SAHPRA

South African
Health Products
Regulatory Authority

ANNUAL REPORT
2023/24

CONTENTS

PART A
GENERAL INFORMATION

1. PUBLIC ENTITY'S GENERAL INFORMATION

REGISTERED NAME:	South African Health Products Regulatory Authority (SAHPRA)
REGISTRATION NUMBER (if applicable):	Not applicable
PHYSICAL ADDRESS:	Building A, Loftus Park 402 Kirkness Street, Arcadia Pretoria, 0083
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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
AEFI	Adverse Events Following Immunisation
AGSA	Auditor-General of South Africa
AUDA	African Union Development Agency
B-BBEE	Broad-Based Black Economic Empowerment
BMGF	Bill and Melinda Gates Foundation
CDC	Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
COIDA	Compensation for Occupational Injuries and Diseases Act
COVID-19	Coronavirus Disease
CPD	Corporation for Public Deposits
CSIR	Council for Scientific and Industrial Research
DPSA	Department of Public Service and Administration
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
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
HR	Human Resources
HRREMCO	Human Resource and Remuneration Committee
ICT	Information and Communication Technology
INCB	International Narcotics Control Board
N/A	Not applicable
NCE	New Chemical Entity
NCL	National Control Laboratory
NDoH	National Department of Health
NEPAD	New Partnership for Africa's Development
OHS	Occupational Health and Safety
PERSAL	Personal and Salary System
PFMA	Public Finance Management Act
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
SARS	South African Revenue Service
SDL	Skills Development Levy
TORS	Technical Oversight and Regulatory Strategy Committee
USTDA	United States Trade and Development Agency
VEC	Ventilator Evaluation Committee
WHO	World Health Organization

2. FOREWORD BY THE CHAIRPERSON

Professor Helen Rees

Introduction

I am pleased to present the 2023/24 Annual Report for SAHPRA which is mandated by the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) to regulate all health products and the use in South Africa.

Like the rest of the world, South Africa is still recovering from the COVID-19 pandemic and is struggling with a weakened economy and political uncertainty. This has impacted SAHPRA both financially and in terms of staff morale. Despite this, SAHPRA has delivered on its mandate to ensure that health products for human and veterinary use are safe, efficacious and of good quality. SAHPRA's portfolio of responsibilities is many and varied. Throughout COVID-19 pandemic, SAHPRA played a critical role in facilitating the emergency licensure of health products and is currently supporting the Department of Health's emergency response to the current Mpox outbreak, ensuring access to critical therapeutics and vaccines. SAHPRA also managed to work on new horizons such as cannabis licensure, digitisation and regional harmonisation initiatives. Further objective demonstrations of SAHPRA's growing effectiveness include an unqualified audit (2022/23), a reduction in irregular, fruitless and wasteful expenditure and a revised structure for service fees, which is in progress.

High-level overview of the public entity's strategy and the performance of the public entity in its respective sector

During the 2023/24 financial year, SAHPRA had six outcomes addressing Priority 3 of the country's Medium-Term Strategic Framework, "Education Skills and Health", which are:

- Effective compliance, finance and performance management
- Financial sustainability achieved by stakeholders
- Responsive to stakeholder needs
- A positive and enabling work culture created
- Access and retention
- Digital transformation

Reduced funding from National Treasury for the 2023/24 financial year put SAHPRA under enormous financial constraints. To address this, cost containment measures were introduced, including a reduction in consultancy costs and new staff hires, as well as an increase in revenue collection. Despite the challenging environment, SAHPRA achieved 68% of its annual targets while operating 15% of its reduced budget allocation, complemented by significant client-driven funding earmarked for specific projects.

The Board, which is in its second term, has had a major focus on good governance and ensuring that SAHPRA's strategic plan is fit for the purpose of achieving the regulator's ambitions. This ambition has been supported by the Minister of Health, Dr Joe Phaahla, who has appointed the most reliable DDG to sit on the SAHPRA Board.

Strategic Relationships

The post-COVID period has increased the global understanding of the importance of developing competent regulatory authorities in low- and middle-income countries, especially in the African region. SAHPRA is regarded as a leading African regulator and functions closely with other African and global regulators, the newly emerging African Medicines Agency, and the World Health Organisation (WHO). In the 2023/24

financial year, SAHPRA signed a Memorandum of Understanding (MoU) with the Medicines Control Authority of Zimbabwe (MCAZ). In August 2023, the Africa Centre for Disease Control and Prevention (Africa CDC) donated equipment worth USD 750 000 to SAHPRA to support its regulatory functions relating specifically to vaccine manufacturing. Using its new accreditation process, the WHO awarded SAHPRA the status of Maturity Level 3 for vaccine production, and SAHPRA has the short-to-medium-term ambition of improving its WHO competency level.

Challenges faced by the Board

In 2023 the Board had some governance challenges, which were addressed through significant Board engagement supported by the Minister of Health and the Department of Health. Throughout this period, the Board worked closely with the CEO and the executive team, and this constructive and respectful relationship continues. The Board and its committees work well and effectively with their respective secretariat support teams. In 2023, an independent review of Board functions was undertaken, resulting in helpful recommendations, many of which have been addressed and others which continue to be acted upon. Some of the suggestions included enhancing the use of technology, such as digitisation, and other operational considerations which have been significantly addressed by the appointment of a new and experienced Board Secretary.

The strategic focus over the medium- to long-term period

Worldwide, the importance of regulatory authorities has grown over the past ten years. The scope of work for SAHPRA has expanded to include complementary medicines, medical devices, radionuclides, and a renewed focus on a regulatory framework to support local manufacturers. A major strategic change has been the utilisation of reliance mechanisms and harmonisation initiatives. These approaches allow alignment between regulatory authorities regionally and worldwide, thus optimising regulatory efforts and aligning global thinking in licensing and clinical trial approvals.

A new opportunity will be the use of artificial intelligence (AI). SAHPRA has recognised that AI will enhance its functioning by optimising operational processes, but it will also create new challenges. Many medical devices requiring regulatory approval will include AI in their development and implementation. Worldwide, there are yet to be blueprints for how such devices will be reviewed, approved and monitored, and this will be a global challenge that SAHPRA will tackle in partnership with other regulators in the years to come.

For the MTEF period, SAHPRA has the following targets under core business:

- 80% New Chemical Entities finalised within 300 working days.
- 75% generic medicines finalised within 250 working days.
- 90% permits finalised within 20 working days.
- 75% regulatory compliance investigation reports produced within 30 working days.
- 90% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days.
- 80% human clinical trial applications finalised within 90 working days.
- 95% lot release requests finalised within 50 working days.
- 80% medical device establishment licence applications finalised within 90 working days.
- 70% applications for radionuclide authorities (licences) finalised within 30 working days.
- 90% licence applications for listed electronic products finalised within 30 working days.

These are ambitious targets which, if achieved, will increase SAHPRA's recognition as a world-class African regulator.

Acknowledgements/Appreciation & Conclusion

SAHPRA has grown in stature and competency since its inception seven years ago. As a new statutory entity that started afresh based on the work of its predecessor, the Medicines Control Council, the path has sometimes been challenging. However, SAHPRA is in a sturdy space as it grows to fulfil its legal mandate for South Africa and address the new challenges regulators worldwide are tackling. My sincere appreciation goes out to all the Board members who have worked with incredible dedication on the Board and its committees. The Board is only as good as its supporting executive team. Thanks to the CEO, Dr Tumi Semela, who has been outstanding in her role, ably supported by a committed and competent executive team, and to Advocate Mpho Mphelo, the newly appointed Board Secretary. I suspect that the importance of a health products regulatory authority was not fully appreciated until the COVID-19 pandemic hit the world in 2020, but the importance of an independent, evidence-based regulator is now recognised as a critical pillar for an effective health service.

Prof. Helen Rees
Board Chairperson
SAHPRA
31 May 2024

3. CHIEF EXECUTIVE OFFICER'S OVERVIEW

The end of the financial year 2023/24 presents the South African Health Products Regulatory Authority (SAHPRA) an opportunity to account on its performance for the year 2023/24. The Annual Report does not only highlight the Authority's performance and successes, but also indicates its challenges encountered during the year under review. The Regulator's activities are guided by key government policies and plans including but not limited to the National Development Plan Vision 2030.


Dr Sedzani Zamxaka-Makoziwa

In terms of performance against the 2023/24 Annual Performance Plan (APP), SAHPRA committed to achieve 20 annual targets during the reporting period. The Authority achieved 17 targets (85%) of its annual targets, while spending 100% of its budget allocation. The difference between the performance achieved and the budget spent is due to the spending on the business and operational plans as well as the monthly administrative commitments of the Authority. Over the medium term, SAHPRA will continue implementing programmes that ensure the attainment of its vision of being "An agile and responsive African health products regulator that is globally recognised as an enabler of access to safe, effective and quality health products in South Africa".

General financial review of SAHPRA

The collection of collection of licence fees has been a challenge over the past few financial years. To overcome this challenge SAHPRA appointed a debt collecting agent to assist with collection of long outstanding balances. SAHPRA's total revenue amounted to R435.4 million against a budget of R381 million. The variance of R54.4 million was mainly due to additional external funding support received during the year and additional fee revenue of R15.4 million recognised. SAHPRA spent R484 million against the total approved budget of R381 million. The additional expenditure was allowed due to unbudgeted for external financial support received as well as above budgeted for fee income generated during the year. The overall result was an accounting surplus amounting to R11 million and exceeding the annual cash flow ratio 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 (2022/23)
- Ensured financial and supply chain policies and standards resulting in a reduction of irregular, fruitless and wasteful expenditure
- Revised service fees structures submitted for approval and Gazetting

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

Supply chain management

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

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

A significant portion of SAHPRA's assets for the 2023/24 financial year comprises newly-acquired assets. These acquisitions amounted to R13 million on 31 March 2024. The new material acquisitions: motor vehicles (R2 million) and intangible assets (R8.6 million). The disposals for the year comprised of old furniture and computer equipment that were no longer in use or had been replaced, which were either sold or donated. A significant portion of these assets was fully depreciated.

Whether SCM processes and systems in place

Supply chain management systems are well established and maintained throughout the financial year. Management did not identify any new irregular, fruitless and wasteful expenditure and all historical transgressions have been addressed in line with the National Treasury guidelines.

Spending trends per programme are outlined below:

Programme 1: Leadership & Support

The programme had a final budget of R134.9 million and expenditure amounted to R186.8 million or (43.8%) in the current financial year of 2023/24, compared to R140.5 million expenditure in the 2022/23 financial year.

Programme 2: Health Products Authorisation

The programme had a final budget of R36.2 million and expenditure amounted to R34.0 million or (6.02%) in the current financial year of 2023/24, compared to R46.9 million expenditure in the 2022/23 financial year.

Programme 3: Inspectorate & Regulatory Compliance

The programme had a final budget of R63.1 million and expenditure amounted to R69.2 million or (11.6%) in the current financial year of 2023/24, compared to R42.3 million expenditure in the 2022/23 financial year.

Programme 4: Clinical & Pharmaceutical Evaluation

The programme had a final budget of R126.6 million and expenditure amounted to R119.4 million or (28.14%) in the current financial year of 2023/24, compared to R108.2 million expenditure in the 2022/23 financial year.

Programme 5: Medical Devices & Radiation Control

The programme had a final budget of R44.8 million and expenditure amounted to R38.4 million or (8.34%) in the current financial year of 2023/24, compared to R33.1 million expenditure in the 2022/23 financial year.

Capacity constraints and challenges facing SAHPRA

For the year under review, SAHPRA had the following targets to bolster its capacity:

- Conduct Employee Satisfaction Survey and Implement the Action Plan to address recommendations from the survey report.
- Ensuring that 70% employees are trained to develop their skills they need to perform their duties, advance their careers, and keep abreast of continually changing business operations.
- Ensuring that 95% budgeted positions on the Recruitment Plan are filled to capacitate SAHPRA in achieving its mandate.
- Ensuring that the staff turnover rate is less than 10% or below to retain complete and experienced employees.

SAHPRA's recruitment, selection and retention difficulties persisted. Forty-six (46) positions were funded to be filled for the 2023/24 financial year, however, only 67.4% (31/46) of these positions were filled as at 31 March 2024. Delays in the filling of the positions were caused by the completion of compulsory candidate pre-suitability checks (verification processes), re-advertising of positions because no suitable candidates were found during the selection processes and offers being declined by candidates to mention a few issues. This resulted in serious capacity constraints within SAHPRA and also placed additional strain on the remaining employees who had to carry the additional workload.

SAHPRA has made considerable progress in ensuring that its employee profile is highly representative of the demographic profile of South Africa. In achieving EE targets, as set in the EE Plan, during the year 2023/24, 61% (19/31) of new appointments were women. The entity had the highest representation of Africans at 84% (260/309), followed by Indians at 6% (19/309), Whites at 5.5% (17/309) and the Coloureds with just 4.5% (14/309). The overall female representation is at 62% and 62.5% females occupying senior and executive positions. Disability representativity is currently standing at 2%, maintained from the previous reporting year of 2022/23 financial year.

The staff turnover rate for the 2023/24 FY was at 8.1%, a decrease by 0.35% compared to last year. SAHPRA continued to experience staff turnover on critical and scarce positions resulting in instability and a lack of continuity at management and operational levels. The turnover is attributable to terminations with reasons related to job security, career growth, work-life balance, remuneration and benefits, retirement and contract expiry were reasons why employees leave the services.

During the period 2023/24 FY, SAHPRA was under enormous constraints due to reduced funding from National Treasury. Therefore, the organisation had to embark on strategies to cut operational costs and increase revenue collection, which included the reduction in advertisements of some of the funded positions. As a result, Business Units had to prioritise activities and utilise some of the external experts in achieving its mandate.

Discontinued key activities / activities to be discontinued

None

New or proposed key activities

To be decided at the Authority's Strategic Planning Session, taking into consideration the upcoming 7th Administration of the new government following South Africa's general elections.

Requests for roll over of funds

Previous requests for retention of surpluses have been approved by National Treasury and SAHPRA intends to submit a request for retention of surpluses in line with the National Treasury guidelines by 30 September 2024 for approval.

All concluded unsolicited bid proposals for the year under review

None

Challenges experienced and how resolved

The main challenge on financial systems and processes relate to the manual processes utilised to track and recognise revenue from applications received. SAHPRA has embarked on a digitisation process to mitigate some of the risks relating to manual processing.

Audit report matters in the previous year and how would be addressed

Various matters were raised on receivables that had control deficiencies and misstatements, which management addressed by updating the applicable policies, expediting relevant processes and developing action plans. Management resolved to appoint additional resources while awaiting implementation of an electronic system to ensure revenue is correctly recognised and amended the policy to include deviations that may be encountered upon processing of new applications.

Further engagements were held with AGSA post the audit to seek to establish operational and technical

alignment and agreed way to process transactions, where there was difference in interpretation on expenditure recorded in incorrect financial years.

Plans for the future to address financial challenges

The main financial challenge relates to available funding to fill vacancies. SAHPRA has obtained essential funding and has revised its fee regulation which was submitted for approval and expects gazetting in the 2024/25 financial year to address this matter.

Events after the reporting date

SAHPRA signed a Memorandum of Understanding (MoU) with the Rwanda Food and Drug Authority (Rwanda FDA) on 12 April 2024. The MOU between SAHPRA and Rwanda FDA will allow the regulators to develop a cooperative partnership towards ensuring access to safe, quality, and effective health products in the respective countries.

Economic Viability

The annual financial statements have been prepared on the basis of accounting policies applicable to a going concern. Following an assessment on our current financial position and projected future cashflows, there is an indication 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.

I would like to take this occasion to thank the Chairperson of the Board and the Members for their strategic leadership and guidance they provided throughout the financial year. I also acknowledge and appreciate the SAHPRA's employees and the executive team for their determined dedication and commitment during the period under review. Finally, my congratulations to the Board for their direction on good governance, accountability and instilling sound financial management and, most importantly, congratulations to all SAHPRA employees who worked unwaveringly in the background on ensuring SAHPRA achieves a noteworthy milestone, a clean audit for the 2023/24 financial year.

Dr Boitumelo Semele-Rakokotlela
Chief Executive Officer

4. STATEMENT OF RESPONSIBILITY & CONFIRMATION OF ACCURACY FOR THE ANNUAL REPORT

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

All information and amounts disclosed in the annual report are consistent with the Annual Financial Statements audited by the Auditor General 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 for the annual report 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 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 2024.

Yours faithfully,

Chief Executive Officer
Dr Boitumelo Semete-Makokotlela
Date: 31 August 2024

Chairperson of the Board
Prof. Helen Rees
Date: 31 August 2024

5. STRATEGIC OVERVIEW

5.1 Vision

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

5.2 Mission

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

5.3 Values

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

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 concerning 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 monitoring, evaluating, regulating, investigating, inspecting, registering and controlling 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 have 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').

- Under 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 National Health Act, 61 of 2003

This Act provides a framework for a structured, uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws of national, provincial and local governments with regard to health services. The objectives of the National Health Act, as underscoring 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 cooperative governance and management of health services within national guidelines, norms and standards, in which each province, municipality and health district must add its questions of health policy and delivery of quality health care services;
- Establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourage public participation;
- Promote a spirit of cooperation 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 Medicines and Related Substances Act, 101 of 1965, as amended

Amended by the Medicines and Related Substances Amendment Act, 72 of 2008, and Medicines and Related Substances Amendment Act, 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.

Under the Medicines Act, the Authority's objects are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration, and control of medicines, scheduled substances, medical devices, regulated control, clinical trials, and other matters related to the public interest.

The Act also provides for the regulation and control of veterinary medicines in such a way as to ensure that they are produced, distributed and used in a manner compromising human and animal health. Any medicines intended for animal use 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, in order to achieve its objects, ensure:

- The efficient, effective and ethical evaluation or assessment and regulation of medicines, medical devices, radiation-emitting devices and radioactive nuclides that meet the defined standards of quality, safety, efficacy and performance, where applicable;
- That the process of evaluating or assessing and registering medicines, medical devices, radiation emitting devices and radioactive nuclides is transparent, fair, objective and concludes in a timely;
- The periodic re-evaluation or re-assessment and ongoing monitoring of medicines, medical devices, radiation emitting devices and radioactive nuclides;
- 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;
- The 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 cooperate with any regulatory authority to achieve the objects of the Medicines Act.

6.2.3 Hazardous Substances Act, 15 of 1973

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

SAHPRA is only responsible for regulating Group II and Group V hazardous substances.

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

6.3 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, 36 of 1947**

This Act provides for the registration of fertilisers, farm feeds, agricultural remedies, stock remedies, sterilising plants and pest control operators; to regulate or prohibit the importation, sale, acquisition, disposal or use of fertilisers, farm feeds, agricultural remedies, and stock remedies. Furthermore, it governs the use of antimicrobials for growth promotion and prophylaxis/metaphylaxis and the purchase of over-the-counter antimicrobials by the public (chiefly farmers).

- **Animal Diseases Act, 35 of 1984**

This Act provides for the control of animal diseases and parasites; measures to promote animal health; and related matters.

- **Veterinary and Para-Veterinary Professions Act, 19 of 1982**

This Act provides for the establishment, powers and functions of the South African Veterinary Council; the registration of persons practising veterinary and para-veterinary professions; control over the practising of veterinary and quasi-veterinary professions; and incidental matters. It furthermore provides 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, 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 association 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 incidental 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)(ii) of the Medicines and Related Substances Act, 1965, read with Schedule 7 of Government Notice No. R. 509 of 2000 to be unconstitutional in the sense 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.

Pending consultation with stakeholders, amendments to the Schedules of the Medicines Act aligned with the Constitutional Court judgement were published in Government Notice No. 980, 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, 54 of 1972, as amended**

This legislation regulates foodstuffs, cosmetics and disinfectants, particularly quality standards that manufacturers must comply with as well as the importation and exportation of these items.

- **Environmental Management Act; Waste Management Act, 107 of 1998**

It provides for cooperative 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, 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, 33 of 1978**

Provides for consolidation and amending the laws relating to the professions of registered or enrolled

nurses, nursing auxiliaries and midwives and related matters.

- **Pharmacy Act, 53 of 1974**

The South African Pharmacy Council (SAPC), in terms of Section 35A of the Pharmacy Act, 53 of 1974, regulates the practice of pharmacy within South Africa. The SAPC ensures that all responsible pharmacists, pharmacy support personnel and pharmacy owners provide pharmaceutical services that comply with good pharmacy practice standards prescribed in the Pharmacy Act and relevant provisions of the Medicines and Related Substances Act. The Medicines Act, in Section 19(b), provides for the possession of medicines in scheduled substances for sale by pharmacists or a person licenced to own a pharmacy, in terms of the Pharmacy Act, 1974 or a person who is the holder of a licence as contained in section 22C of the Medicines Act. The SAPC has, in terms of Section 35A of the Pharmacy Act, appointed inspection officers to monitor pharmacies for compliance. The provisions of the Pharmacy Act include investigating complaints received alleging misconduct or unprofessional conduct.

- **Customs and Excise Act, 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 the effective execution of its mandate. Notable developments in SAHPRA's operating environment have necessitated a review of its legislative and policy framework.

In the first instance, SAHPRA exists to operate within an extremely complex legislative context where other players are involved and SAHPRA has only a limited yet important regulatory role. A case in point is a role SAHPRA should be fulfilling through its presence at all key ports of entry where goods that come into the country 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 and Petroleum Resources. Another cross-entity is cannabis regulation, which involves multiple ministries such as the Department of Justice and Constitutional Development, the Department of Correctional Services and the Department of Agriculture, to effect 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".

5.4 Policy Mandate

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

7. ORGANISATIONAL STRUCTURE

8. MEMBERS OF THE BOARD

9. EXECUTIVE MANAGEMENT

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer

Mr Regardt Gouws
Chief Financial Officer

Ms Portia Nkambule
Chief Regulatory Officer

Ms Christelna Reynecke
Chief Operations Officer

Vacant
Executive Manager: Human Resources

Adv. Mpho Mpholo
Board Secretary

PART B
PERFORMANCE INFORMATION

1. AUDITOR'S REPORT: PREDETERMINED OBJECTIVES

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

Refer to page 111 of the Report of the Auditor-General, published as Part F: Financial Information.

2. OVERVIEW OF PERFORMANCE

2.1 Service delivery environment

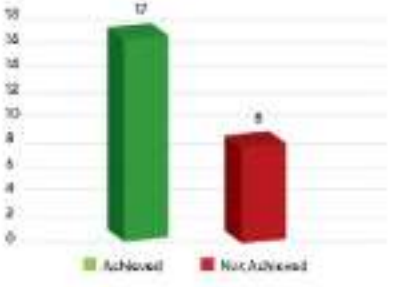
During the reporting period of 2023/24 financial year, National Treasury has in real-terms budget and funded programmes owing to fiscal challenges faced by government in the financial year under review. Accounting Officers and Accounting authorities were advised on specific measures required to achieve much-needed savings thereby, implementing cost containment measures and budget cuts within government institutions including SAHPRA.

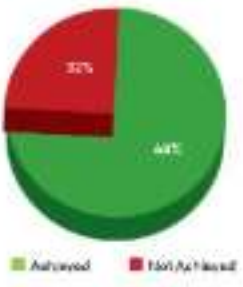
The collection or retention of license fees has been a challenge over the past two financial years. To overcome this challenge SAHPRA appointed a debt collecting agent to assist with collection of long outstanding balances. There were 11 petition cases brought against SAHPRA during the year under review. These cases were primarily about challenging SAHPRA's Regulatory Mandate and powers of SAHPRA in taking decisions. The Authority has been fostering better relationships with law enforcement and other regulatory agencies such as the South African Veterinary Council, South African Pharmacy Council and HPCSA in order to address contraventions to the Medicines Act and other legislation. The rise in demands for increased cannabis related economic activity in the medicines space has maintained high demand for the Authority' services. The Authority continues to have high demand for licensing and cannabis cultivation inspections, while the prosecutions unit seeing more demand for inspections related to manufacturing of extracts and testing of cannabis and medicines. As the Regulatory Authority and its functions becomes more visible in the public, the reporting of non-compliances to the Medicines Act has seen a doubling of investigations over the last two years, that the Authority's Regulatory Compliance unit is required to investigate within 30 working days, as per the Annual Performance Plan Target. High demand also exists for the review of shipments being imported, especially through the port of OR Tambo International Airport, which has resulted in an additional Border Medicines Control Technician being recruited at this port.

In terms of the performance against its 2023/24 Annual Performance Plan, the Authority planned to achieve 25 targets. Of the 25 planned targets, the Authority was able to achieve 17 targets which equates to 68% achievement, as detailed in the graphs on page 30.

During the period under review the South African Health Products Regulatory Authority was able to deliver on 17 of its 25 predetermined targets. Such key achievements can be summarised as follows:

- Current ratio of 1:1 was maintained by achieving 1.16:1. In essence, SAHPRA's total revenue amounted to R415.8 million against a budget of R381 million due to additional external funding support received during the year.
- 100 % New Chemical Entities were finalised within 400 working days.
- 86% generic medicines finalised within 250 working days.
- SAHPRA successfully managed to attain the International Organisation for Standardisation (ISO) 9001 Certification by SABS.
- 94% permits were finalised within 20 working days.
- 90% applications for the sale of unregistered





Category A (human) medicines were finalised within 3 working days.

- 91% human clinical trial applications finalised within 60 working days.
- 126.5% medical device establishment license applications were finalised within 90 working days.
- 116% applications for listed electronic products finalised within 30 working days.

The Authority did however experience varying levels of under-achievement against planned targets due under-capacitated business units struggle to attract and retain the best talent especially in the technical field due to competition for best talent in the health, regulatory and pharmaceutical market. In terms of the targets that experienced challenges resulting in non-achievement, the Authority has identified the reasons for such deviation and has put in place relevant catch-up plans and mitigating measures so as to ensure success going forward.

2.2 Organisational environment

During the year under review, employees indicated several dissatisfaction matters that have led SAHPRA to commissioned Enterprises University of Pretoria to conduct an employee satisfaction survey. The survey was conducted from 18 - 28 September 2023. The aim of the survey was to gain an understanding of employees opinions and feelings about their workplace, their job and their work environment for SAHPRA to be able to address those areas where employees' experiences are less than ideal. The report shows that staff is excited to work for SAHPRA. They have a strong sense of purpose and direction at SAHPRA, and they want to be part of SAHPRA's future, believing that their work contributes to the overall success of SAHPRA and the future vision of SAHPRA is important to them. Most employees have also indicated that they enjoy the hybrid working model as it creates flexibility and believes to improve staff morale, which shows that the entity has remote working capabilities than other organisations.

During the period 2023/24 FY, SAHPRA was under enormous constraints due to reduced funding from National Treasury, therefore, the organisation had to embark on strategies to cut operational costs and increase revenue collection, which included the reduction in advertisements of some of the funded positions. As a result, Business Units had to prioritise activities and utilise some of the external experts in achieving its mandate.

The implementation of the presence of SAHPRA technicians at the port has been effective in highlighting import non-compliances, thus being an effective mechanism for the detection and prevention of substandard, falsified or unauthorised product. To improve transparency in the processes for processing shipments, the Regulatory Compliance unit published workflows on the SAHPRA website to guide applicants and importers on requirements for importing health

products subject to SAHPRA mandate. Improved processes and escalation procedures were implemented to improve service delivery and prevent delays at the ports. The Licensing Unit improved the regulation of the import of scheduled substances by completing the guideline for the Licence to Distribute Scheduled Substances and also successfully licensed two establishments. Controls in this framework includes the requirement to submit to SAHPRA for authorisation the details of each consignment imported.

For the year under review, SAHPRA had the following targets to bolster its capacity:

- Conduct Employee Satisfaction Survey and implement the Action Plan to address recommendations from the survey results.
- Ensuring that 70% employees are trained to develop their skills they need to perform their duties, advance in their careers, and keep abreast of continually changing business operations.
- Ensuring that 85% budgeted positions on the Recruitment Plan are filled to capacitate SAHPRA in achieving its mandate.
- Ensuring that the staff turnover rate is less than 10% in order to retain complete and experienced employees.

SAHPRA's recruitment and retention difficulties persisted. Forty-six (46) positions were funded to be filled for the 2023/24 financial year however only 67.4% (31/46) of these positions were filled as at 31 March 2024. Delays in filling of the positions were caused by completion of compulsory candidate suitability checks (verification processes), re-advertising of positions because no suitable candidates were found during the selection processes or offers were declined by suitable candidates, just to mention few. This resulted in serious capacity constraints within SAHPRA and also placed additional strain on the remaining employees who had to carry the additional workloads.

SAHPRA has made considerable progress in ensuring that its employee profile is highly representative of the demographic profile of South Africa. In achieving Employment Equity (EE) targets, as set in the EE Plan, during the year (2023/24), 61% (19/31) of new appointments were women. The entity had the highest representation of Africans at 84% (26/31/46) followed by Indians at 9% (1/9/339). Whites at 5.8% (17/339) and the Coloureds with just 4.5% (14/309). The overall female representation is 52% and 52.9% of females occupy senior and executive positions. Disability representation is currently standing at 2%, mainly due from the previous reporting year of 2022/23.

The staff turnover rate for the 2023/24 FY was at 9.4%, a decrease by 0.58% compared to last year. SAHPRA continues to experience a turnover on critical and scarce positions resulting in instability and a lack of continuity at management and operational levels. The turnover is attributable to terminations with reasons related to job security, career growth, work / life balance, remuneration and benefits, retirement and contract expiry were reasons why employees leave the services.

Delays in appointment or vacant position due to retirements and resignations. Below are challenges experienced by SAHPRA on Medical Devices regulation. Delays in the finalisation of the second version of the Medical Device Regulations. The document initially was published for public comments in April of 2021 and republished for public comment in August of 2023 but still not yet finalised for implementation. Upon review of the latest comments received and engagement with the industry, further delays are anticipated as the industry are requesting a Regulatory Impact Assessment (RIA) report regarding the version 2 of the Medical Device Regulations. Manual processes for tracking supervisions and approval statuses still persist. Manual tracking systems of large data can result in human error. At the end of 2023-24 FY, the tracking system used involved the manual recording of large amounts of data at key steps in the process for new inspection registrations on Google Sheet. The limited functionality on Google Sheets resulted in manual calculations for performance reporting as there is no step code mechanism available to perform the required calculations for timelines. The use of manual systems, especially for collection, maintenance of database, and follow-up on retention fees with the applicants, tends to be unreliable. Changes in the

approval system (i.e., SignFlow) within the organisation effected the uploading and downloading of approved licenses and permits on the system.

The Authority has attained ISO 9001:2015 Certification following a rigorous audit by the South African Bureau of Standards (SABS), a milestone that serves as a testament to the implementation of an effective and robust organisation-wide Quality Management System (QMS). A fully functioning QMS is core to achieving quality objectives that ensure that health products in South Africa meet statutory and regulatory standards of quality, safety, and efficacy. The continuous improvement to the Quality Management Systems (QMS) that brought awareness required to ensure the correct and use of current policies and documents, training on new and revised processes. Varied collaboration with other units such as Regulatory Compliance, client-focused approach solutions, through engagement and transparency. Effective utilisation of resources. Implementation of the evaluation coordinator role in the new medicines workstream. The evaluator coordinator role played a significant role in closing the gap on the misalignment of allocations of technical screenings and evaluations in the different technical units. This resulted in overachievement in Q3 and Q4 and the overall success of the targets in the 2023/24 FY. Resignation of the HPA Senior Manager at the end of Q1 2023. However, the delegation of responsibilities was to a very experienced Manager in HPA. There was no resultant impact on the Annual Performance Plan for this unit.

With regard to capacity building and skills development, the Authority's Inspectorate Unit participated in the surveys on competency for a SAHPRA competency standard, where various Inspectors participated covering a wide scope. To enhance the issuing of permits and to improve the accuracy of reporting to the INCB, discussions were held with the UNODC/INCB regarding the procurement of the I2ES7 tool, which will digitise the receipt, processing and issuing of permits. This will allow better control on reporting on narcotics and psychotropics. Due to ongoing discussions about the ability of the supplier of the tool to meet SAHPRA procurement process requirements, the procurement of the system was delayed. With the support of the South African Mission in Vienna in the fourth quarter, progress towards procuring the system was made and implementation is expected in the new financial year. The goal is expected to become more effective with the accuracy of data capture required by the INCB in the control of narcotic and psychotropic substances. The use of online system will assist in ensuring that resources are allocated job specific function and ensure continuous improvement of the Authority's business units. Various strategies are being utilised by the evaluation time which include the implementation of different forms of reliance including participating in ZAZIBONA, which is a collaborative process for the evaluation of new medicine applications and making use of assessment reports from Recognised Regulatory Authorities and SAHPRA.

2.3 Key policy developments and legislative changes

SAHPRA amended the Schedule 6 exception for Tetrahydrocannabinol to make provision for a wider industrial application and use of the cannabis plant, which would then be subject to regulation under other government departments such as the Department of Health Food Directorate and the Department of Agriculture, Land Reform and Rural Development. These amendments were published for comment, and the action of the comments and publishing of the amended schedule exception is expected in the new financial year.

As a result of an amendment to Regulation 3 of the Medicines Act, SAHPRA was required to develop and publish a draft guideline for medicine compounding for comment. The comments were received and are currently under review. The publishing of a finalised compounding guideline will add further regulation to the area of compounding.

2.4 Progress towards achievement of institutional impacts and Outcomes

SAHPRA's revised 2020/21 – 2025/26 Strategic Plan was approved in January 2023. The revisions were made to the to ensure alignment with revisions in the

Annual Performance Plan based on the recommendations from the audit by Internal Audit. Outcome Indicators, 5-year targets and method of calculation in the Technical Indicator Descriptions.

2.4.1 Progress on Outcomes

MEDIUM TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH			
OUTCOMES	**OUTCOME INDICATORS**	**FIVE-YEAR TARGET**	**PROGRESS**
Effective financial management (1)	1.1 Unqualified audit opinion obtained on the annual financial statements	Clean audit opinion obtained for the 2023/24 financial year	Unqualified audit opinion is obtained for the 2022/23 financial year
Financial sustainability achieved through revenue generated and enhanced operational efficiencies (2)	1.2 Total revenue generated from fees in the financial year	Annual revenue of R185 million generated from fees	Total revenue generated from fees amounts to R228 million the positive variance is mainly due to the impact of the 2020 Fee Regulation and increase in finalisation of applications.
Continuously respond to the needs and expectations of SAHPRA stakeholders (3)	1.3 Percentage of accepted recommendations from the stakeholder perception survey implemented	100% accepted recommendations from the stakeholder perception survey implemented	2023/24 Stakeholder perception survey was conducted, and outcomes of such survey were presented at EXCO. The Implementation Plan to address Recommendations was approved by EXCO. Progress report on the implementation plan from the 2023/24 Stakeholder Perception Survey was submitted to the Executive Committee.
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	Staff satisfaction survey was conducted during the year under the review, the Implementation Plan to address Recommendations was approved by the Executive Committee, furthermore, the Progress report on the implementation plan from the staff satisfaction survey was submitted to the Executive Committee covering aspects of culture and communication.
Attract and retain superior talent (5)	1.5 Percentage of positions in the staff establishment filled	80% of core business positions in the staff establishment filled	The turnover rate in quarter 4 was at 1% (3/307), still within the target of 10%. Annual staff turnover rate for 2023/24 FY is at 9.4%, still within the target of 10 %.

MEDIUM TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH			
OUTCOMES	**OUTCOME INDICATORS**	**FIVE-YEAR TARGET**	**PROGRESS**
Strengthened Information and Communication Technology and digitisation (6) (6)	1.6 Enterprise Architecture developed	Phase 2 of the roadmap on the Enterprise Architecture implemented	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 completed. Draft URS for Batch Management tool completed. The server warranty was renewed for an additional two (2) years. (81.25% completed for Q4)
High levels of organisational operational efficiency and effectiveness in the regulatory function maintained (7)	1.7 Percentage of medicine registrations in the backlog cleared	100% medicine registrations backlog cleared	100 % medicine registrations backlog cleared
	1.8 Percentage of medicine variation applications in the backlog cleared	100% medicine variation applications backlog cleared	100% medicine variation applications backlog cleared
	1.9 Percentage of New Chemical Entities finalised within 360 working days	80% New Chemical Entities finalised within 360 working days	100 % New Chemical Entities finalised within 400 working days. Out of 224 applications received, 30 (13 %) were due for finalisation. Although 30 applications were due for finalisation, 103 (100%) were finalised, of which 91 (100 %) were finalised within 400 workings days.
	1.10 WHO maturity level obtained	WHO maturity level 4 obtained	Maturity Level 4 self-assessment was not conducted.
	1.11 Percentage of new Good Manufacturing Practice (GMP) and Good Warehouse Practice (GWP) related licenses finalised within 125 working days	80% new GMP and GWP related licenses finalised within 125 working days	27% new Good Manufacturing Practice and Good Warehouse Practice related licenses finalised within 125 working days. Out of 76 applications received, 60 (79%) were due for finalisation. Out of 60 due for finalisation, 20 (33%) were finalised, of which 16 (27%) were finalised within 125 workings days.

MEDIUM TERM STRATEGIC FRAMEWORK PRIORITY 3: EDUCATION, SKILLS AND HEALTH			
OUTCOMES	OUTCOME INDICATORS	FIVE-YEAR TARGET	PROGRESS
	1.12 Percentage of human clinical trial applications finalised within 90 working days	60% human clinical trial applications finalised within 90 working days	92% human clinical trial applications finalised within 60 working days Out of 249 applications received, 207 (83%) were due for finalisation Out of 207 due for finalisation, 218 (105%) were finalised, of which 190 (92%) were finalised within 60 working days
	1.13 Medical device registration regulations implemented	Call up of Class D (high risk)	Call-up notice of pilot Class D (Expression of interest for Medical device) voluntary registration feasibility study approved and published for coming engagement towards implementation. The upcoming Feasibility study (previously referred to as Call-up Notice of pilot Class D) update published on social media platforms.

3. INSTITUTIONAL PROGRAMME PERFORMANCE INFORMATION

3.1 Programme 1: Leadership and Support

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

Sub-programmes

Sub-Programme	Purpose
Financial and Supply Chain Management	To serve all business units in SAHPRA, the senior management team, and the Board by maintaining an efficient, effective and transparent system of financial and risk management that complies with the applicable legislation.
Communication and Public Relations	To provide comprehensive communication and public relations management services that enhance public health, stakeholder engagement and the reputation of SAHPRA.
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.

- Effective compliance, financial and performance management (1)
- Financial sustainability achieved (2)
- Responsive to stakeholder needs (3)
- A positive and enabling working culture created (4)
- Attract and retain talent (5)
- Digital transformation (6)

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

Financial and Supply Chain Management

SAHPRA's total revenue amounted to R435.4 million against a budget of R381 million. The variance of R54.5 million was mainly due to additional external funding support received during the year and additional fee revenue derived. SAHPRA spent R424 million against the total approved budget of R381 million. The additional expenditure was utilised due to unbudgeted for external financial support received as well as above-budgeted for fee income generated during the year. The overall result was an accounting surplus amounting to R11 million and exceeding the annual cash flow ratio target of 1:1.

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

- Achieved an unqualified audit (2022/23)
- Enforced finance and supply chain policies and standards, reducing irregular, fruitless and wasteful expenditure
- Revised service fee structures submitted for approval and gazetting

Communication and Public Relations

The annual achievement in the unit is the implementation of the communication strategy through tailored and targeted messaging via communication channels (website, emails, webinars/workshops, social media channels) across different audiences (public/industry/healthcare professionals/regulatory organisations, etc.) to enhance and instil safe medicine claims on key public issues around the safety of health products in the country.

The anti-counterfeit campaigns (enhancing awareness of the dangers of substandard/falsified medications by reporting side effects to name a few) directed to external stakeholders (customs/industry/healthcare professionals/partner organisations etc.) continue to bring awareness of SAHPRA's mandate of protecting the health and well-being of South Africans, with a direct impact on one of government's strategic priorities of education. SAHPRA's messaging is about informing and educating stakeholders about the Regulator's work to protect the public's health and well-being. Lack of budget to support the unit's needs in terms of collateral production (like pamphlets, manuals, guides, etc.) led to the unit being unable to deliver better access to information for key stakeholders such as public and healthcare professionals. The retirement of the Manager: Communication and PR created challenges for the Acting team member to address key deliverables and their targets.

Human Resource Management

During the year under review, employees indicated several areas of dissatisfaction that led SAHPRA to commission an external service provider, Stellenbosch University, of Pretoria, to conduct an employee satisfaction survey. The survey was conducted from 18 - 28 September 2023. The survey aimed to gain an understanding of employees' opinions and feelings about their workplace, their job and their work environment for the organisation to be able to address those areas where employees' experiences are less than ideal. The result shows that the staff is excited to work for SAHPRA. They have a strong sense of purpose and direction at SAHPRA and want to be part of SAHPRA's future, believing that their work contributes to the overall success of SAHPRA and the future vision of the entity is essential to them. Most employees have also indicated that they enjoy the hybrid working mode as it creates flexibility and balance. It contributes to improving staff morale, which shows that the entity has remote working capabilities.

SAHPRA provided training and learning opportunities to employees to further their qualifications and develop the skills they need to perform their duties, advance their careers and keep abreast of continuously changing business operations. For 2023/24, the target was to train 70% (215) employees. A total of 351 (114.7%) employees were trained from April 2023 to March 2024. Most of the training was offered by various independent external industry stakeholders. The entity has made considerable progress in ensuring that its employee profile is highly representative of South Africa's demographic profile. The entity's composition: a 62% women, 27% youth (20 – 35 years) and 2% people with disability. Women's representation in senior and executive management (SL 13 – 16) is at 52.5%. The entity has achieved the national target of 50% women at senior management level and 2% of people living with disabilities as set by Parliament. In the new financial year, the entity will enter partnerships with NGOs and continue to support youth employment initiatives through the implementation of the Community Service Programme for graduates in a bid to address youth unemployment thus providing them with an opportunity to gain relevant experience.

Information and Communication Technology (ICT)

The ICT service delivery for SAHPRA is aligned with the Corporate Governance ICT Framework (CGICT) and is aimed at enabling the Authority to produce measurable results while achieving its ICT strategies and goals. The implementation of the Regulatory Information Management System (RIMS) together with the technology consultancy projects are aimed at enhancing the Authority's service delivery to the industry. The Authority faced challenges and delays in sourcing the correct service provider for the RIMS project, but eventually awarded it in the last quarter of the financial year 2023/24. RIMS and a technology consultancy service provider were appointed to implement a digital strategy and significant progress has been made in the digitisation project directly related to the Health Products Authorisation (HPA), Licensing, and Section 21 units.

The delivery of online digitised services relies heavily on the availability of Internet services via Internet Service providers. National and global Internet disruptions can create delays in the delivery of services. The Authority's ICT staff has set up redundancies to ensure business continuity. Limited resources remain a challenge within the ICT Unit in the delivery of services. However, a total number of 4 527 calls were received through our Service Desk on all categories; 8% of total calls breached the SLA, and 94% of the total calls were resolved within the SLA for the financial year 2023/24. This is achieved by ensuring that incidents are closed only after providing a proper resolution and confirming with the end user, and applying the appropriate closure notes on the knowledge database. The ICT Architecture Framework is being used to translate SAHPRAs Digitisation business strategy through the Single Cloud Framework. The SAHPRA environment maintained a security patch compliance rate of more than 95% during the fiscal year 2023/24.

PROGRAMME 1 ADMINISTRATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	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	Qualified audit opinion obtained (2020/21 financial year)	Unqualified audit opinion obtained for 2021/22 financial year	Unqualified audit opinion obtained for the 2022/23 financial year	Unqualified audit opinion is obtained for the 2022/23 financial year	N/A	N/A
Financial sustainability achieved (2)	Liquidity ratio of ≥ 1	Current assets ≥ than current liabilities	-	-	Current ratio of 1≥1 maintained	Current ratio of 1.16:1 achieved	Target exceeded by 0.16	Higher than expected revenues generated and under expenditure of cost of employment

PROGRAMME 1 ADMINISTRATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
Responsive to stakeholder needs (3)	Survey conducted	Stakeholder survey conducted	67% prioritised recommendations from the survey implemented Out of 3 prioritised recommendations from the survey, the following 2 (67%) were implemented:	60% accepted recommendations from the 2020/21 stakeholder perception survey implemented Out of 5 accepted recommendations from the 2020/21 stakeholder perception survey, the following 3 (60%) were implemented: • Document management system • Online application system was tested • Online medicines register is live	2023/24 Stakeholder perception survey conducted. Progress report on the implementation plan from the 2023/24 Stakeholder Perception Survey submitted to the Executive Committee	2023/24 Stakeholder perception survey was conducted, and outcomes of such survey were presented at EXCO. The implementation Plan to address Recommendations was approved by EXCO. Progress report on the implementation plan from the 2023/24 Stakeholder Perception Survey was submitted to the Executive Committee.	N/A	N/A

PROGRAMME 1 ADMINISTRATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
A positive and enabling working culture created (4)	Survey conducted	Progress report on the implementation plan produced	-	-	Staff satisfaction survey conducted Progress report on the implementation plan from the staff satisfaction survey submitted to the Executive Committee	Staff satisfaction survey was conducted during the year under the review, the implementation Plan to address Recommendations was approved by the Executive Committee, furthermore, the Progress report on the implementation plan from the staff satisfaction survey was submitted to the Executive Committee covering aspects of culture and communication.	N/A	N/A

PROGRAMME 1 ADMINISTRATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
	Learning and development Initiatives implemented	Percentage of learning and development initiatives implemented	39% of the WSP implemented Out of 23 planned training interventions in the WSP, 9 (39%) were implemented	Out of 458 training Initiatives planned, 68 (15%) were implemented	70% employees trained	Total number of employees trained as per the training matrix is 354 and the total number of employees for the year ended 31 March 2024 is 307 resulting in 115,31 % Employees trained.	SAHPRA employees attended more external training offered by various independent stakeholders of the industry	N/A

PROGRAMME 1 ADMINISTRATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
Attract and retain talent (5)	Budgeted positions filled	Percentage of budgeted positions filled	96% budgeted positions filled Out of 55 budgeted positions, 53 (96%) were filled	65% budgeted positions filled, 48 budgeted positions and 26 positions funded through Global Fund which 18 have been filled, (65%) was achieved.	95% budgeted positions filled	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.	Availability of panel members for the selection process. Completion of compulsory candidate pre-suitability checks (verification processes). Offers declined by suitable candidates. Re-advertising because no suitable candidates were found during the selection processes there by prolonging the recruitment and selection processes.	Business Units to appoint dedicated panel members to improve turnaround times in filling the positions and ensuring that appointed panel members are available by 30 April 2024. Capacitate HR Unit, to be able to deal with administrative challenges by 30 September 2024.

PROGRAMME 1 ADMINISTRATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
	Technical staff retained	Percentage of staff retained	-	-	Staff turnover rate less than 10%	The turnover rate in quarter 4 was at 1% (3/307), still within the target of 10%. Annual staff turnover rate for 2023/24 FY is at 9,4%, still within the target of 10 %.	N/A	N/A

PROGRAMME 1 ADMINISTRATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
Digital transformation (6)	Enterprise Architecture	Percentage of Phase 1 Enterprise Architecture implemented	Section 21 business process was digitised in June 2021 Development of an online application submission system was in progress Leave application process was digitalised	The Enterprise Architecture has not been approved by the Board. The EA approved in Q3 2023/24 by the board.	100% Enterprise Architecture Phase 1 implemented	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 completed. Draft URS for Batch Management tool completed. The server warranty was renewed for an additional two (2) years. (81.25% completed for Q4)	18.75% not completed	the non-achievement of 100% is delayed in the appointment of RIMS service provider, NDS7 and Pharmacovigilance appointment delays due to various reasons. A pricing change from MHRA delayed pharmacovigilance procurement due to the new license structure

3.1.2 Linking performance with budgets:

	2023/2024			2022/2023		
Programme/ activity/objective	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	134 908	185 829	(50 921)	127 736	140 920	(11 324)
Total	134 908	185 829	(50 921)	127 736	140 920	(11 324)

3.1.3 Strategy to overcome areas of under performance

Across the entity, recruitment, selection and retention difficulties persisted during the year under review. Forty-six (46) positions were funded to be filled for the 2023/24 financial year. However, only 67.4% (31/46) of those positions were filled as at 31 March 2024. Delays in filling of the positions were caused by the completion of compulsory candidate pre-suitability checks (verification processes), re-advertising of positions because no suitable candidates were found during the selection processes and some offers were declined by suitable candidates and budget cuts implemented by National Treasury. some positions were unfunded to remain within the allocated Cost of Employment (CoE) budget. This resulted in severe capacity constraints within the entity and placed additional strain on the remaining employees carrying the additional workloads. In correcting the situation, business units will appoint dedicated panel members to improve turnaround times in filling the positions and ensuring that appointed panel members are available. The HR unit will be capacitated to deal with administrative and technical challenges. Digitisation of business processes, particularly the automation of SCV and claims processes through the appointment of service providers to develop such systems, continued to be applied to overcome under-performance in certain areas. The negative expenditure variance is mainly due to external funding received which was not budgeted for and the retention of prior year surpluses.

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 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 for receiving, recording, and distributing all documents submitted to SAHPRA.

Sub-programmes

Sub-Programme	Purpose
Document reception and registration	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, allocation 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 actioning of data through various approaches, monitoring, analysis, and responsive action, including the provision of feedback. In addition, a fully staffed backlog project team led by a senior project manager and linked to this sub-programme will be established.
Project office – clinical trials, Section 21 applications, 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 applications 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 points to management	The purpose is to manage and coordinate the process of licensing and enforcements 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.

Outcomes

- Efficient and effective regulatory practices maintained (7)
- Global best practices maintained (8)

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

Health Products Authorisation (HPA)

Out of 224 (220 human plus four veterinary) New Chemical Entity (NCE) applications received (inclusive of applications carried over from the previous Quarter), 158 (154 human plus one veterinary) (49%) NCEs were finalised. Thirty (29 human plus four veterinary) (13%) NCE applications were due for finalisation in the fourth quarter (Q4); 91 (100%) were finalised within 400 working days from the date of completion of technical screening. Out of 2 315 (2 277 human plus 38 veterinary generic applications received (inclusive of applications carried over from the previous quarter), 715 (707 human plus eight veterinary) (31%) were due for registration by the end of the fourth quarter (Q4). Out of the 715 due for registration, 652 (100 %) were finalised, of which 619 (95%) were finalised with in 360 working days from the date of completion of technical screening. The rest of the applications were finalised between 361 and 647 working days.

The evaluation teams are refining various strategies, including implementing different forms of reliance and looking in 24/7/365/A, a collaborative process for the evaluation of new medicines applications, and using assessment reports from IRMs and SAHPRA.

The registered products encompass therapeutic areas such as serum cholesterol reducers, antihypertensives, antiretrovirals, anticonvulsants, antidepressants, anticoagulants, antacids, anti-infectives, oncology, ant

hypoglycaemics, sedatives, vascular medicines, ophthalmic preparations, immunosuppressants, contraceptive preparations, migraine preparations, corticosteroids, anti-parkinsonism preparations, and antiviral drugs.

HPA had some challenges during the year under the review. Manual processes for tracking submissions and approval statuses. Such kind of tracking systems of large data usually resulted in human error. In a nutshell, the tracking system used by HPA involved the manual recording of large amounts of data at critical steps of 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 stopping clock mechanism available to perform the required calculations for timelines. Furthermore, the resignation of the HPA Senior Manager at the end of Q1 2023 left huge responsibilities. However, the new Senior Manager was appointed at the end of Quarter 4. SAHPRA continues its digital transformation journey by implementing RIMS with enhanced tracking and reporting capabilities. Data automation will result in faster and more accurate information handling and report generation.

Quality Management System (QMS)

During the year under review, SAHPRA underwent a voluntary independent certification audit conducted by the SABS to test the implementation of SAHPRA's Quality Management System against the International Organisation for Standardisation (ISO) 9001 standard, a globally recognised standard for quality management systems developed by the International Organisation for Standardisation (ISO).

SAHPRA successfully attained the ISO 9001 certification by SABS. This milestone serves as a testament to the implementation of an effective and robust organisation-wide quality management system. This international certification confirms SAHPRA's position among global peers as a provider of globally acceptable regulatory services that comply with or exceed the ISO 9001 international standard on quality management. The Authority continues its digital transformation journey with the implementation of RIMS with enhanced tracking and reporting capabilities.

PROGRAMME 2: HEALTH PRODUCTS AUTHORISATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
Efficient and effective regulatory practices maintained (7)	New Chemical Entities (NCEs) applications finalised	Percentage of New Chemicals Entities finalised within 490 working days	100% New Chemicals Entities finalised within 590 working days Out of 246 NCEs applications received, 44 (18%) were finalised. Out of the 44 finalised, all 44 (100%) were finalised within 590 working days	100 % New Chemical Entities finalised within 490 working days Out of 342 applications received, 0 (0 %) were due for finalisation Although no applications were due for finalisation, 89 (100%) were finalised within 490 workings days	80% New Chemicals Entities finalised within 490 working days	100 % New Chemical Entities finalised within 490 working days. Out of 224 applications received, 30 (13 %) were due for finalisation. Although 30 applications were due for finalisation, 103 (100%) were finalized, of which 91 (100 %) were finalised within 490 workings days	+25% overachievement	Adherence to evaluation timelines by evaluators More efficient collaboration and coordination between units. Different reliance mechanisms employed by the evaluation teams.
	Generic medicines applications finalised	Percentage of generic medicines finalised within 250 working days	80% generic medicines finalised within 250 working days	57 % generic medicines finalised within 250 working days	70% generic medicines finalised within 250 working days	85% generic medicines finalised within 250 working days.	+15% Overachievement	Adherence to evaluation timelines by evaluators. More efficient collaboration and coordination between units. Different reliance mechanisms employed by the evaluation teams.

PROGRAMME 2: HEALTH PRODUCTS AUTHORISATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
			Out of 2 075 generic medicine applications received, 184 (9%) were finalised. Out of the 184 finalised, 148 (80%) were finalised within 250 working days	Out of 2 832 applications received, 520 (18 %) were due for finalisation Out of 520 due for finalisation, 514 (99 %) were finalised, of which 296 (57 %) were finalised within 250 workings days		Out of 2016 applications received, 715 (31%) were due for finalisation. Out of 715 due for finalization, 832(100%) were finalised, of which 619 (86%) were finalised within 250 workings days		
Global best practices maintained (8)	International Organization for Standardization (ISO) 9001: 2015 certified	International Organization for Standardization 9001: 2015 certification obtained	73% Quality Management System Requirements implemented	All planned activities in the implementation roadmap have been concluded.	International Organization for Standardization 9001: 2015 certified	International Organization for Standardization 9001: 2015 was certified	N/A	N/A
	World Health Organization Global benchmarking conducted	World Health Organization Maturity level assessed	Based on the World Health Organisation provisional assessment report received November 2021, an Institutional Development Plan was created to address the recommendations	WHO Maturity level 3 obtained	World Health Organisation Maturity Level 4 self-assessment conducted	Maturity Level 4 self-assessment was not conducted.	Maturity Level 4 self-assessment was not conducted.	Global benchmarking activities towards attainment of ML4 are deferred to Q4 of 2024/25 FY due to overlapping projects

3.2.3 Linking performance with budgets:

Programme/ activity/objective	2023/2024			2022/2023		
	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	36 268	34 046	2 222	51 615	46 979	926
Total	36 268	34 046	2 222	51 615	46 979	926

3.2.4 Strategy to overcome areas of underperformance

Various strategies are being utilised by the evaluation teams, which include the implementation of different forms of reliance, including participating in ZAZIBONA, which is a collaborative process for the evaluation of new medicine applications and making use of assessment reports from RRAs and SAHPRA. Furthermore, capacitating the organisation with the right skills is significant in achieving the objectives of the Authority. The implementation of RIMS will continue together with the technology consultancy projects; in a nutshell, the digitation of the processes remains the priority of the organisation to ensure operational efficiencies.

3.3 Programme 3: Inspectorate and Regulatory Compliance

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

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

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

- Efficient and effective regulatory practices maintained (7)

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

Of the three targets for Inspectorate and Regulatory Compliance, the programme consistently achieved the target for issuing permits within 20 working days. This contributed to the successful importation of narcotics and psychotropics needed for public health requirements as per the National Drug Policy, as well as contributing to the control of import and export of these controlled substances in line with South Africa's requirement to adhere to INCB's requirements.

Due to the significant increase in reporting of the Medicines' Act non-compliances, the resources assigned to the Regulatory Compliance Unit for investigations could not achieve the target set. This was also affected by the delay in input by stakeholders that SAHPRA collaborates with to investigate and enforce compliance through legislation. Due to a further expected increase in reported non-compliances, the target will be revised to align with resources and process requirements for the new financial year.

The target for issuing GMP- and GWP related licences within 125 working days was not achieved due to the Inspectorate Unit's capacity constraints and delays caused by applicant inspection readiness delays. For the coming financial year, the calculation of this target will not include time spent with the applicant where the applicant has delayed inspections due to the site not being ready for inspection.

Regulatory Compliance

The Regulatory Compliance Unit consistently met its target for the issuing of permits in this financial year. To enhance the business process for issuing permits and to improve the accuracy of reporting to the INCB, discussions were held with the UNODC/IVCB regarding the procurement of the NDST tool, which will digitise the receipt, processing and issuing of permits. This will allow better control of reporting on narcotics and psychotropics. Due to ongoing discussions about the ability of the supplier of the tool to meet SAHPRA's procurement process requirements, the system's procurement was delayed.

Inspectorate

The Inspectorate Unit focused on training and capacitating newly recruited inspectors in the GMP area. Together with the Regulatory Compliance Unit, the GMP Inspectorate's sub-unit underwent a risk-based GMP inspection training, provided by the WHO Regulatory System Strengthening team, which focused on sterile and biological manufacturing. Regarding capacity building and skills development, the Inspectorate Unit participated in initial surveys on competency for a SAHPRA competency standard, where various inspectors participated covering a broad skill set. The unit also focused on recruitment of GMP inspectors, which is expected to continue into the new financial year.

Licensing

The Licensing Unit performed well in meeting its target for licence renewals and amendments. However, the target for new licence applications was not achieved due to capacity challenges in the Inspectorate Unit and applicants' inspection readiness. The inspection rate of new licence applications was insufficient to accomplish the APP target for new GMP and GWP licences. In the coming financial year, the time delayed as a result of the applicant's readiness for inspection will be removed from the performance calculation.

PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	*Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
Efficient and effective regulatory practices maintained (7)	New Good Manufacturing Practice and Good Warehouse Practice related licenses finalised	Percentage of new Good Manufacturing Practice and Good Warehouse Practice related licenses finalised within 125 working days	42% new GMP- and GWP-related licences finalised within 125 working days Out of 64 new GMP- and GWP-related licence applications received, 31 (48%) were finalised. Out of the 31 finalised, 13 (42%) were finalised within 125 working days	22% new GMP and GWP related licenses finalised within 125 working days Out of 73 applications received, 54 (74%) were due for finalisation Out of 54 due for finalisation, 39 (51%) were finalised, of which 12 (22%) were finalised within 125 workings days	70% new Good Manufacturing Practice and Good Warehouse Practice related licenses finalised within 125 working days	27% new Good Manufacturing Practice and Good Warehouse Practice related licenses finalised within 125 working days. Out of 76 applications received, 60 (79%) were due for finalisation. Out of 60 due for finalisation, 20 (33%) were finalised, of which 16 (27%) were finalised within 125 workings days	-43% new Good Manufacturing Practice and Good Warehouse Practice related licenses were not finalised within 125 working days	Resource constraints in the Inspectorate. Applicants not ready for inspection by inspection readiness date or by inspectorate planned date.
	Permits finalised	Percentage of permits finalised within 20 working days	71% permits finalised within 20 working days Out of 4 553 permit applications received, 4 474 (98%) were finalised. Out of the 4 474 finalised, 3 189 (71%) were 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 3 406 (79%) were finalised within 20 working days	80% permits finalised within 20 working days	94% permits finalised within 20 working days. Out of 4448 applications received, 4276 (96%) were finalised, out of which 4171 (94%) were finalised within 20 working days.	14% Overachievement	Improved adherence to business processes

PROGRAMME 3: INSPECTORATE AND REGULATORY COMPLIANCE								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
	Regulatory compliance investigation reports	Percentage of regulatory compliance investigation reports produced within 30 working days	72% health product quality complaints reports produced within 30 working days Out of 130 health product quality complaints received, 93 (72%) reports were produced within 30 working days	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	80% regulatory compliance investigation reports produced within 30 working days	72% Regulatory compliance investigation reports produced within 30 working days. Out of 438 complaints received, 400 (100%) reports were produced, of which 310 (72%) were produced within 30 working days.	-8% regulatory compliance investigation reports were not produced within 30 working days	Delays in stakeholder contributions required to investigate complaints.

3.3.2 Linking performance with budgets:

	2023/2024			2022/2023		
Programme/activity/ objective	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	53 154	49 232	3 921	37 314	42 399	(5 085)
Total	53 154	49 232	3 921	37 314	42 399	(5 085)

3.3.3 Strategy to overcome areas of underperformance

To improve the operations at ports of entry, measures have been put in place and the appointment of personnel, to be stationed at major ports of entry, has been prioritised. To ensure improved coordination at ports of entry, SAHPRA has been engaging with relevant stakeholders such as the South African Revenue Services (SARS) and the NDoH (Port Health). Furthermore, capacitating the organisation with the right skills is significant in achieving the objectives of the Authority. The implementation of the RIMS will continue together with the technology consultancy projects; in a nutshell, the digitisation of the processes remains the priority of the organisation to ensure operational efficiencies.

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 legislative mandate in part 1a of the strategic plan.

Sub-programmes

Sub-Programme	Purpose
Clinical Evaluation	To evaluate the safety and efficacy of orthodox medicines.
Clinical Trials	To evaluate clinical trial applications of orthodox medicines, complementary medicines, and medical devices to ensure that 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 in order 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.

Outcomes

- Efficient and effective regulatory practices maintained (7)

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

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 unavailable or does not meet the identified medical needs of the patient. The Medicines Act, therefore, allows access to health products not registered in South Africa but available in other markets. This is a significant public health intervention to ensure prompt access to life-saving health products if these are not otherwise available to prevent disease complications. Ninety-six percent of applications for selling unregistered Category A (human) medicines were finalised within three working days. This is a result of consistent swift reviews of unregistered medicines enabled by an efficient in-house regulatory review team, including the section manager, who continued to contribute to SAHPRA's revenue-generation from the private sector. Section 21 applications as well as improved website information so that it is user-friendly and accessible.

Human Clinical Trials

To ensure Good Clinical Practices in 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. Most trials received were in pulmonology, followed by oncology, and similar distributions in the following therapeutic areas: infectious diseases, including tuberculosis and Human Immunodeficiency Virus, and cardiology. The number of COVID-19-related clinical trials has tapered off significantly since April 2023.

Health Product Safety Signals

Medicines are not without risk. To this end, SAHPRA is mandated by the Medicines Act to monitor and evaluate the safety, efficacy, and quality of health products distributed and sold in South Africa. Such monitoring is comprehensive and responsive. Any signals of safety concerns and/or lack of clinical efficacy are evaluated promptly based on available evidence. Considerable effort is made to respond to safety signals despite inadequate resources. As a result of constrained resources, serious signals and those of high public health impact are prioritised and concluded. However, the set target of 70% in the 40 working days timeframe was not reached. Only 44% of the safety concerns received were finalised within 40 working days.

For the Authority to be aware of the safety issues, there is a need for healthcare professionals and consumers to report adverse events following the use of a medicine. SAHPRA has therefore developed, finalised and printed a pharmacovigilance training manual on three basic pharmacovigilance modules as it continues to intensify safety awareness and training healthcare professionals on these modules:

- the importance of pharmacovigilance
- recognising ADRs in clinical practice and
- learning how to report.

The training manual covering the above modules was finalised and printed during the year under the review, which will be made available to HCPs trained in the above.

PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	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	57% applications for the sale of unregistered Category A (human) medicines finalised within 24 working hours Out of the 16 435 applications received, 14 780 (90%) were finalised, of which 9 385 (57%) were finalised 24 working hours	87% of applications finalised within 3 working days. Out of 169409 received and responded to, 15 918 were finalised with 14 784 (87%) applications finalised within 3 working days	90% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	96% applications for the sale of unregistered Category A (human) medicines finalised within 3 working days: Number of applications received: 18 083 Number of applications responded to: 18 083 (efficiency indicator) Number of applications finalised: 18 055 Number of applications finalised within 3 working days: 17 404 Actual: 17 404 /18083 *100% = 96%	+6 Overachievement	Efficient business processes and working late hours.

PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
	Human clinical trial applications finalised	Percentage of human clinical trial applications finalised within 60 working days	95% human clinical trial applications finalised within 90 working days Out of 274 human clinical trial applications received, 246 (91%) were finalised Out of the 246 finalised, 235 (95%) were finalised within 90 working days	104% human clinical trial applications finalised within 90 working days Out of 239 applications received, 163 (68%) were due for finalisation Out of 163 due for finalisation, 184 (113%) were finalised, of which 169 (104%) were finalised within 90 workings days	80% human clinical trial applications finalised within 60 working days	91% human clinical trial applications finalised within 60 working days Out of 249 applications received, 207 (83%) were due for finalisation Out of 207 due for finalisation, 216 (109%) were finalised, of which 189 (91%) were finalised within 60 working days	+11% Overachievement	Due to reviewed Business process that have shown efficiencies
	Health product safety signals issued	Percentage of reports on health product safety signals issued within 40 working days	28% reports on health product safety signals issued within 40 working days Out of the 235 applications received, 95 (40%) reports were issued, of which 65 (28%) were issued within 40 working days	Out of 298 signals received, 251 (84.2%) signals were due for finalisation. Out of 251 signals due for finalisation, 169 (67.3%) reports were issued, of which 101 (40.2%) were issued within 40 working days	70% reports on health product safety signals issued within 40 working days	Out of 456 signals received, 445 (97.81%) were due for finalisation by end March 2024 Out of 446 due for finalisation, 343 (76.91 %) reports were issued, of which 196 (43.95%) were issued within 40 workings days.	-26.05% (116) reports on health product safety signals were not issued within 40 working days	Short-staffed & Paucity of reviewers in the unit

PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
	Number of safety awareness campaigns held	Number of safety awareness campaigns held	13 safety awareness webinars held	Six safety webinars on medication errors was held in 2023)	6 safety awareness campaigns held	12 safety awareness activities held: 1. 14-15 KZN (virtual) - April 2023 2. Limpopo (Face-to-face) - 2 May 2023 3. EC Province – 3 to 7 July 2023 4 Gauteng Province – 17 Aug 2023 5. SANAC Training 6. Charlotte Maqheke Hospital – 29 Sep 2023. 7. Tshwane District Hospital – 24/25-01-2024 8. Ekurhuleni – 04/03/2024 9. SAPHEX Exhibition – 13/14-03-2024 10. CMJAH – 22/03/2024 11. Video for accessing safety information on SAHPRA website for HCPs – 05 & 19/03/2024 (6 languages)	6 more safety awareness campaigns were held.	Increased demand for training as we consolidate a National PV framework with SAHPRA at the centre.

PROGRAMME 4: CLINICAL AND PHARMACEUTICAL EVALUATION								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
						12. Videos for HCPs on how to report suspected ADRs & AEFIs – 05 & 19/03/2024 (6 languages)		
	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 for finalisation, 192 (105.50%) were finalised – including 20 that were not due for finalisation, of which 147/192 (76.5%) were finalised within 30 working days. Although it appears that 147 were finalised on time, only 127 (70%) were finalised within 30 working days (note 20 were not due for finalisation). Hence, 147/182*100 = 80.78% rounded off to 81% is reported as performance.	95% lot release requests finalised within 50 working days	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 (102.94%) were finalised within 50 working days. Although it appears that 175 were finalised on time, only 151 (89%) were finalised within 50 working days (note that 24 were not due for finalisation). Hence, Hence, 175/170*100 = 102.94% rounded off to 103% is reported as performance for financial year 2023/24.		

3.4.3 Linking performance with budgets:

	2023/2024			2022/2023		
	R'000	R'000	R'000	R'000	R'000	R'000
Programme 4	125 618	119 413	6 204	109 293	109 931	(638)
Total	125 618	119 413	6 204	109 293	109 931	(638)

Strategy to overcome areas of underperformance

The use of external regional reviewers for Quality and RE reviews to increase turnaround timelines and aid in reduced lag times in a location with more reviewers' presence. The implementation of the overtime to add value in more applications is to be finalised. Furthermore, capacitating the organisation with the right skills is significant in achieving the objectives of the Authority. The implementation of RMS will continue together with the technology consultancy projects, in a nutshell, the digitalisation of the processes remains the priority of the organisation to ensure operational efficiencies.

3.5 Programme 5: Medical Devices and Radiation Control

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

Sub-programmes

Sub-Programme	Purpose
Medical Devices	To implement and strengthen the regulatory oversight of medical devices through the development and maintenance of relevant regulations and guidelines.
Radiation Control	To efficiently, effectively and ethically evaluate 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

- Efficient and effective regulatory practices maintained (7)

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

Medical Devices

The 2023/2024 financial year proved to be the most challenging year for South Africa in terms of allocation and utilisation of much-needed funds. SAHPRA, as a Schedule 3A public entity, faced similar challenges and had to cut down expenses, which affected a number of strategic and operational functions, such as training, the appointment and/or replacement of team members such as the Technical Officer, Licensing and Vigilance, while upholding the promise of increasing access to medical devices and IVDs that meet the requisite standards of safety, efficacy and quality, to protect the health and well-being of South Africans, through the achievement of the APP targets. The results of the year under the review certainly highlighted all the efforts that the executive and management had committed during the 2022/2023 and 2023/2024 financial years to strengthening the business processes, yielded exceptional outcomes and saw the unit achieve over and above the expected results. These efforts continued to avert the creation of a new backlog and, in turn, guaranteed increased collection of licence fees.

Radiation Control

The Radiation Control Subprogramme continues to improve its turnaround times on processing applications to achieve its annual performance plan targets. For the financial year 2023/2024, the team finalised 100% of applications for fixed electronic products and 70% of applications of radioactive substances. The target of 80% of fixed electronic product applications to be finalised within 30 working days was exceeded by 20%. The target of 80% of radioactive applications for authorities was exceeded by 20%. The subprogramme continued to monitor, enforce, and improve compliance by completing applications of X-ray licences and performing inspections. For this financial year, the subprogramme completed over 500 X-ray applications and performed more than 500 inspections covering radiotherapy units, nuclear medicine units, industrial radiography units, nuclear medicine units, mines, and veterinary units.

The continued improvement of the quality management systems (QMS) has helped the team finalise standard operating procedures (SOP) and guidelines. The subprogramme successfully completed 16 SOPs, migrated 33 guidelines to the new templates and published two new guidelines. The subprogramme participated in the QMS audit for the financial year 2023/2024 and received eight audit findings. The teams have completed and submitted all eight corrective actions requests forms and continue to work with the risk QMS team for finalisation.

The subprogramme has also continued to improve awareness and compliance by engaging with various stakeholders. For the financial year 2023/2024, the team has engaged with these stakeholders: International Atomic Energy Agency (IAEA), South African National Accreditation System (SANAS), National Nuclear Regulator (NNR), Department of Mineral Resources and Energy (DMRE), National Regulator for Compulsory Specifications (NRCS), provincial departments of health in Limpopo, Mpumalanga, and the North West. The Medical Devices and Radiation Control team had stakeholder engagements with The Office of Radiation Safety and Oak Ridge National Laboratory where they held a workshop on the development of a guidance for reducing doses for the implementation of Category 3 and 4 sources.

While the subprogramme generally continued to function in many areas, there has been a challenge of open vacancies where personnel have either resigned or retired. For this financial year, there are five open vacancies: Assistant Manager in Inspectorate based in Durban, Administration Screener for the Inspectorate subunit based in Durban, Inspectorate Assistant Manager based in Pretoria, Radiation Scientist for Non-Ionising radiation and medical devices (NIR/MED), Radiation Scientist for Radionuclides and Deputy Manager for Radionuclides and Radiation Control manager. The team has successfully managed to close the Inspectorate Assistance Manager post(Durban) and conducted interviews for the Inspectorate Administration Screener (Durban). For the Inspectorate Assistant Manager, the date for shortlisting is set. For NIR/MED (Non-Ionising Radiation Devices), Radiation Scientist, the shortlisting is also set; for Radiation Scientist in Radionuclides, interviews have been conducted; for Deputy Manager in Radionuclides, interview dates has been set and Radiation Control Manager post will be re-advertised. The challenges for the programme (both Radiation Control and Medical Devices) has been delays in filling of open positions and also turnaround of new people to execute the operational activities.

PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
Efficient and effective regulatory practices maintained (7)	Medical device establishment license applications finalised	Percentage of medical device establishment license applications finalised within 90 working days	76% medical device establishment licence applications finalised within 90 days Out of 1 105 medical device establishment licence applications received, 804 (73%) were finalised. Out of the 804 finalised, 613 (76%) were finalised within 90 working days	136% medical device establishment licence applications finalised within 90 working days 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	70% medical device establishment license applications finalised within 90 working days	126,6% medical device establishment licence applications 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.	56,6% Overachievement	Well established business processes resulted in the efficient processing of the license applications. Applications not due for finalisation were finalised earlier than anticipated.

PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
	Medical device registration regulations implemented	Notice of medical device products published	19 guidelines to support the medical device registration regulations were drafted	Guidelines have been placed on hold until the regulations are finalised from NDOH	Call-up notice of pilot Class D (high-risk) medical device products published	Expression of interest for Medical device voluntary registration feasibility study approved and published on social media platforms for gaining engagement towards implementation. The upcoming Feasibility study must first be conducted prior embarking on Call-up Notice of pilot Class D update being published.	Call-up notice of pilot Class D (high-risk) medical device products was not Published in the Government Gazette	Call-up notice of pilot Class D (high-risk) medical device products was later changed to Feasibility study, hence it could not be published in the Government Gazette.
	Radionuclide authorities (licenses) finalised	Percentage of applications for radionuclide authorities (licenses) finalised within 30 working days	72% applications for radionuclide authorities finalised within 30 working days Out of 4 740 applications for radionuclide authorities received, 3 803 (80%) were finalised. Out of the 3 803 finalised, 2 747 (72%) were finalised within 30 working day	83% applications for radionuclide authorities were finalised within 30 working days Out of the 2742 applications received 2360(86%) were due for finalisation Out of 2360 due for finalisation 2354(100%) were finalised of which 1956(83%) were finalised within 30 working days.	60% applications for radionuclide authorities (licenses) finalised within 30 working days	78% application for authorities were finalised with in 30 working days 2486 application received. Of 2486 applicati n received, 2311 applications were due for completion before 31 March 2024. 846 applications that were due for completion were issued. 674(78%) of the issued authorities were issued within 30 working days	18% Overachievement	Well established business processes resulted in the efficient processing of the license applicati ns. Applications not due for finalisation were finalised earlier than anticipated.

PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
	License applications for listed-electronic products finalised	Percentage of license applications for listed-electronic products finalised within 30 working days	99% licence applications for listed-electronic products finalised within 30 working days Out of 944 licence applications for listed-electronic products received, 934 (99%) were finalised. Out of the 934 finalised, 924 (99%) were finalised within 30 working days	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	90% license applications for listed-electronic products finalised within 30 working days	116% applications for listed-electronic products finalised 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.	26% Overachievement	Well established business processes resulted in the efficient processing of the license applications. Applications not due for finalisation were finalised earlier than anticipated.

PROGRAMME 5: MEDICAL DEVICES AND RADIATION CONTROL								
Outcome	Output	Output Indicator	Audited Actual Performance 2021/2022	Audited Actual Performance 2022/2023	Planned Annual Target 2023/2024	**Actual Achievement 2023/2024	Deviation from planned target to Actual Achievement 2023/2024	Reasons for deviations
	Guidelines produced	Number of approved guidelines for the management of medical device vigilance	-	-	3 approved guidelines for the management of medical device vigilance	Three (3) Medical Device vigilance guidelines - Public comments (closed on the 28th April) received and to be collated	Three (3) Medical Device vigilance guidelines not published for implementation	Delay in publishing the guidelines on time led to delay in finalising the guidelines to be shared with EXCO for approval. Resignation of 1 dedicated technical person for AE's resigned in December 2023. There is no dedicated person to focus on collating the information.

3.5.2 Linking performance with budgets:

	2023/2024			2022/2023		
Programme/activity/ objective	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	44 848	35 408	9 441	32 399	33 144	(745)
Total	44 848	35 408	9 441	32 399	33 144	(745)

3.5.3 Strategy to overcome areas of underperformance

Finalisation of the three vigilance guidelines, Licensing, Vigilance, and Compliance Manager to manage induction and operational training of the candidate. Furthermore, capacitating the organisation with the right skills is significant in achieving the objectives of the Authority. The implementation of the Regulatory Information Management Systems (RIMS) will continue together with the Technology Consultancy projects. In a nutshell, the digitation of the processes remains the priority of the organisation to ensure operational efficiencies.

4. REVENUE COLLECTION

	2023/2024			2022/2023		
Sources of revenue	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	212 672	228 078	(15 406)	170 037	197 351	(27 314)
Total	212 672	228 078	(15 406)	170 037	197 351	(27 314)

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

5. CAPITAL INVESTMENT

SAHPRA is a public entity under the Public Finance Management Act (PFMA, 1999, as amended) Schedule 3A under NDoH. It manages its assets in accordance with its Asset Management Policy. During this financial year under review, SAHPRA did not embark on any infrastructure projects, and did not close down or dismantle any facilities during the year.

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

A significant portion of SAHPRA's assets for the 2023/24 financial year comprises newly acquired assets. These acquisitions amounted to R13 million as at 31 March 2024. The new material acquisitions were motor vehicles (R2 million) and intangible assets (R8.6 million). The disposals for the year comprised old furniture and computer equipment that were no longer in use or had been replaced, which were either sold or donated. A significant portion of these assets was fully depreciated.

	2023/2024			2022/2023		
Infrastructure projects	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						
Total						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PART C
GOVERNANCE

1. INTRODUCTION

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

Parliament, 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 the service delivery performance of the public entities reporting to the NDoH.

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

Date	Parliamentary Structure	Activity/ Focus
19/04/2023	Portfolio Committee on Health	Presentation of the Strategic Plan, Annual Performance Plan (APP) and Budget 2023/2024 Financial Year
10/10/2023	Portfolio Committee on Health	Presentation of the Annual Financial Statements and Annual Report 2022/2023
19/03/2024	Portfolio Committee on Health	Presentation of the Strategic Plan, Annual Performance Plan and Budget 2024/2025 Financial Year

3. EXECUTIVE AUTHORITY

The Minister of Health is the Executive Authority. The Regulator 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 Minister of Health appoints the Board 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 ongoing development of best practices.

Independence of the Board

The Minister of Health appoints Board members. The Board considers management submissions and recommendations and makes independent decisions based on their fiduciary responsibilities and the Authority's strategic direction.

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

The Audit, Risk, and Governance Committee (RAG) regularly meets individually with representatives from 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 Board's discretion.

5. Board Charter

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

6. Board Composition

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

Regarding 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:

Name	Designation *(in terms of the Public Entity Board structure)*	Date appointed	Date resigned	Qualifications	Area of Expertise	Board Directorships (List the entities)	Other Committees or Task Teams (e.g: Audit committee / Ministerial task team)	No. of Meetings attended
Prof. Helen Rees	Chairperson	October 2021		Harvard Business School Senior Executive Programme Member of the Royal College of General Practitioners Doctor Instructor for Family Planning Diploma of Child Health Diploma of the Royal College of Obstetricians and Gynaecologists UK M.A Social and Political Sciences MB BChir	Clinical trials	N/A	N/A	26
Dr Obakeng Khaole	Vice -Chair	October 2021	N/A	MBChB Bachelor of Surgery Diploma in HIV Management Postgraduate in Occupational Medicine	Medical research and clinical trials	N/A	HR&Remco	25

Name	Designation *(in terms of the Public Entity Board structure)*	Date appointed	Date resigned	Qualifications	Area of Expertise	Board Directorships (List the entities)	Other Committees or Task Teams (e.g: Audit committee / Ministerial task team)	No. of Meetings attended
Mr Norman Baloyi	Member	October 2021	14/11/2023	Master of Science in Electronics (Information Security; Computer Networks) Master of Science in Electrical Engineering (Telecommunication) BSc Honours in Computational and Applied Mathematics; Higher Diploma in Computer Auditing; Bachelor of Science (BSc) in Computer Science and Information Systems; BSc. Mathematics and Computational & Applied Mathematics; Diploma in Network Security; Diploma in Datametrics (Computer Science Certified Information Systems Auditor Certified Information Systems Security Professional Certified Information Security Manager	Information technology	N/A	Finance HRRemco RAG	14
Ms. Lerato Mothae	Member	October 2021	N/A	Bachelor of Accounting CTA (B.Compt Honours CA (SA)	Finance and accounting	N/A	RAG Finance	23

Name	Designation (in terms of the Public Entity Board structure)	Date appointed	Date resigned	Qualifications	Area of Expertise	Board Directorships (List the entities)	Other Committees or Task Teams (e.g: Audit committee / Ministerial task team)	No. of Meetings attended
Mr. Itani Mashau	Member	October 2021	N/A	BPharm Diploma in Production Diploma in Q Management and Q Assurance Master of Business Administration Diploma in Small Business Management	Good Manufacturing Practice	N/A	TORS HRRemco	26
Prof. Patrick Demana	Member	October 2021	N/A	PhD in Pharmaceutics BSc (Hons) in Pharmacy MSc in Pharmaceutics Post-doctoral Fellowship in Drug Discovery A-level courses (chemistry, biology and mathematics & statistics)	Virologist	N/A	TORS	21
Adv. Hasina Cassim	Member	October 2021	N/A	BPharm LLB Certificate in Medicine Law Certificate in Pharmacoepidemiology Medical mediation training	Law	N/A	RAG TORS	23
Ms Mandisa Sikhosana	Member	October 2021	N/A	National Diploma in Biomedical Technology BTech Degree in Biomedical Technology MA in Medical Science	Laboratory medicine, quality control and clinical research	N/A	TORS	24
Prof.Joyce Tlaka-Gwegweni	Member	October 2021	N/A	BA Hons (Social Science Psychology) BSc Hons-Zoology & Microbiology PhD in Public Health MPH in Public Health	Public health medicine	N/A	TORS	14

Name	Designation (in terms of the Public Entity Board structure)	Date appointed	Date resigned	Qualifications	Area of Expertise	Board Directorships (List the entities)	Other Committees or Task Teams (e.g: Audit committee / Ministerial task team)	No. of Meetings attended
Dr Xolani Ngobese	Member	October 2021	N/A	PhD in Business Administration Master in Business Administration	Independent consultant	N/A	HRRemco RAG Finance	21
Ms Lucy Dhaba Maraka	Member	October 2021	N/A	Bachelor of Art Bachelor of Education Baccalaureus Adium Honores Diploma in HR Training and Development Ethics Officer Certification Psychometrist Effective Audit Committees Effective Remuneration Committees Social & Ethics Committees	Independent psychometrist	N/A	HRRemco	21
Dr Alfred Kgasi	Member	December 2021	N/A	Bachelor of Veterinary Medicine LLB Master of Business Leadership	Veterinary	N/A	TORS RAG	26
Dr Zinhle Makatini	Member	December 2021	N/A	BSc (Honors) Biochemistry Masters in Immunology of Infectious Diseases MBChB PhD Virology Registrar in Virology Diploma in Travel Medicine Diploma in Tropical Medicine Diploma in HIV Management in the Workplace Diploma in HIV Management MMED in Biostatstos & Epidemiology (completed2/3) PhD in Medical Virology	Virology	N/A	TORS	22

Name	Designation *(in terms of the Public Entity Board structure)*	Date appointed	Date resigned	Qualifications	Area of Expertise	Board Directorships (List the entities)	Other Committees or Task Teams (e.g: Audit committee / Ministerial task team)	No. of Meetings attended
Prof. Yahya Choonara	Member	December 2021	N/A	BPharm MPharm PhD	Medical devices	N/A	TORS	13
Prof. Johanna Meyer	Member	December 2021	N/A	BPharm MSc (Med.) PhD in Pharmacy	Pharmacovigilance Public Health	N/A	TORS	24

Changes in Board Membership

The Minister of Health withdrew the appointment of Mr Norman Baloyi from the Board with effect from 14 November 2023 in line with Section 2F(2) of the Medicines and Related Substances Act. The table below indicates changes in Board membership that took place during the financial year under review:

Name	Area of expertise	Date of appointment/ * reappointment	Date of resignation/ * retirement
Mr Norman Baloyi	Information Technology	October 2021	14 November 2023

Committees of the Board

The Board, as the Accounting Authority, takes full ownership of the overall decision-making across the entity to ensure that it retains the proper direction and control of SAHPRA.

The Board has delegated certain powers to the Chief Executive Officer and management but has reserved certain exclusive powers, which are set out in the Board Charter.

The Board has also appointed committees to help it meet these responsibilities. The Board has delegated various functions and authorities to the committees and management. However, this does not absolve the Board and its members of their duties and responsibilities.

The Board has delegated certain functions without abdicating its responsibilities to the following committees:

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

These Committees of the Board have formal terms of reference embodied in their Charters, which further define their mandates, roles, and responsibilities. The Charters are reviewed and updated annually.

Committee	No. of meetings held	No. of members	Name of members
Finance	7	4	Ms Lerato Mothae Mr Norman Baloyi Dr Xolani Ngobese Mr Rajesh Mahabeer

Committee	No. of meetings held	No. of members	Name of members
Technical Oversight and Regulation	4	9	Mr Mashau Elias Ithani Ms Mandisa Sikhosana Adv. Hasina Cassim Dr Kgesi Alfred Dr Zinhle Makatini Prof. Yahya Choonara Prof. Patrick Demana Prof. Joyce Tsoka-Gwegweni Prof. Johanna Meyer
Risk Audit and Governance	7	8	Ms Lerato Mothae Mr Bruce Gordon Adv. Hasina Cassim Mr Norman Baloyi Dr Xolani Ngobese Mr Rajesh Mahabeer Dr Kgesi Alfred Ms Adila Chowan
Human Resources and Remuneration	17	5	Ms Dibabe Maraka Mr Mashau Elias Ithani Mr Norman Baloyi Dr Obakeng Khaole Dr Xolani Ngobese

Remuneration of Board members

The Board has approved a Board Remuneration Policy that guides how Board members are remunerated. Board members who are employed by the state are not eligible to claim attendance and preparation fees. Members are reimbursed for out-of-pocket expenses incurred whilst furthering SAHPRA's interests. The summary of remuneration and Board emoluments is outlined in the table below:

Name	Remuneration	Other allowance	Other reimbursements	Total
Prof. Helen Vera Rees	R147 427			R147 427
Adv. Hasina Cassim	R167 389			R167 389
Mr Tinyiko Norman Baloyi – vacated November 2020	R27 876			R27 876
Mr Elias Ithani Mashau	R181 376			R181 376
Prof. Hullsani F Demana	R79 109			R79 109
Lerato Mothae	R207 814			R207 814
Dr Obakeng Khaole	R175 133			R175 133
Prof. Joyce Tsoka-Gwegweni	R100 760			R100 760
Dr Xolani Ngobese	R245 584			R245 584
Ms Dibabe Maraka	R125 118			R125 118
Prof. Yahya Choonara	R44 509			R44 509

Name	Remuneration	Other allowance	Other reimbursements	Total
Prof. Johanna Meyer	R87 409			R87 409
Ms Musetsa Sithebane	R125 858			R125 858
Dr Alfred Ngobe	R183 142			R183 142
Dr Zhakhu Manudu	R0			R0

7. RISK MANAGEMENT

- The Board approved the SAHPRA Risk Management Policy and Framework to ensure implementation and embedment of risk management within the Authority. The Enterprise Risk Management (ERM) Policy and Framework guide the identification and management of all risks faced by SAHPRA in achieving its objectives.
- Risk assessments are conducted annually and reviewed quarterly across the Authority at their respective levels, i.e., strategic and operational. Risk assessments are not limited to being conducted annually; as and when the need arises or a significant change happens, risks will be reviewed, updated and communicated to the relevant governance structures. Risk assessments are conducted through workshops, meetings, and reports to manage current risks and identify new and emerging risks.
- The Board established a Risk, Audit and Governance (RAG) committee, which is an independent committee responsible for overseeing SAHPRA's control, governance, and risk management. RAG appraises the Board on a quarterly basis on risk and internal control measures.
- RAG monitors the risk system's effectiveness through reviewing the quarterly reports submitted by management on risk management activities and the actual risk performance. RAG guides management in the effort to improve the risk management system of the Authority.
- SAHPRA continuously monitors its risks to ensure the achievement of its objectives and the effectiveness of those objectives. Operations have improved in that processes are now streamlined, resulting in increased efficiencies and favourable outcomes.

8. INTERNAL CONTROL UNIT

- Management, as the first line of defence, continuously monitors and implements internal controls within their operations to ensure an adequate and effective internal control environment. These include the development of policies and procedures in line with QMS.
- The support functions, as the second line of defence, assist in evaluating the controls implemented by management. The third line is an internal and external audit, which provides independent assurance on the control.
- SAHPRA is still envisaging a streamlined process of combined assurance to ensure alignment and a reduction in the duplication of efforts.

9. INTERNAL AUDIT AND AUDIT COMMITTEES

- SAHPRA has an Internal Audit function that provides independent assurance to management and the RAG Committee on the adequacy and effectiveness of the organisation's internal control environment.
- The internal audit function implements a three-year rolling plan approved by RAG annually, which lists all audit assignments to be conducted.
- The internal audit function conducted audits related to financial, ICT, performance information, specific programme operations as well as special assignments and investigations requested by management and the RAG.
- RAG reviews the independence and effectiveness of the internal audit function through the reports submitted quarterly on the work done and holds management accountable for the implementation of recommendations proposed to improve the internal

control system within SAHPRA. Some of the RAG activities include but are not limited to:

- establishing the Internal Audit Charter to guide the internal audit approach;
- reviewing SAHPRAs risk areas to be covered in the annual scope of work for internal audit and coordinate internal and external auditors work;
- reviewing activities of internal audit, risk management and other corporate governance related functions;
- reviewing the reports of investigations and the responses of management to specific recommendations and
- reviewing the effectiveness and evaluate the performance of internal audit.

10. INTERNAL AUDIT AND AUDIT COMMITTEES

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

Name	Qualifications	Internal or external	If internal, position in the public entity	Date appointed	Date Resigned	No. of Meetings attended
Ms Lerato Mothae	Bachelor of Accounting CTA (B.Compt Honours CA (SA)	Internal	Board Member	October 2021	N/A	7
Dr Kgasi Alfred	Bachelor of Veterinary Medicine LLB Master of Business Leadership	Internal	Board Member	December 2021	N/A	6
Ms Adlie Chowan	CA(SA) Bachelor of Accountancy Post Graduate Diploma in Accounting (CTA) LLB (Cum Laude)	External	N/A	31 May 2023	N/A	4
Dr Xolani Ngobese	PhD in Business Administration Master of Business Administration	Internal	Board Member	October 2021	N/A	7
Mr Bruce Gordon	B.Compt (Hons) CA	External	N/A	01 April 2023	N/A	3
Adv. Hasina Cassim	BPharm LLB Certificate in Medicine Law Certificate in Pharmacoepidemiology Medical mediation training	Internal	Board Member	October 2021	N/A	7

Name	Qualifications	Internal or external	If internal, position in the public entity	Date appointed	Date Resigned	No. of Meetings attended
Mr Norman Baloyi	Master of Science in Electronics (Information Security; Computer Networks) Master of Science in Electrical Engineering (Telecommunication) BSc Honours in Computational and Applied Mathematics; Higher Diploma in Computer Auditing; Bachelor of Science (B.Sc.) in Computer Science and Information Systems; B.Sc. Mathematics and Computational & Applied Mathematics; Diploma in Network Security Diploma in Datametrics (Computer Science Certified Information Systems Auditor Certified Information Systems Security Professional Certified Information Security Manager	Internal	Board Member	October 2021	14 November 2023	3
Mr Rajesh Mahabeer	CA(SA) FCMA CGMA FCCA FCA BFP CIA FIISA SARIPA INSOL MBA MCom PGDA NDip (COST) ACC PhD (Candidate)	External	N/A	16 May 2023	N/A	6

11. COMPLIANCE WITH LAWS AND REGULATIONS

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 non-compliance is identified, corrective actions are developed. The Office of the Board Secretary monitors compliance with legislation and regulations.

12. FRAUD AND CORRUPTION

- SAHPRA has an approved Fraud Prevention Policy aimed at setting the tone for the Authority regarding fraud and corruption. The Fraud Prevention Strategy and plan are aimed at guiding the implementation of fraud prevention activities within SAHPRA. There has been extensive progress on the implementation of the plan, in that the majority of activities have been established and embedded into the operations of the Authority, and continuous monitoring has been effected.
- SAHPRA has a hotline and a whistleblowing hotline and has been active over the past two years. The hotline has been effective in reporting cash thefts and industry fraud and corruption affecting SAHPRA's operations. Although SAHPRA has other dedicated reporting mechanisms for product issues, the hotline has been instrumental in reporting these.
- Management encourages staff to report fraud and corruption through the facilitation of awareness sessions and guides them on other mechanisms available for reporting other issues. Staff is encouraged to use the correct platform to report to ensure timely responses and adequate tracking of the reported matters, especially since there is an opportunity to remain anonymous.
- SAHPRA will continue to investigate all reported cases to reduce fraud and corruption by sanctioning those accountable. All reported cases and their outcomes are reported to the RAC for their assessment on a quarterly basis.

13. MINIMISING CONFLICT OF INTEREST

The Board has approved a Management of Conflict of Interest Policy which is reviewed annually. There are procedures 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 an annual basis. At every Board and Committee meeting, members are required to sign or declare their declaration of interest forms, and these are captured as standing agenda items for each meeting. This approach is also 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 committee member is excused from participating in the discussion.

14. CODE OF CONDUCT

SAHPRA is committed to an exemplary standard of business ethics and transparency in all its dealings with stakeholders. The Code of Conduct binds Board members and employees. Receipt of gifts, sponsorships, hospitalities and favours are managed through the Gifts Declaration Policy. SAHPRA condemns, in the strongest terms, any act of corruption, bribery and dishonesty. Disciplinary actions are applied consistently to any employee who is found to be involved in any act of corruption and/or related misconduct.

15. HEALTH SAFETY AND ENVIRONMENTAL ISSUES

The Authority has a Safety, Health, Environment, Risk and Quality (SHERQ) Policy in place which is aimed at the provision of a positive health and safety working environment. The Authority continues to demonstrate commitment to the health and safety of its employees through its occupational health and safety structures. This is done by virtue of it creating a conducive environment for all staff members. Furthermore, the OHS Committee consisting of OHS representatives has been established to ensure that health and safety matters at SAHPRA are attended to.

16. BOARD SECRETARY

The SAHPRA Board appointed a Deputy Board Secretary and Board Secretary in July and October 2020, respectively. The Board Secretary plays a critical role in providing secretariat and advisory services to

the Board and its Committees. Moreover, 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 principles. The Board Secretary is the custodian of the register of Board and Committees decisions.

The Board Secretary guides 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 and advising the Board on ethical matters and good governance principles
- Recording of Board and committee proceedings

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

17. SOCIAL RESPONSIBILITY

SAHPRA had the opportunity to contribute to its Corporate Social Responsibility (CSR) by participating in two activities supported by dedicated and committed staff members. Firstly, in honour of Nelson Mandela Day, the organisation's staff members volunteered their time at Leamogetsane Safety Home in Atteridgeville on 18 July 2023. The SAHPRA team spent quality time playing games, conducting fun workshops and fostering positive interactions with the young children of the home. In addition to their time spent with the children, the team also contributed to the home by delivering essential food parcels and toiletries. This initiative was part of SAHPRA's commitment to positively impacting the lives of the less fortunate and underserved communities. Secondly, on 11 October 2023, the entity partnered with humanitarian organisation Gift of the Givers to distribute food hampers to flood victims in the Western Cape.

Nelson Mandela Day

18. AUDIT COMMITTEE REPORT

Risk, Audit and Governance (RAG) Committee Report

Introduction

The RAG Committee is pleased to present its report for the financial year ended 31 March 2024.

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

Composition

The Committee composition is outlined on the below table. The CEO is an ex officio member of the Committee. The Chief Operating Officer, Chief Financial Officer, Chief Regulatory Officer, Executive HR, Manager: Risk & Internal Audit, Manager: Strategic Business Planning, Monitoring and Evaluation and the Legal & Regulatory Advisor are standing invitees to the RAG meetings. Representatives of Nexia SAB&T (Internal Auditors) and the Auditor-General (AGSA) are also standing invitees to the RAG meetings.

Name	Qualifications	Board or External member	Date appointed	No. of Meetings attended
Ms Lerato Mothae	Bachelor of Accounting CTA (B.Compt Honours CA (SA)	Board Member	April 2023 to March 2024	7 out of 7
Adv Hasina Cassim	B Pharm LLB. Certificate in Medicine Law Certificate in pharmacoepidemiology Medical Mediation training	Board Member	April 2023 to March 2024	7 out of 7
Dr Kgasi Alfred	Bachelor of Veterinary Medicine LLB Master of Business Leadership	Board Member	April 2023 to March 2024	6 out of 7
Dr Xolani Ngobese	PhD in Business Administration Master's in Business Administration	Board Member	April 2023 to March 2024	7 out of 7
Mr Bruce Gordon	B Compt (Hons) (External Member) CA(SA)	External Member	April 2023 to March 2024	3 out of 7

Name	Qualifications	If internal, position in the public entity	Date appointed	No. of Meetings attended
Mr Norman Baloyi	Master of Science in Electronics (Information Security; Computer Networks) Master of Science in Electrical Engineering (Telecommunication) BSc Honours in Computational and Applied Mathematics; Higher Diploma in Computer Auditing; Bachelor of Science (B.Sc.) in Computer Science and Information Systems; BSc Mathematics and Computational & Applied Mathematics; Diploma in Network Security Diploma in Datametrics (Computer Science Certified Information Systems Auditor Certified Information Systems Security Professional Certified Information Security Manager	Board Member	April 2023 to November 2023	3 out of 7
Ms Adila Chowan	CA(SA) Bachelor of Accountancy Post Graduate Diploma in Accounting (CTA) LLB (Cum Laude)	External Member	31 May 2023 to March 2024	4 out of 7
Mr Rajesh Mahabeer	CA(SA) IFCMA CGMA FCCA FCA BFP CIA FIISA SARIPA INSOL MBA MCOM PGDA NDIP (COST) ACC PH.D. (CANDIDATE)	External Member	15 May 2023 to March 2024	6 out of 7

Audit Committee Responsibility

The Audit 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 3.1.10. The Committee also reports that it has adopted appropriate formal terms of reference as its RAG Committee Charter has regulated its affairs in compliance with this charter and has discharged all its responsibilities as contained therein, except that we have not reviewed changes in accounting policies and practices. These includes the requirements of the King IV 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 the SAHPRA's day-to-day management of its business;
- To facilitate and promote communication between the Board, Management, the External Auditors and Internal Auditors on matters which fall within the responsibilities of the Committee;
- To ensure the risk and compliance areas of SAHPRA operations are covered in the scope of Internal (Nexia SAB&T) and External (AGSA) audits;

- To ensure the accounting and auditing concerns identified from the Internal and AGSA audits conducted during the period under review are addressed.
- To ensure SAHPRA compliance with legal and regulatory provisions, the Medicines Act and the PFMA as well as the Treasury Regulations; and
- To ensure the independence and objectivity of the Internal and External Auditors.

Whistleblowing

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

External Auditors' Report

The Committee has noted the audit outcome as issued by the AGSA, with the resultant unqualified audit opinion for the third 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 the 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 Auditor General which are to be expressed in accordance with the mitigation action plans as agreed to between SAHPRA and the AGSA. The Committee reviewed the public entity's implementation plan for audit issues raised in the prior year and is satisfied that the 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 Control

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

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

- Reviewed Risk and Compliance Management Reports.
- Reviewed SCM and ICT reports.
- Reviewed the Audit Action Plans.
- Reviewed the quarterly legal reports.
- Reviewed the framework for establishing effectiveness of policies and procedures relevant to this Committee.
- Established a framework for determining the Authority's compliance with significant legal and regulatory provisions.
- Reviewed the controls over significant financial and operational risks.
- Tabled and discussed Internal Audit Reports at each meeting.
- Reviewed the annual report and financial statements to ensure that they present a balanced and understandable assessment of the position, performance, and prospects of the Authority. The key outcomes following the above assessment procedures include:
  - The Internal Financial controls and systems, although enhanced from the prior years, still have room for improvement.

Governance of Risk

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

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

Internal Audit

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

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

In-Year Management and Monthly/Quarterly Report

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

Evaluation of Financial Statements

The RAG 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 RAG Committee recommended the approval of the audited March 2024 annual financial statements and the audit opinion thereon at its meeting held on 26 July 2024 and these annual financial statements and audit opinion were duly approved by the Board on 30 July 2024 for inclusion in the March 2024 Annual Report.

Chairperson of the RAG

19. B-BBEE COMPLIANCE PERFORMANCE INFORMATION

The following table has been completed in compliance with the B-BBEE requirements of the B-BBEE 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 (include a discussion on your response and indicate what measures have been taken to comply)
Determining qualification criteria for the issuing of licenses, concessions or other authorisations in respect of economic activity in terms of any law?	Yes	Draft Policy for issuance of licenses as per section 22c of the medicines act developed and pending approval. Implementation planned for financial year 2024/25
Developing and implementing a preferential procurement policy?	Yes	Policy approved and applied
Determining qualification criteria for the sale of state-owned enterprises?	N/A	
Developing criteria for entering into partnerships with the private sector?	N/A	
Determining criteria for the awarding of incentives, grants and investment schemes in support of Broad Based Black Economic Empowerment?	N/A	

PART D
HUMAN RESOURCE MANAGEMENT

1. OVERVIEW OF HR MATTERS AT SAHPRA

The Human Resources function plays a fantastic role by providing business partnering to management (support) functions attracting, maintaining, developing, and retaining an effective workforce in the organisation.

Set HR priorities for the year under review and the impact of these priorities:

Human resource priorities for the year under review were to:

- Conduct an Employee Satisfaction Survey and implement the Action Plan to address recommendations from the survey report.
- Ensuring that 70% of employees are trained in develop the skills they need to perform their duties, advance their careers and keep abreast of continually changing business conditions.
- Ensuring that 95% of budgeted positions on the Recruitment Plan are filled to capacitate SAHPRA in achieving its mandate.
- Ensuring that the staff turnover rate is less than 10% or below, to retain competent and experienced employees.

Workforce planning framework and key strategies

In planning workforce supply and demand, assessing gaps and determining target talent management interventions that will ensure that SAHPRA has the right people with the right skills in the right quotas at the right time to fulfil its mandate. Approximately 46 positions were funded to be filled for 2023/24. The entity is also reviewing its fit-for-purpose functional structure that is aligned with strategic objectives and available budget for the compensation of employees. A service provider will be appointed to conduct job analyses, profiling, evaluations and graded. Once the project is completed, the appointed service provider to undertake salary benchmarking ensuring that salaries are in line with related to scales and retain competent and experienced employees.

Conducted the Employee Satisfactory Survey

During the year under review, SAHPRA commissioned Enterprises University of Pretoria to conduct an Employee Satisfaction Survey. The purpose of the survey was to:

- Assess the commitment of SAHPRA employees and the relationship team.
- To embrace and drive the ongoing strategic direction, assess the impact and effectiveness of the enterprise work processes and systems.
- Assessing mindsets in terms of how SAHPRA employees think, feel and their overall sense of belonging.
- Gather feedback and ideas from SAHPRA employees on continuous improvement; and
- To identify strategic drivers for change and potential barriers.

Colleagues participated in the Employee Satisfaction Survey from 18 – 28 September 2023. Although there were only 181 respondents, the survey had many in-depth questions that allowed staff members to share their many and varied opinions anonymously.

The overall insights of the survey showed:

- Purpose: One of the strengths is that staff members have a strong sense of purpose and direction within the organisation. They clearly understand the impact their work has on society and the contribution they make to the country and its people.
- Culture: One of the weakest points shown through the survey is that many staff members feel the culture as toxic, uncaring, confusing, bad, segregated, and dysfunctional. As a result, some perceived feelings of disparity, unhappiness, and disengagement, while some found it to be peaceful, supportive and good.
- Growth: The survey showed that staff members have a growth mindset. They find the work

challenging and rewarding. Nearly half feel that they are not challenged in work and develop.

- Fairness: In terms of fairness, a major concern for staff was around pay parity across grades and industry.
- Transparency: Some staff members indicated that there is not transparent communication.
- Communication: The survey showed a level of satisfaction and improvement regarding inter-team communication. Teamwork and support are also a positive in the work environment.
- Treatment of employees: There was a clear indication that bullying was an issue across all job levels. Employees shared that they are not treated with respect, and wellbeing is not prioritized. There is also a concern of burnout and undue work stress.

To improve satisfaction levels in the workplace, staff and management need to work together and incorporate all the SAHPRA six (6) values of ubuntu, responsiveness, integrity, transparency, efficiency and excellence (URTEEE) in all workplace activities to achieve the vision and the mission of the entity. An Action Plan was developed, and it will be shared with staff and implemented in the new financial year.

Implementation of Learning and Development Initiatives

SAHPRA has gone beyond compliance in implementing skills development initiatives, improving individual skills and areas of expertise to perform their jobs. A total of 331 employees were trained on various training interventions from April 2023 to March 2024. Most of the training was offered by various independent external industry stakeholders. Furthermore, 20 employees were provided with study assistance opportunities in enhance their knowledge and experience.

Prioritisation of budgeted positions filled

Across the entity, recruitment, selection, and retention difficulties persist. Forty-six (46) positions were funded to be filled for the 2023/24 financial year. Only 67.4% (31/46) of these positions were filled as of 31 March 2024. In this area, we have not done well in managing vacancies by filling positions within the turnaround times stipulated in the Recruitment Plan.

Delays in filling of the positions were caused by the non-availability of panel members for the selection process, completion of compulsory candidate pre-suitability checks (verification processes), readvertising of positions because no suitable candidates were found during the selection processes or offers were declined by suitable candidates and budget cuts implemented by National Treasury. Some positions were unfunded to remain within the allocated cost of employment (CoE) budget. This resulted in serious capacity constraints within the entity and placed additional pressure on the remaining employees carrying additional workloads.

In correcting the situation, business units will appoint dedicated selection committees possessing technical expertise to improve turnaround times in filling the positions and ensuring that appointed panel members are available. This will ensure that vacant positions are filled within six (6) months after becoming vacant. The HR Unit will be capacitated to deal with administrative and technical challenges related to recruitment and selection processes.

Employment Equity

SAHPRA has made considerable progress in ensuring that its employee profile is highly representative of the demographic profile of South Africa. In achieving EE targets as set in the EE Plan during the year (2023/24), 61% (19/31) of new appointments were women. The entity had the highest representation of Africans at 64% (258/399), followed by Indians at 8% (18/399), Whites at 6.5% (17/399) and Coloureds with just 4.5% (14/399).

The entity has exceeded the equitable target rate representation targets for Africans by 4% and Indians by 3%. The underrepresentation of Coloureds and Whites will be addressed in the new EE Plan for 2024/ 2027 (Medium Term Expenditure Framework (MTEF) period.

The overall female representation is at 60% and 52.6% of females occupy senior and executive positions.

Disability representativity is currently at 2% which has been maintained from the previous reporting year.

During the recruitment and selection processes, SAHPRA will attempt to pursue a 50/50 gender representation across all occupational levels even though it will be challenging because the health sector is a female-dominated sector (industry).

Retention of technical staff

Exit interviews offer a deeper look at your workplace culture, day-to-day processes, management solutions, and employee morale. These interviews were conducted to identify areas of improvement that can assist in establishing SAHPRA as an employer of choice and, where possible, reduce staff turnover.

With a staff turnover rate of 9.4%, SAHPRA intends to prioritise the development of a Retention and Succession Strategy that will contribute towards retaining critical skills. In the new financial year, posts descriptions will be reviewed to address salary disparities. HR policies are being reviewed, and a Remuneration Policy will be developed. The entity will continue to implement the Action Plan to address the issues that were raised from the Employee Satisfaction Survey.

Employee Performance Management Framework

SAHPRA has an approved Performance Management System (PMS) Policy for all employees, which requires that all employees enter into performance agreements yearly and within three months of appointment.

Mid-term reviews for 2023/24 were submitted in October 2023. Of 359 employees eligible to submit, only 217 submissions were received.

Annual performance assessments for 2022/23 were conducted, moderated, and concluded. Two hundred forty (240) employees who are eligible for performance incentives were paid. The results of employees in level 05 – 14 were communicated and paid in October 2023 and EXCO in December 2023, respectively.

Employee Wellness Programmes

The HR Unit hosted a well-attended Wellness Day on 28 November 2023 at Head Office while the Cape Town Office had their day on 12 December 2023. HR's drive to host this event was to allow staff members to apply some self-care in today's demanding work environment. Many staff members participated and engaged with the various service providers in attendance. The service providers that participated in the Wellness Day were:

- Old Mutual Financial Advisor X2
- Dental Therapist
- Dental Assistant
- Orthotist
- Audiologist
- Optometrist
- Optometrist Assistant
- Podiatrist
- AIDSA Sales Consultants X2
- Forever Spa - Massage therapists X2
- Physiotherapist
- Dietician
- Professional Nurse X2

Attendance was very good, especially with an increase in male participation. The service providers also commended the participation of SAHPRA employees, with the majority of them stating that they will avail themselves for future wellness events.

Some colleagues shared with HR that they were happy about the wellness event because of the various service providers that were available, and most of the colleagues consulted with more than two health professionals. In addition, regular health and wellness-related talk shows were also shared with staff.

Policy development

The entity is in the process of reviewing HR policies to ensure the policies are aligned to relevant prescripts as well as the best practice. The reviewing of policies will ensure that policy processes are implemented to prevent and detect non-compliance. The following reviewed/new policies were consulted with Organised Labour:

- Grievance Procedure
- Remuneration Policy
- Recruitment & Selection
- Performance Management System Policy
- Training & Development Policy
- Leave Management Policy
- Employee Health & Wellness Policy

In November 2023, Picketing Rules were agreed.

Non-compliance with Acts and Policies

On 08 August 2023, organised labour held an illegal protest. They went to the offices of the Chief Executive Officer (CEO) and Chief Finance Officer (CFO), while singing. Five (5) shop stewards were charged as they were involved in the illegal protest. A meeting was held with the CEO and the chief negotiator of the Public Service Association (PSA). PSA acknowledged that it was an illegal protest that was conducted and that it would never happen again. CEO requested that charges be withdrawn and the shop stewards be given final written warnings. Counselling was provided, and the chief negotiator indicated that there will be training provided for shop stewards in October 2023 to upskill shop stewards on how to deal with issues of discipline.

The reviewing of policies will ensure that policy processes and controls are transparent and implemented to prevent and detect non-compliance with regulations and procedures. Empowerment sessions to capacitate employees and management on policy processes will be conducted to lay guidance on policy implementation, procedures, and processes to accomplish day-to-day operations. Non-compliance with any of the provisions of the policies shall constitute misconduct which may lead to a disciplinary action being instituted against any person in contravention of these policies.

Salary Negotiations

Level 05 – 12 salary negotiations for 2023/24 were concluded in November 2023. The parties agreed that the salary increment is for a single term for the 2023/24 financial year. The final agreed salary adjustment for salary levels 5 to 12, effective from 01 April 2023 were as follows:

- For levels 05 to 08, there will be a 6% increase and for level 09 to 12, there will be 5.5% increase. The increase will be applied on the basic salary, 13th cheque, pension, medical aid, housing, and cash gratuity.
- With regards to the employees on Task Grade Company, the 6% for the employees on levels 05 to 08 and the 5.5% for the employees on levels 09 to 12 were applied to the total package.
- By October 2023, employees of SAHPRA on salary levels 05 to 12 received a one-off cash payment of R10 000.
- Payback on salary increment for salary levels 05 – 12 was paid in November 2023.

The salary adjustment and payback of salary increments for employees on salary level 13 and onwards were paid in December 2023. The Senior Manager salary adjustment was 4.5%, and for EXCO, it was 0%.

In March 2024, a SAHPRA Bargaining Forum (SBF) meeting was held where the following issues were discussed:

- The SAHPRA Bargaining Forum shall Constitution and SAHPRA Organisational Rights Integreement, where parties agreed to submit their inputs in April 2024 with a view to subsequently obtaining a mandate in sign.
- Salary demands for 2024/2025 Wherein Organised Labour demanded an increase of 12%. Organised Labour was formally informed that SAHPRA will follow their internal process for to obtain a mandate. The item once it is presented at EXCO, FINCOM, RISKCO and to the Board for a proper mandate. Salary negotiations shall commence in May 2024 or upon receipt of appropriate mandate from the Board.
- Eleven (11) Appeals Misconduct Authority members from different organisations were appointed.

Future HR plans/goals

- Capacitate the HR Unit by appointing an HR Executive and two (2) Human Resource Business Partners.
- Conducting a skills audit within the HR Unit to identify competencies and experience and ensure training and development where gaps will be identified.
- Addressing outstanding staff grievances and training all staff on the Labour Relations Act and procedures and various SAHPRA policies.
- Filling critical positions in the core business units as per the recruitment plan.
- Review and evaluation of all SAHPRA jobs/job descriptions to address salary disparities.
- Continue with the review of the HR policies, including the development of a SAHPRA Remuneration Policy.
- Implement the Action Plans to address the issues raised from the Staff Satisfaction Survey.

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	R151 322	R55 689	37%	48	R819
Programme 2	R94 046	R34 031	100%	66	R618
Programme 3	R89 232	R62 681	97%	49	R871
Programme 4	R119 413	R70 043	59%	78	R922
Programme 5	R39 409	R32 114	91%	42	R765
Contract (external funders)	R34 507	R13 552	39%	19	R713
TOTAL	R423 928	R248 077	59%	303	R893

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	R9 712	4%	4	R2 428
Senior Management	R20 835	8%	17	R1 226
Professional qualified	R170 230	69%	186	R915
Skilled	R31 971	13%	63	R508
Semi-skilled	R15 329	6%	38	R403
Unskilled	R0	0%	0	R0
TOTAL	R248 077	100%	303	R868

Performance rewards

Programme/activity/ objective	Performance rewards (R'000)	Personnel Expenditure (R'000)	% of performance rewards to total personnel cost (R'000)
Top Management	R508	R9 931	5,39%
Senior Management	R821	R20 053	4,09%
Professional qualified	R4 458	R162 848	2,74%
Skilled	R753	R28 818	2,61%
Semi-skilled	R305	R13 998	2,2%
Unskilled	R0	R0	0%
TOTAL	R6 844	R249 077	2,91%

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 (R'000)
Programme 1	R52 685	R695	1,3%	68	R10
Programme 2	R31 612	R0	0%	35	R0
Programme 3	R40 460	R141	0,3%	49	R3
Programme 4	R85 555	R0	0%	75	R0
Programme 5	R30 209	R69	0,2%	42	R1
Contract (external funders)	R13 552	R0	0%	19	R0
TOTAL	R254 913	R904	0,4%	309	R3

Employment and vacancies

Programme	2023/2024 No. of Employees	2023/2024 Approved Posts	2023/2024 No. of Employees	2023/2024 Vacancies	% of vacancies
Programme 1	68	80	68	12	15%
Programme 2	56	79	53	09	11,4%
Programme 3	49	70	49	12	17,1%
Programme 4	76	130	76	38	35,8%
Programme 5	42	71	42	15	21,1%
Contract (external funders)	19	0	19	0	0%
TOTAL	309	430	309	83	19,3%

Programme	2023/2024 No. of Employees	2023/2024 Approved Posts	2023/2024 No. of Employees	2023/2024 Vacancies	% of vacancies
Top Management	4	5	4	1	20%
Senior Management	15	19	15	4	21,1%
Professional qualified	188	336	188	66	39%
Skilled	89	130	89	8	6,2%
Semi-skilled	39	60	39	4	10%
Unskilled	0	0	0	00	0%
TOTAL	309	430	309	83	19,3%

All funded and vacant positions (newly created and vacated) for senior management and highly skilled supervisors are advertised immediately to ensure that they are filled within six (6) months after becoming vacant. As SA-PPA is a newly created entity operating in a scarce skills health environment, it has limited capabilities and resources

Internally. As we are on a journey of growth and continuous transformation, we advertised our position nationwide to enhance the ability to attract skilled and competent employees from all sectors, particularly in the health sector, to improve the competitiveness in attracting critical and scarce skills in the market.

Human Resources, in consultation with the Office of the Chief Financial Officer and line managers adopted a proactive approach in identifying critical vacant positions earmarked for filling. The staff establishment was audited and 139 positions were vacant. Due to budget cuts implemented by National Treasury, 92 positions were unfunded to remain within the allocated cost of employment (CoE) budget, while the vacancy rate was 19.3% excluding unfunded positions.

Employment changes

Salary Band	Employment at beginning of period	Appointments	Terminations	Employment at end of the period
Top Management	4	0	0	4
Senior Management	17	4	6	15
Professional qualified	187	21	18	188
Skilled	60	6	2	64
Semi-skilled	43	0	3	38
Unskilled	0	0	0	0
TOTAL	311	31	29	309

Reasons for staff leaving

Reason	Number	% of total no. of staff leaving
Death	0	0%
Resignation	19	66%
Dismissal	0	0%
Retirement	4	14%
Ill health	0	0%
Expiry of contract	5	17%
Other	1	3%
TOTAL	29	9%

Explanations: *Explanations for staff leaving and who attempts are made to replace these staff.*

Staff turnover rate for the 2023/24 financial year was 9.4%, a decrease of 0.39% compared to last year. SAHPRA continued to experience a turnover in critical and scarce positions, resulting in instability and a lack of continuity at management and operational levels. The turnover is attributable to termination reasons related to job security, career growth, work-life balance, remuneration and benefits, retirement, and contract expirations were reasons why employees leave the organisation.

SAHPRA will focus on filling critical and scarce positions in the core business units as per the Recruitment Plan and filling all vacated funded positions within six (6) months of becoming vacant. The average age at SAHPRA is 43, and 40.1% of employees are between the ages of 40 and 49. This impacts manpower planning, as well as employee benefits and retention strategies.

Labour Relations: Misconduct and disciplinary action

Nature of disciplinary Action	Number
Verbal Warning	
Written Warning	8
Final Written warning	
Dismissal	
TOTAL	8

Equity Target and Employment Equity Status

Explanations for major variances between target and current and attempts made by the public entity to address the variances

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	7	1	1	1	0	1	0	1
Professional qualified	60	45	3	10	0	4	3	7
Skilled	23	0	0	4	0	1	1	3
Semi-skilled	17	0	1	2	0	1	0	1
Unskilled								
TOTAL	107	47	5	17	0	7	5	12

Levels	FEMALE							
	AFRICAN		COLOURED		INDIAN		WHITE	
	Current	Target	Current	Target	Current	Target	Current	Target
Top Management	2	0	0	0	0	0	1	0
Senior Management	6	0	0	0	1	0	0	0
Professional qualified	55	0	4	0	17	0	6	0
Skilled	34		2		2		1	
Semi-skilled	15		2		4		0	
Unskilled								
TOTAL	152		8		24		8	

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	0
Skilled	0	1	0	0
Semi-skilled	1		2	0
Unskilled	0		0	0
TOTAL	1	2	5	0

The entity exceeded the economically active race representation targets for Africans by 4% and Indians by 3%.

The underrepresentation of Coloureds and Whites will be addressed in the new EE Plan for 2024/ 2027 (Medium Term Expenditure Framework (MTEF) period and during recruitment and selection processes.

The overall female representation is 62% and 52.6% of females occupy senior and executive positions. The underrepresentation of males will be addressed in the new EE Plan for 2024/ 2027 MTEF period.

Disability representativity is currently at 2% maintained from the previous reporting year.

During the recruitment and selection processes, SAHPRA will attempt to achieve a 50/50 gender representation across all occupation levels, even though it will be challenging because the health sector is the most female-dominated sector (industry).

PART E
PFMA COMPLIANCE REPORT

1. IRREGULAR, FRUITLESS AND WASTEFUL EXPENDITURE AND MATERIAL LOSSES

1.1 Irregular expenditure

a) Reconciliation of irregular expenditure

Description	2023/24	2022/23
	R'000	R'000
Opening balance	-	3 010
Add: Irregular expenditure confirmed	163	-
Less: Irregular expenditure condoned	(163)	(3 010)
Less: Irregular expenditure not condoned and removed	-	-
Less: Irregular expenditure recoverable	-	-
Less: Irregular expenditure not recovered and written off	-	-
Closing balance	-	-

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

Reconciling notes

Description	2023/24	2022/23
	R'000	R'000
Irregular expenditure that was under assessment	-	-
Irregular expenditure that relates to 2022/23 and identified in 2023/24	-	-
Irregular expenditure for the current year	163	3 010
Total	163	3 010

b) Details of current and previous year irregular expenditure (under assessment, determination, and investigation)

Description[1]	2023/24	2022/23
	R'000	R'000
Irregular expenditure under assessment	-	-
Irregular expenditure under determination	-	-
Irregular expenditure under investigation	-	-
Total[2]	-	-

SAHRA does not have any unconfirmed irregular expenditure

c) Details of current and previous year irregular expenditure condoned

Description	2023/24	2022/23
	R'000	R'000
Irregular expenditure condoned	163	3 010
Total	163	3 010

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

d) Details of current and previous year irregular expenditure removed - (not condoned)

Description	2023/24	2022/23
	R'000	R'000
Irregular expenditure NOT condoned and removed	-	-
Total	-	-

All irregular expenditure confirmed were subsequently condoned by the National Treasury

e) Details of current and previous year irregular expenditure recovered

Description	2023/24	2022/23
	R'000	R'000
Irregular expenditure recovered	-	-
Total	-	-

No irregular expenditure confirmed required recovery in line with the National Treasury guidelines

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

Description	2023/24	2022/23
	R'000	R'000
Irregular expenditure written off	-	-
Total	-	-

No irregular expenditure was identified for recovery or resolved to be written off

g) Details of current and previous year disciplinary or criminal steps taken as a result of irregular expenditure

Disciplinary steps taken
2022/23 - 3 warnings issued to implicated staff following a determination process
2023/24 – 1 warning issued to implicated staff following a determination process

Disciplinary action 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	2023/24	2022/23
	R'000	R'000
Opening balance	342	32
Add: Fruitless and wasteful expenditure confirmed	-	342
Less: Fruitless and wasteful expenditure written off	(342)	-
Less: Fruitless and wasteful expenditure recoverable	-	(32)
Closing balance	-	342

Additional fruitless and wasteful expenditure identified during the 2022/23 financial year related to interest and penalties issued by SARS due to underpayment of PAYE. A determination test was completed, which did not recommend recovery against liable officials and was subsequently written off.

Reconciling notes

Description	2023/24	2022/23
	R'000	R'000
Fruitless and wasteful expenditure that was under assessment	-	-
Fruitless and wasteful expenditure that relates to 2022/23 and identified in 2023/24	-	-
Fruitless and wasteful expenditure for the current year	-	342
Total	-	342

b) Details of current and previous years fruitless and wasteful expenditure (under assessment, determination, and investigation)

Description	2023/24	2022/23
	R'000	R'000
Fruitless and wasteful expenditure under assessment	-	-
Fruitless and wasteful expenditure under determination	-	-
Fruitless and wasteful expenditure under investigation	-	-
Total	-	-

SAHRRA does not have any unconfirmed fruitless and wasteful expenditure

c) Details of current and previous year fruitless and wasteful expenditure recovered

Description	2023/24	2022/23
	R'000	R'000
Fruitless and wasteful expenditure recovered	-	-
Total	-	-

d) Details of current and previous year fruitless and wasteful expenditure not recovered and written off

Description	2023/24	2022/23
	R'000	R'000
Fruitless and wasteful expenditure written off	342	-
Total	342	-

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

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

Disciplinary steps taken
2022/23 – A determination has been initiated to determine the cause of the transgression and liable officials. The determination was completed in 2023/24, which did not recommend recovery against liable officials and was subsequently written off

1.3 Additional disclosure relating to material losses in terms of PFMA Section 55(2)(b)(i) &(iii))

a) Details of current and previous year material losses through criminal conduct

Material losses through criminal conduct	2023/24	2022/23
	R'000	R'000
Theft	-	-
Other material losses	-	-
Less: Recovered	-	-
Less: Not recovered and written off	-	-
Total	-	-

No material losses identified

b) Details of other material losses

Nature of other material losses	2023/24	2022/23
	R'000	R'000
None	-	-
Total	-	-

2. LATE AND/OR NON-PAYMENT OF SUPPLIERS

Description	Number of invoices	Consolidated Value
		R'000
Valid invoices received	781	105 916
Invoices paid within 30 days or agreed period	726	99 274
Invoices paid after 30 days or agreed period	47	6 132
Invoices older than 30 days or agreed period (unpaid and without dispute)	2	246
Invoices older than 30 days or agreed period (unpaid and in dispute)	1	18

Invoices paid after 30 days or agreed period due to queries raised with the service provider or internally for correction/clarification before payment was processed.

Older than 30 days (unpaid and in dispute) is mainly due to queries raised with service providers not as yet resolved.

3. SUPPLY CHAIN MANAGEMENT

3.1 Procurement by other means

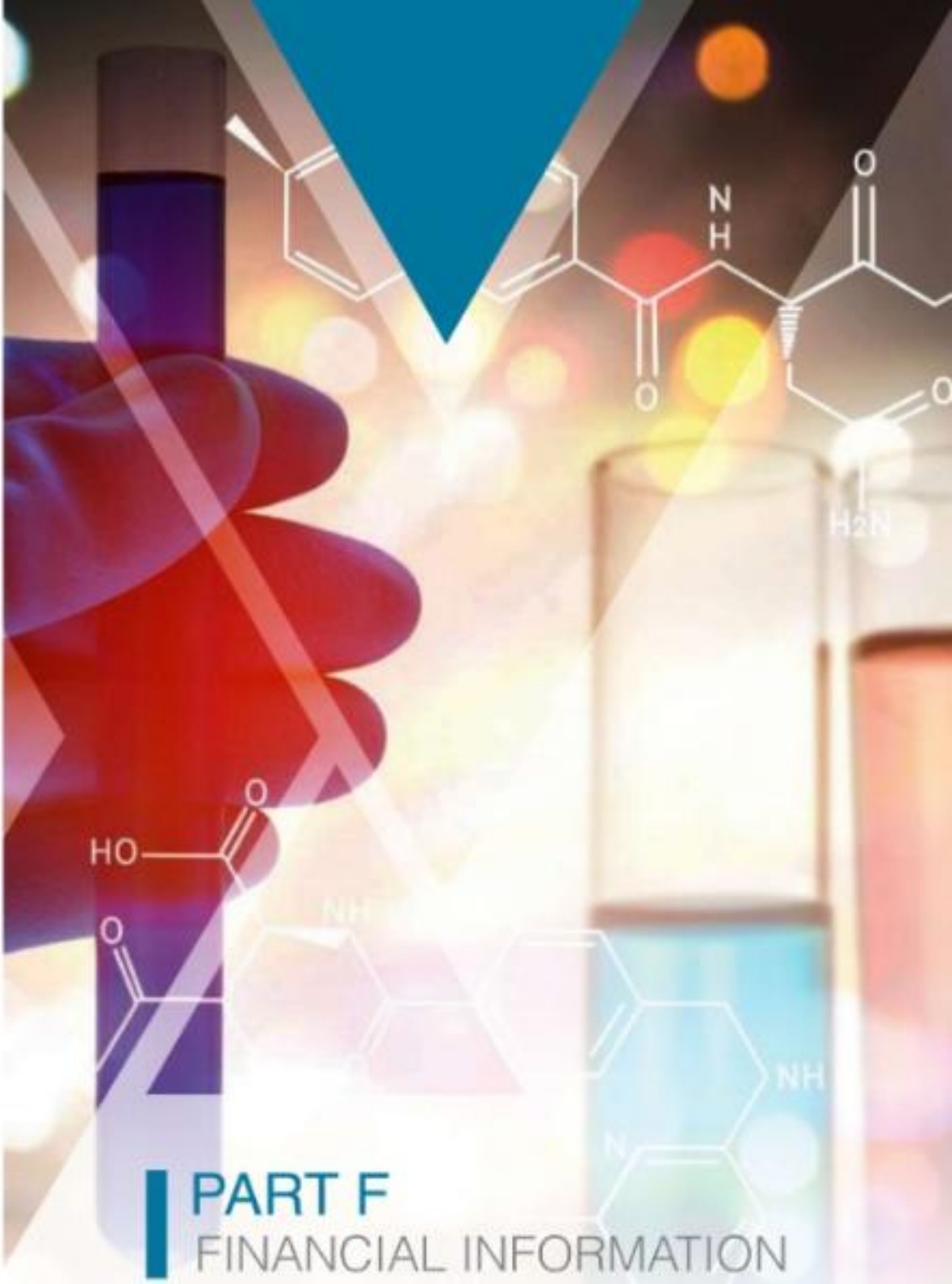
Project description	Name of supplier	Type of procurement by other means	Contract number	Value of contract R'000
Annual Conference on Pharmacoepidemiology in Africa	Conference Management 10	Sole source	PO0338	18
Procurement of vaccine lot release testing service from sole supplier	NCLBP	Sole Source	PO0344	24 757
Legislative drafting workshop	Robert Edwin Conferences	Single source	PO0354	11

Project description	Name of supplier	Type of procurement by other means	Contract number	Value of contract R'000
PV Training catering	Walter Sisulu University - Queenstown Health Resource Centre	Single source	PO0380	13
PV Training catering	Walter Sisulu University - Mthatha Health Resource Centre	Single source	PO0381	14
PV Training catering	Walter Sisulu University - East London Health Resource Centre	Single source	PO0382	17
Quantum	Therefore Strategic Technology Service	Single source	PO0385	1 264
Publication of notice of registrations in the gazette in terms of section 17	Government printing	Sole Source	PO0391	11
Publication of notice of registrations in the gazette in terms of section 17	Government printing	Sole Source	PO0318	11
Exam Fee	IODSA	Single source	PO0392	6
Conduct a measurement of indoor air quality, carbon dioxide, lux levels and noise levels	Eezo Environmental and Occupational Health Services	Single source	PO0400	2
Border medicines control technicians parking space	ACSA OR Tambo International	Single source	PO0410	57
Border Medicines Control Technicians Parking (Cape Town International Airport)	Serviest facilities services	Single source	PO0422	22
Border Medicines Control Technicians Parking (Port Elizabeth)	ACSA	Single source	PO0426	13
Basement storage	Shrive Real Estate Specialists	Single source	PO0425	70
Testing Laboratory	Northwest University	Single source	PO0448	1885
Publication of Notification of retention fee payment	Government Printing Works	Sole Source	PO0456	6
Notification of medicine registration - Publication	Government Printing Works	Sole Source	PO0457	12
Publication of approved schedules for Cannabis	Government Printing Works	Sole Source	PO0461	13
Licence Renewal	Uppsala Monitoring Center Government printing	Sole Source	PO0464	91
Publication of notice of registrations in the gazette in terms of section 17	Government Printing Works	Sole Source	PO0467	12
Casemare software	Adapt IT	Sole Source	PO0475	126
Pharmacokinetics Workshop	Stellenbosch University	Single source	PO0476	8
Catering for BEE Policy meeting	Jemz Tshid	Single source	PO0478	7
HVAC Aircon Controllers Installation	HVAC Maintenance	Single Source	PO0488	2

Project description	Name of supplier	Type of procurement by other means	Contract number	Value of contract R'000
Radiation Control Storage Facility	City Property	Single Source	PO0492	199
Deployment and Support of National Drug Control System (Software)	NDS UNODC	Single source	PO0497	4 103
Total				30 876

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
MTN cloud connect	MTN	Variation	PO0305	4 547	415	111
Medicine Control Technician Office Space	AIRPORTS COMPANY SOUTH AFRICA (ACSA)	Variation	PO0319	1 691	-	253
Payroll consultants	XFour Solutions	Variation	PO0321	84	-	193
RealSign extension	BCX	Variation	PO0390	382	-	52
Additional Security	Omega	Variation	PO0396	678	-	45
Additional training scope – VMware NSX	Tongue Technical Computer Training	Variation	PO0405	39	-	1
Insurance cover for additional assets	Lateral Unison	Variation	PO0440	1 024	21	32
Cleaning Service	Bidvest Prestige	Variation	PO0481	184	-	4
Additional Capacity on Microsoft Power Platform	Microsoft Ireland	Variation	PO0488	11 534	-	12
Total						703



PART F
FINANCIAL INFORMATION

Index

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

Accounting Authority's Responsibilities and Approval

The Accounting Authority is required by the Public Finance Management Act (Act 1 of 1999), to maintain adequate accounting records and are responsible for the content and integrity of the annual financial statements and related financial information included in this report. It is the responsibility of the Accounting Authority to ensure that the annual financial statements fairly present the state of affairs of SAHPRA as at the end of the financial year and the results of its operations and cash flows for the period then ended. The external auditors are engaged to express an independent opinion on the annual financial statements and was given unrestricted access to all financial records and related data.

The annual financial statements have been prepared in accordance with Standards of Generally Recognised Accounting Practice (GRAP) including any interpretations, guidelines and directives issued by the Accounting Standards Board.

The annual financial statements are based on 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 is 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 SAHPRA'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 its 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 111.

The annual financial statements set out on page 118 to 164, 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 Sollomon Semele-Ebrahim Bela
Chief Executive Officer

Prof. Helen Rees
Chairperson of the Board

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

Report on the audit of the financial statements

Opinion

1. I have audited the financial statements of the South African Health Products Regulatory Authority (SAHPRA) set out on pages 118 to 164, which comprise the statement of financial position as at 31 March 2024, 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 2024 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 matters

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

Restatement of corresponding figures

7. As disclosed in note 34 to the financial statements, the corresponding figures for 31 March 2023 were restated due to errors in the entity's financial statements for the year ended 31 March 2024.

Material impairments

8. As disclosed in note 3 to the financial statements, a material impairment of R4 753 792 (2023: R5 155 308) was incurred due to the entity not recovering the monies owed.

Responsibilities of the accounting authority for the financial statements

9. The accounting authority is responsible for the preparation and fair presentation of the financial statements in accordance with 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.

10. 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

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

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

Report on the annual performance report

13. 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 against predetermined objectives for the selected programme presented in the annual performance report. The accounting authority is responsible for the preparation of the annual performance report.

14. I selected the following material performance indicators related to programme 4: Clinical and pharmacodicelevaluation presented in the annual performance report for the year ended 31 March 2024 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 90 working days
- Percentage of for release requests finalised within 60 working days

15. 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.

16. 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 objectives 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.

17. I performed the procedures to report material findings only; and not to express an assurance opinion or conclusion.

18. I did not identify any material findings on the reported performance information for the selected indicators.

Other matters

19. I draw attention to the matter below.

Achievement of planned targets

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

21. The table that follows provides information on the achievement of planned targets and lists the key indicators that were not achieved as reported in the annual performance report. The reasons for any underachievement of targets are included in the annual performance report on pages 38 to 86.

Clinical and pharmaceutical evaluation

Targets achieved: 43.59% Budget spent: 85%		
Key indicator not achieved	**Planned target**	**Reported achievement**
Percentage of reports on health product safety signals issued within 40 working days	70% reports on health product safety signals issued within 40 working days	Out of 456 signals received, 446 (97.81%) were due for finalization by the end March 2018. Out of 446 due for finalisation, 343 (76.91 %) reports were issued, of which 196 (43.95%) were issued within 40 working days.

Report on compliance with legislation

22. 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.

23. 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.

24. 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.

25. I did not identify any material non-compliance with the selected legislative requirements.

Other information in the annual report

26. 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.

27. 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.

28. 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.

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

Internal control deficiencies

30. 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.

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

Auditor-General

Pretoria

30 July 2024

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 programmes 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; 16A9.116A9; 16A9.1(b)(i); 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)(ii) 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)
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

Legislation	Sections or regulations
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 2024

	Note(s)	2024 R	2023 Restated* R
Assets			
Current Assets			
Receivables from exchange transactions	3	9 264 217	6 421 029
Receivables from non-exchange transactions	4	7 996 864	2 397 554
Prepayments	5	9 642 933	6 323 206
Cash and cash equivalents	6	371 616 710	329 603 895
		398 520 714	344 745 684
Non-Current Assets			
Property, plant and equipment	7	25 818 999	28 352 240
Intangible assets	8	10 963 954	2 888 007
		36 782 953	31 240 247
Total Assets		435 303 667	375 985 931
Liabilities			
Current Liabilities			
Operating lease liability	9	3 518 705	4 083 589
Payables from exchange transactions	10	12 147 766	10 560 049
Employee benefit obligation	11	908 394	993 930
Unspent conditional grants	12	9 759 759	4 317 696
Provisions	13	23 880 336	20 287 054
Income received in advance	14	292 720 106	256 218 751
		342 935 068	296 439 069
Non-Current Liabilities			
Employee benefit obligation	11	9 967 596	8 559 108
Total Liabilities		352 902 664	304 998 177
Net Assets		82 401 013	70 987 754
Accumulated surplus		82 401 013	70 987 754
Total Net Assets		82 401 013	70 987 754

*See Note 34

Statement of Financial Performance

For the year ended 31 March 2024

	Note(s)	2024 R	2023 Restated* R
Revenue			
Revenue from exchange transactions			
Fee income	15	228 077 641	208 044 494
Sundry income	16	12 230	65 135
Interest received	17	32 529 429	20 681 972
Actuarial gains	11	702 130	1 930 448
Total revenue from exchange transactions		261 321 430	229 702 049
Revenue from non-exchange transactions			
Transfer payment received	18	137 873 000	149 965 000
Service in kind	19	8 840 687	3 699 397
Grant realised and income	20	27 305 838	13 700 412
Assets donated		-	208 500
Total revenue from non-exchange transactions		174 019 425	167 473 309
Total revenue		435 340 855	396 176 358
Expenditure			
Employee related costs	21	(248 076 856)	(223 420 809)
Backlog reduction project	22	-	(20 157 015)
Depreciation and amortisation	25	(7 394 116)	(6 110 595)
Impairment of assets		(84 574)	(6 952)
Auda Nlenet project expenditure		(870 020)	(105 774)
Lease rentals on operating lease		(21 018 152)	(20 474 650)
Bad debts written off		(2 303 683)	(1 590 189)
Global fund project expenditure	23	(20 971 537)	(3 709 919)
GIZ project expenditure	24	(5 161 901)	-
Laboratory services	26	(23 604 708)	(22 636 215)
Loss on disposal of assets		(139 940)	(136 414)
Loss on foreign exchange		(140 570)	(46 350)
Operating expenditure	27	(94 161 539)	(74 314 442)
Total expenditure		(423 927 596)	(372 652 325)
Surplus for the year		11 413 259	23 523 033

* See Note 34

Statement of Changes in Net Assets

For the year ended 31 March 2024

	Note(s)	Accumulated surplus R	Total net assets R
Balance at 01 April 2022		47 464 721	47 464 721
Surplus for the year		23 523 033	23 523 033
Total		23 523 033	23 523 033
Opening balance as previously reported		69 971 958	69 971 958
Adjustments:			
Correction of errors	34	1 015 796	1 015 796
Restated balance at 01 April 2023		70 987 754	70 987 754
Surplus for the period		11 413 259	11 413 259
Total		11 413 259	11 413 259
Balance at 31 March 2024		82 401 013	82 401 013

Cash Flow Statement

For the year ended 31 March 2024

	Note(s)	2024 R	2023 Restated* R
Cash flows from operating activities			
Receipts			
Fees and deferred income		261 486 204	272 761 089
Transfer payment received		137 873 000	149 955 000
Interest income		32 844 311	20 644 791
Grants received		26 988 852	14 574 523
		459 172 367	457 945 403
Payments			
Employee costs		(258 889 002)	(225 817 782)
Suppliers		(146 358 606)	(139 508 642)
		(405 247 608)	(365 326 424)
Net cash flows from operating activities	28	53 924 759	92 618 979
Cash flows from investing activities			
Purchase of property, plant and equipment	7	(3 279 718)	(7 429 028)
Proceeds from sale of property, plant and equipment	7	12 230	40 640
Purchase of other intangible assets	8	(8 644 456)	-
Net cash flows from investing activities		(11 911 944)	(7 388 388)
Net increase in cash and cash equivalents		42 012 815	85 230 591
Cash and cash equivalents at the beginning of the year		329 603 895	244 373 304
Cash and cash equivalents at the end of the year	6	371 616 710	329 603 895

* See Note 34

Statement of Comparison of Budget and Actual Amounts

For the year ended 31 March 2024

Budget on Cash Basis	Approved budget	Adjustments	Final Budget	Actual Amounts	Difference between final budget and actual	Reference
Statement of Financial Performance						
Revenue						
Revenue from exchange transactions						
Fee income	212 671 860	-	212 671 860	228 077 641	15 405 781	40.1
Sundry income	-	-	-	12 200	12 200	40.1
Interest received	15 670 741	-	15 670 741	27 529 429	11 858 688	40.2
Total revenue from exchange transactions	228 342 601	-	228 342 601	260 619 360	32 276 669	
Revenue from non-exchange transactions						
Transfer revenue						
Transfer payment	152 993 000	(14 680 000)	137 873 000	137 873 000	-	
Service in kind	-	-	-	8 840 587	8 840 587	40.8
Grants realised	-	-	-	27 305 838	27 305 838	40.4
Total revenue from non-exchange transactions	152 993 000	(14 680 000)	137 873 000	174 019 425	36 146 425	
Total revenue	380 335 601	(14 680 000)	365 215 601	434 638 725	68 423 094	
Expenditure						
Employee cost	(260 006 636)	7 300 210	(267 706 346)	(248 076 858)	9 629 488	40.3
Depreciation and amortisation	-	-	-	(7 394 116)	(7 394 116)	40.4
Impairment loss	-	-	-	(84 574)	(84 574)	40.4
Auto Nepad grant expenditure	-	-	-	(870 020)	(870 020)	40.10
Lease rentals on operating lease	(21 287 636)	-	(21 287 636)	(21 018 152)	269 384	40.7
Bad debts written off	-	-	-	(2 303 683)	(2 303 683)	40.9
Global fund expenditure	-	-	-	(20 971 537)	(20 971 537)	40.10
GIZ project expenditure	-	-	-	(5 161 901)	(5 161 901)	40.10
Laboratory services	(24 116 794)	-	(24 116 794)	(23 604 708)	512 086	40.6
Operating Expenses	(84 384 795)	7 379 790	(77 005 005)	(94 101 539)	(17 156 534)	40.5
Total expenditure	(390 795 631)	14 680 000	(380 116 631)	(423 647 088)	(43 530 457)	
Operating surplus / (deficit)	(13 900 000)	-	(13 900 000)	10 991 639	24 891 639	40.11
Loss on disposal of assets and liabilities	-	-	-	(139 943)	(139 943)	40.4
Loss on foreign exchange	-	-	-	(140 570)	(140 570)	40.9
Actuarial gains/losses	-	-	-	702 130	702 130	40.2
	-	-	-	421 630	421 630	
Surplus / (deficit)	(13 900 000)	-	(13 900 000)	11 413 269	25 313 269	
Actual Amount Presented in	-	-	-	11 413 269	11 413 269	
the Budget and Actual						
Comparative Statement						

SAHPRA applied and received approval from National Treasury to budget for a deficit for the 2023-26 financial year.

Significant Accounting Polices

For the year ended 31 March 2024

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 have 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 SAHPRA. Amounts are rounded to the nearest Rand.

1.2 Going concern assumption

These annual financial statements have been prepared based on the expectation that SAHPRA 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 in items such as the following:

Trade receivables

SAHPRA assesses its trade receivables for impairment at the end of each reporting period. In deciding 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 rates are applied to balances in the portfolio and scaled to the estimated loss emergence period.

1.3 Significant judgements and sources of estimation uncertainty (continued)

Impairment testing

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

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

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

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.

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.

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.

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.

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

1.4 Property, plant and equipment (continued)

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

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

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

Property, plant and equipment is carried at cost less accumulated depreciation and any impairment losses. The useful lives of items of property, plant and equipment have been assessed as follows:

Item	Depreciation method	Useful life
Furniture and fixtures	Straight-line	10-14 years
Motor vehicles	Straight-line	3 years
Computer equipment	Straight-line	5-7 years
Leasehold improvements	Straight-line	5-10 years
Other fixed assets	Straight-line	10-15 years

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

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. This change is accounted for as a change in an accounting estimate.

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

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

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

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

1.5 Intangible assets (continued)

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.

Expenditure on research (or on the research phase of an internal project) is recognised as an expense when it is incurred. Intangible assets are carried at cost less any accumulated amortisation and any impairment losses.

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

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

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

Internally generated goodwill is not recognised as an intangible asset.

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

Item	Depreciation method	Average useful life
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 uncollectability.

1.5 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.
Travel cards	Financial liabilities measured at amortised cost, which, due to their short-term nature, closely approximate their fair values. SAHPRA recognises travel lodge liability and fleet cards that are due in the ordinary course of operations.
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. Financial liabilities measured at amortised cost, which, due to their short-term nature, closely approximate their fair value. 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

1.6 Financial instruments (continued)

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.

1.7 Statutory receivables (continued)

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 entity transfers to another party substantially all of the risks and rewards of ownership of the receivable; or
- the entity, despite having retained some significant risks and rewards of ownership of the receivable, has transferred control of the receivable to another party and the other party has the practical ability to sell the receivable in its entirety to an unrelated third party, and is able to exercise that ability unilaterally and without needing to impose additional restrictions on the transfer. In this case, the entity:

  - derecognises the receivable; and
  - recognises separately any rights and obligations created or retained in the transfer.

The carrying amounts of any statutory receivables transferred are allocated between the rights or obligations retained and those transferred on the basis of their relative fair values at the transfer date. 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

A prepaid expense is an expense paid for in one accounting period but for which the underlying asset will not be consumed until a future period.

A prepaid expense is 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 recorded in that period as an expense on the Statement of Financial Performance.

1.9 Leases

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

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 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 call with banks and other short-term highly liquid investments with original maturities of three months or less which are available on demand.

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.
- The 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.

1.12 Employee benefits [worked]

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. The contributions expensed is measured at the undiscounted amount of the contributions 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 in 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.

Assets held by a long-term employee benefit fund are assets (other than non-transferable financial instruments issued by the reporting entity) that are held by an entity (a fund) that is legally separate from the reporting entity and exists solely to pay or fund employee benefits and are available to be used only to pay or fund employee benefits, are not available to the reporting entity's own creditors (even in liquidation), and cannot be returned to the reporting entity, unless either:

- the remaining assets of the fund are sufficient to meet all the related employee benefit obligations of the plan or the reporting entity; or
- the assets are returned to the reporting entity to reimburse it for employee benefits already paid.

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 a long-term employee benefit fund and qualifying insurance policies.

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, dividends or similar distributions and other income derived from the plan assets, together with realised and unrealised gains or losses on the plan assets, less any costs of administering the plan (other than those included in the actuarial assumptions used to measure the defined benefit obligation) and less any tax payable by the plan itself.

The entity account not only for its legal obligation under the formal terms of a defined benefit plan, but also for any constructive obligation that arises from the entity's informal practices. Informal practices give rise to a constructive obligation where the entity has no realistic alternative but to pay employee benefits. An example of a constructive obligation is where a change in the entity's informal practices would cause unacceptable damage to its relationship with employees.

The amount recognised as a defined benefit liability 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;
- plus any liability that may arise as a result of a minimum funding requirement.

The amount determined as a defined benefit liability may be negative (an asset). The entity measures the resulting asset at the lower of:

1.13 Employee benefits (continued)

- the amount determined above; and
- the present value of any economic benefits available in the form of refunds from the plan or reductions in future contributions to the plan. The present value of these economic benefits is determined using a discount rate which reflects the time value of money.

Any adjustments arising from the limit above is recognised in surplus or deficit.

The entity determines the present value of defined benefit obligations and the fair value of any plan assets with sufficient regularity such that the amounts recognised in the annual financial statements do not differ materially from the amounts that would be determined at the reporting date.

The entity recognises the net total of the following amounts in surplus or deficit, 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 rights;
- actuarial gains and losses;
- past service cost;
- the effect of any curtailments or settlements; and
- the effect of applying the limit on a defined benefit asset (negative defined benefit liability).

The entity uses the Projected Unit Credit Method to determine the present value of its defined benefit obligations and the related current service cost and, where applicable, past service cost. The Projected Unit Credit Method (sometimes known as the accrued benefit method pro-rated on service or as the benefit/years of service method) sees each period of service as giving rise to an additional unit of benefit entitlement and measures each unit separately to build up the final obligation.

In determining the present value of its defined benefit obligations and the related current service cost and, where applicable, past service cost, an entity shall attribute benefit to periods of service under the plan's benefit formula. However, if an employee's service in later years will lead to a materially higher level of benefit than in earlier years, an entity shall attribute benefit on a straight-line basis from:

- the date when service by the employee first leads to benefits under the plan (whether or not the benefits are conditional on further service); until
- the date when further service by the employee will lead to no material amount of further benefits under the plan, other than from further salary increases.

Actuarial valuations are conducted on an annual basis by independent actuaries separately for each plan. 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.

The entity 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.

Before determining the effect of a curtailment or settlement, the entity re-measure the obligation (and the related plan assets, if any) using current actuarial assumptions (including current market interest rates and other current market prices).

When it is virtually certain that another party will reimburse some or all of the expenditure required to settle a defined benefit obligation, the right to reimbursement is recognised as a separate asset. The asset is measured at fair value. In all other respects, the asset is treated in the same way as plan assets. In surplus or deficit, the expense relating to a defined benefit plan is presented as the net of the amount recognised for a reimbursement.

1.13 Employee benefits (continued)

The entity offsets an asset relating to one plan against a liability relating to another plan when the entity has a legally enforceable right to use a surplus in one plan to settle obligations under the other plan and intends either to settle the obligations on a net basis, or to realise the surplus in one plan and settle its obligation under the other plan simultaneously.

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.

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

The entity 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.

The entity 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.

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 wholly in 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 30.

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

Rendering of services

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

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

1.15 Revenue from exchange transactions (continued)

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 at 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.

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 SAHPRA; 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 focus 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.

1.16 Revenue from non-exchange transactions (continued)

Transfers

Apart from Services in kind, which are not recognised, 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 disclosed the nature and type of services in-kind received during the reporting period.

1.17 Comparative figures

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

1.18 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.

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 2023/04/01 to 2024/03/31.

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 39 & 40.

1.20 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.

	2024 R	2023 R

2. New standards and interpretations

2.1 Standards and interpretations issued, but not yet effective

SAHPRA has not applied the following standards and interpretations, which have been published and are mandatory for SAHPRA's accounting periods beginning on or after 01 April 2024 or later periods:

Standard/ Interpretation:	Effective date: Years beginning on or after	Expected impact:
• GRAP 2023 Improvements to the Standards of GRAP 2023	not yet determined	Unlikely there will be a material impact
• GRAP 1 (amended): Presentation of Financial Statements (Going Concern)	not yet determined	Unlikely there will be a material impact
• GRAP 22 Foreign Currency Transactions and Advance Consideration	01 April 2025	Unlikely there will be a material impact
• GRAP 104 (as revised): Financial Instruments	01 April 2025	Impact is currently being assessed
• GRAP 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

3. Receivables from exchange transactions

Trade debtors	9 623 911	8 034 866
Provision for impairment	(4 753 782)	(5 155 309)
Deposits	4 394 088	3 541 472
	9 264 217	6 421 029

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

Retention fees	5 941 308	6 175 703
Licence collection fees	1 503 260	1 027 260
Inspection fees	2 117 345	799 903
New registrations	62 000	32 000
	9 623 911	8 034 866
Provision for impairments	(4 753 782)	(5 155 309)
Financial asset receivables included in receivables from exchange transactions above	4 394 088	3 541 472
Total receivables from exchange transactions	9 264 217	6 421 029

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 application fees and inspections fees. All fees are charged in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended.

The increase in statutory receivables increased due to the review of retention fee register resulting in the identification of outstanding fees due.

Rental deposit increased due to additions in deposits during the year. The current leased accommodation received 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 Substances 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 2024 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 1965: 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 assessed on a class of service basis. The impairment of trade receivables has been determined with reference to past default experience, historical collection and debt off of bad debts and and the current economic environment in which these entities trade.

	2024 R	2023 R
3. Receivables from exchange transactions (continued)		
Reconciliation of provision for impairment		
Relating specifically to Statutory Receivables		
Opening balance	5 155 309	4 691 161
Provision for impairment	2 303 683	1 473 599
Amounts written off as uncollectable	(2 705 200)	(1 009 451)
	4 753 792	5 155 309
Provision for impairment breakdown:		
Retention fees	3 476 999	4 570 723
Collection fees	1 276 793	584 586
	4 753 792	5 155 309

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 2024, R2 179 346 (2023: R830 903) were past due but not impaired.

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

9 months past due	2 179 346	830 903

Factors the entity considered in assessing statutory receivables impaired

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

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

Receivables impaired
Relating specifically to Statutory Receivables

As of 31 March 2024, statutory receivables of R7 444 566 (2023: R7 203 983) were impaired and provided for.

The amount of the provision was R4 753 792 31 March 2024 (2023: R5 155 309).

The ageing of these loans is as follows:		
3 to 6 months	745 136	427 200
6 - 12 months	4 884 600	3 998 093
Over 12 months	1 814 830	2 807 670
Total	7 444 566	7 203 963

	2024 R	2023 R

3. Receivables from exchange transactions (continued)

Factors the entity considered in assessing statutory receivables impaired

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

- Debtors did not respond to follow request, 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.

4. Receivables from non-exchange transactions

Other receivables	96 337	-
Grant receivable	5 879 534	60 326
Staff debtors	2 020 983	2 337 228
	7 996 854	2 397 554

Other receivables relates to the prior year contingent asset which the tax master finalised in February 2024 relating to an arbitration process which ruled in favour of SAHPRA and dismissing the claimants claim.

Grant receivable includes grant(s) to be received from the GIZ and the Global Fund as conditions were met.

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

5. Prepayments

Prepayments	9 642 939	6 323 206

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

6. Cash and cash equivalents

Cash and cash equivalents consist of:		
Petty cash	10 000	5 650
Bank balances held at ABSA bank	2 627 171	1 692 549
Corporation for Public Deposits held at SA Reserve Bank	360 430 295	326 919 620
Call account - Global fund project	8 549 244	986 076
	371 616 710	329 603 895

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

6. Cash and cash equivalents (continued)

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 2024. 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

	2024			2023		
	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value
Furniture and fixtures	9 424 631	(3 215 094)	6 208 537	9 346 417	(2 274 260)	7 072 157
Motor vehicles	5 342 724	(1 136 847)	4 205 877	3 289 766	(291 475)	2 998 291
Computer equipment	23 049 186	(13 181 181)	9 868 005	25 482 451	(12 180 351)	13 302 102
Leasehold improvements [1]	7 084 612	(4 976 647)	2 087 965	6 989 440	(3 578 438)	3 411 002
Other fixed assets [2]	5 288 036	(1 840 421)	3 447 615	3 129 540	(1 560 853)	1 568 687
Total	58 189 185	(24 350 186)	33 818 999	48 237 617	(17 885 377)	28 352 240

Reconciliation of property, plant and equipment - 2024

	Opening balance	Additions	Disposals	Depreciation	Impairment loss	Total
Furniture and fixtures	7 072 157	81 300	-	(945 920)	-	6 208 537
Motor vehicles	2 998 291	2 052 982	-	(845 396)	-	4 205 877
Computer equipment	13 302 102	122 335	(126 492)	(3 345 367)	(84 574)	9 868 005
Leasehold improvements [1]	3 411 002	75 171	-	(1 398 208)	-	2 087 965
Other fixed assets [2]	1 568 687	2 185 129	(12 448)	(292 746)	-	3 447 615
	28 352 240	4 516 990	(139 040)	(6 826 887)	(84 574)	33 818 999

Reconciliation of property, plant and equipment - 2023

	Opening balance	Additions	Disposals	Depreciation	Impairment loss	Total
Furniture and fixtures	6 660 917	1 224 519	(7 281)	(875 998)	-	7 072 157
Motor vehicles	971 954	2 317 812	-	(291 475)	-	2 998 291
Computer equipment	12 772 667	3 456 155	(126 245)	(2 795 383)	(6 939)	13 302 102
Leasehold improvements [1]	4 531 850	238 615	-	(1 359 463)	-	3 411 002
Other fixed assets [2]	1 683 123	119 689	(2 847)	(231 265)	(13)	1 568 687
	26 620 501	7 459 028	(136 373)	(5 553 784)	(6 952)	28 352 240

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 27.

[1] Leasehold improvements include improvements made to leased office accommodation. Refer to note 8.

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

	2024 R	2023 R

5. Intangible assets

	2024			2023		
	Cost / Valuation	Accumulated amortisation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated amortisation and accumulated impairment	Carrying value
Computer software	12 614 340	(1 650 386)	10 963 954	3 969 894	(1 081 077)	2 888 817

Reconciliation of intangible assets - 2024

	Opening balance	Additions	Amortisation	Total
Computer software	2 888 817	8 644 446	(569 309)	10 963 954

Reconciliation of intangible assets - 2023

	Opening balance	Additions	Amortisation	Total
Computer software	2 818 059	626 760	(556 802)	2 888 017

Other information

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

6. Operating lease liability

Operating lease liability	3 518 706	4 093 589

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 one year	22 205 521	20 400 835
- in second to fifth year inclusive	13 888 309	34 643 949
	36 093 830	55 044 784

	2024 R	2023 R
10. Payables from exchange transactions		
Trade payables	3 919 306	3 987 998
Salary accruals	3 860 237	1 320 175
Accrued thirteenth cheque	1 824 099	1 555 011
Accrued expenditure	2 243 113	3 210 797
Travel cards	707 011	505 468
	12 147 766	10 569 049

SAHPRA considers that the carrying value of trade and other payables approximates the fair value.

Salary accruals relate to acting allowances, travel, expert committee, local and foreign evaluator fees not yet paid.

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 2024 the aggregate membership of the qualifying employees was 86 (2023:90). In service employees were 86 (2023:90) retired employees a total of 3 (2023:1) employees. Ponson Consulting conducted a valuation of the post-retirement liability as at 31 March 2024. 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	(10 875 980)	(9 553 038)
Non-current liabilities	(9 967 586)	(8 559 108)
Current liabilities	(908 394)	(993 930)
	(10 875 980)	(9 553 038)

Changes in the present value of the defined benefit obligation are as follows:

Opening balance	9 553 038	9 384 332
Net expense recognised in the statement of financial performance	1 322 942	168 706
	10 875 980	9 553 038

Net expense recognised in the statement of financial performance are as follows:

Service cost		
- Current service cost	993 930	1 147 605
Net interest on the net defined benefit liability (asset)	1 080 013	982 805
Remeasurements of the net defined benefit liability (asset)		
- Actuarial gains and losses arising from:		
- Changes in financial assumptions	(702 130)	(1 930 449)
Benefits paid	(48 871)	(31 056)
	1 322 942	168 706

Calculation of actuarial gains and losses

Actuarial (gains) losses – Obligation	(702 130)	(1 930 449)

	2024 R	2023 R

11. Employee benefit obligations (continued)

Key assumptions used

Assumptions used at the reporting date:

Health care cost inflation	8,76 %	7,65 %
Discount rates used	12,67 %	10,48 %
Real discount rate	3,69 %	2,62 %
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:

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

2023	One percentage point increase	One percentage point decrease
Effect on the service cost	1 233 480	811 686
Effect on interest cost	1 319 987	893 039
Effect on defined benefit obligation	11 674 631	7 909 628

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	2 953	38 995	20 515 732	20 557 681
Continuation members (pensioners)	52 698	118 019	147 071	317 788
	55 651	157 014	20 662 803	20 875 469

Amounts for the current and previous four years as follows:	2024	2023	2022	2021	2020
Defined benefit plan	10 875 660	9 553 036	9 354 322	-	-

	2024 R	2023 R
12. Unspent conditional grants		
Unspent conditional grants and receipts comprises of:		
Unspent conditional grants and receipts		
Nepad Austa grant	988 604	851 570
GIZ grant	182 021	3 626 236
SAMRC grant	39 890	39 890
Global Fund grant	8 549 244	-
	9 759 759	4 317 696
Movement during the year		
Balance at the beginning of the year	4 317 696	3 383 259
Additions during the year	27 518 937	14 574 523
Conditions not met - refund to the grantor	(851 570)	-
Income recognition during the year - refer to note 20	(21 225 304)	(13 640 086)
	9 759 759	4 317 696

These amounts are in a ring-fenced investment at the Corporation for Public Deposits and ABSA Call Account as disclosed in Note 5 until utilised. Should the conditions not be met, a repayment to the grantor will include interest accrued at a rate of 8.00 percent.

13. Provisions		
Leave provision	11 153 008	13 311 576
PMDS provision	10 048 307	6 975 378
COIDA provision	2 078 833	-
	23 280 336	20 287 054

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 in April 2021 which enables the employer to incentivise employees based on performance.

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

The target setting percentage of the policy was utilised as a benchmark and adjusted to accommodate and consider:
- Actual scores for the 2022/23 assessment
- That more staff will strive to comply and achieve with evidence available based on understanding and experiences of the 2022/23 assessment
- The inability to retain staff or failed recruitment due to inadequate package offering

COIDA

SAHPRA did not submit its workmens compensation returns in previous years. All outstanding submission were submitted during the current year.

	2024 R	2023 R

13. Provisions (continued)

	Current Cycle Leave	Previous Cycle Leave	Capped	PMDS	COIDA	Total
As at 1 April 2023	4 459 538	5 350 835	501 302	8 975 379	-	20 287 054
Additions for the year	4 963 572	5 694 666	-	9 917 778	2 678 933	23 254 091
Reversal during the year	(4 459 538)	(5 350 835)	(5 584)	(8 844 650)	-	(19 660 607)
As at 31 March 2024	4 963 572	5 694 666	495 718	10 048 307	2 678 933	23 880 538

	Current Cycle Leave	Previous Cycle Leave	Capped	PMDS	Total
As at 1 April 2022	2 516 091	5 538 899	783 643	5 358 516	14 197 149
Additions for the year	4 459 538	5 350 835	-	8 975 439	19 188 812
Reversal during the year	(2 516 091)	(5 538 899)	(282 341)	(4 781 576)	(13 099 907)
As at 31 March 2023	4 459 538	5 350 835	501 302	8 975 379	20 287 054

14. Income received in advance

Reconciliation		
Unallocated deposits received	164 527 904	125 116 304
Revenue received in advance	128 192 202	131 100 447
	292 720 106	256 216 751

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.

15. Fee income

Amendments	27 556 280	25 802 430
Backlog reduction project	-	8 815 150
Biological medicine	6 012 700	3 857 600
Cannabis inspection	441 600	723 200
Cannabis licences	970 260	1 097 640
Certificates	663 600	781 199
Clinical trials	14 691 300	13 463 300
Evaluations	91 542 638	98 675 450
Inspection fees	10 191 153	8 175 359
Licence retention fee	2 725 150	2 679 040
License fees	8 342 000	8 087 600
MD clinical trials	287 100	282 100
MD licence fees	20 042 500	18 533 040
Permits	7 134 900	6 198 775
Registration fee	1 008 400	1 145 430
Retention fees	71 625 900	67 589 700
Section 21: Human	4 784 650	4 012 021
Section 21: CMS	43 750	7 700
Section 21: Veterinary	133 370	136 650
	220 077 841	209 044 434

	2024 R	2023 R
15. Fee Income (continued)		
Fees received per function		
Medicines evaluation, registration and product lifecycle	171 941 228	156 358 030
Inspections, permits and licences issued	51 174 463	45 529 893
The use of unregistered medicines	4 961 950	4 156 571
Total	228 077 641	205 044 494
16. Sundry income		
Proceeds from sale of assets	12 230	65 135
17. Investment revenue		
Interest revenue		
Bank	32 502 235	20 644 791
Accrued interest	27 194	17 181
	32 529 429	20 661 972

Included in interest revenue is total interest earned from cash held at ABSA bank based on the average interest rate of 5.00% (2023: 5.00%) and cash held at SA Reserve Bank Corporation for Public Deposits bank based on the average interest rate of 8.25% (2023: 6.04%) per annum. Interest on the rental deposit held by the lessor in a interest bearing call account at an average rate of 7.00% (2023: 5.00%) 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	137 873 000	149 965 000

Changes in level of government grants

The total allocation to the South African Health Products Regulatory Authority (SAHPRA) has been revised as a result of the Cost Containment measures implemented by the National Treasury in the 2023/24 financial year, to address the current fiscal challenges faced by government. The National Treasury in the 2023 Adjusted Estimates of National Expenditure tabled in Parliament on the 1st of November 2023 reduced the SAHPRA's allocation by R14 680 000.00.

	2024 R	2023 R
18. 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	1 227 169	-
SAHPRA received an in-kind benefit as donated assets were received from Africa CDC.		
Customer relations system	-	2 252 735
SAHPRA received an in-kind benefit as services for intangible assets and other costs were paid directly by a 3rd party - FDCO.		
Quality management system	-	1 346 662
SAHPRA received an in-kind benefit as a quality management system was paid directly by a 3rd party - Clinton Health Access Initiative.		
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 processes and support which was facilitated through the Boston Consulting Group.		
	8 830 593	3 599 397
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	19 998 345	-
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.		
	19 998 345	-
20. Grant realised and income		
BMGF grant	-	9 558 629
Nepad Aude grant	870 020	108 774
IAEA grant	141 520	-
Global Fund grant	21 132 297	3 709 919
SAMRC grant	-	483 090
GIZ grant	5 181 901	-
	27 325 838	13 700 612
Reconciliation of conditional contributions		
Current-year receipts	31 185 064	14 508 169
Conditions met - transferred to revenue relating to unspent conditional grants	(21 426 304)	(9 990 493)
Conditions met - transferred to revenue relating to receivables	(5 879 534)	(60 326)
Grant receivable - note 4	5 879 534	60 326
Balance of unspent conditional grants - note 12	(9 759 760)	(4 317 695)
	-	-

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

	2024 R	2023 R
21. Employee related costs		
Basic and pensionable salaries	187 269 031	169 894 363
Bargaining council	8 647	7 709
Cellphone allowances	1 556 941	1 443 558
Housing benefits and allowances	2 142 124	2 109 704
Leave accrued	(830 880)	5 797 619
Medical aid	8 051 441	8 635 128
Post retirement medical aid adjustment	2 025 073	168 000
Overtime payments	1 233 436	93 891
Pension fund	23 926 584	20 877 644
SARS penalty	-	348 656
SDL and UIF	3 328 600	2 949 653
Standby allowances	60 265	97 604
Thirteenth cheque and performance bonus	15 428 505	10 757 852
Travel, subsistence and other allowances	1 207 964	239 529
COIDA	2 676 933	-
	248 076 856	223 420 809
22. Backlog reduction project		
Bank charges	-	103 612
Foreign evaluators	-	6 083 364
Local evaluators	-	2 064 581
Catering	-	70 675
Extedo System	-	1 498 955
Publication of journal	-	58 861
Compensation of employees	-	10 276 978
	-	20 157 016

Services in kind received for the funding of foreign evaluators. Refer to note 19. Share of expenses discontinued in 2022-23 due to the backlog reductions staff transferred / appointed into the SAHPRA structure. The backlog reduction project ended December 2022.

	2024 R	2023 R
23. Global Fund project expenditure		
Professional services	12 600	-
Travel and related expenditure	266 205	-
Legal committee fees	291 060	-
Local evaluators	4 198 116	-
Foreign evaluators	2 468 246	-
Compensation of employees	13 715 310	3 709 919
	20 971 537	3 709 919
24. GIZ project expenditure		
Technology consulting services	5 161 901	-
25. Depreciation and amortisation		
Property, plant and equipment	6 825 607	5 553 794
Intangible assets	568 509	556 801
	7 394 116	6 110 595
26. Laboratory services		
Outsourced services		
NCL Laboratory	23 604 708	22 636 216

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

	2024 R	2023 R
27. Operating expenses		
Advertising	131 194	207 188
Bank charges	324 206	197 853
Board costs	1 990 452	2 623 563
Bursaries	1 096 510	8 810
Catering	343 589	357 757
Cleaning	733 706	655 785
Communication	2 781 288	1 644 012
Computer expenses	316 790	945 655
Conferences	355 267	138 344
Consulting and professional fees [1]	4 518 004	3 057 794
Consumables	-	8 277
Electricity and utilities	1 305 914	297 748
External audit fees	3 016 733	4 278 390
Foreign evaluators	7 221 969	6 213 263
General expenses	-	6 881
Insurance	382 858	388 664
Internal audit fees	2 365 277	2 703 765
Legal fees	8 122 542	5 531 380
Licences	15 003 621	7 384 428
Local evaluators and expert committees	18 585 007	19 835 955
Marketing, printing and publication	2 040 758	2 112 909
Medicine testing	169 856	401 145
Membership fees	723 229	607 452
Minor assets	243 244	140 389
Motor vehicle expenses	4 299 692	3 492 370
Postage and courier	15 267	14 474
Printing and stationary	187 004	246 380
Protective clothing	99 000	118 524
Relocation of SAHPRA	654 357	947 822
Repairs and maintenance	392 570	300 196
Security	267 134	222 284
Services in kind	7 603 424	2 972 646
Staff training and welfare	1 014 615	1 827 699
Travel - local	5 649 053	5 112 074
Travel - non-employees	320 500	281 809
Travel - overseas	1 806 775	2 189 923
Venue and facilities	-	160 712
	94 161 539	74 316 442

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

	2024 R	2023 R
35. Cash generated from operations		
Surplus	11 415 259	25 583 033
Adjustments for:		
Depreciation and amortisation	7 284 116	6 110 595
Loss on sale of assets and liabilities	139 940	126 414
Impairment deficit	84 574	6 952
Bad debts written off	2 303 083	1 530 109
Movements in operating lease assets and accruals	(544 884)	804 383
Movements in retirement benefit assets and liabilities	1 322 942	168 708
Movements in provisions	3 593 264	6 069 805
Accrued interest on rental deposit and debtors	(276 532)	176 553
Gain on foreign exchange	140 570	142 407
Assets donated	(1 237 163)	209 500
Proceeds from disposal of assets	(12 230)	(40 640)
Changes in working capital:		
Receivables from exchange transactions	(4 897 553)	(2 559 092)
Other receivables from non-exchange transactions	(5 572 106)	7 060 718
Prepayments	(3 319 727)	(1 187 589)
Investing in payables	-	(850 080)
Payables from exchange transactions	1 447 148	(4 953 805)
Unspent conditional grant	5 442 083	934 437
Income received in advance	36 503 355	64 889 943
Deferred income - backlog reduction project	-	(9 272 200)
	53 924 789	92 519 979
36. Commitments		
Authorised expenditure		
Already contracted for but not provided for		
• National Control Laboratory contract	3 804 243	5 742 084
• Supply of facilities services	3 972 251	1 956 506
• Supply of IT equipment and related IT expenditure	27 138 222	3 128 670
• Supply of finance services	70 678	3 353 112
• Open purchase orders	22 175 590	18 645 545
• Supply of communication services	1 136 486	-
• Office accommodation	33 839 807	51 209 869
• Supply of legal services	8 203 442	8 203 971
• Supply of secretarial services	364 414	471 019
• Supply of risk management	337 674	741 485
• Supply of HR services	273 402	898 730
• Supply of parking services	20 352	-
	119 146 559	84 371 011
Total operational commitments		
Already contracted for but not provided for	119 146 559	84 371 011

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

30. Contingencies

Contingent assets Cost order

Various litigation was filed against SAHPRA and other respondents during the 2021/22 and 2022/23 financial years relating to:

- Vaccines being made available to children of the age of 12 to 17. The matter was ruled in favour of SAHPRA with costs during the 2021/22 financial year.
- The registration and sale of a certain vaccine. The application was dismissed by the court and the applicant's application for leave to appeal was also dismissed in April 2023 with costs in favour of SAHPRA.
- Interdicting government on the roll out of Covid-19 vaccines and to provide detailed information. The applicants filed the matter in two courts of which one has already dismissed the applications with costs in favour of SAHPRA in February 2023.

For all the above matters the favourable outcomes results in a contingent asset of which a reliable estimate cannot be made due to:

- No informal settlement reached as yet
- No indication of allocation of costs such as client-attorney and party and party costs
- The bill of costs still to be finalised by the taxing master.

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 2024. However should the submission not be approved, SAHPRA will be required to surrender the current year's surplus as per the calculation of R25 532 695. The calculation determined by National Treasury utilising available cash balances less liabilities.

	2024 R	2023 R

31. Related parties

Relationships	Nature of related party
Executive Authority	Dr J Phaahla
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 Damana - Member Mr TN Baloyi - Member (vacated - November 2023) 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
Members of key management	Dr B Semete-Makokotlela - CEO Mr RB Gouws - CFO Ms P Nkambule - CRO Ms C Reynecke - COO
Other related parties	All public entities under the National Department of Health South African Medical Research Council (SAMRC)

Related party balances		
Conditional grant		
SAMRC	39 890	39 890
Related party transactions		
National Department of Health		
Government grant received	137 873 000	149 965 000

31. Related parties (continued)

Remuneration of Executive Authority and Management

	2024	
Board fees [1]	Board Fees	Total
Prof H.V. Rees - Chairperson	147 427	147 427
Adv H. Cassim - Member	167 369	167 369
Mr T.N. Baloyi - Member [2]	27 876	27 876
Prof H. P. Damana - Member	79 109	79 109
Mr I. Mashou - 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 Ngcobo - Member	245 584	245 584
Ms D Marais - Member	125 118	125 118
Prof Y Choonara - Member	44 509	44 509
Prof J Meyer - Member	87 489	87 489
Ms M Skhosana - Member	126 858	126 858
Dr A Kgasi - Member	180 142	180 142
Dr Z Makatini - Member [3]	-	-
	1 898 603	1 898 603

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

Executive management

2024	Basic salary	Bonuses and performance related payments [4]	Other short- term employee benefits	Termination benefits	Other benefits received	Total
Name						
Dr B Semete-Makokotlela - Chief Executive Officer	3 242 182	122 026	-	-	116 953	3 481 171
Ms. P Nkambule - Chief Regulatory Officer	1 577 983	85 149	149 909	-	41 141	1 834 182
Mr C Reynecke - Chief Operating Officer	2 384 011	89 012	-	-	47 269	2 591 192
Mr RB Gouws - Chief Financial Officer	2 047 694	187 686	-	-	45 084	2 280 464
Mr G Makati - HR Executive [1]	849 966	-	-	1 478 585	37 411	2 363 963
	10 081 806	484 773	149 909	1 478 585	287 858	12 480 944

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

[1] Mr Makati exited SAHPRA 31 October 2023

[2] Payments for performance bonus relates to 2021/22 and 2022/23 financial year.

	2024 R	2023 R

31. Related parties (continued)

Remuneration of Executive Authority and Management

	2023	
Board fees	Board Fees	Total
Prof H.V. Rees - Chairperson	180 992	180 992
Adv H. Cassim - Member	124 999	124 999
Mr T.N. Baloyi - Member	209 150	209 150
Prof H.P. Demana - Member	96 025	96 025
Mr L Mashau - Member	228 429	228 429
Ms L. Mothae - Member	268 541	268 541
Dr O. Khaole - Vice Chair	280 074	280 074
Dr J. Tsota-Gwegweni - Member	79 091	79 091
Dr X. Ngobeso - Member	293 385	293 385
Ms D. Marole - Member	226 654	226 654
Prof Y. Choonara - Member	69 764	69 764
Prof J. Meyer - Member	96 950	96 950
Ms M. Skosana - Member	148 305	148 305
Dr A. Kgasi - Member	150 167	150 167
Dr Z Makatini - Member [2]	-	-
	2 462 526	2 462 526

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

Executive management

2023	Basic salary	Post-employment benefits	Other benefits received	Total
Name				
Dr B Semete-Makokotlela - Chief Executive Officer	3 005 567	-	56 421	3 061 988
Ms P Nkambule - Chief Regulatory Officer	1 459 917	142 826	36 505	1 639 248
Ms C. Reynecke - Chief Operating Officer	2 247 800	-	36 505	2 284 305
Mr G. Miskell - HR Executive	1 394 373	-	36 673	1 431 046
Mr R.B. Gouws - Chief Financial Officer	1 698 253	-	41 712	1 939 965
	10 805 910	142 826	207 816	10 356 552

32. Independent audit committee members remuneration

Independent audit committee members - fee for attending meetings		
Mr E.O. Omolo [1]	-	25 875
Ms Y. Pamla [2]	600	91 526
Mr R Mahabeer [3]	66 833	-
Ms A Chetram [3]	24 326	-
	91 849	120 401

[1] Appointed 2 May 2022 - Resigned September 2022
[2] Appointed 1 April 2021 - Contract ended March 2023
[3] Appointed 1 April 2023

33. Financial instruments disclosure

Categories of financial instruments

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

Financial liabilities

2024	At amortised cost	Total
Trade 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	292 720 106	292 720 106
	299 583 536	299 583 539

Financial assets

2023	At amortised cost	Total
Receivables from non-exchange transactions	2 397 554	2 397 554
Rental deposits	3 541 472	3 541 472
Cash and cash equivalents	329 603 895	329 603 895
	335 542 921	335 542 921

Financial liabilities

2023	At amortised cost	Total
Trade and other payables from exchange transactions	3 967 598	3 967 598
Accrued expenditure	3 210 797	3 210 797
Travel lodge card	606 468	606 468
Income received in advance	256 216 751	256 216 751
	263 901 614	263 901 614

34. Prior period errors

a) During 2022/23 financial year there were refunds that were processed back into the travel fudge card. The refunds represent travel bookings that were cancelled within the airlines' refund policies. The full invoice amount of these cancelled bookings were recognised as expenditure when the travel agency submitted their management fee claim.

b) Take on balances relating to the asset module on Sage evolution resulted in the incorrect accumulated depreciation

c) Thirteenth cheque calculation incorrectly included employees with benefits. The accrual is meant to include cost-to-company employees that has structured a thirteenth cheque.

d) Receivables from exchange transactions were previously accounted for however payments were received in the relevant financial year but not allocated.

e) Additional disclosures were made to the Financial Instruments disclosure. Prior year information relating to Deposits was added

f) Corrections to the calculations for office accomodation commitments resulted in a revised disclosure.

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

Statement of Financial Position		
Property, plant and equipment	-	173 356
Intangible assets	-	2 129
Receivables from exchange transactions	-	(679 000)
Payables from exchange transactions	-	959 709
Income received in advance	-	559 600
Statement of financial performance		
Depreciation and amortisation expense	-	(175 487)
Operating expenditure	-	(138 184)
Employee related costs	-	(821 515)
Fee income	-	119 400

34.1 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

2023	Note	As previously reported	Correction of error	Restated
Receivables from exchange transactions	3	7 100 029	(679 000)	6 421 029
Property, plant and equipment	7	28 179 692	173 356	28 352 048
Intangible assets	8	2 886 878	2 129	2 889 007
Payables from exchange transactions	13	(11 619 758)	959 709	(10 660 049)
Income received in advance	14	(256 776 501)	559 600	(256 216 751)
		(230 131 330)	1 015 796	(229 115 534)

34.1 Prior year adjustments (continued)

Statement of financial performance

2023	Note	As previously reported	Correction of error	Restated
Fee income	19	(206 163 894)	119 400	(206 044 494)
Operating expenditure	27	74 561 410	(246 968)	74 314 442
Audit fees paid		-	108 774	108 774
Depreciation and amortisation	25	6 286 082	(175 497)	6 110 585
Employee related cost	21	224 242 324	(821 515)	223 420 809
Surplus for the year		88 025 932	(1 015 796)	87 010 136

Disclosure

2023	Note	As previously reported	Correction of error	Restated
Financial instruments disclosure				
Financial assets - Deposits	33	-	3 541 472	3 541 472
Commitments	29	110 946 389	(16 575 378)	94 371 011
		110 946 389	(13 033 906)	97 912 483

35. 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 2024	later than 1 month	later than 1 month no later than 3 months	later than 3 months no later than 1 year	later than 1 year and no later than 5 years
• Trade payables from exchange transactions	3 913 306	-	-	-
• Income received in advance	-	-	292 720 106	-
• Travel cards	707 011	-	-	-
• Accrued expenditure	-	2 243 113	-	-

At 31 March 2023	later than 1 month	later than 1 month no later than 3 months	later than 3 months no later than 1 year	later than 1 year and no later than 5 years
• Trade payables from exchange transactions	3 867 568	-	-	-
• Income received in advance	-	-	355 216 751	-
• Travel cards	556 468	-	-	-
• Accrued expenditure	-	3 210 797	-	-

Concentration of risk	Neither past due nor impaired	Past due but not impaired less than two months	Past due but impaired more than two months	Total
Revenue received in advance	292 720 106	-	-	292 720 106
Receivable from non-exchange transactions	-	-	7 996 854	7 996 854
Deposits	4 394 098	-	-	4 394 098
	297 114 204	-	7 996 854	305 111 058

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:

	2024 R	2023 R
35. Risk management (continued)		
Financial instrument		
Cash and cash equivalents	371 616 710	329 609 865
Receivables from non-exchange transactions	7 995 854	2 397 554
Deposits	4 284 068	3 541 472

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

36. 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.

37. Grant funding

37.1 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

37.2 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-55 Target Countries towards strengthening of Safety Monitoring Systems for COVID-19 Vaccines. Refer to note 20 for the grant realised.

37.3 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.

37.4 Global Fund

The NDOH has through Global Fund received 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

	2024 R	2023 R

37.8 United States Trade and Development Agency (USTDA)

SAHPRA received a grant for technical assistance relating to reliance-based protocols for healthcare products training and support which was facilitated through the Boston Consulting Group.

35. Irregular and Fruitless and Wasteful Expenditure [1]

Fruitless and wasteful expenditure	-	342 885

[1] Refer to reconciling notes in Part E the annual report

36. 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	11 413 259	23 923 033
Adjusted for:		
(under) / over expenditure on backlog reduction project	-	(3 791 825)
Aids Nepad	870 020	-
Increase / decrease in backlog reduction project - grant received	-	11 396 700
Increase / decrease in service in kind	(8 840 987)	(3 599 387)
Grant realised	(27 805 836)	(9 990 493)
Over expenditure on impairment of assets	64 574	6 952
Over expenditure on GIZ grant expense	6 161 901	-
Over expenditure on Global fund project expenditure	20 971 537	-
(Increase) / decrease in fee income	(15 405 751)	(27 154 749)
(Increase) / decrease in interest income	(16 858 685)	(11 511 406)
Over / (under) expenditure in employee related costs	(9 629 440)	13 872 103
(Under) / over expenditure on operating leases	(269 384)	1 211 030
Over / under expenditure on operating expenses	17 156 534	799 803
Over expenditure on depreciation	7 394 116	6 001 821
(Under) / over expenditure on contracted services	(512 088)	773 531
Over expenditure on loss of disposal of assets	139 940	136 414
Over expenditure on bad debts	2 303 883	1 530 159
Increase in gain on foreign exchange	140 570	46 350
Increase in sundry income	(12 230)	(55 135)
Increase in asset donated	-	(206 500)
Increase in actuarial gain	(702 130)	(1 930 448)
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.

40. Budgeted differences

Material differences between budget and actual amounts

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

40.2 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.

40.3 Employee Related Costs
Employee related costs are lower than the budget due to vacancies not filled as planned.

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

40.5 Operating Expenses
Operating expenses are higher than budget due to surplus retention approval obtained, therefore funding increased cost on foreign and local external evaluators and expert committees. Also included in operating expenditure is service in kind expenditure which was externally funded by USTDA.

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

40.7 Lease rentals on operating lease
Expenditure is lower due to later occupation than expected of some regional offices.

40.8 Grant revenue
Grant revenue not budgeted for

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

40.10 Grant expenditure
Grant expenditure not budgeted for.

40.11 Operating surplus / (deficit)
SAHPRA received an approval from National Treasury to budget for a deficit.

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