Annual Report
2021/22

SAHPRA
South African
Health Products
Regulatory Authority

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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 0083
Postal Address:	Private Bag X828 Pretoria 0001
Telephone Number/s:	(012) 501 0300
Email Address:	enquiries@sahpra.org.za
Website Address:	www.sahpra.org.za
External Auditors:	Auditor-General of South Africa
Bankers:	ABSA
Company/Board Secretary:	Dr (Adv.) Nazreen Shaik-Peremanov

2. LIST OF ABBREVIATIONS/ACRONYMS

ABBREVIATION	EXPLANATION
AEFI	Adverse Event Following Immunisation
AESI	Adverse Events of Special Interest
AFS	Annual Financial Statements
AGSA	Auditor-General of South Africa
AMRH	African Medicines Regulatory Harmonisation
AU	African Union
AUDA	African Union Development Agency
AVAREF	African Vaccine Regulatory Forum
B-BBEE	Broad-Based Black Economic Empowerment
BMGF	Bill and Melinda Gates Foundation
CDC	Centres for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
COVID-19	Coronavirus Disease
CPD	Corporation for Public Deposits
CSIR	Council for Scientific and Industrial Research
DPSA	Department of Public Service and Administration
DTG	Dolutegravir
EMA	European Medicines Agency
GCIS	Government Communication and Information System
GMP	Good Manufacturing Practice
GRAP	Standards of Generally Recognised Accounting Practice
GWP	Good Warehouse Practice
GxP	Good Manufacturing Practice, Good Warehouse Practice, Good Clinical Practice, Good Distribution Practice and Good Vigilance Practice
HIV	Human Immunodeficiency Virus
HR	Human Resource
HRRemco	Human Resource and Remuneration Committee
ICMRA	International Coalition of Medicines Regulatory Authorities
ICT	Information and Communications Technology
INCB	International Narcotics Control Board
IT	Information Technology
IVD	*In vitro* diagnostics
J&J	Johnson and Johnson
MD	Medical Device
MHRA	Medicines and Healthcare Products Regulatory
N/A	Not Applicable
NCE	New Chemical Entity
NCL	National Control Laboratory
NDoH	National Department of Health
NEPAD	New Partnership for Africa's Development
OHS	Occupational Health and Safety
PAYE	Pay As You Earn
PERSAL	Personnel and Salaries Management System
PFMA	Public Finance Management Act
PMDS	Performance Management and Development System
QMS	Quality Management System
RAG	Risk Audit and Governance Committee
SAHPRA	South African Health Products Regulatory Authority
SAPC	South African Pharmacy Council
SDL	Skills Development Levy
TB	Tuberculosis
TLD	Thermoluminescence Dosimetry
TORS	Technical Oversight and Regulatory Strategy Committee
UIF	Unemployment Insurance Fund
USFDA	United States Food and Drug Administration
VEC	Ventilator Evaluation Committee
WHO	World Health Organization

FOREWORD BY THE CHAIRPERSON

PROFESSOR HELEN REES

National regulatory authorities ensure the legal and regulatory compliance of the drug development process including clinical development, licensing, registration, manufacturing, marketing, labelling and safety monitoring of health products. This means that the pharmaceutical industry is of necessity one of the most highly regulated industries worldwide. Whenever I am asked to give the elevator speech about the importance of a health products regulatory authority, the easiest pitch is to ask people if they trust the medicines they buy from a pharmacy, or the antibiotic they give to their sick child, or the anaesthetic they are given before life-saving surgery. If the answers are yes, then the important role of the South African Health Products Regulatory Authority (SAHPRA) is quickly understood. The past three years of the Coronavirus Disease (COVID-19) pandemic has taught the world tough lessons about what's required to respond to a pandemic. Social responses, behavioural change, and the rapid development of medicines and vaccines were all urgently required. Having a skilled, principled, and effective regulatory authority has proved critical during this time of crisis. From the early efforts to approve diagnostics, to the ongoing efforts to approve COVID-19 vaccines against the backdrop of changing variants, SAHPRA has continued to deliver for South Africans.

In September 2021, the new SAHPRA Board was established, composed of members who had served on the inaugural SAHPRA Board complemented by new members. The legislation requires that five of the fifteen Board members have specific skills associated with good governance while the other ten members have technical skills associated broadly with medicines regulation. One of the many lessons learnt from the COVID-19 pandemic is the challenge of introducing colleagues to each other through virtual platforms. The Board has grappled with this challenge and is maturing into a dedicated group of experts committed to the ongoing development of a well governed, effective, and ethical regulatory authority. This shared vision is being realised by the dedicated efforts of the Chief Executive Officer (CEO), Dr Tumi Semete, supported by her executive team, staff and SAHPRA's many external experts.

The lack of access to COVID-19 vaccines in the early phases of the pandemic resulted in a call from the African Union (AU) for the development of local vaccine manufacturing. Initiatives led by the AU with the World Health Organization (WHO) and the Department of Science and Innovation, have supported the establishment of new national manufacturing hubs. What is often not understood is that the success of the pharmaceutical industry depends on

the effective oversight of a competent national regulatory authority that is able to independently confirm that health products are safe, effective and of good quality.

Neither foreign investors nor the WHO will support new manufacturing sites unless the national regulator can enforce predetermined global standards. The old language used by the WHO to describe the capabilities of national regulatory authorities was limited to the word 'stringent' applied only to high-income country's national regulators. Until recently, the WHO had no mechanism to grade the competency of other less well-resourced national regulators. In the newly introduced WHO system, all regulatory authorities can apply to be objectively assessed for their maturity level which ranges from one to a maximum of four. SAHPRA is in the process of applying for a maturity level three which includes the ability to regulate vaccine manufacturing.

The COVID-19 pandemic has shown that South Africa's academic and commercial institutions can advance public health rapidly through innovation in the development of medical products including new vaccines, diagnostics, and therapeutics. To support this, SAHPRA has developed the capacity to evaluate clinical trials rapidly and carefully, to fast-track the evaluation of new health products, and to undertake post-marketing surveillance. These new processes allowed rapid access to many urgently required COVID-19 products. The systems developed for the COVID-19 emergency are now being adapted for the post emergency setting so that other products required for new and ongoing priority public health needs can be more efficiently reviewed.

As with any newly founded institution, SAHPRA has had to capacitate itself so that it can address old problems as well as newly emerging challenges. The Backlog Project, started in 2019, aimed to clear the queue of 16 000 products awaiting evaluation that was inherited from the old Medicines Control Council. Independent funding was secured, and a dedicated Backlog Project management structure was implemented. The Backlog Project has changed the way that dossiers are evaluated by using proven techniques to accelerate reviews, and by sharing product evaluations with other regulatory authorities. After two years of dedicated work by the secretariat and external evaluators, the Backlog Project is now on track to be completed by December 2022. The strategies used in the project are regarded as best practice and are being introduced into the 'Business as Usual' department. In addition, next year will see the implementation of an ambitious plan to enhance the efficiency of SAHPRA's systems through digitisation. These initiatives are being undertaken in close consultation with industry to ensure that new approaches achieve the aim of maintaining quality review while increasing efficiency. Both are essential if the country is to achieve the economic and public health ambitions of a stronger national health products' industry.

Another responsibility of the regulator is communication. Regulatory authorities of high-income countries have huge departments dedicated to public communication and safe use of health products. Currently SAHPRA has a small Communications Department, but it has nonetheless prioritised public messaging to professionals and the public, covering issues such as SAHPRA's COVID-19 response, vaccine safety, codeine abuse, and public interest issues relating to regulatory functioning. Over the next year, the ambition is to implement an expanded communication strategy and to identify priority issues for communication, such as the dangers of overusing antibiotics in both human and veterinary medicine.

SAHPRA is a young institution that has many more challenges ahead of it. This includes the development of appropriate oversight for medical devices, complementary medicines, cannabis, and radiation control. The emerging issue of 'One Health' that addresses the interface between animal and human health is another priority area for SAHPRA. The regulatory framework for veterinary medicines must be reviewed by SAHPRA and its veterinary colleagues, to ensure that it protects both animal and human health and addresses the emerging concern of antimicrobial resistance.

Regulatory structures that fairly enforce legislation are an essential component of a healthy democracy. I am confident that with the combined efforts of the executive leadership team, the SAHPRA staff and the Board, priority areas will be addressed and SAHPRA will continue along the path of becoming a world-class regulatory authority.

Professor Helen Rees
Chairperson: SAHPRA Board
31 August 2022

CHIEF EXECUTIVE OFFICER'S OVERVIEW

Dr Boitumelo Semete-Makokotlela

Leading regulations through excellence and evidence-based decision-making

'Chaos' and 'disruption' are the best words that encapsulate how COVID-19 impacted the world, our country and SAHPRA.

In spite of concerted efforts to fight the COVID-19 pandemic, it is still a threat. However, thanks to our efforts and those of other role players in South Africa, the continent and the world at large, it is subdued. As the regulator of national health products, SAHPRA was at the core of the South African national response strategy for a pandemic that wreaked havoc within both South Africa and the world.

SAHPRA had to continue ramping up its operations and its business processes in order to address the areas of need. This involved staff recruitment to bolster much-needed capacity and also streamlining digital processes. All COVID-19 related applications for vaccines, therapeutics and *in vitro* diagnostic tests remained a priority for the authority.

As vaccines offered the proverbial saving grace, SAHPRA had to be responsive to the regulation of vaccines, as well as to monitor all reports on adverse reactions to the vaccines and other health products. SAHPRA, together with various stakeholders, implemented a Med Safety App and launched it successfully. Following the launch of the Med Safety App, a microsite was created for regular reporting of adverse events following immunisation (AEFIs) as well as adverse events of special interest (AESIs) after vaccination. SAHPRA led the pack by playing a decisive role in making evidence-based decisions and monitoring the adverse effects of COVID-19 related health products.

The national scientific community must be applauded for championing several COVID-19 clinical trials, ranging from therapeutic to vaccine trials. In total, SAHPRA authorised 52 therapeutic trials and 23 vaccine trials during the 2021/22 financial year. These approvals were finalised in record time, due to the extended hours worked by both the internal team and external evaluators in an effort to support the national and global endeavours to fight the pandemic.

When a pandemic of mammoth proportions makes its appearance, partnerships and knowledge exchange are key interventions. SAHPRA forged several partnerships nationally, regionally and globally: regulators such as the

United States Food and Drug Administration (USFDA), the Medicines and Healthcare Products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) as well as participation in global harmonisation programmes and associations such as the International Coalition of Medicines Regulatory Authorities (ICMRA), the WHO, and the African Vaccine Regulatory Forum (AVAREF) proved to be most beneficial. Furthermore, SAHPRA's internal and external experts as well as committee members participated in collaborative review processes with the WHO and AVAREF for a number of the vaccines.

SAHPRA also recognises the need to build capacity not only in South Africa, but also on the African continent. The need to ramp up capacity in regulatory sciences was echoed by many African regulatory authorities, the WHO and the African Medicines Regulatory Harmonisation (AMRH) initiative. To this end, a number of SAHPRA's staff received training in a variety of regulatory functions to ensure that SAHPRA's skill sets remain on par with global standards.

While science-based efforts were progressing, there was an emerging threat that sought to undermine these efforts. Fake news and a lack of science-based information began circulating on, especially, social media platforms and this gained traction with lightning speed. SAHPRA engaged media proactively and held 10 webinars on priority issues and used this as a platform for public engagement of the functions of the regulator. SAHPRA's social media platforms were also abuzz to debunk myths and to present credible scientific evidence. Apart from many media appearances, SAHPRA also created videos and infographics to convey information in a palatable format. SAHPRA media spokespersons were trained on engaging the media and the public on various media and social media platforms to disseminate vital information optimally. Partnerships with entities such as PATH, the National Press Club, the Government Communication and Information System (GCIS), Daily Maverick, Bhekisisa, and the Solidarity Fund proved to be most favourable.

During the 2021/22 financial year, SAHPRA had realised a significant year-on-year increase in fee income generated which amounted to R169 million from R87 million in the 2019/20 financial year. The increase in revenue generation was mainly due to the impact of the revised Fee Gazette issued in December 2020.

An accounting surplus amounting to R28 million was posted for the 2021/22 financial year compared to a deficit of R19.6 million in the prior year resulting in an increase in our net asset position. We will be continuing as a going concern for the foreseeable future due to the strong cash position held at year end and the material liabilities that relate to revenue received in advance which will be recognised in future financial periods.

A strong focus was placed on strengthening governance and internal control processes resulting in an unqualified audit for the 2021/22 financial year as well as the implementation of consequence management processes in an effort to build a culture of accountability plus the capacitation of the Supply Chain Management Unit, thereby limiting the risk in the supply chain management area.

As we look forward to the year ahead, there is much work to be done; however, strong foundations in innovation, monitoring and evaluation processes are steadily progressing. We are also firmly working towards growing capacity within the organisation. We aim to continue engaging, collaborating and growing new partnerships in the global fight against the COVID-19 pandemic.

I must express my deep gratitude to the SAHPRA team for their unwavering support and dedication as they work under extraordinary circumstances and at equally extraordinary times in order to execute their duties with gusto.

I must also thank the SAHPRA Board for providing me with significant guidance in terms of strong governing frameworks, policies, and practices. Where required, they provided technical and legal guidance to the team, yet in doing so remained absolutely clear of their fiduciary roles and duties.

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer
31 August 2022

5. STATEMENT OF RESPONSIBILITY AND CONFIRMATION OF THE 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 is consistent with the Annual Financial Statements (AFS) audited by the Auditor-General of South Africa (AGSA).

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

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

The AFS (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 AFS 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 AFS.

The external auditors are engaged to express an independent opinion on the AFS.

In our opinion, the annual report fairly reflects the operations, the performance information, the human resources information and the financial affairs of the entity for the financial year ended 31 March 2022.

Yours faithfully

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer
31 August 2022

Prof. Helen Rees
Chairperson of the Board
31 August 2022

6. STRATEGIC OVERVIEW

Vision

6.1

An agile and responsive African health products regulator that is globally recognised as an enabler of access to safe, effective, and quality health products in South Africa.

Mission

6.2

To promote access to health products and protect human and animal health in South Africa through making science-based regulatory decisions.

Values

6.3

- Ubuntu
- Responsiveness
- Integrity
- Transparency
- Efficiency
- Excellence

7. LEGISLATIVE AND OTHER MANDATES

7.1 Constitutional Mandate

The Constitution of the Republic of South Africa (1996), places an obligation on the state to progressively realise socio-economic rights, including access to healthcare. Section 27 of Chapter 2 of the Bill of Rights of the Constitution (1996) 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 as well as appropriate social assistance if they are unable to support themselves and their dependants.
- The State must take reasonable legislative and other measures within the ambit of its available resources to achieve the progressive realisation of each of these rights, and no one may be refused emergency medical treatment.

7.2 Legislative Mandate

SAHPRA's objective is to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices, in vitro diagnostics and further matters related to the public interest.

Since its establishment in February 2018, as a schedule 3A entity of the National Department of Health (NDoH), there has been no updates to its legislative and policy mandates. The cornerstone legislative mandates of SAHPRA are derived from the national Constitution (1996), the National Health Act, 2003 (Act No. 61 of 2003) 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 which, *inter alia,* includes the regulation and control of radiation emitting devices and radioactive materials, it is important to consider that the following pieces of legislation define the legislative framework within which SAHPRA executes its mandate:

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

This 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 of national, provincial, and local government with regard to health services. The objectives of the National Health Act (2003), as understood alongside other laws and policies that relate to health, are to:

- Unite the various elements of the national health system into a common goal so as to actively promote and improve the national health system in South Africa.
- Provide 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 health care services.
- Establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourage participation.
- Promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans.
- Create the foundations of the health care system.

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

Amended by the 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 and the regulation of medical devices.

In terms of the Medicines Act (1965, as amended), the objectives of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, medical devices, radiation control, clinical trials and further matters related to the public interest.

The Medicines Act (1965, as amended) 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 (1965, as amended) can only be administered or prescribed by a veterinarian.

As per section 2b (1) of the Medicines Act (1965, as amended), the Authority must, in order to achieve its objectives, ensure:

- The efficient, effective and ethical evaluation or assessment and regulation of medicines, medical devices, radiation-emitting devices and radioactive nuclides that meet the defined standards of quality, safety, efficacy and performance, where applicable.
- 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 radionuclides.
- The investigation, monitoring and analysis of evidence of existing and new adverse events as well as reactions, interactions and signals emerging from post-marketing surveillance and vigilance activities, while ensuring that these are acted upon.
- That compliance with existing legislation is promoted and achieved through a process of active inspection and investigation.
- That clinical trial or clinical performance study protocols are assessed according to prescribed scientific, ethical, and professional criteria and defined standards.

In executing its functions, the Authority may:

- Liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority or institution in respect of:
  - Matters of common interest.
  - A specific investigation.
  - Entering into agreements to co-operate with any regulatory authority in order to achieve the objects of the Medicines Act (1965, as amended).

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

The Hazardous Substances Act (1973) provides for the efficient, effective and ethical evaluation and licensing of radionuclides (Group IV hazardous substances) and listed electronic products (Group III hazardous substances – including but not limited to electronic generators of ionising or non-ionising radiation).

SAHPRA is only responsible for the regulation of Group III and Group IV hazardous substances.

Section 3 of the Act refers to regulation of Group III hazardous substances, that is, listed electronic products, and section 3A refers to Group IV hazardous substances, that is, radionuclides.

7.2.4 Other Related Legislations

Due to the complex environment within which SAHPRA operates, it is necessary to list a series of related legislation impacting on and influencing its functioning:

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

This Act provides for the registration of fertilisers, farm feeds, agricultural remedies, stock remedies, sterilising plants, and pest control operators with the aim of regulating or prohibiting 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 over-the-counter antimicrobials 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 related matters.

- **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, the registration of persons practising veterinary professions and para-veterinary professions, control over the practising of veterinary professions and para-veterinary profession and related matters. It further makes provision for the compounding and/or dispensing of any medicine prescribed by the veterinarian for use in the treatment of an animal under his or her professional care.

- **Drugs and Drug 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, the obligation to report certain information to the police, the exercise of the powers of entry, search, seizure and detention in specified circumstances, the recovery of the proceeds of drug trafficking and related matters.

In relation to cannabis, on 18 September 2018 the Constitutional Court declared sections 4(b) and 5(b) (use and possession) read with Part III of Schedule 2 of the Drugs and Drug Trafficking Act (1992); and section 22A(9)(a)(i) of the Medicines and Related Substances Act (1965), read with Schedule 7 of Government Notice No. R. 509 of 2003 unconstitutional on the premises that they amount to an impermissible limitation of the right to privacy. The Court suspended the order of invalidity for 24 months from 18 September 2018 to September 2020.

Following consultation with stakeholders, amendments to the Schedules of the Medicines Act (1965) aligned with the Constitutional Court judgement were published in Government Notice No. 586, Government Gazette No. 43347, issued on 22 May 2020. The Department of Justice and Constitutional Development responsible for the Drugs and Drug Trafficking Act (1992) amendments is in the process of addressing the Constitutional Court judgement.

- **Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972, as Amended)**

Provides for the regulation of foodstuffs, cosmetics and disinfectants and, in particular, quality standards that must be complied with by manufacturers as well as the importation and exportation of these items.

- **Environmental Management Act: Waste Management Act, 1998 (Act No. 107 of 1998)**

Provides for co-operative, environmental governance by establishing principles for decision-making on matters affecting the environment, institutions that will promote cooperative governance and procedures for coordinating environmental functions exercised by organs of State and related matters.

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

Provides for the control over the education, training and registration for practising of health professions registered under the Act and matters incidental thereto.

- **Nursing Act, 1978 (Act No. 50 of 1978)**

Provides for consolidation and amending of the laws relating to the professions of registered or enrolled nurses, nursing auxiliaries and midwives and related matters.

- **Pharmacy Act, 1974 (Act No. 53 of 1974)**

The South African Pharmacy Council (SAPC) in terms of section 35A of the Pharmacy Act (1974) regulates the practice of pharmacy within South Africa. The SAPC ensures that all responsible pharmacists, pharmacy support personnel and pharmacy owners provide pharmaceutical services that comply with good pharmacy practice standards prescribed in the Pharmacy Act (1974) and relevant provisions of the Medicines and Related Substances Act (1965, as amended). The Medicines and Related Substances Act (1965, as amended), in section 16(d), provides for possession of medicines or scheduled substances for sale by the pharmacists or a person licenced to own a pharmacy in terms of the Pharmacy Act (1974) or a person who is the holder of a licence as completed in section 22C of the Medicines and Related Substances Act (1965, as amended). The SAPC has, in terms of section 38A of the Pharmacy Act (1974), appointed inspection officers with a view to monitoring pharmacies for compliance. The provisions of the Pharmacy Act (1974) include investigation of complaints received alleging misconduct or unprofessional conduct.

- **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 related matters.

A favourable legislative environment is fundamental to the operations of a regulator such as SAHPRA when it comes to supporting an effective execution of its mandate. There have been notable developments in SAHPRA's operating environment that have necessitated a review of its legislative and policy framework.

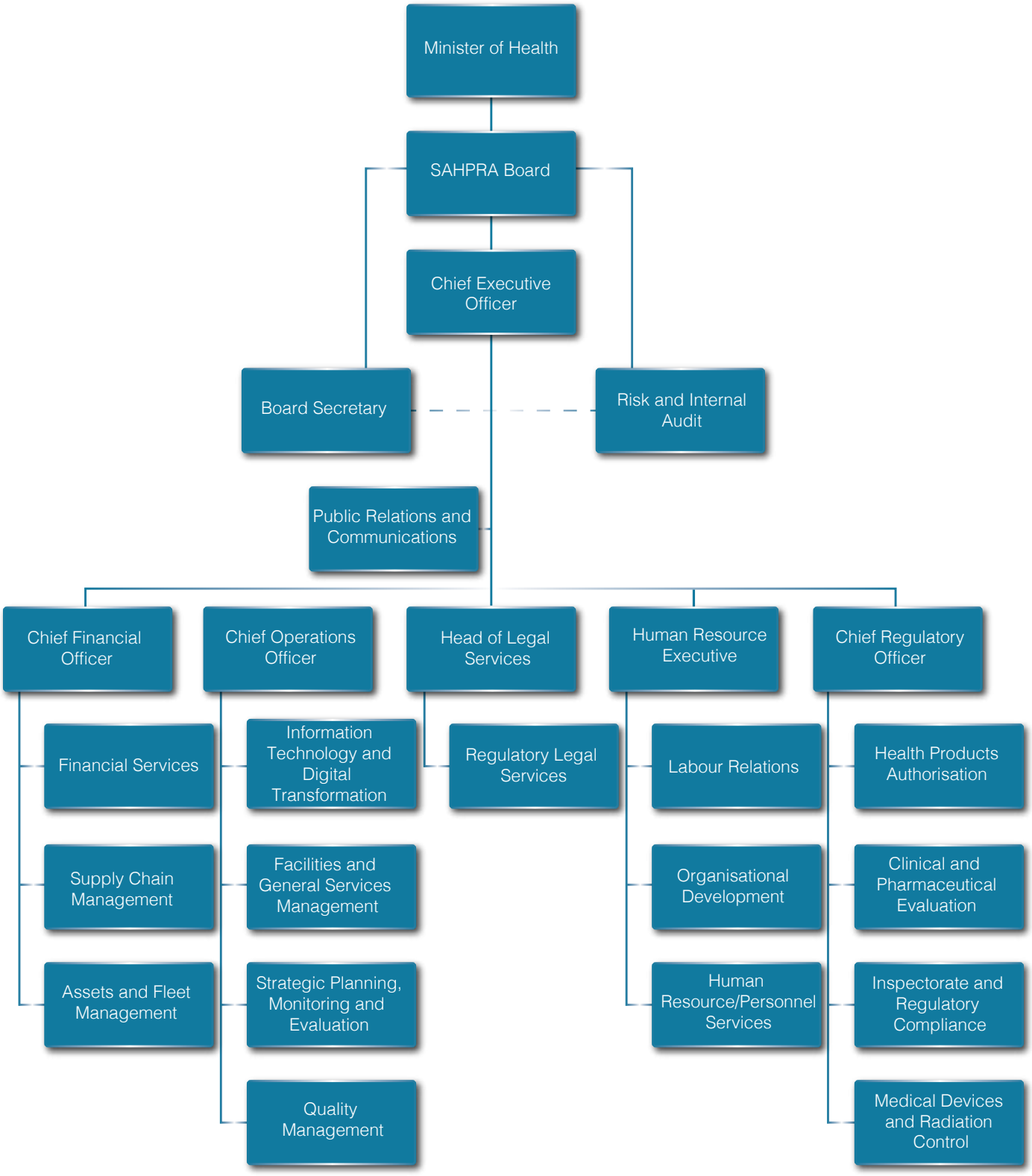
In the first instance, SAHPRA enacts its role within an extremely complex legislative context where a series of other players are involved and where SAHPRA has only a limited yet important regulatory role. A case in point is a role SAHPRA should be fulfilling through its representation at key ports of entry where there are goods that come into the country that fall within its legislative obligations, for its inspection, as per the Customs and Excise Act (1964), cited above.

One of the key new responsibilities emanating from SAHPRA's extended mandate relates to radiation control, which has crucial elements within the ambit of the jurisdiction of the Department of Mineral Resources and Energy. Another responsibility is cannabis regulation, which involves multiple ministries such as the Department of Justice and Correctional Services and the Department of Agriculture and Rural Development, to affect the country's enhancement of 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 to avert the risk of an internal leadership vacuum or duplication of efforts and subsequent potential "conflict."

7.3 Policy Mandate

The court ruling on the recreational use of cannabis has spurred considerable public interest and debate in relation to the concomitant implications for medicinal applications of cannabis. In addition, commercial interest is tied to a significant potential economic gain based on the legalisation and the subsequent industrialisation of cannabis. This is evidenced by small-scale growers who seek to play in that space, a vast majority of whom have been growing the cannabis herb illegally for many years. It is imperative that, as an agile regulator, SAHPRA take the proactive action of tackling the regulatory framework relating to this area and strengthen collaborative partnerships with various government departments to create alignment among the various legislations supporting enhanced and broader access to cannabis-based products. The entity therefore anticipates that it will participate in national policy discussions that pertain to legislative and policy framework considerations related to cannabis and its industrialisation.

8. ORGANISATIONAL STRUCTURE



9. MEMBERS OF THE BOARD

Prof. Helen Rees
(Chairperson)

Dr Obakeng Khaole
(Vice Chairperson)

Mr Itani Mashau

Ms Ditaba Maraka

Prof. Patrick Hulisani Demana

Adv. Hasina Cassim

Mr Tinyiko Norman Baloyi

Dr Xolani Ngobese

Ms Lerato Mothae

Prof. Joyce Tsoka-Gwegweni

Dr Alfred Kgasi

Prof. Hannelie Meyer

Ms Mandisa Skhosana

Prof. Yahya Choonara

Dr Zinhle Makatini

10.EXECUTIVE MANAGEMENT

Dr Boitumelo Semete-Makokotlela
(Chief Executive Officer)

Mr Regardt Gouws
(Chief Financial Officer)

Ms Portia Nkambule
(Chief Regulatory Officer)

Ms Christelna Reynecke
(Chief Operations Officer)

Mr Gordon Mtakati
(Human Resource Executive)

Dr (Adv.) Nazreen Shaik-Peremanov
(Board Secretary) – from July 2022

PART B

PERFORMANCE INFORMATION

1. AUDITOR'S REPORT: PREDETERMINED OBJECTIVES

The AGSA 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 90 of the Report of the Auditor-General, published as Part E: Financial Information.

2. OVERVIEW OF PERFORMANCE

2.1 Service Delivery Environment

In executing its mandate, SAHPRA was challenged through public protests, and it experienced political pressure in areas such as cannabis. In its defence, SAHPRA continuously expressed that its decisions relied on science and evidence. During the public protests, there was minimal disruption to business operations although security measures were enhanced due to safety concerns for staff. SAHPRA requires the continued support from the State to ensure that its autonomy is protected.

Several litigation cases were brought against SAHPRA during the year under review. These cases were primarily challenging the regulatory mandate and powers of SAHPRA, including among others, the application for the approval of the use of Ivermectin, SAHPRA's decisions on COVID-19 vaccines, classification of cannabidiol and the regulations on complementary medicines. Some of the court cases have been finalised while others are still pending.

The country continues to deal with the COVID-19 pandemic. As a responsive regulator, SAHPRA reduced the time taken to register COVID-19 vaccines to less than three months, where the required standard of data is available, compared to the average of 20 months it takes to approve new medicines/vaccines. SAHPRA did this while continuing to adhere to strict guidelines to ensure the safety of South Africans. The continued receipt of applications electronically has proven to improve the turnaround times as compared to the manual physical submissions.

Seven months into the implementation of the Backlog Clearance Project in March 2020, the COVID-19 lockdown was instituted worldwide. The lockdown resulted in many global research and development, manufacturing and testing facilities operating on skeleton staff. This severely impacted the project as the majority of local subsidiaries and applicants requested long extensions to respond to queries from SAHPRA. As staff members had adapted to the "new normal" way of working, the COVID-19 pandemic posed less challenges than the previous reporting period.

In response to numerous requests from applicants regarding priority review of variations and new applications encompassing vaccines, human immunodeficiency virus, oncology and tuberculosis, SAHPRA approved and implemented the Policy on Priority Review Pathways for medicines. The Policy provides for priority review to facilitate greater accessibility and availability of medicines:

- That address an unmet clinical need in the South African market (novel/innovative medicine/New Chemical Entities).
- That show a major therapeutic advantage in safety or efficacy to existing treatment options.
- For life threatening or seriously debilitating conditions.
- For public health and animal health emergencies.
- For a limited target disease for a patient population (orphan disease).
- In the event of national priorities guided by NDoH.
- Where security of supplies is a concern (guided by NDoH needs) and the Department of Agriculture, Land Reform and Rural Development.

This policy applies to New Chemical Entities, New Biological Medicines, interchangeable multi-source (generic) medicines and Biosimilars for both new registrations and their lifecycle management.

SAHPRA piloted a process which involves the introduction of pre-submission meetings as a first step in the application process. The pilot study was conducted with applications submitted between August and September 2021. Pre-submission meetings were

scheduled between SAHPRA and the applicant to discuss the applications to be included in the pilot. The pre-submission meetings provided a common understanding of what supporting documentation is required to evaluate an application as well as resolve any issues before the application is submitted. This resulted in proper planning for submissions and enhanced the management of both timeframes and resources.

To reduce the backlog building up in generic medicine registrations in the Business-As-Usual area, evaluation teams implemented strategies which encompass implementing various forms of reliance that involve making use of assessment reports from recognised regulatory authorities and SAHPRA. This reduced the review timelines of applications.

SAHPRA conducted inspections related to Good Manufacturing Practice, Good Warehouse Practice, Good Clinical Practice, Good Distribution Practice and Good Vigilance Practice (GxPs) as well as inspections related to complaints and matters of regulatory non-compliance. Through co-operation with law enforcement agencies such as the South African Police Service, arrests were made that lead to the prosecution of individuals who contravened the Medicines and Related Substances Act (1965, as amended). Contraventions ranged from illegal importation to illegal manufacturing. Furthermore, through co-operation with the South African Pharmacy Council, SAHPRA witnessed increased actions against registered and unregistered personnel contravening the Pharmacy Act (1974).

Having spearheaded and implementing cannabis frameworks for cultivation of medicinal cannabis to produce scheduled substances, SAHPRA was faced with public protests regarding the limited market for the cannabis plant and its uses. The Cannabis Master Plan, headed by the Department of Agriculture, Land Reform and Rural Development, requires swift implementation so that all economic aspects of the cannabis plant and its uses can be fully realised, with SAHPRA regulating its respective area within its mandate.

With the easing of travel restrictions, local physical onsite inspections increased as full-onsite inspections, or a hybrid method of on-site and remote online inspections were conducted. Several international remote inspections were successfully conducted utilising site readiness meetings to ensure that these inspections were effective. As restrictions on international travel ease for South Africans, plans are to embark on physical onsite international inspections during the 2022/23 financial year.

As part of enhancing the country's COVID-19 regulatory response, SAHPRA approved the majority of unregistered medicines that treat COVID-19 infections within 24 working hours. Furthermore, SAHPRA continued to provide access to Ivermectin for the treatment of COVID-19 through the controlled compassionate use programme for approved unregistered Ivermectin products. There were quick turnaround times for evaluating clinical trial protocols for vaccines and therapeutics intended for COVID-19. Approved clinical trials were monitored closely for participant safety and well-being. There was an increase in the utilisation of the Med Safety App as a convenient mobile tool for safety reporting of adverse drug reactions to medicines, and AEFIs for vaccines (see Section 3.4.1). The country's vigilance system was strengthened through the development of a National Vigilance Framework in collaboration with NDoH. To urgently address both awareness about vigilance and the decline in vaccine uptake due to public safety concerns, SAHPRA participated in several campaigns and webinars.

During the 2021/22 financial year, there was an increase in the number of applications for medical device establishment licences. This increase can be attributed to the following:

- Requirements set by various government departments and healthcare facilities (both private and public) requesting SAHPRA's medical device establishment licence as a mandatory requirement to service providers.
- Compliance requirements by law enforcement organisations and SAHPRA for organisations importing (port of entry) and selling medical devices in the country.
- The COVID-19 pandemic has led to many organisations selling/distributing medical devices such as COVID-19 test kits, ventilators and masks.

2.2 Organisational Environment

SAHPRA employees are the driving force behind the achievement of the objectives of the Authority. The organisation focused on cultivating and sustaining a high-performance culture under the challenges presented by the COVID-19 pandemic while performing in a hybrid – remote working arrangement.

During the 2021/22 financial year, SAHPRA was able to recruit externally while providing opportunities to internal employees. It was important to ensure that employees grow within SAHPRA, and that key talent is retained.

Staff transferred in terms of the Labour Relations Act 1995 (Act No. 66 of 1995), Section 197 were moved from NDoH to SAHPRA. They were removed from the Public Service Personnel and Salaries Management System (PERSAL) Payroll System and placed on SAHPRA's SAGE P300 Payroll System.

2.3 Key Policy Developments and Legislative Changes

There were no major changes to the relevant policies or legislation that may have affected SAHPRA's operations during the period under review.

2.4 Progress Towards Achievement of Institutional Impacts and Outcomes

SAHPRA's revised 2020/21 – 2024/25 Strategic Plan was approved in January 2021. The revisions were made to the vision, mission, values, and outcome related matters.

2.4.1 Impact Statement

All health products in South Africa meet world class safety, quality, efficacy, and performance standards.

2.4.2 Progress on Outcomes

MEDIUM-TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH			
OUTCOMES	**OUTCOME INDICATORS**	**FIVE-YEAR TARGET**	**PROGRESS**
Effective financial management (1)	1.1 Unqualified audit opinion obtained on the annual financial statements	Unqualified audit opinion obtained	Qualified audit opinion was obtained for the 2020/21 financial year
Financial sustainability achieved through revenue generated and enhanced operational efficiencies (2)	1.2 Total revenue generated from fees in the financial year	Revenue of R230 million generated from fees	Revenue of R169 million was generated from fees
Continuously respond to the needs and expectations of SAHPRA stakeholders (3)	1.3 Percentage of prioritised recommendations from the survey implemented	100% prioritised recommendations from the survey implemented	67% prioritised recommendations from the survey implemented *Out of 3 prioritised recommendations from the survey, 2 (67%) were implemented*
A positive and enabling working culture created (4)	1.4 Percentage of the change management intervention implemented	Review of the change management intervention conducted	Out of 13 change management interventions identified, 12 (92%) were implemented
Attract and retain superior talent (5)	1.5 Percentage of positions in the staff establishment filled	100% of positions in the staff establishment filled	96% of positions in the staff establishment filled *Out of 55 budgeted positions, 53 (96%) were filled*
Strengthened Information and Communication Technology and digitisation (6)	1.6 Number of business processes digitalised	All business processes digitalised	Section 21 business process was digitised in June 2021 Development of an online application submission system was in progress Leave application process was digitalised

MEDIUM-TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH			
OUTCOMES	**OUTCOME INDICATORS**	**FIVE-YEAR TARGET**	**PROGRESS**
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	1.7 Percentage of medicine registrations in the backlog cleared	100% medicine registrations backlog cleared	75% medicine registrations backlog cleared *Out of 3 395 backlog applications for medicine registrations received, 2 557 (75%) were cleared*
	1.8 Percentage of medicine variation applications in the backlog cleared	100% medicine variation applications backlog cleared	95% medicine variation applications backlog cleared *Out of 3 611 backlog applications for medicine variations, 3 428 (95%) were cleared*
	1.9 Percentage of New Chemical Entities (NCE) finalised within 360 working days	80% NCE finalised within 360 working days	100% NCE finalised within 590 working days *Out of 246 NCE applications received, 44 (18%) were finalised. Out of the 44 finalised, all 44 (100%) were finalised within 590 working days*
	1.10 WHO maturity level obtained	WHO maturity level 4 maintained	Based on the WHO provisional assessment report received in November 2021, an Institutional Development Plan was developed to address the recommendations
	1.11 Percentage of new Good Manufacturing Practice (GMP) and Good Warehouse Practice (GWP) related licenses finalised within 125 working days	90% of new GMP and GWP related licenses finalised within 125 working days	42% of new GMP and GWP related licenses finalised within 125 working days *Out of 64 new GMP and GWP related licences applications received, 31 (48%) were finalised. Out of the 31 finalised, 13 (42%), were finalised within 125 working days*
	1.12 Percentage of human clinical trial applications finalised within 60 working days	80% human clinical trial applications finalised within 60 working days	95% human clinical trial applications finalised within 90 working days *Out of 274 human clinical trial applications received, 248 (91%) were finalised. Out of the 248 finalised, 235 (95%) were finalised within 90 working days*
	1.13 Medical Device registration regulations implemented	50% call-up products registered	19 guidelines to support the medical device registration regulations were drafted

3. INSTITUTIONAL PROGRAMME PERFORMANCE INFORMATION

3.1 Programme 1: Leadership and Support

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

Sub-programmes

Sub-Programme	Purpose
Financial and Supply Chain Management	To serve all business units in SAHPRA, the senior management team and the Board by maintaining an efficient, effective and transparent system of financial, and risk management that complies with the applicable legislation.
Governance and Compliance	To provide support services and ensure compliance with relevant legislation; and achieve an unqualified audit outcome by ensuring continuous management practices through compliance with standard 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.
Information and Communications Technology (ICT)	To develop and implement 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, as well as provide a seamless harmonious operational platform by building strong and sustainable relationships with all its stakeholders.
Human Resource Management	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.

Outcomes:

- Effective financial management (1).
- Financial sustainability achieved through revenue generated and enhanced operational efficiencies (2).
- Continuously respond to the needs and expectations of SAHPRA stakeholders (3).
- A positive and enabling working culture created (4).
- Attract and retain superior talent (5).
- Strengthened ICT and digitisation (6).

3.1.1 Outcomes, Outputs, Output Indicators, Targets and Actual Achievements

PROGRAMME 1: LEADERSHIP AND SUPPORT								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
Effective financial management (1)	Attain and maintain an unqualified overall Auditor-General audit outcome on previous year's performance	Unqualified audit opinion obtained on the AFS	Qualified audit opinion obtained for the 2019/20 financial year	Qualified audit opinion obtained for the 2020/21 financial year	**Unqualified audit opinion obtained**	Qualified audit opinion obtained *(2020/21 financial year)*	Target was not achieved	Supporting evidence for comparative figures relating to income received in advance and fee income could not be obtained for audit purposes
Financial sustainability achieved through revenue generated and enhanced operational efficiencies (2)	Total revenue generated from fees	Total revenue generated from fees in the financial year	-	R102 million	**Revenue of R162 million generated from fees**	Revenue of R169 million generated from fees	Target was exceeded by R7 million	Increase in applications received
	Break-even of expenses and revenue by 31 March	Break-even of expenses and revenue by 31 March	-	-R24.7 million	**Zero**	R28 million *The breakeven point was exceeded by R28 million, which is an accounting surplus reported*	Target was exceeded by R28 million	Under-expenditure on Compensa-tion of Employees and operational expenditure

PROGRAMME 1: LEADERSHIP AND SUPPORT								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
Continuously respond to the needs and expectations of SAHPRA stakeholders (3)	Recommend-ations implemented	Percentage of prioritised recommend-ations from the survey implemented	Material developed and disseminated Responses and report to be reviewed in Q1 2020	SAHPRA obtained a 68% positive rating for its effectiveness and efficiency as rated by private and public direct users of SAHPRA's services	**40% prioritised recommend-ations from the survey implemented**	67% prioritised recommendations from the survey implemented *Out of 3 prioritised recommendations from the survey, the following 2 (67%) were implemented:* • *A web query system. Out of the 1 103 queries received, 623 (56%) were responded to* • *Out of a staff establishment of 395, 266 (67%) posts were occupied which included positions that were filled by employees who were placed on higher grades during the administrative placement exercise*	Target was exceeded by 27%	Filling of vacant posts was prioritised

PROGRAMME 1: LEADERSHIP AND SUPPORT								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
A positive and enabling working culture created (4)	Change management intervention implemented	Percentage of the change management intervention implemented	-	-	**50% of the change management intervention implemented**	92% of the change management interventions implemented *Out of 13 change management interventions identified, 12 (92%) were implemented*	Target was exceeded by 42%	Number of staff engagements were increased to address topical organisational matters
	Workplace Skills Plan implemented	Percentage of the Workplace Skills Plan implemented	-	-	**30% of the Workplace Skills Plan implemented**	39% of the Workplace Skills Plan implemented *Out of 23 planned training interventions in the Workplace Skills Plan, 9 (39%) were implemented*	Target was exceeded by 9%	Implementation of training initiatives were accelerated
Attract and retain superior talent (5)	Percentage of positions filled	Percentage of positions in the staff establishment filled	76%	Out of the 375 positions in the approved staff establishment, 265 (71%) were filled	**60% budgeted positions filled**	96% budgeted positions filled *Out of 55 budgeted positions, 53 (96%) were filled*	Target was exceeded by 36%	Recruitment was prioritised to resource under-capacitated units

PROGRAMME 1: LEADERSHIP AND SUPPORT								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
Strengthened ICT and digitisation (6)	9 business processes digitalised	Number of business processes digitalised	-	10% of processes digitised The User Requirements Specification for the Regulatory Information Management Systems was developed and submitted for approval in March 2021	**3 business processes digitalised**	Section 21 business process was digitised in June 2021 Development of an online application submission system was in progress Leave application process was digitalised	Target was missed by 2	Digitisation had to be outsourced due to resignation of the only software developer, resulting in delays due to the lack of financial resources

Finance and Supply Chain Management

SAHPRA's total revenue amounted to R367.5 million against a budget of R357.6 million. The variance of R10 million was mainly due to additional funding support received during the year. SAHPRA spent R339 million against the initial approved budget of R357.6 million. The overall result was an accounting surplus amounting to R28 million, as total revenue exceeded total expenditure due to additional funding support, delays in filling budgeted for vacancies and general under expenditure incurred during the financial year. The accounting surplus resulted in an increase of accumulated surpluses reversing the impact of previous accounting deficits incurred.

The focus was on improving previous audit outcomes as well as positioning SAHPRA for financial sustainability. The entity has:

- Enforced finance and supply chain policies and standards.
- Implemented the General Ledger accounts per services.
- Implemented revenue allocation triggers as an aid to improve revenue allocation.
- Revised service fees structures to align to global trends.
- Generated significant year-on-year revenue growth.

Communication and Public Relations

As part of implementing the recommendations from the Stakeholder Perception Survey conducted during the 2020/21 financial year, the web survey tool was implemented. Furthermore, as part of enhancing SAHPRA's management of its Quality Management System (QMS), the complaints mechanism is featured on the website. The complaints mechanism allows for stakeholders to lodge complaints on SAHPRA's services. These complaints are logged on a register that monitors progress on resolving the complaint within the targeted 30 working days. If SAHPRA is unable to resolve the complaint within the stipulated timeframe, the complainant is notified of the delay.

SAHPRA's stakeholder outreach programme, which focused mainly on public outreach was intensified by engaging mainstream and community media in both English and various other indigenous languages. The outreach also focused on burning issues such as the COVID-19 vaccine safety and AEFIs. SAHPRA hosted and participated in several webinars covering topics such as Ivermectin, vaccine registration and safety, vaccine hesitancy, COVID-19 therapies, and cannabis. The microsite with information on AEFIs was updated weekly and features as a portal on the SAHPRA website. Two videos focusing on AEFIs were developed and translated into five other official languages.

As part of contributing knowledge and participating in the latest debates in the scientific community, SAHPRA contributed to the following articles that were published in the applicable journals:

- Evaluation of the Good Review Practices of Countries Participating in the Southern African Development Community: Alignment and Strategies for Moving Forward - *Frontiers in Medicine Regulatory Science.*
- Evaluation of the Review Models and Approval Timelines of Countries Participating in the Southern African Development Community: Alignment and Strategies for Moving Forward - *Frontiers in Medicine Regulatory Science.*
- South African Regulatory Authority: The Impact of Reliance on the Review Process Leading to Improved Patient Access - *Frontiers in Medicine Regulatory Science.*
- Needs driven talent and competency development for the next generation of regulatory scientists in Africa - *British Journal of Clinical Pharmacology.*
- Building the concept for WHO Evidence Considerations for Vaccine Policy: Tuberculosis vaccines intended for adults and adolescents as a test case - *Vaccine.*

SAHPRA provided live streaming services during an event held running parallel with the World Conference on Pharmacometrics in Cape Town. The purpose of the parallel event was to discuss regulatory capacity development on the African continent.

Human Resources

In creating an organisational culture of open communication, concerted effort was made to ensure that there were frequent employee engagement sessions

held and the first Human Resource Indaba was held in June 2021. The Chief Executive Officer also held a staff meeting as part of the change management efforts. As part of implementing the change management initiatives, 15 employees volunteered to be change agents.

During the financial year, SAHPRA operated with a complete leadership team. The leadership team includes all the executives and senior managers. Recruitment of suitable candidates to fill the prioritised vacant positions were also accelerated to ensure that a level of business continuity could be maintained.

Knowledge and skills development remains a priority and, in this regard, attention was placed on providing training and development. SAHPRA proudly managed to register and submit its Workplace Skills Plan with the Sector Education and Training Authority. The Leadership Coaching Programme which focuses on the development of leadership capacity through improving skills and competencies was implemented. The following policies were approved:

- Performance Management Policy
- Training and Development Policy
- Disciplinary Policy
- Rewards and Recognition Policy

To ensure that the organisation attends to the physical and mental wellness of its employees, SAHPRA launched the ICAS Employee Assistance Programme in May 2021.

Information Technology

The acquisition and implementation of systems to drive the digital transformation of SAHPRA continued to be high on the agenda. While there are challenges and delays in deploying the enterprise-wide regulatory information management system, there were efforts to acquire an online portal to streamline and centralise the submission of applications through external funding. This online portal is being configured and will be implemented during the 2022/23 financial year.

A Vulnerability Assessment was completed and the relevant recommendations from the feedback report was swiftly addressed. This process assisted the organisation strengthen its network and data security.

Further infrastructure projects such as improving the printing and video conferencing facilities and the network relocation for the Cape Town office, that moved office premises at the end of March 2022, was successfully completed.

3.1.2 Linking Performance with Budgets

2021/2022				2020/2021		
Programme	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**
Programme 1	116 510	115 586	924	137 985	110 727	27 258
TOTAL	**116 510**	**115 586**	**924**	**137 985**	**110 727**	**27 258**

3.1.3 Strategy to overcome Areas of Underperformance

To accelerate the digitisation of business processes, the externally funded Quantum System is being implemented that will cater for all SAHPRA's business processes.

3.1.4 Reporting on the Institutional Response to the COVID-19 Pandemic

Programme	Intervention	Geographic Location (Province/ District/ Local municipality) (Where Possible)	No. of Beneficiaries (Where Possible)	Disaggregation of Beneficiaries (Where Possible)	Total Budget Allocation per Intervention (R'000)	Budget Spent per Intervention	Contribution to the Outputs in the APP (Where Applicable)	Immediate Outcomes
Programme 1	Personal protective equipment, sanitisers, fumigation practices post-exposure incidents	Pretoria and Cape Town facilities	+/- 279 staff	Not applicable (N/A)	Operational budget	Operational budget	N/A	N/A

3.2 Programme 2: Health Products Authorisation

Purpose: To provide administration support necessary for SAHPRA to deliver on its mandate and comply with the relevant legislative requirements. The specific purpose of this programme is to coordinate the process of registration and/or licensing or amendment of applications in respect of medicines within a legislative framework that defines the requirements necessary for application to the Authority, to receive record and distribute all documents submitted to SAHPRA.

Sub-programmes

Sub-Programme	Purpose
Document reception and helpdesk	The purpose of this sub-programme is to receive, record and/or direct all documents submitted to SAHPRA.
Project office – regulatory decision for medicines	The purpose is to coordinate the process of the making of a regulatory decision of medicines (screening, dispatch to evaluators, coordinating reports, recommendations, responses, arranging peer and product review meetings). It is also involved in ensuring that regulatory decisions made at the time of registration are in the public interest throughout the products' lifecycle through post-marketing vigilance of registered products. Vigilance includes the soliciting of data through various approaches, monitoring, analysis and responsive action, including the provision of feedback. In addition, a fully staffed backlog project team led by a senior project manager and linked to this sub-programme will be established.
Project office – clinical trials, Section 21 portfolio management	The purpose is to coordinate the vigilance process and authorisation of clinical trials and Section 21 applications for medicines and devices within a legislative framework that defines the requirements necessary for application to the Authority. Details on the assessment procedure and the grounds for approval or rejection of the application, and also the circumstances where authorisation already granted may be cancelled, withdrawn, suspended or revoked, are also catered for.
Licensing, permits and certificates portfolio management	The purpose is to manage and coordinate the process of licensing and amendments in respect of medicines manufacturers, wholesalers and medical device establishments and the issue of permits and registration certificates within a legislative framework that defines the requirements necessary for application to the Authority. Details on the assessment procedure (based on quality, efficacy and safety criteria) and the grounds for approval or rejection of the application, and also the circumstances where registration/licence/authorisation already granted may be cancelled, withdrawn, suspended or revoked, are also catered for.

Outcomes:

- High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7).
- Global best practices maintained (8).

3.2.1 Outcomes, Outputs, Output Indicators, Targets and Actual Achievements

PROGRAMME 2: HEALTH PRODUCTS AUTHORISATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	Backlog in medicine registration cleared	Percentage of medicine registrations in the backlog cleared	*58%* *Denominator was 8 220 (all new registration applications expected in line with industry survey). This figure reflected the total number of applications before opt-outs by applicants, clearance initiatives prior to Go-Live as well as non-resubmissions*	Out of 5 320 backlog applications for medicine registrations, 2 819 (53%) were cleared *Denominator was 5 320 (all new registration applications expected at the Go-Live of the project on 1 August 2019)*	**95% medicine registrations backlog cleared**	75% medicine registrations backlog cleared *Out of 3 395 backlog applications for medicine registrations received, 2 557 (75%) were cleared* *Denominator revised to refer only to applications received after Go-Live. Non-resubmissions excluded (1 925 applications were not resubmitted). Thus % clearance of the 3 395 new registration applications received*	Target was missed by 20%	Limited human resource capacity in the Clinical Pre-Registration Unit, slow finalisation of the Quality-Bio-Equivalence aspects of applications as well as extensions requested by applicants due to COVID-19 pandemic

PROGRAMME 2: HEALTH PRODUCTS AUTHORISATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
	Backlog in medicine variation applications cleared	Percentage of medicine variation applications in the backlog cleared	-	Out of the 7 440 backlog applications for variations, 7 165 (96%) were cleared *Denominator was 7 440 (all variation applications expected after opt-outs by applicants)*	**95% medicine variation applications backlog cleared**	95% medicine variation applications backlog cleared *Out of 3 611 backlog applications for medicine variations received, 3 428 (95%) were cleared* *Denominator revised to refer only to applications received after Go-Live. Prior clearance initiatives and non-resubmissions excluded. Thus % clearance of the 3 611 variation applications received*	Not applicable	Not applicable

PROGRAMME 2: HEALTH PRODUCTS AUTHORISATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
	New Chemical Entities applications finalised	Percentage of New Chemical Entities finalised within 590 working days	100%	Out of the 72 New Chemical Entities registered, all 72 (100%) were finalised within 590 days	**80% New Chemical Entities finalised within 590 working days**	100% New Chemical Entities finalised within 590 working days *Out of 246 New Chemical Entities applications received, 44 (18%) were finalised. Out of the 44 finalised, all 44 (100%) were finalised within 590 working days*	Target was exceeded by 20%	Applications that are novel treatments, for unmet medical needs were prioritised
	Generic medicines applications finalised	Percentage of generic medicines finalised within 250 working days	-	Out of the 240 generic medicines registered, 131 (55%) were finalised within 250 days	**60% generic medicines finalised within 250 working days**	80% generic medicines finalised within 250 working days *Out of 2 075 generic medicine applications received, 184 (9%) were finalised. Out of the 184 finalised, 148 (80%) were finalised within 250 working days*	Target was exceeded by 20%	Applications that are novel treatments, for unmet medical needs were prioritised

PROGRAMME 2: HEALTH PRODUCTS AUTHORISATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
	Quality Management System (QMS) Requirements implemented	Percentage of the Quality Management System requirements implemented	-	The implementation roadmap for the Quality Management System was developed and approved in October 2020 The Quality Management System is being implemented on an ongoing basis	**40% Quality Management System requirements implemented**	73% Quality Management System requirements implemented	Target was exceeded by 33%	Some of the planned activities were completed earlier than planned in preparation for the Global Benchmark-ing Tool by the WHO

PROGRAMME 2: HEALTH PRODUCTS AUTHORISATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
Global best practices maintained (8)	WHO global benchmarking conducted	WHO maturity level obtained benchmark level	-	Commenced with preparations to conduct the survey and engagements were held with WHO to provide support to SAHPRA	**WHO maturity level 3 obtained**	Based on the WHO provisional assessment report received in November 2021, an Institutional Development Plan was developed to address the recommendations	Target was not achieved	The roadmap was adjusted by WHO for the assessment to be concluded during the 2022/23 financial year. The COVID-19 pandemic travel restrictions resulted in the late start of the assessment

Backlog Clearance Programme

In 2018, SAHPRA inherited a backlog of over 16 000 medicine applications (new registrations and variations, i.e., changes to registered products) from its predecessor, the Medicines Control Council. To address this backlog, SAHPRA established a Backlog Clearance Programme, with dedicated staff, to clear all these applications. The Programme was tasked with optimising processes and implementing efficiencies, using totally re-engineered approaches for medicines assessment and registration. This included the introduction of reliance procedures that allowed SAHPRA to exchange information with recognised regional and international regulatory authorities. A further mandate was to establish the feasibility of risk-based assessment of certain aspects of generic applications. SAHPRA receives over 90% generic medicine (multi-source medicine) applications.

To this end, SAHPRA implemented various review approaches to eradicate the backlog of orthodox product registrations (with the exclusion of biological medicines). The Backlog Clearance Programme utilised the following review pathways:

- Full review – conducting complete scientific review for safety, quality, efficacy and Good Manufacturing Practice.
- Reliance pathways, such as:
    - Abridged review – assessing specific, pre-agreed areas of critical importance to SAHPRA's mandate to ensure safety of the South African public.
    - Verified review – validating that application conforms to reference authorisation and provide required information.
    - Risk-based assessment of critical quality attributes for applicable generic applications.

Overall, as at 31 March 2022, the backlog applications were cleared by 94%. This figure comprises the 15 168 applications finalised over the 16 170 applications included via the industry survey in the Backlog Clearance Programme. This figure also takes into account clearance initiatives prior to the Go-Live, such as applicant opt-outs, Starburst, certification variations, as well as non-resubmissions.

On 1 August 2019, the Backlog Clearance Project's official Go-Live was launched. Since the launch of the Go-Live, SAHPRA cleared 86% of the backlog applications. This figure comprises the 5 954 applications finalised over the 6 957 applications received. Furthermore, this figure considers clearance of new registration and variation applications actually submitted after Go-Live and does not include the number of non-resubmissions by applicants after Go-Live. The resubmitted applications were processed through various mechanisms that included official withdrawals by applicants, non-accepting/rejecting non-compliant applications and registering/approving compliant applications.

In an effort to increase the finalisation of new registration applications, the Backlog Clearance Programme initiated a risk-based assessment pilot study that focused on the assessment of critical quality attributes of generic applications. The risk-based assessment study has shown that the quality aspects of approximately 85% of applications were evaluated and finalised within three months. In a measure to reach the project finalisation date of 31 December 2022, the second phase of this pilot study will be rolled-out during the 2022/23 financial year.

Health Products Authorisation

The 246 New Chemical Entity (NCE) applications received included applications carried over from the previous financial year and applications received up until March 2022. Out of the 246 NCE applications received, 44 (18%) NCEs were finalised. Out of the 44 NCEs finalised, 43 (98%) were finalised within 590 working days from date of receipt and all 44 (100%) were finalised within 590 working days from the date of completion of technical screening.

The 2 075 generic applications received included applications carried over from the previous financial year and applications received up until March 2022. Out of the 2 075 generic applications received, 184 (9%) were finalised. Out of the 184 generics finalised, 68 (37%) were finalised within 250 working days from date of receipt and 148 (80%) generics were finalised within 250 working days from the date of completion of technical screening. The registrations encompassed

the therapeutic areas such as antihistamine, anti-acid, anti-infectives, oncology, antiviral and anti-tuberculosis. Generic medicine applications from April 2020 onwards are already in a backlog. Various strategies are being implemented to reduce and clear this backlog. These strategies include the implementation of various forms of reliance that involve making use of assessment reports from recognised regulatory authorities and SAHPRA, which contributed towards reducing the review timelines of applications.

Quality Management Systems

SAHPRA continued its effort in implementing an effective QMS. The implementation of the QMS is an important deliverable of the regulatory system required for a mature regulatory agency as advocated by the WHO. Some of the key initiatives implemented during the financial year include the implementation of document management system and the appointment of QMS representatives.

In preparation for ISO 9001 certification, SAHPRA conducted its first annual QMS internal audit and the recommendations emanating from the audit are being addressed. Furthermore, SAHPRA held its first QMS review. The review allowed SAHPRA to reflect on its performance in all the QMS initiatives. This review will be held annually to determine and evaluate management system performance, the need for change and improvement as well as the suitability of business policies and objectives.

A key focus for SAHPRA was to work towards obtaining a Maturity Level 3 rating for regulatory systems based on the WHO Global Benchmarking Tool. The benchmarking assessment was conducted and an Institutional Development Plan was developed for SAHPRA to address areas of weaknesses identified. The final benchmarking assessment will be concluded during the 2022/23 financial year, wherein the maturity level rating will be awarded.

3.2.2 Linking Performance with Budgets

2021/2022				2020/2021		
Programme	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**
Programme 2	72 534	73 660	(1 126)	69 098	34 223	34 875
TOTAL	**72 534**	**73 660**	**(1 126)**	**69 098**	**34 223**	**34 875**

3.2.3 Strategy to overcome Areas of Underperformance

To improve the number of backlog applications for medicine registrations cleared, a risk-based assessment pilot study was initiated in September 2021. This has resulted in shortened review and applicant response timeframes. The implementation of the second phase is scheduled during the 2022/23 financial year. This will further assist in mitigating the long extension requests from applicants to respond to quality and bioequivalence queries. The Backlog Clearance Programme will, moreover, continue to assess extensions granted to applicants, taking cognisance of the nature of the queries as well as external impediments experienced by individual applicants.

In preparation for the final WHO benchmarking assessment to determine SAHPRA's maturity level, the implementation of recommendations from the Institutional Development Plan are being accelerated.

3.2.4 Reporting on the Institutional Response to the COVID-19 Pandemic

Programme	Intervention	Geographic Location (Province/ District/ Local municipality) (Where Possible)	No. of Beneficiaries (Where Possible)	Disaggregation of Beneficiaries (Where Possible)	Total Budget Allocation per Intervention (R'000)	Budget Spent per Intervention	Contribution to the Outputs in the APP (Where Applicable)	Immediate Outcomes
Not applicable								

3.3 Programme 3: Inspectorate and Regulatory Compliance

Purpose: To ensure public access to safe health products (include disclaimer) through inspections and regulatory compliance. The focus of this programme includes assessment of site compliance, with good regulatory and vigilance practices, including the following:

- Good Manufacturing Practice
- Good Clinical Practice
- Good Warehouse Practice
- Good Distribution Practice
- Good Laboratory Practice
- Good Vigilance Practice

Sub-programmes

Sub-Programme	Purpose
Inspections	To ensure that GxP's inspection activities are actively managed to facilitate the running of an effective inspection programme monitored against pre-defined timelines and commitments communicated to stakeholders.
Regulatory Compliance	To ensure public access to safe medicines through regulatory compliance and monitoring of compliance with applicable legislation as mandated.

Outcomes:

- High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7).

3.3.1 Outcomes, Outputs, Output Indicators, Targets and Actual Achievements

PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	New GMP and GWP related licences finalised	Percentage of new GMP and GWP related licenses finalised within 125 working days	77%	Out of the 39 new GMP licence applications received, 29 (74%) new GMP licences were issued Out of the 29 new GMP licences issued, 17 (59%) were issued within 125 working days	**60% new GMP and GWP related licenses finalised within 125 working days**	42% new GMP and GWP related licenses finalised within 125 working days *Out of 64 new GMP and GWP related licences applications received, 31 (48%) were finalised. Out of the 31 finalised, 13 (42%), were finalised within 125 working days*	Target was missed by 18%	8 out of the 31 (26%) licenses finalised were affected by the COVID-19 lockdown restrictions as inspections could not be conducted
	Permits finalised	Percentage of permits finalised within 20 working days	-	-	**70% permits finalised within 20 working days**	71% permits finalised within 20 working days *Out of 4 553 permit applications received, 4 474 (98%) were finalised. Out of the 4 474 finalised, 3 186 (71%) were finalised within 20 working days*	Target was exceeded by 1%	Improve-ments in impleme-nting business processes

PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
	Health product quality complaint reports	Percentage of health product quality complaint reports produced within 30 working days	-	Out of the 101 health product quality complaints received, 84 (83%) were investigated and reports produced	**70% health product quality complaints reports produced within 30 working days**	72% health product quality complaints reports produced within 30 working days *Out of 130 health product quality complaints received, 93 (72%) reports were produced within 30 working days*	Target was exceeded by 2%	Additional human resources were obtained

Licensing

During the 2021/22 financial year, 31 Good Warehouse Practice and Good Manufacturing Practice related licences were finalised for first time applicants. There was a decrease in the issuing of licences for manufacturers of alcohol-based hand-rubs who were prioritised in response to COVID-19 in the previous financial year. The processing of 28 licence amendments and 33 licence renewals were also conducted.

Inspectorate

Support was provided to the Business-As-Usual and backlog registration streams in terms of evaluation and/or inspection requirements for Good Manufacturing Practice to support the registration of products. To reduce the backlog of Business-As-Usual registrations, additional resources were allocated to assist in increasing dossier evaluations for Good Manufacturing Practice clearance. In total, 168 GxP inspections were conducted.

Regulatory Compliance

The medicinal cannabis market continues to expand, requiring engagement at a national level. SAHPRA remains an integral stakeholder in the Cannabis Master Plan, whilst maintaining its current role as an enabler of the increasing cultivation market for medical cannabis export. During the financial year, 74 cannabis cultivation inspections were completed.

During the 65th Session of the Commission on Narcotic Drugs held in March 2022, SAHPRA was invited by the International Narcotics Control Board (INCB) to co-sponsor at their parallel event on International Standards for Reporting Cannabis and Cannabis-Related Substances for Medical Purposes by sharing its experience with INCB. The speakers at the session included the President of INCB and other speakers from the United Nations Office on Drugs and Crime, Japan, United States of America, Germany, United Kingdom and New Zealand. In addition, during the session, SAHPRA also participated at the RSA Vienna Mission led parallel event on cannabis.

3.3.2 Linking Performance with Budgets

	2021/2022			2020/2021		
Programme	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**	**Budget R'000**	**Actual Expenditure R'000**	**(Over)/Under Expenditure R'000**
Programme 3	35 827	35 370	457	38 504	35 696	2 808
TOTAL	**35 827**	**35 370**	**457**	**38 504**	**35 696**	**2 808**

3.3.3 Strategy to overcome Areas of Underperformance

To improve the finalisation of new Good Manufacturing and Good Warehouse Practice related licenses, internal mechanisms have been initiated and prioritised to ensure improved communication and cooperation for inspections of these new licences.

3.3.4 Reporting on the Institutional Response to the COVID-19 Pandemic

Programme	Intervention	Geographic Location (Province/ District/ Local municipality) (Where Possible)	No. of Beneficiaries (Where Possible)	Disaggregation of Beneficiaries (Where Possible)	Total Budget Allocation per Intervention (R'000)	Budget Spent per Intervention	Contribution to the Outputs in the APP (Where Applicable)	Immediate Outcomes
Programme 3	Remote/ Hybrid inspections	Inspection sites	-	-	Operational budget	Operational budget	Inspections for new licence applicants could be conducted, leading to licenses being issued	New licenses issued

The guideline for conducting inspections during the COVID-19 pandemic remained operational whilst the country remained under lockdown restrictions. The guidelines assisted the inspectors to assess and manage the risk of exposure in interactions during inspections. International inspections commenced through virtual inspection, which required a readiness test with site prior to commencing the inspection.

The issuing of physical licences continued, and this was managed by ensuring that appointments were made for applicants to collect their licences.

3.4 Programme 4: Clinical and Pharmaceutical Evaluation

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

Sub-programmes

Sub-Programme	Purpose
Clinical Evaluation	To evaluate the safety and efficacy of orthodox medicines.
Clinical Trials	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 rights of patients.
Pharmaceutical Evaluations	To perform pharmaceutical and analytical evaluations of new and registered medicines inclusive of clinical aspects of veterinary medicines and biological.
Authorisation of the Sale of Unregistered Medicines	To conduct an abbreviated evaluation of applications to authorise the sale of unregistered medicines based on based on quality, safety, and efficacy standards.
Vigilance and Post-Marketing Surveillance	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.
Complementary and Alternative Medicines	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.
Veterinary Medicines	To evaluate the safety, efficacy and quality of veterinary medicines.

Outcomes:

- High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7).

3.4.1 Outcomes, Outputs, Output Indicators, Targets and Actual Achievements

PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	Applications for the sale of unregistered Category A (human) medicines finalised	Percentage applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours	96%	Out of the 19 346 applications for the sale of unregistered Category A (human) medicines – Section 21 received, 17 658 (91%) were finalised Out of the 17 658 applications finalised, 16 182 (92%) were finalised within 24 working hours	**85% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours**	57% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours *Out of the 16 435 applications received, 14 780 (90%) were finalised, of which 9 385 (57%) were finalised 24 working hours*	Target was missed by 28%	PowerApps portal does not reflect the correct submission/ re-submission dates and insufficient technical staff to manually record the correct re-submission dates whilst ensuring quick turnaround times for finalisation of applications

PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
	Human clinical trial applications finalised	Percentage of human clinical trial applications finalised within 90 working days	100%	Out of the 233 human clinical trial applications received, 203 (87%) were finalised Out of the 203 applications finalised, 194 (96%) were finalised within 120 working days	**80% human clinical trial applications finalised within 90 working days**	95% human clinical trial applications finalised within 90 working days *Out of 274 human clinical trial applications received, 248 (91%) were finalised. Out of the 248 finalised, 235 (95%) were finalised within 90 working days*	Target was exceeded by 15%	COVID-19 trial protocols received were prioritised

PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATION								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
	Health product safety signals issued	Percentage of reports on health product safety signals issued within 40 working days	4 quarterly reports	Out of the 86 health product safety signals identified, all 86 (100%) were actioned (investigated and finalised) Out of the 86 health product safety signals actioned, 37 (43%) were actioned within 20 working days	**70% reports on health product safety signals issued within 40 working days**	28% reports on health product safety signals issued within 40 working days *Out of the 235 applications received, 95 (40%) reports were issued, of which 66 (28%) were issued within 40 working days*	Target was missed by 42%	Lack of human resources and appropriate training
	Safety awareness webinars held	Number of safety awareness webinars held	-	-	**4 safety awareness webinars held**	13 safety awareness webinars held	Target was exceeded by 9	COVID-19 vaccinations resulted in an increased need for safety information

Category A (Human) Medicines

As part of enhancing the country's COVID-19 regulatory response, SAHPRA continued to provide access to Ivermectin for the treatment of COVID-19 through the controlled compassionate use programme for approved unregistered Ivermectin products. The majority of unregistered medicines that treat COVID-19 infections were approved within 24 working hours. Out of 9 385 applications finalised within 24 working hours, the following categories were reported:

- Named patients: 5 207 (55%)
- Bulk stock: 4 140 (44%)
- Reauthorisations – named patients: 23 (0.25%)
- Reauthorisations – bulk stock: 15 (0.16%)

For the 2021/22 financial year, the following top 10 Section 21 product requests were approved or rejected as indicated in the table below:

Approved/Rejected Product	Number of Applications
1. Colistimethate sodium	1 146 (approved: 1 123, rejected: 23)
2. Ivermectin	778 (approved: 758, rejected: 20)
3. Remdesivir	598 (approved: 598, rejected: 0)
4. Colistin	366 (approved: 363, rejected: 3)
5. Upadacitinib	261 (approved: 261, rejected: 0)
6. Dexamethasone	185 (approved: 185, rejected: 0)
7. Progesterone (natural)	165 (approved: 165, rejected: 0)
8. Etoposide	140 (approved: 132, rejected: 8)
9. Total parenteral nutrition	140 (approved: 140, rejected: 0)
10. Mitomycin	134 (approved: 134, rejected: 0)

Human Clinical Trials

To promote the conduct of clinical trials related to the ongoing COVID-19 pandemic, SAHPRA's clinical trial protocol submission guidelines were amended and implemented. The review of COVID-19 clinical trials was expedited to enhance the country's COVID-19 emergency response and the approval turn-around time was between 7 to 10 working days.

Pharmacovigilance

The Med Safety App was launched in April 2021 to facilitate the reporting of AEFIs for vaccines and to act as a platform for collecting adverse drug reactions for other health products going forward. During the course of the financial year, there was an increase in the utilisation of the Med Safety App. To further enhance the safety monitoring of registered medicines, medicines' safety reporting guidelines were published for implementation. Furthermore, CoviVig, a dedicated pharmacovigilance project to closely monitor treatment outcomes of medicines used off-label for COVID-19 is in place to further obtain safety and efficacy data on repurposed registered medicines and novel unregistered medicines used to treat COVID-19 and its complications.

To promote vigilance awareness within the country, for both healthcare professionals and the public, the National Vigilance Framework in South Africa was developed and will be implemented during the 2022/23 financial year.

3.4.2 Linking Performance with Budgets

2021/2022				2020/2021		
Programme	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000
Programme 4	92 962	80 402	12 560	88 217	73 666	14 551
TOTAL	**92 962**	**80 402**	**12 560**	**88 217**	**73 666**	**14 551**

3.4.3 Strategy to overcome Areas of Underperformance

To improve the turnaround time for the authorisation of Section 21 applications, the ICT system utilised is being improved to accurately calculate the processing timelines from when a complete application is submitted and finalised.

Additional human resources will be obtained to deal with health product safety signals. Furthermore, to reduce the reliance on external experts, a training programme for internal employees of SAHPRA has commenced.

3.4.4 Reporting on the Institutional Response to the COVID-19 Pandemic

Programme	Intervention	Geographic Location (Province/ District/ Local municipality) (Where Possible)	No. of Beneficiaries (Where Possible)	Disaggregation of Beneficiaries (Where Possible)	Total Budget Allocation per Intervention (R'000)	Budget Spent per Intervention	Contribution to the Outputs in the APP (Where Applicable)	Immediate Outcomes
Not applicable								

In addition to the above-mentioned initiatives under 3.4.1, SAHPRA authorised COVID-19 vaccines under Section 21 as the emergency use authorisation mechanism for Covishield, Pfizer (Cominarty®), COVID-19 Vaccine Janssen® and SinoVac CoronaVac vaccines. Section 21 Sputnik V Lamar application was rejected, and approval was granted for Pfizer (Cominarty®) third dose for booster (homologous) and COVID-19 Vaccine Janssen® booster (homologous and heterologous).

As South Africans continued to receive immunisations, SAHPRA closely monitored the COVID-19 AEFIs. Although the overall achievement for health product safety signals was low, there was a reasonable turnover for COVID-19 related safety signals where 65% were processed within the target timeline, with a median processing timeline of 21 days.

Collaboration with the Council for Scientific and Industrial Research (CSIR) resulted in the analysis of COVID-19 vaccine safety data, resulting in the weekly publication of the vaccine safety statistics on SAHPRA's website (https://aefi-reporting.sahpra.org.za/). This has promoted transparency in terms of emerging and known vaccine safety concerns and how SAHPRA in collaboration with NDoH, tracks these safety concerns and utilises the data to further mitigate safety concerns around COVID-19 vaccines.

3.5 Programme 5: Medical Devices and Radiation Control

Purpose: To develop and maintain regulations and guidelines pertaining to the regulatory oversight of medical devices, radionuclides, and listed electronic products.

Sub-programmes

Sub-Programme	Purpose
Medical Devices	To implement and strengthen the regulatory oversight of medical devices through the development and maintenance of relevant regulations and guidelines.
Radiation Control	To efficiently, effectively and ethically evaluate and radionuclides and listed electronic products. To protect patients, radiation workers, the public and the environment against possible adverse effects of ionising radiation without limiting its beneficial uses.

Outcomes:

- High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7).

3.5.1 Outcomes, Outputs, Output Indicators, Targets and Actual Achievements

PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	Medical device establishment licence applications finalised	Percentage of medical device establishment licence applications finalised within 90 days	99%	Out of the 1 116 medical device establishment licence applications received, 757 (68%) were finalised Out of the 757 applications finalised, 629 (83%) were finalised within 90 days	**70% medical device establishment licence applications finalised within 90 days**	76% medical device establishment licence applications finalised within 90 days *Out of 1 105 medical device establishment licence applications received, 804 (73%) were finalised. Out of the 804 finalised, 613 (76%) were finalised within 90 working days*	Target was exceeded by 6%	Monitoring system was put in place and the closure of old applications was initiated

PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
	Medical device registration regulations implemented	Medical device registration regulations implemented	The medical device system has not been implemented Regulations, fees schedule, guidelines and Standard Operating Procedures to be implemented	The draft regulations, which will form part of the medical registration framework, were re-submitted to the State Law Adviser for review in September 2020	**Guidelines to support the medical device registration regulations approved by the Executive Committee**	19 guidelines to support the medical device registration regulations were drafted	Target was not achieved	Guidelines can only be approved once the Medical Device Regulations are approved, which are under review

PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
	Radionuclide authorities finalised	Percentage of applications for radionuclide authorities finalised within 30 working days	99%	Out of the 2 719 new application licences for ionising radiation emitting devices and radioactive nuclides authorities received, 2 519 (92%) were issued Out of the 2 519 issued, 2 302 (91%) were issued within 30 working days	**70% applications for radionuclide authorities finalised within 30 working days**	72% applications for radionuclide authorities finalised within 30 working days *Out of 4 740 applications for radionuclide authorities received, 3 803 (80%) were finalised. Out of the 3 803 finalised, 2 747 (72%) were finalised within 30 working days*	Target was exceeded by 2%	Effective monitoring tools put in place for new applications and the closure of old applications

PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL								
Outcome	**Output**	**Output Indicator**	**Audited Actual Performance 2019/2020**	**Audited Actual Performance 2020/2021**	**Planned Annual Target 2021/2022**	**Actual Achievement 2021/2022**	**Deviation from Planned Target to Actual Achievement 2021/2022**	**Reasons for Deviations**
	Licence applications for listed-electronic products finalised	Percentage of licence applications for listed-electronic products finalised within 30 working days			70% licence applications for listed-electronic products finalised within 30 working days	99% licence applications for listed-electronic products finalised within 30 working days *Out of 944 licence applications for listed-electronic products received, 934 (99%) were finalised. Out of the 934 finalised, 924 (99%) were finalised within 30 working days*	Target was exceeded by 29%	Well-established business processes resulted in the efficient processing of applications
	Co-Regulation Model	Approved Co-Regulation Model	-	-	**Board approved Co-Regulation Model with the National Nuclear Regulator**	Terms of Reference with the National Nuclear Regulator was signed Draft Cooperate Governance and Co-Regulation Recommendation were developed	Target was not achieved	Further work had to be undertaken to strengthen the initial Co-Regulation Recommen-dation and the unavailability of members to attend meetings

Medical Devices and Radiation Control

Standard Operating Procedures (SOPs) were implemented to ensure that there is efficient regulatory management. The streamlining and re-focusing of functions also assisted in ensuring that there are efficient operations.

To improve communication with the industry and process efficiencies, stakeholder engagements were increased with the following engagements held:

- Industry workshop (Licence renewals and conformity assessment bodies). Communication to industry.
- Workshop with the International Atomic Energy Agency (Disused source and transportation of active sources).

The availability of the community service pharmacist for 12 months assisted in improving the performance with regards to the finalisation of medical device applications. The adoption of digital solutions remains imperative to ensure the efficient functioning of the regulation of medical devices. SAHPRA received public comments on the regulations for medical devices and three workshops were held with respondents and members of the Industry Technical Working Group as well as the Medical Device Committee to discuss the areas that received the most comments. The collaboration with industry assisted with understanding the comments from them in addition to offering SAHPRA the opportunity to state its standpoint on certain topics within the regulations.

SAHPRA is working in collaboration with other national regulatory authorities in creating and reviewing various guidance documents using platforms such as the African Medical Device Forum, of which SAHPRA is co-chair. As part of the WHO Global Model Regulatory Framework Working Group for medical devices including in vitro diagnostics, SAHPRA participated in updating the WHO Global Benchmarking Tool and the tool for medical devices. Furthermore, SAHPRA is participating in the WHO Collaborative Registration Procedure. This procedure is for WHO-prequalified products, and it accelerates registration through improved information sharing between the WHO Prequalification Process of Medicines Programme, national regulatory authorities, and the WHO National Regulatory Authority Strengthening Programme.

Radiation Control implemented robust business processes that resulted in efficient processing of applications and issuing of licences. The achievements are an indication that the regulatory framework for radionuclides and listed-electronic products licensing has been effective and ensures compliance monitoring of licence and authority holders across the entire country.

SAHPRA continued to engage with the Department of Minerals and Energy and the National Nuclear Regulator on legislative and regulatory matters with the intention to define the co-regulation framework among the stakeholders as well as the revision of respective Acts.

3.5.2 Linking Performance with Budgets

	2021/2022			2020/2021		
Programme	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000
Programme 5	39 717	34 290	5 427	53 959	38 128	15 831
TOTAL	**39 717**	**34 290**	**5 427**	**53 959**	**38 128**	**15 831**

3.5.3 Strategy to overcome Areas of Underperformance

With regards to the medical device registration regulations, additional capacity will be sourced to ensure the speedy finalisation of the regulations. Policies, guidelines, and SOPs to manage the internal and external engagements will be developed. The technical expert committee will assist with the implementation of the policies, regulations, and guidelines.

It is anticipated that the co-regulations between SAHPRA and the National Nuclear Regulator will be completed during the 2022/23 financial year. Feedback on progress will be requested from the working group on a regular basis.

3.5.4 Reporting on the Institutional Response to the COVID-19 Pandemic

Programme	Intervention	Geographic Location (Province/ District/ Local municipality) (Where Possible)	No. of Beneficiaries (Where Possible)	Disaggregation of Beneficiaries (Where Possible)	Total Budget Allocation per Intervention (R'000)	Budget Spent per Intervention	Contribution to the Outputs in the APP (Where Applicable)	Immediate Outcomes
Programme 5	Formed a COVID-19 Evaluation Committee to evaluate COVID-19 medical device applications	Gauteng	8 members	-	-	Each evaluator allocated R650 / hour	Maximum of 20 applications reviewed per month and 2 meetings per week, depending on number applications for peer review	73 antigen test kits approved 127 molecular test kits approved 53 serological test kits approved
	Employed Ventilator Evaluation Committee	Gauteng	4 members	-	-	Each evaluator allocated R650 / hour	Maximum of 5 applications per month Meetings are *ad hoc*	14 ventilators approved
	Oversight and tasks assigned to the Experts Advisory Committee at no cost to develop regulatory requirements/ guidance for COVID-19 self-test kits	Gauteng	9 advisory experts	-	-	N/A	SAHPRA medical device guidance for COVID-19 self-test kits published	Implemented the guidance

Engagements were held with multidisciplinary stakeholders such as the National Institute of Communicable Diseases of South Africa, the National Health Laboratory Services, WHO, the Medicines and Healthcare Products Regulatory Agency, HIV research organisation - Ezintsha and the Clinton Health Access Initiative to approve the use of self-test/home-based SARS COVID-19 test kits.

4. REVENUE COLLECTION

2021/2022				2020/2021		
Sources of Revenue	Estimate R'000	Actual Amount Collected R'000	(Over)/Under Collection R'000	Estimate R'000	Actual Amount Collected R'000	(Over)/Under Collection R'000
Fee income	162 264	169 450	(7 186)	196 771	101 734	95 037
TOTAL	**162 264**	**169 450**	**(7 186)**	**196 771**	**101 734**	**95 037**

Better than anticipated revenue collection occurred due to new medicine registration percentage completion reached for certain applications.

Revenue recognition will improve as SAHPRA fills funded vacancies in the 2022/23 financial year.

5. CAPITAL INVESTMENT

2021/2022				2020/2021		
Infrastructure Projects	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000	Budget R'000	Actual Expenditure R'000	(Over)/Under Expenditure R'000
None						

SAHPRA is a Public Finance Management Act (PFMA, 1999, as amended) Schedule 3A public entity under NDoH. SAHPRA manages its assets in line with its Asset Management Policy and has not embarked on any infrastructure projects and did not close down or downgrade any facilities during the year.

No maintenance activities were undertaken during the year as the entity did not own significant infrastructure or moveable assets that required continuous maintenance. SAHPRA has current office accommodation lease arrangements for its head and regional offices and the rental expenses associated with the new operating lease agreement was appropriately disclosed in the notes of annual financial statements.

A significant portion of SAHPRA's assets for the 2021/22 financial year comprises newly-acquired assets. These acquisitions amounted to R5.6 million on 31 March 2022. The new acquisitions include other fixed assets (R295 243), computer equipment (R2 857 938), furniture (R63 592), motor vehicles (R971 954) and intangible assets (R1 294 018). The disposals for the year comprised old furniture and computer equipment which were transferred from NDoH and were no longer in use or had been replaced, which were either sold or donated. A significant portion of these assets was fully depreciated.

SAHPRA has an Asset Management Unit within its Finance Department that is responsible for updating the asset register including all asset transactions such as receipts, movements, disposals, useful life assessments and other changes. The unit conducts asset verifications at least twice a year in terms of the approved Asset Management Policy.

PART C

GOVERNANCE

1. INTRODUCTION

The Board and its four committees reviewed the systems and processes of the organisation timeously. They recognised the role of governance as critical to the efficient and effective functioning of the Regulator. The Board provided assurance to the Authority's stakeholders that strengthening the existing framework for governance and compliance remained high on SAHPRA's agenda.

2. PORTFOLIO COMMITTEES

The following presentations were made by SAHPRA to the Portfolio Committees in Parliament:

- 28 April 2021 - Portfolio Committee on Health: Johnson & Johnson clinical trials, vaccines procurement and progress on the vaccination roll-out programme.
- 5 May 2021 - Portfolio Committee on Health: 2021/22 Annual Performance Plan and budget.
- 25 August 2021 - Portfolio Committee on Justice and Correctional Services: Progress regarding its investigations into the procurement and transportation conditions of Heberon by the Department of Defence.

3. EXECUTIVE AUTHORITY

The Regulator submits quarterly reports on its performance and activities to the Executive Authority as mandated by the Medicines and Related Substances Act (1965, as amended) and the PFMA (1999, as amended). In addition, the Executive Authority was briefed on three critical matters:

- SAHPRA's progress on the registration of COVID-19 vaccines. There were a few engagements that culminated in SAHPRA's participation in various COVID-19 structures.
- SAHPRA's position on Ivermectin. This matter led to litigation against the Minister and the Regulator and reports in this regard were submitted to the Executive Authority.
- SAHPRA's position on cannabis. Various reports were submitted to the Executive Authority on the activities of SAHPRA together with its narrow mandate on medicinal cannabis.

4. THE ACCOUNTING AUTHORITY/BOARD

Introduction

The Board is the Accounting Authority in terms of the PFMA (1999, as amended) and is appointed for a renewable period of three years by the Minister of Health in terms of the Medicines and Related Substances Act (1965, as amended). The Minister extended the term of the Board by a further 12 months. The term of the current board expired on 30 September 2021 and the new board was appointed in October 2021 wherein six previous members were retained for continuity. The Regulator is governed and controlled in accordance with the Medicines and Related Substances Act (1965, as amended). The Board ensures compliance with this Act. During the period under review, SAHPRA appointed the Institute of Directors to conduct a Board assessment.

Role of the Board

The Board executes 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 towards 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 acknowledging their responsibilities and duties in terms of governance, regulatory and legislative requirements.

Board Charter

The Board has approved its Charter as an overall guiding tool for the execution of its mandate. The Charter sets out the responsibilities of members and procedures for meetings. The Board resolved to review the Charter on an annual basis to ensure that it remains relevant. Accordingly, during the reporting period 2021/22, the Charter was reviewed in May 2021.

Composition of the Board

Name	Designation *(in terms of the Public Entity Board structure)*	Date Appointed	Date of Termination	Date of New term of the Board	Qualifications	Area of Expertise	Board Directorships	Other Committees or Task Teams	No. of Meetings Attended
Prof. Helen Rees	Chairperson	17 November 2017	N/A	Re-appointed in October 2021	Harvard Business School Senior Executive Programme Member of the Royal College of General Practitioners Doctor instructor for Family Planning Diploma of Child Health Diploma of Royal College of Obstetricians and Gynaecologists MA Social and Political Sciences	Clinical trials	N/A	N/A	21
Ms Mandisa Hela	Vice-Chair	17 November 2017	30 September 2021	N/A	BPharm BSC MPH	Public health	N/A	Human Resource and Remuneration Committee (HRRemco) Risk Audit and Governance Committee (RAG)	12
Dr Obakeng Khaole	Vice-Chair	N/A	N/A	Newly-appointed in October 2021	MBChB Bachelor of Surgery Diploma in HIV Management Postgraduate in Occupational Medicine	Medical research and clinical trials	N/A	RAG HRRemco	9

Name	Designation *(in terms of the Public Entity Board structure)*	Date Appointed	Date of Termination	Date of New term of the Board	Qualifications	Area of Expertise	Board Directorships	Other Committees or Task Teams	No. of Meetings Attended
Mr Norman Baloyi	Member	17 November 2017	N/A	Re-appointed in October 2021	Master of Science in Electronics (Information Security; Computer Networks) Master of Science in Electrical Engineering (Telecommunications) BSc Honours in Computational and Applied Mathematics Higher Diploma in Computer Auditing Bachelor of Science BSc in Computer Science and Information Systems BSc Mathematics and Computational & Applied Mathematics Diploma in Network Security Diploma in Datametrics (Computer Science Certified Information Systems Auditor Certified Information Systems Security Professional Certified Information Security Manager	Information technology	N/A	RAG Finance HRRemco Technical Oversight and Regulatory Strategy Committee (TORS)	20
Prof. Shabir Banoo	Member and Chairperson TORS	17 November 2017	30 September 2021	N/A	BPharm PhD	Medicine regulation	N/A	RAG TORS	10

Name	Designation *(in terms of the Public Entity Board structure)*	Date Appointed	Date of Termination	Date of New term of the Board	Qualifications	Area of Expertise	Board Directorships	Other Committees or Task Teams	No. of Meetings Attended
Prof. Ames Dhai	Member	17 November 2017	30 September 2021	N/A	MBChB FCOG LLM	Bio-Ethics	N/A	RAG TORS	12
Prof. Jeffrey Mphahlele	Member and Chairperson HRRemco	17 November 2017	30 September 2021	N/A	BSc (Biological Sciences) BSc Med Honours PHD (Medical Virology)	Epidemiology and virology	N/A	HRRemco Finance	9
Dr Ushma Mehta	Member	17 November 2017	30 September 2021	N/A	BPharm DrPharm	Pharmacovigilance	N/A	TORS	10
Prof. Craig Household	Member	17 November 2017	30 September 2021	N/A	MBChB MD	Human Resource	N/A	RAG HRRemco Finance	6
Ms Lerato Mothae	Member	1 May 2021	N/A	Re-appointed in October 2021	Bachelor of Accounting CTA (BComm Honours) CA (SA) CTA (BCompt Honours) BCompt (Bachelor of Accounting)	Finance and Accounting	N/A	RAG Finance	12
Mr Itani Mashau	Member	25 April 2019	N/A	Re-appointed in October 2021	BPharm Diploma in Production Diploma in Quality Management and Quality Assurance Masters of Business Administration Diploma in Small Business Management	Good Manufacturing Practice	N/A	TORS HRRemco	20

Name	Designation *(in terms of the Public Entity Board structure)*	Date Appointed	Date of Termination	Date of New term of the Board	Qualifications	Area of Expertise	Board Directorships	Other Committees or Task Teams	No. of Meetings Attended
Prof. Patrick Demana	Member	25 April 2019	N/A	Re-appointed in October 2021	PhD in Pharmaceutics BSc (Hons) in Pharmacy MSc in Pharmaceutics Post-doctoral Fellowship in Drug Discovery A-level courses (Chemistry, Biology, Mathematics & Statistics)	Virologist	N/A	TORS	15
Adv. Hasina Cassim	Member	17 November 2017	N/A	Re-appointed in October 2021	BPharm LLB Certificate in Medicine Law Certificate in pharmacoepidemiology Medical Mediation training	Law	N/A	RAG TORS	19
Dr Edith Madela-Mntla	Member	17 November 2017	30 September 2021	N/A	DCur MCur BCur	Clinical trials	N/A	TORS HRRemco	10
Dr Thabelo Motshudi	Member	17 November 2017	30 September 2021	N/A	MBChB FC Rad Diag (Diagnostic Radiology)	Radiology	N/A	RAG	7
Dr Mphane Molefe	Member	17 November 2017	30 September 2021	N/A	Bachelor of Veterinary Medicine and Surgery	Veterinary public health	N/A	TORS RAG	5
Ms Mandisa Skhosana	Member	Newly-appointed 1 October 2021	N/A	N/A	National Diploma in Biomedical Technology BTech Degree in Biomedical Technology Masters Degree in Medical Science	Laboratory medicine, quality control and clinical research	N/A	TORS	3

Name	Designation *(in terms of the Public Entity Board structure)*	Date Appointed	Date of Termination	Date of New term of the Board	Qualifications	Area of Expertise	Board Directorships	Other Committees or Task Teams	No. of Meetings Attended
Prof. Joyce Tsako-Gwegweni	Member	Newly-appointed 1 October 2021	N/A	N/A	BA Hons (Social science psychology) B.Sc. Hons- Zoology & Microbiology PhD in Public Health MPH in Public Health	Public health medicine	N/A	TORS	9
Dr Alfred Kgasi	Member	Newly appointed 23 December 2021	N/A	N/A	Bachelor of Veterinary Medicine LLB Masters of Business Leadership	Veterinary	N/A	TORS	4
Dr Zinhle Makatini	Member	Newly-appointed 23 December 2021	N/A	N/A	BSc (Honors) Biochemistry Masters in Immunology of Infectious Diseases MBChB PhD Virology Registrar in Virology Diploma in Travel Medicine Diploma in Tropical Medicine Diploma in HIV Management in the Workplace Diploma in HIV Management MMED in Biostatistics & Epidemiology (completed2/3) PhD in Medical Virology	Virology	N/A	TORS	4

Name	Designation *(in terms of the Public Entity Board structure)*	Date Appointed	Date of Termination	Date of New term of the Board	Qualifications	Area of Expertise	Board Directorships	Other Committees or Task Teams	No. of Meetings Attended
Dr Xolani Ngobese	Member	Newly-appointed 1 October 2021	N/A	N/A	PhD in Business Administration Masters in Business Administration	Independent consultant	N/A	HRRemco Finance	9
Ms Lucy Ditaba Maraka	Member	Newly appointed 1 October 2021	N/A	N/A	Bachelor of Arts Bachelor of Education Baccalaureus Atium Honores Masters Diploma in HR Training and Development Ethics Officer Certification Psychometrist Effective Audit Committees Effective Remuneration Committees Social & Ethics Committees	Independent Psychometrist	N/A	HRRemco	9
Prof. Yahya Choonara	Member	Newly-appointed 23 December 2021	N/A	N/A	BPharm MPharm PhD	Medical devices	N/A	TORS	4
Prof. Hannelie Meyer	Member	Newly-appointed 23 December 2021	N/A	N/A	BPharm MSc (Med) PhD in Pharmacy	Pharmacovigilance, Public Health	N/A	TORS	4

Committees

Committee	No. of Meetings Held	No. of Members	Name of Members
Finance Committee	5	4	Ms Lerato Mothae Mr Norman Baloyi Dr Xolani Ngobese
Technical Oversight and Regulatory Strategy Committee	6	9	Prof. Shabir Banoo Prof. Johanna Meyer Dr Ushma Mehta Prof Ames Dhai Mr Norman Baloyi Ms Mandisa Hela Prof. Patrick Demana Adv. Hasina Cassim Dr Mphane Molefe Mr Itani Mashau Dr Alfred Kgasi Ms Mandisa Skhosana Dr Zinhle Makatini Prof. Yahya Choonara Prof. Joyce Tsoka-Gwegweni
Risk Audit and Governance Committee	7	6	Prof. Craig Household Prof. Shabir Banoo Mr Norman Baloyi Ms Lerato Mothae Adv. Hasina Cassim Ms Yongama Pamla (External member) Mr Bruce Gordon (External member) Mr Edward Okaro Omolo (External member)
Human Resource and Remuneration Committee	6	5	Prof. Jeffrey Mphahlele Mr Itani Mashau Dr Edith Madela-Mntla Ms Mandisa Hela Dr Xolani Ngobese Dr Obakeng Kaole Ms Lucy Ditaba Maraka Mr Norman Baloyi

Remuneration of Board Members

Name	Remuneration	Other Allowance	Other Re-imbursements	Total
Prof. Helen Rees	R227 569	-	-	R227 569
Ms Mandisa Hela	R56 607	-	-	R56 607
Dr Obakeng Khaole	R79 184	-	-	R79 184
Mr Norman Baloyi	R172 500	-	-	R172 500
Prof. Shabir Banoo	-	-	-	-
Prof. Ames Dhai	R57 152	-	-	R57 152
Prof. Jeffrey Mphahlele	R12 462	-	-	R12 462
Dr Ushma Mehta	R37 294	-	-	R37 294
Prof. Craig Household	R10 731	-	-	R10 731
Ms Lerato Mothae	R95 059	-	-	R95 059
Mr Itani Mashau	R118 909	-	-	R118 909
Prof. Patrick Demana	R49 408	-	-	R49 408
Adv. Hasina Cassim	R192 521	-	-	R192 521
Dr Edith Madela-Mntla	R45 527	-	-	R45 527
Dr Thabelo Motshudi	R51 861	-	-	R51 861
Dr Mphane Molefe	-	-	-	-
Ms Mandisa Skhosana	R27 749	-	-	R27 749
Prof. Joyce Tsoka-Gwegweni	R25 348	-	-	R25 348
Dr Alfred Kgasi	R20 955	-	-	R20 955
Dr Zinhle Makatini	R26 830	-	-	R26 830
Dr Xolani Ngobese	R63 224	-	-	R63 224
Ms Lucy Ditaba Maraka	R34 630	-	-	R34 630
Prof. Yahya Choonara	R29 570	-	-	R29 570
Prof. Johanna Meyer	R21 836	-	-	R21 836

5. RISK MANAGEMENT

SAHPRA has approved the Risk Management Policy and Framework, to embed the risk management activities into the daily operations of the Authority. Periodically, risk assessments are conducted at strategic and operational levels of the Authority to identify and manage risks that may hamper the achievement of its strategic objectives.

The Risk Management Committee has been established to assist the Chief Executive Officer in reviewing the effectiveness of risk management and internal controls through the evaluation of mitigation plans implemented to address identified risks. The Committee meets quarterly and provides recommendations for improvement and facilitates reporting to RAG and the Board.

RAG reviews the risk management report with the objective to assess the risks identified, the effectiveness of mitigation plans and monitoring of the risk management

activities against the risk management implementation plan. RAG is responsible for providing assurance on the effectiveness of risk management and internal control to the Board. The Board is responsible for risk management but has delegated the role to the RAG.

There has been a slight improvement in the management of risks in that the entity has developed and implemented appropriate governance documents and structures, there is stable reporting on strategic risks and risk management at operational level is strengthening with management also taking accountability of risks within their areas. Assessment of the risk maturity will also determine the progress achieved in managing risks within the Authority.

6. INTERNAL CONTROL UNIT

To improve its internal control environment, SAHPRA has intensified the development and review of policies and standard operating procedures within all business units, with the Quality Management Unit driving the process.

Management is responsible for the development and maintenance of internal controls to fulfil its responsibility in providing reliable financial and operational information, while Internal Audit is responsible for the assurance of internal controls.

SAHPRA has outsourced the internal audit function to manage the capacity constraints while providing assurance on the risk and control environment. Internal audit is expected to conduct amongst others audits on operations, finance, ICT, performance information and any other special assignments and investigations on behalf of the Chief Executive Officer and RAG.

7. INTERNAL AUDIT AND AUDIT COMMITTEES

Name	Qualifications	Internal or External	If Internal, Position in the Public Entity	Date Appointed	Date Resigned	No. of Meetings Attended
Prof. Craig Household	MBChB MD	Internal	Board member	17 November 2017	N/A	5
Mr Norman Baloyi	MBA BSC Masters in Science	Internal	Board member	17 November 2017	N/A	6
Prof. Shabir Banoo	BPharm PhD	Internal	Board member	17 November 2017	N/A	4
Adv. Hasina Cassim	BPharm LLB	Internal	Board member	17 November 2017	N/A	5
Ms Lerato Mothae	BCompt CTA CA	Internal	Board member	24 April 2020	N/A	6
Mr Edward Okaro	BComm MBA CPA CA	External	N/A	2 May 2020	N/A	6
Ms Yongama Pamla	BComm (Accounting) Postgraduate Diploma in accounting (CTA) Postgraduate Diploma in Management (Financial Accounting) CA	External	N/A	1 April 2021	N/A	4
Mr Bruce Gordon	BCompt (Hons) CA	External	N/A	1 April 2021	N/A	4

The internal audit function was outsourced for the 2021/22 financial year with the annual coverage plan approved by RAG. The key activities for the function entailed:

- The development of a risk based three-year rolling Internal Audit Plan together with the annual Plan, where the plans also indicated the scope, cost and timelines of each planned audit assignment.
- Reporting on the performance and progress against the plan to allow effective monitoring and intervention, when necessary.
- Coordination with both internal and external providers of assurance to ensure proper coverage and minimal duplication of effort.

Based on the prescripts and best practice, the internal audit function assisted SAHPRA to accomplish its objectives by bringing a systematic and disciplined approach to evaluate and improve the effectiveness of risk management, internal control, and governance processes.

Listed below are the objectives of the internal audit function, which prompts the review of:

- Internal control processes across the business.
- The reliability and integrity of both financial and performance information.
- The information systems environment.
- Compliance with policies, guidelines, regulations and controls.
- The safeguarding of assets.

The internal audit service provider conducted a series of audit assignments approved by RAG in the annual audit plan which include but not limited to:

- Performance of audit assignments across the business.
- Verification of both internal and external audit action plans with the objective to provide assurance on the corrective actions implemented on previous findings.
- Assessed the portfolio of evidence for performance information which contributes to the agreed achievement of organisational targets.

RAG has an oversight responsibility, and its role entails provision of an independent assurance and assistance to the Board as the Accounting Authority on controls, governance, and risk management. RAG is not an executive committee and does not replace established management responsibilities, accountability, and delegations.

The internal audit function reports functionally to RAG and administratively to the Chief Executive Officer, to ensure independence of the function as outlined in the Internal Audit Charter. In turn, RAG approves all decisions regarding the performance and monitoring of the internal audit activities.

The internal audit function assists the RAG and the Accounting Authority to maintain effective controls through assessment and evaluation of internal controls, thereafter, develop recommendations for enhancement or improvement of the inefficiencies identified.

During the 2021/22 financial year, RAG conducted the following activities but not limited to:

- Reviewed effectiveness and approval of internal audit activities, internal controls, risk management, fraud prevention and compliance management.
- Reviewed reporting on financial and performance information to the SAHPRA Board.

8. 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 (1999, as amended), and National Treasury Regulations published under the PFMA (1999, as amended) 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 Board 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.

A PFMA compliance checklist is used to monitor compliance with the PFMA (1999, as amended), and reporting is done on a quarterly basis to National Treasury and the Minister of Health. The checklist is part of management's reporting responsibilities to the Board through its sub-committees, especially RAG and finance committees.

9. FRAUD AND CORRUPTION

SAHPRA continues to fight fraud and corruption through the implementation of its Fraud Prevention Policy, Strategy and Plan. The Fraud Prevention Strategy and Plan was approved in the 2021/22 financial year and resulted in the development of the fraud risk register together with the facilitation of several risk awareness sessions. The fraud risk register identified areas of concern which required strengthening and monitoring of controls. This also entailed the development and communication of several policies and standard operating procedures within SAHPRA.

In the previous years, SAHPRA depended on the National Anti-Fraud Hotline and NDoH Hotline for the reporting of its anonymous calls. However, in September 2021, the Authority launched its own Whistleblowing Hotline with an independent service provider, which can now take full responsibility of all calls reporting fraud, corruption, and non-compliances.

Since the launch of the hotline, there has been several cases reported ranging from health products non-compliances and allegations of fraud and corruption. These cases are then referred to the Chief Executive Officer, RAG and Board chairpersons for further action to be instituted such as investigations or reviews.

10. MINIMISING CONFLICT OF INTEREST

The Board has approved a Management of Conflict of Interest Policy and has procedures in place to manage issues of conflict of interest (perceived, potential or actual) to minimise if not prevent them. Board members, the SAHPRA Executive Committee 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 information is captured as standing agenda items 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 form. This approach is also extended to the external evaluators and the Chief Executive Officer's committee's members.

11. CODE OF CONDUCT

SAHPRA is committed to an exemplary standard of business ethics and transparency in all its dealings with stakeholders. 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.

12. HEALTH SAFETY AND ENVIRONMENTAL ISSUES

During this reporting period, SAHPRA continued to implement planned Occupational Health and Safety (OHS) management activities. These activities entailed the effective identification and mitigation of safety, health and environment risks through ensuring ongoing safety, health and environment compliance and training. OHS monthly meetings were held, and all compliance measures are up to date. SAHPRA continues to demonstrate commitment to health and safety of its employees through its occupational health and safety structures. This is to ensure that it creates a conducive environment for all staff members.

SAHPRA regards a proper working environment as key to service delivery. It, therefore, has an approved OHS Policy that guides management on health and safety matters within the organisation. SAHPRA's OHS Policy was approved by the Chief Executive Officer in June 2021 and the amended OHS Policy was approved in October 2021.

Section 8(1) of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993) as amended requires the Accounting Officer to provide as reasonably practicable, working environment that is safe and without risk to the health of its employees. SAHPRA established the OHS Committee which consists of OHS representatives who are assigned with duties of responsibility as outlined in Section 17 and 18 of the OHS Act (1993). SAHPRA complied with the provisions of the Occupational Health and Safety Act (1993) to ensure health and safety in the workplace.

SAHPRA has appointed an OHS Committee, and Safety, Health and Environment representatives from regional offices are part of the OHS Committee. The Committee is functional, and meetings are held on a quarterly

basis. OHS representatives have also been appointed to identify hazards within SAHPRA's offices.

The new Safety, Health and Environment representatives from the Cape Town Regional Office have been appointed. SAHPRA's OHS Committee comprises of employees, management, and unions. Its function is to ensure continuous improvement to health and safety systems within the SAHPRA. The Cape Town Regional Office Safety, Health and Environment representatives have undergone accredited training on evacuation and management procedure, to ensure the team is capacitated to assist in responding to emergencies in order prevent or mitigate adverse consequences.

SAHPRA also has a COVID-19 Steering Committee. The Committee is functional and meetings are held on a bi-weekly basis. The committee plays a key role in ensuring that employees comply with COVID-19 protocols aimed at protecting them against the virus.

An Emergency Plan for SAHPRA's Head Office and Cape Town office was approved as well as SAHPRA's Risk Assessment Plan.

13. COMPANY/BOARD SECRETARY

SAHPRA is a Schedule 3A public entity with an appointed Board Secretary. With effect from March 2022, Ms Letjubana Chokoe was appointed as the acting Board Secretary, following the departure of Advocate Peter Nthotso. She provides advice and supports the Board and is vital to its efficient functioning. As such, the position plays a central role in the governance and administration of the organisation's affairs. In the discharge of her duties, she makes members aware of any laws and regulations relevant to or affecting the Authority.

14. SOCIAL RESPONSIBILITY

For this financial period, SAHPRA was not involved in any Corporate Social Responsibility initiatives. However, SAHPRA is making in-roads for the next financial year.

15. AUDIT COMMITTEE REPORT

Risk, Audit and Governance (RAG) Committee Report

Introduction

The RAG Committee is pleased to present its report for the financial year ended 31 March 2022.

The RAG has operated within the approved Committee Charter and complied with all governing legislation in executing its responsibilities in terms of the PFMA and Treasury Regulations and requirements of King IV.

Composition

The Committee comprises of five Independent Board Members and three Independent External Members. The CEO is an *ex officio* member of the Committee.

The Chief Operating Officer, Chief Financial Officer, Chief Risk Officer, Executive HR, Audit & Manager: Risk & Internal Audit, Manager: Strategic Business Planning, Monitoring and Reporting are standing invitees to the RAG meetings. Representatives of Nexia SAB&T (Internal Auditors) and the Auditor General (AGSA) are invited to the RAG meetings.

The table below discloses the relevant information on the RAG members:

Name	Qualifications	Board or External Member	No. of meetings attended
Professor S. Banoo	B.Pharm PhD	Board Member	3 out of 5*
Professor C. Household	MBChB MD	Board Member	5 out of 5*
Bruce Gordon	B Compt (Hons) (External Member) CA(SA)	External Member	5 out of 7
Adv. H. Cassim	B.Pharm LLB	Board Member	5 out of 7

Name	Qualifications	Board or External Member	No. of meetings attended
Mr B Gordon	B Compt (Hons) CA(SA)	External Member	5 out of 7
Ms Y Pamla	B.Comm (Accounting) Post Diploma in Management Postgraduate Diploma in accounting CA(SA)	External Member	5 out of 7
Mr N Baloyi	MBA BSC Masters in Science in electronics and electrical engineering	Board Member	6 out of 7
Mr. E. Okaro	B.Comm MBA CPA CA(SA)	External Member	7 out of 7
Ms. L. Mothae	CA (SA)	Board Member	7 out of 7

*Term ended on 30 September 2021

Key Committee Activities

Statutory Duties

The roles and responsibilities of the Committee as per Section 51(1) (a)(ii) and Section 76(4)d of the Public Finance Management Act ("PFMA"), Treasury Regulations Section 27 (1) and the requirements of the KING 1V Code of Corporate Governance include:

- To assist the Board in its evaluation of the adequacy and effectiveness of the internal control systems, governance, accounting practices, information systems, risk management and auditing processes applied within the SAHPRA's day to day management of its business;
- To facilitate and promote communication between the Board, Management, the External Auditors and Internal Auditors on matters which fall within the responsibilities of the Committee;
- To ensure the risk and compliance areas of SAHPRA operations are covered in the scope of Internal and AGSA audits;
- To ensure the accounting and auditing concerns identified from the Internal and AGSA audits conducted during the period under review are addressed;
- To ensure SAHPRA compliance with legal and regulatory provisions, the Medicines Act and the PFMA as well as the Treasury Regulations; and
- To ensure the independence and objectivity of the Internal and External Auditors.

Internal Controls

The RAG Committee undertook the following primary activities in assessing the effectiveness of the internal controls:

- Reviewed Risk and Compliance Management Reports.
- Reviewed SCM and ICT reports.
- Reviewed the Audit Action Plans.
- Reviewed the quarterly legal reports.
- Reviewed the framework for establishing effectiveness of policies and procedures relevant to this Committee.
- Established a framework for determining the Authority's compliance with significant legal and regulatory provisions.
- Reviewed the controls over significant financial and operational risks.
- Tabled and discussed Internal Audit Reports at each

meeting.

- Reviewed the annual report and financial statements to ensure that they present a balanced and understandable assessment of the position, performance, and prospects of the Authority.

The key outcomes following the above assessment procedures include:

- The internal financial controls and systems, although enhanced from the prior years, still require improvement.

Whistle-Blowing

The Committee considered complaints received relating to SAHPRA via the whistleblowing hotline.

External Auditors

The Committee has noted the improvement in the audit outcome as issued by the Auditor General, with the resultant unqualified audit opinion.

The RAG Committee independently engaged with the AGSA, and is satisfied that it has adequately discharged its legal and regulatory responsibilities.

The Committee has reviewed and accepted the AGSA's final Management Report and Audit Opinion relating the Annual Financial Statements, Audit of Performance Information and Compliance with legislation as well as the audit findings issued by the Auditor General which are to be addressed in accordance with the mitigation action plans as agreed between SAHPRA and the AGSA.

Evaluation of Annual Financial Statements

The Committee has:

- Reviewed the appropriateness of accounting policies;
- Reviewed the appropriateness of assumptions made by Management in preparing the annual financial statements;
- Reviewed the significant accounting and reporting issues, and understood their impact on the annual financial statements;
- Reviewed the annual financial statements and considered that they are complete, consistent with prescribed accounting practices and information known by the Committee; and
- Obtained assurance from Management with respect to the completeness and accuracy of the annual financial statements

Governance of Risk

The RAG Committee has continued to fulfill its oversight role regarding:

- Enterprise risk management;
- Compliance Management;
- Anti-Corruption and Fraud;
- Business Continuity Management; and
- Combined Assurance.

Internal Audit

The Committee discharged its responsibility to approve the annual and three-year rolling plan and consider Internal Audits quarterly reports and the mitigation action plans as agreed between SAHPRA and Internal Audit.

The Committee further ensured that Internal Audit remained independent, objective and had the necessary resources, standing and authority within SAHPRA to enable it to discharge its duties.

Conclusion

The RAG Committee recommended the approval of the audited March 2022 annual financial statements and the audit opinion thereon at its meeting held on 25 July 2022 and these annual financial statements and audit opinion were duly approved by the Board on 29 July 2022 to be included in the SAHPRA Annual Report for the financial year ended March 2022.

I thank the Board, Independent External Members and Management for their efforts which contributed to the continued improvement in the external audit results.

Ms Lerato Mothae
Chairperson: Risk, Audit and Governance Committee
Date: 31 August 2022

16. BROAD-BASED BLACK ECONOMIC EMPOWERMENT COMPLIANCE PERFORMANCE INFORMATION

The following table has been completed in accordance with the compliance to the Broad-Based Black Economic Empowerment (B-BBEE) requirements of the B-BBEE Act (Act No. 53 of 2003) and as determined by the Department of Trade and Industry.

Has the Department / Public Entity applied any relevant Code of Good Practice (B-BBEE Certificate Levels 1 – 8) with regards to the following:		
Criteria	**Response Yes / No**	**Discussion** (***include a discussion on your response and indicate what measures have been taken to comply***)
Determining qualification criteria for the issuing of licences, concessions or other authorisations in respect of economic activity in terms of any law?	N/A	
Developing and implementing a preferential procurement policy?	Yes	Policy approved and applied
Determining qualification criteria for the sale of state-owned enterprises?	N/A	
Developing criteria for entering into partnerships with the private sector?	N/A	
Determining criteria for the awarding of incentives, grants and investment schemes in support of Broad Based Black Economic Empowerment?	N/A	

PART D

HUMAN RESOURCE MANAGEMENT

1. INTRODUCTION

The process of satisfying the achievement of SAHPRA's objectives requires that the Authority be capacitated with the required resources. The organisation was able to recruit 96% of the prioritised, budgeted vacant positions. During the 2021/22 financial year, SAHPRA was able to recruit externally while giving opportunities to internal employees. It is important that the organisation ensures that employees grow within the Authority and that key talent is retained.

SAHPRA was able to transfer staff members from NDoH to the Authority according to the Labour Relations Act (1995, Section 197). They were discontinued on the Public Service PERSAL Payroll System and thereafter moved onto the SAHPRA SAGE P300 Payroll System. This was not an easy exercise especially as NDoH were moving offices at the same time.

The backlog on the Performance Management and Development System (PMDS) since 2018 was addressed. Moderation committees were formed to address all the outstanding matters and the incentives to qualifying employees were paid out.

SAHPRA implements its own Performance Management System, through the Individual Development Plan for employees to conduct performance contracting. In September 2021, the mid-year reviews were conducted. It will be the first time that employees are performance appraised with the new Performance Management System for the end of the financial year. All employees have been trained on the new Performance Management System and continue to be guided in the performance management system process.

Employees have been oriented on the Rewards and Recognition Policy especially on the process of nominating their colleagues for recognition as best performing employees in the categories that are associated with living the Authority's values.

The Human Resource Strategy was implemented to create employee relations, which supports the organisation in terms of its transformation path. The aim of the strategy is to build capacity for the effective management and retention of employees with core, scarce and critical skills.

The Talent Management Policy is enroute for approval. This policy will enable and ensure operational continuity and the sustainability of the Authority as well as having staff members with proper skills to achieve SAHPRA's objectives.

Employee engagements which are known as the Human Resource Indaba sessions were held. The aim of the engagements is to unify SAHPRA's employees to ensure a shared vision and an increased sense of belonging. During the financial year, four Human Resource Indaba sessions were held. The change agents, who are members of staff representing all business units, participated in the change management process to help plan and implement change at the floor level.

During the financial year, the Authority was able to acquire services for Leadership Coaching. Sixteen managers and executives are participating in the Leadership Coaching Programme. This programme will result in the advancement of leadership capacity through the development of skills and competencies.

SAHPRA commenced with the process of developing its Salary/Pay Scale, which is intended to be introduced in the new financial year. This will result in SAHPRA discontinuing its use of the Department of Public Service and Administration's Public Service remuneration system.

The Authority has introduced an employee wellness program which is administered by the ICAS. Such services are critical, especially during the current times of the COVID-19 pandemic.

Improvements are being made to the human resource systems. Employees are now able to apply for leave through the Employee Self Service System and there are plans to improve and automate additional functions including the Performance Management System.

2. HUMAN RESOURCE OVERSIGHT STATISTICS

2.1 Personnel Related Expenditure

Personnel Cost by Programme

Programme	Total Expenditure for the Entity (R'000)	Personnel Expenditure (R'000)	Personnel Expenditure as a % of Total Expenditure (R'000)	No. of Employees	Average Personnel Cost per Employee (R'000)
Programme 1	115 586	48 773	42%	63	774
Programme 2	73 660	21 341	29%	71	300
Programme 3	35 370	31 155	88%	36	865
Programme 4	80 402	50 594	63%	67	755
Programme 5	34 290	30 086	88%	37	813
TOTAL	**339 307**	**181 949**	**54%**	**274**	

Personnel Cost by Salary Band

Level	Personnel Expenditure (R'000)	% of Personnel Expenditure to Total Personnel Cost (R'000)	No. of Employees	Average Personnel Cost per Employee (R'000)
Top management	10 755	12%	5	4 327
Senior management	21 632	12%	18	6 064
Professional qualified	109 160	60%	136	802
Skilled	13 644	9%	36	379
Semi-skilled	26 750	15%	79	338
Unskilled	0	0%	0	0
TOTAL	**181 949**		**274**	

The professionally qualified level is where SAHPRA's technical skills are located. The technical skills are the core business of SAHPRA, thus the highest number. The senior managers are inclusive of core business senior managers and support units' business heads.

Performance Rewards

Level	Performance Rewards	Personnel Expenditure	% of Performance Rewards to Total Personnel Cost
		(R'000)	(R'000)
Top management	-	48 772	-
Senior management	42 061	21 341	0,2%
Professional qualified	1 432 390	31 155	4.6%
Skilled	165 495	50 594	0.33%
Semi-skilled	229 183	30 086	0.76%
TOTAL	**1 869 129**	**181 949**	

The majority of top management were recruited during the 2021/22 financial year, thus did not qualify for performance rewards. The highest percentage was awarded to the core business as a proportion of the headcount.

Training Costs

Programme	Personnel Expenditure (R'000)	Training Expenditure (R'000)	Training Expenditure as a % of Personnel Cost (R'000)	No. of Employees Trained	Average Training Cost per Employee
Programme 1 to 5	181 949	863	0.5%	274	3 153
TOTAL	**181 949**	**863**	**0.5%**	**274**	**3 153**

Virtual training proved to be more cost effective, and it enabled more employees to be trained at a particular time. The group trainings, where employees were trained on a particular competency, for example, computer skills were effective in ensuring employees support each other on their learning journey while their understanding of each other's roles and responsibilities were also enhanced.

The Workplace Skills Plan guided the training interventions to a greater extent, complementing the technical training interventions.

Level	2021/2022 No. of Employees	2021/2022 Approved Posts	2021/2022 No. of Employees	2021/20212 Vacancies	% of Vacancies
Top management	5	0	5	0	0
Senior management	14	1	13	2	1%
Professional qualified	122	8	114	8	3%
Skilled	59	3	61	0	0
Semi-skilled	70	8	78	0	0
Community service	16	0	3	0	0
TOTAL	**277**	**23**	**274**	**10**	

The recruitment of technical skills remains a challenge as it is a lengthy and costly process (some positions had to be re-advertised) as the required skill is more expensive than what the organisation can afford.

Employment Changes

Salary Band	Employment at the Beginning of Period	Appointments	Terminations	Employment at End of the Period
Top management	5	0	0	5
Senior management	14	1	2	13
Professional qualified	122	23	22	114
Skilled	59	2	0	61
Semi-skilled	70	13	5	78
Unskilled	0	0	0	0
Community service	16	0	13	3
TOTAL	**277**	**39**	**42**	**274**

Staff turnover was more prevalent in the technical skills areas and SAHPRA's recruitment efforts focuses on this area. In future, the focus will be on ensuring the retention of technical skills as it is both expensive and time consuming to source. High employment changes in the professional levels are an operational risk to SAHPRA's deliverables, thus the need to ensure that this area is stabilised. Overall, SAHPRA's headcount increased from the previous financial year considering the exclusion of community service recruits during the 2021/22 financial year.

Reasons for Staff Leaving

Reason	Number	% of Total No. of Staff Leaving
Death	1	2,38%
Resignation	17	40,48%
Dismissal	2	4,76%
Retirement	3	7,14%
Ill health	0	0,00%
Expiry of contract	18	42,86%
Other	1	2,38%
TOTAL	**42**	

The exit interviews conducted suggests remuneration and benefits as an attraction to the job market for the technical skills. At least 80% of the terminations were replaced or are currently being recruited. The replacements excluded the community service recruits as SAHPRA did not have a new intake during the 2021/22 financial year.

Labour Relations: Misconduct and Disciplinary Action

Nature of Disciplinary Action	Number
Verbal warning	5
Written warning	4
Final written warning	
Dismissal	2

Employment Equity Status

The following tables present the employment equity numeric data for both male and female employees.

The employment equity target was not set for the 2021/22 financial year as the organisation will implement the three-year Employment Equity Plan from the 2022/23 financial year. The equity targets will focus on areas where representation of a certain race or gender is minimal across all the employment levels, especially in core business. There were no declared disabilities during the period under review.

Levels	MALE							
	African		Coloured		Indian		White	
	Current	Target	Current	Target	Current	Target	Current	Target
Top management	1	-	-	-	-	-	1	-
Senior management	3	-	1	-	1	-	-	-
Professional qualified	44	-	2	-	-	-	3	-
Skilled	3	-	-	-	-	-	-	-
Semi-skilled	33	-	3	-	-	-	1	-
Unskilled	0	-	-	-	-	-	-	-
Community service	1	-	-	-	-	-	-	-
TOTAL	**85**	**0**	**6**	**0**	**1**	**0**	**5**	**0**

Levels	FEMALE							
	African		Coloured		Indian		White	
	Current	Target	Current	Target	Current	Target	Current	Target
Top management	2	-	-	-	-	-	1	-
Senior management	6	-	-	-	1	-	1	-
Professional qualified	68	-	8	-	13	-	4	-
Skilled	17	-	3	-	2	-	1	-
Semi-skilled	37	-	4	-	2	-	5	-
Unskilled	0	-	-	-	-	-	-	-
Community service	2	-	-	-	-	-	-	-
Total	**132**	**0**	**15**	**0**	**18**	**0**	**12**	**0**

PART E

FINANCIAL INFORMATION

Index

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

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Accounting Authority's Responsibilities and Approval

The Accounting Authority is required by the Public Finance Management Act (Act 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 was 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 judgments and estimates.

The Accounting Authority acknowledge 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 2023 and, in the light of this review and the current financial position, they are satisfied that the entity has and have access to adequate resources to continue in operational existence for the foreseeable future.

The entity is partially dependent on the National Department of Health for continued funding of operations. The annual financial statements are prepared on the basis that the entity is a going concern and that the entity have neither the intention nor the need to liquidate or curtail materially the scale of the entity.

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 page 92 - 96.

The annual financial statements set out on page 97 to 151, which have been prepared on the going concern basis, were approved by the accounting authority on 29 July 2022 and were signed on its behalf by:

Dr. B. Semete-Makokotlela
Chief Executive Officer

Prof H V Rees
Chairperson

Report of the Auditor-General to Parliament on South African Health Products Regulatory Authority

Report on the audit of the financial statements

Opinion

1. I have audited the financial statements of the South Africa Health Products Regulatory Authority (SAHPRA) set out on pages 97 to 151, which comprise statement of financial position as at 31 March 2022, statement of financial performance, statement of changes in net assets and cash flow statement and statement of comparison of budget information with actual information for the year then ended, as well as 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 SAHPRA as at 31 March 2022, and its financial performance and cash flows for the year then ended in accordance with the Standards of Generally Recognised Accounting Practice (GRAP) and the requirements of the Public Finance Management Act 1 of 1999 (PFMA).

Basis for opinion

3. 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 my report.

4. I am independent of the entity in accordance with the International Ethics Standards Board for Accountants' *International code of ethics for professional accountants (including International Independence Standards)* (IESBA code) as well as other 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 code.

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

Emphasis of matters

6. I draw attention to the matters below. My opinion is not modified in respect of these matters.

Restatement of corresponding figures

7. As disclosed in note 31 to the financial statements, the corresponding figures for 31 March 2021 were restated as a result of an error in the financial statements of the entity at, and for the year ended, 31 March 2022.

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 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 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 programme 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 entity's approved performance planning documents. 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 do not extend to any disclosures or assertions relating to the extent of achievements in the current year or 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 programme presented in the entity's annual performance report for the year ended 31 March 2022.

Programmes objectives	Pages in the annual performance report
Programme 4: clinical and pharmaceutical evaluation	47 - 52

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. I did not identify any material findings on the usefulness and reliability of the reported performance information for this programme, programme 4 – clinical and pharmaceutical evaluation

Other matters

17. I draw attention to the matters below.

Achievement of planned targets

18. Refer to the annual performance report on pages 26 - 59 for information on the achievement of planned targets for the year and management's explanations provided for the under and over achievement of targets.

Adjustment of material misstatements

19. I identified material misstatements in the annual performance report submitted for auditing. These material misstatements were in the reported performance information of programme 4: clinical and pharmaceutical evaluation. As management subsequently corrected the misstatements, I did not raise any material findings on the usefulness and reliability of the reported performance information.

Report on the audit of compliance with legislation

Introduction and scope

20. 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.

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

Annual financial statements, performance and annual reports

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

23. Material misstatements of expenditure and disclosure items identified by the auditors in the submitted financial statement were corrected and the supporting records were provided subsequently, resulting in the financial statements receiving an unqualified audit opinion.

Expenditure management

24. Effective and appropriate steps were not taken to prevent irregular expenditure amounting to R3 009 867 as disclosed in note 37 to the annual financial statements, as required by section 51(1)(b)(ii) of the PFMA. The majority of the irregular expenditure was caused by contract variations that were not approved by the relevant authority.

Revenue management

25. Effective and appropriate steps were not taken to collect all revenue due, as required by section 51(1)(b)(i) of the PFMA.

Other information

26. 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 programme presented in the annual performance report that have been specifically reported in this auditor's report.

27. 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 on it.

28. 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.

29. The following paragraphs will be included in the auditor's report to highlight to the users whether any inconsistencies in the other information exist.

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

31. 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 findings on compliance with legislation included in this report.

32. The entity did not implement proper record keeping to ensuring complete, relevant and accurate information is accessible and available to support financial statements.

33. Management did not ensure appropriate review and monitoring of compliance with revenue and debt management policies, which led to ineffective collection of revenue earned.

34. Management did not ensure appropriate review and monitoring of compliance with procurement laws and regulations, which resulted to re-occurrence of irregular expenditure.

Auditor-General

Pretoria

31 July 2022

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 programme and on the entity's compliance with respect to the selected subject matters.

Financial statements

35. 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 accounting authority's use of the going concern basis of accounting in the preparation of the financial statements. I also conclude, based on the audit evidence obtained, whether a material uncertainty exists relating to events or conditions that may cast significant doubt on the ability of 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

36. 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.

37. I also provide the accounting authority with a statement that I have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on my independence and, where applicable, actions taken to eliminate threats or safeguards applied.

Statement of Financial Position as at 31 March 2022

	Note(s)	2022	2021 Restated*
Assets			
Current Assets			
Receivables from exchange transactions	3	5 738 767	10 436 964
Receivables from non-exchange transactions	4	9 452 146	34 674
Prepayments		5 141 662	3 110 306
Cash and cash equivalents	5	244 373 304	150 764 296
		264 705 879	**164 346 240**
Non-Current Assets			
Property, plant and equipment	6	26 620 331	29 824 703
Intangible assets	7	2 818 059	1 872 911
		29 438 390	**31 697 614**
Total Assets		**294 144 269**	**196 043 854**
Liabilities			
Current Liabilities			
Operating lease liability	8	3 259 196	1 600 515
Payables from exchange transactions	9	15 656 404	32 065 786
Unspent conditional grants	10	3 383 259	-
Provisions	11	14 197 149	14 188 396
Income received in advance	12	191 526 908	97 761 244
Deferred income: Backlog reduction project	13	12 476 800	25 020 697
		240 499 716	**170 636 638**
Total Liabilities		**240 499 716**	**170 636 638**
Net Assets		**53 644 553**	**25 407 216**
Accumulated surplus		**53 644 553**	**25 407 216**

Statement of Financial Performance for the year ended 31 March 2022

	Note(s)	2022	2021 Restated*
Revenue			
Revenue from exchange transactions			
Fee income	14	181 794 887	107 228 542
Sundry income	15	217 309	2 325 801
Interest received	16	9 557 126	4 006 563
Gain on foreign exchange		127 249	171 284
Total revenue from exchange transactions		**191 696 571**	**113 732 190**
Revenue from non-exchange transactions			
Transfer revenue			
Transfer payment received	17	146 287 000	156 572 000
Services in kind: Backlog reduction project	18	15 348 507	20 763 998
Grant realised	19	5 389 733	-
Grant income	20	8 822 956	2 104 925
Transfer of assets received from National Department of Health		-	767 922
Total revenue from non-exchange transactions		**175 848 196**	**180 208 845**
Total revenue		**367 544 767**	**293 941 035**
Expenditure			
Employee related costs	21	(181 949 226)	(147 089 885)
Backlog reduction project	22	(52 275 755)	(67 516 871)
Depreciation	23	(7 016 149)	(5 558 241)
Impairment of assets		(404 044)	(624 618)
Lease rentals on operating lease		(19 518 295)	(15 502 556)
Bad debts written off		(6 179 867)	(2 795 929)
Laboratory services	24	(20 797 520)	(19 922 033)
Loss on disposal of assets		(412 627)	(1 228 163)
Operating Expenses	25	(50 753 947)	(53 359 607)
Total expenditure		**(339 307 430)**	**(313 597 903)**
Surplus (deficit) for the year		**28 237 337**	**(19 656 868)**

Statement of Changes in Net Assets for the year ended 31 March 2022

	Note(s)	Accumulated surplus / deficit	Total net assets
Balance at 01 April 2020		**45 064 084**	**45 064 084**
Deficit for the period		(19 656 868)	(19 656 868)
Opening balance as previously reported		**20 306 128**	**20 306 128**
Adjustments:			
Correction of errors	31	5 101 088	5 101 088
Restated* Balance at 01 April 2021		**25 407 216**	**25 407 216**
Surplus for the period		28 237 337	28 237 337
Balance at 31 March 2022		**53 644 553**	**53 644 553**

Cash Flow Statement for the year ended 31 March 2022

	Note(s)	2022	2021 Restated*
Cash flows from operating activities			
Receipts			
Fee and deferred income		261 125 028	146 895 718
Government grants		146 287 000	156 572 000
Interest income		9 474 299	3 962 298
Grant received		8 772 992	16 704 382
		425 659 319	**324 134 398**
Payments			
Employee costs		(185 008 774)	(171 886 679)
Suppliers		(142 882 457)	(102 364 911)
		(327 891 231)	**(274 251 590)**
Net cash flows from operating activities	26	**97 768 088**	**49 882 808**
Cash flows from investing activities			
Purchase of property, plant and equipment		(3 307 623)	(19 328 064)
Proceeds from sale of property, plant and equipment		201 061	19 130
Purchase of other intangible assets		(1 052 518)	(1 767 133)
Net cash flows from investing activities		**(4 159 080)**	**(21 076 067)**
Cash flows from financing activities			
Net increase in cash and cash equivalents		**93 609 008**	**28 806 741**
Cash and cash equivalents at the beginning of the year		150 764 296	121 957 555
Cash and cash equivalents at the end of the year	5	**244 373 304**	**150 764 296**

Statement of Comparison of Budget and Actual Amounts for the year ended 31 March 2022

Budget on Cash Basis	Approved budget	Adjustments	Final budget	Actual amounts on comparable basis	Difference between final budget and actual	Reference
Statement of Financial Performance						
Revenue						
Revenue from exchange transactions						
Fee income	162 263 982	-	**162 263 982**	169 449 590	**7 185 608**	39.1
Backlog fee income	45 000 000	-	**45 000 000**	12 345 297	**(32 654 703)**	39.1
Sundry income	-	-	**-**	217 309	**217 309**	39.1
Interest received	3 999 014	-	**3 999 014**	9 557 126	**5 558 112**	39.2
Total revenue from exchange transactions	**211 262 996**	**-**	**211 262 996**	**191 569 322**	**(19 693 674)**	
Revenue from non-exchange transactions						
Transfer revenue						
Government grants	146 287 000	-	**146 287 000**	146 287 000	**-**	
Services in kind	-	-	**-**	15 348 507	**15 348 507**	39.8
Grants realised	-	-	**-**	5 389 733	**5 389 733**	39.8
Grant received	-	-	**-**	8 822 956	**8 822 956**	39.8
Total revenue from non-exchange transactions	**146 287 000**	**-**	**146 287 000**	**175 848 196**	**29 561 196**	
Total revenue	**357 549 996**	**-**	**357 549 996**	**367 417 518**	**9 867 522**	
Expenditure						
Employee related costs	(187 574 141)	-	**(187 574 141)**	(181 949 226)	**5 624 915**	39.3
Backlog reduction project	(47 000 000)	-	**(47 000 000)**	(52 275 755)	**(5 275 755)**	39.6
Depreciation	-		**-**	(7 016 149)	**(7 016 149)**	39.4
Impairment of assets	-		**-**	(404 044)	**(404 044)**	39.4
Lease rentals on operating lease	(22 730 570)		**(22 730 570)**	(19 518 295)	**3 212 275**	39.7
Bad debts written off	-		**-**	(6 179 867)	**(6 179 867)**	39.9
Contracted services	(20 800 000)	-	**(20 800 000)**	(20 797 520)	**2 480**	
Operating expenses	(79 445 285)	-	**(79 445 285)**	(50 753 947)	**28 691 338**	39.5
Total expenditure	**(357 549 996)**	**-**	**(357 549 996)**	**(338 894 803)**	**18 655 193**	
Operating surplus	**-**	**-**	**-**	**28 522 715**	**28 522 715**	
Loss on disposal of assets and liabilities	-	-	**-**	(412 627)	**(412 627)**	39.4
Gain on foreign exchange	-	-	**-**	127 249	**127 249**	
	-	**-**	**-**	**(285 378)**	**(285 378)**	
Surplus before taxation	**-**	**-**	**-**	**28 237 337**	**28 237 337**	
Actual Amount on Comparable Basis as Presented in the Budget and Actual Comparative Statement	**-**	**-**	**-**	**28 237 337**	**28 237 337**	

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 1 of 1999) and the 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 convention as the basis of measurement, unless specified otherwise.

In the absence of an issued and effective Standard of GRAP, accounting policies for material transactions, events or conditions were developed in accordance with paragraphs 8, 10 and 11 of GRAP 3 as read with Directive 5 issued by the Accounting Standards Board..

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

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

When the presentation or classification of items in the annual financial statements is amended, prior period comparative amounts are restated if material. The nature and reason for the reclassification is disclosed. Where the accounting errors have been identified in the current year, the correction is made retrospectively as far as it is practical, and prior year comparatives are restated accordingly. Where there has been a change in accounting policy in the current year, the adjustment is made retrospectively as far as practicable, and the prior year comparatives are restated accordingly.

These accounting policies are consistent with the previous period.

1.1 Presentation currency

These annual financial statements are presented in South African Rand, which is the functional currency of the entity.

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

In preparing the annual financial statements, management is required to make estimates and assumptions that affect the amounts represented in the annual financial statements and related disclosures. Use of available information and the application of judgement is inherent in the formation of estimates. Actual results in the future could differ from these estimates which may be material to 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.

Other significant judgements, sources of estimation uncertainty and/or relating information, have been disclosed in the relating notes. In applying the entity's accounting policies estimates shall be made on items such as the following:

Trade receivables

The entity assesses its trade receivables for impairment at the end of each reporting period. In determining whether an impairment loss should be recorded in surplus or deficit, the entity makes judgements as to whether there is observable data indicating a measurable decrease in the estimated future cash flows from a financial asset.

The impairment for trade receivables is calculated on a portfolio basis, based on historical loss ratios, adjusted for national and industry-specific economic conditions and other indicators present at the reporting date that correlate with defaults on the portfolio. These annual loss ratios are applied to loan balances in the portfolio and scaled to the estimated loss emergence period.

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 6 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.

1.4 Significant judgements and sources of estimation uncertainty (continued)

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

Additional disclosure of these estimates of provisions are included in note 11 - 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.

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

Contingencies

Management uses its best estimate of the value of the contingencies to be disclosed based on historical experience and assumptions per case.

1.5 Property, plant and equipment

Property, plant and equipment are tangible non-current assets (including infrastructure 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.

1.5 Property, plant and equipment (continued)

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 residual value.

Recognition of costs in the carrying amount of an item of property, plant and equipment ceases when the item is in the location and condition necessary for it to be capable of operating in the manner intended by management.

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 fixtures	Straight-line	10-14 years
Motor vehicles	Straight-line	5 years
Computer equipment	Straight-line	5-7 years
Leasehold improvements	Straight-line	5-10 years
Other fixed assets	Straight-line	10-16 years

The depreciation method used reflects the pattern in which the asset's future economic benefits or service potential are expected to be consumed by the entity. The depreciation method applied to an asset is reviewed at least at each reporting date and, if there has been a significant change in the expected pattern of consumption of the future economic benefits or service potential embodied in the asset, the method is changed to reflect the changed pattern. Such a change is accounted for as a change in an accounting estimate.

The entity assesses at each reporting date whether there is any indication that the entity expectations about the residual value and the useful life of an asset have changed since the preceding reporting date. If any such indication exists, the entity revises the expected useful life and/or residual value accordingly. The change is accounted for as a change in an accounting estimate.

The depreciation charge for each period is recognised in surplus or deficit unless it is included in the carrying amount of another asset.

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.

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

Internally generated brands, mastheads, publishing titles, customer lists and items similar in substance are not recognised as intangible assets.

1.6 Intangible assets (continued)

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
Acquired software	Straight-line	7 years

1.7 Financial instruments

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or a residual interest of another entity.

The amortised cost of a financial asset or financial liability is the amount at which the financial asset or financial liability is measured at initial recognition minus principal repayments, plus or minus the cumulative amortisation using the effective interest method of any difference between that initial amount and the maturity amount, and minus any reduction (directly or through the use of an allowance account) for impairment or uncollectibility.

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation.

Derecognition is the removal of a previously recognised financial asset or financial liability from an entity's statement of financial position.

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.

A financial asset is:

- cash;
- a residual interest of another entity; or
- a contractual right to:
  - receive cash or another financial asset from another entity; or
  - exchange financial assets or financial liabilities with another entity under conditions that are potentially favourable to the entity.

A financial liability is any liability that is a contractual obligation to:

- deliver cash or another financial asset to another entity; or
- exchange financial assets or financial liabilities under conditions that are potentially unfavourable to the entity.

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

Liquidity risk is the risk encountered by an entity in the event of difficulty in meeting obligations associated with financial liabilities that are settled by delivering cash or another financial asset.

1.7 Financial instruments (continued)

A financial asset is past due when a counterparty has failed to make a payment when contractually due.

Initial recognition

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

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

Initial measurement of financial assets and financial liabilities

When a financial instrument is recognised, SAHPRA 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.

The entity measures a financial asset and financial liability initially at its fair value.

Subsequent measurement of financial assets and financial liabilities

SAHPRA measures all financial assets and financial liabilities after initial recognition at amortised cost. All financial assets measured at amortised cost, or cost, are subject to an impairment review.

Gains and losses

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.

1.7 Financial instruments (continued)

Derecognition of 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 Statutory receivables

Identification

Statutory receivables are receivables that arise from legislation, supporting regulations, or similar means, and require settlement by another entity in cash or another financial asset.

Carrying amount is the amount at which an asset is recognised in the statement of financial position.

The cost method is the method used to account for statutory receivables that requires such receivables to be measured at their transaction amount, plus any accrued interest or other charges (where applicable) and, less any accumulated impairment losses and any amounts derecognised.

Nominal interest rate is the interest rate and/or basis specified in legislation, supporting regulations or similar means.

The transaction amount for a statutory receivable means the amount specified in, or calculated, levied or charged in accordance with, legislation, supporting regulations, or similar means.

Recognition

The entity recognises statutory receivables as follows:

- if the transaction is an exchange transaction, using the policy on Revenue from exchange transactions;
- if the transaction is a non-exchange transaction, using the policy on Revenue from non-exchange transactions (Taxes and transfers); or
- if the transaction is not within the scope of the policies listed in the above or another Standard of GRAP, the receivable is recognised when the definition of an asset is met and, when it is probable that the future economic benefits or service potential associated with the asset will flow to the entity and the transaction amount can be measured reliably.

1.8 Statutory receivables (continued)

Initial measurement

The entity initially measures statutory receivables at their transaction amount.

Subsequent measurement

The entity measures statutory receivables after initial recognition using the cost method. Under the cost method, the initial measurement of the receivable is changed subsequent to initial recognition to reflect any:

- interest or other charges that may have accrued on the receivable (where applicable);
- impairment losses; and
- amounts derecognised.

Impairment losses

The entity assesses at each reporting date whether there is any indication that a statutory receivable, or a group of statutory receivables, may be impaired.

In assessing whether there is any indication that a statutory receivable, or group of statutory receivables, may be impaired, the entity considers, as a minimum, the following indicators:

- Significant financial difficulty of the debtor, which may be evidenced by an application for debt counselling, business rescue or an equivalent.
- It is probable that the debtor will enter sequestration, liquidation or other financial re-organisation.
- A breach of the terms of the transaction, such as default or delinquency in principal or interest payments (where levied).
- Adverse changes in international, national or local economic conditions, such as a decline in growth, an increase in debt levels and unemployment, or changes in migration rates and patterns.

If there is an indication that a statutory receivable, or a group of statutory receivables, may be impaired, the entity measures the impairment loss as the difference between the estimated future cash flows and the carrying amount. Where the carrying amount is higher than the estimated future cash flows, the carrying amount of the statutory receivable, or group of statutory receivables, is reduced, either directly or through the use of an allowance account. The amount of the losses is recognised in surplus or deficit.

In estimating the future cash flows, an entity considers both the amount and timing of the cash flows that it will receive in future. Consequently, where the effect of the time value of money is material, the entity discounts the estimated future cash flows using a rate that reflects the current risk-free rate and, if applicable, any risks specific to the statutory receivable, or group of statutory receivables, for which the future cash flow estimates have not been adjusted.

An impairment loss recognised in prior periods for a statutory receivable is revised if there has been a change in the estimates used since the last impairment loss was recognised, or to reflect the effect of discounting the estimated cash flows.

Any previously recognised impairment loss is adjusted either directly or by adjusting the allowance account. The adjustment does not result in the carrying amount of the statutory receivable or group of statutory receivables exceeding what the carrying amount of the receivable(s) would have been had the impairment loss not been recognised at the date the impairment is revised. The amount of any adjustment is recognised in surplus or deficit.

1.8 Statutory receivables (continued)

Derecognition

The entity derecognises a statutory receivable, or a part thereof, when:

- the rights to the cash flows from the receivable are settled, have expired or are waived;
- the entity transfers to another party substantially all of the risks and rewards of ownership of the receivable; or
- the entity, despite having retained some significant risks and rewards of ownership of the receivable, has transferred control of the receivable to another party and the other party has the practical ability to sell the receivable 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 receivable; and
  - recognise separately any rights and obligations created or retained in the transfer.

The carrying amounts of any statutory receivables transferred are allocated between the rights or obligations retained and those transferred on the basis of their relative fair values at the transfer date. The entity considers whether any newly created rights and obligations are within the scope of the Standard of GRAP on Financial Instruments or another Standard of GRAP. Any difference between the consideration received and the amounts derecognised and, those amounts recognised, are recognised in surplus or deficit in the period of the transfer.

1.9 Leases

A lease is classified as a finance lease if it transfers substantially all the risks and rewards incidental to ownership. A lease is classified as an operating lease if it does not transfer substantially all the risks and rewards incidental to ownership.

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.

The discount rate used in calculating the present value of the minimum lease payments is the government incremental borrowing rate, if it is impractical to determine the interest rate implicit in the lease.

The present value of the lease is considered to be substantial if the fair value exceeds 95% of the leased assets.

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.

Operating leases - lessee

Operating lease payments are recognised as an expense on a straight-line basis over the lease term. The difference between the amounts recognised as an expense and the contractual payments are recognised as an operating lease asset or liability.

The lease expense recognised for operating leases over the straight-line lease payments and the contractual lease payments.

1.10 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.

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

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

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

Identification

When the carrying amount of a cash-generating asset exceeds its recoverable amount, it is impaired.

The entity assesses at each reporting date whether there is any indication that a cash-generating asset may be impaired. If any such indication exists, the entity estimates the recoverable amount of the asset.

Irrespective of whether there is any indication of impairment, the entity also tests a cash-generating intangible asset with an indefinite useful life or a cash-generating intangible asset not yet available for use for impairment annually by comparing its carrying amount with its recoverable amount. This impairment test is performed at the same time every year. If an intangible asset was initially recognised during the current reporting period, that intangible asset was tested for impairment before the end of the current reporting period.

Value in use

Value in use of a cash-generating asset is the present value of the estimated future cash flows expected to be derived from the continuing use of an asset and from its disposal at the end of its useful life.

When estimating the value in use of an asset, the entity estimates the future cash inflows and outflows to be derived from continuing use of the asset and from its ultimate disposal and the entity applies the appropriate discount rate to those future cash flows.

1.11 Impairment of non-cash-generating assets

Recognition and measurement

If the recoverable service amount of a non-cash-generating asset is less than its carrying amount, the carrying amount of the asset is reduced to its recoverable service amount. This reduction is an impairment loss.

1.11 Impairment of non-cash-generating assets Recognition and measurement (continued)

An impairment loss is recognised immediately in surplus or deficit.

When the amount estimated for an impairment loss is greater than the carrying amount of the non-cash-generating asset to which it relates, the entity recognises a liability only to the extent that is a requirement in the Standards of GRAP.

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

The entity assesses at each reporting date whether there is any indication that an impairment loss recognised in prior periods for a non-cash-generating asset may no longer exist or may have decreased. If any such indication exists, the entity estimates the recoverable service amount of that asset.

An impairment loss recognised in prior periods for a non-cash-generating asset is reversed if there has been a change in the estimates used to determine the asset's recoverable service amount since the last impairment loss was recognised. The carrying amount of the asset is increased to its recoverable service amount. The increase is a reversal of an impairment loss. The increased carrying amount of an asset attributable to a reversal of an impairment loss does not exceed the carrying amount that would have been determined (net of depreciation or amortisation) had no impairment loss been recognised for the asset in prior periods.

A reversal of an impairment loss for a non-cash-generating asset is recognised immediately in surplus or deficit.

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.

1.11 Impairment of non-cash-generating assets Recognition and measurement (continued)

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.

1.12 Employee benefits short-term employee benefits

Short-term employee benefits are employee benefits (other than termination benefits) that are due to be settled within twelve months after the end of the period in which the employees render the related service.

Short-term employee benefits include items such as:

- wages, salaries and social security contributions;
- short-term compensated absences (such as paid annual leave and paid sick leave) where the compensation for the absences is due to be settled within twelve months after the end of the reporting period in which the employees render the related employee service;
- bonus, incentive and performance related payments payable within twelve months after the end of the reporting period in which the employees render the related service; and
- non-monetary benefits (for example, medical care, and free or subsidised goods or services such as housing, cars and cellphones) for current employees.

When an employee has rendered service to the entity during a reporting period, the entity recognises the undiscounted amount of short-term employee benefits expected to be paid in exchange for that service:

- as a liability (accrued expense), after deducting any amount already paid. If the amount already paid exceeds the undiscounted amount of the benefits, the entity recognises that excess as an asset (prepaid expense) to the extent that the prepayment will lead to, for example, a reduction in future payments or a cash refund; and
- as an expense, unless another standard requires or permits the inclusion of the benefits in the cost of an asset.

The expected cost of compensated absences is recognised as an expense as the employees render services that increase their entitlement or, in the case of non-accumulating absences, when the absence occurs. The entity measures the expected cost of accumulating compensated absences as the additional amount that the entity expects to pay as a result of the unused entitlement that has accumulated at the reporting date.

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.

The entity recognises the expected cost of bonus, incentive and performance related payments when the entity has a present legal or constructive obligation to make such payments as a result of past events and a reliable estimate of the obligation can be made. A present obligation exists when the entity has no realistic alternative but to make the payments.

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.

1.13 Provisions and contingencies

Provisions are recognised when:

- the entity has a present obligation as a result of a past event;
- it is probable that an outflow of resources embodying economic benefits or service potential will be required to settle the obligation; and
- a reliable estimate can be made of the obligation.

The amount of a provision is the best estimate of the expenditure expected to be required to settle the present obligation at the reporting date.

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.

Where some or all of the expenditure required to settle a provision is expected to be reimbursed by another party, the reimbursement is recognised when, and only when, it is virtually certain that reimbursement will be received if the entity settles the obligation. The reimbursement is treated as a separate asset. The amount recognised for the reimbursement does not exceed the amount of the provision.

Provisions are reviewed at each reporting date and adjusted to reflect the current best estimate. Provisions are reversed if it is no longer probable that an outflow of resources embodying economic benefits or service potential will be required, to settle the obligation.

A provision is used only for expenditures for which the provision was originally recognised.

Contingent assets and contingent liabilities are not recognised. Contingencies are disclosed in note 28.

1.14 Commitments

Items are classified as commitments when an entity has committed itself to future transactions that will normally result in the outflow of cash.

Disclosures are required in respect of unrecognised contractual commitments. Commitments are recorded at cost in the notes of the annual financial statements.

Commitments for which disclosure is necessary to achieve a fair presentation should be disclosed in a note to the financial statements, if both the following criteria are met:

- Contracts should be non-cancellable or only cancellable at significant cost (for example, contracts for computer or building maintenance services); and
- Contracts should relate to something other than the routine, steady, state business of the entity – therefore salary commitments relating to employment contracts or social security benefit commitments are excluded.

1.15 Revenue from exchange transactions

Revenue is the gross inflow of economic benefits or service potential during the reporting period when those inflows result in an increase in net assets, other than increases relating to contributions from owners.

An exchange transaction is one in which the entity receives assets or services, or has liabilities extinguished, and directly gives approximately equal value (primarily in the form of goods, services or use of assets) to the other party in exchange.

1.15 Revenue from exchange transactions (continued)

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.

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.

Service revenue is recognised by reference to the stage of completion of the transaction at the reporting date. Stage of completion is determined by services performed to date as a percentage of total services to be performed or total services to be performed or when a specific act is more significant than any other acts, the recognition is postponed until the significant act is executed

Interest received

Revenue arising from the use by others of entity assets yielding interest, royalties and dividends or similar distributions is recognised when:

- It is 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.

Interest is recognised in surplus or deficit using the effective interest rate method.

1.16 Revenue from non-exchange transactions

Revenue comprises gross inflows of economic benefits or service potential received and receivable by an entity, which represents an increase in net assets, other than increases relating to contributions from owners.

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 anotherentity without directly receiving approximately equal value in exchange.

1.16 Revenue from non-exchange transactions (continued)

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 the entity 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 the entity.

When, as a result of a non-exchange transaction, the entity 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, unless it is also required to recognise a liability. Where a liability is required to be recognised it will be measured as the best estimate of the amount required to settle the obligation at the reporting date, and the amount of the increase in net assets, if any, recognised as revenue. When a liability is subsequently reduced, because the taxable event occurs or a condition is satisfied, the amount of the reduction in the liability is recognised as revenue.

Transfers

Apart from services in-kind, which are not recognised, the entity recognises an asset in respect of transfers when the transferred resources meet the definition of an asset and satisfy the criteria for recognition as an asset.

The entity recognises an asset in respect of transfers when the transferred resources meet the definition of an asset and satisfy the criteria for recognition as an asset.

Transferred assets are measured at their fair value as at the date of acquisition.

Services in-kind

The entity recognise services in-kind that are significant to its operations and/or service delivery objectives as assets and recognise the related revenue when it is probable that the future economic benefits or service potential will flow to theentity and the fair value of the assets can be measured reliably.

Where services in-kind are not significant to the entity's operations and/or service delivery objectives and/or do not satisfy the criteria for recognition, the entity disclose the nature and type of services in-kind received during the reporting period.

1.17 Comparative figures

Where necessary, comparative figures have been reclassified to conform to changes in presentation in the current year.

1.18 Fruitless and wasteful expenditure

Fruitless 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.

1.19 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 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 in line with the relevant guidelines issued by National Treasury.

If amounts of irregular expenditure are condoned by the relevant authority, amounts are disclosed in the irregular expenditure note as amounts condoned.

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 a liability for the irregular expenditure can be attributed to a person or company and is liable in law, a receivable should be raised for recovery from the irregular expenditure note.

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

1.20 Segment information

A segment is an activity of an entity:

- that generates economic benefits or service potential (including economic benefits or service potential relating to transactions between activities of the same entity);
- whose results are regularly reviewed by management to make decisions about resources to be allocated to that activity and in assessing its performance; and
- for which separate financial information is available.

1.20 Segment information (continued)

Reportable segments are the actual segments which are reported on in the segment report. They are the segments identified above or alternatively an aggregation of two or more of those segments where the aggregation criteria are met.

SAHPRA operates in a single segment as budgets are not decentralised into regional activities.

1.21 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 modified cash basis and presented by economic classification linked to performance outcome objectives.

The approved budget covers the fiscal period from 2021/04/01 to 2022/03/31.

The annual financial statements and the budget are not on the same basis of accounting therefore a reconciliation between the statement of financial performance and the budget have been included in the annual financial statements. Refer to notes 35 & 38.

1.22 Related parties

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

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

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

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

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

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

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

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

1.22 Related parties (continued)

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.

1.23 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.

	2022	2021

2. New standards and interpretations

2.1 Standards and interpretations effective and adopted in the current year

In the current year, the entity had no new standards and interpretations that are effective for the current financial year and that are relevant to its operations.

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 01 April 2022 or later periods:

Standard/Interpretation:	Effective date: Years beginning on or after	Expected impact:
GRAP 25 (as revised): Employee Benefits	01 April 2022	Unlikely there will be a material impact
GRAP 104 (as revised): Financial Instruments	01 April 2025	Unlikely there will be a material impact
iGRAP 21: The Effect of Past Decisions on Materiality	01 April 2023	Unlikely there will be a material impact
GRAP 2020: Improvements to the standards of GRAP 2020	01 April 2023	Unlikely there will be a material impact
GRAP 1 (amended): Presentation of Financial Statements	01 April 2023	Unlikely there will be a material impact

3. Receivables from exchange transactions

Trade debtors	9 587 352	9 296 319
Provision for impairment	(6 639 699)	(2 088 973)
Rental deposit	2 791 114	3 229 618
	5 738 767	**10 436 964**

Statutory receivables included in receivables from exchange transactions above are as follows:

Retention fees	8 764 638	7 091 538
Licence collection fees	303 060	77 611
Inspection fees	519 654	532 703
Section 21	-	1 594 467
	9 587 352	**9 296 319**
Provision for impairments	(6 639 699)	(2 088 973)
Financial asset receivables included in receivables from exchange transactions above	**2 791 114**	**3 229 618**
Total receivables from exchange transactions	**5 738 767**	**10 436 964**

3. Receivables from exchange transactions (continued)

Statutory receivables general information

Transaction(s) arising from statute

The statutory receivables of SAHPRA relates to Retention fees, License collection fees and Inspections fees. All fees are charged in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended.

The increase in statutory receivables increased due to the review of retention fee register.

Rental deposit decreased due to the payback of the rental deposit due relating to the previous lease agreement. The current leased accommodation required an annual deposit increase that was paid. This rental deposit is held in an interest bearing call account by the lessor and interest accrued to SAHPRA for the year.

Determination of transaction amount

SAHPRA is required to ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation. The Minister may make regulations prescribing the fee to be paid to SAHPRA in respect of an application for the registration, and in respect of the registration of a medicine, medical device or IVD, the fee to be paid annually to SAHPRA in respect of the retention of the certification or the registration of a medicine, medical device or IVD and the date on which such annual fee shall be paid and he may also make regulations prescribing the fee payable in respect of the authorisation of the use of unregistered medicines, medical devices or IVDs, the issuing of permits and certificates under the Medicines and Related Substance Act, the issuing or renewal of any licence under this Act, the performance of inspections to assess the safety, quality and efficacy of medicines, scheduled substances, medical devices or IVDs for the purpose of registration, the evaluation of technical amendments and changes to the particulars contained in registers and the testing for batch release of biological medicines.

All fees regulated in the Medicine and Related Substances Act, as amended are published in the Government Gazette.

Interest or other charges levied/charged

There was no interest charged on the statutory receivable arising from exchange transactions at 31 March 2022 in line with SAHPRA's revenue policy.

Basis used to assess and test whether a statutory receivable is impaired

If the person who is the holder of the certificate of registration issued in respect of any medicine, medical device or IVD fails to pay the prescribed annual fee in respect of the retention of the registration of that medicine, medical device or IVD before or on the prescribed date or such later date as the Chief Executive Officer may determine on application by that person, the Chief Executive Officer shall cancel the registration of that medicine, medical device or IVD.

Receivables from exchange transactions are impaired on a class of service basis. The impairment of trade receivables has been determined with reference to past default experience and the current economic environment in which these entities trade.

	2022	2021

3. Receivables from exchange transactions (continued)

Reconciliation of provision for impairment

Relating specifically to Statutory Receivables

Opening balance	2 088 973	-
Provision for impairment	6 145 193	2 088 973
Amounts written off as uncollectable	(1 594 467)	-
	6 639 699	**2 088 973**

Receivables past due but not impaired

Relating specifically to Statutory Receivables

Statutory receivables which are less than 1 year past due are not considered to be impaired. At 31 March 2022, R508 103 (2021: R6 894 638) were past due but not impaired.

The ageing of amounts past due but not impaired is as follows:

9 months past due	508 103	6 894 638

Factors the entity considered in assessing statutory receivables impaired

The following is considered as objective evidence that a trade receivable is impaired:

- Debtors did not respond to follow request or indicate financial difficulty;
- Judgement awarded in favour of the entity;
- Uneconomical to initiate or continue with legal proceedings; and
- Official transfers, cancellations and licenced site that have closed down and liquidated.

Receivables impaired

Relating specifically to Statutory Receivables

As of 31 March 2022, statutory receivables of R9 079 250 (2021: R2 170 899) were impaired and provided for.
The amount of the provision was R6 639 699 31 March 2022 (2021: R2 088 973).
The ageing of these receivables are as follows:

3 to 6 months	207 400	856 673
6 - 12 months	4 792 000	1 314 226
Over 12 months	4 079 850	-
	9 079 250	**2 170 899**

	2022	2021

3. Receivables from exchange transactions (continued)

Factors the entity considered in assessing statutory receivables impaired

The following is considered as objective evidence that a trade receivable is impaired:

- Debtors did not respond to follow request or indicate financial difficulty;
- Customer in liquidation;
- Judgement awarded in favour of the entity;
- Uneconomical to initiate or to continue with legal proceedings; and
- Official transfers, cancellations and licenced site that have closed down and liquidated.

Trade and other receivables past due but not impaired

Trade and other receivables which are less than 1 year past due are not considered to be impaired. At 31 March 2022, R- (2021: R716 856) were past due but not impaired.

A past due rental deposit was paid over to SAHPRA during the 2021/22 financial year. The ageing of amounts past due but not impaired is as follows:

3 months past due	-	716 856

Trade and other receivables written off

As of 31 March 2022, trade and other receivables of R1 594 467 were written off and provided for and (2021: R706 955) were written off.

4. Receivables from non - exchange transactions

Grant receivable	8 822 956	34 674
Staff debtors	629 190	-
	9 452 146	**34 674**

Grant receivables includes grant received from the Centres for Disease Control and Prevention (CDC), the Clinton Health Access Initiative (CHAI) and the Global Fund.

Staff debtors relate to section 197 transfer process of employees taken on from the NDoH where some employees were not removed from the NDoH persal system, two months medical aid contributions were not deducted from the employees' salary during the transfer from persal to SAHPRA's payroll.

	2022	2021

5. Cash and cash equivalents

Cash and cash equivalents consist of:

Petty cash	8 031	-
Bank balances held at ABSA bank	2 370 048	150 764 296
Corporation for public deposits held at SA Reserve Bank	241 995 225	-
	244 373 304	**150 764 296**

No cash and cash equivalents balances are restricted except for unspent conditional grants as disclosed in note 10.

Credit quality of cash at bank

The credit quality of cash at bank held at ABSA Bank and SA Reserve Bank's Corporation for Public Deposits that are neither past due nor impaired can be assessed by reference to external credit rating of Ba3 (long term) as per the Moody's rating agency as at 31 March 2022. The entity's maximum exposure to credit risk as a result of bank balances held is limited to the carrying value of these balances as detailed above.

6. Property, plant and equipment

	2022			2021		
	Cost / Valuation	Accumulated Depreciation and Accumulated Impairment	Carrying value	Cost / Valuation	Accumulated Depreciation and Accumulated Impairment	Carrying Value
Furniture and fixtures	8 074 818	(1 413 901)	6 660 917	9 461 220	(1 915 252)	7 545 968
Motor vehicles	971 954	-	971 954	-	-	-
Computer equipment	21 467 037	(8 694 350)	12 772 687	19 224 842	(4 551 884)	14 672 958
Leasehold improvements [1]	6 750 625	(2 218 975)	4 531 650	6 659 775	(878 853)	5 780 922
Other fixed assets [2]	3 062 061	(1 378 938)	1 683 123	2 799 822	(974 967)	1 824 855
Total	**40 326 495**	**(13 706 164)**	**26 620 331**	**38 145 659**	**(8 320 956)**	**29 824 703**

Reconciliation of property, plant and equipment - 2022

	Opening Balance	Additions	Disposals	Depreciation	Impairment Loss	Total
Furniture and fixtures	7 545 968	63 592	(100 068)	(843 903)	(4 672)	**6 660 917**
Motor vehicles	-	971 954	-	-	-	**971 954**
Computer equipment	14 672 958	2 857 938	(301 707)	(4 078 255)	(378 247)	**12 772 687**
Leasehold improvements [1]	5 780 922	90 850	-	(1 340 122)	-	**4 531 650**
Other fixed assets [2]	1 824 855	295 243	(10 852)	(404 999)	(21 124)	**1 683 123**
	29 824 703	**4 279 577**	**(412 627)**	**(6 667 279)**	**(404 043)**	**26 620 331**

6. Property, plant and equipment (continued)

Reconciliation of property, plant and equipment - 2021

	Opening Balance	Additions	Disposals	Transfers Received	Depreciation	Impairment Loss	Total
Furniture and fixtures	2 397 116	7 622 383	(947 615)	16 875	(918 173)	(624 618)	**7 545 968**
Computer equipment	10 603 804	6 707 221	(222 535)	751 047	(3 166 579)	-	**14 672 958**
Leasehold improvements [1]	-	6 659 776	-	-	(878 854)	-	**5 780 922**
Other fixed assets [2]	1 670 545	645 356	(58 013)	-	(433 033)	-	**1 824 855**
	14 671 465	**21 634 736**	**(1 228 163)**	**767 922**	**(5 396 639)**	**(624 618)**	**29 824 703**

Other information

None of the property, plant and equipment for the current and prior year were pledged as security for any obligation. No expenditure has been incurred relating to capital maintenance

[1] Leasehold improvements include improvements made to leased office accomodation. Refer to note 8 and 27.

[2] Other assets relates to other office related equipments.

7. Intangible assets

	2022			2021		
	Cost/ Valuation	Accumulated Amortisation and Accumulated Impairment	Carrying Value	Cost / Valuation	Accumulated Amortisation and Accumulated Impairment	Carrying Value
Computer software	**3 343 134**	**(525 075)**	**2 818 059**	**2 049 116**	**(176 205)**	**1 872 911**

	2022	2021

7. Intangible assets (continued)

Reconciliation of intangible assets - 2022

	Opening Balance	Additions	Amortisation	Total
Computer software	1 872 911	1 294 018	(348 870)	**2 818 059**

Reconciliation of intangible assets - 2021

	Opening Balance	Additions	Amortisation	Total
Computer software	267 380	1 767 133	(161 602)	**1 872 911**

Other information

Intangible assets consists of acquired computer software and there are no internally generated computer software in use.

8. Operating lease liability

Operating lease liability	3 259 196	1 600 515

The operating lease liability relates to the straight-line effect to recognising the lease expense over the lease term effect as per the GRAP 13 requirements. Refer to note 27 for lease commitment disclosures.

9. Payables from exchange transactions

Trade payables	4 763 825	13 242 087
Salary accrual	1 584 383	1 551 333
Accrued thirteenth cheque	2 251 260	-
Accrued expenditure	6 673 294	17 272 366
Travel lodge card	383 642	-
	15 656 404	**32 065 786**

Overall trade payables from exchange transactions decreased due to amounts paid to the National Department of Health for expenditure incurred on behalf of SAHPRA.

SAHPRA considers that the carrying value of trade and other payables approximates the fair value. Salary accruals relates to acting allowances, travel and evaluator fees.

Accrued thirteenth cheque: During the 2021-22 financial year, the entity absorbed the Section 197 employees in its payroll system. These employees have a thirteenth cheque component that is either in their cost to company or as an employer benefit. The thirteenth cheque is paid in the employees' birthday month and its accrued to year end.

Accrued expenditure decreased from prior year due to the entity improving expenditure management and travel expenditure incurred by the appointed SAHPRA travel agency.

	2022	2021

10. Unspent conditional grants

Unspent conditional grants and receipts comprises of:

Nepad Auda grant	297 630	-
BMGF grant	3 085 629	-
	3 383 259	**-**

Movement during the year		
Additions during the year	8 772 992	-
Income recognition during the year	(5 389 733)	-
	3 383 259	**-**

These amounts are invested in a ring-fenced investment at the Corporation for Public Deposits as disclosed in Note 5 until utilised. Should the conditions not be met, a repayment to the grantor will include interest accrued at a rate of 3.00 percent.

11. Provisions

Leave provision	8 838 633	10 588 084
PMDS provision	5 358 516	2 110 939
Provision for notch increase	-	1 489 373
	14 197 149	**14 188 396**

Leave provision

SAHPRA 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

SAHPRA has a newly approved performance management policy approved by the Board in April 2021 which enables the employer to incentivise employees based on performance.

In prior years, SAHPRA has paid performance bonuses based on the Department of Public Service and Administration (DPSA) approved Performance Management Development Scheme (PMDS) which limits performance payments on a percentage of the Cost of Employment budget.

The new approved policy requires SAHPRA to apply new assumptions to enable the estimation of performance bonuses based on the new policy, historical pay-out data and availability of funding.

11. Provisions (continued)

The target setting percentage of the policy was utilised as a benchmark and adjusted to accommodate and consider:

- Actual scores for the 2020/21 assessment
- That more staff will strive to comply and achieve with evidence available based on understanding and experiences of the 2020/21 assessment
- The inability to retain staff or failed recruitment due to inadequate package offering

Notch provision

Notch: The 2020-21 PMDS assessments will be moderated starting June 2021. The delay is attributed to the COVID-19 pandemic and extended lock down periods. Performance contracts were finalised later than normal for the majority of employees and those who did not contract are excluded from the Performance Management Cycle. The PMDS rewards for the 2020/2021 and the resultant notch-increase will be effected as per the PMDS policy after the moderation process. The provision was utilised in the 2021-22 financial year.

	Current Cycle Leave	Previous Cycle Leave	Capped Leave	PMDS	Notch Increase	Total
As at 1 April 2021	2 635 350	7 293 766	658 969	2 110 938	1 489 373	14 188 396
Additions for the year	2 518 091	5 536 899	261 933	5 358 516	-	13 675 439
Reversal during the year	(2 635 350)	(7 293 766)	(137 259)	(2 110 938)	(1 489 373)	(13 666 686)
As at 31 March 2022	**2 518 091**	**5 536 899**	**783 643**	**5 358 516**	**-**	**14 197 149**

	Current Cycle Leave	Previous Cycle Leave	Capped Leave	PMDS	Notch Increase	Total
As at 1 April 2020	3 086 240	3 117 512	937 822	4 967 201	-	12 108 775
Additions for the year	2 635 350	7 415 690	-	1 078 859	1 489 373	12 497 348
Reversal during the year	(3 086 240)	(3 117 512)	(278 853)	(3 935 122)	-	(10 417 727)
As at 31 March 2021	**2 635 350**	**7 293 766**	**658 969**	**2 110 938**	**1 489 373**	**14 188 396**

	2022	2021

12. Income received in advance

Reconciliation

Unallocated deposits received	72 348 162	35 981 594
Revenue received in advance	119 178 746	61 779 650
	191 526 908	**97 761 244**

The income received in advance relates to application fees received in advance for services to be rendered in future financials periods.

Unallocated deposits refer to the those payments received by SAHPRA in the ABSA bank account that is not matched to an application for service rendered by SAHPRA.

13. Deferred income : Backlog reduction project

Deferred income	12 476 800	25 020 697

The deferred income balance relates to the fees received in prior years for the backlog reduction project. Revenue is realised as service is rendered relating to applications relating to the backlog reduction project.

	2022	2021
14. Fee Income		
Section 21	3 517 338	5 356 420
Section 21 veterinary	169 320	133 990
Section 21 CMS	11 370	23 170
Screening	193 600	1 148 000
Clinical trials	13 344 180	3 636 730
Pharma licence fee	1 968 780	1 910 150
Licence retention fees	8 227 400	6 140 000
Cannabis	740 890	494 140
Cannabis inspection	857 839	-
Evaluations	18 317 125	8 736 190
Permits	5 553 389	5 482 613
Amendments	28 895 360	5 451 359
Inspection fees	6 344 579	1 941 250
Retention fees	65 347 000	29 367 600
Certificates	751 800	472 000
Registration fee	423 960	758 920
Backlog reduction project	12 345 297	20 031 550
MD licence fees	9 772 960	12 416 560
Biological medicine	5 012 700	3 727 900
	181 794 887	**107 228 542**
Fees received per function		
Medicines evaluation, registration and product life cycle	143 879 222	71 691 152
Inspections, permits and licences issued	34 217 637	30 023 810
The use of unregistered medicines	3 698 028	5 513 580
	181 794 887	**107 228 542**
15. Sundry income		
Discount received	-	2 306 671
Proceeds from sale of assets and insurance	217 309	19 130
	217 309	**2 325 801**

	2022	2021

16. Interest received

Interest revenue

Interest received	9 557 126	4 006 563

Included in interest received is total interest income earned from cash held at ABSA bank based on the average interest rate of 3% (2021: 2%) and cash held at SA Reserve Bank Corporation for Public Deposits bank based on the average interest rate of 3.77% (2021: 0 %) per annum. Accrued interest on the rental deposit held by the lessor in a interest bearing call account at an average rate of 3.00% (2021: 3%) per annum.

17. Transfer payments

Operating grants

Transfer payment from the NDoH	146 287 000	156 572 000

18. Service in-kind

The nature and type of major classes of services in-kind received, are as follows:

Services in-kind that are significant to the entities operations and/or service delivery objectives		
Backlog reduction project	15 348 507	20 763 998
SAHPRA received an in-kind benefit as services from international evaluators were paid directly by a third party. Other costs were incurred to render the services including bank charges and management fees.		
	15 348 507	**20 763 998**
Services in-kind not significant to the entity's operations and/or service delivery objectives and/or do not satisfy the criteria for recognition		
CHAI CSIR Project	2 236 152	-
CSIR incurred cost on behalf of SAHPRA through the CHAI grant whereby CSIR assists SAHPRA with Data anlaytics and analyse Healthcare professionals' COVID-19 vaccination data.		
	2 236 152	**-**

	2022	2021
19. Grant realised		
BMGF grant	3 954 011	-
Nepad Auda grant	1 435 722	-
	5 389 733	**-**
Reconciliation of conditional contributions		
Current-year receipts	8 772 992	-
Conditions met - transferred to revenue	(5 389 733)	-
Unspent - balance remaining	(3 383 259)	-
	-	**-**

Refer to note 10 for the remaining balance of funds where conditions are still to be met.

20. Grant income		
Backlog reduction project: Global fund grant	7 889 314	-
Backlog reduction project: Center for Disease Control and Prevention (CDC) grant	-	2 104 925
Clinton Health Access Initiative (CHAI) grant	933 642	-
	8 822 956	**2 104 925**
21. Employee related costs		
Basic and non-pensionable salaries	151 184 083	113 984 081
Thirteenth cheque and performance bonus	12 922 352	4 550 898
Medical aid	3 257 193	3 563 753
SDL and UIF	1 756 899	415 844
Bargaining council	3 470	14 919
Pension fund	9 991 270	9 829 263
PAYE	108 000	8 359 202
Travel allowances	65 843	-
Housing benefits and allowances	2 241 772	2 646 222
Leave accrued	(571 803)	3 484 164
Cellphone allowances	947 726	144 048
Standby allowances	42 421	97 491
	181 949 226	**147 089 885**

	2022	2021
22. Backlog reduction project		
Backlog clearance project	-	3 813
Bank charges	101 811	65 743
Backlog foreign evaluators	7 000 996	11 764 046
Local evaluators	7 490 649	10 866 433
Services in-kind	15 348 507	20 763 998
Share of communication	95 000	1 044 920
Extedo system	1 282 909	2 177 546
Portal variations	-	83 029
Share of rental	779 120	745 796
Training	11 843	-
Compensation of employees	20 164 920	20 001 546
	52 275 755	**67 516 870**

Included in foreign evaluators is a portion funded via services in-kind. Refer to note 18.

23. Depreciation and amortisation		
Property, plant and equipment	6 667 279	5 396 639
Intangible assets	348 870	161 602
	7 016 149	**5 558 241**

24. Laboratory services		
Outsourced services		
NCL Laboratory	20 797 520	19 922 033

The National Control Laboratory (NCL) is an outsourced service for testing of biological medicines and vaccines on behalf of SAHPRA.

25. Operating expenses

	2022	2021
Administrative costs	-	114 052
Advertising	180 624	191 394
Auda Nepad expenses	1 228 733	-
Auditors remuneration	3 351 670	4 925 961
Bank charges	133 344	66 009
Board costs	1 733 687	1 645 841
Bursaries	72 069	10 140
Catering	135 383	21 498
Cleaning	535 441	534 593
Communication	2 407 161	5 189 433
Computer expenses	1 779 241	3 403 153
Conferences	73 489	34 160
Consulting and professional fees [2]	1 439 892	9 098 050
Expert committees	17 075 693	13 515 251
General expenses	910	42 741
Insurance	295 234	-
Legal fees	7 516 893	2 091 262
Licences	3 380 027	1 888 853
Medicine testing	155 616	-
Membership fees	328 169	292 958
Minor assets	44 182	95 895
Motor vehicle expenses	1 711 586	2 535 672
Postage and courier	13 222	118 220
Printing and publications	348 785	206 115
Printing and stationery	501 253	1 009 452
Protective clothing	17 038	106 168
Refreshments	40 974	21 489
Relocation of SAHPRA	753 190	2 410 879
Repairs and maintenance	212 115	32 958
Research and development costs	-	256 210
Security	278 712	57 931
Staff training and welfare	1 072 912	764 658
Travel - local and overseas	4 026 234	1 819 636
Utilities	(89 532)	842 732
Venues and facilities	-	16 243
	50 753 947	**53 359 607**

[2] Consulting and professional fees consist of payments made to service providers for recruitment, accounting, professional services and supply chain.

26. Cash generated from operations

	2022	2021
Surplus (deficit)	28 237 337	(19 656 868)
Adjustments for:		
Depreciation and amortisation	7 016 149	5 558 241
Loss on disposal of assets and liabilities	412 627	1 228 163
Impairment deficit	404 044	624 618
Movements in operating lease liabilities	1 658 681	1 600 515
Movements in provisions	8 754	2 079 619
Assets transferred from NDoH	-	(767 922)
Proceeds from disposal of assets	(201 062)	(19 130)
Discount received	-	(2 306 671)
Changes in working capital:		
Receivables from exchange transactions	4 698 197	(7 740 129)
Other receivables from non-exchange transactions	(9 417 472)	14 599 457
Prepayments	(2 031 352)	(2 658 726)
Investing in payables	(1 213 454)	-
Payables from exchange transactions	(16 409 387)	10 695 935
Unspent conditional grant	3 383 259	-
Income received in advance	93 765 664	46 645 706
Deferred income - backlog reduction project	(12 543 897)	-
	97 768 088	**49 882 808**

	2022	2021
27. Commitments		
Authorised expenditure		
Already contracted for but not provided for		
• National Control Laboratory contract	3 495 905	3 318 000
• Supply of facilities services	2 408 338	-
• Supply of IT equipment and related IT expenditure	5 044 548	4 305 223
• Parking services	-	116 597
• Open purchase orders	8 424 632	5 929 468
• Supply of communication services	571 869	855 347
• Office accommodation	68 834 418	75 435 857
• Supply of legal services	4 841 843	-
• Supply of risk management	2 574 904	-
• Supply of HR services	1 878 446	-
	98 074 903	**89 960 492**
Total operational commitments		
Already contracted for but not provided for	98 074 903	89 960 492

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

Operating leases - as lessee (expense)

Minimum lease payments due

- within one year	18 575 725	15 493 062
- in second to fifth year inclusive	52 948 510	60 431 677
	71 524 235	**75 924 739**

Operating lease payments represent rentals payable by SAHPRA for leased office properties for two locations. No restrictions, contingent rent or sublease payments apply. Annual escalation percentage over the terms of the lease. Refer to note 8 for lease straight-line liability.

	2022	2021

28. Contingencies

Contingent liabilities

Claim against SAHPRA for services rendered

During the 2020/21 financial year, a letter of demand for services rendered were received from a recruitment consultant claiming that full services were rendered as per the Master Services agreement signed in the 2019/20 financial year. Management has previously disputed the claim that services were rendered in full and submitted that payment made to date is consistent with services rendered. The matter is currently following an arbitration process.

The letter of demand and intention to seek relief gives rise to a possible obligation, yet to be confirmed whether there is a present obligation that could lead to the payment of services in dispute.

Although SAHPRA still requires evidence and dispute that the services were rendered the possibility of an arbitration award is not remote. The estimated potential liability amounts to R1.3 million.

Contingent assets

Cost order

On 10 June 2021, SAHPRA was served with a court application in the Pretoria High Court and other respondents relating to the registration and sale of the J&J Vaccine.

The court dismissed the application on 1 July 2021 with costs and on 22 March 2022 the applicants filed an application for leave to appeal the cost order and SAHPRA is opposing the application for leave to appeal.

The court dismissal and subsequent leave to appeal gives rise to a contingent asset, yet to be confirmed through the court hearing the leave of appeal and the appeal. SAHPRA has good prospects of success, and the estimated contingent asset amounts to R594 378.

29. Related parties

Relationships	**Nature of related party**
Executive Authority	Dr J Phaahla
National Department of Health (controlling entity of SAHPRA) Authority	National Department of Health Accounting Appointed Board members of SAHPRA
Members of key management	SAHPRA executive management
Council for Scientific and Industrial Research	Public entity in National sphere
Other related parties	All public entities in National sphere
Appointed Board members of SAHPRA	Wits Health Consortium

Related party balances

National Department of Health

Creditors balance - owing to NDOH	(1 073 324)	(14 105 167)
Debtors balance - owing by the NDOH	-	34 674

A related party transaction was identified with the Wits Health Consortium relating to medicine testing services procured. The transactions were at arms length and no outstanding balances are due.

No other balances due or owing to other related entities and all transactions entered into were at arms length.

Related party transactions

National Department of Health

Government grant received	146 287 000	156 572 000
Council for Scientific and Industrial Research		
Rental expense	-	2 493 996

29. Related parties (continued)

Remuneration of Executive Authority and Management

Board fees 2022

	Board Fees	Total
Prof. H.V. Rees - Chairperson [3 & 4]	227 569	227 569
Ms M. Hela - Deputy Chairperson [3]	56 607	56 607
Prof. M.S. Banoo - Member [1 & 3]	-	-
Dr E.N. Madela-Mntla - Member [3]	45 527	45 527
Dr T.M. Motshudi - Member [3]	51 861	51 861
Prof. A. Dhai - Member [3]	57 152	57 152
Prof. M.J. Mphahlele - Member [3]	12 462	12 462
Dr U. Mehta - Member [3]	37 294	37 294
Adv H. Cassim - Member [3 & 4]	192 521	192 521
Dr M.S.M. Molefe - Member [2]	-	-
Mr T.N. Baloyi - Member [3 & 4]	172 500	172 500
Prof. K.C. Household - Member [3]	10 731	10 731
Prof. H. P. Demana - Member [3 & 4]	49 408	49 408
Mr I. Mashau - Member [3 & 4]	118 909	118 909
Ms L. Mothae - Member [3 & 4]	95 059	95 059
Dr O. Khaole - Vice Chair [4]	79 184	79 184
Dr J. Tsoka-Gwegweni - Member [4]	25 348	25 348
Dr X Ngobese - Member [4]	63 224	63 224
Ms D Maraka - Member [4]	34 630	34 630
Prof. Y Choonara - Member [5]	29 570	29 570
Prof. J Meyer - Member [5]	21 836	21 836
Ms M Skhosana - Member [5]	27 749	27 749
Dr A Kgasi - Member [5]	20 955	20 955
Dr Z Makatini - Member [5]	26 830	26 830
	1 456 926	**1 456 926**

[1] The Board fees reflects the actual claims incurred. At times Board members opt not to claim for meetings attended.

[2] Member employed in the public sector - no fees claimed

[3] 1st Board term expired 30 September 2021

[4] 2nd Board term commenced 1 October 2021

[5] Appointed December 2021

29. Related parties (continued)

Executive Management 2022

Name	Basic Salary	Post-Employment	Other Benefits Received Benefits	Total
Dr B Semete-Makokotlela - Chief Executive Officer	2 892 750	-	77 157	2 969 907
Ms P Nkambule - Chief Regulatory Officer	1 536 809	140 542	53 437	1 730 788
Ms C. Reynecke - Chief Operating Officer	2 163 426	-	64 737	2 228 163
Mr R.B. Gouws - Chief Financial Officer	1 827 000	-	61 372	1 888 372
Mr G. Mtakati - HR Executive	1 327 974	-	35 982	1 363 956
	9 747 959	**140 542**	**292 685**	**10 181 186**

Board Fees 2021 [1]

	Board Fees	Total
Prof. H.V. Rees - Chairperson	193 024	193 024
Ms M. Hela - Deputy Chairperson	136 357	136 357
Prof. M.S. Banoo - Member [1]	-	-
Dr E.N. Madela-Mntla - Member	102 547	102 547
Dr T.M. Motshudi - Member	86 595	86 595
Prof. A. Dhai - Member	133 569	133 569
Prof. M.J. Mphahlele - Member [2]	-	-
Dr U. Mehta - Member	61 965	61 965
Dr M.S.M. Molefe - Member [2]	-	-
Adv. H. Cassim - Member	160 527	160 527
Mr T.N. Baloyi - Member	166 387	166 387
Prof. K.C. Household - Member	184 269	184 269
Prof. H.P. Demana - Member	60 818	60 818
Mr I. Mashau - Member	72 811	72 811
Ms L Mothae - Member	245 149	245 149
	1 604 018	**1 604 018**

[1] The Board fees reflect the actual claims submitted. At times board members opt not to claim for meetings attended.
[2] Prof. J Mphahlele and Dr MSM Molefe are employees in the public sector – no fees claimed.

	2022	2021

29. Related parties (continued)

Executive Management 2021

Name	Basic Salary	Post-Employment Benefits	OTher Benefits Received	Total
Dr B Semete-Makokotlela - Chief Executive Officer	2 850 000	-	44 945	2 894 945
Ms P Nkambule - Chief Regulatory Officer	1 521 591	103 654	44 844	1 670 089
Ms C Reyneke - Chief Operations Officer [1]	478 210	-	10 379	488 589
Mr M Kgauwe - Chief Financial Officer [2]	1 205 620	-	22 539	1 228 160
Mr R.B Gouws - Chief Financial Officer [3]	300 000	-	6 731	306 731
Mr G Mtakati - HR Executive [4]	654 173	-	12 585	666 758
	7 009 594	**103 654**	**142 023**	**7 255 272**

[1]Appointed - January 2021
[2]Resigned - November 2020
[3]Appointed - February 2021
[4]Appointed - October 2020

30. Independent audit committee members remuneration

Independent audit committee members - fees for attending meetings

Mr. E.O. Omolo[1]	41 413	35 113
Mr. M.A.E Amod[2]	-	3 572
Ms. Y. Pamla[3]	30 741	-
Mr. B. Gordon[4]	-	-
	72 154	**38 685**

[1] Appointed 2 May 2020
[2] Appointed 2 May 2020, Resigned July 2020
[3] Appointed 1 April 2021
[4] Appointed 1 April 2021 - Member appointed in the public sector - no fees claimed.

	2022	2021

31. Prior period errors

Services in-kind received from the Bill and Melinda Gates Foundation (BMGF) were previously disclosed in the Notes to the Financial Statements. The services in-kind received from BMGF are significant to SAHPRA's operation and the service delivery objectives. Based on the significance of the services, the prior period disclosure was insufficient as the recognition of the services in-kind needs to be recognised on the face of the Statement of Financial Performance.

The clearing of the deferred income qualification has resulted in the re-classification of deferred income balances that relates to backlog but were previously disclosed under normal business operations. Previous services rendered in the backlog project were not allocated to payments received and this has resulted in an understatement in prior year's revenue recognised. The clearing excercise also resulted in reclassification between unallocated deposits received and income received in advance.

Recognition of revenue for Inspection fees were reversed due to apply SAHPRA's revenue recognition policy - date of report versus date of inspection - as the revenue recognition point. Additional retention fees were recognised and a receivable was raised after a completeness of register test was performed.

Certain claims from local evaluators paid in the Backlog reduction project were incorrectly processed to the current year instead of the prior year. This resulted in additional expenditure in the prior year.

Commitments relating to office accomodation was restated after taking into account the leasehold improvements not previously taken into account.

The correction of the error(s) results in adjustments as follows:

Statement of financial position

Deferred income - Backlog reduction project	3 152 597
Income received in advance	(11 660 327)
Receivables from exchange transactions	(815 097)
Unallocated deposits received in advance	2 197 680
Payables from exchange transactions	(393 865)

Statement of financial performance

Fee income	5 494 953
Backlog reduction project - expenditure	(21 157 863)
Service in-kind-Backlog reduction project	20 763 998

31. Prior period errors (continued)

31.1Prior-year adjustments

Presented below are those items contained in the statement of financial position, statement of financial performance and disclosure that have been affected by prior-year adjustments:

Statement of financial position

2021

	Note	As Previously Reported	Correction of Error	Restated
Deferred income - Backlog reduction project		(21 868 100)	(3 152 597)	(25 020 697)
Income received in advance		(107 223 891)	9 462 647	(97 761 244)
Receivables from exchange transactions		11 252 061	(815 097)	10 436 964
Payables from exchange transactions		(31 671 921)	(393 865)	(32 065 786)
		(149 511 851)	**5 101 088**	**(144 410 763)**

Statement of financial performance

2021

	Note	As Previously Reported	Correction of Error	Restated
Fee income		(101 733 589)	(5 494 953)	(107 228 542)
Backlog reduction project		46 359 007	21 157 863	67 516 870
Service in-kind-Backlog reduction project		-	(20 763 998)	(20 763 998)
Surplus for the year		**(55 374 582)**	**(5 101 088)**	**(60 475 670)**

Commitments

2021

	Note	As Previously Reported	Correction of Error	Restated
Office accommodation		88 263 391	(12 827 534)	75 435 857

32. Financial instruments disclosure

Categories of financial instruments

2022

Financial assets

	At Amortised Cost	Total
Trade and other receivables from exchange transactions	5 738 767	5 738 767
Other receivables from non-exchange transactions	9 452 150	9 452 150
Cash and cash equivalents	244 373 304	244 373 304
	259 564 221	**259 564 221**

Financial liabilities

	At Amortised Cost	Total
Trade and other payables from exchange transactions	15 656 404	15 656 404
Income received in advance	191 526 908	191 526 908
Deferred income - Backlog reduction project	12 476 800	12 476 800
	219 660 112	**219 660 112**

2021

Financial assets

	At Amortised Cost	Total
Trade and other receivables from exchange transactions	10 436 964	10 436 964
Other receivables from non-exchange transactions	34 674	34 674
Cash and cash equivalents	150 764 296	150 764 296
	161 235 934	**161 235 934**

Financial liabilities

	At Amortised Cost	Total
Trade and other payables from exchange transactions	32 065 786	32 065 786
Income received in advance	97 761 244	97 761 244
Deferred income - Backlog reduction project	25 020 697	25 020 697
	154 847 727	**154 847 727**

33. Risk management

Financial risk management

The entity's activities expose it to a variety of financial risks: market risk (including currency risk, fair value interest rate risk, cash flow interest rate risk and price risk), credit risk and liquidity risk.

SAHPRA's s risk management policies are established to identify and analyse the risks faced by SAHPRA to set appropriate risk limits and controls and to monitor risk and adherence to limits. Risk management policies and systems are reviewed regularly to reflect changes in SAHPRA's activities. SAHPRA, through its training and management standards and procedures, aims to develop a disciplined and effective control environment in which all employees understand their roles and obligations. The Audit and Risk Committee oversees how management monitors compliance with SAHPRA's risk policies and procedures, and review the adequacy of the risk management framework in relation to the risk faced by the entity. The Audit and Risk Committee is assisted in its oversight role by the Internal Audit. The internal audit undertakes both regular and adhoc financial reviews of controls in place to mitigate the risk which are reported to the Risk, Audit and Governance Committee. There are no significant changes compared to the prior year.

Debtors are assessed at year end for recoverability and the necessary provision for write off will be raised if deemed material.

SAHPRA's financial instruments consist mainly of cash and cash equivalents, receivable and payables. Bank deposits and balances, receivables and payables approximate their fair values due to the short-term nature of these instruments. The fair values together with the carrying amounts have been determined by using available market information and are presented in the statement of financial position.

Liquidity risk

The entity's risk to liquidity is a result of the funds available to cover future commitments. The entity manages liquidity risk through an ongoing review of future commitments and credit facilities.

The table below analyses SAHPRA's financial liabilities into relevant maturity groupings based on the remaining period at the statement of financial position to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

Maturity groupings	Later than one month	Later than one month and no three months	Later than one month and no three months	Later than one month and no later later than five	Total
Trade payables from exchange transactions	-	4 763 825	-	-	4 763 825
Revenue received in advance	-	-	-	204 003 708	204 003 708
Provisions	-	-	14 197 149	-	14 197 149
Operating lease payable	-	-	3 259 196	-	3 259 196
Accrued expenditure	-	-	6 673 294	-	6 673 294
Salary accruals	-	-	1 584 383	-	1 584 383
Accrued thirteenth cheque	-	-	2 251 260	-	2 251 260
Travel lodge card	383 642	-	-	-	383 642
	383 642	**4 763 825**	**27 965 282**	**204 003 708**	**237 116 457**

	2022	2021

33. Risk management (continued)

Concentration of risk

	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
Revenue received in advance	204 003 708	-	-	204 003 708
Receivables from exchange and non-exchange transactions	-	-	15 190 917	15 190 917
	204 003 708	**-**	**15 190 917**	**219 194 625**

Credit risk

No credit limits were exceeded during the reporting period, and management does not expect any surplus (deficit) from non- performance by these counterparties.

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

Cash and cash equivalents	244 373 304	150 764 296
Receivables from exchange and non-exchange transactions	15 190 917	10 471 638

Market risk

Market risk is the risk that changes in the market prices such as interest rates, will affect SAHPRA's income and value of its holdings of financial instruments. The objective of market risk management is to manage and control market risk exposure within acceptable parameters, whilst optimising the return. SAHPRA's is then exposed to one primary type of market risk, namely, interest rate risk.

Interest rate risk

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

34. 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 SAHPRA and is considered to have an insignificant impact on the ability to continue as a going concern.

35. Grant funding

35.1 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:

- Providing ongoing backlog clearance project management support in the development to the official launch of the project and harmonisation of 'business as usual' with backlog 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 R15,3 million (2021: R19,9 million).

Refer to note 22 for more information regarding the Backlog reduction project expenditure and note 18 for the services in-kind note

35.2 Centers for Disease Control and Prevention - (Centers for Disease Control and Prevention - NDoH)

During the arior years , SAHPRA received a grant from the NDoH-Center for Disease Control and Prevention partnership (NDoH-CDC). NDoH-CDC Cooperative Agreement will provide R27 million towards SAHPRA's Backlog Clearance.

Programme for the specific purpose of clearing applications related to HIV and TB drugs including DTG and TLD as first priorities. The benefit for the period under review amounts to R nil (2021: R2,1 million).

35.3 The African Union Development Agency - New Partnership for Africa's Development (Auda-Nepad)

SAHPRA received a grant from Auda-Nepad to complement and support activities implemented in the AU-3S Target Countries towards strengthening of Safety Monitoring Systems for COVID-19 Vaccines. Refer to note 18 for the grant realised.

35.4 Clinton Health Access Initiative (CHAI)

CHAI has committed to support SAHPRA with necessary funding to ensure that SAHPRA can licence local pharmaceutical manufactures to produce and export their products globally but ensuring that these products are safe and efficacious.

Refer to Note 4 for amount invoiced for the project.

CHAI has also funded SAHPRA through CSIR to assist SAHPRA with data analytics and analyse healthcare professionals' COVID-19 vaccination data generated through the Sisonke project and data that will be generated from subsequent vaccination rounds, all of it captured through the Vigilance Hub.

Refer to note 18 for the service in-kind note showing benefit received.

35.5 Global fund

The NDoH has through Global Fund resolved to fund SAHPRA to speedup the finalisation of the backlog of the registration of all applications for health products, ensure access to medicines to the public and to ensure effective medicine regulation in the Republic.

Refer to note 20 for for breakdown of grant received and note 10 for unspent grant.

	2022	2021
36. Fruitless and wasteful expenditure		
Opening balance as previously reported	47 232	-
Add: Fruitless and wasteful expenditure identified - current year	32 000	47 232
Less: Amount written off - current year	(47 232)	-
Closing balance	**32 000**	**47 232**

The determination relating to the prior year transgression has been concluded and the amount was subsequently written off. The transgression identified in the current year related to the payment for the replacement of lost spare keys. Determination on this matter is under way.

37. Irregular expenditure		
Opening balance as previously reported	10 369 881	5 038 900
Add: Irregular expenditure - current year	3 009 868	-
Add: Irregular expenditure - prior period	-	6 268 808
Less: Amount recovered - current year	(12 750)	-
Less: Amount incorrectly classified as irregular expenditure	-	(6 335)
Less: Amount condoned	(10 357 132)	(931 492)
Closing balance	**3 009 867**	**10 369 881**

All irregular expenditure raised in previous financial years has been condoned by the National Treasury following the implementation of consequence management.

Three transgressions were identified in the current year relating to non-approval of contract variations and incorrect B-BBEE score utlised. Determinations were conducted for the new transgressions and consequence management to follow.

38. Reconciliation between budget and statement of financial performance

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

	2022	2021
Net surplus (deficit) per the statement of financial performance	28 237 337	(19 656 868)
Adjusted for:		
(Under) / over expenditure on backog reduction project	4 797 228	20 752 872
Prior period error adjustment	-	(6 310 050)
Increase / decrease in backlog reduction project - grant received	28 855 396	23 735 075
(Increase) Services in-kind	(15 348 507)	-
Grants realised	(1 435 722)	-
Backlog reduction project - grant received	(7 889 314)	-
Over expenditure on impairment of assets	404 044	624 618
(Increase) / decrease in fee income	(6 950 264)	95 852 523
(Increase) / decrease in interest received	(5 558 112)	1 993 438
Under expenditure on employee related costs	(5 790 060)	(68 681 994)
Over expenditure on operating leases	(3 212 275)	(9 616 144)
Under expenditure on operating expenses	(28 702 061)	(47 540 829)
Over expenditure on depreciation	7 016 149	5 558 241
Over expenditure on contracted services	2 480	(49 967)
Over expenditure on loss of disposal of assets	376 028	1 228 163
Over expenditure on bad debts	5 537 961	2 795 929
Increase in transfer of assets	-	(767 922)
Increase in gain on foreign exchange	(127 249)	(171 284)
Increase in sundry income	(213 059)	(2 325 801)
Decrease in grant received	-	2 580 000
Net surplus per approved budget	**-**	**-**

39. Budgeted differences

Material differences between budget and actual amounts

39.1 Fee and sundry income

Fee income is higher than budget due to the effect of fees gazetted and more applications received than anticipated. Sundry income is more than budget due to proceeds received, previously not budgeted for.

39.2 Interest received

Interest received is higher than the budget due to a higher interest rate received on invested cash at the Corporation for Public Deposits.

39.3 Employee-related costs

Employee related costs are lower than the budget due to delay in appointments.

39.4 Asset-related expenditure

Depreciation, impairments and loss on disposal are not budgeted for as SAHPRA utilises a cash basis for budgeting.

39.5 Operating expenses

Operating expenses are lower than budget due to planned expenditure not finalised as anticipated.

39.6 Backlog reduction project

Expenditure is more than budget due to applications not finalised as anticipated.

39.7 Lease rentals on operating lease

Expenditure is lower than budget due to delay in relocation of the Cape Town and Durban offices and the reassessment on levy rates which resulted in a significant credit note applied by the lessor.

39.8 Grant revenue

Grant revenue not budgeted for.

39.9 Non-cash expenditure

Non-cash expenditure is not budgeted for as SAHPRA utilises a cash basis for budgeting.

SAHPRA

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