



ANNUAL REPORT 2025/2026



ANNUAL REPORT 2025|2026



CONTENTS

PART A: GENERAL INFORMATION

2

1.	PUBLIC ENTITY'S GENERAL INFORMATION	3
2.	LIST OF ABBREVIATIONS/ACRONYMS	5
3.	FOREWORD BY THE CHAIRPERSON	7
4.	CHIEF EXECUTIVE OFFICER'S OVERVIEW	9
5.	STATEMENT OF RESPONSIBILITY & CONFIRMATION OF ACCURACY FOR THE ANNUAL REPORT	14
6.	STRATEGIC OVERVIEW	15
6.1.	Vision	15
6.2.	Mission	15
6.3.	Values	15
7.	LEGISLATIVE AND OTHER MANDATES	15
7.1	Constitutional Mandate	15
7.2	Legislative Mandate	15
7.3	Policy Mandate	18
8.	ORGANISATIONAL STRUCTURE	20
9.	MEMBERS OF THE BOARD	21
10.	EXECUTIVE MANAGEMENT	22

PART B: PERFORMANCE INFORMATION

24

1.	AUDITOR'S REPORT: PREDETERMINED OBJECTIVES	25
2.	OVERVIEW OF PERFORMANCE	25
2.1.	Service delivery environment	25
2.2.	Organisational environment	32
2.3.	Key policy developments and legislative changes	35
2.4	Service Delivery Charter: SAHPRA Overall achievements for the year 2025/26	35
2.5.	Progress towards achievement of institutional Impacts and Outcomes	39
3.	INSTITUTIONAL PROGRAMME PERFORMANCE INFORMATION	43
3.1.	Programme 1: Leadership and Support	43
3.2.	Programme 2: Health Products Authorisation	51
3.3.	Programme 3: Inspectorate and Regulatory Compliance	57
3.4.	Programme 4: Clinical and Pharmaceutical Evaluation	62
3.5.	Programme 5: Medical Devices and Radiation Control	67
4.	REVENUE COLLECTION	71
5.	CAPITAL INVESTMENT	72

PART C: GOVERNANCE	74
1. INTRODUCTION	75
2. PORTFOLIO COMMITTEES (if applicable)	75
3. EXECUTIVE AUTHORITY	75
4. THE ACCOUNTING AUTHORITY / BOARD	75
5. RISK MANAGEMENT	84
6. INTERNAL AUDIT	84
7. FRAUD AND CORRUPTION	85
8. MINIMISING CONFLICT OF INTEREST	85
9. CODE OF CONDUCT	86
10. HEALTH SAFETY AND ENVIRONMENTAL ISSUES	86
11. BOARD SECRETARY	86
12. SOCIAL RESPONSIBILITY	86
13. AUDIT COMMITTEE REPORT	87
14. B-BBEE COMPLIANCE PERFORMANCE INFORMATION	92
PART D: HUMAN RESOURCE MANAGEMENT	94
1. INTRODUCTION	95
2. HUMAN RESOURCE OVERSIGHT STATISTICS	101
PART E: PFMA COMPLIANCE REPORT	108
1. IRREGULAR, FRUITLESS AND WASTEFUL EXPENDITURE AND MATERIAL LOSSES	109
1.1. Irregular expenditure	109
1.2. Fruitless and wasteful expenditure	110
1.3. Additional disclosure relating to material losses in terms of PFMA Section 55(2)(b)(i) &(iii)	112
2. LATE AND/OR NON-PAYMENT OF SUPPLIERS	112
3. SUPPLY CHAIN MANAGEMENT	112
3.1. Procurement by other means	112
3.2. Contract variations and expansions	113
PART F: FINANCIAL INFORMATION	114
1. REPORT OF THE EXTERNAL AUDITOR	116
2. ANNUAL FINANCIAL STATEMENTS	124

PART A

General Information

1. PUBLIC ENTITY'S GENERAL INFORMATION

REGISTERED NAME:	South African Health Products Regulatory Authority (SAHPRA)
REGISTRATION NUMBER (if applicable):	Not applicable
PHYSICAL ADDRESS:	Building A, Loftus Park 402 Kirkness Street, Arcadia Pretoria, 0083
POSTAL ADDRESS:	Private Bag X828 Pretoria 0001
TELEPHONE NUMBER/S:	(012) 501 0300
EMAIL ADDRESS:	enquiries@sahpra.org.za
WEBSITE ADDRESS:	www.sahpra.org.za
EXTERNAL AUDITORS:	Auditor-General of South Africa
PHYSICAL ADDRESS:	4 Daventry Street, Lynnwood Bridge Office Park, Lynnwood Manor, Pretoria
BANKERS:	ABSA
PHYSICAL ADDRESS:	7th Floor, Absa Towers West, 15 Troye Street, Johannesburg, 2001, South Africa
COMPANY/ BOARD SECRETARY	Advocate Mpho Mphelo

LIST OF TABLES

Table 1: Continental Partners	19
Table 2: Africa Medicines Agency (AMA)	29
Table 2.4.4.1 Leadership and Support	45
Table 2.4.4.2 Health Products Authorisation	53
Table 2.4.4.3 Inspectorate and Regulatory Compliance	59
Table 2.4.4.4 Clinical and Pharmaceutical Evaluation	63
Table 2.4.4.5 Medical Devices and Radiation Control	68
Table 3: ZAZIBONA	29
Table 4: Service Delivery Support Services	35
Table 5: Regulatory Enforcements	36
Table 6: Service Delivery Core Business	38

LIST OF FIGURES

Figure 1: Continental Partners	19
Figure 2: 2025/26 APP Performance	26
Figure 3: Backlog Status as of 31 March 2026	27
Figure 4: General HPA Performance against Service Delivery Targets for 2025/26 FY	36
Figure 5: Regulatory Compliance Investigations as of 31 March 2026	37

2. LIST OF ABBREVIATIONS/ACRONYMS

ABBREVIATION	EXPLANATION
AFS	Annual Financial Statements
ADR	Adverse Drug Reaction
AEFI	Adverse Event Following Immunisation
AGSA	Auditor-General of South Africa
AI	Artificial Intelligence
AMA	African Medicines Agency
AOP	Annual Operational Plan
AUDA	African Union Development Agency
B-BBEE	Broad-Based Black Economic Empowerment
CEO	Chief Executive Officer
COVID-19	Coronavirus Disease
CSIR	Council for Scientific and Industrial Research
DPSA	Department of Public Service and Administration
EE	Employment Equity
EWHP	Employee Wellness and Health Programme
FINCO	Finance Committee
FY	Financial Year
GMP	Good Manufacturing Practice
GRAP	Standards of Generally Recognised Accounting Practice
GWP	Good Warehouse Practice
GxP	Good Manufacturing Practice, Good Warehouse Practice, Good Clinical Practice, Good Distribution Practice and Good Vigilance Practice
HPA	Health Products Authorisation
HR	Human Resource
HRREMCO	Human Resource and Remuneration Committee
ICT	Information Technology and Communication
INCB	International Narcotics Control Board
IVDs	In Vitro Diagnostics
MD	Medical Device
ML	Maturity Level

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

3. FOREWORD BY THE CHAIRPERSON



Dr Thapelo Motshudi

Chairperson of the Board

3.1 Introduction

A cursory assessment of the sociopolitical and economic landscape, both locally and internationally, demonstrates the increasing role of regulators across all fields of human endeavour. Regulation is becoming progressively essential, not to hamper growth, innovation, or human activity, but rather to provide guardrails and protection to the public in a rapidly changing world.

3.2 Overview of the entity's strategy and the performance of the entity

The entity continues to pursue regulatory excellence guided by the latest internationally recognised practices, strides made on harmonisation efforts and leveraging knowledge sharing systems in the regulatory environment. We are also cognisant of the gaps in the current legislative framework, particularly in the use of artificial intelligence and regulation of advanced therapies medicinal products. We will work various stakeholders and role players to propose solutions for the identified gaps in the regulatory framework and continually assess the preparedness of the regulator responding to the innovations and areas that the current legislative framework did not anticipate.

3.3 Strategic Relationships

We continue to engage with continental and international partners in the pursuit of attaining all the requisite global benchmarks and markers of excellence.

3.4 Challenges faced by Board

Regulators are challenged to build excellent internal capacity to keep pace with novel technologies and increasing demands and do so under austerity measures and poor economic growth. Both latter conditions conspire to reduce the amount of funding available to meet key objectives and expanding mandates.

Anxieties are persistently expressed about the potential risks of unregulated AI, counterfeit medicines, predatory financial service providers, and many other areas of concern.

However, SAHPRA intends to meet these increasing challenges head-on, grounded in our ongoing commitment to public health, and through strong governance, integrity, and an unambiguous regulatory regime. One of the central pillars of this strategy is the prioritisation of reducing the regulatory backlog.

3. FOREWORD BY THE CHAIRPERSON

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

The Board has identified the backlog as one of the key areas whose resolution will enhance public confidence in the work of the regulator. This commitment is evidenced by ongoing investment in digital tools and quality systems. The Board's long-term vision is to maintain good governance and strategic oversight, while providing the mandatory leadership necessary to ensure SAHPRA remains one of the credible, responsive, and respected players in South Africa's healthcare system.

3.6 Acknowledgements /Appreciation

On behalf of the Board, I would like to sincerely thank all the committed and diligent staff of SAHPRA for all the work they do, guided by the conscientious CEO and management team. Our work is also enabled by the Ministry of Health and related officials, whose efforts and support are not unnoticed. We also acknowledge the role of industry in holding us to account and sharing knowledge, the expertise of external specialists, and feedback from the broader public.

3.7 Conclusion

We remain committed to protecting public health, refining our regulatory processes to achieve our mandate while working together with our stakeholders, and enabling access to health products by embracing innovation. Patients will always be at the core of our operational imperatives and ensuring that there is no compromise on our mandate. Our strategy, among other aspects, is to unlock efficiency through digitalisation of our regulatory pathways and enabling access to health products.



Dr Thapelo Motshudi

Chairperson of the Board

South African Health Products Regulatory Authority

31 August 2026

4. CHIEF EXECUTIVE OFFICER'S OVERVIEW



Dr Boitumelo Semete-Makokotlela

Chief Executive Officer

It is my privilege to present the South African Health Products Regulatory Authority (SAHPRA) Annual Report for 2025/26. This year underscored the vital role of a strong, science-based regulator in protecting public health. In a complex healthcare landscape compounded by widespread distribution of unregistered medicines, SAHPRA remained committed to ensuring that medicines, medical devices, and other regulated health products available in South Africa are safe, effective, of high quality and good performance. Every decision was guided by our core principle: safeguarding the health and wellbeing of South Africans. A defining feature of this financial year was SAHPRA's strengthened enforcement and regulatory oversight to protect public health.

Through product recalls, inspections, post-market surveillance, and decisive action against unregistered and non-compliant health products, we demonstrated that South Africa's regulatory system is responsive and effective. Working closely with industry, healthcare professionals and law enforcement partners, we acted swiftly to identify and address risks, reinforcing public confidence while keeping patient safety at the centre of everything we do.

4.1 General financial review of the public entity

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, except for the changes set out in the changes of accounting policy note. Assets, liabilities, revenues and expenses were not offset, except where offsetting is either required or permitted by a Standard of GRAP.

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.

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

4.2 Spending trends of the public entity

SAHPRA's total revenue from a budgeted on the comparative basis amounted to R515.7 million against an adjusted budget of R495.5 million. The variance of R20.2 million was mainly due to exceeding the budget for revenue and additional external funding support received during the year.

The additional expenditure was allowed due to an unbudgeted external financial support received which is accounted for as additional revenue. The overall result on an accrual accounting basis was an accounting surplus amounting to R33.7 million and exceeding the current ratio target of 1:1 which is mainly due to delayed implementation of the job evaluation project and delayed filling of vacancies. The focus was on maintaining previous audit outcomes as well as positioning SAHPRA for financial sustainability.

The following are worth noting:

- Achieved an unqualified audit with no material findings (Clean Audit 2024/25).
- Exceeded the budget set for fee income.
- Identified irregular, fruitless and wasteful expenditure were condoned, written off or recovered during the financial year.
- Enforced implementation of Regulated fees to ensure financial sustainability.
- Completion of a project to review deferred revenue balances for the periods 2018/19 to 2022/23 resulting in identification and correction of revenue recognition during these periods, reducing the deferred revenue liability balance and increase in retained surpluses.

4.3 Capacity constraints and challenges facing the public entity

SAHPRA continues to experience challenges in attracting and retaining scarce and critical skills, particularly in highly technical areas, due to intense competition within the regulatory and pharmaceutical sectors. By the close of the 2025/26 financial year, the workforce expanded from 331 to 376 employees. These comprised contract appointments, permanent placements, Community Service Pharmacists, and learnership participants.

Despite available funding, only 82% of the budgeted positions (106 out of 129) were successfully filled. Recruitment delays were primarily attributed to the limited availability of panel members for selection processes, the time required to complete mandatory pre-employment verification checks, and the need to re-advertise positions due to unsuitable candidate pools or declined offers. These constraints have contributed to capacity gaps across the organisation and have placed additional workload pressures on existing employees.

To mitigate these challenges, SAHPRA has established strategic partnerships with universities and industry stakeholders to broaden the reach of recruitment advertisements and access a larger pool of potentially suitable candidates. This collaborative approach aims to strengthen talent acquisition efforts and ensure the organisation's ability to deliver on its mandate

4.4 Discontinued key activities / activities to be discontinued

There are no activities that have been discontinued in the year under review.

4.5 New or proposed key activities

SAHPRA is amongst Africa's national medicine regulatory authorities that have achieved the ML3 ranking for Vaccines. Attaining ICH membership, SAHPRA has been accepted as a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), following an ICH assessment of compliance with requirements for membership including a formal presentation outlining SAHPRA's interest, progress, and milestones in implementing ICH principles.

SAHPRA was designated an RCORE in all nine (9) regulatory functions as per the WHO GBT framework with regards to regulatory oversight of vaccines including the lot release function. Since 2024, SAHPRA has been on a journey of capacity building and training in vaccine regulatory oversight across the above-mentioned regulatory functions, with the aim of achieving this milestone by 2026.

4.6 Requests for rollover of funds

SAHPRA annually declares all surpluses or deficits to the relevant Treasury from the period 1 August to 31 August of each year, using its audited annual financial statements as the basis for calculation of surpluses or deficits. SAHPRA 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, SAHPRA invests surplus funds with the Corporation for Public Deposits.

SAHPRA's applications to retain surpluses have been approved by National Treasury. Based on historical experiences, a request to retain the current year surplus will be made before 31 August 2026

4.7 Supply chain management

SAHPRA continued with engagements with internal and external stakeholders to support the stabilisation of the Stakeholder Portals and Systems including user acceptance testing (UAT) and other relevant ICT updates related to service delivery, operational efficiency and security awareness. This was to address challenges with the Business process that were digitised and continue to be addressed.

4.8 All concluded unsolicited bid proposals for the year under review

The organisation did not receive any unsolicited bids in the financial year under review.

4.9 Whether SCM processes and systems are in place

SAHPRA, a Schedule 3A public entity under the Public Finance Management Act (PFMA), manages its assets according to its Asset Management Policy. Key highlights include: No infrastructure projects were undertaken, and no facilities were closed or downgraded. Lease arrangements for office accommodation are in place and appropriately disclosed. Asset acquisitions for the year totalled R11.5 million and intangible asset work in progress amounting to R14.6 million relating to AI software tools received in kind to assist with the

regulatory evaluation processes. Obsolete assets, such as old furniture and IT equipment, were disposed of responsibly, with most items fully depreciated. The SCM systems remain functional and compliant with a R0 value balance reported for irregular, fruitless and wasteful expenditure.

4.10 Challenges experienced and how resolved

SAHPRA experienced challenges that affected performance, resulting in the underachievement of certain planned targets. This was primarily due to capacity constraints, which impacted time-bound regulatory indicators and functions requiring a high level of technical expertise and inter-programme coordination. To address these challenges, additional staff were appointed to strengthen technical functions. Throughput and reporting timelines were affected by delays arising from initial challenges associated with the implementation of the new system. These challenges were mitigated through stakeholder engagement and continuous refinement of the system.

SAHPRA experienced challenges in attracting and retaining talent, particularly in technical functions due to competition in the health, regulatory and pharmaceutical job market. This was mitigated by growing the staff complement utilising external grant funding as an interim approach to appoint staff on fixed term contracts then absorb the candidates onto SAHPRA funded positions

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

We have reviewed the public entity's implementation plan for audit issues raised in the prior year and we are satisfied that the matters have been adequately resolved except for the following:

HR policies approved by Board and submitted to the Minister for consultation. More policies recommended by HRRESCO for Board approval during March 2026. Digitisation: Phase 2 of implementation of the Regulatory system in progress. Four business processes digitised and additional four would be produced in the new financial year.

The committee has noted the audit outcome as issued by the Auditor General of South Africa (“AGSA”) who conducted the audit, with the resultant unqualified audit opinion for the period under review. The committee independently engaged with the AGSA where necessary and is satisfied that it has adequately discharged its legal and regulatory responsibilities. The committee has reviewed and accepted AGSA’s final Management Report and Audit Opinion relating to the Annual Financial Statements, Audit of Performance Information and compliance with legislation as well as the audit findings issued by the AGSA which are to be addressed in accordance with the mitigation action plans agreed to between SAHPRA and the AGSA. The committee reviewed SAHPRA’s audit action plan for the audit issues raised in the prior year and is satisfied that matters continue to be satisfactorily resolved.

The committee concurs and accepts the conclusions of the AGSA on the annual financial statements and concluded that the audited annual financial statements be accepted and read together with the report of the Auditor-General.

4.12 Outlook/ Plans for the future to address financial challenges

In assessing the achievement of outputs against the planned targets, the public entity should consider the relationship between performance and the resources available to it, particularly its financial resources. Accordingly, the following financial information is presented. The information is consistent with the Annual Financial Statements.

4.13 Events after the reporting date

There are no events that have been identified after the reporting date.

4.14 Economic Viability

SAHPRA’s total revenue from a budgeted for comparative basis amounted to R515.7 million against an adjusted budget of R495.5 million. The variance of R20.2

million was mainly due to better than expected fee income generation of R20.6 million due to the revised fee regulation implemented in February 2025.

Better than anticipated revenue collection occurred due to the impact of the revised Medicines Fee Regulation Gazetted in February 2025 and projects relating to clearing of backlogs in certain evaluation areas.

4.15 Acknowledgement/s or Appreciation

SAHPRA’s maturity is reflected in its growing global reputation. Our staff played active roles in international and regional regulatory harmonisation initiatives such as those led by the African Medicines Agency, contributing to global standards and sharing South Africa’s expertise. Participation in international committees, collaborative reviews, and capacity-building initiatives helps shape regulatory science and align SAHPRA with best practices. This strengthens our capability and benefits patients, healthcare providers, and industry.

None of these achievements would have been possible without the dedication and professionalism of the SAHPRA Board, Executive Management, employees, expert committees, and partners across government, academia, industry, and the international community. Every milestone reflects the commitment of individuals who uphold the highest standards of excellence, integrity, and public service. I extend my sincere appreciation to all who support our mission to safeguard public health.

4.16 Other (information that needs to be communicated to users of AFS)

The organisation does not have any other information to report to the users of the annual financial statements.



Dr Boitumelo Semete-Makokotlela

Chief Executive Officer

South African Health Products Regulatory Authority

Date: 31 August 2026

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

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

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

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

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

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

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

The Accounting Authority is responsible for establishing and implementing a system of internal control 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 2026.

Yours faithfully



Chief Executive Officer
Dr Boitumelo Semete-Makokotlela
Date: 31 August 2026



Chairperson of the Board
Dr Thapelo Motshudi
Date: 31 August 2026

6. STRATEGIC OVERVIEW



7. LEGISLATIVE AND OTHER MANDATES

7.1 Constitutional Mandate

The Constitution of the Republic of South Africa, 1996, places an obligation on the state to progressively realise socio-economic rights, including access to healthcare. Section 27 of Chapter 2 of the Bill of Rights of the Constitution states the following about healthcare, food, water and social security:

- Everyone has the right to have access to healthcare services, including reproductive healthcare, sufficient food and water and social security as well as appropriate social assistance if they are unable to support themselves and their dependants.
- The state must take reasonable legislative and other measures within the ambit of its available resources to achieve the progressive realisation of each of these rights, and no one may be refused emergency medical treatment

7.2 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 (hereinafter 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.

7.2.1 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 understood alongside other laws and policies that relate to health, are to:

- Unite the various elements of the national health system into a common goal to actively promote and improve the national health system in South Africa;
- Provide a system of cooperative governance and management of health services within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality health care services;
- Establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourage participation;
- Promote a spirit of 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.

7.2.2 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, radiation control, clinical trials, and other matters related to the public interest.

The Act also provides for the registration and control of veterinary medicines in such a way as to ensure that they are produced, distributed and used without compromising human and animal health. Antimicrobials intended for 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 concluded timeously;
- The periodic re-evaluation or re-assessment and ongoing monitoring of medicines, medical devices, radiation-emitting devices and radionuclides;
- The investigation, monitoring and analysis of evidence of existing and new adverse events as well as reactions, interactions and signals emerging from

post-marketing surveillance and vigilance activities, while ensuring that these are acted upon;

- That compliance with existing legislation is promoted and achieved through a process of active inspection and investigation; and
- That clinical trial or clinical performance study protocols are assessed according to prescribed scientific, ethical and professional criteria and defined standards.

In executing its functions, the Authority may:

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

7.2.3 Hazardous Substances Act, 15 of 1973

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

SAHPRA is only responsible for regulating Group III and Group IV hazardous substances.

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

7.2.4 Other Related Legislation

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

Drugs and Drug Trafficking Act, 140 of 1992

Provides for the prohibition of the use or possession of, or the dealing in, drugs and of certain acts relating to the manufacture or supply of certain substances or the acquisition or conversion of the proceeds of certain crimes, the obligation to report certain information to the police, the exercise of the powers of entry, search, seizure and detention in specified circumstances, the recovery of the proceeds of drug trafficking and related matters.

In relation to cannabis, on 18 September 2018, the Constitutional Court declared sections 4(b) and 5(b)

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

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

Foodstuffs, Cosmetics and Disinfectants Act, 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, 50 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 16(d), provides for the possession of medicines or 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 license as contemplated in section 22C of the Medicines and Related Substances Act. The SAPC has, in terms of Section 38A 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 enacts its role 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 representation at 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 responsibility 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 affect the country's enhancement of access to this medicinal product. As SAHPRA continues to mature into its role, it is becoming increasingly evident that there is a critical need to harmonise roles and responsibilities to avert the risk of an internal leadership vacuum or duplication of efforts and subsequent potential "conflict".

7.3 Policy Mandate

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

percentage of Cannabinoids and Tetrahydrocannabinol in these products. In addition the Department of Agriculture will also report to the International Narcotics Control Board (INCB) on the THC quantities utilised under the permits it issues.

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

Continental Partners

One of SAHPRA's key strategic objectives is strengthening regulatory collaborations with other national regulatory agencies or similar organisations. The objectives of entering into these agreements are to:

1. Confidentiality Agreements
Facilitate the sharing of confidential regulatory documents, including, but not limited to, assessment reports and policy documents.
2. Memoranda of Understanding (MoUs)
Build capacity in regulatory science and provide training in specific regulatory areas.
Promote the exchange of information and the sharing of documentation to strengthen regulatory processes and decision-making.
3. Facilitate access to confidential information relating to medicines, medical devices and in vitro diagnostics (IVDs).
4. Share regulatory best practices

SAHPRA has entered into agreements with regulators across the African continent, including SADC regulators, to strengthen regulatory collaboration and facilitate joint reviews.

Figure 1: Continental Partners



Table 1: Continental Partners

ZAZIBONA (Zambia, Zimbabwe, Botswana, Namibia, The Democratic Republic of Congo, Tanzania, Malawi, and Mozambique, SAHPRA).

The Egyptian Drug Authority (EDA)

Ghana Food and Drugs Authority (Ghana FDA)

Botswana Medicines Regulatory Authority (BOMRA)

Nigeria National Agency for Food and Drug Administration and Control (NAFDAC)

Medicines Control Authority of Zimbabwe (MCAZ)

Ethiopian Food and Drug Authority (EFDA)

Namibia Medicines Regulatory Council (NMRC)

Rwanda Food and Drugs Authority FDA

WHO ML3 African Regulators: Ghana's (FDA), (NAFDAC) of Nigeria, Rwanda (FDA), the Senegalese Pharmaceutical Regulatory Agency (ARP), SAHPRA, Tanzania Medicines & Medical Devices Authority (TMDA), MCAZ

8. ORGANISATIONAL STRUCTURE



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

			
Dr Thapelo Motshudi (Chairperson)	Prof Glenda Gray (Vice-Chairperson)	Dr Alfred Kgasi	Dr Chevon Clark
			
Dr Johanna Gouws	Dr Tobeka Boltina	Ms Mmatebogo Nkoenyane	Mr Anthony Ngcezula
			
Prof Rajesh Mahabeer	Mr Nkosenhle Ngongoma	Mr Moses Moselekwa	

10. EXECUTIVE MANAGEMENT

		
Dr Boitumelo Semete-Makokotlela Chief Executive Officer	Mr Regardt Gouws Chief Financial Officer	Mrs Thavendree Gopal Chief Regulatory Officer
		
Ms Christelna Reynecke Chief Operations Officer	Ms Lindiwe Modisakeng Executive Manager: Human Resources	Adv Mpho Mphelo Board Secretary





PART B

Performance Information

1. AUDITOR'S REPORT: PREDETERMINED OBJECTIVES

The AGSA/auditor currently performs certain audit procedures on the performance information. The level of assurance provided may be reasonable (an opinion) or limited (a conclusion) or none (findings) as predetermined by the AGSA. Assurance in the form of an audit opinion or conclusion on the usefulness and reliability of the reported performance information is currently included in the management report. Material findings are reported in the auditor's report.

Refer to page 121 of the Report of the Auditors, published as Part F: Financial Information.

2. OVERVIEW OF PERFORMANCE

2.1 Service delivery environment

2.1.1 Overall performance

SAHPRA is an autonomous public entity accountable to the Minister of Health. SAHPRA has made significant progress in implementing organisational transformation including;

- Digitalisation of business processes in the core business functions to sustain business as usual
- Building internal capabilities and expertise to limit reliance on external experts
- Align the organisation with global standards in the context in which it operates; and interacts, responds and adapts to situations, its stakeholders, and the external environment

SAHPRA remains among the Africa's national medicine regulatory authorities that have achieved the ML3 ranking for Vaccines.

Attaining ICH membership, SAHPRA has been accepted as a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), following an ICH assessment of compliance with requirements for membership, including a formal presentation outlining SAHPRA's interest, progress, and milestones in implementing ICH principles.

SAHPRA was designated an RCORE in all nine (9) regulatory functions as per the WHO GBT framework with regards to regulatory oversight of vaccines including the lot release function. SAHPRA since 2024 has been on a journey of capacity development and training in vaccine regulatory oversight for the above- mentioned regulatory functions, an implementation it hopes to reach by 2026.

Maintaining ISO 9001 certification has aligned SAHPRA with the Regional Strategy for the Regulation of Medicinal Products which provides that all member states must have national regulatory authorities for medicines that are functional and with systems of quality management by 2026.

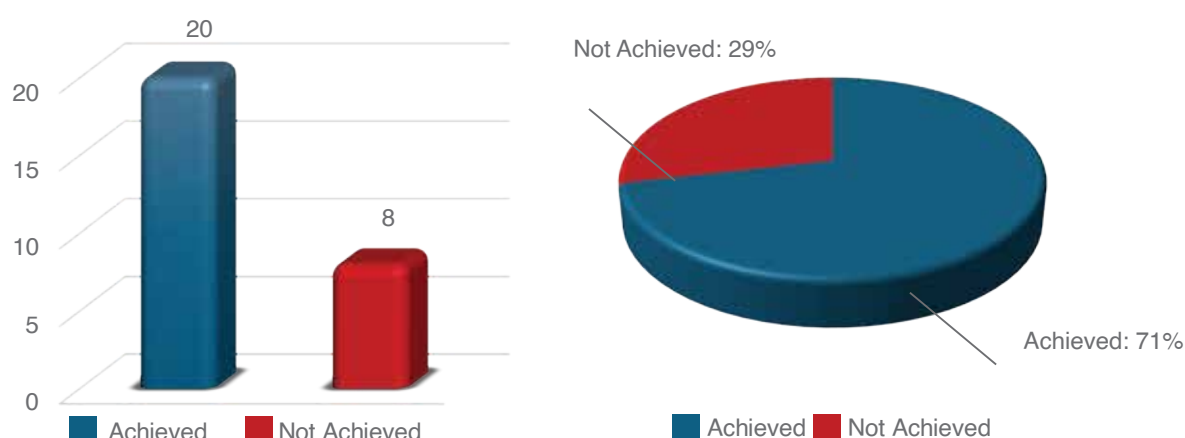
SAHPRA's areas that still need improvement relates to full implementation of the digital transformation strategy and subsequent multi-year roadmap, financing and filling of critical roles, achievement of all targets in the core function of the Authority:

- Issuance of licences for new Good Manufacturing Practice and Good Warehouse Practice within the target timelines.

- Finalisation of new product and generic applications in the target timelines.
- Publications and implementation of regulations for Medical Devices and IVDs as well as Complementary Medicines.
- Implementation of pharmacovigilance strategy at a national level in partnership with the NDOH and Provincial health departments.
- Regular post market surveillance of health products.

According to the planned outcomes outlined in the 2025/2026 Annual Performance Plan, 28 targets were planned and 20 were achieved, preserving the audited 71% result.

Figure 2: 2025/26 APP Performance



During the period under review, SAHPRA performance can be summarised as follows:

- Current ratio of 1≥1 was maintained by achieving 1:1.4.
- Clean audit opinion is obtained for the 2024/25 financial year.
- 94 New Chemical Entities were finalised within for the financial year.
- 82.48% of type II variations finalised within 200 working days.
- SAHPRA successfully managed to maintain the International Organisation for Standardisation (ISO) 9001 Certification by SABS.
- 70% of new GWP related licences finalised within 125 Days.
- 92% permits were finalised within 20 working days.
- 82% of recalls and related alerts published within 7 working days.
- 133% medical device establishment license applications were finalised within 90 working days
- 126% applications for listed-electronic products finalised within 50 Working days.

2.1.2 Challenges

The Authority experienced challenges that affected performance, resulting in the underachievement of certain planned targets. This was primarily due to capacity constraints, which impacted time-bound regulatory indicators and functions requiring a high level of technical expertise and inter-programme coordination. To address these challenges, additional staff were appointed to strengthen technical functions. Delays linked to teething challenges on new system and portal

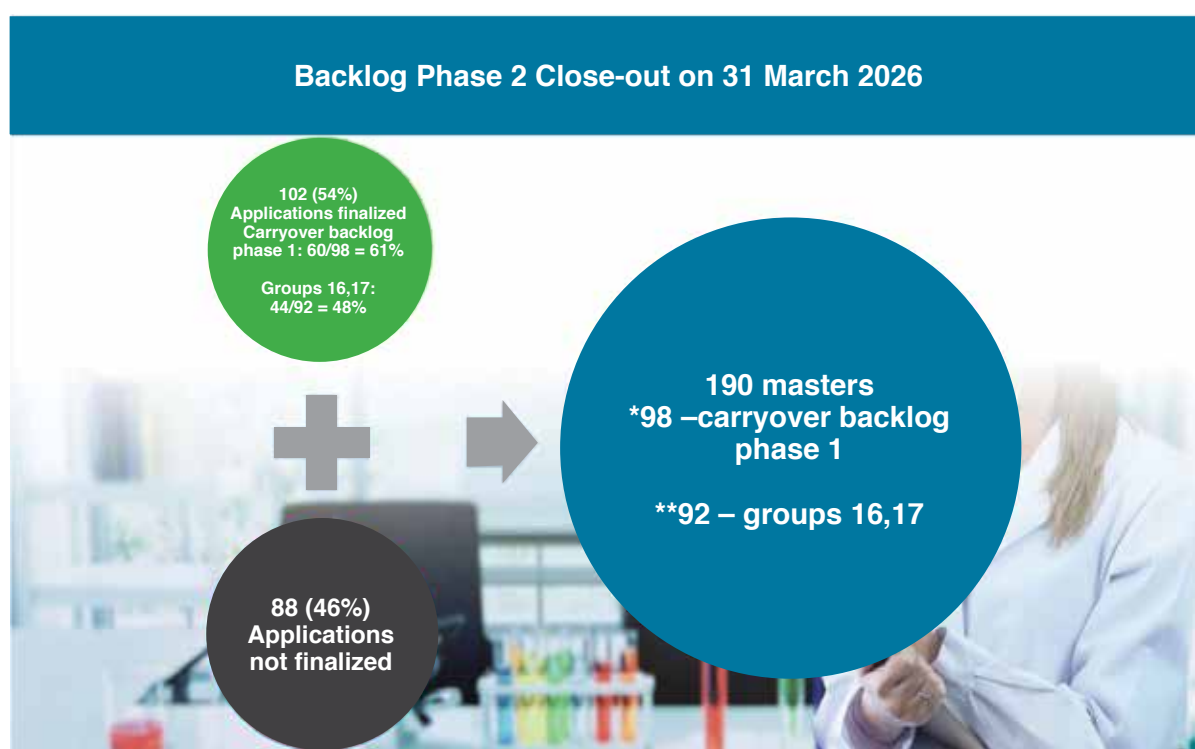
challenges, which affected throughput and reporting timelines were addressed through stakeholder engagements and refinement of the systems.

Challenges in attracting and retaining talent, particularly in technical functions due to competition in the health, regulatory and pharmaceutical job market. This was mitigated by growing the staff complement utilising external grant funding as an interim approach to appoint staff on fixed term contracts then absorb the candidates onto SAHPRA funded positions.

In terms of the targets that experienced challenges resulting in non-achievement, the Authority has identified the reasons for deviations and has put in place relevant plans and mitigating measures.

SAHPRA closed out phase 2 of the **Backlog** project. Backlog Phase 1 & Phase 2 completed, 81% & 54% reduction in applications backlog respectively. Phase 3 commenced 01 April 2026 with 340 ringfenced applications.

Figure 3: Backlog Status as of 31 March 2026



Medical Devices, including IVDs and Radiation Control had challenges retaining talent due to resignations/retirement/dismissal. The manual handling of applications and management of review process remained a challenge within programme 5. The medical device registration was unable to manage the feasibility through digital system and resorted to an excel tracker. The radiation control function still requires stabilising its systems to operate an efficient database while the new solution is still under configuration.

2.1.3 Developments

Health Products Authorisation (HPA) delivered a strong overall performance during the 2025/26 financial year, maintaining its strategic role in ensuring timely access to safe, effective and quality medicines for the South African public through efficient regulatory authorisation processes. In alignment with SAHPRA's strategic outcome of "Efficient

and effective regulatory practices maintained”, the programme achieved 100% of its Annual Operational Plan (AOP) indicators and 67% of its Annual Performance Plan (APP) targets, reflecting sustained operational resilience despite capacity constraints.

Key outputs included finalisation of 94 New Chemical Entity (NCE) master applications against an annual target of 60, significantly exceeding target performance and the annual goal. The strong performance was driven by improved adherence to evaluation timelines and stronger coordination between technical evaluation units.

The programme also finalised 376 generic master applications against an annual target of 420, achieving 90% of the annual target. Whilst below target, this remained a substantial output given the operational pressures experienced during the reporting period. Additionally, 83% of Type II variations were finalised within 200 working days, significantly exceeding the target of 50%, while screening efficiency for Marketing Authorisation applications reached 90% cumulative within 90 working days. Priority and reliance pathways achieved 100% compliance with applicable timelines, supporting faster access to critical medicines and improving stakeholder confidence in regulatory responsiveness.

The primary challenge during the year related to temporary decline in generic medicines throughput, particularly during Quarters 3 and 4. This was largely due to competing priorities within the Inspectorate Unit, where inspectors and external evaluators were redirected toward backlog clearance activities between January and February 2026. This created temporary capacity constraints for generic application reviews.

Corrective measures implemented included additional evaluator placements, weekly resource allocation reviews, greater use of external reviewers, targeted recruitment, and increased process automation through DocuBridge scripting and digital workflow improvements. These interventions are expected to restore full generic throughput by the end of Q2 of 2026/27 and strengthen long-term operational sustainability.

No significant external legislative or regulatory developments outside SAHPRA's control materially affected service demand or programme delivery during the reporting period. Stakeholder engagement remained strong through Regulatory Technical Forum (RTF) meetings held in 2025/26 (4 in total), where industry associations expressed support for the reliance and variation pilot initiatives, particularly in relation to new registrations and variations management.

Programme 2 contributed directly to SAHPRA's strategic outcome of “Efficient and effective regulatory practices maintained” and supported the broader 2024-2029 Medium Term Development Plan objective of improving access to safe, effective and quality health products for the South African public.

These outcomes directly contributed to faster market access for critical medicines, strengthened reliance pathway implementation, and improved regulatory turnaround times for both industry stakeholders and public health priorities. Backlog reduction initiatives and process automation reduced administrative burden and improved predictability in regulatory delivery.

Programme 2 also supported financial sustainability through revised variation pricing logic, new combined variation codes, and strengthened digital workflow controls that improved fee recognition and operational transparency.

PEM Unit has performed exceptionally well regarding the Lot Release, the APP target, despite that some operational obligations were dependent on other stakeholders and ICT systems.

Lot Release is a function of SAHPRA in terms of Regulation 15 of the Medicines and Related substances Act as amended. This ensures that all vaccines intended for use in South Africa are Lot tested to provide independent assurance of the quality of the vaccines for public use. SAHPRA issues Lot Release certificates to confirm approval and rejection notices where vaccines are not approved.

The Lot Release function of the Biologicals unit has maintained a high level of performance in the Lot Release function having achieved 98% of Lot Release requests finalised within 50 working days and has exceeded the target of 95%. This is attributable to efficiency of the SAHPRA Service Desk Portal and ongoing process optimisation by both SAHPRA staff and SANCLBP (Laboratory). This included close collaboration with industry stakeholders and reliance partners.

Continental Review through AMA and ZAZIBONA

The ZAZIBONA is a centralised evaluation pathway for the purpose of issuing a recommendation, for registration or non-registration, of a product after evaluation of the quality and safety aspects of the product under consideration. Following a recommendation for registration of a particular product, an Applicant may submit the products' application for consideration for registration by SAHPRA through the ZAZIBONA reliance procedure. The scope of the ZAZIBONA reliance procedure includes product applications that have received a recommendation for registration from ZAZIBONA.

Table 2: Africa Medicines Agency (AMA)

Application No	Generic Name	AMA Ref No.	Applicant Name	SAHPRA Application Status	Days tracking with SAHPRA
610291 610292	Capivasertib 160 mg Capivasertib 200 mg	AMA-00008 AMA-00009	AstraZeneca Pharmaceuticals	Registered 03/02/2025	120 days
610848	Avelumab 20 mg/mL	AMA0043	Merck (Pty) Ltd	Registered 31/03/2026	63 days
610587610588	Asfotase alfa 40 mg/ml & 100 mg/ml	AMA0048AMA0049	AstraZeneca Pharmaceuticals	Registered 31/03/2026	68 days
610807	Eculizumab Each vial of 30 mL contains 300 mg of eculizumab (10 mg/mL)	AMA0047	AstraZeneca Pharmaceuticals (Pty) Ltd	Registered 17/03/2026	54 days

Table 3: ZAZIBONA

SAHPRA Application No	Generic Name	Applicant Name	RC meeting date	Working days (WDs) to final decision (should be within 90 WDs)
610186	ROCURONIUM BROMIDE 10 mg/mL injections	Innovata Pharmaceuticals (Pty) Ltd	20 January 2026	93

Clinical Evaluation Management (CEM) delivered a strong overall performance during the 2025/26 financial year, maintaining its strategic role in ensuring:

- Timely access to unregistered medication (Category A).
- Approval to conduct the clinical trials.
- Review the safety and efficacy of orthodox medicine for registration and life cycle management.
- Continuously detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) to protect patients and promote public health.

The output for the sale of unregistered Category A (human) medicines (Section 21) finalised within 3 working days was 93% as compared to annual target of 95%. In quarter 1 and quarter 2, the programme experienced challenges with the new system (Section 21 SAHPRA Engagement portal) employed to authorise unregistered Category A applications. Corrective measures implemented included working closely with the system developers to stabilise and optimise the Section 21 portal.

The programme was able to detect and mitigate 23% of Clinical Trials safety signals within 80 working days against 50%. This is due to increased number of reports received, manual and fragmented processes, limited technical and administrative capacity to manage the applications. The corrective measures to be implemented in the next financial year was to recruit 2 additional Administrative Officers to assist with capturing SAE on the Vigiflow system, improve on the process efficiencies by digitisation of the work streams and implementation of E2B platform for SAE reporting.

The programme is responsible for reviewing a possible causal relationship between an adverse event and drug safety. This ability of the pharmacovigilance system to detect signals underscores its relevance in ensuring the safe use of medicines. The reports that were reviewed by the programme did not detect any safety signals that have had a high impact on public health.

The programme managed to assess 51.45% of reports on health product significant safety issues within 60 working days, as compared to an annual target of 70%. The primary challenge is limited resources to support the function. The corrective measures to be implemented in the next financial year is to appoint internal assessors.

The output of safety awareness held 32 against the annual target 12, significantly exceeding the target performance and the annual goal of 20. The additional contract resource contributed to improvement of pharmacovigilance outreach.

The Inspectorate and Regulatory Compliance in 2025/26 FY, delivered 75% of its Annual Performance Plan (APP) targets, achieving 3 of 4 set targets.

This outcome reflects a positive trajectory in overall performance. To sustain this momentum and ensure full target achievement within the SAHPRA's core mandate, priority attention is required in the following areas:

- Timely issuance of licences for new Good Manufacturing Practice (GMP) facilities within prescribed turnaround times.
- Development and implementation of an effective backlog reduction strategy for GMP inspections.

As part of continuous strategic partnership goals to deepen SAHPRA collaborative efforts through implementation of specific projects and to remain agile and effective. In October 2025, the Inspectorate Unit in collaboration with CSIR African Bio-Manufacturing Workforce Development and Training Programme offered a Biomanufacturing and Good

Manufacturing Practice course. The course ran for over four weeks, comprising two weeks of online sessions and another two weeks of compulsory in-person training at the CSIR. The course was offered to 27 African manufacturers, scientists and regulators showcasing biomanufacturing considerations, as well as the insights of the regulatory framework. A key objective of this programme was to assist in growing and developing the biomanufacturing sector on the African continent through training and innovative bioprocess solutions and biomanufacturing considerations, as well as the insights of the regulatory framework. A key aspect of this course was to provide hands-on training and skills development that will enable local manufacturing of biopharmaceutical and other biological products.

SAHPRA's work on the continent also involved having experienced representation on the Good Manufacturing Practices (GMP) Technical Committee for the African Medicines Regulatory Harmonisation (AMRH), where SAHPRA chaired the committee and participated in facilitating and overseeing the training of African Inspectors.

PIC/S reassessment 2025/26

PIC/S finalised their reassessment of SAHPRA in June 2025. SAHPRA CAPA response was submitted to PIC/S in October 2025. The outcome of the reassessment will be finalised by PIC/S in the annual meeting in 2026. SAHPRA attended the PIC/S annual meeting in Hong Kong in November 2025 and participated in the PIC/S Executive Committee discussion meeting. GMP inspectors also attended the PIC/S training on Advanced Technologies in Pharmaceutical Manufacturing in Hong Kong.

The Launch of the National Action Plan (NAP) in September 2025 for Prevention, Detection, and Response Strategies on Substandard and Falsified Medical Products.

Substandard and Falsified (SF) medical products present a significant and escalating threat to national and global health systems. The global reach and routes to market of SF medical products have grown exponentially with the ever-increasing demand for medical products. Their entry into the supply chain undermines efforts to ensure access to quality, safe, and efficacious medicines. WHO developed a Draft Handbook for National Action Planning for Prevention, Detection and Response Strategies on Substandard and Falsified Medical Products. This document outlines a structured approach across 13 pillars. Launch of the National Action Plan on Substandard and Falsified (SF) Medical Products. The South African pilot seeks to adapt, test, and implement the handbook's framework. This serves both the objectives of strengthening the national health system and contributing to WHO's global learning agenda. The outcome of the South African NAP pilot will inform the WHO on its implementation regarding the NAP Handbook to member states globally. The WHO selected South Africa to pilot a National Action Plan (NAP) to combat SF medical products. The support for the South African Health Products Regulatory Authority (SAHPRA) to lead this pilot was formally received from the Director-General of the National Department of Health on 31 January 2024. In September 2025 SAHPRA through the leadership of the Minister of Health, Dr Aaron Motsoaledi launched a successful, inclusive, and collaborative process initiative. The Steering Committee comprised key national stakeholders including the National Department of Health, South African Revenue Service, Department of Justice, South African Police Service, National Prosecuting Authority, Agriculture, Social Development, Border Management Authority, and others. This Committee has provided governance oversight, and a Technical Working Groups (TWGs) were established to develop and implement activities aligned with the WHO pillars.

NDS7 Launch 2025/26

As part of SAHPRA's commitment to innovation, process efficiency, and digital transformation and to enable expedited access to life-saving medicines and to drive the operational efficiencies. SAHPRA launched the NDS7 electronic system in June 2025 for submissions of applications for narcotics and psychotropics permits and finalisation within the

20 business days timeline. Possession permits are not included in the NDS7 scope and are still processed manually. In the 2025/26 FY, 87% of permit applications were finalised within 20 working days during the period under review.

Post-Market Surveillance and Lab Testing initiatives 2025/26

One of the areas that was identified as still needing improvement in the previous financial year (2024/25FY) was the regular post-market surveillance of health products to support SAHPRA's core functions of monitoring and investigation of registered health products. SAHPRA was initially outsourcing to only one analytical testing laboratory. An additional analytical laboratory was added to boost capacity due to the increase in the number of PMS samples collected.

Medical Devices, including IVDs and Radiation Control, the updated medical device regulations draft was completed and submitted to the National Department for consideration to gazette for public comments while the socio-economic impact assessment system (SEIAS) process is underway. Similarly, the radiation control fees regulation draft was completed and submitted to the National Department of Health, awaiting feedback and confirmation to resume SEIAS. The program will be revising and developing guidelines to align with the proposed regulations. The medical device registration unit has commenced with phase II feasibility study of product registration of class C&D medical devices and IVDs of cancer products.

2.2 Organisational environment

2.2.1 Health Products Authorisation strengthened both capacity and systems resilience during the 2025/26 financial year through targeted recruitment, operational restructuring, and digital transformation initiatives aimed at improving service delivery efficiency.

Key personnel appointments included the appointment of six (6) technical resources. These appointments were critical in supporting backlog reduction, strengthening technical review capacity, and improving workflow management across HPA workstreams.

Significant progress has been made in digital transformation. DocuBridge scripting was successfully completed for archiving, bulk status updates, DMS movement, and "not applicable" settings across most operational units including renewals, pre-registration, clinical post-registration, quality and names and scheduling screening in the renewals workstream reached 100% digital processing, while evaluation digitisation continued to progress. Validation of outputs from the AI Technical Screening Tool (AI TST) also commenced, with technical screeners comparing manual screening reports against system outputs to establish a future baseline for automated dossier screening.

Challenges relating to the Engagement Portal and incomplete automation within RIMS and DocuBridge remain unresolved. Legacy clean-up, automated validation of fees and sequences, resubmission completeness checks, and applicant-facing visibility through the Variations Status Checker remain areas requiring further improvement. Manual workarounds were implemented to mitigate these issues, while monthly RIMS database issue meetings and Vector SOP and Work Instruction rollouts supported operational continuity. No major system failures occurred during the reporting period, and personnel demonstrated strong adaptability to new systems and revised workflows.

Revised variation pricing logic and new combined variation codes were approved during March 2026, supporting revenue accuracy and financial sustainability. These changes also improve pricing consistency for inspectorate and clinical variations and strengthened the integrity of sales order generation processes within the portal environment. Programme 2 remains on track to fully recover generic throughput during 2026/27 through sustained recruitment,

capacity building, and continued digital enhancements, further strengthening SAHPRA's contribution to national health outcomes and regulatory excellence.

Overall, the organisational environment remained stable, adaptive, and focused on continuous improvement, despite ongoing reliance on manual trackers and temporary capacity limitations.

2.2.2 Pharmaceutical Evaluations Management, SAHPRA experienced several staff resignations as employees accepted more competitive remuneration packages elsewhere. To address this challenge, additional staff were appointed. Community service practitioners and interns also made valuable contributions, enabling the Authority to carry out operational tasks effectively.

Challenges encountered that affected the achievement of the planned targets included having manual trackers requiring resources for tracking. The proposed way forward was to expand the digital systems to enable real-time capturing that will serve as a live database.

System migration delays for the complementary medicines portal as well as waiting for a decision of requirements of responsible pharmacist vs responsible person have resulted in delay of licenses issued.

The absence of a SEIAS (Socio Economic Impact Assessment Survey) required for Regulations has resulted in the regulations not being published by the Minister of Health, and this was outside of SAHPRA's control.

SAHPRA attained International Council for Harmonisation (ICH) membership and participated in ICH EWG meetings: ICHQ6; M4, M13 and Long-term safety studies with CIOMS.

SAHPRA further participated in Continental and International training, committees, workshops and conferences:

- Veterinary Continental Harmonisation Workshop
- VICH SC,
- SCoMRA, ZAZIBONA, AU-3S, AUDA-NEPAD, AMA, AMRH.
- IPRP Working group for Biosimilars
- Vaccine Manufacturing Training
- Lot release workshop in Ghana
- Attended the ABRF meeting in Kigali
- The GHPP training in March 2026 for advanced training on Biosimilars and training on BE evaluation and API assessment held in Lusaka, Zambia.

2.2.3 Clinical Evaluations Management (CEM), the program effectively managed staff turnover with addition of community service personnel and learnership intern assumed duty between 01 January 2025 (contract ended 31 December 2025). These appointments are critical in supporting backlog reduction, strengthening technical review capacity and management of review processes within Programme CEM.

The manual handling of applications and management of review process remains a challenge within programme 4. Though there is progress made in digitalising some workstreams in CEM, the programme is still faced with challenges with Section 21 Engagement Portal. Major system challenges were experienced in Quarter 1 and Quarter 2 as applications are received through emails and tracked using excel spreadsheets in Clinical Trials Unit and Pharmacovigilance Unit. Digital transformation will be beneficial for many streams with Clinical Trials Electronic System engagements in progress.

Clinical Trials Unit conducted training with SANCTR, NDOH and SAHPRA, NHREC/Ethics Committees stakeholder. MedDRA and VigiMobile Training.

The Pharmacovigilance Unit continued with the training for the FY2025/26, internal and external training in preparation for the WHO GBT ML3 assessment, and MedDRA & VigiMobile/VigiFlow training for staff, across eight (8) provinces and industry. A strategic plan convened with participation by the UCT, MIC, UWC, SMU, NDOH, Ghana FDA and NDA.

Names and Scheduling Unit engaged several stakeholders to provide clarity regarding regulatory requirements during the financial year.

2.2.4 Inspectorate and Regulatory Compliance (IRC). The target for finalising applications for GWP licences was achieved. However, IRC Unit fell short of achieving the target for GMP licences due to capacity challenges experienced in the period under review.

The Inspectorate Unit is focused on balancing priorities in terms of demands on the inspection plan and additional external evaluator resources were recruited to oversee the new registration and Type I evaluation workstream work within the Inspectorate to free up inspectors to conduct new license application inspections. This has contributed to some improvements noted in the APP target, even though the GMP target was not achieved. The inspectorate will continue to focus on clearing the backlog on inspections and implementing new strategies to improve this workstream in the new 2026/27 FY. Resources were increased in the Inspectorate with the allocation of additional inspectors and external evaluators.

Establishment of Health Products Recalls Committee

To effectively coordinate and implement product recalls SAHPRA established a multi-disciplinary recalls committee in 2025/26 FY. This committee forms part of the systems of controls established to facilitate the implementation of an Applicant or SAHPRA initiated recall based on product quality defects. SAHPRA recalled 22 medical products in the 2025/26 financial year and 82% of them were published on the organisation's website within seven (7) working days from the date they were finalised.

2.2.5 Medical Devices, including IVDs and Radiation Control

SAHPRA in this period completed phase I feasibility study and report was published. The draft updated Regulation and SEIAS process is still underway. In addition, related fees for registration were developed.

During the 2025/26 financial year, SAHPRA delivered its targets regarding registration of Medical Devices and IVDs during the Phase I of feasibility study for Class C and D products after receiving 20 technical dossiers. The applications for establishment licences were finalised within 90 working days. By the 3rd quarter of the 2025/26 financial year, Medical Devices Unit had collected more than 80% for annual retention fees, above 75% of the projected budget. This included WHO GBT + assessment workshop with focus on evaluation of the Regulatory system, licensing, and post-marketing surveillance.

Applications for listed electronic products licenses were finalised within 50 working days. Applications for radionuclides authorities were finalised within 60 working days.

Radiation Control continued to conduct inspections and issuing sealing letters for non-compliance. In addition, applications related to the use of X-ray units were processed. The organisation was represented at the 69th IAEA general conference as part of the strategic objective of being internationally visible. SAHPRA visited facilities operating specialised electronic products. In relation to inspections, SAHPRA also visited mines authorised to possess and use radioisotopes for non-medical purposes.

2.3 Key policy developments and legislative changes

No major amendments to the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), or subordinate legislation directly impacting operations occurred during the 2025/26 financial year. SAHPRA therefore continued to execute its mandate within the existing legislative framework governing the evaluation, registration, and control of medicines and scheduled substances.

In September 2025, SAHPRA published the guideline on regulatory requirements of artificial intelligence and machine learning (AI/ML) enabled medical devices.

Revised Regulation six (6) was submitted to the Department of Health for consideration.

2.4 Service Delivery Charter: SAHPRA Overall achievements for the year 2025/26 include:

Table 4: Service Delivery Support Services

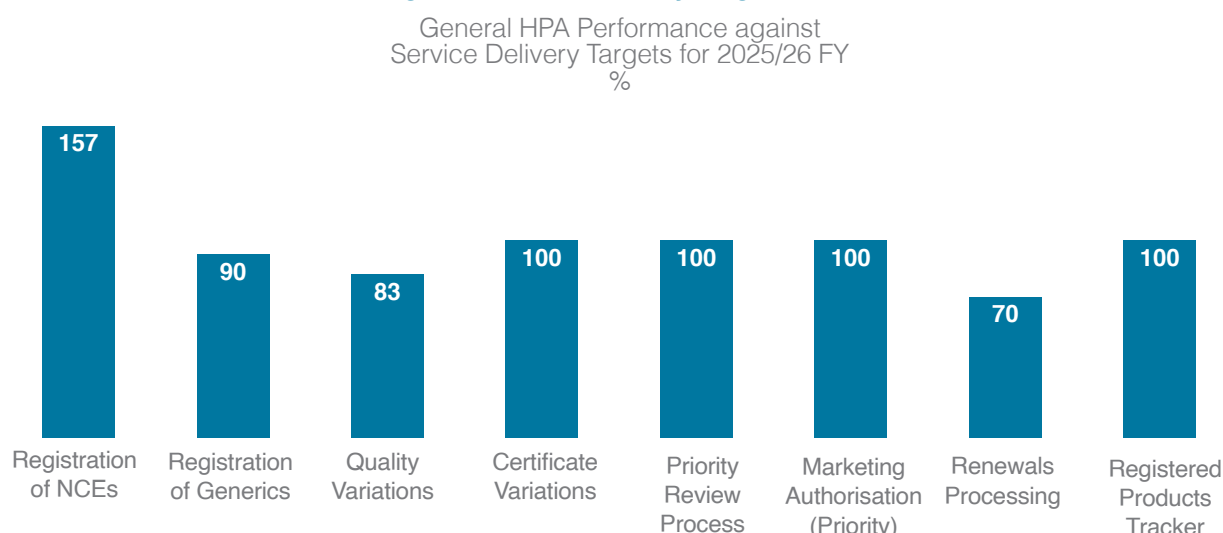
Support Services	
Payment of SAHPRA Service Providers Within 30 days of receipt of an invoice	Refunds Within 3 months of receipt of a refund request with completed required documents
Handling of Complaints/Queries 83% of complaints/queries resolved within 30 business days	Payment for SAHPRA services on application for services Within 30 days of receipt of an invoice
Engagement with SAHPRA 87% of stakeholder satisfaction with SAHPRA communication and engagement efforts obtained	Debt collection 2-3 months after service delivery or regulated fee

GENERAL HEALTH PRODUCTS AUTHORISATION

Health Product Application Status Checker, availability of a real-time status checker through the portal.

Registered Health Products, Medicines register updated weekly / a real-time register.

Figure 4: General HPA Performance against Service Delivery Targets for 2025/26 FY



IRC Enforcement Actions

SAHPRA is continuously working to strengthen its regulatory and inspection capacity to fully comply with PIC/S requirements. In an effort to further ensure inspection and manufacturing standards align with PIC/S and to improve quality assurance in pharmaceutical production, facilitating global trade and partnerships, SAHPRA has fully implemented the PIC/S Guidance on Classification of GMP Deficiencies. This guidance document ensures the harmonisation of the classification of GMP deficiencies to facilitate harmonised reporting of GMP deficiencies from inspections across all PIC/S inspectorates. Harmonisation helps ensure that there is a consistent view across inspectorates of what constitutes a “Critical” deficiency and what constitutes a “Major” deficiency. Furthermore, the PIC/S Guidance on Classification of GMP Deficiencies compels its member countries to implement market actions in response to the critical and major deficiencies identified during inspections and in an effort to ensure public safety. In the 2025/26 financial year, Inspectorate and Regulatory Compliance Unit issued a total of 18 regulatory enforcement actions. The objective of enforcement actions is to safeguard public health, ensure quality, safety, and efficacy of medicinal products, from manufacturing and throughout the supply chain and to promote timely and sustainable compliance.

Table 5: Regulatory Enforcements

Total of regulatory enforcement actions	18
GxP sites	• testing laboratories • sterile manufacturing sites • oral solid dosage form • manufacturing sites • wholesalers • clinical trial sites
Deficiencies during GxP inspections	• cross-contamination and containment failure • breakdown of sterility assurance, • systemic data integrity and governance failure • gross facility disrepair and pest infiltration • inadequate deviation • CAPA • complaint management • illegal operations and license violations

IRC Compliance Investigations

The set target for the indicator was to ensure that 70% of contraventions of the Medicines Act are investigated and initial reports produced within 30 business days. The Unit achieved 74% of this target in 2025/26 FY and ensured that regulatory compliance investigation reports were produced within 30 working days. This means out of 588 complaints received, 542 (92%) reports were produced, of which 433 (74%) were produced within 30 working days. A further development in the fight against SF medicines was the initiation of the pilot and launch of the WHO Handbook for National Action Plans (NAPs) in September 2025.

Figure 5: Regulatory Compliance Investigations as of 31 March 2026

Regulatory Compliance Investigations (74% achievement)

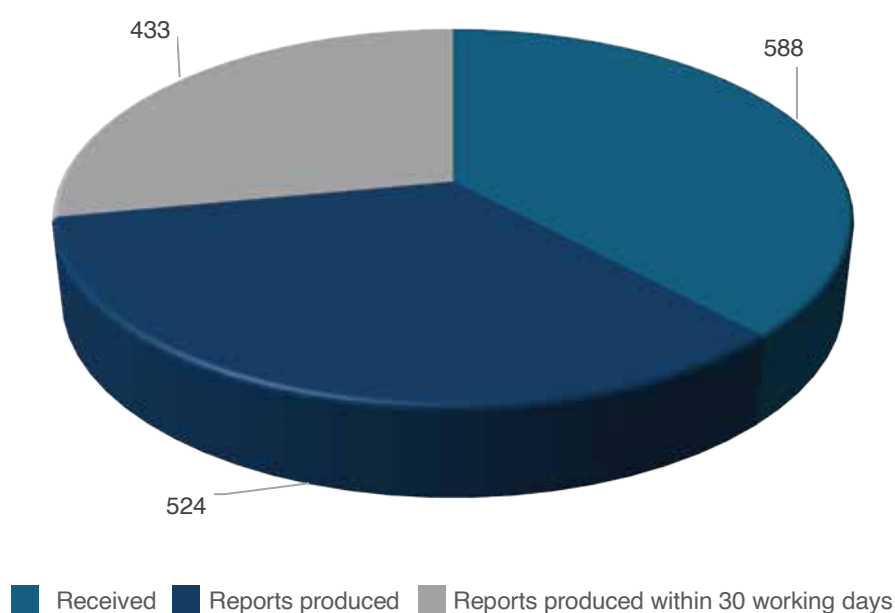
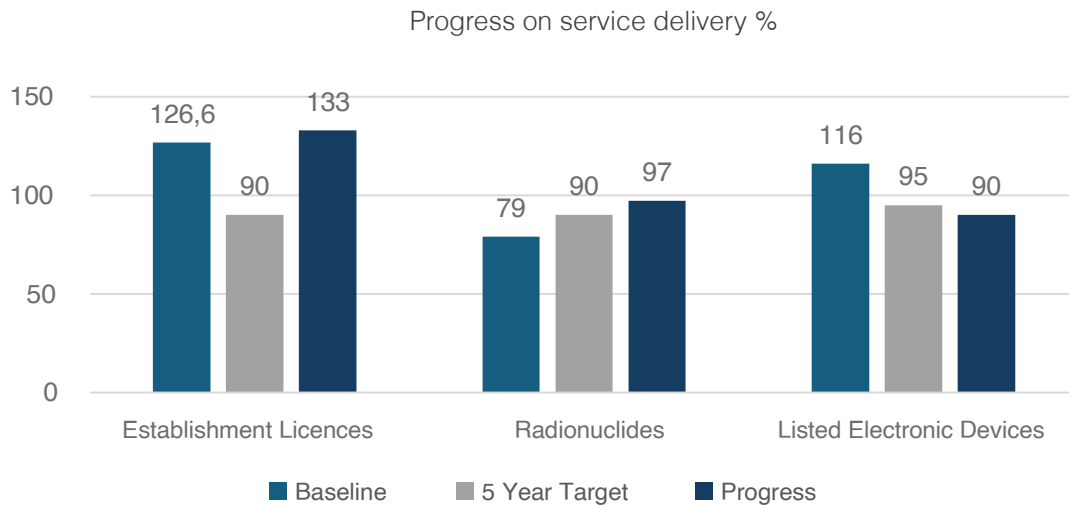


Table 6: Service Delivery Core Business

INSPECTORATE AND REGULATORY COMPLIANCE		
Licencing 11 New GMP related licenses are issued within 125 working days		
16 New GWP related licenses are issued within 125 working days	22 recalls and related alerts published within 7 working days	
5389 Permits issued within 20 working days	Regulatory Compliance Investigation Reports, 433 regulatory compliance investigation reports produced within 30 working days	
SECTION 21 APPLICATIONS Online Submission Portal for Section 21 Applications 93% processed with a decision within 3 working days from date of receipt of complete application		
CLINICAL TRIALS, Human clinical trial applications finalised 83% of new clinical trial applications finalised within 80 working days		
PHARMACOVIGILANCE		
Health product safety signals issued All high public health impact safety signals detected and mitigated within 40 working days		
Reports on health product safety signals assessed , 104 Reports on health product significant safety issues assessed within 60 working days		
ADRs/ AEFIs reports which are shared with the WHO global database of ICSR (VigiBase)		

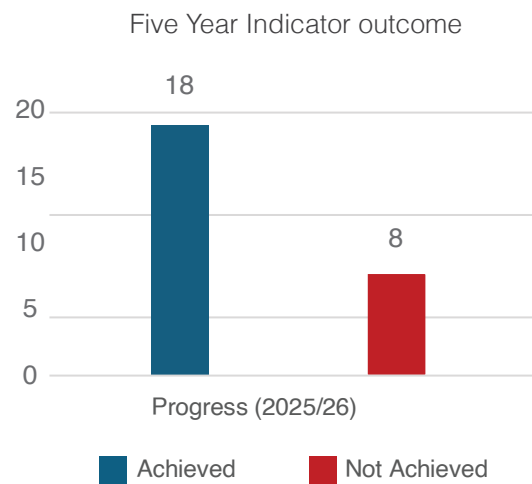
Services	Current Standard of Service
MEDICAL DEVICES	
Medical Device Clinical Trials	87% Clinical trials and 97% (RUO) applications within 60 working days
Medical device section 36 applications finalised	100% medical device section 36 applications finalised within 30 working days April 2025 to March 2026. Completed 4/4
RADIATION CONTROL	
Dental X-ray License Applications Finalised	86% (968) licence applications for dental X-rays finalised within 30 working days
Radiation Protection and Safety	71% (36 radiation over-exposures investigations completed within 60 working days
Radiation Incidents Investigations	94% (17) radiation incident investigations completed within 90 working days.

Medical Devices, including IVDs and Radiation Control



2.5 Progress towards achievement of institutional Impacts and Outcomes

SAHPRA's 2025/26 Annual Performance Plan was approved by the Minister of Health in January 2026. No revisions to the 2025/26 APP were approved by the Minister. Amendments to the Strategic Plan or Annual Performance Plan required during the year were approved for implementation in 2026/27 Financial year.



2.5.1 Progress on Outcomes

MEDIUM -TERM DEVELOPMENT PLAN PRIORITY 2: REDUCE POVERTY AND TACKLE THE HIGH COST OF LIVING			
OUTCOMES	OUTCOME INDICATORS	FIVE-YEAR TARGET	PROGRESS AT 2025/26
Effective compliance, financial and performance management (1)	1.1 Unqualified audit opinion with no material findings obtained on the annual financial statements	Unqualified audit outcome with no material findings audit outcome	Unqualified audit opinion with no material findings obtained on the annual financial statements 2024/25
Financial sustainability achieved (2)	1.2 Total revenue generated from fees in the financial year	Current ratio of 1≥1 maintained	Current ratio of 1:1.4 maintained
Responsive to stakeholder needs (3)	1.3 Percentage of accepted recommendations from the conducted stakeholder perception survey implemented	95% accepted recommendations from the conducted stakeholder perception survey implemented	Implementation plan and report approved by EXCO.
A positive and enabling working culture created (4)	1.4.1 Percentage of accepted recommendations from the conducted Staff satisfaction survey implemented	95% accepted recommendations from the conducted Staff satisfaction survey implemented	Current state remains 80% (28/35) of key activities are completed based on Survey recommendations.
	1.4.2 Percentage of positions in the staff establishment filled	95% positions in the staff establishment filled	Out of the 430 positions in the approved structure, 311 positions filled as of 31 March 2026. 376 staff complement as of 31 March with 292 permanent, and 84 fixed term contract positions filled within the 2025/26 FY. The turnover rate remained below 10% year on year.

MEDIUM -TERM DEVELOPMENT PLAN PRIORITY 2: REDUCE POVERTY AND TACKLE THE HIGH COST OF LIVING				
OUTCOMES	OUTCOME INDICATORS		FIVE-YEAR TARGET	PROGRESS AT 2025/26
Attract and retain talent (5)	1.5	Percentage of learning and development initiatives implemented	95% of learning and development initiatives implemented	31 interventions were implemented. A total of 95% of employees (359 out of 376) successfully completed training programmes aligned with Learning and Development
	1.6	Enterprise Architecture developed.	95% Enterprise Architecture implemented	Enterprise Architecture partially implemented. - Applications Architecture - Security Architecture - Technology Architecture - Data Architecture
Digital transformation (6)	1.7.1	Number of New Chemical Entities Master Applications finalised annually	60 New Chemical Entities Master Applications finalised annually	94 NCE applications have been finalised in the 2025/26 financial year
	1.7.2	Number of Generics master applications finalised annually	510 Generic Master Applications finalised annually	Target not achieved. 376 applications have been finalised in the 2025/26 financial year against a target of 420, achieving 90% of the annual goal
	1.7.3	Percentage of type II variations finalised within 200 working days	95% of type II variations finalised within 160 working days	82.48% (358/434) of type II variations finalised within 200 working days.
	1.7.4	ISO 9001: 2015 certification obtained	Certification status of the ISO 9001: 2015 maintained	Certification status of the ISO 9001: 2015 maintained
	1.7.5	World Health Organization Maturity Level assessed	WHO Listed Authority (WLA) status achieved Level 4 obtained	Target not achieved. Maturity level 3 assessed, and the process is ongoing
	1.7.6	Percentage of new GWP related licenses finalised within 125 days	95% of new GWP related licenses finalised within 125 days	Target achieved. 70% were finalised within 125 working days.
	1.7.7	Percentage of new GMP related licenses (local manufacture) finalised within 125 days	95% of new GMP related licenses (local manufacture) finalised within	Target not achieved. 38% of new GMP related licenses finalised within 125 business days.
	1.7.8	% of recalls and related alerts published within 7 working days	95% of recalls and related alerts published within seven (7) working days	Target achieved. 82% of recalls were published within 7 working days.
	1.7.9	Percentage applications for the sale of unregistered Category A (human) medicines finalised within 3 working days	95% applications for the sale of unregistered Category A (human) medicines finalised within two (2) working days	Target not achieved. 93% of applications for the sale of unregistered Category A (human) medicines were finalised within 3 working days.

MEDIUM -TERM DEVELOPMENT PLAN PRIORITY 2: REDUCE POVERTY AND TACKLE THE HIGH COST OF LIVING			
OUTCOMES	OUTCOME INDICATORS	FIVE-YEAR TARGET	PROGRESS AT 2025/26
	1.7.10 Percentage of Clinical Trials safety signal detected and mitigated within 80 working days	90% Percentage of Clinical Trials safety signal detected and mitigated within 80 working days	Initials SAE Reports Received: 887 Met Criteria: 505 Due for finalisation: 324 Mitigation within 80 working days: 76 Achievement: $76/324 = 23\%$
	1.7.11 Percentage of all high public health impact safety signals detected and mitigated within 40 working days.	90% of all high public health impact safety signals detected and mitigated within 40 working days.	100% (1) health impact signals detected and mitigated within 40 working days.
	1.7.12 Percentage of reports on health product safety signals assessed within 60 working days	90% reports on health product significant safety signals assessed within 60 working days	Target not achieved. 142/276 (51.45%) reports on health product significant safety signals assessed within 60 working days
	1.7.13 Percentage of safety communications published within 10 working days	90% of the safety communications published within 10 working days	Target not achieved. 12 safety communications were received in the financial year, 1 media release within required timelines and 7 DHCPLs. and $1/12 = 8.33\%$ completed within 10 working days.
	1.7.14 Number of safety awareness trainings held	20 safety awareness campaigns held	32 safety awareness campaigns held
	1.7.15 Percentage of lot release requests finalised within 40 working days	* 90% lot release requests finalised within 40 working days	98% lot release requests finalised within 50 working days
	1.7.16 Percentage of medical device establishment license applications finalised within 90 working days	90% medical device establishment license applications finalised within 90 working days	133% medical device establishment license applications finalised within 90 working days
	1.7.17 Notice of medical device products published	Call-up notice for product registration for medical device products published for specific/selected disease criteria	The unit received 20 technical dossiers for product registration feasibility study, 09 products were recommended for approval.
	1.7.18 Percentage of applications for radionuclide authorities (licenses) finalised within 60 working days	90% applications for radionuclide authorities (licenses), due for finalisation, finalised within 60 working days	90% applications for radionuclide authorities (licenses), due for finalisation, finalised within 60 working days
	1.7.19 Percentage of license applications for listed-electronic products finalised within 30 working days	95% license applications for listed-electronic products finalised within 40 working days	126% license applications for listed-electronic products finalised within 50 working days

*Error/Typo in the 2025/26 APP under Output indicator for Lot Release p77 (Percentage of lot release requests finalised which should reflect "within 50 working days"). Submission made to the Minister, approval to revise the APP acceptable for 2026/27 FY. The reported performance under Lot Release requests of 98% is against the 50 working days target.

3. INSTITUTIONAL PROGRAMME PERFORMANCE INFORMATION

3.1 Programme 1: Leadership and Support

Purpose	Purpose: To provide the leadership and administrative support necessary for SAHPRA to deliver on its mandate and comply with all legislative requirements.
Sub-Programme	
Financial and Supply Chain Management	To serve all business units in SAHPRA, the senior management team, and the Board by maintaining an efficient, effective and transparent system of financial and risk management that complies with the applicable legislation.
Governance and Compliance	To provide support services, ensure compliance with relevant legislation, and achieve an unqualified audit outcome by ensuring continuous management practices in compliance with standard operating procedures (SOPs) and systems within SAHPRA. Furthermore, to review existing operational processes and recommend new or changed processes and work methods to ensure optimal organisational effectiveness and to measure and monitor the Authority's performance.
ICT	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.
HR 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.
Communication and Public Relations	To provide comprehensive communication and public relations management services that enhance public health, stakeholder engagement and the reputation of SAHPRA.

Financial and Supply Chain Management

SAHPRA's total revenue from a budgeted for comparative basis amounted to R515.7 million against an adjusted budget of R495.5 million. The variance of R20.2 million was mainly due to exceeding budget for revenue and additional external funding support received during the year.

The additional expenditure was allowed due to an unbudgeted external financial support received which is accounted for as additional revenue.

The overall result was an operational budget surplus amounting to R51.8 million and exceeding the annual current ratio target of 1:1 which is mainly due to delayed implementation of the job evaluation project and delayed filling of vacancies.

The focus was on maintaining previous audit outcomes as well as positioning SAHPRA for financial sustainability.

The following are worth noting:

- Achieved an unqualified audit with no material findings (Clean Audit 2024/25).
- Exceeded the budget set for fee income.
- No irregular, fruitless and wasteful expenditure remaining balance for 2025/26.
- Enforced implementation of Regulated fees to ensure financial sustainability
- Completion of a project to review deferred revenue balances for the periods 2018/19 to 2022/23 resulting in the

identification and correction of revenue recognition during these periods resulting in a decrease in the deferred revenue liability balance and increase in retained surpluses.

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

HEAD COUNT	2025/26 FINANCIAL YEAR STAFF COMPLEMENT WITH QUARTERLY STATISTICS							
	Q1 2025/26	Staff %	Q2 2025/26	Staff %	Q3 2025/26	Staff %	Q4 2025/26	Staff %
No: Permanent Employees	282	83.9%	285	83.3%	280	76.5%	292	77.47%
No: Fixed Term Contractors (5 years)	10	3.0%	10	2.9%	10	2.7%	10	2.7%
No: Fixed Term Contractors (2 years)	7	2.1%	8	2.3%	9	2.5%	24	6.4%
No: Short Term Contractors	37	11.0%	39	11.4%	67	18.3%	50	13.3%
Total No: of Employees	336		342		366		376	

Information and Communication Technology

SAHPRA continued with engagements with internal and external stakeholders to support the stabilisation of the Stakeholder Portals and Systems including user acceptance testing (UAT) and other relevant ICT updates related to service delivery, operational efficiency and security awareness. This was to address challenges with the business process that were digitised and continue to be addressed.

Communication and Public Relations

The Communications Unit successfully implemented the Perceptions Survey to assess stakeholder perceptions of SAHPRA's reputation, performance, and communication effectiveness. The findings will inform strategic decision-making and targeted communication interventions.

Proactive media engagement increased during the financial year, resulting in improved coverage of regulatory updates, safety alerts, and public health messaging. Media sentiment and awareness showed a gradual improvement, supported by ongoing monitoring and responsiveness.

Digital platforms were strengthened through continuous website updates and enhanced social media activity to improve information accessibility and real-time stakeholder engagement.

Targeted social media campaigns were executed to raise awareness on emerging issues, including sanitary pads, immune boosters, and the Citro-Soda recall.

SAHPRA published a thought leadership article in Conviction, reaching an estimated audience of over 100,000 readers. The articles addressed emerging regulatory and public health concerns and reinforced SAHPRA's role in safeguarding public health and guiding informed consumer decisions.

Table 2.4.4.1

Programme / Sub-programme: Leadership and Support								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	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 with no material findings obtained on the annual financial statements.	Unqualified audit opinion obtained for the 2022/23 financial year	Clean audit opinion is obtained for the 2023/24 financial year	Unqualified audit opinion with no material findings obtained for the 2024/25 financial year	Unqualified audit opinion with no material findings obtained for the 2024/25 financial year.	Target achieved.	None
Financial sustainability achieved (2)	Liquidity ratio of ≥ 1	Current assets $\geq$ than current liabilities	-	The target of a more than 1:1 current ratio has been achieved at: 1:1.27		Current Ratio of 1:1 maintained and remains above target. Q4 average current ratio is 1:1.4	Target overachieved	The liquidity ratio remains above the targeted 1:1

Programme / Sub-programme: Leadership and Support							
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026
Responsive to stakeholder needs (3)	*Survey conducted	Stakeholder survey conducted	2023/24 Stakeholder perception survey was conducted, and outcomes of such survey were presented at EXCO.	100% of the recommendations implemented, against a target of 60%: Conducted a campaign on “How to contact SAHPRA” indicating how SAHPRA can be contacted for general enquiries and where to access contact details for specific services, web content relating specifically to contacting SAHPRA, comprising Frequently Asked Questions and guidance of where to direct questions and follow-ups would be developed.	2025/26 stakeholder perception survey conducted Implementation plan of the recommendations from the 2025/26 Stakeholder Perception Survey approved by the Executive Committee.	2025/26 stakeholder perception survey Implementation plan and report approved by EXCO.	Target achieved.
							None

Programme / Sub-programme: Leadership and Support								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	** Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
A positive and enabling working culture created (4)	*Survey conducted	Staff survey conducted	Plan to address Recommendations were approved by EXCO. Progress report on The implementation plan from the 2023/24 Stakeholder Perception Survey was submitted to the Executive Committee.	Progress report on implementation of 70% Recommendations from the conducted 2023/24 Staff satisfaction survey submitted to EXCO: implementation of EHWP initiatives, the Job Evaluation Project in progress. The Ongoing communication with employees is maintained through HR circulars, Bi-weekly meetings with Unit Managers and quarterly meetings with Staff	Progress report on implementation of 75% Recommendations from the conducted 2023/24 Staff satisfaction survey submitted to EXCO	Current state remains at 80% (28/35) of key activities are completed based on Survey recommendations. Progress report tabled to EXCO quarterly through HR report.	Target achieved.	None

Programme / Sub-programme: Leadership and Support								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
A positive and enabling work-culture created (4)	Learning and development initiatives implemented	Percentage of learning and development initiatives implemented	-	85% (280/331) of employees trained on an approved Learning and Development Initiatives Plan.	75% employees trained on the planned learning and development initiatives	A total of 95% of employees (359 out of 376) successfully completed training programmes aligned with Learning and Development initiatives.	Target overachieved	Strong training progress toward organisational capacity-building goals for the 2025/26 financial year.
	Attract and retain talent (5)	Budgeted positions filled	Percentage of 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.	72% (67 out of 93) of the budgeted positions have been filled, including Community Service positions planned for recruitment in the 2024/25 financial year.	75% critical business positions in the staff establishment filled	Overall, 73 positions out of 89 were filled, representing 82% of the total budgeted posts.	Target achieved.

Programme / Sub-programme: Leadership and Support								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	** Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
Attract and retain talent (5)	Technical staff retained	Percentage of staff retained	-	The turnover rate remained at 1.2% (4 out of 331 employees), remaining well below the target of 10%. Over the period from April 2024 to March 2025, staff turnover stood at 6.9% (23 out of 331 employees) left SAHPRA, which is still within the target of 10%.	Staff turnover rate below 10%	The turnover rate for the period April 2025 to March 2026 is 7.4% (28/376 employees).	Target achieved.	The figure remains within the organisation's set target of 10%, demonstrating continued stability in workforce retention.
	Enterprise Architecture	Percentage of Phase 4 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	100% Enterprise Architecture Phase 2 implemented. Conducted User AT on Engagement Portal and Operationalised four core business processes on Stakeholder engagement portal – Section 21, New Registration, Amendments and Renewals	90% Enterprise Architecture Phase 4 implemented	Successfully completed all planned activities. - Applications Architecture - Security Architecture - Technology Architecture - Data Architecture Licensing and Learner Module finalised later than 31 Mar 2026.	Target not achieved.	Phase 4 partially implemented by 31 Mar 2026.

Linking performance with budgets:

In assessing the achievement of the outputs in comparison to the planned targets, the public entity must consider the linkages and relationship to the resources available to the public entity, in particular the financial resources. Therefore, the following financial information should be presented. The financial information must agree to the information in the annual financial statements.

Programme/ activity/objective	2025/2026			2024/2025		
	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	181 765	228 605	(46 839)	162 157	194 849	(32 332)
Total	181 765	228 605	(46 839)	162 157	194 849	(32 332)

Over expenditure against the programme budget relates to external funding support received during the financial year, which is not included in the SAHPRA budget

Strategy to overcome areas of underperformance

The strategies to improve performance related to filling of vacancies included addressing manual selection processes that continue to slow down recruitment timelines. Finalising the implementation of the e-recruitment system to streamline and modernise recruitment practices. Broadening sourcing channels includes strategic collaboration with universities and industry partners to strengthen the talent pool.



3.2 Programme 2: Health Products Authorisation

Purpose	Purpose To provide administration support necessary for SAHPRA to deliver on its mandate and comply with the relevant legislative requirements. The specific purpose of this programme is to coordinate the process of registration and/or licensing or amendment of applications in respect of medicines within a legislative framework. This framework defines the requirements for application to the Authority, and to receive, record and distribute all documents submitted to SAHPRA.
Sub-Programme	
Document reception and helpdesk	The purpose of this sub-programme is to receive, record and/or direct all documents submitted to SAHPRA.
Project office – regulatory decision for medicines	The purpose is to coordinate the process of making regulatory decisions about medicines (screening, dispatch to evaluators, coordinating reports, recommendations, responses, and arranging peer and product review meetings). It is also involved in ensuring that regulatory decisions made at the time of registration are in the public interest throughout the product lifecycle through post-marketing vigilance of registered products. Vigilance includes the soliciting of data through various approaches, monitoring, analysis, and responsive action, including the provision of feedback.
Project office – clinical trials, Section 21 portfolio management	The purpose is to coordinate the vigilance process and authorisation of clinical trials and Section 21 applications for medicines and devices within a legislative framework that defines the requirements for application to the Authority. Details on the assessment procedure, the grounds for approval or rejection of the application, and the circumstances where authorisation already granted may be cancelled, withdrawn, suspended, or revoked are provided.
Licensing, permits and certificates portfolio management	The purpose is to manage and coordinate the process of licensing and amendments in respect of medicine manufacturers, wholesalers and medical device establishments and the issue of permits and registration certificates within a legislative framework that defines the requirements for application to the Authority. Details on the assessment procedure (based on quality, efficacy and safety criteria), the grounds for approval or rejection of the application, and the circumstances where a registration, license or authorisation already granted may be cancelled, withdrawn, suspended, or revoked are provided.
Quality Management System	The purpose of the Quality Management System (QMS) is to ensure that all organisational activities are aligned with SAHPRA's strategic goals and relevant regulatory standards. The QMS provides a structured framework for maintaining compliance, consistency, and excellence in operations. It serves as the cornerstone for embedding a culture of quality and accountability across the organisation.

New Chemical Entities (Human and Veterinary Medicines): As at the end of March 2026, SAHPRA had 289 (271 **human** and 18 **veterinary**) New Chemical Entity (NCE) master applications that were in progress. 207 (189 human and 18 veterinary) master applications were carried over from previous years, with 14 (14 human and 0 veterinary) at the end of 2025/26 Financial year.

Generic Medicines (Human and Veterinary Medicines): As at the end of March 2026, SAHPRA had 1113 (1088 human and 25 veterinary) Generic master applications that were in progress. 747 (734 human and 13 veterinary) master applications were carried over from previous years, with 76 (75 human and 1 veterinary) received in Quarter 4. There was a significant decline in terms of throughput, however management has put mitigations in place to improve the area.

Variations (Human Medicines): In Quarter 4, 432 type II variations were due for finalisation within 200 working days across the clinical, quality, veterinary, biological, naming and scheduling and inspectorate units. 358 type II variations were finalised within 200 working days across the units (83%).

Various strategies were implemented, including the implementation of reliance reviews including participating in collaborative process such as ZAZIBONA, AMA Continental Reviews, and EU M4ALL, for the evaluation of new medicine applications and making use of assessment reports from Recognised Regulatory Authorities and SAHPRA.

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

Quality Management System primary focus was on addressing non-conformances identified through the QMS internal audits conducted across all functions. Successfully underwent the second ISO 9001:2015 surveillance audit, which confirmed continued compliance.

The ML3 reassessment process facilitated by the QMS ON follow-up sessions with WHO GBT assessors to track progress on the implemented IDPs. This was to ensure alignment with expectations and reinforced the organisation's readiness for the finalisation of the assessment.

Table 2.4.4.2

Programme / Sub-programme: Health Products Authorisation								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
Efficient and effective regulatory practices maintained (7)	New Chemical Entities (NCEs) applications Finalised	Number of New Chemical Entities Master Applications finalised annually	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	Out of 350 applications received, 46 (13%) were due for finalisation. Although 46 applications were due for finalisation, 134 (100%) were finalised, of which 122 (100%) were finalised within 360 working days	60 New Chemical Entities Master Applications finalised annually	SAHPRA finalised 94 new chemical entity (NCE) master applications in the 2025/26 financial year	Target overachieved.	Targeted capacity enhancements in evaluation teams, resource allocation aligned to the Phase 2 backlog project increased throughput, particularly for NCE dossiers. Successful implementation of reliance and priority review pathways. Process improvements and automation. Focused operational prioritisation.

Programme / Sub-programme: Health Products Authorisation								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	** Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
Efficient and effective regulatory practices maintained (7)	Generic medicines applications finalised	Number of Generic Master Applications finalised within a quarter	86% generic medicines finalised within 250 working days.	100% generic medicines finalised within 250 working days. Out of 2 691 applications received, 149 (6%) were due for finalisation. Although 149 applications were due for finalisation, 568 (100%) were finalised, of which 468 (100%) were finalised within 250 working days	420 Generic Master Applications finalised annually	376 applications have been finalised in the 2025/26 financial year against a target of 420, achieving 90% of the annual goal	Variance confirmed as significant decline in throughput. High carryover backlog from. The generic medicines target was impacted by competing priorities in the other business units. The focus was on allocation of resources toward backlog clearance in January – February 2026 temporarily constrained capacity for generic master applications	Overall: Strong performance on NCE's demonstrates that reliance strategies combined with internal process optimisations are yielding measurable gains in regulatory efficiency for innovative products
								Mitigating actions implemented include additional evaluator placements, weekly resource allocation and use of external reviewers, and process automation, are expected to restore and sustain improved throughput for 2026/27 onward.

Programme / Sub-programme: Health Products Authorisation								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	** Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
	Type II variations finalised.	Percentage of type II variations finalised within 200 working days.	-	-	50% of type II variations finalised within 200 working days.	82.48% (358/434) of type II variations finalised within 200 working days.	Target overachieved.	Type II variations pilot programme structured submission windows continue to bring predictability and batch processing discipline. Digital and system enhancements. Reliance mechanisms for type II variations that qualify for reliance on RRA approvals benefit from abridged assessments. Improved cross unit coordination and monitoring. Overall insight, the combination of the pilot windows, system automation and reliance pathways transformed type II variation processing into a high performing area.

Programme / Sub-programme: Health Products Authorisation								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
Global best practices maintained (8)	International Organization for Standardization ISO 9001: 2015 certified	Certification status of the ISO 9001: 2015 obtained	International Organization for Standardization 9001: 2015 was certified	Certification status of the ISO 9001: 2015 maintained	Certification status of the ISO 9001: 2015 maintained.	ISO 9001:2015 certification maintained	Target achieved.	None
	WHO global benchmarking conducted.	World Health Organization maturity level assessed	Maturity Level 4 self-assessment was not conducted.	Target not achieved. Maturity level 3 for medicines not obtained.	WHO Maturity Level 3 obtained for medicines	Benchmarking process still in progress.	Target not Achieved. Assessment still in progress.	Final ML3 assessment schedule for Q1 of the new FY 2026/27

Linking performance with budgets:

In assessing the achievement of outputs against the planned targets, the public entity should consider the relationship between performance and the resources available to it, particularly its financial resources. Accordingly, the following financial information is presented. The information is consistent with the Annual Financial Statements.

Programme/ activity/objective	2025/2026			2024/2025		
	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	50 476	45 233	5 243	42 410	41 704	706
Total	50 476	45 233	5 243	42 410	41 704	706

Under expenditure related to external funding support received and delayed filling of vacancies

Strategy to overcome areas of underperformance

SAHPRA will ensure targeted capacity enhancements required are implemented, continued implementation of reliance and priority review pathways, process improvements and automation coupled with focused operational prioritisation encompassing reliance strategies with internal process optimisations.

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)

Purpose	
Sub-Programme	
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.

Inspectorate, remains with major challenges related to new product evaluations and mechanisms have been put in place to address the challenges with monthly monitoring of throughput. As part of the interventions additional resources were appointed.

Licencing, Licencing follows successful inspectorate outcomes for both Inspections and Evaluations. Thus, licensing is intertwined with Inspectorate. The unit has seen improvements in Performance for New GMP and GWP-related licenses in comparison to the previous two (2) financial years.

Regulatory Compliance continued stakeholder engagements related to collaborations with the Police and SAPC and successful implementation of product recalls.

SAHPRA LICENCED SITES DURING OCTOBER 2025 TO FEBRUARY 2026					
CATEGORY OF LICENCE	Oct 2025	Nov 2025	Dec 2025	Jan 2026	Feb 2026
Manufacturers & Packer	67	67	66	66	66
HCRs (Importers & Exporters)	178	178	175	175	174
Gas Manufacturers	2	2	2	2	2
API Manufacturers	8	8	8	8	8
Testing Laboratories	24	24	22	22	21
Provincial Depots	7	7	6	6	6
Bond Stores (Private)	2	2	2	2	3
Private Wholesalers	150	150	136	136	136
Distributors of APIs (Brokers)	6	6	6	6	6
Cannabis Cultivation	103	105	92	92	92
Total	547	549	515	515	514

Total number of GXP inspections performed 2025/26 FY					
GXP Inspections	Q1	Q2	Q3	Q4	Total
GCP	18	25	16	19	78
GMP/GDP	34	25	27	28	114
GWP	19	113	14	17	163
GVP	7	7	6	12	32
Total					387

Table 2.4.4.3

Programme / Sub-programme: Inspectorate and Regulatory Compliance								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
Efficient and effective regulatory practices maintained (7)	New GMP- and GWP-related licences finalised.	Percentage of new GWP related licences finalised within 125 days	27% new Good Manufacturing Practice and Good Warehouse Practice related licences finalised within 125 working days. Out of 76 applications received, 60 (79%) were due for finalisation. Out of 60 due for finalisation, 20 (33%) were finalised, of which 16 (27%) were finalised within 125 workings days	50% new GMP and GWP related licences finalised within 125 working days. Out of 90 applications received, 60 (67%) were due for finalisation. Out of 60 due for finalisation, 35 (58%) were finalised, of which 30 (50%) were finalised within 125 workings days	70% of new GWP related licences finalised within 125 days	70% finalised within 125 working days. Out of 30 applications received, 23 (77%) were due for finalisation	Target achieved.	None
	New GMP- and GWP-related licences finalised.	Percentage of new GWP related licences (local manufacturer) finalised within 125 days			50% of new GMP related licences (local manufacturer) finalised within 125 days	38% new GMP related licenses finalised within 125 business days.	Target not achieved. Inadequate communication resulted in delays in the issuance of resolutions and inefficient scheduling of inspections.	Improving communication. Capacitated the Inspectorate with new resources and ensure prioritisation of functions.

Programme / Sub-programme: Inspectorate and Regulatory Compliance								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	** Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
Efficient and effective regulatory practices maintained (7)	Permits Finalised	Percentage of permits finalised within 20 working days	94% permits finalised within 20 days. Out of 4448 applications received, 4275 (96%) were finalised, out of which 4171 (94%) were finalised within 20 working days	93% permits finalised within 20 days. Out of 5123 applications received, 5103 (100%) were finalised, out of which 4749 (93%) were finalised within 20 working days	85% permits finalised within 20 working days	92% were finalised within 20 working days. Out of 5155 applications received, 4913 (95%) were finalised, out of which 4751/5155 (92% cumulative) permits finalised within 20 working days.	Target achieved.	Improved adherence to business processes
						Out of 44 applications received, 29 (66%) were due for finalisation. Out of 29 due for finalisation, 17 (58%) were finalised, of which 11 (38%) were finalised within 125 working days.		

Programme / Sub-programme: Inspectorate and Regulatory Compliance								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
	Notification of recalls and alerts	Percentage (%) of recalls and related alerts published within seven (7) working days	-	-	80% of recalls and related alerts published within seven (7) working days	82% of recalls were published within 7 working days. In 2025/26 a total of 22 recalls, of which 18 were published within seven(7) working days= 82% cumulative.	Target achieved.	None

Linking performance with budgets

In assessing the achievement of outputs against the planned targets, the public entity should consider the relationship between performance and the resources available to it, particularly its financial resources. Accordingly, the following financial information is presented. The information is consistent with the Annual Financial Statements.

Programme/activity/objective	2025/2026			2024/2025		
	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	67 035	57 847	9 187	55 570	56 365	(795)
Total	67 035	57 847	9 187	55 570	56 365	(795)

Under expenditure related to external funding support received and delayed filling of vacancies

Strategy to overcome areas of underperformance

The entity implemented mitigation measures by revising its inspection plans to incorporate prioritisation and monthly performance monitoring. Additional resources were appointed, and targeted training was provided to improve performance.

3.4 Programme 4: Clinical and Pharmaceutical Evaluation

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

Sale of Unregistered Category A (Human) Medicines 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.

Human Clinical Trials, to ensure Good Clinical Practices in the conduct of clinical trials on humans, SAHPRA has regulatory oversight of human clinical trials conducted within South Africa.

Health Product Safety Signals, the unit convened a Pharmacovigilance strategic meeting with participation by the Universities and other NRAs within the continent. MedDRA & Vigimobile/Vigiflow training for SAHPRA staff, provinces and industry continued in eight (8) provinces.

Lot release, the lot release function is a critical post authorisation vaccine testing step that ensures vaccines made available in South Africa are effective and safe. SAHPRA conduct these tests at the South African National Control Laboratory for Biological Products (SANCLBP). SAHPRA monitors the time it takes to finalise the tests and release products for market access.

Table 2.4.4.4

Programme / Sub-programme: Clinical and Pharmaceutical Evaluation								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	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 three (3) working days	81% of Regulatory compliance investigation reports produced within 30 working days. Out of 507 complaints received, 505 (100%) reports were produced, of which 410 (81%) were produced within 30 working days	Number of applications received: 18 083 Number of applications responded to: 18 083 Number of applications finalised: 18 055 Number of applications finalised within 3 working days: 17 404 Actual: 17 404/18083 *100% = 96%	95% applications for the sale of unregistered Category A (human) medicines finalised within three(3) 3 working days	Number of applications received: 17017 Number of applications finalised: 16984 Number of applications finalised within 3 working days: 15827 Actual: 15827/17017 *100% = 93%	Target not achieved due to delays in processing applications.	System modification implemented based on an approved Delegation of Authority (DoA). Project plan in place for the system amendments.

Programme / Sub-programme: Clinical and Pharmaceutical Evaluation								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
	Clinical Trials safety signal detected and mitigated.	Percentage of Clinical Trials safety signal detected and mitigated within 80 working days	-	-	50% Percentage of Clinical Trials safety signal detected and mitigated within 80 working days	Initials SAE Reports Received: 887 Met Criteria: 505 Due for finalisation: 324 Mitigation within 80 working days: 76 Achievement: 76/324 = 23%	Target not achieved. Backlog of reports Manual submission of reports Lack of human resource – admin and dedicated technical staff to focus exclusively on SAEs. 2026/2027 process to be streamlined.	Motivation for technical support - to capture cases on Vigiflow x2 in recruitment E2B standard implementation Evaluator - Motivation in progress. Increased/prompt allocation to external experts or assessors Electronic system (limit manual entries) Tracker review for 2026/2027
Efficient and effective regulatory practices maintained (7)	High public health impact safety signals detected and mitigated.	Percentage of all high public health impact safety signals detected and mitigated within 40 working days.	-	-	60% of all high public health impact safety signals detected and mitigated within 40 working days.	100% (1) health impact signals detected and mitigated within 40 working days.	Target Achieved.	Revised the KPI and TID for 2026/27

Programme / Sub-programme: Clinical and Pharmaceutical Evaluation								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	** Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
	Health product significant safety issues assessed.	Percentage of reports on health product safety signals assessed within 60 working days	-	-	70% reports on health product significant safety issues assessed within 60 working days	Overall: Of the 288 finalised, 17 were in backlog, 233 were due in 2025/2026 and 38 are due in 2026/2027. Cumulatively, 142/276(51,45%) of the reports were completed within 40/60 working days.	Target not achieved. Numerous challenges with focus on WHO GBT preparations and Limited resources.	Additional staff recruited, performance should improve.
	Health product safety signals issued.	Percentage of safety communications published within 10 working days.	Out of 456 signals received, 446 (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	185 reports on health product safety signals issued within 40 working days Out of 301 signals received, 321 (106,64 %) cumulative were due for finalisation by end Mar 2025 Out of 321 due for finalisation, 427 (133,02%) cumulative reports were issued, of which 185 (57%) were issued within 40 workings days	90% of the safety communications published within 10 working days	1 media release was issued 12 DHCPL safety communications received 7 DHCPL safety communications finalised. 1/12 (8.33%) finalised within 10 working days	Target not achieved. Administrative delays between SAHPRA and the applicants impacted finalisation within the required timeline.	Continuous monitoring of incoming DHCPLs to ensure timely review within target timelines.

Programme / Sub-programme: Clinical and Pharmaceutical Evaluation								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	** Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
	Number of safety awareness campaigns held.	Number of safety awareness campaigns held	Twelve safety awareness campaigns held	19 safety awareness campaigns were held	12 safety awareness campaigns held	32 safety awareness campaigns were held in eight (8) Provinces for the FY 2025/26.	Target overachieved.	Intensified provincial and districts VigilMobile/VigilFlow training to implement GBT recommendations.
	Lot release requests finalised	Percentage of lot release requests finalised within *40 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	200 requests for lot release were received in the cycle 2024-25. 150 (100%) of 200 was due for finalisation within 50WD. 183 (122%) were finalised and of these 150 (100%) were completed within the 50WD.	90% lot release requests finalised within 50 working days	From a total number of 169 lot release requests received as at the end of the 2025/2026 financial year (From April 2025), 182 applications were due for finalisation. Out of 182 due for finalisation, 182 (100%) was finalised, of which 178 (98%) were finalised within 50 working days. Hence, $178/182 \times 100 = \mathbf{98\%}$, which is reported as cumulative performance for the 2025/26 Financial Year.	Target Overachieved.	Improved processes.

*Error/Typo in the 2025/26 APP under Output indicator for Lot Release p77 (Percentage of lot release requests finalised which should reflect "within 50 working days"). Submission made to the Minister, approval to revise the APP acceptable for 2026/27 FY. The reported performance under Lot Release requests of 98% is against the 50 working days target.

Linking performance with budgets

In assessing the achievement of outputs against the planned targets, the public entity should consider the relationship between performance and the resources available to it, particularly its financial resources. Accordingly, the following financial information is presented. The information is consistent with the Annual Financial Statements.

Programme/activity/objective	2025/2026			2024/2025		
	Budget	Actual Expenditure	(Over)/Under Expenditure	Budget	Actual Expenditure	(Over)/Under Expenditure
	R'000	R'000	R'000	R'000	R'000	R'000
Programme 4	141 441	139 070	2 371	120 033	115 526	4 506
Total	141 441	139 070	2 371	120 033	115 526	4 506

Under expenditure related to external funding support received and delayed filling of vacancies

Strategy to overcome areas of underperformance

Sale of Unregistered Category A (Human) Medicines, SAHPRA has a system implemented in S21 that is being monitored and reviewed to address delays related to authorisation of S21 applications.

Human Clinical Trials function remained a pain point due to capacity constraints and the lack of a resource-optimal operating system to process applications. As part of intervention in this area, SAHPRA has initiated implementation of Clinical Trials Electronic System planned July 2026 and recruitment of additional external reviewers.

Health Product Safety, the main challenges remained due to resource constraints on personnel to process submissions in a timely manner. This was mitigated by recruitment of an additional permanent staff member(s).

3.5 Programme 5: Medical Devices and Radiation Control

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

The Medical device licensing has successfully approved 1419 applications with **Medical Device Registration**, the external product registration feasibility outcome report was published on 31 March 2026. To date, SAHPRA has successfully recommended approval for 11 products through the feasibility study.

The revised Medical Devices Regulations still undergoing internal reviews, Socio-Economic Impact Assessment System (SEIAS), also referred to as a Regulatory Impact Assessment (RIA).

Radiation Control conducted inspections and issued sealing letters for non-compliance. SAHPRA visited facilities operating specialised electronic products including mines authorised to possess and use radioisotopes for non-medical purposes.

Table 2.4.4.5:

Programme / Sub-programme: Medical Devices and Radiation Control								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	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	126,6% of 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.	128,4% of medical device establishment licence applications finalised within 90 working days	80% medical device establishment licence applications finalised within 90 working days	133% of medical device establishment licence applications were finalised within 90 working days. Out of 1541 applications received, 1067 (69,2%) were due for finalisation. Out of 1067 due to finalisation, 1458 (136,5%) were finalised, of which 1419 (133%) were finalised within 90 working days	Target overachieved.	Well established business processes resulted in the efficient processing of the license applications.
	Medical device registration regulations implemented	Notice of medical device products published.	Expression of interest for medical device voluntary registration feasibility study approved and published on social media platforms for coming engagement towards implementation.	Pilot Call-up Notice of Class D (high-risk) for specific / selected disease criteria medical device products were not published.	Implementing and finalising product registration feasibility study for high-risk class C and D for selected priority diseases criteria	The unit received 20 technical dossiers for product registration feasibility study, with 09 products recommended for approval, 2x products excluded from the study, 4 x withdrawn after submission by the applicants.	Target achieved.	None

Programme / Sub-programme: Medical Devices and Radiation Control								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
			The upcoming feasibility study must first be conducted prior to embarking on Call-Up Notice of pilot Class D update being published.	Publication of Expression of Interest (Eoi) for feasibility was published on the first quarter 2024/25FY social media platforms for coming engagement towards implementation.				
				The upcoming Feasibility study must first be conducted prior to embarking on Call-up Notice of pilot Class D) update being published		Feasibility report on product registration feasibility study was published on 31/01/2026		
	Radionuclide authorities (licenses) finalised	Percentage of applications for radionuclide authorities (licences) finalised within 60 working days	79% application for authorities were finalised within 30 working days 2486 application received of 2486 application received, 2311 applications were due for completion before 31 March 2024. 846 applications that were due for completion	86% application for authorities were finalised within 30 working days 2397 Applications received.	70% applications for radionuclide authorities (licences) finalised within 60 working days	90% of applications for authorities were finalised within 60 working days.	Target overachieved.	Well established business processes resulted in the efficient processing of the license applications.

Programme / Sub-programme: Medical Devices and Radiation Control								
Outcome	Output	Output Indicator	Audited Actual Performance 2023/2024	Audited Actual Performance 2024/2025	Planned Annual Target 2025/2026	**Actual Achievement 2025/2026	Deviation from planned target to Actual Achievement 2025/2026	Reasons for deviations
				2191 applications were due for completion before 31 March 2025. 2086 (95%) applications were completed		2294 Applications received. 1667 applications were due for finalisation before end of March 2026. 1936 applications were finalised with 795 Applications that were due for completion were issued. 713 (90%) Of the issued Authorities were issued within 60 workdays.		Applications not due for finalisation were finalised earlier than anticipated. Improved tracking sheets, quality checks and SOPs.
	License applications for listed-electronic products finalised	Percentage of licence applications for listed-electronic products finalised within 50 working days	116% applications for listed-electronic products finalised within 30 Working days. 851 applications were received, out of 837 received 720(84%) were due for finalisation. Out of 720 due for finalisation 851(118%) were finalised. Out of 851 finalised, 836 (116%) were finalised within 30 working days	92% applications for listed-electronic products finalised within 30 Working days. 1624 applications were received, out of 1624 received 1534(94%) were due for finalisation. Out of 1534 due for finalisation 1624(106%) were finalised. Out of 1624 finalised, 1412(92%) were finalised within 30 working days	90% licence applications for listed-electronic products finalised within 50 working days	126% applications for listed-electronic products finalised within 50 Working days. 1024 applications were received, out of 1024 received 743(73%) were due for finalisation. Out of 743 due for finalisation, 944(127%) were finalised. Out of 944 finalised, 936 (126%) were finalised within 50 working days	The target was overachieved.	Well established business processes resulted in the efficient processing of the license applications Applications not due for finalisation were finalised earlier than anticipated. Improved tracking sheets, quality checks and SOPs

Linking performance with budgets

In assessing the achievement of the outputs in comparison to the planned targets, the public entity must consider the linkages and the relation to the resources available to the public entity, in particular the financial resources. Therefore, the following financial information should be presented. The financial information must agree to the information in the annual financial statements.

Programme/activity/objective	2025/2026			2024/2025		
	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	44 643	43 165	1 478	43 913	40 664	3 249
Total	44 643	43 165	1 478	43 913	40 664	3 249

Under expenditure related to external funding support received and delayed filling of vacancies

Strategy to overcome areas of underperformance

SAHPRA has not recorded underperformance in this function.

4. REVENUE COLLECTION

Sources of revenue	2025/2026			2024/2025		
	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	284 377	303 507	(19 130)	248 508	254 853	(6 345)
Total	284 377	303 507	(19 130)	248 508	254 853	(6 345)

Better than anticipated revenue collection occurred due to the impact of the revised Medicines Fee Regulation Gazetted in February 2025 and projects relating to clearing of backlogs in certain evaluation areas.

5. CAPITAL INVESTMENT

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

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

For the 2025/26 financial year, SAHPRA acquired assets worth R26.1 million by March 2026. These included, Furniture, Leasehold improvements (R1.1 million), motor vehicles (R1.1 million), computer equipment (R6.4 million), office equipment (R2.9 million), and intangible assets that are still work in progress (R14.6 million).

Disposals involved outdated furniture and computer equipment, which were sold or donated, with many fully depreciated.

Infrastructure projects	2025/2026			2024/2025		
	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						





PART C

Governance

1. INTRODUCTION

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

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

2. PORTFOLIO COMMITTEES

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

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

Date	Parliamentary Structure	Activity/ Focus
08 October 2025	Portfolio Committee on Health	Presentation of the Annual Financial Statements and Report for 2024/2025 financial year.
23 April 2026	Portfolio Committee on Health	Presentation of the Strategic Plan, Annual Performance Plan and Budget for 2025/2026 financial year.

3. EXECUTIVE AUTHORITY

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

4. THE ACCOUNTING AUTHORITY/BOARD

Introduction

SAHPRA is a schedule 3A public entity established in terms of the Medicines and Related Substances Act and functions through its Board. The Board is the Accounting Authority appointed by the Minister of Health in line with the provisions of the Medicines and Related Substances Act. The Minister of Health has appointed a new SAHPRA Board for a period of five (5) years effective from 01 July 2025.

Independence of the Board

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

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

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

The Role of the Board

The general responsibilities of the Board are governed largely by the Medicines and Related Substances Act, Public Finance Management Act and all other relevant applicable Regulations and legislation. The Board is guided by all other relevant legislation including the King V Report on Corporate Governance for South Africa where applicable. The Board sets the strategic direction and provides guidance and oversight and monitors the implementation of SAHPRA's objectives, strategies, performance plan and budget. Detailed functions and responsibilities of the SAHPRA Board are set out in the Board Charter.

Board Charter

The mandate of the SAHPRA Board is set out in the Medicines and Related Substances Act and has been encapsulated in the Board Charter. The Board Charter is reviewed every year to ensure compliance with relevant legislation and new developments in the corporate governance environment. The mandate of the Board as set out in the Board Charter is aligned to the requirements stipulated by the Protocol on Governance in Public Entities and King Code in Good Governance.

Composition of the Board

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

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

The term of office of the Board that was appointed in 2021 came to an end on 30 June 2025. The Minister of Health appointed new members to serve on the SAHPRA Board with effect from 01 July 2025. The composition of the Board and changes thereto is outlined below.

Composition of the Board during the period 01 April 2025 to 30 June 2025 is as follows:

Name	Designation (in terms of the Public Entity Board structure)	Date appointed	Date resigned/ termination/ end of term	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 Vera Rees	Board Chairperson	Appointed 17 November 2017 Re-appointed 25 April 2024	30 June 2025	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		4
Adv Hasina Cassim	Board Member	Appointed 17 Nov 2017 Re-appointed 25 April 2024	30 June 2025	B Pharm LLB Certificate in Medicine Law Certificate in pharmacoepidemiology Medical Mediation training	Law	N/A	RAG TORS	4
Mr Elias Ithani Mashau	Board Member	Appointed 25 April 2019 Re-appointed 25 April 2024	30 June 2025	B Pharm Diploma in Production Diploma in Quality Management and Assurance Master of Business Administration Diploma in Small Business Management	Good Manufacturing Practice	N/A	TORS HRREMCO	4
Prof Hulisani P Demana	Board Member	Appointed 25 April 2019 Re-appointed 25 April 2024	30 June 2025	Ph.D. in Pharmaceutics B.Sc. (Hons) in Pharmacy M.Sc. in Pharmaceutics Post-doctoral Fellowship in Drug Discovery A-level courses (chemistry, biology and mathematics & statistics)	Virologist	N/A	TORS	4
Ms Lerato Mothae	Board Member	Appointed 1 Oct 2021 Re-appointed 25 April 2024	30 June 2025	Bachelor of Accounting CTA (B.Compt Honours CA (SA)	Finance and Accounting	N/A	RAG FINCO	4
Dr. Obakeng Khaole	Deputy Chairperson of the Board	Appointed 1 Oct 2021 Re-appointed 25 April 2024	30 June 2025	MBChB Bachelor of Surgery Diploma in HIV Management Postgraduate in Occupational Medicine	Medical research and clinical trials	N/A	HRREMCO	4

Name	Designation (in terms of the Public Entity Board structure)	Date appointed	Date resigned/ termination/ end of term	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 Joyce Tsoka-Gwegweni	Board Member	Appointed 1 Oct 2021 Re-appointed 25 April 2024	30 June 2025	B.A. Hons (Social Science psychology) B.Sc. Hons- Zoology & Microbiology PHD in Public Health MPH in Public Health	Public health medicine	N/A	TORS	3
Dr Xolani Ngobese	Board Member	Appointed 1 Oct 2021 Re-appointed 25 April 2024	30 June 2025	PHD in Business Administration Master's in Business Administration	Independent consultant	N/A	HRREMCO RAG FINCO	4
Ms Ditaba Maraka	Board Member	Appointed 1 Oct 2021 Re-appointed 25 April 2024	30 June 2025	Bachelor of Art Bachelor of Education Baccalaureus Artium Honores Masters Diploma in HR Training and Development Ethics Officer Certification Psychometrist Effective Audit Committees Effective Remuneration Committees Social & Ethics Committees	Independent Psychometrist	N/A	HRREMCO	4
Dr Alfred Kgasi	Board Member	Appointed 23 Dec 2021	30 June 2025	Bachelor of Veterinary Medicine LLB Master of Business Leadership	Veterinary	N/A	TORS RAG	3
Prof Yahya Choonara	Board Member	Appointed 23 Dec 2021	30 June 2025	BPharm MPharm PhD	Medical devices	N/A	TORS	-
Prof Johanna Meyer	Board Member	Appointed 23 Dec 2021	30 June 2025	BPharm MSc (Med) PhD in Pharmacy	Pharmacovigilance, Public Health	N/A	TORS	2
Ms Mandisa Skhosana	Board Member	Appointed 1 Oct 2021 Re-appointed 25 April 2024	30 June 2025	National Diploma in Biomedical Technology B-Tech Degree in Biomedical Technology Master's degree in medical science	Laboratory medicine, quality control and clinical research	N/A	TORS	4

Name	Designation (in terms of the Public Entity Board structure)	Date appointed	Date resigned/ termination/ end of term	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 Faizal Dockrat	Board Member	Appointed 18 June 2024	30 June 2025	Master of Business Administration Chartered Director Information Systems Audit and Control Association Certified Information Security Manager Certified Information Systems Auditor Certified in the Governance of Enterprise Information Technology Institute of Risk Management South Africa (IRMSA)-Certified Risk Management Practitioner Management Advancement Program Total Quality Management Computer Users Council Computer Operations Proficiency Examination	Information technology	N/A	RAG FINCO	4
The Minister of Health Appointed the following members to serve on the SAHPRA Board with effect from 01 July 2025								
Name	Designation	Date appointed	Date of termination	Qualifications	Area of Expertise	Board Directorship	Other Committees or Task Teams	No. of meetings attended
Dr Thapelo Motshudi	Board Chairperson	01 July 2025	N/A	FC Rad Diag (Diagnostic Radiology) MBCChB (Bachelor of Medicine & Bachelor of Surgery) International Radiation Protection School OECD Nuclear Energy Agency (NEA), Radiation Protection in Medical Applications, Decommissioning of Nuclear Facilities, BSc Chemical Engineering	Radiology	N/A	N/A	6
Prof Glenda Gray	Deputy Chairperson	01 July 2025	N/A	MBBCh, FCPaeds (SA) DSC Honoris- Simon Fraser University, DSC Honoris Causa (Stellenbosch University), Honorary Doctorate in Laws (LLD (hc) (Rhodes University)	Clinical research	N/A	HRREMCO	4
Dr Chevron Clark	Board Member	01 July 2025	N/A	Doctorate Technologiae Degree in Clinical Technology (D.Tech. Clinical Technology), Master of Laws (LLM), Master of Business Administration (MBA) and a Bachelor of Science (BSC)	Clinical	N/A	HRREMCO FINCO & TORS	3

Name	Designation (in terms of the Public Entity Board structure)	Date appointed	Date resigned/ termination/ end of term	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 Johanna Gouws	Board Member	01 July 2025	N/A	Science degree (BSc), Pharmacy degree (BPharm), Honours degree in Pharmacology (B Pharm Hons), Pharmacy master's degree in pharmacology (MPharm) Doctorate in Pharmaceutics (PhD), MBA	Virologist	N/A	HRREMCO TORS	3
Dr Tobeka Boltina	Board Member	01 July 2025	N/A	MBCHB, Diploma in Occupational Health, Certificate in Pharmaco-Economics.	Public Health	N/A	RAG TORS	6
Ms Ntebo Nkoenyane	Board Member	01 July 2025	N/A	Admitted attorney in South Africa LLM, LLB, B-IURIS,	Law	N/A	HRREMCO TORS RAG	5
Mr. Anthony Ngcezula	Board Member	01 July 2025	N/A	BSc (Hons) in mathematical studies, MSc in Pure Maths, BCom, MBA, Postgraduate qualifications in corporate finance, public finance and fiscal management, municipal finance.	Finance and governance	N/A	FINCO RAG	6
Prof. Rajesh Mahabeer	Board Member	01 July 2025	N/A	CA(SA) FCMA CGMA FCA (England & Wales) BFP FCCA CIA FIIASA M.Inst.D SARIIPA INSOL MBA (Derby) MCom (UKZN) Post Grad Dip Acc (UKZN) N Dip Cost Acc (DUT) PhD (Candidate) (WITS)	Audit and Risk	N/A	FINCO RAG	6
Mr. Nkosenhle Ngongoma	Board Member	01 July 2025	N/A	Postgraduate Diploma in Management in the field of Digital Business, BTech in Information Technology, National Diploma in IT (Software Development) from academic certifications, including Leadership Development and IT Operations Management.	IT	N/A	FINCO RAG TORS	6
Mr. Moses Moselekwa	Board Member	01 July 2025	N/A	B. ADMIN Financial Management Management Development MS OFFICE Leadership Development IR Payroll Management Performance Management Counselling Equity, Skills Development, Levies, NQF AND SAQA	Management	N/A	FINCO HRREMCO RAG	6
Dr AT Kgasi	Board Member	01 July 2025	N/A	Bachelor of Veterinary Medicine LLB Master of Business Leadership	Veterinary	N/A	HRREMCO TORS	6

Board Committees

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

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

Each Committee has formal terms of reference that define their mandate, roles and responsibilities. The terms of reference are reviewed annually to ensure that they are aligned to the new trend, governance practices and updated prescripts.

Committee	No. of meetings held	No. of members	Name of members
Finance Committee	2	4	Ms Lerato Mothae Prof Rajesh Mahabeer (External Independent member) Dr Xolani Ngobese Mr Faizal Dockrat
	2	5	Appointed to serve in the committee w.e.f 10 July 2025 Mr Anthony Ngcezula (Chair) Prof Rajesh Mahabeer Mr Moses Moselekwa Mr Nkosenhle Ngongoma Dr Chevon Clark
Technical Oversight and Regulatory Strategy Committee	1	8	Prof Johanna Meyer Prof. Patrick Demana Adv Hasina Cassim Mr Itani Mashau Dr Alfred Kgasi Ms Mandisa Skhosana Prof Yahya Choonara Prof Joyce Tsoka-Gwegweni
	3	7	Appointed to serve in the Committee w.e.f 10 July 2025 Dr Johanna Gouws (Chair) Prof Glenda Gray Dr Alfred Kgasi Dr Tobeka Boltina Dr Chevon Clark Ms Ntebo Nkoenyane Mr Nkosenhle Ngongoma

Prof Rajesh Mahabeer was appointed as an independent member of the Committee until 30 June 2025.

Risk Audit and Governance Committee	4	8	Ms Lerato Mothae Dr Xolani Ngobese Dr Alfred Kgasi Adv. Hasina Cassim Ms Adila Chowan (External member) Mr Bruce Gordon (External member) Prof Rajesh Mahabeer (External member) Mr Faizal Dockrat Appointed to serve in the Committee w.e.f 10 July 2025 Prof Rajesh Mahabeer (Chair) Ms Ntebo Nkoenyane Mr Nkosenhle Ngongoma Mr Anthony Ngcezula Dr Tobeka Boltina Mr Bruce Gordon Adv Adila Chowan Mr Moses Moselekwa (06/11/2025)
	9	8	
Human Resource and Remuneration Committee	3	4	Mr Itani Mashau Dr Xolani Ngobese Dr Obakeng Khaole Ms Lucy Ditaba Maraka Appointed to serve in the Committee w.e.f 10 July 2025 Mr Moses Moselekwa (Chair) Dr Alfred Kgasi Ms Ntebo Nkoenyane Prof Glenda Gray Dr Johanna Gouws Mr. Anthony Ngcezula Dr Chevon Clark
	8	7	

The Board took a decision to integrate the Finance Committee (FINCO) responsibilities into Risk, Audit and Governance Committee (RAG) to minimise duplication of activities. The Terms of Reference for RAG were duly amended.

Remuneration of Board Members

The Board has approved a Remuneration Policy guiding how members are paid. State-employed members cannot claim attendance and preparation fees for meetings. Members are reimbursed for expenses incurred while furthering the interests or attending to the business of SAHPRA. The applicable remuneration rate is approved by the Minister of Health in consultation with the Minister of Finance.

A summary of remuneration and emoluments is provided in the table below:

Name	Remuneration	Other allowance	Other re-imbursements	Total
Prof Helen Vera Rees	R41 569	-	-	R41 569
Adv Hasina Cassim	R54 086	-	-	R54 086
Mr Elias Ithani Mashau	R49 764	-	-	R49 764
Prof Hulisani P Demana	R37 790	-	-	R37 790
Ms Lerato Mothae	R67 567	-	-	R67 567
Dr. Obakeng Khaole	R45 865	-	-	R45 865
Prof Joyce Tsoka-Gwegweni	R32 592	-	-	R32 592
Dr Xolani Ngobese	R67 653	-	-	R67 653
Ms Ditaba Maraka	R35 466	-	-	R35 466
Prof Yahya Choonara	R7 558	-	-	R7 558
Prof Johanna Meyer	R22 674	-	-	R22 674
Ms Mandisa Skhosana	R37 790	-	-	R37 790
Mr Faizal Dockrat	R48 712	-	-	R48 712
Board members appointed effective 01 July 2025				
Dr Thapelo Motshudi	R64 788	-	-	R64 788
Prof Glenda Gray	R109 423	-	-	R109 423
Dr Chevon Clark	R85 002	-	-	R85 002
Dr Johanna Gouws	-	-	-	-
Dr Tobeka Boltina	R115 259	-	-	R115 259
Ms Ntebo Nkoenyane	R121 469	-	-	R121 469
Mr Anthony Ngcezula	R130 409	-	-	R130 409
Prof Rajesh Mahabeer	R101 746	-	-	R101 746
Mr Nkosenhle Ngongoma	R 96 382	-	-	R 96 382
Mr Moses Moselekwa	R126 402	-	-	R126 402
Dr AT Kgasi	R154 374	-	-	R154 374

5. RISK MANAGEMENT

- SAHPRA continues to promote a proactive and accountable risk management culture across the entity, by ensuring that its embedment is rooted in strategic planning and operational processes.
- SAHPRA continued to maintain a proactive and accountable approach to risk management during the 2025/26 financial year. Risk management was embedded in governance and operational processes, with management responsible for identifying, assessing, mitigating and reporting risks within their areas of accountability. The control environment was supported by governance structures, internal audit, compliance and management forums. While capacity constraints remained in some specialised and technical areas, the entity showed improving risk awareness through targeted recruitment, training, process improvements and stronger systems and controls. Employees were expected to understand their responsibilities in relation to risk ownership, escalation and compliance, while management remained accountable for ensuring that risks were monitored and mitigation actions implemented.
- Risk Management within SAHPRA is overseen by the Board through the Risk, Audit and Governance Committee (RAG), which reviews the risk management activities, evaluates effectiveness of controls for identified risks and any emerging risks. While management and staff are encouraged to continuously identify and monitor risks within their units; and on a quarterly basis report these to the internal Risk Management Committee.
- The risk management governance documents entail the following:
 - Enterprise Risk Management Policy and Framework
 - Risk Appetite Statement
 - Fraud Prevention Policy and,
 - Whistle-blowing Policy
- These documents are reviewed periodically to ensure alignment with operational and legislative changes that may arise. Communication of these and related documents, is facilitated through the quarterly socialisation and induction session throughout the financial year.
- Risk workshops are conducted quarterly with monthly monitoring and escalations as required. Risk identification is initiated from the entity's outcomes articulated in the strategy and performance documents.

6. INTERNAL AUDIT

SAHPRA has an outsourced Internal Audit function which provides independent and objective assurance to management, the Risk, Audit and Governance Committee (RAG), and the Board.

- Internal Audit function reviews the internal control environment and provides assurance on its adequacy and effectiveness. In addition, its role entails the value -add component of consultancy as provided under corporate governance.
- In executing its strategy, the function adopts a risk-based approach linked to the risk profile of SAHPRA, which is articulated in the rolling and annual plans approved and monitored by the RAG on a quarterly basis.
- Internal Audit reports functionally to the RAG and administratively to the CEO, thereby ensuring its independence and objectivity from management.
- Stakeholder relationships for Internal Audit include, but are not limited to the RAG and external audit (AGSA). There is constant engagement with stakeholders especially the AGSA to optimise the concept of combined assurance within SAHPRA and avoid duplication of efforts.

- Value add of internal auditing is linked to identification of control weaknesses, process improvement opportunities, advisory services; and the monitoring and verification of implemented audit action plans.
- Internal Audit managed to finalise all scheduled audit assignments for the financial year 2025/26 with the exception of one, which was at the reporting phase as of 31 March 2026. The RAG noted this report back from Internal Audit in alignment with the approved annual plan.

	Number of findings	Total Addressed	Not Yet Due	Total Not Addressed	No. of recurring findings Last 3 Financial Years
IAF Findings	111	96	16	16	3
AGSA Findings	15	13	2	2	0

7. FRAUD AND CORRUPTION

- SAHPRA is committed to the commitment of eradicating fraud and corruption within the public service through the fraud prevention mechanisms undertaken and monitored.
- Periodic review and socialisation of the Fraud Prevention Policy and Plan, including the Whistle-Blowing policy are undertaken to ensure alignment with the required changes and relevant updates, which are then communicated to staff through awareness and induction sessions.
- SAHPRA has provided the whistleblowing hotline which staff and the public can use to anonymously report on any actual or perceived fraud and corruption activity suspected. In an effort to protect whistleblowers, SAHPRA encourages anonymous reporting to the hotline, where the caller's identity will not be revealed to anyone. Staff are also appraised on other platforms within and outside the entity which can be used to report suspected fraud and corruption.
- All reported cases are screened to ensure they are routed to the correct unit for investigation or further assessment. The Risk and Internal Audit unit works closely with the Regulatory Compliance unit to investigate reported cases concerning non-compliances with SAHPRA regulations and business.
- SAHPRA will attempt to investigate all reported cases and report these and their outcomes to the Risk, Audit and Governance Committee (RAG). SAHPRA will also report cases of a criminal nature to the relevant authorities for further investigations and sanctions according to the South African law.
- In the financial year 2025/26 one (1) case of employee fraud was detected and following an HR process the employee was dismissed.

8. MINIMISING CONFLICT OF INTEREST

The Board has approved a Management of Conflict-of-Interest Policy which is renewable on a three-year basis or when the need arises. The new Management and Declaration of Interest was approved in 2025. There are procedures in place to manage and minimise the risks related to conflict of interest (perceived, potential or actual). Board members and all employees within SAHPRA are required to disclose and declare their financial interest on an annual basis. At all Board and Committees' meeting members are required to sign and submit their declaration of interest forms, and these are captured as standing agenda item for each meeting. This approach is extended to members of the different advisory committees in SAHPRA. Where a potential conflict of interest has been identified and/or declared such interest is recorded and the conflicted member is recused from participating in the discussion.

9. CODE OF CONDUCT

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

10. HEALTH SAFETY AND ENVIRONMENTAL ISSUES

No Injury on Duty cases were reported during the reporting period. In compliance with the Occupational Health and Safety Act, SAHPRA held three meetings of the Occupational Health and Safety (OHS) Committee and employed air quality assessors to conduct a baseline-risk assessment of indoor air quality in April 2025, followed by continuous exposure monitoring assessments in September 2025, January, February and March 2026. Additionally, SAHPRA approved a Standard Operating Procedure on Sustainable Environmental Management and participated in an evacuation simulation in July 2025 to enhance emergency preparedness.

11. BOARD SECRETARY

The Board Secretary and Deputy Board Secretary are appointed to provide secretarial and advisory services to the Board and its Committees. Furthermore, the Board Secretary is a liaison officer between the Management and the Board, and between the Board and Shareholder on issues relating to governance, thus giving effect to governance protocols. The Board Secretary is the custodian of the register of Board and Committees decisions.

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

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

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

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

12. SOCIAL RESPONSIBILITY

CSI initiative completed successfully on 5 December at the Leamogetswe Home. Volunteers performed cleaning and painting. SAHPRA also donated groceries and lunch packs to residents in July 2025.

SAHPRA donated laptops to Sefako Makgatho University (SMU), Ga-Rankuwa Campus, in February 2026.

13. AUDIT COMMITTEE REPORT

INTRODUCTION

The Risk, Audit and Governance Committee (“RAG”) is pleased to present its report for the financial year ended 31 March 2026.

The Committee operates within the approved Terms of Reference (ToR) and complies with all governing legislation in executing its responsibilities in terms of the PFMA and Treasury Regulations and requirements of King Code of Corporate Governance.

COMPOSITION

The Committee is composed of non-executive members who are appointed by the Board for a period equivalent to their term of office as Board members. The independent members of the committee are appointed for a period of three (3) years renewable for a further term not exceeding three years.

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 Committee’s meetings.

Representatives of Nexia SAB&T (Internal Auditors) and the Auditor General (AGSA) are also standing invitees to the RAG meetings.

The table below discloses the relevant information of the 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 Hons CA SA)	External	Board Member	October 2021	June 2025	4
Dr Alfred Kgasi	Bachelor of Veterinary Medicine; LLB; Master of Business Leadership	External	Board Member	October 2021	June 2025	4
Dr Xolani Ngobese	PHD in Business Administration; Master of Business Administration	External	Board Member	October 2021	June 2025	3
Adv Hasina Cassim	BPharm; LLB; Certificate in Pharmacoepidemiology; Medical Mediation Training	External	Board Member	October 2021	June 2025	4
Mr Faizal Dockrat	Master of Business Administration; Chartered Director Information Systems; Audit and Control Association; Certified Information Systems Auditor; Certified in Governance of Enterprise Information Technology; Institute of Risk Management South Africa; Certified Risk Management Practitioner; Management Advancement Program; Total Quality Management; Computer Users Council; Computer Operations Proficiency Examination.	External	Board Member	June 2024	June 2025	4

Name	Qualifications	Internal or external	If internal, position in the public entity	Date appointed	Date Resigned	No. of Meetings attended
Adv Adila Chowan	CA(SA); Bachelor of Accounting; Post Graduate Diploma in Accounting (CTA); LLB (Cum Laude)	External	Independent Member	May 2023	N/A	10
Mr Bruce Gordon	B.Compt (Hons); CA (SA)	External	Independent Member	April 2023	N/A	10
Prof Rajesh Mahabeer	CA(SA) FCMA CGMA FCCA FCA BFP CIA FIISA SARIPA INSOL MBA MCOM PGDA NDIP (COST) ACC PH.D. (CANDIDATE)	External	Board Member	July 2025	N/A	9
Ms. Ntebo Nkoenyane	Admitted attorney in South Africa LLM, LLB, B-IURIS,	External	Board Member	July 2025	N/A	6
Mr. Nkosenhle Ngongoma	Postgraduate Diploma in Management in the field of Digital Business, BTech in Information Technology, National Diploma in IT (Software Development) from academic certifications, including Leadership Development and IT Operations Management.	External	Board Member	July 2025	N/A	5
Mr. Anthony Ngcezula	BSc (Hons) in Mathematics, MSc in Pure Mathematics, BCom and MBA, postgraduate qualifications in Corporate Finance, Public Finance & Fiscal Management, Municipal Finance	External	Board Member	July 2025	N/A	6
Dr Tobeka Boltina	MBCHB, Diploma in Occupational Health, Certificate in Pharmacoeconomics.	External	Board Member	July 2025	N/A	6
Mr. Moses Moselekwa	B. ADMIN Financial Management Management Development MS OFFICE Leadership Development IR Payroll Management Performance Management Counselling Equity, Skills Development, Levies, NQF AND SAQA	External	Board Member	November 2025	N/A	3

COMMITTEE RESPONSIBILITIES

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

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

WHISTLEBLOWING

Anonymous tip-off platform for reporting fraud, corruption, and unethical conduct is administered by an independent service provider. The reported allegations are investigated, thereafter findings, conclusions, and recommendations are presented to management and the committee. The committee monitors progress on all initiated investigations and outcomes. Where the investigations have identified any wrongdoing either by negligence, intention or omission, consequence management steps are recommended against the perpetrator.

AUDITOR'S REPORT

The committee has noted the audit outcome as issued by the Auditor General of South Africa ("AGSA") who conducted the audit, with the resultant unqualified audit opinion for the period under review. The committee independently engaged with the AGSA where necessary and is satisfied that it has adequately discharged its legal and regulatory responsibilities.

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

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

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

THE EFFECTIVENESS OF INTERNAL CONTROLS

SAHPRA has outsourced internal audit functions. Nexia SAB&T is appointed for a period of five (5) years (2024-2029) to perform internal audit functions, and its performance is assessed on annual basis by the Committee.

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

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

- Reviewed Risk and Compliance Management Reports.
- Reviewed SCM, ICT and QMS reports.
- Reviewed the Audit Action Plans.
- Reviewed the quarterly legal reports.
- Reviewed the framework for establishing the effectiveness of policies and procedures relevant to this Committee.
- Established a framework for determining the Authority's compliance with significant legal and regulatory provisions.
- Reviewed the controls over significant financial and operational risks.
- Tabled and discussed Internal Audit Reports at each meeting.
- Reviewed the annual report and financial statements to ensure that they present a balanced and understandable assessment of the position, performance, and prospects of the Authority.

The key outcomes following the above assessment found that the internal financial controls and systems, although enhanced from the prior years, still have room for improvement. Overall internal controls within SAHPRA are adequate. Management continues to implement additional controls to ensure effectiveness, especially in areas where there are high volumes of manual reporting. Focused monitoring and review of audit action plans will ensure closure of these gaps and continuous improvement, thereby enhancing effectiveness of controls.

GOVERNANCE OF RISK

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

The committee has continued to fulfil its oversight role regarding:

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

INTERNAL AUDIT

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

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

IN-YEAR MANAGEMENT AND MONTHLY/QUARTERLY REPORT

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

EVALUATION OF FINANCIAL STATEMENTS

The committee reviewed the annual financial statements prepared by management.

The committee has:

- Reviewed the appropriateness of accounting policies.
- Reviewed the appropriateness of assumptions made by management in preparing the annual financial statements and ensured that compliance to GRAP 104 standards.
- Reviewed the significant accounting and reporting issues and understood their impact on the annual financial statements.
- Reviewed the annual financial statements and considered that they are complete, consistent with prescribed accounting practices and information known by the committee; and
- Obtained assurance from management with respect to the completeness and accuracy of the annual financial statements

CONCLUSION

The committee recommended the approval of the audited annual financial statements for the year ended 31 March 2026 and the audit opinion thereon at its meeting held on 28 July 2026 and these annual financial statements and audit opinion were duly approved by the Board on 31 July 2026 for inclusion in the Annual Report for the period ended 31 March 2026.



Prof Rajesh Mahabeer
Chairperson of RAG

14. B-BBEE COMPLIANCE PERFORMANCE INFORMATION

The following table has been completed in accordance with the compliance to 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 <i>(include a discussion on your response and indicate what measures have been taken to comply)</i>
Determining qualification criteria for the issuing of licences, concessions or other authorisations in respect of economic activity in terms of any law?	No	Policy for issuance of licences as per section 22c of the Medicines Act developed and approved by the Board. Published for Implementation.
Developing and implementing a preferential procurement policy?	Yes	Policy approved and applied.
Determining qualification criteria for the sale of state-owned enterprises?	N/A	
Developing criteria for entering into partnerships with the private sector?	N/A	
Determining criteria for the awarding of incentives, grants and investment schemes in support of Broad Based Black Economic Empowerment?	N/A	



PART D

Human Resource Management

1. INTRODUCTION

Overview of HR matters at the public entity

The Human Resources Management function is recognised as a strategic partner, playing an important role in enabling SAHPRA to achieve its organisational objectives through the delivery of efficient and effective HR services. By providing business partnering support to both core and support functions, HR contributes to attracting, developing, retaining, and sustaining a highly skilled and engaged workforce.

To further strengthen this capability, the Human Resource Management Unit has been capacitated through the appointment of two Learning and Development Specialists, one funded by the Right to Care NGO until mid-May 2026 and the other by SAHPRA. These appointments enhance HR's business partnering capacity, enabling the Unit to effectively address administrative and technical challenges associated with training, learning, and development processes, thereby driving organisational growth and workforce capability.

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

- Achieve implementation of 75% of the recommendations identified in the 2023/24 staff employee satisfaction survey.
- Ensure that 75% of employees participate in the planned learning and development programs to enhance workforce capability, strengthen knowledge, and improve overall performance
- Ensure that 75% of critical business positions identified in the approved Recruitment Plan are successfully filled, to strengthen SAHPRA's organisational capacity to deliver on its mandate.
- Maintain an annual staff turnover rate below 10%, supporting workforce stability and retention of institutional knowledge while sustaining an experienced workforce.

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

SAHPRA continues to experience challenges in attracting and retaining scarce and critical skills, particularly in highly technical areas, due to intense competition within the regulatory and pharmaceutical sectors. By the close of the 2025/26 financial year, the workforce expanded from 331 to 376 employees. During the reporting period, 103 appointment transactions were recorded. Of these, 15 related to internal appointments, including appointments to management roles, and therefore did not result in an increase in the overall headcount. The remaining 88 appointments contributed to the increase in the workforce. The 103 appointment transactions comprised 26 contract appointments, 43 permanent placements, 14 Community Service Pharmacists, three (3) interns, and 17 learnership participants.

Despite available funding, only 82% of the budgeted positions (106 out of 129) were successfully filled. Recruitment delays were primarily attributed to the limited availability of panel members for selection processes, the time required to complete mandatory pre-employment verification checks, and the need to re-advertise positions due to unsuitable candidate pools or declined offers. These constraints have contributed to capacity gaps across the organisation and have placed additional workload pressures on existing employees.

To mitigate these challenges, SAHPRA has established strategic partnerships with universities and industry stakeholders to broaden the reach of recruitment advertisements and access a larger pool of potentially suitable candidates. This collaborative approach aims to strengthen talent acquisition efforts and ensure the organisation's ability to deliver on its mandate.

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

Following the 2023/24 Staff Satisfaction Survey, SAHPRA developed a structured Action Plan to address key improvement areas such as employee engagement, organisational culture, leadership effectiveness, communication, and HR service delivery. The implementation period spans 2024/25 – 2026/27. Progress Achieved, is that 80% of initiatives completed (28 out of 35), exceeding the target of 75% implementation. Remaining initiatives are either ongoing or in progress.

Key Areas of Impact

- HR Governance and Policy Development: Sixteen policies approved by the Board, strengthening compliance and governance.
- Recruitment Transparency: Salary ranges included in job adverts; structured HR–management engagement sessions introduced.
- Employee Wellness: Appointment of Health 1st as wellness service provider; wellness programmes and sporting initiatives launched.
- Organisational Culture and Values: Introduction of TRUE-ICE values (2025) and leadership development initiatives to embed culture.
- HR Service Delivery: Adoption of HR Business Partnering model; enhanced communication through circulars, meetings, and Town-Hall sessions.
- Job Evaluation Project: Approved by the Board, with ongoing feedback sessions marking a milestone in organisational restructuring.

The implementation of the Action Plan has led to improved employee engagement and morale, stronger organisational culture, greater trust in leadership and HR processes and better alignment between workforce practices and SAHPRA's strategic objectives.

Progress will continue to be monitored through HR governance structures, with a follow-up Staff Satisfaction Survey scheduled for the last quarter of 2026/27 to assess improvements and identify new priorities.

Continue with the implementation of Learning and Development initiatives

Community Service Programme: in 2025/26 Financial Year, fourteen (14) Community Service professionals joined SAHPRA. From the cohort that joined SAHPRA during the 2024/25 financial year, four (4) Community Service professionals have successfully transitioned into various roles within the organisation.

This outcome demonstrates the programme's effectiveness as a strategic talent pipeline, enabling the absorption of skilled professionals into either permanent or contract positions. It also reinforces SAHPRA's commitment to building long-term capacity in critical technical roles essential to fulfilling its mandate and the effectiveness of the programme.

Internship Programme: During the 2024/25 financial year, six interns from the South African Medical Research Council (SAMRC) were placed within SAHPRA. By July 2025, three interns were formally transferred to continue their internship programme at SAHPRA. By year-end, two interns were successfully appointed, one in a permanent role and the other on a fixed-term contract. The remaining four interns were shortlisted and interviewed for various positions. Of these, one secured a permanent appointment and another a fixed-term contract, while two candidates are still awaiting the outcomes of the recruitment process.

These results highlight the success of the internship programme as a strategic talent pipeline, enabling the transition of interns into longer-term employment opportunities, while simultaneously strengthening SAHPRA's internal capacity and supporting organisational sustainability.

For the 2026/27 financial year, SAHPRA has allocated a dedicated budget to support the appointment of six (6) interns. This initiative reinforces the organisation's commitment to talent development and strategic partnerships.

Learnership Programme: In the 2025/26 financial year, SAHPRA introduced the Business Administration Learnership Programme, placing 16 unemployed learners across both core and support units. The programme provided structured workplace exposure and practical skills development, thereby enhancing employability and workplace readiness.

During the 2025/26 financial year, a total of 20 employees benefitted from study assistance support.

Employment Equity

Currently, the sectoral targets for the Economically Active Population (EAP) by race group are as follows: African: 77.9%, Coloured: 9.8%, Indian/Asian: 2.8%, White: 9.5%. As of 31 March 2026, SAHPRA's workforce demographic profile reflects both areas of overrepresentation and underrepresentation relative to the Economically Active Population (EAP) sectoral targets.

Africans constitute 81.6% (307/376) of the workforce, exceeding the target by 3.7%, while Indians are overrepresented at 7.7% (29/376), exceeding the target by 4.9%. Whites (5.3%) (20/376), and Coloureds (5.3%) (20/376), remain underrepresented, by 4.4% and 4.2% respectively. Women from African and Indian groups are also overrepresented, resulting in a predominance of female representation.

To strengthen workplace equity, targeted recruitment initiatives are being implemented to address underrepresentation, particularly among Indian and White males, while managing areas of overrepresentation. These interventions form part of the five-year Employment Equity (EE) Plan, designed to enhance diversity and fairness across the organisation.

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

Between April 2025 until March 2026, a total of 28 employees exited the organisation for various reasons: 22 resignations, 3 retirements, 1 death, 1 case of abscondment, and 1 dismissal. Based on these figures, the organisation's annual turnover rate is 7.4% (28/376), which remains below the targeted threshold of 10%.

From the Exit interview report, analysis for resignations, reasons indicate a pattern of workplace environment concerns, including perceptions of toxic leadership, unfair treatment, excessive workload, and limited career growth opportunities. These issues highlight underlying organisational culture and management challenges that require strategic intervention.

Furthermore, several employees have expressed dissatisfaction with remuneration and benefits, particularly regarding medical aid and pension contributions. This underscores the importance of maintaining competitive compensation structures to support employee retention and engagement.

The HR Team has received verbal feedback from staff members highlighting challenges in communication between managers and employees. This indicates that employer–employee relations require focused attention.

To address these concerns, SAHPRA has introduced Leadership Coaching for Managers, structured Senior Management and Management Development Programmes. These initiatives are designed to strengthen managerial communication capabilities, foster constructive workplace relationships and enhance overall organisational effectiveness.

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 7,4%, SAHPRA intends to prioritise the development of a Retention and Succession Strategy that will contribute toward retaining critical skills. In the new financial year, jobs/job 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

Performance management remains a strategic priority for SAHPRA. Revised Performance Management and Development System (PMDS) principles were approved in 2024/25 to strengthen alignment between individual performance contracts, the Annual Performance Plan (APP), and the Annual Operational Plan (AOP). The reviewed PMDS Policy was formally approved by the Board in January 2026, ensuring integration and adoption of best practices.

To support implementation, training sessions were provided to guide employees on aligning their performance contracts with organisational deliverables. In addition, managers received specialised training (through GIZ support) on managing poor performance, with emphasis on early intervention, documentation, and coaching. These interventions are designed to embed a performance-driven culture, equipping managers with the tools to drive accountability and continuous improvement, while ensuring alignment between individual contributions and organisational objectives.

In March 2026, SAHPRA successfully transitioned from a manual, paper-based PMDS to an electronic platform (e-PMDS) using SAGE 300 People. Training on the new system is scheduled for all employees in April 2026 to ensure effective adoption and utilisation. At present, the APP and AOP are being uploaded manually onto the SAGE system to enable performance contracting, as the system does not support automated importing of information.

- As of 31 March 2026, compliance with PMDS policy reflected strong progress:
- 97% (303/311) of performance agreements were submitted for the 2025/26 cycle.
- 93% (288/311) of mid-term reviews were received.
- 82% (28/34) probation reports were submitted for employees appointed between April and November 2025.
- Forty employees did not qualify for incentives due to insufficient service duration.

As of 31 March 2026, non-compliance (submission) was recorded in 23 cases, sixteen (16) mid-term reviews and seven (7) performance agreements that were not submitted. These matters were escalated to managers, with formal follow-up letters issued to the seven (7) employees concerned.

The key challenges contributing to non-compliance included delayed managerial action, a weak compliance culture and inefficiencies in follow-up processes. To address these gaps, HR is collaborating closely with the Labour Relations Specialist to strengthen accountability and ensure adherence to performance management requirements.

In addition, SAHPRA has introduced Leadership Coaching for Managers, alongside structured Senior Management and Management Development Programmes. These initiatives are specifically designed to enhance managerial capability, improve communication and oversight, and ultimately close the gap on non-compliance by embedding a stronger performance-driven culture across the organisation.

Policy Development

In the period under review, SAHPRA has since developed and reviewed eighteen (18) Human Resources policies. Out of the eighteen (18) policies, sixteen (16) policies were approved by the Board on 29 January 2026 and 26 March 2026, only two (2) Human Resources policies are outstanding which are currently being consulted with recognised and admitted unions at SAHPRA. This initiative aims to ensure legal compliance and risk mitigation, improve transparency and communication, support effective talent management, and foster a positive workplace culture.

The project to review and develop these policies began in January 2025. Once the review and development process is complete, a socialising phase will commence wherein staff members will be capacitated on all the approved policies. SAHPRA has since embarked on developing numerous frameworks which will further address gaps identified on Human Resources issues which will require Executive Committee members to approve. Currently, there are eighteen (18) frameworks that have been developed and are being consulted in different structures.

Salary Negotiations

On 16 October 2025, SAHPRA and Public Servants Association of South Africa (PSA) which is the majority union recognised trade unions at SAHPRA in accordance with SAHPRA Bargaining Constitution reached a collective agreement on salary negotiations for the 2025/2026 period. The parties agreed to a 5.5% salary increase for employees at salary levels 05 to 12, with a single salary adjustment term for the 2025/26 financial year. The back pay related to this salary increase was disbursed in November 2025.

For employees at salary level 13 and above, the adjusted salary and back pay for the 2025/26 increment were also paid in November 2025. Senior managers received a 5.5% salary adjustment, while EXCO members were granted a 5% increase.

During the 2025/26 financial year, collective bargaining activities included four standard SAHPRA Bargaining Forum (SBF) meetings and numerous Task Team meetings which dealt with consultation Human Resources policies and such Team includes members from Organised labour.

Key topics discussed during these meetings included:

- Levy Agreement
- Salary negotiations
- Challenges faced by Inspectors
- Review of Human Resources Policies
- SAHPRA employment contracts
- Job Evaluation project
- Alternative Pension Fund
- Agency Fee Draft Agreement
- Pension
- Housing subsidies for employees transferred from the National Department of Health

- Head Office Safety Updates
- Restructuring the workplace including introduction of new technology and new methods

Future HR plans / goals

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

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



2. HUMAN RESOURCE OVERSIGHT STATISTICS

The public entity must provide the following key information on human resources. All the financial amounts must agree to the amounts disclosed in the annual financial statements. Where considered appropriate provide reasons for variances.

2.1 Personnel-related expenditure

Personnel Cost by programme/ activity/ objective

Programme/ activity/ objective	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	195 255	89 784	46%	84	1 069
Programme 2	45 233	41 258	91%	62	665
Programme 3	57 847	49 873	86%	53	940
Programme 4	139 070	84 134	60%	100	892
Programme 5	43 165	40 262	93%	51	789
Contract (external funders)	33 349	23 771	71%	26	914
TOTAL	513 920	329 081	64%	376	875

Employee cost per AFS Note 21 amounts to R305.3 million and Contracts (external funders) are disclosed in AFS notes 22 - 26

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	13 205	4%	5	2 641
Senior Management	29 453	9%	24	1 227
Professional qualified	238 840	72.6%	246	971
Skilled	31 509	9.6%	67	470
Semi-skilled	15 697	4.8%	58	271
Unskilled	377	0.1%	17	22
TOTAL	329 081	100%	417	789

Performance Rewards

Programme//activity/ objective	Performance rewards	Personnel Expenditure (R'000)	% of performance rewards to total personnel cost (R'000)
Top Management	418	13 205	3.2%
Senior Management	767	29 453	2.6%
Professional qualified	8 169	238 840	3.4%
Skilled	1 311	31 509	4.2%
Semi-skilled	471	15 697	3%
Unskilled	0	377	0%
TOTAL	11 136	329 081	3.4%

Training Costs

Programme// activity/ objective	Personnel Expenditure (R'000)	Training Expenditure (R'000)	Training Expenditure as a % of Personnel Cost.	No. of employees trained	Avg training cost per employee
Programme 1	13 205	1 514	1.8%	359	4
Programme 2	29 453	-			
Programme 3	238 840	-			
Programme 4	31 509	-	-	-	-
Programme 5	15 697	-	-	-	-
Contract (external funders)	377	-	-	-	-
TOTAL	329 081	1 514	1.8%	359	4

Employment and vacancies

Programme/Activity/ Objective	2024/2025 No: Employees	2025/2026 Approved Posts	2025/2026 No: Employees	2025/2026 Vacancies	% of Vacancies
Programme 1	72	86	84	3	3.5%
Programme 2	58	79	62	1	1.3%
Programme 3	51	70	53	8	11.4%
Programme 4	80	130	100	4	3.1%
Programme 5	47	71	51	3	4.2%
Contract External Funders	23	26	26	0	0.0%
TOTAL	331	462	376	19	4.1%

*462 approved – 67 unfunded – 376 employees = 19 funded vacancies.

Programme/ Activity/ Objective	2024/2025 No: Employees	2025/2026 Approved Posts	2025/2026 No: Employees	2025/2026 Vacancies	% of Vacancies
Top Management	5	5	5	0	0,0%
Senior Management	17	19	17	2	10.5%
Professional qualified	210	236	217	14	5.9%
Skilled	60	130	65	1	0.8%
Semi-skilled	39	56	56	2	3.6%
Unskilled	0	16	16	0	0%
TOTAL	331	462	376	19	4.1%

SAHPRA operates within a health sector characterised by scarce skills and limited internal capacity. To mitigate this challenge, all funded and vacant key positions, whether newly created or vacated are advertised promptly, with the objective of filling them within 90 working days of being advertised. Vacancies are advertised nationally to broaden reach and attract skilled candidates across sectors, particularly within the health sector, thereby strengthening SAHPRA's competitiveness in securing critical and scarce skills.

The Human Resources Management Unit, in collaboration with the Office of the Chief Financial Officer and line managers, has proactively identified critical roles for recruitment. SAHPRA's approved structure stood at 430 posts. For the 2025/26 financial year, this was expanded to 462 posts, including 32 additional positions on the establishment and 26 funded by external partners. Of the 462 posts, 67 remain unfunded due to budget constraints, ensuring compliance with the approved Cost of Employment (CoE) budget. By March 2026, the vacancy rate (excluding unfunded positions) decreased significantly from 11.2% to 4.1%. This improvement was driven by broadened sourcing channels, including strategic collaborations with universities and industry partners, which expanded the talent pool and enhanced access to qualified applicants.

Between April 2025 and March 2026, a total of 103 appointments were made. These included twenty-six (26) on contract and forty-three (43) on permanent, fourteen (14) Community Service Pharmacists, three (3) interns, and seventeen (17) learnership.

Employment changes

Salary Band	Employment at the beginning of period	Appointments	Terminations	Employment at end of the period
Top Management	5	0	0	5
Senior Management	17	4	4	17
Professional qualified	210	34	27	217
Skilled	60	6	1	65
Semi-skilled	39	26	9	56
Unskilled	0	18	2	16
TOTAL	331	88	43	376

Reasons for staff leaving

Reason	Number	% of Total No. of Staff Leaving
Death	1	0.3%
Resignation	22	5.9%
Dismissal	1	0.3%
Retirement	3	0.8%
Ill health	0	0.0%
Expiry of contract	15 (0)	(0%)
Other	1	0.3%
TOTAL	43 (28)	11.4% (7.4%)

*The figures in brackets represent employees whose fixed-term contracts ended naturally. These exits are excluded from the turnover-rate calculation, as this does not constitute turnover for this purpose.

During the 2025/26 period, various people-focused initiatives were implemented, resulting in a staff turnover rate of 7.4% compared to the previous year 6.9%, and remains well within the target of 10%.

Despite this improvement Management undertook a review of turnover data to ensure accuracy and consistency in reporting. As part of this process, employee terminations were reclassified into specific categories to enable more precise measurement of turnover rates. Importantly, cases of contract expiry were excluded from turnover calculations, as these do not reflect voluntary separation but rather the natural conclusion of fixed-term employment. This adjustment was implemented to ensure that turnover reporting provides a more accurate representation of workforce stability and organisational retention trends.

Contract Expiry Community Services (Development Programme)

Community Service contracts are excluded from turnover reporting as they form part of structured 12-month graduate development initiatives. These programmes are designed to empower graduates with workplace exposure and skills. In line with regulatory requirements, the duration is fixed at 12 months. Upon completion, participants are expected to transition into the labour market.

Contract Expiry – Compensation of Employees (COE) Budget

The organisation operates within an annual Compensation of Employees (COE) budget allocation approved by National Treasury. In compliance with the Public Finance Management Act (PFMA), overspending on COE is strictly prohibited, as it could result in future retrenchments. Consequently, fixed-term contracts are not renewed, ensuring adherence to budgetary limits and safeguarding organisational sustainability.

The organisation defines turnover strictly as employees who voluntarily resigned (whether permanent or contract) and those who exited due to natural attrition (either retirement or death)

Annual Turnover Statistics

Between April 2025 until March 2026, a total of 28 employees exited the organisation for various reasons: 22 resignations, 3 retirements, 1 death, 1 case of abscondment, and 1 dismissal. Based on these figures, the organisation's annual turnover rate is 7.4% (28/376), which remains below the targeted threshold of 10%.

By distinguishing between natural attrition, avoidable and unavoidable turnover, management aims to present a more accurate reflection of workforce dynamics and organisational accountability.

Labour Relations: Misconduct and disciplinary action

Grievances: during the 2025/2026 financial year, thirteen (13) disputes were filed at the CCMA by SAHPRA employees, out of the thirteen (13) disputes, nine (9) disputes were finalised in 2025/2026 financial period and four (4) disputes were pending. Twelve (12) misconduct cases were received in 2025/2026, out of the twelve (12) misconduct cases received, eleven (11) misconduct cases were finalised in 2025/2026 and one (1) misconduct case was pending.

Misconduct Cases: 12, eleven cases were finalised, and one (1) case remained pending in 2025/2026.

Nature of disciplinary Action	Number
Verbal Warnings	0
Written Warnings	4
Final Written Warnings	7
Dismissals	1
Suspensions without Pay	2
TOTAL	A variance of 14 resulted from two (2) cases that were issued with combined sanctions.

Equity Target and Employment Equity Status

As at 31 March 2026, SAHPRA continued to monitor its workforce composition against the applicable Economically Active Population (EAP) sectoral targets. The prescribed targets are 77.9% for African employees, 9.8% for Coloured employees, 2.8% for Indian/Asian employees and 9.5% for White employees.

The organisation's workforce profile indicates that African employees accounted for **81.6% (307 of 376)** of the total workforce, which is **3.7 percentage points above** the applicable EAP target. Indian/Asian employees represented **7.7% (29 of 376)**, which is **4.9 percentage points above** the target. Conversely, White employees constituted **5.3% (20 of 376)** and Coloured employees **5.3% (20 of 376)**, reflecting underrepresentation of **4.4 and 4.2 percentage points**, respectively.

The demographic analysis further indicates higher representation of African and Indian women within the workforce. Management will continue to use workforce demographic information to inform recruitment and workforce planning interventions, with particular attention to addressing identified areas of underrepresentation, including White males.

These interventions are aligned to the organisation's **five-year Employment Equity Plan** and are intended to support a more representative, diverse and equitable workforce while ensuring that recruitment and selection processes contribute to the achievement of the organisation's employment equity objectives.

Levels	MALE							
	African		Coloured		Indian		White	
	Current	Target	Current	Target	Current	Target	Current	Target
Top Management	0	0	0	0	0	0	1	0
Senior Management	7	0	0	1	0	1	0	1
Professional qualified	69	10	7	4	2	2	1	10
Skilled	21	0	2	0	0	1	0	2
Semi-skilled	17	6	1	3	1	0	2	3
Unskilled	3	0	0	0	0	0	0	0
TOTAL	117	16	10	8	3	4	4	16

Levels	FEMALE							
	AFRICAN		COLOURED		INDIAN		WHITE	
	Current	Target	Current	Target	Current	Target	Current	Target
Top Management	2	0	0	0	1	0	1	0
Senior Management	8	0	0	1	2	0	0	1
Professional qualified	109	0	5	2	18	0	6	1
Skilled	38	0	2	2	1	1	1	2
Semi-skilled	20	0	4	1	4	0	8	1
Unskilled	13	0	0	1	0	1	0	1
TOTAL	190	0	11	7	26	2	15	6

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	4	3
Skilled	1	1	1	1
Semi-skilled	0	1	1	1
Unskilled	2	1	0	0
TOTAL	3	4	6	5

Women's Day



PART E

PFMA Compliance Report

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

1.1 Irregular expenditure

a) Reconciliation of irregular expenditure

Description	2025/26	2024/25
	R'000	R'000
Opening balance	-	-
Add: Irregular expenditure confirmed	-	-
Less: Irregular expenditure condoned	-	-
Less: Irregular expenditure not condoned and removed	-	-
Less: Irregular expenditure recoverable ¹	-	-
Less: Irregular expenditure not recovered and written off	-	-
Closing balance	-	-

No transgressions were identified in 2025/26 or 2024/25

Reconciling notes

Description	2025/26	2024/25
	R'000	R'000
Irregular expenditure that was under assessment	-	-
Irregular expenditure that relates to the prior year and identified in the current year	-	-
Irregular expenditure for the current year	-	-
Total	-	-

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

Description ²	2025/26	2024/25
	R'000	R'000
Irregular expenditure under assessment	-	-
Irregular expenditure under determination	-	-
Irregular expenditure under investigation	-	-
Total	-	-

No possible irregular expenditure is currently under assessment

c) Details of current and previous year irregular expenditure condoned

Description	2025/26	2024/25
	R'000	R'000
Irregular expenditure condoned	-	-
Total	-	-

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

Description	2025/26	2024/25
	R'000	R'000
Irregular expenditure NOT condoned and removed	-	-
Total	-	-

e) Details of irregular expenditure recoverable

Description	2025/26	2024/25
	R'000	R'000
Irregular expenditure recovered	-	-
Total	-	-

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

Description	2025/26	2024/25
	R'000	R'000
Irregular expenditure written off	-	-
Total	-	-

1.2 Fruitless and wasteful expenditure

a) Reconciliation of fruitless and wasteful expenditure

Description	2025/26	2024/25
	R'000	R'000
Opening balance	-	-
Adjustment to opening balance	-	-
Opening balance as restated	-	-
Add: Fruitless and wasteful expenditure confirmed	107	-
Less: Fruitless and wasteful expenditure recoverable ³	(75)	-
Less: Fruitless and wasteful expenditure not recoverable and written off	(32)	-
Closing balance	-	-

One transgression which relates to vehicle repairs

¹ Transfer to receivables

² Group similar items

Reconciling notes

Description	2025/26	2024/25
	R'000	R'000
Fruitless and wasteful expenditure that was under assessment	-	-
Fruitless and wasteful expenditure that relates to the prior year and identified in the current year	-	-
Fruitless and wasteful expenditure for the current year	107	-
Total	107	-

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

Description ³	2025/26	2024/25
	R'000	R'000
Fruitless and wasteful expenditure under assessment	-	-
Fruitless and wasteful expenditure under determination	-	-
Fruitless and wasteful expenditure under investigation	-	-
Total	-	-

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

Description	2025/26	2024/25
	R'000	R'000
Fruitless and wasteful expenditure recovered	75	-
Total	75	-

The SAHPRA Loss Control function resolved to recover 70% of the amount from the liable official

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

Description	2025/26	2024/25
	R'000	R'000
Fruitless and wasteful expenditure written off	32	-
Total	32	-

The SAHPRA Loss Control function resolved to write off 30% of the amount recoverable considering mitigating factors relating to the matter

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

Disciplinary steps taken

A written warning was issued to the official involved in the transgression

1.3 Additional disclosure relating to material losses in terms of PFMA Section 55(2)(b)(i) &(iii))⁴

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

Material losses through criminal conduct	2025/26	2024/25
	R'000	R'000
Theft	-	-
Other material losses	-	-
Less: Recovered	-	-
Less: Not recovered and written off	-	-
Total	-	-

2. LATE AND/OR NON-PAYMENT OF SUPPLIERS

Description	Number of invoices	Consolidated Value
		R'000
Valid invoices received	1 000	124 175
Invoices paid within 30 days or agreed period	950	123 158
Invoices paid after 30 days or agreed period	50	1 017
Invoices older than 30 days or agreed period (unpaid and without dispute)	0	-
Invoices older than 30 days or agreed period (unpaid and in dispute)	0	-

Reasons for late payment include late submission by end-user, verification of service performed taking longer to complete, dispute taking longer to be resolved, SCM related challenges, etc

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
HR Virtual EE workshop	KM Executive solution	Deviation	PO0804	27
Registrations in the Government Gazette	Government Printing	Deviation	PO0806	11
Human Vaccine Lot Release Testing and WHO PQ Vaccine Contract	University of the Free State: NCL	Deviation	PO0821	25 380
Calibration of Radiation Monitors	National Metrology Institute of South Africa (NMISA)	Deviation	PO0829	106
Subscription license	Worldwide Information Services	Deviation	PO0827	16
Indoor Air Quality Measurement	Indoor Air Quality	Deviation	PO0887	158
Microsoft renewal	Microsoft Ireland Operations	Deviation	PO0908	15 734
Registrations in the Government Gazette	Government Printing	Deviation	PO0930	6

Project description	Name of supplier	Type of procurement by other means	Contract number	Value of contract R'000
ESS enhancement	X4 solutions	Deviation	PO0953	73
Catering	Walter Sisulu University-Mthatha Health Resource Centre	Deviation	PO1014	44
Notice of Registration in the gazette in terms of section 17 of the Medicines and Related Substances act	Government Printing	Deviation	PO1049	39
CASEWARE Software from sole supplier	AdaptIt Pty Ltd	Deviation	PO1033	145
North-West Provincial HAST / CCMDD and Pharmacovigilance Committee Meeting	Rennies BCD Travel	Deviation	PO1037	107
Total				41 846

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
Half-day conferencing for TTT Pharmacovigilance	Rennies BCD Travel	Variation	PO0798	362	-	26
Internet service	Merafong	Variation	PO0856	5 866	-	1 668
Catering for HPA Prince2 training	Maximum Dev Institute Primary co-operative limited	Variation	PO0852	19	-	3
Legal Opinion	Madhlopa and Thenga Inc	Variation	PO0705	87	-	300
Employee health and wellness	Center of occupational and wellness services	Variation	PO0974	47	-	32
Provision of personal dosimetry services	SABS	Variation	PO1017	38	-	7
Remote Desktop Services	Microsoft Ireland Operations	Variation	PO1031	15 734	-	201
Microphones for conference	Rennies BCD Travel	Variation	PO1059	92	-	12
Total						2 249



PART F

Financial Information

Index

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

	PAGE
Accounting Authority's Responsibilities and Approval	116
Report of the Auditor-General to the Parliament on the South African Health Products Regulatory Authority	117
Statement of Financial Position	124
Statement of Financial Performance	125
Statement of Changes in Net Assets	126
Cash Flow Statement	127
Statement of Comparison of Budget and Actual Amounts	128-129
Significant Accounting Policies	130-144
Notes to the Annual Financial Statements	145-177

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 were given unrestricted access to all financial records and related data.

The annual financial statements have been prepared in accordance with Standards of Generally Recognised Accounting Practice (GRAP) including any interpretations, guidelines and directives issued by the Accounting Standards Board. The annual financial statements are based upon appropriate accounting policies consistently applied and supported by reasonable and prudent judgements and estimates.

The Accounting Authority acknowledge that it is 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 2027 and, in the light of this review and the current financial position, they are satisfied that SAHPRA has and have access to adequate resources to continue in operational existence for the foreseeable future.

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

Although the Accounting Authority is primarily responsible for the financial affairs of SAHPRA, they are supported by SAHPRA's external auditors.

The external auditors are responsible for independently reviewing and reporting on SAHPRA's annual financial statements. The annual financial statements have been examined by SAHPRA's external auditors and their report is presented on page 117.

The annual financial statements set out on page 124 to 177, which have been prepared on the going concern basis, is approved by the Accounting Authority on 31 July 2026 and were signed on its behalf by:



Dr Boitumelo Semete-Makokotlela
Chief Executive Officer



Dr Thapelo Motshudi
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 (the public entity) set out on pages 124 to 177, which comprise the statement of financial position as at 31 March 2026, statement of financial performance, statement of changes in net assets, cash-flow statement and statement of comparison of budget and actual amounts for the year then ended, as well as 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 public entity as at 31 March 2026 and its financial performance and cash flows for the year then ended in accordance with the Standards of Generally Recognised Accounting Practice (GRAP) as issued by the Accounting Standards Board and the requirements of the Public Finance Management Act 1 of 1999 (PFMA).

Basis for opinion

3. I conducted my audit in accordance with the International Standards on Auditing (ISAs). My responsibilities under those standards are further described in the responsibilities of the auditor-general for the audit of the financial statements section of my report.
4. I am independent of the public entity in accordance with the International Ethics Standards Board for Accountants' *International code of ethics for professional accountants (including International Independence Standards)* (IESBA code) as well as other ethical requirements that are relevant to my audit in South Africa. I have fulfilled my other ethical responsibilities in accordance with these requirements and the IESBA code.
5. I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Emphasis of matter

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

Restatement of corresponding figures

7. As disclosed in note 35 to the financial statements, the corresponding figures for 31 March 2025 were restated as a result of errors in the financial statements of the public entity at and for the year ended 31 March 2026.

Responsibilities of the accounting authority for the financial statements

8. The accounting authority is responsible for the preparation and fair presentation of the financial statements in accordance with GRAP as issued by the Accounting Standards Board and the requirements of the PFMA; and for such internal control as the Accounting Authority determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.
9. In preparing the financial statements, the accounting authority is responsible for assessing the public entity's ability to continue as a going concern; disclosing, as applicable, matters relating to going concern; and using the going concern basis of accounting unless the appropriate governance structure either intends to liquidate the public entity or to cease operations or has no realistic alternative but to do so.

Responsibilities of the auditor-general for the audit of the financial statements

10. My objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error; and to issue an auditor's report that includes my opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.
11. A further description of my responsibilities for the audit of the financial statements is included in the annexure to this auditor's report. This description, which is located on page 7, forms part of my auditor's report.

Report on the annual performance report

12. In accordance with the Public Audit Act 25 of 2004 (PAA) and the general notice issued in terms thereof; I must audit and report on the usefulness and reliability of the reported performance against predetermined objectives for the selected material performance indicators presented in the annual performance report. The accounting authority is responsible for the preparation of the annual performance report.
13. I selected the following material performance indicators related to Programme 4: Clinical and pharmaceutical evaluation presented in the annual performance report for the year ended 31 March 2026. I selected those indicators that measure the public entity's performance on its primary mandated functions and that are of significant national, community or public interest.
 - Percentage applications for the sale of unregistered category A (human) medicines finalised within three working days
 - Percentage of clinical trial applications finalised within 80 working days
 - Percentage of all high public health impact safety signals detected and mitigated within 40 working days.

- Percentage of reports on health product safety signals assessed within 60 working days
 - Percentage of safety communications published within 10 working days
 - Percentage of lot release requests finalised within 50 working days
14. I evaluated the reported performance information for the selected material performance indicators against the criteria developed from the performance management and reporting framework, as defined in the general notice. When an annual performance report is prepared using these criteria, it provides useful and reliable information and insights to users on the public entity's planning and delivery on its mandate and objectives.
15. I performed procedures to test whether:
- the indicators used for planning and reporting on performance can be linked directly to the public entity's mandate and the achievement of its planned objectives
 - all the indicators relevant for measuring the public entity's performance against its primary mandated and prioritised functions and planned objectives are included
 - the indicators are well defined and verifiable to ensure that they are easy to understand and apply consistently and 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 what was committed to in the approved initial or revised planning documents
 - the reported performance information is presented in the annual performance report in the prescribed manner
 - there is adequate supporting evidence for the achievements reported and for the reasons provided for any over- or underachievement of targets.
16. I performed the procedures to report material findings only; and not to express an assurance opinion or conclusion.

Other matters

17. I draw attention to the matters below.

Achievement of planned targets

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

Programme 4: Clinical and pharmaceutical evaluation

<i>Targets achieved: 57%</i> <i>Budget spent: 98%</i>		
Key indicator not achieved	Planned target	Reported achievement
Percentage applications for the sale of unregistered category A (human) medicines finalised within three working days	95%	93%
Percentage of clinical trials safety signal detected and mitigated within 80 working days	50%	23%
Percentage of reports on health product safety signals assessed within 60 working days	70%	51,45%
Percentage of safety communications published within 10 working days	90%	8,33%

Material misstatements

19. I identified material misstatements in the annual performance report submitted for auditing. These material misstatements were in the reported performance information for Percentage of safety communications published within 10 working days. Management subsequently corrected all the misstatements, and I did not include any material findings in this report.

Report on compliance with legislation

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

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

Other information in the annual report

24. The accounting authority is responsible for the other information included in the annual report. The other information does not include the financial statements, the auditor's report and those selected material performance indicators presented in the annual performance report that have been specifically reported on in this auditor's report.
25. My opinion on the financial statements and my reports on the audit of the annual performance report and compliance with legislation do not cover the other information included in the annual report and I do not express an audit opinion or any form of assurance conclusion on it.
26. My responsibility is to read this other information and, in doing so, consider whether it is materially inconsistent with the financial statements and the selected material indicators in the scoped-in programme presented in the annual performance report or my knowledge obtained in the audit, or otherwise appears to be materially misstated.
27. If, based on the work I have performed, I conclude that there is a material misstatement in this other information, I am required to report that fact.

Internal control deficiencies

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

Auditor General

Pretoria

31 July 2026



AUDITOR - GENERAL
SOUTH AFRICA

Auditing to build public confidence

Annexure to the auditor's report

The annexure includes the following:

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

Auditor-general's responsibility for the audit

Professional judgement and professional scepticism

As part of an audit in accordance with the ISAs, I exercise professional judgement and maintain professional scepticism throughout my audit of the financial statements and the procedures performed on reported performance information for selected material performance indicators and on the public 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 to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the public 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 public 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 the public 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, paragraphs or regulations
Public Finance Management Act 1 of 1999	Sections 51(1)(a)(iv); 51(1)(b)(i); 51(1)(b)(ii); 51(1)(e)(iii); 53(4); 54(2)(d); 55(1)(a); 55(1)(b); 55(1)(c)(i); 56(1); 56(2); 57(b); 66(3) 66(5)
Treasury Regulations, for departments, trading entities, constitutional institutions and public entities	Regulations 8.2.1; 8.2.2; 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; 16A9.1(b)(ii); 16A9.1(c); 16A 9.1(d); 16A 9.1(e); 16A9.1(f); 16A 9.2; 16A 9.2(a)(ii); TR 16A 9.2(a)(iii); 30.1.1; 30.1.3(a); 30.1.3(b); 30.1.3(d); 30.2.1; 31.1.2(c'); 31.2.1; 31.2.5; 31.2.7(a); 31.3.3; 32.1.1(a); 32.1.1(b); 32.1.1(c'); 33.1.1; 33.1.3
Prevention and Combating of Corrupt Activities Act 12 of 2004	Section 34(1)
Construction Industry Development Board Act 38 of 2000 (CIDB)	Section 18(1)
CIDB Regulations,	Regulations 17; 25(7A)
Preferential Procurement Policy Framework Act 5 of 2000	Section 2.1(a); 2.1(b); 2.1(f)
Preferential Procurement Regulations (PPR) 2017	Paragraphs 4.1; 4.2; 5.1; 5.3; 5.6; 5.7; 8.2; 8.5 9.1; 9.2; 12.1 and 12.2
PPR 2022	Paragraphs 4.1; 4.2; 4.3; 4.4; 5.1; 5.2; 5.3; 5.4
National Treasury (NT) Instruction No.1 of 2015/16	Paragraphs 3.1; 4.1; 4.2
NT Supply Chain Management (SCM) Instruction Note 03 2021/22	Paragraphs 4.3; 4.4; 4.4 (a); 4.4 (c) -(d)
NT SCM Instruction Note 11 2020/21	Paragraphs 3.1; and (b); 3.9
NT SCM Instruction Note 2 of 2021/22	Paragraphs 3.2.1; 3.2.4(a); 3.3.1
NT Instruction Note 4 of 2015/16	Paragraph 3.4
Second amendment of NT Instruction 05 of 2020/21	Paragraphs 4.8; 4.9; 5.1; 5.3

Legislation	Sections, paragraphs or regulations
Erratum NT Instruction 5 of 2020/21	Paragraph 1
Erratum NT Instruction 5 of 2020/21	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 2026

	Note(s)	2026 R	2025 Restated* R
Assets			
Current Assets			
Receivables from exchange transactions	3	11 075 754	11 110 173
Receivables from non-exchange transactions	4	13 163 992	1 302 138
Prepayments	5	14 445 879	12 346 415
Cash and cash equivalents	6	536 602 036	451 455 333
		575 287 661	476 214 059
Non-Current Assets			
Property, plant and equipment	7	33 004 228	30 032 717
Intangible assets	8	33 967 445	23 098 859
		66 971 673	53 131 576
Total Assets		642 259 334	529 345 635
Liabilities			
Current Liabilities			
Operating lease liability	9	889 524	1 462 457
Payables from exchange transactions	10	17 832 178	13 557 928
Employee benefit obligation	11	1 050 916	931 868
Unspent conditional grants	12	22 609 991	10 060 420
Employee benefit cost provision	13	26 996 964	29 712 142
Income received in advance	14	341 247 756	280 977 776
		410 627 329	336 702 591
Non-Current Liabilities			
Employee benefit obligation	11	15 822 335	10 532 034
Total Liabilities		426 449 664	347 234 625
Net Assets		215 809 670	182 111 010
Accumulated surplus		215 809 670	182 111 010
Total Net Assets		215 809 670	182 111 010

* See Note 36 & 35

Statement of Financial Performance

for the year ended 31 March 2026

	Note(s)	2026 R	2025 Restated* R
Revenue			
Revenue from exchange transactions			
Fee income	15	303 507 444	254 852 799
Sundry income	16	-	369 101
Interest received	17	38 301 545	36 476 673
Actuarial gains	11	-	1 675 165
Total revenue from exchange transactions		341 808 989	293 373 738
Revenue from non-exchange transactions			
Transfer revenue			
Transfer payment received	18	149 301 000	143 518 000
Goods and service in kind	19	22 650 991	13 632 283
Grant realised and income	20	33 439 842	51 561 930
Seta grant received		418 010	1 012 362
Total revenue from non-exchange transactions		205 809 843	209 724 575
Total revenue		547 618 832	503 098 313
Expenditure			
Employee related costs	21	(305 310 347)	(277 327 431)
BMGF project expenditure	24	(2 946 123)	(798 347)
Depreciation and amortisation	27	(11 907 055)	(9 708 322)
Impairment of assets		68 432	(292 373)
Auda Nepad project expenditure	25	(255 168)	(1 513 202)
Lease rentals on operating lease	9	(22 053 747)	(21 167 894)
Bad debts written off		(1 069 157)	-
Global fund project expenditure	22	(19 343 429)	(38 591 319)
GiZ project expenditure	23	(1 935 913)	(1 023 242)
Laboratory services	28	(24 127 300)	(21 276 216)
Loss on disposal of assets		(427 944)	(69 213)
Loss on exchange differences		-	(18 873)
Actuarial losses	11	(3 343 548)	-
Operating expenditure	29	(112 400 170)	(75 844 736)
MPP project expenditure	26	(7 942 204)	(1 477 344)
FCDO project expenditure		(926 499)	-
Total expenditure		(513 920 172)	(449 108 512)
Surplus for the year		33 698 660	53 989 801

* See Note 36 & 35

Statement of Changes in Net Assets

for the year ended 31 March 2026

	Note(s)	Accumulated surplus R	Total net assets R
Opening balance as previously reported		90 729 796	90 729 796
Adjustments:			
Correction of errors	35	37 689 599	37 689 599
Change in accounting policy	36	(298 186)	(298 186)
Balance at 01 April 2024 as restated*		128 121 209	128 121 209
Surplus for the year		53 989 801	53 989 801
Total changes		53 989 801	53 989 801
Opening balance as previously reported		144 603 997	144 603 997
Adjustments:			
Correction of errors	35	37 805 199	37 805 199
Change in accounting policy	36	(298 186)	(298 186)
Restated balance at 01 April 2025		182 111 010	182 111 010
Surplus for the period		33 698 660	33 698 660
Total		33 698 660	33 698 660
Balance at 31 March 2026		215 809 670	215 809 670

* See Note 36 & 35

Cash Flow Statement

for the year ended 31 March 2026

	Note(s)	2026 R	2025 Restated* R
Cash flows from operating activities			
Receipts			
Fees and deferred income		382 723 072	285 422 165
Transfer payment received		149 301 000	143 518 000
Interest income		38 324 210	36 754 575
Grants received		34 794 833	56 110 986
		605 143 115	521 805 726
Payments			
Employee costs		(307 441 793)	(290 039 336)
Suppliers		(202 925 165)	(136 605 199)
		(510 366 958)	(426 644 535)
Net cash flows from operating activities	30	94 776 157	95 161 191
Cash flows from investing activities			
Purchase of property, plant and equipment	7	(9 681 325)	(6 324 509)
Proceeds from sale of property, plant and equipment	7	41 850	-
Purchase of other intangible assets	8	-	(8 980 565)
Net cash flows from investing activities		(9 639 475)	(15 305 074)
Net increase/(decrease) in cash and cash equivalents		85 136 682	79 856 117
Cash and cash equivalents at the beginning of the year		451 455 333	371 616 710
Effect of expected credit loss movement on cash balances		10 021	(17 494)
Cash and cash equivalents at the end of the year	6	536 602 036	451 455 333

Statement of Comparison of Budget and Actual Amounts

for the year ended 31 March 2026

Budget on Modified Cash Basis	Approved budget	Adjustments	Final Budget	Actual Amounts on comparable basis	Difference between final budget and actual	Reference
Figures in Rand						
Budget as per Annual Performance Plan						
Revenue						
Revenue from exchange transactions						
Fee income	284 377 797	-	284 377 797	303 507 444	19 129 647	41.1
Interest received	36 797 400	-	36 797 400	38 301 545	1 504 145	41.2
Total revenue from exchange transactions	321 175 197	-	321 175 197	341 808 989	20 633 792	
Revenue from non-exchange transactions						
Transfer revenue						
Transfer payment	149 301 000	-	149 301 000	149 301 000	-	
Prior year surplus approved	-	24 155 396	24 155 396	24 155 396	-	41.9
Seta grant received	850 000	-	850 000	418 010	(431 990)	41.7
Total revenue from non-exchange transactions	150 151 000	24 155 396	174 306 396	173 874 406	(431 990)	
Total revenue	471 326 197	24 155 396	495 481 593	515 683 395	20 201 802	
Expenditure						
Employee cost	(307 429 478)	(835 184)	(308 264 662)	(305 310 347)	2 954 315	41.3
Directors remuneration	(2 344 256)	-	(2 344 256)	(1 814 294)	529 962	
Lease rentals on operating lease	(23 577 627)	-	(23 577 627)	(22 053 747)	1 523 880	41.6
Laboratory services	(23 612 750)	-	(23 612 750)	(24 127 300)	(514 550)	41.5
Operating expenses	(106 213 420)	(21 347 101)	(127 560 521)	(110 585 876)	16 974 645	41.4
Total expenditure	(463 177 531)	(22 182 285)	(485 359 816)	(463 891 564)	21 468 252	
Budget surplus	8 148 666	1 973 111	10 121 777	51 791 831	41 670 054	
Capital expenditure budget	(8 148 666)	(1 973 111)	(10 121 777)	(9 681 325)	440 452	41.8
Actual Amount Presented in the Budget and Actual Comparative Statement	-	-	-	42 110 506	42 110 506	

Statement of Comparison of Budget and Actual Amounts

for the year ended 31 March 2026

Budget on Modified Cash Basis	Approved budget	Adjustments	Final Budget	Actual Amounts on comparable basis	Difference between final budget and actual	Reference
Figures in Rand						
Reconciliation						
Operating activities						
Budget surplus				51 791 831		
Basis differences						
Movement in grant income				18 967		
Service in kind				22 650 991		
Movement in operating leases				(572 933)		
Movement in retirement benefits				2 065 801		
Movement in provisions				(2 715 178)		
Asset donated				(16 475 125)		
Receivables from exchange transactions				(928 857)		
Other receivables from non-exchange transactions				(11 977 757)		
Prepayments				(2 099 464)		
Payables from exchange transactions				4 282 186		
Unspent conditional grant				12 621 111		
Income received in advance				60 269 980		
Prior period surplus approval				(24 155 396)		
Total net cash flows from operating activities				94 776 157		
Investing activities						
Capital expenditure				(9 681 325)		
Basis differences						
Proceeds from sale				41 850		
Total net cash flows from investing activities				(9 639 475)		
Net increase in cash and cash equivalents				85 136 682		

Significant Accounting Policies

for the year ended 31 March 2026

1. Presentation of Annual Financial Statements

The annual financial statements have been prepared in accordance and are in compliance with the Standards of Generally Recognised Accounting Practice (GRAP), issued by the Accounting Standards Board in accordance with Section 91(1) of the Public Finance Management Act (Act 1 of 1999).

These annual financial statements have been prepared on an accrual basis of accounting and are in accordance with historical cost convention as the basis of measurement, unless specified otherwise. These accounting policies are consistent with the previous period.

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

A summary of the significant accounting policies is 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.

Significant judgements:

Revenue

SAHPRA applied a significant judgement on the uncertainty that exist regarding on-going assessment of revenue, however no non-compliance has been identified other than the prior period errors identified as at reporting date. Management is of the view that the current judgement applied is reasonable and supportable.

Statement of Financial Performance

SAHPRA applied a significant judgement on the presentation of the Statement of Financial Performance; where grant project expenditure is classified on a functional basis, which is not consistent with SAHPRA's nature expenditure classification. This is due to relevance and significance of the grant funding per project.

Significant Accounting Policies

for the year ended 31 March 2026

1.3 Significant judgements and sources of estimation uncertainty (continued)

Financial assets

Management performed an assessment of expected credit losses using the general approach for financial assets. In determining the appropriate level of impairment, management applied significant judgement and considered the following indicators of increased credit risk:

- The receivable is significantly past due with no settlement as at reporting date.
- Repeated follow ups with the debtor have not resulted in payment.
- There is no confirmed repayment plan.
- Available information indicates heightened uncertainty over the customer's ability or willingness to settle the balance.

Based on the above factors, management concluded that the recoverability of the financial asset is uncertain. Consequently, management determined that it is appropriate to recognise an impairment allowance against the financial asset to reflect lifetime expected credit losses as required by GRAP 104.

Notwithstanding the impairment recognised, management continues to pursue recovery of the outstanding balance through active credit management processes.

Significant estimates

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

Trade receivables and other receivables

SAHPRA assesses its trade receivables and other receivables for impairment at the end of each reporting period. In determining whether an impairment loss should be recorded in surplus or deficit, SAHPRA makes judgements as to whether there is observable data indicating a measurable decrease in the estimated future cash flows from a financial asset. The impairment for trade receivables and other receivables is calculated on a portfolio basis, based on a review of the full trade debtors book, adjusted for national and industry-specific economic conditions and other indicators present at the reporting date that correlate with defaults on the portfolio.

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

These annual loss ratios are applied to balances in the portfolio and scaled to the estimated loss emergence period. Refer to note 3 and note 4 for details regarding impairment considerations.

Impairment testing

SAHPRA reviews and tests the carrying value of current and non-current assets when events or changes in circumstances suggest that the carrying amount may not be recoverable. Assets are grouped at the lowest level for which identifiable cash flows are largely independent of cash flows of other assets and liabilities. If there are indications that impairment may have occurred, estimates are prepared of expected future cash flows for each group of assets. Expected future cash flows used to determine the value in use of tangible assets are inherently uncertain and could materially change over time. They are significantly affected by a number of factors including supply demand, together with economic factors such as research units closed as part of the revitalisation process.

Significant Accounting Policies

for the year ended 31 March 2026

1.3 Significant judgements and sources of estimation uncertainty (continued)

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

Employee benefit cost 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 - Employee benefit cost 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.

Performance management and development system provision (PMDS)

The PMDS provision is estimated annually using the number of qualifying employees, average salary, historical and expected scoring and expected percentage award per policy category.

Refer to note 13 for details regarding the PMDS provision.

Post-retirement benefits

The present value of the post-retirement obligation depends on a number of factors that are determined on an actuarial basis using a number of assumptions. The assumptions used in determining the net cost (income) include the discount rate. Any changes in these assumptions will impact on the carrying amount of post-retirement obligations.

SAHPRA determines the appropriate discount rate at the end of each year. This is the interest rate that should be used to determine the present value of estimated future cash outflows expected to be required to settle the pension obligations. In determining the appropriate discount rate, SAHPRA considers the interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms to maturity approximating the terms of the related pension liability.

Other key assumptions for pension obligations are based on current market conditions. Additional information is disclosed in Note 11.

Useful lives of property, plant and equipment and intangible assets

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

The assumptions used for useful lives assessment:

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

Significant Accounting Policies

for the year ended 31 March 2026

1.3 Significant judgements and sources of estimation uncertainty (continued)

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. Refer to note 31.

1.4 Property, plant and equipment

Property, plant and equipment is initially measured at cost.

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

Where an item of property, plant and equipment is acquired in exchange for a non-monetary asset or monetary assets, or a combination of monetary and non-monetary assets, the asset acquired is initially measured at fair value (the cost). If the acquired item's fair value was not determinable, its deemed cost is the carrying amount of the asset(s) given up.

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

Property, plant and equipment is carried at cost less accumulated depreciation and any impairment losses.

The useful lives of items of property, plant and equipment have been assessed as follows:

Item	Depreciation method	Useful life
Furniture and fixtures	Straight-line	10-14 years
Motor vehicles	Straight-line	5-years
Computer equipment	Straight-line	5-7 years
Leasehold improvements	Straight-line	5-10 years
Other fixed assets	Straight-line	10-16 years

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. As per the recent useful life assessment at reporting date, computer equipment's useful lives has indicated an increase in number of years between 5 - 10 years. The change is accounted for as a change in an accounting estimate in note 7.

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.

Significant Accounting Policies

for the year ended 31 March 2026

1.5 Intangible assets

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

Intangible assets are carried at cost less any accumulated amortisation and any impairment losses. SAHPRA does not have intangible assets with indefinite useful lives.

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

Amortisation is provided to write down the intangible assets, on a straight-line basis, to a zero value as the majority of SAHPRA intangible assets are not expected to be sold at disposal values as follows:

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

1.6 Financial instruments

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

SAHPRA's receivables from exchange transaction includes statutory receivables which are specifically excluded from financial instruments as per GRAP 1.3 (g) and these financial assets are not pledged as collateral.

The following liabilities are not considered financial liabilities in line with the definitions for financial instruments: income received in advance (unallocated deposits and revenue received in advance), operating lease liability, unspent conditional grants, and employee benefits

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

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:

Financial assets is classified based on the management model for managing these. Financial assets are only held to collect contractual cash flows and are classified accordingly.

Non exchange transactions	
Class	Category
Grant receivables	Financial assets measured at amortised cost, which, due to their short-term nature, closely approximate their fair value. A contractual agreement is in place giving rise to a financial asset
Other receivables	Financial assets measured at amortised cost, which, due to their short-term nature, closely approximate their fair value

Significant Accounting Policies

for the year ended 31 March 2026

1.6 Financial instruments (continued)

Exchange transactions	
Class	Category
Cash and cash equivalents	Financial assets measured at amortised cost, which, due to their short-term nature, closely approximate their fair value.
Deposit	Financial assets measured at amortised cost, which, due to their short-term nature, closely approximate their fair value.
Staff debtors	Financial assets measured at amortised cost, which, due to their short-term nature, closely approximate their fair value.
Class	Category
Trade payables	SAHPRA recognises trade payables from exchange transactions that are due in the ordinary course of operations. Financial liabilities measured at amortised cost, which, due to their short-term nature, closely approximate their fair value.
Accrued expenditure	SAHPRA accrues expenditure where services have been rendered but not yet invoiced by financial year end in the ordinary course of operations. Financial liabilities measured at amortised cost, which, due to their short-term nature, closely approximate their fair value.
Travel cards	SAHPRA recognises travel lodge liability and fleet cards that are due in the ordinary course of operations. Financial liabilities measured at amortised cost, which, due to their short-term nature, closely approximate their fair value.

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 and includes transaction costs.

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

Impairment and uncollectability of financial assets

SAHPRA recognises a loss allowance for Expected Credit Losses (ECL) on all financial assets measured at amortised cost. The measurement of ECL reflects an unbiased, probability-weighted amount determined by evaluating a range of possible outcomes, the time value of money, and reasonable, supportable forward-looking information available at the reporting date.

For all financial instruments, including staff loans, long-term receivables, and cash equivalents, SAHPRA applies the General Approach via a 3-Stage Model:

- On initial recognition (and where credit risk remains low), a loss allowance is recognised based on 12-Month ECL (defaults possible within the next 12 months). Interest is calculated on the gross carrying amount.
- Where a Significant Increase in Credit Risk (SICR) has occurred since day one, the allowance is upgraded to Lifetime ECL. Interest continues to be calculated on the gross carrying amount.
- Where the asset meets the technical definition of default, the provision remains at Lifetime ECL, but interest revenue is calculated dynamically on the net balance (gross balance less impairment allowance)

Significant Accounting Policies

for the year ended 31 March 2026

1.6 Financial instruments (continued)

SAHPRA defines a financial asset as being in default when it meets one or both of the following objective, quantitative criteria:

The debtor account balance is outstanding for more than 90 days past due.

Forward looking indicators consider whether operational indicators exist demonstrating that the debtor is facing severe financial distress, which includes accounts handed over to legal collections, formal business rescue proceedings, liquidations, loss given default and probability, or defaults are taken into account.

Presentation

Interest relating to a financial instrument is recognised as revenue in surplus or deficit.

Losses and gains relating to a financial instrument or a component that is a financial liability is recognised as revenue or expense in surplus or deficit

Derecognition

Financial assets

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

Financial liabilities

SAHPRA removes a financial liability (or a part of a financial liability) from its statement of financial position when it is extinguished – i.e. when the obligation specified in the contract is discharged, cancelled, expires or waived.

1.7 Statutory receivables

Identification

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

SAHPRA's revenue generated from regulated fees are not discretionary or commercial in nature, but rather a legislated regulatory function executed in fulfilment of the Authority's statutory mandate to safeguard public health. These powers are not voluntary, they exist because the Act grants them.

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 derecognised amounts.

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.

Significant Accounting Policies

for the year ended 31 March 2026

1.7 Statutory receivables (continued)

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 and the incurred loss approach will be followed.

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

- Significant financial difficulty of the debtor, which may be evidenced by an application for debt counselling, business rescue or an equivalent.
- It is probable that the debtor will enter sequestration, liquidation or other financial re-organisation.
- A breach of the terms of the transaction, such as default (above 90 days) or delinquency in principal or interest payments (where levied).

Derecognition

SAHPRA derecognises a statutory receivable, or a part thereof,

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

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

Significant Accounting Policies

for the year ended 31 March 2026

1.8 Prepayments

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

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

1.9 Leases

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

Operating leases - lessee

An Operating lease is a lease other than a finance lease and for SAHPRA it is the rental of various office buildings. Operating lease payments are recognised as an expense on a straight-line basis over the lease term. The difference between the amounts recognised as an expense and the contractual payments are recognised as an operating lease asset or liability.

1.10 Cash and cash equivalents

Cash 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 Corporation of Public Deposits which are available on demand.

1.11 Impairment of cash-generating assets

SAHPRA does not have any cash generating assets.

1.12 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 exists 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 asset's recoverable amount is the higher of the fair value less costs to sell, and the value-in-use of the asset.

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

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

Significant Accounting Policies

for the year ended 31 March 2026

1.13 Employee benefits

Identification

Short-term employee benefits

Short-term employee benefits include remuneration, compensated absences, thirteenth cheque. Some employee benefits like compensated absences and bonuses are disclosed under note 13 - Employee benefit cost provisions in line with applicable GRAP standard.

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

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

SAHPRA recognises the expected cost of bonus, incentive and performance related payments when there is a present legal or constructive obligation to make such payments as a result of past events and a reliable estimate of the obligation can be made.

Post-employment benefits: Defined benefit plans

Contributions made towards the Government Employees Pension Fund are recognised as an expense in the Statement of Financial Performance in the period that such contributions become payable. This contribution expense is measured at the undiscounted amount of the contribution paid or payable for the fund. A liability is recognised to the extent that any of the contributions have not yet been paid. Conversely an asset is recognised to the extent that any contributions have been paid in advance.

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

SAHPRA recognises gains or losses on the curtailment or settlement of a defined benefit plan when the curtailment or settlement occurs. The gain or loss on a curtailment or settlement comprises:

- any resulting change in the present value of the defined benefit obligation; and
- any resulting change in the fair value of the plan assets.

The employee benefit that is classified as current is expected to be realised within 12 months after reporting date.

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.

Significant Accounting Policies

for the year ended 31 March 2026

1.13 Employee benefits (continued)

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

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

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

Other post retirement obligations

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

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

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

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

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

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

Significant Accounting Policies

for the year ended 31 March 2026

1.14 Provisions and contingencies

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

Provisions are reviewed at each reporting date and adjusted to reflect the current best estimate. Provisions are reversed if it is no longer probable that an outflow of resources embodying economic benefits or service potential will be required, to settle the obligation. Provisions are disclosed in note 13.

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

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

1.15 Commitments

Disclosure will be made that is useful in evaluating SAHPRA's ability to finance its activities and to meet its commitments, specifically unrecognised contractual commitments for PPE and IA.

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. Capital commitments are recorded at cost in the note 7 and 8 of the annual financial statements.

1.16 Revenue from exchange transactions

Measurement

Revenue is measured at the fair value of the consideration received or receivable. Fair value is the amount for which an asset could be exchanged, or a liability settled, between knowledgeable, willing parties in an arm's length transaction.

The majority of SAHPRA's revenue from exchange transactions are paid for on application before services are rendered and are classified as income received in advance which are further disclosed as unallocated deposits or revenue received in advance. The amount received is therefore deferred and recognised as revenue over the period during which the service is performed or when a specific act occurs.

Rendering of services

The method used to determine the stage of completion relates to services performed to date as a percentage of total services to be performed. This is the most reliable method that measures the services performed as each stage of evaluation carries the same weight as the other stages unless indicated otherwise.

New application for registration

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

- Names and Scheduling Unit – 25%
- Inspectorate – 25%
- Clinical Evaluation Management (CEM) – 25%

Significant Accounting Policies

for the year ended 31 March 2026

1.16 Revenue from exchange transactions (continued)

- Pharmaceutical Evaluation Management (PEM) – 25%
- Biologicals – 50% - carries more weight due to its inclusion of the Quality process which is normally performed in PEM and excludes CEM at an evaluation stage.

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. Failure to respond adequately to the query letter will result in a rejection of the application and revenue will be recognised.

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

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

Interest received

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

- It is probable that the economic benefits or service potential associated with the transaction will flow to SAHPRA, and
- The amount of the revenue can be measured reliably.

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

1.17 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 and taxed cost orders issued by the Court in favour of SAHPRA.

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

Measurement

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

When, as a result of a non-exchange transaction, SAHPRA recognises an asset, it also recognises revenue equivalent to the amount of the asset measured at its fair value as at the date of acquisition, unless it is also required to recognise a liability. Where a liability is required to be recognised it will be measured as the best estimate of the amount required to settle the obligation at the reporting date, and the amount of the increase in net assets, if any, recognised as revenue.

When a liability is subsequently reduced, because the taxable event occurs or a condition is satisfied, the amount of the reduction in the liability is recognised as revenue.

Transfers

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

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

Significant Accounting Policies

for the year ended 31 March 2026

1.17 Revenue from non-exchange transactions (continued)

Conditional Grants

Grant funding relates 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.

Goods and services in-kind

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

1.18 Comparative figures

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

These changes were made in accordance with GRAP3. Refer to note 36 for changes made to comparative figures.

1.19 Segment information

A segment is an activity of an entity

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

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

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

1.20 Budget information

The budget is prepared using a modified cash basis of accounting whereby certain accruals relating to revenue and expenditure are recognised, while non-cash accounting adjustments such as depreciation, impairment losses, provisions and bad debt write-offs are excluded.

The approved budget covers the fiscal period from 01 Apr 2025 to 31 Mar 2026.

External funding support is excluded from the SAHPRA budget as it does not form part of the approved appropriation to SAHPRA.

Significant Accounting Policies

for the year ended 31 March 2026

1.21 Related parties

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

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

1.22 Translation of foreign currencies

Foreign transactions

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

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

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

Foreign evaluator payments

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

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

Reporting date

At each reporting date:

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

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

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

2. New standards and interpretations

2.1 Standards and interpretations effective and adopted in the current year

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

Standard/ Interpretation:	Effective date: Years beginning on or after	Expected impact:
GRAP 104 (as revised): Financial Instruments	01 April 2025	The impact of the change is set out in note 36 - Changes in accounting policy.

2.2 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 107 (as revised) Mergers	not yet determined	Unlikely there will be a material impact
GRAP 106 (as revised) Transfer of Functions Between Entities Not Under Common Control	not yet determined	Unlikely there will be a material impact
GRAP 105 Transfer of Functions Between Entities Under Common Control	not yet determined	Unlikely there will be a material impact
GRAP 2023 Improvements to the Standards of GRAP 2023	not yet determined	Impact is currently being assessed
GRAP 1 (amended): Presentation of Financial Statements (Going Concern)	not yet determined	Unlikely there will be a material impact
GRAP 103 (amended): Heritage Assets	not yet determined	Unlikely there will be a material impact

3. Receivables from exchange transactions

Trade debtors	5 472 194	7 173 773
Provision for impairment	(796 563)	(1 273 261)
Expected credit loss allowance	(184 069)	(217 646)
Deposits	6 166 291	4 904 464
Staff debtors	417 901	522 843
	11 075 754	11 110 173

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
3. Receivables from exchange transactions (continued)		
Statutory receivables included in receivables from exchange transactions above are as follows:		
Retention fees	1 293 600	1 743 218
Licence fees	766 500	619 640
Inspection fees	1 701 394	2 115 035
New registrations	115 400	257 580
Renewals of medicine applications	92 300	2 199 900
Response reviews	1 503 000	-
Biological amendments	-	238 400
	5 472 194	7 173 773
Provision for impairments	(796 563)	(1 273 261)
Net financial asset receivables included in receivables from exchange transactions above	6 400 123	5 209 661
Total receivables from exchange transactions	11 075 754	11 110 173

Statutory receivables general information

Transaction(s) arising from statute

The statutory receivables of SAHPRA relates to Retention fees, License collection fees, Renewal of medicines, New registration fees, and Inspections fees. Renewal of medicines, New registration fees, and Inspections fees. All fees are charged in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended. SAHPRA's revenue generated from regulated fees are not discretionary or commercial in nature, but rather a legislated regulatory function executed in fulfilment of the Authority's statutory mandate to safeguard public health. These powers are not voluntary, they exist because the Act grants them.

Determination of transaction amount

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

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

Financial asset receivables included in receivables from exchange transaction.

Deposits consist of fleet and rental deposit. The deposits increased due to additions in rental deposits during the year. The current leased accommodation required an annual deposit increase that was paid. This rental deposit is held in an interest bearing call account by the lessor and interest accrued to SAHPRA for the year

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

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026	2025
	R	R

3. Receivables from exchange transactions (continued)

Interest or other charges levied/charged

There was no interest charged on the statutory receivable arising from exchange transactions at 31 March 2026 in line with SAHPRA's revenue policy. Interest is also not charged when a debt has been handed over to debt collectors.

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

In terms of the Medicines and Related Substances Act, as amended 16(4): If the person who is the holder of the certificate of registration issued in respect of any medicine, medical device or IVD fails to pay the prescribed annual fee in respect of the retention of the registration of that medicine, medical device or IVD before or on the prescribe date or such later date as the Chief Executive Officer may determine on application by that person, the Chief Executive Officer shall cancel the registration of that medicine, medical device or IVD.

Receivables from exchange transactions are impaired on a class of service basis. The impairment of trade receivables has been determined with reference to past default experience, historical collection and write off of bad debts and the progress made with regards to the cancellation process of a license.

Receivables from exchange transactions written off are not subject to a recovery process.

Discount rate applied to the estimated future cash flows

Prime lending rates were used to estimate future cash flows.

Reconciliation of provision for impairment

Relating specifically to Statutory Receivables

Opening balance	1 273 261	4 753 792
Provision for impairment / (reversal of impairment)	905 975	(322 499)
Amounts written off as uncollectable	(1 382 673)	(3 158 032)
	796 563	1 273 261

Provision for impairment breakdown:

Retention fees	796 563	913 669
Collection fees	-	359 592
	796 563	1 273 261

Receivables past due but not impaired

Relating specifically to Statutory Receivables

Statutory receivables which are less than 3 months past due are not considered to be impaired. At 31 March 2026, R2 781 605 (2025: R4 903 515) were past due but not impaired.

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

3 months past due	2 781 605	4 903 515
-------------------	-----------	-----------

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

3. Receivables from exchange transactions (continued)

Receivables impaired

Relating specifically to Statutory Receivables

As of 31 March 2026, statutory receivables of R2 690 589 (2025: R2 270 258) were impaired and provided for.

The amount of the provision was R796 563 as at 31 March 2026 (2025: R1 273 261).

The ageing of these loans is as follows:

3 to 6 months	647 697	1 051 858
6 - 12 months	2 042 892	1 218 400
Total	2 690 589	2 270 258

Factors the entity considered in assessing statutory receivables impaired

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

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

Credit quality of trade and other receivables

The credit quality of trade and other receivables that are neither past nor due nor impaired can be assessed by reference to historical information about the specific debtor.

Trade receivables

Other receivables impaired

As of 31 March 2026, Other receivables of R6 584 192 (2025: R5 427 307) were impaired and provided for.

The amount of the expected credit loss allowance was R184 069 as of 31 March 2026 (2025: R217 646).

The maximum exposure to credit risk at the reporting date is the fair value of each class of receivables mentioned above. The SAHPRA does not hold any collateral as security.

4. Receivables from non-exchange transactions

Other receivables	1 062 626	315 230
Grant receivable	12 313 891	1 049 954
Expected credit loss allowance	(212 525)	(63 046)
	13 163 992	1 302 138

Other receivables relate to the prior years' contingent assets which the tax master finalised relating to an arbitration processes which ruled in favour of SAHPRA and dismissing the claimant's claim.

Grant receivables includes grant(s) to be received from the Auda Nepad, FCDO and the Global Fund as conditions were met.

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026	2025
	R	R

4. Receivables from non-exchange transactions (continued)

Receivables from non-exchange transactions past due but not impaired

At 31 March 2026: R12 313 891 (2025: R1 049 954) were past due but not impaired.

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

less than 12 months past due	11 534 124	1 049 954
more than 12 months past due	779 767	-

Receivables from non-exchange transactions which are less than 12 months past due are not considered to be impaired.

Receivables from non-exchange transactions which are more than 12 months past due are considered for impairment applying financial risk management as per note 37 of which no impairments were made based on expected recovery.

The receivables relate to court orders from litigation which are favourable to SAHPRA and is executable, hence expected recovery is 100%. The grants receivable are valid due to funding activities are on-going and no funder withdrawals are anticipated on the legal contracts.

Factors SAHPRA considered in assessing non-exchange receivables from impairment:

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

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

Receivables from non-exchange transactions impaired

As of 31 March 2026, other receivables from non-exchange transactions of R1 062 626 (2025: R315 230) were impaired and provided for.

The amount of the expected credit loss allowance was R212 525 as of 31 March 2026 (2025: R63 046).

less than 12 months past due	767 396	218 893
more than 12 months past due	295 230	96 337

5. Prepayments

Prepayments	14 445 879	12 346 415
-------------	------------	------------

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

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
6. Cash and cash equivalents		
Cash and cash equivalents consist of:		
Petty cash	16 993	10 000
Bank balances held at ABSA bank	1 411 347	2 690 135
Corporation for Public Deposits held at SA Reserve Bank	534 948 846	447 585 273
Expected credit loss allowance	(7 473)	(17 494)
Call account - Global fund project	232 323	1 187 419
	536 602 036	451 455 333

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

Credit quality of cash at bank

The credit quality of cash at bank held at ABSA Bank and SA Reserve Bank's Corporation for Public Deposits that are neither past due nor impaired can be assessed by reference to external credit rating of Ba2 (long term) as per the Moody's rating agency as at 31 March 2026. SAHPRA'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

	2026			2025		
	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated depreciation and accumulated impairment	Carrying value
Furniture and fixtures	9 781 416	(4 975 918)	4 805 498	9 707 574	(4 204 471)	5 503 103
Motor vehicles	7 921 701	(3 938 327)	3 983 374	6 801 227	(2 428 687)	4 372 540
Computer equipment	32 244 109	(19 802 390)	12 441 719	26 912 609	(16 530 185)	10 382 424
Leasehold improvements ¹	7 743 222	(6 716 378)	1 026 844	7 064 612	(6 381 946)	682 666
Other fixed assets ²	14 660 298	(3 913 505)	10 746 793	11 791 151	(2 699 167)	9 091 984
Total	72 350 746	(39 346 518)	33 004 228	62 277 173	(32 244 456)	30 032 717

Reconciliation of property, plant and equipment - 2026

	Opening balance	Additions	Disposals	Depreciation	Impairment loss	Impairment reversal	Total
Furniture and fixtures	5 503 103	431 595	(158 273)	(979 334)	-	8 407	4 805 498
Motor vehicles	4 372 540	1 120 475	-	(1 509 641)	-	-	3 983 374
Computer equipment	10 382 424	6 392 817	(136 604)	(4 091 259)	(105 659)	-	12 441 719
Leasehold improvements ¹	682 666	678 611	-	(334 433)	-	-	1 026 844
Other fixed assets ²	9 091 984	2 904 989	(17 169)	(1 233 011)	-	-	10 746 793
	30 032 717	11 528 487	(312 046)	(8 147 678)	(105 659)	8 407	33 004 228

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

7. Property, plant and equipment (continued)

Reconciliation of property, plant and equipment - 2025

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

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 29.

Motor Vehicles	29 079	-
Computer equipment	2 022	-

¹ Leasehold improvements include improvements made to leased office accommodation. Refer to notes 9 and 29.

² Other fixed assets relates to office related equipment.

Impairment losses relate to computer equipment is no longer in use due to end of its useful life or in poor condition and awaiting disposal.

Capital commitments

Furniture and fixtures	155 945	-
Motor vehicles	4 865 891	1 120 475
Office equipment	3 118 667	-
Leasehold improvements	535 469	769 319
Other fixed assets	45 991	30 200
	8 721 963	1 919 994

Proceeds received for disposal of property, plant and equipment – included losses.

Furniture and fixtures	21 850	-
Computer equipment	20 000	-
	41 850	-

Other information

Property, plant and equipment useful lives were reassessed in the current year and the impact were as follows:

Computer equipment	107 517	232 021
Leasehold improvements	400 622	-
Other fixed assets	7 334	-
Furniture and fixtures	16 341	-
	531 814	232 021

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

8. Intangible assets

	2026			2025		
	Cost / Valuation	Accumulated amortisation and accumulated impairment	Carrying value	Cost / Valuation	Accumulated amortisation and accumulated impairment	Carrying value
Computer software	40 928 898	(6 961 453)	33 967 445	26 719 061	(3 620 202)	23 098 859

Reconciliation of intangible assets - 2026

	Opening balance	Work in progress	Amortisation	Total
Computer software	23 098 859	14 627 963	(3 759 377)	33 967 445

Reconciliation of intangible assets - 2025

	Opening balance	Additions	Disposals	Amortisation	Total
Computer software	16 123 213	8 942 819	(165 964)	(1 801 209)	23 098 859

Intangible assets in the process of being constructed or developed

Cumulative expenditure recognised in the carrying value of Intangible assets

Computer software	14 627 963	-
-------------------	------------	---

Computer software work-in progress relates to AI development on the SAHPRA engagement portal for application. This is a service in kind. Refer to note 19

No computer software is restricted.

Other information

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

No reassessment of useful lives for intangible assets.

9. Operating lease liability

Current liabilities	889 524	1 462 457
---------------------	---------	-----------

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.

The head office lease came to an end in July 2025 and a two-year extension has been applied on the original lease term.

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026	2025
	R	R

9. Operating lease liability (continued)

Operating leases commitment - as lessee (expense)

Minimum lease payments due

within one year	23 470 021	9 706 736
2 - 5 years	7 646 968	4 139 520
	31 116 989	13 846 256

Operating lease expenditure

Lease expenses	22 053 747	21 167 894
----------------	------------	------------

10. Payables from exchange transactions

Trade payables	5 328 730	5 227 687
Employee benefits	4 628 893	3 143 475
Accrued expenditure	6 911 744	4 803 393
Travel cards	962 811	383 373
	17 832 178	13 557 928

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

Financial liabilities include above

Trade payables	5 328 730	5 227 687
Accrued expenditure	6 911 744	4 803 393
Travel cards	962 811	383 373
	13 203 285	10 414 453

Financial liabilities exclude employee benefits

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 2026 the aggregate membership of the qualifying employees was 78 (2025:86). In-service employees were 78 (2025:86) retired employees a total of 5 (2025:1) employees. Poneso Consulting conducted a valuation of the post-retirement liability as at 31 March 2026. The valuation takes into consideration the current service 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	(16 873 251)	(11 463 902)
Non-current liabilities	(15 822 335)	(10 532 034)
Current liabilities	(1 050 916)	(931 868)
	(16 873 251)	(11 463 902)

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

11. Employee benefit obligations (continued)

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

Opening balance	11 463 902	10 875 980
Net expense recognised in the statement of financial performance	5 409 349	587 922
	16 873 251	11 463 902

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

Current service cost	931 868	908 394
Net interest on the net defined benefit liability (asset)	1 303 110	1 377 612
Actuarial gains and losses arising from:		
Changes in financial assumptions	3 343 548	(1 675 165)
Benefits paid	(169 177)	(22 919)
	5 409 349	587 922

Calculation of actuarial gains and losses

(Increase)/decrease in net discount rate	1 952 485	186 652
Earning increases lower than assumed	(212 079)	539 905
Change in membership profile	329 171	(569 682)
Change in cap, medical options and others	(1 497 788)	(1 832 040)
Increase in continuation members	2 771 759	-
	3 343 548	(1 675 165)

Key assumptions used

Assumptions used at the reporting date:

Health care cost inflation	6.46 %	7.56 %
Discount rates used	9.55 %	11.37 %
Real discount rate	2.90 %	3.54 %
Continuation at retirement	75.00 %	75.00 %
Proportion married	75.00 %	80.00 %

Sensitivity analysis for significant assumptions

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:

2026	One percentage point increase	One percentage point decrease
Effect on the service cost	1 301 654	856 221
Effect on interest cost	1 932 371	1 355 067
Effect on defined benefit obligation	20 237 208	14 192 139

Notes to the Annual Financial Statements

for the year ended 31 March 2026

11. Employee benefit obligations (continued)

2025	One percentage point increase	One percentage point decrease
Effect on the service cost	1 149 755	762 243
Effect on interest cost	1 580 108	1 083 487
Effect on defined benefit obligation	13 900 122	9 532 201

Demographic assumptions

The demographic assumptions used to calculate include withdrawals, ill-health, retirement-age, mortality, dependants, proportion married, age of spouse, medical scheme and income category.

Discount rate

The nominal discount rate of 9.55% has been set as the return from R214 long-term fixed coupon gilt as at 31 March 2026. Assumed discount rates have a significant effect on the amounts recognised in surplus or deficit. A one percentage point change in assumed discount rate would have the following effects:

2026	One percentage point increase	One percentage point decrease
Effect on the service cost	859 021	1 301 796
Effect on interest cost	1 499 624	1 731 771
Effect on defined benefit obligation	14 217 403	20 257 586

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

Proportion married

The proportion married has been assumed as 75% of in-service members reaching retirement as at 31 March 2026. A ten-percentage-point change in assumed discount rate would have the following effects:

2026	Ten percentage point increase	Ten percentage point decrease
Effect on the service cost	1 069 182	1 023 516
Effect on interest cost	1 628 615	1 584 862
Effect on defined benefit obligation	17 056 510	16 598 362

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

11. Employee benefit obligations (continued)

Asset-liability matching strategies to manage risk

SAHPRA's post retirement benefit liability is wholly unfunded by a planned asset. However, SAHPRA applies annually to National Treasury to retain its surplus to fund the liability.

Expected contributions

The expected contributions to the plan for the next reporting period are R73 304.

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	21 862	47 129	24 977 809	25 046 800
Continuation members (pensioners)	51 442	110 954	127 953	290 349
	73 304	158 083	25 105 762	25 337 149

Amounts for the current and previous four years as follows:	2026	2025	2024	2023	2022
Defined benefit plan	16 873 251	11 463 902	10 875 980	9 553 038	9 384 322

12. Unspent conditional grants

Unspent conditional grants and receipts comprises of:

Unspent conditional grants and receipts

BMGF grant	13 225 409	6 407 664
GiZ grant	5 680 121	2 465 767
Global Fund grant	232 323	1 186 989
MPP grant	3 236 000	-
IVI grant	236 138	-
	22 609 991	10 060 420

Movement during the year

Balance at the beginning of the year	10 060 420	9 759 759
Additions during the year	45 989 413	51 902 481
Conditions not met - refund to the grantor	-	(39 890)
Income recognition during the year	(33 439 842)	(51 561 930)
	22 609 991	10 060 420

These amounts are in a ring-fenced investment at the Corporation for Public Deposits and ABSA Call Account as disclosed in note 6 until utilised. Should the conditions not be met, a repayment to the grantor will include interest accrued at a rate of 7.00 percent.

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
13. Employee benefit cost provision		
Leave provision	13 763 392	13 996 937
PMDS provision	12 373 267	12 225 437
COIDA provision	860 305	3 489 768
	26 996 964	29 712 142

Leave provision

SAHPRA does not have an unconditional right to defer settlement of its leave liabilities and its policies stipulate that leave is forfeited if not used within 6 months after the start of the following calendar year, except for capped leave.

Performance management and development system provision (PMDS)

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

The approved policy requires SAHPRA to apply assumptions to enable the estimation of performance bonuses for the 2025/26 individual performance assessments based on the policy, historical pay-out data, number of qualifying employees, average salary and availability of funding.

COIDA

SAHPRA did not submit its workmen's compensation returns in previous years. All outstanding submissions were submitted during 2023/24. In 2025/26 Department of Labour resolved that SAHPRA will not be liable for penalties and interest and requested a resubmission of all years' assessments since inception. SAHPRA is currently disputing three years' assessment that were incorrectly calculated after the re-submission and the other years were correctly invoiced and the accrual raised. Refer to note 10. The provision raised below is an estimate of the amount owing.

	Current Cycle Leave	Previous Cycle Leave	Capped Leave	PMDS	COIDA	Total
As at 1 April 2025	6 068 447	7 406 315	522 175	12 225 437	3 489 768	29 712 142
Additions for the year	6 578 018	6 641 199	22 000	11 168 795	-	24 410 012
Reversal during the year	(6 068 447)	(7 406 315)	-	(11 020 965)	(2 629 463)	(27 125 190)
As at 31 March 2026	6 578 018	6 641 199	544 175	12 373 267	860 305	26 996 964

	Current Cycle Leave	Previous Cycle Leave	Capped Leave	PMDS	COIDA	Total
As at 1 April 2024	4 962 572	5 694 808	495 718	10 048 307	2 978 933	23 880 338
Additions for the year	6 068 447	7 406 315	46 006	11 056 338	810 835	25 387 941
Reversal during the year	(4 962 572)	(5 694 808)	(19 549)	(8 879 208)	-	(19 556 137)
As at 31 March 2025	6 068 447	7 406 315	522 175	12 225 437	3 489 768	29 712 142

14. Income received in advance

Reconciliation

Unallocated deposits received	23 629 438	25 736 980
Revenue received in advance	317 618 318	255 240 796
	341 247 756	280 977 776

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
14. Income received in advance (continued)		
Opening balance	280 977 776	289 756 591
Net movements		
Current year receipts	382 723 072	285 422 165
Realised against revenue and receivables	(303 801 750)	(254 205 487)
Prior period adjustment	-	(37 628 799)
Refund to applicant	(18 651 342)	(2 366 694)
	341 247 756	280 977 776

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.

Repayment (refunds) is limited only when an application is withdrawn before services are rendered or when refund conditions are met.

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

15. Fee Income

Amendments	50 476 480	30 298 650
Biological medicine	10 802 400	5 149 200
Cannabis inspection	788 500	400 000
Cannabis licences	869 600	476 680
Certificates	420 380	469 360
Clinical trials	11 924 800	12 575 600
Evaluations	58 596 950	58 224 400
Inspection fees	13 285 543	11 354 104
License fees	3 571 400	5 288 080
Licence retention fee	14 237 000	10 957 800
MD clinical trials	186 500	238 000
MD licence fees	26 023 000	23 852 600
New medicine renewals	14 614 500	6 253 400
Permits	8 586 550	8 083 385
Response reviews	4 221 000	-
Registration fee	1 729 700	1 337 500
Retention fees	77 254 000	74 242 500
Section 21 Human	5 685 561	5 400 820
Section 21 Veterinary	144 250	150 700
Section 21 CMS	89 330	100 020
	303 507 444	254 852 799
Fees received per function		
Medicines evaluation, registration and product lifecycle	223 354 571	181 469 640
Inspections, permits and licences issued	74 764 923	68 265 909
The use of unregistered medicines	5 387 950	5 117 250
Total	303 507 444	254 852 799

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

16. Sundry income

Debt impairment reversed	-	369 101
--------------------------	---	---------

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

17. Investment revenue

Interest revenue

Bank	38 301 545	36 443 498
Accrued interest	-	33 175
	38 301 545	36 476 673

Included in interest revenue is total interest earned from cash held at ABSA bank based on the average interest rate of 5.00% (2025: 5.00%) and cash held at SA Reserve Bank Corporation for Public Deposits bank based on the average interest rate of 7.03% (2025: 7.99%) per annum. Interest on the rental deposit held by the lessor in a interest bearing call account at an average rate of 7.00% (2025: 7.00%) per annum.

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

18. Transfer payments

Operating grants

Transfer payment from the National Department of Health	149 301 000	143 518 000
---	-------------	-------------

19. Goods and services in-kind

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

Goods and services in-kind that are significant to SAHPRA's operations and/or service delivery objectives

US Department of Energy	1 964 649	5 922 745
SAHPRA received an in-kind benefit as donated laboratory equipment was received from Africa CDC in the prior year.		
SAHPRA received an in-kind benefit as donated radiation control equipment were received from the US Department of Energy in the current year		
Gates Foundation	180 101	973 435
SAHPRA received an in-kind benefit as compensation of the Renewal Manager was paid directly by a 3rd party BMGF via the Wits Health Consortium.		
USAID - JHPIEGO	3 789 499	6 736 103
SAHPRA received an in-kind benefit as a Pharmacovigilance officers deployed to head office and various provinces for implementation of integrated systems for post marketing safety surveillance systems were paid directly by a 3rd party - USAID JHPIEGO		
Gates Foundation	11 906 602	-
The Gates Foundation contracted a South African-based (and registered in the United States of America) software developer for the development of AI tools for SAHPRA for technical screening tool development and deployment and for risk-weighting tool for generic product assessment.		
SAMRC	4 810 140	-
SAMRC incurred costs on behalf of SAHPRA through an agent for software development support and maintenance		
	22 650 991	13 632 283

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

19. Goods and services in-kind (continued)

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

SAMRC 7	700 000	766 667
SAMRC incurred costs on behalf of SAHPRA through workplace training of interns.		
GiZ - GFA / RCore / SAVax	12 253 247	10 121 632
GiZ incurred costs on behalf of SAHPRA through a grant to provide technical expert advisory services to support organisational development, sustainability modelling and training interventions.		
Right to Care	760 096	272 860
Right to Care incurred costs on behalf of SAHPRA through a placement of a training specialist.		
	13 713 343	11 161 159

20. Grant realised and income

Auda-Nepad grant	255 168	1 513 202
FCDO grant	926 499	-
Global Fund grant	19 303 315	38 580 323
BMGF grant	2 946 123	798 347
MPP grant	8 072 824	1 477 344
GIZ grant	1 935 913	9 192 714
	33 439 842	51 561 930

Reconciliation of conditional contributions

Current-year receipts	56 049 833	61 622 351
Conditions met - realised against revenue	(33 439 842)	(51 561 930)
Conditions met - realised against receivables	(12 313 892)	(1 049 954)
Grant receivable - note 4	12 313 892	1 049 954
Balance of unspent conditional grants - note 12	(22 609 991)	(10 060 421)
	-	-

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

21. Employee related costs

Bargaining council	-	8 595
Basic and pensionable salaries	234 283 075	200 363 485
Cellphone allowances	1 654 040	1 600 585
COIDA	(1 236 894)	810 835
Housing benefits and allowances	2 252 778	2 516 877
Leave accrued	1 265 694	3 680 076
Medical aid	8 860 912	9 988 861
Overtime	253 940	1 210 626
Pension fund	29 626 148	27 223 187
Post retirement medical aid adjustment	2 065 801	587 922
SDL and UIF	3 520 807	3 462 461
Services in kind*	3 969 600	7 709 538
Standby allowances	66 980	97 589
Thirteenth cheque and performance bonus	17 288 039	17 203 777
Travel, subsistence and other allowances	1 439 427	863 017
	305 310 347	277 327 431

* Refer to note 19 for details relating to services in kind

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
22. Global Fund project expenditure		
Professional services	207 000	873 277
Travel and related expenditure	59 640	1 176 996
Legal committee fees	-	1 830 470
Local evaluators	5 755 325	10 999 056
Foreign evaluators	-	4 615 649
Compensation of employees	13 321 464	19 095 871
	19 343 429	38 591 319
23. GiZ project expenditure		
Technology consulting services	618 345	157 559
Compensation of employees	1 317 568	865 683
	1 935 913	1 023 242
SAHPRA capitalised technology consulting services of R8 169 472 in the prior year. Refer to note 8 and note 35.		
24. BMGF project expenditure		
Compensation of employees	2 312 230	724 047
Technical consulting services	589 487	74 300
Travel and related expenses	44 406	-
	2 946 123	798 347
25. Auda Nepad project expenditure		
Compensation of employees	255 168	1 230 337
Technical consulting services	-	282 865
	255 168	1 513 202
26. MPP project expenditure		
Compensation of employees	6 604 018	1 477 344
Training costs	976 727	-
Professional services	59 800	-
Foreign evaluators	301 659	-
	7 942 204	1 477 344
27. Depreciation and amortisation		
Property, plant and equipment	8 147 678	7 907 113
Intangible assets	3 759 377	1 801 209
	11 907 055	9 708 322

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026	2025
	R	R

28. Laboratory services

Outsourced services

NCL Laboratory	24 127 300	21 276 216
----------------	------------	------------

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

29. Operating expenses

Advertising	118 692	338 226
Bank charges	437 917	328 524
Board costs	1 814 294	1 849 939
Bursaries	459 272	601 128
Catering	653 717	444 467
Cleaning	1 028 685	865 614
Communication	3 022 884	2 696 204
Conferences	2 726 882	987 351
Consulting and professional fees ¹	9 160 542	6 621 448
Electricity and utilities	4 739 690	2 499 727
External audit fees	3 918 963	3 611 127
Foreign evaluators	13 241 579	6 015 360
Insurance	913 589	753 047
Internal audit fees	2 494 707	2 346 341
Legal fees	10 321 285	8 326 175
Licences	14 386 270	12 219 442
Local evaluators and expert committees	16 547 029	7 543 248
Marketing, printing and publication	2 083 629	1 097 270
Medicine testing	1 865 474	286 471
Membership fees	1 230 423	823 669
Minor assets	495 598	190 492
Motor vehicle expenses	1 188 580	2 280 540
Photocopy lease	317 932	335 310
Postage and courier	227 544	35 200
Printing and stationery	331 758	366 351
Protective clothing	209 402	-
Repairs and maintenance [^]	562 091	595 636
Security	198 263	203 980
Services in kind	2 088 779	-
Staff training and welfare	1 896 575	871 541
Storage	882 077	581 084
Travel - board members	86 307	32 906
Travel - international	2 673 345	2 690 196
Travel - local	7 958 437	6 793 399
Travel - non employees	2 117 959	613 323
	112 400 170	75 844 736

¹ Consulting and professional fees consist of payments made to service providers for job grading, policy review, actuarial services, HR and Financial systems, debt collection and ICT consultants.

² Repairs and maintenance relates to leasehold improvement and computer repairs

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
30. Cash generated from operations		
Surplus	33 698 660	53 989 801
Adjustments for:		
Depreciation and amortisation	11 907 055	9 708 322
Loss on sale of assets and liabilities	427 944	69 213
Impairment	(68 432)	292 373
Bad debts written off / (impairment reversal)	963 276	(369 101)
Movements in operating lease	(572 933)	(2 056 248)
Movements in retirement benefits	2 065 801	2 263 087
Movements in provisions	(2 715 178)	5 831 804
Non cash interest on grant liability	(71 540)	-
Accrued interest on rental deposit and debtors	-	(33 175)
Expected credit loss movement on receivables	115 903	280 691
Loss on foreign exchange	-	18 873
Assets donated	(16 475 125)	(5 922 745)
Expected credit loss movement on cash	(10 021)	17 494
Actuarial loss / (gain)	3 343 548	(1 675 165)
Changes in working capital:		
Receivables from exchange transactions	(928 857)	(1 306 870)
Other receivables from non-exchange transactions	(11 977 757)	6 414 025
Prepayments	(2 099 464)	(2 703 482)
Payables from exchange transactions	4 282 186	1 429 035
Unspent conditional grant	12 621 111	300 661
Income received in advance	60 269 980	(8 778 815)
Prior period affecting opening surplus	-	37 391 413
	94 776 157	95 161 191

31. Contingencies

Contingent assets

Cost orders in favour of SAHPRA

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

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

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

Registration and sale of a certain vaccine:

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

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

Notes to the Annual Financial Statements

for the year ended 31 March 2026

Approval and registration of vaccines:

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

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

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

Contingent liabilities

Discrimination

A SAHPRA employee has filed a claim with the labour court citing racial discrimination at the workplace as contemplated in section 6 (1) of the Employment Equity Act, 55 of 1998 and that SAHPRA, as the employer failed to take the appropriate steps to protect her.

SAHPRA filed an exception to the Applicant's claim on the basis that the employee has failed to allege and prove that the said discrimination was immediately reported to the employer as contemplated in section 60 of the EEA.

Although SAHPRA's prospects of success in this matter is good, it is still to be fully considered by the Labour Court whether there is possible liability amounting to the claimed amount of R532 516.

Wrongful search and seizure

The plaintiff alleges that on or about 26 May 2023 the SAPS and SAHPRA conducted an unlawful and wrongful search on its premises and that general damages were suffered in the sum of R200 000.

Therefore, there is a possible obligation for SAHPRA relating to this matter, although SAHPRA has good prospects of success based on the available information related to this claim the likelihood of an outflow of resources regarding this claim is not remote and a contingent liability will be disclosed of R200 000 relating to wrongful search.

Constructive dismissal

A SAHPRA employee resigned in December 2025 and in March 2026 filed an application for constructive dismissal with the CCMA citing intolerable working environment and had no option but to resign.

Although SAHPRA's prospects of success in this matter is good, it is still to be fully considered by the CCMA and the possible liability is estimated at R257 613.

Surrender of surpluses

SAHPRA annually declares all surpluses or deficits to the relevant Treasury from the period 1 August to 31 August of each year, using its audited annual financial statements as the basis for calculation of surpluses or deficits.

SAHPRA 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, SAHPRA 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 31 August 2026. However, should the submission not be approved, SAHPRA will be required to surrender the current year's surplus as per the calculation of R89 809 284. The calculation is based on previous submissions approved by the National Treasury.

Notes to the Annual Financial Statements

for the year ended 31 March 2026

32. Related parties

Relationships	Nature of related party
Executive Authority (controlling entity of SAHPRA)	The executive authority as defined in section 1 of the PFMA, is the Minister of Health as SAHPRA falls under the portfolio of the Department of Health
Accounting authority	Dr TM Motshudi - Chairperson (appointed 1 July 2025) Prof G Gray - Vice chairperson (appointed 1 July 2025) Dr C Clark - Member (appointed 1 July 2025) Dr J Gouws - Member (appointed 1 July 2025) Dr T Boltina - Member (appointed 1 July 2025) Ms N Nkoenyane - Member (appointed 1 July 2025) Mr. A Ngcezula - Member (appointed 1 July 2025) Mr. R Mahabeer – Member (appointed 1 July 2025) Mr. N Ngongoma - Member (appointed 1 July 2025) Mr. M Moselekwa – Member (appointed 1 July 2025) Dr AT Kgasi - Member (reappointed 1 July 2025) Prof HV Rees – Chairperson (term ended 30 June 2025) Dr O Khaole - Vice-Chair (term ended 30 June 2025) Adv H Cassim – Member (term ended 30 June 2025) Prof HP Demana – Member (term ended 30 June 2025) Mr F Dockrat – Member (term ended 30 June 2025) Mr I Mashau – Member (term ended 30 June 2025) Ms L Mothae – Member (term ended 30 June 2025) Dr J Tsoka-Gwegweni – Member (term ended 30 June 2025) Dr X Ngobese – Member (term ended 30 June 2025) Prof Y Choonara – Member (term ended 30 June 2025) Prof J Meyer – Member (term ended 30 June 2025) Ms M Skhosana Member (term ended 30 June 2025)
Members of key management	Dr B Semete-Makokotlela - CEO Mr RB Gouws - CFO Ms C Reynecke - COO Ms L Modisakeng - HR Executive Ms T Gopal - CRO
Other related parties	All public entities under the National Department of Health All public entities in National Sphere South African Medical Research Council (SAMRC)

Related party balances

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

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

32. Related parties (continued)

Related party transactions

National Department of Health (Controlling entity)

Government grant received	149 301 000	143 518 000
---------------------------	-------------	-------------

SAMRC (other related party)

Employee related costs - refer to note 19	700 000	766 667
Software development and maintenance - refer to note 19	4 810 140	-

Remuneration of Executive Authority and Management

2026

Board fees ¹	Board Fees	Total
Prof H.V. Rees - Chairperson ²	41 569	41 569
Adv H. Cassim - Member ²	54 086	54 086
Mr F. Dockrat - Member ²	48 712	48 712
Prof H. P. Demana - Member ²	37 790	37 790
Mr I. Mashau - Member ²	49 764	49 764
Ms L. Mothae - Member ²	67 567	67 567
Dr O. Khaole - Vice Chair ²	45 865	45 865
Dr J. Tsoka-Gwegweni - Member ²	32 592	32 592
Dr X Ngobese - Member ²	67 653	67 653
Ms D Maraka - Member ²	35 466	35 466
Prof Y Choonara - Member ²	7 558	7 558
Prof J Meyer - Member ²	22 674	22 674
Ms M Skhosana - Member ²	37 790	37 790
Dr A Kgasi - Member ⁵	154 374	154 374
Dr Z Makatini - Member ^{2 3}	-	-
Dr TM Motshudi - Chairperson ⁴	64 788	64 788
Prof G Gray - Vice Chair ⁴	109 423	109 423
Dr C Clark - Member ⁴	85 002	85 002
Dr J Gouws - Member ^{4 3}	-	-
Dr T Boltina - Member ⁴	115 259	115 259
Ms N Nkoenyane - Member ⁴	121 469	121 469
Mr A Ngcezula - Member ⁴	130 409	130 409
Mr R Mahabeer - Member ⁴	101 746	101 746
Mr N Ngongoma - Member ⁴	96 382	96 382
Mr M Moselekwa - Member ⁴	126 402	126 402
	1 654 340	1 654 340

¹ The board fees reflect the actual claims incurred. At times board members opt not to claim for meetings attended.

² Previous board term ended 30 June 2025

³ No fees claimed

⁴ Appointed 1 July 2025

⁵ Reappointed from the previous board

Notes to the Annual Financial Statements

for the year ended 31 March 2026

32. Related parties (continued)

Executive management

2026	Basic Salary	Bonuses and performance related payments	Post employment benefits	Other benefits received	Total
Dr B Semete-Makokotlela - Chief Executive Officer	3 711 368	142 745	-	103 423	3 957 536
Ms. T Gopal - Chief Regulatory Officer	2 079 792	-	208 208	80 596	2 368 596
Ms. C Reynecke - Chief Operating Officer	2 618 894	100 606	-	49 254	2 768 754
Mr. RB Gouws - Chief Financial Officer	2 275 751	175 058	-	48 736	2 499 545
Ms. L Modisakeng - HR Executive	1 909 742	-	14 027	46 654	1 970 423
	12 595 547	418 409	222 235	328 663	13 564 854

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

2025 ¹

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

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

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

32. Related parties (continued)

Executive management

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

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

¹ Ms Nkambule resigned from SAHPRA in September 2024

² Ms L Modisakeng appointed September 2024

³ Ms T Gopal appointed March 2025.

33. Independent audit committee members remuneration

Independent audit committee members - fee for attending meeting

Mr B Gordon	46 166	45 106
Mr R Mahabeer ¹	17 948	65 650
Ms A Chowan	46 186	44 162
	110 300	154 918

¹ Appointed as a board member 1 July 2025

Notes to the Annual Financial Statements

for the year ended 31 March 2026

34. Financial instruments disclosure

Categories of financial instruments

Financial assets

2026	At amortised cost	Total
Deposits - note 3	6 138 543	6 138 543
Other receivables from non-exchange transactions - note 4	13 163 992	13 163 992
Staff debtors - note 3	261 580	261 580
Cash and cash equivalents - note 6	536 602 036	536 602 036
	556 166 151	556 166 151

Financial liabilities

2026	At amortised cost	Total
Trade payables from exchange transactions - note 10	5 328 730	5 328 730
Accrued expenditure - note 10	6 911 744	6 911 744
Travel cards - note 10	962 811	962 811
	13 203 285	13 203 285

Financial assets

2025	At amortised cost	Total
Other receivables from non-exchange transactions - note 4	1 302 138	1 302 138
Deposits - note 3	4 882 394	4 882 394
Cash and cash equivalents - note 6	451 455 333	451 455 333
Staff debtors - note 3	327 267	327 267
	457 967 132	457 967 132

Financial liabilities

2025	At amortised cost	Total
Trade and other payables from exchange transactions - note 10	5 227 687	5 227 687
Accrued expenditure - note 10	4 803 393	4 803 393
Travel cards - note 10	383 373	383 373
	10 414 453	10 414 453

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

Financial instruments in Statement of financial performance

2026	At amortised cost	Total
Expected credit loss on financial assets	105 882	105 882

2025	At amortised cost	Total
Expected credit loss on financial assets	298 186	298 186

35. Prior period errors

- Since inception SAHPRA incorrectly classified its Income received in advance as financial instruments and has been removed from note 34.
- Staff debtors were incorrectly classified as non-exchange transactions, however it should have been exchange transactions due to its nature. This has been reclassified from note 4 to note 3.
- Revenue was incorrectly omitted due to insufficient supporting evidence (proof of service) submitted in prior financial years. The correction was made to opening retained earnings. Following a detailed review of historical revenue received in advance balances dating back to 2018/19 supporting evidence was obtained to do the recognition to revenue.
- Receivables from exchange transactions relating to cannabis inspections that was incorrectly calculated and excluded in the prior year.

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

Statement of Financial Position

Receivables from exchange transactions	-	699 243
Receivables from non-exchange transactions	-	(522 843)
Income received in advance	-	37 628 799
Opening Accumulated Surplus	-	(37 805 200)

Statement of financial performance

Fee income	-	(115 600)
------------	---	-----------

35.1 Prior-year adjustments

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

Statement of financial position

2025	Note	As previously reported	Correction of error	Change in accounting policy	Total
Receivables from exchange transactions	3	10 628 576	699 243	(217 646)	11 110 173
Receivables from non-exchange transactions	4	1 888 027	(522 843)	(63 046)	1 302 138
Cash and cash equivalents	6	451 472 827	-	(17 494)	451 455 333
Accumulated surplus		(144 603 997)	(37 805 199)	298 186	(182 111 010)
Income received in advance	14	(318 606 575)	37 628 799	-	(280 977 776)
		778 858	-	-	778 858

Notes to the Annual Financial Statements

for the year ended 31 March 2026

35.1 Prior-year adjustments (continued)

Statement of financial performance

2025	Note	As previously reported	Correction of error	Restated
Revenue from exchange transactions	15	(254 737 199)	(115 600)	(254 852 799)

Disclosure

2025	Note	As previously reported	Correction of error	Change in accounting policy	Re-classification	Total
Note 34 - Financial instrument						
Other financial liabilities (Income received in advance)	34	(318 606 575)	318 606 575	-	-	-
Other receivables from non-exchange transactions	34	1 888 027	-	(63 046)	(522 843)	1 302 138
Staff debtors	34	-	-	(195 576)	522 843	327 267
		(316 718 548)	318 606 575	(258 622)	-	1 629 405
Note 3 - Receivables from exchange transactions						
Staff debtors	3	-	-	-	522 843	522 843
Note 4 - Receivables from non-exchange transactions						
Staff debtors	4	522 843	-	-	(522 843)	-

36. Changes in accounting policy and estimates

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

SAHPRA has adopted the revised standards of GRAP 104: Financial Assets, and as permitted by the transitional provisions, the comparative information has not been restated. The expected credit loss has been recognised as a direct remeasurement adjustment to the opening accumulated surplus on date of initial application.

SAHPRA has chosen to only disclose capital commitments as per GRAP 1: Presentation of Financial Statements. The prior year note for Commitments is now included within the relevant sections of the financial statements to avoid fragmentation and ensure a comprehensive view of SAHPRA's financial position. The remaining balance is included in note 7. The adjustment relates to operational commitments being excluded and additional capital commitments that were not included in the prior year. The aggregate effect of the changes in accounting policy on the annual financial statements for the year ended 31 March 2025 is as follows:

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
36. Changes in accounting policy and estimates (continued)		
Statement of Financial Position		
Financial assets from exchange transactions		
Previously stated	-	5 427 307
Adjustment - expected credit loss		(217 646)
	-	5 209 661
Financial assets from non-exchange transactions		
Previously stated	-	1 365 184
Adjustment		(63 046)
	-	1 302 138
Cash and cash equivalents		
Previously stated	-	451 472 827
Adjustment		(17 494)
	-	451 455 333
Statement of Financial Performance		
Expected credit loss		
Previously stated	-	-
Adjustment	-	298 186
	-	298 186
Disclosure		
Commitments		
Previously stated	-	95 261 225
Adjustment	-	(93 341 230)
	-	1 919 995

37. Risk management

Financial risk management

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

SAHPRA's risk management policies are established to identify and analyse the risks faced by SAHPRA to set appropriate risk limits and controls and to monitor risk and adherence to limits. Risk management policies and systems are reviewed regularly to reflect changes in SAHPRA's activities. SAHPRA through its training and management standards and procedures aims to develop a disciplined and effective control environment in which all employees understand their roles and obligations.

The Audit and Risk Committee oversees how management monitors compliance with SAHPRA's risk policies and procedures, and reviews the adequacy of the risk management framework in relation to the risk faced by SAHPRA. The Audit and Risk Committee is assisted in its oversight role by the Internal Audit. The internal audit undertakes both regular and ad hoc 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.

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
--	-----------	-----------

37. Risk management (continued)

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, receivables 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

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

Trade and other payables are due within 12 months and equal their carrying balances as the impact of discounting is not significant. SAHPRA's primary source of income is government grants and revenue generated, funds receivable is estimated when preparing the MTEF. Budgets are prepared for each revenue stream and spend is monitored on an ongoing basis to ensure the liquidity of SAHPRA.

The table below analyses SAHPRA's financial liabilities into relevant maturity groupings based on the remaining period at the statement of financial position to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows. Balances due within 12 months equal their carrying balances as the impact of discounting is not significant.

At 31 March 2026	30 days	60 days	90 days	120 days
Trade payables from exchange transactions - note 10	5 328 730	-	-	-
Travel cards - note 10	-	962 811	-	-
Accrued expenditure - note 10	6 911 744	-	-	-

At 31 March 2025	30 days	60 days	90 days	120 days
Trade payables from exchange transactions - note 10	5 227 687	-	-	-
Travel cards - note 10	-	383 373	-	-
Accrued expenditure - note 10	4 803 393	-	-	-

Credit risk

This is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation. Management has a debtors policy in place, and this makes provision for impairment evaluation for customers with slow payment trends.

The general/staging approach is used and that there were no significant changes in the gross carrying amounts of financial instruments due to changes in the credit loss allowance and no renegotiation of terms or held as collateral.

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

SAHPRA cash and cash equivalents primarily consists of deposits held with the Reserve Bank of South Africa, of which the probability of default is zero percent. Other deposits are held at South African commercial banks with Moody rating of BB (stable) and probability of default is one percent.

For staff debtors, the average probability of default was calculated based on history of payments over a period of 4 years due to the debt incorporating both current and former employees with different risk profiles.

Other receivables consists legal judgements awarded in favour of SAHPRA. The default risk based on nature of business being small to medium or uninsured individuals has been set as a medium risk of 50%.

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026	2025
	R	R

37. Risk management (continued)

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

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

Financial instrument

Cash and cash equivalents - note 6	536 602 036	451 455 333
Receivables from non-exchange transactions - note 4	13 163 992	1 302 138
Deposits - note 3	6 138 543	4 882 394
Staff debtors - note 3	261 580	327 267

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 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. SAHPRA manages movements in interest rate risk during the budgeting process.

38. Grant funding

38.1 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.

38.2 The African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD)

SAHPRA received a grant from Auda-Nepad to complement and support activities implemented in the AU-3S Target Countries towards strengthening of Safety Monitoring Systems for COVID-19 Vaccines. Refer to note 20 for the grant realised.

38.3 Medicines Patent Pool (MPP)

SAHPRA entered into an agreement to provide for technical assistance across core business units. The development of training programmes, human resource support and other technical assistance. Refer to note 20 for grant realised.

38.4 Global Fund

The NDOH has through Global Fund resolved to fund SAHPRA to speed up the finalisation 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. This is through human resource support and local evaluator cost Refer to note 20 for breakdown of grant realised.

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026	2025
	R	R

38. Grant funding (continued)

38.5 Gates Foundation (BMGF)

SAHPRA entered into an agreement to strengthen SAHPRA's Regulatory Talent Recruitment and management (HR Business Partner, Lab Manager), HR strategy, policies and to assist with improving market surveillance control activities including liaising with externally contracted lab testing entities. Another agreement was entered into to support SAHPRA in achieving WHO-Listed Authority (WLA) status. Refer to note 20 for grant realised.

38.6 The British High Commission - Foreign, Commonwealth and Development Office (FCDO)

SAHPRA entered into an agreement to support the clearance of the biological variations backlog. Refer to note 20 for grant realised.

38.7 The International Vaccine Institute (IVI)

SAHPRA entered into an agreement to support capacity development and strengthen partnerships for a suitable vaccine ecosystem in Africa.

39. Irregular and Fruitless and Wasteful Expenditure *

Irregular and Fruitless and wasteful expenditure	-	-
--	---	---

Identified irregular, fruitless and wasteful expenditure were condoned, written off or recovered during the financial year.

*Refer to reconciling notes in the annual report

Notes to the Annual Financial Statements

for the year ended 31 March 2026

	2026 R	2025 R
40. 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	33 698 660	53 989 801
Adjusted for:		
Auda Nepad grant	255 168	1 513 202
(Increase) / decrease in service in kind	(22 650 991)	(13 632 283)
Grant realised	(33 439 842)	(51 561 930)
Over / (under) expenditure on impairment of assets	(68 432)	292 373
Capital expenditure budget	(10 121 777)	-
GiZ grant expenditure	1 935 913	1 023 242
Global Fund project expenditure	19 343 429	38 591 319
(Increase) / decrease in fee income	(19 129 647)	(6 642 984)
(Increase) / decrease in interest income	(1 504 145)	(10 923 673)
Over / (under) expenditure in employee cost	(2 954 315)	3 367 533
(Under) / over expenditure in operating leases	(1 523 880)	(1 017 890)
Over / (under) expenditure on operating expenditure	(17 504 607)	(19 637 778)
Over expenditure on depreciation	11 907 055	9 708 322
(Under) / over expenditure on contracted services	514 550	(4 674 589)
Over expenditure on loss of disposal of assets	427 944	69 213
Over expenditure on bad debts	1 069 157	(369 101)
Increase in gain on foreign exchange	-	18 873
Increase in credit loss allowance	-	298 186
(Increase) / decrease in sundry income	431 990	(1 012 362)
(Increase) / decrease in actuarial (gain) or losses	3 343 548	(1 675 165)
BMGF grant expenditure	2 946 123	798 347
FCDO grant expenditure	926 499	-
MPP grant expenditure	7 942 204	1 477 344
Prior year surplus approved	24 155 396	-
Net surplus per approved budget	-	-

The executive authority approved an adjustment to SAHPRA's 2025-26 budget in January 2026 after the surplus retention for 2024-25 was approved by National Treasury.

Notes to the Annual Financial Statements

for the year ended 31 March 2026

41. Budgeted differences

Material differences between budget and actual amounts

41.1 Fee and Sundry Income

Fee income is higher than budget due to the effect of new fees gazetted in February 2025 and increased output due to an increase in resources.

41.2 Interest Received

Interest received higher than 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.

41.3 Employee Related Costs

Employee related costs are low due to vacancies not filled. Some non-cash year-end entries made relating to leave and bonus provision adjustments. Also included in operating expenditure is service in kind expenditure which was externally funded.

41.4 Operating Expenses

Operating expenses were lower than budgeted for due to the receipt of external funding for foreign and local external evaluators and expert committees resulting in under utilisation of the original budget set for these expenditure items. Also included in operating expenditure is service in kind expenditure which was externally funded. Adjustment to the budget after approval from National Treasury relating to the 2024-25 surplus contributed to under expenditure due to the limited time between approval and financial year end.

41.5 Laboratory service

NCL expenditure is higher than budget due to an increase in scope however some activities are externally funded.

41.6 Lease rentals on operating lease

Expenditure is lower due to reduced rental rates negotiated for.

41.7 Seta grant received

SAHPRA received a grant from Seta after submitting the workplace skills plan however the grant received was less than budgeted for.

41.8 Capital expenditure budget

SAHPRA included capital expenditure budget on the cash basis however capital expenditure is capitalised and not expensed. This amount represents the basis difference between the cash budget and the financial statements.

41.9 Prior period surplus approval

The adjustment to the budget results from the 2024-25 request for surplus approved by National Treasury and applied to the current year budget relating to expenditure.

NOTES

[illegible]

Head Office

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

Tel: (012) 501 0300

Email: enquiries@sahpra.org.za

www.sahpra.org.za

