

ANNUAL REPORT 2024/25

SAHPRA
South African
Health Products
Regulatory Authority



ANNUAL REPORT

FOR THE 2024/25 FINANCIAL YEAR



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PART



GENERAL INFORMATION

1. PUBLIC ENTITY'S GENERAL INFORMATION

REGISTERED NAME:	South African Health Products Regulatory Authority (SAHPRA)
REGISTRATION NUMBER (if applicable):	Not applicable
PHYSICAL ADDRESS:	Building A, Loftus Park 402 Kirkness Street, Arcadia Pretoria, 0083
POSTAL ADDRESS:	Private Bag X828 Pretoria 0001
TELEPHONE NUMBER/S:	(012) 501 0300
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.

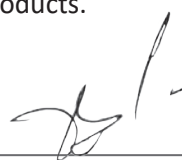
- The Board encountered several challenges during the reporting period, including limited resources, capacity constraints, regulatory backlogs, and global supply chain disruptions. Nevertheless, SAHPRA demonstrated resilience and adaptability. The accelerated adoption of digital systems has enhanced 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.

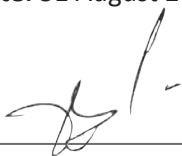
In our opinion, the annual report fairly reflects the operations, the performance information, the human resources information and the financial affairs of the public entity for the financial year ended 31 March 2025.

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 addition 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

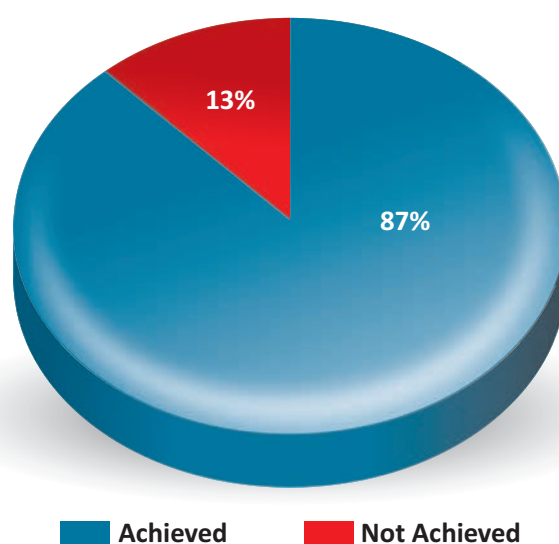
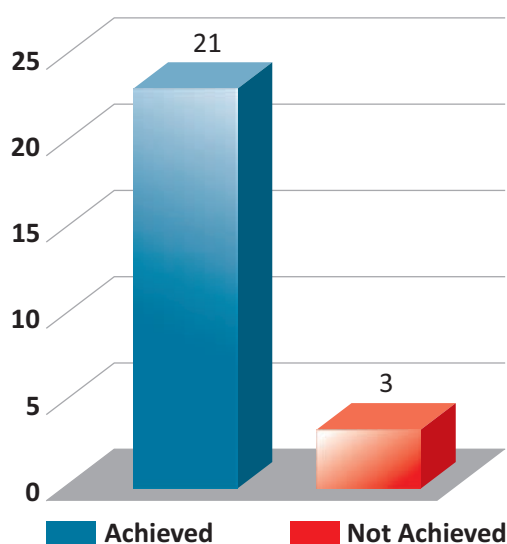
In Africa, a continent with 54 countries, SAHPRA is amongst Africa's six (6) national medicine regulatory authorities that have achieved the ML3 ranking. Maintaining of ISO 9001 certification has aligned SAHPRA with the Regional Strategy for the Regulation of Medicinal Products which provides that all 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. 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. 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 100% medicine variation applications backlog cleared	100% of applications cleared. Backlog project concluded. 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 Practice related licences finalised within 125 working days	50% new GMP and GWP related licences finalised within 125 working days. Out of 90 applications received, 60 (67%) were due for finalisation. 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 Out of 166 applications received, 130 were due for finalisation 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. 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 $\geq$ than current liabilities	-	Current ratio of 1:16.1 achieved	Current ratio of ≥ 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 commentations from the 2020/21 stakeholder perception survey the following 3 (60%) were implemented: • Document management system • 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
A positive and enabling working culture created (4)			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.		
	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 Out of 342 applications received, 0 (0 %) were due for finalisation	100 % New Chemical Entities finalised within 400 working days. Out of 224 applications received, 30 (13 %) were due for finalisation.	80% New Chemical Entities finalised within 360 working days	Out of 350 applications received, 46 (13%) were due for finalisation. 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. Efficient collaboration and coordination between units maintained.
			Although no applications were due for finalisation, 89 (100%) were finalised within 490 workings days	Although 30 applications were due for finalisation, 103 (100%) were finalised, of which 91 (100 %) were finalised within 400 workings days				
	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% over-achievement

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. 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. 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, <u>calculated from the date when an application passes technical screening at Inspectorate Unit.</u>
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, <u>calculated from</u> 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 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 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. 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. 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 finalised, 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 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. 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 Category A (human) medicines finalised	Percentage applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	Number of applications received: 18 083. 7% of applications finalised within 3 working days. 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. 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 Number of applications responded to 20 245 Number of applications finalised: 20 225 Number of applications finalised within 3 working days: 19 509 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 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
	Health product safety signals issued	Percentage on health product safety signals issued within 40 working days	Out of 239 applications received, 163 (68%) were due for finalisation.	Out of 249 applications received, 207 (83%) were due for finalisation.		Out of 166 applications received, 130 were due for finalisation		
			Out of 163 due for finalisation, 184 (113%) were finalised, of which 169 (104%) were produced within 30 working days.	Out of 207 due for finalisation, 218 (105%) were finalised of which 189 (91%) were finalised within 80 working days.		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.	Out of 456 signals received, 446 (97.81%) were due for finalisation by end March 2024	50% reports on health product safety signals issued within 40 working days	185 reports on health product safety signals issued within 40 working days	Positive variance of 7%	Attributed to improved systems and dedicated staff.
			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 446 due for finalisation, 343 (76.91 %) reports were issued, of which 196 (43.95%) were issued within 40 workings days.		Out of 301 signals received, 321 (106,64 %) cumulative were due for finalisation by end Mar 2025		

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 working 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:	Overachievement	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
	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 licence applications finalised	Percentage of medical device licence applications finalised within 90 working days	136% of medical device establishment licence applications finalised within 90 working days	126,6% of medical device establishment licence applications 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	48.6 overachievement	Continuous improvement of business processes and efficient collaboration and coordination between units maintained.
			Out of 1 379 applications received, 692 (50%) were due for finalisation Out of the 692 due for finalisation, 1206 (174%) were finalised, of which 943 (136%) were finalised within 90 working days	Out of 1298 applications received, 880 (67,8%) were due for finalisation. Out of the 880 due for finalisation, 1205 (136,9%) were finalised, of which 1114 (126,6%) were finalised within 90 working days.		Out of 1475 applications received, 1051 (71.3%) were due for finalisation. Out of 1475 applications received, 1051 (71.3%) were due for finalisation.		

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
	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.	Target not met.
						Publication of Expression of Interest (Eoi) for feasibility study published on the first quarter 2024/25FY social media platforms for coming engagement towards implementation. The upcoming Feasibility study must first be conducted prior embarking on Call-up Notice of pilot Class D) update being published.	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
	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. 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. 2191 applications were due for completion before 31 March 2025. 2086 (95%) applications were completed 930 Applications that were due for completion were issued. 804 (86%) Of the issued Authorities were issued within 30 workdays.	16% Overachievement Continued improvement of business process and SOP 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
	License applications for listed electronic products finalised	Percentage of licence applications for listed electronic products finalised within 30 working days	169% licence applications for listed-electronic products were finalised within 30 working days Out of 1115 applications were received, of which 627 (56%) were due for finalisation. 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. 851 applications were received, out of 837 received 720(84%) were due for finalisation. Out of 720 due for finalisation 851(118%) were finalised. 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. 1624 applications were received, out of 1624 received 1534(94%) were due for finalisation. Out of 1534 due for finalisation 1624(106%) were finalised. Out of 1624 finalised, 1412(92%) were finalised within 30 working days	2% overachievement Continued improvement of business process and SOP 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

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 Bachelor of Surgery Diploma in HIV Management 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 CTA (B. Compt Honours CA (SA)	Finance and Accounting	N/A	RAG Finance	8
Mr. Itani Mashau	Member	25 April 2019	N/A	Re- appointed 25/04/2024	B Pharm Diploma in Production D in Q Management and Q Assurance Master of Business Administration D in Small Business Management	Good Man- ufacturing Practice	N/A	TORS HRRemco	12
Prof. Patrick Demana	Member	25 April 2019	N/A	Re- appointed 25/04/2024	Ph.D. in Pharmaceutics B.Sc. (Hons) in Pharmacy M.Sc. in Pharmaceutics Post-doctoral Fellowship in Drug Discovery 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 LLB Certificate in Medicine Law Certificate in pharmacoepidemiology Medical Mediation training	Law	N/A	RAG TORS	11
Ms Mandisa Skhosana	Member	Newly Appointed 1 October 2021	N/A	Re- appointed 25/04/2024	National Diploma in Biomedical Technology B-Tech Degree in Biomedical Technology 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) B.Sc. Hons- Zoology & Microbiology PHD in Public Health 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 LLB Master of Business Leadership	Veterinary	N/A	TORS 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 Masters in Immunology of Infectious Diseases MBChB PhD Virology Registrar in Virology Diploma in Travel Medicine Diploma in Tropical Medicine Diploma in HIV Management in the Workplace Diploma in HIV Management MMED in Biostatistics & Epidemiology (completed 2/3) 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 Masters in business administration	Independ- ent consult- ant	N/A	HRRemco RAG 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 Bachelor of Education Baccalaureus Atium Honores Masters Diploma in HR Training and Development Ethics Officer Certification Psychometrist Effective Audit Committees Effective Remuneration Committees Social & Ethics Committees	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 MPharm PhD N	Medical devices	N/A	TORS	5
Prof. Johanna Meyer	Member	Newly Appointed 23 December 2021	N/A	Re- appointed 25/04/2024	BPharm MSc (Med) 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 Mr Rajesh Mahabeer (Independent Member) Dr Xolani Ngobese Mr Faizal Docrat
Technical Oversight and Regulatory Strategy Committee	6	9	Prof. Johanna Meyer Prof. Patrick Demana Adv. Hasina Cassim Mr. Itani Mashau Dr Alfred Kgasi Ms Mandisa Skhosana Dr Zinhle Makatini Prof. Yahya Choonara 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 Dr Xolani Ngobese Dr Alfred Kgasi Adv. Hasina Cassim Ms Adila Chowan (Independent Member) Mr. Bruce Gordon (Independent Member) Mr. Rajesh Mahabeer (Independent Member) Mr Faizal Docrat
Human Resource and Remuneration Committee	8	4	Mr. Itani Mashau Dr Xolani Ngobese Dr Obakeng Khaole 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 table 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 Docrat¹	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 CGMA FCCA FCA BFP CIA FIISA SARIPA INSOL MBA MCOM 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.

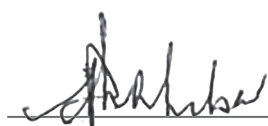
Evaluation of Financial Statements

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

Number of sessions conducted	Type of session	Type of intervention/ topics covered
		• Musculoskeletal session: I Pulled Something • The Power of Small Wins: How to Create Big Change through Small Habits Session • World Cancer Day • Disability Rights Awareness Month: Understanding how disability is defined • International Day of Persons with Disabilities: Disability and mental health • International Day of Persons with Disabilities: Embracing Strength and Diversity • 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	2023/24
	R'000	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	2023/24
	R'000	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	2023/24
	R'000	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	2023/24
	R'000	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



FINANCIAL INFORMATION

Index

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

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Accounting Authority's Responsibilities and Approval

The Accounting Authority is required by the Public Finance Management Act (Act 1 of 1999), to maintain adequate accounting records and are responsible for the content and integrity of the annual financial statements and related financial information included in this report. It is the responsibility of the Accounting Authority to ensure that the annual financial statements fairly present the state of affairs of 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) Section 53(4) Section 54(2) (c'); 54(2)(d) Section 55(1)(a); 55(1)(b); 55(1)(c)(i) Section 56(1); 56(2) Section 57(b); 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 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) Treasury Regulation 30.1.1; 30.1.3(a); 30.1.3(b); 30.1.3(d); 30.2.1 Treasury Regulation 31.1.2(c') Treasury Regulation 31.2.1; 31.2.5; 31.2.7(a) Treasury Regulation 31.3.3 Treasury Regulation 32.1.1(a); 32.1.1(b); 32.1.1(c') 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 Paragraph 5.1; 5.3; 5.6; 5.7 Paragraph 8.2; 8.5 Paragraph 9.1; 9.2 Paragraph 12.1 and 12.2
PPR 2022	Paragraph 4.1; 4.2; 4.3; 4.4 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 R	2024 Restated* 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 R	2024 Restated* 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)	-
Laboratory 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 R	2024 Restated* 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						
Transfer 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. 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. 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. 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 R	2024 R
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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 R	2024 R
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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
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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
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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
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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. Property, 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 R	2024 R
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9. Operating lease liability

Current liabilities	1 462 457	3 518 705
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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
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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
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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

Unspent conditional grants and receipts comprises of:

Unspent conditional grants and receipts

	2025 R	2024 R
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
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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
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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
Clinical 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 R	2024 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
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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 pharmacovigilance 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
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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 R	2024 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

¹Refer 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 R	2024 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 R	2024 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		
Operational - 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 SAHPRA.

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 R	2024 R
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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 Dr O Khaole - Vice-Chair Adv H Cassim - Member Prof HP Demana - Member Mr F Dockrat - Member (appointed - June 2024) Mr I Mashau - Member Ms L Mothae - Member Dr J Tsoka-Gwegweni - Member Dr X Ngobese - Member Prof Y Choonara - Member Prof J Meyer - Member Ms M Skhosana - Member Dr A Kgasi - Member Dr Z Makatini - Member (resigned - August 2024)
Member of key management	Dr B Semete-Makokotlela - CEO Mr RB Gouws - CFO Ms P Nkambule - CRO (resigned September 2024) Ms C Reynecke - COO Ms L Modisakeng - HR Executive (appointed September 2024) 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 All public entities in National Sphere South African Medical Research Council (SAMRC)

Related party balances

Conditional grant

SAMRC	-	39 890
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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
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SAMRC

Employee related costs - refer to note 19	766 667	-
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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

Board fees

	2024 ¹	
	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
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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:

Statement of Financial Position

	2025 R	2024 R
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
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Cash flow from investing activities

Purchase of intangible assets	-	(5 161 901)
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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 R	2024 R
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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 amortisation of property, plant and equipment, and intangible assets. The SAHPRA now depreciates 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

Intangible assets

Previously stated	-	10 963 954
Adjustment	-	(2 643)
	-	10 961 311

Statement of Financial Performance

Depreciation and amortisation

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 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 R	2024 R
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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
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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 Expenditure¹

Irregular, fruitless and wasteful expenditure	-	-
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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.

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Head Office:

Building A, Loftus Park,
402 Kirkness Street,
Arcadia, Pretoria

Tel: (012) 501 0300

Email: enquiries@sahpra.org.za

www.sahpra.org.za