# ANNUAL REPORT 2024/25


SAHPRA

South African
Health Products
Regulatory Authority

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Health Products
Regulatory Authority

# ANNUAL REPORT

FOR THE 2024/25 FINANCIAL YEAR


THE WINNER IS
SAHPRA
CERTIFICATE
SAHPRA
THE CEO'S AWARD

# CONTENTS

# PART A

## GENERAL INFORMATION

# 1. PUBLIC ENTITY'S GENERAL INFORMATION

| | |
|---|---|
| **REGISTERED NAME:** | South African Health Products Regulatory Authority (SAHPRA) |
| **REGISTRATION NUMBER (if applicable):** | Not applicable |
| **PHYSICAL ADDRESS:** | Building A, Loftus Park<br>402 Kirkness Street, Arcadia<br>Pretoria, 0083 |
| **POSTAL ADDRESS:** | Private Bag X828<br>Pretoria<br>0001 |
| **TELEPHONE NUMBER/S:** | (012) 501 0300 |
| **FAX NUMBER:** | Not Available |
| **EMAIL ADDRESS:** | enquiries@sahpra.org.za |
| **WEBSITE ADDRESS:** | www.sahpra.org.za |
| **EXTERNAL AUDITORS:** | Auditor-General of South Africa |
| **BANKERS:** | ABSA |
| **COMPANY/BOARD SECRETARY** | Advocate Mpho Mphelo |

# LIST OF ABBREVIATIONS/ACRONYMS

| ABBREVIATION | EXPLANATION |
|---|---|
| AFS | Annual Financial Statements |
| ADR | Adverse Drug Reaction |
| AEFI | Adverse Event Following Immunisation |
| AGSA | Auditor-General of South Africa |
| AI | Artificial Intelligence |
| AMA | African Medicines Agency |
| AMDF | African Medical Devices Forum |
| AMHPRA | African Medicines and Health Products Regulatory Authority |
| AOP | Annual Operational Plan |
| AUDA | African Union Development Agency |
| B-BBEE | Broad-Based Black Economic Empowerment |
| BMGF | Bill and Melinda Gates Foundation |
| CEO | Chief Executive Officer |
| 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 |
| EE | Employment Equity |
| EWHP | Employee Wellness and Health Programme |
| FY | Financial Year |
| 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 |
| HPA | Health Products Authorisation |
| HR | Human Resource |
| HRREMCO | Human Resource and Remuneration Committee |
| HVAC | Heating, Ventilation, and Air Conditioning |
| ICT | Information Technology and Communication |
| INCB | International Narcotics Control Board |
| IVDs | In Vitro Diagnostics |
| MD | Medical Device |
| ML | Maturity Level |
| MOU | Memorandum of Understanding |
| NAP | National Action Plan |

| | |
|---|---|
| **N/A** | Not Applicable |
| **NCE** | New Chemical Entity |
| **NCL** | National Control Laboratory |
| **NDoH** | National Department of Health |
| **NEPAD** | New Partnership for Africa's Development |
| **NRA** | National Regulatory Authority |
| **OHS** | Occupational Health and Safety |
| **PERSAL** | Personal and Salary System |
| **PFMA** | Public Finance Management Act |
| **PIC/S** | Pharmaceutical Inspection Co-operation Scheme |
| **PMDS** | Performance Management Dispensation System |
| **QMS** | Quality Management System |
| **RAG** | Risk Audit and Governance Committee |
| **SAHPRA** | South African Health Products Regulatory Authority |
| **SAPC** | South African Pharmacy Council |
| **SANCL** | South African National Control Laboratory |
| **SCM** | Supply Chain Management |
| **SEIAS** | Socio-Economic Impact Assessment System |
| **SFMP** | Substandard and Falsified Medical Products |
| **TORS** | Technical Oversight and Regulatory Strategy Committee |
| **VEC** | Ventilator Evaluation Committee |
| **WHO** | World Health Organization |
| **WSP** | Workplace Skills Plan |

# 2. FOREWORD BY THE CHAIRPERSON

**DR. THAPELO MOTSHUDI**
***Chairperson Of The Board***

## 2.1. INTRODUCTION

As Chairperson of the South African Health Products Regulatory Authority (SAHPRA), I am pleased to present the Annual Report from April 2024 to March 2025. This year has been marked by significant progress and notable challenges as we continue to navigate the dynamic landscape of public health regulation in South Africa. Our steadfast commitment to safeguarding human and animal health through science-based regulatory decisions remains the foundation of our mandate. Over the next five years, we will prioritise digital transformation—including integrating Artificial Intelligence (AI)—while responding to stakeholder needs and securing financial sustainability.

Aligned with the strategic objectives of the National Department of Health (NDoH) and the National Health Insurance (NHI), SAHPRA focused on five priority outcomes during the 2024/25 financial year:

- Enhanced stakeholder engagement
- Streamlined internal processes
- Strengthened organisational capacity
- Financial sustainability
- Improved accountability and performance monitoring

Despite ongoing funding constraints, SAHPRA successfully achieved a significant proportion of its targets within the confines of a reduced budget. The Board, concluding its final term, has exercised rigorous oversight to ensure alignment with national health priorities, grounded in transparency, accountability, and ethical governance.

SAHPRA has further solidified its position as a leading regulatory authority on the African continent through strategic collaborations. Our partnerships with the World Health Organization (WHO), African Medicines Agency (AMA), industry stakeholders, academic institutions, and the Department of Health have been instrumental in our regulatory advancement.

**Key milestones include:**

- Signing a Memorandum of Understanding (MoU) with the Africa Centres for Disease Control and Prevention (Africa CDC) and AUDA-NEPAD to streamline regulatory processes across WHO Maturity Level 3 National Regulatory Authorities.
- MoUs with international counterparts, including the Therapeutic Goods Administration (Australia), BoMRA (Botswana), Rwanda FDA, and MCAZ (Zimbabwe), aimed at

enhancing cooperation to combat substandard and falsified medicines and facilitate access to innovative therapies.

- The Board encountered several challenges during the reporting period, including limited resources, capacity constraints, regulatory backlogs, and global supply chain disruptions. Nevertheless, SAHPRA demonstrated resilience and adaptability. The accelerated adoption of digital systems has enhanced our responsiveness to emerging health threats and improved the efficiency of our regulatory processes.
- Risk management and ethical governance remain pillars of SAHPRA's operations. Strengthened internal controls and positive audit outcomes underscore our commitment to accountability. Our comprehensive risk mitigation frameworks ensure regulatory integrity and adherence to high compliance standards.
- SAHPRA will continue to drive regional regulatory harmonisation, particularly in collaboration with the African Medicines Agency (AMA). We are committed to ongoing innovation in our regulatory practices to address evolving public health challenges.
- In partnership with the NDoH, SAHPRA has piloted the WHO's Draft Handbook on National Action Planning for the Prevention, Detection, and Response to Substandard and Falsified Medical Products (SFMPs). Given Africa's disproportionate burden of SFMPs, this year-long initiative aims to develop robust, collaborative strategies to combat such threats and support achieving Sustainable Development Goal 3.
- A significant achievement during the year was SAHPRA's successful attainment of ISO 9001:2015 certification. This certification reflects the implementation of a comprehensive Quality Management System and affirms our commitment to the quality, safety, and efficacy of health products.

I wish to express my sincere gratitude to Dr Boitumelo Semete-Makokotlela, the executive leadership team, and all SAHPRA staff for their performance and professionalism throughout the year. Their dedication has been instrumental in advancing our regulatory mandate.

To our stakeholders—government entities, industry partners, academic institutions, and the public—thank you for your continued partnership and collaboration. And lastly, I would like to thank the second SAHPRA Board for their commitment to building SAHPRA into a world-class regulatory authority. All these stakeholders have worked to ensure that South Africans and other global citizens have access to safe, effective, and quality health products.

**Dr. Thapelo Motshudi**
*Chairperson of the Board*

**Date:** 31 August 2025

# 3. CHIEF EXECUTIVE OFFICER'S OVERVIEW

**DR. BOITUMELO SEMETE-MAKOKOTLELA**
**Chief Executive Officer**

## 3.1. INTRODUCTION

Reflecting on the year under review, it is important to contextualise our performance and achievements against SAHPRA's journey since its inception in 2018. Despite facing numerous challenges, including budgetary constraints, undergoing a transition during a global pandemic and limited resources, we have made steady and impactful progress. SAHPRA has remained resolute in safeguarding public health in South Africa. Our commitment to ensuring health products' safety, efficacy, and quality has been unwavering, and this financial year has been marked by significant achievements and strategic advancements.

### Key Strategic Achievements

SAHPRA has made notable progress across several regulatory oversight areas, reinforcing its role as a leading regulatory authority:

- **Regulatory Efficiency:** Streamlined the approval of health products and implemented innovative regulatory review practices.
- **Pharmacovigilance:** Strengthened pharmacovigilance systems across various provinces to ensure the safe use of health products and maintain public trust.
- **Digital Transformation:** Advanced digital technologies to improve regulatory efficiency, data management and stakeholder engagement.

### Stakeholder Engagement

Effective communication and collaboration with stakeholders are critical to SAHPRA's success. During the year, we enhanced stakeholder relationships through various initiatives:

- Conducted public awareness campaigns and webinars to promote medicine safety, appropriate usage, and regulatory compliance.
- Collaborated with industry partners and healthcare providers to advance SAHPRA's mandate.
- Participated in national, regional and global forums to share knowledge, exchange best practices and improve regulatory capabilities.

### Governance and Operational Excellence

SAHPRA continues to uphold the highest standards of governance and operational integrity:

- **Compliance with Governance Acts:** Achieved effective implementation of its core governing Acts, being the Medicines and Related Substances Act and the Hazardous Substances Act.
- **Sustainable Operations:** Revised service fee structure which was approved and subsequently gazetted.
- **Staff Development:** Promoted a skilled workforce by investing in professional development aligned with evolving regulatory demands.
- **Risk Management:** Applied a robust risk management framework to ensure regulatory compliance and public safety.

## Financial Performance

SAHPRA's total revenue amounted to R502.9 million against a budget of R417.6 million. The variance of R85.3 million was mainly due to an exceeding budget for revenue and additional external funding support received during the year.

SAHPRA spent R449.1 million against the initial approved budget of R417.6 million. The additional expenditure was allowed due to an unbudgeted external financial support received.

The overall result was an accounting surplus amounting to R53.9 million and exceeding the annual cash flow ration target of 1:1. The focus was on improving previous audit outcomes as well as positioning SAHPRA for financial sustainability.

**The entity has:**

- Achieved an unqualified audit with no material matters raised (2023/24).
- Enforced finance and supply chain policies and standards resulting in minimising of irregular, fruitless and wasteful expenditure.
- A significant revision of the fee regulation was approved and implemented on 13 February 2025.

## Supply Chain and Asset Management

SAHPRA, a Schedule 3A public entity under the Public Finance Management Act (PFMA), manages its assets according to its Asset Management Policy.

**Key highlights include:**

- No infrastructure projects were undertaken, and no facilities were closed or downgraded.
- Lease arrangements for office accommodation are in place and appropriately disclosed.
- Asset acquisitions for the year totalled R12.2 million and intangible asset additions amounting to R8.9 million.
- Obsolete assets, such as old furniture and IT equipment, were disposed of responsibly, with most items fully depreciated.

## Supply Chain Management (SCM)

- SCM systems remain functional and compliant.
- No new irregular or wasteful expenditure was reported.
- All historical transgressions have been resolved in line with National Treasury guidelines.

## Capacity Limitations and Challenges Facing SAHPRA

For the year under review, SAHPRA set specific targets to enhance its capacity. These included:

- Achieve implementation of 70% of the recommendations identified in the 2023/24 staff employee satisfaction survey.
- Ensure that 80% of employees participate in the planned learning and development programmes to improve skills, knowledge, and overall performance.
- Fill at least 70% of the budgeted positions outlined in the Recruitment Plan to strengthen SAHPRA's capacity to achieve its mandate.
- Maintain a staff turnover rate below 10% to retain a competitive and experienced workforce.

Due to strong competition within the regulatory and pharmaceutical sectors, SAHPRA faces challenges in attracting and retaining skilled professionals, particularly in technical areas. By the end of the 2024/25 financial year, SAHPRA's workforce grew

from 309 to 331 employees, with 22 new hires. Only 72% (67 out of 93) of the budgeted positions were filled despite available funding. Delays in candidate suitability checks mainly caused this shortfall, offer negotiations and the need to re-advertise positions after candidates declined offers. These recruitment difficulties have increased the workload and pressure on existing staff.

To address capacity limitations, this includes reviewing current approved policies and developing more policies to establish consistent regulations and standards for managing personnel. This includes enhancing areas such as recruitment, onboarding, career development, retention, training, and performance management, all aimed at ensuring fair and equitable treatment of employees. These initiatives seek to reinforce internal capabilities and boost operational efficiency in the face of ongoing workforce challenges.

The entity implemented 70% of the recommendations from the 2023/24 staff employee satisfaction survey:

- By appointing Lyra (formerly ICAS) to promote employee welfare and well-being through the Employee Health and Wellness Programmes (EHWP). This initiative has notably increased employee engagement, reaching 65.5% participation.
- In November 2024, the entity hosted Wellness Days across three locations - Head Office on 08 November, Durban Regional Office on 18 November, and Cape Town Regional Office on 26 November. These events featured diverse activities focusing on physical exercise, health screenings, financial planning, and nutrition to enhance employees' overall well-being.
- Additionally, the entity held its first Annual General Meeting (AGM) on 29 November 2024, linking Pretoria and Cape Town in real-time via advanced audio-visual technology. During the AGM, 64 employees received long-service certificates recognising 5, 10, 15, and 25 years of continuous service. Thirteen (13) Staff Recognition Awards were also presented in categories such as the CEO Award, Ubuntu, Responsiveness, Integrity, Customer Satisfaction, Transparency, Efficiency, Excellence, and Technical Outputs.
- The Employee Wellness Programme included 31 health and wellness initiatives, such as trauma debriefing, grief and loss sessions, health awareness on hypertension, mental health, autism, financial wellness, lifestyle sessions, wellness marketing, and individual support sessions.
- To further enhance the programme, the entity established Memoranda of Understanding (MoUs) with Virgin Active for fitness benefits and Absa for financial benefits, reinforcing its commitment to comprehensive employee wellness.
- This comprehensive approach aligns with best practices in employee engagement, emphasising assessment, recognition, and provision of resources to support physical, mental, and financial well-being.

SAHPRA is committed to enhancing service delivery through comprehensive training and development programmes. The Workplace Skills Plan (WSP) was implemented to equip and empower officials with the necessary skills to improve service delivery. During the reporting period, 280 employees participated in various skills development programmes, and 16 youth graduates were recruited into graduate internships and community service initiatives. Despite financial constraints, SAHPRA successfully awarded bursaries to 22 employees to support their studies further, demonstrating its dedication to staff development and capacity building.

The organisation has the largest representation of African employees, comprising 81.5% of the total workforce (270 out of 331). Indian employees make up 7.5% (25 out of 331). White employees account for 6.3% (21 out of 331, while Coloured employees represent 4.5% (15 out of 331).

Women within the African and Indian groups contribute to an overall surplus of female employees. To promote workplace equity, addressing the underrepresentation of certain groups is essential. Recruitment strategies will focus on attracting more males, particularly Indian males, to achieve a more balanced workforce.

Targeted interventions will be implemented in areas identified as either over- or under represented to improve equity. These initiatives will be part of the upcoming five-year Employment Equity (EE) Plan.

During the 2024/25 period, various people-focused initiatives were implemented, resulting in a staff turnover rate of 6.9%, which is a 2.5% decrease compared to the previous year and remains well within the target of 10%. Despite this improvement, SAHPRA continues to experience difficulties with turnover in critical and scarce roles, leading to instability and disruption at both management and operational levels.

## Future Plans to Address Financial Challenges

In response to the African local manufacturing agenda, we have developed a policy to support local manufacturers of pharmaceutical products. In alignment with the African Union's agenda for health sovereignty and economic resilience, our government has formulated a comprehensive policy framework aimed at strengthening local pharmaceutical manufacturing. This policy is designed to reduce dependency on imported medicines, enhance national health security, and stimulate industrial development.

We are overhauling the Medicines Act to ensure that it is current and enabling in nature. To create a more responsive and innovation-friendly regulatory environment, we are undertaking a comprehensive overhaul of the Medicines Act. The revised legislation will be modernised to reflect international best practices and to support the growth of a robust local pharmaceutical industry.

I am excited about the positive developments on the continent that have seen SAHPRA enter into Memoranda of Understanding (MOUs) with the other seven Member States of the African Medicines and Health Products Regulatory Authority (AMHPRA), thus facilitating efficient access to medicines.

In South Africa, SAHPRA works closely with various stakeholders, including government agencies, healthcare providers, industry partners, and international regulatory bodies. By fostering strong partnerships, we can leverage collective expertise and resources to address complex health challenges. We intend to continue strengthening our partnerships with national regulatory authorities worldwide, as well as with the WHO.

Lastly, we have embraced Artificial Intelligence (AI) and will be implementing several pilots as part of the SAHPRA digital migration interventions. The digital transformation journey has streamlined capabilities and systems that ensure an efficient and responsive regulatory process. The first significant breakthrough was the successful deployment of DocuBridge in April 2024 - an advanced regulatory document management system that significantly improved submission quality through mandatory validations. This was the precursor to the Engagement Portal, launched on April 1, 2025, which integrates all regulatory systems under one platform, offering a single-entry point for applicants to manage applications, submissions, queries, and communication.

## Forward Outlook

In the year ahead, SAHPRA will prioritise:

- **Collaboration with the African Medicines Agency (AMA):** To harmonise regulatory standards and expand access to quality health products across the continent.
- **Innovation in Regulation:** To keep pace with rapid advancements in medical technologies and facilitate timely access to novel therapies.

## Acknowledgements and Conclusion

I would like to express my sincere gratitude to the SAHPRA Board, Executive Team, staff, and stakeholders for their unwavering support. Together, we have made tremendous progress in advancing public health and ensuring the safety and efficacy of health products in South Africa. We look forward to continuing regulatory excellence, innovation, and collaboration in the year ahead.

**Dr. Boitumelo Semete-Makokotlela**
*Chief Executive Officer*
SAHPRA

**Date:** 31 August 2025

# 4. STATEMENT OF RESPONSIBILITY AND CONFIRMATION OF ACCURACY FOR THE ANNUAL REPORT

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

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

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 Annual Financial Statements (Part F) have been prepared in accordance with the GRAP standards applicable to the public entity.

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

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

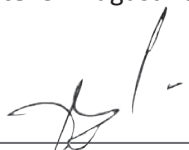
The external auditors are engaged to express an independent opinion on the annual financial statements.

In our opinion, the annual report fairly reflects the operations, the performance information, the human resources information and the financial affairs of the public entity for the financial year ended 31 March 2025.

Yours faithfully

**Dr. Boitumelo Semete-Makokotlela**
*Chief Executive Officer*

**Date:** 31 August 2025



**Dr. Thapelo Motshudi**
*Chairperson of the Board*

**Date:** 31 August 2025

# 5. STRATEGIC OVERVIEW

**VISION**

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

**MISSION**

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

**VALUES**

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

# 6. LEGISLATIVE AND OTHER MANDATES

## 6.1 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 states the following about 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

## 6.2 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, 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

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

This Act provides a framework for a structured uniform health system within the Republic, considering the obligations imposed by the Constitution and other laws of national, provincial and local government regarding health services. The objectives of the National Health Act, 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 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 about 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 encourages participation.
- Promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans; and
- Create the foundations of the health care system.

### *6.2.2 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, the objects of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, medical devices, radiation control, clinical trials and further matters related to the public interest.

The Act also provides for registration and control of veterinary medicines in such a way as to ensure that they are produced, distributed and used without compromising human and animal health. Antimicrobials intended for use in animals and registered under the Medicines Act can only be administered or prescribed by a veterinarian.

As per section 2b (1) of the Medicines Act, the Authority must, 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; and
- That clinical trial or clinical performance study protocols are assessed according to prescribed scientific, ethical and professional criteria and defined standards.

In executing its functions, the Authority may:

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

### *6.2.3 Hazardous Substances Act, 1973 (Act No. 15 of 1973)*

The Hazardous Substances Act provides for 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 ionizing or non-ionizing 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.

### *6.2.4 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 paraveterinary 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 (the Drugs Act); 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 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 Act 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 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 (Act No. 53 of 1974) regulates the practice of pharmacy within South Africa. 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 and relevant provisions of the Medicines and Related Substances Act. The Medicines Act, 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 license as completed in section 22C of the Medicines Act. The SAPC has, in terms of section 38A of the Pharmacy Act, appointed inspection officers with a view to monitoring pharmacies for compliance. The provisions of the Pharmacy Act 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, 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."

## 6.3 POLICY MANDATE

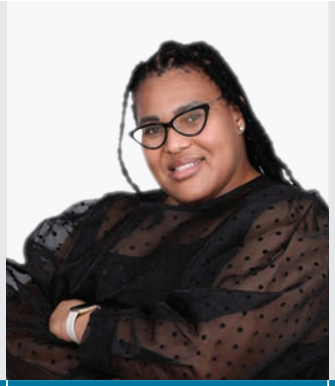
In 2018, the Constitutional Court of South Africa ruled that the personal and private use of cannabis is no longer a criminal offence. This decision means that the Authority needs to navigate how cannabis is regulated, especially regarding its non-medicinal use. The Authority has the mandate to regulate scheduled medicines, and cannabis remains a Schedule 6 drug in South Africa, except in specific medical contexts. With the ruling, the agency needs to determine how to regulate non-medical cannabis, which now exists in a legal grey area for personal use. The Authority already regulates medical cannabis, but with broader acceptance of recreational use, the Authority needs to refine and strengthen regulations to differentiate between recreational and medicinal cannabis use to prevent misuse or confusion. It is imperative that as an agile regulator, SAHPRA takes proactive action in tackling the regulatory framework relating to this area and strengthen collaborative partnerships with various government departments in bringing alignment to the various legislations supporting enhanced and broader access to cannabis-based products. The entity therefore currently participates in the national policy discussions that pertain to legislative and policy framework considerations related to cannabis and the industrialisation thereof. To this effect, SAHPRA has transferred all non-medical cannabis permits to the Department of Agriculture and has also indicated that the Department of Agriculture will set its limits of the percentage of Cannabinoids and Tetrahydrocannabinol in these products. In additional the Department of Agriculture will also report to the International Narcotics Control Board (INCB) on the THC quantities utilised under the permits it issues.

Secondly, SAHPRA as an organ of state and a public entity is required to align itself to the local support and with the national imperatives to support the national response in public health emergencies through supporting local manufacturers of health products. To this end, in accordance with its vision of being responsive and an enabler, SAHPRA has taken the position that, within its mandate of enabling access to medicines based on their safety, quality and therapeutic efficacy as per Section 1(3) of the Medicines Act, it will take steps to enable local manufacturing of health products needed to address critical public health needs.

# 7. ORGANISATIONAL STRUCTURE

# 8. MEMBERS OF THE BOARD (as at end of the FY)

**Prof. Helen Rees**
(Chairperson)

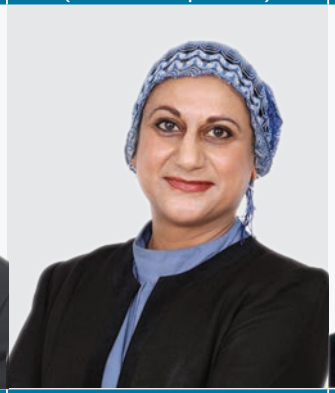


**Dr Obakeng Khaole**
(Vice-Chairperson)

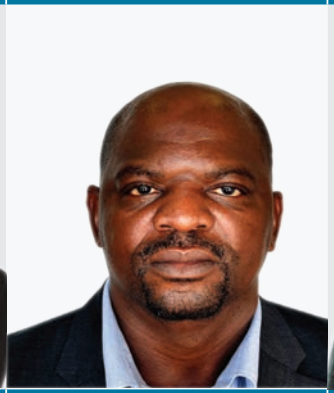
**Mr Itani Mashau**

**Ms Ditaba Maraka**

**Prof. Patrick Demana**



**Adv. Hasina Cassim**



**Dr Xolani Ngobese**

**Ms Lerato Mothae**

**Prof. Joyce Tsoka-Gwegweni**

**Dr Alfred Kgasi**

**Prof. Johanna C Meyer**

**Ms Mandisa Skhosana**

**Prof. Yahya Choonara**

**Dr Zinhle Makatini**

# 9. EXECUTIVE MANAGEMENT

**Dr Boitumelo Semete-Makokotlela**
*Chief Executive Officer (CEO)*

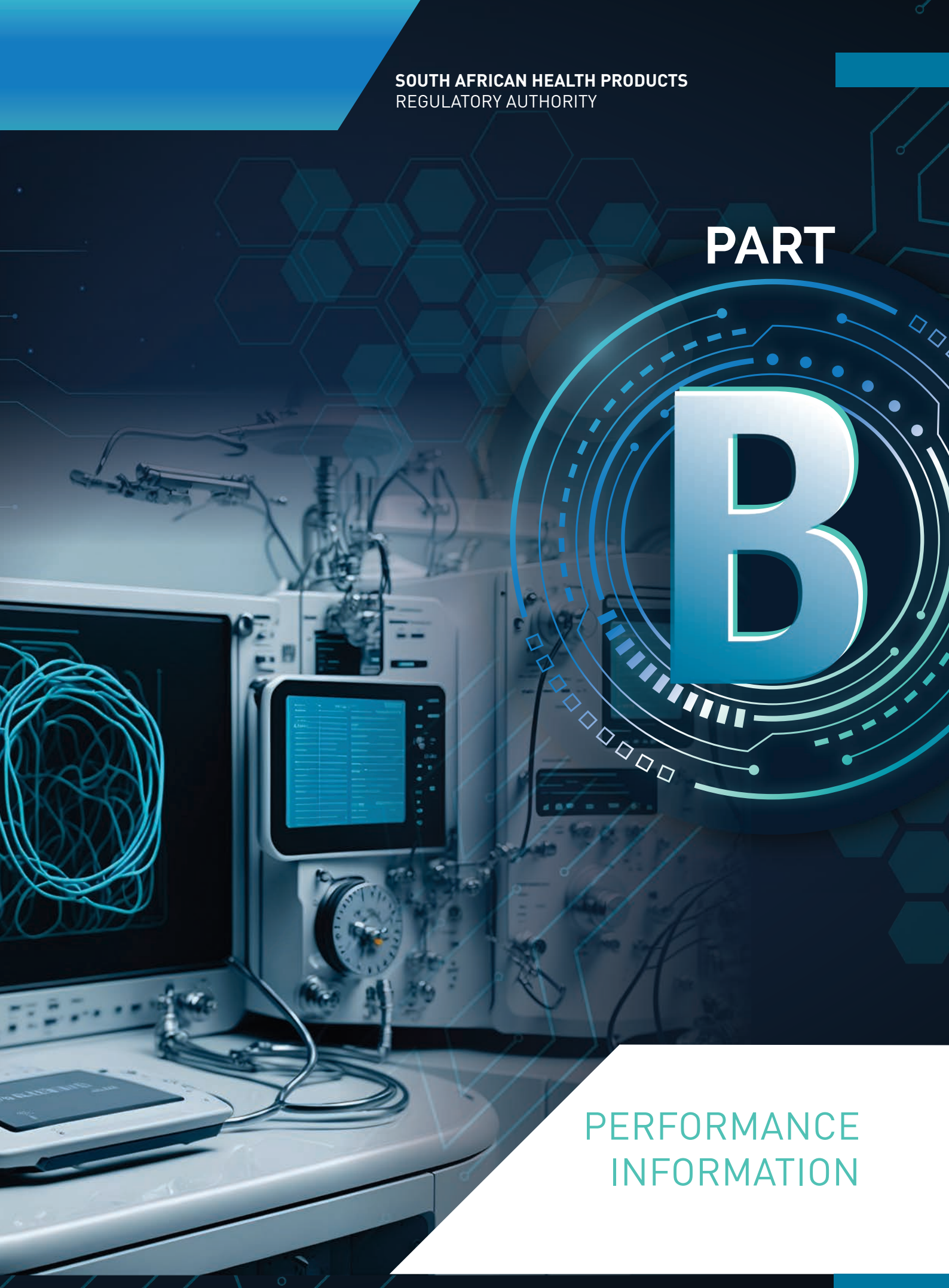
**Thavendree (Tammy) Gopal**
*Chief Regulatory Officer*

**Mr Regardt Gouws**
*Chief Financial Officer*

**Ms Lindiwe Johannah Modisakeng**
*Executive Manager: Human Resources*

**Ms Christelna Reynecke**
*Chief Operations Officer*

**Advocate Mpho Mphelo**
*Board Secretary*



# PART B

# PERFORMANCE INFORMATION

# 1. AUDITOR'S REPORT: PREDETERMINED OBJECTIVES

The AGSA currently performs the necessary audit procedures on the performance information in accordance with the AGSA findings engagement methodology. The engagement is not an assurance engagement and therefore an assurance opinion or conclusion is not expressed in the audit report.

Refer to page 100 of the Report of the Auditors Report, published as Part F: Financial Information.

# 2. OVERVIEW OF PERFORMANCE

## 2.1. Service Delivery Environment

### *2.1.1 Overall performance*

Since inception over 6 years ago, SAHPRA has been on a transformation journey into an autonomous public entity accountable to the Minister of Health. As part of this transition journey, SAHPRA has already made significant progress in implementing several organisational shifts including:

- Re-engineered processes to clear the backlog and sustain business as usual
- Building internal capabilities and expertise to limit reliance on external experts
- Cultural renewal to ensure the organisation is sensitive to the context in which it operates; and interacts, responds and adapts to situations, its stakeholders, and the external environment

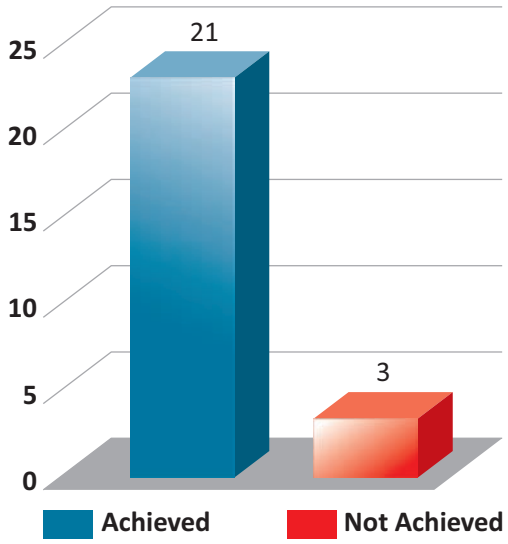
In Africa, a continent with 54 countries, SAHPRA is amongst Africa's six (6) national medicine regulatory authorities that have achieved the ML3 ranking. Maintaining of ISO 9001 certification has aligned SAHPRA with the Regional Strategy for the Regulation of Medicinal Products which provides that all member states must have national regulatory authorities for medicines that are functional and with systems of quality management the year 2025.

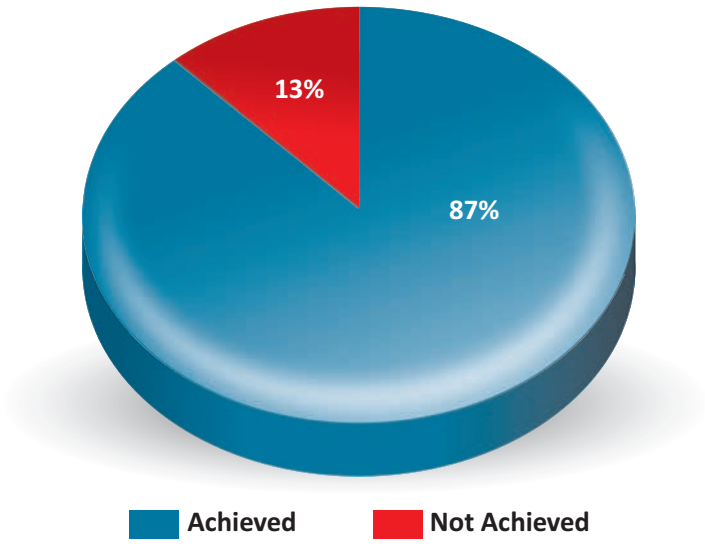
SAHPRA's areas that still need improvement relates to full Implementation of the digital transformation strategy and subsequent multi-year road map, financing and filling of critical roles, achievement of all targets in the core function of the Authority:

- Issuance of licences for new Good Manufacturing Practice and Good Warehouse Practice within the target times lines
- Finalisation of new product and generic applications in the target time lines
- Publications and implementation of regulations for Medical Devices and IVDs as well as Complementary Medicines
- Implementation of pharmacovigilance strategy at a national level in partnership with the NDoH and Provincial health departments
- Regular post-market surveillance of health products

In terms of the performance against its 2024/25 Annual Performance Plan, the Authority planned to achieve 24 targets. Of the 24 planned targets, the Authority was able to achieve 21 targets which equates to 87% achievement, as depicted in the graphs below:

**SAHPRA's 2024/25 ORGANISATIONAL PERFORMANCE**




During the period under review the South African Health Products Regulatory Authority was able to deliver on 21 of its 24 predetermined targets. Such key achievements can be summarised as follows:

- Current ratio of 1≥1 was maintained by achieving 1:1.27. SAHPRA's total revenue amounted to R502.9 million against a budget of R417.6 million. The variance of R85.3 million was mainly due to additional external funding support received during the year.
- 100 % of new chemical entities were finalised within 360 working days.
- 100% of generic medicines were finalised within 250 working days.
- SAHPRA successfully managed to maintain the International Organisation for Standardisation (ISO) 9001 Certification by SABS.
- 93% of permits were finalised within 20 working days.
- 96% of applications for the sale of unregistered Category A (human) medicines were finalised within 3 working days.
- 94% of human clinical trial applications finalised within 80 working days.
- 128,4% medical device establishment license applications were finalised within 90 working days
- 92% of applications for listed-electronic products finalised within 30 working days.

The Authority encountered various levels of underachievement against planned targets due to under-capacitated business units and challenges in attracting and retaining top talent, particularly in the technical field, because of competition in the health, regulatory, and pharmaceutical sectors. For targets that faced difficulties resulting in non-achievement, the Authority has identified the reasons for these deviations and has implemented relevant plans and mitigating measures.

### *2.1.2 Challenges*

The global supply chain provided a challenge to SAHPRA's IRC program, particularly regarding the glucagon-like peptide (GLP-1) agonist molecules. With the growing demand for these molecules and short supply from manufacturers, this created a prime situation for illicit products, this being unauthorised, substandard or falsified medicines. This resulted in an increase in demand for SAHPRA's regulatory compliance resources to investigate and enforce the requirements of the Medicines Act. At the end of the financial year, SAHPRA had initiated an intention to declare the compounding of GLP-1 and GIP/GLP-1 medicines, to reduce the occurrence of unauthorised high-risk products being made available to the public.

Locally, the capacitation of the OR Tambo port with 2 border medicine control technicians has maintained the flow of authorisations for incoming shipments, however, supplier concerns in terms of Airports Company South Africa (ACSA) posed a risk to presence of SAHPRA at the border and acceptable service delivery, where SAHPRA technicians were not able to have office accommodations to service the review of incoming shipments. An eventual contract with ACSA provided the necessary accommodation for the border technicians and service delivery recommended. This highlighted the need for collaboration at the ports of entry between various port authorities. As a result, the SAHPRA the Border Management Authority (BMA) initiated a Memorandum of Understanding to further collaborate efforts for prevention, detection and response to SF Medicines and ensure regulation of the authorised supply chain for medicinal products.

Lot Release function is dependent on a few aspects such as submission of complete information from applicants, the reliance on the SANCL to perform testing within expected timelines and lastly the dependence on the SAHPRA Service Desk System where post implementation support is dependent on an external administrator. The most challenges encountered were delays caused when the system administrator is unable to assist due to contract clauses which must be resolved before addressing the system issues.

Medical Devices and Radiation Control, the use of a manual system for application management and financial reporting always remains the challenge for both the unit and the applicant. This leads to delays in processing applications and delays in the payment of retention fees. Even though there are processes in place to mitigate the risks, it is however a risk that cannot be entirely avoided and implemented processes are not sustainable. This does not only affect the application process and collection of the applicable fees but also data quality, security of documents and efficient use of human resources within the sub-unit due to the manual capturing of data on various databases/platforms. In addition to the document security, several fraudulent medical device establishment licences were identified in a project where the unit was collaborating with the other stakeholders within the National Department of Health to verify licences upon issuing requests for quotation.

Human Clinical Trials: To ensure Good Clinical Practices in the conduct of clinical trials on humans, SAHPRA has regulatory oversight of human clinical trials conducted within South Africa. This oversight and monitoring ensure and facilitate the effective processing of clinical trial protocol applications to allow for approval of the conduct of clinical trials. Efficient approval of the conduct of clinical trials enables timely access to health research and development within an environment that guarantees the safety of clinical trial participants. The main challenges encountered in the area where resource constraints pertaining to personnel a optimal operating system to process applications. These were mitigated by recruitment of an additional two Medicines Registration Officers and commissioning of a more appropriate operating system to streamline processes.

Complementary Medicine Regulations. in response to the Supreme Court of Appeal (SCA) judgment on 11 April 2022, the Minister, published the amended Regulations of the General Regulations made in terms of the Medicines and Related Substances Act for comment. Following publication, the National Department of Health (NDoH) received comment from stakeholders and transmitted such comments to SAHPRA for review and consideration. During the review of the comments, SAHPRA noted that there were no substantive comments which necessitated rewriting of the Regulations of the draft amendments to the General Regulations, however the stakeholders mainly sought clarity on certain aspects of the regulations. Amendment to the Regulation focused on deletion of the existing definitions of complementary medicine with replacement of reference to regulation 9 and the existing establishment of Category D medicines. The draft Amendments seek to address the deficiencies identified by the court and align with the SCA and High Court judgments, which stated that only substances classified as "medicines", or "scheduled substances" as defined in section 1 of the Medicines Act should be subject to regulation and included in the scope of Category D medicines. The revised Regulations as submitted now align with the definition of a medicine and provide for anything that is a medicine or scheduled substance to be regulated under the Medicines Act.

The proposed amendment to the General Regulation has been recommended by South African Health Products Regulatory Authority (SAHPRA) and referred to National Department of Health Legal Services Unit for further scrutiny and for facilitation of publication in the Gazette. In addition to this legal scrutiny, the Department has recommended that a Socio-Economic Impact Assessment System (SEIAS) be conducted, which SAHPRA is currently engaging and consulting on.

### *2.1.3 Developments*

Inspectorate and Regulatory Compliance, Although the acute phase of the COVID-19 pandemic had passed, its long-term effects continued to influence public health priorities. This affected the IRC program and its strategies, especially regarding demand for more oversight of vaccines and the need for capacity building in this area, not only for South Africa but for the African continent. SAHPRA's response to this included the recruitment of specialists in the areas of GMP to facilitate local capacity building and the commencement of plans to capacitate an NRA on the African continent. SAHPRA's work on the continent also involved having experienced representation on the Good Manufacturing Practices (GMP) Technical Committee for the African Medicines Regulatory Harmonization (AMRH), where SAHPRA chaired the committee and participated in overseeing the training of African Inspectors.

Since its inception, SAHPRA has communicated its mandate more effectively to the public, educating them on its regulatory roles and enforcement actions. Consequently, the Regulatory Compliance Unit has frequently collaborated with law enforcement and other agencies to enhance the enforcement of the Medicines Act.

Lot Release, in the last cycle the measles outbreak continued from 2023 to most of 2024 impacting on prioritising the release of measles vaccines. The Mpox outbreak required for Lot release to be considered in absence of registration and no method transfer therefore the lots released for Mpox relied primarily on certification from recognised NCLs.

Medical Devices and Radiation Control, the finalisation of the updated Medical Device Regulations is underway. Comments were received from various stakeholders. The fees for Radiation Control have also been proposed. The Medical Device Regulations and Radiation Control fees will be submitted to the National Department of Health, pending the SEIAS report.

In 2024, the Africa CDC declared an emergency on Mpox due to the increase in the number of clinical cases in different countries within the continent including South Africa. Against the backdrop the continental joint review was initiated for an Mpox related in-vitro diagnostic. SAHPRA had representatives participating as assessors and committee members in the Medical Device Assessment Technical Committee (MDA-TC) in the 2nd Session of the Continental Joint Review of Mpox in-vitro diagnostics facilitated by the AMRH African Medical Devices Forum (AMDF) held in Rwanda.

This year saw the unit actively and routinely updating the Medical Device licence online database every six weeks for all establishment license holders. This provides the industry, the Departments of Health, Treasury and all interested parties with an up-to-date list of companies that are in possession of current and valid medical device establishment licences, and complaint as per Section 22C(1)(b) of the Medicines and Related Substances Act of 1965, as amended.

In the 2024/25 financial year, the Quality Management Systems (QMS) Unit continued to play a critical role in ensuring service excellence and regulatory compliance within SAHPRA's operations. The external service delivery environment remained complex, with evolving stakeholder expectations and heightened regulatory scrutiny requiring the QMS Unit to remain responsive and resilient.

Clinical Evaluations Management, Health Product Safety Signals: SAHPRA (The Authority) has fully embraced the e-reporting of adverse drug reactions (ADRs) and adverse events following immunisation (AEFIs), for both the public and healthcare workers. To this end, SAHPRA is central to the promotion of the Med Safety App in the Republic, which has been internationally adopted as the e-reporting platform of choice for both ADRs and AEFIs. SAHPRA's Pharmacovigilance Unit has also initiated the train-the-trainer (TTT) programme to mitigate the national pharmacovigilance shortcomings identified by the World Health Organization (WHO) in its ongoing assessments of medicine regulatory systems as part of health systems strengthening. This training programme is intended to improve knowledge and awareness of pharmacovigilance amongst healthcare professionals as the first port of call for patients who may not easily recognise ADRs and AEFIs and thereby improve the reporting of suspected ADRs. Supporting measures in increasing reporting and capturing of ADRs and AEFIs have entailed capacitation of SAHPRA Pharmacovigilance by continuous recruitment of additional Medicines Registration Officers and Pharmacovigilance Specialists to increase ADR and AEFI causality assessment capabilities within the Authority, supported by AUDA/NEPAD through the continental A3S medicine safety data collection and analytic initiative.

## 2.2. ORGANISATIONAL ENVIRONMENT

Manual processes for tracking submissions and approval statuses remains to be a challenge. Manual tracking systems of large data can result in human errors, thus compromising the data. At the end of 2023-24 FY, the tracking system used by HPA involved the manual recording of large amounts of data at key steps in the process for new medicine registrations on Google Sheets. The limited functionality on Google Sheets resulted in manual calculations for performance reporting as there is no stop clock mechanism available to perform the required calculations for timelines. However, in 2024/25, the new digital portal was implemented for functions such as applications, variations and response submissions.

Filling of the critical roles of the HR Executive, Chief Regulatory Officer and appointment of community service.

Digital operations were implemented for different workstreams in the organisation.

The internal environment during the 2024/25 financial year presented the QMS Unit with a strategic opportunity to strengthen SAHPRA's internal capabilities, promote compliance, and deepen the culture of quality across the organisation.

Health Products Authorisation (HPA) experienced challenges in terms of postponement of the deployment of the SAHPRA Engagement Portal that resulted in manual processes for tracking submissions, approval statuses and performance reporting. Manual tracking systems of large data can result in human error. However, with the appointment of the Senior Manager HPA, Renewals Manager, External evaluators for Renewals, Technical screeners and Community Service Pharmacists, supported the streamlining of processes in HPA. Importing of submissions to the evaluation tool was automated and significantly reduced the manual ways of working and the timeline for submissions to be accessible for review.

Inspectorate and Regulatory Compliance, in this financial year, the Licensing unit achieved more than double its achieved percentage in 2023/2024, year on year, assisted by the amended Technical Indicator Descriptor removing application time spent with applicants, however, the target was still not achieved due to continued experience capacity challenges in the Inspectorate. The rate of inspection of new license applications was insufficient to achieve the licensing target. The Inspectorate Unit is focused on balancing priorities in terms of demands on the inspection plan and resources are being recruited to handle evaluation workstream work within the Inspectorate to free up inspectors to conduct new license application inspections.

The Inspectorate focused on delayed dossier reviews for the purposes of product registration, with improved coordination within the HPA assisting in the tracking and completion of delayed and priority applications. To alleviate the workload on internal inspectors used within the dossier review process, the Inspectorate Unit initiated recruitment of six external evaluators in Quarter 1. Although improvement was seen within this workstream, internal targets for the reduction of the backlog was not achieved. This resulted in management recalling the inspectors from the inspections process and allocating them to evaluation workstream processes. The Inspectorate will continue to balance resources to maintain momentum and keep the inspections process ongoing to avoid backlog in inspections. Resources were increased in the Inspectorate with the allocation of a community service pharmacist.

Due to the increased number of investigations logged, the achievement of the target related to regulatory compliance investigations was not achieved during the year, however, the unit focused on solutions within the process to achieve this target at the end of the financial year. The unit is experiencing more regulatory compliance investigation triggers than previous years, adding to the strain on current resources to initiate and provide reports for investigations within 30 working days as per the performance indicator.

A further development in the fight against SF medicines was the initiation of the pilot of the WHO Handbook for National Action Plans (NAPs) for SF Medicines in Quarter 2. SAHPRA initiated its situational analysis and stakeholder mapping in preparation for the pilot implementation in Quarter 2. Within Quarter 4, SAHPRA formed the Steering Committees and Working Groups which form the basis of the governance model required for the NAP and by the close of the financial year, the operational plan for the NAP was in development. It is anticipated that the NAP pilot will be completed and launched within the next financial year, which will enhance collaborative efforts in the detection, prevention and response to SF Medical Products.

Quarter 4 saw SAHPRA undergoing its PIC/S reassessment as a Participating Authority, with the initial report from the assessors expected in Quarter 1 2025/2026. Lot Release- SAHPRA challenges experienced on Lot Release during the 2024/25FY relates to an increased number of local manufactured vaccines mostly intended for export. The South African National Control Laboratory (SANCL) has proposed a model for consideration based on risk approach and which will be further developed into a framework by the BMU. Hence the need for the BMU to be developing processes and systems to accommodate for this purpose.

Medical Devices Unit, the medical device registration subunit is still busy with the Medical Device (MD) Registration feasibility study and to date a total of 15 applicants are participating voluntarily in the study. Thirty-two (32) products were targeted for study, however, the unit to date received 22 products for the study from voluntary participants as per expression of interest (EoI). In quarter four, 18 products applications were received from 12 applicants. This includes products categorised under the product risk classification- Class C and D In Vitro diagnostics (IVDs) and non-IVDs products for HIV and TB. The technical team continued to evaluate and by end of the financial year one product was tabled for approval.

Clinical Evaluations Management, Sale of Unregistered Category A (Human) Medicines: The Medicines Act (Act 101 of 1965, as amended) provides for the sale of unregistered medicines and other health products under certain circumstances. These include compassionate use for unmet medical needs. This occurs when a registered alternative is either not available or does not meet the identified medical need of the patient. The Medicines Act, therefore, allows for access to health products that are not registered in South Africa but are available in other markets. This is an important public health intervention to ensure prompt access to life-saving health products if these are not otherwise available to prevent disease complications. The main challenges encountered in the area were constraints pertaining to a manual system to process applications. The new financial year will see the implementation of an online operating system

**Measures SAHPRA adopted to mitigate the impact mentioned above:**

- Enforced finance and supply chain policies and standards result in a reduction of irregular, fruitless and wasteful expenditure.
- Efficient working capital management has been implemented that will ensure SAHPRA can meet its short-term obligations. This was achieved through quarterly monitoring of the liquidity ratio.
- Revised service fees structures approved and gazette.
- The Authority will use Technology Consultancy services to finalise the implementation of custom development solutions across the Core Business and Support units.

## 2.3. KEY POLICY DEVELOPMENTS AND LEGISLATIVE CHANGES

The change in the schedules regarding tetrahydrocannabinol (THC), amended the requirement for SAHPRA to licence all activities related to cultivation of cannabis for medicinal purposes. The responsibility for cultivation of cannabis (cultivation to harvesting of the plant) was moved to the Plant Improvement Act, which is under the Department of Agriculture. At the end of the financial year, SAHPRA was still awaiting the publishing of the Good Agriculture Practice standard and certification system by the Department of Agriculture, in order for SAHPRA to make the necessary amendments to the licencing guidelines with respect to steps required to be licenced by SAHPRA.

B-BBEE policy position for SAHPRA was approved by the Board and published.

New SAHPRA fees gazetted in February 2025.

## 2.4. PROGRESS TOWARDS ACHIEVEMENT OF INSTITUTIONAL IMPACTS AND OUTCOMES

SAHPRA's revised 2024/25 Annual Performance Plan was approved in January 2025 as approved by the Minister. The revisions were made to the technical indicator description for 2.1 and 2.2 Programme 2 Health Products Authorisation.

### *2.4.1 Progress on Outcomes*

| MEDIUM TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH | | | |
|---|---|---|---|
| **OUTCOMES** | **OUTCOME INDICATORS** | **FIVE-YEAR TARGET** | **PROGRESS AT 2024/25** |
| **Effective compliance, financial and performance management (1)** | 1.1 Unqualified audit opinion with no material findings obtained on the annual financial statements | Clean audit opinion obtained for the 2023/24 financial year. | Clean audit opinion is obtained for the 2023/24 financial year |
| **Financial sustainability achieved (2)** | 1.2 Total revenue generated from fees in the financial year | Annual revenue of R185million generated from fees | Total Revenue generated from fees R254.7. |
| **Continuously respond to the needs and expectations of SAHPRA stakeholders (3)** | 1.3 Percentage of accepted recommendations from the stakeholder perception survey implemented | 100% prioritised recommendations from the survey implemented | 100% of the recommendations implemented: Conducted a campaign on "How to contact SAHPRA" indicating how SAHPRA can be contacted for general enquiries and where to access contact details for specific services, web content relating specifically to contacting SAHPRA, comprising Frequently Asked Questions and guidance of where to direct questions and follow-ups would be developed. |
| **A positive and enabling working culture created (4)** | 1.4 Percentage of recommendations from the staff satisfaction survey implemented | Review of the change management intervention conducted | Progress report on implementation of 70% recommendations from the conducted 2023/24 Staff satisfaction survey submitted to EXCO: implementation of EHWP initiatives, the Job Evaluation Project in progress.<br>The ongoing communication with employees is maintained through HR circulars, Bi-weekly meetings with Unit Managers and quarterly meetings with Staff |
| **Attract and retain talent (5)** | 1.5 Percentage of positions in the staff establishment filled | 80% of positions in the staff establishment filled | Out of the 430 positions in the approved staff establishment, 311 staff compliment to date with 296 positions filled since 2020/21.<br>The turnover rate remained below 10% year on year. |

| MEDIUM TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH | | | |
|---|---|---|---|
| **OUTCOMES** | **OUTCOME INDICATORS** | **FIVE-YEAR TARGET** | **PROGRESS AT 2024/25** |
| **Strengthened Information and Communication Technology and digitisation (6)** | 1.6 Enterprise Architecture developed. | Phase 2 of the roadmap on the Enterprise Architecture implemented | 100% Enterprise Architecture Phase 2 implemented. Conducted User AT on Engagement Portal and Operationalise 4 core business on Stakeholder engagement portal – Section 21, New Registration, Amendments and Renewals. |
| **High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)** | 1.7 Number of New Chemical Entities Master Applications finalised annually. Number of Generics master applications finalised annually | 100% medicine registrations backlog cleared<br>100% medicine variation applications backlog cleared | 100% of applications cleared. Backlog project concluded.<br>100% of applications cleared. Backlog project concluded. |
| | World Health Organization Maturity Level obtained | World Health Organization Maturity Level 4 obtained | Maturity level 3 achieved for vaccines not for medicines. |
| **Efficient and effective regulatory practices maintained (8)** | 1.8 Percentage of new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days | 80% new Good Manufacturing Practice and Good Warehouse<br>Practice related licences finalised within 125 working days | 50% new GMP and GWP related licences finalised within 125 working days.<br>Out of 90 applications received, 60 (67%) were due for finalisation.<br>Out of 60 due for finalisation, 35 (58%) were finalised, of which 30 (50%) were finalised within 125 workings days |
| | Percentage of human clinical trial applications finalised within 90 working days | 80% human clinical trial applications finalised within 90 working days | 94% of human clinical trial applications finalised within 80 working days<br>Out of 166 applications received, 130 were due for finalisation<br>Out of 130 due for finalisation, 94% were finalised within 80 working days |
| | Medical device registration regulations implemented | Call-up of Class D (high-risk) | Pilot Call-up Notice of Class D (high-risk) for specific /selected disease criteria medical device products were not published.<br>Publication of Expression of Interest (EoI) for feasibility was published on the first quarter 2024/25FY |

# 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.

### *3.1.1 Sub-programmes*

| 2023/2024 | 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, ensure compliance with relevant legislation, and achieve an unqualified audit outcome by ensuring continuous management practices in compliance with standard operating procedures (SOPs) and systems within SAHPRA. Furthermore, to review existing operational processes and recommend new or changed processes and work methods to ensure optimal organisational effectiveness and to measure and monitor the Authority's performance. |
| **Information Technology and Communication** | To develop and implement an ICT-integrated governance framework by focusing on the business continuity plan and supporting the needs and requirements of end users. Furthermore, to manage public relations, information and communication services to ensure proper management and dissemination of information to internal and external stakeholders, and to ensure a seamless, harmonious operational platform by building strong and sustainable relationships with all stakeholders. |
| **Human Resource Management** | To provide HR and organisational development systems and solutions that meet the needs of the organisation and support the achievement of the Authority's strategic objectives. |

#### Financial and Supply Chain Management

SAHPRA's total revenue amounted to R502.9 million against a budget of R417.6 million. The variance of R85.3 million was mainly due to additional external funding support received during the year.

SAHPRA spent R449.1 million against the initial approved budget of R417.6 million. The additional expenditure was allowed due to unbudgeted for external financial support received.

The overall result was an accounting surplus amounting to R53.9 million and exceeding the annual cash flow ration target of 1:1. The focus was on improving previous audit outcomes as well as positioning SAHPRA for financial sustainability.

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

- Achieved an unqualified audit with no material matters (Clean Audit 2023/24).
- Exceeded the budget set for fee income.
- Enforced finance and supply chain policies and standards resulting in a reduction of irregular, fruitless and wasteful expenditure.
- Revised fee regulation approved and implemented to ensure future sustainability.

**Human Resources Management** is acknowledged as a strategic partner, playing a vital role in fulfilling the Authority's goals by offering efficient and effective HR services. It also collaborates with both core and support functions, supporting efforts to attract, develop, retain, and sustain a skilled and capable workforce within SAHPRA.

For the reporting year, SAHPRA established clear objectives to build its organisational capacity. These goals included:

- Implementing 70% of the action items identified in the 2023/24 employee satisfaction survey.
- Ensuring that at least 80% of staff members take part in scheduled learning and development initiatives to enhance their skills, knowledge, and overall job performance.
- Filling a minimum of 70% of the positions budgeted in the Recruitment Plan, thereby reinforcing SAHPRA's ability to fulfil its mandate.
- Keeping staff turnover below 10% to retain a skilled and experienced workforce.

## OUTCOMES, OUTPUTS, OUTPUT INDICATORS, TARGETS AND ACTUAL ACHIEVEMENTS

| PROGRAMME 1 ADMINISTRATION | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| **Effective compliance, financial and performance management (1)** | Attain and maintain an unqualified overall Auditor General Audit outcome on the previous year's performance | Unqualified audit opinion obtained on the annual financial statements | Unqualified audit opinion obtained for the 2021/22 financial year | Unqualified audit opinion obtained for the 2022/23 financial year | Unqualified audit opinion obtained for the 2023/24 financial year | Clean audit opinion is obtained for the 2023/24 financial year | None | None |
| **Financial sustainability achieved (2)** | Liquidity ratio of ≥ 1 | Current assets ≥ than current liabilities | - | Current ratio of 1:16.1 achieved | Current ratio of 1≥1 maintained | The target of a more than 1:1 current ratio has been achieved at: 1:1.27 | None | None |
| **Responsive to stakeholder needs (3)** | Survey conducted | Stakeholder survey conducted | Out of 5 accepted commendations from the 2020/21 stakeholder perception survey the following 3 (60%) were implemented:<br>• Document management system<br>• Online application system was tested | 2023/24 Stakeholder perception survey was conducted, and outcomes of such survey were presented at EXCO. | Progress report on implementation of 60% recommendations of the conducted 2023/24 stakeholder perception survey submitted to EXCO for approval. Plan to address Recommendations were approved by EXCO. Progress report on the implementation plan from the 2023/24 | 100% of the recommendations implemented, against a target of 60%: Conducted a campaign on "How to contact SAHPRA" indicating how SAHPRA can be contacted for general enquiries and where to access contact details for specific services, web content relating specifically to contacting SAHPRA. | None | None |

| PROGRAMME 1 ADMINISTRATION | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | | | • Online medicines register is live | | Stakeholder Perception Survey was submitted to the Executive Committee. | comprising Frequently Asked Questions and guidance of where to direct questions and follow-ups would be developed. | | |
| **A positive and enabling working culture created (4)** | Survey conducted. | Progress report on the implementation plan from the 2023/24 Stakeholder Perception Survey was submitted to the Executive Committee. | - | Plan to address Recommendations were approved by EXCO. | Progress report on implementation of 70% Recommendations from the conducted 2023/24 Staff satisfaction survey submitted to EXCO | Progress report on implementation of 70% Recommendations from the conducted 2023/24 Staff satisfaction survey submitted to EXCO: implementation of EHWP initiatives, the Job Evaluation Project in progress. The Ongoing communication with employees is maintained through HR circulars, Bi-weekly meetings with Unit Managers and quarterly meetings with Staff | None | None |

| PROGRAMME 1 ADMINISTRATION | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | Learning and development initiatives implemented | Percentage of learning and development initiatives implemented | 80% employees trained on out of 459 training initiative planned, 68 (15%) were implemented the planned learning and development initiatives | Total number of employees trained as per the training matrix - 354 and the total number of employees for the year ended 31 March 2024 is 307 resulting in 115,31% employees trained. | 80% of employees trained on an approved Learning and Development Initiatives Plan | 85% (280/331) of employees trained on an approved Learning and Development Initiatives Plan. | None | SAHPRA employees attended more external training offered by various independent stakeholders of the industry |
| **Attract and retain talent (5)** | Budgeted positions filled | Percentage of budgeted positions filled | 65% budgeted positions filled, 48 budgeted positions and 26 positions funded through Global Fund which 18 have been filled, (65%) was achieved. | 46 positions were funded to be filled for 2023/24 financial year, however, 67,4% (31/46) only of these positions were filled as of 31st March 2024 | 70% budgeted positions filled | 72% (67 out of 93) of the budgeted positions have been filled, including Community Service positions planned for recruitment in the 2024/25 financial year. | None | None |
| | Technical staff retained | Percentage of staff retained | - | Annual staff turnover rate was 9.4%. remained below 10% target | Staff turnover rate less than 10% | The turnover remained at 1.2% (4 out of 331 employees), remaining below the target of 10%. Over April 2024 to | None | None |

| PROGRAMME 1 ADMINISTRATION | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | | | | | | March 2025, staff turnover at 6.9% (23 out of 331 employees) left SAHPRA, still within target of 10%. | | |
| **Digital transformation (6)** | Enterprise Architecture | Percentage of Phase 1 Enterprise Architecture implemented | The Enterprise Architecture has not been approved by the Board. | Implementation of 100% Enterprise Architecture Phase 1 was not completed. However, RIMS and TC service provider appointed Draft URS for Data Management tool and Analytics | 100% Enterprise Architecture Phase 2 implemented | 100% Enterprise Architecture Phase 2 implemented. Conducted User AT on Engagement Portal and Operationalise 4 core business on Stakeholder engagement portal – Section 21, New Registration, Amendments and Renewals | None | None |

## Strategy to overcome areas of underperformance

HR successfully achieved all four of its committed annual targets for the 2024/25 financial year. When comparing staffing progress to the previous year, there has been a notable improvement: in the 2023/24 financial year, **67.4%** of funded positions were filled **(31 out of 46)**, whereas in 2024/25, **71%** of budgeted positions have been filled **(56 out of 93)**, which includes the recruitment of 12 Community Service positions planned for this period. This demonstrates both an increase in the total number of positions and a higher proportion of roles filled compared to the previous year.

### Linking performance with budgets

| Programme /activity / objective | 2024/2025 | | | 2023/2024 | | |
|---|---|---|---|---|---|---|
| | Budget | Actual Expenditure | (Over)/ Under Expenditure | Budget | Actual Expenditure | (Over) / Under Expenditure |
| | R'000 | R'000 | R'000 | R'000 | R'000 | R'000 |
| Programme 1 | 168 129 | 194 849 | (26 720) | 134 908 | 180 600 | (45 692) |
| **Total** | **168 129** | **194 849** | **(26 720)** | **134 908** | **180 600** | **(45 692)** |

### Strategy to overcome areas of under performance

The over -expenditure against budget is mainly due to external funding support received that is not included in the SAHPRA budget.

Digitisation of business processes, particularly the automation of SCM and Claims processes through appointment of service providers to develop such systems, continued to be applied as the strategy to overcome areas of underperformance.

HR successfully achieved all four of its committed annual targets for the 2024/25 financial year. When comparing staffing progress to the previous year, there has been a notable improvement: in the 2023/24 financial year, **67.4%** of funded positions were filled **(31 out of 46),** whereas in 2024/25, **71%** of budgeted positions have been filled **(56 out of 93),** which includes the recruitment of 12 Community Service positions planned for this period. This demonstrates both an increase in the total number of positions and a higher proportion of roles filled compared to the previous year.

## 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. This framework defines the requirements for application to the Authority, and to receive, record and distribute all documents submitted to SAHPRA.

### *3.2.1 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 making regulatory decisions about medicines (screening, dispatching to evaluators, coordinating reports, recommendations, responses, and 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 product lifecycle through post-marketing vigilance of registered products. Vigilance includes the soliciting of data through various approaches, monitoring, analysis, and responsive action, including the provision of feedback. In addition, a fully staffed backlog project team led by a senior project manager and linked to this sub-programme will be established. |

| Sub-Programme | Purpose |
|---|---|
| **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 for application to the Authority. Details on the assessment procedure, the grounds for approval or rejection of the application, and the circumstances where authorisation already granted may be cancelled, withdrawn, suspended, or revoked are provided. |
| **Licensing, permits and certificates portfolio management** | The purpose is to manage and coordinate the process of licensing and amendments in respect of medicine manufacturers, wholesalers and medical device establishments and the issue of permits and registration certificates within a legislative framework that defines the requirements for application to the Authority. Details on the assessment procedure (based on quality, efficacy and safety criteria), the grounds for approval or rejection of the application, and the circumstances where a registration, licence or authorisation already granted may be cancelled, withdrawn, suspended, or revoked are provided. |
| **Quality Management System** | The purpose of the Quality Management Systems (QMS) Unit is to establish, maintain, and continuously improve a structured framework that ensures SAHPRA consistently delivers regulatory services of the highest quality. Through the implementation of ISO 9001:2015 standards, the QMS Unit promotes compliance with applicable laws and regulations, enhances operational efficiency, and fosters a culture of quality and accountability across the organisation. |
| **Health Products Authorisation** | 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. This framework defines the requirements for application to the Authority, and to receive, record and distribute all documents submitted to SAHPRA. |

Out of 350 (340 human plus 10 veterinary) New Chemical Entity (NCE) applications received (inclusive of applications carried over from the previous financial year 2024/2025), 46 (41 human plus 5 veterinary) (13%) NCEs were due for finalisation by the end of the financial year 2024/2025. Although 46 applications were due for finalisation, 134 (100%) were finalised, of which 122 (100%) were finalised within 360 working days from the date of completion of technical screening at Inspectorate. The rest of the applications were finalised between 362 and 683 working days.

Out of 2 691 (2 653 human plus 38 veterinary) generic applications received (inclusive of applications carried over from the previous financial year 2024/2025), 149 (133 human plus 16 veterinary) (6%) were due for finalisation by the end of the financial year 2024/2025. Although 149 applications were due for finalisation, 568 (100%) were finalised, of which 469 (100%) were finalised within 250 working days from the date of completion of technical screening at Inspectorate. The rest of the applications were finalised between 259 and 671 working days.

Various strategies are being utilised by the evaluation teams which include the implementation of different forms of reliance including participating in ZAZIBONA, Swissmedic MAGHP and EU M4ALL, which are collaborative process, for the evaluation of new medicine applications and making use of assessment reports from Recognised Regulatory Authorities and SAHPRA.

The products registered encompass therapeutic areas such as serum-cholesterol reducers, anti-hypertensives, antihistamines, anti-convulsants, anti-depressants, anti-coagulants, anti-acids, anti-infectives, oncology, oral hypoglycaemics, sedatives, vascular medicines, ophthalmic preparations, immunosuppressants, contraceptive preparations, migraine preparations, corticosteroids, anti-parkinsonism preparations, tuberculostatics and antivirals.

## OUTCOMES, OUTPUTS, OUTPUT INDICATORS, TARGETS AND ACTUAL ACHIEVEMENTS

| PROGRAMME 2: HEALTH PRODUCTS AUTHORISATION | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| **Efficient and effective regulatory practices maintained (7)** | New Chemical Entities (NCEs) applications finalised | Percentage of New Chemicals Entities finalised within 360 working days | 100 % New Chemical Entities finalised within 490 working days<br>Out of 342 applications received, 0 (0 %) were due for finalisation<br>Although no applications were due for finalisation, 89 (100%) were finalised within 490 workings days | 100 % New Chemical Entities finalised within 400 working days.<br>Out of 224 applications received, 30 (13 %) were due for finalisation.<br>Although 30 applications were due for finalisation, 103 (100%) were finalised, of which 91 (100 %) were finalised within 400 workings days | 80% New Chemical Entities finalised within 360 working days | Out of 350 applications received, 46 (13%) were due for finalisation.<br>Although 46 applications were due for finalisation, 134 (100%) were finalised, of which 122 (100%) were finalised within 360 working days | +25% over-achieved | Adherence to evaluation timelines by evaluators.<br>Efficient collaboration and coordination between units maintained. |
| | Generic medicines applications finalised | Percentage of generic medicines finalised within 250 working days | 57 % generic medicines finalised within 250 working days | 86% generic medicines finalised within 250 working days. | 75% generic medicines finalised within 250 working days | 100% generic medicines finalised within 250 working days. | None | +33% overa-chievement |

| PROGRAMME 2: HEALTH PRODUCTS AUTHORISATION | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | | | | | | Out of 2 691 applications received, 149 (6%) were due for finalisation.<br>Although 149 applications were due for finalisation, 568 (100%) were finalised, of which 468 (100%) were finalised within 250 working days. | | |
| **Global best practices maintained (8)** | International Organization for standardisation (ISO) 9001: 2015 certified | International Organization for standardisation 9001: 2015 certification obtained | All planned activities in the Implementation roadmap have been concluded. | International Organization for Standardization 9001: 2015 was certified | Certification status of the ISO 9001: 2015 maintained | Certification status of the ISO 9001: 2015 maintained | None | None |
| | World Health Organization Global benchmarking conducted | World Health Organization Maturity level assessed | WHO Maturity level 3 obtained | Maturity Level 4 self-assessment was not conducted. | WHO Maturity Level 3 obtained for medicines | Target not achieved.<br>Maturity level 3 for medicines not obtained. | Target not met. | WHO ML3 assessment was deferred to Q3 of the 2025/26 FY. WHO ML3 assessment is scheduled for November 2025. |

*Report is against the originally tabled Annual Performance Plan with changes approved by the Minister on 29/01/2025 as per below:)*

### Technical Indicator Descriptions 2.1 and 2.2 for Programme 2: Health Products

| | |
|---|---|
| **2.1 Indicator Title: Percentage of New Chemical Entities (NCEs) finalised* within 360 working days** | Revised indicator definition: Quantification of NCEs (active substances that have not yet been registered by the Regulator) finalised within 360 working days, calculated from the date when an application passes technical screening at Inspectorate Unit. |
| **2.2 Indicator Title: Percentage of generic medicines finalised* within 250 working days** | Revised indicator definition: Quantification of generics (multi-source medicines that contain the same chemical substance as the NCE) finalised within 250 working days, calculated from the date when an application passes technical screening at Inspectorate Unit. |

### Linking performance with budgets:

| Programme/activity/ objective | 2024/2025 | | | 2023/2024 | | |
|---|---|---|---|---|---|---|
| | Budget | Actual Expenditure | (Over)/ Under Expenditure | Budget | Actual Expenditure | (Over)/ Under Expenditure |
| | R'000 | R'000 | R'000 | R'000 | R'000 | R'000 |
| Programme 2 | 42 410 | 41 704 | 706 | 36 268 | 34 058 | 2 209 |
| **Total** | **42 410** | **41 704** | **706** | **36 268** | **34 058** | **2 209** |

## 3.3 PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE

**Purpose:** To ensure public access to safe health products through inspections and regulatory compliance. This program evaluates site adherence to good regulatory and vigilance practices, including disclaimers.

- Good Manufacturing Practice (GMP)
- Good Clinical Practice (GCP)
- Good Warehouse Practice (GWP)
- Good Distribution Practice (GDP)
- Good Laboratory Practice (GLP)
- Good Vigilance Practice (GVP)

#### *3.3.1 Sub-programmes*

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

## OUTCOMES, OUTPUTS, OUTPUT INDICATORS, TARGETS AND ACTUAL ACHIEVEMENTS

| PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| Efficient and effective regulatory practices maintained (7) | New Good Manufacturing Practice and Good Warehouse Practice related licences finalised | Percentage of new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days | 22% new GMP and GWP related licences finalised within 125 working days<br>Out of 73 applications received, 54 (74%) were due for finalisation | 27% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days.<br>Out of 76 applications received, 60 (79%) were due for finalisation. | 60 % new Good Manufacturing Practice - and Good Warehouse Practice -related licences finalised within 125 working days | 50% new GMP and GWP related licences finalised within 125 working days.<br>Out of 90 applications received, 60 (67%) were due for finalisation. | Target not met. | The target was not met due to the complexity and volume of applications received, which required additional time for verification of compliance to GMP and GWP standards.<br>Additionally, the coordination between the Licensing and Inspectorate units, as well as the prioritisation of new license applications on the inspection plan, impacted the timely finalisation of licences. |

| PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | | | Out of 54 due for finalisation, 28 (51%) were finalised, of which 12 (22%) were finalised within 125 workings days | Out of 60 due for finalisation, 20 (33%) were finalised, of which 16 (27%) were finalised within 125 workings days | | Out of 60 due for finalisation, 35 (58%) were finalsed, of which 30 (50%) were finalised within 125 workings days | | |
| | Permits finalised | Percentage of permits finalised within 20 working days | 79% permits finalised within 20 working days<br>Out of 4 305 applications received, 4 285 (99.5%) were finalised, of which 3 | 94% permits finalised within 20 days. Out of 4448 applications received, 4275 (96%) were finalised, out of which 4171 (94%) were finalised within 20 working days | 80% permits finalised within 20 working days | 93% permits finalised within 20 days.<br>Out of 5123 applications received, 5103 (100%) were finalised, out of which 4749 (93%) were finalised within 20 working days | None | None |
| | Regulatory compliance investigation reports | Percentage of regulatory compliance investigation reports produced within 30 working days | 72% regulatory compliance investigation reports produced within 30 working days 297 complaints received, 290 (97%) reports were produced, of which 215 (72%) were produced within 30 working days | 72% Regulatory compliance investigation reports produced within 30 working days. | 75% regulatory compliance investigation reports produced within 30 working days | 81% Regulatory compliance investigation reports produced within 30 working days. | None | Improved adherence to business processes. |

| PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | | | | Out of 430 complaints received, 400 (100%) reports were produced, of which 310 (72%) were produced within 30 working days. | | Out of 507 complaints received, 505 (100%) reports were produced, of which 410 (81%) were produced within 30 working days. | | |

### Linking performance with budgets:

| Programme/activity/ objective | 2024/2025 | | | 2023/2024 | | |
|---|---|---|---|---|---|---|
| | Budget | Actual Expenditure | (Over)/ Under Expenditure | Budget | Actual Expenditure | (Over)/ Under Expenditure |
| | R'000 | R'000 | R'000 | R'000 | R'000 | R'000 |
| Programme 3 | 55 570 | 56 365 | (795) | 53 154 | 49 220 | 3 934 |
| **Total** | **55 570** | **56 365** | **(795)** | **53 154** | **49 220** | **3 934** |

### Strategy to overcome areas of under performance

To address evaluation backlogs, the Inspectorate recalled all GMP inspectors in mid-February, boosting new product registrations in Q4. They will continue balancing resources to maintain inspection momentum and prevent future delays. A community service pharmacist was added to increase resources. SAHPRA underwent its PIC/S reassessment as a Participating Authority, with the initial report expected in Q1 2025/2026.

## 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 the delegated authority and in terms of the relevant legislation, as listed in the legal mandate in part 1a of the strategic plan.

### *3.4.1 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 trials conducted are scientifically sound, in accordance with the South African GCP guidelines and to ensure the safety and protection of the 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 quality, safety and efficacy (QSE) 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 to determine their QSE, and to register and/or regulate them for use where applicable. |
| **Veterinary Medicines** | To evaluate the safety, efficacy and quality of veterinary medicines. |
| **Lot Release** | Lot release is the process of evaluating each individual lot of a registered vaccine in South Africa before giving approval for its release into the market. The processing of lot release by SAHPRA involves review of the lot summary protocols with independent testing or review of lot summary protocol with recognition of tests (acceptance of lot release certificates) from the responsible National Regulatory Authorities or National Control Laboratories that SAHPRA aligns with. To date, lot release has been performed on all vaccines for use by the South African public and hence regulatory oversight on vaccines by SAHPRA is ensured |

Lot Release, the timeous release of vaccine lots enables access to vaccines within acceptable timelines. This provides assurance of SAHPRA's meeting annual targets of enabling timeous access to vaccines.

### Sale of Unregistered Category A (Human) Medicines

The Medicines Act (Act 101 of 1965, as amended) provides for the sale of unregistered medicines and other health products under certain circumstances. These include compassionate use for unmet medical needs. This occurs when a registered alternative is either not available or does not meet the identified medical need of the patient. The Medicines Act, therefore, allows for access to health products that are not registered in South Africa but are available in other markets. This is an important public health intervention to ensure prompt access to life-saving health products if these are not otherwise available to prevent disease complications. The main challenges encountered in the area where resource constraints pertaining to both personnel and optimal operating system to process applications.

### Human Clinical Trials

To ensure Good Clinical Practices in the conduct of clinical trials on humans, SAHPRA has regulatory oversight of human clinical trials conducted within South Africa. This oversight and monitoring ensure and facilitate the effective processing of clinical trial protocol applications to allow for approval of the conduct of clinical trials. Efficient approval of the conduct of clinical trials enables timely access to health research and development within an environment that guarantees the safety of clinical trial participants.

### Health Product Safety Signals

SAHPRA participated in the world Med Safety App week which took place from the 4th to 10th November 2024. To commemorate this important event, SAHPRA held a Med Safety Webinar on the 13th of November 2024 with the intention to promote safe use of medicine and encourage members of the public to always report suspected ADRs using Med Safety APP. The pharmacovigilance unit has initiated the train-the-trainer planning in response to the pharmacovigilance shortcomings identified during the WHO GBT assessment in 2022. The unit has started with implementation of the train-the-trainer, and the Free State province was first to be trained. This training is meant to improve the knowledge and awareness of pharmacovigilance amongst healthcare professionals and therefore improve the reporting of suspected adverse drug reactions.

## OUTCOMES, OUTPUTS, OUTPUT INDICATORS, TARGETS AND ACTUAL ACHIEVEMENTS

| PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATIONS | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| **Efficient and effective regulatory practices maintained (7)** | Applications for the sale of unregistered<br>Category A (human) medicines finalised | Percentage applications for the sale of unregistered<br>Category A (human) medicines<br>finalised within 3 working days | Number of applications received: 18 083. 7% of applications finalised within 3 working days.<br>Out of 169409 received and responded to, 15918 were finalised within 14 784 (87%) applications finalised within 3 working days. | 81% of Regulatory compliance investigation reports produced within 30 working days.<br>Out of 507 complaints received, 505 (100%) reports were produced, of which 410 (81%) were produced within 30 working days. | 90% of applications for the sale of unregistered Category A (human) medicines finalised within 3 working days | Number of applications received (cumulative): 20 245<br>Number of applications responded to 20 245<br>Number of applications finalised: 20 225<br>Number of applications finalised within 3 working days: 19 509<br>Actual: 19 509/20 245 *100% = 96% | Positive variance of 6% | Result of staff dedication |
| | Human clinical trial applications finalised | Percentage of human clinical trial applications finalised within 80 working days | 104% human clinical trial applications finalised within 90 working days. | 91% of human clinical trial applications finalised within 80 working days. | 80% of human clinical trial applications finalised within 80 working days | 94% of human clinical trial applications finalised within 80 working days | 14% over -achievement | Continued improvement of business process and SOP<br>Improved quality checks |

| PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATIONS | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | | | Out of 239 applications received, 163 (68%) were due for finalisation.<br>Out of 163 due for finalisation, 184 (113%) were finalised, of which 169 (104%) were produced within 30 working days. | Out of 249 applications received, 207 (83%) were due for finalisation.<br>Out of 207 due for finalisation, 218 (105%) were were finalised of which 189 (91%) were finalised within 80 working days. | | Out of 166 applications received, 130 were due for finalisation<br>Out of 130 due for finalisation, 94% were finalised within 80 working days | | |
| | Health product safety signals issued | Percentage on health product safety signals issued within 40 working days | Out of 298 signals received, 251 (84.2%) signals were due for finalisation.<br>Out of 251 signals due for finalisation, 169 (67.3%) reports were issued, of which 101 (40.2%) were issued within 40 working days | Out of 456 signals received, 446 (97.81%) were due for finalisation by end March 2024<br>Out of 446 due for finalisation, 343 (76.91 %) reports were issued, of which 196 (43.95%) were issued within 40 workings days. | 50% reports on health product safety signals issued within 40 working days | 185 reports on health product safety signals issued within 40 working days<br>Out of 301 signals received, 321 (106,64 %) cumulative were due for finalisation by end Mar 2025 | Positive variance of 7% | Attributed to improved systems and dedicated staff. |

| PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATIONS | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | | | | | | Out of 321 due for finalisation, 427 (133,02%) cumulative reports were issued, of which 185 (57%) were issued within 40 workings days | | |
| | Number of awareness campaigns held | Number of awareness campaigns held | Six safety webinars on medication errors were held in 2023) | Twelve safety awareness campaigns held | Eight safety awareness campaigns held | 19 safety awareness campaigns were held: | Overachieve-ment | Webinars and face-to-face campaigns held for the year |

| PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATIONS | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | Lot release requests finalised | Percentage of lot release requests finalised within 50 working days | 81%, From a total number of 226 lot release requests received since the commencement of the SAHPRA lot release process to the 31st of March 2023, 182 (81%) were due for finalisation. Out of 182 due | 220 lot release requests received for 2023/24 FY, 170 (77.27%) were due for finalisation. 170 were finalised with 24 more which were not due for finalisation, that aggregates to 194 (113.53%) finalised. 175/170 | 95% of lot release requests finalised within 50 working days lot release requests finalised | 200 requests for lot release were received in the cycle 2024-25. 150 (100%) of 200 was due for finalisation within 50WD. 183 (122%) were finalised and of these 150 (100%) were completed within the 50WD. | Target achieved | Enhancements in the handling of lot release requests including streamlined workflows, faster document review cycles, and improved communication with stakeholders have significantly increased efficiency and turnaround times. |

### Linking performance with budgets:

| Programme/activity/ objective | 2024/2025 | | | 2023/2024 | | |
|---|---|---|---|---|---|---|
| | Budget | Actual Expenditure | (Over)/ Under Expenditure | Budget | Actual Expenditure | (Over)/ Under Expenditure |
| | R'000 | R'000 | R'000 | R'000 | R'000 | R'000 |
| Programme 4 | 120 033 | 115 526 | 4 506 | 125 618 | 119 413 | 6 204 |
| **Total** | **120 033** | **115 526** | **4 506** | **125 618** | **119 413** | **6 204** |

### Strategy to overcome areas of under performance

**Sale of Unregistered Category A (Human) Medicines,** these were mitigated by recruitment of an additional Medicines Registrations Officer and introduction of a more appropriate operating system to streamline processes.

**Human Clinical Trials,** the main challenges encountered in the area where resource constraints pertaining to personnel and optimal operating system to process applications. These were mitigated by recruitment of an additional two Medicines Registrations Officers and commissioning of a more appropriate operating system to streamline processes.

**Health Product Safety Signals,** the main challenges encountered in the area where resource constraints pertaining to personnel to process submissions in a timely manner. This was mitigated by recruitment of an additional Medicines Registrations Officer and a Pharmacovigilance Specialist.

Lot Release, Whilst the targets set at 95% finalised within 50 working days as calculated in terms of technical indicator descriptor it must be emphasised that this included lots that were not due for finalisation and that there were batches due for finalisation within 50 working days that may not have been finalised within the 50 working days. The root cause for these which were permissible for 5% (100-95) % will be investigated to reduce any possible risk of not being finalised on time.

## 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.

### *3.5.1 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 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, OUTPUTS, OUTPUT INDICATORS, TARGETS AND ACTUAL ACHIEVEMENTS

| PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| **Efficient and effective regulatory practices maintained (7)** | Medical device establishment license applications finalised | Percentage of medical device license applications finalised within 90 working days | 136% of medical device establishment licence applications finalised within 90 working days<br>Out of 1 379 applications received, 692 (50%) were due for finalisation<br>Out of the 692 due for finalisation, 1206 (174%) were finalised, of which 943 (136%) were finalised within 90 working days | 126,6% of medical device establishment licence applications finalised within 90 working days<br>Out of 1298 applications received, 880 (67,8%) were due for finalisation.<br>Out of the 880 due for finalisation, 1205 (136,9%) were finalised, of which 1114 (126,6%) were finalised within 90 working days. | 80% of medical device establishment licence applications finalised within 90 working days | 128.4% of medical device establishment licence applications finalised within 90 working days<br>Out of 1475 applications received, 1051 (71.3%) were due for finalisation.<br>Out of 1475 applications received, 1051 (71.3%) were due for finalisation. | 48.6 overa-chievement | Continuous improvement of business processes and efficient collaboration and coordination between units maintained. |

| PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | Medical device registration regulations implemented | Notice of medical device products published | Guidelines have been placed on hold until the regulations are finalised from NDOH | Expression of interest for medical device voluntary registration feasibility study approved and published on social media platforms for coming engagement towards implementation. The upcoming feasibility study must first be conducted prior to embarking on Call-Up Notice of pilot Class D update being published. | Pilot Call-up Notice of Class D (high-risk) for specific selected disease Pilot Call-up Notice of Class D (high-risk) for specific selected disease criteria medical device products published | Pilot Call-up Notice of Class D (high-risk) for specific / selected disease criteria medical device products were not published.<br>Publication of Expression of Interest (EoI) for feasibility was published on the first quarter 2024/25FY social media platforms for coming engagement towards implementation.<br>The upcoming Feasibility study must first be conducted prior embarking on Call-up Notice of pilot Class D) update being published. | Target not met. | Legal department has advised medical device registration subunit to change the APP Target from call up notice of pilot (high-risk) product published to Publish EoI for product registration feasibility study for high-risk class C and D for selected priority diseases criteria, as the outcome will not be registration/n certification but report of the outcome/ learnings of the process. study, hence it could not be published in the Government Gazette. |

| PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | Radionuclide authorities (licences) finalised | Percentage of applications for radionuclide authorities (licences) finalised within 30 working days | 83% applications for radionuclide authorities were finalised within 30 working days Out of the 2742 applications received 2380 (86%) were due for finalisation.<br>Out of 2380 due for finalisation 2384(100%) were finalised of which | 79% application for authorities were finalised within 30 working days 2486 application received of 2486 application received, 2311 applications were due for completion before 31 March 2024. 846 applications that were due for completion | 70% applications for radionuclide authorities (licences) finalised within 30 working days | 86% application for authorities were finalised within 30 working days 2397 Applications received.<br>2191 applications were due for completion before 31 March 2025.<br>2086 (95%) applications were completed<br>930 Applications that were due for completion were issued.<br>804 (86%) Of the issued Authorities were issued within 30 workdays. | 16% Overa-chievement | Continued improvement of business process and SOP<br>Improved quality checks |

| PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Outcome** | **Output** | **Output Indicator** | **Audited Actual Performance 2022/2023** | **Audited Actual Performance 2023/2024** | **Planned Annual Target 2024/2025** | **Actual Achievement 2024/2025** | **Deviation from planned target to Actual Achievement 2024/2025** | **Reasons for deviations** |
| | License applications for listed electronic products finalised | Percentage of license applications for listed electronic products finalised within 30 working days | 169% licence applications for listed-electronic products were finalised within 30 working days<br>Out of 1115 applications were received, of which 627 (56%) were due for finalisation.<br>Out of 627 due for finalisation, 1115 (178%) were finalised of which 1057 (169%) were finalised within 30 working days | 116% applications for listed-electronic products finalised within 30 Working days.<br>851 applications were received, out of 837 received 720(84%) were due for finalisation.<br>Out of 720 due for finalisation 851(118%) were finalised.<br>Out of 851 finalised, 836 (116%) were finalised within 30 working days. | 90% licence applications for listed-electronic products finalised within 30 working days | 92% applications for listed-electronic products finalised within 30 Working days.<br>1624 applications were received, out of 1624 received 1534(94%) were due for finalisation.<br>Out of 1534 due for finalisation 1624(106%) were finalised.<br>Out of 1624 finalised, 1412(92%) were finalised within 30 working days | 2% overachieve-ment | Continued improvement of business process and SOP<br>Improved quality checks |

### Linking performance with budgets:

| Programme/activity/ objective | 2024/2025 | | | 2023/2024 | | |
|---|---|---|---|---|---|---|
| | Budget | Actual Expenditure | (Over)/ Under Expenditure | Budget | Actual Expenditure | (Over)/ Under Expenditure |
| | R'000 | R'000 | R'000 | R'000 | R'000 | R'000 |
| Programme 5 | 43 913 | 40 664 | 3 249 | 44 848 | 35 408 | 9 441 |
| **Total** | **43 913** | **40 664** | **3 249** | **44 848** | **35 408** | **9 441** |

## 4. REVENUE COLLECTION

| Sources of revenue | 2024/2025 | | | 2023/2024 | | |
|---|---|---|---|---|---|---|
| | Estimate | Actual Amount Collected | (Over)/Under Collection | Estimate | Actual Amount Collected | (Over)/Under Collection |
| | R'000 | R'000 | R'000 | R'000 | R'000 | R'000 |
| Fee income | 248 508 | 254 737 | (6 229) | 212 672 | 231 178 | (18 506) |
| **Total** | **248 508** | **254 737** | **(6 229)** | **212 672** | **231 178** | **(18 506)** |

Better than anticipated revenue collection occurred due to higher-than-expected application numbers received for evaluation of clinical trials, medical device licensing, improvement of retention fee collection and an increased output rate on new medicine applications. Revenue recognition will improve as SAHPRA fills funded vacancies over the MTEF period.

# 5. CAPITAL INVESTMENT

**Provide commentary on the following:**

SAHPRA, a Schedule 3A public entity under NDoH, adheres to its Asset Management Policy per the PFMA (1999, as amended). It did not undertake any infrastructure projects or close/downgrade facilities this year.

No maintenance activities occurred during the year as the entity lacked significant infrastructure or moveable assets needing regular upkeep. SAHPRA's office lease expenses were properly disclosed in the annual financial statements.

For the 2024/25 financial year, SAHPRA acquired assets worth R21.2 million by March 31, 2025. These included motor vehicles (R1.5 million), computer equipment (R4 million), laboratory and office equipment (R6.5 million), and intangible assets (R8.9 million). Disposals involved outdated furniture and computer equipment, which were sold or donated, with many fully depreciated.

| Infrastructure projects | 2024/25 | | | 2023/24 | | |
|---|---|---|---|---|---|---|
| | Budget | Actual Expenditure | (Over)/Under Expenditure | Budget | Actual Expenditure | (Over)/Under Expenditure |
| | R'000 | R'000 | R'000 | R'000 | R'000 | R'000 |
| None | - | - | - | - | - | - |

# PART C

## GOVERNANCE

# 1. INTRODUCTION

Corporate governance embodies processes and systems by which SAHPRA is directed, controlled and held to account. In addition to legislative requirements based on a public entity's enabling legislation, and the Companies Act, corporate governance regarding public entities is applied through the precepts of the Public Finance Management Act (PFMA) and run in tandem with the principles contained in the King's Report on Corporate Governance.

Parliament, Minister of Health, the Executive and the Accounting Authority of the public entity are responsible for corporate governance.

# 2. PORTFOLIO COMMITTEES

The Parliamentary Portfolio Committee on Health exercises oversight over service delivery performance of the public entities reporting to the National Department of Health.

SAHPRA appeared before the Parliamentary Portfolio Committee on Health on the dates set out below:

| Date | Parliamentary Structure | Activity/ Focus |
|---|---|---|
| 21 August 2024 | Portfolio Committee on Health | Induction of newly appointed members serving on the Portfolio on Health. |
| 16 October 2024 | Portfolio Committee on Health | Presentation of the Annual Financial Statements and Annual Report 2023/2024 |
| 23 April 2025 | Portfolio Committee on Health | Presentation of the Strategic Plan, Annual Performance Plan and Budget 2025/2026 Financial Year. |

# 3. EXECUTIVE AUTHORITY

The Minister of Health is the Executive Authority. SAHPRA submits quarterly reports on its performance and activities to the Executive as mandated by the Medicines and Related Substances Act, Public Finance Management Act and National Treasury Regulations.

# 4. THE ACCOUNTING AUTHORITY/BOARD

SAHPRA is a Schedule 3A public entity that functions through its Board. The Board is appointed by the Minister of Health in line with the provisions of the Medicines and Related Substances Act. The Accounting Authority reports to the Minister of Health.

### Statement of Commitment

The Accounting Authority is committed to business integrity, transparency and professionalism in all its activities. As part of this commitment, the Accounting Authority supports the highest standards of corporate governance and the on-going development of best practice.

### Independence of the Board

Board members are appointed by the Minister of Health. The Board considers submissions and recommendations made by management and makes independent decisions based on their fiduciary responsibilities and the strategic direction of the authority.

The various Board committees meet independently and then report back to the Board. Each committee has a formal Terms of Reference that clearly defines its roles and responsibilities.

The Audit, Risk and Governance Committee (RAG) regularly meets individually with representatives of the Auditor-General South Africa (AGSA) and internal audit service providers. Furthermore, the Board, its committees and individual Board members may engage independent counsel and advisors upon request and at the discretion of the Board.

## 5. BOARD CHARTER

The mandate of the SAPHRA Board is set out in the Medicines and Related Substances Act, 101 of 1965 as amended and has been encapsulated in the Board Charter. The mandate of the Board as set out in the Board Charter is aligned to the requirements stipulated by the Protocol on Governance in Public Entities and King IV.

## 6. BOARD COMPOSITION

The SAHPRA Board is a unitary Board comprising of a majority of non- executive members. The members of the Board are appointed by the Minister of Health in accordance with the provisions set out in Medicines and Related Substances Act, 101 of 1965 as amended.

In terms of Section 2C of the Medicines and Related Substances Act, 101 of 1965, the Board of the Authority consists of not less than ten (10) but not more than fifteen (15) members appointed by the Minister of Health. The Chief Executive Officer is by virtue of her office a member of the Board with no voting rights. The Minister of Health has appointed a chairperson and a vice-chairperson in terms of Section 2E (1) of the Medicines and Related Substances Act.

The members of the entity during the year and to the date of this report are contained in the table below:

| Name | Designation (in terms of the Public Entity Board structure) | Date Appointed | Date 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 25/04/2024 | 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 the Royal College of Obstetricians and Gynaecologists UK; M.A Social and Political Sciences; MB BChir | Clinical trials | N/A | N/A | 12 |
| Dr Obakeng Masondo | Vice Chair | Appointed 1 October 2021 | N/A | Re-appointed 25/04/2024 | MBCHB<br>Bachelor of Surgery<br>Diploma in HIV Management<br>Postgraduate in Occupational Medicine | Medical research and clinical trials | N/A | HRRemco | 13 |
| Mr Faizail Docrat | Member | 18 June 2024 | N/A | N/A | Master of Business Administration; Chartered Director Information Systems; Audit and Control Association Certified Information Security Manager; Certified Information Systems Auditor; Certified in the Governance of Enterprise Information Technology; Institute of Risk Management South Africa (IRMSA); Certified Risk Management Practitioner Management Advancement Program; Total Quality Management; Computer Users Council; Computer Operations Proficiency Examination | Information technology | N/A | RAG Finance | 9 |

| Name | Designation (in terms of the Public Entity Board structure) | Date Appointed | Date Termination | Date of New term of the Board | Qualifications | Area of Expertise | Board Directorships | Other Committees or Task Teams | No. of Meetings Attended |
|---|---|---|---|---|---|---|---|---|---|
| Ms Lerato Mothae | Member | 1 May 2021 | N/A | Re-appointed 25/04/2024 | Bachelor of Accounting<br>CTA (B. Compt Honours<br>CA (SA) | Finance and Accounting | N/A | RAG<br>Finance | 8 |
| Mr. Itani Mashau | Member | 25 April 2019 | N/A | Re-appointed 25/04/2024 | B Pharm<br>Diploma in Production<br>D in Q Management and Q Assurance<br>Master of Business Administration<br>D in Small Business Management | Good Man-ufacturing Practice | N/A | TORS<br><br>HRRemco | 12 |
| Prof. Patrick Demana | Member | 25 April 2019 | N/A | Re-appointed 25/04/2024 | Ph.D. in Pharmaceutics<br>B.Sc. (Hons) in Pharmacy<br>M.Sc. in Pharmaceutics<br>Post-doctoral Fellowship in Drug Discovery<br>A-level courses (chemistry, biology and mathematics & statistics) | Virologist | N/A | TORS | 9 |
| Adv. Hasina Cassim | Member | 17 November 2017 | N/A | Re-appointed in October 2021 Re-appointed 25/04/2024 | B Pharm<br>LLB<br>Certificate in Medicine Law<br>Certificate in pharmacoepidemiology<br>Medical Mediation training | Law | N/A | RAG<br><br>TORS | 11 |
| Ms Mandisa Skhosana | Member | Newly Appointed 1 October 2021 | N/A | Re-appointed 25/04/2024 | National Diploma in Biomedical Technology<br>B-Tech Degree in Biomedical Technology<br>Master's degree in medical science | Laboratory medicine, quality control and clinical research | N/A | TORS | 10 |

| Name | Designation (in terms of the Public Entity Board structure) | Date Appointed | Date 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 Re-appointed 25/04/2024 | B.A. Hons (Social Science psychology)<br>B.Sc. Hons-Zoology & Microbiology<br>PHD in Public Health<br>MPH in Public Health | Public health medicine | N/A | TORS | 8 |
| Dr Alfred Kgasi | Member | Newly Appointed 23 December 2021 | N/A | Re-appointed 25/04/2024 | Bachelor of Veterinary Medicine<br>LLB<br>Master of Business Leadership | Veterinary | N/A | TORS<br>RAG | 11 |
| Dr Zinhle Makatini | Member | Newly Appointed 23 December 2021 | N/A | Re-appointed 25/04/2024. Resigned 29/08/2024 | BSc (Honors) Biochemistry<br>Masters in Immunology of Infectious Diseases<br>MBChB<br>PhD Virology<br>Registrar in Virology<br>Diploma in Travel Medicine<br>Diploma in Tropical Medicine<br>Diploma in HIV Management in the Workplace<br>Diploma in HIV Management<br>MMED in Biostatistics & Epidemiology (completed2/3)<br>PHD in Medical Virology | Virology | N/A | TORS | 3 |
| Dr Xolani Ngobese | Member | Newly Appointed 1 October 2021 | N/A | Re-appointed 25/04/2024 | PHD in Business Administration<br>Masters in business administration | Independ-ent consult-ant | N/A | HRRemco<br>RAG<br>Finance | N/A |

| Name | Designation (in terms of the Public Entity Board structure) | Date Appointed | Date Termination | Date of New term of the Board | Qualifications | Area of Expertise | Board Directorships | Other Committees or Task Teams | No. of Meetings Attended |
|---|---|---|---|---|---|---|---|---|---|
| Ms Lucy Ditaba Maraka | Member | Newly Appointed 1 October 2021 | N/A | Re-appointed 25/04/2024 | Bachelor of Art<br>Bachelor of Education<br>Baccalaureus Atium Honores<br>Masters Diploma in HR<br>Training and Development<br>Ethics Officer Certification<br>Psychometrist<br>Effective Audit Committees<br>Effective Remuneration Committees<br>Social & Ethics Committees | Independ-ent Psycho-metrist | N/A | HRRemco | 8 |
| Prof. Yahya Choonara | Member | Newly Appointed 23 December 2021 | N/A | Re-appointed 25/04/2024 | BPharm<br>MPharm<br>PhD<br>N | Medical devices | N/A | TORS | 5 |
| Prof. Johanna Meyer | Member | Newly Appointed 23 December 2021 | N/A | Re-appointed 25/04/2024 | BPharm<br>MSc (Med)<br>PhD in Pharmacy | Pharma-covigilance, Public Health | N/A | TORS | 10 |

## Changes in Board membership

The Minister of Health has appointed Mr. Faizal Docrat to serve on the SAHPRA Board, effective 18 June 2024, in accordance with Section 2C (2) (e) read in conjunction with Sec 2F (3) of the Medicines and Related Substances Act 101 of 1965, as amended. Dr. Zinhle Makatini resigned from the Board, effective 29 August 2024. The following table outlines the changes to Board membership that occurred during the financial year under review:

| Name | Area of expertise | Date of appointment/ reappointment | Date of resignation/ retirement |
|---|---|---|---|
| **Mr Faizal Docrat** | Information Technology, Administration and Governance | 18 June 2024 | N/A |
| **Dr Zinhle Makatini** | Virology | 23 December 2021 | 29 August 2024 |

## Committees of the Board

The Board, as the Accounting Authority, oversees decision-making to ensure SAHPRA's proper direction and control. Certain powers are delegated to the CEO and management, with exclusive powers outlined in the Board Charter. Committees are appointed to aid the Board in its responsibilities, without absolving members of their duties. Delegated committees include:

- Finance Committee (FINCO)
- Technical Oversight and Regulation Committee (TORS)
- Audit, Risk and Governance Committee (RAG)
- Human Resources and Remuneration Committee (HRREMCO)

Each committee has formal Terms of Reference that define their mandates, roles, and responsibilities, reviewed annually.

| Committee | No. of Meetings Held | No. of Members | Name of Members |
|---|---|---|---|
| **Finance Committee** | 7 | 8 | Ms Lerato Mothae<br>Mr Rajesh Mahabeer (Independent Member)<br>Dr Xolani Ngobese<br>Mr Faizal Docrat |
| **Technical Oversight and Regulatory Strategy Committee** | 6 | 9 | Prof. Johanna Meyer<br>Prof. Patrick Demana<br>Adv. Hasina Cassim<br>Mr. Itani Mashau<br>Dr Alfred Kgasi<br>Ms Mandisa Skhosana<br>Dr Zinhle Makatini<br>Prof. Yahya Choonara<br>Prof. Joyce Tsoka-Gwegweni |

| Committee | No. of Meetings Held | No. of Members | Name of Members |
|---|---|---|---|
| **Risk Audit and Governance Committee** | 7 | 8 | Ms Lerato Mothae<br>Dr Xolani Ngobese<br>Dr Alfred Kgasi<br>Adv. Hasina Cassim<br>Ms Adila Chowan (Independent Member)<br>Mr. Bruce Gordon (Independent Member)<br>Mr. Rajesh Mahabeer (Independent Member)<br>Mr Faizal Docrat |
| **Human Resource and Remuneration Committee** | 8 | 4 | Mr. Itani Mashau<br>Dr Xolani Ngobese<br>Dr Obakeng Khaole<br>Ms Lucy Ditaba Maraka |

## Remuneration of Board Members

The Board has approved a Remuneration Policy guiding how members are paid. State-employed members cannot claim attendance and preparation fees. Members are reimbursed for expenses incurred while furthering SAHPRA's interests. A summary of remuneration and emoluments is provided in the table below:

| Name | Remuneration | Other Allowance | Other Re-imbursements | Total |
|---|---|---|---|---|
| Prof. Helen Rees | R100 185 | - | - | R100 185 |
| Dr Obakeng Khaole | R142 737 | - | - | R142 737 |
| Ms Lerato Mothae | R190 612 | - | - | R190 612 |
| Mr. Itani Mashau | R153 894 | - | - | R153 894 |
| Prof. Patrick Demana | R78 176 | - | - | R78 176 |
| Adv. Hasina Cassim | R151 390 | - | - | R151 390 |
| Ms Mandisa Skhosana | R107 700 | - | - | R107 700 |
| Prof. Joyce Tsoka-Gwegweni | R103 918 | - | - | R103 918 |
| Dr Alfred Kgasi | R167 686 | - | - | R167 686 |
| Dr Zinhle Makatini | - | - | - | - |
| Dr Xolani Ngobese | R190 994 | - | - | R190 994 |
| Ms Lucy Ditaba Maraka | R82 841 | - | - | R82 841 |
| Prof. Yahya Choonara | R53 850 | - | - | R53 850 |
| Prof. Johanna Meyer | R85 734 | - | - | R85 734 |
| Mr. Faizal Docrat | R85 304 | - | - | R85 304 |

## 7. RISK MANAGEMENT

- The SAHPRA Risk Management policy and framework were reviewed and approved by the Board, as per the review schedules, to ensure relevant implementation and embedment of risk management within the Authority. The Policy and framework aim to direct the process of identification and management of all risks faced by SAHPRA in the achievement of its objectives.
- Risk assessments are conducted annually and reviewed quarterly across the Authority according to their respective levels, i.e., Strategic, and operational. Risk assessments are also conducted as and when the need arises or a significant change happens, wherein risks will be reviewed, updated and communicated to the relevant governance structures.
- Risk, Audit and Governance (RAG) committee, is an independent committee responsible for oversight on SAHPRA's control, governance, and risk management. RAG, which is established by the SAHPRA Board, appraises the Board on a quarterly basis on risk and internal control measures.
- It monitors effectiveness of the risk system through the review of the quarterly reports submitted by management on risk management activities and the risk performance. RAG is also responsible to provide guidance to management regarding risk management within the authority.

## 8. INTERNAL CONTROL ENVIRONMENT

- Management, as the first line of defence, is responsible for the continuous review and implementation of internal controls within operations to ensure an adequate and effective internal control environment.
- The support functions, as the second line of defence assist in evaluating the controls implemented by management. While the third line being internal and external audit provide independent assurance on the control environment.
- SAHPRA continuously strives for a streamlined process of combined assurance to ensure alignment and reduce duplication of efforts.

## 9. INTERNAL AUDIT AND AUDIT COMMITTEES

- SAHPRA has an outsourced Internal Audit function which provides independent assurance to management, the Risk, Audit and Governance Committee (RAG), and the Board on the adequacy and effectiveness of the internal control environment.
- The Internal Audit function implements a 3-year rolling plan approved by RAG on an annual basis, which lists all audit assignments to be conducted.
- Internal audit function applies a risk-based approach covering the scope of audits conducted in the annual Internal Audit plan approved by the RAG. Scope of audit covers audits related to Finance, Information Communication Technology (ICT), Performance Information and core operations. Additionally, Internal audit performs special assignments and investigations requested by management and the RAG.
- RAG reviews independence and effectiveness of the internal audit function through the reports submitted quarterly on the work done and hold management accountable for implementation of recommendations proposed to improve the internal control system within SAHPRA. Some of the RAG activities, include but is not limited to:
- establish the Internal audit charter to guide the Internal Audit approach.

- review SAHPRA's risk areas to be covered in the annual scope of work for internal audit and coordinate internal and external auditors' work.
- review activities of internal audit, risk management and other corporate governance related functions.
- review the reports of investigations and the responses of management to specific recommendations; and
- review effectiveness and evaluate performance of internal audit.

SAHPRA as a Schedule 3A public entity is governed by the founding legislation (Medicines and Related Substances Act, 101 of 1965), Public Finance Management Act and National Treasury Regulations. SAHPRA complies with the governing legislation and compliance is an ongoing activity. Compliance is tracked regularly by the respective Executive, and where a non-compliance is noted, corrective actions are developed. The office of the Board Secretary monitors the compliance to legislation and regulations.

## 10. FRAUD AND CORRUPTION

- SAHPRA has set a tone of "non -tolerance to fraud and corruption" through its fraud prevention policy and Whistleblowing Policy.
- SAHPRA has provided a whistle blowing tool aimed at affording the callers an opportunity to report anonymously. The hotline has been effective in reporting both internal and industry fraud and corruption affecting SAHPRA operations. Although SAHPRA has other dedicated reporting mechanisms for product issues, the hotline has been instrumental in the reporting of these as well.
- Management appraise staff on how to report fraud and corruption through the facilitation of awareness sessions but also guides on other mechanisms available for reporting other issues. Staff is encouraged to use the correct platform to report, to ensure timely response and adequate handling of the reported matters, especially since there is an opportunity to remain anonymous.
- SAHPRA will attempt to investigate all reported cases to reduce fraud and corruption by sanctioning those accountable. All reported cases and the outcome or progress status are reported quarterly to the RAG for oversight.
- SAHPRA will attempt to investigate all reported cases to reduce fraud and corruption by sanctioning those accountable. All reported cases and their outcome are reported to the RAG for their assessment, on a quarterly basis.

## 11. MINIMISING CONFLICT OF INTEREST

The Board has approved a Declaration and Management of Conflict-of-Interest Policy which is reviewed every three years or as and when it is necessary. There are procedures in place to manage and minimise the risks related to conflict of interest (perceived, potential or actual). Board members and all employees within SAHPRA are required to disclose and declare their financial interest on annual basis. At every Board and Committees' meeting members are required to sign and submit their declaration of interest forms, and these are captured as standing agenda item for each meeting. This approach is extended to members of the different advisory committees in SAHPRA. Where a potential conflict of interest has been identified and/or declared such interest is recorded and the conflicted member is recused from participating in the discussion.

## 12. 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 the Code of Conduct. Receipt of gifts, sponsorships, hospitalities and favours is managed through the Declaration and management of Conflict-of Interests Policy. SAHPRA condemns in the strongest term any act of corruption, bribery and dishonesty and encourages its employees and stakeholders to uphold highest degree of ethical conduct. Disciplinary actions are applied indiscriminately to any employees who is found to be involved in any act of corruption and/or related misconduct.

## 13. HEALTH SAFETY AND ENVIRONMENTAL ISSUES

The Authority's premises in the head office in Pretoria had challenges with bad odour from (-2 basement parking). The bad odour had an impact on staff related to breathing, with other staff complaining about headaches.

Leakages in some of the offices with four (4) offices continuous leaks at the Head office in Pretoria. Repairs were done. However, the leak re-appears. To mitigate this, the Facilities Management Unit (FMU) conducted tests, and the outcome was the walls have developed bad mould. Further, a service provider was appointed to conduct more tests with recommendations provided to solve the leakage challenges.

### HVAC Systems

- The HVAC system is centralised, and it makes it more difficult to control the temperature according to the needs or requirements of all.
- FMU has installed separate controllers in some areas of the open plan to have control of regulating the temperature.

Security upgrades related matters as per the security assessment conducted, cameras will be installed on all SAHPRA offices floor entrances. Changes would be made on the access control from access cards to face/biometrics readers for more security control.

The Authority achieved accommodating all staff personal following back to office work. All offices in the ports of entry are well equipped with the necessary equipment. The head office centre management was engaged to make ablutions cleaner io install the seat sanitisers.

## 14. BOARD SECRETARY

The SAHPRA Board Secretary and Deputy Board Secretary's roles play a critical role in providing secretarial and advisory services to the Board and its Committees. Furthermore, the Board Secretary is a liaison officer between Management and the Board, and between the Board and Shareholder on issues relating to governance, thus giving effect to governance protocols. The Board Secretary is the custodian of the register of Board and Committees decisions.

The Board Secretary provides guidance to both the executives and non-executive members of the Board in the discharge of their fiduciary duties and ensures that Board proceedings are carried out in accordance with the relevant legislative requirements.

**The Board Secretary is well experienced and qualified to fulfil the following roles:**

- Induction of new Board members.
- Providing Board members collectively and individually with guidance as to their duties, responsibilities and powers.
- Making Board members aware of any law relevant to or affecting the entity.
- Providing guidance to and advising the Board on ethical matters and good governance principles.
- Recording of Board and Committees proceedings.

Board members have unlimited access to the advice and services of the Board Secretary.

## 15. SOCIAL RESPONSIBILITY

As part of the organisation's annual Corporate Social Investment (CSI) Outreach programme, SAHPRA colleagues volunteered their time during a visit to Leamogetswe Safety Home, our adopted home based in Atteridgeville, Pretoria.

The SAHPRA team, under the leadership of the SAHPRA CEO, Dr Tumi Semete-Makokotlela, spent time with the children and helped with chores. In addition to their time spent with the children, the SAHPRA team also made valuable contributions to the home by donating an industrial gas stove with an oven, ten taped curtains, and ten mattresses. This initiative is part of SAHPRA's commitment to making a positive impact on the lives of the less fortunate and underserved communities.

## 16. AUDIT COMMITTEE REPORT

We are pleased to present our report for the financial year ended 31 March 2025.

### Introduction

The Risk, Audit and Governance Committee (RAG) is pleased to present its report for the financial year that ended on 31 March 2025.

The RAG has operated within the approved terms of reference and complied with all governing legislation in executing its responsibilities in terms of the PFMA and Treasury Regulations and requirements of King Code on good governance.

### Composition of the committee

The committee composition is outlined on the table below.

The Chief Executive Officer is an ex officio member of the committee. The Chief Financial Officer, Chief Operating Officer, Chief Regulatory Officer, Human Resources Executive Manager, Internal Audit and Risk Manager are standing invitees to committee meetings.

Representatives of Nexia SAB&T (Internal Auditors) and the Auditor General of South Africa (AGSA) are invited to attend committee meetings.

### The tabled below discloses relevant information on the audit committee members

| Name | Qualifications | Internal or external | If internal, position in the public entity | Date appointed | Date Resigned | No. of Meetings attended |
|---|---|---|---|---|---|---|
| **Ms Lerato Mothae** | Bachelor of Accounting CTA (B. Compt Honours CA (SA) | External | Board Member | October 2021 | N/A | 7 |
| **Dr Kgasi Alfred** | Bachelor of Veterinary Medicine; LLB; Masters in business leadership | External | Board Member | December 2021 | N/A | 6 |
| **Ms Adila Chowan** | CA(SA); Bachelor of Accountancy; Post Graduate Diploma in Accounting (CTA) LLB (Cum Laude) | External | Independent Member | 31 May 2023 | N/A | 6 |
| **Dr Xolani Ngobese** | PHD in Business Administration; Masters in business administration | External | Board Member | October 2021 | N/A | 7 |
| **Mr Bruce Gordon** | B. Compt (Hons); CA | External | Independent Member | 01 April 2023 | N/A | 7 |
| **Adv. Hasina. Cassim** | B Pharm LLB. Certificate in Medicine Law; Certificate in pharmacoepidemiology Medical Mediation training | External | Board Member | October 2021 | N/A | 6 |
| **Mr Faizal Docrat**[1] | Master of Business Administration; Chartered Director Information Systems; Audit and Control Association Certified Information Security Manager; Certified Information Systems Auditor Certified in the Governance of Enterprise Information Technology; Institute of Risk Management South Africa (IRMSA); Certified Risk Management Practitioner Management Advancement Program; Total Quality Management; Computer Users Council; Computer Operations Proficiency Examination | External | Board Member | 18 June 2024 | N/A | 3 |

[1] Mr Faizal Docrat was appointed as a member of RAG effective 30 July 2024.

| Name | Qualifications | Internal or external | If internal, position in the public entity | Date appointed | Date Resigned | No. of Meetings attended |
|---|---|---|---|---|---|---|
| **Mr Rajesh Mahabeer** | CA(SA) FCMA<br>CGMA FCCA<br>FCA BFP<br>CIA FIISA<br>SARIPA INSOL MBA MCOM<br>PGDA NDIP (COST) ACC PH.D. (CANDIDATE) | External | Independent Member | 15 May 2023 | N/A | 5 |

## Committee responsibilities

The committee reports that it has complied with its responsibilities arising from Section 51(1) (a)(ii) and Section 76(4)d of the Public Finance Management Act (PFMA) and Treasury Regulation. The committee also reports that it has adopted appropriate formal terms of reference that regulate its affairs and has discharged all its responsibilities as contained therein, these include the requirements of the King Report on the Code of Corporate Governance:

- 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 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 are 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 and Related Substances Act and the PFMA as well as the Treasury Regulations; and
- To ensure the independence and objectivity of the Internal and External Auditors.

## Whistleblowing

Anonymous tip-off platform for reporting fraud, corruption, and unethical conduct is administered by an independent service provider. The reported allegations are investigated, thereafter findings, conclusions, and recommendations are presented to management and the committee. The committee monitors progress on all initiated investigations and outcomes.

## Auditor's Report

The committee has noted the audit outcome as issued by the Auditor General of South Africa (AGSA), with the resultant clean audit opinion for the second consecutive year. The RAG committee independently engaged with the AGSA where necessary and is satisfied that it has adequately discharged its legal and regulatory responsibilities.

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

The Committee reviewed SAHPRA's implementation plan for the audit issues raised in the prior year and is satisfied that matters continue to be satisfactorily resolved.

The RAG committee concurs and accepts the conclusions of the external auditor on the annual financial statements and concluded that the audited annual financial statements be accepted and read together with the report of the AGSA.

## The Effectiveness of Internal Controls

Our review of the findings of the Internal Auditors, which was risk-based, revealed certain control weaknesses, which were then raised with the public entity.

**The committee undertook the following primary activities in assessing the effectiveness of 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 the 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 have room for improvement.

## Governance of Risk

SAHPRA has an Enterprise Risk Management (ERM) framework designed to assist it to manage anticipated risks and increase the likelihood of achieving its objectives. The responsibility for risk management resides with management, while the Board plays an oversight role. The Board discharges its responsibility through the Risk, Audit and Governance committee (RAG). SAHPRA has a dedicated Risk and Internal Audit Unit that coordinates the implementation of the risk management strategy. Risk management processes are embedded throughout SAHPRA with strategic and operational risk assessment workshops facilitated annually.

**The 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 is satisfied with the effective role played by the Internal Audit. The committee has reviewed internal audit reports. The committee discharged its responsibility to approve the annual and three-year rolling plan and considered quarterly reports.

The committee ensured that the Internal Auditors remained independent, objective and had the necessary resources, standing and authority to discharge their duties effectively.

## In-Year Management and Monthly/Quarterly Report

SAHPRA has submitted monthly and quarterly reports to the Executive Authority.

## Evaluation of Financial Statements

The committee reviewed the annual financial statements prepared by the SAHPRA. 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.

## Conclusion

The committee recommended the approval of the audited annual financial statements for the year ended 31 March 2025 and the audit opinion thereon at its meeting held on 24 July 2025 and these annual financial statements and audit opinion were duly approved by the Board on 30 July 2025 for inclusion in the Annual Report for the period ended March 2025.

**MR RAJESH MAHABEER**
*Chairperson of the RAG*

# 17. B-BBEE COMPLIANCE PERFORMANCE INFORMATION

The following table has been completed in accordance with the compliance to the B-BBEE requirements of the BBBEE Act of 2013 and as determined by the Department of Trade, Industry and Competition.

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 |
|---|---|---|
| Determining qualification criteria for the issuing of licences, concessions or other authorisations in respect of economic activity in terms of any law? | **No** | Draft Policy for issuance of licences as per section 22c of the medicines act developed and approved by the board. Published for Implementation. |
| 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 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

## Overview of HR matters at the public entity

The Human Resources Management is recognised as a strategic partner and plays a crucial role in achieving the Authority's objectives by delivering efficient and effective HR services. It also provides business partnership to core and support functions, helping to attract, develop, retain, and maintain a skilled and effective workforce within SAHPRA.

The Human Resource Management Unit was capacitated; appointment of HR Executive was concluded in September 2024. As part of human resource ongoing and strengthening its services, SAHPRA adopted Human Resource Business Partnering model to enhance service delivery. Two HR Business Partners were added to the HR team and were appointed in September and October 2024, to deal with administrative and technical challenges related to human resource management processes.

**For the year under review, SAHPRA set specific targets to enhance its capacity. These included:**

- Achieve implementation of 70% of the recommendations identified in the 2023/24 staff employee satisfaction survey.
- Ensure that 80% of employees participate in the planned learning and development programs to improve skills, knowledge, and overall performance.
- Fill at least 70% of the budgeted positions outlined in the Recruitment Plan to strengthen SAHPRA's capacity to achieve SAHPRA mandate.
- Maintain a staff turnover rate below 10% to retain a competitive and experienced workforce.

## Workforce planning framework and key strategies to attract and recruit a skilled and capable workforce and prioritisation of budgeted position filled

SAHPRA faces challenges in attracting and retaining scarce skilled professionals, particularly in technical areas, due to strong competition within the regulatory and pharmaceutical sectors. By the end of the 2024/25 financial year, SAHPRA's workforce grew from 309 to 331 employees, with 22 new hires. Only 71% (56 out of 93) of the budgeted positions were filled despite available funding. This shortfall primarily resulted from delays in verifying candidate suitability checks, extended offer negotiations periods, and the necessity to re-advertise positions after initial offers were declined. These recruitment -challenges have increased the workload and additional pressure on existing staff

In this area, we have encountered challenges to fill positions within the turnaround times outlined in the Recruitment Plan. Delays we due to the unavailability of panel members for the selection process, the time required to complete mandatory candidate pre-suitability checks (verification procedures), the necessity to re-advertise positions due to a lack of suitable candidates or declined offers, and some positions being unfunded to stay within the allocated cost of employment (CoE) budget. These challenges have resulted in considerable capacity shortfalls within the entity and have increased workload on the current employees.

To address these challenges, each business unit has assigned HR Business Partners responsible for assisting in appointing dedicated selection committees with the required technical expertise to accelerate the recruitment process. They ensure that mandatory candidate pre-suitability checks (verification procedures) are expedited to quickly fill open positions. Furthermore, pre-interviews are conducted with shortlisted candidates to confirm that their salary expectations are aligned with the advertised salary range for the positions.

## Implementation of the action plan derived from the 2023 Employee Staff Satisfaction Survey to resolve various areas of dissatisfaction

Seventy percent (70%) of the recommendations from the 2023/24 staff employee satisfaction survey have been addressed by appointing Lyra (formerly ICAS) to support the Employee Health and Wellness Programmes (EHWP), aimed at promoting employee welfare and well-being. This initiative has significantly boosted employee participation, achieving a 65.5% engagement rate.

The Employee Wellness Programme featured 31 initiatives, such as trauma debriefing, grief and loss support, health awareness sessions on hypertension, mental health, autism, financial wellness, lifestyle guidance, wellness marketing, and personalised support sessions.

In November 2024, Wellness Days were hosted at three locations: the Head Office on November 8, the Durban Regional Office on November 18, and the Cape Town Regional Office on November 26. These events offered a variety of activities focused on physical fitness, health screenings, financial planning, and nutrition, all designed to improve employees' overall health and well-being.

Thirty-one (31) EHWP Programme various initiatives including trauma debriefing, grief and loss support, health awareness sessions on hypertension, mental health, autism, financial wellness, lifestyle guidance, wellness marketing, and personalised support sessions were conducted.

### The following psychosocial sessions were delivered:

| Number of sessions conducted | Type of session | Type of intervention/ topics covered |
|---|---|---|
| 03 | Awareness/ educational sessions – Virtual presentations | Persons With Disability – Virtual presentation<br>HIV/AIDS world day – Virtual presentation<br>Return to workspace - Virtual presentation |
| 12 | LYRA wellbeing | • Valuable tools and tips to support your personal and professional growth in 2025<br>• Rethinking time<br>• Why is family important?<br>• Love is in the air, and we're thriving!<br>• Your relationships affect your wellbeing<br>• What do you need to know about STIs?<br>• March Money Move: Get clear on credit health<br>• Women leading the charge in innovation and technology<br>• How music and frequencies can supercharge your brain<br>• Learn about salt<br>• Financial well-being<br>• World Diabetes Day: How to spot the signs of diabetes |
| 12 | Global webinars | • Social media and Mental Health<br>• Get Ready for Love<br>• Creating a Thriving Corporate Environment<br>• Parenting children at risk<br>• Global Mental Health Trends |

| Number of sessions conducted | Type of session | Type of intervention/ topics covered |
|---|---|---|
| | | • Musculoskeletal session: I Pulled Something<br>• The Power of Small Wins: How to Create Big Change through Small Habits Session<br>• World Cancer Day<br>• Disability Rights Awareness Month: Understanding how disability is defined<br>• International Day of Persons with Disabilities: Disability and mental health<br>• International Day of Persons with Disabilities: Embracing Strength and Diversity<br>• International Day for the Elimination of Violence Against Women |

To further strengthen the EHWP, the entity established Memoranda of Understanding (MOUs) with Virgin Active to provide fitness benefits and with Absa to offer financial wellbeing, underscoring its dedication to comprehensive employee wellness.

Furthermore, the entity conducted its bi-city Annual General Meeting (AGM) on November 29, 2024, connecting Pretoria and Cape Town in real-time through advanced audio-visual technology. During the AGM, 64 employees were honoured with Long-service certificates for 5, 10, 15, and 25 years of continuous service. In alignment with SAHPRA's core values, thirteen (13) Staff Recognition awards were presented various categories including the CEO Award, Ubuntu, Responsiveness, Integrity, Customer Satisfaction, Transparency, Efficiency, Excellence, and Technical Outputs.

Since its inception, SAHPRA has been undergoing a transformation, evolving from the Medicines Control Council (MCC), which served as a secretariat for the National Department of Health (NDoH), into an independent public entity. As part of this transition, in June 2024, SAHPRA initiated a Job Evaluation Project aimed at reviewing job profiles (descriptions) and titles, and where needed, redefining them to ensure they remain accurate, appropriate, and aligned with the organisational structure.

During the profiling process, it was discovered that SAHPRA has around 130 job titles needing detailed profiling because some specialised roles were not anticipated in the initial specification phase. As a result, the scope of the job evaluation had to be broadened to encompass all these roles, causing a delay in the project timeline.

At the end of March 2025, 127 jobs have been analysed and profiled, with 87 already graded. The remaining 39 jobs will be independently assessed by the SAHPRA Job Evaluation Committee, working alongside Emergence Growth to ensure a thorough understanding of the evaluation methodology. This strategic approach enables SAHPRA to control costs effectively while still leveraging expert guidance where necessary.

### Continue with the implementation of Learning and Development initiatives

Education, Training, and Development Programmes are essential strategies for both employees and employer, aimed at enhancing skills, knowledge, and overall job performance. SAHPRA takes pride in its commitment to upskilling employees by offering study assistance opportunities to staff members, helping them to advance their expertise and knowledge. During the reporting period, a total of twenty-two (22) employees received support through study assistance.

In partnership with the Medical Research Council (MRC) and the National Department of Health (NDoH), the Entity has implemented the Internship and Community Service Programme as part of its youth development initiatives. Through this collaboration, sixteen (16) graduates were placed, with six (6) participating in the Internship Programme and ten (10) in the Pharmacist Community Service Programme.

SAHPRA has exceeded compliance requirements by actively implementing skills development initiatives that enhance individual capabilities and professional expertise. Between April 2024 and March 31, 2025, a total of 280 employees participated in various training programs, most of which were provided by independent external industry stakeholders.

## Employment Equity

The organisation has the largest representation of African employees, comprising **81.5%** of the total workforce **(270 out of 331),** which indicates an overrepresentation of **3.9%**. Indian employees make up **7.5% (25 out of 331),** reflecting an overrepresentation of **4.7%**. White employees account for **6.3% (21 out of 331),** showing an underrepresentation of **3.9%,** while Coloured employees represent **4.5% (15 out of 331),** with an underrepresentation of **5.5%**.

The overall representation of women is at **62%,** with women holding **50%** of senior and executive roles. Disability representation remains steady at 2%, consistent with the previous 2023/2024 financial year.

Women within the African and Indian groups are overrepresented, contributing to an overall surplus of female employees. To promote workplace equity, it is essential to address the underrepresentation of certain groups. Recruitment strategies will focus on attracting more males, particularly Indian males, to achieve a more balanced workforce. Targeted interventions will be implemented in areas identified as either over- or underrepresented to improve equity. These initiatives will be incorporated into the forthcoming five-year Employment Equity (EE) Plan, aligned with the latest regulatory updates and sector target revisions that came into effect on 1 January 2025, as introduced by the Department of Employment and Labour.

## Retention of technical staff to maintain staff turnover under 10% or below

An exit interview, as a final discussion conducted with a departing employee, aimed at understanding the reasons for their departure and gathering feedback to improve the organisation. As part of the offboarding process, it helps in identifying areas for improvement in culture, management, and employee retention.

During the 2024/25 period, various people-focused initiatives were implemented, resulting in a staff turnover rate of 6.9%, which is a 2.5% decrease compared to the previous year and remains well within the target of 10%. Despite this improvement, SAHPRA continues to experience turnover difficulties in critical and scarce roles, leading to instability and disruption at both management and operational levels. The main factors contributing to employee departures include concerns over job security, limited opportunities for career progression, challenges with work-life balance, dissatisfaction with remuneration and benefits, retirement, and contract expirations.

## Employee performance management framework

For the 2024/25 cycle, mid-term review, out of 317 employees eligible to submit these reviews, only (81%) 257/317 have submitted their mid-term performance assessments.

In the 2024/25 financial year, SAHPRA introduced a performance framework comprising the Annual Performance Plan (APP), Annual Operational Plan (AOP), and Individual Performance Plans (IPPs). These instruments are designed to align strategic objectives with operational execution and individual accountability.

The APP outlines the organisation's strategic goals, the AOP translates these into departmental/units targets, and the IPPs ensure that each employee's contributions are directly linked to SAHPRA's broader performance outcomes. Together, these tools enhance organisational effectiveness and support the achievement of equity and representativity targets.

Annual performance evaluations for 2023/24 were completed, moderated, and finalised. A total of 282 employees were eligible for performance-based incentives, which were paid in December 2024.

Of these, 84% (234/282) employees qualified for performance bonuses and notch progression and 12% (33/282) employees received notch progression only. Meanwhile, 1% (3/282 employees were rated as poor performers, and 2% (7/282) employees failed to submit their performance agreements and assessments, resulting in no incentive payments.

The HRM Unit is currently reviewing the policy to address issues related to poor performance and the failure to submit performance agreements and assessments. The revised policy will clearly outline the PMDS timelines, detail the roles and responsibilities of both supervisors and supervisees, and set forth consequences for non-compliance.

## Policy Development

The entity is currently undertaking a review of its HR policies to ensure alignment with applicable legislation, case law, and contemporary best practices. It has been determined that the Human Resource Management Unit needs a total of forty-four (44) HR policies for optimal organisational efficiency. This initiative aims to ensure legal compliance and risk mitigation, improve transparency and communication, support effective talent management, and foster a positive workplace culture.

The project to review and develop these policies began in January 2025, with the goal of completing all fifty-four policies by the end of October 2025. As of 30 March 2025, eight (8) existing HR policies have been reviewed, and eleven (11) new policies have been developed. Once the review and development process is complete, a consultation phase with relevant stakeholders will take place, in accordance with sections 84 and 85 of the Labour Relations Act 66 of 1995. The reviewed and newly developed policies will be discussed with organised labour as part of this consultation.

## Salary Negotiations

On 04 October 2024, SAHPRA and the recognised trade unions represented in the SAHPRA Bargaining Forum reached a collective agreement on salary negotiations for the 2024/2025 period. The parties agreed to a 6.5% salary increase for employees at salary levels 05 to 12, with a single salary adjustment term for the 2024/25 financial year. The back pay related to this salary increase was disbursed in November 2024.

For employees at salary level 13 and above, the adjusted salary and back pay for the 2024/25 increment were also paid in November 2024. Senior managers received a 6.5% salary adjustment, while EXCO members were granted a 6% increase.

During the 2024/25 financial year, collective bargaining activities included three regular SAHPRA Bargaining Forum (SBF) meetings and one special Bargaining Forum meeting with organised labour. Additionally, one meeting took place between the HR Team and organised labour.

**Key topics discussed during these meetings included:**

- Draft Constitution of the Bargaining Forum
- Signing of the 2024/2025 Wage Agreement

- Draft Organisational Rights
- Draft Levy Agreement
- Challenges faced by Inspectors
- Review of Human Resources Policies
- SAHPRA employment contracts
- Salary disparities
- Housing subsidies for employees transferred from the National Department of Health

The Constitution for the SAHPRA Bargaining Forum will be officially signed in April 2025 by SAHPRA and the majority union, the Public Servants Association of South Africa.

## Future HR plans / goals

HR is currently undertaking a comprehensive transformation to cultivate a more positive and performance operating workplace. These initiatives collectively aim to create a more efficient, supportive, and engaging work environment, ultimately fostering positive employee attitudes and behaviours. The following key initiative are implemented:

- **HR Information System Implementation:** As the RT approaches, HR is rolling out an HRIS to streamline operations and improve data management.
- **HR Process Automation:** Following the HRIS implementation, HR plans to automate various processes to increase efficiency and reduce manual tasks.
- **Policy and Document Review:** HR is actively developing and reviewing policies, standard operating procedures, and all HR-related documents to ensure they are up-to-date and aligned with organisational goals.
- **Job Evaluation and Benchmarking:** A project in progress to evaluate job roles and benchmark them against industry standards, ensuring fair compensation and clear career paths.
- **Employee Health and Wellness Programs:** Ongoing initiatives are being implemented to create a positive work environment and support employee well-being.
- **New Employee Induction Programme:** An induction program for newly employees hired in 2025/26 implemented to integrate new staff effectively.
- **Development Programmes:** Launch unemployment and employment learnerships, training for scarce skills, and health initiatives.

# 2. HUMAN RESOURCE OVERSIGHT STATISTICS

The financial amounts disclosed in oversight statistics were discussed and agreed with Office of the Chief Financial Officer.

## 2.1 PERSONNEL RELATED EXPENDITURE

### Personnel Cost by programme

| Programme | Total Expenditure for the entity (R'000) | Personnel Expenditure (R'000) | Personnel exp. as a % of total exp. (R'000) | No. of employees | Average personnel cost per employee (R'000) |
|---|---|---|---|---|---|
| Programme 1 | 156 258 | 69 427 | 44% | 82 | 847 |
| Programme 2 | 41 704 | 40 360 | 97% | 61 | 662 |
| Programme 3 | 56 365 | 48 971 | 87% | 53 | 924 |
| Programme 4 | 115 526 | 79 893 | 69% | 87 | 918 |
| Programme 5 | 40 664 | 38 675 | 95% | 48 | 806 |
| Contract (external funders) | 38 591 | 19 096 | 49% | 24 | 796 |
| **Total** | **449 108** | **296 422** | **66%** | **355** | **835** |

### Personnel cost by salary band

| Level | Personnel Expenditure (R'000) | % of personnel exp. to total personnel cost (R'000) | No. of employees | Average personnel cost per employee (R'000) |
|---|---|---|---|---|
| Top Management | 11 309 | 3.82% | 6 | 1 812 1 885 |
| Senior Management | 26 589 | 8.97% | 18 | 1 420 1 477 |
| Professional qualified | 207 704 | 70.07% | 223 | 895 931 |
| Skilled | 35 455 | 11.96% | 69 | 494 514 |
| Semi-skilled | 15 367 | 5.18% | 39 | 378 394 |
| Unskilled | | | | |
| **Total** | **296 423** | **100%** | **355** | **803 835** |

### Performance Rewards

| Programme/activity/ objective | Performance rewards (R,000) | Personnel Expenditure (R'000) | % of performance rewards to total personnel cost (R'000) |
|---|---|---|---|
| Top Management | R331 | 10 877 | 3.04 |
| Senior Management | R553 | 25 574 | 2.16 |
| Professional qualified | 6 649 | 198 483 | 3.35 |
| Skilled | 1 004 | 33 793 | 2.97 |
| Semi-skilled | 379 | 14 834 | 2.55 |
| Unskilled | R0 | 0 | 0% |
| **Total** | **8 916** | **296 423** | **3.14** |

## Training Costs

| Programme | Personnel Expenditure (R'000) | Training Expenditure (R'000) | Training Expenditure as a % of Personnel Cost. | Number of employees trained | Average Training Cost per Employee |
|---|---|---|---|---|---|
| Programme 1 | 69 427 | 802 | 0,98% | 213 | 4 |
| Programme 2 | 40 360 | 139 | 0,36% | 18 | - |
| Programme 3 | 48 971 | R 2 | 0.04% | 13 | 11 |
| Programme 4 | 79 893 | - | - | - | - |
| Programme 5 | – 38 675 | - | - | - | - |
| Contract (external funders) | 19 096 | - | - | - | - |
| **Total** | **296 423** | **943** | **1.38%** | **244** | **4** |

## Employment and vacancies

| Programme | 2024/2025 No. of Employees | 2024/2025 Approved Posts | 2024/2025 No. of Employees | 2024/2025 Vacancies | % of vacancies |
|---|---|---|---|---|---|
| Programme 1 | 72 | 80 | 72 | 9 | 11.3% |
| Programme 2 | 58 | 79 | 58 | 4 | 5.1% |
| Programme 3 | 51 | 70 | 51 | 8 | 11.4% |
| Programme 4 | 80 | 130 | 80 | 21 | 16.2% |
| Programme 5 | 47 | 71 | 47 | 6 | 8.5% |
| External Funders | 23 | 0 | 23 | 0 | 0.0% |
| **Total** | **331** | **430** | **331** | **48** | **11.2%** |

| Programme | 2024/2025 No. of Employees | 2024/2025 Approved Posts | 2024/2025 No. of Employees | 2024/2025 Vacancies | % of vacancies |
|---|---|---|---|---|---|
| Top Management | 5 | 5 | 5 | 0 | 0.0% |
| Senior Management | 17 | 19 | 17 | 2 | 10.5% |
| Professional qualified | 208 | 236 | 208 | 37 | 15.7% |
| Skilled | 62 | 130 | 62 | 6 | 4.6% |
| Semi-skilled | 39 | 40 | 39 | 3 | 7.5% |
| Unskilled | 0 | 0 | 0 | 0 | 0.0% |
| **Total** | **331** | **430** | **331** | **48** | **11.2%** |

SAHPRA is operating within a health sector characterised by scarce skills, internal capabilities and resources are limited. All funded and vacant key positions and highly skilled positions, whether newly created or vacated are advertised promptly to ensure they are filled within six months of becoming available.

Vacancies are advertised nationwide to broaden our reach and attract skilled and competent candidates from across various sectors, particularly the health sector, thereby enhancing our competitiveness in securing critical and scarce skills.

The Human Resources Management Unit, working together with the Office of the Chief Financial Officer and line managers, has proactively identified critical vacant roles for recruitment. A recent staff establishment audit found 118 vacancies, with 51 of these positions remaining unfunded due to budget limitations, ensuring that SAHPRA remains to the approved cost of employment (CoE) budget. By March 2025, the vacancy rate (excluding unfunded positions) had decreased from 19.3% to 11.2%.

## Employment changes

| Salary Band | Employment at beginning of period | Appointments | Terminations | Employment at end of the period |
|---|---|---|---|---|
| Top Management | 4 | 2 | 1 | 5 |
| Senior Management | 15 | 3 | 1 | 17 |
| Professional qualified | 188 | 38 | 16 | 210 |
| Skilled | 63 | 5 | 8 | 60 |
| Semi-skilled | 39 | 1 | 1 | 39 |
| Unskilled | 0 | 0 | 0 | 0 |
| **Total** | **309** | **49** | **27** | **331** |

## Reasons for staff leaving

| Reason | Number | % of total no. of staff leaving |
|---|---|---|
| Death | 0 | 0% |
| Resignation | 19 | 5.7% |
| Dismissal | 1 | 0,3% |
| Retirement | 0 | 0% |
| Ill health | 0 | 0% |
| Expiry of contract | 3 | 0.9% |
| Other | 0 | 0% |
| **Total** | **23** | **6,9%** |

During the 2024/25 period, various people-focused initiatives were implemented, resulting in a staff turnover rate of 6.9%, which is a 2.5% decrease compared to the previous year and remains well within the target of 10%. Despite this improvement, SAHPRA continues to experience turnover difficulties in critical and scarce roles, leading to instability and disruption at both management and operational levels. The main factors contributing to employee departures include concerns over job security, limited opportunities for career progression, challenges with work-life balance, dissatisfaction with remuneration and benefits, retirement, and contract expirations.

## Labour Relations: Misconduct and disciplinary action

**Grievances:** during the 2024/2025 financial year, a total of eight (8) grievances were submitted. All of these grievances were addressed and resolved within the same financial year, leaving no outstanding grievances.

**Disputes:** in the 2024/2025 financial year, nine (9) disputes were lodged. All nine disputes were concluded during the period under review, with none remaining unresolved. Among these disputes: three (3) were withdrawn by the applicants, one (1) was decided against SAHPRA, three (3) were decided in favour of SAHPRA, one (1) resulted in a settlement agreement between the parties, and one (1) ended in a deadlock where picketing rules were mutually agreed upon.

**Misconduct Cases:** A total of fourteen (14) misconduct cases were reported in the 2024/2025 financial year. Of these, nine (9) cases were finalised, two (2) were closed due to insufficient evidence or lack of witnesses, and three (3) cases remained pending at the end of the review period.

### The sanctions imposed on SAHPRA employees are detailed as follows:

| Nature of Disciplinary Action | Number |
|---|---|
| Verbal Warning | 0 |
| Written Warning | 5 |
| Final Written warning | 2 |
| Suspension Without Pay | 1 |
| Dismissal | 1 |
| **Total** | **09** |

### Equity Target and Employment Equity Status

| Levels | MALE | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | African | | Coloured | | Indian | | White | |
| | Current | Target | Current | Target | Current | Target | Current | Target |
| Top Management | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 |
| Senior Management | 8 | 1 | 1 | 1 | 0 | 1 | 0 | 1 |
| Professional qualified | 67 | 45 | 3 | 10 | 2 | 4 | 4 | 7 |
| Skilled | 19 | 0 | 1 | 4 | 0 | 1 | 1 | 3 |
| Semi-skilled | 17 | 0 | 1 | 2 | 0 | 1 | 0 | 1 |
| Unskilled | | | | | | | | |
| **Total** | **111** | **47** | **6** | **17** | **2** | **7** | **6** | **12** |

African employees constitute the majority of the organisation's workforce, representing 81.5% (270 out of 331 employees which indicates an overrepresentation of 3.9%. Indian employees make up 7.5% (25 out of 331), reflecting an overrepresentation of 4.7%. White employees account for 6.3% (21 out of 331), showing an underrepresentation of 3.9%, while Coloured employees represent 4.5% (15 out of 331), with an underrepresentation of 5.5%.

| Levels | FEMALE | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | African | | Coloured | | Indian | | White | |
| | Current | Target | Current | Target | Current | Target | Current | Target |
| Top Management | 2 | 0 | 0 | 0 | 1 | 0 | 1 | 0 |
| Senior Management | 6 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| Professional qualified | 100 | | 5 | 3 | 18 | 0 | 9 | 0 |
| Skilled | 36 | 0 | 2 | 1 | 2 | 0 | 1 | 0 |
| Semi-skilled | 15 | 0 | 2 | 0 | 0 | 0 | 4 | 0 |
| Unskilled | | 0 | | 0 | | 0 | | 0 |
| **Total** | **159** | **0** | **9** | **4** | **23** | **0** | **15** | **0** |

| Levels | Disabled Staff | | | |
|---|---|---|---|---|
| | Male | | Female | |
| | Current | Target | Current | Target |
| Top Management | 0 | 0 | 0 | 0 |
| Senior Management | 0 | 0 | 0 | 0 |
| Professional qualified | 0 | 1 | 3 | 3 |
| Skilled | 0 | 1 | 0 | 0 |
| Semi-skilled | 1 | 1 | 2 | 2 |
| Unskilled | 0 | 0 | 0 | 0 |
| **Total** | **1** | **3** | **5** | **5** |

African employees constitute the majority of the organisation's workforce, representing 81.5% (270 out of 331 employees which indicates an overrepresentation of 3.9%. Indian employees make up 7.5% (25 out of 331), reflecting an overrepresentation of 4.7%. White employees account for 6.3% (21 out of 331), showing an underrepresentation of 3.9%, while Coloured employees represent 4.5% (15 out of 331), with an underrepresentation of 5.5%.

The overall representation of women is at 62%, with women holding 50% of senior and executive roles. Disability representation remains steady at 2%, consistent with the previous 2023/2024 financial year.

Women within the African and Indian groups are overrepresented, contributing to an overall surplus of female employees. To promote workplace equity, it is essential to address the underrepresentation of certain groups. Recruitment strategies will focus on attracting more males, particularly Indian males, to achieve a more balanced workforce. Targeted interventions will be implemented in areas identified as either over- or underrepresented to improve equity. These initiatives will be incorporated into the forthcoming five-year Employment Equity (EE) Plan, aligned with the latest regulatory updates and sector target revisions that came into effect on 1 January 2025, as introduced by the Department of Employment and Labour.

# PART E

## PFMA COMPLIANCE REPORT

# 1. IRREGULAR, FRUITLESS AND WASTEFUL EXPENDITURE AND MATERIAL LOSSES

## 1.1. Irregular expenditure

### a) Reconciliation of irregular expenditure

| Description | 2024/25 | 2023/24 |
|---|---|---|
| | R'000 | R'000 |
| Opening balance | - | - |
| Add: Irregular expenditure confirmed | - | 163 |
| Less: Irregular expenditure condoned | - | (163) |
| Less: Irregular expenditure not condoned and removed | - | - |
| Less: Irregular expenditure recoverable[1] | - | - |
| Less: Irregular expenditure not recoverable and written off | - | - |
| **Closing balance** | **-** | **-** |

*2023/24 Irregular expenditure condoned by the National Treasury in line with the guidelines issued.*
*No new transgressions identified for the 2024/25 financial year.*

### Reconciling notes

| Description | 2024/25 | 2023/24 |
|---|---|---|
| | R'000 | R'000 |
| Irregular expenditure that was under assessment | - | - |
| Irregular expenditure that relates to the prior year and identified in the current year | - | - |
| Irregular expenditure for the current year | - | 163 |
| **Total** | **-** | **163** |

### b) Details of irregular expenditure (under assessment, determination, and investigation

| Description[2] | 2024/25 | 2023/24 |
|---|---|---|
| | R'000 | R'000 |
| Irregular expenditure under assessment | - | - |
| Irregular expenditure under determination | - | - |
| Irregular expenditure under investigation | - | - |
| **Total** | **-** | **-** |

*Possible fruitless and wasteful expenditure currently under assessment*

[1] Transfer to receivables
[2] Group similar items

### c) Details of irregular expenditure condoned

| Description | 2024/25 R'000 | 2023/24 R'000 |
|---|---|---|
| Irregular expenditure condoned | - | 163 |
| **Total** | **-** | **163** |

2023/24 Irregular expenditure condoned by the National Treasury in line with the guidelines issued

### d) Details of irregular expenditure removed - (not condoned)

| Description | 2024/25 R'000 | 2023/24 R'000 |
|---|---|---|
| Irregular expenditure recoverable | - | - |
| **Total** | **-** | **-** |

*All irregular expenditure confirmed were subsequently condoned by the National Treasury*

### e) Details of irregular expenditure recoverable

| Description | 2024/25 R'000 | 2023/24 R'000 |
|---|---|---|
| Irregular expenditure recoverable | - | - |
| **Total** | **-** | **-** |

*Confirmed irregular expenditure did not require recovery in line with the National Treasury Guidelines*

### f) Details of current and previous year irregular expenditure written off (irrecoverable)

| Description | 2024/25 R'000 | 2023/24 R'000 |
|---|---|---|
| Irregular expenditure written off | - | - |
| **Total** | **-** | **-** |

*Confirmed irregular expenditure did not require to be written off*

## ADDITIONAL DISCLOSURE RELATING TO INTER-INSTITUTIONAL ARRANGEMENTS

### g) Details of disciplinary or criminal steps taken as a result of irregular expenditure

| Disciplinary steps taken |
|---|
| 2023/24 – 1 warning issued to implicated staff following a determination process |
| 2024/25 – N/A |

*Disciplinary action taken appears to be effective as subsequent similar transgressions were not noted.*

## 1.2. FRUITLESS AND WASTEFUL EXPENDITURE

### a) Reconciliation of fruitless and wasteful expenditure

| Description | 2024/25 | 2023/24 |
|---|---|---|
| | R'000 | R'000 |
| Opening balance | - | 342 |
| Add: Fruitless and wasteful expenditure confirmed | - | - |
| Less: Fruitless and wasteful expenditure recoverable[3] | - | - |
| Less: Fruitless and wasteful expenditure not recoverable and written off | - | (342) |
| **Closing balance** | - | - |

*Identified during the 2022/23 financial year and related to interest and penalties issued by SARS due to under payment of PAYE. A determination was completed which did not recommend recovery and were subsequently written off.*

### Reconciling notes

| Description | 2024/25 | 2023/24 |
|---|---|---|
| | R'000 | R'000 |
| Fruitless and wasteful expenditure that was under assessment | - | - |
| Fruitless and wasteful expenditure that relates to the prior year and identified in the current year | - | - |
| Fruitless and wasteful expenditure for the current year | - | - |
| **Total** | - | - |

### b) Details of fruitless and wasteful expenditure (under assessment, determination, and investigation)

| Description | 2024/25 | 2023/24 |
|---|---|---|
| | R'000 | R'000 |
| Fruitless and wasteful expenditure under assessment | - | - |
| Fruitless and wasteful expenditure under determination | - | - |
| Fruitless and wasteful expenditure under investigation | - | - |
| **Total** | - | - |

### c) Details of fruitless and wasteful expenditure recoverable

| Description | 2024/25 | 2023/24 |
|---|---|---|
| | R'000 | R'000 |
| Fruitless and wasteful expenditure recoverable | - | - |
| **Total** | - | - |

[3] Transfer to receivables

### d) Details of fruitless and wasteful expenditure not recoverable and written off

| Description | 2024/25 | 2023/24 |
|---|---|---|
| | R'000 | R'000 |
| Fruitless and wasteful expenditure written off | - | 342 |
| **Total** | **-** | **342** |

*A determination was completed and found no liable official due to resignations as well as unforeseen system error resulting in overdue payment penalties and interest being written off*

### e) Details of disciplinary or criminal steps taken as a result of fruitless and wasteful expenditure

| Disciplinary steps taken |
|---|
| A determination was completed and found no liable official due to resignations as well as unforeseen system error resulting in late payment penalties and interest being written off |

## 1.3. ADDITIONAL DISCLOSURE RELATING TO MATERIAL LOSSES IN TERMS OF PFMA SECTION 55(2)(B)(I) &(III))[4]

### a) Details of material losses through criminal conduct

| Description | 2024/25 | 2023/24 |
|---|---|---|
| | R'000 | R'000 |
| Theft | - | - |
| Other material losses | - | - |
| Less: Recoverable | - | - |
| Less: Not recoverable and written off | - | - |
| **Total** | **-** | **-** |

*No material losses were identified*

# 2. LATE AND/OR NON-PAYMENT OF SUPPLIERS

| Description | Number of invoices | Consolidated Value |
|---|---|---|
| | | R'000 |
| Valid invoices received | 848 | 109 351 |
| Invoices paid **within** 30 days or agreed period | 779 | 101 768 |
| Invoices paid **after** 30 days or agreed period | 68 | 7 576 |
| Invoices older than 30 days or agreed period ***(unpaid and without dispute)*** | 1 | 7 |
| Invoices older than 30 days or agreed period ***(unpaid and in dispute)*** | 0 | - |

*Invoices older than 30 days and not in dispute remained unpaid due to queries raised with the service provider, internal clarifications required before processing payment or late submission to the finance department for payment*

[4] Information related to material losses must also be disclosed in the annual financial statements.

# 3. SUPPLY CHAIN MANAGEMENT

## 3.1. PROCUREMENT BY OTHER MEANS

| Project description | Name of supplier | Type of procurement by other means | Contract number | Value of contract R'000 |
|---|---|---|---|---|
| Cloud self-management sever to host Stake holder engagement Portal and RIMS | InfoTech Integrated Solutions | Single Source | PO0518 | 986 |
| Notification of registration of medicines in terms of section 17 | Government Printing Works | Sole Source | PO0539 | 14 |
| Provision of Human Vaccine Lot Release Testing and WHO PQ Vaccine Contract Testing for a period of three (3) years | South African National Control Laboratory for Biological Products | Sole Source | PO0599 | 23 093 |
| Training for building access permit purposes | Airports Company South Africa | Single Source | PO0568 | 2 |
| Erratum tender notice advertised on 28 July 2024 in the Sunday Times | Kashan Advertising | Single Source | PO0580 | 23 |
| Renewal of Quantum System support and maintenance for 12 months. | Therefore, Strategic Technology Services | Single Source | PO0590 | 129 |
| CIPS Membership | Chartered Institute of Procurement and Supply | Sole Source | PO0591 | 14 |
| Notification of registration of medicines in terms of section 17 | Government Printing | Sole Source | PO0595 | 8 |
| IODSA annual membership fee | Institute of Directors South Africa | Sole Source | PO0599 | 48 |
| FIP World Congress registration fee for 4 SAHPRA Bill Working Group members | FIP | Single Source | PO0604 | 75 |
| Category C veterinary medicine – notice publication | Government Printing Works | Sole source | PO0616 | 8 |
| Vigiflow software licence renewal | Uppsala | Single Source | PO0621 | 90 |
| Subscription – Monthly Index of Medical Specialities and Mims Desk Reference | Arena Holdings | Sole Source | PO0268 | 12 |
| Notice of Registrations in the Gazette in terms of Section 17 | Government Printing Works | Sole Source | PO0648 | 9 |
| Extension to the exemption of medical devices and in-vitro diagnostics (IVDs) | Government Printing Works | Sole Source | PO0701 | 3 |
| ICH annual membership | ICH | Single Source | PO0702 | 176 |

| Project description | Name of supplier | Type of procurement by other means | Contract number | Value of contract R'000 |
|---|---|---|---|---|
| SAGE 300 people and midyear submissions training | SAGE South Africa | Single Source | PO0693 | 78 |
| CaseWare software | Adapt IT (Pty) Ltd | Sole Source | PO0732 | 135 |
| SAAHIP annual conference | SAAHIP | Single Source | PO0761 | 24 |
| Total | | | | **24 792** |

## 3.2. CONTRACT VARIATIONS AND EXPANSIONS

| Project description | Name of supplier | Contract modification type (Expansion or Variation) | Contract number | Original contract value | Value of previous contract expansion/s or variation/s (if applicable) | Value of current contract expansion or variation |
|---|---|---|---|---|---|---|
| | | | | R'000 | R'000 | R'000 |
| Deman controllers (Aircon) | HVAC | Variation | PO0511 | 29 | - | 3 |
| MTN contact extension | MTN | Expansion | PO0690 | 4 548 | 1 283 | 446 |
| Additional SAO to attend HPA Supervisory Training | African Skills Village | Expansion | PO0540 | 115 | - | 7 |
| Office space for Border Technicians | ACSA | Variation | PO0545 | 1 691 | 253 | 427 |
| IT Storeroom Door Additional 5 POLO hatch vehicle | Spec Africa Holdings | Variation | PO0564 | 605 | - | 31 |
| Additional 5 VW Polo Hatch | Tracker Connect | Expansion | PO0605 | 177 | - | 52 |
| Additional insurance cover for new assets | Lateral Unison | Expansion | PO0609 | 1,024 | 131 | 78 |
| Clinical Stakeholder meeting | Travel with Flair | Expansion | PO0610 | 61 | - | 9 |
| Security Services extension | Omega Risk Solutions | Expansion | PO0636 | 686 | 45 | 74 |
| Extension of technology consultancy tender to include enhancement | Nuvo3 (Pty | Variation | PO0765 | 14 741 | - | 2 210 |
| Job Profiling -additional positions | Emergence Growth | Expansion | PO0781 | 988 | - | 171 |
| **Total** | | | | **29 213** | **2 535** | **3 968** |

# PART F

## FINANCIAL INFORMATION

# Index

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

# 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 SAHPRA 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 judgements and estimates.

The Accounting Authority acknowledge that they are ultimately responsible for the system of internal financial control established by SAHPRA 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 SAHPRA and all employees are required to maintain the highest ethical standards in ensuring SAHPRA's business is conducted in a manner that in all reasonable circumstances is above reproach. The focus of risk management in SAHPRA is on identifying, assessing, managing and monitoring all known forms of risk across SAHPRA. While operating risk cannot be fully eliminated, SAHPRA 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 entity's cash flow forecast for the year to 31 March 2026 and, in the light of this review and the current financial position, they are satisfied that SAHPRA has and have access to adequate resources to continue in operational existence for the foreseeable future. SAHPRA is partially dependent on the National Department of Health for continued funding of operations. The annual financial statements are prepared on the basis that SAHPRA is a going concern and that SAHPRA have neither the intention nor the need to liquidate or curtail materially the scale of SAHPRA business operations.

Although the accounting authority is primarily responsible for the financial affairs of SAHPRA, they are supported by SAHPRA's external auditors. The external auditors are responsible for independently reviewing and reporting on SAHPRA's annual financial statements. The annual financial statements have been examined by SAHPRA's external auditors and their report is presented on page 100.

The annual financial statements set out on page 107 to 153, which has been prepared on the going concern basis, was approved by the accounting authority on 30 July 2025 and were signed on its behalf by:

**Dr. Boitumelo Semete-Makokotlela**
Chief Executive Officer

**Dr. Thapelo Motshudi**
Chairperson

# REPORT OF THE AUDITOR-GENERAL TO PARLIAMENT ON THE SOUTH AFRICAN HEALTH PRODUCTS REGULARITY AUTHORITY

## REPORT ON THE AUDIT OF THE FINANCIAL STATEMENTS

### Opinion

1. I have audited the financial statements of the South African Health Products Regulatory Authority (SAHPRA) set out on pages 107 to 153, which comprise the statement of financial position as at 31 March 2025, statement of financial performance, statement of changes in net assets, 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 the South African Health Products Regulatory Authority as at 31 March 2025 and its financial performance and cash flows for the year then ended in accordance with Generally Recognised Accounting Practice (GRAP) and the requirements of the Public Finance Management Act (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 responsibilities of the auditor-general for the audit of the financial statements section of my report.
4. I am independent of the public 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 matter

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

#### Restatement of corresponding figures

7. As disclosed in note 35 to the financial statements, the corresponding figures for 31 March 2024 were restated due to errors in the entity's financial statements for the year ended 31 March 2025.

### Responsibilities of the accounting authority for the financial statements

8. The accounting authority is responsible for the preparation and fair presentation of the financial statements in accordance with the 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 public 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 public entity or to cease operations or has no realistic alternative but to do so.

**Responsibilities of the auditor-general 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 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. This description, which is located at page 104, forms part of my auditor's report.

## Report on the annual performance report

12. In accordance with the Public Audit Act 25 of 2004 (PAA) and the general notice issued in terms thereof; I must audit and report on the usefulness and reliability of the reported performance information against predetermined objectives for the selected material performance indicators presented in the annual performance report. The accounting authority is responsible for the preparation of the annual performance report.

13. I selected the following material performance indicators related to programme 4: Clinical and pharmaceutical evaluation presented in the annual performance report for the year ended 31 March 2025 for auditing. I selected those indicators that measures the entity's performance on its primary mandated functions and is of significant national, community, or public interest.

    - Percentage applications for the sale of unregistered Category A (human) medicines finalised within 3 working days
    - Percentage of human clinical trial applications finalised within 80 working days
    - Percentage of lot release requests finalised within 50 working days
    - Percentage of reports on health product safety signals issued within 40 working days

14. I evaluated the reported performance information for the selected material performance indicators against the criteria developed from the performance management and reporting framework, as defined in the general notice. When an annual performance report is prepared using these criteria, it provides useful and reliable information and insights to users on the entity's planning and delivery on its mandate and objectives.

15. I performed procedures to test whether:

    - the indicators used for planning and reporting on performance can be linked directly to the entity's mandate and the achievement of its planned objectives
    - all the indicators relevant for measuring the entity's performance against its primary mandated and prioritised functions and planned objectives are included
    - the indicators are well defined to ensure that they are easy to understand and can be applied consistently, as well as verifiable so that I can confirm the methods and processes to be used for measuring achievements
    - the targets can be linked directly to the achievement of the indicators and are specific, time bound and measurable to ensure that it is easy to understand what should be delivered and by when, the required level of performance as well as how performance will be evaluated

- the indicators and targets reported on in the annual performance report are the same as those committed to in the approved initial or revised planning documents
- the reported performance information is presented in the annual performance report in the prescribed manner
- there is adequate supporting evidence for the achievements reported and for the reasons provided for any over or underachievement of targets.

16. I performed the procedures to report material findings only; and not to express an assurance opinion or conclusion.
17. I did not identify any material findings on the reported performance information for the selected indicators.

**Other matter**

18. I draw attention to the matter below.

## Achievement of planned targets

19. The annual performance report includes information on reported achievements against planned targets and provides explanations for over- or under- achievements.

## Report on compliance with legislation

20. In accordance with the PAA and the general notice issued in terms thereof, I must audit and report on compliance with applicable legislation relating to financial matters, financial management and other related matters. The accounting authority is responsible for the entity's compliance with legislation.
21. I performed procedures to test compliance with selected requirements in key legislation in accordance with the findings engagement methodology of the Auditor-General of South Africa (AGSA). This engagement is not an assurance engagement. Accordingly, I do not express an assurance opinion or conclusion.
22. Through an established AGSA process, I selected requirements in key legislation for compliance testing that are relevant to the financial and performance management of the entity, clear to allow consistent measurement and evaluation, while also sufficiently detailed and readily available to report in an understandable manner. The selected legislative requirements are included in the annexure to this auditor's report.
23. I did not identify any material non-compliance with the selected legislative requirements.

## Other information in the annual report

24. The accounting authority is responsible for the other information included in the annual report which includes the audit committee's report. The other information referred to does not include the financial statements, the auditor's report and those selected material indicators in the scoped-in programme presented in the annual performance report that have been specifically reported on in this auditor's report.
25. My opinion on the financial statements, the report on the audit of the annual performance report and the report on compliance with legislation do not cover the other information included in the annual report and I do not express an audit opinion or any form of assurance conclusion on it.

26. My responsibility is to read this other information and, in doing so, consider whether it is materially inconsistent with the financial statements and the selected material indicators in the scoped-in programme presented in the annual performance report or my knowledge obtained in the audit, or otherwise appears to be materially misstated.

27. If, based on the work I have performed, I conclude that there is a material misstatement in this other information, I am required to report that fact. I have nothing to report in this regard.

## Internal control deficiencies

28. I considered internal control relevant to my audit of the financial statements, annual performance report and compliance with applicable legislation; however, my objective was not to express any form of assurance on it.

29. I did not identify any significant deficiencies in internal control.

Auditor General

Pretoria
30 July 2025

AUDITOR-GENERAL
SOUTH AFRICA

# ANNEXURE TO THE AUDITOR'S REPORT

The annexure includes the following:

- The auditor-general's responsibility for the audit
- The selected legislative requirements for compliance testing

## Auditor-general's responsibility for the audit

**Professional judgement and professional scepticism**

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 material performance indicators and on the entity's compliance with selected requirements in key legislation.

**Financial statements**

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
- conclude on the appropriateness of the 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 the entity 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**

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.

I also provide the accounting authority with a statement that I have complied with relevant ethical requirements regarding independence and 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.

**Compliance with legislation – selected legislative requirements**

The selected legislative requirements are as follows:

| Legislation | Sections or regulations |
|---|---|
| Public Finance Management Act No.1 of 1999 (PFMA) | Section 51(1)(a)(iv); 51(1)(b)(i); 51(1)(b)(ii); 51(1)(e)(iii)<br>Section 53(4)<br>Section 54(2) (c'); 54(2)(d)<br>Section 55(1)(a); 55(1)(b); 55(1)(c)(i)<br>Section 56(1); 56(2)<br>Section 57(b);<br>Section 66(3) (c'); 66(5) |
| Treasury Regulations for departments, trading entities, constitutional institutions and public entities (TR) | Treasury Regulation 8.2.1; 8.2.2<br>Treasury Regulation ; 16A 6.1; 16A6.2(a) & (b); 16A6.2(e);16A 6.3(a); ; 16A 6.3(b); 16A 6.3(c); 16A 6.3(d); 16A 6.3(e); 16A 6.4; 16A 6.5; 16A 6.6; TR 16A.7.1; 16A.7.3; 16A.7.6; 16A.7.7; 16A 8.2(1); 16A 8.2(2); 16A 8.3; 16A 8.3(d); 16A 8.4; 16A9.1 16A9; 16A9.1(b)(ii); 16A9.1(c); 16A 9.1(d); 16A 9.1(e); 16A9.1(f); 16A 9.2; 16A 9.2(a)(ii); TR 16A 9.2(a)(iii)<br>Treasury Regulation 30.1.1; 30.1.3(a); 30.1.3(b); 30.1.3(d); 30.2.1<br>Treasury Regulation 31.1.2(c')<br>Treasury Regulation 31.2.1; 31.2.5; 31.2.7(a)<br>Treasury Regulation 31.3.3<br>Treasury Regulation 32.1.1(a); 32.1.1(b); 32.1.1(c')<br>Treasury Regulation 33.1.1; 33.1.3 |
| Prevention and Combating of Corrupt Activities Act No.12 of 2004 (PRECCA) | Section 34(1) |

| Legislation | Sections or regulations |
|---|---|
| Construction Industry Development Board Act No.38 of 2000 (CIDB) | Section 18(1) |
| CIDB Regulations | CIDB regulation 17; & 25(7A) |
| PPPFA | Section 2.1(a); 2.1(b); 2.1(f) |
| PPR 2017 | Paragraph 4.1; 4.2<br>Paragraph 5.1; 5.3; 5.6; 5.7<br>Paragraph 8.2; 8.5<br>Paragraph 9.1; 9.2<br>Paragraph 12.1 and 12.2 |
| PPR 2022 | Paragraph 4.1; 4.2; 4.3; 4.4<br>Paragraph 5.1; 5.2; 5.3; 5.4 |
| National Treasury Instruction No.1 of 2015/16 | Paragraph 3.1; 4.1; 4.2 |
| NT SCM Instruction Note 03 2021/22 | Paragraph 4.3; 4.4; 4.4 (a); 4.4 (c) -(d); |
| NT SCM Instruction Note 11 2020/21 | Paragraph 3.1; and (b); 3.9; |
| NT SCM Instruction Note 2 of 2021/22 | Paragraph 3.2.1; 3.2.4(a); 3.3.1; |
| NT Instruction Note 4 of 2015/16 | Paragraph 3.4 |
| Second amendment of NTI 05 of 2020/21 | Paragraph 4.8; 4.9; 5.1; 5.3 |
| Erratum NTI 5 of 202/21 | Paragraph 1 |
| Erratum NTI 5 of 202/21 | Paragraph 2 |
| Practice Note 7 of 2009/10 | Paragraph 4.1.2 |
| NT instruction note 1 of 2021/22 | Paragraph 4.1 |

# Statement of Financial Position

As at 31 March 2025

| | Note(s) | 2025<br>R | 2024<br>Restated*<br>R |
|---|---|---|---|
| **Assets** | | | |
| **Current Assets** | | | |
| Receivables from exchange transactions | 3 | 10 628 576 | 9 401 027 |
| Receivables from non-exchange transactions | 4 | 1 888 027 | 7 996 854 |
| Prepayments | 5 | 12 346 415 | 9 642 933 |
| Cash and cash equivalents | 6 | 451 472 827 | 371 616 710 |
| | | **476 335 845** | **398 657 524** |
| **Non-Current Assets** | | | |
| Property, plant and equipment | 7 | 30 032 717 | 25 888 198 |
| Intangible assets | 8 | 23 098 859 | 16 123 213 |
| | | **53 131 576** | **42 011 411** |
| **Total Assets** | | **529 467 421** | **440 668 935** |
| **Liabilities** | | | |
| **Current Liabilities** | | | |
| Operating lease liability | 9 | 1 462 457 | 3 518 705 |
| Payables from exchange transactions | 10 | 13 557 928 | 12 147 766 |
| Employee benefit obligation | 11 | 931 868 | 908 394 |
| Unspent conditional grants and receipts | 12 | 10 060 420 | 9 759 759 |
| Provisions | 13 | 29 712 142 | 23 880 338 |
| Income received in advance | 14 | 318 606 575 | 289 756 591 |
| | | **374 331 390** | **339 971 553** |
| **Non-Current Liabilities** | | | |
| Employee benefit obligation | 11 | 10 532 034 | 9 967 586 |
| **Total Liabilities** | | **384 863 424** | **349 939 139** |
| **Net Assets** | | **144 603 997** | **90 729 796** |
| Accumulated surplus | | 144 603 997 | 90 729 796 |
| **Total Net Assets** | | **144 603 997** | **90 729 796** |

* Refer to note 35 and 36

# Statement of Financial Performance

For the year ended 31 March 2025

| | Note(s) | 2025<br>R | 2024<br>Restated*<br>R |
|---|---|---|---|
| **Revenue** | | | |
| **Revenue from exchange transactions** | | | |
| Fee income | 15 | 254 737 199 | 231 177 966 |
| Sundry income | 16 | 369 101 | 12 230 |
| Interest received | 17 | 36 476 673 | 32 529 429 |
| Actuarial gains | 11 | 1 675 165 | 702 130 |
| **Total revenue from exchange transactions** | | **293 258 138** | **264 421 755** |
| **Revenue from non-exchange transactions** | | | |
| Transfer payment received | 18 | 143 518 000 | 137 873 000 |
| Service in kind | 19 | 13 632 283 | 8 840 587 |
| Grant realised and income | 20 | 51 561 930 | 27 305 838 |
| Seta grant received | | 1 012 362 | - |
| **Total revenue from non-exchange transactions** | | **209 724 575** | **174 019 425** |
| **Total revenue** | | **502 982 713** | **438 441 180** |
| **Expenditure** | | | |
| Employee related costs | 21 | (277 327 431) | (248 076 856) |
| BMGF project expenditure | 24 | (798 347) | - |
| Depreciation and amortisation | 26 | (9 708 322) | (7 327 559) |
| Impairment of assets | | (292 373) | (84 574) |
| Auda Nepad project expenditure | 25 | (1 513 202) | (870 020) |
| Lease rentals on operating lease | | (21 167 894) | (21 018 152) |
| Bad debts written off | | - | (2 303 683) |
| Global fund project expenditure | 22 | (38 591 319) | (20 971 537) |
| GiZ project expenditure | 23 | (1 023 242) | - |
| Labororatory services | 27 | (21 276 216) | (23 604 708) |
| Loss on disposal of assets | | (69 213) | (139 940) |
| Loss on foreign exchange | | (18 873) | (140 570) |
| Operating expenditure | 28 | (75 844 736) | (94 161 539) |
| MPP project expenditure | | (1 477 344) | - |
| **Total expenditure** | | **(449 108 512)** | **(418 699 138)** |
| **Surplus for the year** | | **53 874 201** | **19 742 042** |

* Refer to note 35 and 36

# Statement of Changes in Net Assets

For the year ended 31 March 2025

| | Note(s) | Accumulated surplus R | Total net assets R |
|---|---|---|---|
| **Balance at 01 April 2023** | | **70 987 754** | **70 987 754** |
| Surplus for the year | | 19 742 042 | 19 742 042 |
| **Total changes** | | **19 742 042** | **19 742 042** |
| **Opening balance as previously reported** | | **82 401 013** | **82 401 013** |
| Adjustments: | | | |
| Correction of errors | 35 | 8 262 226 | 8 262 226 |
| Adoption of new accounting policy for depreciation and ammortisation | 36 | 66 557 | 66 557 |
| **Restated balance at 01 April 2024** | | **90 729 796** | **90 729 796** |
| Surplus for the period | | 53 874 201 | 53 874 201 |
| **Total** | | **53 874 201** | **53 874 201** |
| **Balance at 31 March 2025** | | **144 603 997** | **144 603 997** |

# Cash Flow Statement

For the year ended 31 March 2025

| | Note(s) | 2025<br>R | 2024<br>Restated*<br>R |
|---|---|---|---|
| **Cash flows from operating activities** | | | |
| **Receipts** | | | |
| Fees and deferred income | | 285 422 165 | 261 466 204 |
| Transfer payment received | | 143 518 000 | 137 873 000 |
| Interest income | | 36 754 575 | 32 844 311 |
| Grants received | | 56 110 986 | 26 988 852 |
| | | **521 805 726** | **459 172 367** |
| **Payments** | | | |
| Employee costs | | (290 039 336) | (258 889 002) |
| Suppliers | | (136 605 199) | (141 196 705) |
| | | **(426 644 535)** | **(400 085 707)** |
| **Net cash flows from operating activities** | 29 | **95 161 191** | **59 086 660** |
| **Cash flows from investing activities** | | | |
| Purchase of property, plant and equipment | 7 | (6 324 509) | (3 279 718) |
| Proceeds from sale of property, plant and equipment | 7 | - | 12 230 |
| Purchase of other intangible assets | 8 | (8 980 565) | (13 806 357) |
| **Net cash flows from investing activities** | | **(15 305 074)** | **(17 073 845)** |
| **Net increase/(decrease) in cash and cash equivalents** | | **79 856 117** | **42 012 815** |
| Cash and cash equivalents at the beginning of the year | | 371 616 710 | 329 603 895 |
| **Cash and cash equivalents at the end of the year** | 6 | **451 472 827** | **371 616 710** |

* Refer to note 35 and 36

# Statement of Comparison of Budget and Actual Amounts

For the year ended 31 March 2025

| 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 from exchange transactions** | | | | | | |
| Fee income | 248 508 000 | - | **248 508 000** | 254 737 199 | **6 229 199** | 42.1 |
| Sundry income | - | - | **-** | 369 101 | **369 101** | 42.1 |
| Interest received | 25 553 000 | - | **25 553 000** | 36 476 673 | **10 923 673** | 42.2 |
| **Total revenue from exchange transactions** | **274 061 000** | **-** | **274 061 000** | **291 582 973** | **17 521 973** | |
| **Revenue from non-exchange transactions** | | | | | | |
| **Transfer revenue** | | | | | | |
| ransfer payment | 143 518 000 | - | **143 518 000** | 143 518 000 | **-** | |
| Service in-kind | - | - | **-** | 13 632 283 | **13 632 283** | 42.8 |
| Grants realised | - | - | **-** | 51 561 930 | **51 561 930** | 42.8 |
| Seta grant received | - | - | **-** | 1 012 362 | **1 012 362** | 42.11 |
| **Total revenue from non-exchange transactions** | **143 518 000** | **-** | **143 518 000** | **209 724 575** | **66 206 575** | |
| **Total revenue** | **417 579 000** | **-** | **417 579 000** | **501 307 548** | **83 728 548** | |
| **Expenditure** | | | | | | |
| Employee cost | (273 959 896) | - | **(273 959 896)** | (277 327 431) | **(3 367 535)** | 42.3 |
| BMGF grant expenditure | - | - | **-** | (798 347) | **(798 347)** | 42.10 |
| Depreciation and amortisation | - | - | **-** | (9 708 322) | **(9 708 322)** | 42.4 |
| Impairment loss | - | - | **-** | (292 373) | **(292 373)** | 42.4 |
| Auda Nepad grant expenditure | - | - | **-** | (1 513 202) | **(1 513 202)** | 42.10 |
| Lease rentals on operating lease | (22 185 784) | - | **(22 185 784)** | (21 167 894) | **1 017 890** | 42.7 |
| Global fund expenditure | - | - | **-** | (38 591 319) | **(38 591 319)** | 42.10 |
| GiZ project expenditure | - | - | **-** | (1 023 242) | **(1 023 242)** | 42.10 |
| Laboratory services | (25 950 805) | - | **(25 950 805)** | (21 276 216) | **4 674 589** | 42.6 |
| MPP grant expenditure | - | - | **-** | (1 477 344) | **(1 477 344)** | 42.10 |
| Operating Expenses | (95 482 515) | (12 474 664) | **(107 957 179)** | (75 844 736) | **32 112 443** | 42.5 |
| **Total expenditure** | **(417 579 000)** | **(12 474 664)** | **(430 053 664)** | **(449 020 426)** | **(18 966 762)** | |
| **Operating surplus / (deficit)** | **-** | **(12 474 664)** | **(12 474 664)** | **52 287 122** | **64 761 786** | |
| Loss on disposal of assets and liabilities | - | - | **-** | (69 213) | **(69 213)** | 42.4 |
| Loss on foreign exchange | - | - | **-** | (18 873) | **(18 873)** | 42.9 |
| Actuarial gains/losses | - | - | **-** | 1 675 165 | **1 675 165** | 42.9 |
| | **-** | **-** | **-** | **1 587 079** | **1 587 079** | |
| **Surplus / (deficit)** | **-** | **(12 474 664)** | **(12 474 664)** | **53 874 201** | **66 348 865** | |
| **Actual Amount - the Budget and Actual Comparative Statement** | | **(12 474 664)** | **(12 474 664)** | **53 874 201** | **66 348 865** | |

# Significant Accounting Policies

For the year ended 31 March 2025

## 1. Presentation of Annual Financial Statements

The annual financial statements have been prepared in accordance and are in compliance 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).

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. These accounting policies are consistent with the previous period.

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

A summary of the significant accounting policies are disclosed below. These accounting policies are consistent with the previous period, except for the changes set out in the changes of accounting policy note.

### 1.1 Presentation currency

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

### 1.2 Going concern assumption

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

### 1.3 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.

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 SAHPRA's accounting policies estimates shall be made on items such as the following:

#### Significant estimates

**Trade receivables**

SAHPRA 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, judgements are made 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 balances in the portfolio and scaled to the estimated loss emergence period. Refer to note 3 and note 4 for details regarding impairment considerations.

**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).

### 1.3 Significant judgements and sources of estimation uncertainty (continued)

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

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

**Provisions**

All provisions were raised and management determined an estimate based on information available to settle the obligation in the near future. Additional disclosure of these estimates of provisions are included in note 13 - 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. The provision is only required when staff resigns as unused leave is forfeited 6 months after the year in which it accrued.

Refer to note 13 for the details regarding the leave provision.

**Useful lives of property, plant and equipment and intangible assets**

At the end of each financial year, management assesses whether there is any indication that the residual value and useful life of assets included in property, plant and equipment have changed since the preceding reporting date. If any such indication exists, the changes are accounted for as a change in accounting estimate in accordance with the Standards of GRAP on accounting policies, Changes in Accounting Estimates and Errors.

The assumptions used for useful lives assessment:

1. Condition of the asset through physical inspections and operational effectiveness
2. Whether the asset is in use or not
3. Assets with a R1 or R0 carrying amount and still in use
4. The intended use in the future financial period
5. Intention to dispose of the asset in future
6. Whether the asset is approaching the end of its useful life

Refer to note 7 and 8 for details regarding the change in estimate following the revision of useful lives of property, plant and equipment in the current year.

### Significant judgements

**Contingencies**

Management uses its best estimate of the value of the contingencies to be disclosed based on historical experience and assumptions per case and if no reliable estimate can be made, the reason thereof will be disclosed. Refer to note 31.

### 1.4 Property, plant and equipment

Property, plant and equipment is initially measured at 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, its deemed cost is the carrying amount of the asset(s) given up.

Costs include costs incurred initially to acquire an item of property, plant and equipment and costs incurred subsequently to add to, replace part of, or service it.

Property plant and equipment are depreciated on the straight line basis over their expected useful lives to to a zero value as the majority of SAHPRA assets are disposed through donation. 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.

### 1.4 Property, plant and equipment (continued)

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 | 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 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.

SAHPRA assesses at each reporting date whether there is any indication that 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 expected useful life and/or residual value will be revised accordingly. The change is accounted for as a change in an accounting estimate.

The useful lives of the various components of property, plant and equipment have changed from the prior period to the current year.

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.

### 1.5 Intangible assets

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 entity; and
- the cost or fair value of the asset can be measured reliably.

SAHPRA 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.

Intangible assets are carried at cost less any accumulated amortisation and any impairment losses. SAHPRA does not have intangible assets with indefinite useful lives. The amortisation period and the amortisation method for intangible assets are reviewed at each reporting date. Amortisation is provided to write down the intangible assets, on a straight-line basis, to a zero value as the majority of SAHPRA intangible assets are not expected to be sold at disposal values as follows:

| Item | Depreciation method | Average useful life |
|---|---|---|
| Acquired software | Straight-line | 7 years |

### 1.6 Financial instruments

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

SAHPRA's receivables from exchange transaction includes statutory receivables which are specifically excluded from financial instruments as per GRAP 1.3 (g)

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.

### 1.6 Financial instruments (continued)

**Classification**

SAHPRA has the following types of financial assets (classes and category) as reflected on the face of the Statement of Financial Position or in the notes thereto:

| Class | Category |
|---|---|
| Receivables from non-exchange transactions | Financial assets measured at amortised cost, which, due to their short-term nature, closely approximate their fair value |
| Cash and cash equivalents | Financial assets measured at amortised cost, which, due to their short-term nature, closely approximate their fair value |
| Rental deposit | Financial assets measured at amortised cost, which, due to their short-term nature, closely approximate their fair value |

| Class | Category |
|---|---|
| Trade payables | SAHPRA recognises trade payables from exchange transactions that are due in the ordinary course of operations.<br>Financial liabilities measured at amortised cost, which, due to their short-term nature, closely approximate their fair value |
| Accrued expenditure | SAHPRA accrues expenditure where services have been rendered but not yet invoiced by financial year end in the ordinary course of operations.<br>Financial liabilities measured at amortised cost, which, due to their short-term nature, closely approximate their fair value |
| Travel cards | SAHPRA recognises travel lodge liability and fleet cards that are due in the ordinary course of operations.<br>Financial liabilities measured at amortised cost, which, due to their short-term nature, closely approximate their fair value |
| Income received in advance | SAHPRA recognises income received in advance as a current liability as application fees are received prior to service delivery and are refundable until service is rendered. Applicants are entitled to a refund if the application has not yet review stage. Financial liabilities measured at amortised cost, which, due to their short-term nature, closely approximate their fair value |

**Initial recognition**

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

**Initial measurement of financial assets and financial liabilities**

SAHPRA 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. Any gain or loss is recognised in the surplus or deficit

### Derecognition

**Financial assets**

SAHPRA derecognises financial assets using trade date accounting and derecognises a financial asset only when the contractual rights to the cash flows from the financial asset expire, are settled or waived;

**Financial liabilities**

SAHPRA 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.

## 1.7 Statutory receivables

### Identification

Statutory receivables are receivables that arise from legislation and supporting regulations for fees incurred by industry relating various activities performed by SAHPRA in accordance with the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), and require settlement by another entity in cash or another financial asset as disclosed in note 3 of the financial statements.

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.

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**

SAHPRA 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 SAHPRA and the transaction amount can be measured reliably.

**Initial measurement**

SAHPRA initially measures statutory receivables at their transaction amount.

**Subsequent measurement**

SAHPRA 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**

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

**Derecognition**

SAHPRA derecognises a statutory receivable, or a part thereof, when:

- the rights to the cash flows from the receivable are settled, expire or are waived;

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. SAHPRA 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.

## 1.8 Prepayments

SAHPRA's prepaid expenses consist mainly of computer software annual licences. This expense is paid for in one accounting period but for which the underlying asset will not be consumed until a future period.

These prepaid expenses are carried on the Statement of Financial Position of SAHPRA as a current asset until it is consumed. Once consumption has occurred, the prepaid expense is removed from the Statement of Financial Position and is instead reported in that period as an expense on the Statement of Financial Performance.

### 1.9 Leases

SAHPRA leases office buildings and are classified as operating leases as all the risks and rewards incidental to ownership is not substantially transferred.

**Operating leases - lessee**

An Operating lease is a lease other than a finance lease and for SAHPRA it is the rental of various office buildings. 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.

### 1.10 Cash and cash equivalents

Cash comprises cash on hand and on-demand deposits.

Cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

Cash equivalents are held for the purpose of meeting short-term cash commitments rather than for investment or other purposes. Cash and cash equivalents comprise bank balances, cash on hand, deposits held at Co-operation of Public Deposits.

### 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.

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, SAHPRA recognises a liability only to the extent that is a requirement in the Standards of GRAP.

SAHPRA assesses at each reporting date whether there is an indication that an asset may be impaired or a previous loss no longer exist or has decreased. 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.

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

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

**Reversal of an impairment loss**

SAHPRA 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 recoverable service amount of that asset will be estimated.

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.

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

## 1.12 Employee benefits

### Identification

**Employee benefits**

Employee benefits are all forms of consideration given by an entity in exchange for service rendered by employees or for the termination of employment.

**Short-term employee benefits**

Short-term employee benefits are employee benefits (other than termination benefits) that are due to be settled wholly before twelve months after the end of the reporting period in which the employees render the related service. Therefore, short term employee benefits include remuneration, compensated absences, thirteenth cheque. Some employee benefits like compensated absences and bonuses are disclosed under note 13 - provisions in line with applicable GRAP standard.

The expected cost of compensated absences is recognised as an expense as the employees render the services that increase their entitlement or, in the case of non-accumulating absences, when the absence occurs.

The provision for employees entitled to annual leave represents the present obligation that the SAHPRA has to pay as a result of employees' services provided up to the reporting date. The provision has been calculated at the undiscounted amounts based on salary rates effective on the reporting date.

SAHPRA recognises the expected cost of bonus, incentive and performance related payments when there is 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.

**Post-employment benefits: Defined benefit 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 contributions expenses is measured at the undiscounted amount of the contribution paid or payable for 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

Defined benefit plans are post-employment benefit plans other than defined contributions plans.

Actuarial gains and losses comprise experience adjustments (the effects of differences between the previous actuarial assumptions and what has actually occurred) and the effects of changes in actuarial assumptions. In measuring its defined benefit liability the entity recognises actuarial gains and losses in surplus or deficit in the reporting period in which they occur.

Current service cost is the increase in the present value of the defined benefit obligation resulting from employee service in the current period. Interest cost is the increase during a period in the present value of a defined benefit obligation which arises because the benefits are one period closer to settlement.

Plan assets comprise assets held by of SAHPRA cash held in reserve and invested in the Corporation of Public Deposits. The present value of a defined benefit obligation is the present value, without deducting any plan assets, of expected future payments required to settle the obligation resulting from employee service in the current and prior periods.

The return on plan assets is interest, less any costs of administering the plan (other than those included in the actuarial assumptions used to measure the defined benefit obligation).

Actuarial valuations are conducted on an annual basis by independent actuaries. The results of the valuation are updated for any material transactions and other material changes in circumstances (including changes in market prices and interest rates) up to the reporting date.

SAHPRA recognises gains or losses on the curtailment or settlement of a defined benefit plan when the curtailment or settlement occurs. The gain or loss on a curtailment or settlement comprises: any resulting change in the present value of the defined benefit obligation; and any resulting change in the fair value of the plan assets.

**Actuarial assumptions**

Actuarial assumptions are unbiased and mutually compatible. Financial assumptions are based on market expectations, at the reporting date, for the period over which the obligations are to be settled.

The rate used to discount post-employment benefit obligations (both funded and unfunded) reflect the time value of money. The currency and term of the financial instrument selected to reflect the time value of money is consistent with the currency and estimated term of the post-employment benefit obligations.

### 1.12 Employee benefits (continued)

Post-employment benefit obligations are measured on a basis that reflects:

- estimated future salary increases;
- the benefits set out in the terms of the plan (or resulting from any constructive obligation that goes beyond those terms) at the reporting date; and
- estimated future changes in the level of any state benefits that affect the benefits payable under a defined benefit plan, if, and only if, either:
- those changes were enacted before the reporting date; or
- past history, or other reliable evidence, indicates that those state benefits will change in some predictable manner, for example, in line with future changes in general price levels or general salary levels.

Assumptions about medical costs take account of estimated future changes in the cost of medical services, resulting from both inflation and specific changes in medical costs.

**Other post retirement obligations**

SAHPRA provides post-retirement health care benefits upon retirement to some retirees.

The entitlement to post-retirement health care benefits is based on the employee remaining in service up to retirement age and the completion of a minimum service period. The expected costs of these benefits are accrued over the period of employment. Independent qualified actuaries carry out valuations of these obligations.

The amount recognised as a liability for other long-term employee benefits is the net total of the following amounts:

- the present value of the defined benefit obligation at the reporting date;
- minus the fair value at the reporting date of plan assets (if any) out of which the obligations are to be settled directly.

SAHPRA shall recognise the net total of the following amounts as expense or revenue, except to the extent that another Standard requires or permits their inclusion in the cost of an asset:

- current service cost;
- interest cost;
- the expected return on any plan assets and on any reimbursement right recognised as an asset;
- actuarial gains and losses, which shall all be recognised immediately;
- past service cost, which shall all be recognised immediately; and
- the effect of any curtailments or settlements.

### 1.13 Provisions and contingencies

Provisions are recognised when:

- SAHPRA 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 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. Provisions are disclosed in note 13.

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

Contingent Assets and Liabilities are recorded in the notes to the financial statements when there is a possible obligation or asset that arises from past events; and where existence will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not within the control of SAHPRA or when there is a present obligation that is not recognised because it is not probable that an outflow of resources will be required to settle the obligation, or the amount of the obligation cannot be measured reliably. Contingencies are disclosed in note 31.

### 1.14 Commitments

Items are classified as commitments when SAHPRA 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 SAHPRA– therefore salary commitments relating to employment contracts or social security benefit commitments are excluded.

### 1.15 Revenue from exchange transactions

**Measurement**

Revenue is measured at the fair value of the consideration received or receivable. 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

**New application for registration**

Due to the extensive evaluations performed and duration over multiple financial years for new medicine applications by various units, revenue will be recognised on a stage of completion basis based on a certain % of completion when the initial evaluator query (% of total services to be performed) per unit is issued as follows:

Names and Scheduling Unit – 25% Inspectorate – 25%

Clinical Evaluation Management (CEM) – 25%

Pharmaceutical Evaluation Management (PEM) – 25%

Biologicals – 50% - carries more weight due to its inclusion of the Quality process which is normally performed in PEM

**Other fee types**

Fee types not recognised by stage of completion will be recognised when a specific act occurs such as:

A specific act will be utilised that is more significant to any other act which is the initial evaluator query letter issued due to most of the work performed and related costs has been completed at this point, the applicant is to correct and respond and no refunds can be applied for at this point.

Other specific acts outside a required evaluation process will be approvals; rejections; inspector reports, or approval and anniversary of retention fees.

Annual license fees are deemed exchange revenue as the license issued permits the licensee to conduct a business and is in substance a sale in accordance with IPSAS 9.

### Interest received

Revenue arising from the use by others of SAHPRA assets yielding interest is recognised when:

- It is probable that the economic benefits or service potential associated with the transaction will flow to 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

Non-exchange transactions are transactions that are not exchange transactions. SAHPRA recognises donor funds as non- exchange revenue as grant realised or grant income on the date the revenue becomes effective if the expenditure associated with the revenue has been incurred.

SAHPRA receives a transfer payment from the National Department of Health as its fiscus allocation.

**Measurement**

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

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

SAHPRA 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.

SAHPRA 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.

**Conditional Grants**

Grant funding relate to cash received or to be received for a limited period, to be used as per the conditions of the agreement with the funder which mainly relates to the achievement of SAHPRA's mandate. The funds received are separately accounted for in line with the relevant GRAP standards.

**Services in-kind**

SAHPRA 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 SAHPRA and the fair value of the assets can be measured reliably.

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

## 1.17 Comparative figures

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

## 1.18 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.

SAHPRA operates in a single segment as budgets are not decentralised into regional activities. SAHPRA's management accounts, internal and external reports are not per programme or cost centre. All decisions are made centrally and no geographical decisions are made.

SAHPRA Head Office is located in Gauteng with regional offices in Cape Town and Durban and representation at the main ports of entry.

### 1.19 Budget information

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 2024/04/01 to 2025/03/31.

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 note 41 & 42.

### 1.20 Related parties

SAHPRA 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 SAHPRA 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 SAHPRA's legal mandate.

Where SAHPRA is exempt from the disclosures in accordance with the above, SAHPRA discloses narrative information about the nature of the transactions and the related outstanding balances, to enable users of SAHPRA's financial statements to understand the effect of related party transactions on its annual financial statements.

### 1.21 Translation of foreign currencies

**Foreign transactions**

A foreign currency transaction shall be recorded, on initial recognition in South African Rand, by applying to the foreign currency amount the spot exchange rate between the South African Rand and the foreign currency at the date of the transaction.

Exchange differences arising on the settlement of monetary items or on translating monetary items at rates different from those at which they were translated on initial recognition during the period or in previous annual financial statements are recognised in surplus or deficit in the period in which they arise.

Non-monetary items, such as pre-payments, shall be translated using the exchange rate at the date of the transaction date which is the date of payment.

**Foreign evaluator payments**

Transactions relating to foreign evaluator payments, due to practical reasons, will apply a rate that approximates the actual rate at the date of the transaction. Evaluators are paid once a month and the translation rate used that approximates the actual rate will be the date of payment.

Cash flows arising from transactions in a foreign currency are recorded in Rands by applying to the foreign currency amount the exchange rate between the Rand and the foreign currency at the date of the cash flow.

**Reporting date**

At each reporting date:

- Foreign currency monetary items, such as trade payables and evaluator accruals shall be translated using the closing rate.
- Non-monetary items, such as pre-payments, that are measured in terms of historical cost in a foreign currency shall be translated using the exchange rate at the date of the transaction.

Cash flows arising from transactions in a foreign currency are recorded in Rands by applying to the foreign currency amount the exchange rate between the Rand and the foreign currency at the date of the cash flow.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025<br>R | 2024<br>R |
|---|---|---|

## 2. New standards and interpretations

### 2.1 Standards and interpretations issued, but not yet effective

SAHPRA has not applied the following standards and interpretations, which have been published and are mandatory for SAHPRA's accounting periods beginning on or after 01 April 2025 or later periods:

| Standard/ Interpretation: | Effective date: Years beginning on or after | Expected impact: |
|---|---|---|
| • GRAP 1 (amended): Presentation of Financial Statements (Going Concern) | not yet determined | Unlikely there will be a material impact |
| • GRAP 104 (as revised): Financial Instruments | 01 April 2025 | Impact is currently being assessed |
| • iGRAP 21: The Effect of Past Decisions on Materiality | not yet determined | Unlikely there will be a material impact |
| • GRAP 106: Transfer of Functions Between Entities Not Under Common Control | not yet determined | Unlikely there will be a material impact |
| • iGRAP 7 (as revised): Limit on defined benefit asset, minimum funding requirements and their interaction | 01 April 2025 | Impact is currently being assessed |

## 3. Receivables from exchange transactions

| | | |
|---|---|---|
| Trade debtors | 6 997 373 | 9 760 721 |
| Provision for impairment | (1 273 261) | (4 753 792) |
| Deposits | 4 904 464 | 4 394 098 |
| | **10 628 576** | **9 401 027** |
| **Statutory receivables included in receivables from exchange transactions above are as follows:** | | |
| Retention fees | 1 650 618 | 6 165 905 |
| Licence collection fees | 619 640 | 1 177 070 |
| Inspection fees | 2 116 635 | 2 117 346 |
| New registrations | 257 580 | 62 000 |
| Renewals of medicine applications | 2 114 500 | - |
| Biological amendments | 238 400 | 238 400 |
| | **6 997 373** | **9 760 721** |
| Provision for impairments | (1 273 261) | (4 753 792) |
| **Financial asset receivables included in receivables from exchange transactions above** | **4 904 464** | **4 394 098** |
| **Total receivables from exchange transactions** | **10 628 576** | **9 401 027** |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

## 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, Renewal of medicines, New registration 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.

Rental deposit increased due to additions in deposits during the year. 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 in vitro diagnostics (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 2025 in line with SAHPRA's revenue policy

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

In terms of the Medicines and Related Substances Act, as amended 16(4): 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 prescribe 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, historical collection and write off of bad debts and the progress made with regards to the cancellation process of a license.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025<br>R | 2024<br>R |
|---|---|---|
| **3. Receivables from exchange transactions (continued)** | | |
| **Reconciliation of provision for impairment** | | |
| **Relating specifically to Statutory Receivables** | | |
| Opening balance | 4 753 792 | 5 155 309 |
| Provision for impairment | (322 499) | 2 303 683 |
| Amounts written off as uncollectable | (3 158 032) | (2 705 200) |
| | **1 273 261** | **4 753 792** |
| **Provision for impairment breakdown:** | | |
| Retention fees | 913 669 | 3 476 999 |
| Licence collection fees | 359 592 | 1 276 793 |
| | **1 273 261** | **4 753 792** |

**Receivables past due but not impaired**

**Relating specifically to Statutory Receivables**

Statutory receivables which are less than 9 months past due are not considered to be impaired.
At 31 March 2025, R4 727 115 (2024: R2 179 346) were past due but not impaired

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

| | | |
|---|---|---|
| 9 months past due | 4 727 115 | 2 179 346 |

## Receivables impaired

**Relating specifically to Statutory Receivables**

As of 31 March 2025, statutory receivables of R2 270 258 (2024: R7 581 376) were impaired and provided for.

The amount of the provision was R1 273 261 31 March 2025 (2024: R4 753 792).

The ageing of these loans is as follows:

| | | |
|---|---|---|
| 3 to 6 months | 1 051 858 | 745 136 |
| 6 - 12 months | 1 218 400 | 5 021 410 |
| Over 12 months | - | 1 814 830 |
| | **2 270 258** | **7 581 376** |

**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-up request, are in dispute or indicate financial difficulty;
- Customer in liquidation;
- Judgment 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.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025 R | 2024 R |
|---|---|---|

## 4. Receivables from non-exchange transactions

| | | |
|---|---|---|
| Other receivables | 315 230 | 96 337 |
| Grant receivable | 1 049 954 | 5 879 534 |
| Staff debtors | 522 843 | 2 020 983 |
| | **1 888 027** | **7 996 854** |

Other receivables relates to the prior year contingent assets which the tax master finalised relating to an arbitration processes which ruled in favour of SAHPRA and dismissing the claimants claim. Grant receivables includes grant(s) to be received from the GiZ, Auda Nepad, MPP and the Global Fund as conditions were met.

Staff debtors relate to some employees that have not been removed from the NDOH persal system after being transferred to SAHPRA receiving additional salaried benefits. During the 2022/23 period additional staff debt were raised relating to PAYE payments made on behalf of employees. A recovery process was implemented in April 2024.

**Receivables from non-exchange transactions past due but not impaired**

At 31 March 2025, R1 888 027 (2024: R7 996 854) were past due but not impaired.

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

| | | |
|---|---|---|
| less than 12 month past due | 1 049 954 | 5 879 534 |
| more than 12 months past due | 838 073 | 2 117 320 |

Receivables from non-exchange transactions which are less than 12 months past due are not considered to be impaired. Receivables from non-exchange transactions which are more than 12 months past due are considered for impairment applying financial risk management as per note 37 of which no impairments were made based on expected recovery.

**Factors the entity considered in assessing non-exchange receivables from impairment:**

The following is considered as objective evidence that a non-exchange receivable is impaired:

- Debtors did not respond to follow request, are in dispute or indicate financial difficulty;
- Debtor in liquidation;
- Judgment awarded in favour of the entity;
- Uneconomical to initiate or to continue with legal proceedings.

## 5. Prepayments

| | | |
|---|---|---|
| Prepayments | 12 346 415 | 9 642 933 |

Prepayments relates mainly to computer licences expenditure and office rental paid in advance for services to be rendered in future financial periods.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025 R | 2024 R |
|---|---|---|

## 6. Cash and cash equivalents

| | | |
|---|---|---|
| Cash and cash equivalents consist of: | | |
| Petty cash | 10 000 | 10 000 |
| Bank balances held at ABSA bank | 2 690 135 | 2 627 171 |
| Corporation for Public Deposits held at SA Reserve Bank | 447 585 273 | 360 430 295 |
| Call account - Global fund project | 1 187 419 | 8 549 244 |
| | **451 472 827** | **371 616 710** |

No cash and cash equivalents balances are restricted except for unspent conditional grants as disclosed in note 12.

**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 Ba2 (long term) as per the Moody's rating agency as at 31 March 2025. 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.

## 7. Property, plant and equipment

| | 2025 | | | 2024 | | |
|---|---|---|---|---|---|---|
| | Cost / Valuation | Accumulated depreciation and accumulated impairment | Carrying value | Cost / Valuation | Accumulated depreciation and accumulated impairment | Carrying value |
| Furniture and fixtures | 9 707 574 | (4 204 471) | 5 503 103 | 9 424 631 | (3 225 371) | 6 199 260 |
| Motor vehicles | 6 801 227 | (2 428 687) | 4 372 540 | 5 342 724 | (1 117 059) | 4 225 665 |
| Computer equipment | 26 912 609 | (16 530 185) | 10 382 424 | 23 049 186 | (13 123 267) | 9 925 919 |
| Leasehold improvements[1] | 7 064 612 | (6 381 946) | 682 666 | 7 064 612 | (4 975 076) | 2 089 536 |
| Other fixed assets[2] | 11 791 151 | (2 699 167) | 9 091 984 | 5 288 036 | (1 840 218) | 3 447 818 |
| **Total** | **62 277 173** | **(32 244 456)** | **30 032 717** | **50 169 189** | **(24 280 991)** | **25 888 198** |

**Reconciliation of property, plant and equipment - 2025**

| | Opening balance | Additions | Disposals | Depreciation | Impairment loss | Total |
|---|---|---|---|---|---|---|
| Furniture and fixtures | 6 199 260 | 282 943 | - | (970 691) | (8 409) | 5 503 103 |
| Motor vehicles | 4 225 665 | 1 458 503 | - | (1 311 628) | - | 4 372 540 |
| Computer equipment | 9 925 919 | 4 002 694 | (69 213) | (3 476 722) | (254) | 10 382 424 |
| Leasehold improvements[1] | 2 089 536 | - | - | (1 406 870) | - | 682 666 |
| Other fixed assets[2] | 3 447 818 | 6 503 114 | - | (741 202) | (117 746) | 9 091 984 |
| | **25 888 198** | **12 247 254** | **(69 213)** | **(7 907 113)** | **(126 409)** | **30 032 717** |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

## 7. Poperty, plant and equipment (continued)

**Reconciliation of property, plant and equipment - 2024**

| | Opening balance | Additions | Disposals | Depreciation | Impairment loss | Total |
|---|---|---|---|---|---|---|
| Furniture and fixtures | 7 072 157 | 81 300 | - | (954 197) | - | 6 199 260 |
| Motor vehicles | 2 998 291 | 2 052 952 | - | (825 578) | - | 4 225 665 |
| Computer equipment | 13 302 103 | 122 335 | (126 492) | (3 287 453) | (84 574) | 9 925 919 |
| Leasehold improvements[1] | 3 411 002 | 75 171 | - | (1 396 637) | - | 2 089 536 |
| Other fixed assets[2] | 1 568 686 | 2 185 122 | (13 448) | (292 542) | - | 3 447 818 |
| | **28 352 239** | **4 516 880** | **(139 940)** | **(6 756 407)** | **(84 574)** | **25 888 198** |

**Other information**

None of the property, plant and equipment for the current and prior year were pledged as security for any obligation. Minor expenditure has been incurred relating to capital maintenance. Refer to note 28.

[1] Leasehold improvements include improvements made to leased office accommodation. Refer to notes 9 and 28.

[2] Other fixed assets relates to office related equipment.

## 8. Intangible assets

| | 2025 | | | 2024 | | |
|---|---|---|---|---|---|---|
| | Cost / Valuation | Accumulated amortisation and accumulated impairment | Carrying value | Cost / Valuation | Accumulated amortisation and accumulated impairment | Carrying value |
| Computer software | **26 719 061** | **(3 620 202)** | **23 098 859** | **17 776 242** | **(1 653 029)** | **16 123 213** |

**Reconciliation of intangible assets - 2025**

| | Opening balance | Additions | Amortisation | Impairment loss | Total |
|---|---|---|---|---|---|
| Computer software | 16 123 213 | 8 942 819 | (1 801 209) | (165 964) | **23 098 859** |

**Reconciliation of intangible assets - 2024**

| | Opening balance | Additions | Amortisation | Total |
|---|---|---|---|---|
| Computer software | 2 888 007 | 13 806 358 | (571 152) | **16 123 213** |

**Other information**

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

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025<br>R | 2024<br>R |
|---|---|---|
| **9. Operating lease liability** | | |
| Current liabilities | 1 462 457 | 3 518 705 |

The operating lease liability relates to the straight-line effect to recognising the lease expense over the lease term effect per the GRAP 13 requirements.

Operating lease payments represent rentals payable by SAHPRA for leased office properties for six locations. No restrictions, contingent rent or sublease payments apply. Annual escalation percentage is applied over the terms of the lease.

Operating leases commitment - as lessee (expense)

| | | |
|---|---|---|
| **Minimum lease payments due** | | |
| within 1 year | 9 706 736 | 22 205 521 |
| 2 to 5 years | 4 139 520 | 13 888 309 |
| | **13 846 256** | **36 093 830** |

| | | |
|---|---|---|
| **10. PAYABLES FROM EXCHANGE TRANSACTIONS** | | |
| Trade payables | 5 227 687 | 3 913 306 |
| Salary accruals | 1 361 788 | 3 660 237 |
| Accrued thirteenth cheque | 1 781 687 | 1 624 099 |
| Accrued expenditure | 4 803 393 | 2 243 113 |
| Travel cards | 383 373 | 707 011 |
| | **13 557 928** | **12 147 766** |

Salary accruals relate to acting allowances, travel, expert committee, local and foreign evaluator fees not yet paid. SAHPRA considers that the carrying value of payables from exchange transactions approximates the fair value.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025 R | 2024 R |
|---|---|---|

## 11. Employee benefit obligations

### Defined benefit plans - General information

**Defined benefit plan**

The healthcare benefits that the South African Health Products Regulatory Authority gives to its employees are provided by Government Employee Medical Aid Scheme (GEMS). On 31 March 2025 the aggregate membership of the qualifying employees was 86 (2024:86). In-service employees were 86 (2024:86) retired employees a total of 1 (2024:3) employees. Poneso Consulting conducted a valuation of the post-retirement liability as at 31 March 2025. The valuation takes into consideration the current services cost, interest costs and benefits paid.

The amounts recognised in the statement of financial position are as follows:

| | | |
|---|---|---|
| **Carrying value** | | |
| Present value of the defined benefit obligation-wholly unfunded | (11 463 902) | (10 875 980) |
| Non-current liabilities | (10 532 034) | (9 967 586) |
| Current liabilities | (931 868) | (908 394) |
| | **(11 463 902)** | **(10 875 980)** |
| **Changes in the present value of the defined benefit obligation are as follows:** | | |
| Opening balance | 10 875 980 | 9 553 038 |
| Net expense recognised in the statement of financial performance | 587 922 | 1 322 942 |
| | **11 463 902** | **10 875 980** |
| **Net expense recognised in the statement of financial performance are as follows:** | | |
| **Service cost** | | |
| Current service cost | 908 394 | 993 930 |
| Net interest on the net defined benefit liability (asset) | 1 377 612 | 1 080 013 |
| **Remeasurements of the net defined benefit liability (asset)** | | |
| **Actuarial gains and losses arising from:** | | |
| Changes in financial assumptions | (1 675 165) | (702 130) |
| Benefits paid | (22 919) | (48 871) |
| | **587 922** | **1 322 942** |
| **Calculation of actuarial gains and losses** | | |
| (Increase) / Decrease in net discount rate | 186 652 | (1 232 143) |
| Earning increases lower than assumed | 539 905 | 477 442 |
| Change in membership profile | (569 682) | 586 420 |
| Change in cap, medical aid options and others | (1 832 040) | (533 849) |
| | **(1 675 165)** | **(702 130)** |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025 R | 2024 R |
|---|---|---|

## 11. Employee benefit obligations (continued)

**Key assumptions used**

Assumptions used at the reporting date:

| | | |
|---|---|---|
| Health care cost inflation | 7.56 % | 8.76 % |
| Discount rates used | 11.37 % | 12.67 % |
| Real discount rate | 3.54 % | 3.60 % |
| Continuation at retirement | 75.00 % | 75.00 % |
| Proportion married | 80.00 % | 80.00 % |

### Sensitivity analysis

**Healthcare cost trends**

Assumed healthcare cost trends rates have a significant effect on the amounts recognised in surplus or deficit. A one percentage point change in assumed healthcare cost trends rates would have the following effects:

| 2025 | One percentage point increase | One percentage point decrease |
|---|---|---|
| Effect on the service cost | 1 149 755 | 762 243 |
| Effect on interest cost | 1 580 108 | 1 083 487 |
| Effect on defined benefit obligation | 13 900 122 | 9 532 301 |

| 2024 | One percentage point increase | One percentage point decrease |
|---|---|---|
| Effect on the service cost | 1 115 553 | 746 610 |
| Effect on interest cost | 1 652 929 | 1 157 626 |
| Effect on defined benefit obligation | 13 049 899 | 9 140 639 |

**Discount rate**

The nominal discount rate of 11.37% has been set as the return from R214 long-term fixed coupon gilt as at 31 March 2025. Assumed discount rate have a significant effect on the amounts recognised in surplus or deficit. A one percentage point change in assumed discount rate would have the following effects:

| 2025 | One percentage point increase | One percentage point decrease |
|---|---|---|
| Effect on the service cost | 765 797 | 1 148 006 |
| Effect on interest cost | 1 182 990 | 1 440 128 |
| Effect on defined benefit obligation | 9 566 333 | 13 890 398 |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| 2024 | One percentage point increase | One percentage point decrease |
|---|---|---|
| Effect on the service cost | 750 037 | 1 113 764 |
| Effect on interest cost | 1 161 366 | 1 652 189 |
| Effect on defined benefit obligation | 9 169 221 | 13 043 116 |

**Maturity analysis of the defined benefit obligations**

The following table presents information about the distribution of the timing of benefit payments:

| | 1 year | Payable in 1-5 years | >5 years | Total |
|---|---|---|---|---|
| Current (in service) members | 783 | 52 640 | 21 493 619 | 21 547 042 |
| Continuation members (pensioners) | 52 083 | 114 482 | 137 173 | 303 738 |
| | **52 866** | **167 122** | **21 630 792** | **21 850 780** |

| **Amounts for the current and previous four years as follows:** | 2025 | 2024 | 2023 | 2022 | 2021 |
|---|---|---|---|---|---|
| Defined benefit plan | 11 463 902 | 10 875 980 | 9 553 038 | 9 384 322 | - |

## 12. Unspent conditional grants and receipts

| | 2025 R | 2024 R |
|---|---|---|
| **Unspent conditional grants and receipts comprises of:** | | |
| **Unspent conditional grants and receipts** | | |
| Auda-Nepad grant | - | 988 604 |
| BMGF grant | 6 407 664 | - |
| GiZ grant | 2 465 767 | 182 021 |
| SAMRC grant | - | 39 890 |
| Global Fund grant | 1 186 989 | 8 549 244 |
| | **10 060 420** | **9 759 759** |
| **Movement during the year** | | |
| Balance at the beginning of the year | 9 759 759 | 4 317 696 |
| Additions during the year | 51 902 481 | 27 519 937 |
| Conditions not met - refund to grantor | (39 890) | (651 570) |
| Income recognition during the year | (51 561 930) | (21 426 304) |
| | **10 060 420** | **9 759 759** |

These amounts are in a ring-fenced investment at the Corporation for Public Deposits and ABSA Call Account as disclosed in Note 6 until utilised. Should the conditions not be met, a repayment to the grantor will include interest accrued at a rate of 6.00 percent.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025 R | 2024 R |
|---|---|---|

## 13. Provisions

| | | |
|---|---|---|
| Leave provision | 13 996 937 | 11 153 098 |
| PMDS provision | 12 225 437 | 10 048 307 |
| COIDA provision | 3 489 768 | 2 678 933 |
| | **29 712 142** | **23 880 338** |

**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 the following calendar year, except for capped leave.

**Performance management and development system provision (PMDS)**

SAHPRA has an approved performance management policy approved by the Board which enables the employer to incentivise employees based on performance.

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

**COIDA**

SAHPRA did not submit its workmans compensation returns in previous years. All outstanding submission were submitted during 2023/24. SAHPRA is currently disputing the latest assessment and the provision raised below is an estimate of the amount owing.

| | Current Cycle Leave | Previous Cycle Leave | Capped Leave | PMDS | COIDA | Total |
|---|---|---|---|---|---|---|
| As at 1 April 2024 | 4 962 572 | 5 694 808 | 495 718 | 10 048 307 | 2 678 933 | 23 880 338 |
| Additions for the year | 6 068 447 | 7 406 315 | 46 006 | 11 056 338 | 810 835 | 25 387 941 |
| Reversal during the year | (4 962 572) | (5 694 808) | (19 549) | (8 879 208) | - | (19 556 137) |
| **As at 31 March 2025** | **6 068 447** | **7 406 315** | **522 175** | **12 225 437** | **3 489 768** | **29 712 142** |

| | Current Cycle Leave | Previous Cycle Leave | Capped Leave | PMDS | COIDA | Total |
|---|---|---|---|---|---|---|
| As at 1 April 2023 | 4 459 538 | 8 350 835 | 501 302 | 6 975 379 | - | 20 287 054 |
| Additions for the year | 4 962 572 | 5 694 808 | - | 9 917 778 | 2 678 933 | 23 254 091 |
| Reversal during the year | (4 459 538) | (8 350 835) | (5 584) | (6 844 850) | - | (19 660 807) |
| **As at 31 March 2024** | **4 962 572** | **5 694 808** | **495 718** | **10 048 307** | **2 678 933** | **23 880 338** |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025 R | 2024 R |
|---|---|---|

## 14. Income received in advance

**Reconciliation**

| | | |
|---|---|---|
| Unallocated deposits | 33 625 644 | 32 580 494 |
| Revenue received in advance | 284 980 931 | 257 176 097 |
| | **318 606 575** | **289 756 591** |

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

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

See note 35 for details about correction of error and reclassification of prior year amounts.

## 15. Fee Income

| | | |
|---|---|---|
| Amendments | 30 298 650 | 27 794 690 |
| Biological medicine | 5 149 200 | 5 012 700 |
| Cannabis inspection | 401 600 | 441 600 |
| Cannabis licences | 476 680 | 970 260 |
| Certificates | 469 360 | 663 800 |
| Clinincal trials | 12 575 600 | 14 691 300 |
| Evaluations | 58 224 400 | 53 404 963 |
| Inspection fees | 11 354 104 | 10 191 153 |
| Licence fees | 5 288 080 | 2 725 150 |
| Licence retention fees | 10 928 400 | 9 341 600 |
| MD clinical trials | 238 000 | 267 100 |
| MD licence fees | 23 852 600 | 20 042 500 |
| Permits | 8 083 385 | 7 134 900 |
| New medicines renewals | 6 165 600 | - |
| Registration fee | 1 337 500 | 1 908 400 |
| Retention fees | 74 242 500 | 71 625 900 |
| Section 21 Human | 5 400 820 | 4 784 850 |
| Section 21 CMS | 100 020 | 43 750 |
| Section 21 Veterinary | 150 700 | 133 350 |
| | **254 737 199** | **231 177 966** |

**Fees received per function**

| | | |
|---|---|---|
| Medicines evaluation, registration and product lifecycle | 188 430 050 | 174 040 352 |
| Inspections, permits and licences issued | 60 655 609 | 52 175 664 |
| The use of unregistered medicines | 5 651 540 | 4 961 950 |
| **Total** | **254 737 199** | **231 177 966** |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025<br>R | 2024<br>R |
|---|---|---|
| **16. Sundry income** | | |
| Debt impairment reversed | 369 101 | - |
| Proceeds from sale of assets | - | 12 230 |
| | **369 101** | **12 230** |

Included in debt impairment are bad debts recovered, written off and movement in current year provision.

| | | |
|---|---|---|
| **17. Investment revenue** | | |
| **Interest revenue** | | |
| Bank | 36 443 498 | 32 502 235 |
| Accrued interest | 33 175 | 27 194 |
| | **36 476 673** | **32 529 429** |

Included in interest revenue is total interest earned from cash held at ABSA bank based on the average interest rate of 5.00% (2024: 5.00%) and cash held at SA Reserve Bank Corporation for Public Deposits bank based on the average interest rate of 7.99% (2024: 8.25%) per annum. Interest on the rental deposit held by the lessor in a interest bearing call account at an average rate of 7.00% (2024: 7.00%) per annum.

Accrued interest relates to interest on staff debt for employees that have left the organisation.

| | | |
|---|---|---|
| **18. Transfer payments** | | |
| **Operating grants** | | |
| Transfer payment from the National Department of Health | 143 518 000 | 137 873 000 |

| | | |
|---|---|---|
| **19. Services 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** | | |
| **Assets donated** | 5 922 745 | 1 237 163 |
| SAHPRA received an in-kind benefit as donated laboratory equipment were received from Africa CDC. | | |
| **BMGF** | 973 435 | - |
| SAHPRA received an in-kind benefit as compensation of the Renewal Manager was paid directly by a 3rd party BMGF via the Wits Health Consortium. | | |
| **USAID - JHPIEGO** | 6 736 103 | - |
| SAHPRA received an in-kind benefit as a pharmacoviligance officers deployed to head office and various provinces for implementation of intergrated systems for post marketing safety surveillance systems were paid directly by a 3rd party - USAID JHPIEGO | | |
| **USTDA** | - | 7 603 424 |
| USTDA incurred cost on behalf of SAHPRA through a grant for technical assistance relating to reliance-based protocols for a healthcare products training, medical devices registration framework and assessment and enhancement of reliance processess and support which was facilitated through the Boston Consulting Group. | | |
| | **13 632 283** | **8 840 587** |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025 R | 2024 R |
|---|---|---|

## 19. Services in-kind (continued)

**Services in-kind not significant to the entity's operations and/or service delivery objectives and/or do not satisfy the criteria for recognition**

| | | |
|---|---|---|
| **USTDA** | - | 19 986 345 |
| USTDA incurred cost on behalf of SAHPRA through a grant for technical assistance relating to reliance-based protocols for healthcare products training and support which was facilitated through the Boston Consulting Group. | | |
| **SAMRC** | 766 667 | - |
| SAMRC incurred costs on behalf of SAHPRA through a work place training of interns. | | |
| **GiZ - GFA** | 10 121 632 | - |
| GFA incurred costs on behalf of SAHPRA through a grant to provide technical expert advisory services to support organisational development, sustainability modelling and training interventions. | | |
| **Right to Care** | 272 860 | - |
| Right to Care incurred costs on behalf of SAHPRA through a placement of a training specialist. | | |
| | **11 161 159** | **19 986 345** |

## 20. Grant realised and income

| | | |
|---|---|---|
| Auda-Nepad grant | 1 513 202 | 870 020 |
| IAEA grant | - | 141 620 |
| Global Fund grant | 38 580 323 | 21 132 297 |
| BMGF grant | 798 347 | - |
| MPP grant | 1 477 344 | - |
| GIZ grant | 9 192 714 | 5 161 901 |
| | **51 561 930** | **27 305 838** |

**Reconciliation of conditional contributions**

| | | |
|---|---|---|
| Current-year receipts | 61 622 351 | 31 186 064 |
| Conditions met - transferred to revenue | (51 561 930) | (21 426 304) |
| Conditions met - transferred to revenue relating to receivables | (1 049 954) | (5 879 534) |
| Grant receivables - note 4 | 1 049 954 | 5 879 534 |
| Balance of unspent conditional grants - note 12 | (10 060 421) | (9 759 760) |
| | - | - |

Refer to note 4 for the grant receivable and note 12 for the remaining balance of funds where conditions are still to be met.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025<br>R | 2024<br>R |
|---|---|---|
| **21. Employee related costs** | | |
| Bargaining council | 8 595 | 8 847 |
| Basic and pensionable salaries | 200 363 485 | 187 269 031 |
| Cellphone allowances | 1 600 585 | 1 556 941 |
| COIDA | 810 835 | 2 678 933 |
| Housing benefits and allowances | 2 516 877 | 2 142 124 |
| Leave accrued | 3 680 076 | (830 890) |
| Medical aid | 9 988 861 | 8 051 441 |
| Overtime | 1 210 626 | 1 233 438 |
| Pension fund | 27 223 187 | 23 926 584 |
| Post retirement medical aid adjustment | 587 922 | 2 025 073 |
| SDL and UIF | 3 462 461 | 3 328 600 |
| Services in kind[1] | 7 709 538 | - |
| Standby allowances | 97 589 | 50 265 |
| Thirteenth cheque and performance bonus | 17 203 777 | 15 428 505 |
| Travel, subsistence and other allowances | 863 017 | 1 207 964 |
| | **277 327 431** | **248 076 856** |

[1]Refer to note 19 for details relating to services in kind

| | | |
|---|---|---|
| **22. Global Fund project expenditure** | | |
| Professional services | 873 277 | 12 600 |
| Travel and related expenditure | 1 176 996 | 266 205 |
| Legal committee fees | 1 830 470 | 291 060 |
| Local evaluators | 10 999 056 | 4 198 116 |
| Foreign evaluators | 4 615 649 | 2 488 246 |
| Compensation of employees | 19 095 871 | 13 715 310 |
| | **38 591 319** | **20 971 537** |

| | | |
|---|---|---|
| **23. GiZ project expenditure** | | |
| Technology consulting services[1] | 157 559 | - |
| Compensation of employees | 865 683 | - |
| | **1 023 242** | **-** |

[1] SAHPRA capitalised technology consultants services of R8 169 472 (2024: R5 161 903). Refer to note 8 and note 35.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025 R | 2024 R |
|---|---|---|
| **24. BMGF project expenditure** | | |
| Compensation of employees | 724 047 | - |
| Technical consulting services | 74 300 | - |
| | **798 347** | **-** |
| **25. Auda Nepad project expenditure** | | |
| Compensation of employees | 1 230 337 | 210 000 |
| Technical consulting services | 282 865 | 660 020 |
| | **1 513 202** | **870 020** |
| **26. Depreciation and amortisation** | | |
| Property, plant and equipment | 7 907 113 | 6 756 407 |
| Intangible assets | 1 801 209 | 571 152 |
| | **9 708 322** | **7 327 559** |
| **27. Laboratory services** | | |
| **Outsourced services** | | |
| NCL Laboratory | 21 276 216 | 23 604 708 |

The National Control Laboratory (NCL) is an appointed service provider for testing of biological medicines and vaccines.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025<br>R | 2024<br>R |
|---|---|---|
| **28. Operating expenses** | | |
| Advertising | 338 226 | 131 194 |
| Bank charges | 328 524 | 324 206 |
| Board costs | 1 849 939 | 1 990 452 |
| Bursaries | 601 128 | 1 096 510 |
| Catering | 444 467 | 343 589 |
| Cleaning | 865 614 | 733 708 |
| Communication | 2 696 204 | 2 781 289 |
| Computer expenses | 335 310 | 316 790 |
| Conferences | 987 351 | 355 267 |
| Consulting and professional fees[1] | 6 621 448 | 4 518 004 |
| Electricity and utilities | 2 499 727 | 1 305 914 |
| External audit fees | 3 611 127 | 3 016 733 |
| Foreign evaluators | 6 015 360 | 7 221 989 |
| Insurance | 753 047 | 582 958 |
| Internal audit fees | 2 346 341 | 2 365 277 |
| Legal fees | 8 326 175 | 8 122 542 |
| Licences | 12 219 442 | 15 003 621 |
| Local evaluators and expert committees | 7 543 248 | 18 565 007 |
| Marketing, printing and publication | 1 097 270 | 2 040 759 |
| Medicine testing | 286 471 | 169 856 |
| Membership fees | 823 669 | 723 229 |
| Minor assets | 190 492 | 243 244 |
| Motor vehicle expenses | 2 280 540 | 4 299 692 |
| Postage and courier | 35 200 | 15 267 |
| Printing and stationery | 366 351 | 187 004 |
| Protective clothing | - | 39 000 |
| Repairs and maintenance[2] | 595 636 | 352 570 |
| Security | 203 980 | 267 134 |
| Services in kind | - | 7 603 424 |
| Staff training and welfare | 871 541 | 1 014 615 |
| Storage | 581 084 | 654 357 |
| Travel - local | 6 793 399 | 5 649 063 |
| Travel - non-employees | 613 323 | 320 500 |
| Travel - international | 2 723 102 | 1 806 775 |
| | **75 844 736** | **94 161 539** |

[1] Consulting and professional fees consist of payments made to service providers for job grading, policy review, actuarial services, HR and Financial systems, debt collection and ICT consultants. [2] Maintenance relates to leasehold improvement and computer repairs.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025 R | 2024 R |
|---|---|---|
| **29. Cash generated from operations** | | |
| Surplus | 53 874 201 | 19 742 042 |
| **Adjustments for:** | | |
| Depreciation and amortisation | 9 708 322 | 7 327 559 |
| Loss on sale of assets and liabilities | 69 213 | 139 940 |
| Impairment deficit | 292 373 | 84 574 |
| Bad debts written off / (impairment reversal) | (369 101) | 2 303 683 |
| Movements in operating lease assets and accruals | (2 056 248) | (544 884) |
| Movements in retirement benefit assets and liabilities | 587 922 | 1 322 942 |
| Movements in provisions | 5 831 804 | 3 593 284 |
| Accrued interest on rental deposit and debtors | (33 175) | (276 532) |
| Loss on foreign exchange | 18 873 | 140 570 |
| Assets donated | (5 922 745) | (1 237 163) |
| Proceeds from disposal of assets | - | (12 230) |
| **Changes in working capital:** | | |
| Receivables from exchange transactions | (858 448) | (5 034 343) |
| Other receivables from non-exchange transactions | 6 142 002 | (5 572 106) |
| Prepayments | (2 703 482) | (3 319 727) |
| Payables from exchange transactions | 1 429 035 | 1 447 148 |
| Unspent conditional grant | 300 661 | 5 442 063 |
| Income received in advance | 28 849 984 | 33 539 840 |
| | **95 161 191** | **59 086 660** |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025<br>R | 2024<br>R |
|---|---|---|
| **30. Commitments** | | |
| **Authorised expenditure** | | |
| Already contracted for but not provided for | | |
| • National control laboratory contract | 3 848 763 | 3 604 243 |
| • Supply of facilities services | 2 909 766 | 3 972 281 |
| • Supply of IT equipments and related IT expenditure | 35 510 070 | 37 138 222 |
| • Supply of finance services | 2 565 359 | 79 676 |
| • Open purchase orders | 9 175 157 | 22 175 590 |
| • Supply of communication services | 960 998 | 1 136 456 |
| • Office accommodation | 20 314 260 | 32 839 807 |
| • Supply of legal services | 13 326 598 | 8 203 442 |
| • Supply of secretarial services | - | 364 414 |
| • Supply of risk management | 710 885 | 337 674 |
| • Supply of HR services | 1 657 260 | 273 402 |
| • Supply of parking services | 17 099 | 20 352 |
| • Inspectorate and regulatory compliance | 4 265 010 | - |
| | **95 261 225** | **110 145 559** |
| **Total commitments** | | |
| Opearational - Already contracted for but not provided for | 91 878 015 | 101 069 027 |
| Capital - Already contracted for but not provided for | 3 383 210 | 9 076 532 |
| | **95 261 225** | **110 145 559** |

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

## 31. Contingencies

### Contingent assets

**Cost orders in favour of SAHPRA**

Contingent asset estimates were based on a finalised bill of cost that was submitted for taxation

Favourable outcomes resulting in a contingent asset of which a reliable estimate cannot be made were due to:

- No informal settlement reached as yet
- No taxation of costs has taken place in order determine the scale of costs applicable, such as client-attorney and party and party costs
- The bill of costs still to be finalised by the taxing master

**Interdicting the rollout of vaccines:**

Interdicting government on the roll out of Covid-19 vaccines and to provide detailed information. The applicants filed the matter in two courts, and both have dismissed with costs in favour of SAHPRA.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

## 31. Contingencies (continued)

The bill of costs amounting to R200 286.50 were submitted for taxing giving rise to a contingent asset as the inflow of economic benefits are probable due to the favourable court outcome.

**Importation without a license**

An urgent court application challenging SAHPRA's decision not to allow the applicant to import without the requisite licence, Active Pharmaceutical Ingredients ("API")

The application was struck off the roll for lack of urgency with costs. The bill of costs have been drawn up amounting to R295 877 for the purposes of taxation giving rise to a contingent asset as the inflow of economic benefits are probable due to the favourable court outcome.

**Registration and sale of a certain vaccine:**

The applications were dismissed by the court and the applicant's application for leave to appeal was also dismissed with a costs order in favour of SAHRPA.

The dismissal of the application with costs gives rise to a possible contingent asset as the inflow of economic benefits are probable due to the favourable court outcome of which a reliable estimate cannot be made.

**Approval and registration of vaccines:**

The applicant is seeking an order, Inter alia, that all the decisions to approve and register any COVID-19 vaccines in terms of sections 15 of the Medicines Act to be reviewed, declared unconstitutional, invalid, and set aside.

Rule 30A application was heard and the application was dismissed with costs. An application for leave to appeal was heard and it was granted a leave to appeal.

The dismissal of the application with costs gives rise to a possible contingent asset as the inflow of economic benefits are probable due to the favourable court outcome of which a reliable estimate cannot be made.

## Contingent liabilities

**Surrender of surpluses**

The entity annually declares all surpluses or deficits to the relevant Treasury from the period 1 August to 30 September of each year, using its audited annual financial statements as the basis for calculation of surpluses or deficits.

The entity submits requests to the relevant Treasury to retain surpluses in terms of section 53(3) of the PFMA, as and when appropriate. Unless exempted by the National Treasury, the entity invests surplus funds with the Corporation for Public Deposits.

Since inception of SAHPRA, surplus request application to National Treasury has been approved. Based on historical experiences, a request to retain the current year surplus will be made before 30 September 2025. However should the submission not be approved, SAHPRA will be required to surrender the current year's surplus as per the calculation of R73 244 746. The calculation is based on previous submissions approved by the National Treasury.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025<br>R | 2024<br>R |
|---|---|---|

## 32. Related parties

| Relationships | Nature of related party |
|---|---|
| **Executive Authority** | Dr Pakishe Aaron Motsoaledi |
| **Executive Authority (controlling entity of SAHPRA)** | National Department of Health |
| **Accounting Authority** | Prof HV Rees - Chairperson<br>Dr O Khaole - Vice-Chair<br>Adv H Cassim - Member<br>Prof HP Demana - Member<br>Mr F Dockrat - Member (appointed - June 2024)<br>Mr I Mashau - Member<br>Ms L Mothae - Member<br>Dr J Tsoka-Gwegweni - Member<br>Dr X Ngobese - Member<br>Prof Y Choonara - Member<br>Prof J Meyer - Member<br>Ms M Skhosana - Member<br>Dr A Kgasi - Member<br>Dr Z Makatini - Member (resigned - August 2024) |
| **Member of key management** | Dr B Semete-Makokotlela - CEO<br>Mr RB Gouws - CFO<br>Ms P Nkambule - CRO (resigned September 2024)<br>Ms C Reynecke - COO<br>Ms L Modisakeng - HR Executive (appointed September 2024)<br>Ms T Gopal - CRO (appointed March 2025) |
| **Appointed Board member of SAHPRA** | Wits Health Consortium (WHC) |
| **Other related parties** | All public entities under the National Department of Health<br>All public entities in National Sphere<br>South African Medical Research Council (SAMRC) |

### Related party balances

| | | |
|---|---|---|
| **Conditional grant** | | |
| SAMRC | - | 39 890 |

Related party transactions to other public entities and WHC were identified. These transactions were at arms length relating to operational expenditure and SAHPRA fees charged and no outstanding balances are due.

| | | |
|---|---|---|
| **Related party transactions** | | |
| **National Department of Health** | | |
| Government grant received | 143 518 000 | 137 873 000 |
| **SAMRC** | | |
| Employee related costs - refer to note 19 | 766 667 | - |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

## 32. Related parties (continued)

**Remuneration of Executive Authority and Management**

| **Board fees** [1] | 2025 | |
|---|---|---|
| | Board Fees | Total |
| Prof H.V. Rees - Chairperson | 100 185 | 100 185 |
| Adv H. Cassim - Member | 151 390 | 151 390 |
| Mr F. Dockrat - Member [2] | 85 304 | 85 304 |
| Prof H. P. Demana - Member | 78 176 | 78 176 |
| Mr I. Mashau - Member | 153 894 | 153 894 |
| Ms L. Mothae - Member | 190 612 | 190 612 |
| Dr O. Khaole - Vice Chair | 142 737 | 142 737 |
| Dr J. Tsoka-Gwegweni - Member | 103 918 | 103 918 |
| Dr X Ngobese - Member | 190 994 | 190 994 |
| Ms D Maraka - Member | 82 841 | 82 841 |
| Prof Y Choonara - Member | 53 850 | 53 850 |
| Prof J Meyer - Member | 85 734 | 85 734 |
| Ms M Skhosana - Member | 107 700 | 107 700 |
| Dr A Kgasi - Member | 167 686 | 167 686 |
| Dr Z Makatini - Member [3] | - | - |
| | **1 695 021** | **1 695 021** |

[1] The board fees reflects the actual claims incurred. At times board members opt not to claim for meetings attended.
[2] Member appointed June 2024.
[3] Member employed in the public sector - no fees claimed, resigned August 2024

**Executive management**

| 2025 | Basic salary | Bonuses and performance related payments | Other employment benefits | Termination benefits | Other benefits received | Total |
|---|---|---|---|---|---|---|
| Dr B Semete-Makokotlela - Chief Executive Officer | 3 477 869 | 161 013 | - | - | 92 037 | 3 730 919 |
| Ms. P Nkambule - Chief Regulatory Officer[1] | 675 486 | 68 771 | 72 290 | 148 760 | 143 819 | 1 109 126 |
| Ms. C Reynecke - Chief Operating Officer | 2 515 144 | - | - | - | 47 881 | 2 563 025 |
| Mr RB Gouws - Chief Financial Officer | 2 180 138 | 101 693 | - | - | 50 653 | 2 332 484 |
| Ms. L Modisakeng - HR Executive[2] | 980 845 | - | 98 192 | - | 24 802 | 1 103 839 |
| Ms T Gopal - Chief Regulatory Officer[3] | 166 650 | - | 16 683 | - | 3 464 | 186 797 |
| | **9 996 132** | **331 477** | **187 165** | **148 760** | **362 656** | **11 026 190** |

Other benefits include cellphone allowance, UIF and SDL company contribution.

[1] Ms Nkambule resigned from SAHPRA in September 2024.
[2] Ms L Modisakeng appointed September 2024
[3] Ms T Gopal appointed March 2025.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

## 32. Related parties (continued)

**Remuneration of Executive Authority and Management**

| | 2024[1] | |
|---|---|---|
| **Board fees** | Board Fees | Total |
| Prof H.V. Rees - Chairperson | 147 427 | 147 427 |
| Adv H. Cassim - Member | 167 389 | 167 389 |
| Mr T.N. Baloyi - Member[2] | 27 876 | 27 876 |
| Prof H.P. Demana - Member | 79 109 | 79 109 |
| Mr I. Mashau - Member | 181 375 | 181 375 |
| Ms L. Mothae - Member | 207 814 | 207 814 |
| Dr O. Khaole - Vice Chair | 175 133 | 175 133 |
| Dr J. Tsoka-Gwegweni - Member | 100 780 | 100 780 |
| Dr X. Nogobese - Member | 245 584 | 245 584 |
| Ms D. Maraka - Member | 125 118 | 125 118 |
| Prof Y. Choonara - Member | 44 509 | 44 509 |
| Prof J. Meyer - Member | 87 489 | 87 489 |
| Ms M. Skosana - Member | 125 858 | 125 858 |
| Dr A. Kgasi - Member | 183 142 | 183 142 |
| Dr Z Makatini - Member[3] | - | - |
| | **1 898 603** | **1 898 603** |

[1] The board fees reflect the actual claims submitted. At times board members opt not to claim for meetings attended.
[2] Member resigned 14 November 2023
[3] Member employed in the public sector - no fees claimed

**Executive management**

| 2024 | Basic salary | Bonuses and performance related payments[2] | Other employment benefits | Termination benefits | Other benefits received | Total |
|---|---|---|---|---|---|---|
| Dr B Semete-Makokotlela - Chief Executive Officer | 3 242 182 | 122 026 | - | - | 116 963 | 3 481 171 |
| Ms P Nkambule - Chief Regulatory Officer | 1 577 933 | 65 149 | 149 909 | - | 41 141 | 1 834 132 |
| Ms C. Reynecke - Chief Operating Officer | 2 364 011 | 89 912 | - | - | 47 269 | 2 501 192 |
| Mr G. Mtakati - HR Executive [1] | 849 986 | - | - | 1 476 588 | 37 411 | 2 363 985 |
| Mr R.B. Gouws - Chief Financial Officer[2] | 2 047 694 | 187 686 | - | - | 45 084 | 2 280 464 |
| | **10 081 806** | **464 773** | **149 909** | **1 476 588** | **287 868** | **12 460 944** |

Other benefits include cellphone allowance, UIF and SDL company contribution.

[1] Mr Mtakati resigned from SAHPRA in October 2023.
[2] Payments for performance bonus relates to 2021/22 and 2022/23 financial year.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025 R | 2024 R |
|---|---|---|

## 33. Independent audit committee members remuneration

**Independent audit committee members - fees for attending meetings**

| | | |
|---|---|---|
| Mr B Gordon[1] | 45 106 | - |
| Ms Y Pamla[2] | - | 690 |
| Mr R Mahabeer[3] | 65 650 | 66 833 |
| Ms A Chowan[3] | 44 162 | 24 326 |
| | **154 918** | **91 849** |

[1] Appointed 1 October 2024
[2] Appointed 1 April 2021 - Contract ended March 2023
[3] Appointed 1 April 2023

## 34. Financial instruments disclosure

**Categories of financial instruments**

**Financial assets**

| 2025 | At amortised cost | Total |
|---|---|---|
| Deposits | 4 904 464 | 4 904 464 |
| Other receivables from non-exchange transactions | 1 888 027 | 1 888 027 |
| Cash and cash equivalents | 451 472 827 | 451 472 827 |
| | **458 265 318** | **458 265 318** |

**Financial liabilities**

| 2025 | At amortised cost | Total |
|---|---|---|
| Trade and other payables from exchange transactions | 5 227 687 | 5 227 687 |
| Accrued expenditure | 4 803 393 | 4 803 393 |
| Travel cards | 383 373 | 383 373 |
| Income received in advance | 318 606 575 | 318 606 575 |
| | **329 021 028** | **329 021 028** |

**Financial assets**

| 2024 | At amortised cost | Total |
|---|---|---|
| Deposits | 4 394 098 | 4 394 098 |
| Other receivables from non-exchange transactions | 7 996 854 | 7 996 854 |
| Cash and cash equivalents | 371 616 710 | 371 616 710 |
| | **384 007 662** | **384 007 662** |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

## 34. Financial instruments disclosure (continued)

**Financial liabilities**

| 2024 | At amortised cost | Total |
|---|---|---|
| Trade and other payables from exchange transactions | 3 913 306 | 3 913 306 |
| Accrued expenditure | 2 243 113 | 2 243 113 |
| Travel cards | 707 011 | 707 011 |
| Income received in advance | 289 756 591 | 289 756 591 |
| | **296 620 021** | **296 620 021** |

## 35. Prior period errors

During 2023/24 financial year, income relating to biological medicine amendments and evaluation of new medicine was incorrectly omitted due to incorrect calculation on cost of service and also incorrect treatment of clones and replicas stage of completion.

Receivables from exchange transactions relating to medical devices, pharma retention fees and collection fees were previously accounted for however payments were received in the relevant financial year but not allocated.

Some invoices relating to technology consulting services funded by the GiZ grant meets the definition of intangible assets that was not classified as work in progress in the previous year.

A reclassification between unallocated deposits and revenue received in advance was corrected after extensive review of information received relating to applications.

A reclassification between capital and operational commitments was done for enhanced presentation and disclosure.

| The correction of the error(s) results in adjustments as follows: | 2025 R | 2024 R |
|---|---|---|
| **Statement of Financial Position** | | |
| Receivables from exchange transactions | - | 136 810 |
| Income received in advance | - | 2 963 515 |
| Intangible assets | - | 5 161 901 |
| **Statement of financial performance** | | |
| Fee income | - | (3 100 325) |
| GiZ project expenses | - | (5 161 901) |
| **Cash Flow Statement** | | |
| **Cash flow from operating activities** | | |
| Suppliers | - | 5 161 901 |
| **Cash flow from investing activities** | | |
| Purchase of intangible assets | - | (5 161 901) |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

## 35.1 Prior-year adjustments

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

**Statement of financial position**

| 2024 | Notes | Previously reported | Corrections | Change in accounting policy | Restated |
|---|---|---|---|---|---|
| Receivables from exchange transactions | 3 | 9 264 217 | 136 810 | - | 9 401 027 |
| Income received in advance | 14 | (292 720 106) | 2 963 515 | - | (289 756 591) |
| Intangible assets | 8 | 10 963 954 | 5 161 901 | (2 643) | 16 123 213 |
| | | **(272 491 935)** | **8 262 226** | **(2 643)** | **(264 232 351)** |

**Statement of financial performance**

| 2024 | Notes | Previously reported | Corrections | Restated |
|---|---|---|---|---|
| Revenue from exchange transactions | 15 | (228 077 641) | (3 100 325) | (231 177 966) |
| GiZ project expenditure | 23 | 5 161 901 | (5 161 901) | - |
| Surplus for the year | | **(222 915 740)** | **(8 262 226)** | **(231 177 966)** |

**Disclosure**

| 2024 | Notes | Previously reported | Corrections | Restated |
|---|---|---|---|---|
| **Cash flow from operating activities** | | | | |
| Suppliers | | (146 358 606) | 5 161 901 | (141 196 705) |
| | | | | |
| **Cash flow from investing activities** | | | | |
| Purchase of intangible assets | 8 | (8 644 456) | (5 161 901) | (13 806 357) |
| | | | | |
| **Note 14 - Income received in advance** | | | | |
| Unallocated deposits | 14 | 164 527 904 | (131 947 410) | 32 580 494 |
| Income received in advance | 14 | 125 228 687 | 131 947 410 | 257 176 097 |
| | | **289 756 591** | **-** | **289 756 591** |
| **Note 30 - Commitments** | | | | |
| Operational commitments | 30 | 110 145 559 | (9 076 532) | 101 069 027 |
| Capital commitments | 30 | - | 9 076 532 | 9 076 532 |
| | | **110 145 559** | **-** | **110 145 559** |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025<br>R | 2024<br>R |
|---|---|---|

## 36. Changes in accounting policy and estimates

The annual financial statements have been prepared in accordance with Standards of Generally Recognised Accounting Practice on a basis consistent with the prior year except for the adoption of the following new or revised standards.

- Property, plant and equipment
- Intangible assets

During the year, the SAHPRA changed its accounting policy with respect to the treatment of depreciation and ammortisation of property, plant and equipment, and intagible assets. The SAHPRA now depreciations its assets on a monthly basis compared to the previous policy of daily depreciation.

The aggregate effect of the changes in accounting policy on the annual financial statements for the year ended 31 March 2024 is as follows:

### Statement of Financial Position

| | | |
|---|---|---|
| **Property, plant and equipment** | | |
| Previously stated | - | 25 818 999 |
| Adjustment - change in accounting policy | - | 39 635 |
| Adjustment - change in estimate | - | 29 564 |
| | **-** | **25 888 198** |
| **Intagible assets** | | |
| Previously stated | - | 10 963 954 |
| Adjustment | - | (2 643) |
| | **-** | **10 961 311** |
| **Statement of Financial Performance** | | |
| **Depreciation and ammortisation** | | |
| Previously stated | - | (7 394 116) |
| Adjustment | - | 66 557 |
| | **-** | **(7 327 559)** |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

## 37. Risk Management

### Financial risk management

SAHPRA'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 the 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. Balances due within 12 months equal their carrying balances as the impact of discounting is not significant.

| At 31 March 2025 | Less than 1 year | Between 1 and 2 years | Between 2 and 5 years | Over 5 years |
|---|---|---|---|---|
| Trade payables from exchange transactions | 5 227 687 | - | - | - |
| Income received in advance | 318 606 575 | - | - | - |
| Travel cards | 383 373 | - | - | - |
| Accrued expenditure | 4 803 393 | - | - | - |

| At 31 March 2024 | Less than 1 year | Between 1 and 2 years | Between 2 and 5 years | Over 5 years |
|---|---|---|---|---|
| Trade payables from exchange transactions | 3 913 306 | - | - | - |
| Income received in advance | 289 756 591 | - | - | - |
| Travel cards | 707 011 | - | - | - |
| Accrued expenditure | 2 243 113 | - | - | - |

| Concentration of risk - 2025 | Neither past due nor impaired | Past due but not impaired less than two months | Past due but not impaired more than two months | Total |
|---|---|---|---|---|
| Revenue received in advance | 318 606 575 | - | - | 318 606 575 |
| Receivable from non-exchange transactions | - | - | 1 888 027 | 1 888 027 |
| Deposits | 4 904 464 | - | - | 4 904 464 |
| | **323 511 039** | **-** | **1 888 027** | **325 399 066** |

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025<br>R | 2024<br>R |
|---|---|---|

## 37. Risk Management (continued)

### Credit risk

Credit risk consists mainly of cash deposits, cash equivalents and trade debtors. The entity only deposits cash with major banks with high quality credit standing and limits exposure to any one counter-party.

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:

| **Financial instrument** | | |
|---|---|---|
| Cash and cash equivalents | 451 472 827 | 371 616 710 |
| Receivables from non-exchange transactions | 1 888 027 | 7 996 854 |
| Deposits | 4 904 464 | 4 394 098 |

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

## 38. 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.

## 39. Grant funding

### 39.1 Deutsche Gesellschaft fur Internationale Zusammenarbeit (GIZ)

SAHPRA received grants from GIZ for pharmacovigilance digitalisation; control of import and export of scheduled substances through software application, National Drug Control system (NDS7); service provider for the development of software; and project manager contracting. Refer to note 20 for grant realised.

### 39.2 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 20 for the grant realised.

### 39.3 Medicines Pool Patent (MPP)

SAHPRA entered into an agreement to provide for technical assistance with regards to Inspections. The development of a GMP training programme and other technical assistance. Refer to note 20 for grant realised.

### 39.4 Global Fund

The NDOH has through Global Fund resolved to fund SAHPRA to speed up 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 breakdown of grant realised.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

| | 2025 R | 2024 R |
|---|---|---|

## 39. Grant funding (continued)

### 39.5 Bill and Melinda Gates Foundation (BMGF)

SAHPRA entered into an agreement to strengthen SAHPRA's Regulatory Talent Recruitment and management (HR Business Partner), HR strategy, policies and to assist with improving market surveillance control activities including liaising with externally contracted lab testing entities. Refer to note 20 for grant realised.

## 40. Irregular and Fruitless and Wasteful Expenditure[1]

| | | |
|---|---|---|
| Irregular, fruitless and wasteful expenditure | - | - |

No irregular, fruitless and wasteful expenditure incurred in the current or prior year.

[1] Refer to reconciling notes in the annual report

## 41. Reconciliation between budget and statement of financial performance

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

| | | |
|---|---|---|
| Net surplus per the statement of financial performance | 53 874 201 | 19 742 042 |
| **Adjusted for:** | | |
| Auda Nepad grant expenditure | 1 513 202 | 870 020 |
| Increase / decrease in service in kind expenditure | (13 632 283) | (8 840 587) |
| Grant realised | (51 561 930) | (27 305 838) |
| Over expenditure on impairment of assets | 292 373 | 84 574 |
| GiZ grant expenditure | 1 023 242 | - |
| Global fund project expenditure | 38 591 319 | 20 971 537 |
| (Increase) / decrease in fee income | (6 229 198) | (18 506 076) |
| (Increase) / decrease in interest income | (10 923 673) | (16 858 688) |
| Over / (under) expenditure in employee related costs | 3 367 533 | (9 629 440) |
| (Under) / over expenditure on operating leases | (1 017 890) | (269 384) |
| Over / under expenditure on operating expenditure | (19 637 778) | 17 156 534 |
| Over expenditure on depreciation | 9 708 322 | 7 327 559 |
| (Under) / over expenditure on contracted services | (4 674 589) | (512 086) |
| Over expenditure on loss of disposal of assets | 69 213 | 139 940 |
| Over expenditure on bad debts | (369 101) | 2 303 683 |
| Increase in gain on foreign exchange | 18 873 | 140 570 |
| Increase in sundry income | (1 012 362) | (12 230) |
| Increase in actuarial gain | (1 675 165) | (702 130) |
| BMGF grant expenditure | 798 347 | - |
| MPP grant expenditure | 1 477 344 | - |
| **Net deficit per approved budget** | **-** | **(13 900 000)** |

SAHPRA applied and received approval from National Treasury to budget for a deficit for the 2023-24 financial year.

# Notes to the Annual Financial Statements

For the year ended 31 March 2025

## 42. Budgeted differences

**Material differences between budget and actual amounts**

### 42.1 Fee and Sundry Income

Fee income is higher than budget due to the effect of new fees gazetted in February 2025.
Sundry income is more than budget due to proceeds received and impairments reversed, previously not budgeted for.

### 42.2 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 and a higher than expected cash balance maintained during the year.

### 42.3 Employee Related Costs

Employee related costs are higher due to non cash year end entries made relating to leave and bonus provision adjustments. Also included in operating expenditure is service in kind expenditure which was externally funded.

### 42.4 Asset related expenditure

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

### 42.5 Operating Expenses

Operating expenses are lower than budget, due to external funding for foreign and local external evaluators and expert committees increased. Also included in operating expenditure is service in kind expenditure which was externally funded. Adjustment to the budget after approval from National Treasury relating to the 2023-24 surplus.

### 42.6 Laboratory service

NCL expenditure is lower than budget due to in year cost reductions identified.

### 42.7 Lease rentals on operating lease

Expenditure is lower due to later occupation than expected of some regional offices.

### 42.8 Grant revenue

Grant revenue not budgeted for

### 42.9 Non-cash expenditure

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

### 42.10 Grant expenditure

Grant expenditure not budgeted for.

### 42.11 Seta grant received

SAHPRA received a grant from Seta after submitting the workplace skills plan. This was not budgeted for.

## Notes

## Notes

## Notes

SAHPRA
South African
Health Products
Regulatory Authority

**Head Office:**
Building A, Loftus Park,
402 Kirkness Street,
Arcadia, Pretoria

**Tel:** (012) 501 0300
**Email:** enquiries@sahpra.org.za

**www.sahpra.org.za**