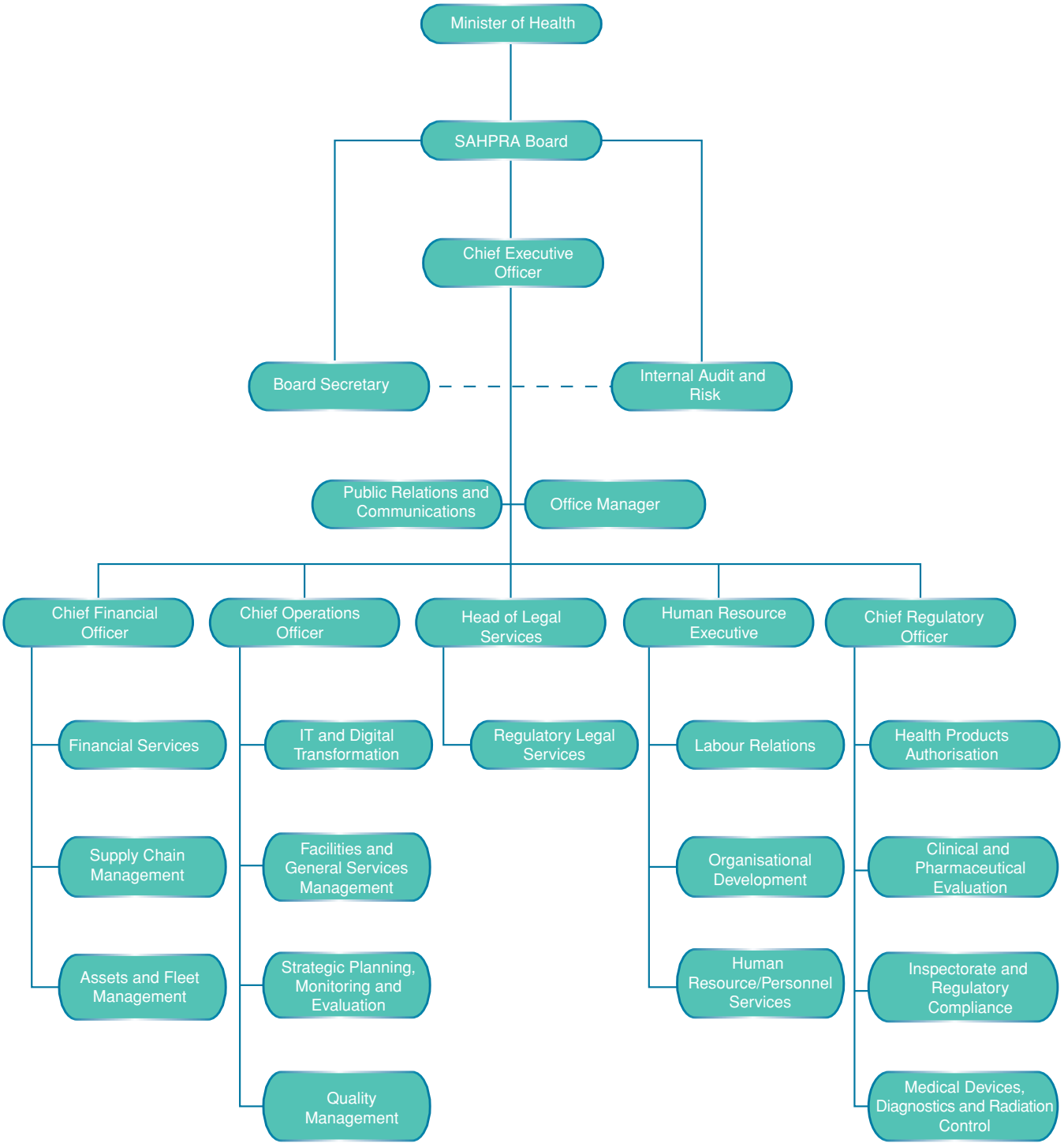
8.2.2 Policy Mandate

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.

NDP Goals 2030	MTSF Priorities	NDoH Strategic Goals 2014–2019
Average male and female life expectancy at birth increased to 70 years	Human Immunodeficiency Virus, Aquired Immunodeficiency Syndrome (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	Strengthening implementation of HIV/AIDS and TB prevention and management programmes	Prevent disease and reduce its burden and promote health through the multi-stakeholder National Health Commission
Maternal, infant and child mortality reduced	Expand access to sexual reproductive health by improving the availability of diverse contraception methods; Reduce unwanted pregnancies with special focus on teenage pregnancies	
Prevalence of non-communicable diseases reduced	Promote healthy lifestyles and encourage regular screening for non-communicable diseases	
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 the 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

9. ORGANISATIONAL STRUCTURE

FIGURE 1: SAHPRA MACROSTRUCTURE



SAHPRA Board

Prof. Helen Rees
Chairperson

Ms Mandisa Hela
Vice-Chairperson

Mr Norman Baloyi
Member

Prof. Shabir Banoo
Member

Prof. Craig Household
Member

Dr Ushma Mehta
Member

Prof. Jeffrey Mphahlele
Member

Ms Lesibana Fosu
Member

Adv Hasina Cassim
Member

Prof. Ames Dhai
Member

Dr Edith Madela-Mntla
Member

Dr Mphane Molefe
Member

Dr Thapelo Motshudi
Member

Prof. Patrick Demana
Member

Mr Itani Mashau
Member

SAHPRA Executive Management

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer

Mr Molatlhegi Kgauwe
Chief Financial Officer

Ms Portia Nkambule
Chief Regulatory Officer

Adv Teboho Nthotso
Company Secretary

Vacant: ***Chief Operations Officer***
Vacant: ***Human Resource Executive***

SAHPRA Senior Management

Senior Manager: Medical Devices and Radiation Control	Senior Manager: Clinical Evaluation Management	Senior Manager: Pharmaceutical Evaluation Management
Senior Manager: Inspectorate and Regulatory Compliance	Senior Manager: Health Products Authorisation	


RESULTS

PART B:

PERFORMANCE INFORMATION

1. AUDITOR'S REPORT: PREDETERMINED OBJECTIVES

The Auditor-General of South Africa (AGSA)/auditor currently performs the necessary audit procedures on the performance information to provide reasonable assurance in the form of an audit conclusion. The audit conclusion 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 auditor's report.

Refer to page 86 of the Report of the Auditor-General, published as Part E: Financial Information.

2. SITUATIONAL ANALYSIS

2.1 Service Delivery Environment

This is SAHPRA's 2nd financial year following its establishment in February 2018. The organisation prioritised delivering on its critical public health mandates, while balancing the process of change that is a consequence of a transitional environment. In the 2019/20 financial year, SAHPRA implemented a new business model and organogram to support growth towards a globally benchmarked health product regulatory authority. The organisation focused on stabilising both the core and corporates services environments through this developmental period and has performed satisfactorily in the 2019/20 financial year.

The organisation faced challenges of working in a temporary environment with immature systems. Tremendous focus was placed on establishing basic functioning in this impermanent space without incurring wasteful expenditure.

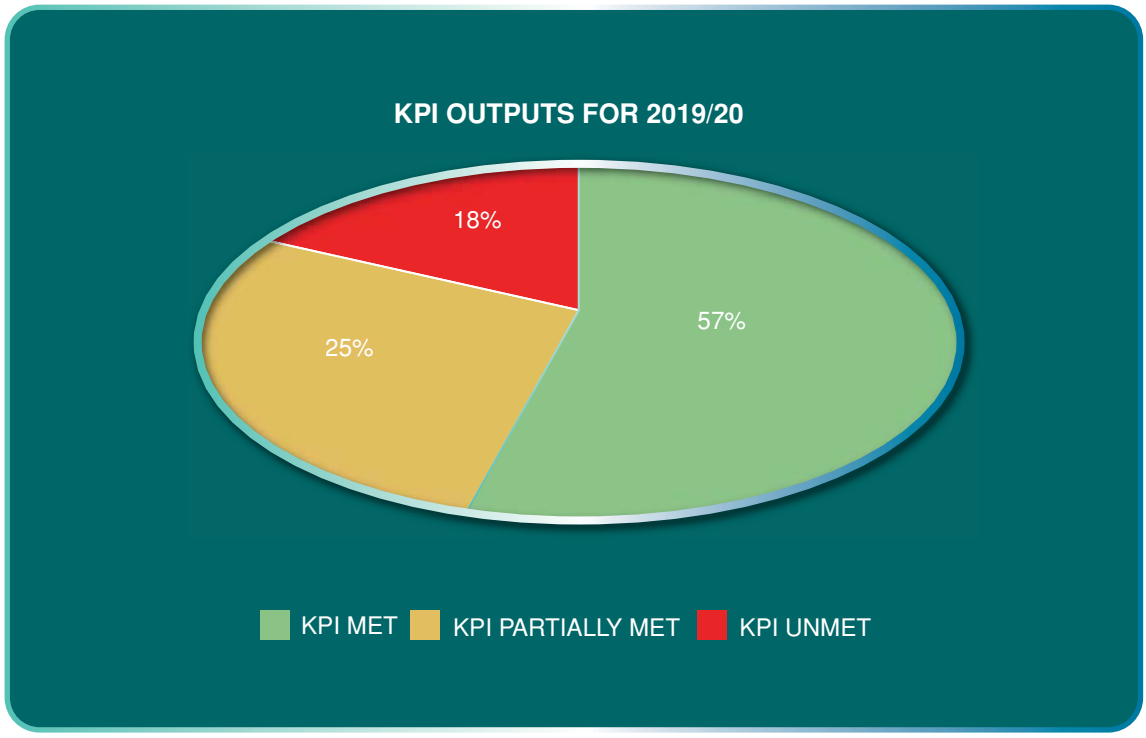
Furthermore, the organisation secured the positions of Chief Executive Officer and Human Resource Executive in the 4th quarter. These critical positions came at a late juncture, therefore placing strain on the organisation's ability to appoint other incumbents into critical posts more timeously. This resulted in the current leadership performing dual functions for most of the financial year. The organisation nevertheless persisted with the transition and ensured the planned operational transformation proceeded. This state of transition affected the delivery of outputs but was invested in to ensure long-term improvement of systems and operations.

The Memorandum of Understanding (MOU) between the NDoH and SAHPRA to provide critical support was hampered by ongoing labour actions in the NDoH.

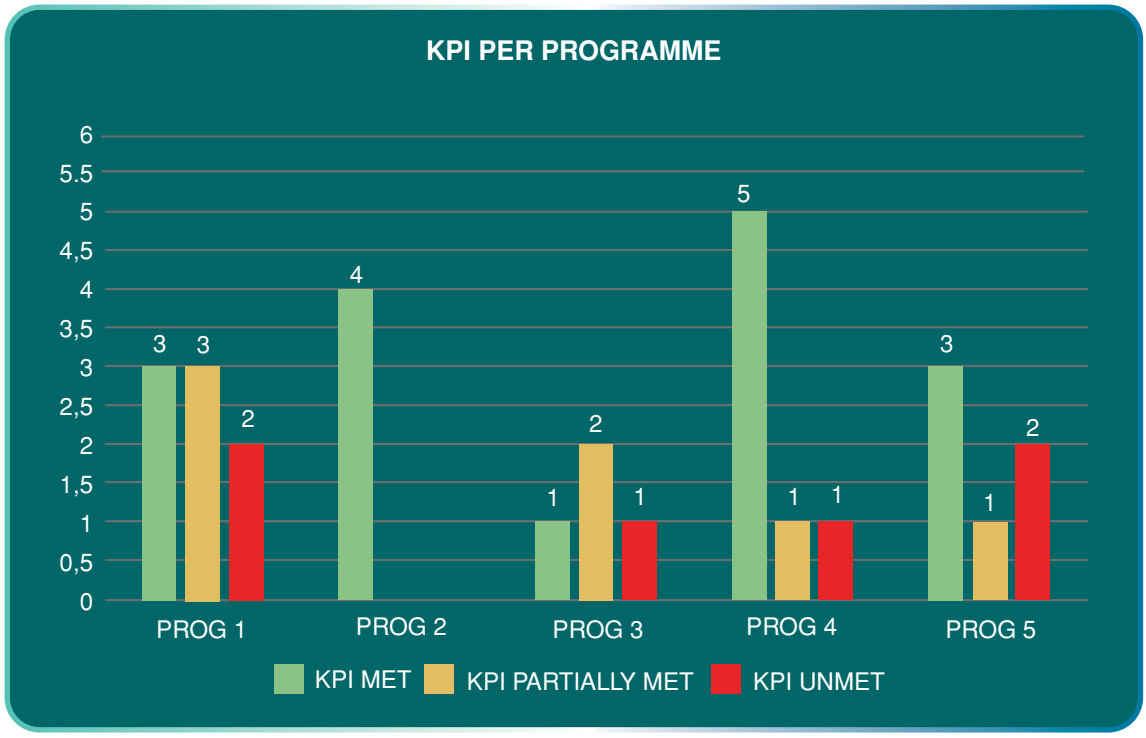
Despite these challenges, SAHPRA performed satisfactorily in the 2019/20 financial year, as shown by the following outputs:

- ► Met or exceeded 16 of the 28 (57%) KPIs [100% achieved]
- ► Partially met 7 of the 28 (25%) KPIs [between 50% to 99% achieved]
- ► Did not meet 5 of the 28 (18%) KPIs. [i.e. deviated by more than 50% and achieved less than 50%]

The overall KPI outputs for the 2019/20 financial year are as follows:

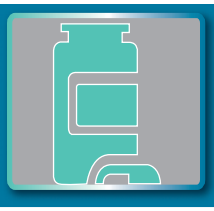


The KPI output achieved per programme is as follows: [1]



1
Programme 1: Leadership and Support
Programme 2: Health Product Authorisation
Programme 3: Inspectorate and Regulatory Compliance
Programme 4: Medicine Evaluation and Registrations
Programme 5: Medical Devices and Radiation Control

SAHPRA's overall achievements were significant in the 2019/20 financial year, and include:



Registered 262 new medicines

Reduced the backlog by 58%, clearing 6 732 applications with regulatory decisions

Issued 168 site licences for manufacture, wholesale and distribution

Issued 3 277 permits for narcotics and psychotropic substances

Issued 14 resolutions for cannabis site applications and conducted 48 inspections for sites with narcotic and psychotropic permits

Conducted 171 inspections and reliance reviews for manufacture, wholesale, clinical trials sites

Resolved 86 matters under investigation in the regulatory compliance unit

Evaluated 140 clinical trial applications for Good Clinical Practice (GCP) compliance and evaluated 980 protocol amendments, additional sites and investigators for clinical trials

Reviewed 16 396 applications for the sale of unregistered health products

Issued 916 medical device establishment licences

Issued 1 849 radionuclide licences

Issued 1 546 licences for non-ionizing radiation emitting devices

Law enforcement successfully investigated 61 cases for illegal products, resulting in 12 sentences and convictions for these cases

Recalled 12 medicines and 30 medical devices/IVDs

Issued 15 Dear Healthcare Professional (DHCP) letters, two media releases on health product safety and reviewed and committed 5 158 Adverse Drug Reaction (ADRS) in total to the ADR reporting systems

2.2 Organisational Environment

In the 2019/20 financial year, SAHPRA revised its organogram to acquire a more fit-for-purpose organisational structure. The recruitment process followed a phased approach with a focus on first securing the organisation's leadership. In this period, the following key executive and senior management appointments were made:

- Chief Executive Officer
- Chief Regulatory Officer
- Senior Manager: Clinical Evaluations
- Senior Manager: Pharmaceutical Evaluations
- Human Resource Service Manager (short-term contract).

The momentum of the recruitment process has increased significantly and the following posts will be secured by the 1st quarter of the 2020/21 financial year:

- Chief Operations Officer
- Human Resource Executive
- Senior Manager: Inspectorate and Regulatory Compliance
- Senior Manager: Medical Devices, Diagnostics and Radiation Control
- Senior Manager: Health Product Authorisation.

SAHPRA recognises its role as an essential component in an effective health system. This underpinning purpose has stimulated SAHPRA's leadership to focus its efforts towards securing its status as a well-functioning regulatory authority. SAHPRA, therefore, prioritised its re-engineering and digitisation of operations, with the aim of realising a more agile, globally benchmarked national health product regulator.

SAHPRA has also worked extensively towards strengthening its corporate services functions. In this period, SAHPRA appointed crucial interim service providers to support the Finance, Human Resources, Information Technology, Supply Chain Management, Strategic Planning, Internal Audit and Enterprise Risk Management functions while it implements a longer-term approach on the appointment of permanent staff into these functions. This has significantly re-inforced the operational, governance and compliance environment.

SAHPRA also secured the services of a forensic auditor, and continues to work with the Special Investigations Unit in addressing the pending investigations into SAHPRA's operations. SAHPRA further aims to ensure that accountability and transparency is embedded as a cultural norm, within the organisation.

In keeping with reviving a positive organisational culture, SAHPRA endeavoured to enhance the organisation's corporate identity. In the 2019/20 financial year, SAHPRA re-branded the organisation and strengthened stakeholder communications and collaborative relationships. These efforts have helped to reinforce a culture of common purpose of public health service with both the internal and external stakeholders.

A key step towards providing a safe and conducive work environment that builds positive staff morale was securing fit-for-purpose accommodation to adequately support the functioning and well-being of the Regulator's staff. Occupancy in the new premises is planned for early in the 2020/21 financial year, pending the relaxation of the lockdown restrictions which would permit the relocation.

The financial year was constrained by challenges in the human resources unit that delayed placement of incumbents in the 110 posts advertised early in May 2019. The finalisation of the implementation of aspects of the Labour Relations Act, 1995 (Act No. 66 of 1995) Section 197 transfer from the NDoH to SAHPRA was also delayed. Nevertheless, the entity persevered and was able to inject momentum into both these areas in the 4th quarter. Substantial progress is anticipated in these two performance areas early in the 2020/21 financial year.

3. PERFORMANCE INFORMATION BY PROGRAMME/ACTIVITY/OBJECTIVE

3.1 Programme 1: Leadership and Support

Programme	Leadership and Support
Purpose	To provide the leadership and administrative support necessary for SAHPRA to deliver on its mandate and comply with legislative requirements
Sub-Programme 1	**Financial and Supply Chain Management**
Purpose	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 oversight that complies with the applicable legislation
Sub-Programme 2	**Governance and Compliance**
Purpose	To provide support services and ensure compliance with relevant legislation, and achieve an unqualified audit outcome by ensuring continuous management practices through compliance with standards operating procedures and systems within SAHPRA. Further, to review existing operational processes and recommend new or changed processes and work methods to ensure optimal organisational effectiveness, and measure and monitor the Authority's performance
Sub-Programme 3	**Information and Communication Technology (ICT)**
Purpose	To develop and implement an ICT-integrated governance framework by focusing on the business continuity plan and support the needs and requirements of the end users. Further, to manage public relations, information and communication services to ensure proper management and dissemination of information to internal and external stakeholders, to ensure a seamless harmonious operational platform by building strong and sustainable relationships with all its stakeholders
Sub-Programme 4	**Human Resource Management**
Purpose	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

Finance and Supply Chain

- SAHPRA generated R261.6 million in revenue against a budget of R308.3 million. The variance of R46.7 million was mainly due to the lower number of applications and the late implementation of new fees.
- SAHPRA spent R230.4 million against the budget of R308.3 million, which resulted in an underspend of R77.9 million. The underspend relates predominantly to compensation of employees as a result of vacancies not being filled, as well as goods and services owing to some of the planned activities that did not materialise in the financial year such as the move to the new facility.

The sub-programme focused on improving the previous audit outcomes as well as positioning the Authority towards financial sustainability.

The entity has:

- enforced finance and supply chain policies and standards;
- implemented the General Ledger (GL) accounts per services;
- implemented revenue allocation triggers as an aid to improve revenue allocation; and
- revised service fees structures to align to global trends.

- The recruitment for the 19 finance posts identified on the organogram has commenced. However, these positions will mainly be filled in the 2020/21 financial year.

Governance and Compliance

SAHPRA recognises the role of strong governance and compliance as integral to its maturity. To this end, the entity:

- Completed its 1st audit on 15 September 2019. The Annual Report for 2018/19 financial year was published and tabled on 28 September 2019;
- Commenced with the internal audit process on 1 March 2020 for the 2019/20 financial year. The 2019/20 financial year AGSA audit commenced in July 2020;
- Developed, approved and submitted the 5-year 2020/25 Strategic Plan and 2020/21 Annual Performance Plan aligning to the newly elected 6th government. The planning documents were submitted in compliance with the 31 January legislated date. Tabling was delayed as a result of the COVID-19 lockdown;
- Developed, approved and implemented the Enterprise Risk Management (ERM) framework and related strategies, policies and registers to manage the risk of the entity to within the appetite set by the Board; and
- Developed and implemented the COVID-19 business continuity plan.

Information Technology (IT) and Communication

Information management and security is a critical determinant of SAHPRA's maturity as a global regulator. The momentum to progress this was restricted by the short-term residence at the Council for Scientific and Industrial Research (CSIR). Significant progress is noted in this year. This includes:

- Approval and implementation of the IT governance policies and IT strategies in 2019
- Commencing with development of policies and procedures to govern operating systems, security, change management, IT service continuity and incident and problem management; and
- Automation of the dossier review.
- The IT unit filled 9 of the 14 positions.

The communication-related activities of the unit focused on building SAHPRA's internal and external stakeholder relationships to enhance its operations. Public outreach was effected through active media engagements and social media presence around current affairs in public health and safety. The industry stakeholder meetings promoted bi-directional information by sharing enhancing responsiveness without losing autonomy. The internal stakeholder communications were enriched with intensified staff engagements, intensified social media engagements and in general promotion of a positive communication-oriented organisational culture. SAHPRA commenced with stakeholder engagement surveys to understand the quality of its stakeholder relationships, the results of which will advise actions in the 2020/21 financial year.

Human Resources

A public health consultant was appointed early in 2019 to develop and finalise SAHPRA's organisational structure. A total of 110 positions were budgeted and advertised. Of these, 85 were for permanent positions across management, technical and administrative support staff designations. To date, 18 of the 85 positions have been secured. Of the 110 positions, 25 were for contract posts in the Backlog Clearance Project. All 25 of these were filled.

The organisation was resourced with a Human Resource Manager on a short-term contract to support the recruitment process and completion of the Section 197 transfer process. SAHPRA has intensified its efforts to secure the Human Resource Executive in the early part of the 2020/21 financial year as well as filling the remaining human resource roles.

COVID-19 Impact

On 16 March 2020, President Cyril Ramaphosa declared the COVID-19 pandemic as a National Emergency under the Disaster Management Act, 2002 (Act No. 57 of 2002), promulgated in 2003. SAHPRA's response to the subsequent COVID-19 lockdown on 26 March 2020 under this Act resulted in the establishment of a COVID-19 task team and the development and implementation of a business continuity plan that enabled a remote access work arrangement. Stakeholder communication was intensified to ensure all staff were trained on all COVID-19 related safety measures and protocols, both in and outside the office environment,

and external stakeholders were fully prepared for the process of ongoing business engagement with the National Regulator.

The business continuity plan identified the core functions needed to ensure that public health needs and safety were not compromised. Further, the COVID-19 related work focus for SAHPRA included:

- Regulation of importation and manufacture of personal protective equipment (PPE) to ensure quality, safety and efficacy standards;
- Registration of medical device test kits to ensure quality, safety and performance;
- Registration of COVID-19 related medication to ensure supply; and
- Timeous approval of vaccine clinical trials.

SAHPRA stepped up to the constraints of the lockdown environment and facilitated the adoption of some positive business IT solutions. These included the establishment of a fully online submission process for all applications, implementation of remote access work tools, and enhanced utilisation of cloud-based services for secure information sharing.

The impact of the COVID-19 pandemic on the financial sustainability of the entity is limited to changes to the budget which include a reduction in revenue generated from fees. This is owing to an anticipated decrease in applications that will be received by the entity. This decrease is anticipated against a diminished economy due to the COVID-19 pandemic, as well as the inability of local applicants to get required information from their respective overseas headquarters during the lockdown period. The diminished revenue is considered immaterial as the entity will balance this against applying financial austerity measures to tighten operational costs.

Table 1: Strategic Objectives, Performance Indicators, Planned Targets and Actual Achievements

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achievement 2019/20	Variance	Reason for Variance	Notes on Achievement
1	1	Establish, in a phased approach, a fully functional Authority suitably staffed to execute the mandate and goals of SAHPRA	Percentage of funded positions filled	**80%**	72%	88%	71.7%	76%	**76%**	-5%	The HR Senior Manager position was advertised. SAHPRA was unable to secure an incumbent despite offers being made to two candidates. This has impacted output on HR-related activities to support recruitment	An HR manager was appointed in Q4. A greater momentum has been achieved towards recruitment of staff owing to having HR support. Greater output will be evident in the 2020/21 financial year
1	2	Maximise performance to improve organisa-tional efficiency	Implement a renewed and more effective Performance Management and Develop-ment System (PMDS), both for manage-ment and staff	**Workforce perform-ance measured by new PMDS**	PMDS working group established Draft PMDS framework developed	PMDS Policy and Procedure framework not piloted	PMDS Policy and Procedure framework not implemented	New PMDS not developed or implemented	**Workforce performance not measured by new PMDS**		Lack of a dedicated HR team has diminished momentum and output towards a new PMDS	An HR manager was appointed in Q4. A plan for this matter is to be addressed in 2021

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achievement 2019/20	Variance	Reason for Variance	Notes on Achievement
1	3	Develop a communi-cation strategy to support improved external stakeholder interactions and relations	Establish a framework for more regular and efficient interactions with all stakeholders and partner agencies: a) patients and consumers and their representative organisations b) healthcare professionals c) academic and research institutions d) health products industry and their representative associations e) the media f) local and international partners	**Report of framework published on website**	Engaged internal stakeholders Draft strategy developed	Draft framework not published for comment	The framework approved by Board on 25/26 November 2019. This framework was subsequently published for public comment. Board re-approval was requested from the communications committee	The draft framework was published on the website and comments were received. No report can be published until the framework is re-approved	**The draft framework was published on the website and comments were received. No report can be published until the framework is re-approved**		A full report on stakeholder communi-cations could not be published on the website until Board approval of the framework	The framework was subsequently approved in Q1 2020. A complete report on all categories of stakeholder communications will be published. Publication is anticipated for Q2 of 2020

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achievement 2019/20	Variance	Reason for Variance	Notes on Achievement
1	4	Create public and stakeholder awareness about the mandate of SAHPRA	Annual Stake-holder Communi-cations Report	**Annual Report to Board and Communi-cations Committee on SAHPRA communica-tions with key stakehold-ers**	Not applicable in Quarter 1	One report tabled at Communications Committee and Board	Not applicable in Quarter 3	Not applicable in Quarter 4	**Annual report tabled at Communica-tions Committee and Board**		No variance	Report tabled as planned at Communications Committee and Board
1	5	Create public and stakeholder awareness about the mandate of SAHPRA	Independent stakeholder surveys on SAHPRA	**Material developed and in process dissemina-ted with a 25% response**	Not applicable in Quarter 1	Project not commenced	Not applicable in Quarter 3	Material developed. Dissemination in process	**Material developed and dissemina-ted. Responses and report to be reviewed in Q1 2020**		The project commence-ment date was deferred due to the completion of the appointment of the Senior Manager: Communica-tions in Q2 in 2019/20	One out of two components of the target was achieved despite delayed commencement. The responses and report derived from stakeholder surveys will be reviewed in Q2 of 2020

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achievement 2019/20	Variance	Reason for Variance	Notes on Achievement
1	6	Implement good governance, oversight and accountability through appropriate delegation, including financial management and compliance with PFMA requirements	Audit outcome	**Unqualified audit outcome**	Not applicable in Quarter 1	Unqualified audit outcome	Not applicable in Quarter 3	Not applicable in Quarter 4	**Qualified audit outcome**		Lack of structured record management and ineffective operating system	An audit action plan will be developed to monitor progress on addressing the audit findings

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achievement 2019/20	Variance	Reason for Variance	Notes on Achievement
1	7	Ensure that the monitoring and inspection of information stored on SAHPRA's ICT facilities and services are done in an appropri-ate and responsible manner	Fully functioning regulatory information management system that permits tracking of all business activities	**90%**	95%	95%	99%	95%	**96%**	+7%	Insignificant variance	Average of downtime estimated per quarter based on power outages and system upgrades An environmental solution was secured to ensure backup power was available during power failures The full measure of functionality of an information management system (IMS) for operation can only be deduced once the IMS is implemented

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achievement 2019/20	Variance	Reason for Variance	Notes on Achievement
1	8	Mandated publication of health products registers on the Authority's website for public information	Updated Medicine and Medical Device registers published on the Regulator's website quarterly	**Updated Medicine and Medical Device registers published on the Regulator's website quarterly**	Updated Medicine and Medical Device registers published on the Regulator's website	Updated Medicine and Medical Device registers not published on the Regulator's website	Updated Medicine and Medical Device registers published on the Regulators website	Updated Medicine and Medical Device registers published on the Regulators website	**Updated Medicine and Medical Device Registers published on the Regulator's website on time for three out of four quarters**	-25%	The Medicine and Medical Device registers were not published in Q2 due to capacity constraints that prevented securing timeous feedback from applicants on outstanding information	Registers were published on time for three out of four quarters. One register was published late. All four registers were published for the year

3.2 Programme 2: Authorisation Management

Programme	Authorisation Management
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 co-ordinate 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
Sub-Programme 1	**Document Reception and Helpdesk**
Purpose	The purpose of this sub-programme is to receive, record and/or direct all documents submitted to SAHPRA
Sub-Programme 2	**Records Management**
Purpose	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**
Purpose	The purpose is to co-ordinate the process of the making of a regulatory decision of medicines (screening, dispatch to evaluators, co-ordinating 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' lifecycles 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 Clearance Project has been implemented
Sub-Programme 4	**Project Office – Clinical Trials, Section 21 Portfolio Management**
Purpose	The purpose is to co-ordinate 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 catered for
Sub-Programme 5	**Licensing, Permits and Certificates Portfolio Management**
Purpose	The purpose is to manage and co-ordinate 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 catered for
Special Project	**Backlog Clearance Project**
Purpose	The purpose is to support clearance of its inherited backlog. The backlog is defined as all applications (including new registrations, variations, duplicates, clones, multiple doses and different dosage forms) submitted which are yet to receive final approval (including certification), as of 31 January 2018

Backlog

SAHPRA inherited a backlog of ~16 170 medicine applications (new registrations and variations, i.e. changes to registered products).

To address this backlog, SAHPRA introduced several optimisation processes and efficiencies which are expected to significantly improve turnaround times for registration in both the backlog and business-as-usual (BAU) units. These include implementation of the reliance and recognition pathways with identified regulatory authorities. Various mechanisms have been applied to clear the backlog.

- Out of the 16 170 medicine applications,
  - 3 410 were cleared through the opt-out process by 31 January 2020;
  - 3 100 were cleared through certification and the starburst registration project in the 2019/20 financial year; and
  - 3 464 were cleared as variation applications and new registrations in the 2019/20 financial year.

Thus, of the 12 760 applications remaining post opt-out at the beginning of the 2019/20 financial year, 6 732 have been cleared through regulatory decisions, resulting in 58% of the backlog being cleared through regulatory decision processes.

Licensing

The licensing unit operations were scrutinised to help address the previous year's audit findings. Review of operations, people and policies commenced in the 2019/20 financial year to ensure this critical function is operating optimally and is well governed. This has resulted in the appointment of a Senior Manager for the Programme to lead the changes, secondment of staff into this programme to ensure business continuity and output and adoption of digital solutions to support its functions. The unit issued 168 licences for medicine manufacturers, wholesalers and distributors against a total of 218 applications received.

Regulatory Compliance

- The unit is currently not fully capacitated. The capacity issues will be addressed in the 2020/21 financial year as part of the phased recruitment plan.
- Despite capacity constraints, the unit was able to issue 3 819 narcotic, psychotropic and Schedules 5 and 6 import and export permits against the target of 2 874.
- The unit also issued 14 resolutions for the 161 cannabis applications received in the 2019/20 financial year. The unit conducted 62 of the 70 planned inspections for cannabis cultivation. Inspections were suspended with the COVID-19 related lockdown in the 4th quarter.

Medicine Registration/Certification

- The unit has undergone several structural, operational and policy changes to improve operational efficiency as a project office to support the projected increased outputs times for the 2020/21 financial year. The unit has also implemented a quarterly registration plan in conjunction with Programme 4 to permit better oversight of applications in the pipeline and areas of evaluation that need greater scrutiny and reinforcement. The adoption of online submission by applicants has reduced the manual burden and improved document management. Semi-automated tracking systems and registers are in place as a further assurance of document management and security.
- The unit tabled 262 applications from core business at the Registration Committee. All 262 certificates were issued, with 241 issued within the desired 7-day period.

Table 2: Strategic Objectives, Performance Indicators, Planned Targets and Actual Achievements

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achieve-ment 2019/20	Variance	Reason for Variance	Notes on Achievement
2	9	Take regulatory decision on all Backlog Applications	Percentage of backlog applications with a regulatory decision taken	**40%**	0%*	0%*	0%*	34%*	**58%**	45%	The exceeded output can be attributed to focused projects and adoption of new regulatory mechanisms. This number includes certification, starburst new registrations and variations	11 570 applications were recorded in the backlog as at 1 February 2019 over the 2019/20 financial year. **6 732 applications were cleared through the certification project, new product registration, the starburst project and variations project** **6 732/11 570 = 58%**

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achieve-ment 2019/20	Variance	Reason for Variance	Notes on Achievement
2	10	Issue of licence, permits, registration certificates, certificates of establishments and health products for applications received for medicines within a specified timeline after regulatory decision taken	Percentage of licences issued within predefined timelines on a quarterly basis	**60%**	31.9%	84.9%	73.7%	119.5%	**77%**	+28%	Focused initiatives taken to address previous year's operational issues reflected in improved output per quarter	218 licence applications were received. 168 licences were issued within the predefined timeline
2	11	Issue of licence, permits, registration certificates, certificates of establishments and health products for applications received for medicines within a specified timeline after regulatory decision taken	Percentage of permits issued within predefined timelines on a quarterly basis	**65%**	98%	93%	93%	99%	**95%**	+46%	Focused initiatives to ensure public health work is prioritised and efforts to address previous year's operational issues reflect an improved output	3 435 applications for permits were received. 3 277 permits were issued within the predefined timelines

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achieve-ment 2019/20	Variance	Reason for Variance	Notes on Achievement
2	12	Issue of licence, permits, registration certificates, certificates of establishments and health products for applications received for medicines within a specified timeline after regulatory decision taken	Percentage of certificates prepared for new registrations within seven days of a completed review	**90%**	100%	100%	63%	100%	**92%**	2%	Variance is positive	262 applications served at the Regulatory Committee in the 2019/20 financial year. 241 certificates were prepared and issued within seven days of a regulatory decision taken. 262 certificates were issued in total in the 2019/20 financial year

*The reporting of the KPI in Q1/2/3/4 did not take into account all regulatory decisions in the backlog, including certification, starburst new registrations and variations.

3.3 Programme 3: Inspectorate and Regulatory Compliance

Programme	Inspectorate and Regulatory Compliance
Purpose	To ensure public access to safe health products through inspections and regulatory compliance. The focus of this programme includes assessment of site compliance, with Good Regulatory and Vigilance (GXP) practices, including: ▸ Good Manufacturing Practice (GMP); ▸ Good Clinical Practice (GCP); ▸ Good Warehouse Practice (GWP); ▸ Good Distribution Practice (GDP); ▸ Good Laboratory Practice (GLP); and ▸ Good Vigilance Practice (GVP)
Sub-Programme 1	**Inspections**
Purpose	To ensure that GxP inspection activities are actively managed to facilitate the running of an effective inspection programme monitored against pre-defined timelines and commitments communicated to stakeholders
Sub-Programme 2	**Regulatory Compliance**
Purpose	To ensure public access to safe medicines through regulatory compliance and monitoring of compliance with applicable legislation as mandated

The process to secure a Senior Manager for this programme was finalised in Q1 of the 2020/21 financial year. This programme supports both the Backlog Clearance Project and BAU for all inspections. The programme has also prioritised cannabis advocacy and remained committed to establishing the cannabis regulation framework. In the 2019/20 financial year, the unit completed:

- 101 GXP inspections and reliance reviews against a target of 112 in the pre-defined timeline; and
- 171 GXP inspections and reliance reviews in total for the year (inspections completed within and exceeding the pre-defined timeline).

The inspections sub-categories include:

- 55 Good Clinical Practice
- 38 Good Distribution Practice
- 36 Good Manufacturing Practice
- 42 Good Wholesale Practice.

Additional progress included the following:

- 48 inspections of permit holders/establishments/sites of narcotic and psychotropic substances, including cannabis, were concluded against a target of 35.
- 86 investigations of the 123 investigations initiated were completed.
- Of the 61 investigated cases related to illegal products, 12 resulted in convictions and sentencing.

With regard to Medicine Recalls, the unit completed:

- 12 for the Medicines category; and
- 30 for the Medical Device & IVDs category.

Table 3: Strategic Objectives, Performance Indicators, Planned Targets and Actual Achievements

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achieve-ment 2019/20	Variance	Reason for Variance	Notes on Achievement
3	13	To run an effective and efficient GXP and vigilance programme with defined timelines	Percentage of establishments due for inspections inspected annually	**50%**	48%	33%	38%	58%	**45%**	-10%	Changes in operations in Q 2 impacted the output. Capacity constraints also impacted the output	The unit completed 101 inspections with reports of the 225 planned for the year
3	14	To run an effective and efficient GXP and vigilance programme with defined timelines	Percentage of reliance reviews completed	**85%**	25%	33.3%	0%	85%	**22%**	-74%	The unit refocused efforts towards KP1 13 output (inspections) during the 1st three quarters until staffing and operational issues were addressed for reliance reviews	The unit completed four reliance reviews out of the 18 applications received

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achieve-ment 2019/20	Variance	Reason for Variance	Notes on Achievement
3	15	To run an effective and efficient inspection and vigilance programme with defined timelines	Percentage of permit holders/ establish-ments/sites of narcotic and psychotropic substances inspected annually	**20%**	7%	61.5%	63%	80%	**27%**	+40%	There was an increased work focus on cannabis inspections. This was not anticipated when setting the Annual Performance Plan target	The unit completed 48 inspections out of the 175 inspections planned
3	16	To run an effective and efficient inspection and vigilance programme with defined timelines	Percentage of investigations completed	**85%**	35%	100%	53.6%	83%	**70%**	-18%	The unit is under-capacitated and without a digital solution to support the output. This has resulted in inconsistent output over the quarters, which has negatively impacted the final achievement of the unit	The unit resolved 86 matters that were brought to its attention through various means, out of the 123 matters received

3.4 Programme 4: Medicine Evaluation and Registration

Programme	Medicine Evaluation and Registration
Purpose	To evaluate the safety, quality and therapeutic efficacy of medicines and register them for use in terms of relevant legislation as listed in the legal mandate of part 1a of the Strategic Plan
Sub-Programme 1	**Clinical Evaluation**
Purpose	To evaluate the safety and efficacy of orthodox medicines, vaccines, biologicals, complementary medicines and medical devices
Sub-Programme 2	**Clinical Trials**
Purpose	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 protection of the rights of patients
Sub-Programme 3	**Pharmaceutical Evaluation**
Purpose	To perform pharmaceutical and analytical evaluations of new and registered medicines, inclusive of clinical aspects of veterinary medicines and biological
Sub-Programme 4	**Authorisation of the Sale of Unregistered Medicines**
Purpose	To conduct an abbreviated evaluation of applications to authorise the sale of unregistered medicines based on quality, safety and efficacy standards
Sub-Programme 5	**Vigilance and Post-Marketing Surveillance**
Purpose	To establish a regimen of vigilance for the collection and evaluation of information relevant to the benefit-to-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
Sub-Programme 6	**Complementary and Alternative Medicines**
Purpose	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
Sub-Programme 7	**Veterinary Medicines**
Purpose	To evaluate the safety, efficacy and quality of veterinary medicines

Programme 4 fulfils the greatest part of SAPHRA's core mandate. In the 2019/20 financial year, the programme undertook extensive re-engineering and digitisation. This includes the development of new policies that would permit applying for recognition and reliance with recognised regulatory authorities to support abbreviated evaluations, batch process evaluations, and self-recognition registration for clones and applications for different dosages of registered products. These policies are being piloted in the backlog and will be adopted in the BAU. Furthermore, the senior managers for both pharmaceutical as well as clinical evaluations were appointed. A key focus of the unit is to build technical in-house capacity to support the transformed business processes adopted. In addition, to support deepening the capabilities and offerings in the area of pharmacovigilance, an online adverse event reporting portal was introduced to facilitate online reporting of adverse drug events, and the pilot of electronic submission of adverse event reports by the pharmaceutical industry was successfully completed.

In this financial year, the unit:

- Reviewed 140 clinical trials against a target of 126;
- Evaluated 980 clinical trials amendments against a target of 728;
- Evaluated 16 936 applications for the sale of unregistered health products against a target of 13 735;

- Evaluated and issued registration certificates for 93 public health priority products;
- Published four reports on public safety on the SAHPRA website for the year (one per quarter as per target);
- Published 15 *Dear Healthcare Professional Letters* and two media releases with public safety-related communications derived from Pharmacovigilance reviews;
- Received and processed 5 158 ADR reports. All reports were captured on the Vigiflow system within SAHPRA and communicated to the UPPSALA monitoring centre's global monitoring system for adverse drug reactions; and
- Made significant progress towards developing a new vigilance framework for all health products. The draft policy and framework were developed and, as at 31 March 2020, was awaiting public and stakeholder comment as per the review process.

Table 4: Strategic Objectives, Performance Indicators, Planned Targets and Actual Achievements

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achieve-ment 2019/20	Variance	Reason for Variance	Notes on Achievement
4	17	Evaluate clinical trial protocols in accordance with defined standards	Percentage of clinical trial applications evaluated within an evaluation cycle	**90%**	100%	100%	100%	100%	**100%**	0%	Use of community service pharmacists to expedite and ensure output of all clinical trial applications received	The unit received and evaluated 140 clinical trial applications for humans within the pre-defined timelines
4	18	Evaluate clinical trial protocol amendments in accordance with defined standards	Percentage of clinical trial protocol amendments evaluated within predefined timelines	**65%**	91%	88%	85%	72%	**88%**	+35%	Use of community service pharmacists to expedite and ensure output of all clinical trial applications received	The unit evaluated and approved 980 clinical trial protocol amendments for human clinical trials within the predefined timelines, out of the 1 120 applications received

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achieve-ment 2019/20	Variance	Reason for Variance	Notes on Achievement
4	19	Ensure that unregistered health product applications received are evaluated in accordance with defined standards to ensure access only to safe, efficacious and quality unregistered health products	Percentage of applications for the sale of an unregistered health product evaluated within a specified timeline	**80%**	94%	93%	96%	95%	**96%**	+20%	Use of community service doctors and pharmacists and implementation of semi-automated systems have permitted greater than targeted output	The unit evaluated 16 396 applications for the sale of unregistered medicines within the predefined timelines, out of a total of 17 169 applications received This comprised: S21 Human = 15 198 out of 15 852 S21 Vet = 1 161 out of 1 280 S21 CMs= 37 out of 37

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achieve-ment 2019/20	Variance	Reason for Variance	Notes on Achievement
4	20	Scientific evaluation of all New Chemical Entity biological applications submitted for regulatory decision and scientific evaluation of all generic/ biosi-milar applications submitted for regulatory decision	Percentage of medicines with a public health priority evaluated with a regulatory decision every quarter	**60%**	100%	100%	100%	100%	**100%**	+67%	During the re-engineering of operations within the transition period, SAHPRA reviewed fewer products. Products with a public health focus were prioritised for evaluation and reviewed during this transition period. The target was therefore exceeded	93 applications that qualified as public health priority products served at the Regulatory Committee in the 2019/20 financial year. All 93 products were registered

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achieve-ment 2019/20	Variance	Reason for Variance	Notes on Achievement
4	21	Investigate, monitor, analyse, solicit and act upon existing and new adverse events, interactions, and information with regards to post-marketing surveillance and vigilance	Published quarterly reports of new adverse events and signals that have been assessed, actioned and concluded	**4**	1	1	1	1	**4**	0%	No variance	Reports published on SAHPRA's website
4	22	Investigate, monitor, analyse, solicit and act upon existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance	An inclusive vigilance framework for all health products developed for approval	**Draft policy and stake-holder engage-ment completed**	Not applicable for Q1	Stakeholder meetings not completed	Not applicable for Q3	Draft policy completed	**Draft policy developed. Stake-holder com-ment period still in process**		Capacity constraints to support expedited output only permitted one of the two components of the output to be completed within this period	The draft policy was developed and published in May 2020 on the website for comment for a period of three months

3.5 Programme 5: Medical Devices, Diagnostics and Radiation Control

Programme	Medical Devices, Diagnostics and Radiation Control
Purpose	To develop and maintain regulations and guidelines pertaining to the regulatory oversight of medical devices, ionising and non-ionising radiation emitting devices, and radioactive nuclides
Sub-Programme 1	**Medical Devices**
Purpose	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**
Purpose	To efficiently, effectively and ethically evaluate and register non-ionising radiation emitting devices and radioactive nuclides

This fledgling programme hosts medical device regulation which is still a relatively new functional area, as well as radiation control, adopted from the National Department of Health during SAHPRA's transition to a public entity. Adoption of digital solutions, which remains a high priority for this unit's efficient functioning, commenced in the 2019/20 financial year and will fully materialise in the 2020/21 financial year.

The National Nuclear Regulator and the DMRE were engaged by the SAHPRA Board and Executive to develop a framework to ensure co-regulation of the radiation control function, including revisions of the respective Acts. The unit, in a phased approach, is also implementing the medical device regulation framework to align to the World Health Organisation (WHO) Global Model Regulatory Framework. Furthermore, SAHPRA currently chairs the African Medical Devices Regulatory Forum.

The unit outputs for the financial year includes:

- Issued 916 medical device establishment licences against a target of 388;
- Issued 1 695 licences for radionuclides; and
- Issued 1 623 licences for non-ionising radiation emitting devices.

Table 5: Strategic Objectives, Performance Indicators, Planned Targets and Actual Achievements

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achievement 2019/20	Variance	Reason for Variance	Notes on Achievement
5	23	License medical device establishments that are compliant with prescribed reference standards	Percentage of licence applications finalised within a defined timeline	**40%**	86%	105%	100%	159%	**99%**	+88%	The unit was capacitated with three community service pharmacists who were a dedicated resource to support this licence process	The unit evaluated 944 medical device establishment licences out of the 916 medical device establishment licence applications received. * Note: Deficiencies are identified in some licence applications. The applicant is required to respond to the deficiencies identified. The response from the applicant will be evaluated. In these cases, the same application will be evaluated multiple times. As a result, some quarters exceeded 100%

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achievement 2019/20	Variance	Reason for Variance	Notes on Achievement
5	24	Implement a system to register medical devices	A system to register medical devices is developed and implemented	**20%**	No endpoints achieved in Q1	No endpoints achieved in Q2	Fees schedule for medical devices drafted	Regulations approved Submission to Minister requesting publication for 3-month comment period	**The medical device system has not been implemented. Regulations, fees schedule, guidelines and Standard Operating Procedures to be implemented. Online registration system to be developed. Technical staff to be recruited and trained**		The process to develop and implement the system is an ongoing process with endpoints that needed to be re-visited and many external dependencies	Several endpoints need to be achieved in order to facilitate the implementation of a system to register medical devices. While some of these endpoints have been achieved, there are several endpoints that need to be achieved in the upcoming performance period

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achievement 2019/20	Variance	Reason for Variance	Notes on Achievement
5	25	Implement a system to register medical devices	Percentage of regulatory decisions taken on medical device applications within a predefined timeline	**20%**	0%	0%	0%	0%	**Achievement of KPI 25 was dependent on the achievement of KPI 24.** **KPI 24 was not achieved and as a result KPI 25 could not be achieved**	-100%	The percentage of regulatory decisions taken on medical device applications could not be calculated as no regulatory decisions on medical device applications for registration of medical devices were made. No applications for registration of medical devices, in terms of the Medicines Act, were received as the system to register medical devices (KPI 24) has not been implemented	Due to the vacancies within Programme 5, there was limited capacity to implement a system to register medical devices (KPI 24). As a result, it was not possible to achieve the target for KPI 25 as this KPI was dependent on the achievement of KPI 24

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achievement 2019/20	Variance	Reason for Variance	Notes on Achievement
5	26	Optimise business processes of radiation control functional area to ensure public health safety needs are met	Percentage of licence applications finalised within a defined timeline	**70%**	90%	122%	85%	82%	**91%**	14%	In certain instances, a single licence application resulted in multiple licences due to the several activities that are inherent to the management of radionuclide licence applications	The unit issued 1 849 radionuclide licences from the 2 022 radionuclide licence applications received. Some applications resulted in multiple licences. As a result, some quarters exceeded 100%
5	27	Optimise business processes of radiation control functional area to ensure public health safety needs are met	Percentage of licences issued for non-ionising radiation emitting devices and radio active nucleides	**40%**	92%	102%	89%	99%	**99%**	148%	In certain instances, a single licence application resulted in multiple licences due to the several activities that are inherent to the several activities required in the management of non-ionising radiation emitting devices and radio active nucleides	The unit issued 1 546 non-ionising licences from the 1 569 non-ionising licence applications received. Some applications resulted in multiple licences. As a result, some quarters exceeded 100%

Prog	KPI	Strategic Objective	KPI as per APP	Target for 2019/20	Q1	Q2	Q3	Q4	Annual Achievement 2019/20	Variance	Reason for Variance	Notes on Achievement
5	28	Optimise business processes of radiation control functional area to ensure public health safety needs are met	Roadmap for system improve-ments to be developed and approved	**Roadmap developed and approved by the Board**	Not applicable in Q1	Stakeholder engagement not completed	Not applicable in Q3	Roadmap not approved by the Board	**Roadmap not developed and not approved by the Board**		The SAHPRA Executive and Board are engaging with the National Nuclear Regulator, (NNR), the DMRE, and the NDoH in an effort to finalise the position taken	A working group will be established representative of all organisations to develop the legislative framework and Cabinet Memorandum

Overall Mitigation Strategies to Overcome Areas of Underperformance

SAHPRA has made good strides since its inception in February 2018 to establish a strong, efficient and responsive Authority. The implementation of re-engineering systems and processes had led to some gains; however, significant improvement is still required. In an effort to improve performance against its key performance indicators, SAHPRA anticipates that the following measures already in process will mitigate the areas of underperformance:

1. Definition of KPIs as per SMART principles:
    - Ensure that the indicators defined are SPECIFIC to ensure tracking, MEASURABLE to ensure consistency in assessment, ATTAINABLE within the nature of work that SAHPRA conducts, REALISTIC in that they reflect the expected outputs within the available resources and TIMEBOUND to ensure consistency in assessment and limited ambiguity.
2. Capacitation and resourcing of the organisation:
    - Capacitate the various units with the required skills sets and the required numbers of staff to support full execution of the unit's business imperatives;
    - Ensure that the published fees are implemented at the planned time to ensure adequate resourcing of the organisation;
    - Finalise key strategic partnerships with other recognised regulators internationally, in the region and the continent to support capacity building; and
    - Strengthen its efforts to raise funding for specific strategic projects of the organisation.
3. Implementation of systems to support efficient storage and tracking of performance information:
    - Digital adoption to ensure that complete reporting for monitoring and evaluation of operations is complete and comprehensive, including adequate supporting evidence.
4. Improve outputs through efficient implementation of the re-engineered processes:
    - Ensure pilot recognition in the Backlog Clearance Project;
    - Efficiently implement reliance and ensure that the learning from the Backlog Clearance Project is transferred to BAU; and
    - Develop a risk benefit framework to ensure that SAHPRA's regulatory decisions are transparent and scientifically sound.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PART C:

GOVERNANCE

1. INTRODUCTION

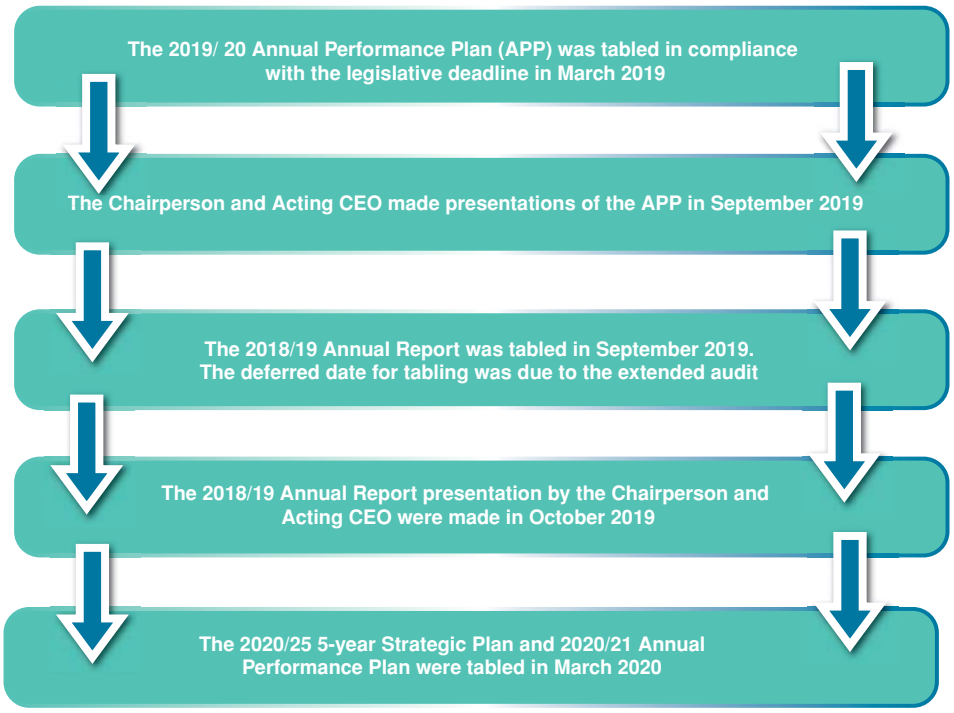
The Board and its six committees review the systems and processes of the organisation timeously. They recognise the role of governance as critical to the efficient and effective functioning of the Regulator. The Board provides assurance to the Authority's stakeholders that strengthening the existing framework for governance and compliance remain high on the priorities of SAHPRA's agenda.

2. ENGAGEMENT WITH THE PORTFOLIO COMMITTE

- The following presentations were made by SAHPRA to the Portfolio Committee for Health in Parliament:

3. EXECUTIVE AUTHORITY

- The 2019/20 Annual Performance Plan, 2020/25 Strategic Plan and 2020/21 Annual Performance Plan were submitted in compliance with the legislated deadlines.
- An extension was granted for the submission of the 2018/19 Annual Report due to the extended audit. The 2018/19 Annual Report was submitted in September 2019.



4. THE ACCOUNTING AUTHORITY/BOARD

The Board is the Accounting Authority in terms of the PFMA and is appointed for a renewable period of three years by the Minister of Health in terms of the Medicines Act. The Regulator is governed and controlled in accordance with the Medicines Act No. 101 of 1965, as amended. The Board ensures that the objects of the Act THE are carried out and exercises general oversight over the performance of the Regulator's functions. The Board embraces the principles of good corporate governance and considers these as the underlying philosophy in creating organisational excellence at all levels within the Regulator. The Board sets the tone in driving the ethics of good governance, and members, collectively and individually, acknowledge their responsibilities and duties in terms of governance, regulatory and legislative requirements.

4.1 Composition of the Board

	Name	Designation	Date Appointed	Date Resigned	Number of Meetings Attended
1.	Prof. Helen Rees	Chairperson	17 November 2017		17
2.	Ms Mandisa Hela	Vice-Chairperson	17 November 2017		15
3.	Mr Norman Baloyi	Member and Chairperson (ICT)	17 November 2017		14
4.	Prof. Shabir Banoo	Member and Chairperson (TORS)	17 November 2017		18
5	Dr Craig Household	Member and Chairperson (RAG)	17 November 2017		15
6.	Dr Ushma Mehta	Member and Chairperson (Stakeholder Communications)	17 November 2017		14
7.	Prof. Jeffrey Mphahlele	Member and Chairperson (HR&Remco)	17 November 2017		13
8.	Adv Hasina Cassim	Member	17 November 2017		16
9.	Dr Mphane Molefe	Member	17 November 2017		11
10.	Prof. Ames Dhai	Member	17 November 2017		10
11.	Ms Lesibana Fosu	Member and Chairperson (Finance)	17 November 2017	1 October 2019	9
12.	Dr Edith Madela-Mntla	Member	17 November 2017		16
13.	Prof. Patrick Demana	Member	25 April 2019		9
14.	Dr Thapelo Motshudi	Member	17 November 2017		14
15.	Mr Itani Mashau	Member	25 April 2019		11

4.2 Meetings of the Board

Board Meetings

Quarters	Dates
Quarter 1	9 - 10 April 2019
	12 April 2019
	29 April 2019
	30 May 2019
Quarter 2	3 July 2019
	9 July 2019
	26 - 27 August 2019
	10 September 2019
	25 - 26 September 2019

Quarters	Dates
Quarter 3	1 November 2019
	25 - 26 November 2019
Quarter 4	27 - 28 January 2020
	16 March 2020

The Board approved the Backlog Clearance Project as a key strategic project in 2018. A special steering committee was set up to oversee the inception and progress of the project. The Backlog Steering Committee is composed of Prof Helen Rees, Prof Shabir Banoo, Ms Mandisa Hela, the CEO, the CRO and the backlog project team. Monthly meetings in this regard were held by the Steering Committee members with the executive and project team, wherein updates on the progress of the project were discussed, including various interventions to improve the performance.

Furthermore, the Board established a Board EXCO which was responsible to oversee specific aspects as per the request of the Board. The Board EXCO comprised the Board Chair, Vice Chair, and the chairs of the Technical Oversight and Regulatory Strategy Committee (TORS), Human Resources and Remuneration Committee (HR&Remco), Information Technology Committee and the Risk, Audit and Governance (RAG) committees. Advocate Cassim was a co-opted member of the Board EXCO. The specific meetings held by the Board EXCO are indicated below, wherein matters pertaining to the Backlog Clearance Project were addressed.

Special Board EXCO Meetings

Name	Designation	Meeting	Number of Meeting Days Attended
Prof. Helen Rees	Chairperson	19 February & 12 March 2020 (to deal with Backlog Clearance matters)	2
Ms Mandisa Hela	Vice-Chairperson	19 February & 12 March 2020 (Board EXCO to deal with Backlog Clearance matters)	2
Prof. Craig Household	Chairperson of RAG	19 February & 12 March 2020 (Board EXCO to deal with Backlog Clearance matters)	2
Prof. Banoo Shabir	Chairperson of TORS	19 February & 12 March 2020 (Board EXCO to deal with Backlog Clearance matters)	2
Prof. Jeffrey Mphahlele	Chairperson of HR&RemCo	19 February 2020 (Board EXCO to deal with Backlog Clearance matters)	1
Adv Hasina Cassim	Member	19 February & 12 March 2020 (Board EXCO to deal with Backlog Clearance matters)	2

4.3 Committees

The following Board Committees assisted the Board in discharging its mandate over the period under review:

- Finance
- Human Resource and Remuneration
- Technical Oversight and Regulatory Strategy
- Risk, Audit and Governance
- Information, Communication and Technology
- Stakeholder Engagement Communication.

Board Committees provided feedback to the Board through committee reports. Board Committees have each adopted formal terms of reference, which are

reviewed annually to ensure continued relevance. Meetings of the sub-committees are listed in Tables 6 - 10.

4.3.1 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:

- 25 April 2019
- 24 May 2019 (Joint RAG and FinCo)
- 9 September 2019 (Joint RAG and FinCo)

Table 6: Finance Committee Membership and Meeting Attendance

No.	Name	Designation	Number of Meetings Attended
1.	Ms Lesibana Fosu	Chairperson	3
2.	Prof. Jeffrey Mphahlele	Member	3
3.	Mr Norman Baloyi	Member	3
4.	Prof. Craig Household	Member	3

In this financial year, the Finance Committee:

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

4.3.2 Human Resources and Remuneration Committee (HR&Remco)

This committee is responsible for ensuring that SAHPRA has a transparent, ethical and professional human resources management framework, acts in good faith, takes care of the total well-being 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:

- 28 May 2019
- 5 August 2019
- 17 January 2020
- 23 March 2020.

Table 7: HR&REMCO Membership and Meeting Attendance

No.	Name	Designation	Number of Meetings Attended
1.	Prof. Jeffrey Mphahlele	Chairperson	4
2.	Ms Mandisa Hela	Member	2
3.	Dr Edith Madela-Mntla	Member	4
4.	Prof. Craig Household	Member	4

Key outputs from this committee for the reporting period include:

- Recommended for approval six critical Executive Management posts in the 2018/19 financial year;
- Recommended for approval the SAHPRA structure as presented by the newly appointed CEO; and

- Recommended for approval Cost of Living Adjustment for the 2019/20 financial year.

4.3.3 Information and Communication Technology (ICT) Committee

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:

- 7 May 2019
- 17 July 2019
- 2 November 2019.

Table 8: ICT Committee Membership and Meetings

No.	Name	Designation	Number of Meetings Attended
1.	Mr Norman Baloyi	Chairperson	3
2.	Dr Edith Madela-Mntla	Member	3
3.	Dr Thapelo Motshudi	Member	2
4.	Dr Ushma Mehta	Member	2

Key outputs from this committee for the reporting period include:

- Recommended to the Board the approval of the IT Governance Policy.

4.3.4 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 SAHPRA. The report from the RAG Committee can be reviewed on section 5.

The Risk, Audit and Governance Committee met on:

- 24 May 2019
- 24 June 2019 (Joint RAG and FinCo)
- 9 September 2019 (Joint RAG and FinCo)
- 17 January 2020
- 23 January 2020
- 4 March 2020
- 31 March 2020.

Table 9: RAG Committee Membership and Meetings

No.	Name	Designation	Number of Meetings Attended
1.	Prof. Craig Household	Chairperson	7
2.	Prof. Amaboo Dhai	Member	5
3.	Dr Thapelo Motshudi	Member	6
4.	Adv Hasina Cassim	Member	7

No.	Name	Designation	Number of Meetings Attended
5.	Dr Mphane Molefe	Member	5
6.	Prof. Shabir Banoo	Member	7

Key outputs from this committee for the reporting period include:

- Recommended for approval the 2018/19 Annual Report, five-year Strategic Plan 2020–2024 and 2019/20 Annual Performance Plan;
- Recommended for approval the quarterly performance reports and compliance check lists;
- Recommended for approval the Compliance Framework and Enterprise Risk Management Framework; and
- Provided oversight over the Internal Audit Plan and Annual Performance Plan.

4.3.5 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:

- 5 April 2019
- 6 June 2019
- 11 November 2019
- 20 January 2020.

Table 10: TORS Committee Membership and Meetings

No.	Name	Designation	Number of Meetings Attended
1	Prof. Shabir Banoo	Chairperson	4
2	Ms Mandisa Hela	Member	4
3	Adv Hasina Cassim	Member	3
4	Dr Ushma Mehta	Member	4
5	Dr Mphane Molefe	Member	3
6	Prof. Amaboo Dhai	Member	3

Key outputs from this committee for the reporting period include:

- Providing oversight support on the Backlog Clearance Project;
- Providing oversight support on business and usual deliverables; and
- Recommended improvement of various processes under core business.

4.3.6 Stakeholder Communication Committee

The role of the Committee is to advise the SAHPRA Board and Communications Unit on how the communication 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 advises the Board on all communications-related resource requirements and allocations in collaboration with the Communications Unit of the Authority. The Committee provides guidance to the Board, if necessary in consultation with legal

experts, on how the legal framework that governs stakeholder engagement informs regulatory interactions and communications with stakeholders. The Committee approves and monitors performance measures for communication with key stakeholders and partners.

The Communications Committee met on:

- 7 May 2019
- 17 July 2019
- 21 November 2019
- 24 March 2020.

Table 11: Stakeholder Engagement and Communications Committee Membership and Meetings

No.	Name	Designation	Number of Meetings Attended
1.	Dr Ushma Meta	Chairperson	4
2.	Prof. Shabir Banoo	Member	4
3.	Adv Hasina Cassim	Member	4
4.	Dr Edith Madela-Mntla	Member	4
5.	Dr Amaboo Dhai	Member	3

Key outputs from this committee for the reporting period include:

- Provided oversight support for media and brand communication;
- Recommended the SAHPRA corporate identity manual for Board approval;
- Provided oversight support on website development; and
- Recommended approval of various communication policies.

4.4 Remuneration of Board members

Table 11: Remuneration of Board Members for 2019/20

No	Name	Designation	Board Fees	Total Travel (D)	Total	
1.	Prof. Helen Rees	Chairperson	33 625	-	33 625	
2.	Ms Mandisa Hela	Vice – Chair	86 075	10 870	96 945	
3.	Mr Norman Baloyi	Member	58 396	23 076	81 472	
4.	Prof. Shabir Banoo	Member	25 064	2 243	27 307	
5.	Prof. Craig Household	Member	57 605	-	57 605	
6.	Dr Ushma Mehta	Member	55 506	-	55 506	
7.	Prof. Jeffrey Mphahlele	Member	-	-	-	A
8.	Adv Hasina Cassim	Member	109 810	2 035	111 845	
9.	Prof. Amaboo Dhai	Member	35 319	-	35 319	
10.	Ms Lesibana Fosu	Member	24 465	-	24 465	B
11.	Dr Edith Madela-Mntla	Member	124 050	4 563	128 613	
12.	Dr Mphane Molefe	Member	-	-	-	A
13.	Dr Thapelo Montgomery Motshudi	Member	29 015	1 708	30 723	
14.	Prof. Patrick Demana	Member	32 707	794	33 501	
15.	Mr Itani Mashau	Member	29 352	1 131	30 483	
16.	Ms Lerato Mothae	Member	-	-	-	C
			700 989	**46 420**	**747 409**	

Notes

The Board fees reflect the actual claims submitted. At times, Board members opt not to claim for meetings attended.

A Prof Mphahlele and Dr Molefe are employees in the public sector – no fees claimed

B Resigned August 2019

C Appointed April 2020 (event after reporting date)

D Total travel relates to expenditure incurred by SAHPRA for flights, accommodation, etc. and kilometre re-imbursement (paid by NDoH and SAHPRA)

5. RISK MANAGEMENT

The Board is ultimately responsible for and assumes ownership of risk management as the accounting authority in line with Section 51 of the PFMA. In this regard, the Board, through the RAG Committee provides guidance and direction to management in respect of risk management and would undertake to determine the following for SAHPRA:

- Setting an appetite for risk for SAHPRA;
- Determining the risk-bearing capacity; and
- Determine the tolerance level for key risks.

The RAG committee monitors and reviews the extent to which the authority has:

- Established effective risk management measures in the respective units;
- Ensured that management has implemented an ongoing process to identify, assess and manage risks;
- Formed its own opinion about the effectiveness of the risk management process; and
- Ensured that the risk management process is formally evaluated on an annual basis.

As a newly established Schedule 3A public entity, risk management practices, guided by a risk management policy, had to be established. These would enable the Board and management to fully execute their respective roles. To this end, a service provider was appointed in February 2020, tasked with having to establish the Risk Management Policy, associated strategy and the framework aimed at optimal management of risks for the entity to achieve its vision and mission, key strategic objectives and to protect the core values of the organisation.

Under the risk management policy, management would have to conduct regular risk assessments to determine the effectiveness of the risk management strategy and identify new and emerging risks. This would be a key focus for the 2020/21 financial year.

6. INTERNAL CONTROL AND INTERNAL AUDIT

Internal Control

SAHPRA commenced implementing internal control systems in this financial year to create confidence in the financial position of SAHPRA and ensure the safeguarding of assets (including the security of information) and compliance with applicable laws, regulations and government policy.

The internal auditors commenced with monitoring the functioning and effectiveness of the internal control systems on 1 March 2020. The initial focus would be to make recommendations to management and the RAG and Finance Committees on the current status of controls and to recommend improvements.

Some of the internal control systems, noted as part of the 2018/19 audit outcome, are in the process of implementation and, once completely in place, will provide reasonable assurance about the integrity and reliability of the financial statements; safeguard, verify and maintain accountability of assets; detect fraud, potential liability, and loss and material misstatement; and comply with applicable laws and regulations.

Internal Audit

The internal audit function was outsourced and the function commenced work on the approved Internal Audit Coverage Plan on 1 March 2020. The Internal Audit Coverage Plan was compiled based on the following:

- Input from the Auditor-General;
- The Strategic and Annual Performance Plan;
- Service Level Agreement; and
- Input on the audit universe by senior management.

The major roles and responsibilities of the internal audit function as approved by the Risk and Audit Committee would be to address the following:

- Evaluate and provide reasonable assurance that risk management, control, and governance systems are functioning as intended and will enable the organisation's objectives and goals to be met;
- Report risk management issues and internal

controls deficiencies identified directly to the audit committee and provide recommendations for improving the organisation's operations, in terms of both efficient and effective performance;
- Evaluate information security and associated risk exposures;
- Evaluate the regulatory compliance programme with consultation from legal counsel;
- Evaluate the organisation's readiness in case of business interruption;
- Maintain open communication with management and the audit committee;
- Engage in continuous education and staff development; and
- Provide support to the company's anti-fraud programmes.

Internal Audit aimed to accomplish the following audit goals during the 1st quarter of the 2020/21 financial year to support the 2019/20 external audit preparation:

- To give reasonable assurance that controls implemented in the 2019/20 financial year are functioning as intended;
- To assess the status of the portfolio of performance evidence that contributes to the performance indicators of the organisation; and
- To assess and make recommendations on the status of internal finance controls, supply chain
- management controls and IT risk controls.

7. COMPLIANCE WITH LAWS AND REGULATIONS

Adherence and compliance to applicable laws and regulations remain a Board priority as the organisation finds its feet. As a Schedule 3A public entity, SAHPRA is governed by the PFMA and National Treasury Regulations published under the PFMA and other legislative prescripts. Compliance is an ongoing activity within the organisation and monitoring of any non-compliance with legislative regulations resides with the office of the Company Secretary and the respective Executive Authority. Compliance is tracked regularly by the respective Executive and, where non-compliance is noted, corrective actions are immediately developed and implemented.

A PFMA compliance checklist is used to monitor compliance with the PFMA and reporting is done on a quarterly basis to National Treasury and Minister of the NDoH. The checklist is part of management's reporting responsibilities to the Board through its sub-committees, especially the RAG Committee and Finance Committee.

8. FRAUD AND CORRUPTION

The Board and Executive have committed to combating all forms of fraud and corruption and have commenced with a proactive focus on addressing all activities deemed to be considered corrupt. In the 2019/20 financial year, a presidential proclamation on investigation of allegations as contemplated in Section 2(2) of the Special Investigating Units and Special Tribunals Act, 1996 (Act No. 74 of 1996) were made in respect of the affairs of SAHPRA. The terms of reference of the Special Investigating Unit were to investigate the following allegations, as contemplated in the Act:

- Serious maladministration in connection with the affairs of SAHPRA;
- Improper or unlawful conduct by employees of SAHPRA;
- Offence referred to in Parts 1 to 4, or sections 17, 20 or 21 of Chapter 2 of the Prevention and Combating of Corrupt Activities Act, 2004 (Act No. 12 of 2004), and which offences were committed in connection with the affairs of SAHPRA; and
- Unlawful or improper conduct by any person, which has caused or may cause serious harm to the interests of the public or any category thereof.

The investigation would focus on the period from 1 January 2015 - October 2019 when the proclamation was published. The Special Investigations Unit (SIU) only commenced with the investigation in March 2020 and at the time of this report the investigation was still ongoing.

In addition, SAHPRA appointed Ngubane and Co to conduct a forensic investigation into allegations of fraud and corruption, primarily focusing on the Inspectorate and Regulatory Compliance Unit of SAHPRA. This

focus was based on specific allegations that were made against the staff in this unit. The investigation commenced on 4 November 2019 and was concluded on 28 February 2020. The recommendation was that further investigation be conducted on all the allegations that were inconclusive due to lack of information or evidence as well as the lifestyle audits that Ngubane and Co could not conduct. On the conclusive matters, SAHPRA followed up with relevant disciplinary procedures against the specific individuals. The matters that were inconclusive were handed over to the SIU for further investigation.

9. MINIMISING CONFLICT OF INTEREST

The Board has approved a Conflict of Interest Policy and has procedures to manage issues of conflict of interest (perceived, potential or actual) to minimise if not prevent them. The Board members, SAHPRA EXCO and senior management are required to disclose financial interests on an annual basis. The disclosures are meant to ensure that there is no conflict of interest when decisions are made by anyone within SAHPRA's governance structures. Furthermore, at every Board meeting, members sign a declaration of interest form and these are captured as a standing agenda item for discussion to identify any conflict, while members recuse themselves from the meeting during the discussion of the item of conflict. SAHPRA employees also complete an annual declaration of any interest. This approach is also extended to the external evaluators and the CEO committee's members.

10. CODE OF CONDUCT

SAHPRA is committed to an exemplary standard of business ethics and transparency in all its dealings with stakeholders. Both Board members and employees are bound by a code of conduct. Gifts received, if accepted, are declared in line with good corporate governance and the gift declaration policy.

11. HEALTH, SAFETY AND ENVIRONMENTAL ISSUES

The health, safety and wellbeing of all staff remains a key consideration of SAHPRA. As such SAHPRA ensures that health, safety and environmental issues are addressed adequately. In this financial year, SAHPRA employees were accommodated in five buildings across the CSIR campus in Pretoria, as well as leased offices in Durban and Cape Town. SAHPRA worked closely with the landlords of the facilities and management of all campuses to ensure adherence to security, health, safety and environmental protocols. This was especially rigorous and crucial during the COVID-19 lockdown. Staff screening, training, capacity, testing and management of positive cases were aligned to national guidelines and the requirements as stipulated by tenants. The building in Durban was, however, non-complaint with safety requirements. SAHPRA is currently negotiating exiting the current lease agreement with the aim to identify a suitable, safe and OHSC-compliant building for its employees. These employees are currently working from home.

12. COMPANY/BOARD SECRETARY

SAHPRA is a Schedule 3A public entity with an appointed Board Secretary as mandated by Section 86 of the Companies Act. Advocate Peter Nthotso was appointed by SAHPRA as the Board Secretary in 2019. He provides advice and support to the Board and is vital to the efficient functioning of the Board. As such the position plays a central role in the governance and administration of the organisation's affairs. In the discharge of his duties, he makes the members aware of any laws and regulations relevant to or affecting the Authority.

13. AUDIT COMMITTEE REPORT

As required by the Treasury Regulation 27.1.10, the Audit Committee submits the Audit Committee's report.

The Risk, Audit and Governance Committee met on the following dates to fulfil the requirements of its functions:

- 24 May 2019
- 24 June 2019 (Joint RAG and Finance Committees)
- 9 September 2019 (Joint RAG and Finance Committees)
- 17 January 2020
- 23 January 2020
- 4 March 2020
- 31 March 2020.

Functions of the Audit Committee

The Audit Committee has adopted formal terms of reference as its Audit Committee Charter, as required by Treasury Regulations 27.1.6 and 27.1.7. The Audit Committee hereby confirms that it has discharged limited functions to those embodied in its charter as ascribed to it in terms of the Treasury Regulations 27.1.8 and 27.1.10.

Internal controls, systems, and processes

The Audit Committee undertook the following activities:

- reviewed the framework for establishing the effectiveness of policies, systems, and procedures.
- established a framework for determining the authority's compliance with significant legal and regulatory provisions.
- reviewed the controls over significant financial and operational risks.
- reviewed the accounting and auditing concerns identified by the Auditor-General in the prior year.
- reviewed the annual report and financial statements taken as a whole to ensure that they present a balanced and understandable assessment of the position, performance, and prospects of the Authority.

The Committee has noted with a degree of concern the significant weaknesses that have been identified by the Auditor-General, with the resultant qualified opinion.

Qualification

The Audit Committee has noted all the weaknesses that have been emphasised by the Auditor-General and have requested management together with Internal Audit to develop an action plan to address these issues. The Audit Committee assisted by Internal Audit will monitor and verify the implementation of these actions on a regular basis.

Attendance

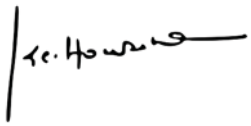
The audit committee meetings were attended by both management board members, with the relevant senior managers always reporting at the meeting as per standing invitation.

Confidential Meetings

The nature of the meetings and its agenda provided for confidential deliberations between committee members.

Independence and the opinion of the External Auditor

The Audit Committee has considered the independence of the Auditor-General and is satisfied in this regard. The Committee also has considered the Auditor-General's findings and conclusions on the Annual Financial Statements and is of the opinion that the audited Annual Financial Statements be accepted when read together with the report of the Auditor-General as well as the context provided in the Annual Report.



Professor Craig Household

Chairperson: Risk, Audit and Governance Committee

Date: 30 October 2020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PART D:

HUMAN RESOURCE MANAGEMENT

1. INTRODUCTION

The HR Management function is the custodian of the overall Human Capital utilisation to ensure SAHPRA delivers on its mandate and achieves its strategic goals. Core to the function is ensuring compliance and managing operational risk to pave a fertile environment for employee empowerment in creating a sustained culture of high performance.

The Authority's HR function is in its infancy and was reliant on consultants and the NDoH HR team for the reporting period as the employee transfer process from the NDoH to SAHPRA was initiated as guided by Section 197 of the Labour Relations Act.

The transfer process included 196 employees from the Medical Control Council, which was a directorate in the Department of Health. The total headcount of employees at the end of March 2020 was 241, inclusive of SAHPRA-appointed employees.

1.1 Resource Priorities and Plans

The financial year was preceded by the approval of the organisational structure, which prompted the population of the structure with critical skills as a strategic priority. The Authority sought the assistance/ services of recruitment agencies and HR consultants to effect the recruitment function, with targeted selection methodologies to ensure the right skills are attracted.

SAHPRA's HR operations remained guided by NDoH policies and practices for the period to bolster potential transitional discomforts and cultural changes presented by the transfer. New policies and processes will be introduced gradually through employees' engagements for holistic ownership and adaptation.

The appointment of the CEO, which signified stability, leadership and direction, was a highlight for the organisation. The appointment complemented the Chief Financial Officer (CFO) and was later complemented by the appointment of the CRO to form an executive committee.

There is an acknowledgement that work needs to be done to build the new organisational culture and practices, and to this effect change management processes and a wellness programme will be prioritised in the new financial year to support employee transition. The 2020/21 financial year will be characterised by the appointment of the HR team, development and imbedding of HR policies and processes, enhancing HR business partnering and support throughout the organisation and driving the culture of accountability and high performance.

2. HUMAN RESOURCE OVERSIGHT STATISTICS

The tables below provide an overview of employee demographics, costs and changes. Each table is defined with the summary of statistic details.

2.1 Executive Team

The following are the approved executive positions for the SAHPRA structure:

Chief Executive Officer Dr Boitumelo Semete-Makokotlela
Chief Regulatory Officer Ms Portia Nkambule
Chief Financial Officer Mr Molatlhegi Kgauwe
Chief Operations Officer Vacant
HR Executive Vacant

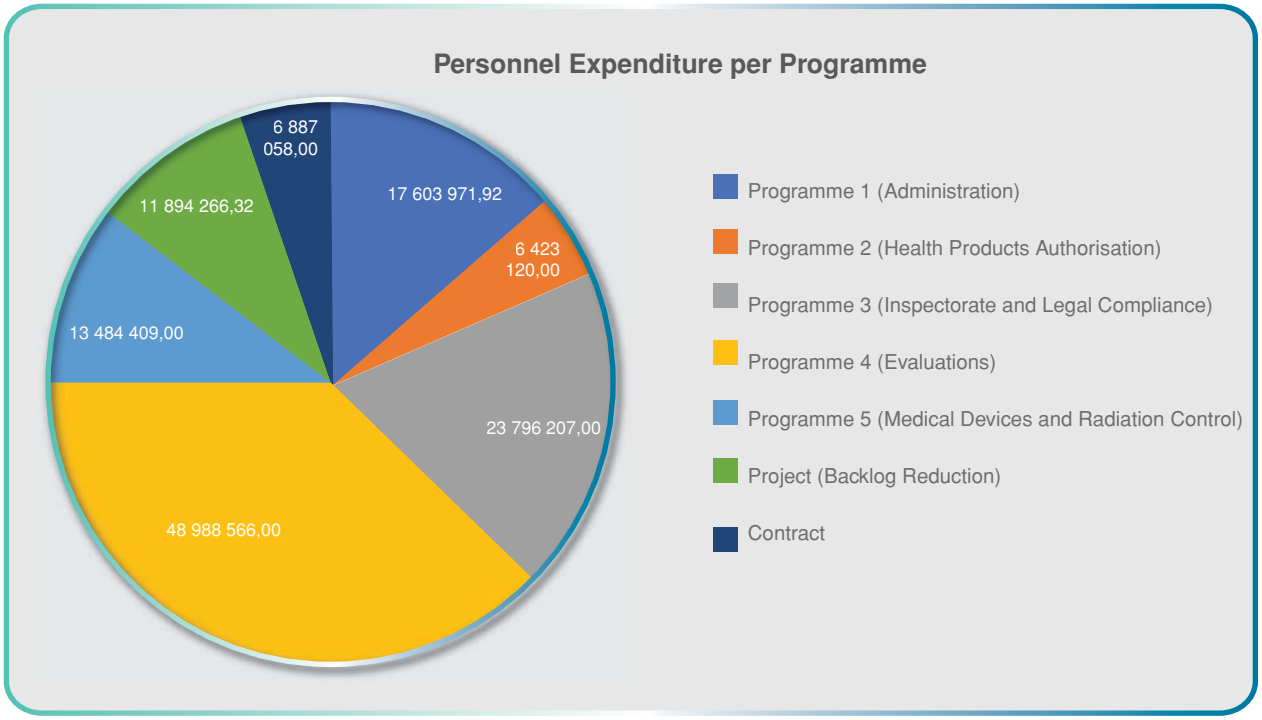
The composition of the executive team incorporated diversity principles to maximise the synergy of different backgrounds, competencies and experiences required to lead and drive the culture of high performance and accountability. The appointment of other executive Team members will be finalised in the new financial year with the objective to ensure the final team remains representative and will continue to encompass innovative ideas and new perspectives in driving

SAHPRA's mandate.

2.2 Personnel Cost by Programme

The purpose of the table is to present the distribution of employee costs in different business areas (programmes). The chart depicts Programme 4 as the major consumer of the personnel costs which is attributed to the number of employees in the programme as it is further subdivided into Clinical Evaluations and Pharmaceutical Evaluations, each with a dedicated unit head.

The least number depicted are contractors (5%) who are fixed-term medical and pharmaceutical interns doing their community service practicals in Programme 3 (5%), an administration-intensive unit.



The table below depicts the monetary value of the allocations as depicted in the chart above.

Programme	Personnel Expenditure	Number of Employees	Average Personnel Cost per Employee
Programme 1 **Leadership and Support**	17 603 971.92	25	704 158.88
Programme 2 **Health Products Authorisation**	6 423 120.00	26	247 043.08
Programme 3 **Inspectorate and Legal Compliance**	23 796 207.00	40	594 905.18

Programme	Personnel Expenditure	Number of Employees	Average Personnel Cost per Employee
Programme 4 **Evaluations**	48 988 566.00	92	532 484.41
Programme 5 **Medical Devices and Radiation Control**	13 484 409.00	27	499 422.56
Project (Backlog Reduction)	11 894 266.32	20	594 713.32
Contract	6 887 058.00	11	626 096.18
Total	**129 077 598.24**	**241**	

Personnel expenditure increased by 29% from R100 083 960 in the 2018/19 financial year to R129 007 598.24 in 2019/20 financial year.

2.3 Personnel Cost by Employment Level

The table depicts the allocation of employee cost per employment levels. The highest employee number and cost allocation apply to the professional qualified level, reflecting the preservation of a critical technical skills set which is core to the delivery of SAHPRA's mandate. The professional qualified level is the vehicle to implementing strategic objectives and other priorities.

Employment Level	Personnel Expenditure	Percentage of Personnel Expenditure to Total Personnel Cost	No. of Employees	Average Personnel Cost per Employee
Top Management	6 101 319.00	4.73%	3	2 033 773.00
Senior Management	1 251 183.00	0.97%	1	1 251 183.00
Professional Qualified	82 205 085.00	63.69%	105	782 905.57
Skilled	20 446 166.40	15.84%	51	400 905.22
Semi-skilled	13 210 431.84	10.23%	71	186 062.42
Unskilled	-	0.00%	0	-
Interns	5 863 413.00	4.54%	10	586 341.30
TOTAL	**129 077 598.24**	**100%**	**241**	**535 591.69**

2.4 Employment Changes and Vacancies

Employment changes for the 2019/20 financial year are presented in the table below. Recruitment efforts were intensified with the focus on populating the approved structure with critical positions. The total number of appointments in the period was 35, with the majority appointed at the skilled personnel level, which is the technical operational level for the organisation.

The appointment of the CEO and the CRO enhanced the executive level of the organisation in leading and guiding

the transition period.

Employment Level	Number employed at beginning of period (April 2019)	Appointments	Terminations	Number of employed at end of the period (March 2020)
Top Management	1	2	0	3
Senior Management	0	1	0	1
Professional Qualified	104	6	5	105
Skilled	35	19	3	51
Semi-skilled	71	4	4	71
Unskilled	0	0	0	0
Intern/Community Service	22	3	15	10
Total	**233**	**35**	**27**	**241**

Turnover Calculation = Voluntary resignations/Employees at the beginning of the period + employees at the end of the period / 2 X 100

2.4.1 Employee Turnover

The total number of terminations is two, rendering a turnover rate of 3.8% (the calculation includes only voluntary resignations, which were nine) for the reporting period. The intention is to maintain this at its lowest to ensure retention of critical and scarce skills and the institutional memory which remains key during for the transition period. The increase in the retention rate will also have a positive impact on reducing the need for new recruitment and associated costs, however with the acknowledgement of the need for "new blood" to encourage and enhance diversity within the organisation. The termination reasons are presented below.

Termination Reason	Number of Terminations
Resignation	9
Retirement	2
Expiry of contract	15
Other	1
Total	**27**

2.5 Age Profile of Employees per Salary Level (Average Age)

The average age of a SAHPRA employee is 41 and this reflects the age diversity within the organisation, an element that can be to SAHPRA's competitive advantage if managed well. The age diversity (as presented below) brings about different experiences, expectations, styles and perspectives, which can be a source of strengthening teams and other organisational efforts.

Employment Level	Average age
Top Management	42.81
Senior Management	51.27
Professional Qualified	44.23
Skilled	42.28
Semi-skilled	40.0
Intern/Community Service	27.28

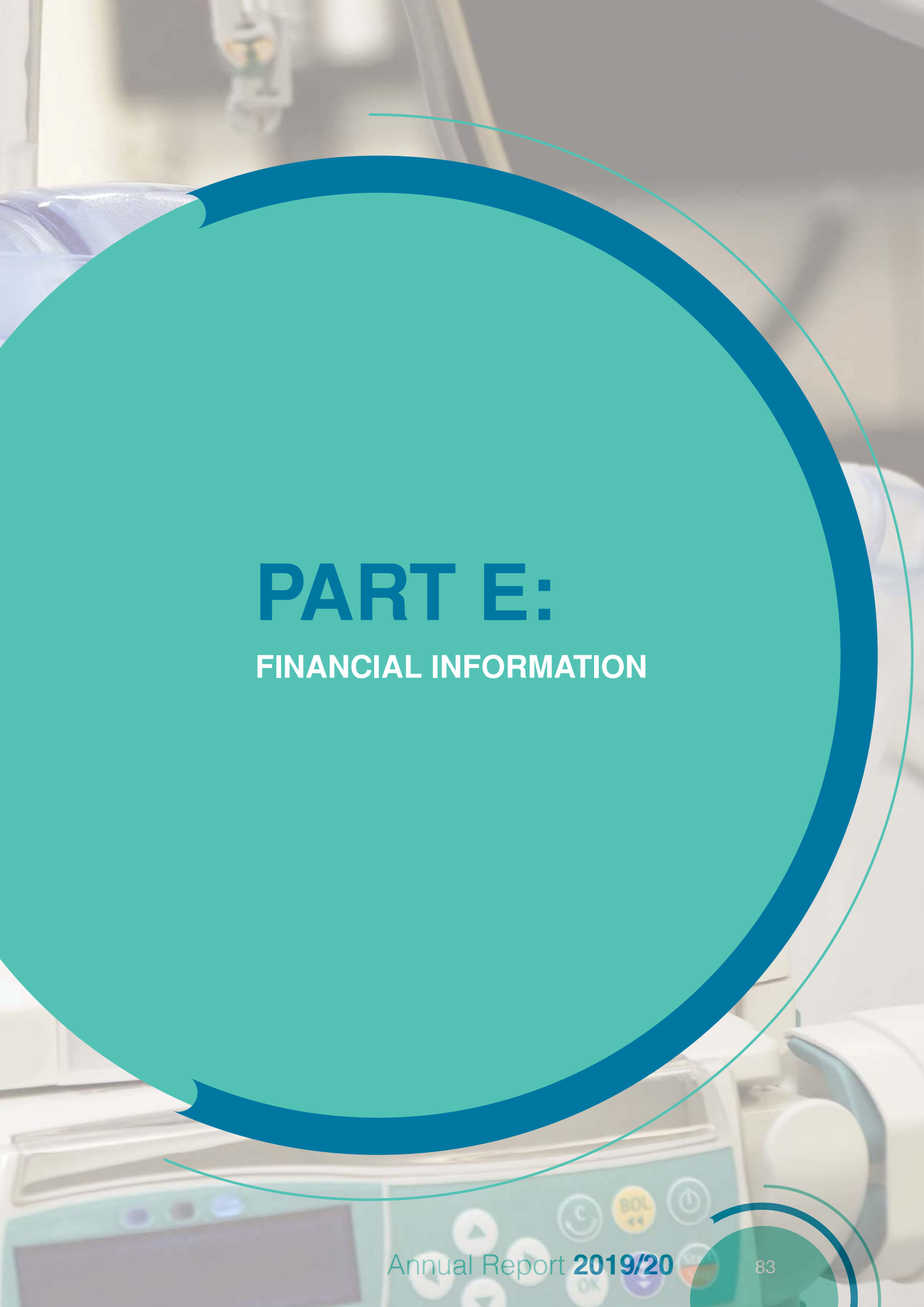
There are no anticipated retirements as at 31 March 2020.

2.6 Training Costs

Personnel Expenditure	Training Expenditure	Training Expenditure as a Percentage of Personnel Cost
R129 077 598.24	R551 677.46	43%

2.7 Labour Relations: Misconduct and Disciplinary Action

Nature of Disciplinary Action	Number
Verbal Warning	1
Written Warning	0
Final Written Warning	0
Dismissal	0
Total	**1**



PART E:

FINANCIAL INFORMATION

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY
ANNUAL FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 MARCH 2020

INDEX

The reports and statements set out below comprise the annual financial statements presented to Parliament:

ACCOUNTING AUTHORITY'S RESPONSIBILITIES AND APPROVAL

The accounting authority's members 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 annual financial statements and related financial information included in this report. It is the responsibility of the accounting authority to ensure that the annual 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 annual financial statements and were given unrestricted access to all financial records and related data.

The annual 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 annual financial statements are based upon appropriate accounting policies consistently applied and supported by reasonable and prudent judgements and estimates.

The accounting authority acknowledges that they are ultimately responsible for the system of internal financial control established by the entity and place considerable importance on maintaining a strong control environment. To enable the accounting authority to meet these responsibilities, the accounting authority 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 authority 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 annual financial statements. However, any system of internal financial control can provide only reasonable, and not absolute, assurance against material misstatement or deficit.

The accounting authority have reviewed the entity's cash flow forecast for the year to 31 March 2021 and, in 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 accounting authority 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 annual financial statements. The annual financial statements have been examined by the entity's external auditors and their report is presented on pages 86 to 92.

The annual financial statements set out on pages 93 to 126, which have been prepared on the going concern basis, were approved by the accounting authority on 30 October 2020 and were signed on its behalf by:

Dr B. Semete-Makokotlela

Chief Executive Officer

Prof H VRees

Chairperson

Report of the Auditor-General to Parliament on the South African Health Products 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 93 to 126, which comprise the statement of financial position as at 31 March 2020, statement of financial performance, statement of changes in net assets, cash flow statement and statement of comparison of budget and actual amounts 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, the financial statements present fairly, in all material respects, the financial position of the SAHPRA as at 31 March 2020, 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 deferred income for the current and previous years had been properly accounted for, due to the status of the accounting records. In addition, I was unable to obtain sufficient appropriate audit evidence for the restatement of the corresponding figure for deferred income. As described in note 37 to the financial statements, the restatement was made to rectify a previous year misstatement, but the restatement could not be substantiated by supporting audit evidence. I was unable to confirm the deferred income by alternative means. Consequently, I was unable to determine whether any adjustment was necessary to deferred income stated at R76 136 236 (2019: R56 684 486) in the financial statements.

Fee income

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 R54 178 520 (2019: R50 964 886) in the financial statements.

Context for the opinion

5. 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.

6. I am independent of the entity in accordance with sections 290 and 291 of the *Code of ethics for professional accountants and parts 1 and 3 of the International Code of Ethics for Professional Accountants (including International Independence Standards)* of the International Ethics Standards Board for Accountants (IESBA codes) as well as 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.

7. 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

8. The board of directors, which constitutes the accounting authority is responsible for the preparation and fair presentation of the financial statements in accordance with the 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.

9. In preparing the financial statements, the accounting authority is responsible for assessing the entity'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

10. 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.

11. 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

12. 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 on the usefulness and reliability of the reported performance information against predetermined objectives for selected programmes presented in the annual performance report. I performed procedures to identify material findings but not to gather evidence to express assurance.

13. My procedures address the usefulness and reliability of 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 included in the planning documents. My procedures do not examine whether the actions taken by the entity enabled service delivery. My procedures also do 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.

14. 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 2020:

Programmes	Pages in the annual performance report
Programme 2 – authorisation management	39 – 43
Programme 5 - medical device, diagnostic and radiation control	53 – 58

15. 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.

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

Programme 2 – Authorisation management

KPI 09 Percentage of backlog application with a regulatory decision taken

17. I was unable to obtain sufficient appropriate audit evidence for the achievement of 58% reported against a target of 40% in the annual performance report, due to the lack of accurate and complete records. I was unable to confirm the reported achievement by alternative means. Consequently, I was unable to determine whether any adjustments were required to the reported achievement.

Various indicators

18. The achievements below were reported in the annual performance report for the listed indicators. However, some supporting evidence provided materially differed from the reported achievements, while in other instances was unable to obtain sufficient appropriate audit evidence. This was due to a lack of accurate and complete records. we were unable to confirm the reported achievements by alternative means. Consequently, was unable to determine whether any further adjustments were required to these reported achievements.

Indicator description	Reported achievement
KPI 10 Percentage of licence issued within predetermined timelines on a quarterly basis	77%
KPI 11 Percentage of permits issued within predetermined timelines on a quarterly basis	95%
KPI 12 Percentage of certificates prepared for new registrations within seven days of a completed review	92%

Programme 5 - medical device, diagnostic and radiation control

Various indicators

19. The achievements below were reported in the annual performance report for the listed indicators. However, some supporting evidence provided materially differed from the reported achievements, while in other instances I was unable to obtain sufficient appropriate audit evidence. This was due to a lack of accurate and complete records. I was unable to confirm the reported achievements by alternative means. Consequently, I was unable to determine whether any further adjustments were required to these reported achievements.

Indicator description	Reported achievement
KPI 23 Percentage of licence applications finalised within a defined timeline. (medical device establishments)	99%
KPI 26 Percentage of licence applications finalised within a defined timeline.	91%
KPI 27 Percentage of licences issued for non-ionising radiation emitting devices and radioactive nucleides	99%

Other matters

20. I draw attention to the matters below.

Achievement of planned targets

21. Refer to the annual performance report on pages 30 to 59 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 material findings on the usefulness and reliability of the reported performance information in paragraph(s) [15 to 19] of this report.

Adjustment of material misstatements

22. I identified material misstatements in the annual performance report submitted for auditing. These material misstatements were in the reported performance information of programme 2 – authorisation management and programme 5 - medical device, diagnostic and radiation control. As management subsequently corrected only some of the misstatements, I raised material findings on the usefulness and reliability of the reported performance information. Those that were not corrected are reported above.

Report on the audit of compliance with legislation

Introduction and scope

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

24. The material findings on compliance with specific matters in key legislation are as follows:

Annual financial statements, performance and annual reports matter

25. 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.

26. Material misstatements of revenue, receivables and 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

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

Other information

28. The accounting authority is responsible for the other information. The other information comprises the information included in the annual report which includes, the audit committee's report. 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.

29. 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.

30. 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.

31. I did not receive the other information prior to the date of this auditor's report. When I do receive and read this information, if we conclude that there is a material misstatement therein, 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

32. 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 annual performance report and the findings on compliance with legislation included in this report.

Oversight responsibility

33. Leadership did not exercise oversight responsibility regarding financial and performance management reporting, compliance and related internal controls.

Financial and performance management

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

35. Management did not prepare accurate and complete financial and performance reports that were supported and evidenced by reliable information.

36. Management did not properly review and monitor the requirements for compliance with legislation.

Governance

37. The internal audit function was only operational after year end, and therefore was not able to identify internal control deficiencies and recommend corrective action effectively.

38. Leadership did not adequately implement appropriate risk management activities to ensure that regular risk assessments, including the consideration of information technology risks and fraud prevention, were conducted and that a risk strategy to address the risks was developed and monitored.

Auditor General

Pretoria

1 November 2020

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 the board of directors, which constitutes the accounting authority
   - conclude on the appropriateness of the use of the going concern basis of accounting by the board of directors, which constitutes the accounting in the preparation of the financial statements. I also conclude, based on the audit evidence obtained, whether a material uncertainty exists relating to events or conditions that may cast significant doubt on the ability of the SAHPRA 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 my 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 operating as a going concern
   - evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and determine whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

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, actions taken to eliminate threats or safeguards applied.

Statement of Financial Position
As at 31 March 2020

	Note(s)	31 March 2020 R	31 March 2019 Restated* R
Assets			
Current Assets			
Receivables from exchange transactions	3	2 696 835	3 367 301
Receivables from non-exchange transactions	4	14 634 131	-
Prepayments	5	451 580	269 927
Cash and cash equivalents	6	121 957 555	103 656 936
		139 740 101	**107 294 164**
Non-Current Assets			
Property, plant and equipment	7	14 671 465	7 080 511
Intangible assets	8	267 380	-
		14 938 845	**7 080 511**
Total Assets		**154 678 946**	**114 374 675**
Liabilities			
Current Liabilities			
Payables from exchange transactions	9	21 369 850	33 036 195
Conditional grant	10	-	1 441 170
Provisions	11	12 108 776	9 463 516
Deferred income	12	76 136 236	56 684 486
		109 614 862	**100 625 367**
Total Liabilities		**109 614 862**	**100 625 367**
Net Assets		**45 064 084**	**13 749 308**
Accumulated surplus		**45 064 084**	**13 749 308**

**See note 36 for details about property plant and equipment restatement and revision of useful lives, note 37 for details about restatements for changes in accounting policies and note 38 for details regarding the restatement as a result of an error.*

Statement of Financial Performance
for the year ended 31 March 2020

	Note(s)	12 months ended 31 March 2020 R	14 months ended 31 March 2019 Restated* R
Revenue			
Revenue from exchange transactions			
Fee income	13	54 178 520	50 964 886
Interest received	14	8 094 788	4 907 134
Total revenue from exchange transactions		**62 273 308**	**55 872 020**
Revenue from non-exchange transactions			
Transfer revenue			
Transfer payment received	15	183 274 000	125 189 000
Goods and services in-kind from National Department of Health	16	-	29 124 227
Backlog reduction project – grant received	17	16 075 301	-
Total revenue from non-exchange transactions		**199 349 301**	**154 313 227**
Total revenue		**261 622 609**	**210 185 247**
Expenditure			
Employee related costs	18	(131 598 533)	(119 066 656)
Backlog reduction project	19	(17 409 082)	-
Depreciation	20	(2 203 533)	(965 527)
Impairment of assets	21	(46 733)	-
Lease rentals on operating lease	22	(6 543 404)	(1 857 473)
Contracted services	23	(19 992 200)	(19 992 200)
Goods and services in-kind from the National Department of Health	16	-	(29 124 227)
Loss on disposal of assets		(66 635)	(21 968)
Loss on foreign exchange		(59 360)	-
Operating Expenses	24	(52 497 838)	(29 209 137)
Total expenditure		**(230 417 318)**	**(200 237 188)**
Surplus for the year		**31 205 291**	**9 948 059**

**See note 36 for details about property plant and equipment restatement and revision of useful lives, note 37 for details about restatements for changes in accounting policies and note 38 for details regarding the restatement as a result of an error.*

Statement of Changes in Net Assets

For the year ended 31 March 2020

	Accumulated surplus	Total net assets
	R	R
Balance at 1 April 2018	**-**	**-**
Changes in net assets		
Surplus for the period	31 414 395	31 414 395
Assets and liabilities transferred from NDOH	3 804 939	3 804 939
Total changes	**35 219 334**	**35 219 334**
Opening balance as previously reported	34 977 171	34 977 171
Adjustments		
Correction of error in calculating depreciation	(132 977)	(132 977)
Adoption of new accounting policy for revenue	(21 094 886)	(21 094 886)
Balance at 01 April 2019 as restated*	**13 749 308**	**13 749 308**
Changes in net assets		
Surplus for the period	31 205 291	31 205 291
Assets and liabilities transferred from NDOH	109 485	109 485
Total changes	**31 314 776**	**31 314 776**
Balance at 31 March 2020	**45 064 084**	**45 064 084**

**See note 36 for details about property plant and equipment restatement and revision of useful lives, note 37 for details about restatements for changes in accounting policies and note 38 for details regarding the restatement as a result of an error.*

Cash Flow Statement
for the year ended 31 March 2020

	Note(s)	12 months ended 31 March 2020 R	14 months ended 31 March 2019 Restated* R
Cash flows from operating activities			
Receipts			
Fee and deferred income		71 874 849	104 988 875
Government grants		183 274 000	125 189 000
Interest received		8 125 225	4 907 134
Conditional grant		-	1 441 170
		263 274 074	236 526 179
Payments			
Employee related costs		(131 942 136)	(104 310 872)
Suppliers		(102 962 077)	(28 369 849)
		(234 904 213)	(132 680 721)
Net cash flows from operating activities	25	**28 369 861**	**103 845 458**
Cash flows from investing activities			
Purchase of property, plant and equipment	7	(9 787 259)	(188 522)
Purchase of other intangible assets	8	(281 983)	-
Net cash flows from investing activities		**(10 069 242)**	**(188 522)**
Net cash and cash equivalents		18 300 619	103 656 936
Cash and cash equivalents at the beginning of the year		103 656 936	-
Cash and cash equivalents at the end of the year	6	**121 957 555**	**103 656 936**

**See note 36 for details about property plant and equipment restatement and revision of useful lives, note 37 for details about restatements for changes in accounting policies and note 38 for details regarding the restatement as a result of an error.*

Statement of Comparison of Budget and Actual Amounts

for the year ended 31 march 2020

Budget on Cash Basis	Approved budget R	Adjustments R	Final budget R	Actual amounts comparable basis R	Difference between finalbudget and actual R	Reference
Statement of Financial Performance						
Revenue						
Revenue from exchange transactions						
Fee income	122 000 000	-	**122 000 000**	54 178 520	**(67 821 480)**	31.1
Interest received	3 000 000	-	**3 000 000**	8 094 788	**5 094 788**	31.2
Total revenue from exchange transactions	**125 000 000**	**-**	**125 000 000**	**62 273 308**	**(62 726 692)**	
Revenue from non-exchange transactions						
Transfer revenue						
Government grants	183 274 000	-	**183 274 000**	183 274 000	**-**	
Backlog reduction project – grant received	-	-	-	16 075 301	**16 075 301**	31.7
Total revenue from non-exchange transactions	**183 274 000**	**-**	**183 274 000**	**199 349 301**	**16 075 301**	
Total revenue	**308 274 000**	**-**	**308 274 000**	**261 622 609**	**(46 651 391)**	
Expenditure						
Employee Related Costs	(137 610553)	-	**(137 610 553)**	(131 598 533)	**6 012 020**	31.3
Backlog reduction project	(50 000 000)	-	**(50 000 000)**	(17 409 082)	**32 590 918**	31.8
Depreciation	-	-	-	(2 203 533)	**(2 203 533)**	31.4
Impairment of assets	-	-	-	(46 733)	**(46 733)**	
Lease rentals on operating lease	(19 183 000)	-	**(19 183 000)**	(6 543 404)	**12 639 596**	31.9
Contracted Services	(18 000 000)	-	**(18 000 000)**	(19 992 200)	**(1 992 200)**	31.5
Operating expenses	(83 480 447)	-	**(83 480 447)**	(52 497 838)	**30 982 609**	31.6
Total expenditure	**(308 274 000)**	**-**	**(308 274 000)**	**(230 291 323)**	**77 982 677**	
Operating surplus	-	-	-	**31 331 286**	**31 331 286**	
Loss on disposal of assets and liabilities	-	-	-	(66 635)	**(66 635)**	
Loss on foreign exchange	-	-	-	(59 360)	**(59 360)**	
	-	**-**	**-**	**(125 995)**	**(125 995)**	
Surplus before taxation	**-**	**-**	**-**	**31 205 291**	**31 205 291**	
Actual Amount on Comparable Basis as Presented in the Budget and Actual Comparative Statement	**-**	**-**	**-**	**31 205 291**	**31 205 291**	

Accounting Policies

1. Presentation of Annual Financial Statements

The annual 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 annual 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 are disclosed below. These accounting policies have been consistently applied in the preparation of these annual financial statements, except for the change in the accounting policy related to revenue recognition. Refer to note 35 for details regarding the change in the accounting policy.

Comparative amounts for certain statements such as the statement of financial performance, changes in net assets, cash flows and related notes are not entirely comparable. The prior period presents a 14-month period, because the entity started operational activities on 1 February 2018.

1.1 Presentation currency

These annual financial statements are presented in South African Rand.

1.2 Going concern assumption

These annual 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.

Refer to note 7 for details regarding the impairment loss recognised in the current year.

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.

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.

Refer to note 11 for details regarding the leave provisions.

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.

Refer to note 14 for details regarding the interest income recognised.

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.

Refer to note 36 for details regarding the change in estimate following the revision of useful lives of property, plant and equipment in the current year.

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 entity; 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	3 – 7 years
Other assets	Straight line	3 – 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 useful lives of the various components of property, plant and equipment have changed from the prior period to the current year. Refer to note 36 for details regarding the change in estimate following the revision of useful lives of property, plant and equipment in the current year.

The residual values and the useful lives of the assets have been reviewed at least at each annual reporting date.

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.

1.6 Intangible assets

An asset is identifiable if it either:

- is separable, i.e. is capable of being separated or divided from an entity and sold, transferred, licensed,rented or exchanged, either individually or together with a related contract, identifiable assets or liability, regardless of whether the entity intends to do so; or
- arises from binding arrangements (including rights from contracts), regardless of whether those rights are transferable or separable from the entity or from other rights and obligations.

A binding arrangement describes an arrangement that confers similar rights and obligations on the parties to it as if it were inthe form of a contract.

An intangible asset is recognised when:

- it is probable that the expected future economic benefits or service potential that are attributable to the asset will flow to the entity;and
- the cost or fair value of the asset can be measured reliably.

The entity assesses the probability of expected future economic benefits or service potential using reasonable and supportable assumptions that represent management's best estimate of the set of economic conditions that will exist over the useful life of the asset.

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

Expenditure on research (or on the research phase of an internal project) is recognised as an expense when it is incurred. An intangible asset arising from development (or from the development phase of an internal project) is recognised when:

- it is technically feasible to complete the asset so that it will be available for use or sale.
- there is an intention to complete and use or sell it.
- there is an ability to use or sell it.
- it will generate probable future economic benef its or service potential.
- there are available technical, financial and other resources to complete the development and to use or sell the asset.
- the expenditure attributable to the asset during its development can be measured reliably.

Intangible assets are carried at cost less any accumulated amortisation and any impairment losses.

An intangible asset is regarded as having an indefinite useful life when, based on all relevant factors, there is no foreseeable limit to the period over which the asset is expected to generate net cash inflows or service potential. Amortisation is not provided for these intangible assets, but they are tested for impairment annually and whenever there is an indication that the asset may be impaired. For all other intangible assets amortisation is provided on a straight line basis over their useful life.

The entity does not hold any intangible assets with indefinite useful lives.

The amortisation period and the amortisation method for intangible assets are reviewed at each reporting date.

Reassessing the useful life of an intangible asset with a finite useful life after it was classified as indefinite is an indicator that the asset may be impaired. As a result the asset is tested for impairment and the remaining carrying amount is amortised over its useful life.

Internally generated goodwill is not recognised as an intangible asset.

Amortisation is provided to write down the intangible assets, on a straight line basis, to their residual values as follows:

Item	Depreciation method	Average useful life
Developed software	Straight line	7 Years

1.7 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 afinancial 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 non-derivative financial assets or non-derivative 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.

The entity's financial assets consist of receivables from exchange transactions, prepayments and cash and cash equivalents. The entity's financial liabilities consist of payables from exchange transactions and deferred income.

The company does not have financial instruments measured at fair value.

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;
- 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.

1.8 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

The entity is only a lessee in an operating lease and was not a lessee in any finance leases in the current and prior year.

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.

1.9 Impairment of cash-generating assets

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 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.

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.

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.

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

1.10 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:

1. 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.
2. 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.

Reversal of an impairment loss

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.

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.

1.11 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.

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.

1.12 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.

1.13 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.

Interest received

Interest income, where is it probable that the economic benefits or service potential associated with the transaction will flow to the entity, and the amount of the revenue can be measured reliably, are recognized on a time proportion basis that takes into account the effective yield on the asset.

1.14 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.

1.15 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 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.

1.16 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.

Confirmed irregular expenditure is investigated in-order to establish facts whether the transgression is related to fraudulent, corrupt and other criminal conduct. Irregular expenditure is recorded in the irregular expenditure register as soon as it is identified.

If losses were incurred and the entity did not achieve value for money and it can be demonstrated that it is impractical to determine total losses incurred, details and reasons as to why the amount cannot be quantified details and reasons as to why the amount cannot be quantified are disclosed.

If losses can be quantified and losses incurred are irrecoverable, amount of losses irrecoverable are disclosed in the irregular expenditure note.

If losses were not incurred and value for money was achieved and the transgression was free of fraudulent, corrupt or other criminal conduct; condonation of irregular expenditure is requested from the relevant authority; and

If amounts of irregular expenditure are condoned by the relevant authority, amounts are disclosed in the irregular expenditure note as current year amounts condoned and/or prior year amounts condoned for amounts relating to prior year irregular expenditure.

If irregular expenditure was not condoned by the relevant authority, amounts are disclosed as amounts of losses irrecoverable in the irregular expenditure note under “amounts not condoned and not recoverable”

If fraudulent, corrupt or other criminal conduct is alleged or confirmed Treasury Regulations 33 and the debt management policy of the SAHPRA is followed.

1.17 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 annual 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.

1.18 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 ventures).

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 overthose 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 accounting authority of the family of a person are considered to be those family accounting authority 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 with in 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 related outstanding balances, to enable users of the entity's financial statements to understand the effect of related party transactions on its annual financial statements.

1.19 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.

1.20 Commitments

Commitments are recorded at cost in the notes to the financial statements

1.21 Translation of foreign currencies

Cash flows arising from foreign currency transactions are translated into South African Rands using the spot exchange rates prevailing at the date of payment/receipt.

1.22 Comparative figures

Prior period comparative information has been presented in the current year's financial statements. Where necessary figures included in the prior period financial statements have been restated to ensure fair presentation in the current year's financial statements.

2. New standards and interpretations

2.1 Standards and interpretations effective and adopted in the current year

In the current year, the entity has adopted the following standards and interpretations that are effective for the current financial year and that are relevant to its operations:

Standard/Interpretation:	Effective date: Years beginning on or after	Expected impact:
• GRAP 20: Relatedparties	1 April 2019	The impact is not material

2.2 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 1 April 2020 or later periods:

Standard/Interpretation:	Effective date: Years beginning on or after	Expected impact:
• GRAP 104 (amended): Financial Instruments	1 April 2021	Unlikely there will be a material impact
• Guideline: Guideline on the Application of Materiality to Financial Statements	1 April 2020	Unlikely there will be a material impact
• IGRAP 20: Accounting for Adjustments to Revenue	1 April 2020	Unlikely there will be a material impact
• GRAP 1 (amended): Presentation of Financial Statements	1 April 2020	Unlikely there will be a material impact
• GRAP 34: Separate Financial Statements	1 April 2020	Unlikely there will be a material impact
• GRAP 110 (as amended 2016): Living and Non-living Resources	1 April 2020	Unlikely there will be a material impact
• GRAP 1 (revised): Applying the Probability Test on Initial Recognition of Revenue	1 April 2020	Unlikely there will be a material impact
• Directive 7 (revised): The Application of Deemed Cost	1 April 2020	Unlikely there will be a material impact

The changes to the above standards and interpretation were considered and it was established that they will not have a material impact.

3. Receivables from exchange transactions

	31 March 2020 R	31 March 2019 R
Trade debtors	1 979 979	2 660 447
Rental deposit	716 856	706 854
	2 696 835	**3 367 301**

Trade debtors relates to inspectorate services provided and license fees for medical devices not yet invoiced as at year end.

Trade and other Receivables pledged as security

None of the trade and other receivables for current and prior year were pledged as security for any obligation.

4. Receivables from non-exchange transactions

	31 March 2020 R	31 March 2019 R
Grant receivable (Centre for Disease Control and Prevention – NDoH)	14 634 131	-

5. Prepayments

	31 March 2020 R	31 March 2019 R
Prepayments	451 580	269 927

The balance relates to Extedo licence fees and membership fees of International organisations.

6. Cash and cash equivalents

	31 March 2020 R	31 March 2019 R
Cash and cash equivalents consist of:		
Bank balance held at ABSA bank	121 957 555	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 Aa3.za (long term) was ascribed by the Moody's rating agency as at 31 March 2020. 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.

7. Property, plant and equipment

	2020			2019		
	Cost/ Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost/ Valuation	Accumulated depreciation and accumulated impairment	Carrying value
Furniture and fixtures	3 234 484	(837 368)	2 397 116	3 140 934	(271 565)	2 869 369
Computer equipment	12 385 674	(1 781 870)	10 603 804	3 220 767	(512 496)	2 708 271
Other fixed assets	2 236 270	(565 725)	1 670 545	1 684 334	(181 463)	1 502 871
Total	**17 856 428**	**(3 184 963)**	**14 671 465**	**8 046 035**	**(965 524)**	**7 080 511**

Reconciliation of property, plant and equipment – 2020

	Opening balance	Additions	Disposals	Transfers received	Depreciation	Impairment loss	Total
Furniture and fixtures	2 869 369	82 227	(40 108)	60 363	(551 558)	(23 177)	2 397 116
Computer equipment	2 708 271	9 153 096	(25 971)	49 122	(1 266 794)	(13 920)	10 603 804
Other fixed assets	1 502 871	551 936	-	-	(374 626)	(9 636)	1 670 545
	7 080 511	**9 787 259**	**(66 079)**	**109 485**	**(2 192 978)**	**(46 733)**	**14 671 465**

Reconciliation of property, plant and equipment – 2019 Restated*

	Opening balance	Additions	Disposals	Transfers received	Depreciation	Total
Furniture and fixtures	-	53 979	-	3 086 955	(271 565)	2 869 369
Computer equipment	-	134 545	(25 663)	3 111 888	(512 499)	2 708 271
Other fixed assets	-	-	-	1 684 334	(181 463)	1 502 871
	-	**188 524**	**(25 663)**	**7 883 177**	**(965 527)**	**7 080 511**

Pledged assecurity

None of the property plant and equipment for current and prior year were pledged as security for any obligation.

8. Intangible assets

	2020			2019		
	Cost/ Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost/ Valuation	Accumulated depreciation and accumulated impairment	Carrying value
Computer software	281 983	(14 603)	267 380	-	-	-

Reconciliation of intangible assets – 2020

	Opening balance	Additions	Amortisation	Total
Computer software	-	281 983	(14 603)	267 380

9. Payables from exchange transactions

	31 March 2020 R	31 March 2019 R
Trade payables	19 209 806	29 964 711
Refunds due	141 049	443 519
Salary accrual	2 018 995	2 346 285
PAYE	-	261 453
UIF	-	7 733
SDL	-	12 494
	21 369 850	**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. The Authority considers that the carrying value of trade and other payables approximates the fair value.

Salary accrual relates to acting, travel and inconvenience allowances.

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

10. Conditional grant

	31 March 2020 R	31 March 2019 R
Clinton Health Access Initiative Grant	-	1 441 170

This relates to funding provided to the entity by Clinton Health Access Initiative (a non-profit organization) to support the backlog reduction project to be implemented in the current 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.

11. Provisions

	31 March 2020 R	31 March 2019 R
Leave provision	7 141 574	6 263 516
Performance management and development system provision	4 967 201	3 200 000
	12 108 775	**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 the entity.

Performance management and development system provision

The Performance management and development system (PMDS) bonus individual assessment process for the prior period was not concluded at the time of finalisation of the financial statements. Management has made a provision for the current and prior period based on a constructive obligation as a result of past performance bonus payments. The provision calculations for 2019-2020 financial year was based on the actual amounts paid for 2018-2019 and an estimate for 2019-2020 PMDS cycle.

The provision for 2018-2019 financial year is an estimate based on the payment of 2017-2018 PMDS cycle.

	Current Cycle Pro-Rata	Previous Cycle	Capped Leave	PMDS	Total
As at 1 April 2019	2 325 164	3 055 841	882 511	3 200 000	9 463 516
Movement for the year	761 076	61 671	55 311	1 767 201	2 645 259
As at 31 March 2020	**3 086 240**	**3 117 512**	**937 822**	**4 967 201**	**12 108 775**

	Current Cycle Pro-Rata	Previous Cycle	Capped Leave	PMDS	Total
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	3 200 000	5 385 276
As at 31 March 2019	**2 325 164**	**3 055 841**	**882 511**	**3 200 000**	**9 463 516**

12. Deferred income

	2020 R	2019 Restated* R
Deferred income	76 136 236	56 684 486

The deferred income relates to revenue received in advance for services to be rendered in future financials periods. See note 37 for details about restatements for changes in the accounting policy related to revenue recognition.

13. Fee Income

	31 March 2020 R	31 March 2019 R
Section 21	3 163 110	3 746 589
Section 21 Veterinary	156 940	240 755
Section 21 – CAMs	7 080	2 700
Screening	450 720	1 065 760
Clinincal trials	1 334 725	4 019 403
Licence fee	1 546 680	481 900
Licence retention fees	12 953 293	11 870 819
Cannabis cultivation licence	296 480	21 800
Post screening	2 682 600	310 638
Permits	2 928 033	4 682 961
Veterinary	172 750	277 160
Amendments	965 760	2 153 316
Inspection fees	1 748 769	5 543 138
Retention fees	14 425 940	12 584 337
Certificates	184 760	629 620
Registration fee	223 040	122 400
Backlog reduction project	198 600	-
MD Licence fees	7 989 240	3 211 590
Biological medicine	2 750 000	-
	54 178 520	**50 964 886**
Fees received per function		
Medicines evaluation, registration and product lifecycle	23 388 895	21 162 633
Inspections, permits and licences issued	27 462 495	25 812 208
The use of unregistered medicines	3 327 130	3 990 045
Total	**54 178 520**	**50 964 886**

14. Interest received

	31 March 2020 R	31 March 2019 R
Interest revenue		
Interest received	8 094 788	4 907 134

Interest received from current account held at ABSA Bank at an average interest rate of 4.91% (2019: 5.25%) per annum.

15. Transfer payment

	31 March 2020 R	31 March 2019 R
Operating grants		
Transfer payment from the NDOH	183 274 000	125 189 000

16. Good and services in-kind from NDOH

	31 March 2020 R	31 March 2019 R
Revenue from non exchange transactions in-kind donation	-	(29 124 227)
Expenditure relating to in-kind donation	-	29 124 227
	-	**-**

At the commencement of the entity'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 the entity. As a result the entity 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.

17. Backlog reduction project – grant received

	31 March 2020 R	31 March 2019 R
Clinton Health Access Initiative (CHAI) grant	1 441 170	-
Centers for Disease Control and Prevention (CDC) grant	14 634 131	-
	16 075 301	**-**

18. Employee related costs

	31 March 2020 R	31 March 2019 R
Basic and non-pensionable salaries	100 773 102	90 622 649
Service and performance bonus	7 745 876	11 063 433
Medical aid	3 405 285	2 484 515
UIF	38 592	7 733
SDL	384 204	12 494
Bargaining council	15 233	14 724
Pension fund	9 902 056	8 652 606
PAYE	4 921 339	321 830
Travel allowances	514 338	5 850
Overtime payments	-	90
Housing benefits and allowances	2 391 479	2 419 396
Leave accrued	1 153 338	2 436 039
Sundry HR Costs*	-	920 140
Standby allowances	353 691	105 157
	131 598 533	**119 066 656**

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

19. Backlog reduction project

	31 March 2020 R	31 March 2019 R
Portal Variations	394 673	-
CEO comm/evaluators	4 139 751	-
Conference	45 330	-
Extedo System	1 008 955	-
Magazines/Peri	1 449	-
Printing &Stationery	1 306	-
Catering	38 350	-
Travel	3 510	-
Salaries	7 349 676	-
SDL	99 273	-
Sundry HR	92 232	-
UIF	64 134	-
PAYE	2 499 978	-
Relocation cost	65 765	-
Recruitment	1 604 700	-
	17 409 082	**-**

Refer to note 33 for more information on the donor funding received to support this project.

20. Depreciation

	31 March 2020 R	31 March 2019 R
Property, plant and equipment	2 203 533	965 527

21. Impairment of assets

	31 March 2020 R	31 March 2019 R
Impairments		
Property, plant and equipment	46 733	-

22. Lease rentals on operating lease

	31 March 2020 R	31 March 2019 R
Premises		
Contractual amounts	6 543 404	1 857 473

The prior period contractual amount represented temporary rental of office space at the CSIR campus in Pretoria – the contract was entered into in December 2018 and will expire in July 2020. A new five-year rental agreement was entered into for office space at Loftus Park as of 1 August 2020.

23. Contracted services

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

	31 March 2020 R	31 March 2019 R
Outsourced Services		
NCL Laboratory	19 992 200	19 992 200

24. Operating expenses

	31 March 2020 R	31 March 2019 R
Advertising	595 501	637 629
Auditors remuneration	6 261 301	-
Bank charges	114 770	55 304
Board Costs	865 855	1 022 550
Bursaries	5 158	-
Catering	247 744	217 962
Cleaning	31 589	-
Communication	1 167 994	750 774
Computer expenses	2 002 370	548 648
Conferences and seminars	202 059	13 500
Consulting and professional fees *	12 099 643	551 857
Entertainment	36 266	-
Licences	2 160 189	-
Expert committees	7 327 719	7 351 581
General expenses	64 146	9 787
Legal fees – contracted	567 036	-
Medical expenses	168 709	-
Membership fees	301 405	36 318
Motor vehicle expenses	3 478 299	7 436 229
Photocopiers rental expense	37 503	450 623
Postage and courier	377 833	197 768
Printing and publication	504 699	169 158
Printing and stationery	1 503 365	418 015
Psychometric assessments	57 002	107 470
Refunds processed	-	15 147
Relocation of SAHPRA	482 327	1 117 379
Repairs and maintenance	68 232	8 097
Research and development costs	45 281	49 214
Staff relocation	-	35 076
Staff training	218 517	78 067
Staff welfare	60 508	8 897
Travel – local and overseas **	10 964 361	7 449 437
Travel local and overseas- SAHPRA Board	53 463	471 550
Venues and facilities	426 994	1 100
	52 497 838	**29 209 137**

**Consulting and professional fees consist of payments made to service providers for recruitment, accounting, professional services and supply chain*

***Travel expenditure consists of expenditure incurred via the NDOH travel management company and travel and subsistence payments*

25. Cash generated from operations

	31 March 2020 R	31 March 2019 R
Surplus	31 205 291	9 705 896
Adjustments for:		
Depreciation and amortisation	2 203 533	969 220
Loss on disposal of assets and liabilities	66 637	21 970
Loss on foreign exchange	59 360	-
Impairment deficit	46 733	-
Movements in provisions	2 645 260	5 385 279
Changes in working capital:		
Receivables from exchange and non-exchange transactions	670 466	(3 367 301)
Other receivables from non-exchange transactions	(14 634 131)	-
Prepayments	(181 653)	(269 927)
Payables from exchange transactions	(11 666 345)	33 036 195
Conditional grant	(1 441 170)	1 441 170
Fee and deferred income	19 395 880	56 922 956
	28 369 861	**103 845 458**

26. Commitments

	31 March 2020 R	31 March 2019 R
Authorised expenditure		
Already contracted for but not provided for:		
Extension of NCL contract	3 028 548	3 028 548
Single supplier of eCTD software	1 448 712	2 700 000
Supply of IT equipment and related IT expenditure	4 163 161	1 201 902
Consultants	-	1 130 384
Open purchase orders (SAHPRA and NDOH)	2 725 698	997 192
Legal services	-	85 000
Office accommodation	85 758 720	-
	97 124 839	**9 143 026**
Total commitments		
Already contracted for but not provided for	97 124 839	-
This committed expenditure will be financed by allocated operational budget of future years.		
Operating leases – as lessee (expense)		
Minimum lease commitments as at 31 March 2020		
-within one year	9 833 981	1 859 211
-in second to fifth year inclusive	70 574 003	-
-later than five years	6 783 536	-
	87 191 520	**1 859 211**

27. Risk management

Financial risk management

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

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 entity's exposure to liquidity risk from financial liabilities:

	2020			
	Carrying amount	Total Cashflow	Contractual Cashflow with one year	Contractual Cashflow with five year
Payables from exchange transactions	18 907 239	18 907 239	18 907 239	-

Concentration of risk	2020			
	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	121 957 555	-	-	121 957 555
Receivables from exchange and non-exchange transactions	2 696 835	-	-	2 696 835
	124 654 390	**-**	**-**	**124 654 390**

	2019			
	Carrying amount	Total Cashflow	Contractual Cashflow with one year	Contractual Cashflow with five year
Payables from exchange transactions	24 953 836	24 953 836	24 953 836	-

Concentration of risk	2019			
	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 and non-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.

Financial assets exposed to credit risk at year end were as follows:

	31 March 2020 R	31 March 2019 R
Financial instrument		
Cash and cash equivalents	121 957 555	103 656 936

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.

28. Going concern

The annual 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.

The potential adverse impact of Covid-19 has been considered by the entity and is considered to have an insignificant impact on the ability to continue as a going concern.

29. Reconciliation between budget and statement of financial performance

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

	31 March 2020 R	31 March 2019 R
Net surplus per the statement of financial performance	31 205 291	31 172 232
Adjusted for:		
Under expenditure on backlog reduction project	(32 590 918)	-
Over expenditure on impairment of assets	46 733	-
Increase in backlog reduction project – grant received	(16 075 301)	-
Decrease in fee income	67 821 480	18 621 228
Increase in interest received	(5 094 788)	(4 907 134)
Under expenditure on employee related costs	(6 012 020)	(30 078 724)
Under expenditure on administration fees	-	(135 000)
Over expenditure on operating lease	(12 639 596)	737 473
Under expenditure on operating expenses	(30 982 609)	(36 260 484)
Over expenditure on depreciation	2 203 533	836 240
Over expenditure on contracted services	1 992 200	19 992 200
Over expenditure on loss of disposal of assets	125 995	21 969
Net surplus per approved budget	**-**	**-**

30. Related parties

Relationships	Nature of related party
Accounting authority of key management	Accounting authority of the Executive Authority
National Department of Health (controlling entity of SAHPRA)	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
Provincial Department of Health – Gauteng	Provincial Department
Provincial Department of Health – NorthernCape	Provincial Department

	31 March 2020 R	31 March 2019 R
Related party balances		
The National Department of Health		
Creditors – balance owing to NDOH	(10 868 849)	(26 719 222)
Debtors – balance owing to SAHPRA	14 634 131	-
Related party transactions		
National Department of Health		
Government grant received	183 274 000	125 189 000
Provincial Department of Health – Western Cape		
Inspection depot	-	5 500
Provincial Department of Health – Limpopo		
Inspection of depots	-	11 000
Provincial Department of Health – Gauteng		
Inspection of depots	6 050	-
Provincial Department of Health – Northern Cape		
Inspection of depots	6 050	-
Council for Scientific and Industrial Research		
Rental expense	6 776 577	1 857 473

Remuneration of Executive Authority and Management

2020

	Board Fees	Travel	Salary	Total
Board fees***				
Prof H.V. Rees – Chairperson	33 625	-	-	33 625
Ms M. Hela – Deputy Chairperson*	86 075	10 870	589 186	686 131
Prof M.S. Banoo – Member	25 064	2 243	-	27 307
Dr E.N. Madela-Mntla – Member	124 050	4 563	-	128 613
Dr T.M. Motshudi – Member	29 015	1 708	-	30 723
Prof A. Dhai – Member	35 319	-	-	35 319
Prof M.J. Mphahlele – Member**	-	-	-	-
Dr U. Mehta – Member	55 506	-	-	55 506
Dr M.S.M. Molefe – Member**	-	-	-	-
Adv H. Cassim – Member	109 810	2 035	-	111 845
Ms L.J. Fosu – Member***	24 465	-	-	24 465
Mr T.N. Baloyi – Member	58 396	23 076	-	81 472
Prof K.C. Household – Member	57 605	-	-	57 605
Prof H. P. Demana – Member	32 707	794	-	33 501
Mr I. Mashau – Member	29 352	1 131	-	30 483
Ms L. Mothae – Member****	-	-	-	-
	700 989	**46 420**	**589 186**	**1 336 595**

**Ms Hela was seconded to the role of CRO by the Minister from February to July 2019*

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

****Resigned August 2019*

*****Appointed 24 April 2020 – event after reporting date*

******The board fees reflects the actual claims incurred. At times board accounting authority opt not to claim for meetings attended.*

Executive management

2020

Name	Basic salary	Post-employment benefits	Other benefits received	Total
P. Nkambule – Chief Regulatory Officer**	1 661 299	103 654	25 997	1 790 950
M.K. Kgauwe – Chief Financial Officer	1 819 674	-	-	1 819 674
Dr. B Semete-Makokotlela – Chief Executive Officer*	694 227	-	-	694 227
	4 175 200	103 654	25 997	4 304 851

**Appointed January 2020*

***Appointed CRO – September 2019. Acting CEO to December 2019*

2019

	Board Fees	Travel	Total
Board fees***			
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	39 422
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	99 249
Mr T.N. Baloyi – Member	69 988	50 018	120 006
Prof K.C. Household – Member	111 853	-	111 853
	923 635	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 reflect the actual claims submitted. At times board accounting authority opt not to claim for meetings attended.*

Executive management

2019

Name	Basic salary	Post-employment benefits	Other benefits received	Total
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*

31. Budget differences

Material differences between budget and actual amounts

31.1 Fee Income

Fee income is below budget due to less applications received than anticipated.

31.2 Interest Received

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

31.3 Employee Related Costs

Employee related costs are lower than budget due to vacancies.

31.4 Depreciation

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

31.5 Contracted Services

Contracted services is higher than budget due to under-budgeting.

31.6 Operating Expenses

Operating expenses is lower than budget due to deferral of some activities to the next financial year.

31.7 Backlog reduction project – grant received

The over recovery is due to grant received that was not budgeted for.

31.8 Backlog reduction project

Expenditure is less than budget due to less applications evaluated than planned.

31.9 Lease rentals on operating lease

Expenditure is less than budget due to delay in relocation of offices.

32. Contingent liabilities

Claim against SAHPRA

A medical device company instituted a legal action amounting to R3.82 million (2019: 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 practioner application as opposed to individual application. At this stage the possible outcome is inconclusive.

33. Donor funding

33.1 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 project management support in the development to the official launch of the project and harmonization of ‘business as usual’ with back log processes
- Recruitment, management and payment of international evaluators to support backlog clearance programme
- Development of guidelines and procedures.

The maximum benefit for the period under review amounts to R45,4 million (2019: R27,6 million). Refer to note 19 for more information regarding the Backlog reduction project costs.

33.2 Public Health Enhancement Fund

During the prior 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 oflives
- 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 Rnil million (2019: R2.58 million).

33.3 Right to Care

During the prior 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 Rnil million (2019: R94 204).

33.4 Centers for Disease Control and Prevention – (Centers for Disease Control and Prevention – NDoH)

During the year under review, SAHPRA received a grant from the NDoH-Centers for Disease Control and Prevention partnership (CDC). NDoH-CDC Cooperative Agreement will provide R27 million towards SAHPRA's Backlog Clearance Program for the specific purpose of clearing applications related to HIV and TB drugs including DT Gand TLD as first priorities.

The benefit for the period under review amounts to R14,6 million (2019: Rnil).

34. 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

	31 March 2020 R	31 March 2019 R
Assets acquired		
Property, plant and equipment	109 485	7 883 177
Liabilities assumed		
Provision for leave	-	4 070 241
Difference between assets and liabilities transferred	**109 485**	**3 812 936**

35. Irregular expenditure

	31 March 2020 R	31 March 2019 R
Opening balance	1 206 785	-
Add: Irregular Expenditure – current year	3 876 396	1 206 785
Less: Amounts condoned	-	-
Less: Amount incorrectly classified as irregular expenditure	(44 281)	-
	5 038 900	1 206 785

The irregular expenditure relates to non-compliance with Supply Chain Management regulations.

This balance will be addressed in line with the Irregular Expenditure Framework issued by National Treasury.

36. Change in estimate – revision of use ful lives of property, plant and equipment

During the year, the estimated total useful lives of certain items of property, plant and equipment were revised. The net effect of the changes in the current financial year was a decrease in depreciation expense of R230 012.

Assuming the assets are held until the end of their estimated useful lives, depreciation in the current year in relation to these assets will be decreased by the following amounts:

	2020				
	Useful lives before revision	Depreciation before revision	Useful lives after revision	Depreciation after revision	Decrease in Depreciation
Computer Equipment	5 – 7 years	1 484 474	3 – 7 years	1 266 798	217 677
Furniture and fittings	10 – 14 years	555 487	10 – 14 years	551 558	3 929
Other assets	10 years	383 033	3 – 10 years	374 627	8 406
Grand Total		**2 422 994**		**2 192 983**	**230 012**

37. Changes in accounting policy

In the current year the entity changed the timing of revenue recognition of fee income from a modified cash basis to recognising revenue on an accrual basis. In the prior year fee income was recognised upon an application whereas the change in accounting policy resulted in fee income recognised based on the stages of completion of the service provided – therefore only upon conclusion of an application is fee income recognised. This change in accounting policy resulted in an understatement of deferred income recognised for the prior period and a corresponding overstatement of fee income.

The chance in accounting policy has retrospectively impacted each of the affected financial statement line items for the prior period as follows:

The aggregate effect of the changes in accounting policy on the annual financial statements for the year ended 31 March 2019 is as follows:

Statement of financial position

		2019		
	Note	As previously reported	Correction	Restated
Change in policy				
Deferred income	12	35 589 600	(21 094 886)	56 684 486
Total Liabilities		79 530 481	(21 094 886)	100 625 367
Accumulated surplus		34 977 173	21 227 865	13 749 308

Statement of Financial Performance

		2019		
	Note	As previously reported	Correction	Restated
Change in policy				
Fee Income		72 059 772	21 094 886	50 964 886
Total revenue		231 280 133	21 094 886	210 185 247
Surplus for the year		31 172 232	21 224 173	9 948 059

38. Prior-year adjustments

In the current year the entity discovered a computational start date error in calculating depreciation of its property, plant and equipment. The error resulted in an understatement of depreciation recognised for the prior period and a corresponding overstatement of property, plant and equipment.

In the current year the entity discovered errors with casting in certain disclosures notes for the prior period.

The errors has been corrected by restating each of the affected financial statement line items for the prior period as follows:

Statement of financial position

		2019		
	Note	As previously reported	Correction	Restated
Property, plant and equipment	7	7 213 490	(132 979)	7 080 511
Total assets		114 507 654	(132 979)	114 374 675
Accumulated surplus		34 977 173	(21 227 865)	13 749 308

Statement of financial performance and disclosure notes

		2019		
	Note	As previously reported	Correction	Restated
Depreciation	20	836 240	129 287	965 527
Surplus for the year		31 172 232	(21 224 173)	9 948 059
Total expenditure		200 107 901	129 287	200 237 188
Transfer of functions between entities under common control	34	3 804 939	7 997	3 812 936
Commitments	26	9 109 684	33 342	9 143 026

39. Events after the reporting date

Non-adjusting event

A new board member, Ms L Mothae, was appointed 24 April 2020.

In March 2020, the World Health Organization formally recognized COVID-19, the novel strain of coronavirus, as a pandemic. As a result of various actions taken by federal and local governments worldwide to curb the pandemic, including the temporary closure of certain businesses, various travel restrictions, and the mandatory containment of large segments of the global population within their geographic regions, global economic output has shown signs of short-term contraction and there remains significant uncertainty as to the extent and duration of the global economic impact.

As of the date of this report, the pandemic has not resulted in a significant impact to the entity's revenue, its results of operations or its overall access to liquidity to manage operations on an ongoing basis. Given the continued uncertainty regarding the ultimate impact of this pandemic, however, any future related financial impact cannot be reasonably estimated at this time.

Except as described above, there have been no other facts or circumstances of a material nature that have occurred between the reporting date and date of this report that have a material impact on the financial position at 31 March 2020.

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